Aspects to consider when introducing IoMT-solutions into the healthcare system in Sweden

Fanny Holmqvist & Johanna Ihrfelt

LUND UNIVERSITY

LTH

FACULTY OF ENGINEERING

MIOM05 Degree Project in Production Management
Division of Production Management
Faculty of Engineering LTH
Lund University
Supervisor: Ingela Elofsson
Examiner: Ola Alexanderson

Preface

This Master Thesis is done by Fanny Holmqvist and Johanna Ihrfelt during the spring semester of 2023 as a final project of Industrial Engineering and Management at LTH, Faculty of Engineering, at Lund University.

The authors would like to express gratitude towards Ingela Elofsson who has supervised the thesis. Also, to all medical professionals, patients, consultants at BearingPoint and representatives from the regions and Swedish MedTech who have kindly participated in interviews which have provided the study with nuanced perspectives and interesting insights.

A special thanks to the case company for believing in us and providing the task and especially to our supervisor from the company for their continuous engagement and support.

The authors have through the journey become even more passionate about digital transformation in the healthcare sector.

I vårt och torrt

Fanny Holmqvist

Johanna Ihrfelt

Abstract

Authors: Fanny Holmqvist, Johanna Ihrfelt
Supervisor: Ingela Elofsson, Division of Production Management, Faculty of Engineering, Lund University
Purpose: The purpose of this study is to identify, describe and analyze aspects to consider when introducing IoMT-solutions into the healthcare system in Sweden.

The healthcare system in Sweden is currently facing major challenges, particularly with regards to rising healthcare costs, an aging population, and an increase in chronic diseases. To overcome these challenges, the healthcare system requires innovative solutions that can provide cost-effective care while maintaining quality standards. Internet of Medical Things (IoMT) solutions have the potential to address these challenges by utilizing emerging technologies and data-driven approaches to healthcare.

The thesis aims to have an explorative, describing and explaining approach and is based on a case study. The work includes a literary study and interviews with representatives of identified stakeholders.

Through applying the master thesis' theoretical framework on the collected empirical data, the following conclusion could be made. The thesis identifies challenges such as a complex procurement process, healthcare's current compensation model and a lack of clear pathways for product subsidies. In addition, the study emphasizes the need for active engagement with stakeholders and a sense of urgency to drive change. To facilitate the introduction, the study recommends sellers to address stakeholder needs, provide evidence of benefits, actively engage in the market, and tailoring your approach to different stakeholders. Developing appropriate clinic routines for the product and leverage on regional initiatives promoting innovation in healthcare. Overall, the findings offer valuable insights for introducing IoMT-solutions in other healthcare domains in Sweden.

Keywords: IoMT, Public procurement, Urinary Incontinence, Digital transformation, Change management

Sammanfattning

Författare: Fanny Holmqvist, Johanna Ihrfelt
Handledare: Ingela Elofsson, Avdelningen för produktionsekonomi, Lunds Tekniska Högskola, Lunds universitet
Syfte: Syftet med denna studie är att identifiera, beskriva och analysera aspekter att beakta vid införandet av IoMT-lösningar i hälso- och sjukvårdssystemet i Sverige.

Hälso- och sjukvårdssystemet i Sverige står för närvarande inför stora utmaningar, särskilt när det gäller stigande sjukvårdskostnader, en åldrande befolkning och en ökning av kroniska sjukdomar. För att övervinna dessa utmaningar behöver hälso- och sjukvårdssystemet innovativa lösningar som kan ge kostnadseffektiv vård med bibehållen kvalitetsstandard. Lösningar med Internet of Medical Things (IoMT) har potential att ta itu med dessa utmaningar genom att utnyttja framväxande teknik och datadrivna tillvägagångssätt inom hälso- och sjukvården.

Examensarbetet syftar till att ha ett utforskande, beskrivande och förklarande tillvägagångssätt och bygger på en fallstudie. Arbetet omfattar en litteraturstudie och intervjuer med företrädare för identifierade intressenter.

Genom att tillämpa examensarbetets teoretiska ramverk i det genomförda materialet kunde följande slutsats dras. I avhandlingen identifieras utmaningar såsom en komplex upphandlingsprocess och en brist på tydliga vägar för produktsubventioner. Dessutom betonar studien behovet av ett aktivt engagemang med intressenter och en känsla av brådska för att driva förändring. För att underlätta genomförandet rekommenderas i studien att skräddarsy budskap till olika intressenters värderingar, utveckla lämpliga klinikrutiner och utnyttja regionala initiativ som främjar innovation inom hälso- och sjukvården. Sammantaget erbjuder resultaten värdefulla insikter för att införa IoMT-lösningar inom andra sjukvårdsområden i Sverige.

Nyckelord: IoMT, Public procurement, Urinary Incontinence, Digital transformation, Change management

Glossary

ICU - Intensive Care Unit
UI - Urinary Incontinence
IoMT - Internet of medical things
Medtech - Medical Technology
Micturition - The action of urinating
Urologist - Physician specialized in urology
Urotherapist - Nurse specialized in urology
End consumer - Final user of the product in question

Table of contents

Chapter 1- Background

In this chapter the reader will be given a background and context to the thesis. Starting with a description of the problem the thesis aims to investigate and highlight why this topic is relevant to study. The problem formulation, aim, objectives and structure will later be presented and concluded with a review of relevant concepts and abbreviations.

1.1 Background

With the advancement of technology, the world is changing at a rapid pace. Much manual labor has been replaced by automated machinery over the years. Industry 4.0 is emerging, with its concepts such as artificial intelligence, big data analytics, Internet of Things (IoT) and more, yet it is still early days. It is expected that the healthcare sector will be affected to a great extent by this development. (Koul 2022) The health care in Sweden has in recent years become increasingly strained in terms of availability and financially and will be in great need for increased productivity in coming years. Most of the prognosis presenting this takes its stand in the fact that the Swedish population is aging and will have more chronic diseases requiring treatment. (Socialstyrelsen 2018) This increase implies several challenges with the cost and capacity for healthcare. Introducing technology that is well-adapted, accessible and useful for the health industry could have a sincere impact on this challenge. (Wendin, Kylefors & Mjörnell 2013)

1.1.1 Industry 4.0

At present, an evolvement known as the fourth industrial revolution, or perhaps as *"Industry 4.0",* is taking place across the globe. The main attribute for this alteration is the incorporation of IoT, artificial intelligence and robotics into industries with the aim of increasing efficiency and quality. (Marr 2018) Industry 4.0 started within production and supply chain but the number of applications Industry 4.0 is used for is increasing and the concept has

broadened to new sectors, with health care included. (Koul 2022) IoT is the connection and communication of physical objects and has emerged as one of the fundamental trends underlying the digital transformation of business and economy. The benefits can be in the form of improving operations, the management of physical effects and health and well-being. (Chui, M et. al 2021) (Cardona, M et. al 2021)

Since a large part of the challenge that the development of Industry 4.0 is facing is digital competency, an overview of the current state of Sweden is of relevance. Most sectors in Sweden have a digital competency corresponding to the OECD average level. In a whole, Sweden places itself either high or around the average in all categories that are comparable internationally. (Myndigheten för tillväxtpolitiska utvärderingar och analyser 2018) Regarding the digital competence amongst healthcare providers in Sweden a study concludes that the current education provided for the use of digital tools in the workplace is inadequate and that more thorough and continuous training is needed. (Andersson & Henningstam 2021)

1.1.2 Demographic changes in the Swedish population

Economic, medical, and social advancements over the past decades have resulted in a substantial increase in life expectancy across most countries since the mid-20th century. (Harris 2022) In 1980, 13% of the population were older than 65 in Europe, today that share is 20% and it is expected to increase with 50% by 2080. (Östlund 2017) The same trend is clear when studying Sweden specifically. Life expectancy has increased substantially without interruption in Sweden for the last 250 years at a rate corresponding to two months longer per year. The proportion of people older than 65 years will be larger in all of Sweden's regions in 2040 compared to 2021's levels. (Statistikmyndigheten 2022)

The increase of people older than 80 years will be specifically large, 76%, between the years 2020 and 2030, due to the many children born in Sweden in the 1940s. This can be put in relation to the number of people of professional

age (25-65) that is expected to grow by only 9,4%. The so-called *support ratio,* which indicates how many youths and elderly a person of professional age must support including herself, is expected to increase from 1,75 to 1,84 between the years 2017 and 2040. (Prochazka 2022)

The global trend is that people are living longer lives but many countries are unequipped to deal with the new social and economic dynamics of an older population. The G20 Summit of 2019 declared aging populations a "global risk", urging member states to pursue structural policies to meet the new demands. (Harris 2022) The shrinking working-age and the aging population entails the need to adapt the public health care system to accommodate the increased demand for accessible and affordable quality health care and long-term care. The European commission means that to sustain economic growth the working-age must increase, labor-force participation rates must increase and/or productivity has to increase through technological advances and/or skills development. (European commission 2023)

1.1.3 Health care in Sweden

In autumn 2015, UN member states adopted the 2030 Agenda and the Global Goals for Sustainable Development. Goal number 3 of this action plan is to ensure healthy lives and promote well-being for all, at all ages. (Harris 2022) The health care in Sweden and its daily work capacity have in recent years become increasingly strained. It is visible in the decrease in availability and lower productivity. All the prognosis on future needs and resources for healthcare indicates that the needs will increase, and productivity must increase with it. Most of the prognosis takes its stand in the demographic changes with an aging population and the elderly's health and functionality. The population will be older and have more chronic diseases requiring treatment. (Socialstyrelsen 2018)

Statistics Sweden have highlighted that the health care in Sweden is facing a huge challenge in terms of skills supply. The Regions in Sweden currently employ 6% of the working population but need to employ 38% of the additional

working age population to maintain current staffing densities. (Spak 2022) Statistics Sweden's trends and prognosis show that today's shortage of skilled workers in health and social care will remain until 2035. (Statistikmyndigheten 2021) To be able to reduce length of care and increase productivity it is important to work preventatively with health promotion activities, structural changes and new working methods based on digitalisation. In order to realize this, health care will have to undergo extensive digitalisation where health determinants and activities are automatically measured and can be evaluated in real time with the help of medical technology solutions. (Socialstyrelsen 2018)

There is a great potential to use IoT in the human-health setting. McKinsey sees application of IoT in human-health as where the technology has the second greatest potential for value creation, after in the factory setting. (Chui, M et. al 2021) IoT in healthcare is known under the concept Internet of Medical Things (IoMT). Benefits of IoMt is that it can be used for remote medical assistance, instantaneous tracking and alerts, automated reporting and ease of healthcare research. Cardon, M. et al (2022) claim in their book Internet of Medical Things: Paradigm of Wearable Devices that the easiest and most optimal way to provide medical facilities is using a low-cost, portable wearable remote monitoring system. (Cardona, M. et. al 2021)

1.2 Purpose

The purpose of this study is to identify, describe and analyze aspects to consider when introducing IoMT-solutions into the healthcare system in Sweden.

1.3 Delimitations

The chosen country to examine is Sweden. The project's case study is limited to the healthcare domain of urinary incontinence (UI) and people seeking care for their symptoms. The complimentary literary study is limited to the scope of the findings from the case study.

1.4 Aims for the authors, academia, and industry

The authors aim to thoroughly research UI in Sweden at present and to utilize various learned theories on marketing and business in practice.

The case company will gain insights on how an introduction of an IoMT-product can be introduced to the Swedish healthcare market.

Contribution to academia will be new research on the subject of IoMT-solutions in Sweden and also a stable foundation for further projects within the same area.

The industry is to gain insights on how Industry 4.0 can affect the health segment of UI care and the healthcare system as a whole.

1.5 Structure

The report has the following structure:

Chapter 1 - Introduction - Including a background to the subject and problem statement, purpose, delimitations and aims.
Chapter 2 - Method - Description of chosen research structure, techniques, and procedures.
Chapter 3 - Theory - Description of chosen theoretical framework.
Chapter 4 - Empirics - Presentation of collected data.
Chapter 5 - Analysis - Analysis on collected data referenced to theoretical framework.
Chapter 6 - Conclusion and Reflection - Summary of findings and reflection of study

Chapter 2 - Method

The following chapter aims to synthesize the methodic structure behind the master thesis and to acknowledge all aspects of academic validation.

2.1 Research structure

The structure of the method follows that of "The Research Onion" in accordance with the authors; Saunders, M. , Lewis, P. and Thornhill, A. This model starts with the choice of a research philosophy to understand the author's point of view. After that the method of reasoning is presented and with each layer of the onion the overall method of the project is uncovered. (Saunders, Lewis & Thornhill 2009, 100-102) See figure 2.1 for visualization.

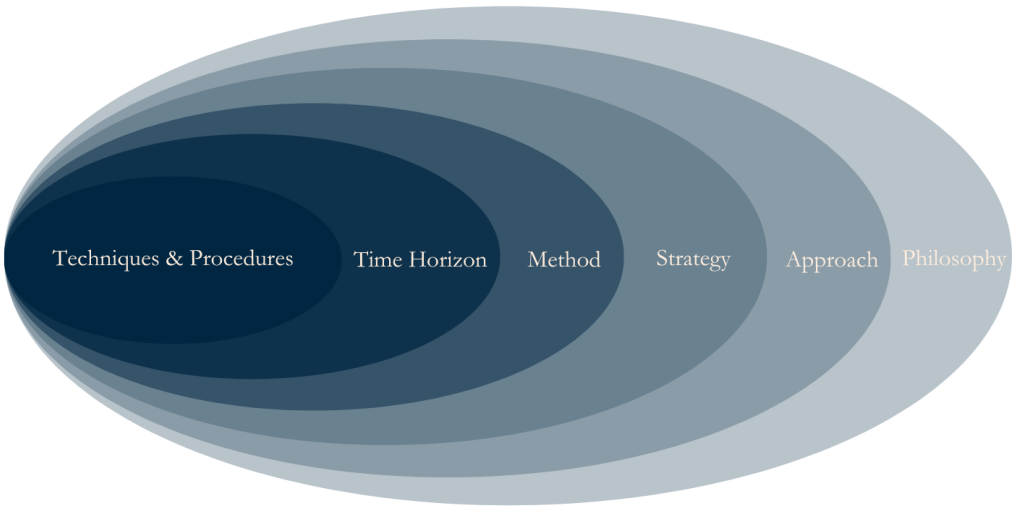

Figure 2.1 - The Research Onion (Adapted from Saunders, Lewis & Thornhill 2009, 100-102)

2.1.1 Research philosophy

Several different research philosophies exist and are in the following chapter regarded and considered by the authors of this thesis, in aim of choosing the correct way to further approach the thesis. Overarching categories within research philosophy are epistemology, ontology, and axiology. Epistemology is a branch of philosophy concerned with the study of knowledge and belief, and the methods and criteria used to acquire knowledge.
Epistemologists examine the role of perception, reasoning, testimony, and other sources of knowledge, as well as the ways in which language, culture, and experience shape our beliefs and understanding of the world. It is therefore the way of defining what is acceptable knowledge. Ontology is another branch of philosophy that deals with questions about the nature of reality and existence, meaning the way that an author regards themselves and their approach to the study. Axiology, on the other hand, is concerned with values and ethics. Axiologists study questions such as what is valuable, what is the nature of good and evil, and what is the basis of ethical decision-making. In conclusion, while epistemology is concerned with knowledge and belief, ontology is concerned with existence and reality, and axiology is concerned with values and ethics. Each of these branches of philosophy play a crucial role in understanding the world and human experience. (Saunders, Lewis & Thornhill 2009, 102-111)
The following sections will elaborate further on epistemology and ontology. As axiology covers ethical approaches it will not be covered here as this thesis is deemed to not have the need to undergo ethical trials.

2.1.1.1 Epistemology

Epistemology concerns the philosophy of what is acceptable knowledge. It consists of the different approaches namely, positivism, realism, and interpretivism, all explained below.

Positivism is a philosophical approach that emphasizes the use of empirical evidence, scientific methods, and logical positivism to gain knowledge about the world. According to this view, scientific methods can be used to explain and

predict natural phenomena and human behavior. (Saunders, Lewis & Thornhill 2009, 103-104)

The realistic research philosophy sees the world without influence from the views that the observer itself possesses. (Saunders, Lewis & Thornhill 2009, 104-105)

This philosophy emphasizes that the human being is to great extent affected by social circumstances. This means that when studying humans rather than objects the researcher is colored by the human's empathy. It can be argued that this philosophy is of great use when studying cases based on business and especially organizations. (Saunders, Lewis & Thornhill 2009, 106-107)

When regarding these different philosophical approaches, the authors deem it most appropriate to take standpoint in the perspective of interpretivism. This is because the study to be conducted is based on businesses and involves complex organizational structures. Different parties in the study will be colored by different incentives and have different opinions and depending on who the authors get in contact with, social structures such as empathy will play a role.

2.1.1.2 Ontology

Ontology is the philosophy of what approach an author has towards a study, regarding the author's own stance. The different ways of approaching ontologistically are by objectivism, subjectivism, or pragmatism.

Objectivism separates external social factors from existing social entities. It is best applicable on quantitative studies detached from social structures. (Saunders, Lewis & Thornhill 2009, 108)

Subjectivism stands in opposition to objectivism. It builds on the interpretivist approach that one must acknowledge human incentives in different situations, which is social constructivism. (Saunders, Lewis & Thornhill 2009, 108-109)

A pragmatic point of view favors the use of both qualitative and quantitative data. It is useful for solving realistic problems and not as much for finding ideal theoretical solutions. Pragmatism also recognizes that choosing one approach and sticking to it is difficult as one might need to switch between different ones over time. (Saunders, Lewis & Thornhill 2009, p. 110)

As this project will be on an actual, real-life problem, and interpretivism is already chosen, subjectivism would be a valid choice. But as the authors do not want to limit to solely qualitative data the research philosophy of pragmatism will fit the project best.

2.1.1.3 Summary of choice of research philosophy

In summary the epistemological approach of choice is interpretivism meaning that what will be acceptable knowledge will have influence from social structures. The ontological approach is decided be pragmatism, opening for switches dependent on the type of data being studied at a specific point of the project.

2.1.2 Research approach

There are two different ways to approach a research problem. Those are whether the research should use the deductive or the inductive approach. The deductive approach is closely related to positivism in terms of research philosophy and induction to interpretivism. (Saunders, Lewis & Thornhill 2009, pp 124-125) Easterby-Simith et al. suggest it is important for three reasons to decide on the research approach. First, it enables the researcher to make more informed decisions on the research design. Secondly, it helps the researcher think about the research strategies and choices that will, and will not, work for the research in question. Thirdly, the authors argue that knowledge of different research traditions enables researchers to adapt the research design to cater for constraints. (Easterby-Simith et al. 2002)

In the deductive approach a theory and a hypothesis are developed, and the research strategy is designed to be able to test this hypothesis. A deductive

approach is dominating in research in the natural sciences domain where it is important to be able to generalize the results. To generalize the research demands that the method is possible to replicate, that the selection is large enough and that the hypothesis is possible to evaluate. (Saunders, Lewis & Thornhill 2009, p. 124-125)

For an inductive approach the research process goes in the opposite direction. The researcher begins with an empirical data collection, using that to formulate a theory and a hypothesis. The inductive approach is used more in social science research. Followers of the inductive approach argue that when studying human behavior, a deductive approach is not to recommend as it enables a cause-effect link to be made between variables without an understanding of the way in which humans interpret their social world. They argue that it is more realistic to treat workers as humans whose behavior is a consequence of the way in which they perceive their work experience rather than as unthinking research objects. Another criticism is that deduction is a too rigid methodology that does not permit alternative explanations of observations. (Saunders, Lewis & Thornhill 2009, p. 125-126)

If the two research approaches are combined, it is called abductive research. It means that the researcher creates a hypothesis based on a literature review to onwards collect empirical data that the hypothesis is compared to and from that draw more general conclusions. Abductive research allows the researcher to move between theory and empirical data continuously and in an interactive process find new theories. It often starts with a real-life observation that is then combined with theory with the goals to find links and connections and in the end of the process draw new, and correct, conclusions. (Saunders, Lewis & Thornhill 2009, p. 127- 128) From a research perspective, abductive reasoning means relying on the fact that it can be favorable to make use of mixed methods data collection, i.e., combining qualitative and quantitative data. Wheeldon and Åhberg mean that this “can produce more robust measures of association while allowing that multiple path to meaning exist”. (Wheeldon and Åhlberg 2012)

For this report an abductive approach is chosen. As the authors share a pragmatic view of research philosophy, an abductive reasoning approach will naturally play a role in the creation of this master thesis. To achieve the purpose of this study, it is necessary for the authors to be able to move iteratively between theory and empirical data. Conclusions may also have to be drawn from incomplete data sets and any recommendations will be based on the best information available.

2.1.3 Research strategy

All researchers need to have a clear research strategy. Several aspects determine what research method a researcher chooses for their work. The choice of research strategy will be guided by the research question(s) and your objectives, the extent of existing knowledge, the amount of time and other resources' availability. The author's philosophical underpinnings will also affect the research strategy. The strategies to be considered for this research are experiment, survey, case study, action research, grounded theory, ethnography and archival research.

Experiment is a classic research method and highly connected to natural science, but it is also found in social science and particularly psychology. The purpose is to study causal links and answer the questions "why" and "how". In an experiment one experiment group and a test group is used. This is done to be able to control all impacting factors as carefully as possible to be able to draw generalized conclusions of the results. An experimental strategy is not feasible for many businesses and management research questions. (Saunders, Lewis & Thornhill 2009, ss. 142-144)

A second strategy is the survey strategy. It is usually associated with the deductive approach and is a popular strategy in business and management research. Using surveys enables the researchers to collect large amounts of data without demanding large economical resources. It can be used to answer the questions "who", "what", "how much" and "how many". (Saunders, Lewis & Thornhill 2009, p. 144-145)

A case study can be seen as the opposite to an experiment. In an experiment the research is undertaken within a highly controlled context. In a case study the researcher does an empirical study of a temporary phenomenon in its natural environment using several different sources. A case study generates answers to the questions “what?”, “why?” and “how?” and gives the researcher an in-depth understanding of the chosen research object. (Saunders, Lewis & Thornhill 2009, p. 145-147)

An action research strategy is an iterative process where focus is on action and change. With this strategy the question “how?” can be answered. It is based on the four steps, diagnostics, planning, action, and evaluation. (Saunders, Lewis & Thornhill 2009, p. 147- 148)

Grounded theory can be thought of as “theory building” through a combination of induction and deduction. (Saunders, Lewis & Thornhill 2009, p. 148-149) According to Goulding (2002) a grounded theory strategy is particularly helpful for research to predict and explain behavior, where the emphasis is on developing and building theory. The research process starts with collecting data and allows that to be the base for a theoretical framework. The next step is to formulate theories and predictions from observations. The theories and observations are then tested through more observations that either confirm or dispute. Based on the results of the observation in relation to the theory the process is done again. (Saunders, Lewis & Thornhill 2009, p. 148-149)

Ethnography is rooted in the inductive approach. The purpose is to describe the research and explain the social world that the research object inhabits in a way that they would have described the environment themselves. The strategy is time demanding but is good if a specific context wants to be understood on a deeper level. (Saunders, Lewis & Thornhill 2009, p. 149-150)

The last strategy in consideration is archival research which makes use of administrative records and documents as the principal source of information. It

can refer both to recent as well as historical documents. This type of data can help researchers to answer research questions that highlight issues or changes that have happened in the past. (Saunders, Lewis & Thornhill 2009, p. 150)

The research strategy chosen for this master is a case study. The purpose of this thesis requires the questions of "what?", "why?" and "how?" to be answered, which are the basic questions in the strategy case studies. Only one case company has been selected due to the delimitations of the thesis.

2.1.4 Research method

Before discussing research choices, it is important to recognize the meaning of quantitative and qualitative data. Quantitative data is numerical and can for example be collected via questionnaires. Data that classifies as qualitative is non-numeric and commonly results based on for example interviews, in the form of text, pictures or videos. For the analysis of data, quantitative analysis is for example graphs and qualitative analysis is for example categorization. When choosing research method, one may either have a mono method or multiple methods. A mono choice utilizes the combination of a quantitative data set that is analyzed quantitatively or a qualitative data set that is analyzed qualitatively. A multiple choice opens for four different combinations, as seen in figure 2.2. (Saunders, Lewis & Thornhill 2009, p. 145-147)

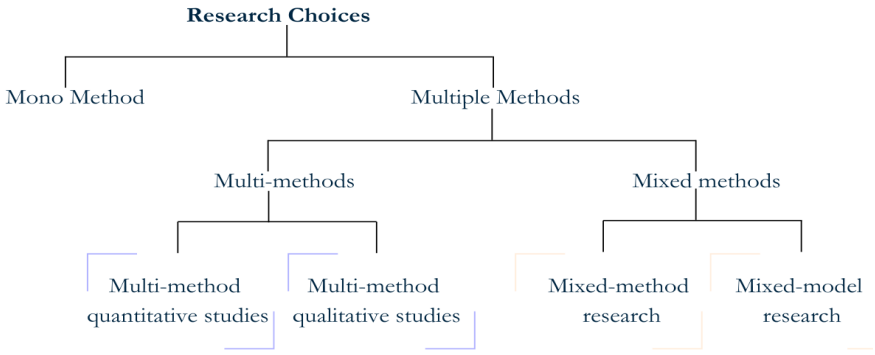

Figure 2.2 - Research choices (Adapted from Saunders, Lewis & Thornhill 2009, 145-147)

In the case of multiple methods, one might either choose multi-methods or mixed methods. By a multi-methods path one stays restricted to either quantitative or qualitative but combines different data collection and analysis methods. Mixed methods on the other hand, combine quantitative and qualitative. Mixed-method research is the case of data collection quantitatively and qualitatively meanwhile not combining analytical methods so that the quantitative data is analyzed quantitatively, respectively the qualitative data is analyzed qualitatively. The final alternative is mixed methods that combine quantitative and qualitative data collection and analysis methods. This case also opens for conversion over the data types meaning that for example quantitative data can be qualitative and qualitative data can be quantized.

Several advantages of using multiple methods exist as it can in many cases be useful to use different methods for different parts of a study. Perhaps a study fulfills its purpose by being both exploratory and descriptive, meaning both qualitative and quantitative. Another advantage of multiple methods is that it opens for triangulation that can help cancel out the disadvantages of the different methods used. (Saunders, Lewis & Thornhill 2009, p. 145-147)

In the case of this thesis the authors value the advantages of using multiple methods and aim to achieve triangulation. Therefore, different data collection methods and analysis methods will be used. Some aspects of the study will call for exploratory studies and others for descriptive, therefore both qualitative and quantitative data is to be collected. By that, the research choice will be mixed methods. As conversion of data types will be done, the final choice is mixed-model research.

2.1.5 Time horizon

When starting a project of thesis character, it is of importance to acknowledge if the study is to be cross-sectional or longitudinal. Cross sectional implies a study of the research object at a particular point of time whereas longitudinal opens for the possibility of regarding the research object for a prolonged period.

Longitudinal studies can evaluate the perspective of change over time which also affects the amount of time that the study requires. Due to the limitations of this master thesis, a cross-sectional study is the optimal choice for the practitioners. (Saunders, Lewis & Thornhill 2009, p. 148)

2.2 Techniques and procedures

In the following section the work process for this study will be described. It will report for the literature review, selection of the case study and how the data collection process was done and the analysis of the data.

2.2.1 Literature review

To create a knowledge base and in extension a theoretical model a literature review has been done. The review aimed at finding relevant and contemporary literature appropriate for this study. These frameworks and models were used to describe and analyze the product to be introduced, the end user's and the business buyer's characteristics and how they both may respond to the product as well as how the product will affect internal processes in the care chain. This created a basis for the analysis where perspectives of relevance to consider when introducing such a high-tech product, could be identified. The Lund University's search engines LUBSearch and LUBcat were used to find relevant academic literature in the domain and the search words were chosen carefully to cover as much previous research as possible. The keywords used were; principles of marketing, fundamentals of strategy, consumer buying behavior, consumer change willingness, buying decision behavior and change management.

"Subject pearl growing" was used as a search strategy to deepen the search in relevant subjects and key concepts. "Subject pearl growing" is useful in databases containing subject or keyword descriptions. By clicking on subjects or key words the searcher can find other related articles useful for the purpose of the literature search. (Lunds Universitet 2019)

2.2.2 Case product

The limitations of the master thesis project implied that one single case product is to be studied. In reference to the purpose of the thesis several demands for the case product exist. The purpose required the company to be operating on the Swedish market and to be developing or already selling products for medical use. To be able to study solutions related to the IoMT, the product had to be classified as such. The product chosen will be further referred to as Product X. The authors saw it as an advantage that the identified company was global, stable, and experienced in the industry, reliable market research data would be available. A high tech, medical solution to be used in urinary incontinence care, currently being developed by a global hygiene company from Sweden, further referred to as Company X, fulfilled all the mentioned requirements and preferred characteristics, and was therefore chosen.

