Reimbursement landscape analysis for digital medicine and demands in future healthcare

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Abstract

The Swedish healthcare is predicted to meet major pressure in the future due to a growing and aging population where e.g. chronic diseases are expected to increase drastically. To cope with this pressure, new innovations and digitalization of systems are needed. Products within digital medicine i.e. tools that monitor, log and share biological patient data, are expected to create new treatment possibilities. However, digital medicine companies are currently struggling to find proper payment models while navigating through regulatory systems and implementation in healthcare seem slower than the development of new products. This study aimed to obtain valuable knowledge to assist implementation of digital medicine solutions in healthcare by: exploring the reimbursement landscape, mapping digitalization trends in healthcare and highlighting challenges and opportunities with digital medicine. A qualitative study approach was applied with semi-structured interviews as well as conventional content analysis. The respondents were representatives from eight organizations influencing medical devices and reimbursement in Sweden. The results show that, even though digital medicine is not a term used in Sweden and only a few digital medicine products has yet reached healthcare, digital medicine will be crucial in the future. Several benefits such as: distant monitoring, virtual appointments, homecare and patient empowerment are believed to be the solution to lower cost and maintain a high quality healthcare. However, several challenges are to be faced in the process of digitalization. Many of these challenges such as competition, costly validations and health economic evidence will fall on companies, but the major challenges await the entire healthcare system where substantial structure changes in reimbursement models, communication systems and disease management are needed. Sweden is only in the beginning of a process towards digitalization that will require major efforts, but the winnings are huge and digital medicine will most probably be the future of a revolutionizing healthcare.

Keywords: Reimbursement, Healthcare, Digitalization, Digital medicine, Medical technology

Popular science summary

The Swedish healthcare is currently facing a breaking point introducing new innovations and systems that will revolutionize the future care. This transformation is called digitalization and is made possible by the introduction of IT-based solutions measuring biological parameters, called digital medicine products. The Swedish healthcare has for a long time been under an economical pressure that are expected to grow rapidly in a close future. Digital medicine is believed to be the solution to cut costs in future healthcare, but digital medicine companies are struggling to find whom to pay for their products and how to implement them in healthcare. This study aimed to obtain valuable information to assist implementation of digital medicine products by investigation of the reimbursement landscape, structures in healthcare and opportunities and challenges with digital medicine. Eight representatives from organizations with in depth knowledge in the area were interviewed and the results were analyzed and discussed upon. The findings were clear showing both huge advantages with and hurdles in implementation of digital medicine. Events such as monitoring out of hospital, improved communication between patient and physician and increased patient involvement are a few of the visualized opportunities. However, in the process towards a digitalized healthcare several challenges are to be faced. There is a need for structural changes, not only in payment models and product testing, but also within the whole healthcare system where changes in reimbursement models, communication routes and disease management are needed. Sweden is facing beginning of a major transformation of the current healthcare system, there is a massive work ahead but the benefits and the cost savings are expected to be huge. Digitalization of healthcare assisted by products within digital medicine, has the potential to increase quality of care, lower healthcare expenses and completely break the traditions of Swedish healthcare.

List of abbreviation

Abbreviation	Explanation
CE	Conformité Européene
CAGR	Compound annual growth rate
IoT	Internet of things
MS	Multiple Sclerosis
CNS	Central nervous system
WHO	World Health Organization
US	United States
DRG	Diagnose Related Groups
HTA	Health Technology Assessments
UK	United Kingdom
TLV	Dental and Pharmaceutical Benefits Board
SBU	The Swedish Council on Technology Assessment in Healthcare
SME	Small and medium-sized enterprise
SLL	Stockholm County Council
LUL	Uppsala County Council
KTH	Royal Institute of Technology
SKL	Swedish Association of Local Authorities and regions

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1. Background

Major changes in healthcare are predicted to become reality in a foreseeable future (1). Historically, healthcare has been one of few industries lacking behind in the idea that the customer comes first (1). Today changes towards a patient centred care and digitalisations of care are planned and made possible by new and emerging technology, with biosensing technology as one of them (1). The digitalisation of healthcare is initiated in countries all over the world to meet the increased pressure in healthcare. However it is suggested that Sweden is lagging behind in the digitalisation trend (2). The healthcare system in Sweden is mainly steered on a regional level with different systems, which limit communication as well as complicates data/information handling (2). New ideas and medical device innovations are needed in the future care due to the growing and aging population where e.g. chronic disease prevalence are expected to rise (3). If the trend continues the expenses of Swedish healthcare is estimated to increase with 30% in 2050, a cost that will be unviable for an already pressured economy (3). In Sweden there are initiatives towards digitalisation and both on a governmental and an industrial level and several products within the area of digital medicine and are on the way to market. However, there are several questions remaining and digital medicine companies are struggling with dilemmas of implementation, usage and payment for these products that seem to have a potential to revolutionize healthcare.

1.1 Digital health and digital medicine

Digital health is the convergence of the digital revolution within health, healthcare, living and society that is empowering us to manage and track our behaviour on a daily basis (4). The field of digital health is growing rapidly on several levels and disciplines all over the world and the growth is estimated to continue at an even higher pace in the future. Digital health has several subsectors such as "telehealthcare", "mHealth", "health analytics" and "digitised health systems" (5). As a part of the umbrella term "digital health" the term "digital medicine" was coined in 2002 due to the emergence of new technologies containing biosensors (6). The definition of digital medicine is according to Elenko et. al. "that technology and those products that are undergoing rigorous clinical validation and/or that ultimately will have a direct impact on diagnosing, preventing, monitoring or treating disease, condition or syndrome" (6, 457). Digital medicine as a part of medical devices has the potential to disrupt the current healthcare system where new innovations and more efficient systems are needed to meet the economical pressure that will be a fact in the future (7).

The term digital health is widely used and contains products from consumer apps with no clinical validation to solutions for patients, physicians and clinical pathologists with where Conformité Européene (CE) marking and validation is required (6). Several digital health products, such as wristwatches, patches, broaches and different applications, within the area of wearable technologies have emerged containing biosensors and the aim to capture and log data (6). There are today a rising number of people using wearable self-tracking devices all over the world and the wearable device market is growing at high pace. For the global market, it was worth $3.3 billion in 2015 and estimated to be growing at a 17.7% Compound annual growth rate (CAGR), to cross $7.8 billion by 2020 (8). Whilst the European market was worth more than $820 million in revenue in 2014 and is expected to cross $2.6 billion in 2019, growing at a CAGR of 27.94% (9). The wearable devices can according to Mordor Intelligence LLP (8) be categorized into four segments: Disease Management, Monitoring & Feedback, Rehabilitation and Health & Fitness

processes. The Monitoring and Feedback solutions accounted for more than 70% share of the global medical device wearable market in 2015 (8). Data collected from wearable devices can be saved, visualised and analysed in different mobile applications and stored in cloud databases with the aim to connect patients with relatives and physicians (10). The use of wearable technology and digital medicine in healthcare have the potential to increase efficiency in care as well as to secure patient safety and treatment quality by improving the physician-patient relationship, gathering real time patient data, personalize the care as well as to cut healthcare costs and reallocate resources (11). However, there are of course challenges to find a proper regulatory framework etc. for medical usage of these new products (12). These challenges will be described later on in the report.

1.2 Big Data
Big data can be defined as datasets whose size is beyond the ability of typical database software tools to capture, manage, store and analyse (13). Collecting and storing data has been an important part of healthcare for ages. Record keeping, compliance studies, regulatory requirements, and patient care have driven data collection forward. Due to the trend towards rapid digitalization and due to the significantly decreased cost in data storage, big data has got an enormous potential to increase the quality of healthcare and at the same time, lower healthcare expenses (14). Products within the field of digital medicine will ensure the possibility to measure and collect real time patient data on a daily basis. Meaning that digital medicine products such as wearable's with biosensors or mobile applications, that gather huge amounts of important information, will offer more accurate diagnosis and personalized care but also on a higher level, increase the access to medical information that could be used in future research (15).

1.3 Digital medicine and chronic disease management
Chronic diseases are leading causes of death and disability globally and prevention as well as early intervention of chronic disease is important steps in the management of chronic diseases (16). Digital medicine is believed to become a major part of the healthcare with new innovations to improve the management of chronic disease (17). Traditionally, therapies needed in chronic disease care such as; cognitive behaviour therapy, support groups and coaching, was hard to structure and scale (18). However with the emergence of wearable technology, the Internet of Things (IoT) and mobile computing platforms we can envision easy deliver of these therapies to the whole population (18). Customised products and services with for example, sensors that measure biological parameters or applications that save, share and analyse data will be useful tools for chronic patients all over the world (19). These products have the potential to motivate engagement and behavioural changes among patients in a sustainable and in a health economic manner (19). Products within digital medicine will promote chronic disease management since it for example, will bring real-time patient data to the physician, enable faster and more convenient communication, improve care planning, and support patient empowerment (20).

