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An Investigation of the Market Potential for Connected CTG Telemonitoring Solutions in Health Care Systems

The Case of Antenatal Care Setting

Master's thesis in Management and Economics of Innovation

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SUMMARY

During the two last decades, the use of medical technologies in the home setting has increased considerably and is anticipated to further do so in the near future. With the entrance and increased demand for new ways of delivering care, the healthcare sector and MedTech industry is reacting and transforming. However, the successful adoption of telemedicine is still a challenging task in the healthcare sector. There is a trend for health solutions being offered as B2C to cope with the non-readiness of health facilities and medical technology companies face challenges when trying to adjust, develop and transform in a landscape characterized by an increasing demand for the integration of IoMT. Antenatal care is a suitable domain for establishment of telemedicine. A shift in standard monitoring of pregnant women from the hospital to the home could contribute to meeting the problem of continuous strain on the healthcare sector and give pregnant women more control over actions affecting their health. This thesis aims at investigating what factors influence the adoption and market opportunity of a proposed CTG telemonitoring solution for antenatal care on one promising market within the OECD. In order to conduct this research, a survey was performed to gain insights from potential customers, as well as a screening analysis to identify a promising market. In addition, qualitative interviews were held with actors within the industry, medical professionals and potential end users. Moreover, a literature review was made in order to gain further insights. The information gathered was then analysed using a framework built up by Roger's diffusion of innovations theory, Porter's Diamond Model and the Market Opportunity Navigator, to enable examination of the data from different point of views. The analysis shows that there are several factors that influence the adoption of a CTG telemonitoring solution. The main barrier to adoption of connected medical technologies involves acceptance by both healthcare systems and individual healthcare professionals. There are some factors that apply to the technology independent of how it is offered, such as industry readiness and some rules and regulations. However, it is evident that these main factors vary depending on the customer offer. Furthermore, there is a market opportunity for a complete solution with connection to electronic health records and possibility for end user to receive a summary of the findings from a local CTG interpretation team, on the US market as a promising market. If taking into account that the solution would be offered by a company focused at revenues and sales, the solution would need to be introduced to early adopters with strong purchasing power. However, the technology would contradictory be of largest significance in countries associated with lower socioeconomic status, where antenatal care is lacking most. The issue of the technology currently not being biologically suitable for every woman is moreover largely discriminating, and the uncertain clinical value of the CTG technology is problematic. These concerns need to be overcome by further research and development. In conclusion, it is evident that the market of connected medical devices is expanding and will continue to do so. Consequently, MedTech companies will be forced to develop new skill sets and take innovative responsible decisions to remain competitive in a changing environment, going in a direction that can not be stopped.

Keywords:

Cardiotocography, Telemonitoring, IoMT, Antenatal Care, Diffusion, Adoption, Market Opportunity

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Contents

Acronyms

ACOG American College of Obstetricians and Gynecologists. 20, 53, 61

AIC Actual Individual Consumption. 51, 59, 60

B2B Business-to-Business. 19, 26, 41, 49–52, 55, 58–60, 64

B2C Business-to-Consumer. 3, 18, 19, 22, 26, 41, 47–52, 54, 55, 57–61, 63, 64

BioTech Biology Technology. 9, 53

BMI Body Mass Index. 13, 57

C-section caesarean section. 1, 12, 13, 62, 63

CAGR Compound Annual Growth Rate. 18

CMS Centers for Medicare & Medicaid Services. 21

CTG cardiotocography. 1–5, 10–16, 19–21, 23–27, 29–32, 36–41, 46–64, 100, 102, 105

ECG Electrocardiogram. 14, 41

eHealth Electronic Health. 3, 6, 17–19, 21, 22, 42, 43, 52, 57, 61

EHR Electronic Health Record. 17, 54, 55, 57, 58, 64

EU European Union. 19–22, 54

FDA Food and Drug Administration. 21, 54, 57, 60, 61

FECG Fetal Electrocardiogram. 14

FHIR Fast Healthcare Interoperability Resources. 21, 54, 60

FHR fetal heart rate. 1, 2, 11–15, 20

FIGO the International Federation of Gynecology and Obstetrics. 20

GDP Gross Domestic Product. 51, 59, 60

HI hypoxic-ischaemic. 1, 12

ICT Information and communications technology. 14

IHI Institute of Healthcare Improvement. 19

IoMT Internet of Medical Things. 3, 14, 18, 19, 21, 52, 54, 56–61, 63, 64

IoT Internet of Things. 3, 16, 18, 54, 60

IT information technologies. 5, 6, 17, 18, 50

MDR Medical Device Regulation. 21

MedTech Medical Technology. 3, 8, 9, 17, 18, 21, 53, 54, 57–59, 61, 64

mHealth Mobile Health. 2, 3, 6, 17, 21

MON Market Opportunity Navigator. 5, 9, 23, 54, 56, 59, 63

NICE the National Institute of Clinical Excellence. 20

NICHHD the National Institute of Child Health and Human Development. 20, 53, 61

OECD Organization for Economic Co-operation and Development. 3, 4, 24, 28, 59, 60, 62–64, 70

QMS Quality Management System. 21

R&D research & development. 8, 9, 18, 57

RCOG the Royal College of Obstetricians and Gynaecologists. 20

UN United Nations. 20

USA United States of America. 8, 9, 21, 22, 26, 30, 43, 51–54, 59–64

WHO World Health Organization. 2, 20

1

Introduction

The following chapter aims to create a background to understand the issue underlying the study.

1.1 Background

Neonatal asphyxia, the state of deprivation of oxygen, and trauma for the fetus, accounted for 10% of all child deaths in 2017 (Roser et al., 2017). Moreover, hypoxic-ischaemic (HI) events, described as shortage of oxygen in the blood as well as blood flow to the brain, in infants from birth to the 28th day of life is the most significant contributor to disability globally. A tenth of all "disability adjusted life years" (DALY) (GBD 2015 Disease and Injury Incidence and Collaborators, 2016), a measurement over the number of years lost to early death, disability and ill-health, are attributed to these HI events. Antenatal care, which aims to reduce maternal as well as neonatal mortality and morbidity, needs to be improved worldwide in order to reach the Sustainable Development Goals (United Nations, 2020) covering good health and well-being. Two of the goal targets are aimed at reducing the global maternal mortality ratio as well as end preventable neonatal deaths worldwide. During the antenatal period, frequent medical care visits are recommended by global guidelines to promote the health of both mother and child (Ali et al., 2020). Antenatal care is the preventive health care provided to women throughout their pregnancy, aiming to identify early deviations from normality, such lack of oxygen supply to the fetus (Dhillon et al., 2018).

In a recent topical review (Dhillon et al., 2018), it is argued that the indistinct terminology in this field, does not do well in separating the cause of oxygen deficiency with the labour stage. For example, "birth asphyxia" is restricting the idea time at which key HI events take place, that later on gives rise to long-term issues to the birth stage. Asphyxia and birth are two words intertwined, and often used almost synonymously. But in reality; isolated, acute, chronic or a combination of negative events can affect the fetus during the time also *before* birth. It is, for example, emphasised that the antenatal origins of cases of permanent moving disorders such as cerebral palsy was affected by antenatal HI (Novak et al., 2017; Tan, 2014). Evidence moreover suggest that antenatal hypoxia plays a role in postnatal brain development as well as contribute to the risk of developing neurodegenerative disorders later in life (Nalivaeva et al., 2018). HI insults before birth is moreover correlated to a fetus being small for its gestational age and intrauterine growth retardation, which in turn is related to chronic antenatal hypoxia and elevated lactate levels. The antenatal period consequently plays a large role in the outcome of events later on, like oxygen deprivation during birth. During birth, the fetus is naturally exposed to events of oxygen deficiency, for example during contractions. It is therefore vital that the fetus is well prepared with sufficient oxygen reservoirs in the placenta. A fetus that has been under repeated oxygen deficiency during the antenatal period, will risk damage as a result of asphyxia early on during birth (Dhillon et al., 2018). Today, cardiotocography (CTG) technology is used at the time for antenatal care visits to varying degrees as a means of detecting stages of fetal oxygen deficiency. Since its introduction, CTG has remained the golden standard of fetal monitoring (Schramm et al., 2018). CTG is a technical method of recording the fetal heart rate (FHR), by means of Doppler ultrasound, and the uterine contractions of the mother, by means of a tocodynamometer. These two main components are connected to the mother (Boatin et al., 2015). The technology is not only used intrapartum, during labor, but also in the antenatal care. For diagnosing of common diseases, and indications on the fetus oxygen levels, CTG recordings can be highly informative and data collected during the antenatal care can contribute to clinicians' decision making process necessary during labor, as for example if the woman is in need of caesarean section (C-section) or other interventions (Rosén & Mårtendal, 2014). Additionally, correct diagnosis based on CTG demands specific competence from clinicians (Kazantsev et al., 2012).

However, not only life-saving activities are at focus in today's healthcare sector. Cost-minimization is likewise a central subject matter. Hospital stays, in Obstetrics Departments being no exception, are urged to be held as short as possible. Today, pregnant women, in particular stabilized high-risk pregnant women, often stay in hospitals for monitoring reasons only (Buysse et al., 2008) as an cautionary action during the late antenatal period. However, a pregnancy is often planned which means that the patient, in this case being a pregnant woman, can plan and make an active care choice beforehand. As pregnant women are not sick per se, they are not classically patients. This is unique in relation to other types

of chains of care. Therefore, it is argued that obstetric care is a suitable domain for establishment of telemedicine (Schramm et al., 2018). Telemonitoring is described as "the observation at a distance by telecommunication of industrial processes, operational equipment, natural phenomena or individuals" (Alves et al., 2020). Further, telemonitoring system is defined as "a system or IT service that remotely records the vital signs and metabolic data (e.g. blood pressure) and environment data (e.g. ambient air temperature) in the home and out-of-home environment of a patient by his or her doctor in charge or by a telemedical care center" (Alves et al., 2020). Thus, telemonitoring systems can be used in different settings, such as the patients home environment, and the goal of the system is to improve care without the requirement of traveling (Alves et al., 2020). CTG technology has the potential to be performed by the woman herself, in her home. Studies piloting wireless fetal monitoring, that transmits data via Bluetooth, have shown that pregnant women found the implementation and use of the technology acceptable and feasible (Boatin et al., 2015). In addition, studies carried out in the Netherlands, show that monitoring by portable CTG from home is feasible, safe and that it reduce antenatal costs. However, trained midwives did conduct the monitoring in these studies. Another study demonstrates that telemonitoring of the FHR at home for high-risk pregnant women is technologically as secure as traditional hospitalization (Buysse et al., 2008).

A shift in standard monitoring of pregnant women from the hospital to the home could contribute to meeting the problem of the continuous strain on the healthcare sector and give pregnant women more control over actions affecting their health (Schramm et al., 2018). In addition, significant budgetary savings would most likely be the outcome, if home telemonitoring would allow high-risk pregnant women to remain at home while being monitored with CTG instead of being hospitalized (Buysse et al., 2008). Additionally, others argue that autonomous remote monitoring could reduce the rate of nonurgent emergency visits for pregnant women, which furthermore would have a positive effect on the healthcare sectors' economics (Schramm et al., 2018). Telemonitoring can moreover support the improvement of gestational outcomes as a result of early detection and prevention of complications due to closer attention (Alves et al., 2020). As mentioned earlier, failure to discover complications early on during the pregnancy can have serious consequences (Kazantsev et al., 2012). Moreover, in most cases, perinatal diseases and complications occur due to insufficient medical supervision (Kazantsev et al., 2012). The current methods of antenatal fetal CTG monitoring is used during regular time intervals, often no longer than 90 minutes, resulting in only a representation of the current fetal well-being in that particular moment (Tamber et al., 2020). Thus, a false sense of reassurance could occur and important signs of fetal demise could in this way come to remain unnoticed. A way to cope with these issues could be to use more continuous methods of fetal monitoring, that could provide a more comprehensive and objective overview of the fetal status (Tamber et al., 2020). CTG telemonitoring allow for more frequent monitoring without the need for the woman to travel to a healthcare facility, or being hospitalized.

During the two last decades, the use of medical technologies in home settings has increased considerably and is strongly anticipated to further do so in the near future (ten Haken et al., 2018). The development of Mobile Health (mHealth) has improved the diffusion of telemedicine and World Health Organization (WHO) argue that the advancement supports the medical and public health practice (Parimbelli et al., 2018). Today's widespread use of mobile devices, such as smartphones and wearable devices, support the acceptance and implementation of a novel remote fetal monitoring device, particularly within younger generations (Schramm et al., 2018). In addition to reducing technological barriers, the rapid expansion of mobile devices, especially smartphones, has reduced the development costs for telemedicine applications (Parimbelli et al., 2018). Yet, to ensure patient safety and quality of care when using medical technologies at home, data on practical experiences and usage trends are necessary (ten Haken et al., 2018).

Useful criterias for telemonitoring was identified a long time ago, however, more research is need as the areas are not fully examined until this day. This is especially true for clinical outcomes, diagnostic equivalence and feasibility as the technological landscape is constantly transforming. The usefulness criteria are cost-effectiveness, improved access to healthcare, similarity in neonatal and maternal outcomes as well as feasibility in patient's use and diagnostic similarity to traditional methods, clinician and patient satisfaction (Pilarczyk et al., 2020). Except for the usefulness criteria, a key aspect in the success of telemonitoring systems is emphasized to be usability. However, current telemonitoring systems used in different areas of medicine have, in general, often unfamiliar and ill-defined features. This makes health workflows unclear to healthcare professionals, being an aspect that may lead to the failure of telemonitoring interventions (Alves et al., 2020). Other identified challenges of wireless fetal monitoring

is connectivity and strength to a reliable Wi-Fi system, for timely transmission of data between internet and smartphone (Boatin et al., 2015). Acceptance of new devices are also affected by the level at which it meets users requested features and possesses desired attributes. The study showed that a high level of comfort and position independent measurements are desired features for a remote fetal monitoring device (Schramm et al., 2018). Furthermore, a case-control study of a prototype technology for fetal telemonitoring showed that safety and reliability are major issues that need to be taken into consideration. Safety aspects are highly relevant, as compliance, acceptance and a successful application will be guided and effected by a positive and reliable approach of such new technologies. Therefore, there is a need of studies to provide evidence strengthening trust in such novel technologies (Schramm et al., 2018).

1.2 Problem Analysis

The development of mHealth has improved the diffusion of telemedicine (Parimbelli et al., 2018) and the use of medical technologies in home settings has increased considerably and is anticipated to further do so in the near future (ten Haken et al., 2018). With the entrance and increased demand for new ways of delivering care, the healthcare sector and Medical Technology (MedTech) industry is reacting and transforming (Eysenbach, 2001). More MedTech companies are investing in connected devices (The Deloitte Center for Health Solutions, 2018) and the change of roles and mindsets, not only for MedTech companies but also for professionals working within the healthcare systems, are of importance for the establishment of Internet of Medical Things (IoMT) within the sector (The Deloitte Center for Health Solutions, 2018). The advancement of Internet of Things (IoT) technology will allow transformed models of care, more focused on prediction, prevention, customization and participation between caregiver and patient (Taylor et al., 2018). There are hopes that technology, process and business model innovation based on these trends will change the way we look at, and use healthcare services tremendously.

Acceptance of new devices are also affected by the level at which it meets users requested features and possesses desired attributes. To fulfill desired features for a remote fetal monitoring device is therefore of importance (Schramm et al., 2018). Unfamiliar and ill-defined features make health workflows unclear to health professionals, being an aspect that may lead to the failure of telemonitoring interventions (Alves et al., 2020). The problem of scalability in telemonitoring comes with regulatory challenges in the healthcare industry (Grustam et al., 2018). The medical device industry is bound to develop, expand and adjust depending on laws, regulations and guidelines which shape the healthcare landscape. Thus, the use of CTG telemonitoring from home is regulated by international and national rules and norms that differs globally, nationally, and even locally (Ayres-de-Campos & Bernardes, 2010).

Today's widespread use of mobile devices supports the acceptance and implementation of a novel remote fetal monitoring device, particularly within younger generations (Schramm et al., 2018). In addition to reducing technological barriers, the rapid expansion of mobile devices, especially smartphones, has reduced the development costs for telemedicine applications (Parimbelli et al., 2018). However, the successful adoption of telemedicine is still a challenging task in the healthcare sector (Gadeikienė et al., 2021). For instance, reimbursement issues are delaying the widespread adoption of Electronic Health (eHealth) in all sections of hospital care (van Den Heuvel et al., 2020) and limits the services that can be offered (Kruse et al., 2020). Financial constraints and the fact that telemonitoring is not integrated in routine care in most healthcare settings makes change management in the conservative medical community a challenge (Grustam et al., 2018). The nations within the Organization for Economic Co-operation and Development (OECD) are interesting since they are all economically stable countries with promising prerequisites to be able to support the implementation of a CTG telemonitoring solution, despite the challenges mentioned. Additionally, many companies delivering CTG solutions to the existing care setting can be found among the OECD countries today. There is a trend for Business-to-Consumer (B2C) telemonitoring instead of reaching out to healthcare providers and governments to cope with the readiness from health facilities (Taylor et al., 2018), which might pave the way to population-wide health monitoring (Grustam et al., 2018). Thus, medical technology companies face challenges when trying to adjust, develop and transform in a landscape characterized by an increasing demand of the integration of IoMT.

1.3 Aim of Study

The purpose of this thesis is to identify what factors that influence the market opportunity for the proposed CTG telemonitoring solution. This purpose results in the following research questions:

1. What main factors influence the adoption of a CTG telemonitoring solution on a global market?
2. When taking influential factors for adoption into account, is there a market opportunity for a CTG telemonitoring solution on one promising market within the OECD?

1.4 Limitations of Study

Clearly stated limitations need to be formulated in order to fulfil the purpose of this thesis and to address the formulated research questions. Specifying boundaries for this thesis also aims to give a better understanding of the provided results as well as the chosen methodology. Therefore, limitations are an important aspect of understanding what might be expected of this thesis in terms of results and what could potentially be of interest in future research.

All potential factors are not explored and the focus of the subset of factors will be based on the theoretical framework. The empirical findings will be based on a selective sample, as it is not a representative sample of the population, and will therefore only illustrate examples and characteristics, complementary to the existing research and literature that constitutes the literature foundation. In the literature review, the most eminent and known research was selected, limited to being more recent than a publication date of 2015. A few exceptions where made where more recent alternatives were lacking or when older findings still were relevant and referred to by others. The empirical findings will be based on the conducted interviews and the information obtained from the interviews is therefore highly dependent on what the interviewees chose to present. The context of the technology will be studied with the present legislation as for spring of 2021. Since some factors of rules and regulations varies greatly on a national level, some generalizability will be applied. Also, the thesis will give a snapshot in time, not looking at a long period of time.

How the technology of CTG works from a technical aspect will not be extensively investigated. Nor will actors that are currently introducing CTG telemonitoring with different business models be taken into account for the market opportunity, since the spread of the technology is still in its early phase. Only countries within the OECD were considered in the screening for potential markets, to limit the scope of the thesis. The final analysis about the market opportunity for the technology will be limited to one application and how it could be implemented practically will not be investigated further. Also, all rules and regulations that will affect the market opportunity for this application will not be extensively investigated.

2

Theoretical Framework

To help centre the study in extant literature, Rogers' diffusion of innovations theory is used as a theoretical lens to analyze the impact of factors on the adoption of a CTG telemonitoring solution in healthcare systems. Furthermore, Porter's Diamond Model is introduced that to help understand the competitive advantage and market opportunity for the telemonitoring solution. Lastly, the Market Opportunity Navigator (MON) is presented that can help identify the best market opportunity and value proposition.

2.1 Diffusion of Innovations Theory

One of the most popular theories for studying the process of adoption of information technologies (IT) is Rogers' diffusion of innovations theory. According to Rogers, innovation is a process, idea or technology that is perceived as unfamiliar to individuals in a particular social system. Diffusion is the process in which information about an innovation is communicated through certain channels over time among the members of a social system (Zhang et al., 2015). The diffusion model is characterized by an s-shaped curve representing the increasing cumulative adoption over time. It is a widely used theoretical framework in the area of technology adoption and diffusion and can be used in many areas, but is most suitable for investigating the adoption of technology in higher educational environments (Sahin, 2006). The four main determinants of success of an innovation is the attributes of the innovation, communication channels, the characteristics of the adopters, and the social system. In addition, time is necessary for the adoption of innovations to happen (Rogers, 2003).

The adoption of new products involves the management of uncertainty and risk. During the innovation-decision process, individuals look for information to reduce uncertainties about the advantages and disadvantages of an innovation. The process includes five stages: knowledge, persuasion, decision, implementation, and confirmation. The newness characteristic of adoption is related to the stages; knowledge, persuasion and decision of the innovation-decision process. In the knowledge stage, the individual seeks information about the innovation forming awareness-knowledge, how-to-knowledge and principles-knowledge. The persuasion stage is more feelings-centered than knowledge-centered. In the decision stage, the individual choose to adopt or not to adopt. The adoption rate becomes faster if the individual can try the product as uncertainties are then lower. At the implementation stage, the innovation is put into practice but there are still uncertainties about the outcomes from the innovation. The more reinvention that takes place, the more rapidly an innovation is adopted and becomes institutionalized. In the last stage, the confirmation stage, the innovation-decision has been made but can still be reversed. The individual tend to seek information that supports the decision at this stage (Rogers, 2003).

The innovation-diffusion process is a process of reducing uncertainties. Rogers (2003) proposes five attributes of innovations that helps to reduce such uncertainties. The five attributes of an innovation are relative advantage, compatibility, complexity, trialability and observability. The relative advantage is the degree of perceived benefits or improvements of adopting an innovation, upon the existing technology. The compatibility is the degree of which an innovation is consistent with existing values and experiences, and needs of the potential adopters. Complexity is the degree of which an innovation is difficult to use and implement, hence, it is negatively correlated to the adoption of an innovation. The trialability is the degree of which an innovation can be put on trial without total commitment and with minimal investment. The more an innovation is tried, the faster its adoption is. The observability is the degree to which the results and benefits of an innovation are visible to potential adopters. The individuals perception of these attributes predicts the adoption rate for an innovation. All attributes, except for complexity, are positively correlated with the adoption rate of an innovation. The four perceived attributes; relative advantages, compatibility, complexity and trialability, of an innovation influence the adoption and use of the innovation (Rogers, 2003).

Furthermore, Rogers (2003) categorized members of a social system in terms of their innovativeness, that is if adoption of new ideas is done earlier than for other members of a system, into different adopter categories. The distribution of adopters is a normal distribution. Innovativeness helped Rogers understand the desired and main behavior in the innovation-decision process. However, in this adopter, classification

is only generated for successful innovations and non-adoption as well as incomplete adoption do not form this adopter classification (Sahin, 2006). The adopter categories are innovators, early adopters, early majority, late majority and laggards. Innovators are willing to experience new ideas and are prepared to cope with unprofitable and unsuccessful innovations. Early adopters hold leadership roles in the social system as other members come to them to get advice or information about the innovation. Their leadership in adopting the innovation decreases uncertainties about the innovation in the diffusion process. Early adopters are indicators for the future. The early majority are neither first nor last to adopt. They have a good interaction with other members of the social system but do not have the leadership roles as the early adopters do. Furthermore, the late majority are skeptical about the innovation and its outcome. However, economic necessity and peer pressure may lead them to the adoption of the innovation. Lastly, laggards are the members that wait to see whether the innovation is successfully adopted by other members of the social system in the past. Thus, their innovation-decision period is relatively long. It is important to know which adopter category that is addressed at a given time, as it is not possible to address them all at the same time and in the same way as they are distinctly different (Robinson, 2009).

However, Holmström and Stalder (2001) argues that diffusion theory is too simplistic in providing oversimplified explanations of failed diffusion. Early work in diffusion theory is dominated by a linear model, which is commonly represented in the market-pull or technology-push approaches to diffusion. The linear model of diffusion describes technology transfer as a process with two choices, the rejection or adoption of the technology. The choice is analyzed on three levels. The individual level based on personal attitudes, that categorize individuals into different adopter categories. The social environment level based on the values, culture and norms of a given environment. Lastly, the third level based on the properties of the technology. The mutual constitution of society and the technology can not be taken for granted, and has to be considered in explanations. Norms, values, history, and competencies matter more than what economic models like the diffusion theory suggest (Holmström & Stalder, 2001).

The diffusion of innovation has in more recent years been acknowledged as a complex and non-linear process. The desired properties of a technology does not have to be fixed. It is not uncommon that problems that are not significant enough to justify a big change or even exist is addressed by designers if there is a difference in designers' expectations and the experience of users. The properties of a technology set and attitudes of users and the social and institutional environment are to change, as designers believe they understand users' needs better that the users do themselves. The gap between users and designers is hard to solve with the linear notion of diffusion (Holmström & Stalder, 2001).

2.1.1 Diffusion of medical devices

According to research on healthcare innovations shaped by Rogers' diffusion of innovations theory, the rate of diffusion for healthcare innovations are higher if certain conditions are favourable such as its compatibility with values and norms of the adopting system. Also, when homogeneous groups of people are involved and the innovation is supported by key opinion leaders (Barnett et al., 2011).