2.2.3 Healthcare domain

The limitations of the master thesis project implied that one single healthcare domain was to be studied. The authors' preferences were that the area was considered an endemic disease, so that the outcome of the thesis had the possibility to improve quality of life for many people. Another preference was that treatments already exist today so that current value chains of care could be studied and current alternatives to compare with. The final preference was that the already chosen company was a valuable player on the market for the domain so that market knowledge and experience was available. This resulted in the choice of the domain of UI. Below follows a short informative piece on why UI fulfills these preferences:

UI occurs among both men and women but is more common among women and it also increases with age. 10% of all women in their forties and 25% of everyone in their eighties are suffering from UI problems in Sweden. (Nationellt kliniskt kunskapsstöd 2021) Within the elderly care special accommodation, 50-80% have problems. (Vårdhandboken 2021) The problem

is widespread classified as an endemic disease (SBU 2013) and recognized as one of Sweden's largest. (Vårdhandboken 2021)

For many, UI affects daily life. The fear of leakage results in avoiding social contexts and exercising. Even with the decrease in quality of life, many avoid seeking medical care due to the existing taboo and lack of knowledge about what help there is. (Vårdhandboken 2021) The problem is likely to be larger as only half of the women seek medical care for their UI problems. Results from the municipalities show that only half of those with leakage had their problems investigated. Lack of investigation and lack of action causes unnecessary suffering and increases the risk of complications, which in turn can lead to increased costs for society. (Socialstyrelsen 2016)

In summary, Company X was chosen as they met all requirements and so did the domain of UI. The case study will therefore be carried out on a specific high tech (IoMT) medical product, Product X, that Company X is developing as a treatment for UI.

2.2.4 Data collection

The, earlier mentioned, theoretical framework acts as a basis for what data to collect to fulfill the purpose of the thesis. Most of the theory formulates questions of qualitative nature that are most reasonably answered by primary sources in the form of interviews. This aims at the descriptive aspects of the study. For this specific thesis, interviews are a reasonable fit as several parties exist and interviews act as a viable method to collect data on their different perspectives. The interview guides formulated have been done in accordance with the methods presented in the course; MION20 Applied Business Analysis[1]. This data collection method is preferably complemented by a different type of data collection method and archival research has been chosen for that due to the thesis being done at a prestigious university (Lund

[1] Jan Bjerseth, Visiting lecturer at Production Management, Lectures in Applied Business Analysis, spring 2022

University, Faculty of Engineering, LTH) with access to valuable and most importantly, relevant, sources.

In summary qualitative data for the descriptive aspects of the study is collected by interviews and archival research for the exploratory aspects are collected by relevant documents.

2.2.5 Method for analysis

The research has been done by a case study and a single product has been used as a focal point in the analysis. Both primary and secondary data has been collected and due to that, it is important to decide on how the two different data types should be weighed against each other. In this case study it is a real case that is being studied and focus should be on the primary data retrieved from the case study. Secondary data will be used to further understand the primary data collected and to find correlations between the case study and previous studies.

After structuring the theory relevant for the problem statement into a theoretical framework, empirical data was collected. The empirical data was structured after the framework and the analysis followed the same structure and hence the analysis is based on the theory base presented in the beginning of the study.

The qualitative data will be analyzed qualitatively, and the quantitative data will be converted to qualitative data and analyzed qualitatively. This will be done by analytic reasoning, categorization, and comparison.

2.2.6 Research credibility

As the thesis is to great extent based on interviews the reliability of the study is of importance to regard. Reliability is deemed by how probable it is that the results are the same if the study is conducted a second time. The authors have to their greatest ability curated interview questions that have a minimal amount of bias to them to ensure reliability. The authors also ensured that they interviewees from all different roles involved in the care value chain to gain a

holistic view, increasing the reliability. Although, this cannot eliminate all forms of participant bias from the data collected. When analyzing the data there exists no exact way of interpretation and therefore the observer's bias, i.e. the authors, is inevitable to some extent. The authors have therefore complemented the interviews with archival research, to further ensure reliability (Saunders, Lewis & Thornhill 2009, p. 149-150)

The validity of the study is measured in how well what was supposed to be studied, was studied and that it was done correctly and controlled. The authors will ensure this by being precise in the structure of the empirical data collected and in the structure of the analysis, to ensure that it all leads to fulfill the purpose of the thesis. To ensure correct data interpretation the interviewees will have the possibility to proof-read the parts they contributed to. (Saunders, Lewis & Thornhill 2009, p. 150)

2.3 Summary of chosen research method

In summary, see figure 2.3 for visualization, the authors have concluded a research method that has its roots in a interpretivist and pragmatic philosophy. The project is then approached abductively by a case study that is done as a cross-sectional study. The research method chosen is a mixed-model research design combining both qualitative and quantitative.

First a literature review is done to construct a theoretical framework to cater to the purpose of the study. Then a case company, Company X, developing a high-tech medical product for treatment of UI is chosen as the case study object. Data is then collected by interviews, archival research, and relevant documents, and analyzed by analytical reasoning, comparison, and categorization. Reliability and validity are considered.

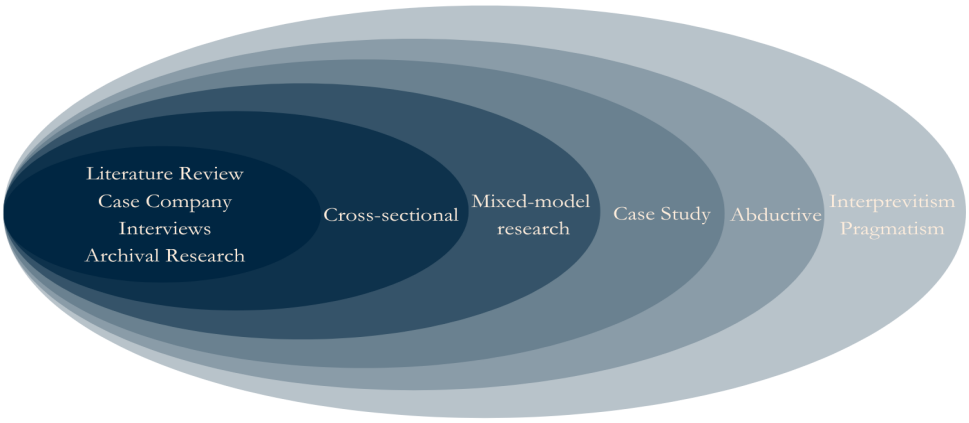

Figure 2.3 - Summary of chosen research method

The authors intended to employ a mixed-model research approach. However, during their study, it became evident that the availability of quantitative data was not as extensive as initially anticipated. Consequently, the research methodology shifted towards a mono method characterized by the exclusive use of qualitative data and subsequent qualitative analysis. The authors exerted diligent efforts to gather qualitative data from diverse sources and multiple perspectives, aiming to achieve a robust triangulation to the greatest feasible extent.

Chapter 3 - Theory

In this chapter relevant theories are introduced that together make up this report's theoretical framework. The framework will serve as a scientific basis from which the report's purpose shall be answered. Based on the problem statement in Chapter 1.2 the theory chapter has been divided into the four following areas: *what, who, where and how.* The first three parts, what, who and where are to describe the current situation and the last part, how, aims at focusing on how the change efforts needed can be implemented. This *what* aims to describe the theory of mapping out what is offered. The *who* aims to describe the theory of ways to map out who the customer is and describe its characteristics. The *where* aims to describe the theory of ways to map out the end user journey and how the end user is reached. The *how* section aims to describe the theory of ways to map out how to reach the market.

To describe, explain and analyze perspectives of relevance when introducing IoMT-solutions in healthcare in Sweden it is needed to understand the product, the end user, the business buyer and both parties' change willingness. Theories related to *marketing, industrial purchasing, production management* and *business process management* together make up the report's theoretical framework and will be presented at the end of this chapter.

3. 1 What?

This section aims to describe the theory of mapping out what is offered.

3.1.1 Kotler's three levels of a product

With the goal of satisfying a want or a need, a product is something that is offered to the market. It can be developed with the idea that it will be consumed, acquired, or used. A product can be solely a physical object or solely a service, or a combination. It can also be a place, a person, an organization or simply an idea.

To fully map out the customer value of a product a study of its three levels may be done. The three levels are core product, actual product, and augmented product, see figure 3.1. When regarding the most basic level of the product, the core product, it is referring to the main benefits with the product or the core problem it is meant to solve. The actual product is the second level and refers to five characteristics: the level of quality, product and service features, design, brand identity, and packaging. The augmented product is the final level and declares the complete product including additional services and features. This level aims to add enough to ensure that the total bundle of the product fully satisfies the customers wants and needs. (Kotler et al 2004)

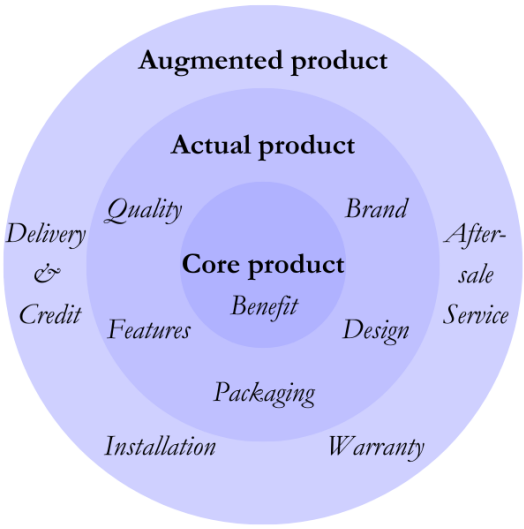

Figure 3.1 - Illustration of the three levels of a product (Adapted from Kotler et al 2004)

3.2 Who?

This section aims to describe the theory of ways to map out who the customer is and describe its characteristics.

3.2.1 The End User

This section aims to theorize a customer and the consumer market. The theory of this section is onwards going to be used to map out who will be using the product and their characteristics.

3.2.1.1 Consumer markets

The consumer market is made up of the seven billion people that inhabit this planet which comes with large variations in age, income, education level, values and preferences. For companies this implies challenges in understanding how these variations affect the consumers buying decisions and buying behaviors. The supply of services and goods has great variation and each year consumers purchase them for approximately 500 trillion SEK in Sweden. Meaning that consumers make several buyer decisions every day and companies do a lot of research to understand what they want to buy, when they want to buy it, how they want to buy it and also why they want to buy it. The reasons why are particularly hard to map out and often the consumer does not even know why themselves. (Kotler, 2012)

To start recognizing the consumer market when aiming to sell to one, it is important to recognize the customers' differences to become aware of the target audience and the different mixes of the product that they appeal to. Companies practice this to different extents meaning that some carry out mass marketing whilst others execute complete market segmentation (micro marketing). Those in between more or less fall under segment marketing.

For those who do segmentize, they study the buyer’s needs, perceptions, and buying behaviors. Then they create isolated segments that build up a whole market and adjust their offerings accordingly. Segmenting a market generates several benefits in comparison with mass marketing such as marketing efficiency, marketing effectiveness, and a chance to rule out competitors when specializing.

There is no exact way to segment a market because it all depends on the market structure, and therefore different segmentation variables weigh in differently. Although, four major variables that are commonly used in segmenting consumer markets are geographic, demographic, psychographic, and behavioral.

Geographic segmentation implies division into nations, regions, cities, or even neighborhoods. Other factors such as climate and lifestyle, weigh in in this segmentation. Demographic segmentation calls for group formations based on age, gender, family, occupation, and nationality, which are often easily measured by official statistics. This means that even when other variables are utilized to define a market segment, the demographics must be studied to determine the size of the population quota. Psychographic segmentation divides the potential buyers by social class, lifestyle or personality characteristics. Psychographics within overlapping demographic groups may vary significantly. Behavioral segmentation instead creates formations by knowledge, attitudes, or responses to a product. In this variable user status is weighed in.

As mentioned earlier these four variables do not always create a fully comprehensive market segmentation as not all relevant aspects are covered. Meaning that the application of market segmentation must be customized to the situation. (Kotler et al 2004)

3.2.1.2 Consumer characteristics

To successfully sell a product, a company needs to understand how the consumer will respond to different types of marketing stimuli, such as different product features, prices, and advertising. The model of buying behavior shows how marketing and other stimuli enter the *consumer's black box* and produce a certain response, see figure 3.2. It is crucial to understand the buyer's black box to understand how the buyer will respond to a product. Marketing stimuli, such as product, price, place, and promotion together with other stimuli, economic, technological, political, and cultural enter the buyer's black where they are turned into a set of observable responses from the buyer. The response can be

the product choice, brand choice, dealer choice, purchase timing and purchase amount.

The buyer's characteristics and the buyer's decision process itself will both affect the buyer's behavior. Characteristics of the buyer are affected by many different factors such as cultural, social, personal, and psychological factors. (Kotler et al 2004) Buying decision processes will be further elaborated in 3.4.1 and from this theory chapter the main takeaways are the buyers' characteristics.

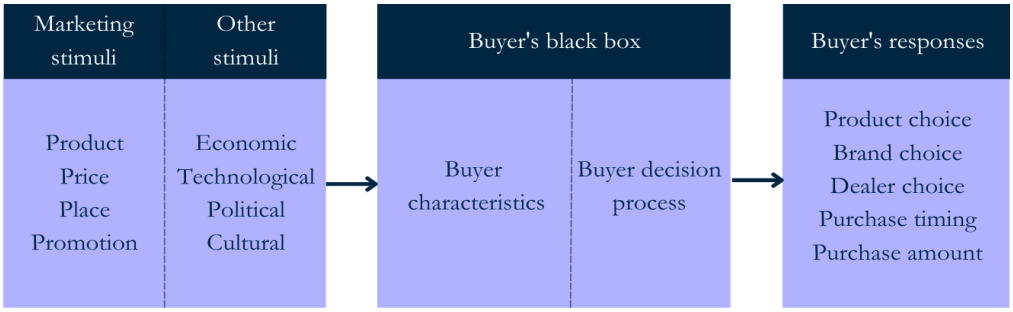

Figure 3.2 - Model of consumer behavior (Adapted from Kotler et al 2004)

The buyer characteristics in the black box can be summarized as follows: Cultural factors are the broadest and deepest values for a customer adapted by being a member of society surrounded by institutions and family. Social factors are smaller and caused by the groups of people surrounding the consumer. Personal factors are individual characteristics such as personality, age, and life cycle. Psychological factors are factors that affect the consumers level of motivation and perception.

3.2.2 The Business Buyer

This section aims to theorize a business buyer organization. The theory of this section is going to be used to map out who is involved in procurement to the health care sector in Sweden.

3.2.2.1 Industrial markets

Most larger organizations, both private and public, sell something to other organizations. In some terms the consumer and industrial market are similar, but they are different in terms of market structure, demand patterns, the buyer characteristics, and different types of buying process. The industrial market is characterized by fewer but larger transactions compared to the consumer market as well as fewer buyers making up for a larger part of the revenue. The demand is less elastic and is not as affected by price differences in the short term. The demand fluctuates more and faster.

The demand on the industrial market is derived from the demand that occurs on the end market. The demand can almost always be derived from the consumer market. When Volvo buys more steel to their factories it is due to an increased demand for cars. Industrial markets are also characterized by inelastic demand. The demand on products bought on the industrial markets is not as affected by price changes. Even though the price on leather falls, the shoe producer will probably not buy more leather than necessary if the market price on shoes doesn't decrease as well which would increase the demand. In terms of the fluctuation on demand, the demand on the industrial market tends to change more and faster than on the consumer market. A small change in the demand on the consumer market will imply a large increase of demand for a producer. (Kotler, 2012)

3.2.2.2 Business buyer characteristics

Marketers working with business-to-business sales need to understand who participates in the buying process and how the business buyer will react to marketing stimuli. Figure 3.3 shows a model over the business buyer's buying behavior. Marketing stimuli and other stimuli affect the buying organization and produce certain responses. Within the organization, buying activity often consists of two main parts; the buying center which is made up of all the people involved in the buying decision and the buying decision process itself. The buying center and the buying decision process are influenced by internal stimuli

as well. Organizational, interpersonal and individual factors all impact the buying decisions.

To show how business buyers will respond to various marketing stimuli, Kotler et al have developed a model of business buyer behavior, *see figure 3.3.*

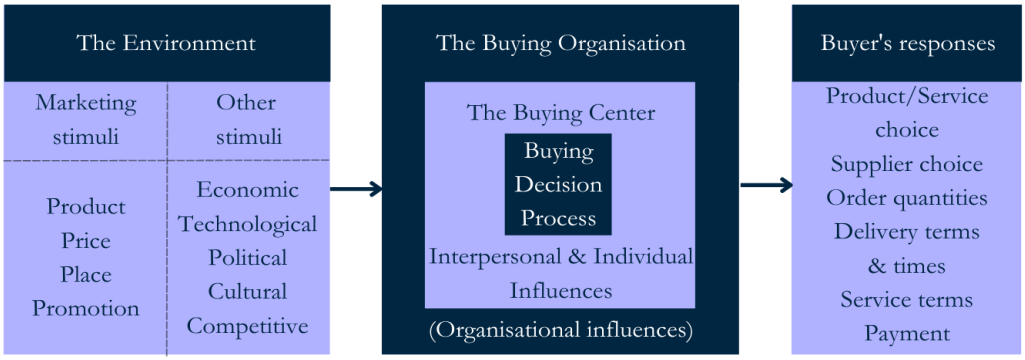

Figure 3.3 - Model of business buyer behavior (Adapted from Kotler et al 2004)

The model suggests that the business buyer can be analyzed in three levels, the buying organization, the buying center, and the buying decision process and that four questions need to be answered; What buying decisions do business buyers make? Who participates in the buying process? What are the strongest influences on buyers? How do business buyers make their buying decisions? (Kotler et al 2004) This will be further examined in section 3.4.2.1.

3.3 Where?

This section aims to describe the theory of ways to map out the end user journey and how the end user is reached.

Different process maps are used to highlight different accepts of a process, and hence several different process mapping models are presented here. They will be used to map out different aspects of the UI care processes in Sweden today. The models presented are therefore models that are today used in the healthcare industry.

A process map is a diagram that can provide a visual representation of a process flow, sequence of activities or steps that take place in process, from start to finish. Process mapping enables organizations to focus on customers, outputs, both physical and service products, boundaries, or flows. Process mapping can help organizations increase visibility and understand cross functional processes. It can also be useful for change and improvement efforts as well as education and training. Process modeling in business is common and used for efficient increases in quality by identifying bottlenecks and resource, time, and cost allocation.[2]

Different process mapping can be used to visualize different aspects of more complex processes. In the healthcare industry modeling is not as widespread. To close the knowledge, gap the authors of the article, *Health care process modelling: which method when?* Jun et al. aimed at summarizing different models used in the healthcare industry and ended up with flowcharts, swim lanes, state transition diagrams and communication diagrams. The following process map figures all use the discharging of a patient as an example. (Jun et. al 2004)

Flowcharts are very widely used to describe the sequence of activities as figure 3.4 shows. They are considered particularly helpful in understanding the overall sequence of care processes.

[2] Dag Näslund, Senior lecturer in Engineering Logistics, Lecture in Business process management, spring 2022

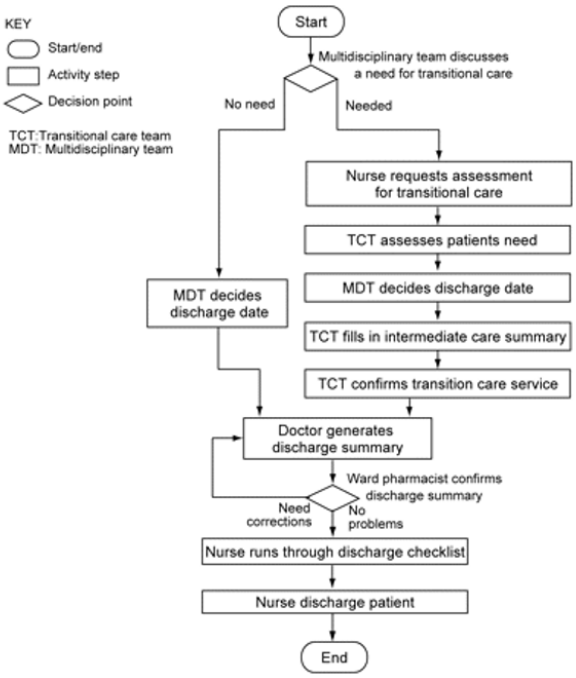

Figure 3.4 - Flowcharts (Jun et. al 2004)

Swim lane activity diagrams are designed to show a sequence of activities that have differing responsible roles. The design then arranges activities according to responsibilities, see figure 3.5.(Jun et. al 2004)

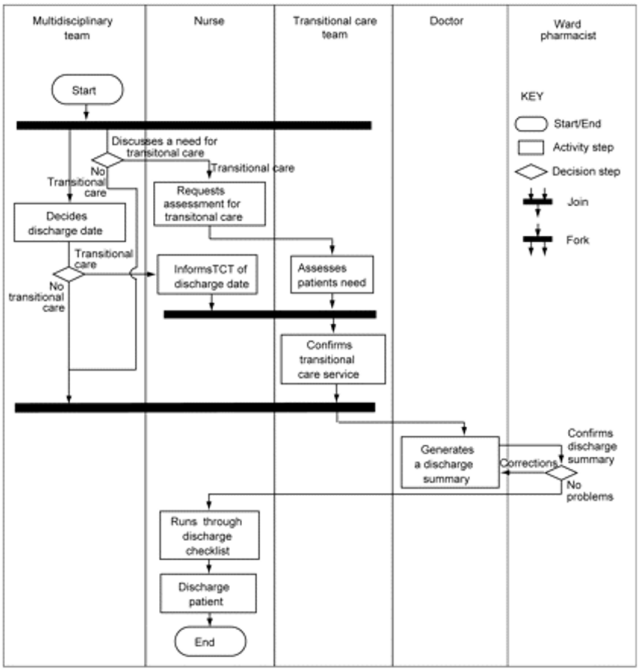

Figure 3.5 - Swim lane activity diagram (Jun et. al 2004)

State transition diagrams were initially created to depict the changing behavior of a system over time by presenting its states (nodes), transition conditions (text between nodes with underlining), and transition actions (text between nodes without underlining). To utilize this concept in health care processes, the states of the system are defined as patient-centered states such as the patient's physical condition, location, and information status. Figure 3.6 depicts a state transition diagram. (Jun et. al 2004)

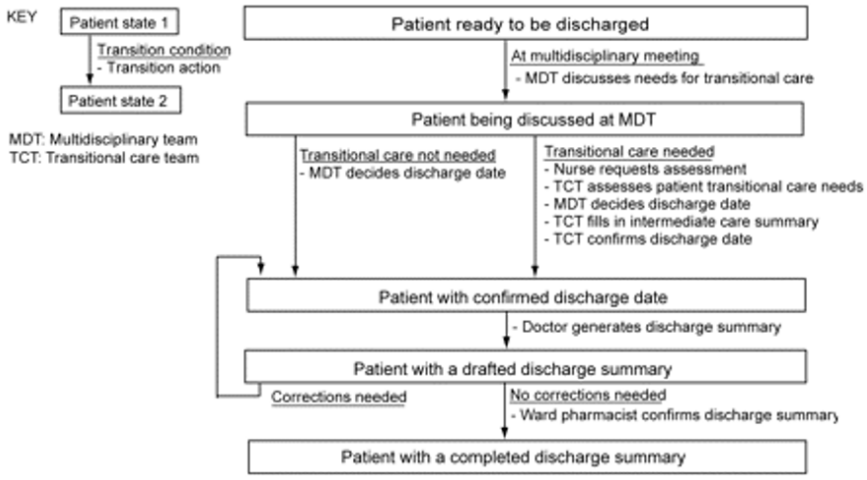

Figure 3.6 - State transition diagram (Jun et. al 2004)

Communication diagrams show interactions of materialistic type or informative type, between stakeholders. They are considered particularly helpful in understanding interactions between trusts, departments, teams, and individuals as shown in figure 3.7. (Jun et. al 2004)

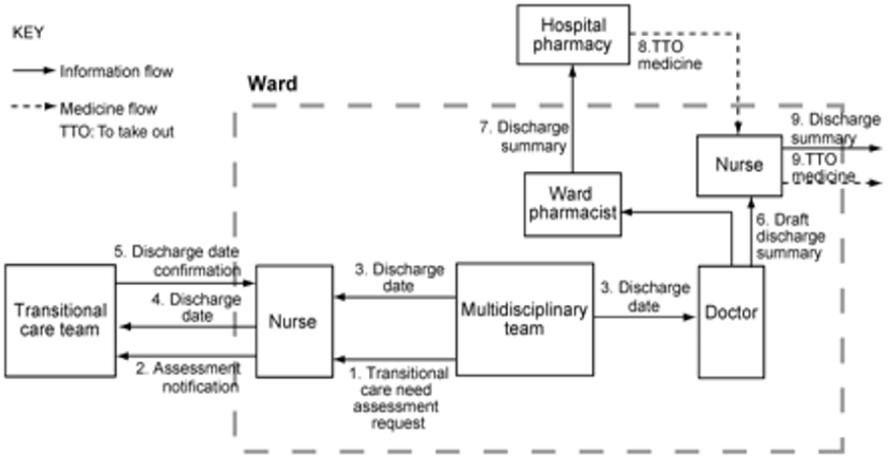

Figure 3.7 - Communication diagram (Jun et. al 2004)

3.4 How?

This section aims to describe the theory to be used to understand how the end consumer and the business buyer make their buying decisions.

3.4.1 The end consumer buying behaviors, decision processes and change adaption

This section aims to describe the theory of consumer behavior, decision processes and how individuals respond to change.

3.4.1.1 End consumer buying behaviors

For marketers to have success it is important to create products that appeal to customers and know who to target. The customer's decision making is complex in its structure and is influenced by various factors, such as influence from others and culture. Although companies cannot change how and why customers make their buying decisions, they can use their understanding of them to shape successful product offers. It is important to understand that depending on what the consumer is looking to purchase there are different types of consumers buying behaviors.

Complex buying behavior often occurs when the product to be purchased is characterized as risky, expensive, or highly self-expressive. For these cases the buyer wants to research the product category and it is important for companies to ensure that the information is easily accessible. Otherwise, there is a risk that the product is rolled out simply because it was hard to find information. Companies also must ensure that the acquaintances a person might have in connection with the product, for example with sales executives, are positive.

A behavior that also can occur when purchasing something characterized as risky, expensive, or highly self-expressive is the dissonance-reducing buying behavior. The difference from complex buying behavior is that the distinctions between brands from the customer's point of view is hard to see. These companies have an important role of after-sales marketing to ensure the

customer feels they made the correct decision, otherwise they might experience post-purchase dissonance.

Habitual buying behavior is when consumers show low levels of involvement and there is little differentiation between the brands. A product like this is for example salt. The buyer develops a habit for which salt to buy and seldom after-evaluates the decision. Marketing for these types of products should be based on simple conditioning theory that states that a consumer will choose what they are familiar with.

Variety-seeking buying behavior is the case when the products have low consumer involvement, but the customer still has strong opinions about the different brands. This causes consumers to often switch brands for the sake of switching and gaining variety, and not necessarily due to dissatisfaction. Marketing effectively through these types of segments depends on the company's market position. The market leader should for example make up as much shelf-space as possible and competing companies should encourage variation by for example deals. (Kotler et al 2004)

3.4.1.2 End consumer buying decision process

For further success it is helpful for companies to understand how the customer makes a purchase decision. With this information they can further develop the offer to ensure a purchase is made. The following figure, figure 3.8, illustrates the different steps in a typical consumer buying decision.

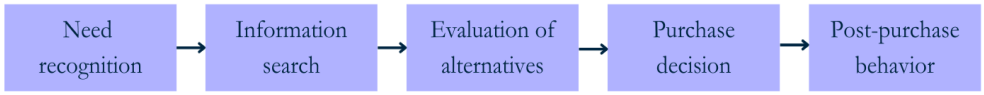

Figure 3.8 - Consumer buying decision (Adapted from Kotler et al 2004)

The need for recognition is the first step in the consumer buying decision process. This is when the customer recognizes a gap between one's current state and the desired one. This is triggered by stimulus that can emerge internally, such as hunger and thirst, or externally. External stimuli are the channel for

companies. They need to collect information on which stimulus that raise need recognition for their developed product and incorporate this to the target group's life. External stimuli for humans are often effective by visual representation or by smell.

Information search is the next step and the extent of it depends on the consumer's drive. The buyer can either have a passive or active research behavior. Either the consumer simply enters a state of heightened attention and is attentive to information or they actively search for information about the product. The information sources can be personal, commercial, public, and experiential. The marketers can control the commercial sources and ensure that these are correctly formulated and targeted. The companies need to ensure that they know which sources of information the customers value the most.