One example of a chronic disease where digital medicine is believed to improve current treatment is Multiple Sclerosis (MS). MS is a chronic autoimmune disease that causes demyelination of the neurons in the brain as well as the spinal chord (21). Demyelination of the cells causes a disruption of the nervous signal. Currently the number of patients suffering from MS is estimated to be more than 2.3million people worldwide (21).

There is a wide spectre of MS symptoms and no patient have the exact same as another (22) The symptoms can change over time, making the disease unpredictable and hard to control (22). Some of the most common symptoms are however: walking difficulties, fatigue, spasticity, vision problem, pain, cognitive changes, emotional changes and depression (22). Patients with MS can occasionally experience exacerbation also known as relapses, which causes worsening of old symptoms due to inflammation of the central nervous system (CNS) that further damages the myelin (22). Acute exacerbation is followed by remissions as the inflammation comes to an end, however some of the symptoms usually still remain (22). Several studies show that stress has a strong correlation to relapses and increased stress-levels increases the risk of MS exacerbations (23). To continuously measure the stress-levels of a patient suffering from MS with biosensor technology, can help patients to learn how to avoid stressful situations and thereby minimize the risk for MS exacerbations (24). MS is therefore a good example on a chronic condition where digital medicine tools can participate in prevention and management (24).

1.4 Patient empowerment

According to World Health Organization (WHO), chronic disease account for about 86% of all deaths and 77% of the disease burden in Europe, numbers that are continuously growing (25). This development will result in an unrealistic burden on the chronic disease care and a fundamental shift in the system might be necessary to cope with the increasing pressure (25). Today there is a trend where patients are taking control over their own condition, learning about different types of medication and preventions in order to manage their own life; a trend that will be important in the future management of chronic disease as well as general care (26). Patient empowerment is a concept that are putting the patient in the centre of service by offering tools to take control of own healthcare needs (26). This could be to help the patient understand the condition and how it affects the body. Information that in turn will help the patient to participate in decisions regarding treatment and take more responsibility for the personal health (27). It has been shown that patients that are engaged in the treatment process have a higher rate of compliance are more responsive to the treatment (25). WHO define patient empowerment as "a process through which people gain greater control over decisions and actions affecting their health" and following four components has been reported fundamental for the patient empowerment process (28):

- Patient understanding of his/her role in the treatment and care
- Patient acquisition of relevant knowledge to be able to engage with the physician and participate in discussions regarding disease management
- Patient skills
- Presence of a facilitating environment

Based on these components, patient empowerment is a process that promotes patient participation and engagement, but it is important to create an environment where patients are provided with tools to find the right information (28). New technology such as products within digital medicine can assist patient empowerment by offering new knowledge and recording/analysing patient data that can motivate the user to learn more about their specific condition and engage in the personal health (29). Which will be important in the shift towards personalized care where patients are decision makers and in the centre of their own care process (25).

1.5 Business model in digital medicine companies

Throughout the years, medical innovation has been expensive and it has required a lot of if time and resources for a new device/drug to reach market due to clinical validation and development processes (30). This stands in clear contrast to the general technology industry where new innovations can reach market in weeks and to a significantly lower price (30). Additionally, the revenue stream from medical innovations has usually been stable due to patent protection whilst the competition and rapid development of the technology industry usually causes uncertainties (30). Today countless of new innovative business models are created and new industries are emerging to replace the old (31). Business model innovation has a high impact on the industry transformation and therefore is the business model not only important to the company, but to all parts of the chain, from supplier to end user as well as to competitors (31). Ultimately, business model innovation is about creating value for companies, customers and society as well as to replace old models with new and disruptive ones (31). Digital medicine is a fusion between the different areas of medical drugs, medical devices and technology. This mean, according to Steinberg et. al. (30) that a successful digital medicine business model must consider key characteristics of established models from these three areas. With Steinberg's way of thinking, the key building blocks for a digital medicine business model, based on key characteristics from the business models of medical drugs, medical devices and technology, would be as following:

- Product/Service: The core of any digital medicine business
- Technology: The core platform that underpins the product
- User/Customer: For whom the product are indented
- Data: The information the product will collet/deliver
- Delivery: The channel to the customer
- Validation: Demonstration of clinical effect and safety
- Economic model: Reimbursed prescription, user payment or monetization of aggregated data

There are still many unanswered questions regarding business models in this new and emerging area, it is however clear that clinical validation and strategies towards reimbursement of the product will be essential for a successful business model in digital medicine (30).

1.6 Reimbursement

Reimbursement of medical drugs and medical devices are applied in order to make products affordable for people in need (32). Most countries use Diagnosis Related Groups (DRG) system to set a price for medical procedures and products. Health Technology Assessments (HTA) is also used to evaluate and recommend products based on safety and cost efficiency (33). The reimbursement systems of the European countries have both differences and similarities (34). Each country has its own national system to establish payment for reimbursement, where some countries have a centralized system like France; meanwhile United Kingdom (UK) and Sweden for instance have a system that operates on both national and regional level (34). There are also countries such as United States (US), Germany and The Netherlands, that have systems where insurance companies finance healthcare (35).

The Swedish health care system is a national care service funded mainly by taxes levied by county councils or municipalities, but also through user charges and state subsidies.

Overall, health care decisions are made on a national level however, some reimbursement decisions are made regionally by county councils (36). In order for a product to be reimbursed on a national level it must be approved by the Dental and Pharmaceutical Benefits Board (TLV) (36). The Swedish Council on Technology Assessment in Health Care (SBU) and TLV are performing HTA recommendations that stand as a ground for reimbursement decisions (36). Medical devices and medical drugs have different reimbursement routes in Sweden. TLV only decides over a few medical devices called "consumables" while county councils or hospitals reimburse the great majority of medical technology products (32).

1.7 Challenges in the field of digital medicine

The field of digital medicine is a completely new area with high potential. The area is currently under development and many innovations are on their way to reach the market. The growth of mobile technology in improving well being has the opportunity to transform healthcare and empower citizens to take charge of the own health (37). However there are still many challenges to be dealt with in the area, which currently might hinder the implementation of new digital medicine innovations in healthcare. In both US and Europe a regulatory framework regarding these products are emerging but there are still regulatory challenges to be met such as structures for how to test and clinically validate these products as well as creating a regulatory framework for good manufacturing practises (12). It will be important to find a balance in protecting the patient and at the same time avoiding over-regulations that might limit companies when developing new innovations and creating business models (12).

According to a study made by Arthur D. Little (38), big pharmaceutical companies are getting more aware of the potential benefits of being a part of the digital medicine trend. The vast majority believes that pharmaceutical companies are in need of a digital health strategy and that digital medicine will have great impact on the future competitive advantage (38). This change might be feasible for big pharmaceutical companies with huge resources and development possibilities. However, there are a rising number of small to medium sized companies with limited resources, presenting ideas that might have a huge impact on the future healthcare. One key challenge for these companies, developing new digital medicine innovations, is how to define revenue streams and to identify the proper payer for the product/service. Today patients with high engagement might be willing to pay in order to receive the best care possible (39). However, to limit inequality in treatment there might be a need for other methods of payment within this area.

Reimbursement has historically both been a driver and a limitation to market uptake of new innovations in the medicine technology field whereas digital medicine will not be an exception (9). Reimbursement of digital medicine products might be an important solution since it could be challenging for companies to keep premium pricing compared to solutions that are not in need of an expensive validation process (39). Since reimbursement is widely used in the business model of medical drugs and devices it could be an essential part in the business model of digital medicine (30). However, there is a problem with unclear reimbursement mechanisms for products within this area (8). Although there is a willingness among patients to use the products, these unclear reimbursement mechanisms might reduce the incentives for digital medicine companies to focus on healthcare as a customer (12). Structured payment models with reimbursement as a part, is a key factor in the business model of a digital medicine small and medium

enterprise (SME) where it is important to secure high levels of investment and/ or scale compared to other global competitors (8).

Today, the implementation of new technology in healthcare seems to be slower than the development of new innovations, a fact that might be devastating for digital medicine SME's (30). It is also disadvantageous for healthcare, patients and society since digital medicine interventions has the potential to alter they way medicine is practiced and experienced (9).

1.8 The Bioentrepreneurship perspective

Bioentrepreneurship is the process from ideation and discovery to development and commercialization of life science products. It can be defined as the process of creating value from a life science innovation (40). This study is reflecting the last step in Bioentrepreneurship, focusing on commercialization and implementation of existing products as well as creating valuable knowledge in "willingness to pay" to be considered before development of new innovations. In the definition of Bioentrepreneurship there are three different element discussed. The first is described as a process of expensive and extensive research and development in a field with strict regulations and a difficult reimbursement environment, the second is a process to create value in a market and the third to utilize life science processes in commercial markets (40). This study touches upon the first element mainly focusing on reimbursement for products within digital medicine, an emerging part of life science. Knowledge in the reimbursement landscape and future plans healthcare will assist in e.g. the hardship of building a business model.