Rogers' diffusion of innovation theory is argued to be a model useful for examining the influencing factors of the emerging use of mHealth apps (Lin & Bautista, 2017) and for conceptualization of technology adoption in the context of eHealth (Zhang et al., 2015). However, others argue that traditional diffusion theories are insufficient in trying to explain the adoption and diffusion of complex technology systems. They emphasize decisions of individual actors and describe innovations as able to diffuse among users in a linear and unproblematic way (Nielsen & Mengiste, 2014). Others argue that innovation diffusion is a nonlinear process of activities that may repeat at different organisational levels and over time (Barnett et al., 2011). The diffusion and use of mobile IT in health care systems is complex and the environment within which organizations are embedded has to be considered. Nevertheless, drawing upon traditional diffusion theories, like Rogers' diffusion of innovations theory, can give valuable insights about the adoption of mobile IT in health care systems. Technologies like these have interpretive flexibility and different meanings about the technology are constructed by stakeholders. Therefore, the adoption is characterized by network effects and ambiguity as heterogeneous stakeholders are involved. The technology evolve while crossing to new social contexts as the enrolment of new actors change the meaning of the technology over time. Thus, the sociopolitical environment shape the diffusion of mobile IT, not only organizational decision making, as the process is heavily supported by key stakeholders (Nielsen & Mengiste, 2014).

2.2 Porter's Diamond Model

The Porter Diamond Model was first presented by Michael Porter in his book The competitive Advantage of Nations (M. E. Porter, 1990). Porter emphasises that the role of the nation has become increasingly important for the global competition, since it is in the localized process that advantage is emerging. In this process, companies will benefit from a dynamic and challenging home environment where customers are demanding, suppliers are aggressive and domestic rivals are considerable. The Diamond Model is used for identifying why one region, often a nation, is more successful in a particular industry than another. The most competitive region is referred by Porter as the "home base", one example of a home base for car manufacturing is Germany. When using the Diamond Model, there are according to Porter two questions that one should be able to answer, and the responses will point to the determinants of competitive advantage:

1. Why does one nation become the most competitive for a certain industry?
2. Why are companies from one country or region able to sustain competitive advantage in a particular industry?

In order to be able to find the right answer, the external competitive environment is analyzed based on the model seen in Figure 2.1. The diamond is not depicting the whole country, but is only thought as the closer environment of a company, a cluster. The Diamond Model is primarily based on the four following determinants, which act interdependently, as an interlinking system.

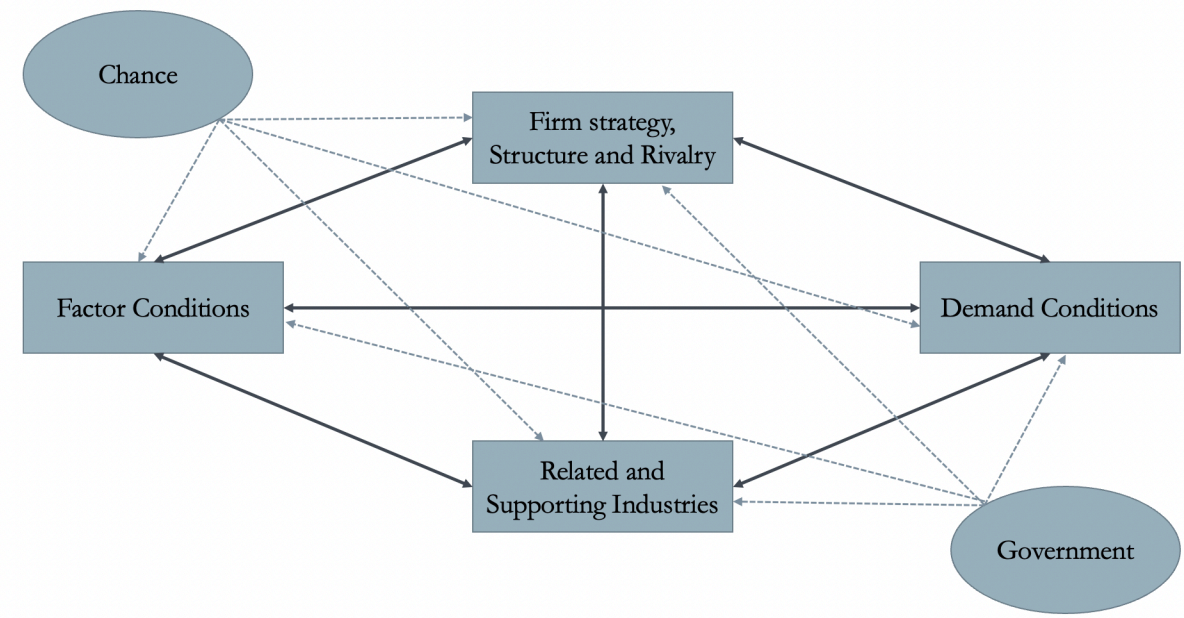

Figure 2.1: Visualisation of the complete system of Porter's Diamond Model, Reproduced from M. E. Porter (1990).

2.2.1 The Four Determinants in the Diamond Model

The following description of the determinants are based on the framework of Porter's original works (M. E. Porter, 1990).

Firstly is the factor conditions. These are made up by the various sorts of resources that could potentially be found in a region, such as natural resources, infrastructure or skilled labour. Porter moreover distinguish them into basic and advanced factors, where the former will provide the region with an initial advantage which, when investing in advanced factors, has the potential to be reinforced. As Porter argues, the basic factors do not constitute an competitive advantage in regards to knowledge-intensive industries. Instead, it is the efficiency and rate to which a nation can create, upgrade and position their advanced factors in the right industry that is of importance. The author goes as far as to deeming the lack of basic factors to be an potential advantage in the dynamic model since selective disadvantages

such as lack of basic labour, force companies to innovate and upgrade to be able to stay competitive. (M. E. Porter, 1990).

The second determinant, demand conditions, evaluates the characteristics and compositions of the home base demand. Even for globalized competition, a nation will according to Porter have a competitive advantage if the home market is a fit. The home demand is said to have a disproportionately large effect on the perception, interpretation and response to buyer needs. It will provide with earlier and clearer signs of the emerging buyer needs than for foreign comparison (M. E. Porter, 1990).

The third determinant, related and supporting industries, evaluates the presence of internationally competitive companies that are connected in the home base. Close working relationships between end users, suppliers and non-rivalrous firms in the industry will enable an advantage in innovation and upgrading. As an example, the lines of communication can be shorter, as well as the flow of information and idea exchange, including the possibility to influence the suppliers' technical development. Moreover, it is easier and more efficient to serve as test sites for research & development (R&D), and the innovation pace can be accelerated (M. E. Porter, 1990).

The last determinant, firm strategy, structure and rivalry, identifies national differences regarding the creation, organization and management of firms, as well as individual attitudes, goals and the intensity of national competition. Porter emphasises that nations are prone to be successful in industries which the individuals of the nation depend on and admire. The domestic rivalry is moreover the most important determinant due to its natural stimulating and pressuring effect (M. E. Porter, 1990). This while being more intense than international competition, due to among other things, the emotive and personal aspect of competing in the same domestic environment. This determinant is related to Porters five forces (M. Porter, 1979).

Additionally, the two determinants, chance and government, play a role in influencing one or many of the four primary aspects. They are however not a part of Porter's original works, but have been added in later developments of the model (Vlados, 2019). Moreover, to be able to transform the diamond into a system, M. E. Porter (1990) states domestic rivalry and geographic concentration to be of greatest power.

Porter's Diamond Model (M. E. Porter, 1990) is used today as a fundamental tool for strategic analysis, and the essence lies in the interdependence between four determinants of the model, as well as how they individually influence the ability of companies in a nation to gain advantages in a certain industry. A strong industry is defined as having high density and strength in the interconnections between the determinants (Reve & Sasson, 2012). For example, companies want to be located in national regions that give access to knowledge and capital as well as promotes innovation and R&D, in clusters. This aspect is especially relevant for knowledge-intensive industries as for example MedTech (Reve & Sasson, 2012).

2.2.2 Early Criticism Towards the Diamond Model

The possibility for a firm to only innovate in a geographically restricted and small area that Porter presented during the 1990's has been criticized and questioned in the few years after by among others; Reinert, Rugman, Dunning, Tryggestad, McKelvey, Yetton et al., Darroch and Litvak, Stewart, Dalum et al. and Reinikainen (Penttinen, 1994). The models weak understanding and inclusion of international business activity, especially in the form of multinational enterprises activities is argued to be the most criticized theme (Penttinen, 1994). It is argued that the importance of international competition is underestimated, and that Porter is too focused on the characteristics of a large nation, such as the United States of America (USA) (Bellak & Weiss, 1993). Dunning (1993) goes so far as to reversing the global influence that Porter considers being an "add-on" to the domestic influences. He oppositely consider the domestic influences on Porter's Diamond Model to only make up for a special case of international influence. Moreover, Reinert (1993) discusses that the gradual development of regional clusters into national clusters, can be applied also to the national clusters evolving into transnational ones. Rugman (1991) is stressing how firms can source factors, seek related and supporting industries, and meet demand and rivalry in clusters crossing the national boundaries, in a transnational setting. Oppositely to Porter's arguing, Rugman emphasizes the lack of reasons for a multinational firm to be in need of a home base.

Reinert (1993) moreover states that small national areas are unable to both support local rivalry and gain economies of scale, due to the restricted size of a local market. Porter uses Switzerland as an example of a nation that has competitive advantage despite their small local market. Yetton et al. (1992) however, criticise this, since their neighbouring countries are made up of dense and largely populated areas with

resembling standard of living. He moreover takes New Zealand as an example of an isolated country that actually is reliant on international markets. It is however important to take into account that Porter's view is that a firm might export large quantities, but their ability to innovate is reliant on interaction with demanding domestic customers (M. E. Porter, 1993).

Lastly, Porter's ideas met early criticism for its focus on the clusters that are already existing, as opposed to presenting the way to creation of novel industries. Dunning (1991) means that the model is lacking dynamism. Porter however, gives an answer to this critique by stating that competitiveness is gained most efficiently by tapping into favourable areas, that already show established strength and, entering related fields, instead of trying to create novel industries (M. E. Porter, 1993).

2.2.3 Recent Additions to Theory

Despite the shortcomings of Porter's Diamond Model presented above, it is still used broadly, and in multifaceted ways. Sölvell (2009) is using the classic Porter Diamond Model when evaluating clusters in the successful USA Biology Technology (BioTech) industry. An area with many similarities to the MedTech industry, for example the adjustment to political actions, regulations and legislation's as well as heavy R&D focus and clinical trial periods. The model proves useful to identify success factors such as immense university research, size of the USA economy, attractive international skill sets, accessible venture capital and superior legislation. Moreover, linkages between and across institutions, public science transformed into private science, and knowledge commercialization where other aspect revealed relevant in the analysis. However, when comparing the different clusters, no one-right setting was seen, due to the great differences between scenes in the USA, and consequently, an imitation of "the USA model" was not recommended by the author. As an addition to the cluster scene, Sölvell (2009) discussed how the model is more oriented with the view of market forces, as opposed to governmental steering. He suggests that clusters are best understood as a system where both constructive and evolutionary forces act out. A proposal relevant for the politically governed MedTech industry.

2.3 Market Opportunity Navigator

A market opportunity is a specific application of a firm's abilities for a specific set of customers. The MON is a framework developed by Marc Gruber and Sharon Tal Gruber and Tal (2017). Setting a promising market opportunity strategy requires deep understanding for which market opportunities that exist, what the most attractive market opportunities are and what market opportunity should be focused on. The MON consists of three steps to address these three questions, thus, to discover the most valuable market opportunities. The MON can give perspective when trying to find potential market domains for an innovation, help guide where to start, before starting the customer development process. The three steps of the MON will support your decision making, provide a shared language and offer guidance over time (Gruber & Tal, 2017).

The first step of the MON is to generate the Market Opportunity Set. This step is about assessing the venture's core abilities and identifying valuable market opportunities coming from these abilities. This will help understand of the generic functionalities of core abilities, discover new applications and customer segments and get a wide-lens perspective beyond industry boundaries (Gruber & Tal, 2017).

The second step of the MON is to evaluate Market Opportunity Attractiveness. This step is about evaluating possible market opportunities in a comprehensive manner, to reveal the most attractive options. This will help assess the value creation potential of each market opportunity, estimate the overall challenge in capturing this value and map out opportunities to better grasp their upsides and downsides (Gruber & Tal, 2017).

The third step of the MON is to design the Agile Focus Strategy. This step is about building a smart portfolio of growth and backup options around the chosen market opportunity, to consciously avoid lock-in and remain agile. This will help define the primary market opportunity to focus on, design a smart portfolio of backup and growth options to keep open and to discard other options (Gruber & Tal, 2017).

3

Case Description

The following chapter will firstly describe the basic fetal physiology as a motivation to the use of fetal surveillance technology. Secondly, the technology of CTG will be described, with both its shortcomings and motivations. Lastly, a vision on how a CTG telemonitoring solution could look like is presented.

3.1 Basic Fetal Physiology

An understanding of physiological mechanisms as well as the fetus reaction to stress and ways of coping during non-optimal conditions is of great importance for the development of fetal surveillance technology (Rosén & Mårtendal, 2014). The following section will therefore present the basic physiology of the fetus, with a focus on oxygen supply. The information is based on "The Green book" published by Neoventa (Rosén & Mårtendal, 2014), developed as an information source for midwives and doctors.

The fetus is dependent on the mother's placenta for oxygen and nutrition transfer. A continuous placental blood flow is crucial for the growth and survival of the fetus. When the mother is experiencing strong contractions, typically during active pushing, the maternal flow can be set on pause. This is due to the forces created that exerts pressure blocking the blood flow to the placenta. For a healthy fetus, this is usually not an issue, since it has reserves in the placenta and can additionally survive for some time without oxygen. However, since the fetus can only use the stores for a limited amount of time, it is substantial for the fetus that it was in a satisfactory oxygenated condition before initiation of contractions, for example during antenatal phase.

The deprived state can be categorized in three levels, which can occur in both antenatal and intrapartum stage. A visual overview is displayed in Figure 3.1.

- Hypoxaemia - An abnormally low amount of oxygen content in the arterial blood.
- Hypoxia - Lack of sufficient oxygen content in the peripheral tissues to keep normal body function.
- Asphyxia - An oxygen deficiency so substantial that it affects central organs such as the brain as well.

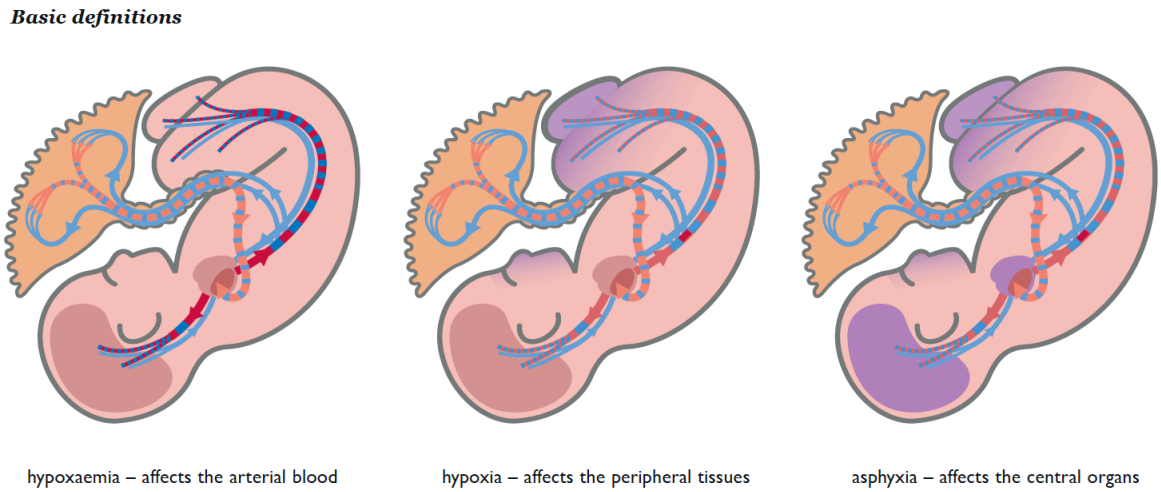

Figure 3.1: Overview of the three major stages of oxygen deficiency for a fetus. From *The Green book of STAN, Fetal surveillance Part 1* (p. 9), by K. G. Rosén and Annika Mårtendal, 2014, Gothenburg, Neoventa AB.

If the fetus is in the initial phase of being low on oxygen (hypoxaemia), it will manage to take up oxygen more efficiently, as well as reducing its activity, in order to keep the energy balance. However consequences

can be seen long-term in growth restrictions, and the fetus will be less able to cope during labour. The fetus can survive in this stage for days or even weeks.

The cellular metabolism of the fetus is as standard aerobic, oxygen-dependent and predominantly uses glucose and oxygen. However, when the fetus is in state of hypoxia, it can utilize blood glucose and stored glycogen, as a result, the aerobic metabolism is supported by an anaerobic non-oxygen-dependent metabolism. The direct fetal response makes it hard to detect oxygen deficiency. However, since the energy produced during this stage only corresponds to 1/20 of the standard oxygen-dependent metabolism, the fetus can typically survive only for hours and lactic acid is moreover created as a waste product.

The most threatening stage is asphyxia, the energy demand can no longer be met when the fetus enters this stage. The anaerobic metabolism is utilized also in the central organs, and metabolic acidosis occurs. There is a high risk of organ failure and the fetus can typically survive in this stage for minutes. A fetus that has previously been under repeated hypoxaemia will only perform a limited reaction in the hypoxia state, since the reserves have already been utilized, and the fetus risks damage as a result of asphyxia early on. This situation would typically occur where there has been antenatal issues, such as restricted growth.

3.2 The CTG Technology

Technology is today a natural part of the antenatal care, it is an aid for midwives and other care professionals to gain knowledge of the status of the fetus well-being. The fetal heart activity gives indications on the well-being of the fetus, and the clinical assessment of the FHR is therefore an important factor during examination. Antenatal cardiotocography is a method commonly used for this purpose. The CTG technology is both measuring the FHR (cardio) and the uterine contractions (toco) of the pregnant woman. It can be used either in isolation to check the FHR, known as the ”non-stress test”, or with the addition of uterine stimulation, to observe the response by the fetal heart, known as the ”contraction stress test” (Owen, 2001).

In the following section the basic principles of cardiotocography will initially be outlined, followed by a description on how CTG technology can be used to interpret the physical signs of fetal distress, as well as a description of the telemonitoring aspect of the technology, including earlier cases of use.

3.2.1 Principles of CTG

There are mainly two types of CTG, invasive (internal) and non-invasive (external) CTG. The invasive recording is performed by inserting a wire electrode through the cervical opening and attaching it to the fetal scalp as seen in Figure 3.2. It gives a more consistent and accurate monitoring of the FHR since external factors such as movement are not affecting the sensors. However, the pregnant woman must have some cervical dilatation for it to be inserted. Additionally, monitoring of the uterine contractions requires an open cervix and a ruptured amniotic sac, meaning that the water has broken. The invasive CTG method is naturally found to be used for the intrapartum phase, when more precise measurements are preferred. Consequently, for antenatal care, non-invasive CTG is mostly used, and that is the technology hereafter referred to when mentioning CTG.

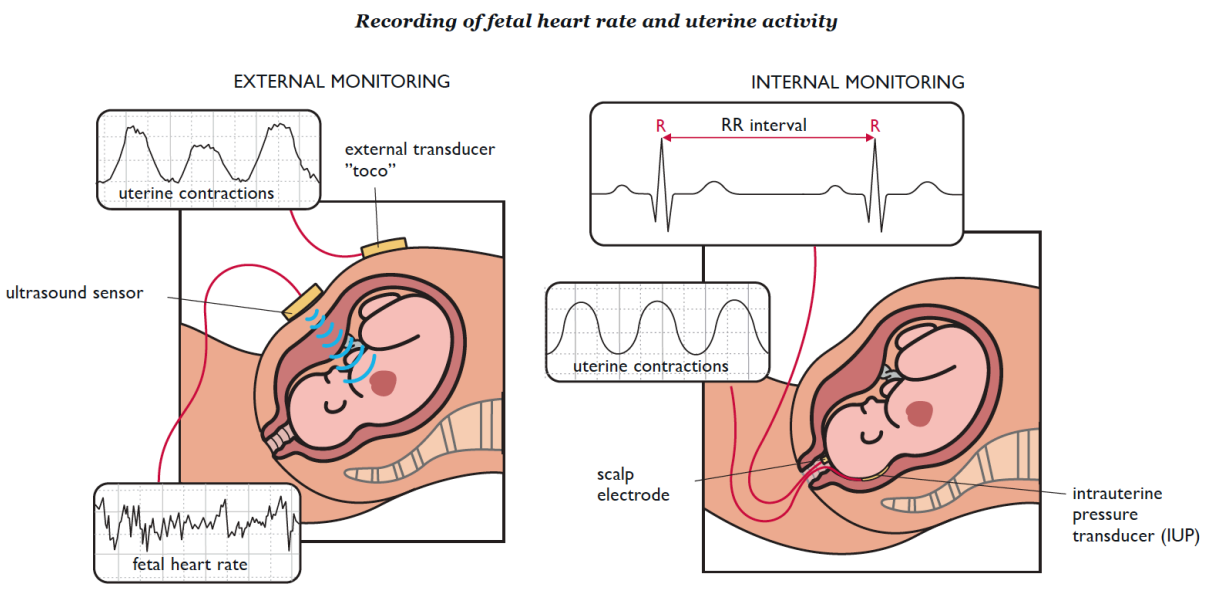

Figure 3.2: Overview of the placement difference between internal and external CTG. From *The Green book of STAN, Fetal surveillance Part 1* (p. 9), by K. G. Rosén and Annika Mårtendal, 2014, Gothenburg, Neoventa AB.

Non-invasive CTG is performed by placing two transducers on the abdomen of the pregnant woman, one aligned with the heart of the fetus and the other aligned with the top of the uterus. The transducers are easy to place, and the monitoring preparation can be performed by a non professional, such as the pregnant woman herself Pilarczyk et al. (2020). Doppler ultrasound technology is then used for the monitoring. In order for the maternal heart rate to not interfere with the fetal heart rate, a separate manual capture or parallel recordings are performed. CTG devices commonly display the pregnant woman's heart rate too. The Doppler transducer sends out pulsed ultrasound signals, sound waves that are high-frequency and travels freely through soft tissues and fluids. For ultrasounds in general, when the signal collides with a more dense surface, the majority of the waves are reflected back as echoes. The various body structures in the fetus and the mother have different densities, and consequently, echoes of different strengths will be picked up by the transducer. The ultrasound does not rupture, or in any way damage membranes or tissues. The Doppler ultrasound is specifically developed to detect structures that are moving, which makes it suitable to monitor the heart rate, since a beating heart moves with its contractions. The transducer can not detect the fetal heart beat one-to-one, instead autocorrelation processing is applied. The algorithm typically requires about five consecutive cycles of the heart to be able to produce a result of the actual FHR without noise and interference. The second transducer can in the same way monitor the tensity of the pregnant women's abdomen, called external tocometry, which gives insight into the contractions of the uterus. It will be able to tell the start and end of them, as well as the frequency. It can however not give information on the strength or exact timing of them.

3.2.2 Criticism Towards CTG

As explained in section 3.1, the fetus is very good at compensating for oxygen deficiency by different means and prioritize vital organs such as the heart. Consequently, signs of fetal distress are not always clearly visible in the CTG reading. The FHR monitoring technology used today assumes that the fetus is well and neurologically stable unless there is evidence pointing out the opposite, and consequently, antenatal HI events risks being overlooked (Dhillon et al., 2018). Moreover, the use of CTG in the healthcare sector has given rise to increased rates of unnecessary interventions such as C-section (Georgoulas & Stylios, 2006). The CTG technology has consequently been questioned as to if it does provide clinical value. However, the increased rates of unnecessary interventions is argued to be a consequence of subjective interpretations and lack of understanding from medical professionals on how to interpret the data given. This is because changes in the fetal heart rate also can appear for healthy fetuses, and the guidelines can be difficult to follow (Ayres-de-Campos & Bernardes, 2010; Kim et al., 2017). The uncertainty among medical professionals on when to take action has in the same way given rise to missed

abnormal CTG patterns and intrapartum asphyxia as a consequence (Rosén & Mårtendal, 2014). The critique is largely aimed at CTG for the use in intrapartum state. Since guidelines are partly lacking for antenatal CTG, the intrapartum guidelines are often applied throughout the pregnancy, despite them being different depending on the gestational age (Ayres-De-Campos et al., 2015).

Moreover, studies dating back more than 15 years have demonstrated that CTG readings are worse in the fetuses of black women, when comparing to the tracings of white women (Ogueh & Steer, 1998; Paine et al., 1988; Paine et al., 1991). It has however historically been a lack of studies investigating weather it is race in itself that is the basis for a worse non-stress test, or if other co-factors play a role in affecting the reading. For example if ethnicity acted as a surrogate endpoint for environmental factors such as for example socioeconomic status. A recent study approached this research gap partially by comparing CTG parameters between the two groups of black and white women (Di Tommaso et al., 2016), while, for the first time, including also paternal ethnicity. The parameters investigated were percentage of signal loss, number of contractions, basal FHR, number of accelerations, number of decelerations; length of high variation episodes, short-term variability, total trace duration time, and number of fetal active movements. The number of active fetal movements were found to be lower in the CTG readings for black patients compared to white patients (Di Tommaso et al., 2016). Moreover, longer periods of low variations could be seen for black women in comparison to white women. The sample size of pregnant women was however low (n = 19+34). A more recent study including 696 pregnant women with different ethnicity compared similar computerized CTG parameters and its nonlinear characteristics (Tagliaferri et al., 2017). It was for example seen that long term irregularity performed better in the white women group compared to the black- and women of color groups. While low frequency, movement frequency, high frequency, and approximate entropy performed more well in the black women group compared to the white women group. According to Tagliaferri et al. (2017) both linear and non-linear components of variability of FHR should be considered in order to avoid misinterpretations of the CTG recording among women with different ethnicity. The result from the use of *computerized* CTG was opposed to earlier studies using CTG that demonstrated more interventions with C-section for black women due to non-reassuring FHR tracings, compared to white women (Getahun et al., 2009; Washington et al., 2012). The increased decision of performing C-section more often on black women was probably a consequence of low-quality visual interpretation of the CTG recordings. The recent study on computerized CTG (Tagliaferri et al., 2017) highlights the importance of acknowledging ethnicity and its source of variation in clinical CTG interpretations, as well as the potential of computerized CTG to avoid unnecessary interventions and equal care regardless of ethnicity.