Evaluation of alternatives is the process of how the customer values alternatives. First, the customer sees the product as a bundle of different features that can in some way satisfy the need. The customer also looks at the benefits from the products and evaluates how they weigh in comparison with other alternatives. The customer then attaches different levels of importance to the different attributes of the product and some of these can be salient, meaning that the customer thinks lower of this attribute but is affected by commercial sources to prioritize it higher. Marketers should, although focus on actual importance of attributes rather than salient attributes and ensure that attributes that are easily forgotten are communicated effectively to the customer. The customers brand belief ways in after thus and then each attribute of the product are assigned a utility degree. The ideal product can now be found as the combination of attribute levels with the highest utility. Finally, the consumer ways in the brands different ratings on the different attributes, and from there the expectancy value model can be laid out. This model can, with help of all the above-mentioned evaluations, calculate the product decision that a customer might make.

When the alternatives are evaluated the attitudes of others and unexpected situational factors can still come in the way of the purchase intention and purchase decisions from being the same. The customer's perceived risk of the purchase, e.g the price, can influence the customer to change the decision (compared to the intention), postpone or avoid the purchase. Marketers must understand the perceived risk factors and supply information that can out way those.

To keep customers and to gain new customers, customer satisfaction is necessary. The marketers must follow up the satisfaction of the original need and by that gain knowledge of how well they are doing and recognize opportunities for improvement. This post purchase behavior is not to be underestimated. (Kotler et al 2004)

3.4.1.3 End consumer change adaption

The figure below, figure 3.9, illustrates five different identified customer groups in terms of adoption rate of new technology. The distribution is approximately equivalent to that of the standard deviation.

From left to right the group divide themselves by their will to adopt new technological solutions meaning that the far-left group, innovators, are technological enthusiasts and likely to invest first. They are important to win over, even though they might not be willing to pay a lot, as they offer reassurance for further customers. The far-right group, laggards, are skeptic and often not even worth pursuing. Although their skepticism can act as valuable feedback on the technology.

There is a gap in the technology adoption life cycle in between the early adopters and the early majority that is known as “The Chasm”. Crossing the chasm opens to the mainstream market and is important to do for market success. The problem is that customers mainly trust those in their own group and if they have not adopted yet then the will for them to do it themselves is low. There is therefore a marketing challenge for companies to break into the

early majority group. This challenge is solved by targeting customers in the early majority to gain the other customers', in the early majority's, reassurance. (Sridharan. M 2017)

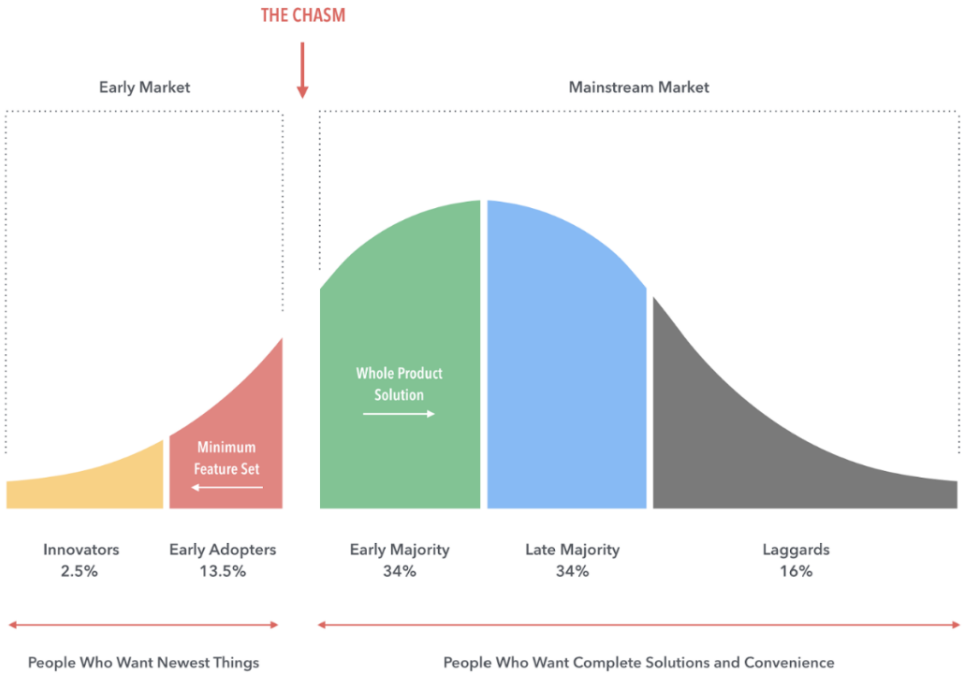

Figure 3.9 - The Technology Adoption Life Cycle (Sridharan. M 2017)

When launching a new, improved product as a substitute to an already existing solution the launch is not always as successful as the innovators might think. When studying a customer's willingness to replace it, it is important to understand the psychology behind these decisions of so-called "eager sellers and stony buyers".

When a product implies that the customer must change a behavior it comes at a psychological cost. This means that while customers overvalue the benefits of the product that they currently possess, developers overvalue the benefits of their innovations. Studies show that the mismatch ratio is a factor of 9, 3 times

overvaluation from the customer's side and 3 overvaluations from the developer’s side.

To help solve this dilemma, the authors of the article “eager sellers and stony buyers” have developed the following matrix, see figure 3.10. The developer side can from that information, consider the customers perception of the replacement decision. By that, they can manage the product offer to appeal to customers.

If the product implies a high degree of behavior change then the company can either be patient and wait for customers to ease into using the new product or ensure that the benefits of the new product are more than 9 times better than what it will be replacing. Companies are in general advised to aim for 10 times improvement, which is generally an uncommon result. Another way around is to develop products that are behaviorally compatible. These solutions require creativity. An example is Toyota who wanted to sell electric vehicles but understood that the behavior changes in terms of charging etc. would be regarded as losses for the customers. The benefits would not out way the losses. They therefore created the hybrid vehicle that let the customers keep the benefits of a regular combustion car and decrease their gas consumption. This vehicle therefore became the first fuel-alternative car to become widely popular and accepted in the US in 2005. (Gourville, J 2006)

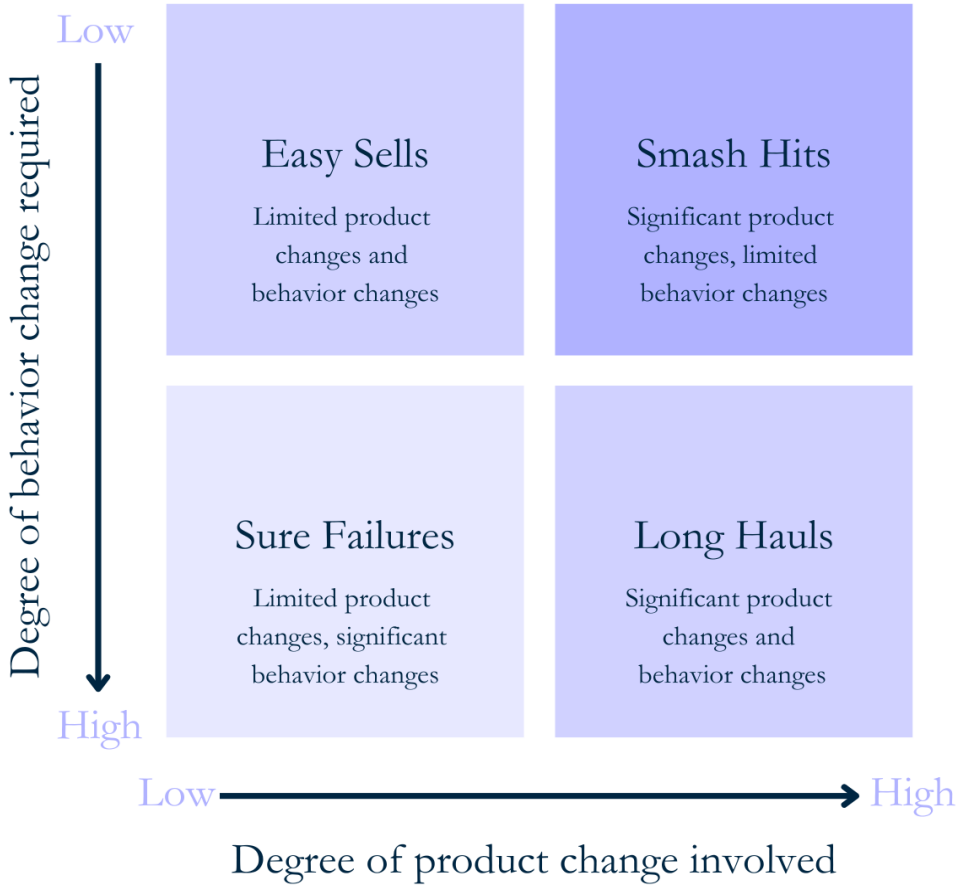

Figure 3.10 - Capturing value from Innovations (Adapted from Gourville, J 2006)

3.4.2 The Business Buyer

This section aims to describe the theory of business buyer behavior and how organizations respond to change. The theory of this section is going to be used to map out the public procurement process in the healthcare industry in Sweden and to understand how procedures in the healthcare industry are affected by new solutions.

3.4.2.1 Business buying decisions

Business buyers usually face more complex buying decisions compared to consumer buyers. They involve large sums of money, complex technical and economic considerations, and the amount of people involved is larger. The process tends to be more formalized with detailed product orders, supplier searches and formal approvals. The buying party might also have policy manuals that detail the purchase process. The following section presents four questions about the business buyer behavior a marketer needs to understand.

3.4.2.1.1 What buying decisions do business buyers make?

The business buyer must make several decisions when purchasing. The number of decisions depends on the type of buying situation. There are three main types of buying situations, see figure 3.11.

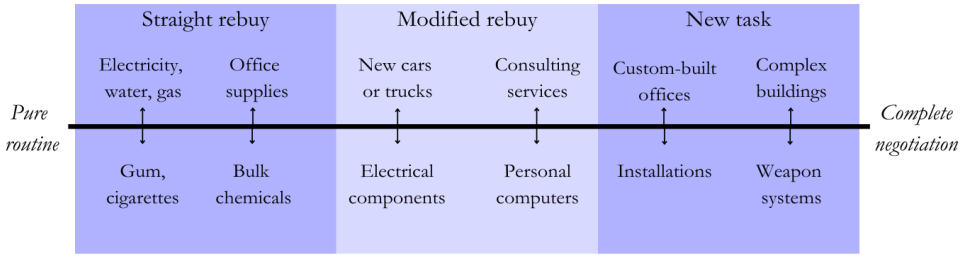

Figure 3.11 - Three main types of buying situations (Adapted from Kotler et al 2004)

At one extreme is the straight rebuy, a routine decision. Based on past buying satisfaction the buyer simply chooses from the supplier on its internal list. Suppliers on the list try to maintain product and service quality. Suppliers wanting to be considered, try to offer something new or exploit dissatisfaction. They aim to start with a small order to over time increase the purchase share over time.

At the other extreme is the new task, which may call for a thorough research process. The risk is larger hence a larger number of decision participants will be involved and there will be a greater effort to collect information. The new-task situation is the marketer's greatest opportunity and challenge. The marketer tries to reach as many key buying influences as possible, but also provide help and information.

The modified rebuy is found in the middle of the scale. The modification of the product specification can involve price, terms or suppliers. The time spent on researching and the number of people involved will be in between the other two types. Suppliers not on the buyers "list" sees this as an opportunity to gain new business. (Kotler et al 2004)

3.4.2.1.2 Who participates in the buying process?

The decision-making unit, the buying center, of a buying organization includes all the individuals and units that participate in the business decision-making process. The following roles can be identified

Users- Members of the organization who will use the product or service.

Influencers- People who can affect the buying decision. They define specifications and provide information for evaluating the different alternatives. Technical personnel are often particularly important influencers.

Buyers- These are the people who formally have the power to select the supplier and arrange terms of purchase. They play their most important role in selecting vendors and in negotiating.

Deciders- They have formal or informal power to select or approve the final suppliers.

Gatekeepers- People who control the information flow between stakeholders. Purchasing agents often have authority to prevent salespersons from seeing users or deciders.

In an international comparison of the United States, Sweden, France and Southeast Asia, Sweden has the highest team buying effort. Swedish firms depend on technical staff, both their own and suppliers to a larger extent than the firms in other countries. (Kotler et al 2004)

3.4.2.1.3 What are the strongest influences on buyers?

Business buyers are influenced by several factors when making their buying decisions. Various groups of influences have been identified by Kotler et al; environmental, organizational, interpersonal, and individual, see figure 3.12.

Environmental factors relate to the current and expected economic environment, such as level of primary demand, the economic outlook, and the cost of money. Culture and customs can have a strong influence as well.

Organizational factors impacting are internal objectives, policies, procedures, systems, and structures. Examples of this can be who and how many have been involved in the buying purchase, what are their evaluative criteria as well as what are the company's policies and limits.

The business marketers can find it difficult to decide what kind of interpersonal factors and group dynamics enter the buying princess. Interpersonal factors are often subtle and business marketers need to understand these factors and design strategies to take them into account.

Each participant also has their own personal motives, perceptions, and preferences. These individual factors are affected by personal characteristics like age, income, education, risk averseness and professional identification. (Kotler et al 2004)

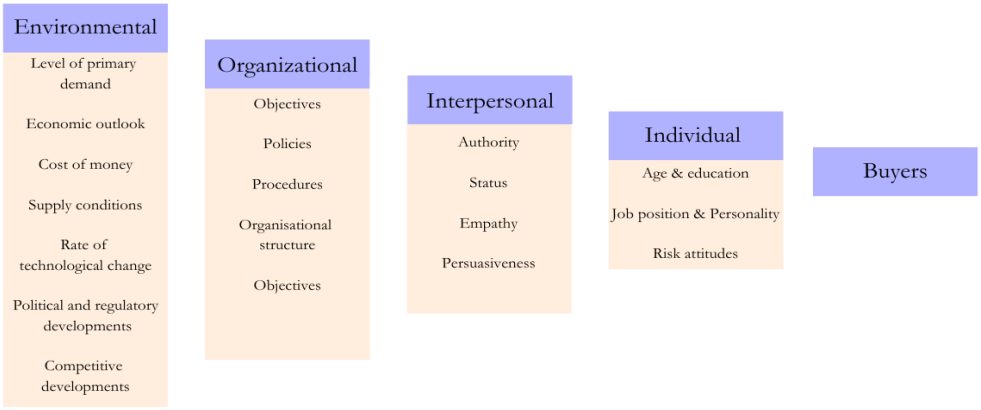

Figure 3.12 - The main influences on buyers (Adapted from Kotler et al 2004)

3.4.2.1.4 How do business buyers make their buying decisions?

Kotler et al. identifies eight stages of the business buying process, see figure 3.13. For modified rebuys or straight rebuys, buyers may modify or skip some of the stages. (Kotler et al 2004)

Stages of the buying process	Buying situations		
	New task	Modified rebuy	Straight rebuy
Problem recognition	Yes	Maybe	No
General need description	Yes	Maybe	No
Product specification	Yes	Yes	Yes
Supplier search	Yes	Maybe	No
Proposal solicitation	Yes	Maybe	No
Supplier selection	Yes	Maybe	No
Order-routine specification	Yes	Maybe	No
Performance review	Yes	Yes	Yes

Figure 3.13 - Eight stages of the buying process (Adapted from Kotler et al 2004)

3.4.2.2 Stakeholder mapping

After identifying the stakeholders, the next step is to map and categorize them. Stakeholder mapping is a process that involves analyzing the stakeholders based on their level of power and interest in the organization's activities. By mapping the stakeholders, organizations can identify which stakeholders are most important to their success and develop appropriate strategies to engage with them effectively.
Once the stakeholders are categorized, organizations can develop tailored strategies to engage with each group and manage their expectations effectively. Overall, stakeholder mapping is an important step in developing a successful business strategy. By understanding the needs and interests of stakeholders, organizations can create strategies that are more likely to be successful and build positive relationships with their stakeholders.

In the book "Fundamentals of Strategy," Johnson et al. discuss the importance of stakeholder mapping in developing a successful business strategy. They emphasize that understanding the needs, interests, and power of various stakeholders is critical to achieving organizational goals and maintaining positive relationships. The authors suggest that stakeholders can be mapped based on their level of power and interest in the organization's activities, see figure 3.14. This mapping can help identify key stakeholders who need to be engaged and managed closely, as well as those who can be managed with less effort. Additionally, the authors recommend considering the potential impact of stakeholders' actions on the organization and developing strategies to mitigate any negative effects. Overall, Johnson et al. argue that stakeholder mapping is a vital tool for creating a comprehensive and effective business strategy. By considering the needs and interests of all stakeholders, organizations can develop strategies that are more likely to be successful in achieving their objectives and building positive relationships with those they interact with. (Johnson 2015)

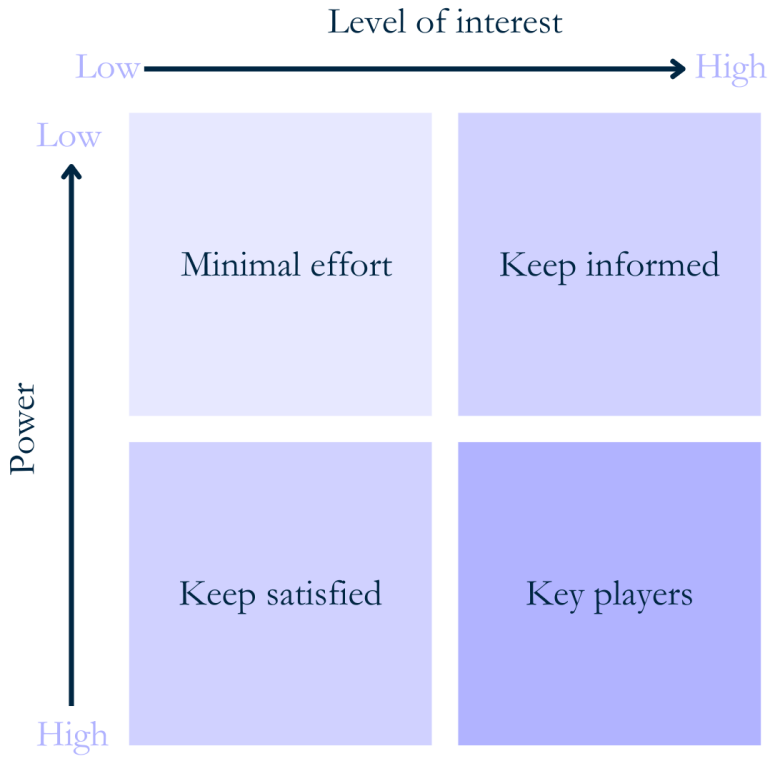

Figure 3.14 - The power/interest matrix (Adapted from Johnson 2015)

3.4.2.3 Change management

A definition of change management is “the application of a structured process and a set of tools for leading the people’s side of change to achieve a desired business outcome; it is both a process and a competency”. (Galli 2018) There are two fundamental goals with most transformations: Increase revenue/profits or decrease costs as well as become more effective or efficient. (Kotter 2014) Johnson et al. identifies four different styles of managing change. An educational approach involves the explanation of the reasons for and means of strategic change. Participation in the change processes is the involvement of those affected by the change in the change agenda, for example letting them be a part of the decision-making process, setting priorities and drawing up action plans. Using an intervention style means coordination of and having authority

over processes of change by a change agent who delegates elements of the change process. Direction involves using personal managerial authority to establish a clear strategy and how the change will happen. Coercion is the most extreme form of direction. This is the explicit use of power and may be necessary if the organization is facing a crisis. (Johnson 2015)

Several articles from academia and reports from consulting firms have tried to define critical success factors for change management. (Näslund 2013). In the McKinsey&Company survey *How to beat the transformation odds* it is concluded that no single action explains the difference between transformational failure or success, implying that the more action an organization takes, the more likely it is that the transformation succeeds. However, some actions have a larger impact than others. *Communication* is the one action contributing the most to a transformation's success. Companies where the senior managers communicate openly and across the organization about the transformation's progress are 8 times more likely to report a successful transformation than when not taking this action. *Lead, don't manage* is also highlighted as an important mantra. Leadership matters as much during a transformation as it does in the company's day-to-day work. Transformational efforts cannot be delegated to a project-management office or central team while executives carry on with business as usual. *Choosing the right people and empowering them* is also of importance. Companies must think about the role the employees play in the change effort. By allocating enough employees and the right ones, chances for the change effort to succeed are increased. *Prepare for continuous improvement* is also highlighted by the surveyed companies as relevant. 40% of the surveyed companies responded that they wish that they had spent more time thinking about how their organizations would continue to improve. (Jacquemont et al. 2015)

Näsund et al. mean that an organization needs to prepare for change. A lack of change readiness can be due to poor understanding of the change impacts, limited focus on employee engagement in planning and inadequate planning processes as well as lack of appropriate organizational diagnosis. To improve

change readiness, organizations need to work with the purpose of the change effort and define clear goals, identify the reason behind change, establish the need for change and develop a sense of urgency. The issues of management support and aligning the change effort with the overall strategy, project management and training as well as the importance of organization culture, is highlighted. Companies often don't spend enough time or resources on the human factors in change efforts, especially when it comes to building the right company culture. (Näslund & Norrman 2022) See the following table, table 3.1, for a summarization of the identified critical success factors for change management.

Table 3.1 - Summary of critical success factors for change management

Strategy alignment
Change purpose
A sense of urgency
Communication
Senior management support
Project management
Organization culture
Training

3.4.2.3.1 Process change

In the end, strategies are delivered through the day-to-day processes and routines of the operational change. Strategic change can therefore be considered in terms of re-engineering of organizational processes. (Fundamentals of strategy). Managing a process means transforming inputs into outputs, adding value for a customer. It emphasizes how work is done and involves having a system view where the entire process is managed. Process management often

involves making sure the process is both efficient and effective. Efficient as in utilizing resources, people, machines, assets, time, and money, with minimum waste while producing the desired effects or results and effective as in how well customer expectations are met and how responsive the process can be to customer needs.[3]

3.5 Summary of theoretical framework

The framework will serve as a scientific basis from which the report's purpose shall be answered. The master thesis theoretical framework is made up of four main areas: what, who where and how. The following section aims to demonstrate the relevance of these four areas in relation to the master thesis's purpose.

To describe, explain and analyze perspectives of relevance when introducing IoMT-solutions in healthcare in Sweden it is needed to understand the product, the end user, the business buyer and both parties' responses to change and their willingness to change. With the aim to understand the product the framework *Kotler's three levels of product* will be used to describe and analyze the product. The analysis of "the who" will be divided into two parts, the end user and the industrial buyer. Theory about their different market characteristics and ways to segmentize it as well as buying behavior characteristics are presented. This will enable identification of the end user and the business buyer as well as an analysis of how the end user and the business buyer might respond to a new high-tech product within the healthcare sector. Theory about processes will be used to map out how a patient moves from problem recognitions to solution implementation. This will enable a comparison between the current process and a potential new one using the new solution. The behavior changing aspect is a crucial aspect of this report and hence the theoretical framework has its focus on the *how.* The theory will enable an analysis on the buying and decision-

[3] Dag Näslund, Senior lecturer in Engineering Logistics, Lecture in Business process management, spring 2022

making behavior on both an individual level and on an organizational level. Theories to analyze change willingness on both individual and organizational level, with a focus on processes change, are therefore introduced.

Together, these areas form the theoretical framework of the thesis will enable an understanding of how a new high-tech solution might impact the individual, the organization and their processes. Figure 3.15 shows how the four aspects interact and create the theoretical framework of the thesis.

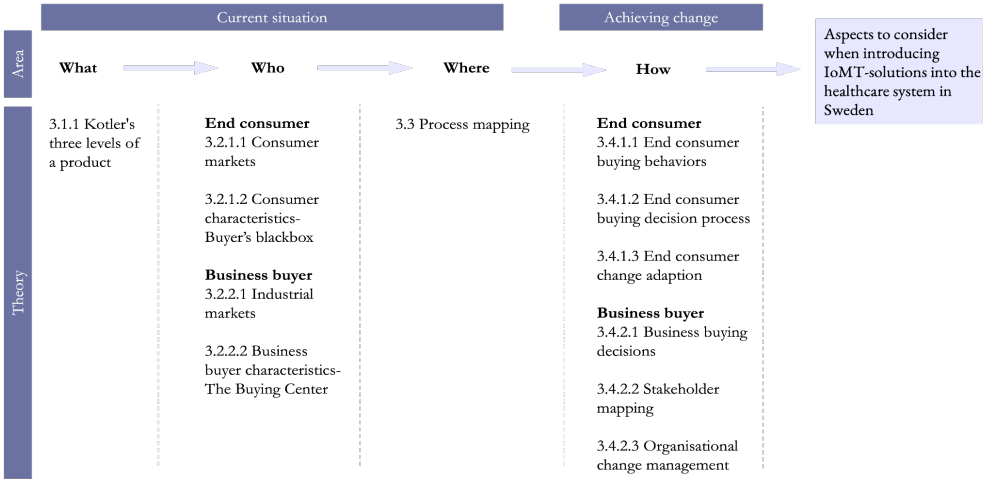

Figure 3.15 - Summary of the theoretical framework

Chapter 4 - Empirics

4. 1 What is the case product?

The case study in this report will be on an ultrasound device for continuous bladder monitoring to prevent and treat UI, in both healthcare and home environment. The product falls under the category of medical technical (MedTech) devices as the definition of a MedTech device is a device, instrument, apparatus, software, implant, reagent, material, or other article which according to the manufacturer is intended, either separately or in combination, to be used on humans for one or more of the following medical purposes, namely: diagnosis, prophylaxis, monitoring, prediction, prognosis, treatment, or alleviation of disease. This definition is a translated version of the definition according to the Health and Social Care Inspectorate (IVO). (IVO n.d.)

Product X specifically will belong to the category of IoMT. In the literature there are many definitions for the IoT. In general, it can be said that IoT implies a world where everything, houses, home appliances, cars, urban furniture, and industrial machinery are connected to the Internet at any given time, creating real-time data that facilitates decision making, offering the user comfort while saving time and money. Some characteristics that identify IoT are; the actual "thing" equipped with sensor and actuators, connectivity enabling communication and integration using etc. WIFI, WiMAX, Bluetooth and LoRa, the data obtained is IoT's value and is enhanced using collected data and last characteristic with autonomy making the devices able to carry out tasks without intervention of humans. As mentioned in section 1.1.3 IoT used in a medical setting can be used for remote medical assistance, instantaneous tracking, and automated reporting. Product X can with all the above in mind therefore be classified as an IoMT solution. (Cardona, M et. al 2021)

4.1.1 Kotler's three levels of a product

4.1.1.1 Core product

The main purpose of this product is to continuously measure the amount of urine in the bladder. The problem that it is meant to solve is to prevent involuntary urine leakage. [4]

4.1.1.2 Actual product

The actual product is a wearable ultrasonic bladder sensor connected to a smartphone and/or a smart watch using Bluetooth. The product's hardware is a device attached to the user's body, specifically on the lower stomach where the bladder is located, using double-sided adhesive tape in combination with ultrasound gel. The device is 75x61x14 mm. Through ultrasound technology it measures the level of urine in the bladder and sends information to an app. The device sends the user signals in the form of vibrations and the app sends push notifications when the user's bladder is almost full, and voiding is needed.

The product package includes ultrasound gel to enable the ultrasound transmission into the body, adhesive patches to attach the sensor to the body, a charger, and a smaller bag to carry the product in when not in use, and a user manual.[5]

4.1.1.3 Augmented product

To simplify the use of this product, augmented features offered are that the app can guide the user when attaching the device for the first time with images. The app will tell the user when the device is in a position where it can sense as well

[4] Product X Developer and Product X Owner at Company X, Interview via video call, 8 February 2023

[5] Product X Developer and Product X Owner at Company X, Interview via video call, 8 February 2023

as measure the bladder. In the app the user can also add additional information relevant to the user such as notes about a urine leakage.[6]

4.2 Who is the end consumer and who is the business buyer?

4.2.1 The End Consumer

Description of the end consumer

4.2.1.1 Characteristics of the consumer market

Description of the consumer market in general (UI patients) and in specifics (Patient segmentation).

4.2.1.1.1 UI patients

As the chosen market segment for this case study is patients with UI symptoms, the following section will briefly cover the physiological aspects involved, with the aim of a broader understanding for the reader. The following information on patient segments is based on information from Company X, specifically a nurse working for the company who has competencies from Swedish care and current knowledge on the UI situation in Sweden and globally.

Globally, more than 423 million people suffer from UI and the prevalence of it increases with age. The International Continence Society defines UI as “The complaint of any involuntary leakage of urine” and since 1998 the World Health Organization has classified it as a disease. For further understanding of the disease, individual circumstances such as type, severity, frequency, and impact on quality of life, must be considered.