2. Problem Statement

Digital medicine innovations are expected to be important in digitalization, a processes that will be crucial to cope with the future pressure that is a fact, not only in the care of chronic disease but healthcare in general. Currently there are uncertainties in how to implement these new innovations and digital medicine companies are struggling to identify payment models that will secure stable revenue streams. Additionally there are unclear reimbursement mechanisms for these products, which might reduce developer's willingness to go through costly validation processes. This phenomenon will not only slow down development and implementation of new digital innovations but might also result in great variations of product quality and pricing differences that will lead to unequal care.

3. Aim

3.1 Aim

The aim is to obtain valuable knowledge that can assist implementation of digital medicine solutions in healthcare by exploring the reimbursement landscape, mapping digitalization trends in healthcare and visualizing challenges and opportunities with digital medicine.

3.2 Research questions
- How is digital medicine used in healthcare today?
- What opportunities and challenges are observed in the area of digital medicine?
- How does the reimbursement system currently handle digital medicine products and what are the future plans?
- What is needed for structured implementation of digital products in Sweden?

3.3 Delimitations

The project was limited to healthcare systems in Sweden, focusing on reimbursement structures and trends for products within digital medicine. Sweden was chosen due to the increased focus on digitalization and since it is a tax-based healthcare system. Sweden is also the researchers most known market, which makes it a proper country for the study.

4. Methodology

4.1 Research design

A research design is the grand plan of how the research question is approached. The research design is vital for the actual outcome of the study and how the research questions will be answered (41). The research design provides a framework for data collection as well as analysis of the collected data and reflects decisions in how different dimensions of the study are prioritized (42). This research was built on qualitative research methods. Qualitative methods are designed to help understand people in a certain case as well as the context of witch within actions and decisions take place (43). According to Kaplan and Maxwell, the goal of understanding a phenomenon from the point of view of the participants and its particular social and institutional context is largely lost when data is quantified (44). In this study qualitative research was performed to understand the perspective of the participants to obtain knowledge from different stakeholders. Qualitative research methods were also chosen for it's high flexibility and since it has the ability to collect individual information on a specific topic (44).

Since the area is quite new and since no or little research has been done in the area before, a descriptive study design was used. A descriptive design is used to answer factual research questions like: "how", "what" or "how much" (41). A descriptive study design is primary used when the goal is to reveal patterns and connections by looking at one specific point in time (45). Methods used in this approach are usually qualitative interviews to learn about a specific situation or research for specific data (41). Descriptive studies help generating a hypothesis that can be used as a base for further research (46) and the method was chosen since it offered a possibility to look at a broader perspective to obtain a proper overview of digital medicine trends as well as the Swedish reimbursement landscape of digital medicine products.

4.2 Data Collection

Qualitative data collection was applied in the study. Qualitative research tends to be concerning words rather than numbers and it tends to be a more open-ended strategy than quantitative research (42). To obtain knowledge of the current situation and the future strategy for reimbursing products in digital medicine, qualitative interviews were performed with key organizations in Sweden. A semi-structured interview guide with similar questions for all participants was used in order to obtain usable answers. The interview guide was written by the student and changed accordingly to feedback received from the practical supervisor. A semi-structured interview guide is often used to obtain a loose conversation and to give the interviewee, to some extent within the subject, the freedom to talk and describe what is interesting to them. It is also used in order to be able to make smaller changes in the interview guide during the interview as well as to be able to collect additional information asking follow-up questions after or during the interview (47).

Representatives from organizations, influencing reimbursement landscape and medical technology innovation in Sweden were chosen as interviewees and in total eight people in leading positions were interviewed. To find respondents, generic purposive sampling was applied. In generic purposive sampling, the sampling is conducted considering the aim of the project and the participants are not chosen on a random basis but since they fill criteria's needed to answer the research questions (42). The target organizations were chosen based on their connection to the field of medical devices/technology where digital medicine is a part, and medical reimbursement in Sweden. The aim was to reach out to several different organisations to obtain different views and opinions of e.g. the current healthcare system and the future outlook on digitalization. Governmental organizations, county councils as well as private organisations were approached by email and about 90% was willing to participate in the study. The participating organizations were: SwedishMedtech, Inera, SLL Innovation, Stockholm County Council (SLL), Uppsala County Council (LUL), Synergus, Medical product agency of Sweden and The Dental and Pharmaceutical Benefits Agency (TLV). The interview guide was sent out to the respondent in advance to allow preparations before the actual interview. The interview took approximately 30 minutes and was performed face-to-face or by telephone based on the respondent wishes. The interview guide contained three different sections: interviewee and organization background, questions regarding digital medicine, and questions regarding the reimbursement landscape. All questions were quite broad and asked in an open manner to allow a wide set of answers as well as discussions. The interview was recorded and transcribed for the analysis. The interview guide is presented in appendix A.

4.3 Data analysis
Interview data was analysed to obtain an overview of the current reimbursement landscape as well as future plans for reimbursement strategies of digital medicine and trends, challenges and opportunities in the same field. The method for analysing the data was content analysis (48). Content analysis is a widely used method within qualitative research to interpret the content of text data. It is regarded as a flexible method that can be used in different ways and vary in different studies (49). After investigations conventional content analysis was chosen since the aim of the study is to describe a phenomenon where existing theory or literature is limited (49). Many qualitative studies with open-ended interview questions are using conventional content analysis since it is a very transparent, flexible method that can be applied to a wide variety of unstructured information (42). Another advantage with conventional content analysis is the possibility to gain direct information from study participants, without imposing preconceived categories or theoretical perspectives (49).

The data analysis was initiated by verbatim transcriptions of the recorded interviews and followed by close investigation of all material to obtain an overview and first impressions were noted. The data were then read word by word to derive relevant labels by highlighting words that appeared to be connected to key thoughts or concepts. Relevant information connected to the aim of the study was saved as meaning units based on: frequent appearance, surprising information, relation to previous knowledge/theories and/or that the importance was stated by the interview. The meaning units were then rewritten to condensed meaning units, shorter sentences that still include the relevant information and codes of one to three words were created based on the condensed meaning units. The relation between all codes was analysed and different categories was created based on the codes. The categories were labelled and then reflected upon to find

relationships and differences between the interviews as well as connections to literature and previous knowledge. Figure 1 is visualizing the content analysis.
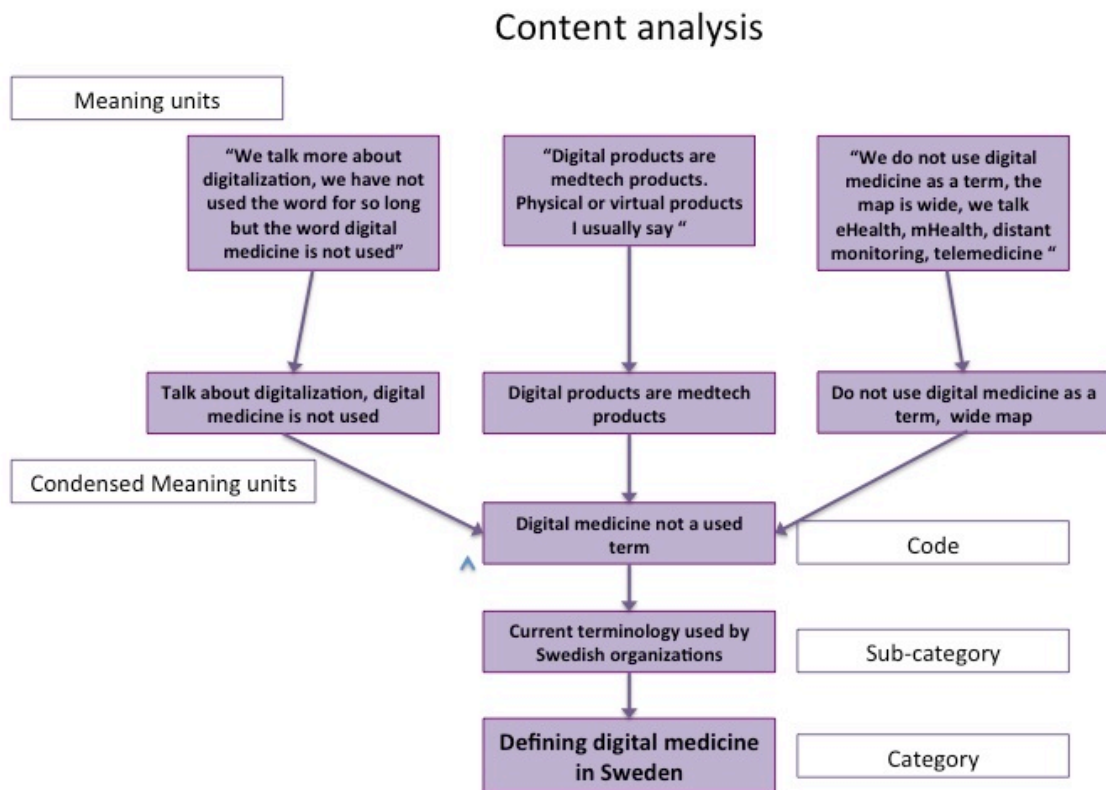
Content analysis

Meaning units		
"We talk more about digitalization, we have not used the word for so long but the word digital medicine is not used"	"Digital products are medtech products. Physical or virtual products I usually say "	"We do not use digital medicine as a term, the map is wide, we talk eHealth, mHealth, distant monitoring, telemedicine "

Talk about digitalization, digital medicine is not used	Digital products are medtech products	Do not use digital medicine as a term, wide map

Condensed Meaning units

Digital medicine not a used term	Code

Current terminology used by Swedish organizations	Sub-category

Defining digital medicine in Sweden	Category

Fig. 1 Visualisation of the content analysis

4.4 Ethical consideration

Ethical principles in business research are according to Bryman and Bell (40), broken down to four areas: Harm to participants, lack of informal consent, invasion to privacy and involvement of deception (41).