Obesity creates potential problems for external monitoring techniques because the expanse of adipose tissue interposed between the abdominal surface instruments and the uterus could degrade the quality of the signals used for CTG (Cohen & Hayes-Gill, 2014). The performance of CTG deteriorates with increasing maternal Body Mass Index (BMI) (Lempersz et al., 2020) as the Doppler ultrasound is negatively affected by a high body mass (Cohen & Hayes-Gill, 2014). The decrease in performance and risk of signal loss in obese patients is one of the major limitations of Doppler ultrasound technology, with the worldwide increasing incidence of obesity contributing greatly to making the issue relevant (Lempersz et al., 2020). Since the risk of unfavorable outcomes is higher in obese women, as one parameter of a pregnancy being considered high-risk, adequate surveillance is even more important (Lempersz et al., 2020).

Ultrasound imaging is generally considered safe when used prudently by appropriately trained health care providers (FDA, 2020). Ultrasound generate diagnostic images using sound waves and does not contribute to ionizing radiation. Thus, it does not have the same risks as other types of imaging systems (Yoon & Slesinger, 2021). However, ultrasound energy has the potential to produce biological effects on the body. For example, the waves can heat the tissues slightly and the long-term consequences of extensive use are still unknown (FDA, 2020). The fetus is more resistant to radiation in the third trimester, but a high dose of radiation may still result in adverse effects. Therefore, medical professionals should counsel the pregnant patient regardless of the gestational age (Yoon & Slesinger, 2021). Organizations, such as the American Institute of Ultrasound in Medicine, have advocated prudent use of ultrasound imaging in pregnancy. Also, because of the particular concern for effects on the fetus, the use of ultrasound for non-medical purposes has been discouraged (FDA, 2020). However, while it is crucial to minimize fetal radiation exposure as much as possible, diagnostic studies should not be avoided for fear of radiation

exposure, especially when these studies can dramatically change patient management (Yoon & Slesinger, 2021).

3.2.3 Basic Principles of CTG Telemonitoring

The following section aims to give a brief introduction on the technical and user principles of CTG telemonitoring. There are currently a few actors on the market providing CTG telemonitoring systems through different business models. However, since a competitor analysis is not part of this study, the following section is based on previous trials and suggestions of fetal telemonitoring solutions from literature. The section will end up in a description of the imagined solution of this thesis, that are based on findings in literature.

The essence of the following fetal telemonitoring system presented by Signorini et al. (2018) is the integration of the monitoring technology with the consumer Information and communications technology (ICT) devices (such as a smartphone), remote data mining, and a clinical decision support system. There are various methods used for FHR monitoring in clinical practice, such as CTG, and the method used in this solution is measurement of the abdominal Electrocardiogram (ECG). Possible methods of Artificial Intelligence and machine learning for FHR can be applied to improve prediction and diagnosis in pregnancy healthcare processes. A computerized solution would expand the time window of maternal and fetal data collection, resulting in enhanced performance of examination, personalized as well as reduce the traditional need of physical supervision. The amount of available data classified in CTG analysis can constitute a reliable clinical reference for the development of a telemonitoring system (Signorini et al., 2018). A ICT device, preferably a smartphone, sends signals to a remote telemonitoring center and receives their results in this proposed solution by Signorini et al. (2018). Thus, this solution serves the same purpose as the fetal telemonitoring system considered in this thesis even thought it is based on another technology, measuring the Fetal Electrocardiogram (FECG).

Another module for fetal telemonitoring, presented by Houzé de l'Aulnoit et al. (2018), is composed by a smart mobile data module, that interface with an existing fetal monitoring device, enabling transmission of FHR recordings via 3G/4G mobile internet connection, if used in home setting, to a server within a hospital information system, and a web-based viewer that enables the FHR to be displayed on a device, such as a smartphone. A web viewer, converting the digitized FHR data, makes easily interpretable graphs of the dataset that are visualized on a ICT device both offline and in real time. The conducted data is archived in the patient's electronic medical records (Houzé de l'Aulnoit et al., 2018). However, this solution only enables the remote transmission of FHR data and the visualization of it on various mobile devices. It was tested out in a hospital setting and did not include a wearable unit that could be used in a home setting, enabling pregnant women to monitor themselves from home. Still, this module could easily be integrated to and used together with a mobile fetal telemonitoring solution (Houzé de l'Aulnoit et al., 2018).

Boatin et al. (2015) moreover tested out a prototype of a fetal monitoring technology based on non-invasive CTG. The components are connected with Bluetooth to a data transmission gateway, such as a smartphone. On this device, the initial fetal CTG can be viewed. When the monitoring session is finished, the collected data is sent from the gateway device in bulk to a Cloud based server, via the Internet, where it is stored. Then, the data can be reviewed on any device capable of web access, once it has been uploaded by access to a web portal (Boatin et al., 2015).

Another solution in literature presented by Li et al. (2021), however measuring the FECG, is a platform constructed of three layers. A sensing layer that enables collection of physiological information, a network layer which supports the information transmission and an application layer for mobile medical service. By using the platform, with wearable intelligent Bluetooth medical devices and linked mobile app, pregnant women can monitor themselves in real time. The FHR recordings are uploaded to a Internet cloud platform and transmitted to the terminal, so that it can be examined and interpreted by doctors in the app at any time to provide targeted guidance. A hospital workstation automatically alerts the pregnant women if the data overreach the normal span, to the hospital for medical treatment (Li et al., 2021).

Lu et al. (2019) presented another process of remote fetal monitoring based on IoMT and computerised CTG. Seamless and real time interaction between hospitals, pregnant women and obstetricians can be accomplished by using intelligent Doppler monitoring and the mobile Internet combined with IoMT technology. Interaction between obstetricians and pregnant women are actualized through a mobile app of the computerised interpretation system for home use and information management platform on a

smartphone. Through the embedded interpretation module and obstetricians' analysis and guidance, remote fetal monitoring at home can be achieved (Lu et al., 2019).

3.2.4 Our Solution

The wearable fetal telemonitoring system, suited for use in the home setting, proposed in this thesis is designed to allow continuous FHR recordings during the pregnancy. This approach can open a new perspective of continuous fetal development monitoring considering fetal states both in stress and in healthy conditions, from where additional information can be derived by increasing the frequency, quality and length of the monitoring period (Signorini et al., 2018). The proposed process of fetal telemonitoring of pregnant women for this thesis is based on a mobile medical device combined with a CTG unit and expert remote analysis of CTG recordings performed by medical professionals at medical telemonitoring centers. This system is accessed through an online medical platform.

The pregnant woman monitor herself whenever it is suitable for her, using a small mobile CTG unit that measures the mother's pulse, the FHR, uterine contractions and fetal movement. The monitoring session lasts about 30 minutes, during which the woman needs to be still for measurements to be registered correctly. The received data, owned by the patient, is transmitted to a telemonitoring centre where it is reviewed by qualified and experienced medical experts. Thus, when owning her own data the patient grants access to doctors and clinics of her choice. The data can be viewed in real time and data cloud storage enables reviewing of data history as well. Medical experts contact the patient if worrisome indicators are identified. In addition, patient's receive adequate feedback continuously via the app. The medical data and service is accessed whenever via the online medical platform.

4

Literature Review

The following chapter will present existing research and literature that constitutes the literature foundation for this thesis. The literature review will lead up to factors affecting the introduction of a CTG telemonitoring solution, such as industry trends, regulations and guidelines, potential business models, data privacy issues and cost aspects.

4.1 Women's Effect and Role in Antenatal Care

Telemonitoring is a promising addition to new care models within antenatal care. According to a survey, with 73 hospitals in the Netherlands participating, advantages of CTG telemonitoring are in particular increased patient satisfaction and autonomy. Other identified advantages in the survey are improved patient-centric care as well as reduced over-medicalization (van Den Heuvel et al., 2020).

In a study, carried out in China by Li et al. (2021), the application of a proposed IoT platform for antenatal care, with wearable devices and cloud computing, was investigated. The study showed that 79% of the participating women, that completed the set of questions, indicated a desire to use wearable devices in their home setting for telemonitoring purposes during their pregnancy. Furthermore, the study showed that the majority of the participating women were willing to use an abdominal belt with hidden electrodes and sensors when monitoring. 44% of the women moreover said that they would use the abdominal belt for up to 1-2 hours a day, and 35% said they would wear the belt for 3-4 hours per day. Nearly half of the women were concerned about their personal privacy associated with using wearable IoT devices. 37% of the women would not be willing to upload the monitoring data to a third party platform, like a non-hospital institution, but a great number, 30% of the pregnant women, said they would like to do so when using mobile wearable devices during pregnancy. However, the women were more willing to share the monitoring data with hospitals and obstetricians, 27%, in contrast to 7% in the previous question, being strongly willing to share the monitoring data and only 4% unwilling to do so. Thus, it is evident that, for this type of technology, women are worried about and value the protection of their personal privacy Li et al. (2021).

The study by Li et al. (2021) showed that there are five factors that to a great degree affect pregnant women's choice of a wearable device. These factors are safety, comfort, function, price and appearance, listed from most important to the relatively less important factor. The study showed that younger people have a higher degree of acceptance for new things, and thought of product function as being more important (Li et al., 2021). A higher degree of acceptance by patients, especially among younger people, due to the popularity of smartphones was also pointed out by Schramm et al. (2018). However, the ownership of this technology, which enables telemedicine, is dependent on socioeconomics (Kruse et al., 2020). Whether or not it is the first pregnancy also had an impact on women's attitudes. Women pregnant with their first child were more willing to use telemonitoring to detect the status of the mother and the fetus during their pregnancy, and thought of product function as being more important. Also, women with a high annual household income and a higher educational background were more willing to accept telemonitoring and intelligent diagnosis functions outside the hospital. The product function and comfort was of more importance the higher the educational background was, and appearance of less importance. Schramm et al. (2018) also identified the comfort of a remote fetal monitoring device as a vital aspect, together with safety and reliability aspects.

4.1.1 Consequences of Hospitalization

Besides women having their own opinions regarding monitoring in general and at home, there are also aspects of hospitalization affecting the woman that should be taken into account. Pregnancy can involve changes that have been linked to a rise in depression and anxiety symptoms. Bed rest, which includes isolation, confinement and movement restrictions, can have extensive negative psychological and physiological effects. High-risk pregnant women appear to have a high rate of bed rest, which in most cases is a component of hospitalization (Gourounti et al., 2015). Women anxious about childbirth have been shown to have less positive expectations about childbirth and their pregnancy. This can lead to fear of attending antenatal care, further maintaining the anxiety concerning childbirth. Through antenatal care,

women can develop coping skills and change their negative expectations about childbirth and labor (Ali et al., 2020). Telemonitoring can enable women to develop feelings of mastery and autonomy, creating positive expectations and better confidence toward childbirth (Allen et al., 2020).

Prenatal hospitalization is connected to several stressors, specific ones, such as bed rest and feelings of lack of control, being experienced by high-risk pregnant women. Prenatal hospitalization is also associated with separation from home and family. Experiencing stressful feelings, depression and anxiety during the prenatal period can quickly lead to other types of diseases harmful to the fetus and mothers health. Studies show that the level of antenatal depression symptoms are higher for those with a high-risk pregnancy than for low-risk pregnant women. Still, the level of depression and anxiety symptoms were similar for women hospitalized to women being bed-rested in their home, which indicates that high-risk pregnant women overall may need psychosocial support regardless of the place of bed-resting (Gourounti et al., 2015). However, the actual pregnancy progress of high-risk pregnant women seem to decrease depression and anxiety symptoms during hospitalization. This could be explained by the feeling of stress relief concerning the outcome as the probability of fetal complications decreases (Gourounti et al., 2015). In addition, concerns have been raised that the use of fetal telemonitoring could lead to more harm than good due to an increased feeling of anxiety and responsibility of pregnant women (Mackintosh et al., 2020). Despite the potential risks of induced negative feelings when monitoring from home, there are inevitably trends moving towards an increase of the use of telehealth (Parimbelli et al., 2018).

4.2 Outlook on the Transformation of the Medical Technology Industry

There is a strong demand for innovative health care that can contribute to solve the challenge of our growing and ageing population, which will put pressure on the existing healthcare systems. In 2015, 8,5% of the population globally where at least 65 years old, a number that is expected to be at 12% by 2030, and then twice as large by 2050 compared to 2015. At the same time, the population fit for work will oppositely see a small decrease in the same time period. Hence, efficient and cost-effective health care is of substantial need in the years to come. The following section will outline how the MedTech industry is reacting and transforming due to increased demand of innovative health care.

4.2.1 What Comprises the MedTech Industry and Is It Growing?

The European Trade association MedTech Europe (2017) defines MedTech as "any technology used to save lives or transform the health of individuals suffering from a wide range of conditions". It is similar to the World Health Organization (2015) definition of Health Technology: "organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of lives". The MedTech industry is characterized by R&D, and is rapidly changing and giving rise to innovations. In 2019, the European Patent Office (2020) received 13,833 patent applications from the MedTech industry alone, placing it as the second largest product field for patent applications. Moreover, digital communication patents had a rise of 19,6% with 14,175 applications, exceeding MedTech for the first time in ten years. The rise of 5G technologies, which can enable high resolution connections in both urban and rural areas, were a major contributor to this increase according to the European Patent Office (2020).

The health care sector is transforming with the entrance of new ways of delivering care with the use of electronic communication, defined as eHealth. eHealth, is outlined by Eysenbach (2001) as a field in the intersection of public health, medical informatics and business with health service and information connected to and retrieved from the internet or similar technologies. It is moreover characterized as a mindset and an attitude for the aim of improving health care by the means of information technology, more than just a technology development. Most commonly, eHealth includes sub-domains such as: virtual health care, Electronic Health Record (EHR), electronic medical records, telehealth, telemedicine health IT systems, consumer health IT data, mHealth (the use of eHealth with a mobile communication device such as mobile phones, smart watches and laptops) and big data systems used in digital health. According to an investigation made by Deloitte (Taylor et al., 2018) companies are increasingly investing in the development of products that are capable of connecting to the internet. eHealth is used to some extent in antenatal care today, and it has been seen that the use of eHealth in this sector, such as telemonitoring, contributes to both higher patient satisfaction and engagement as well as increased health care access and cost-saving opportunities without compromising the health outcome (Schramm et al., 2018; Van Den

Heuvel et al., 2018). According to Van Den Heuvel et al. (2018), the wider implementation is expected to spread globally in the next ten years.

The same expectations as for obstetrics can be seen in other healthcare sectors too. It is estimated that the global medical device market will grow from US$ 426 Billion in 2018 to US$ 613 Billion in 2025, at a Compound Annual Growth Rate (CAGR) of 5,4%, meaning the rate the investments would have grown if they had the same annual growth rate with a yearly reinvestment of profits (Fortune Business Insights, 2020). Medical devices is an accepted definition by regulatory agencies and includes products ranging from bandages to MRI scanners. They are defined to either measure or monitor body functions or having a mechanical or physical effect on the body or another medical device, such as disinfection (the World Health Organization, 2020). However, they are not obliged to have IT connectivity. Comparably, the IoMT market, comprised by medical devices and software applications connectable to healthcare systems and services, is estimated to grow US$ 285 Billion by 2029, with a CAGR of 28% (Wolters Kluwer, 2019). However, it should be noted that forecasts of future market value can vary, depending on included criterias such as how devices are categorized. Moreover, according to a survey made including 22 MedTech companies, all of them are investing in connected devices, while 77% still thinks it is a major challenge to integrate the data from these technologies (The Deloitte Center for Health Solutions, 2018).

4.2.2 Technology Trends Paving the Way for a Transition of Health Care

The World Economic Forum (2016) has communicated, in a white paper in collaboration with Accenture, that they expect the future health care services to have emphasis on connected homes, monitoring, intelligent treatments as well as virtual care teams. It is moreover predicted that one central transition will be to "consumer-centric health care". Similar trends are seen in Gartner's emerging trend barometer (Gartner, 2019). Where predictive analytics, focus on a personalized customer experience, technology for self-monitoring, machine learning, actions on big data and focus on preventive care are among the top 12 trends affecting the health care industry. This shift in focus to connected devices and emphasis on data usage will transform what is considered to be health care. The advancement of IoT technology in combination with improved capability of measuring hardware and faster cellular networks such as 5G, Wifi, Near Field Communication (NFC), Bluetooth Low Energy (BLE) and satellites has made data generation possible on a higher level. The increased volume of data allows for transformed models of care that are more focused on prediction, prevention, customization and participation between caregiver and patient, also called 4P medicine (Taylor et al., 2018). There are hopes that technology, process and business model innovation based on these trends will change the look at, and the use of health care services tremendously.

Another aspect that will change the MedTech landscape profoundly is the required knowledge and capabilities needed to offer value-based MedTech in the field of IoMT. The workforce in general and within R&D will not necessarily be dominated by mechanical and electrical engineers, but also include data-scientists and related roles in digital capabilities. There is however a growing concern that the growth of IoMT will be held back due to lack of skills and flexibility to be acquired among the working population (Taylor et al., 2018). Moreover, in Deloitte's survey 31% of their 237 respondents from connected medical device companies answered that they are moving over to funding models where data is integrated as a service in the health care system to a higher degree (Taylor et al., 2018). However, the survey also showed that 71% of the respondees do not believe that the generation of this data is ready to be utilized by healthcare professionals. Change, flexibility and openness of mindsets and roles for not only the MedTech companies, but also the professionals working within the healthcare systems, such as midwives and obstetricians, will be of importance if IoMT is to be established in traditional health facilities (The Deloitte Center for Health Solutions, 2018).

There is a trend among companies to offer medical devices through B2C instead of reaching out to healthcare providers and governments. The alternative is seen as more profitable since customers are looking into eHealth and IoMT whereas there is a lack of readiness from health facilities. As seen in a survey, 40% of patients would consent to let their personal data be accessible for medical research. Almost the same amount of patients, 35%, would be willing to share it with the manufacturers of medical devices (Taylor et al., 2018). The idea of letting a patient own their data, but at the same time allowing the MedTech companies to monetize the sharing of the same data, in exchange of for example free app use, is an opportunity well noted in the industry (Wolters Kluwer, 2019). It would be a transformation from storing health data in multiple medical records spread out on different health care providers, which is most common today. It would moreover enable the patient to share their previous data with any

healthcare provider. The trends emerging in selling data is on the other hand also a topic for concern, and the industry is expected to face strict data policy regulations in the near future (Taylor et al., 2018).

The fast emerging IoMT industry puts pressure on the evaluation of new technology. There is a need to systematically assess and evaluate the impact that digital health services have. There is scarce research on how eHealth transforms the delivery of care on the organizational as well as the operational level (Ricciardi et al., 2019). There is no doubt that there are strong economic incentives for investors and producers to meet the increased demand for modern health care and medical devices, since profit margins can be significant (Maresova et al., 2020). Pregnant women as a patient is moreover an interesting target group since they are not sick per se, and have been found to be open to technological innovations as well as home-based care (Lanssens et al., 2019; Schramm et al., 2018; Van Den Heuvel et al., 2018). Consequently, there is great potential in integrating IoMT in the field of antenatal care.

4.2.3 Business Model for Telemonitoring

The potential of strong economic incentives to meet meet the increased demand for IoMT devices mentioned previously will most likely give rise to various business models following up on different customer needs. A business model illustrates how a organization plan on creating, delivering and capturing value (Osterwalder & Pigneur, 2010). Argued barriers for the broader uptake of telemonitoring is its cost-effectiveness and business model. The most suitable business model for telemonitoring is still unclear, as well as the aspect if telemonitoring saves costs while improving outcomes. Telemonitoring has mainly been introduced by the not so easily scalable Business-to-Business (B2B) model, but has experienced difficulties becoming mainstream after the pilot testing phase. However, if the cost-effectiveness, consumer and market barriers would be examined, it is believed that scalability could be achieved which is one of the main problems in telemonitoring (Grustam et al., 2018). Patient-centric solutions have both external and internal barriers, such as market forces and weaknesses of medical technology companies. The Institute of Healthcare Improvement (IHI) has developed a framework describing an approach to optimize health system performance. IHI believes that new designs must be developed to pursue three dimensions to be successful: improve the patient experience of care; improve the health of populations; and reduce the per capita cost of health care (Grustam et al., 2018).

Extending toward a B2C model for the introduction of telemonitoring involves improvements in approach and timing of introduction, education and self-management, and cost-effectiveness. The problem of scalability in telemonitoring comes with regulatory challenges in the healthcare industry (Grustam et al., 2018). Hence, this implies that it is favourable for telemonitoring providers to be situated within the European Union (EU) jurisdiction that is most supportive for eHealth, and provide other member states through the internal market clause. Thus, B2C telemonitoring might pave the way to population-wide health monitoring, as companies can reach customers by using for example mass media and referrals by medical practitioners, without the need of physical establishment in the jurisdiction (Grustam et al., 2018).

4.3 Laws, Regulations and Guidelines for Antenatal CTG Monitoring Globally

As highlighted continuously in previous sections, there are many potentials of introducing CTG telemonitoring, but also aspects that need to be taken into account. There are moreover two major aspects to take into account for the use of CTG telemonitoring from home in relation to international and national rules and norms. The first aspect considers the regulations and guidelines that affect the decision from health care providers to use CTG in the antenatal care or not as a monitoring routine. The second aspect considers requirements on the CTG as a medical device used for telehealth. This following section will initially focus on the first aspect, and outline the current rules and norms for CTG monitoring, in order to understand potential barriers for CTG telemonitoring to be accepted within existing guidelines and regulations in different healthcare systems. Secondly, the restrictions and requirements for a medical device to be on the market will be introduced.

4.3.1 CTG as a Monitoring Routine

The routines of offering CTG in the antenatal care differs globally, nationally, and even locally, with standards and procedures depending on the healthcare system the woman is attending to. The inconsistent care set-up is most likely affected by the fact that there is no international consensus regarding

if antenatal CTG monitoring should be performed and its classification criteria (Ayres-de-Campos & Bernardes, 2010). In this subsection the most influential guidelines will be introduced, with a description of the recommendations and shortcomings.

There are no strict regulations on the use of CTG from the United Nations (UN), although the WHO does not recommend routine antenatal CTG, nor is it recommended for high-risk pregnancies (World Health Organization, 2016). Their advice is based on a Cochrane review (Grivell et al., 2015) stating that no eligible studies of routine antenatal CTG were identified, while all six studies included involved women with high-risk pregnancies. Four of the studies were conducted in the 1980s and the other two in the late 1990s. The lack of evidence of positive outcomes from the use of antenatal CTG for high-risk pregnancies in this review is furthermore stated to be the reason why routine CTG for healthy pregnancies is not further researched (World Health Organization, 2016). It is stated in the Cochrane review that "the included studies were not of high quality, and only two had both adequate randomisation sequence generation and allocation concealment". Moreover, the Cochrane review does warrant further studies of computerized CTG in cases where there are increased risks of complications (Grivell et al., 2015), since both monitors and care processes have changed since the 1980s. There is evidence on the outcome being different for computerized CTG, where the mortality rate was significantly reduced compared to traditional CTG (Tamber et al., 2020). Lastly, WHO states their evidence on antenatal CTG in high-risk pregnancies to be of low-certainty. Still, this low certainty evidence is challenging the use of antenatal CTG for all pregnancies, globally.

The most widespread and well-known international guideline for FHR monitoring is the International Federation of Gynecology and Obstetrics (FIGO) "Guidelines for the use of Fetal Monitoring" (FIGO subcommittee on Standards in Perinatal Medicine, 1987). These guidelines were approved by FIGO's executive board in 1986 and constituted the first in-depth agreement of the CTG method, internationally. Naturally, the guidelines have a strong recognition in the field, and 35 years later, they are still referred to, even though they are partly outdated. Most importantly, the FHR features described lacks an objective definition and the rules are considered complex, creating a risk of user error, such as memory decay and lack of understanding, when medical professionals interpret the guidelines (Ayres-de-Campos & Bernardes, 2010). The 1986 FIGO guidelines focus on intrapartum monitoring but cardiotocograph classification criterias are mentioned for antenatal monitoring too (FIGO subcommittee on Standards in Perinatal Medicine, 1987). In 2015, the FIGO guidelines were updated with the purpose of including all current methods available for intrapartum fetal monitoring, as well as adjusting the language to include accessibility for all medical professionals (Ayres-De-Campos & Arulkumaran, 2015). However, the new guidelines do not mention antenatal CTG monitoring (Ayres-De-Campos et al., 2015). To our knowledge, there are no EU regulations or guidelines specifying that CTG should, or should not be used for antenatal monitoring, nor does the EU provide guidelines on classification criteria.