[6] Product X Developer and Product X Owner at Company X, Interview via video call, 8 February 2023

During healthy conditions the urinary system exists to store urine and ensure emptying of urine at a convenient point of time. Urine is produced in the kidneys when blood is cleaned from waste products of metabolic processes. When urine leaves the kidneys via the ureters it enters the bladder which is a muscular sac. For an adult, 1-2 liters of urine is produced every 24 hours and micturition happens 4-8 times during that period with 300-500ml of urine at time.

The bladder functions with the help of pelvic floor muscles that support all the organs above it, see figure 4.1. Men have two passages through the musculature whilst women have three. The pelvic floor muscles normally wrap quite firmly around these holes to keep the passages shut.

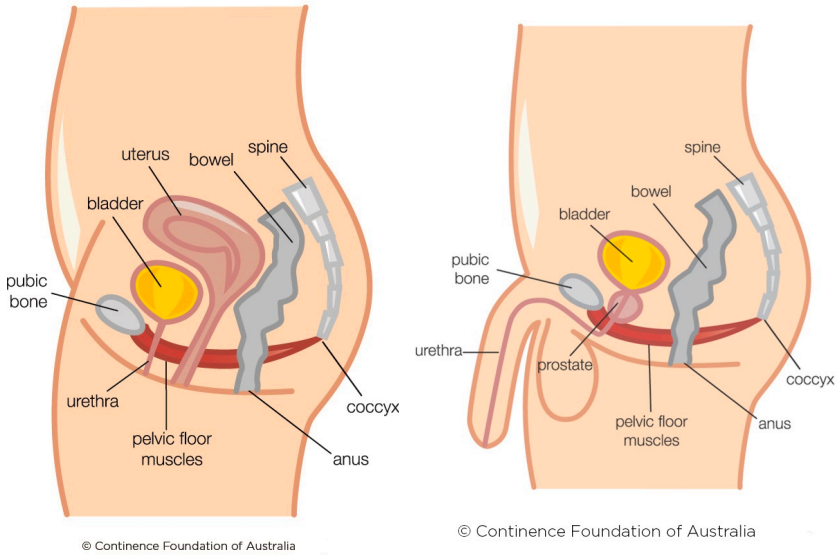

Figure 4.1 - Muscles around bladder (Continence Foundation of Australia 2019)

The urinary system is heavily integrated with the nervous system and has a complex way of working. To simplify one can, say that as the bladder becomes full, nerve receptors in the bladder wall send signals which travel up the spine.

The Pontine Micturition Center (PMC) in the brain receives the signals that emptying of the bladder is needed. A conscious decision is then made whether it is a convenient time now or if the bladder should store the urine for longer. When the conscious decision is to empty, the sphincter opens and the bladder muscle contracts, emptying the bladder. The bladder stays relaxed and sphincters and pelvic floor muscles keep tight to close the urethra. See figure 4.2.

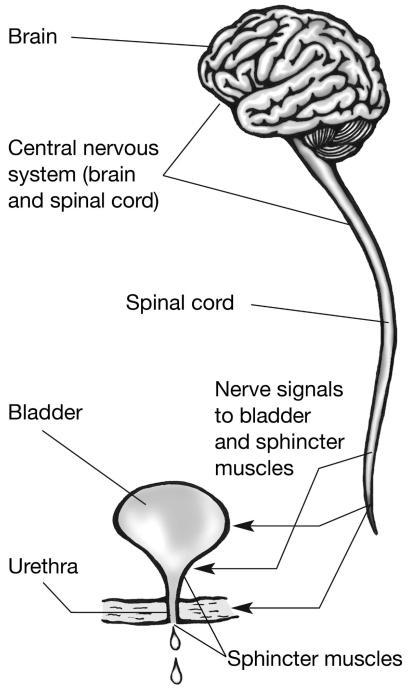

Figure 4.2 - Urinary system (NIDDK 2021)

In the pathological situation, UI types have different prevalence in men and women due to anatomic differences. When women go through menopause changes happen in the urinary tract and for men the changes are caused by the growth of the prostate that occurs with age. Different types of UI can be developed by these causes, but they can also occur due to other reasons and do

not necessarily have to be because of age, for instance in children, but the risk inevitably increases with age. [7] The main types of UI is presented below:

Stress urinary incontinence (SUI)
Stress urinary incontinence is defined as the complaint of involuntary leakage of urine due to any form of strain, such as sneezing or coughing. It can also be a leakage that occurs during physical activity. It normally begins with a few drops defined as “light leakage” and can then develop and become more severe.

The cause of this is that the bladder’s closure muscles cannot contract to prevent leakage and it affects everyone under sufficient stress. Other causes can be consequences from pregnancy/childbirth, genetics, overweight, chronic constipation, prostate surgery, deformations, neurological dysfunctions, and strain on pelvic floor muscles and lack of exercise.

Urge urinary incontinence (UUI)
Urge urinary incontinence is the complaint of involuntary leakage accompanied by or immediately preceded by a sense of urgency. Symptoms may be a sudden compelling desire to urinate which is difficult to defer, leading to small and frequent losses or complete bladder emptying between micturition. The urge sensation makes it difficult to reach the toilet in time.

The causes to UUI can be irritation from the inside or outside of bladder which can be caused by a UTI, bladder stones, a bladder tumor, caffeine, dehydration or malignancy in the bladder or ovary, gynecological diseases such as prolapse, bladder outlet obstruction, e.g., enlarged prostate or obstipation. Other causes are neurological disorders, e.g., MS, medications, e.g., diuretics, polyuria, large fluid intake, uncontrolled diabetes, fragile postmenopausal mucus can cause burning and irritation of the urethra in women or are idiopathic.

Mixed urinary incontinence (MUI)

[7] Nurse, Company ε, Interview in person, 22 February 2023 and via video call 7 February 2023.

Mixed urinary incontinence is a combination of stress and urge incontinence. The causes overlap with those for SUI and UUI.

Urinary retention with incontinence (URI)

Urinary retention with incontinence is when the patient experiences bladder emptying difficulties and has residual urine. This can cause an overexpansion of the bladder. Common symptoms are difficulties starting to urinate, feeling that the bladder is not completely emptied, interrupted stream, weak urinary stream, frequent urge to urinate, frequent urination during the night and dribbling.

The state is entered either by mechanical barriers hindering bladder emptying or a weakened bladder muscle. The mechanical hinders are most commonly by prostate enlargement but can also be due to prolapse. Weakened muscles can be because of medication or nerve damage.

Functional urinary incontinence (FUI)

Functional urinary incontinence is when a patient has barriers to reaching a toilet in time. They can be physical impairments related to aging or disability like inability to remove clothing fast enough or transfer from a wheelchair to a toilet quick enough. Causes can be impaired vision, reduced mobility, state of confusion, and side effects of drug treatments, e g diuretics and sedatives. Environmental barriers further worsen the situations such as poor lighting, sills and carpets in the way.

Neurogenic bladder dysfunction (NBD)

As the urinary system is connected to the nervous system, neurological disorders can cause incontinence. The nerves sending signals between the bladder and the brain can be damaged due a brain, spinal cord, or nerve condition. This can cause a loss of bladder filling sensation or symptoms related to UUI. This is common for patients with neurological disorders such as Parkinson’s disease.
Multiple Sclerosis, spina bifida and spinal cord injuries.

Bladder dysfunction kids (BD)

It is considered problematic if children in the age of 5 to 6 or above are experiencing UI issues. Children with bladder dysfunction are children with UI but who do not have a neurological or anatomic defect. It can be caused by late development of the nervous system's control of the bladder and urinary system. The causes behind the late development may be, an overactive bladder, a strained bladder causing easy access to voiding, retention issues caused by strain to not leak, holding too much urine in for too long, underactive bladder leading to a muscle dysfunction, or constipation. Characteristics are small leakages by urge. (Martinson, A 2021)

Children experiencing UI with urge symptoms often have neuropsychiatric disabilities such as ADHD or ADD, and UI. Simplified they have too much going on to prioritize going to the toilet. [8]

Enuresis

For children 6 years or older the most common health issue after allergy and asthma, is enuresis; urine leakage during nighttime. It is often caused by genetics and if both parents struggled with enuresis the probability of the child to also struggle is high. The factors that are inherited are often a combination of the following three: Not enough vasopressin (a hormone that lowers the bladder's function during nighttime) is produced in the body, an overactive bladder that contracts without it being full, and it being hard to wake up so that the child sleeps through the body's signals to micturate. (Nevéus, T 2020)

4.2.1.1.2 Patient segmentation

In the interviews with urologists, urotherapists and incontinence nurses several application areas for Product X were identified. The interviewees had different opinions on the applications and their opinions in terms of using the product in diagnostics and treatment of UI is summarized in table 4.1 and table 4.2. The

[8] Agneta Sandberg, Children's Urotherapist, Region Blekinge, Interview via video call, 17 April 2023.

interviewees also highlighted that this product will not work for everyone in the chosen patient group either. [9]

Table 4.1 - Use of Product X in diagnostics

Interviewee	**Patient group they are working with**	**Most common types of UI at clinic**	**Thoughts on how the product can be used**
- Agneta Sandberg: Children's Urotherapist, Region Blekinge	Children	BD Neuropsychiatric (ADHD & ADD)	6-8 weeks micturition journal by Product X instead of current analogue version
- Magdalena Vu Minh Arnell: Urotherapist for children with Spina bifida, Region VGR	Children with Spina bifida	NBD Spina Bifida	Not relevant as diagnosed at birth
- Hans Netterling: Urologist at surgical clinic of	Women & Men, Clinic connected to gynecologist and urologist	UUI & MUI Adults with overactive bladder URI	Relevant alternative to weighing pads for

[9] (2) All medical professionals

Västerbotten, Region Västerbotten		Adults struggling with complete emptying NBD Adults with loss of bladder sensation (SUI)	tracking of leakages.
- Caroline Elmér: Urologist at Stockholms Urogynecologist clinic, Region Stockholm	Women, Clinic connected to gynecologist	UUI & MUI Adults with overactive bladder URI Adults struggling with complete emptying NBD Adults with loss of bladder sensation (SUI)	Relevant alternative to weighing pads for tracking of leakages.
- Maria Rudolfsson and Ulrika Hagberg: Incontinence nurse and Urotherapist at Gynecologist clinic at Norra Älvsborgs	Women, Clinic connected to gynecologist	UUI & MUI Adults with overactive bladder NBD Adults with loss of bladder sensation (SUI)	Relevant alternative to weighing pads for tracking of leakages.

Regional Hospital - Region VGR			
- Inger Andersson: Urotherapist at women's clinic at East Hospital, Region VGR	Women, Clinic connected to gynecologist	UUI & MUI Adults with overactive bladder	Not relevant for diagnostics as Andersson believes Product X would interfere with natural patterns hence generating inaccurate data, see 4.4.1.3 for more information

Table 4.2 - Use of Product X in treatment

Interviewee	**Adults/children**	**Patient groups**	**Subgroups**	**Use in treatment**	**Effect**
- Hans Netterling: Urologist at surgical	**Adults (18+)**	Stress UI		N/A (Leakage not connected with	

clinic of Västerbotten, Region Västerbotten - Caroline Elmér: Urologist at Stockholms Urogynecologist clinic, Region Stockholm - Maria Rudolfsson and Ulrika Hagberg: Incontinence nurse and Urotherapist at Gynecologist clinic at Norra Älvsborgs Regional Hospital, Region VGR				bladder activity)	
		Urge UI	Adults with overactive bladder	Upgraded bladder training	Continence management
				Helpful for pattern identification	Sense of relief due to Product X being in control
		Mixed UI (U+S)	Adults with overactive bladder	Upgraded bladder training	Continence management
				Helpful for pattern identification	Sense of relief due to Product X being in control
		UI retention	Adults struggling with complete emptying	Bladder monitoring	Continence management

- Inger Andersson: Urotherapist at women's clinic at East Hospital, Region VGR			(common after botox or due to neurological conditions)		
		Functional UI		N/A (not in health care)	
		Neurogenic UI	Women with postpartum temporary loss of bladder sensation	Temporary bladder monitoring	Continence management
- Agneta Sandberg: Children's Urotherapist, Region Blekinge				Prevention of leakage	Avoidance of leakages
			Adults with loss of bladder sensation	Bladder monitoring	Continence management

				Prevention of leakage	Avoidance of leakages
	Children	Bladder dysfunction	Neuropsychiatric (ADHD & ADD)	Bladder training	Continence management
				Beneficial if the sensor does not stop notifying until the bladder is emptied	Avoidance of leakages
- Magdalena Vu Minh Arnell: Urotherapist for children with Spina bifida, Region VGR				Toilet training	Independence
	Children				

		Neurogenic UI	Spina Bifida	N/A (Not relevant as routine micturition is favored)	
	Children				
		Enuresis		N/A	

4.2.1.1.2.1 Extended users

Chief physician and urologist Hans Netterling identified an extended usage of the Product X. He mentioned patients in hospitals that are in the intensive care unit (ICU) or are recovering from surgery as potential users. The level of urine in the patient's bladder in those cases commonly needs to be monitored. Netterling stated that the nurses caring for these patients could have use for a simple and small device to monitor the urine level in the bladder. Today it is measured by a big and heavy machine that costs around 1 million SEK. If Product X could replace this machine, it would simplify the procedure.[10]

4.2.1.2 Characteristics of Swedish patients with urine incontinence

Description of the end consumers characteristics

4.2.1.2.1 Cultural factors

The UI domain is shaped by a history of taboo. Estimates indicate that half a million people are living with UI related issues in Sweden. 50 percent of people with problems seek care. for their problems. A more open discussion has been seen in the media in recent years, but still a lot of people are avoiding seeking help due to the stigma. An increase in openness and awareness of the subject for nurses and doctors is desirable for better care for patients. The low priority of the subject has led to treatment plans more focused on decreasing the symptoms rather than eliminating the problem. (Janusinfo, 2023 A)
cultural, social, personal, and psychological

4.2.1.2.1.1 Social aspects

The taboo around UI has caused the interviewed patients' problems. First of all, the taboo has forced them to find innovative ways to cover urine leakages to avoid feeling embarrassed. A nurse working at Company X said that some patients feel embarrassed to such an extent that instead of seeking care, they create their own, home-made solutions which often result in worsening the

[10] Hans Netterling, Urologist at surgical clinic of Västerbotten, Region Västerbotten, Interview via video call, 30 March 2023.

problem.[11] An interviewed patient mentioned that she once had a urinary leakage when lecturing, to avoid feeling embarrassed, she spilled a glass of water to make people believe the stain on her pants was water and not urine. [12]

4.2.1.2.1.2 Personal aspects

The interviewed patients stated that they experience the taboo around UI as it is hardly ever spoken of yet they know that the problem is common.[13] Those interviewed that received their first symptoms at a young age thought that it was something that only old people had. The interviewed patients therefore believe the taboo is stronger among younger people.[14]

Interviewed patients emphasize the amount of time and thought they must spend on handling their UI. Activities such as drinking coffee and eating fruit and vegetables, as well as knowing where the closest toilet is, must be planned and controlled throughout the day to minimize symptoms. This takes up a lot of time and negatively affects the person's function in ordinary life. Many patients are hindered socially due to their circumstances and revert to being home-bound.[15] An interviewed patient stated that they avoid leaving the house as much as possible as it is too complicated. An interviewee who has been working for 40 years whilst having UI said that 20% of their thinking power always must be put on UI management. This issue is therefore socioeconomic as the milder symptom a working person has, the more they can focus on work.[16]

[11] Nurse, Company X, Interview in person, 11 February 2023.

[12] Anonymous Patient, Interview via video call, 21 March 2023.

[13] Anonymous Patient, Interview via video call, 21 March 2023.

[14] Anonymous Patients, Interviews via video calls, 21 March 2023.

[15] Nurse, Company X, Interview in person, 11 February 2023.

[16] Anonymous Patients, Interviews via video calls, 21 March 2023.

4.2.1.2.1.3 Psychological aspects

Interviewees have expressed the need to be an active participant in their own care to receive the help they need. One patient said they have been lucky as even though their doctors didn't know how to treat them at first, care professionals did research to find a solution when asked to. That patient had over 50 years of experience with incontinence care and meant that one must "break through the glass ceiling" to receive the right care. Another patient mentioned that they had been trying several types of treatments and that they seldom worked, and if they worked, they got no explanation as to why.[17]

4.2.2 The Business Buyer

Description of the business buyer divided in the public sector, Swedish health and medical care system, and public procurement in the health care sector.

4.2.2.1 The Public Sector

Schools, hospitals, primary care and public transport, e.g., belong to the institutional market. The public sector represents large volumes and large opportunities for many companies. In many terms the public sector is like the private sector and the borders are not then very clear. An important difference is the Public Procurement Law that must be considered in most cases when selling to the public sector. Another difference is the political decision processes. Political coalitions and compromises can be both a barrier and an opportunity for the one who is marketing a service or a product. These markets represent a large amount of money while the budget is tight and there's a large focus on costs. A purchaser with a tight budget has limited incentives to focus on quality. (Kotler 2012)

In Sweden public procurement is governed by the Public Procurement Act. The act is applied by a contracting authority on municipal, regional, and national level. The rules are based on directives from the European Union (EU),

[17] Anonymous Patients, Interviews via video calls, 21 March 2023.

established to promote the free movement of goods and services within the EU. (Konkurrensverket n.d.) Organizations within the public sector must open their purchasing to competition. They need to make sure that tax funds are used in the most efficient way possible and that companies within the EU can do business with the public sector on equal terms. For large public procurements there are several obligations to consider. The tender needs to be published to the public to create transparency and procurers are not allowed to turn directly to a former supplier for a re-buy. Public procurement often takes longer time than in the private sector, especially the larger deals. In Sweden public procurement should also contribute to sustainable development. The public sector in Sweden can be progressive in terms of demanding socially and environmentally sustainable products and services as well as use the supplier's ability to innovate to develop new solutions. (Upphandlingsmyndigheten n.d A)

4.2.2.2 Swedish health and medical care system

There are several instances involved in the Swedish health and medical care system. The responsibility is divided on both national, regional, and municipal level. The parliament, the government and the agencies decide on the regulations that provide the legal conditions. Health care in Sweden is regulated in the Health Care Act, the Patient act and the Patient Safety act, among others. The parliament and the government set the framework for health care in the form of legislation and budget, with general and targeted state subsidies for the services. The government has the overall responsibility for policy direction, decisions on strategy and how public funds are to be used.

Several national authorities are responsible for various aspects of the health care system, such as National Board of Health and Welfare and the Swedish inspectorate for Health and Social Care. They are responsible for creating regulations, knowledge supporting and providing statistics as well as carrying out monitoring, and evaluation activities. Authorities are also responsible for supervision, some licensing, and decisions on what dental care, medicines and consumables to be included in the high-cost coverage. (SKR 2023 A) In Sweden *Tandvård- och läkemedelsförmånsverket* (TLV) decides on which

dental care, medicines and consumables are covered by the high-cost protection scheme. (TLV n.d.)

The regions are responsible for the largest part of the health and medical care system by working with health promotion, prevention and diagnosis, and treatment of diseases and injuries. The political leadership also decides on regional subsidies. There is also a collaboration between the regions, where they have come together and formed six health care regions where they agree on price lists and where certain medical specialists' clinics should be placed. All healthcare regions have a regional hospital. Since 2018 Sweden's regions have a common system for knowledge management. Together they develop ways of working to make sure that healthcare in Sweden is more knowledge based, equal and resource effective.

The municipalities are responsible for the health and care of people that have been granted housing with special services for children and young people as well as housing for special services for adults and daily activities. They also have a certain responsibility for medicines and rehabilitation. A municipality is not, with some exceptions, allowed to provide health care performed by doctors. (SKR 2023 A)

4.2.2.3 Public procurement in the health care sector

In Sweden, public procurement in the healthcare sector is mainly governed by the Public Procurement Act. These laws set out the rules and regulations that must be followed when procuring goods and services for healthcare facilities. The Swedish healthcare sector procures on a regional level and uses a competitive tendering process to select suppliers which helps to ensure that goods and services are procured at the best possible price. The 21 regions in Sweden manage their procurement independently of each other. The tendering process is open to both Swedish and international suppliers, and is designed to promote transparency, fairness, and competition.

In recent years, the Swedish healthcare sector has also focused on promoting sustainable procurement practices, such as reducing waste, promoting energy efficiency, and using environmentally friendly products. This aligns with the Swedish government's commitment to sustainability and reducing its environmental impact. [18]

There are several key actors involved in a public procurement process in the Swedish healthcare sector, including healthcare facilities, The Swedish National Agency for Public Procurement, The Swedish Competition Authority, the suppliers, the evaluation committee, and the contracting authority. Every region in Sweden has a contracting authority responsible for the procurement in their region. When the products or services to be bought are to a specific healthcare domain the purchasers are advised by the affected medical professionals and the evaluation committee. Region Uppsala, for example, has a medical technology and physics unit at the Region to council when purchasing MedTech equipment. [19]

4.2.2.3.1 Threshold values

The monetary threshold value determines which regulations a public procurement must follow, the directive-driven procedures above the thresholds or the national procedures below the thresholds. The European Commission decides the thresholds. For contacts larger than around 7,8 million SEK the tender must be published in a database that is available in the entire European Union and follow certain procurement procedures. If the monetary value of the contract is below the threshold, national procedures are ruling. There is no procurement procedure specific in the law, which means that the contracting authority has the possibility to adapt the process to the specific procurement. The tender must be published in a registered tender database and give the potential suppliers enough time to make an offer. If the purchase is below 700

[18](1) All regions

[19] Anna Harrysson, Team leader- Medical device procurement at Region Uppsala, Interview via video call, 17 March 2023

000 SEK, the law allows for a direct purchase. The purchasing organization can then directly reach out to the supplier of choice and make an agreement. (Upphandlingsmyndigheten 2022)

4.2.2.3.2 Agreements

The law of public procurement applies to several different types of contracts (Upphandlingsmyndigheten n.d. B) The interviewed regions pointed out that framework agreements are the most common agreement type used for consuming goods and services in the health care sector.[20] A large part of all the published tenders are framework agreements and in 2020, 40% of the published tenders concerned framework agreements. (Upphandlingsmyndigheten n.d. C) Framework agreements are an important aspect of the Swedish healthcare sector by helping to facilitate the procurement of goods and services for hospitals, clinics, and other healthcare facilities. These agreements are essentially long-term contracts between the government and private suppliers, which establish the terms and conditions for the supply of specific goods or services over a given period. In the Swedish healthcare sector, framework agreements are typically used to procure a wide range of goods and services, such as medical equipment, pharmaceuticals, laboratory supplies, and healthcare IT systems. The agreements are typically awarded through a competitive tendering process, with suppliers bidding to provide the required goods or services at the best possible price. Once a framework agreement has been established, individual healthcare facilities can then place orders with the suppliers that have been awarded the agreement, without the need for further procurement procedures. This helps streamline the procurement process and reduce administrative burden, while also ensuring that healthcare facilities have access to high-quality goods and services at competitive prices. [21]

The interviewed regions see both advantages and disadvantages with using framework agreements. One of the key benefits of framework agreements is

[20](1) All regions

[21] Key account manager, Company X, Interview via video call, 22 February 2023

that they can help to encourage innovation and competition in the healthcare sector. By establishing long-term partnerships with private suppliers, the government provides a stable market for suppliers to invest in research and development, and to introduce new products and services that can improve patient outcomes and reduce costs. However, there are also some potential negative effects with framework agreements in the healthcare sector. There is a risk that long-term contracts could lead to suppliers becoming complacent and failing to innovate or improve their products or services over time. In framework agreements there is often room for a change of ten percent of the agreed volume. The region also retains the right to try new products during the time of the current agreement.[22]

4.3 Where are the patients and what does their patient journey look like?

According to the interviewed medical professionals, the patient journey for children and adults with UI symptoms are separate. The collected data on this area had emphasis on the aspect of responsibility and therefore a general view of each patient journey is visualized below in swim lane activity diagrams, as they arrange activities according to responsibilities.

4.3.1. Children's patient journey

In the interview with Agneta Sandberg, urotherapist for children in Region Blekinge, the patient journey for children with UI issues were mapped out. Sandberg has also been the fact checker for the national healthcare manual on UI for children. Sandberg means that children have almost always visited another care center before they reach a urotherapist. Children can reach a urotherapist in two ways, either through a specialized clinic or through a general healthcare center. If they come from a specialized clinic the child has other underlying diseases, as described in section 4.2.1.1.1. See figure 4.3 for

[22] (1) All regions

patient journey for children with other underlying diseases and figure 4.4 for children without.

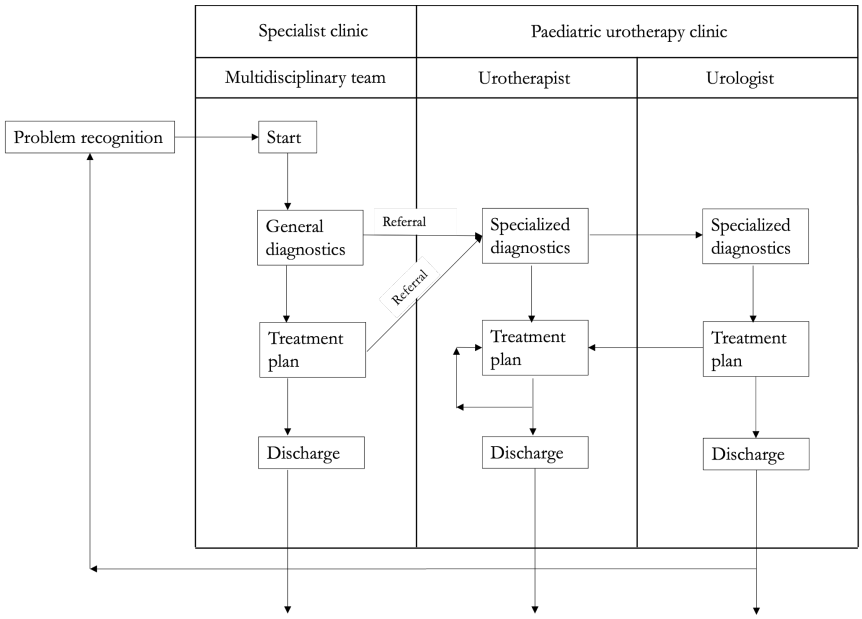

Figure 4.3 - General patient journey for children with UI problems caused by other underlying diseases.

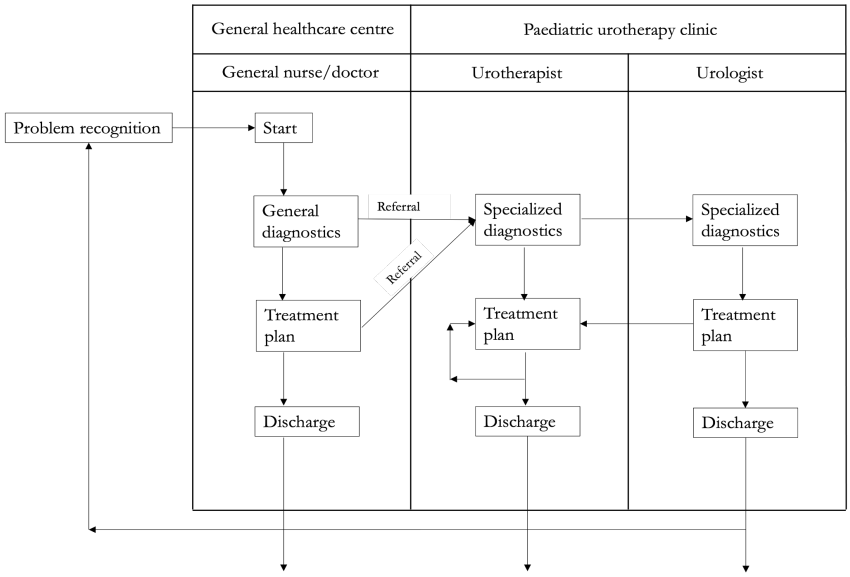

Figure 4.4 - General patient journey for children with UI problems

4.3.2 Adults patient journey

According to the interviewed urotherapists and urologists, adults have also almost always visited another health instance before they reach a clinic specializing in UI problems. The interviewed medical professionals all had the same view that the patient journey for men and women is most often separate. Both sexes can reach the UI clinic through a general healthcare center if they have no other medical condition or via the specialized clinic they belong to if they do. Women can also enter the care chain through a midwifery or a gynecology clinic. Men with issues with their prostate cancer can get a referral from an urologist more focused on cancer. Men and women often end up at different clinics or see doctors as well. Men see an urologist and women most often a gynecologist. In some cases, women also see an urologist. See figure 4.5 for both of men's patient journeys and figure 4.6 for women.