Since the research involves interviews and thereby interviewee's it is of great importance that there is mutual understanding in the aim of the study as well as the interview itself. The interviewee shall have the freedom not to answer a specific question and end the interview at any time. It is also important that confidentiality and anonymity is respected. It is the researchers responsibility that deception does not occur.

This study was performed according to ethical and legal considerations and several actions were made to ensure that the ethical principles were followed. All interviewees were provided with the interview guide before the interview to have a chance to prepare for the questions. The interview guide contained a detailed description of participation terms as well as the aim with the study. All interviewee's were asked in the beginning of the interview if they agreed with the conditions to obtain informal consent. The interviewee's were also informed that they had a possibility to be anonymous in the final report and that they were able to end the interview at any time or chose to skip any question to counteract invasion to privacy. When the report was written, anonymity and

confidentiality was respected when needed to protect the participants. All interviewees agreed that the organization name could be revealed in the final report. Study methods were used to keep the data analysis transparent and unbiased and to show that no deception was involved. After completion of the report and before submission, the report was sent to the interviewee's to give them an opportunity to comment on the content and approve citations.

5. Result

The results are divided into four different parts based on categories from the content analysis of the interview material. The headings of the chapters are: Defining digital medicine in Sweden, Current situation, Challenges and opportunities in digital medicine and future outlook. The results are presented in describing text and supporting quotes from the interviewees representing the responding organizations. An overview of the categories and subcategories can be found in figure 2.

Responding organizations of the study were: SwedishMedtech, Inera, SLL Innovation, Stockholm County Council (SLL), Uppsala County Council (LUL), Synergus, Medical product agency of Sweden and The Dental and Pharmaceutical Benefits Agency (TLV). In the beginning of each interview the respondents were asked to describe the organizations function, work structure and goals in order to understand how they are involved in the reimbursement landscape of Sweden. The result from the background part of the interview guide is described in appendix B.

Categories	Subcategories
Defining digital medicine in Sweden	• **Terminology currently used by Swedish organisations** • **The perception of digital medicine** • **Healthcare situation**
Current situation	• **Digital medicine products and usage** • **Reimbursement of digital medicine**
Challenges and opportunities: Digital medicine	• **Opportunities and advantages** • **Challenges**
Future outlook	• **Future plans and actions** • **Demands for implementation of digital medicine**

Fig. 2 Categories and subcategories from content analysis

5.1 Defining digital medicine in Sweden
The first part is reflecting how digital medicine is perceived in Sweden, the respondent's definition of digital medicine as well as the products within the area and the healthcare need that could be addressed with those products.

5.1.1   Terminology used in Swedish organizations today
Since digital health is a relatively new area with several subgroups it was of interest to learn how the respondents would define the word digital medicine. The results were clear;

there is no existing definition of digital medicine in Swedish law and different terminology is used to describe this area.

"Digitalization is a wide subject and a change in society. We mostly talk about eHealth, which include Telehealth, mHealth and distant monitoring. We never discuss digital medicine."
 - Respondent, SwedishMedtech

In Sweden there are a lot of terms describing different parts of the digitalization process such as eHealth, mHealth and Telehealth. However, digital medicine is not yet a part of that vocabulary. According to the interviewees, products within digital medicine are currently included in the term medical devices as a whole. TLV states that digital medicine is not used as a term and that digital products will either be reflected upon as medical devices or not depending on how the will be used and categorized in the future.

5.1.2   The perception of digital medicine
Even though digital medicine as a term is not used on daily basis or on a professional level in Sweden, there is still an understanding of what products that would fall under this category. The perception of digital medicine products are mainly that these are products that increase communication between physician and patients to allow patients to be monitored from home in a much greater extent. Theses products are expected to gather and store patient data to enable analysis by the physician. Digital medicine products are also described as digital solutions that could change/assist healthcare systems and processes in prevention, diagnosis and treatment.

"New products within medtech give new possibilities for better care and treatment. The data generated from these products can be used in several ways for example in statistics"
 – Respondent, LUL

It is also mentioned that the usage of applications and technology for monitoring and storage of data is an emerging phenomenon, especially when a lot of the responsibility are put on the patient. This area is very new in relation to healthcare and the borders between healthcare and self-care are in some cases unclear.

5.1.3   The healthcare situation
Several respondents were pointing out that there is an environmental change in and an increasing pressure on the Swedish healthcare. There are gigantic challenges to be faced with a rising number of patients, fast medical development, limited human resources and relatively constant tax-levels. The different organizations are working in several ways to meet the demand of healthcare e.g. development of eHealth and the enhancement of digitalization, creation of standardized systems in healthcare as well as assistance of digital medicine companies when developing and implementing new innovations.

"Patients shall have access to data so that they can take part in their own treatment. We want healthcare personnel to have the right information at the right moment to give good care. We want decision makers to access important data to make proper decisions; all for an efficient, safe care with high quality."
- Respondent, LUL

Most respondents described the digitalization and the introduction of digital medicine products in healthcare as a huge opportunity to manage the future demands in healthcare. However, one respondent highlighted the fact that digital medicine might not be the solution to relieve the healthcare due to regulatory hurdles and barriers in finding a proper payer.

5.2 Current situation

The second part is reflecting the current landscape for digital medicine in Sweden; describing digital medicine products used in health care today, current payment methods and reimbursement structures.

5.2.1 Digital medicine products and usage

Even though it is, according to the respondent of SwedishMedtech, not used as much as possible, it is pointed out that there are products within the field of digital medicine that is already being used in healthcare. TLV mentioned that they recently evaluated a product that allows electrocardiography measures at home and according to respondents products to monitor diabetes have been used by patients for a long time. It is stated that there are mobile applications on the market that are used to increase compliance within different therapeutic areas as well as to increase communication between doctor and patient and that many of these new innovations are focusing on chronic disease such as diabetes and Parkinson's disease. Even though there are only a few products within the area that has reached patients it is stated that the development of new innovations are increasing at a high pace.

"There are a plethora of mobile apps that are under development and many are currently undergoing testing"
– Respondent, SLL Innovation

All of the respondents highlight different initiatives where new products within the field of digital medicine are under development or undergoing clinical testing in Sweden. According to the respondents there are virtual care centers in rural areas where patients themselves perform major parts of the health examination, there are projects at the Royal Institute of Technology (KTH), where they test different monitoring solutions such as carpets that sense movement for distant monitoring and there are digital scales tested in Uppsala that where information are directly linked to the patient journal and there are initiatives for virtual doctor appointments. It is also mentioned that there is a planned project in testing advanced surveillance equipment to assist patients living at home to a safer environment. Additionally it is stated by the respondents that many companies are operating within this area developing new solutions to increase efficiency and safety in healthcare not only in Sweden, but allover the world.

5.2.2 Reimbursement/payment strategies for digital medicine

Regarding the Swedish reimbursement system and strategies there are, in all interviewee's opinion, no reimbursement models or standards for reimbursing products within digital medicine. There are only a few medical devices that are evaluated by TLV and where the decision is performed on a national level and these products are categorized as consumables and are a part of the preferential.

"We only reimburse "consumables" for example stoma and diabetic products. We decide if these products shall be reimbursed or not. However, this is just a fraction of all medical devices that are used in healthcare."
– Respondent, TLV

This mean according to the respondents, that the majority of all medical devices, including products within digital medicine, does not fall under a specific reimbursement strategy and reimbursement for these products are not decided on a national level. According to the findings, usually the decision whether to reimburse a product or not, fall on the different county councils and there are no national reimbursement system used by county councils for reimbursing products. SLL is stating that the county council sometimes works unsystematic with medical device questions and that HTA unit's only value special cases and a fraction of all products. According to the interview result, the caregivers make the majority of the decisions. The hospitals are able to decide for and to buy specific products; the cost will then fall on the hospitals budget.