There are a number of national guidelines on fetal monitoring that have been acknowledged internationally and been taken into practice in other countries than where they originated from. Some of the most well known are; the Royal College of Obstetricians and Gynaecologists (RCOG) (publishes via the National Institute of Clinical Excellence (NICE)), American College of Obstetricians and Gynecologists (ACOG) and the National Institute of Child Health and Human Development (NICHHD). However, none of the national guidelines that are available online have any clear or separate instructions for antenatal CTG (Holzmann et al., 2018). Moreover, when looking at the directions of decreased movements of the fetus or intrauterine growth restriction, referral is made to intrapartum CTG interpretations for the surveillance of the fetal heart frequency. The accessible guidelines do not differentiate their guidelines clearly or in a structured way based on the fetus gestational age. Comments are mostly made on the absence of, or a lower amplitude of accelerations in fetuses with lower gestational age. The variability, longitudinal changes in basal frequency or the occurrence of deceleration's is not commented on, despite there being studies showing differences in gestational age also for these parameters (Holzmann et al., 2018).

4.3.2 CTG as a Medical Device

The medical device industry is bound to develop, expand and adjust depending on laws, regulations and guidelines which shape the health care landscape. According to the Porter hypothesis (M. E. Porter, 1991; M. E. Porter & van der Linde, 1995), well-designed and well-enforced regulations is of benefit for both environment and companies, since it suggests that strict environmental regulation gives rise to discovery and entrance of cleaner technology as well as environmental benefits. The innovation effect is also suggested to contribute to a more efficient product and production process (Ambec et al., 2011).

On the other hand, one of the main challenges for small and medium enterprises in the medical device industry is the administrative costs of development that are brought with regulations. Even if small and medium enterprises stand for a large part of the innovation research, and comprise 95% of the MedTech companies in Europe, they are also more prone to a forced market exit due to regulations that requires heavy resources to abide to (Maresova et al., 2020).

In May 2020, the EU Medical Device Directive was replaced with the Medical Device Regulation (MDR) (Germundsson & Kvist, 2020). The new regulations have changed to include device classification, technical file documentation, traceability and a stronger post-market surveillance. As of before the MDR was introduced, medical devices were CE marked under two separate directives (93/42/EEC and 90/385/EEC), whereas after the 21st of May 2021, all new certifications must go through the new directives. Moreover, the medical devices have been divided into four groups depending on their risk. In the MDR guidance it is stated that "manufacturers shall establish, document and implement a quality system, and maintain its effectiveness throughout the entire device life cycle." There are requirements on the Quality Management System (QMS)'s functionality to include procedures for document storage, post-market surveillance as well as an risk-assessment of both new but also already existing devices. The QMS should further be audited by a third party auditor, only class I devices are excepted from this requirement (Germundsson & Kvist, 2020). Daigle and Torsekar (2019) argues that the previously short time-to market that has been beneficial for offering medical devices in the EU risk being challenged by the new MDR. They argue that potential bottlenecks within the supply chain will rise due to the requirement of long-term obligations for manufacturers, lack of notified bodies for the approval of medical devices as well as a large strain on resources and capacity for the government regulatory bodies. While the USA has long been leading in the MedTech industry, with the EU as an important market, it is further argued that delays due to the MDR risks threaten the EU reputation for timely market approvals (Daigle & Torsekar, 2019).

The Food and Drug Administration (FDA) is the equivalent regulatory framework to the MDR, in the USA. Despite both are inspired by international best practices the variations in the standards do give rise to differences in market opportunities. For example, an estimated maximum time to market for high risk devices were 30 months for the USA and only 9 months for the EU in 2019 Daigle and Torsekar (2019). On the other hand, the FDA, has seen tempering in medical device regulations, as opposed to the increased scrutiny of the recent MDR. Consequently, several companies are debating as to whether it is more lucrative to conduct clinical studies in the USA instead of the EU for medical devices (Doerr & Pritchard, 2018). In the light of the Covid-19 crisis, the FDA moreover decided to put an ease on some of their regulations in order to allow for an increased use of mHealth, apps and telehealth services in general (Administration et al., 2020). Additionally, in 2020 the US Centers for Medicare & Medicaid Services (CMS) issued a rule requiring the technical standard Fast Healthcare Interoperability Resources (FHIR) to be used by CMS-regulated payers including state Medicaid programs, Medicare Advantage organizations and qualified health plans in the Federally Facilitated Marketplace by 2021 (CMS Health Informatics and Interoperability Group, 2021). The goal of the introduction of FHIR is to provide with interoperability between healthcare systems. In order to enable information to be shared to individuals and healthcare providers on numerous devices ranging from computers to smart phones to tablets. The required use will make it possible for developers of third party applications to introduce medical applications that can be integrated into existing health care systems (Hecht, 2019).

4.4 Barriers for Telemonitoring

There are various barriers for telemonitoring to be introduced in the healthcare settings, as well as to individuals. Obstacles and risks for implementation of CTG telemonitoring have been mentioned in previous sections, as for example lack of readiness among healthcare professionals, differing attitudes towards data sharing among pregnant women and rules and regulations to get a IoMT device approved to name a few. However, in this final section of the literature review, general barriers for telemonitoring that have been identified in literature will be presented.

The successful adoption of telehealth is still a challenging task in the healthcare sector (Gadeikienė et al., 2021). One significant barrier for telemonitoring is related to reimbursement issues, which are delaying the widespread adoption of eHealth in all sections of hospital care (van Den Heuvel et al., 2020) and limits the services that can be offered (Kruse et al., 2020). Health policy is vital for the spread of telemedicine, as it encourage and allows the use of telemedicine to boost the project management triangle of quality, access and cost (Kruse et al., 2020). In most cases, insurance companies are prone to only cover well-researched

eHealth interventions (van Den Heuvel et al., 2020). Insurance coverage differ both within and between countries and is fragmented within various specialities of health care (Van Den Heuvel et al., 2018). For instance, in the Netherlands, there is no insurance coverage for pregnancy telemonitoring available (van Den Heuvel et al., 2020). Similarly, in the USA, telehealth services are in most cases not included in public or private insurance agreements (Gadeikienė et al., 2021). In addition, the reimbursement for healthcare providers and medical professionals connected to delivering telehealth services has until now been considerably restricted in the American privately oriented healthcare system. It is hard to bill the payers, particularly when the service is administered in a home setting, and telehealth encounters are for these reasons restricted. Thus, the development of insurance reimbursement systems for remote health monitoring could be argued to be crucial for the diffusion of remote monitoring innovations in maternity care. Health insurance companies need to recognise the value of telehealth and reimburse similarly to in-person visits (Gadeikienė et al., 2021). Accordingly, health policies that enforce and implement policies like reimbursement models and cross-state interoperability will expand and influence the diffusion of telemedicine (Kruse et al., 2020). Financial constraints and the fact that telemonitoring is not integrated in routine care makes change management in the conservative medical community a challenge (Grustam et al., 2018).

No sustainable innovation can be introduced successfully on a market without indirect and direct costs being calculated in detail beforehand. For telemonitoring, a few models of implementation by medical groups, individual medical professionals and healthcare systems exist that can be drawn upon. However, assumptions and financial models necessary for making calculations of return on investment and costs do not exist (Grustam et al., 2018). Another critical aspect of health care and remote monitoring is privacy (Lanssens et al., 2019; Ricciardi et al., 2019). The privacy of patients and data security are crucial factors for the adoption of connected medical devices (Lanssens et al., 2019). Therefore, it is essential to create a balance between privacy rights, cyber security and the development of the digital market. If patient data is restricted to the medical professionals involved in current treatment and can not be utilized by the whole healthcare system, several benefits of digitalization are lost. Consequently, there is a conflict between the privacy protection and the data utilization interests in the digital health system (Ricciardi et al., 2019). However, lack of control in data collection and data use by third parties are possible privacy risks connected to the use of eHealth (Van Den Heuvel et al., 2018). Remote patient access to health records and electronic devices moreover increase cyber security threats. To ensure appropriate data protection specialized expertise is required (Ricciardi et al., 2019).

Furthermore, legal concerns, such as use of data and third party control, is another barrier for the use of digital health interventions like pregnancy telemonitoring. External companies providing software, devices and storage of data for telemonitoring in the Netherlands, must for example provide data security assurances (van Den Heuvel et al., 2020). Security is a big limitation also in the USA, as the security of the connection between different patient databases, platforms and exchange is not uncomplicated and identified as a significant barrier related to the adoption of telehealth services (Gadeikienė et al., 2021). Another barrier, related to liability, is the issue of trust between medical professionals and patients. medical professionals have expressed concern about misdiagnosis due to inaccuracy in the patient provided information, related to the extensive legal responsibility on the medical professionals (Gadeikienė et al., 2021). Expectations and experiences of disruption to services is also affecting the participation and adoption of telemonitoring. Technical competence and operation of equipment is necessary for the adoption of telemonitoring through the B2C model (Grustam et al., 2018). The integration of telemonitoring data into medical records have proven to be challenging, based on trends in the EU, as the data is not verifiable, consistent and the transmission can be unsafe (Kruse et al., 2020). Despite challenges of privacy, security and liability, eHealth is likely to diffuse globally in the near future (Van Den Heuvel et al., 2018).

5

Methodology

The following chapter aims to explain the chosen methodology for this study in terms of sampling and collection of data. How the data is analysed is also presented, before a critical discussion about the chosen methodology.

5.1 Methodological Approach

A literature review and initial research was conducted to get an understanding of the current research within the field, create a case description and to be able to present a problem analysis. Thereafter, a theoretical framework was conducted to outline the theoretical foundation to answer the research questions. Data was collected from a database and used to perform a screening analysis with the aim of identifying promising markets for a CTG telemonitoring solution. Moreover, a survey and interviews with relevant actors on the subject was also conducted as a contribution to the aim of investigating a potential market opportunity for the technology. The report is consequently based on both primary and secondary data that is of qualitative and quantitative form. A critical approach was continuously applied during the whole process with the aim of achieving a valid and credible result with high reliability and validation throughout the process.

5.2 Data Collection

The following section will describe the data collection process.

5.2.1 Secondary Data Collection

A secondary data collections were performed in order to get an understanding of the current landscape of the CTG telemonitoring technology. The data collections take the form of insights from literature as well as a large database. The expected outcome was for example insights in the technology landscape and industry, benefits and drawbacks of the use of the product as well as information gathering of the prerequisites from different markets. It was moreover expected to contribute with a deeper understanding of a theoretical framework to be applied. These outcomes were of importance for analysis and discussion. The qualitative data collection method used was a case description and a theoretical framework. The quantitative data collection was a factor rated screening analysis. The following section will describe the collections in more detail.

Case Description and Literature Review

The case description and literature review took form by a secondary data collection of literature and research on the subject. It was conducted in order to get an understanding of the problem situation and create a basis for the investigation of the technology in a new context. The literature used was mostly scientific papers but also relevant literature within the subject, such as guidelines. Studies concerning CTG telemonitoring have been conducted, however there still exist knowledge gaps considering for example safety and financial aspects, and attitudes from customers and users. Consequently, there is a lack of secondary literature sources on the subject. The literature was searched for on Chalmers Library, Google Scholar and DTU Findit. Literature was also found by investigating references mentioned in other studies.

Theoretical Framework

The theoretical framework is based on a secondary data collection of literature on theoretical models. It was conducted in order to get an understanding of how to apply models to a case in order to be able to identify influential factors for market adoption as well as recognizing a market opportunity. The theoretical framework was outlined by choosing among a number of established models on innovation and business generation suggested by supervisors and found in relevant course literature. The three frameworks chosen were the following: The Diffusion of Innovations Theory, Porter's Diamond Model and the MON. They were selected because they fit into the aim of investigating influential factors on a global as well as national level, while also contributing to an understanding of value creation and customer needs for a product or service.

The literature used was scientific papers and business insights. However, there is a knowledge gap on the application of the models on connected medical devices in particular. Consequently, there is no best practice presented in the theoretical framework to follow when applying the models. The literature was searched for on Chalmers Library, Google Scholar and DTU Findit. Literature was also found by investigating references mentioned in other studies.

Data Collection for Screening
A secondary data collection covering five societal parameters on a national level was carried out to enable an initial screening of interesting markets for the product to be launched on. The parameters deemed important for a market potential for the product were chosen based on the information gathered in the literature review. The method used for the screening was an additive aggregation method, with a linear summation of weighted and normalized variables. The outcome was a sum of a country's rank in each of the variables that were chosen to represent the societal parameters.

Data from the OECD statistics site Organisation for Economic Co-operation and Development (2020) was used in order to get a representative market selection. The variables were selected by sorting out 24 variables that would be relevant for defining and classifying the parameters. The variables were sorted out by going through the list available at the OECD.stat site from top to bottom. Eleven final variables were then decided upon by relating their relevance to the case description. They were moreover chosen to not have any conflict or synergy between them. For example, the number of live births were excluded since it was a product of the other two variables fertility (children per women) and fertile women population (number of people). It was moreover assured that the variables were preferentially independent, meaning that the trade-off ratio between the two variables were not dependent of the values of the rest of the variables. The data was customized to include information dating five years back, for the most recent years available ranging from 2013-2017 to 2016-2020. The data was then extracted for every variable, to cover all 37 OECD countries.

5.2.2 Primary Data Collection
In order to try to fill the knowledge gaps, primary data collection in the form of a survey and interviews were performed. The expected outcome was for example insights in attitudes of consumers, medical professionals and industry relevant actors to gain a better understanding of how the product could be implemented in existing healthcare systems or as a private service directly aimed at the user. The quantitative data collection method used was a short survey. The qualitative data collection methods used were individual semi-structured interviews with potential end users, medical professionals and actors within the industry.

Survey
In order to get an understanding of how the end user is reasoning around using technology for health checks, as well as why the end user would like to monitor, a survey was sent out with 22 questions. The questions were partly linked to earlier answers and consequently the typical respondent was not asked all of the questions. The survey took approximately between 5-10 minutes to answer.

The aim of the survey was to get representative insights into the end user market. The target group was pregnant women and/or women planning on getting pregnant as well as women having had at least one earlier pregnancy. The aim was moreover to target potential early adopters of the technology. It was therefore sent out to Facebook groups focused on female technology in particular, where the common aim is either to avoid or conceive a pregnancy with the help of technology, such as algorithm-based basal body thermometers and fertility awareness tracking apps. The survey was separately sent out to groups focused on pregnancy only. However, it was not accepted as a post in all of the the latter groups, since the subject was not considered on topic by the administrators of the groups.

The questions were designed to be easily understood by everyone, including women who had no previous knowledge of CTG, as well as to minimize the risk of interpretation issues. A combination of open and closed questions was moreover used, to enable both comparable and more detailed information gathering. The survey was moreover tested by a few test-persons in three rounds, to ensure its quality. The questions investigating price sensitivity were formulated partly based on Van Westendorp's Price Sensitivity Meter (Ceylana et al., 2014), a market technique for determining consumer price references. The whole questionnaire is presented in F.

Interviews
All interviews performed were of a semi-structured nature. The interviewee's were presented to the topic and the aim of the study. It was emphasised that the research was not made in collaboration with a

company and that both positive and negative opinions were of equal value. The interviews were held on Microsoft Teams and recorded as an audio file and transcribed based on particular themes.

The contact with the end user interviewees was initiated via the respondent's from the survey that chose to leave their email address for further discussions. The aim of the interview was to investigate the level of trust an end user feels toward their health care professional as well as what the job to be done would be for them using CTG telemonitoring. A short video was initially presented showing a suggestion on how the technology could be applied. This was done in order to provide the respondents with a basic understanding of the use and look of the product. The time slots were assigned for 30 minutes but the interviews were all held between 16-20 minutes, starting after describing the study, the technology and the purpose of the interviews. The questionnaire can be found in Appendix H.

The contact with medical professionals was initiated by emailing relevant organizations and individuals of interest, by using the search engine Google and asking personal contacts. The aim of the interview was to gather information about medical professionals experiences and views on CTG, remote monitoring and a possible CTG telemonitoring solution. The questions were formed around the framework presented in Chapter 2, as a help to gain information enough to be able to apply it in the analysis. The time slots were assigned for one hour, and the interview was held to this, starting after describing the study and the purpose of the interview. The questionnaire can be found in Appendix J.

The contact with the industry relevant actors were initiated by emailing companies that were found by using the search engine Google, as well as by asking personal contacts and end users what products and/or distributors they knew of. The aim of the interview was to investigate the landscape which these actors are present in and their view on the market opportunity as well as the challenges and risks they are facing. The questions were formed around the framework presented in Chapter 2, as a help to gain information enough to be able to apply it in the analysis. The time slots were assigned for one hour, and the interviews were all held between 45-60 minutes, starting after describing the study and the purpose of the interviews. The questionnaire can be found in Appendix I.

5.3 Data Analysis

The following section will describe how the qualitative and quantitative data was analysed.

5.3.1 Analysis of Quantitative Data

The data gathered from the survey was divided into two parts, open ended questions and closed ended questions. The closed ended questions were cleaned and organized so that pivot tables could be generated in Excel. Slices were added for all of the closed ended questions to enable analysis for one variable at a time. The result was moreover presented in tables to get a clear overview of the insights from the respondents. One purpose of the survey was to get an understanding of why the end user would like to monitor. Part of the analysis was consequently aimed at investigating if there was a correlation between what an user is prepared to pay for the technology and how they reason around different topics such as intensity of worry and amount of information given from their health care services. The open ended questions were sorted into the categories of the closed ended answers, for example if an answer to a closed ended question was no, the open ended replies elaborating on the no answer was included next to it.

The data presented in the factor screening was processed in several steps in order to enable a comparable rating of the countries market potential. Initially, an average value was calculated for each country over the five year time period the data was extracted for, for every variable. The value for each variable and country was then normalized to be comparable to each other, with formula 5.1.

$$x_{normalized} = (b - a) * \frac{x - y}{z - y} + a \tag{5.1}$$

Where the value to be normalized; x, was the value for each specific country, within the range (y,z) ranging from the individually lowest scoring country to the highest scoring country. Lastly, the normalized range (a,b) was set to 1-5.

The median value was then calculated based on the normalized values. This value was used as an input value for the countries that did not have any stated value included for the last five years for a certain parameter, in order to make those situations neutral in the ranking. This lack of data affected 14 out of

444 data measures (3,15%). Weights were then assigned to the different variables based on how important the aspects were thought to be, and these weights were multiplied with a negative or positive effect (1/-1) in order to state if the parameter was having a negative or positive impact on the market suitability for a country. The weighted effect was then multiplied with the normalized value of each variable and country. The score for each variable was then summarized for every country, so that the end score was a comparable total point for each country. The countries where then ranked from highest (high market potential) to lowest (low market potential).

The weights for the potential and actual sum of pregnancy related issues were varied in three scenarios ranging from low, medium to high relevance in order to see how the factor rating would change depending on if the pregnancy related variables changed while aspects surrounding the overall market suitability of a country were kept static. This comparison was made in order to see if there was a country that for example had very suitable market conditions while not having a strong demand for improvements of antenatal care in general. Such a country could still be highly relevant for a B2C solution, or a B2B solution where other aspects such as shortcomings in hospital spots could create a demand for connected home monitoring CTG.

5.3.2 Analysis of Qualitative Data

All of the interviews were recorded after asking the interviewee for permission to do so. The recordings were then used to transcribe the interviews, which enabled a methodical sorting of the material into the themes the interview questions were based upon. Since the purpose of the interviews was to use the actual information that was gathered, relevant parts were chosen during the transcription. The analysis of the interviews were moreover made continually in order to enable direct use of new information and insights in the coming interviews and working processes.

5.4 Quality of Study

Various methods were used to ensure reliability and validity in the study. One main focus of the study has been on critical thinking while designing the process, in order to obtain a representative result and minimize the impact that bias can have when collecting data and interpreting the result. Triangulation was furthermore used in the research to develop a comprehensive understanding of the subject of study. Here, a combination of qualitative and quantitative data collections were used that were of both primary and secondary nature. Examples of this is the extensive literature review as well as interviews with different stakeholders and the analysis of a large secondary database. Transparency in how the study was conducted has moreover been ensured to enable replication and further analysis.

The results obtained in the survey, interviews and the screening were compared with the literature to enable the identification of deviations that could make the findings questionable. The investigation on how well the results are corresponding to insights from reality aims at creating a high internal validity of the study. External validity, how well the study is carried out in a generalized way, has been ensured by understanding how the selections in the survey, screening and the interviews have been made in order to be able to discuss how it affects the result. The combined results from different methods moreover aims at creating high design validity to ensure that the methods that have been used provide answers to the intended research questions.

Validity have been considered in order to make the findings more general and coherent. Validity in the interviews has been ensured through letting the interviewees speak freely. To further ensure the validity of the thesis, triangulation has been used in the form of data generated from the different actors' perspectives. Through interviews with different kind of actors, their different approaches related to the questions under investigation can be captured. The relatively small sample size is considered a weakness and it is possible that conducting more interviews had generated another result. Also, it would be preferable if more interviews with actors in the USA would have been possible. It should be said that a more actors and customers were invited to participate, but they were not able to participate. due to the global Covid-19 pandemic. It could, therefore, be considered that the views of potential end users are better understood than those of the remaining actors, at least in the parts connected to the USA. The interviews were performed through video calls and there are several limitations by conducting interviews remotely since it is difficult to catch specific nuances of opinions. On the other hand, participants are not as affected by the researchers' reactions by distance and since the outbreak of Covid-19, remote interviews must be considered the most suitable for all participating parties. To conclude, the findings

in the master thesis is limited to the interviewees' knowledge of CTG, telemonitoring and the related market. The result could thus be impacted by the interest and belief of the subject of the interviewees. Thereby, the opinion of the interviewees is not necessarily representative and not constitute a basis for any conclusions.

6

Result

The following chapter will present the empirical findings. Firstly, the result of the screening analysis will be presented, followed by the presentation of the findings from the survey with potential end users. Thereafter the empirical findings from the conducted interviews are presented with the aim to answer the research questions.

6.1 Screening

A screening based on relevant criteria was made based on data from the OECD.stat database (Organisation for Economic Co-operation and Development, 2020) which includes data and metadata for OECD countries. The data was extracted the 24th of March 2021, and includes data ranging from 2013-2020. All 37 OECD member countries were included, and are listed in appendix A.

The criteria resulting in the final screening included the following variables with associated measures. For each variable data from the five latest accessible years was used. The data is presented in appendix E.

1. Low birth weight - measured in % of total live births.
2. Mean age of women at childbirth - measured in years
3. Complications of pregnancy, childbirth and the puerperium (Maternal mortality) - measured in Deaths per 100 000 females (standardised rates).
4. Complications of pregnancy in the antenatal period (Hospitalization of pregnant women) - measured in days that women are being hospitalized.
5. Fertility - measured in children per women aged 15 to 49 years old
6. Female population aged 15-49 years old (Fertile (15-49 y/o) female population) - measured in the number of people.
7. Gross domestic product (GDP) - measured per capita, US$ purchasing power parity
8. Actual individual consumption (AIC) - measured in a price index of (2015=100).
9. Households with Internet access at home - measured in percentage of all households.
10. Computed Tomography scanners, total (Medical Technology access) - measured per million population.
11. Digital Services trade restrictions - measured as the Service Trade Restrictions Index (STRI) with a value from 0 to 1, where complete openness to trade gives a value of 0, and the opposite 1.

Further explanations on the criteria can be seen in Appendix B.

The variables were chosen in order to evaluate the following four aspects for each country; Potential and actual sum of pregnancy related issues (1-4), amount of births and fertile female population (5, 6), economic status (7, 8), technology diffusion (9, 10) and barriers affecting trade for digitally enabled services (11). The effect of the variable was stated to count positively for all variables except the digital services trade restrictions, which was assigned a negative count.

Weights were assigned to the different variables according to Figure 6.1 for a first scenario (Sc. 1). The rating was initially set to medium for potential and actual sum of pregnancy related issues. Medium-high for fertile female population and amount of births, high for economic status, high for technology diffusion and medium-low for trade barriers for digital services. The weights were assigned based on how important the variables were thought to be based on findings from the initial literature review presented in section 4.

Table 6.1: Overview of the weights assigned in the three different scenarios.

Aspect	Potential and actual sum of pregnancy related issues				Fertile women population and amount of births		Economic status		Technology diffusion		Trade barriers for digital services
Measure	% of total live births	Years	Deaths per 100 000 females	Days of being hopsitalized	Children per women aged 15 to 49 years old	Number of people	/capita, US$ purchasing power parity	Price index (2015=100)	Percentage	Per million population	Indicator STRI
Effect (1/-1)	1	1	1	1	1	1	1	1	1	1	-1
Scenario 1											
Rating	Medium				Medium-high		High		High		Medium-low
Weight (1-5)	**3**	**4**	**2**	**3**	4	4	5	5	5	4	3
Scenario 2											
Rating	Low				Medium-high		High		High		Medium-low
Weight (1-5)	**1**	**1**	**1**	**1**	4	4	5	5	5	4	3
Scenario 3											
Rating	High				Medium-high		High		High		Medium-low
Weight (1-5)	**5**	**5**	**5**	**5**	4	4	5	5	5	4	3

The aspect of potential and actual sum of pregnancy related issues was then varied to be low and high in two additional scenarios (Sc. 2 and Sc. 3), whereas the other weights were kept the same, as further presented in Table 6.1. The variation of the aspect of pregnancy related issues in particular was made in order to see if there is a large difference in suitable countries depending on if the country has a lacking antenatal care today or not. The importance of this parameter will vary depending on the customer segment of interest. For example, the introduction of CTG is not only interesting for a hospital that struggles to give sufficient care to pregnant women. It could also be of value for hospitals seeking to lower their costs, to enable better care for women living far away or for the outsourcing of interpretation of the CTG readings to name a few. The solution could moreover be of interest for a customer focused solution that is not necessarily used by recommendation from the care professional, and hence, the degree to which pregnancies is considered a risk might not be the main driver. The result from the different scenarios is presented in Table 6.2, for the 25 highest ranked countries. For the full list of the placement of all 37 countries, see Appendix D.