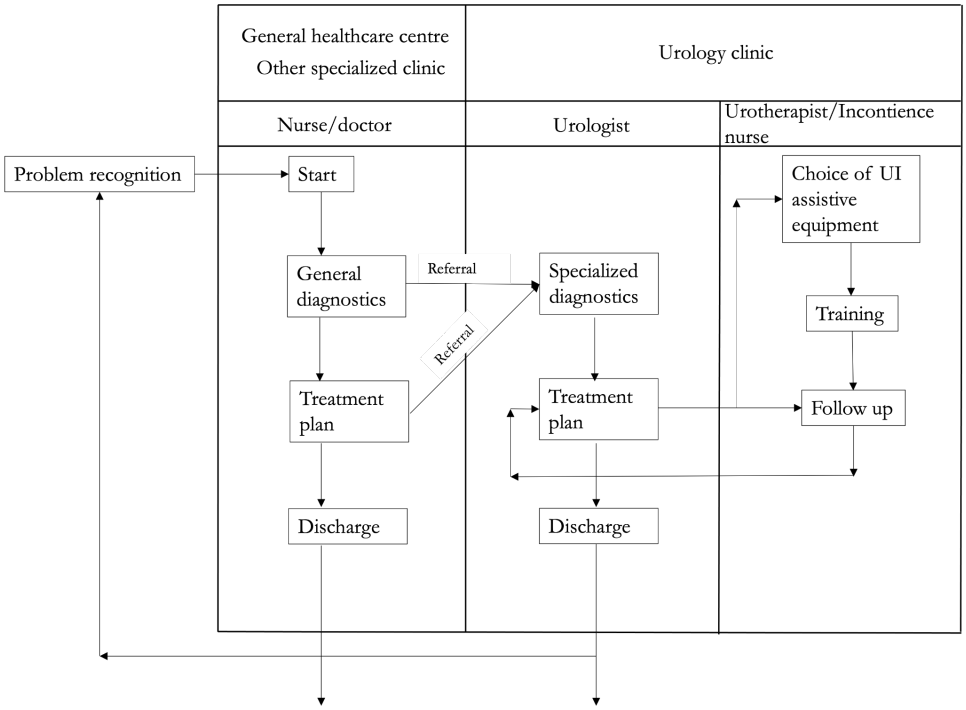

Figure 4.5 - General patient journey for men with UI problems

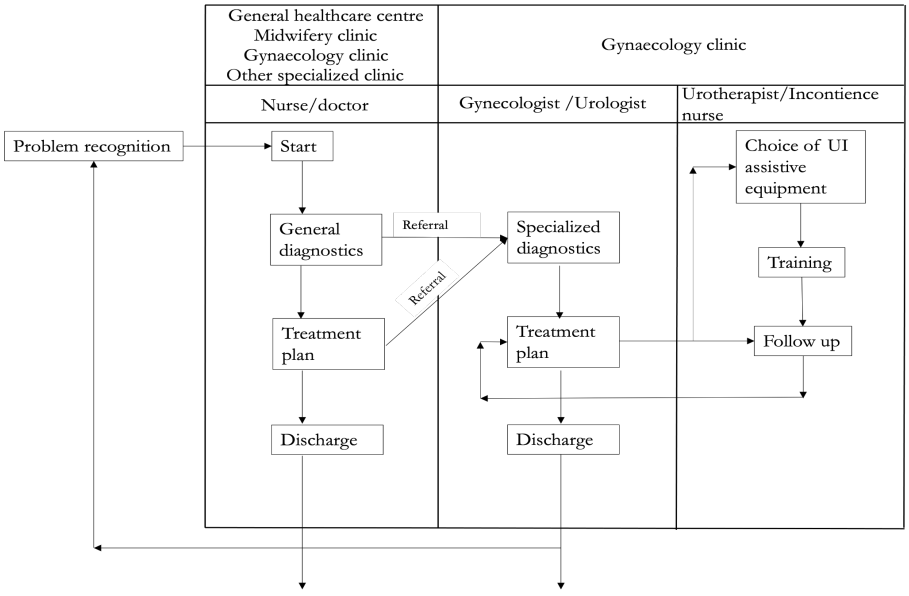

Figure 4.6 - General patient journey for women with UI problems

4.4 How to introduce new IoMT-solutions

To understand how to introduce new IoMT solutions to Swedish health care, end consumers and business buyers were interviewed about their buying decision.

4.4.1 The End Consumer

The data collected about the end consumer's behavior is divided into four categories: consumer buying behavior, consumer buying decision, adoption of solutions and replacement willingness.

4.4.1.1 Consumer buying behaviors

The behavior of buying products for incontinence in Sweden is first characterized by where the product is made available to the end consumer. Incontinence pads are available for purchase in supermarkets and pharmacies, without involvement of the healthcare system. If a patient has sought help for their issues they can get the pads prescribed if the issue is considered serious enough. In that case the end consumer themself, do not have to pay anything.[23] This case study is focused on those products prescribed to UI patients and therefore price from a consumer perspective is irrelevant.

Concerning the choice of brand, interviewed patients claim that it is not of relevance for them. They care about if a product works for them or not. Although, they state that if a product from one brand has worked for them, they are more prone to believe that a similar product from the same brand will work as well.[24]

In the interview with urologist Elmér on the topic of the patients' behaviors it was stated that patients sometimes arrive at their appointment with information

[23] (3) All urotherapists and incontinence nurses

[24] Anonymous Patients, Interviews via video calls, 21 March 2023

on treatment methods that they have heard from doctors on television shows or in newspapers, e.g. “Nyhetsmorgon” or “Expressen”.[25]

4.4.1.2 Consumer buying decision

All interviewed medical professionals claim that treatment of UI is often a question of quality of life and therefore it is the patient’s choice of which treatments or products they want to use. The choice of treatment is made in dialogue between the patient and urotherapist. Different varieties of products and treatments are offered depending on what type of UI the patient has. In cases where the type cannot be determined the patient chooses from different products that may ease the symptoms they are experiencing.[26] Described below is the complete buying decision of the patient.

Need recognition

A patient starts to experience symptoms of UI and chooses to seek care or not to seek care.

Information search

Urologist Elmér describes three different UI patient groups. One group of patients do not seek care for their problems and single-handedly research their symptoms and purchase what they need to solve their UI themselves. Another group of patients enter the care system without previous knowledge on treatment methods and follow the doctor’s recommendations to the point. The third patient group has done research before their appointment and comes to the clinic asking for a specific treatment method. It is seldom the case that that specific treatment will work for the patient, and she must let them down. Urologist Netterling stated that he has seen the same patterns for patient

[25] Caroline Elmér, Urologist at Stockholms Urogynecologist clinic, Region Stockholm, Interview via video call, 17 March 2023

[26] Hans Netterling, Urologist at surgical clinic of Västerbotten, Region Västerbotten, Interview via video call, 30 March 2023 and Caroline Elmér, Urologist at Stockholms Urogynecologist clinic, Region Stockholm, Interview via video call, 17 March 2023

behavior in terms of information search but sees a slight majority of younger patients who have done research before.[27]

Evaluation of alternatives

According to the interviewed urologists and urotherapists, they present different alternatives of treatment to the patient and together they decide what is most likely to work for them and what they would like to try first. The different products presented must be procured in the region for the doctor to be able to prescribe it. For example, if SUI is the diagnosis; pelvic floor training is recommended to begin with and in a later stage surgery is put forward as an alternative. For UUI, bladder training works as a first step and the use of pharmaceuticals as a second. [28]

Purchase decision

The patient has the final say in the choice of treatment and when chosen it is ordered by the medical professionals and either sent by home delivery to the patient or they pick it up at the pharmacy themselves.[29]

Post-purchase behavior

The follow up of the treatment is normally done by the Urotherapist calling the patient. If the patient is satisfied, they are discharged and if not the process circles back to visiting the clinic again to try out a different treatment. Some patients give up at this point.[30]

[27] Hans Netterling, Urologist at surgical clinic of Västerbotten, Region Västerbotten, Interview via video call, 30 March 2023 and Caroline Elmér, Urologist at Stockholms Urogynecologist clinic, Region Stockholm, Interview via video call, 17 March 2023

[28] (2) All medical professionals

[29] (2) All medical professionals

[30] (2) All medical professionals

4.4.1.3 Adoption of solutions

From interviews with patients that have been struggling with UI symptoms for several years it is clear that they become desperate for solutions. This desperation leads them to be willing to try almost everything if there exists a chance that it might work. The interviewed patient did however emphasize on the fact that it is important for them that the solution is recommended by healthcare professionals to use it, otherwise they will not trust the legitimacy of the product.

As no digital, high technological solutions exist in UI care today it was hard for the patient to describe how they would react to the digital aspect and to what extent they would trust the technology to always be working accurately. The interviewed urologists, patients and urotherapists however claim that they do not foresee the digital aspect to be an issue.[31] An interviewed patient expressed interest in trying Product X after a very brief introduction to it. [32]

As digital technology is involved, the question of different generation's digital maturity was raised as a potential barrier. According to urologists, the level of usability of an app and a sensor is possible to use by almost all patients but some resistance might be found in older patient groups.[33] Stephanie Bol, consultant at BearingPoint, working with projects on self-monitoring in health care, contributed with the perspective that many people are interested in their own health parameters and many already use wearable smartwatches for this purpose. Bol also mentioned that there is a strong interest in applications of self-monitoring in regions in Sweden and that some already have it

[31] (5) All medical professionals and patients

[32] Anonymous Patient, Interview via video call, 21 March 2023

[33] Hans Netterling, Urologist at surgical clinic of Västerbotten, Region Västerbotten, Interview via video call, 30 March 2023 and Caroline Elmér, Urologist at Stockholms Urogynecologist clinic, Region Stockholm, Interview via video call, 17 March 2023

implemented, hence the adoption of these types of solutions amongst the Swedish population is growing.[34]

4.4.1.4 Replacement willingness

As mentioned earlier the Swedish patients would not pay for their care therefore it has to be subsidized as the other treatment alternatives.

Patients describe their situation as desperate and that they are willing to try almost anything that might help them even though it is no guarantee. [35]

According to the interviewed urologists Caroline Elmér and Hans Netterling, to be able to recommend Product X as a treatment method they must, as a first step, be aware of its existence. The product must have sufficient clinical evidence of working effectively, is safe and easy to use. The aspect of usability was emphasized. It must be easy for both medical professionals and patients to understand how to use the product.[36]

An interviewed patient that today uses different types of UI protection and occasionally catheters, stated interest in transitioning to Product X. The patient would not care if it was obvious and showed when wearing clothes. The patient expressed some opinions against feeling the device against the body too much, but a little was okay. The patient also mentioned that in their case they would easily be able to handle the notifications in a way that was discreet enough. As the patient has had issues since they were a child, they highlighted the fact that it might be harder for children to handle the notifications if they want to be discreet. They expressed that having a device that could keep track of simple

[34] Stephanie Bol, Consultant at BearingPoint, Interview via video call, 4 April 2023

[35] Anonymous Patient, Interview via video call, 21 March 2023

[36] Hans Netterling, Urologist at surgical clinic of Västerbotten, Region Västerbotten, Interview via video call, 30 March 2023 and Caroline Elmér, Urologist at Stockholms Urogynecologist clinic, Region Stockholm, Interview via video call, 17 March 2023

things such as coffee intake and mitigation volumes would relieve a lot of planning that the patient currently is burdened by. [37]

Incontinence nurse Maria Rudolfsson, urotherapists Ulrika Hagberg and Agneta Sandberg and urologists Caroline Elmér and Hans Netterling, expressed being positive to the usage of Product X in diagnostics of UI have mentioned that they would like to see extended features in Product X to be willing to replace their current process of micturition lists. For example, the current solution offers the option of documenting intake of food and drink and this is data that the urotherapists do not want to lose by shifting to Product X. [38]

According to the interviewed incontinence nurse Maria Rudolfsson and urotherapist Ulrika Hagberg, their routines state that more than 4 hours between micturitions should not occur. They therefore desire Product X to have this feature incorporated for it to be relevant for them to replace current treatments. [39]

The interviewed urotherapist, Inger Andersson, expressed that she would not prefer using Product X over micturition lists. Andersson says that this is because she doesn't want anything impacting the patient's usual urination when they are examining the patient's pattern. Andersson believes that the fact that the patient can know the level of urine in the bladder would impact how they handle their urination. During the time of assessment Andersson wants the patient to act exactly as they usually do and does not want anything impacting their behavior. Andersson did not either see any benefit from having a device

[37] Anonymous Patient, Interview via video call, 21 March 2023

[38] (4) All urologists, 2 urotherapists and 1 incontinence nurse

[39] Maria Rudolfsson and Ulrika Hagberg: Incontinence nurse and Urotherapist at Gynecologist clinic at Norra Älvsborgs Regional Hospital, Region VGR, Interview via video call, 19 April 2023

tracking bladder emptying and leakages compared to the current process of the patient weighing pads and measuring micturitions. [40]

4.4.2 The Business Buyer

The data collected about the business buyer's purchasing behavior is divided into four categories, who is participating in the purchase, what are the macro factors that influence the buying decision and how is the purchasing decision made.

4.2.2.1 What buying decision do business buyers make?

The interviewed regions described the process for buying conventional UI products as a process where they take a standpoint in a previous tender but make modifications if new demands have occurred. Not as many people must be involved and the rebuy is made fairly on routine and the amount of research done before the buy is limited. When there is a new product, they describe a more complex and longer process. If it is a digital product it will have to be integrated in the systems used by hospitals and healthcare today. The interviewed regions all mean that Product X is a new product that would involve a complex buying process. [41]Several participants are involved and described in 4.2.2.2.

4.2.2.2 Who participates in the buying process?

In the conducted interviews several participants in the buying process were identified and described. Their role, motives and objectives are presented below.

[40] Inger Andersson, Urotherapist at women's clinic at East Hospital, Region VGR, Interview via video call, 18 April 2023.

[41](1) All regions

4.2.2.2.1 Users

Patients:

The patients are the end users of the product and are described in section 3.2 and 4.2. The focus for the procurement is the users' needs and how the needs might change over time. (Upphandlingsmyndigheten n.d. D) The Patient Act entered into force in 2015 with the aim of strengthening and clarifying the patient's position and to promote the patient's integrity, self-determination and participation in their own care. The patient's right to information and participation in their own care and treatment is of fundamental importance and is a prerequisite for good care. (Kunskapsguiden 2022) For example, patients with disabilities should be informed about the assistive devices available for them and when there are different choices available, the patient should be given the opportunity to choose the option that he or she prefers according to his or her needs and the cost of the device. (Socialstyrelsen 2021)

Urologist/Gynecologist

The healthcare system for patients with UI is often divided after the sexes. Men most often visit a urologist and women a gynecologist.[42] A urologist specializes in the male reproductive system and diseases of the kidneys and urinary tract in men and women. (Vården.se n.d. A) A gynecologist is a doctor who specializes in the female genital area. (Vården.se n.d. B) Some women also see a urologist but most often it is divided as described. The urologists and gynecologists diagnose the patient and decide on treatment methods. [43]

Concerning their role in the business buying process, urologist Netterling says that when a purchase is going to be made to a clinic, the procurement department in the region has low involvement. The procurement office has access to the money so whenever he wants to buy something he requests it from

[42] Maria Rudolfsson and Ulrika Hagberg: Incontinence nurse and Urotherapist at Gynecologist clinic at Norra Älvsborgs Regional Hospital, Region VGR, Interview via video call, 19 April 2023

[43] Maria Rudolfsson and Ulrika Hagberg: Incontinence nurse and Urotherapist at Gynecologist clinic at Norra Älvsborgs Regional Hospital, Region VGR, Interview via video call, 19 April 2023

the regions. If there are cheaper products the department needs, Netterling can make a purchase himself without going via the region's procurement department. If it is a larger purchase, it can take time to purchase it. [44]

To receive information about the development of the UI field, Netterling attends fair and reads articles. He also gets information from his network of other urologists and urotherapists. The Swedish urologist organization has a yearly conference where they meet and exchange experiences. Companies with products he might be interested in attend the fairs or come to the clinic to showcase their products. Urologist Elmér means that she receives information about new solutions from other colleagues and that it is often the urotherapist that presents new equipment to her. [45]

Urotherapist / Incontinence nurse

The urotherapist is a nurse specified in UI. They work in the same team as the urologist and gynecologist but closer to the patients. When a doctor has decided on the treatment plan the urotherapists are the ones who follow up with the patient on how the treatment is working. They also help the patient choose between different types of incontinence assistive devices and protection. Together with the patient they try out different solutions to agree on which ones and in which size, that fit the patient the best. [46]

4.2.2.2.2 Influencers

Reference groups

The procurement department at the regions uses reference groups to get advice in a procurement. The reference group can consist of people who will use the

[44] Hans Netterling, Urologist at surgical clinic of Västerbotten, Region Västerbotten, Interview via video call, 30 March 2023.

[45] Hans Netterling, Urologist at surgical clinic of Västerbotten, Region Västerbotten, Interview via video call, 30 March 2023 and Caroline Elmér, Urologist at Stockholms Urogynecologist clinic, Region Stockholm, Interview via video call, 17 March 2023.

[46] Caroline Elmér, Urologist at Stockholms Urogynecologist clinic, Region Stockholm, Interview via video call, 17 March 2023.

product directly in their work at the hospitals or clinics or people that have expert knowledge in the domain. If it is a MedTech product it can also involve engineers, hospital physicians, IT architects, sustainability strategics or someone from medical hygiene. [47]

Key opinion leaders

Urologist Caroline Elmér expressed that so-called *Key Opinion Leaders* have a strong influence on what diagnostic and treatment methods are being used in the field. These are often urologists who do research in the domain and are active in the medicine community. [48]

Sinoba

Sinoba is an independent association for people with urinary incontinence and bladder problems in Sweden. The interest group exists to create opportunities for people with the same issues to get in contact with each other and share experiences. The organization also promotes research and new treatment methods in the domain. The members are both patients and caregivers. (Sinoba n.d.)

Swedish MedTech

Several industry organizations are working to promote MedTech and welfare technologies in Sweden. Swedish MedTech is the industry organization for medical technology companies in Sweden and currently has more than 200 member companies. The organization provides a collective voice for the medical technology industry in Sweden. They work long-term with strategic issues that are important for the medical technology industry and Swedish healthcare. According to Louise Reuterhagen, expert in procurement and economics at Swedish MedTech and Petrus Laestadiues, Vice President at

[47] Anna Harrysson, Team leader- Medical device procurement at Region Uppsala, Interview via video call, 17 March 2023

[48] Caroline Elmér, Urologist at Stockholms Urogynecologist clinic, Region Stockholm, Interview via video call, 17 March 2023.

Swedish Medtech, Swedish MedTech works active together with the regions to improve the procurement process by among other things increase the focus on the patients/users' needs and introduce more innovation to Swedish healthcare. [49]

4.2.2.2.3 Buyers

Regional procurers

The purchasers are responsible for the actual procurement process. Their objective is to ensure the process follows Swedish law of public procurement. They are educated and specialized in public procurement and not in the equipment or solutions they procure. Their role is to make sure that the procurement is efficient, legally secure, and utilizes the competition in the market. It should also promote innovative solutions and take into account environmental and social considerations. (Regeringskansliet n.d.)

4.2.2.2.4 Deciders

Regional politicians

The political leadership in the regions is responsible for managing the budget for healthcare services in their respective regions. This includes determining the allocation of funds for various healthcare initiatives, including investments in and promotion of medical technology. The budget process typically involves several steps, including the identification of priority areas for investment, the allocation of funds to different initiatives, such as *Digitala hjälpmedel i samverkan* in Västra Götalands Regionen, (VGR 2023) based on their perceived importance, and ongoing monitoring and evaluation of spending to

[49] Louise Reuterhagen, expert in procurement and economics at Swedish Medtech and Petrus Laestadiues, Vice President at Swedish Medtech, Swedish Medtech, Interview via video call, 5 April 2023

ensure that resources are being used effectively.[50] Regional politicians also decide on what assistive equipment is to be subsided.[51]

Budget responsible at the hospitals

The decided regional budget is divided between hospitals and individual clinics. Requests for purchases to the health care are first prioritized at a clinic level, then in the health care domain level in the region, and finally for the entire healthcare and medical services in the region.[52]

4.2.2.2.5 Gatekeepers

"Tandvård- och läkemedelsförmånsverket" (TLV)

In Sweden TLV decides on which dental care and medicines are covered by the high-cost protection scheme. Concerning medical technology only medical technology products that count as consumables are in the high-cost protection scheme. A consumable product is one that is prescribed to an individual patient and is considered their property. It is typically a relatively simple and low-cost item with a limited useful life. There are three groups of medical technical products that are in the high-cost protection scheme; products for administering medication to the body, such as needles, products for self-monitoring of medication, such as test strips, and products for ostomy care, such as ostomy bags.

TLV also performs health economic evaluations of certain medical technology products that are not included in the benefits. The Medical Technology Product Council makes decisions on which products TLV should conduct a health

[50] (1) All regions

[51] Louise Reuterhagen, expert in procurement and economics at Swedish Medtech and Petrus Laestadiues, Vice President at Swedish Medtech, Swedish Medtech, Interview via video call, 5 April 2023.

[52] (1) All regions

economic evaluation of, within the framework of nationally organized introduction of medical technology products.[53]

"Medicintekniska produktrådet" (MTP)
The MTP is an expert group with representatives from Sweden's regions. The MTP Council has a mandate to make recommendations on the use of certain new medical devices. They decide whether a medical device should be introduced jointly in the national orderly introduction process based on horizon scanning and input from the regions. This includes deciding whether national procedures for introduction and follow-up are needed. The goal is to achieve an equal, cost-effective and appropriate use of a selection of new medical devices for all patients throughout the country, so that Swedish inhabitant's common resources are used in the best possible way. The MTP Council designates product groups of interest to the regions and nominates which medical devices TLV will evaluate therein.

They also assist the procurement activities via the procurement coordinator on issues related to willingness to pay and ethical considerations in procurement. This may concern both new and old medical devices and, if necessary, make recommendations. (Janusinfo 2023 B)

"Vårdhandboken"
"Vårdhandboken" aims to offer comprehensive guidelines for work within health and medical care so that quality and safety levels are maintained and improved throughout Sweden. The Handbook for Healthcare is based on the latest clinical knowledge (best practice, evidence, science, and proven experience). The Handbook for Healthcare is based on the Swedish Health and Medical Service Act (HSL) and Social Services Act (SOL) and is designed to help meet national goals for health and medical care in Sweden. (Vårdhandboken n.d.)

[53]Administrators at the Medical Devices Unit, TLV, Email correspondence.

4.4.2.3 What are the strongest environmental factors that influence buyers?

During the conducted interviews with Swedish MedTech and BearingPoint several environmental factors that influence what is procured to the regions was identified. The following section contains data from the interviews and additional online sources.

4.4.2.3.1 Expected economic environment

The Swedish government announced on the first of March 2023 that the Swedish economy is entering a troublesome phase. The activity in the Swedish market decreased during the fourth quarter of 2022, and several indicators point to an even weaker development onwards. The households have less buying power due to high inflation and increasing interest rates. With increased rates the cost of money will increase. There are also signs that the situation on the labor market is worsening. The frequency of redundancies and bankruptcies have been higher than usual in recent months and unemployment is expected to increase in 2023 and 2024. The Swedish GDP is expected to decrease with 0,7% in 2023. (Regeringskansliet 2023 A) The upcoming recession is expected to last until 2027. (Ekonomifakta 2023)

In the interview with Louise Reuterhagen and Patrus Lastadies from the industry organization Swedish MedTech they said that the amount of investments being made in medtech is correlated to economic development. MedTech stands for 6% of the entire healthcare costs in Sweden today. Health care is needed independently of the economy. A weaker economy puts pressure on the national healthcare budget and then there is a risk that investment in health care.[54] The CEO of Swedish MedTech also confirms that several of the industry organization's member companies report that they receive fewer orders. The smaller R&D companies are however more in the risk zone in comparison to larger, more established companies. (Life Science Sweden n.d.)

[54] Louise Reuterhagen, expert in procurement and economics at Swedish Medtech and Petrus Laestadiues, Vice President at Swedish Medtech, Swedish Medtech, Interview via video call, 5 April 2023

Economic, medical, and socioeconomic advancements over the past decades have resulted in a substantial increase in life expectancy in Sweden. This will have a large impact on the Swedish economy. The so-called *support ratio,* which indicates how many youths and elderly a person of professional age must support including herself, is expected to increase from 1,75 to 1,84 between the years 2017 and 2040 (Prochazka 2022) at the same time as an aging population implies an increased demand for quality healthcare. (European commission 2023) Swedish MedTech expressed a need to continue the investment in MedTech in order to manage this challenge to find more economically effective ways to treat patients.

4.4.2.3.2 Rate of technological change in the healthcare domain

The digitalization trend is strong in all industries and so also in health care. BearingPoint expresses in their report *Digital transformation in Healthcare* that in order to deal with increased demand for healthcare services, healthcare organizations must start investing in digital technologies to support the delivery of their services. Digital technologies have a lot of potential to revolutionize the industry, but recent studies identify that only 40% of healthcare organizations have made significant investments in digital technologies, a figure measurably lower in comparison to other industries. BearingPoint mean that digital transformation in healthcare helps in reshaping the healthcare industry in that it extends medical care and treatment to people's homes and workplaces as well as being a building block of a patient-centric approach to healthcare and deliver integrated yet streamlined services, providing a better patient experience, and building trust and loyalty.

BearingPoint means that digital transformation is not just about implementing new technology, but also re-evaluating how things are done and understanding how they can be done more effectively. Several emerging technologies can be used to improve efficiency and productivity of the healthcare organization. They can be used to implement completely new ways of doing things or to

adapt and integrate in existing solutions, so that change can be introduced incrementally. (Bearingpoint 2022)

BearingPoint highlights two aspects of digital transformation in healthcare; real-time and big data, and digital channels enabling effective communication and telehealth. Modern systems allow healthcare providers to aggregate data from multiple sources and make sense of it in real-time. Big data and advanced analytics technologies make the analysis of huge datasets much more effective. With the rise of the Internet of (Medical) Things (IoMT), mobile and wearable devices are increasingly connected. When devices are connected, they can together create a cohesive medical report accessible anywhere by the healthcare provider. They are not only useful for the patient. When pooled and studied in totality the possibility to predict healthcare trends for entire communities increases. Digital channels give the patient the ability to connect and interact with providers how and when they want. Response times are reduced and unnecessary barriers to care for the patient are removed. (Bearingpoint 2022)

In an interview with the BearingPoint consultant, Stephanie Bol, it was found that Swedish healthcare is integrating more and more distance care and self-monitoring in their processes. [55] Self-monitoring is defined by SKR as continuous recording, monitoring and assessment of values related to a person's health status, where the person themselves performs the recording. Patients use digital assistive devices to measure their values wherever they are. Bol continues by adding that some measurements may even be more accurate when taken at home. The so-called *White Coat Hypertension* describes the phenomenon in which people exhibit a blood pressure level above the normal range in a clinical setting, although they do not exhibit it in other settings. It is believed that the phenomenon is due to anxiety experienced during a clinic visit. Self-monitoring also makes the patients more involved in their diagnostics and treatment plans and helps the regions to work more proactive. Using self-

[55] Stephanie Bol, Consultant at BearingPoint, Interview via video call, 4 April 2023.

monitoring can enable a continuous relation and closer collaboration between the healthcare and the patient. The urgent and unplanned visits can be avoided, and the healthcare's competences and resources can be used in a more efficient way. (SKR 2023 B)

Bol means that it is "prime time" for the interest in self-monitoring and distance care in the healthcare industry and that several regions in Sweden are currently investigating how they can procure the necessary systems and solutions .The regions Östergötland, VGR and Jämtland Härjedalen are already using self-monitoring and the other regions Bearingpoint have been in contact with are interested in adopting this too. It can be especially beneficial in sparsely populated areas where patients must travel far to see a doctor, as self-monitoring can decrease the number of trips patients have to take to the clinic. It can for example decrease the number of routine checkups by letting the patient measure their values at home or enable a post-surgery patient to return home sooner if the only thing keeping them at the hospital is monitoring of some value. Bol sees many healthcare domains that can take advantage of self-monitoring, starting with the most vital values and later progressing to other values possible to measure at home. Several hospitals are also interested in collecting values from activity watches, but many are not CE-marked hence making it more difficult to use in healthcare settings currently.

BearingPoint's report *Digital maturity in distance care- a patient experience,* which is a case study on digital experience of type two diabetes patients in different European countries, shows low numbers for Sweden in terms of how many of the patients have access to a digital tool for their care plan. 63% of the patients in Switzerland say they use digital tools daily or weekly and only 17% in Sweden. At the same time, 65% of those who frequently use a digital tool say it is highly valuable in their diabetes treatment. The report states that a well-functioning digital platform or portal for treatment can increase patient motivation and understanding, which can lead to better compliance to the care plan.