"The product can be procured by the county council and the app is then prescribed, then it is the county council that stand as the payer. There are only a few products that have been reimbursed that way. What we see now is that patients are paying out of pocket for these services."
– Respondent, SwedishMedtech

Many of these products are believed to fall under the category of "self-care" or "life-style". These kinds of products will probably never be reimbursed by the government and are not yet reimbursed by the county councils according to TLV. It is clear from the results that, patients currently have to pay themselves for these services, a phenomenon that is occurring from time to time in Swedish healthcare where the patients are getting more prone to take control over their own condition and the willingness to pay among most patients are believed to be high. It is however stated by the respondents that there are uncertainties in how to categorise these products to learn who is going to stand as the payer and what products are going to be needed and paid for. According to the respondent from Synergus, it is of great importance to learn about the processes in healthcare and not look into a small piece in order to find the products that really are going to have an impact on the health economic situation. However, that is just one challenge to be faced in the process towards digitalization.

5.3 Challenges and opportunities: Digital medicine
The third part is reflecting potential advantages using digital medicine and opportunities that are pointed out by the respondents. It will also highlight the challenges and hurdles mentioned by the respondents that might be occurring in the process of digitalizing healthcare and disease management.

5.3.1   Opportunities and advantages
According the respondents, the growing and ageing population, where the number of patients is expected to increase rapidly, will result in an unbearable pressure on healthcare. New ideas and innovations are needed to manage this pressure and to secure a future of high quality care. All respondents share the impression that the usage of digital medicine products is going to increase and have an impact in future healthcare.

"I believe it will have a quite big role in the future…we wont be able to have hospital appointments that often when the population is growing. They mean that there is a possibility for high-tech and that patients are going to be monitored from home in a much greater extent."
- Respondent, TLV

It is stated by the interviewees that the digitalization process will be important in the future healthcare in several ways. To monitor patients from home could save and reallocate costs as well as avoid overcrowded hospitals and unecessesary routine examinations. To keep patients from hospitals in a greater extent might also lower the risk of spreading contagious diseases, a phenomenon that are a known problem at healthcare centres. The respondents state that there are opportunities to, with the help of digital medicine products, assist patients to empower themselves and obtain new knowledge. People are prone to use these products even in older generations and according to SwedishMedtech, it will be important to take care of the patient's own competence and to give them more power over their own condition. That will in turn, according to the results, lead to a more efficient less costly healthcare where patients understand their condition and compliance are controlled and increased.

"If you are more engaged the probability of better compliance to the recommended care increases… It is much easier when the patient is co-creator of the care… Due to lack of resources in health care, it is important to utilize the patients own competence."
- Respondent, SwedishMedtech

Products within digital medicine are believed to assist the communication between patient and physicians with more opportunities to gather and share data in different ways. The sharing of patient data will, according to LUL, be very useful for not only patients but for healthcare personnel and the healthcare system itself. Data generated from digital products outside of care could be connected and integrated to the existing systems of care and used to make wiser decisions. To aggregate huge amount of data is believed to be very useful in several perspectives and on several levels. It is pointed out by the interviewees that aggregated data in a specific therapeutic area might offer new insights if it is looked upon on a global level.

"Big data has been revolutionizing since it came up, you can see patterns in data that can offer completely new knowledge. In the carer-patient contact it creates completely new possibilities but in other areas as well. However, it awakens ethical and legal questions"
- Respondent 1, SLL

According to the interviews, digital medicine has the potential to decrease health care costs since a significant part of the healthcare burden is related to lifestyle. Preventive care is believed to increase in importance to limit sickness and hospitalization. Personalized treatment with for example adjusted dosages will be valuable for patient wellbeing. This will not be less important in chronic disease management where the disease is life-long and daily monitoring usually are necessary. According to respondents chronic patients might be the most important target group for digital medicine products. It is pointed out that there are clear winnings for patients in need of continuous contact with healthcare to use monitoring tools to obtain valuable information for treatment and limit time spent and the care center. Self-testing and dosage as well as digital connection with the physician would also be advantageous according to Inera.

"There is a risk that chronic disease patients will be a big cost for society as well as a risk of a painful life of the patient. These patients can contribute and live a normal life if treated the right way."
- Respondent, TLV

5.3.2   Challenges
During the interviews a high number of challenges with digital medicine implementation and reimbursement within the area was identified. It was pointed out that the development towards digitalization is a process that will require a change in many of the current systems in healthcare. As in all processes of change, the development is joined with challenges that have to be overcome. It is explained by a respondent that healthcare should operate to meet the needs of tomorrow but are today overloaded thus there are usually not enough recourses allocated to development.

"Now there is a moment 22 where stress levels are elevated and there is no energy to learn new systems or think can we do this differently?"
 - Respondent, Inera

It is also highlighted by the respondents that there is a problem in defining the different areas of digitalization, describing what products and solutions that can be included under each subheading. According to the results, several different names such as eHealth, mHealth and telemedicine are currently used without a clear understanding or set standard for what product or service that belong to a certain definition. Problems occur when to distinguish between self-care tools and products to be used in healthcare, according to the results.

"I believe that a lot of these products will fall under the category of self-care, meaning that you buy it yourself as a patient. The government will never reimburse or comment that type of products…But of course there is a need for a strategy to find out what products are going to be paid for, not going to be paid for and why."
- Respondent, TLV

According to the interviewees, there is a clear lack of understanding in how digital medicine products are going to be reimbursed. There are yet no structures for reimbursement currently hospitals make most decisions. That means that the reimbursement decisions of solutions are varying from case to case, not looking at the overall disease perspective. According to respondents, the development of new innovations in healthcare triggers a lot of question regarding how to distinguish between all products and applications and how to find products that will be beneficial and cost effective with high quality and the potential to have a positive impact on treatment. However, it is stated that the financial part is still unclear.

"There is a need to ask the question; what are we able to pay for? For example there have been discussions regarding apps that could help treatment, but cost money. Shall the county council or the patient pay for these services? …There are these grey areas where you do not know what to do, when it is very expensive and we want equal treatment for all patients. That will be a hard part."
- Respondent, LUL

In many cases, current reimbursement structures hinder the digitalization process. Reimbursement systems used today are not always updated which can cause problems when implementing new solutions in care. It is important not only to look for reimbursement of a certain product but for the whole treatment process. In some cases there is no procurement for patients to be monitored from home and doctors examinations are heavily reimbursed. According to the respondents, reimbursement of physical visits does not stimulate virtual care.

Respondents also consider digital medicine products complex to develop due to a lot of barriers, uncertainties and regulations and one respondent states that there is ignorance among developers to understand the struggle to find someone to pay for the product. Clinical validation process are time demanding and costly but compulsory to obtain CE-marking and be considered a medical technology product. However, currently many app-developers are not prepared to pay for these processes, leading to an imbalance in the market where there are CE-market, clinically validated applications at a higher cost and products sold at a lower cost with no evidence of efficacy nor safety.

" It is different to create a business model for a product that has to be adjusted to the regulatory landscape of healthcare. Everything takes longer time and cost more. There are products that are used in different therapeutic areas that has gone through clinical validations and CE-marking and then there are similar products that have not gone through testing, but are still recommended by healthcare since they are cheaper but not certified. This is a problem…"
- Respondent, SwedishMedtech

Additionally, a major problem in healthcare that is pointed out is that county councils and hospitals throughout the country have different systems for communication. According to several respondents, there are no standard procedures for what language the systems are going to use. County councils procure different products and modern solutions but these are not compatible when it comes to informatics and technique. One key mission according to Inera is to set standards for how technical products communicate. This is also important, according to SLL, to take under consideration in the digitalization process were new devices are planned be integrated with and share information to current systems in health care. To be able to obtain valuable data sharing it might have to be delivered automatically to healthcare in a processed manner.

"If the patients have few visits, maybe one per six months…it will take some kind of aggregation level and logic to sort out important data that this is deviating."
- Respondent 3, SLL

The Swedish healthcare system also experiences an insufficient structure in resource allocation. There is currently a lack of connection between economical steering in relation to how you handle the disease according to Synergus.

"I think we use the money well and our level of cost is fine but it is not thought through on a national level how we should allocate the money, how do we treat diseases and how much are we going to spend in each therapeutic area. That is a key questions before implementing new smart innovations."
 - Respondent, Synergus

Finally it is clear from the results that there are still regulatory and ethical questions to be considered when handling digital medicine products and patient data. Safe systems must be applied and structures for usage. Discussions are suggested to be necessary to state how data can be used to in an ethical manner create value for science and society.

5.4 Future outlook

The last part is reflecting actions planned in the future by the organizations towards digitalization and the usage, reimbursement and payment of digital medicine products. It also touches upon events or actions that is considered necessary to achieve faster implementation of these products in healthcare.