Table 6.2: Overview of the ranking for the three scenarios, with the total points given for each scenario.

Nr.	Country	Sc. 1		Country	Sc. 2		Country	Sc. 3
1	United States	110,37		United States	86,16		United States	134,19
2	Japan	109,27		Luxembourg	81,47		Japan	132,02
3	Luxembourg	108,67		Japan	79,50		Luxembourg	129,15
4	Switzerland	102,05		Turkey	76,78		Switzerland	123,43
5	Korea	99,36		Norway	74,83		Korea	122,61
6	Turkey	98,13		Switzerland	73,64		Turkey	118,88
7	Germany	97,46		Australia	72,87		Germany	117,17
8	Norway	95,38		Germany	71,88		France	116,75
9	Australia	95,33		United Kingdom	71,52		Italy	112,93
10	France	94,81		Denmark	69,65		Australia	112,05
11	United Kingdom	92,31		Ireland	69,43		Norway	110,29
12	Ireland	91,74		Netherlands	68,91		Czech Republic	110,11
13	Italy	91,42		Korea	68,81		Hungary	110,08
14	Netherlands	91,14		France	67,64		Slovak Republic	108,39
15	Denmark	90,00		Sweden	67,13		United Kingdom	108,34
16	Czech Republic	89,14		Iceland	66,21		Belgium	107,49
17	Belgium	88,76		Canada	65,83		Portugal	107,40
18	Spain	87,31		Estonia	65,63		Israel	107,18

Continued on next page

Table 6.2 – *Continued from previous page*

Nr.	Country	Sc. 1		Country	Sc. 2		Country	Sc. 3
19	Israel	87,05		Belgium	64,80		Netherlands	107,00
20	Canada	86,71		Austria	63,92		Spain	106,77
21	Hungary	86,66		Czech Republic	63,16		Ireland	106,40
22	Austria	85,88		Finland	63,11		Denmark	104,41
23	Sweden	85,86		Italy	62,74		Greece	104,28
24	Slovak Republic	85,27		Israel	62,13		Slovenia	102,50
25	Estonia	85,08		Lithuania	60,75		Austria	102,45

For the initial weighting, the 15 highest ranked countries were coloured light blue for an easy and straightforward interpretation when changing weights in a later stage. As seen in Table 6.2, there is not a large difference in the score for countries depending on if they have medium (Sc. 1), low (Sc. 2) or high (Sc. 3) weight for the pregnancy related issues. The top ranked countries are to a high extent coloured blue still.

For scenario three, there were a few countries that shifted place. Denmark, who are known to have good antenatal care for all women, fell behind thirteen positions when that priority was set to high as compared to low. Italy was also changing positions when varying the weight for pregnancy related issues, they moved to a 24th place in the list when lowering the weight, as compared to being on place nine when the priority was set to high. The USA was the highest performing country regardless, this is partly due to their large fertile female population. The ranking would look a bit different if the Fertile (15-49 y/o) female population variable would be excluded. The USA would for example take place number seven when ranking scenario 1, with the exclusion of the female population. The size of population was however included with purpose, since a larger population is probable to present a larger amount of potential buyers too.

The USA is performing best in the aggregated screening analysis, for all three scenarios, it was consequently decided that the USA would be chosen as the nation to examine further.

6.2 Empirical Findings from Survey

The results from the survey performed between the dates 20/4-28/4 - 2021 are presented in the following section. The survey had a reply rate on 38 respondents (n=38), where 36 of the women were approached in Facebook groups aimed at Female Technology. The two other respondents were approached in a Facebook group for general pregnancy related questions. The result will be presented based on the themes that the questionnaire was based upon, starting with the investigation of general demographic information followed by pregnancy related information and finally questions evolving around CTG in general and a telemonitoring solution in particular.

6.2.1 Demographic Information

As seen in Figure 6.1, the respondents were mainly in the age between and 26-30 and 31-35. The respondents were mainly from the US, as seen in Figure 6.3. Most of the respondents lives in cities or town and semi-dense areas, as seen in Figure 6.2.

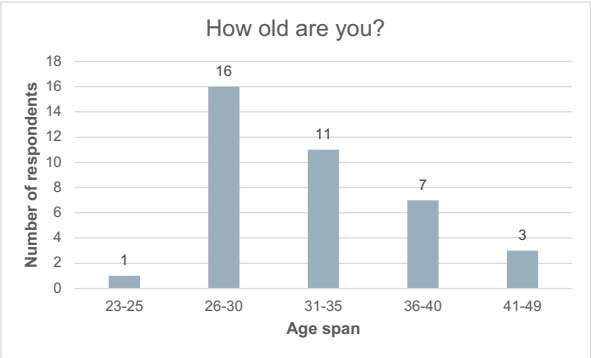

Figure 6.1: Age distribution among survey respondents.

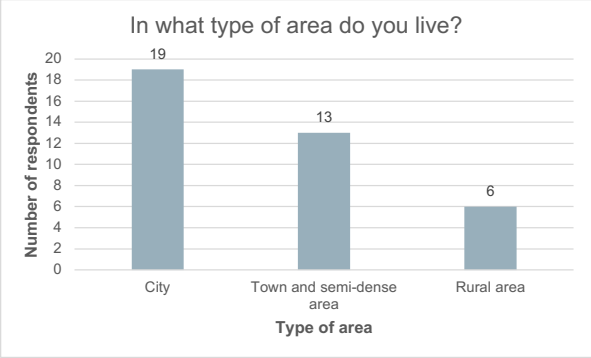

Figure 6.2: Area of living among survey respondents.

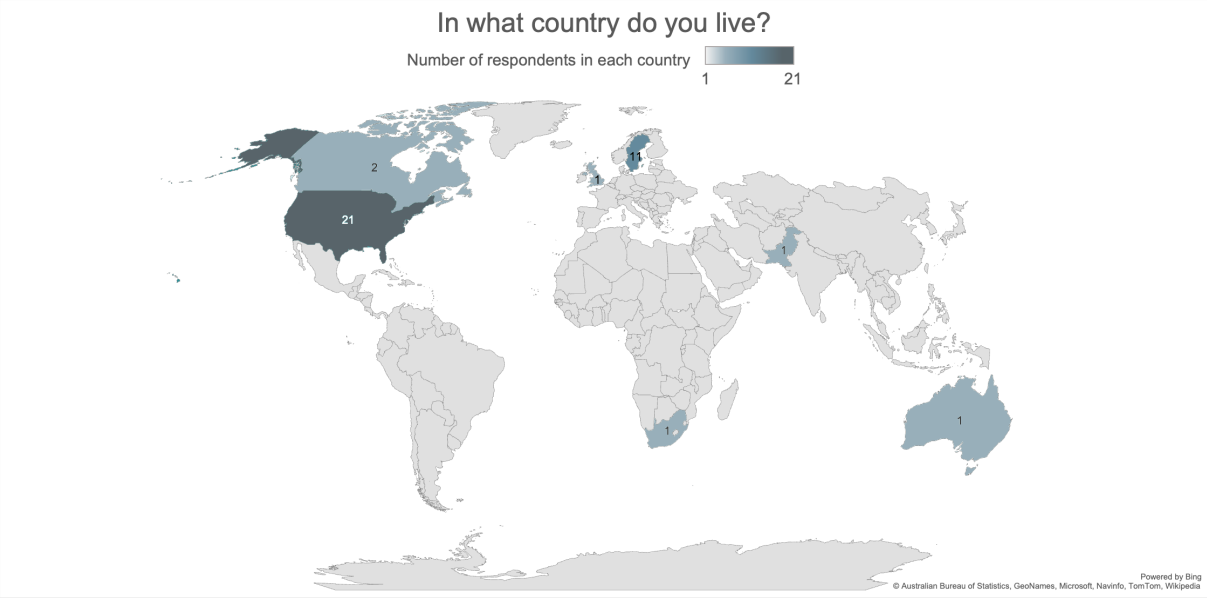

Figure 6.3: Overview of the geographic distribution from respondents globally.

6.2.2 Pregnancy Related Information

As seen in Figure 6.4, 28 out of 38 respondents were not currently pregnant, but 24 had been pregnant before. 12 out of the respondents were however planning on or trying to conceive in the near future. This can be seen in Appendix F. As seen in Figure 6.5, out of the respondents that either were pregnant or had been pregnant before (n=34) there were 41% that had a pregnancy that was considered high-risk by themselves or a medical professional and 53% that did not. The criteria for high-risk was stated to be anything that made the respondent feel like they and/or their fetus were to be in the risk-zone of any unhealthy occurrences. Examples given to the respondents were the following:

- Advanced maternal age
- Lifestyle choices such as smoking cigarettes
- Maternal health problems such as high blood pressure, obesity, diabetes
- Pregnancy complications and or a history of pregnancy complications such as premature birth and preeclampsia

6.2.3 CTG Related Information

27 out of 38 respondents had heard of CTG before, the full result to this question can be seen in Appendix F. Most respondents, 13 out of 38, had not CTG neither included or offered as a service with an additional

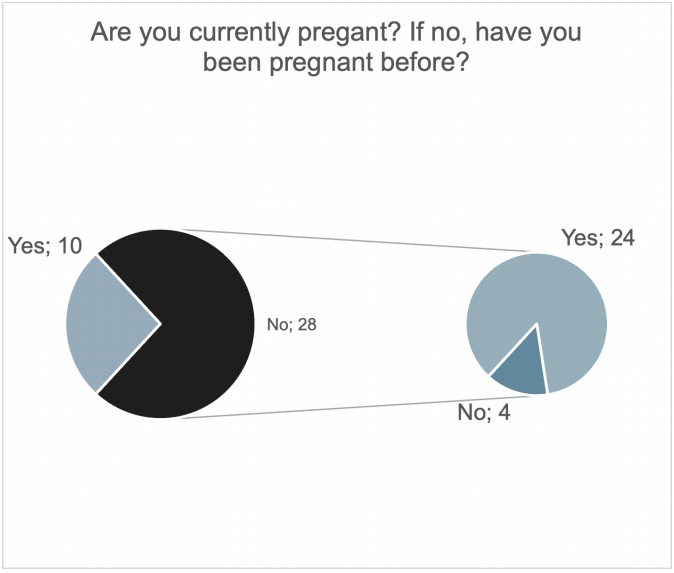

Figure 6.4: Distribution of women that were currently pregnant viewed to the left, and the amount of women that were currently not pregnant, but had been pregnant before to the right.

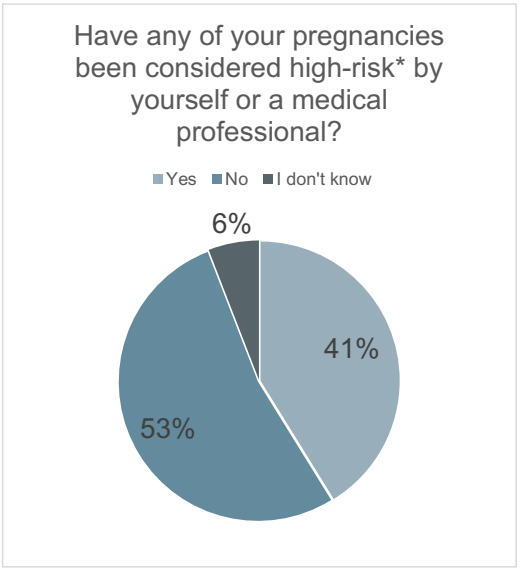

Figure 6.5: Percentage of women that by themselves or a medical professional were considered to have a high-risk pregnancy (n= 34).

cost in their antenatal care routine, as seen in Figure 6.6. The total number of respondents were 27 for this question when excluding those who did not know what CTG was and/or were not currently or had previously been pregnant.

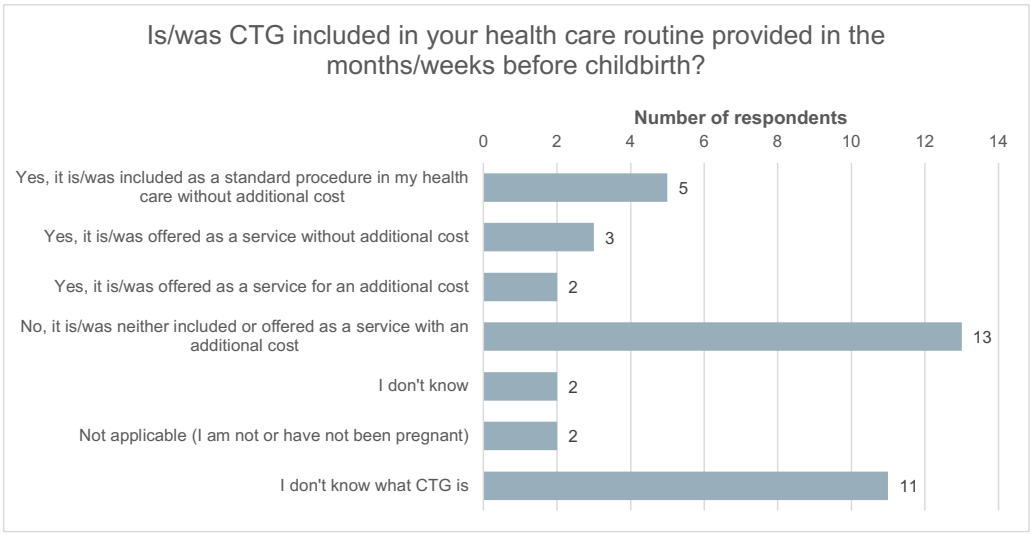

Figure 6.6: Amount of respondents that had previous experience with CTG and what service they had been offered.

6.2.4 Unmet Need

14 out of 38 respondents think that they always get enough information about their fetus's well-being at their appointments with a medical professional, as seen in Figure 6.7. The respondents that answered that they think something is lacking were asked to specify what information they feel is lacking. Some examples, cited from respondents on the question:

- Would like to have done more ultrasounds during my pregnancy
- I had very few ultrasounds so that's the only thing I feel like I lacked, seeing and checking in on

baby. But honestly I try to be more holistic with prenatal care so I didn't opt for any ultrasounds that were optional.

- Sometimes I didn't have enough time to ask all my questions.

Using these examples, it can be discerned that the respondents have a wish for more information about the status of their baby. However, it is not clear if the respondents would like to attend more appointments or if other solutions could satisfy their demand.

A majority of the respondents, 26 out of 38, do always, mostly or sometimes feel worried that their child is not well between their scheduled appointments, as seen in Figure 6.8, this corresponds to a share of 68%. Some examples, cited from respondents on the question about why they are worried:

- When experiencing reduced movements, you want to see/hear the child so that you can feel calm
- Lack of information to calm anxiety about it all. I have no indication that everything is okay in between visits.
- Because I'm a mom! We worry if the baby is moving too much, not enough, if the baby has shifted position, is too big, too small....
- Prior miscarriages

Using these examples, it can be discerned that the respondents answered more decisively that their worries is based on the feeling of wanting more information. Also, some respondents were worried due to prior medical experiences from previous pregnancies. This result shows that the respondents emphasizes the importance information during a pregnancy.

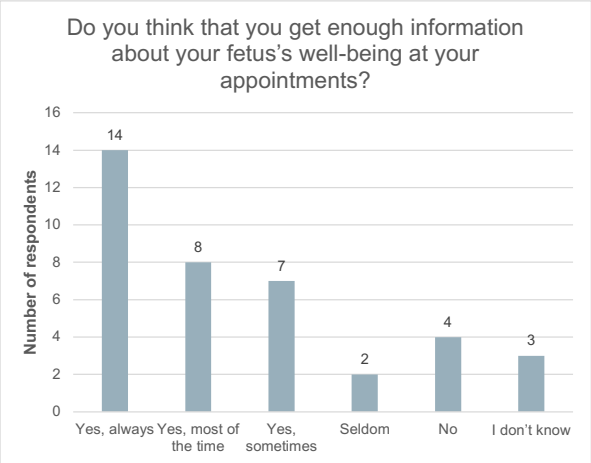

Figure 6.7: Respondents' opinion on their received information at antenatal appointments.

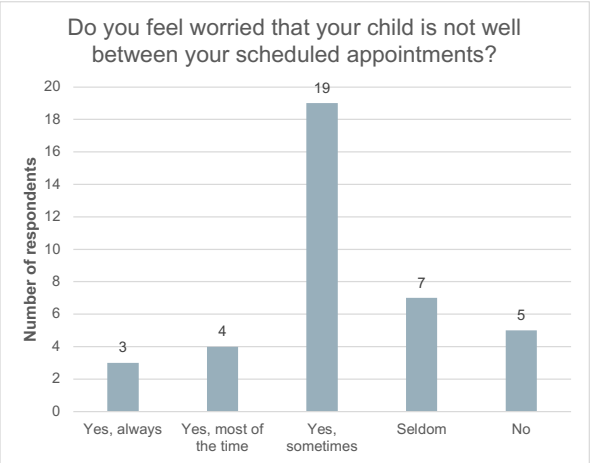

Figure 6.8: Respondents' degree of worry that their child is not well between scheduled appointments.

6.2.5 Better Than Current Solution

As seen in Figure 6.9, 18 out of 38 respondents would consider taking an active care choice based on other sources than from their medical professional (midwife/doctor). The definition of an active care choice was not specified and it could include anything that the respondent themselves considered an active choice.

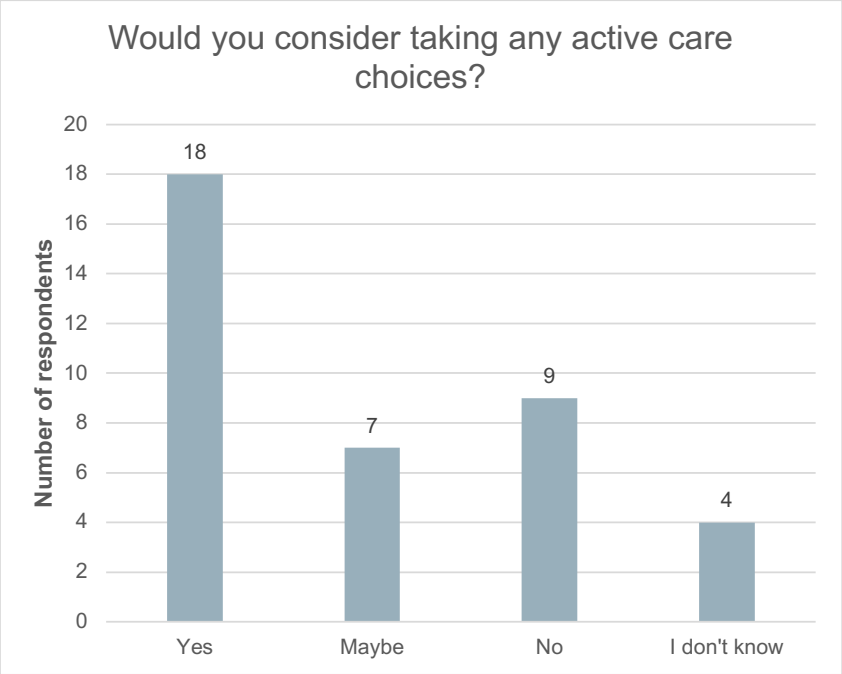

Figure 6.9: Amount of women who could consider taking an active care choice from any other than their contact with a medical professional.

The respondents were asked to motivate their answer on the question on whether they would consider taking any active care choice. Some examples, cited from respondents on this question:

- Home Doppler would have been nice
- Yes. I'd consider monitoring myself, if technology allowed me to do so,
- Depends on what it is and the research behind it
- No, I don't think so. I trust my doctor and she knows my specific information.

Using these examples, it can be discerned that the respondents answered more diffuse on the question about why they would or would not consider taking any active care choice. However, this does not mean that the answers to the question were negative. Some respondents would like to receive more information about their fetus and some respondents trust that the information they need is provided through the health care they are given.

6.2.6 Effective Solution

A vast majority of the respondents would consider using an app to track their fetus's well-being, as seen in Figure 6.10. The respondents were asked if they think it would be beneficial to have regular (daily/weekly) updates about the fetus's heartbeat and if they would be willing to pay to get this update. Some examples, cited from respondents on this question:

- Yes it would be beneficial, but it would depend on the cost and how high risk my pregnancy was
- Absolutely! It would calm me as pregnant with many miscarriages incredibly
- I think it might cause me anxiety to hyper focus on my baby's heartbeat through out the pregnancy
- Depends on the cost

Using these examples, it can be discerned that the respondents answered more diffuse on the question, some thinking it would be beneficial and some thinking it would cause more anxiety. However, the respondents answered more decisively that the cost were a critical factor.

32% (12 out of 38) respondents did have concerns about tracking information about their fetus, while 21% (18 out of 38) respondents do not, as seen in Figure 6.11. The respondents were asked to specify

what type of concerns they had. Some examples, cited from respondents on this question:

- False information/poor readings causing undue stress
- Is it dangerous for baby
- The same concerns with home Dopplers right now. User error leading to undue anxiety or sense of security.
- The security and privacy of my medical information and my baby's medical information. Additionally, any adverse effects of using monitoring of that sort more frequently

Using these examples, it can be discerned that the respondents answered more decisively that the information given, which might be caused due to user error, would lead to increased stress and anxiety. Also, respondents were worried about data privacy issues. This result means that the respondents emphasizes the importance of several safety aspects, such as use of data, the technology being safe to use and it being user friendly.

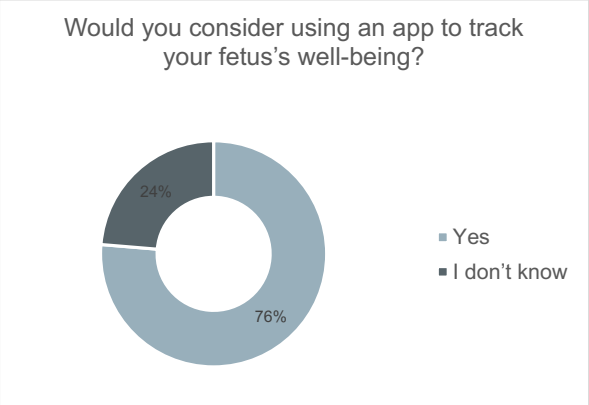

Figure 6.10: Percentage of respondents that would consider using an app to track their fetus well-being (n=38).

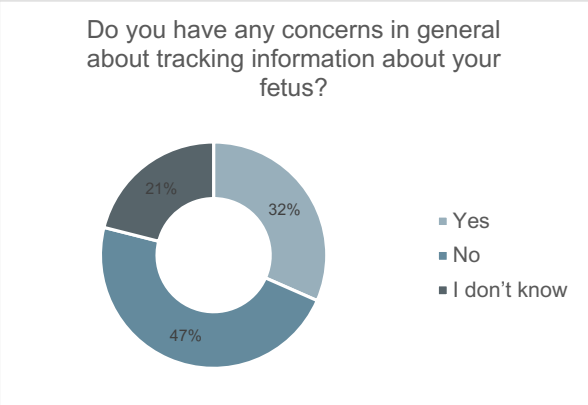

Figure 6.11: Percentage of respondents that express concerns regarding the tracking of information about their fetus (n=38).

6.2.7 Business-to-Customer Offer

Figure 6.12 shows that, 42 % (16 out of 38) of the respondents would consider paying for a service that diagnoses and informs that their fetus's heart is beating (with CTG-technology) while being at home. However, 24% (9 out of 38) respondents say they would not. Most respondents, 14 out of 38, would pay 50-100 EUR for the service, as seen in Figure 6.13, while 10 out of 38 would pay 400-600 EUR. The respondents that would not consider paying for such a service were asked motivate their answer. Some examples, cited from respondents on this question:

- Because if I was concerned about the baby enough to do that I'd want to see my obstetrician
- I think it would cause more fear and possibly unnecessary interventions
- It's unnecessary and I think would just cause stress

Using these examples, it can be discerned that the respondents answered more decisively about them thinking that such a service would cause increased stress, fear and that it might lead to more interventions. Also, some respondents emphasize the importance of personal contact with a medical professional.

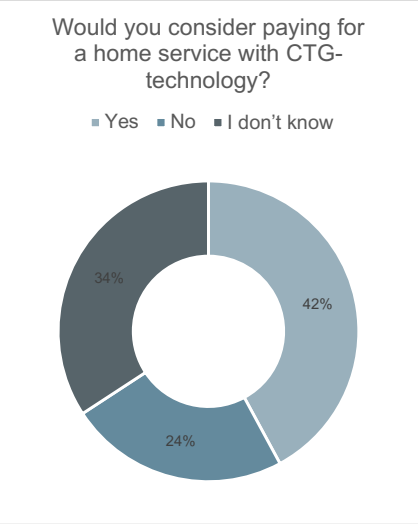

Figure 6.12: Percentage of respondents that would consider paying for CTG telemonitoring (n=38).

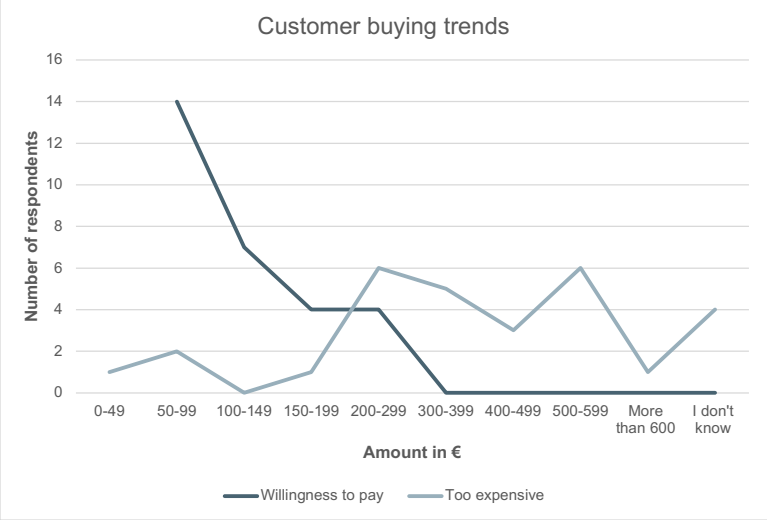

Figure 6.13: Price range that women are willing to pay is illustrated in dark blue and what they consider to be too expensive is illustrated in light blue.