The report draws general conclusions on barriers for this development, those being the new processes that need to be developed, data security and data management. Regarding new ways of working, self-monitoring will require someone to answer questions in chats, take video calls and alarm if any value deviates. Health care guidelines focus on previous evidence and do not induce digital tools. It is not uncommon for guidelines to be based on research carried out years ago. The education and training given to patients and caregivers also need to be sensitive to different digital maturity. In terms of data security, the storage and transfer servers need to be secure. Bol also sees challenges in making sure that the right and relevant data is collected and that it is used and analyzed in a correct way. Improvement needs to be made to integrate IT infrastructure. There is an ongoing discussion on where the data should be stored, and whether it should be allowed to store data in cloud services in other countries.

Bol means that in order to really start this development it is necessary to start gradually somewhere, the solution does not have to be perfect, and the technology today is good enough for pilot projects. A first step can be to find a clinic with capacity and try different routines there that can later be replicated in other clinics.

The current rate of technology development in UI care is described as slow by the urologist Caroline Elmer. In the 1980's researchers discovered that a ribbon can be placed underneath the urinary tract and by that decrease leakage caused by SUI. Urologists started using fillers in the 1990's and medicines but neither works as well as one could hope. In 2013 Botox was approved as a UI treatment which works well. Pads and diapers have over the years become thinner and more discreet. Urologist Netterling means that the development of assistive equipment and medicines for UI have been driven by companies developing new products to create sales.

The image of slow technology development is presented by patients who mean that no new, better innovation has been presented to them in recent years.

Patients describe UI care as a low prioritized health care domain and that quote "Doctors and scientists seem to think cancer and heart diseases are much more interesting to do research on". [56] This was also stated by urologist Hans Netterling who also added that waiting time to their clinic was 9 months and for some surgeries even several years.[57] Maria Rudolfsson and Ulrika Hagberg, Incontinence nurse and Urotherapist at Gynecologist clinic at Norra Älvsborgs Regional Hospital expressed at least a year of wait for a first appointment, this started due to the pandemic of Covid19. [58]

4.4.2.3.3 Level of primary demand

The interviewed patients described a strong demand for better treatment methods. The UI patients often have issues for their entire lives and want to find solutions to increase their quality of life permanently. They feel unprioritized by health care and feel hopeless in their situation when nothing improves their situations. This makes them willing to try new treatment methods. See section 4.4.1 for more information. [59]

4.4.2.3.4 Political and regulatory developments

An environmentally responsible public procurement process is preferred and aimed towards. In the year 2020 the Public Procurement Authority published seven targeting objectives for public procurement in Sweden:

1. Public procurement as a strategic tool for good business
2. Efficient public organizations
3. Diversity of suppliers for effective competition
4. Legally secure public procurement
5. Public procurement that promotes innovation and alternative solutions

---

[56] Anonymous Patient, Interview via video call, 21 March 2023.

[57] Hans Netterling, Urologist at surgical clinic of Västerbotten, Region Västerbotten, Interview via video call, 30 March 2023.

[58] Maria Rudolfsson and Ulrika Hagberg: Incontinence nurse and Urotherapist at Gynecologist clinic at Norra Älvsborgs Regional Hospital, Region VGR, Interview via video call, 19 April 2023.

[59] Anonymous Patient, Interview via video call, 21 March 2023.

6. An environmentally responsible public procurement process
7. Public procurement that contributes to a socially sustainable society

An audit by the Swedish National Audit Office from 2022 however indicates that the government's work on target 6, an environmentally responsible public procurement process, is not yet effective. (Riksrevisionen 2022) The government responded in march 2023 that the public procurement strategy shall be reviewed again. The purpose is to develop measures to support purchasing organizations and make it easier for suppliers to participate in public procurement processes. (Regeringskansliet 2023 B)

4.4.2.4 How do business buyers make their buying decisions?

The procurement departments at the Regions have been interviewed about their procurement process. The results from the interviews are summarized in the following tables, table 4.3 and table 4.5. Summary of data from email correspondences can be found in table 4.4.[60] The interview guides can be found in the appendix and transcripts from interviews will be handed out upon request.

[60] (1) All regions

Table 4.3 - Purchase department for medical technology

Region	Gävleborg	Norrbotten	Uppsala
Interviewee	Jenny Tjällgren: Head of the unit Procurement Department for Healthcare	Monica Uvered: Purchaser of care and staffing services, assistive devices and IT products/services	Anna Harrysson: Team leader- Medical device procurement
Planning of procurement	The investments in medtech are made on a yearly basis. The investment council sets the budget for the region.	N/A	The investments in medtech are planned on a yearly basis. For investments above 48 000 SEK hospitals need to appeal for funds to the political leadership.
Problem recognition	A need is expressed by the hospital organizations, the relevant procurement department is assigned.	A need is expressed by the hospital organizations, the relevant procurement department is assigned.	A need is expressed by the hospital organizations, the relevant procurement department is assigned.
General need description	The hospitals	The hospitals	The hospitals
Participants	N/A	The relevant healthcare organization,	The relevant healthcare organization,

		expert groups from relevant domains, purchaser	expert groups from relevant domains, purchaser
Market research	- Tracks the market through their expert groups - Suppliers come to the regions for hearings and RFIs (Requests for information) - Suppliers present their solutions to the healthcare - Attends industry fairs	- Sends out a RFI (Request For Information) to suppliers before the procurement starts - Suppliers come to the regions for hearings and RFIs (Requests for information) - Look at what other regions are currently doing - Attends industry fairs	- The region takes in information from the market. Not only the hospitals should understand what is the current state-of-the-art - Suppliers do not present their solutions to the region - Look at what other regions are doing - Can do study visits
Requirements specification	- Always includes both mandatory requirements and desirable requirements - In consultation with the hospitals and expert groups	- Always includes both mandatory requirements and desirable requirements - In consultation with the hospitals and expert groups	- Always includes both mandatory requirements and desirable requirements - Uses older procurements as a basis but always makes a new assessment after the current needs

		- Can “pre-launch” the demand specification so that suppliers can come with input - The suppliers can also come with input on the requirements specification when the tender is published and they can be revised to some extent	- Are formed together with the health care organizations and other experts. - Suppliers are not involved in shaping the demands. - Do not change the demands once the tender is published. - Sometimes use function based requirements specification instead of strict product demand to receive new products.
Tender publication	N/A	N/A	N/A
Proposal solicitation	N/A	N/A	N/A
Supplier selection	- According to LOU supplier evaluation can be based on different criteria.	- According to LOU supplier evaluation can be based on different criteria	- According to LOU supplier evaluation can be based on different criteria.

	-Try to have a holistic approach in terms of quality of life for patient and economically beneficial for the society	- Try to have a holistic approach in terms of quality of life for patient and economically beneficial for the society	- Uses the so-called “value-added model” for medtech. Evaluation is to 60% based on quality and 40% on price
Performance review			
General thoughts on future development of public procurement to swedish healthcare	N/A	- Under the IT/MT-department there are staff assigned to look at digitalisation for the future	- Want to work more strategic but limited by resources - No strategy to use more function-based demand requests. - No clear plan or directive to promote for digital solutions
General thoughts on digitalization	N/A	- Sparsely populated areas might benefit more from digital solutions. Patients do not have to travel far as often. District clinics can act as a higher level of care instant.	- The region will have to think in new ways but it is up to the health care organization to adapt their processes. - Many systems will need to be integrated

		- Many systems will need to be integrated	

Table 4.4 - Email correspondences

Region	Blekinge	Jönköping	Örebro
Email correspondence with	Head of unit, Business department	Procurement and supply chain management area, Organization support and services	Department Manager, Regional Services, Medical Technology
Planning of procurement	- The political leadership wants a run through twice a year on what is happening on the procurement side	N/A	- The requested investments are prioritized at the clinic level, area level, and finally for the entire healthcare organization and the final decision is made by the political leadership
Problem recognition	- A need is expressed by the hospital organizations, the relevant procurement department is assigned	- A need is expressed by the hospital organizations, the relevant procurement department is assigned	- A regional IT-system where health care organization sends their request for the following year - Can make request for the coming 3 years

	- To start a procurement they need an approval by the political leadership for purchases over 5 million SEK		
General need description	The hospitals	The hospitals	The hospitals
Market research	- Look at what other regions are doing - It is up to the healthcare organization to know what equipment they need - The procurement office cannot keep track of all products, but they can help out	- The regions invite suppliers to hearings where the procurement office and the affected organizations participates - Can also do RFIs	- Medtech- engineers attend industry fairs to stay updated on what is on the market - The project team for a certain purchase make study visit to other hospitals where the equipment exists - Do so called RFI and suppliers can come and present their solutions at the region
Requirements specification	- Can send the requirement specification	N/A	- Can send the requirements specification to

	draft for external review to suppliers		known suppliers to get their input
Tender publication	N/A	N/A	N/A
Proposal solicitation	N/A	N/A	N/A
Supplier selection	N/A	N/A	- Most often use the so-called “value-added model”. Where 60% is quality and 40% is price
Performanc e review	- The hospitals	- The hospitals	- The hospitals
General thoughts on future developmen t of public procurement to swedish healthcare	- No clear digitalisation strategy	- A strategy to work more with function based requirements specification	N/A
General thoughts on digitalizatio n	N/A	- Lots of integrations and system solutions that need to work	N/A

Table 4.5 - Procurement of consumables

Region	Skåne
Interviewee	Eric Donaldson: Purchasers of incontinence and diabetes devices
Planning of procurement	N/A
Problem recognition	Triggered by the expiry of old contract. The relevant procurement department is assigned.
General need description	Comes from the hospitals
Market research	- Does market analysis to cover all potential suppliers - Suppliers are invited to hearings à 45 minutes - Look to what other regions are doing - Attends industry fairs - Reads newsletters - Other contacts
Demand specification	- Rarely any ”desirable requirements” - Only “mandatory requirements” - In consultation with the hospitals and expert groups - Uses older procurements as a basis but always makes a new assessment after the current needs - The demand specifications are made after all suppliers have presented in order to have the products in mind

	- In the tender there is another category where suppliers can add additional products outside of what is requested. Here suppliers can place new products
Tender publication	N/A
Proposal solicitation	N/A
Supplier selection	- According to LOU supplier evaluation can be based on different criteria - For UI products the main focus is price
General thoughts on future development of public procurement to swedish healthcare	- No directive to procure more digital solutions - Informed the trend is towards more home health care
General thoughts on digitalization	- Sees issues with data security for patient data - No current work to synchronize different regions data management

4.4.2.5 Change Management

4.4.2.5.1 Process change - Clinic level

When a procurement according to all formalities is finalized the implementation of the new product remains. At the very end of the chain is the health care professionals' usage of the product and the routine for this. According to the interviewed urologist, Caroline Elmér, at Stockholms Urogynecologist clinic, this final process is simple. Elmér means that as her clinic is fairly small, not a lot of people are involved in the change process. New equipment and assistive devices are often introduced by the urotherapist in a dialogue with the urologist. The urotherapist simply demonstrates how to use the solution and it can quickly

be implemented. In one day everyone at the clinic can be informed about the new solution. Elmér also said that it is rare that a clinic for urotherapy is located outside of a hospital. [61]

At the workplace of Hans Netterling, which is the surgical clinic of Västerbotten, he is the one that together with a couple of colleagues handles urological cases. The implementation of new products here is also fairly simple according to Netterling. They normally study already functioning routines at other hospitals to find similar ones that can be copied or if they already exist in "Vårdhandboken". Another alternative is that the suppliers deliver complete routines of use of new products. If none of these exist, Netterling means that he and his colleague create them and most often with ease. They also strive towards using the same routines throughout the Region of Västerbotten. When implementing medtech devices they commonly benefit from existing in the "Vårdprogram" as well. [62]

Interviewee, Magdalena Vu Minh Arnell, nurse and urotherapist at the clinic for spina bifida for children, a niche within incontinence care, also stated simple processes when implementing new products. They are normally 4 employees working with these children up to the age of 18 and they handle all children with spina bifida in the western health care region (Västra Götaland, Halland, and Värmland) and when they need something to be developed they normally consult their suppliers. As they are few employees it is simple to implement the ready product but Arnell emphasizes the struggle of the product actually being procured as it is not entirely up to them. [63]

---

[61] Caroline Elmér, Urologist at Stockholms Urogynecologist clinic, Region Stockholm, Interview via video call, 17 March 2023.

[62] Hans Netterling, Urologist at surgical clinic of Västerbotten, Region Västerbotten, Interview via video call, 30 March 2023.

[63] Magdalena Vu Minh Arnell, Urotherapist for children with Spina bifida, Region VGR, Interview via video call, 11 April 2023.

4.4.2.5.2 Process change - National level

When interviewing Louise Reuterhagen, Expert in Procurement and Market Access, and Petrus Laestadius, Executive vice president, at Swedish medtech, about the usage of medtech in Swedish health they describe several barriers for its development. One reason was the fact that healthcare in Sweden has been overfunded for many years and hence investments in efficiency were not made. They mean that Swedish healthcare now sees the consequences of the lack of investments towards efficiency. Today the resources are more strained, limiting the opportunities to make those investments now. [64]

Another challenge they highlight is how new medtech equipment is evaluated and the decision process for what is subsidized. According to Reuterhagen and Lastadius there is not any instance in Sweden that has a clear responsibility to give politicians recommendations on what to subsidize. The MTP mainly recommends on the usage of the product and if they find it necessary they can ask TLV to do a health economic evaluation on the medtech product. MTP were recently involved in their first case of evaluating a product to be subsidized or not, and not their usage that they normally do. The evaluation was on weighted blankets and their recommendation was to not continue to prescribe weighted blankets. Region Kronoberg removed the subsidization on that assistive equipment based on the recommendation from the MTP. (Region Kronoberg 2021)

Reuterhagen and Lastadius means that it can be challenging for MTP and TLV to do correct evaluations due to the large number of medtech products that exist and their large variation. In Europe it increases by around 50 000 new products every year making it a challenge for any organization to keep track of all of them. According to Reuterhagen and Laestadius, The Medical Technology Product Council, only do four evaluations per year so they do not not have

[64] Louise Reuterhagen, expert in procurement and economics at Swedish Medtech and Petrus Laestadiues, Vice President at Swedish Medtech, Swedish Medtech, Interview via video call, 5 April 2023

enough capacity to keep up with the speed that new products are entering the market with.[65]

Like Bol from BearingPoint, Reuterhagen and Lastadius also emphasized the great potential of self-monitoring. However, they highlighted the health care in Sweden's current compensation model and way of budgeting as a barrier to the development of starting to use self-monitoring. In Sweden today, the individual department has its own budget and gets compensated for each patient visit the department has. As self-monitoring would imply patients not visiting the department as often or switching to another one, the individual department would lose revenues. The loss in revenue that the individual clinic sees can slow down the development of self-monitoring. Even though self-monitoring would increase efficiency in a larger sense it is hard for the individual department to change their process for a loss in revenue. Reuterhagen and Lastadies mean that a new way of thinking regarding the health care in Sweden's business model will be necessary to be able to use self-monitoring to a larger extent. [66]

[65] Louise Reuterhagen, expert in procurement and economics at Swedish Medtech and Petrus Laestadiues, Vice President at Swedish Medtech, Swedish Medtech, Interview via video call, 5 April 2023

[66] Louise Reuterhagen, expert in procurement and economics at Swedish Medtech and Petrus Laestadiues, Vice President at Swedish Medtech, Swedish Medtech, Interview via video call, 5 April 2023.

Chapter 5 - Analysis

This chapter aims to analyze the data collected in chapter 4 based on the theoretical framework presented in chapter 3. This will further be used in providing conclusions to consider when introducing IoMT solutions into the healthcare system in Sweden by providing conclusions on how an IoMT solution can be introduced on an operative level and later conclusions on a more strategic level.

The following theoretical framework, see figure 3.1, was presented in 3.5 and will be used throughout this chapter.

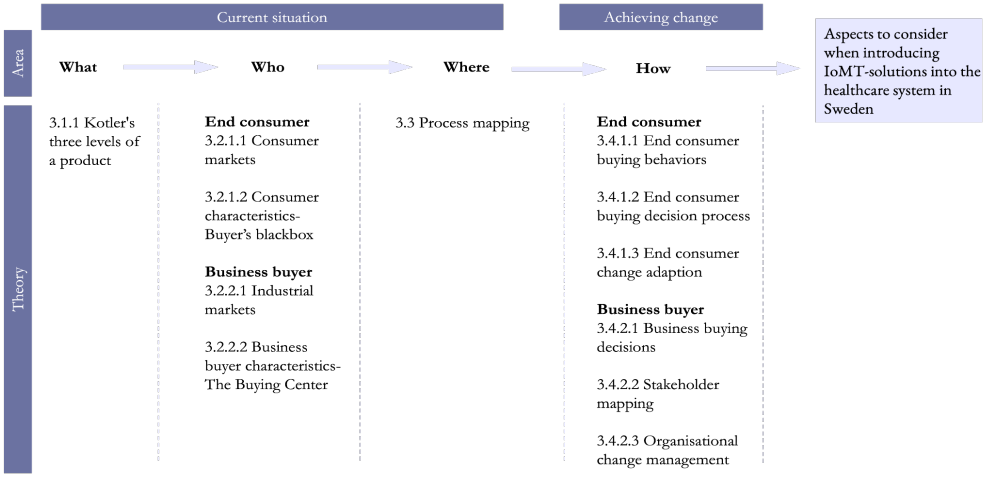

Figure 5.1 - Summary of the theoretical framework

5.1 What - The product

In this figure, figure 5.1, the analysis of the data from 4.1 will be analyzed based on the theory presented in 3.1.

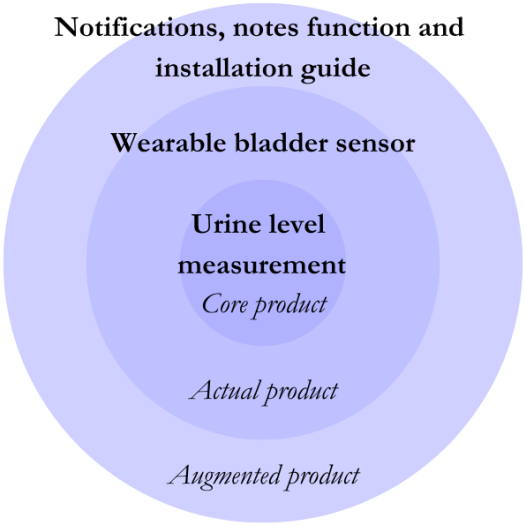

Figure 5.2 - The products three levels

5.2 Who and How - The end consumer

In this part of the analysis data from 4.2.1 and 4.4.1 will be analyzed based on the theory presented in 3.2.1 and 3.4.1.

5.2.1 End consumer characteristics

Data presented in 4.2.1.2.1 on characteristics of end consumers is in the following section analyzed according to the theory of characteristics of the model of consumer behavior in the black box in 3.2.1.2.

Interviewed medical professionals have stated long waiting times to their clinics, low development of new products for UI treatment in the latest years and a quote on incontinence care not as an attractive a field as other health care domains. Patients have mentioned that one must stand up for oneself to receive

the care needed. It can therefore be argued that the UI care domain is experiencing a low priority and that can be a possible reason why only 50 % of patients seek care. Of those who seek care the urologist/urotherapist are the ones responsible for presenting all relevant types of treatment to the patient, as in, if Product X is to be implemented in Swedish health care the medical professionals must be willing to recommend it.

As mentioned in 4.2.1.2.1.2 UI patients are commonly affected in their everyday life as they have to put energy into managing their symptoms that could be going towards work. If Product X can act as a relief, easing them from a part of their burden it can have a positive effect on how much more of their focus that can be shifted towards work, hence a positive socioeconomic affect in the greater perspective.

Also, as UI can be stated to be a low prioritized health care domain, despite UI being an endemic disease, it might be argued that a focus on the domain would have a positive effect. With self-monitoring and the current implementation of it in other healthcare domains being ongoing and a current topic of interest, UI care might be able to leverage in terms of interest and focus from this. An introduction of an IoMT-solution in the UI healthcare domain could show that UI healthcare is keeping up with the development and should not necessarily be a less attractive field to work in compared to other fields. It might also have a positive effect on the taboo. In the best of cases those 50% that do not seek care for their symptoms will understand that there is high-tech- and well-functioning care to receive, motivating them to seek care. This has great potential as fewer patients will remain untreated.

5.2.2 End consumer behavior and decision process

Section 3.4.1.1, Consumer buying behaviors, includes theory on how different consumers behave dependent on the purchase type. Section 3.4.1.2 mentions the steps of a buying decision. In section 4.4.1.1, Consumer buying behaviors, describes what type of purchase this is and in 4.4.1.2, Consumer buying

decision, data is presented on how the end consumer decides. The analysis on 4.4.1.1 and 4.4.1.1 based on 3.4.1.1 and 3.4.1.2 is presented here.

The data collection of this report shows more significance of what treatments medical professionals recommend to patients than the patient's own choice of treatment, when regarding introduction of new treatments. Therefore, analysis on end customer buying behavior is reasonably made on the medical professionals buying behavior. Their behavior is characterized by factors of new products often being expensive and a lot of research needing to be done. This is as explained thoroughly in the chapters on the business buyer, a complex situation and it can thereby be argued that medical professionals buying behavior is complex. According to the theory on customer buying behavior in 3.4.1.1 a complex buying behavior implies that all information on the product must be easily accessible to not be ruled out and that the customer must have positive experiences with the sales executive. In this case that means that the supplier of Product X must make information available to ensure positive experiences for the medical professional when meeting. This will be further explained in 5.6.

5.2.3 End consumer change adaption

The following analysis is based on the theory presented in 3.4.1.3 and the data in 4.4.1.3 and 4.4.1.4.

The interviewed patients expressed curiosity and willingness to try Product X. The patient described their situation as desperate and were therefore open to trying new treatments to improve their situation. This means that they can be classified as early adopters/early majority meaning that the opinions they have on Product X do not represent the majority. For example, when they mentioned not caring about the device showing a bit through clothes, the representative opinion of the majority may have to be altered in the direction of caring more about it showing. Regarding the technological aspect it was not stated as being a barrier for most people according, this opinion might also have to be handled in a less rigid manner as the interviewees only based this on assumptions.

The medical professionals expressed willingness to replace several different current routines with those of Product X. Although, several additional features were requested and not all were willing to replace them for the same use cases. This can be explained by the fact that all of the medical professionals have ingrained routines currently and to change them in practice differs from expressing willingness to change them. Also, as the domain is health care and human wellbeing, people are more cautious in making changes that are not secure and trustworthy. According to the theory a new product must be many times better than the old for implementation to be done.

In figure 5.2 the authors have placed the different use cases of Product X according to the data collected and the theory presented. The product can be argued to imply significant product changes when compared to current procedures of toilet training, bladder monitoring, bladder training and in diagnostics as those are currently analogue. During the interviews the medical professionals expressed most concerns regarding behavior changes when discussing diagnostics and bladder monitoring. If those features requested are not implemented, diagnostics and bladder monitoring will be considered “Long Hauls”. Whereas Toilet training and bladder training have the characteristics of being “Smash Hits”. Finally, bladder monitoring in the ICU is already done digitally and the replacement would simply ease the process by being a lighter tool for the task. This is therefore argued as an “Easy Sell”.

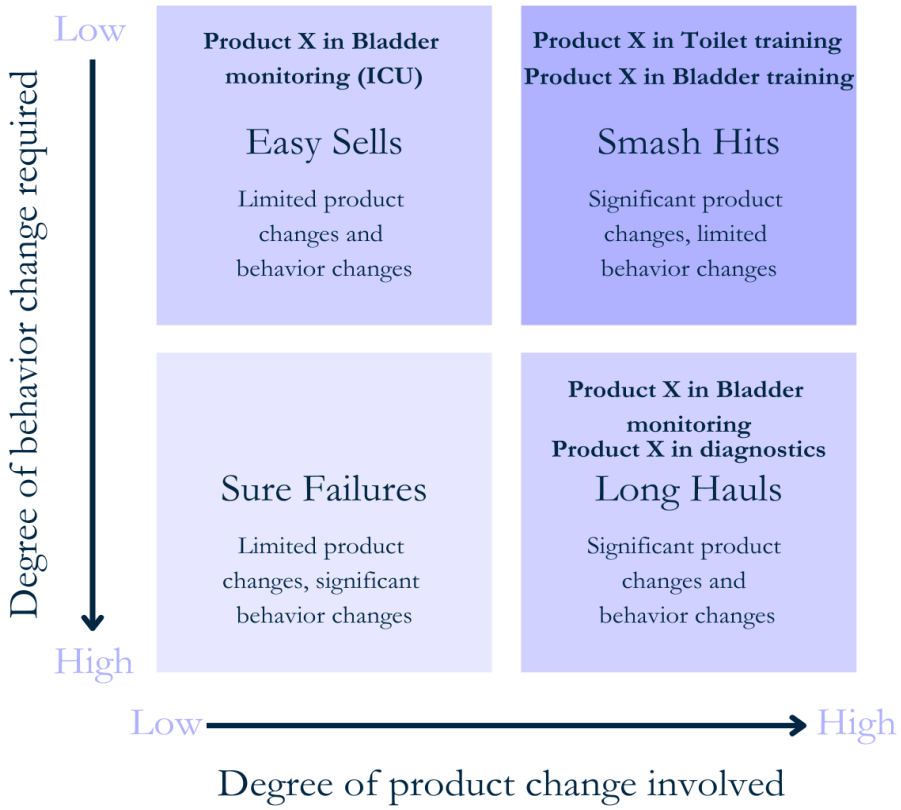

Figure 5.3 - Capturing value from Innovations

5.3 Where - The patient journey

This analysis combines 5.1 and 5.2 with the data from 4.3 and 4.2.1.1.2. Meaning what the product is and who the end customer is, is combined with the patient's journey and the patient segmentation.

All interviewed medical professionals but one have been positive towards the use of Product X in diagnostics. Depending on to what extent this way of diagnosing is implemented the amount of patients affected will vary. As the aim of diagnosis is to ascertain the UI patients type this would potentially affect all patient groups. The routine of diagnosis commonly starts before the patient

reaches the urotherapy clinic so that urologists/urotherapists are presented with the patient's data and can conclude their UI type. The patient is therefore not given much opportunity to research different ways of diagnostics and will most likely choose the method recommended. Therefore, if the medical professionals prefer current analogue micturition lists, where the patients weigh and measure their micturitions and leakages, that will be the method of choice. If they instead learn to like Product X more, that will be the method of choice. It is of importance that the majority of interviewed medical professionals have expressed a willingness to try Product X for diagnostics thereby implicating it has the potential of being a great improvement from the current method, according to the replacement willingness theory in 3.4.1.2.

The current treatment for patients being adults with overactive bladders due to UUI or MUI is primarily bladder training and adults struggling with complete emptying and adults with loss of bladder sensation need bladder monitoring. All medical professionals working with these patients expressed willingness for involvement of Product X during both the treatment of bladder training and as a replacement for bladder monitoring. The interviewed patients also identified several aspects of the use of Product X that would upgrade their lives. Although, according to the theory of technology adoption life cycle it can be argued that those patients willing to agree to an interview for this study have a specifically high interest in new solutions and technology and do not necessarily represent most patients. They were therefore asked to think like other patients they know that are more towards the right end of the technology adoption life cycle. The conclusion from that was that they themselves were very eager to try Product X, hence innovators or early adopters, but the rest would not necessarily be opposed as as earlier mentioned UI patient experience desperation for new products to try due to dissatisfaction with current ones. Instead, the opposing factors may be emphasized on the discretion or ease of use of Product X. As Product X is to great extent discreet and easy to use, it can be argued that most patients would be willing to bladder train or monitor with Product X, either until bladder is trained or as a daily monitor to relieve the patient from managing themselves.

Product X has been expressed as having potential to help children in need of toilet training with the aim of independent continence management. This was especially of relevance as the children in need of training commonly have neuropsychiatric conditions such as ADHD or ADD and need the device to remind them when a visit to the toilet is needed. Adult patients were interviewed and stated on the behalf of children that discretion can be of even higher significance for children than for adults, something that must be regarded when further developing Product X. In summary the medical professionals working with children in need of toilet training would like to try Product X for this. Children with Spina bifida were also asked but stated it to be irrelevant for them.

The final usage of Product X in Swedish health care mentioned in the collected data is in general health care where patients with or without UI need to have their urine level in bladder measures or monitored. Usage of the current machine is a heavy task for medical professionals and Product X would fulfill the same aim but by being lighter and smaller and also offering the possibility of constant monitoring. This idea came from one medical professional and was not regarded by others and therefore needs further study before being stated as a likely area of use.

Product X is concluded to be relevant for replacement of current methods in four areas in UI care (Diagnostics, bladder training, bladder monitoring and toilet training children), and one in general care (bladder monitoring and measuring). Based on this analysis and on when the patient is to be prescribed Product X and empirical data from 4.3 can conclude where the patient is when prescribed. There are five main places, see table 5.1.