5.4.1   Future plans and actions

There is a leap towards digitalization in Sweden on a regional as well as national level. It is mentioned by the respondents that on the 14th of March the Swedish government together with county councils presented a vision regarding Swedish digitalization and eHealth goals. The vision is, according to the interviews, based on the aim that Sweden shall be world leading in capturing the opportunities in the process of digitalization to promote equality in care, patient participation and utilize individual resources.

According to the findings, there are new initiatives made by county councils within the area. In Uppsala there are a new unit for enhancement of eHealth and several county councils are planning for increased usage of virtual doctors appointments. However it is stated by a respondent that Sweden only faces the beginning of this process.

"I believe that we are at a breaking point. We still think very traditional and, now I speak very openly, there are no other areas that allow such waste of resources as in healthcare. Why does that happen? You work extremely traditional... I am sure that it will look totally different in a couple of years. But we are just in the start of a new development."
- Respondent, Inera

Several respondents have identified the need of transforming the reimbursement systems of today. Due to new innovations and changes, current systems are out-dated and sometimes even a hinder for further development. LUL, states that they are aware of the problem but that there is currently no project planned to deal with the question while SLL are a bit ahead in the planning. According to the interview, SLL made changes in major reimbursement models in 2016. For example in primary care, the model that initially was based on number of doctor's appointments is now looking at the number of listed patients. This change is believed to stimulate virtual appointments and saves resources since physical hospital visits are limited. According to the interviewees, models are also created to stimulate uptake of new methods and products.

"There are new reimbursement models that are going to steer towards a need-oriented care and from a production-oriented care."
- Respondent 2, SLL

According to TLV, the common goal among the organisations is that healthcare should be more flexible and less costly. However, due to the current law no reimbursement standards for digital medicine alone will be suggested. Nevertheless there have been initiatives for structured implementation of medical devices and suggestions of new regulations within the field.

"We have a quite good regulated system for drugs, but medtech is not regulated in the same way. These are new continents that we explore as we go, and here are yet no traditions, regulatory support or knowledge in the same way as in pharmacology. There is a lot of pioneer work when it comes to setting up laws, cooperation's and financing. Everything is very rudimentary in my opinion"
- Respondent 2, SLL

It is suggested in the interviews that, due to digitalization of societal systems the traditional way of healthcare might change and new roles and areas of responsibilities will appear. According to SwedishMedtech there are currently already a lot of data and information to be found online. Easy access to information increases the population's knowledge in science and therapies and enables patients to learn about diseases and take part in decision regarding treatment. According to the respondents, this mean that the physician's role will change from diagnosing and treating to guiding and assisting in distinguish relevant information from what is irrelevant.

5.4.2 Demands for implementation of digital medicine
There are many expected challenges to be met on the road to digitalization and implementation of digital medicine in healthcare according to the results. The respondents pointed out several aspects that are believed to be important to consider for both digital medicine companies as well as government, county councils and hospitals.

When it comes to the digital medicine products, several characteristics are believed to be required to enable implementation and usage in healthcare. In order to live up to the standards and demands of healthcare, products within digital medicine should meet the same requirements as other medical devices and be clinically validated to prove efficiency and safety. It is stated by the interviewees that processes for this are costly but should be mandatory for all digital medicine products to obtain al through high quality and limit large variations in pricing. According to the findings, developers have the responsibility of CE-marking products that can affect health and to be considered a medical technology product, CE-marking is required.

"If you have performed the CE-marking correctly, and you need a CE-mark to sell the product, then you have to have done the testing. There is no easy way out, you cannot sell a medical device that is not CE-marked."
- Respondent, TLV

It is highlighted by the respondents, that for developers to able to go through processes of testing and validation there must be a secured market for the product and the chance to achieve revenue. Healthcare and county councils must understand their role in the development of digital medicine products as well as digitalization and take their part. The development should be in close contact to care and co-payment of products that can deliver useful and trustworthy data will be important.

"I believe that reimbursement is needed and I think that you will have to see this products the same way as drugs or physical medical devices. But also have the same requirements for these products as well, so that we obtain a high standard for all of these products."
- Respondent, SwedishMedtech

It is also stated, that for products to be considered reimbursement there has to be clear evidence of cost efficiency and value. The product must show obvious improvement of treatment and/or other huge advantages for decision makers to believe and invest in the product. Health economics will regulate the uptake.

"Can this intelligence offer meaningful value where the doctor are involved as little as possible to save time and money, but give accurate signal when care is needed? Then it is really good. The patients are feeling better, physician's saves time and the healthcare system saves money. Then you as a company can find the financing as well."
- Respondent, Synergus

For the healthcare system to be prepared for the uptake and usage of digital products, several aspects are in need to be addressed according to the interviewees. It will be of importance to look for new reimbursement processes that stimulate development and usage of these digital medicine products. The reimbursement has to not only focus on certain products but also at current and future processes in care. Furthermore it is suggested that systems and structures for reimbursement decisions will be needed to learn what products to reimburse, this might not be specific for digital medicine but for medical devices in general.

"There is a need for a strategy to find out what products are going to be paid for, not going to be paid for, and why. But it wont be specific for just digital medicine products"
- Respondent, TLV

According to the interview results, it is advantageous for healthcare to look at the whole perspective when making decision regarding implementation of new products. With knowledge in disease management and overall processes for a certain disease, there is a possibility to understand and decide for methods and solutions with potential to lower healthcare cost in the long run.

"It has to come from an overall perspective with disease management where you try to optimise the treatment for the disease. From that you can decide over your budget and learn where you can save money. That where IT solutions fit in."
- Respondent, Synergus

6. Discussion

This thesis has aimed to obtain valuable knowledge that can assist implementation of digital medicine solutions in healthcare by exploring the reimbursement landscape, mapping digitalization trends in healthcare and visualizing challenges and opportunities with digital medicine. Knowledge, believed to be important for government, healthcare personnel, patients as well as companies operating within the field of digital medicine. To obtain results for further discussion, qualitative interviews were performed with leaders of Swedish key organizations within the field. The whole study was performed according to the ethical consideration described in the method section. Following is a discussion of the interview results based on the research questions that were stated in the aim section.

6.1 Summary of results in relation to current literature

6.1.1   How is digital medicine used in healthcare today?
The first research question was asked to learn about how digital medicine was looked upon by the organization and if there were any digital medicine products used in

healthcare at the point of the study. According to articles written by Nature (6,457), digital medicine should be defined as: "that technology and those products that are undergoing rigorous clinical validation and/or that ultimately will have a direct impact on diagnosing, preventing, monitoring or treating disease, condition or syndrome". However, it is clearly stated by all respondents that digital medicine as a term is not used in Sweden and that there is no definition in such in the Swedish medical device regulations. Today, the findings show that digital medicine is entitled medical devices in general. In Sweden, according to the results, words such as eHealth, Telehealth, mHealth and distant monitoring are used to describe the area and it is stated that the definition of digitalization increases in use. These definitions also differ from definitions used in other countries such as UK, where eHealth is not defined but telecare, health analytics and digitised health systems (5). In the results it is stated that there is yet no proper way to distinguish these different terms and that it might be problematic to understand what products/solutions that belong to each category, which in turn makes it difficult to distinguish what products to reimburse or not.

Although digital medicine is not yet defined, there is an understanding among Swedish organizations what products to be covered by the definition. Today there are according to the results, only a few digital medicine products used in care but there are plenty of initiatives and testing of these products. It is a common understanding that the challenges of the future care in Sweden mirrors the rest of the world and what has been stated regarding the future demands and an unbearable pressure on the future healthcare (3) is still considered a problem. It is believed that digital medicine will have a key role in future healthcare and that the phenomenon of these products and solutions will increase rapidly. However, it is a limited and unstructured usage of digital medicine in Swedish healthcare today according to the findings.

6.1.2 What opportunities and challenges are observed in the area of digital medicine?

When discussing the opportunities of digital medicine, the results from this study correspond well with previous literature. It is mentioned that new ideas and innovations are needed to manage and lower expenditures in the future care (3). It was mentioned that the Swedish healthcare costs would increase with 30% if the current trend proceed (3). Digital medicine and the digitalization are expected to be a potential solution to maintain a safe, high quality healthcare with a reasonable price tag. As stated in the findings patients will be monitored from home in a much greater extent to limit hospital visits and hospitalization to save time as well as money. Digital medicine products such as; wristwatches, patches, broaches and different applications with biosensors that can capture and log data (6) will be important in the process towards an increased home care. These products will undeniably become a key asset in patient empowerment that is according to both the results and current literature, one of the greatest opportunities and winnings in the digitalization process. The trend of patients wanting control of their own condition (26) is important to capture for better disease management. It will be important to utilize patient own resources and knowledge in the future and allow the patient to be co-creator of the care. There are, according to the result, great winnings with patient empowerment not only will it be time saving it will also increase patient compliance since the patient will have a deeper understanding of the condition and the treatment process. Patient compliance is beneficial both due to desirable clinical outcomes and the decreased economical burden in healthcare, with limited urgent care visits, hospitalizations and lower treatment costs (50).