6.3 Empirical Findings from Interaction with Potential End Users

In the following section, the transcribed material from interviews with potential end users is sorted into the themes the interview questions were based upon.

6.3.1 Interviewee 1

Demographic and Pregnancy Related Information
Canadian woman, between 31-35 years old, living in the city. She has been pregnant before, however not considered high-risk. CTG was included as a standard procedure in her health care without additional cost.

Unmet Need
She feels that she always gets enough information from her appointments at her medical centre, but sometimes feel general worries connected to her pregnancy. Regarding using a CTG telemonitoring app she said that "obviously I'm conflicted, during pregnancy I would love to know the heartbeat constantly, because you are always worried. But at the same time, if something were to go wrong, how much stress does that put on you when there is nothing actually wrong". However, if she would use it, it would be to alleviate stress when she does not feel any fetal movement for example. She thinks that the product would be valuable even though it would not have any clinical value, but rather just indicate that the baby is in there and well by showing the heartbeat.

Better Than Current Solution
The technology seems familiar to the fetal monitoring used by her midwife during her pregnancy and delivery. She has no concerns in general about tracking information about her fetus. She would consider using an app to track her fetus's well-being, but the cost of it would be a critical factor. Due to this, she would not consider paying for a CTG telemonitoring app, because she is not used to paying for healthcare as she lives in Canada.

However, given the pandemic, she would prefer to do CTG monitoring from home as it is more convenient and you are not exposed to any risks. However, if disregarding the pandemic, she would still prefer to do the monitoring at home but it would not make as much of a difference to have to go to her midwife. It is not the typical hospital setting and is located close by to where she lives. However, she does not think that there is any value lost if the monitoring is done from home instead.

Effective Solution
If she had the app, she would like to use it multiple times a day just to be sure, using it in a proactive way. She does not believe that using the app would create any additional connection to her baby, but the

value of it would be to reduce stress. The ability to speak to a medical professional immediately would have to be a part of the app. However, having a nurse on a call, without them being able to see the monitoring results, would not give any value.

She would not consider paying for a CTG telemonitoring app, as she has the free ability to go to her check ups and are with that. However, her health level would affect her decision, if she would go to a check up and there were concerns then she would probably pay for the service. A reasonable price in that case would not be more than around 70 euros probably.

Business-to-Customer Offer
She does not know if she would consider taking any active care choices based on information from other sources than her medical professional. She would, however, definitely use a CTG telemonitoring app if she was offered to do it through her midwife and would then like to monitor daily. All medical professionals in her area takes additional information, from smart watches and other devices, so she thinks that they would use the data collected through the app even though it was not associated to her regular care. In that case, she thinks that the monitoring app would be of value. Her choice on using the app would be based on what her midwife recommends.

6.3.2 Interviewee 2

Demographic and Pregnancy Related Information
American women, between 31-35 years old, living in the city. She has not been pregnant before but is trying to conceive. She is not sure if she has heard about CTG before.

Unmet Need
Imagines that she would feel that she gets enough information from her appointments at her medical centre but that she would sometimes feel general worries connected to her pregnancy. However, she can definitely see people become paranoid and overly use this product. A first pregnancy is stressful, so she can imagine that lack of movement for example, would trigger overuse of the product. ”This could make a person go crazy or feel better, it depends on how that person using the product is”. She herself thinks that she would use it outside the recommended use, as an extra precaution. However, she said that “I don’t think you need technology to feel connection to your baby”.

Better Than Current Solution
She would consider using an app to track her fetus’s well-being and has no concerns in general about tracking information about her fetus. Therefore, she would consider paying for an CTG telemonitoring app. However, if her pregnancy was not considered high-risk, she would not be willing to pay too much for the solution.

She thinks that a CTG telemonitoring app would be great for people that does not have easy access to a a medical office due to distance. ”There need to be access for everyone equally”. Also, she sees value in the product during conditions like the pandemic. If it would for some reason be necessary to monitor often, she would want to do it from home. She does not want to travel to her doctors office as it is very disrupting of work, if the information she is getting would be the same by using a CTG telemonitoring app.

Effective Solution
She has a positive attitude towards a CTG telemonitoring app saying “I would probably feel reassurance that you have a professional set of eyes that can look at it immediately”. She would be willing to pay 100-150 euros for the solution, but does not think that it would be worth more than 500 euros.

If the data collected through the app was connected to her ordinary medical team it would be preferred and super helpful. She does not want to have to be the person having to bring information to her doctor. Having different teams feeding her information that she does not know what to do about, would be stressful. If the technology had no clinical value, she would not pay for the service if it is not going to be helpful to her doctor or give the doctor information they would use. If it would just give her information, she is not going to look at the data, because people have been fine without it before.

Business-to-Customer Offer
She would only consider taking any active care choice based on information from sources and people she trusts, but that does not necessarily have to be her doctor or midwife. She could see herself using a CTG telemonitoring app after hearing from others that used it. This would be true even if her midwife thought it was unnecessary, as it would only be a personal opinion. Then, she would think it would be worth paying for the app, even thought it would be used only as a extra precaution or enable her to not

have to go to the doctors office for the checkups. However, if it was offered or recommended through the midwife, it would be an extra reassurance that the product seems legit which would affect her.

6.3.3 Interviewee 3

Demographic and Pregnancy Related Information
American women, between 31-35 years old, living in the city. She has been pregnant before, however not considered high-risk. CTG was included as a standard procedure in her health care for an additional cost.

Unmet Need
She feels that she gets enough information from her appointments at her medical centre. She sometimes feel worries connected to her pregnancy due to her having had anterior placentas, so she does not normally feel much movement. She thinks that getting too much information during your pregnancy would be more stressful and trigger the feeling of needing to monitor all the time. During her latest pregnancy, she had access to a Doppler device at home, and did not use it, so she thinks that she would not feel the need to use this solution, if her midwife would be of the opinion that it would be unnecessary. However, if she for some reason had to monitor more often, she would prefer to do it from home. Then it would be useful if they taught how to use and put on the device at the doctors office, and having the option to go in to the doctors office if something was not work accordingly in the beginning.

"Especially because I have other children, it is a lot harder for me to go in to the doctors office. So depending on the price, it would be really nice to monitor from home and not have to go in to the hospital". However, she wants the results to be a part of her ordinary medical care. "If someone can't see your whole story and know all your medical information, like your doctor or midwife does, I feel like it's not necessarily as useful if they can't say what is in my range of normal".

Better Than Current Solution
Her doctor had a hard time placing the CTG device during her latest labour, due to her having anterior placenta. Therefore, she sees the risk of experiencing problem to place the monitor correctly on her own. She also thinks the solution looks super expensive. She is also of the opinion that people have been fine without monitoring their babies, so she does think that monitoring can feel a bit unnecessary and extensive. She does not believe that she would catch anything using a CTG telemonitoring app, that they would not catch at her regular appointments.

She had some telehealth visits during her last pregnancy due to the pandemic, because of this her doctors could not identify that her baby was breech. Therefore, she thinks there are information that they can find out at an appointment, that they can not do with a telemonitoring solution. Also, she thinks placement would be difficult if the baby is breech, which would cause unnecessary stress. It would be useful if a doctor could help with placement of the device, but then it feels like they are often stressed.

Effective Solution
She would consider using an app to track her fetus's well-being but would not be willing to pay for an CTG telemonitoring app. She thinks it would be unnecessary and rather cause stress. She believes that too much information can be worrying, and that there is a risk that you start to see patterns where there are not any.

However, if she would use a CTG telemonitoring app, she thinks it would be a hazzle to start using it. Nevertheless, when she would start getting the data or if she was worried for another reason, like when her baby was breech, there could be a risk of her overusing the product. She would like the CTG telemonitoring app to be connected with her regular health care and a part of her regular checkups.

If the product had no clinical value, "for me, finding the time to monitor, I think would be really hard" and "even if people were telling me that this is within the range of normal, if I had all the data, I would start looking at the data and start overanalyzing it, even though they told me everything was fine".

Business-to-Customer Offer
She would trust her midwife's opinion on the technology, because of her professional experience. If her midwife would like her to use the device, she thinks she would do it, otherwise she would not.

6.3.4 Interviewee 4

Demographic and Pregnancy Related Information
American women, between 36-40 years old, living in the city. She has been pregnant before, which was considered high-risk due to advanced maternal age. She does not believe that she has heard about CTG before.

Unmet Need
She thinks that she gets enough information at her appointments at the medical centre, but that it does seem lacking as there is not much information given. She is of the opinion that you only get to hear the heartbeat and that the time between appointments are quite long. She felt worries sometimes connected to her pregnancy, as she did not have a way to monitor her baby other than counting kicks. She thinks it is easy for your mind to jump to worst case scenarios when you do not have any proof to quiet it. "The only way to monitor when you go home is kick counts and as a first time mom, and I had advanced maternal age, it is kind of stressful". The idea to potentially monitor and know that everything is okay between doctors visits would be really nice, she thinks.

Better Than Current Solution
She does have concerns about tracking information about her fetus, saying "my only concern with it is that it will make anxiety worse if you don't know how to interpret the information you get". She also have concerns about standard privacy and data sharing.

However, she said that "I would much rather monitor from home, I have a two-year-old and it is not easy to take him into doctors appointments. So 100% being able to do it from home, not having to drive, not having to arrange childcare or take him with me, not having to sit in a doctors office on a daily or weekly or whatever basis, its just gets to be a lot if you have to go in to the doctors office for something so routine as that"

She would not miss the personal contact at the doctors office if monitoring from home and could see it go very well together with a telehealth solution. Maybe not every visit have to be at home but if you could do it with a telehealth visit, so additional questions could be asked, then it would be great to combine with your regular visits. Today she thinks that some of the appointment just seems silly to have in person, as you come in every week at the end of your pregnancy and the appointments lasts for about five minutes.

Effective Solution
If the device gives additional information, things she does not get at her doctors office, or if she can get information more frequently, then using a CTG telemonitoring app would be beneficial. This is true even if it would not be connected to her regular care. However, she would not be interested if the device had no clinical value, as she did not even do the extra ultrasounds that is offered today.

Nevertheless, she would consider paying for an CTG telemonitoring app, but the cost of it would be a critical factor and also if her pregnancy was considered to be high-risk. "Now that I have experienced a pregnancy, I might be less likely to pay for this service, unless I had factors that made my pregnancy a higher risk than just advanced maternal age". She would be willing to pay 100-150 euros for the solution, but does not think it would be worth more than 200 euros, unless she had a very serious complication and monitoring from home would prevent hospital stay or bed rest.

She would mostly like to use the product in moments of wanting reassurance, which was pretty often during her previous pregnancy. If she had the product, she would like to use it a couple of times a week at a minimum. Personally, she sees the risk for overuse of the product, unless there was a particular reason for it to only be used in specific interval, like if it was harmful to use too often. Then she would do it in those specific intervals and whenever she felt that she needed reassurance.

Business-to-Customer Offer
She would consider taking active care choices based on information from other sources than her medical professional, depending on what it was and what their experience/credentials were and if there was any research to support the opinion.

If the solution was offered through her doctors office and they felt it was a device she should need at home, if she could use it instead of bed rest or would not need to go to the hospital for example, she would definitely use it. She thinks that anytime your doctor recommends something you look at it more seriously than if it is offered through a private company. Nevertheless, if it would help her feel better, she thinks it would be worth a certain amount of money even though it was not offered through her doctors office but by a private company.

However, she says that "my midwife discouraging me to use a CTG telemonitoring app would not affect me, there are a lot of things we do that is not considered necessary but just because we find them helpful. It would just be a cost versus benefit decision for us". She could also see herself wanting to start using a CTG telemonitoring app just because others start using it, depending on their experience of it. Her

decision would be influenced by friends and their experience of the product but she would, however, also do her own research.

6.3.5 Interviewee 5

Demographic and Pregnancy Related Information
Swedish women, between 36-40 years old, living in the city. She has been pregnant before, however not considered high-risk, and is currently trying to conceive. She has heard about CTG before but it was neither included or offered as a service with an additional cost to her during her last pregnancy.

Unmet Need
She thinks that she most of the time gets enough information from her appointments at the medical centre, but that there are few ultrasounds and CTGs. She felt worried sometimes during her pregnancy, due to the amount of weeks between ultrasounds and getting to listen to the fetus's heartbeat. She would consider using an app to track her fetus's well-being but is not sure if she is concerned about tracking information about her fetus. She would like to use a CTG telemonitoring app if she was feeling worried or stressed for some reason. Then she would use it to get reassurance.

Better Than Current Solution
She thinks that this type of monitoring could easily be overused or used in the wrong way, resulting in unwanted effects or an increased strain on the health care system. She also sees the risk that the technology could lead to more anxiety rather than reducing it for women, and see herself might feeling this way. However, she would like to monitor from home, as it would be less stressful to do it in the home setting than at the hospital. In addition, it would be beneficial to not have to go to the hospital, as it would also reduce the stress around the monitoring session.

Effective Solution
If she had a CTG telemonitoring app, she would like to use it regularly. It would be good if there was a schedule on how often you should use the device. If it was free to use it depending on your own feelings, she thinks that the risk of overuse would increase, as she thinks you would start to interpret your feelings, wanting to monitor all the time. She thinks that it would be possible to stick to such a schedule, when thinking of herself.

She would be interested in the product even though the monitoring was not connected to her regular care. She would be interested to monitor, just for the case of monitoring, but also if there was a risk for some type of complication. However, she is not sure if she would consider paying for an CTG telemonitoring app, but if she would she thinks that 50-100 euros would be a reasonable price. She would not pay more than 200 euros for it.

Business-to-Customer Offer
She thinks that if you would to try a CTG telemonitoring app it would have to be offered under controlled conditions, not for everyone being able to order it themselves. It should be a device that women with high-risk pregnancies could have at home, but not a device that everyone should use.

She would not consider paying for a CTG telemonitoring app that was offered through a private company, mostly connected to the probably high price of the product, but rather if it was offered by her medical professional. She would however, consider paying for this solution if it was offered for an additional cost through her health care. Her midwife's personal opinion about the technology would not affect her interest in the product. Also, she would be interested in the product if it would become popular, but not if it was still quite unestablished on the market. She would like to read both research and user reviews on the product before purchasing it herself.

6.4 Empirical Findings from Interaction with the Industry

The following section is an interview with a technology company that offers a remote CTG monitoring service.

6.4.1 About CTG and Comparison to Other Technologies

The product was co-developed with university students that was mainly developed for home use in mind and not for hospital use. It is a light weight product that can be carried around and used anywhere. With this solution, the hardware itself is not the most cost effective, it is the need of an online server that is fully data protected with interoperability to other systems that are most costly. The system is offered to patients by hospitals and midwifes. It is a technology company, not a medical company, so the

company never provide interpretation of the data only the technology. However, technically, this could be set up with the existing product.

Compared to fetal ECG, CTG currently still the more proven and favored method in the market which is an advantage at the moment. A difference between CTG or fetal ECG with 3D-ultrasound is that when using the ultrasound, the mother receives a picture of her baby. With CTG you just have a graph and for a patient that is not something of value in most cases. This is affecting the sense of value these technologies.

The criticism that has been directed towards CTG would be a threat if it goes in the direction that no clinical value of CTG can be seen. If this would become widely accepted , they would have a product that would be of no use. However, this is not something they see threatening their business in the next 2-3 years. This could be the case in the longer term but in the medical area, new technologies take a long time to get introduced or adopted. That means that even CTG would be criticized, it would probably take another 5-10 years before that would be accepted.

Computerized CTG
As a company, they are paying attention to computerized CTG, both looking at it themselves but also at others algorithms that could maybe be used. However, when implementing algorithms into a device it becomes another CE classification and the perspective of the doctor changes, which are challenging. Today, when doctors and midwifes are using the system, they have to interpret the data themselves. There are risk in implementing algorithms as this can create a sense of trust that may not be valid, resulting in some abnormalities being undetected. That is the biggest risk in going into the current algorithms. In addition, the CTG for a baby is completely different during the time before labour and during labour, differences that the algorithm need to know. Nevertheless, algorithms will come in the next years and some will be implemented in the existing product, but if it is the holy grail is not for certain.

6.4.2 Strategic Challenges

There are always potential risks related to expansion. ”The biggest risk i see is loose of focus and you just end up doing nothing everywhere”. Another risk is over-investment as well as trusting and demanding on one product as you become more vulnerable if something were to go wrong. At the other end, if you are a good and healthy company, you are making money off it right now. So risks exists, but they are not seen as so big that it should not be done.

One of the challenges of changing business model, from B2B to B2C, for medical products is the pricing model. For these types of products, the question of who would pay for the product is not as easy as for regular consumer goods. In Sweden and in the Netherlands, among other countries, a lot of things is reimbursed that would have to be paid for by the patient directly if it was a consumer product. In some countries, like the United Arab Emirates, they are completely used to select a care package and paying before receiving care. Also, in a hospital in Ukraine using the current system, it is offered as a luxurious product that can be afforded by wealthy women only.

Developing and changing reimbursement models is a slow process. In countries where patients are used to pay for care, they can as easily choose to pay remote monitoring as to pay for a hospital room. However, in countries like Sweden and the Netherlands where insurance companies pay, the lack of reimbursement models for connected medical devices is a barrier. Also, in these countries, it is a difference in the patient never being in direct contact with their insurance company when wanting to do active care choices, but rather with the hospital. As a patient you need to ask your hospital about care choices and the hospital gets reimbursed by the insurance company.

As long as there is a demand from consumers, there is a market for all business models. For this current system, there is almost no model that is completely the same between different countries. This indicates that there is room for many different business models, but that it will be a push and pull of different models. Suppliers will try to force some models that have worked in other countries, and at the other end the mass might demand for something, which companies will need to try to adapt to and offer. This is not true for all markets, such as the Hungarian market, and would not work with the current system in countries were the average income is so low, making it hard to sell the service from a pricing perspective if still wanting to maintain the same quality.

The lack of government really interacting with the industry is something that is missing in a lot of

countries. In a lot of times, governments does not possess knowledge about the industry, although the pandemic has changed this to some extent because governments have been forced to listen to different people to overcome the pandemic. Health care is slow, but governments are even slower. So if governments could be more involved with networks within the industry and work together with the industry, that could be an advantage over other countries. Such a change has been seen Germany for example, which has been way behind with their eHealth strategy for many years. The last two years, they changed laws making it mandatory for every hospital to have implemented at least one eHealth project within a year, otherwise they will be cut on budget. This is an example of an evolvement of a government that is changing the German market so fast right now and that can be done technically in any country. Another example is the merging of regions in Sweden.

Home Base Market

The home market is the natural habitat, meaning that you do not have to think about the right way to interact with, for example, a doctor. When entering a new market, in another country, these things have to be considered. Germany, for example, is very hierarchical, which means there is still a specific way in talking to someone that is higher in rang. Thus, you can easy insult someone by not paying attention to those rules. On the contrary, in the Netherlands, it is common that you pass by someone if it does not go fast enough. Different ways of doing things is important, having native employees being an important aspect, that knows how to get around. This shows by the fact that the company tried to enter the German market a couple of years ago, not succeeding. They are now trying again, seeing a complete change in their strategy, now having a native German doing the sales, seeing it go much more easily to find the right tone and attitude. They really try to work with country specific targets and approaches right now. Differences between countries needs to be solved, that the company working with country teams to do that is a good thing about their approach at the moment. However, it is a huge investment, but it is a necessary investment.

In the Netherlands, there is a big community of companies helping each other within the same industry. Within this community, competitors sometimes share for example what worked well and what did not in other countries. They know it might be unfavorable to them in the future, but the belief is that their competitors will share useful information in return, making it worth the risk. There are also many country specific networks that can help companies get into a county. As a company, you have to be open to these types of networks, and sometime be willing to pay to be get into those networks.

The strong home care setting in the Netherlands has helped the implementation of the current system, as people do not have to first be convinced that home care is safe, which might be the case in other countries. However, their fair market share today is because they have developed the system for ten years in the Dutch market. In the beginning, the company also had difficulties getting the first ones using the product, only around five hospitals where doing it themselves already. The Dutch market has not been and is not easier than other markets. In this context, the pandemic, has made a big change in all of Europe, because everyone has now somewhat adopted home care as just as good or sometimes even better. However, the pandemic has also been challenging for the company. They are not allowed to go into hospitals to talk to people and hospitals do not have time to start up other project because of Covid-19. However, the interest for the product and the number of hospitals wants to will start implementing the technology as soon as the pandemic is over, is about five times more than before. During the pandemic, the company has made the product available for free for all hospitals in Europe that have had pregnant patients with Covid-19. This has helped hospitals to try the product, so the interest has grown big of hospitals that now see that they can do this, that have tested it, and that now have experience with it.

The acceptance for this technology in hospitals in the Netherlands is the same as in other countries, they all expect the same. However, a difference between Dutch hospitals, compared to other countries, is because they are fairly near to each other and speak the same language which makes it easier contact others about their experiences. It is common to have former colleagues at other hospitals which makes it easy to share experiences, which they see is a common channel for these types of technologies. This is something that is harder to exploit when trying to enter a new market or hospital, as they might not know of any colleagues that has experience of the technology.

The regulatory setting in the Netherlands is very strong, which makes it more difficult to start with a new product. However, once it is accomplished, there is an advantage towards other countries because the worst has probably already been seen. For example, in Israel, there are not a lot of rules and regulations which makes it easy start with a product, that is why many new and promising techniques come from

Israel. However, when these companies try to get into the European market, they almost always have to team up with the European country to make sure that they are compliant with rules and regulations they have never seen before. This results in many of these companies dropping off again, instead going straight to the USA market because they can reach a larger market with the same investments. Thus, the Dutch market is tough but by developing in that climate and the government helping, promoting, and also financially supporting companies to do so, creates a good environment for the development of these types of technologies.

Products are being developed, CE certified and clinically validated in connection to academia and university hospitals. Also, when trying to implement new features, the company always collaborate with university hospitals and academia hospitals. In addition, when trying to enter new countries, the company tries to find the biggest university hospitals to implement the product. University hospitals have room, money and are obligated to develop for research purposes. In addtion, they do not always have to comply to all the rules and regulations within a country immediately, that a region hospital would. complying fully as long as the patients give consent that they know that this is happening. This can be helpful when trying to enter a new market.

Entering a New Market
Challenges like data protection is tough and demands a lot of work. However, requirements connected to areas like this is easy to access and clearly written down. Therefore, a company can in a couple of months comply to all the rules and regulations if they want to, even though it will probably cost them some money. However, the biggest challenges when trying to enter a new market is reimbursement and getting a financial business case in a market. Finding a reimbursement model and first customers is a lot more difficult in a new country. The most costly area is to find ways to comply with rules and regulations, as it is the most expensive part of the product. For a lot of companies the high cost is an issue, but it is technically not difficult. Nevertheless, for start-up companies and other new companies, this is difficult and will become more difficult, if they are not funded well from the beginning. So, a small company with a limited budget, wont be able to launch a new product into the market because of this.

Between countries there are also other differences in the health care sector. For example, there is a big difference in mentality between the Netherlands and the USA connected to legal claiming. In the Netherlands, claims are almost never left if something goes wrong. While in the US, a hospital that wants to start with home monitoring have to take a big risk of legal claims, resulting in many not wanting to do it but does not stop all. The same thing is developing in the UK, because the claim culture is starting to get really high there as well.

6.4.3 Competitive Advantage
One of the company's internal comparative advantage is that, by having set up county teams and not focusing on the whole world but picking a few countries they think is interesting, they can do a more focused job. It gives the opportunity to dive into the rules and regulations of each of those countries, to try to find what the right model is in those markets. Other companies often have one business developer, that works for all countries, which makes it more difficult to succeed. If not paying attention to market and cultural differences, it is hard to make it work.

6.4.4 Competition
The company does not experience big competition on the market today. Also, they have a few advantages, one being them having more experience in home monitoring of pregnant women, maybe even of other types of eHealth, than any company out there. Most companies are five years old at a maximum. In addition, them being fully compliant with EU rules and regulations plus the USA rules, which can only be matched by a few companies. Also, they have always tried to have a high service grade. Any customer can reach the company on mobile phones, any time of day. So a competitor would first need to learn the market, need a product that is fully compliant, and then still need a better proposition. Therefore, the company is not afraid of competitors today. However, they do think competitors will come and take a market share, especially those that come from consumer industries, in a couple of years. A device that would cost a few hundred dollars, that can be bought at any supermarket or pharmacy, would might be a real competitor. However, if looking at the hospitals, they will not use another product as their standard of care product, as they will still look for a well tested, clinically validated product that has a proven track record. For the next 2-3 years the company thinks it will not have to worry about competition, then competition will probably be fierce because a lot of companies can be seen coming into this market right now.

6.4.5 Future Demand

The company is not sure if they can foresee another need in the future. However, they see a change. Today, the product is purely advised through a medical perspective, and pregnant women would probably have to be hospitalized or be overseen by gynecologist before getting into the area of being monitored. Many products within health care are becoming consumer products, so there is a ongoing discussion with companies within the industry if they should focus their sales and marketing more towards the consumer than towards the hospitals. However, this will be a slow change that will go faster in some countries than in others. Today, the use of connected devices, such are smart watches, are used to monitor blood pressure for example, which is a change that will come for other medical technologies as well.