Table 5.1 - Where should Product X exist

Where	**Usage**	**Patients**

Instances of primary care - basic health centers	Diagnostics	All UI
Clinics connected to the hospital via a urologist	Bladder training or bladder monitoring	Men
Clinics connected to the hospital via a gynecologist	Bladder training or bladder monitoring	Women
Children's urotherapy clinics	Toilet training	Children
ICU or in surgical clinics	Bladder monitoring	All patients in need of temporary bladder monitoring

Conclusively as Product X needs to be issued from five different places where two are in general care and not specialty clinics, it may be of importance for Product X to be centrally procured so that it is accessible to all above mentioned places of use.

5.4 Who and How- The business buyer

In this section, the data collected about the business buyer, presented in 4.2.2 and 4.4.2, will be analyzed using the theory presented in 3.2.2 and 3.4.2

5.4.1 What buying decisions do the business buyers make?

According to the theory presented in 3.4.4.1.1 business buyers will behave differently if the purchase is a straight rebuy or a new task. With the data collected on what buying decisions business buyers make in 4.2.2.1 and description of the product in 4.1 the case product will be a *new task* for the business buyer. It will be a new product that healthcare has not used before

requiring new routines and processes. As it is a digital product it needs to be integrated in the systems used by hospitals and healthcare today. This will, according to the regions, require a more thorough research process and a larger number of decision participants, see figure 5.2.

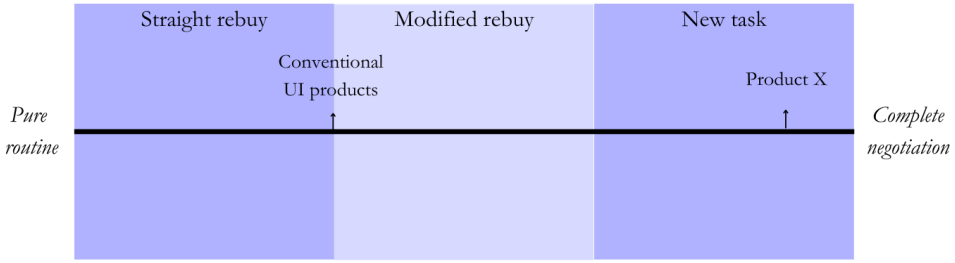

Figure 5.4 - Comparison of buying situations

5.4.2 Stakeholder mapping

According to the theory in section 3.4.2.1.2 and 3.4.2.2 it is necessary to identify and understand the different stakeholders in a process to be able to adapt the strategy to be used for a specific agenda. In this case, the participants in the procurement process to healthcare must be identified and understood in order to know what aspect an impact will have when the agenda is to introduce an IoMT solution to Swedish health. The stakeholders have been identified and analyzed using the data about the stakeholders presented in 4.2.2 and 4.4.2 in combination with the data on the product in section 4.1 an analysis was made on who are stakeholder, what is their role in the procurement of this product and what are their objectives together with the theory presented in 3.2.2 and 3.4.2.

The procurement of a new IoMT solution into Swedish healthcare is a complex process with several instances involved. As the product is new the buying decision becomes more complex, as analyzed in section 5.1 and 5.4.1. The interviews conducted have been made to map out these relationships and the different stakeholder's level of power and interest in the procurement of a new, high tech MedTech product according to the theory in section 3.4.2.2. Their

level of power and interest in the specific procurement process is mapped out relative to each other and they are categorized in the following quadrants: minimal effort, keep satisfied, key players and keep informed.

Keep satisfied

Politicians are outlined as the one with the most power when it comes to procurement of this type of product, see figure 5.3. They are responsible for the region's entire budget and hence the budget for healthcare. They have the final say on what gets subsidized in the region and therefore become the final decision makers. However, their level of interest is low due to the fact that they are politicians responsible for more than just health care in the region and especially more than deciding on what MedTech products to procure. They are also not specifically familiar with MedTech products. Budget responsible at the hospitals also have power to decide on what the specific hospital or clinic wants to purchase. They have their own budget and their own prioritization. They can play a particularly important role in the beginning of the launch of a product as the clinics and hospitals can make direct purchases for smaller amounts. If a clinic wants to buy the product to try it will be on up to the budget responsible to decide if they can do it.

The conducted interviews concluded that there is no specific instance whose recommendation will base the region's decisions on what MedTech product to subsidize. However, TLV plays a role here as they can make health economic evaluations of certain medical technology products that can influence the region's decisions.

Urologist Netterling mentioned "Vårdguiden" as important for a large scale of use of a product. It is a nationwide guidance for medical professionals. If a product is recommended for certain diagnostic and treatment methods, it will be used by a majority of the clinics in the country.

Key players

Reference groups, MTP, procurer and Sinoba can be identified as a key player in the procurement of a new MedTech product based on the conducted interviews. The reference groups members medical professionals and professionals from other relevant fields. In interviews with the procurement office at the regions it was found that the individual procurer is not an expert in the area they procure but uses expert groups to evaluate the different proposals in a tender. As the reference group contains medical professionals that will work with the product in their practice, medical professionals are included in this group. They also have a high level of interest as they are involved in the actual procurement and are hired to evaluate the proposals.

The MTP can also be seen as a key player due to the information given in the interviews. Their recommendations have an impact on the region's decision on what to subsidize and just recently stopped a MedTech product from being subsidized by a region. They evaluate the use of the product so to make sure that the MTP understands the full value of the product is of highest importance. They are also the ones who choses what products TLV should evaluate and are therefore a gatekeeper here. They are also specified on MedTech products which TLV is not and MTP hence have a higher interest.

Sinoba is an organization for patients and medical professionals. The interviewed patients were reached through Sinoba and this is therefore a way to reach the end users. Patients have strong rights according to the Patient Act that state that if a patient needs an assistive device, healthcare in Sweden is obligated by the law to provide it to them. Sinoba is ranked higher in power since the number of members gives them the power of the many.

Keep informed

Both individual patients and medical professionals are ranked lower than average in power. One medical professional can be influential in starting to use the product as a pilot project but to scale the use, one medical professional opinion is not enough. Individual patients are ranked lower as one individual

needs and preferences is not enough to introduce the product to an entire market. They both have however a strong interest in the product according to the interviews and are hence important to inform about the solution so that they can create a demand for the product.

They have a strong impact on both the patients and the procurers. They have the authority to purchase directly to their clinic without going through the procurement office at the regions up to certain monetary values and are often a part of the reference group, influencing the purchasing decisions at the Regions. Interviewed patient also said that for them to start using a new treatment method, is it necessary that they get it recommended from a medical professional for them to trust it.

The above is summarized in figure 5.3.

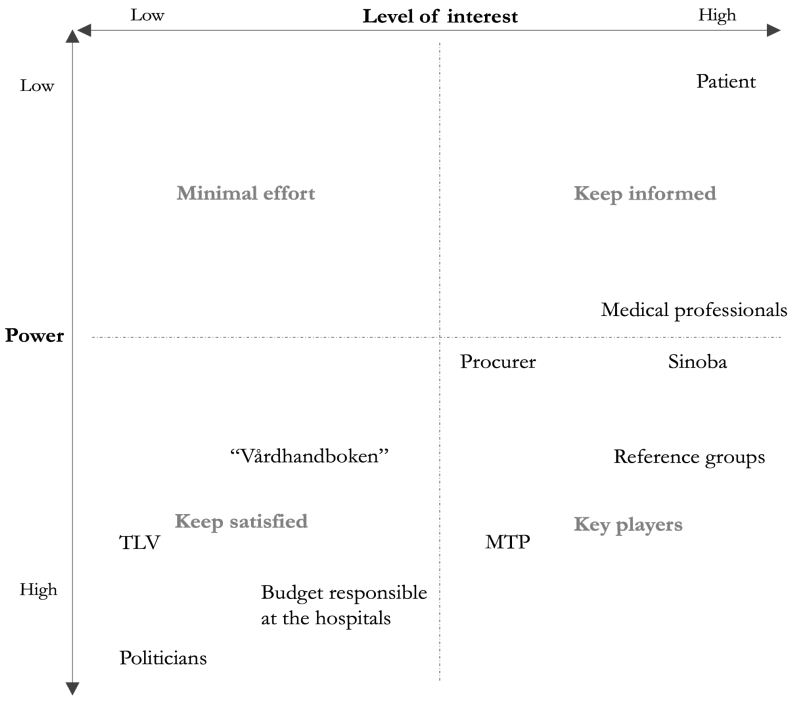

Figure 5.5 - Stakeholder mapping

5.4.3 What are the strongest influences on business buyers

The conducted interviews concluded in several factors that have an impact on the procurement process, presented in 4.4.2.3, 4.4.2.4 and 4.4.2.5. Using the theory in 3.4.2.1.3 these factors are divided into environmental, organizational, interpersonal, and individual factors. After identifying them, they have been divided into threats, if they can be seen as a barrier to an IoMT solution getting purchased and opportunity if it is something that can be in favor of the development. These factors will have an impact in both short and long term as well as micro and macro perspectives. In the tables, 5.2-5.5 the different impacting factors are classified as threat or opportunity. This classification is based on theory in section 3.4.2.

Table 5.2 of the environmental factors points out several impacting threats that need to be considered when introducing an IoMT-solution to Swedish Healthcare. These are all on a macro level and will have implications for a longer period. The current compensation model for hospitals and clinics can be a major threat as it can give individual clinics less incentives to implement solutions that will decrease the number of visits a patient makes. There is also a slight trend towards using more function-based design of tender requirements and the Swedish government also wants to investigate how suppliers can participate more easily in the public procurement process. This would be beneficial for new products trying to enter the market.

Table 5.2 - Environmental factors

Factors	**Threat**	**Opportunity**
Expected economic environment	Regression can lead to less investments in MedTech	-Regression can create a sense of urgency to improve processes -Swedish health care need to undergo

			efficiency improvements to handle the aging population
Rate of techno-logy change in	Swedish Healthcare	- Sweden is ranked low in international comparison for use of digital solutions in diabetes care - No current infrastructure for data management	Shift to self-monitoring and distance care
	UI field	Low priority	Weak competition
Level of primary demand		N/A	High level of primary demand
Political and regulatory developments		- Current compensation model for hospitals and clinics -Scattered market where every region procures to themselves	- Striving for environmentally responsible public procurement process - Swedish government want to make it easier for suppliers to participate in public procurement processes - Strive towards self-monitoring and distance care - Slight trend towards more function-based design of tender requirement

All stakeholders have organizational factors that have an impact on them, see figure 5.3. In public procurement there are a lot of policies and procedures that need to be followed which can slow down the procurement process. However, clinics have the possibility to purchase some equipment up to a certain amount, so selling a sample to one clinic in a pilot project can be easier than going via the procurement office to start with. There is also a matter of willingness to change current procedures. The asked clinics described themselves as open to new ways of working and that this product would not be hard to implement. Changing procedures on a national scale is however described by Swedish MedTech as a slow-moving process. There is no clear division on who is responsible for evaluating MedTech and there is no plan to change that in a short time perspective.

Table 5.3 - Organizational factors

Factor	**Threats**	**Opportunities**
Internal objectives	All parts have different internal objectives	Regions have objectives to buy socioeconomic efficient and sustainable products
Policies	- Strict policies in public procurement that needs to be followed -No clear division of responsibility in terms of evaluating MedTech solutions	-Framework agreements allow a 10% flexibility -Up to a certain value, clinics can make direct purchases

Procedures	-Changing procedures on a macro/national perspective is more complex -Strict regional budget, less resources to act strategically	-Individual health care clinics are open to change their procedures -Procurers at Regions do market research on other regions in the countries to know how they are procuring
Organizational structure	N/A	-Smaller health care clinics, outside a hospital have larger impact on their own procedures
Systems	N/A	N/A

Interpersonal factors that influence the buyers are summarized in table 5.4. The fact that the medical professional who is working closest with the patient, and may feel empathy for the patient, is not the one who makes the final decision can be seen as a threat. If they would have had the final say, a treatment method that could help the patient might have been purchased more easily. Now politicians far away from the patient have the final say.

Table 5.4 - Interpersonal factors

Factor	**Threats**	**Opportunities**
Authority	The medical professionals do not have the authority to buy what they want	N/A
Status	N/A	N/A
Empathy	The medical professionals working	N/A

	closets with the patient do not have the authority to buy what they want	
Persuasiveness	N/A	N/A

In terms of individual factors, findings were that personality and attitude towards risk can have an impact on the purchasing decision. Some regions had active procurement offices where the procurer attended fairs etc., while others had not, which could be signs of different levels of involvement and interest in the procurement. Risk attitude on an individual, but also organizational level may have an impact. See table 5.5 for a summary of the individual factors.

Table 5.5 - Individual factors

Factor	**Threats**	**Opportunities**
Age	N/A	N/A
Education	N/A	N/A
Personality	How active the procurement office at the region is in their market research differs from region to region and seemed to depend on who was working in the department	How active the procurement office at the region is in their market research differs from region to region and seemed to depend on who was working in the department
Job position	N/A	N/A

Risk attitudes	- Working with people's health there is a lower attitude towards risk - The region is handling tax money, and residents have expectations on their political leadership to use the money effectively	N/A

5.5 Conclusion

This section aims to summarize and conclude the findings in the analysis.

5.5.1 Introduction of IoMT solutions into healthcare in Sweden

This section aims to summarize the findings in the analysis and provide aspects to consider when introducing an IoMT solution to healthcare in Sweden on an operative and a strategic level. Using the analysis on the product, the end consumer, the patient journey and at last the business a way forward is presented, both in specific terms for Product X but also on a general level with a generic IoMT solution.

5.5.1.1 Operational level- Introduction of Product X

As this is a case study it is important to highlight what concerns the specific case product, Product X and IoMT solutions in general. Starting with what is specific for Product X it can be concluded that UI care is experiencing low priority and that Product X could face challenges with other care domains prioritized higher and by that receiving the funding. It is therefore of extra importance that the promotion is tailored to the stakeholders so that they fully understand the value of the product. Procurers have objectives to procure

socially and environmentally responsible so to showcase how this product can lower overall costs and decrease material use will be beneficial.

Another element to take into account in terms of Product X in comparison to generic IoMT solutions is that the UI domain is characterized by the fact that the patients have a larger impact on what treatment methods they end up receiving. As the care in this domain is more colored by quality of life compared to domains where the patients are in more critical condition. The patients are therefore more important to target in the UI domain. By creating a demand on the end-user side, medical professionals will be aware of the product, and they can in a later stage request to purchase the product. For patients, creating primary demand can be achieved through targeted advertising and educational campaigns. However, as this a solution that may not fit everyone it is important to target the promotion to the patient identified in 5.4 and not waste resources on patient groups that this solution will not help. Patient networks relevant for the healthcare domain can be used to reach the end consumers.

Section 5.2.3 stated that Product X will have different selling situations in the different use cases. This implies a need to tailor messaging and promotion not only depending on which stakeholder but also after what quadrant the use application is in the Capturing Value from Innovation matrix in terms of customers perception of replacement decision.

5.5.1.2 Operational level- Introduction of an IoMT solution

However, the majority of the aspects to consider when introducing Product X is applicable to a general IoMT solution with similar characteristics. A new, innovative IoMT solution will have to go through the same process no matter the healthcare domain.

What adds complexity to the procurement of a new IoMT solution is the fact that the purchase is taking place outside of the using organization. The ones who will use and for whom it will add value to are not the one who makes the

deciding decision. The one who does it are the politicians, working far away from the practice and with a scattered set of responsibilities. They on the other hand listen to MTP or TLV in what to subsidize, so there is yet another stakeholder influencer. The procurers who at the end of the day procure the solution are working in the region, listening to politicians and the reference groups. To introduce an IoMT solution to the market all stakeholders therefore need to be influenced and the message to each must be tailored after the stakeholders' prioritizations and objectives.

All regional procurement offices stated that the demand must come from the health care itself. In terms of medical professionals an evidence-based approach is needed. Having complete documentation and certification of the product can be considered a barrier to entry as this must be in place before considering selling a product to Swedish Healthcare. Medical professionals can be incentivized to use the product by highlighting how it can improve patient data and outcomes. As products might change processes, providing evidence that the procedures needed for the use of the product is working as well. To start with a pilot project at a clinic where they have larger control over their procedures and budget is a good way to show proof of concept.

The theory on change management and process change in 3.4.2.3 specifically describe it as a challenge providing evidence that the product actually leads to more efficient procedures and better care is therefore necessary. Change is particularly hard to achieve without a sense of urgency so to create this by communicating how the solution will decrease costs and need of staff in the future is a great advantage. However, as stated in 4.4.2.3.2 an IoMT solution in distance care does not have to be perfect in the beginning and if introduced it can be developed together with a clinic to better fit their needs. In section 4.4.3.1 the findings were that the interviewed medical professionals were also positive to introduce new procedures and did not see the change effort as very large. Medical professionals may be influenced by Key Opinion Leaders, so finding a urologist/gynecologist promoting these products could speed up the

usage. Pilot projects at smaller clinics can be an effective way to provide proof of concept and demonstrate the product's value.

Environmental trends and factors can be used to find what motivates the procurer in the region and political leadership in the region. Regions will be interested in the product for cost-efficient and environmental reasons. As there is a current strive towards more self-monitoring and distance care it can be favorable to find a way to communicate how the product will contribute to this. Suppliers aiming to sell their product to Sweden's various regions need to have a clear and succinct product pitch ready. Additionally, they should be actively engaged in the market to ensure that their product appears in any requests for information (RFI). Without this proactive approach, the regions may not be aware of the product's existence and unable to establish the necessary prerequisites for procurement. There are also benefits in helping the region when they are conducting pre-requisite that can enable the product to fit the tender. Finding regional initiatives that promote IoMT-solutions, like *Digitala hjälpmedel i samverkan* in VGR, can help provide visibility and support for the product. As MTP and TLV have a say in the evaluation of the medtech product it is also important that they understand the value of the product.

Stakeholder engagement is critical for the success of the product. With a large and increasing amount of MedTech products being developed and launched it is important to make sure the different stakeholders understand the value of the specific product. As there is no specific, single instance in Sweden dedicated to evaluating MedTech products, it is instead many different stakeholders that need to be influenced. It is important to keep in mind the needs and interests of different stakeholders, such as patients, medical professionals, and regions. It is also important to keep track of the different stakeholders and tailor the promotion strategy accordingly. Overall, selling a IoMT product requires careful consideration of factors such as documentation, routines, implementation, place, promotion, and stakeholder engagement. By taking these factors into account, it is possible to create a successful marketing and

sales strategy that effectively promotes the product and meets the needs of different stakeholders.

5.5.1.3 Strategic level- Introduction of an IoMT solution

This thesis has yielded aspects to consider when introducing IoMT-solutions to Swedish MedTech. Aspects to consider on an operational level were presented in 5.5.1.1 and 5.5.1.2 and below are aspects to consider when introducing IoMT-solutions to healthcare in Sweden on a strategic level.

A barrier for the emergence of IoMT-solutions and distance care is the current compensation model for Swedish healthcare. To avoid clinics not wanting to change to procedures
where
the patient visits the clinic less often, companies wanting to sell these types of solutions need to be active in the debate and lobby for a more appropriate compensation model.

The fact that there is currently no clear pathway for how to get a MedTech product subsidized is also an aspect that is important to consider. New MedTech products also arrive to the market frequently. The regions often take the advice of the MTP and TLV but the two instances only have time to evaluate a certain amount of products per year. Lobbying to make it easier for MedTech products to reach the market is therefore needed.

Theory on change management in section 3.4.2.4 concludes that a burning platform and change purpose is needed to achieve a change effort. The fact healthcare's resources will be more strained in the future can be a trend IoMT solutions can leverage from. If the product is proven to reduce use of resources, the product can leverage on this trend.

Chapter 6 - Summary and reflection

This thesis states aspects to consider when introducing IoMT-solutions in UI care that can be applicable to other kinds of IoMT-solutions in different healthcare domains in Sweden. This chapter aims to provide a summary of the analysis followed by a reflection on the thesis potential shortcomings as well as disclaimers of things occurred during the project that may have affected the results.

6.1 Summary

This master thesis takes its standpoint in the fact that the healthcare system in Sweden is currently facing major challenges, particularly with regards to rising healthcare costs, an aging population, and an increase in cases of chronic diseases. Previous research gave a common view that to overcome these challenges, the healthcare system requires innovative solutions that can provide cost-effective care while maintaining quality standards. Research pointed out that Internet of Medical Things (IoMT) solutions have the potential to address these challenges by utilizing emerging technologies and data-driven approaches to healthcare.

Building on previous research, the authors of the thesis aimed to analyze aspects to consider when introducing IoMT-solutions into the healthcare system in Sweden. First the case product was analyzed to be able to understand how it could fit the end users, patients and medical professionals, needs and wants. A purchase of this kind of product will parallelly occur in different organizations, hence an analysis of the actual buyer, the business buyer, is needed as well. The conclusions made about the product and the end users were utilized in analyzing how the buying process of Product X would be formed. The thesis landed in aspects to consider on an operative and strategic level. Some aspects are only applicable to the case product, Product X, while others can be applied on generic IoMT solutions. Below are the key findings from the analysis. For further elaboration, see chapter 5.

Concerning Product X it is important to take into account the fact that today's UI care is described by relevant stakeholders as a healthcare domain that experiences low priority and that Product X could face challenges with other domains being prioritized higher financially. The treatment in this domain is also more colored by the quality of life compared to domains where the patients are in more critical conditions. The patients are therefore more involved in what type of solution they want to use in the treatment of their UI. For suppliers aiming to sell to this domain it is therefore more important to also target the patient. If patients start requesting the product, medical professionals will become aware of it and they can in a later stage request to purchase the product. As it was found that this product will not help all UI patients it is important to target the promotion to the patients identified.

Aspects to consider on an operative level that can be applied to a generic IoMT solution is the extra complexity that the fact that the procurement of a new IoMT solution takes place outside of the using organization. The ones who will use and for whom it will add value to, are not the ones who make the deciding decision. The regional political leadership decides on what the inhabitants of the region are to get subsidized, and they consult institutions who evaluate MedTech equipment, to make these decisions. After that, it is up to the procurement office to make the final call on what exact product to be purchased. The procurers at the regions seek opinions from reference groups to gain input on what products that are to be procured. In order to introduce an IoMT solution to the market all stakeholders therefore need to be influenced and the message to each, must be tailored after the stakeholders' priorities and objectives.

All regional procurement offices stated that the demand must come from the health care itself. Medical professionals want to see complete documentation and certification of the product to start using it. To start with a pilot project at a clinic where they have larger control over their procedures and budget, is a good way to show proof of concept. The theory on change management

describes the challenges with changing procedures and that it requires a strong change purpose. Providing strong evidence that the product can increase productivity and better care, can therefore create this change purpose. Change effort also often requires a sense of urgency. Using the fact that health care in Sweden will need innovative solutions to face the challenges it is facing to create a sense of urgency and how the product can help is therefore beneficial. However, it was found that for an IoMT solution to be used in distance care and self-monitoring it does not have to be perfect to begin the usage. At this point it is better to start somewhere and from there on continue the development and improve procedures as one proceeds. It was found that medical professionals can be influenced by Key Opinion Leaders, therefore the identification of urologists or gynecologists who endorse the products can accelerate their adoption. Implementing pilot projects at smaller clinics can be an effective way to demonstrate the product's value and validate its feasibility.

Environmental trends and factors that influence the procurer in the region and the political leadership, can be used to find what motivates them. It was found that the region’s value product highly if they are cost-efficient and environmentally beneficial. As there is a current strive towards more self-monitoring and distance care it can be favorable to find a way to communicate how the product will contribute to this. Suppliers aiming to sell their product to Sweden’s various regions must have a clear and succinct product pitch ready. Additionally, they should be actively engaged in the market to ensure that their product appears in any requests for information (RFI). Without this proactive approach, the regions may not be aware of the product’s existence and unable to establish the necessary prerequisites for procurement. There are also benefits in helping the region when they are conducting prerequisites that can enable the product to fit the tender. Finding regional initiatives that promote IoMT-solutions can help provide visibility and support for the product. As MTP and TLV have a say in the evaluation of the MedTech product it is also important that they understand the value of the product.

To conclude aspects to consider when introducing IoMT-solutions to the healthcare system in Sweden on an operative level it can be said that stakeholder engagement is critical for the success of the product. With a large and increasing amount of MedTech products being developed and launched it is important to make sure the different stakeholders understand the value of the specific product. As there is no specific, single instance in Sweden dedicated to evaluating MedTech products, it is instead many different stakeholders that need to be influenced. It is important to keep in mind the needs and interests of different stakeholders, such as patients, medical professionals, and regions. It is also important to keep track of the different stakeholders and tailor the promotion strategy accordingly.

On a strategic level there are three main aspects to consider. A barrier for the emergence of IoMT-solutions and distance care is the current compensation model for Swedish healthcare. To avoid clinics not wanting to change to procedures where the patient visits the clinic less often, companies wanting to sell these types of solutions need to be active in the debate and lobby for a more appropriate compensation model. The fact that there is currently no clear pathway for how to get a MedTech product subsidized is also an aspect that is important to consider. New MedTech products arrive to the market frequently. The regions often take the advice of the MTP and TLV but the two instances only have time to evaluate a certain amount of products per year. Lobbying to make it easier for MedTech products to reach the market is therefore needed.

Overall, the findings offer valuable insights for introducing IoMT-solutions in other healthcare domains in Sweden. The thesis identifies challenges such as a complex procurement process, healthcare's current compensation model and a lack of clear pathways for product subsidies. In addition, the study emphasizes the need for active engagement with stakeholders and a sense of urgency to drive change. To facilitate the introduction, the study recommends sellers to address stakeholder needs, provide evidence of benefits, actively engage in the market, and to tailor the approach to different stakeholders. Developing

appropriate clinic routines for the product and leveraging regional initiatives promoting innovation in healthcare is also of importance.

6.2 Reflection

First of all, it is of importance to mention that both authors have contributed equally to the thesis and that has led to the following contributions:

The academia has received a contribution of new research on the subject of IoMT in Sweden and also a stable foundation for further projects within the same area.

The industry has gained insights on aspects that can have an impact on the procurement process of an IoMT solution.

The thesis will act as an extensive introduction to anyone new to the business of selling IoMT- or high-tech MedTech solutions in Sweden.

The authors have gained academic competence on the construction and carrying through of a master thesis and great knowledge on procurement in the public sector.

After collecting data about the patient journey the author decided to use swim lane to visualize the process in 4.3. Several methods for visualizing the process were presented in 3.3 to give an opportunity to use the one who fit the best once the data was collected. As the processes were best described after responsibility, swim lane was the most appropriate.

Interviews have mainly been done via video call. The reason for this was to be able to reach people from all over Sweden and to travel to all of them individually would not be sustainable economically or timewise. Some sentimental if lost when not meeting in person but the authors also deemed this to be of advantage as it facilitated them to be more objective in the interviews.

Further interviews would have gained even deeper insights and more nuanced views of the situation.

The conclusion of this thesis may as stated be applicable on other healthcare domains. As only UI care was studied it is possible that other healthcare domains work in different ways and cannot apply the same findings. Although it has been indicated through the interviews that healthcare domains in Sweden are similar.

6.3 Further research

A complete study of the socioeconomical effects of the implementation of Product X. Including prognosis on quantitative data and an analysis on the greater effects on society.

A pilot launch of Product X according to this study's presented GTM strategy to test its proof of concept.

A comparative study on another IoMT-solution in a different healthcare domain to find synergies and differences.

A study on what compensation model hospitals should utilize to optimize conditions for self-monitoring.

Appendix

Interview guide - Patients

Har du sökt vård för din inkontinens?
Hur har mottagandet varit?
Har du fått den hjälp du behöver?
Hur gick det till när du sökte vård?
Upplever du tabu när det kommer till att prata om inkontinens?
Har tabun ökat eller minskat genom tiden?
Vet du vilken typ av inkontinens du har?
Hur påverkar inkontinens din vardag?

Vad önskar du varit annorlunda i hur du behandlar din inkontinens?
Hur resonerar du i hur du sköter din inkontinens idag?
Hur mycket tid lägger du på att undersöka behandlingsmetoder för din inkontinens?
Hur ofta köper du inkontinensprodukter?
Hur väljer du produkter?
Använder du det du får förskrivet eller köper du själv det du vill ha?
Vad är högst prioritering vid köp av inkontinensprodukter?
Spelar kvalitet eller pris mest roll?
Är vilket brand viktigt?
Hur tror du att andra med liknande problem resonerar? Hur stora problem tror du man måste ha för att det ska vara värt att göra något större åt det?

Spontant, hur skulle det kännas om du hade en teknisk pryl på magen hela dagen?
Vad tycker du om wearables?
Hade du litat på en teknisk produkt?
Hur mycket bättre måste en lösning vara för att du ska byta?
Hade du sökt hjälp om du visste att det fanns den här typen av hjälpmedel?
Hur tror du andra patienter resonerar kring nya lösningar?