Findings show that digital medicine will result in a more efficient communication between patient and physicians. Patient data can be recorded out of hospital and sent automatically to the healthcare where important information can be analysed. This means that the physician might get the possibility to sort out the patients that are in need of care and limit the number of routine check-ups that are time and resource demanding. The access to logged real-time patient data will be useful in decision making and treatment strategies but also in a bigger perspective. Big amount of aggregated patient data can be used to obtain new knowledge in diseases for better treatment. Big data has got an enormous potential to increase the quality of healthcare and at the same time, lower healthcare expenses (14).

There are many challenges in digital medicine mentioned in the results of this study. Some challenges are expected and correlates well with previous literature and some are quite new to the discussion. In current literature, challenges are mainly formulated from a digital medicine industry perspective, pointing out struggles for companies to find proper payment models (38) as well as finding a way in the tangled regulatory framework of healthcare products (12). According to the results there are indeed a complex regulatory framework and lot of barriers for company's to overcome in order to obtain CE-marking and be considered a medical device. Testing and validation processes for CE-marking are expensive and might potentially reduce the incentives for developers to focus on healthcare as a market (12). In the findings it is stated that developers will need to be assured that there is a marked and revenues in order to prioritize these processes, which are important to obtain high quality and safe products. According to current literature and mentioned in the results, reimbursement structures for products in digital medicine are unclear in most cases un-existing (4). This is clearly a contributing factor to the financing uncertainties in digital medicine companies' business models.

However, what the current literature does not cover is the enormous challenge that awaits healthcare in the process towards digitalization. Literature states that implementation and uptake of new digital technology in healthcare is slower than the development of new tools, a fact that might be devastating for not only companies, but also the system itself (30). The results indicate several challenges that might be the underlying reason for this limited uptake. Firstly, the digitalization will mean structural changes in the entire healthcare system of Sweden. According to the results, the Swedish healthcare is today in a large extent steered on a regional level by county councils and what solutions to be procured are decided on a regional level. This means that there are several different systems at different hospitals that do not communicate. These systems are not compatible when it comes to informatics and technology. A phenomenon that is causing struggles when implementing new digital solutions with the potential to deliver data to these systems. As mentioned in current literature, these incompatible systems make data handling inefficient and increases the workload of healthcare (2). Additionally, the results indicate on out-dated reimbursement models that does not stimulate, and sometimes even hinder, the implementation of new innovations and services.

Findings suggest that the management and direction of Swedish healthcare might also need to be overlooked; most decisions are made on a regional level with limited national steering. There is also dis-transparency in how the financial resources are allocated in different units of care and efforts in one department might lead to savings in a completely different department. It is also believed that there currently are huge wastes of resources in Swedish healthcare. Additionally, the way of thinking in healthcare is suggested by the

interviewees to be obsolete and inefficient. Today there is only a focus towards one specific part of treatment in each single case, instead of a focus towards the whole process of disease management including prevention, treatment and rehabilitation. Lack of communicating systems, proper reimbursement structures, economical steering and disease management overview are definitely challenges to be met in the digitalization process. Major changes are needed but elevated stress levels among personnel and lack of resources might stand in the way or delay a structural shift. These challenges are not mentioned in previous literature.

6.1.3 How does the reimbursement system currently handle digital medicine products and what are the future plans?

According to the findings, products within digital medicine used in healthcare today, are handled the same way as other medical devices. There is no national structure for reimbursing these products and TLV has a role in reimbursing only of a fraction of these products called "consumables" (32). County councils and hospitals are able to procure/buy different products of interest; usually it is the hospital that makes the decision and pay from a set budget. This means that different products will be reimbursed in different county councils and at different hospitals and that the decision is made from case to case. Since there are, as mentioned in the findings, uncertainties in how to define digital medicine products and distinguish them from self-care products it is also hard to know what products to reimburse or not. Currently many of these products are paid out of pocket by patients (39) but that way there is a risk of facing an inequality in care among patients as well as low-quality and unsafe products.

According to the results there are in Sweden initiatives to enhance digitalization. Several digital solutions and products are tested by different organizations and county councils are motivated to enhance eHealth and services. For example, SLL stated that they recently changed a reimbursement model from reimbursing physical hospital visits to reimbursing the number of listed patients. The respondent's states that in most models today, physical visits are largely reimbursed which limits the incentives for physicians to keep patients away from care. It is acknowledged that these models inhibit homecare and virtual doctors appointments, and there are an understanding that new reimbursement models that consider these types of services are needed in future care. Swedish Association of Local Authorities and regions (SKL) is also suggesting that there is a need for a structured implementation of medical devices in general, similar to the system in medical drugs (51). The Swedish government also recently presented a vision for 2025, where the aim is for Sweden to become the world leader in using the possibilities of digitalization and eHealth in order to achieve a good and equal health as well as facilitate with tools for patients to utilize personal resources (52). Several projects and plans are initiated in Sweden, in order to improve systems and open up for a more digital care. However, major changes are to be made in the future and Sweden is currently in a breaking point and in the beginning of a gigantic effort.

6.1.4 What is needed for structured implementation of digital products in Sweden?

Several actions and strategies will have to be considered to enhance the Swedish digitalization as well as to permit and assist an increased implementation of digital medicine products. According to literature, validation and reimbursement strategies should be considered key parts in all digital medicine business models (30). For companies within the area it will be important to consider these parts, and it is stated in the results that products in digital medicine should be considered medical devices, have

similar requirements and require CE-marking to obtain high quality on all products and secure patient safety. Not mentioned in previous literature is the fact that it will be crucial that products show a clear evidence of cost efficiency and obvious improvement from existing treatment strategies, in order to be notable. Development of these products should be in close contact to the care in order to capture patient needs and meet the requirements of healthcare.

In the vision that the Swedish government presented in March 2016, it is stated that there are certain areas that will be mainly focused on in the beginning of the process. Those areas are: regulatory framework, more coherent use of concepts and standards for safe data sharing (52). These as well as several other aspects were highlighted in the results as demands to enable uptake and usage of digital medicine products in healthcare.

As mentioned in the background section, a regulatory framework regarding digital products is emerging in both US and Europe (12). However, it is stated that there are still regulatory and ethical considerations that have to be specified by the government. For example, it is suggested that digital medicine products should be looked upon as medical devices with the same requirements and reimbursement strategies. However, reimbursement standards for medical devices in general are needed as well as structures for how to categorize digital medicine products. Today there are uncertainties in what products county councils should pay for and what products that should be paid out of pocket by patients (8). There is also needed to update reimbursement standards for procedures and modulate reimbursement models to stimulate development and focus on digital medicine. Additionally, in order to enable implementation of products there has to be common standards of systems used in the Swedish healthcare. It is important with systems that can communicate between hospitals and regions in order for data gathered by digital medicine products to made useful within care (2).

Finally, what is not touched upon in current literature is the fact that a change in how disease management is looked upon today might be needed. It is suggested by the respondents that in order to learn in what segments of care digital medicine products are needed and advantageous from a health economic perspective, it is important to look at disease management as a whole in each therapeutic area: from prevention to treatment and rehabilitation and not on one single part of treatment or monitoring. When seeing the whole perspective of disease management it will be clearer where new innovations are needed and where resource savings are possible. It is believed that preventive care, assisted by technology, will be more focused on in the future as an important part in the overall disease management.

6.2 Implication of results
The results from this study do partly correlate with current literature as well as highlight some aspects that are not described in reports regarding digitalization before. What could be found in the results is that all respondents admit the importance of a change in healthcare to sustain quality and lower costs, a change that is stated to be important to afford healthcare in the future. Digital medicine is suggested to be the solution for this problem with huge advantages such as virtual care, home monitoring, patient-empowerment, sharing of patient data, big data, communication and preventive care. It is suggested that there are great winnings with digital medicine in chronic disease care due to the possibility to continuously monitor the patient and lower the number of hospital visits. Digital medicine seems to be important, if not crucial for the future healthcare.

However several challenges, mentioned in the results must be overcome in order for the vision of digitalization to become reality. To begin with the term digital medicine is not yet used in Sweden, instead several other terms are used to define the area. Different terminology might cause uncertainties in decision-making regarding reimbursement and might be confusing on a global level since different terminology is used in different countries. Universal definitions to explain these emerging areas would be beneficial for future collaboration between regions to ease future progression. The idea of universal systems is also applicable to communication systems used in the Swedish healthcare today. In order to implement a product that gather and deliver important patient data, common systems to receive and manage data will be important to facilitate information delivery to physicians.

It is also stated that reimbursement might be necessary to ensure developers that there is a lucrative market for their product and motivate them to perform validations to achieve equal care with high quality and safe products. However, there are still uncertainties in how to reimburse these products. For example, it is suggested that digital medicine products should be looked upon as medical devices with the same requirements and reimbursement strategies. However, today there are no reimbursement standards for medical devices and there are unanswered questions regarding if digital products are to be considered digital medicine or self-care tools. Standards for categorizing products and reimbursing them are needed and healthcare as well as county councils must, according to the respondents, understand their role and take part in the development of new technology and systems.