The expanding digitization within consumer goods is a positive effect from another industry, helping these types of products as well. Everyone that is pregnant right now knows how to use a smartphone, there will be a few exceptions but they will be minimum, because everyone have a smartphone, is not afraid to try new stuff, so consumer electronics is another industry that helps the medical industry a lot.

If the product would be offered to women that does not have what would be considered as high-risk pregnancy, it would be a luxurious or add-on product. It will mean medicalization of pregnancies and the risk of women being more worried, calling their doctor even when there is nothing wrong, that is what most doctors are afraid of. However, as a company, if looking at revenues and sales, this model is everything than worrying. However, in both the Dutch and Scandinavian market, people are a lot more critical on these types of developments than in other countries, where whatever you can buy you can get. In the long term, the power of the mass will probably change the use of these types of product, but for now, at least in the western European countries, hospitals and the care systems still have a quite big voice in what is accepted and not.

6.5 Empirical Findings from Interaction with Distributor

The following section is an interview with a Scandinavian distributor for a company offering a product that monitors the baby's pulse and oxygen level.

6.5.1 About the Technology and Comparison to Other Technologies

The product measures the baby's pulse and oxygen level, together with sleeping trends. If the results deviates from the predetermined safety zone, a connected app gives out an alert indicating that something might be wrong. With its technology, the product breaks a pattern from earlier products existing on the market. It is not a medical device, neither does it takes the same responsibility or claims to be one. The product has to be connected to Wi-Fi to be able to work. The distributor indicates that this is a factor that might make some customers decide not to buy the product as it can not be used as they would like to. However, the product is intended to be used in the home setting and can not be used with mobile network. Thus, users can not utilize the product when being out for a walk for example. Some customers have expressed a demand that the product would be able to connect to a mobile network. There is no recommendation regarding how often the product should be used, it is up to the user to use the product as often as wished.

The distributor claims that current products on the market uses other types of technologies and does not really say anything about how the baby is feeling, only showing how it looks and possibly how it moves. In comparison, this product actually let parents know how their baby is feeling.

The company developing the product spends a lot of resources on data. They anonymize and save data that is used to develop their products, not only looking at the current situation but also to forecast the risks for a baby in the coming days or weeks. The amount of data they have is large and is growing by the hour. Users approves the use of their data, however, the approval is not required to be able to use the product.

6.5.2 Strategic Challenges

The company developing the product has a global approach which is costly. Thus, the distributor thinks that being well funded is a critical factor in implementing this type of product. As a company in this industry, it is also important to have the right set of employees and to keep exploring and developing new and current products.

The fact that the product is not a medical device makes it easier to implement on the consumer market in terms of responsibility, sales and quality control. However, it does close some doors as the product can

not be sold to for example hospitals, as some customers within the segment does not accept a product that is not a medical product. Nevertheless, the product has to be compliant with some rules and regulations as it collects data for example. The distributor thinks that challenges connected to GDPR is probably why it took some time for the company to establish in Europe.

The distributor states that there are big differences in how customers act between the Scandinavian countries. The biggest difference is how quickly markets accept and adopt new products. This also differs between different cities within countries. Between countries, there are also variations in available sales channels and in the competitive environment. The distributor thinks that these differences mainly exist due to a variation in acceptance for new technologies.

6.5.3 Users and Value Proposition

The distributor thinks that the compelling reason to buy this product is the feeling of security. The company does not sell their product on parents worries. The company has done their own studies about what need they fulfill with their product, to see if it is parents worries that are reduced by using the product. These studies showed that parents are rather talking about the product giving them safety, and not talking about their worries. Parents who use the product feel more safe and sleeps better at night as the product gives a deeper understanding of how the baby is feeling. However, the distributor thinks it is hard to talk about the product without bringing up worries.

The distributor thinks that the biggest value of the products is that it gives the user knowledge. Instead of depending on their feelings, parents can see how their baby is actually feeling. However, the distributor do not think that the typical user look at the information given by the product, but only if it indicates that everything is okay or not.

The typical user of this product is first-time parents. As it is a premium product, which is relatively expensive, income is a factor that affects and defines the typical user. Also, the distributor says that income is in most cases conceited to age. ”Young parents typically do not have that much money to spend, but if you are 35 years old or so you might have another ability to pay. Also, where people live is in many cases related to differences in income, resulting in the product being adopted differently in different parts of the country, cities being dominant.

Most users do not question or reflect upon the product not being a medical device. However, it is an issue for some retailers, such as hospitals and some pharmacies, that have other requirements on their products resulting in them not wanting to sell a non medical product.

The distributor states that before users know what their needs are and how they want to use the product, they think that they want to use it all the time, which is not necessary. Parents, before having a baby, wants to maximize the products potential area of use, resulting in them wanting to do as much as possible as often as possible with it. However, when user have access to the product they no longer want to use it all the time, then the need is not the same anymore. Probably, there are some users that would like to use the product most of the time, but they are not the majority. The distributor states that most users are satisfied to use the product as intended, when the baby is asleep.

6.5.4 Competition and Future Demand

The distributor claims that right now the company is the biggest and strongest in their offer of this type of product and that it is the company that puts most resources on product development. There are some competing technologies, on the Scandinavian market being one competing brand that tries to do almost the same thing but does not use quite the same technology measuring in a different way. However, the distributor thinks that the existing competing solutions for this product is almost non existing.

The distributor thinks that there is huge demand from parents in the ability of knowing instead of believing, thinking and guessing that will continue to grow in the future. ”The amount of money consumers are willing to spend on these types of products is large, it has only begun, so competition will definitely come but it will take some time”. However, the distributor does not see competition necessarily as being something negative. All of their other brands have strong competitors and it is easier to open up a market where it already exist a understanding for the product, which is not the case with this product. Thus, the distributor thinks that competition is rather something positive. From the companies point of view, the distributor still sees possibles connected to increased competition, as in most cases it is a sign that a product segment is growing. Even thought competition might lower the price, the market will

expand making it possible to increase the sales volume. As soon as the brand awareness has increased, the distributor thinks that the product will face a future with strong competing solutions probably.

The distributor thinks that medical companies face the decision on whether or not to strictly stay in the medical industry or if they should enter the consumer market. The decision depends on how big the revenues are of their medical products and if they can stay competitive. The distributor thinks that private IT companies will realize that this is a market, together with all tech markets that includes monitoring for an increased understanding, that will explode.

6.6 Empirical Findings from Interaction with Medical Professionals

The following section is an interview with a gynaecologist and an obstetrician-medic that have been a part of the implementation of a remote CTG monitoring service at the medical centre they are working.

6.6.1 Current Solution

The remote CTG monitoring service has been used under antenatal care at the medical centre for many years and it has now become a standard part of family-oriented care for the obstetrics department. Also, its use has increased rapidly during the pandemic.

However, there are strong requirements to be able to participate in the program and women are screened based on different parameters. The service if offered to pregnant women with a medical indication, that may have complications and need to be monitored closely. However, the participants needs to be able to come to the hospital by their own means of transportation within 30 minutes, to be admitted to the program.

Pregnant women, participating in the program, can record daily heart videos at home that are viewed by doctors and obstetricians at the medical centre. Contact via telephone is held between the medical centre and the women, when the monitoring should be performed. This means that the medical centre knows they should look at the data within an hour or so, as they get an alert every time someone has performed the CTG. The data is sent to a secure online portal, allowing a gynaecologist or obstetrician to review the data in real-time or in the time nearby. When the results have been reviewed, feedback is sent to back to the patient.

If the monitoring does not work for some reason, the women needs to go into the hospital that day to perform the monitoring instead. The medical centre seems to be relatively flexible and have close contact to the women participating in the program. However, they are not of the opinion that woman finds it hard to learn how to use the device by herself for the first time. Participating in the program is voluntary and anyone that feels insecure about using the monitoring device can be taken off the program and do it at the hospital. The system seems to be relatively flexible. Today, because of the close contact between the medical centre and pregnant women, there are no cases of overuse of the product. The medical center is alerted when someone has done the CTG, thus, also if it is used more than once a day. If someone uses the device more often than recommended, the patient is no longer allowed to participate in the program if they do not use the device as intended. However, this is not an existing issue, and pregnant women participating in the program are happy to monitor once a day. However, if the contact between the medical centre and pregnant women would not be that thorough, they believe that the risk of misuse of the product would be greater.

6.6.2 The Future of CTG Telemonitoring

They have not noticed any increased interest in the product from pregnant women during the pandemic, even though its use has increased. The medical centre want to maintain the increased use of the system after the pandemic as well, thinking it is a good solution. They do not think there is a historical difference in women's attitude and patterns when it comes to care, them wanting to take more active care choices. They confirm that women in general have worries during their pregnancy, regarding such as lack of movement. They do think that women's existing worries are relieved by using the remote CTG monitoring service, as the use gives a sense of security and reassurance.

However, they say it is about having the right care on the right place, and everyone is looking at telemonitoring today. It is a good solution that allows pregnant women with medical indications to not need to go to the hospital everyday for check-ups. It also prevents women from being hospitalized for

longer periods. It is convenient for women that have to monitor daily, with other children at home, that do not want to come to the hospital, do not have a car or have a long distance to their medical centre. The home setting is also considered less stressful for most women. The biggest possibility with this solution is consider to mainly be the opportunity for woman to not make a hospital visit.

They consider the biggest challenge for the implementation of a remote CTG monitoring service being reimbursement. Hospitals earns more money on women being admitted to the hospital then if they use a telemonitoring solution. Today, hospital have to cover the costs of the system, which is relatively expensive, and does not get reimbursed for it. Therefore, it is more expensive for hospitals to use remote CTG monitoring, since it does not exist a tariff to the insurance companies. It costs less to offer women to do CTG at the hospital. However, women like being at home and insurance companies would earn more money on this technology being further developed. They hope for a solution to this issue and believe that this problem exist due to it being a new type of technology.

With the current solution, the hospital experience a higher failure rate than before, because of more technical problems and problems with connection. However, the system is appreciated and valued by the women using it, and works good in most cases. Further improvements and enhancements of the technology would be to fix technological issues that is experienced with current solutions. Also, they would like to have a CTG telemonitoring solution that could be used for looking on early cases as well.

Offered Through Business-to-Customer

They think the future of this technology is bright, it being used in the future and being appreciated by women. They think it would be favorable that in the future expanding the offer to women that have a long distance to a hospital. However, as professionals they are against the idea of a CTG telemonitoring solution being available to everyone, offered through a B2C model. They do not think that the product should be used by women without a medical condition, as they think there is a risk that it otherwise will create more interventions, if being offered to everyone. ”Of course there can be one or two normal pregnancies that would benefit from using it but in relation to the whole mass it is not worth it”. They think it would result in more pregnant women coming to the hospitals if women were getting answers that would make them worried if using this type of product. Also, they see a risk of patients getting false reassurance that everything is okay. When having an appointment at the hospital, other checks are done as well such as ultrasound, and the medical staff has an opportunity to meet the patient, look at her and have a talk with her. This might lead to other things being discovered that are not well. If the monitoring would be done from the home setting, performed by pregnant women on their own, they see a risk of patients not showing up to their appointments and the interaction with medical professionals would not take place. Other aspects, that medical professionals are looking at in a visit, would therefore be missed. The are of the opinion that the solution does not involve any negative effects in terms of fetal safety, however, if being offered as B2C, this would include risks.

Nevertheless, they still see that private companies will start to offer this solution in the future. However, they do think that the human connection is still important to maintain, even though it is a great technology with several positive aspects. Also, they can imagine a future where the process is more effective, Where they do not interpret the data. However, they stress the fact that they believe that the human connection will still be important for woman, having an actual professional to talk to and not just a machine saying everything is good. Today, they see that their patients really listens to their recommendations, which is an important part of the care given to pregnant women.

7

Analysis

The following chapter will present the analysis based on the empirical findings, literature review and the theoretical framework in order to answer the thesis research questions.

7.1 Diffusion of Innovations Theory

As suggested by Rogers, the attributes of a CTG telemonitoring solution, the communication channels, the characteristics of the consumers, and the social system, all contribute to the adoption rate of a CTG telemonitoring solution.

Remote versions of CTG monitors, allowing pregnant women to perform CTG in the home setting, already exist for example on the Dutch market. Thus, the technology is not totally novel but can still be argued to be unfamiliar to many markets. However, to our knowledge, existing solutions are mainly offered to pregnant women with high-risk pregnancies, in specific countries or regions, on the recommendation from their medical professional. Thus, to offer a telemonitoring solution via the B2C model and as an active care choice for all pregnant women, seems unexploited. As stated in section 4, a growing number of medical practitioners are switching to telemonitoring their patients, which includes both patient benefits but also a strong business case to be made for telemonitoring. Thus, it is likely that the benefits would be great even for a telemonitoring solution offered directly to the user, which is validated by the conducted interviews in section 6.4 and section 6.5. Even though the system is not totally new to all markets, it is still unfamiliar and unestablished in most countries and to most people, as the existing products are mainly offered to women with high-risk pregnancies.

As mentioned in section 2.1, the adoption of new products involves the management of uncertainty and risk. Thus, individuals look for information to reduce uncertainties about the advantages and disadvantages of an innovation before taking the decision on whether to adopt or not. For example in the Netherlands, as seen in section 6.4, uncertainties and risks can be argued to be lower compared to other markets because CTG telemonitoring solutions exist. However, still only for women with some medical indication. The awareness could affect the adoption and diffusion of CTG telemonitoring offered to users directly, in a positive manner, if it would be offered as B2C.

7.1.1 Influence of the Perceived Attributes on Adoption and Use

According to Rogers, there are four perceived attributes of a CTG telemonitoring solution which influence women's adoption and use of the system. They are; relative advantages, compatibility, complexity and trialability. To identify strengths and weaknesses of the innovation using the factors that affect the rate of adoption can be advantageous when designing and implementing the marketing strategy for product commercialisation.

Relative Advantage

As mentioned in section 4.1, one of the advantages of CTG telemonitoring is increased patient satisfaction, which is confirmed by the medical professionals and company interviewed. A CTG telemonitoring solution would result in increased empowerment of users and meet the need of wanting more information, expressed in the survey and seen in section 6.5. Also, the medical professionals interviewed indicate that a CTG telemonitoring solution would lead to decreased hospitalization in the case where the use of CTG is recommended by the health care professional. Except for potential cost savings, hospitalization also includes several negative aspects presented in section 4.1.1. It is clear that the ability to monitor from home is something that is and would be appreciated by women, which is unambiguous from all of the conducted interviews, the survey and the literature review.

Other identified advantages, presented in section 4.1, are improved patient-centric care as well as reduced over-medicalization. However, contradicting to this, the medical professionals interviewed resonates that if the product would be offered to women that do not have what would be considered as a high-risk pregnancy it will lead to unnecessary medicalization of pregnancies. In addition, a CTG telemonitoring solution would result in better service for the users, as they are given more information and the care given being more individualized and potentially preventive in its nature, due to the possibility to monitor more

often and in a proactive manner, as stated in section 4.2. A CTG telemonitoring solution would also result in reduced user effort and save time as pregnant women would not have to travel to their medical centre or the hospital in order to do the monitoring. This is one of the biggest values with the solution, indicated by potential users being interviewed and participating in the survey, as well as in section 6.6. Thus, the relative advantage of not having to travel to the hospital seems to be an imperative attribute of the solution playing a big role in the adoption decision.

As stated in section 2.1, while diffusion of public health innovations is a complex process there should be a relatively straightforward association between the relative advantage and the diffusion of an innovation. Thus, the more effective an innovation is the more it should diffuse, and users understanding the effectiveness of a CTG telemonitoring solution being imperative for its diffusion. However, as indicated in section 6.3 and section 6.4, a perceived crisis like the Covid-19 pandemic could make the widespread diffusion of an innovation possible, even though evidence of its effectiveness is lacking. This is something that could be taken advantage of when introducing telemonitoring, as the pandemic has led to other widespread needs and values emerging. This is especially true for a technology where it is not enough time to fully determine its effectiveness before acting, but some previous theoretical base suggests that the innovation may be effective, as in the case of CTG telemonitoring as mentioned in section 4. Therefore, the diffusion and the association between the effectiveness of the solution does not seem to work as according to Roger in all cases, which is particularly interesting to think about. However, Rogers state that the perceived relative advantage does not have to be based on scientific evidence, but can be determined rather by other factors. The pandemic could have an accelerating effect towards a more extensive virtual care delivery model, also suggested in the interviews with potential users and the industry, which would affect the adoption of CTG telemonitoring in a positive manner. Therefore, looking ahead, it is likely that remote monitoring will be an important part of personalized care for high-risk patients but also in keeping people from visiting hospitals when it is not necessary, also indicated by the medical professionals and company interviewed. This would create a more positive look on this type of technology and enable a more widespread adoption of a CTG telemonitoring solution.

Compatibility
As stated in section 6.6 and section 6.3, women with several children find it hard to go to the doctor's office and would appreciate the option of doing monitoring in the home setting. This is one of the biggest values seen with current solutions as well as future possible solutions. Adopting a CTG telemonitoring solution does not require a huge lifestyle change, users do not have to acquire additional products to make the innovation work but can, on the contrary, use existing technologies such as their smartphone and Wi-Fi. Therefore, it can be argued that users would be able to adopt a CTG telemonitoring solution seamlessly, especially if being offered via B2B.

An important factor addressed in section 6.4 and section 6.5 is to understand current behaviors and values of potential users. If looking at currently existing behaviours that are similar to the behavior being introduced, the product has the potential of being adopted by end users. However, one of the major limitations in the diffusion of a CTG telemonitoring solution is the cost if being offered through B2C, and both section 6.2 and section 6.3 show that a norm of paying for health care or medical devices is not established in many countries. Thus, the biggest opportunities for adoption could be argued to be within countries that do have an existing structure where health care is payed for by patients, if being offered through B2C. Otherwise, for the product to be adopted it would have to become more accessible by the cost of it being decreased. Nevertheless, the interview presented in section 6.5 shows that the reluctance of paying for health care will in many countries come to change in the future, and that parents have a demand for monitoring solutions even though it would be relatively costly.

In a country like the Netherlands, this solution could be argued to be compatible with the existing environment and behaviours, even though many are not familiar with the innovation still. The technology is not novel and the use of telemonitoring is not totally unfamiliar to many users, as well as a the strong culture of health practice in the home setting as confirmed by the company interviewed. A CTG telemonitoring solution can be integrated and coexist with technologies and social patterns already in place, as indicated in section 6.4, which will have a positive effect on the adoption of the technology. However, a part of the adoption is to figure out current behaviors and values, and how they will affect the decision on how the innovation will be introduced to pregnant women. Additionally, current solutions are mainly offered to women with high-risk pregnancies, so it may not be perceived as familiar to other pregnant women. This has to be considered when deciding on the target group for this type of technology.

Complexity
A CTG telemonitoring solution might not be that intuitive for end users, due to its nature as a medical device, lowering the likelihood of it being adopted as it might be perceived as complex. This is consistent with the thought of the device being hard to place correctly, as stated in section 6.3. However, as stated in section 6.6 and section 1.1, women do not seem to have a hard time learning how to use the existing device being offered at some hospitals today. This indicates that how the solution is offered to users might have an imperative impact on the perceived complexity of the product. This implies that the product might have to be introduced through medical professionals, at least when the product is new to the market, for it to be adopted by early adopter categories if offered B2C.

Trialability
To its nature, a CTG telemonitoring solution is intended to be used during a limited time span and it can only be tested in real time, during a woman's pregnancy. Consequently, it can not be tried out to its full potential in beforehand. Therefore, it is hard to offer some kind of trial period to make it possible for potential users to test the product before committing to adopt it or not. Also, as indicated in section 6.5, there is a risk of users having an idea of their demand being greater than what the actual usage will be when having access to the product. If given a trial period, this could then affect the adoption negatively. However, this is not consistent with Rogers idea on trialability. However, if the product would be sold through B2B, hospitals could be given a trial period before committing on whether to adopt the system or not, which seems to have been successful done during the pandemic, mentioned in section 6.4. During the pandemic, the company made the product available for free for all hospitals in Europe that had pregnant patients with Covid-19. This helped hospitals try the product and the interest for the system grew.

7.1.2 Influence of Communication Channels on Adoption
As stated in section 2.1, the diffusion and use of mobile IT in health care systems is complex and the environment within which organizations are embedded has to be considered. In general, telemonitoring is a relatively new way to offer care in, thus it is perceived as unfamiliar, which creates both possibilities but also includes challenges. The perception of uncertainties and risks connected to the adoption of a CTG telemonitoring solution seems to be affected by the way it is offered to the customer, as indicated in section 6.3. Thus, it is imperative to consider which channels should be used for communicating information about the innovation, and to which members of a social system. Today, CTG telemonitoring solutions are offered to pregnant women as a recommendation from medical professionals. As seen in section 6.2 and section 6.3, women's attitudes about a CTG telemonitoring solution is affected by how it is offered and what communication channels are used. The adoption would be affected positively by the product being offered through medical professionals, as the reliability is considered being a critical factor in the decision on adoption. The interviews with potential end users show that midwifes would be a suitable or even necessary communication channel, at least when the product is novel to the market. However, as seen in section 6.5, there is potential for this type of product being offered through B2C, and that the consumer market will continue to grow in the future.

If health centers is an imperative channel for the adoption of a CTG telemonitoring solution is not clear. To inform people about an innovation and to persuade them to adopt it is distinctively different. As indicated in the conducted survey and interviews with potential end users, it is more effective to use closer links and interpersonal channels, than selecting mass media, to persuade people, at least in the early stages of implementation. Also, the target audience affect what the right communication channels will be. Thus, midwives may be a key communication channel for a CTG telemonitoring solution, and it being difficult to successfully offer it through a B2C model. However, as stated in section 6.6, there is a risk that midwives in general will not support this solution being offered to the broader mass, in lack of evidence for its effectiveness and use in normal pregnancies.

7.1.3 Influence of the Patients' Characteristics on Their Adoption
As indicated in section 6.2 and section 6.3, the relative advantages of the product are similar between women with some differences mainly connected to the pregnancy risk. It is important to think about possible differences in characteristics in a target group, for example either hospitals or pregnant women, in order to establish effective communication for fast diffusion to take place. Just because a group of people share the same profession or appear to have similar characteristics, when introduced to something they are not familiar with as a group, their similarities might be overcome by other differences they have. A critical factor of innovators or early adopters willingness to pay for a CTG telemonitoring solution

seems to be how it is offered. Also, as seen in section 6.2 and section 6.3, the medical recommendation, and not the medical value of the product, is of most importance for it being adopted for the early adopter categories. This indicates that, for the product to take off on the market, it would have to be offered through B2B or that the marketing of the product will play a critical role for the successful implementation of the product. Also, the interviews with potential users show that the importance of the product being clinically recommended is decreasing when the product has been further diffused. If the product would become popular and well known, thus adopted by more adopter categories, women would be willing to use and pay for the product, which is also in accordance to Rogers theory. If women would be able to hear about experiences from their friends and read reviews on the product, its medical value would be of less importance, which is also in accordance to the experiences found in section 6.5. Thus, for later groups of adopters, reliability can be received satisfactory from reviews, especially from people they know.

7.1.4 Influence of the Nature of the Social System on Adoption

As explained in Rogers' diffusion of innovation theory in section 2.1, the probability of women adopting a CTG telemonitoring solution is negatively influenced by a lower socioeconomic status. Also, the interview results in section 6.5, suggest that high income in connection to age is an imperative factor of the adoption of a CTG telemonitoring solution if it is being offered through B2C. This indicates that the product would benefit from being introduced on markets with high Gross Domestic Product (GDP) and Actual Individual Consumption (AIC), since the amount of high income people would be higher, which is in line with the market presence of current solutions presented in section 6.5 and section 6.4, for it to possibly be adopted directly by a large amount of end users. However, if the product would be offered through B2B, the income of end users would not be an influential factor. Instead the economic possibility of hospitals to invest in new solutions would be relevant, as it would at least initially be a costly investment.

7.2 Porter's Diamond Model

The following model will be applied partly to the Netherlands as a success country, while relating it in parallel to the USA. The discussion is partly focused on the Netherlands as an example of a country that is successful within antenatal telemonitoring with the help of CTG. Just as the criticism is lifting, mentioned in section 2.2.2, the focus of clusters that are already existing is not the most dynamic approach of finding out the perfect setting for a new cluster. However, it is an effective way of finding areas that are favourable, so that related fields can be tapped into.

7.2.1 Investigating Factor Conditions

The Netherlands have few natural factor conditions that are advantageous in terms of succeeding with a CTG home monitoring device. The device itself is not complicated to manufacture and it does not require scarce resources to do so either. However, one important natural factor is the limited geographical size of the country in combination with being densely populated, with over 500 people per km2 in 2018 (Food and Agriculture Organization and World Bank, 2018). This basic factor condition has successfully been upgraded by the nation to create an environment where there is a strong culture of communicating and sharing experiences between different hospitals. It is a condition that is valuable for an application aimed at the professional care setting, as a medical device. As mentioned by the company in section 6.4, the hospitals are physically close to each other, and they speak the same language. As a health care professional, it is therefore typical to change place of work during your career, and it is consequently common to to have former colleagues at other hospitals. This type of channel, where new technology is recommended (or advised to not be used) by professionals in the same field, is making the awareness spread of the technology on the home market more efficient, and the adoption rate will consequently be high if the technology works well. Contrarily, the USA is a geographically large country with a total population density of 36 people per km2 in 2018 (Food and Agriculture Organization and World Bank, 2018). This geographical setting requires many spread out hospitals and medical professionals. The efficiency and rate of spread of information between care settings is not comparable to the Netherlands, and they do not necessarily share the same culture of informal information sharing.