Hade du kunnat tänka dig ett större engångsköp för att sedan kunna använda mindre produkter?
Hur mycket hade du kunnat tänka dig att betala?

Interview guide - Urologists

Vilka patienter tar du emot?
Hur kommer de till dig? Vad är resan innan?
Vad är era prioriteringar när ni väljer behandlingsmetod?
Känner ni att ni har tillräckligt med resurser och möjlighet att påverka för att ge bästa möjliga vård?
Är budgeten begränsande?
Vem tar "the final decision"?
Vad får ni influenser ifrån?
Hur tar ni till er nya innovationer?
Går ni på mässor? Lyssnar du på föredrag? Key opinion leaders?
Hur kommer ni i kontakt med nya innovationer?
Vad är viktigt för er när ni utvärderar nya läkemedel?
Sker det mycket utveckling inom inkontinensvården?
Har ni ett aktivt utvecklingsarbete på er mottagning?
Är ni vana vid att ta till er nya lösningar och behandlingsmetoder?

Hur villiga är era patienter att testa nya behandlingsmetoder?
Gör era patienter mycket egen research?
Bryr era patienter sig om brand?
Följer dem era råd?

Vilken roll har du när det kommer till att köpa in produkter för diagnostik, behandlingsmetoder och hjälpmedel?
Vad är er prioritering när ni utvärderar hjälpmedel till patienter?
Vad påverkar mest?
Om ni ska implementera en ny behandlingsmetod eller ett nytt sätt att diagnostisera, hur går det till?

Hur går det till när ni ska införa en ny behandlingsmetod eller sätt att diagnostisera?
Vem leder förändringsarbetet?
Vad hade varit ett bra hjälpmedel för att förbättra inkontinensvården i Sverige?
I form av diagnostik?
I form av hjälpmedel?
Hur tror du att denna produkt kan användas inom inkontinensvård idag?
Vilka patienter kan dra nytta av den?
Vilken typ av inkontinens skulle de ha isåfall?
Diagnostik?
Mönsteridentifiering?
Långvarig avlastning?
Vad krävs för att du ska börja använda den? Vilka krav skulle du ställa på den?
Vad mer behöver den kunna göra?
Största fördelen? Möjligheter?
Största nackdelen? Hinder?

Interview guide - Urotherapists and Incontinence nurses

Vad gör du i din roll som uroterapeut?
Vilka patienter jobbar ni med?
Barn och vuxna?
Vilka typer av inkontinens är vanligast?
Kan ni uppskatta procentuellt?
Hur kommer patienter in i vården?
Via vårdcentral?
Via barnmorskor?
Via specialistmottagningar?
Via akuten?
Hela patientens journey? Skickas dem vidare till gynekologer/urologer?
Vem träffar de och när?
Hur går remisserna?
När “skrivs de ut”?

Gäller detta allmänt eller är det olika mellan mottagningar och regioner?
Är det som i vårdhandboken?

Vad hade varit ett bra hjälpmedel för att förbättra inkontinensvården i Sverige?
I form av diagnostik?
I form av hjälpmedel?
Hur tar du till dig nya diagnostik- och behandlingsmetoder?
Hur tror du att denna produkt kan användas inom inkontinensvård idag?
Vilka patienter kan dra nytta av den?
Vilken typ av inkontinens skulle de ha isåfall?
Skulle den kunna användas inom diagnostik?
Skulle den kunna användas inom mönsteridentifiering?
Skulle den kunna användas inom långvarig avlastning?
Vad krävs för att du ska börja använda den? Vilka krav skulle du ställa på den?
Vad mer behöver den kunna göra?
Största fördelen? Möjligheter?
Största nackdelen? Hinder?
Hur går det till när ni ska införa en ny behandlingsmetod eller sätt att diagnostisera?
Vem leder förändringsarbetet?

Interview guide - Procurer departments at Regions

Vad gör du i din roll på Region *XXXX*?
Vilka är inblandade i upphandling av sjukvårdsprodukter i.e. mediciner/patient hjälpmedel/medicinteknik?
Nämn alla intressenter
Vad har de olika för ståndpunkter?
Vad är de olika intressenternas mål och prioriteringar?
Vad har de för inställning till kostnad? Även i form av tidsbesparing på längre sikt?
Vad har de för inställning till mängden nödvändig forskning?
Vad har de för inställning till användarvänlighet?

Vad har de för allmän inställning till avancerad teknik?
Finns det vissa sjukdomar som prioriteras högre än andra?
Finns det egenskaper hos de som utför dem som skiljer dem från inköpare som sköter andra typer av upphandlingar?

- Utbildning?
- Erfarenhet?
- Ålder?
- Intresse?

Är det samma avdelning som köper upp för sjukvård för barn och ungdomar?
Hur går processen för nya, medicintekniskt hjälpmedel till? Dvs produkter som ännu inte finns på marknaden?
Finns det någon särskild budget för en sådan?
Vem skulle vara involverad i den?
Vad skulle deras ståndpunkter vara?
Hur skulle de prioritera?
Hur samarbetar ni? Vad sker och vad sker inte i samråd?
Vad skulle kunna influera dem?

- Diskussion med läkare?
- Key Opinion Leaders?
- Forskning?
- Konferenser/mässor?

Vad behöver hända i varje steg i processen för att det ska leda till ett köp?
Ser processen likadan ut för sjukvård för barn och ungdomar?
Hur skulle processen för ett hjälpmedel för urininkontinens gå till?
Vem skulle vara involverad i den?
Vad skulle deras ståndpunkter vara?
Hur skulle de prioritera?
Vad skulle kunna influera dem?

- Diskussion med urologer?
- Key Opinion Leaders?
- Forskning?
- Konferenser/mässor?

Vad behöver hända i varje steg i processen för att det ska leda till ett köp?

Bibliography Chapter 1

Andersson, E. & Henningstam F. (2021) *Den digitala kompetensen inom äldreomsorgen: En kvalitativ studie ur vårdpersonalen perspektiv.* University West https://www.diva-portal.org/smash/record.jsf?dswid=-3447&pid=diva2%3A1604564

Chui, M., Collins, M. & Patel, M. (2021) *IoT value set to accelerate through 2030: Where and how to capture it.* McKinsey & Company Insights https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/iot-value-set-to-accelerate-through-2030-where-and-how-to-capture-it

Cardona, M., Solanki, V.K., & Cena, C.E.G. (Eds.). (2021). *Internet of Medical Things: Paradigm of Wearable Devices (1st ed.).* CRC Press. https://doi.org/10.1201/9780429296864

European Commission (2023) *The impact of demographic change- in a changing environment.* Commission staff working document. Brussels. SWD (2023) 21 final https://commission.europa.eu/system/files/2023-01/the_impact_of_demographic_change_in_a_changing_environment_2023.PDF

Harris, R. (2022) *Aging Aline: Elder Care Infrastructure in the EU.* Harvard international review https://hir.harvard.edu/elder-care-infrastructure/

Marr, B. (2018) *What is Industry 4.0? Here's A Super Easy Explanation For Anyone* https://www.forbes.com/sites/bernardmarr/2018/09/02/what-is-industry-4-0-heres-a-super-easy-explanation-for-anyone/?sh=6992d3d29788

Myndigheten för tillväxtpolitiska utvärderingar och analyser (2018) *Företagets digitala mognad 2018.* https://www.tillvaxtanalys.se/publikationer/pm/pm/2019-09-16-foretagens-digitala-mognad-2018.html

Koul, S. (2022) *Artificial Intelligence and Industry 4.0 (Chapter 1 - Influence and implementation of Industry 4.0 in health care)* (https://www.sciencedirect.com/science/article/pii/B9780323884686000024

Prochazka, M. (2022) *Vård och Omsorg för äldre - Lägesrapport 2022.* Socialstyrelsen https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2022-3-7791.pdf

Socialstyrelsen (2018) *Kapaciteten i sjukvården- att hantera kritiska lägen* https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2018-12-1.pdf

Statistiskmyndigheten SCB (2022) *Fler äldre i alla län och kommuner 2040* https://www.scb.se/hitta-statistik/statistik-efter-amne/befolkning/befolkningsframskrivningar/befolkningsframskrivningar/pong/statistiknyhet/den-framtida-befolkningen-i-sveriges-lan-och-kommuner-2022-2040/

Statistikmyndigheten SCB (2021) *Trender och Prognoser 2020 Befolkning, utbildning, arbetsmarknad – med sikte på år 2035.* Statistics Sweden, Population and Welfare Department, Forecast Institute. ISSN: 1653-4085 https://www.scb.se/contentassets/3fbf2376d5aa43d6a8c52b7911bd3f59/uf0515_2020i35_br_am85br2101.pdf

Spak, E. (2022) *Vi måste förhålla oss till demografins verklighet.* Vårdbloggen SKR. https://skr.se/skr/tjanster/bloggarfranskr/vardbloggen/artiklar/vimasteforhallaosstilldemografinsverklighet.63353.html#:~:text=Gl%C3%A4djande%20nog%20ser%20vi%20ett,upp%20f%C3%B6r%20antalet%20ST%2Dl%C3%A4kare

Wendin, K., Kylefors, M. & Mjörnell, K. (2013) *En åldrande befolkning.* Sveriges Tekniska Forskningsinstitut https://www.diva-portal.org/smash/get/diva2:962756/FULLTEXT01.pdf

Östlund, B. (2017) *Digitizing health care: Welfare technology as a way to meet digital and demographic challenges in Sweden.* 4th International Conference on Systems and Informatics (ICSAI), Hangzhou, China, 2017, pp. 78-83, doi: 10.1109/ICSAI.2017.8248267. https://ieeexplore.ieee.org/document/8248267

Bibliography Chapter 2

Easterby-Smith, M., Thorpe, R. & Lowe, A. (2002) *Management Research: An Introduction* (2nd edn), London, Sage

Goulding, C. (2002) *Grounded Theory: A Practical Guide for Management, Business and Market Researchers,* London, Sage

Lunds Universitet. (2019). LTH Master's student guide: Citation searching. https://libguides.lub.lu.se/c.php?g=297409&p=1990996 [2020-02-18]

Mitchell, A. (2018) 'A Review of Mixed Methods, Pragmatism and Abduction Techniques',
Electronic Journal of Business Research Methods, 16(3), p. 103–116. Available at:
https://academic-publishing.org/index.php/ejbrm/article/view/1378 . (Accessed: 13 October
2022).

Nationellt kliniskt kunskapsstöd (2021) *Urininkontinens hos kvinnor.* https://nationelltklinisktkunskapsstod.se/dokument/573f8d38-1e4d-4a3a-80a9-d8d728d0cdaf

Saunders, M., Lewis, P. & Thornhill, A. (2009). Research methods for business students. 5:e uppl., Pearson Education Limited.

SBU (2013) *Behandling av urininkontinens hos äldre och sköra äldre* https://www.sbu.se/contentassets/911d0909b43a44b9a35e8a207c164274/Urininkontinens_2013_219.pdf

Socialstyrelsen (2016) *Blåsdysfunktion hos äldre personer.* https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2016-9-33.pdf

Vårdhandboken (2021) *Urininkontinens - Översikt*. https://www.vardhandboken.se/vard-och-behandling/urinvagar/urininkontinens/oversikt/

Wheeldon, J. and Åhlberg, M. K. (2012) *Visualizing Social Science Research: Maps, Methods, & Meaning.* Thousand Oaks, California, United States: SAGE Publications, Inc. doi:10.4135/9781483384528.

Bibliography Chapter 3

Edgren, J. & Skärvad, P.-H. (2014). *Nätverksorganisationer: outsourcing, partnerskap och nya organisationsformer* (2., upplagan). Liber.

Galli, J, B. (2018) *Change Management Models: A Comparative Analysis and Concerns*, in IEEE Engineering Management Review, vol. 46, no. 3, p. 124-132, 1 third quarter,Sept. 2018, doi: 10.1109/EMR.2018.2866860.

Gourville, J. (2006) *Eager Sellers and Stony Buyers: Understanding the Psychology of New-Product Adoption.* Harvard Business Review. https://hbr.org/2006/06/eager-sellers-and-stony-buyers-understanding-the-psychology-of-new-product-adoption

Jacquemont, D., Moar, D. & Reich, A. (2015) *How to beat the transformation odds.* McKinsey & Company. https://www.mckinsey.com/~/media/mckinsey/business%20functions/people%20and%20organizational%20performance/our%20insights/how%20to%20beat%20the%20transformation%20odds/how_to_beat_the_transformation_odds.pdf

Johnson, G., Whittington, R., Scholes, K., Angwin, D. & Regner, P. (2015). *Fundamentals of*

strategy (3. ed.). Pearson.

Jun, G, T., Ward, J.,Morris, Z. & Clarkson, J. *Health care process modeling: which method when?, International Journal for Quality in Health Care,* Volume 21, Issue 3, June 2009, Pages 214–224, https://doi.org/10.1093/intqhc/mzp016

Kotler, P (2012) *Marknadsföring: teori, strategi och praktik.* Pearson Education.

Kotler, P., Eldon, S., Wong, Saunders, W. & J. Armstrong, G. (2004) *Principles of marketing.* Pearson Prentice Hall

Kotter, J (2014) *The 8-step Process for Accelerating Change* E-book https://www.kotterinc.com/methodology/8-steps/

Näslund (2013) *Lean and six sigma- critical success factors revisited.* International Journal of Quality and Service Sciences Vol. 5 No. 1, 2013 pp. 86-100q Emerald Group Publishing Limited 1756-669X DOI 10.1108/17566691311316266

Näslund, D. & Norrman, A. (2022): *A Conceptual Framework for Understanding the Purpose of Change Initiatives,* Journal of Change Management, DOI: 10.1080/14697017.2022.2040571

Skärvad, P.-H. & Olsson, J. (2015). Företagsekonomi 100 (17:e upplagan). Liber.

Sridharan, S. (2017) *Crossing The Chasm – Technology Adoption Lifecycle.* https://thinkinsights.net/strategy/crossing-the-chasm/

Bibliography Chapter 4

Bearingpoint (2022) *Digital transformation in health care* https://www.bearingpoint.com/en-se/download/?item=26967&error=secondTime&module=

Ekonomifakta (2023) *Högkonjunktur eller lågkonjunktur?* https://www.ekonomifakta.se/Fakta/Ekonomi/Tillvaxt/hogkonjunktur-eller-lagkonjunktur/

European Commission (2023) *The impact of demographic change- in a changing environment.* Commission staff working document. Brussels. SWD (2023) 21 final https://commission.europa.eu/system/files/2023-01/the_impact_of_demographic_change_in_a_changing_environment_2023.PDF

IVO (n.d.) *Vad är en medicinteknisk produkt?*. https://www.ivo.se/yrkesverksamma/anmal-uppgifter-till-ivos-olika-register/medicinteknik/vad-ar-en-medicinteknisk-produkt/

Janusinfo (2023 A) *Riktlinjer för behandling av urininkontinens.* https://janusinfo.se/behandling/expertgruppsutlatanden/urinvagssjukdomar/urinvagssjukdomar/riktlinjerforbehandlingavurininkontinens.5.6081a39c160e9b3873180d1.html

Janusinfo (2023 B) *Medicintekniska produktrådet* https://janusinfo.se/nationelltinforandeavmedicinteknik/saarbetarvi/rollerochkontaktuppgifter/roller/medicintekniskaproduktradet.5.74a8b4c1170b06b45db47a84.html

Konkurrensverket (n.d.) *The Public Procurement Act in brief* https://www.konkurrensverket.se/en/public-procurement/laws-and-rules/the-swedish-public-procurement-act/

Kotler, P (2012) *Marknadsföring: teori, strategi och praktik.* Pearson Education.

Kunskapsguiden (2022) *Lagar och regler* https://kunskapsguiden.se/omraden-och-teman/arbetsmetoder-och-perspektiv/hjalpmedel/lagar-och-regler/

Life Science Sweden (n.d.) *”Lågkonjunkturen sätter press på nationella sjukvårdsbudgetar”* https://www.lifesciencesweden.se/article/view/1018517/lagkonjunkturen_satter_press_pa_nationella_sjukvardsbudgetar

Martinson, A (2021) *Urininkontinens hos barn.* Vårdhandboken. https://www.vardhandboken.se/vard-och-behandling/urinvagar/urininkontinens/urininkontinens-hos-barn/

Nevéus, T (2020) *Sängvätning hos barn*. 1177. https://www.1177.se/sjukdomar--besvar/njurar-och-urinvagar/sangvatning-hos-barn/

Prochazka, M. (2022) *Vård och Omsorg för äldre - Lägesrapport 2022.* Socialstyrelsen https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2022-3-7791.pdf

Regeringskansliet (2023 A) *Besvärligt läge i ekonomin* https://www.regeringen.se/artiklar/2023/03/besvarligt-lage-i-ekonomin/

Regeringskansliet (2023 B) *Regeringen ser över den nationella upphandlingsstrategin* https://www.regeringen.se/pressmeddelanden/2023/03/regeringen-ser-over-den-nationella-upphandlingsstrategin/

Regeringskansliet (n.d.) *Offentlig upphandling*

https://www.regeringen.se/regeringens-politik/offentlig-upphandling/

Region Kronoberg (2021) *Subventionering av tyngdtäcken upphör* https://www.regionkronoberg.se/nyhetsarkiv/2021/subventionering-av-tyngdtacken-upphor/

Riksrevisionen (2022) *Miljömässig hållbarhet vid statlig upphandling – på rätt väg men långt kvar (RiR 2022:25)* https://www.riksrevisionen.se/rapporter/granskningsrapporter/2022/miljomassig-hallbarhet-vid-statlig-upphandling---pa-ratt-vag-men-langt-kvar.html

Sinoba (n.d.) https://sinoba.se/

SKR (2023 A) *Så styrs sjukvården i Sverige* https://skr.se/skr/halsasjukvard/vardochbehandling/ansvarsfordelningsjukvard.64151.html#:~:text=Regioner%20och%20kommuners%20ansvar,hemmet%20och%20p%C3%A5%20s%C3%A4rskilda%20boenden

SKR (2023 B) *Egenmonitorering hälso-och sjukvård* https://skr.se/skr/halsasjukvard/utvecklingavverksamhet/ehalsa/egenmonitoreringdigitalaprodukter.15226.html

Socialstyrelsen (2021) *Vem får använda, förskriva och lämna ut medicintekniska produkter? (särskilt reglerad). För hälso- och sjukvården och tandvården* https://www.socialstyrelsen.se/kunskapsstod-och-regler/regler-och-riktlinjer/vem-far-gora-vad/medicinska-produkter/

TLV (n.d.) https://www.tlv.se/

Upphandlingsmyndigheten (2022) *Vad är skillnaden mellan direktupphandlingsgräns och tröskelvärde?*

https://www.upphandlingsmyndigheten.se/frageportalen/2635717/vad-ar-skillnaden-mellan-direktupphandlingsgrans-o/?fromPopularityListing=true

Upphandlingsmyndigheten (n.d. A) *Om offentlig upphandling* https://www.upphandlingsmyndigheten.se/om-offentlig-upphandling/#ska_varna_om_skattemedlen_och_sakra_sund_konkurrens

Upphandlingsmyndigheten (n.d. B) *Ramavtal* https://www.upphandlingsmyndigheten.se/regler-och-lagstiftning/olika-sorters-avtal-och-kontrakt/ramavtal/

Upphandlingsmyndigheten (n.d. C) *Fortsatt ökat intresse för offentliga upphandlingar* https://www.upphandlingsmyndigheten.se/statistik-som-utvecklar-den-offentliga-affaren/fortsatt-okat-intresse-for-offentliga-upphandlingar/

Upphandlingsmyndigheten (n.d. D) *Upphandla eller utkontraktera vård och omsorg* https://www.upphandlingsmyndigheten.se/branscher/vard-och-omsorg/#:~:text=Involvera%20brukare%20och%20patienter,som%20st%C3%A4lls%20m%C3%B6ter%20deras%20behov

VGR (2023) *Digitala hjälpmedel i samverkan* https://www.vardsamverkan.se/pagaende-uppdrag/valfardsteknik-i-samverkan/

Vården.se (n.d. A) Urolog https://www.varden.se/hitta/urolog-c

Vården.se (n.d. B) Gynekolog https://www.varden.se/hitta/gynekolog-c

Vårdhandboken (n.d.) *About us* https://www.vardhandboken.se/om/om-vardhandboken/in-english/

References to interviews

(1) All regions:

Jenny Tjällgren, Head of the unit Procurement Department for Healthcare, Region Gävleborg, 10 March 2023.

Monica Uvered, Purchaser of care and staffing services, assistive devices and IT products/services, Region Norrbotten, 16 March 2023.

Anna Harrysson, Team leader- Medical device procurement, Region Uppsala, Interview via video call, 17 March 2023.

Eric Donaldson, Purchasers of incontinence and diabetes devices, Region Skåne, Interview via video call, 29 March 2023.

Head of unit, Business department, Region Blekinge, Email correspondence.

Procurement and supply chain management area, Organization support and services, Region Jönköping, Email correspondence.

Department Manager, Regional Services, Medical Technology, Region Örebro Län, Email correspondence.

(2) All medical professionals:

Hans Netterling, Urologist at surgical clinic of Västerbotten, Region Västerbotten, Interview via video call, 30 March 2023.

Caroline Elmér, Urologist at Stockholms Urogynecologist clinic, Region Stockholm, Interview via video call, 17 March 2023.

Agneta Sandberg, Children's Urotherapist, Region Blekinge, Interview via video call, 17 April 2023.

Magdalena Vu Minh Arnell, Urotherapist for children with Spina bifida, Region VGR, Interview via video call, 11 April 2023.

Maria Rudolfsson and Ulrika Hagberg, Incontinence nurse and Urotherapist at Gynecologist clinic at Norra Älvsborgs Regional Hospital, Region VGR, Interview via video call, 19 April 2023.

Inger Andersson, Urotherapist at women's clinic at East Hospital, Region VGR, Interview via video call, 18 April 2023.

(3) All urotherapists and incontinence nurses:

Agneta Sandberg, Children's Urotherapist, Region Blekinge, Interview via video call, 17 April 2023.

Magdalena Vu Minh Arnell, Urotherapist for children with Spina bifida, Region VGR, Interview via video call, 11 April 2023.

Maria Rudolfsson and Ulrika Hagberg, Incontinence nurse and Urotherapist at Gynecologist clinic at Norra Älvsborgs Regional Hospital, Region VGR, Interview via video call, 19 April 2023.

Inger Andersson, Urotherapist at women's clinic at East Hospital, Region VGR, Interview via video call, 18 April 2023.

(4) All urologists, 2 urotherapists and 1 incontinence nurse:

Hans Netterling, Urologist at surgical clinic of Västerbotten, Region Västerbotten, Interview via video call, 30 March 2023.

Caroline Elmér, Urologist at Stockholms Urogynecologist clinic, Region Stockholm, Interview via video call, 17 March 2023.

Agneta Sandberg, Children's Urotherapist, Region Blekinge, Interview via video call, 17 April 2023.

Maria Rudolfsson and Ulrika Hagberg, Incontinence nurse and Urotherapist at Gynecologist clinic at Norra Älvsborgs Regional Hospital, Region VGR, Interview via video call, 19 April 2023.

(5) All medical professionals and patients

Hans Netterling, Urologist at surgical clinic of Västerbotten, Region Västerbotten, Interview via video call, 30 March 2023.

Caroline Elmér, Urologist at Stockholms Urogynecologist clinic, Region Stockholm, Interview via video call, 17 March 2023.

Agneta Sandberg, Children's Urotherapist, Region Blekinge, Interview via video call, 17 April 2023.

Magdalena Vu Minh Arnell, Urotherapist for children with Spina bifida, Region VGR, Interview via video call, 11 April 2023.

Maria Rudolfsson and Ulrika Hagberg, Incontinence nurse and Urotherapist at Gynecologist clinic at Norra Älvsborgs Regional Hospital, Region VGR, Interview via video call, 19 April 2023.

Inger Andersson, Urotherapist at women's clinic at East Hospital, Region VGR, Interview via video call, 18 April 2023.

Anonymous Patients, Interviews via video calls, 21 March 2023.

Bibliography - Figures

Figure 2 .1 - Adapted from Saunders, M., Lewis, P. & Thornhill, A. (2009) *The Research Onion.* 100-102. Research methods for business students. 5:th edition., Pearson Education Limited.

Figure 2.2 - Adapted from Saunders, M., Lewis, P. & Thornhill, A. (2009) *Research Choices.* 145-147. Research methods for business students. 5:th edition., Pearson Education Limited.

Figure 2.3 - Own Illustration

Figure 3.1 - Adapted from Kotler, P., Eldon, S., Wong, Saunders, W. & J. Armstrong, G. (2004) *Principles of marketing.* Pearson Prentice Hall

Figure 3.2 - Adapted from Kotler, P., Eldon, S., Wong, Saunders, W. & J. Armstrong, G. (2004) *Principles of marketing.* Pearson Prentice Hall

Figure 3.3 - Adapted from Kotler, P., Eldon, S., Wong, Saunders, W. & J. Armstrong, G. (2004) *Principles of marketing.* Pearson Prentice Hall

Figure 3.4 - Jun, G, T., Ward, J.,Morris, Z. & Clarkson, J. *Health care process modeling: which method when?, International Journal for Quality in Health Care,* Volume 21, Issue 3, June 2009, Pages 214–224, https://doi.org/10.1093/intqhc/mzp016

Figure 3.5 - Jun, G, T., Ward, J.,Morris, Z. & Clarkson, J. *Health care process modeling: which method when?, International Journal for Quality in Health Care,* Volume 21, Issue 3, June 2009, Pages 214–224, https://doi.org/10.1093/intqhc/mzp016

Figure 3.6 - Jun, G, T., Ward, J.,Morris, Z. & Clarkson, J. *Health care process modeling: which method when?, International Journal for Quality in Health*

Care, Volume 21, Issue 3, June 2009, Pages 214–224, https://doi.org/10.1093/intqhc/mzp016

Figure 3.7 - Jun, G, T., Ward, J.,Morris, Z. & Clarkson, J. *Health care process modeling: which method when?, International Journal for Quality in Health Care,* Volume 21, Issue 3, June 2009, Pages 214–224, https://doi.org/10.1093/intqhc/mzp016

Figure 3.8 - Adapted from Kotler, P., Eldon, S., Wong, Saunders, W. & J. Armstrong, G. (2004) *Principles of marketing.* Pearson Prentice Hall

Figure 3.9 - Sridharan, S. (2017) *Crossing The Chasm – Technology Adoption Lifecycle.* https://thinkinsights.net/strategy/crossing-the-chasm/

Figure 3.10 - Adapted from Gourville, J. (2006) *Eager Sellers and Stony Buyers: Understanding the Psychology of New-Product Adoption.* Harvard Business Review. https://hbr.org/2006/06/eager-sellers-and-stony-buyers-understanding-the-psychology-of-new-product-adoption

Figure 3.11 - Adapted from Kotler, P., Eldon, S., Wong, Saunders, W. & J. Armstrong, G. (2004) *Principles of marketing.* Pearson Prentice Hall

Figure 3.12 - Adapted from Kotler, P., Eldon, S., Wong, Saunders, W. & J. Armstrong, G. (2004) *Principles of marketing.* Pearson Prentice Hall

Figure 3.13 - Adapted from Kotler, P., Eldon, S., Wong, Saunders, W. & J. Armstrong, G. (2004) *Principles of marketing.* Pearson Prentice Hall

Figure 3.14 - Adapted from Johnson, G., Whittington, R., Scholes, K., Angwin, D. & Regner, P. (2015). *Fundamentals of strategy* (3. ed.). Pearson.

Figure 3.15 - Own Illustration

Figure 4.1 - Continence Foundation of Australia (2019) *Muscles around bladder.* https://www.pelvicfloorfirst.org.au/news/577/the-hypertonic-pelvic-floor/

Figure 4.2 - NIDDK (2021) *Urinary system*. https://www.niddk.nih.gov/health-information/urologic-diseases/bladder-control-problems/symptoms-causes

Figure 4.3 - Own Illustration

Figure 4.4 - Own Illustration

Figure 4.5 - Own Illustration

Figure 4.6 - Own Illustration

Figure 5.1 - Own Illustration

Figure 5.2 - Own Illustration

Figure 5.3 - Own Illustration

Figure 5.4 - Own Illustration

Figure 5.5 - Own Illustration

Bibliography - Tables

Table 3.1 - Own illustration

Table 4.1 - Own illustration

Table 4.2 - Own illustration

Table 4.3 - Own illustration

Table 4.4 - Own illustration

Table 4.5 - Own illustration

Table 5.1 - Own illustration

Table 5.2 - Own illustration

Table 5.3 - Own illustration

Table 5.4 - Own illustration

Table 5.5 - Own illustration