In current literature it is purposed that it is challenging for digital medicine companies to build their business model, find the proper payer and reach market in this highly competitive industry. It is declared that key factors for the business model are validation and reimbursement. However, the major challenges for implementing digital medicine products in healthcare might not be at the company's table. Company leaders will be motivated to perform costly clinical validation and testing, as long as the company are able to secure future revenues. If there were a defined reimbursement structure for these products, developers would be incentivised to focus on Swedish healthcare as a market. Instead, it seems that the major challenges to be faced are in several levels of the healthcare system and out control of any digital medicine company. There is a need for efforts in restructuring parts of the healthcare, such as reimbursement strategies, disease management overview, economical steering and systems of communication in order to enhance the digitalization process and the implementation of digital medicine products. One future implication could otherwise be that digital medicine companies decide to focus on other markets where the system are more mature and where financial challenges are more easily met. As mentioned in the background, there are countries where insurance systems finances healthcare (35) these markets could be better targets for digital medicine companies if the Swedish system remain unchanged.

Digitalization will require major changes in the entire system; the role of the physician will change as well as traditional treatment. Multi-professional competences, handling for example medicine, technology, economy and innovation might be needed in future healthcare. These changes will be time demanding and costly in a healthcare that already experiences economical pressure. Will digital medicine be the solution to this problem and will today's cost in restructuring the healthcare repay in the future? Currently it seems that digitalization and digital medicine offer our biggest chance to manage future pressure

in healthcare and it is believed to be the only way. However it will take a lot from the Swedish society to reach the vision set by the government in 2025

6.3 Future considerations
For future and further research within the area it would be suggested to in a similar manner discuss the situation with other stakeholder such as healthcare personnel and/or companies operating within the area. It would be of interest to see their point of view and learn more about what they consider to be the major challenges and opportunities in digital medicine. It would also be of interest to learn about reimbursement structures and plans in other countries such as UK and US to understand how different countries handle a similar situation. Additionally, digital medicine companies are proposed to focus on testing and clinical validation of products to achieve CE-marking as well as look into possibilities to state clear evidence of cost efficiency. Randomized controlled clinical trials, the golden standard for evaluation of safety and quality in healthcare (53) could be considered a tool to further prove value since CE-marking usually always is required. To be able to prove health economic benefits will be important for future reimbursement as well as implementation in healthcare. Finally, government, county councils and health care are suggested to look deeper into how to actually change systems towards digitalization and not only look at the surface.

6.4 Limitations
As in any other qualitative study, the missing interviews are a limitation. Not all of the approached organizations were willing to take part in the study and valuable knowledge and thoughts might have been lost. However, the vast majority was willing to participate and the engaged respondents were very knowledgeable, experienced and interested in the subject. The interviews were recorded and transcribed in order to limit information losses or misunderstanding, however in a few cases the recordings were inaudible. Though, this is not believed to have affected the results. To limit misinterpretations the results were sent out to the respondents and at the same time the respondents were able to approve quotations. Finally, when performing a study there is a risk that the researcher evaluates and assesses the data based on own thoughts and experiences, a phenomenon that might limit the credibility of the study. To minimize the risk of deception, the study process was transparent and performed according to a set research methodology.

7. Conclusion

Digital medicine is an emerging area within the life sciences and is in many occasions believed to both aid and revolutionize the Swedish healthcare. A healthcare system that is predicted to face major pressure in the future. There are several opportunities with the introduction of digital medicine, such as patient monitoring and patient empowerment, which has the potential to lower healthcare expenses. However, the change towards digitalization of healthcare entails many challenges. Digital medicine companies will face challenges in financing since there are no structured reimbursement systems for medical devices including digital medicine. However, the vast majority will fall on Swedish healthcare, county councils and the government. Today, Sweden is at a breaking point and several actions towards digitalization are either planned or under progression. Sweden is focusing on e.g. regulatory framework, more coherent use of concepts and standards for safe data sharing, factors that are important in the process. However, to enhance development and implementation of digital medicine products and incentivise developers to go through costly validation processes, new reimbursement strategies for medical devices will be important as well as structural changes in healthcare processes to promote digitalization. If the challenges are overcome, digital medicine products aligned with the digitalization process has the potential to revolutionize the Swedish healthcare, meet the upcoming demands and enable a future healthcare with high quality.

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10. Appendix

Appendix A

Table 1. Interview guide

Interview guide

Background: Interviewee	1. Could you please describe: - Your professional background? - Your current position? - Your tasks and areas of responsibility?
Background: Organization	2. Could you please describe: - The organizations function? - The organizations way of working? - The organizations aim - How the organization work with medical technology?
Digital medicine	3. How does implementation of medical devices look in healthcare today? 4. How would you define digital medicine? 5. Do you know any digital medicine product used in care today? - Product, Paying part, User? 6. What role do you think digital medicine will play in future healthcare? 7. What role do you think digital medicine will play in chronic disease care?
Digital medicine	8. Are there any reimbursement standards for digital medicine products? 9. Have any digital medicine product been reimbursed before? 10. Is there a need for new reimbursement strategies within digital medicine? 11. Are there any plans on implementing reimbursement strategies in this area? 12. What characteristics are needed in digital medicine to get reimbursed?
Other	13. How does your organization work with implementation of digital medicine? 14. Do you consider reimbursement of digital medicine necessary? 15. Is there anything you want to add?

Appendix B

<u>Responding organizations</u>

Uppsala County Council (LUL) unit for eHealth

In the beginning of 2016 a new unit for eHealth was created in the county council of Uppsala with the aim to coordinate and drive the development of eHealth. During 2016 the unit will pin out the strategy for eHealth and collaborations with different parts will be initiated in order to enhance eHealth within the county council. The aim of the organization and the development of eHealth are to give the patient more access to personal data and information so that they have the potential to take part in the treatment process. The aim is also for healthcare personnel and other decision makers to access correct information at the right time for an efficient safe care with high quality. eHealth is, according to the representative of the unit, used to create contact between physicians, relatives and patients before, during and after care.

SwedishMedtech

The association for medical technology is Sweden is called SwedishMedtech. It is an organization that assists and advice medtech companies in their current working process. They have 10 employees and are usually working with different areas, for example the ICT-group that is responsible for companies operating within digital medicine. SwedishMedtech are focusing on issues such as regulatory questions, environmental questions, compliance, ethics and socio-economical perspectives, innovation, growth and communication. They also offer education and conferences to their member organizations. The long-term goal of SwedishMedtech is to create best possible environment for medtech companies to grow both within science and innovation, with a market perspective. Other goals are patient safety and a sustainable healthcare.

Tandvårds och Läkemedelsförmånsverket (TLV)

TLV was put into business 2002 by the Swedish government as a reaction to the high rate of increasing cost for medical drugs. TLV is performing value based pricing and evaluations of medical drugs and medical devices. 2012 received TLV a government commissions to do health economic analysis on medtech products, and that is TLVs latest task. TLV receives applications from companies where they show the value with the product and based on that TLV decides if the product is cost effective and should be reimbursed. According to the law TLV has the authority to reimburse what they call disposable products for example products used in for example diabetes. This only accounts for a fraction of all medtech products and county councils decides for the rest. The vision of TLV is to create most valuable care for the tax money.

Medical product agency of Sweden

The Swedish National Authority responsible for regulation and surveillance of marketing and manufacturing of medical drugs and medical products. Their aim is to secure that healthcare personnel as well as patients have access to safe and effective products. They are also focusing on cost-effective usage of these products.

SLL Innovation

The organization was created 2003 at Danderyds hospital and became a part of the county council 2013. The idea is to capture new ideas and nurture new innovations as well as to keep all needed competence under the same roof. SLL receives ideas from the healthcare

industry and assist companies with things such as CE-marking, risk analysis and need analysis. They can also help implement products in healthcare by provide companies with centers where they can test the product. The organization aim is to implement new innovations to increase efficiency in healthcare.

Stockholm County Council (SLL)

Representatives from two different units of SLL participated during the interview. The different units were the development department for health and healthcare and the department for eHealth. The responsibility areas of SLL are for example to deliver a well working and available healthcare and to plan and create for growth and development of the region.

Synergus

Synergus is an international consulting company operating within the medtech industry offering companies assistance in market access strategies as well as clinical and economical evidence and reimbursement questions. They are currently 20 employees working with west European and Russian companies. There overall goal is to become the word leading company in their area.

Inera

Inera is a public organization owned by all Swedish county councils and regions with a mission to coordinate Swedish eHealth systems and develop solutions valuable for citizens, healthcare systems and decision makers. Inera is led by a political board of directors with a responsibility to make sure that the organization is working with questions important for the head of the organization e.g. the county councils of Sweden.