In the interview with medical professionals in section 6.6, it is moreover mentioned that one prerequisite to use the CTG telemonitoring system in their care setting is that the end user must be able to transport themselves to the hospital within 30 minutes. This requirement is opposed to seeing the best factor conditions for a home monitoring service in a country where patients have large distances from their

home to the hospital. Instead, in the Netherlands the technology fits well into a setting where the patient easily and quickly can come in to the hospital in case the device is not working properly, or if immediate intervention must be taken. The ability to quickly re-position to a hospital lowers the implementation risk and patients can be enrolled already before the system works perfectly. The aspect of responsibility must be considered if the device would be provided directly to the end user. The medical professionals, moreover states that sometimes the technology does not work as intended, and then there is not a problem other than that the patient will have to spend a few minutes on transport in order to get sufficient care. The flexibility the hospital can offer in this matter would be hard to attain with a B2C solution, since it would most likely put additional pressure on the existing care settings. Population density is a prerequisite for living close to a hospital, but also the infrastructure as a factor condition is of importance in minimizing transportation time for the patient. The population density for the Netherlands cannot be compared to the national geography of the USA. However, the country consists of many large cities, with New York city metro area population being more or less equal to the Netherlands total population. The USA consequently have the overall national advantage of geographical dense areas, as a basic factor condition when introducing the technology as a medical device within the existing health care setting. If, however, a new market would be created via the technology, where the CTG telemonitoring solution would be offered without the medical responsibility, then the aspect of close access to hospitals would not be an important factor condition. The advantage of large cities for a country is moreover emphasised in section 6.5, by the interviewee who is distributing a non-medical B2C solution. They can see that innovators and early adopters are predominantly found in urban areas. Consequently, the large cities work as both an enabler for the B2B and the B2C type of solution.

7.2.2 Investigating Demand Conditions

The Netherlands have a strong but declining home birth culture of 16,3% in 2010 (Sandall, 2015), this can be compared to the USA were home births only comprised around 1% of the total births in 2012 (MacDorman et al., 2014). The overall acceptance of home care in the Netherlands is emphasized as one reason that the adoption of telemonitoring of CTG in the hospital setting is high, according to the company mentioned in section 6.4. Since as they state: “people do not have to first be convinced that home care is safe”. The medical professionals in the Netherlands are moreover familiar with the idea of home based health care and eHealth is thus not a completely foreign way to go for antenatal care.

The company interviewee is reasoning that the Netherlands is a natural habitat for them when interacting with, for example a doctor. How they noticed the importance of a home base, when they unsuccessfully tried to approach a new market without the understanding of national differences, is an example of how the company gained competitive advantage because of a strong home base. It gave them a clear and early picture of their buyers requirements and how they should present the product to the hospitals. The same early understanding of demand would most likely be applicable for a solution that would create a new type of health care setting, such as a B2C solution. The character of the home demand is moreover according to Porter more important than the size of the home demand. Even though the company mentioned that it took 10 years for them gain such a large market share, they have had time to achieve a more sophisticated competitive advantage compared to their competitors that entered the market only a few years ago. The decision to focus on hospital solutions has moreover forced them to meet a demanding buyer pressure, and develop a product that meets the medical standards. The outsourcing of the CTG interpretations has lowered the implementation costs, since they do not offer the full solution. This however also means that they cannot satisfy a B2C demand without involving external competence.

The growing market trend in regards to the use of IoMT connected to health care systems and services presented in section 4.2.1, is not only present in the Netherlands, but globally. However, the idea moreover presented that medical professionals are not ready to utilize the data from these devices can be confirmed in the quite slow adaption rate the Dutch company experienced during their establishment in the traditional health care facilities. The increased demand from hospitals for CTG telemonitoring solutions during Covid-19 that the company reports together with the wish from women from the interviews with potential users to have some of the appointments from home is creating strong demand conditions. As mentioned in section 4.2, aging populations will put pressure on existing health care systems, and the USA is no exception. As seen in Appendix E in table E.5, the USA are seeing declining fertility rates on an average of 1,79 since the year of 2015, while life expectancy is increasing.

In combination with a growing demand of consumer-centric solutions and technology for self-monitoring, as mentioned in section 4.2.2, there is a demand for availability of active care choices from American

women. This is seen in the survey performed where only 5 out of 21 women reported that they would not consider taking any other choice of care than from their medical professional. Moreover, 76% replied that they would consider using an app to track their fetus's well-being, while none replied that they would not do so. Porter is moreover emphasizing that competitive advantage for a nation's companies is reached if the domestic buyers are demanding and pressuring, and that a nation's companies can even be a part of global trends if the country succeed in exporting their values and tastes. The USA is undoubtedly a trend-setter for sophisticated technology, with examples such as Apple, IBM and Adobe to name a few. According to McKinsey & Company (2020), China and the USA is home to most of the worlds top ranked technology companies, with heavy private-sector investments as well as large talent pools and technology sectors. The home base demand in the USA, should, according to Porter, open the door into advanced customer needs; forcing improvement, innovation and upgrading. As a consequence, if CTG telemonitoring was introduced in the USA, they could take the lead as a communicator of its value, and be able to set the scene for telemonitoring in a global context.

7.2.3 Investigating Related and Supporting Industries

When investigating the related and supporting industries in the Netherlands, the company highlights in section 6.4 that the extensive collaboration between industry actors, has helped their company getting a competitive advantage. Porter is especially emphasizing that direct cooperation among industry rivals should be limited, which is contradictory to the success the company claims that the community of companies has given them. However, this discrepancy can be explained by looking at the type of information that is shared in this community, and with whom. The company does not mention any information sharing close to their proprietary sources of advantage. Instead, they help each other in regards to more general market information, that is not today seen to create rivalry. The combination of industry collaboration and university research the company is engaging in can be classified as a cluster. When comparing, the USA has extensive established clusters in the technology industry, as mentioned by Sölvell. When Sölvell applied the model to the BioTech industry, as elaborated on in section 2.2.3, the model proved useful to identify successful clusters with factors such as immense university research, attractive international skill sets, accessible venture capital and knowledge commercialization to name a few. The BioTech industry is closely related to the MedTech industry. The criticism mentioned in section 2.2.2, that Porter is focusing on already existing clusters is consequently interesting when applying the model to the USA as a potential country of interest. Even though the research is of a different nature for the two fields, Porter still means that the competitive advantage is gained most efficiently by searching for favourable areas that are already successful, and then entering related fields, as opposed to the aim of creating a novel industry. In the light of this view, the USA, and specifically the "hot spots" in the country, such as Silicon Valley, is suitable for the determinant of related and supporting industries.

Other industry aspects that need to be taken into account are corporations that present guidelines for antenatal care. The USA has a strong reputation for their national guidelines from the ACOG and the NICHHD covering fetal monitoring. However, the lack of clear or separate instructions for antenatal CTG from these organizations does not contribute to a competitive advantage for the nation. Since no pressure is created on the solution to work in a specific way, or reach a certain level of quality. The fact that the American guidelines are used internationally does however qualify the nation to be considered as competitive in the general area of fetal monitoring, and in that way, these corporations can be considered to be of value.

7.2.4 Investigating Firm Strategy, Structure and Rivalry

The firm strategy of a company will, according to Porter, not be the same for every country. Quite the opposite, every country demands its own managerial structure. Porter explains, in his works The Competitive Advantage of Nations (M. E. Porter, 1990), how the USA is at one extreme of large pools of risk capital as well as extensive trading of public firms and a large focus on short-term results by investors. The compensation of management is moreover profoundly based on yearly bonuses directly related to individual success. He means that the USA are successful in relatively young industries, for example in software and biotechnology or in those where strong domestic rivalry is fed by equity funding of new companies, for example specialty electronics and services. Since his work was published in 1990, these are the industries and managerial practices that still define the country, and the software industry is characterized by both strong local rivals as well as heavy investments, as mentioned earlier.

The theory that nations are prone to be competitive in those activities that the inhabitants depend on, or admire, is not only true for the USA but can also be seen in the Netherlands, being the country in the

world with the largest amount of home births. As well as producing a vast amount of research in the area despite its small size, as seen in chapter 4, where many sources originates from the Netherlands. Despite Porter arguing that strong local rivals is the most crucial determinant, the company, as mentioned in section 6.4 does not experience big competition on the market today. They believe that it is partly due to their first mover advantage, and that competitors will emerge in a few years, especially within the consumer goods market. However, Porter moreover states that strong domestic competition will toughen companies to succeed on the global markets. This is an interesting aspect to mention, since the company is currently most successful in the Netherlands. It is not known if the lack of rivalry is the reason for any failed attempts and/or slow diffusion processes elsewhere. However, it could be an indication that it would not necessarily be a disadvantage for them if new companies entered the market. The company does however believe that the strong regulatory setting in the Netherlands, with rules more strict than ones defined by the EU, act as a rival in itself. The company has been forced to get very well equipped on their home market from start, producing a competitive product compliant with the Dutch rules, that has the prerequisites to be launched elsewhere in Europe.

7.2.5 Investigating Additional Determinants

One factor that has had large impact so far on the market opportunity for CTG telemonitoring solutions is the Covid-19 pandemic. During the pandemic, many hospitals realized the benefits of being able to monitor some of their patients from home. Thereby both releasing pressure on hospital beds, but also minimizing the risk of infection of the pregnant woman in the hospital setting. As described in section 6.4, the company reports that although many hospitals are too busy right now to implement a change, they are interested in investing in telemonitoring when the pandemic is over. The Covid-19 pandemic has moreover had an effect on the interviewed women. The result of the customer interaction presented in section 6.3, where women report that Covid-19 made them realize the benefits of working from home, and moreover introducing the idea of also performing some of their monitoring from home. This is most likely a development that would have taken place regardless in the future considering the introduction of smart homes, IoT and the increase of connectivity, as described in section 4.2. However, the advancement was rapidly forced by the discontinuity the pandemic provided, and the effects are thought to be here to stay.

As mentioned in section 2.2.3, the government plays an disproportionately large role in the MedTech regime compared to many other industries. Porter's Diamond Model is heavily oriented with the view of market forces. His view of the government as only a catalyst and a challenger does not fit well into how the MedTech industry is structured in many countries today. He does however emphasize the legitimate role of the government for shaping context and institutional structure. Sölvell's addition to the model, mentioned in section 2.2.3 where the clusters are seen as a system where both constructive and evolutionary forces act out, is interesting. Especially for industries where governments play a large role due to ethical reasons. If the government would not interfere directly with rules such as FDA approval, commercialisation of medical devices with lower quality standard would be the reality.

The structure of the health care system often dictated by governments, plays a crucial role in the success of telemonitoring as seen in the company interview and the literature study. The barrier of unavailability of health care records and data privacy issues could however be avoided. There are nations where governments have acted to catalyst a change towards a digitized, integrated and safe system. In Estonia, every citizen has access to their own EHR, "My eHealth", which got almost one million request per month in 2017 (Metsallik et al., 2018). The doctors are forced by law to transmit data to this record and it is moreover accessible to every medical practitioner that has a licence in Estonia. The safety and integrity is sustained by blockchain technology, and the system has been stated as one of the most ambitious e-health systems globally. In the same way is the introduction of FHIR, as described in section 4.3.2, in the USA acting as a catalyst for the allowance of third-party actors to participate in IoMT devices connected to the existing health care. The system could work as a great determinant for B2C solutions to be marketed as medical devices.

7.3 Market Opportunity Navigator

Parts of the MON will be applied in the following section in order to be able to find and categorise the different market opportunities suggested throughout the report. Firstly, the identification of markets will be applied. Thereafter, one of the opportunities will be investigated further with the use of the worksheet

related to potentials and challenges of a market opportunity. Lastly, the presented applications will be displayed based on their market potential.

7.3.1 Market Opportunity Set

The minimum viable product is a portable wireless CTG device that is connected via Bluetooth to a smartphone through an app, as mentioned in section 3.2.4. Below is an overview of the potential service solutions that could be offered, based on trends seen in the data gathering process. Application 1-3 are B2B opportunities. Application 4-6 are B2C opportunities.

- **Application 1** - Full solution with connection to EHR and possibility for healthcare professionals to see the CTG readings but also a summary of the findings from the local CTG interpretation team.
- **Application 2** - Full solution with connection to EHR and possibility for healthcare professionals to see the CTG readings but also a summary of the findings from a international CTG interpretation team.
- **Application 3** - Full solution excluding CTG interpretation, which needs to be done in-house.
- **Application 4** - Full solution with connection to EHR and possibility for end user to receive a summary of the findings from the local CTG interpretation team.
- **Application 5** - Full solution with possibility for end user to receive a summary of the findings from the local CTG interpretation team.
- **Application 6** - Non-medical solution including commercialized CTG-interpretation.

The six applications can be divided into either B2B or B2C offerings. Potential customer groups have been identified for the two different business offers based on the findings from the literature review, screening, survey and interviews with different stakeholders, as seen in Figure 7.1 and Figure 7.2

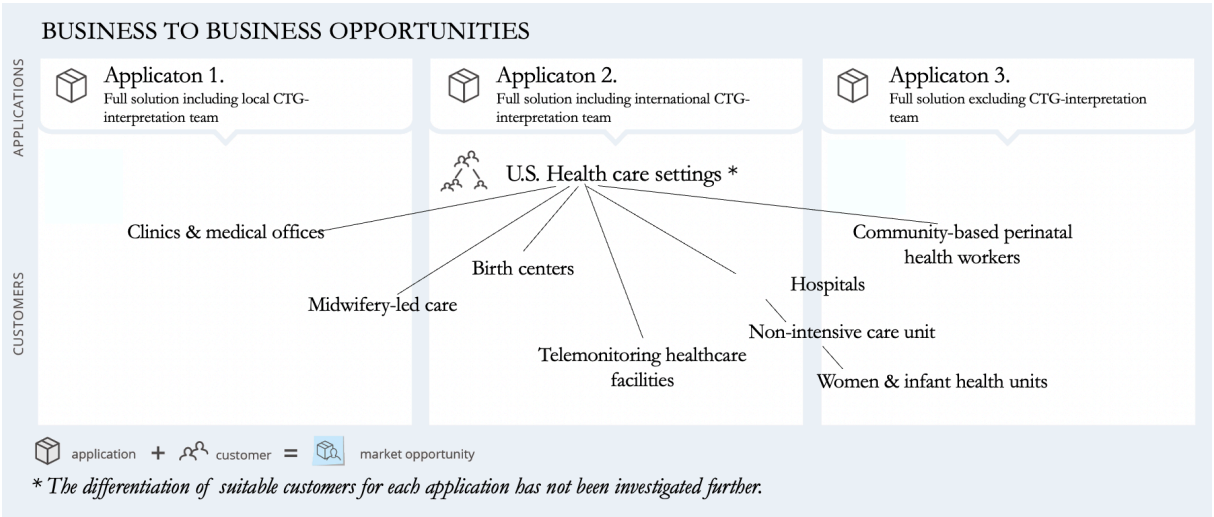

Figure 7.1: The Business-to-Business Opportunities for a CTG telemonitoring solution.

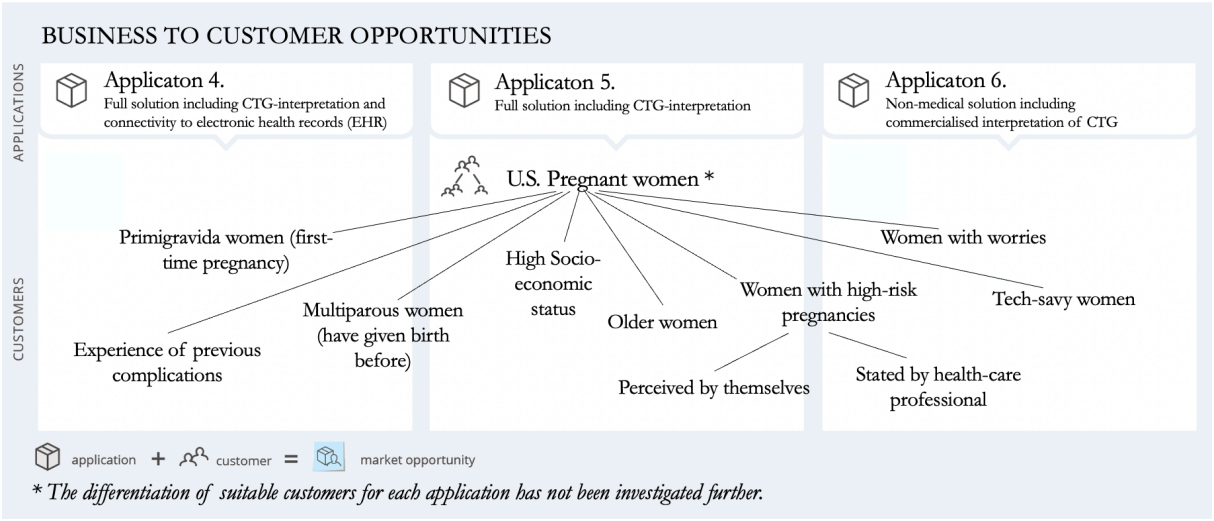

Figure 7.2: The Business-to-Business Opportunities for a CTG telemonitoring solution.

Based on the primary and secondary data collections, Application 4 will further on be analyzed, and consequently, the remaining applications will not be explained in more detail.

7.3.2 Market Opportunity Attractiveness

In the next step of the analysis based on the MON, the attractiveness of the chosen market opportunity will be evaluated. As seen in Figure 7.3, the opportunity is rated on 6 different categories. The ratings are elaborated below.

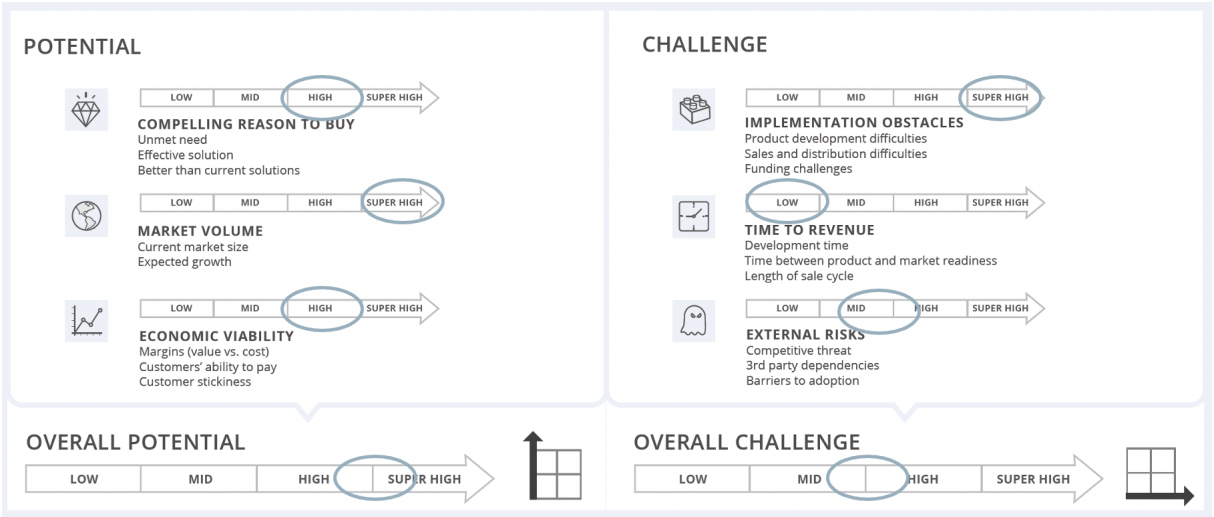

Figure 7.3: Overview of the rating for the opportunities and challenges for the market opportunity attractiveness.

The compelling reason to buy is rated to be high for this application. The strong need for reassurance from parents-to-be, and the wish for more information is an unmet need existing today, that is not close to being fulfilled by any other product on the market. Neither the Doppler's or apps that allows women to monitor fetal movement can give any detailed information, neither are they effective at stating the fetus's well-being. The application is a front-runner for predictions of patient-centric care settings integrated with connected medical devices. The introduction of a solution that originates from the professional care setting, for availability to any woman with a smartphone and Wi-Fi, is challenging the current idea that devices on the IoMT market do not have clinical value. The use of a CTG telemonitoring solution is

however not effective for all, and the issue of discrimination of black women and women with a high BMI that has existed since the introduction of CTG in the care setting is a pressing concern.

The current market volume of this application is rated to be very high. The rating is based on the fact that there are many potential customers that the product would fit well for, depending on what price it can be offered at. The expected growth of the IoMT market plays a large part in the future market volume for this solution, in combination with the increased demand in patient-centric care and connectivity in general. The predicted future shortcomings in the conventional health care setting can moreover play a large role in a scenario where patients seek care elsewhere to avoid long waiting times, and consequently increase the expected spread of this application.

The economic viability for the application is rated to be high. This rating is however stated with low confidence since it is not fully known what the price for this solution would be to maintain and offer it. It is moreover unclear how much customers would be willing to pay for the solution. The survey presented in section 6.2 shows that customers potentially are willing to pay for a CTG telemonitoring solution. Their answer on what would be a good price for it was however rather low, with the majority not wanting to pay more than around 150 EUR. In addition, 16% of the respondents would be willing to pay as much as 500-600 EUR as a maximum price for a good quality service. According to the company interview mentioned in section 6.5, there is a strong willingness to pay for products associated to children's safety, when targeting the right customer segment. The survey was however not directed to attract premium customers specifically, and consequently, it represents an observation from a broader customer perspective. It was moreover performed without any effort to sell the product to the respondents, and the willingness to pay could potentially have been higher with marketing efforts. The customer stickiness for this application is dependent on the customer conceiving more children in the future, or that the application has additional features that can be used more frequently. Alternatively, an additional feature would be another type of monitoring that could be performed postpartum.

The implementation obstacles for the application are rated to be super high. There are no major product development issues or sales and distribution issues. The technical solution in terms of the wireless CTG monitoring device is already existing on the market. What is lacking for it to be a complete solution is mainly the integration with a mobile phone, data security, and compliance with existing rules and regulations as well as a possibility of integrating the data with national healthcare facilities and the EHR. As mentioned in section 3.2.3, parts of these aspects are already covered by actors in the field. Extensive marketing is moreover needed for the product to be commercialized as a B2C solution. The main issue for implementation to be realized is the major funding needed to get the lacking pieces together. The challenges mentioned are not difficult to solve for a company that has previous experience in the industry. It is, however very expensive, which creates a major entry barrier.

The time to revenue has been rated as low for the application. The development time of the solution is relatively short with the right team in place, since the technical readiness is high. The time to get it approved as a medical device could however delay the time to revenue, as mentioned in section 4.3.2, especially if applying for an FDA approval. Even though the commercial viability is unproven, the survey shows that the customer acceptance for the application and the demand for similar products is high. Not all countries have a market readiness for the solution to work well in combination with existing health care settings, the platform readiness for IoMT devices is varying greatly between countries, and the rate to which nations are adopting to and integrating with eHealth is differing as well. Moreover, the length of the sale cycle is considered long for this B2C solution. The interest and awareness of a product from the end users point of view would most likely occur when a pregnancy is confirmed, or alternatively, if a planned decision is made to try to conceive. The decision to buy the product must be made before the third trimester. During this time parents-to-be will, according to the interviews with potential users, spend some time investigating the product by reading reviews, looking at different brands (if other options exist), as well as talking to people such as their health care professional and private contacts. The customer would most likely not just see an ad and make an impulse purchase. The potential customer need to be educated about why this application would be right for them. The stage of awareness, consideration and purchase is therefore estimated to be a process between two-four months of time.

The external risks are rated between mid and high for the application. The nature of MedTech is heavily R&D focused, and is characterised as an industry reliant on investments. Funding is a factor that makes

it difficult for new entrants to compete, but it however also makes it possible for late movers with large monetary capital to enter the market, when the growth for IoMT and demand for telemonitoring solutions is apparent. As seen for the interviewed company presented in section 6.4, technology companies can succeed in offering CTG telemonitoring without superior knowledge in fetal monitoring. The knowledge base from MedTech companies could become secondary, and to avoid risk as either a technology or MedTech company, it is of high importance to utilize the venture's core abilities. For a MedTech company, it would for example be wise to take advantage of their interpretation skills, and offer some sort of service utilizing their expertise connected to fetal heart monitoring. Whereas a technology company should focus on the product and the technical aspects of the solution. If a niche is not sought out, the risk of a competitive threat will be larger. There are third party dependencies that constitutes risks for this application. The solution is reliant on integrated EHR, interoperability between countries (in case of an international interpretation team), reimbursement and similar aspects. The solution will not work if third parties are not cooperative on these aspects. The main risk of the aspect of third party dependencies lies in the issue of slow moving change. It is highly expected that the barriers from these dependencies will decrease, since the issues are mainly connected to adopting a health care transformation. For example, as mentioned by the interviewed medical professionals presented in section 6.6, insurance companies would also benefit from their hospital using a CTG telemonitoring solution. It would be a win-win situation, but the rigid structures of health care systems are challenging as they take time to adjust to new innovations. Another barrier for adoption is the view of medical professionals. A majority of the respondents in the survey stated that they would consider making active care choices, however, in the interviews with potential users it was obvious that a majority would discuss the use of the product with their health care advisor, before making the decision to purchase. As seen in the interview with medical professionals, there is a resistance to encourage patients to outsource their care to third party providers, since the professionals are strong believers that medical devices only should be used in the presence of their decision making.

7.4 Potential of CTG Telemonitoring Solution

This section will comprise an integration of the three frameworks presented above, to try to find an answer to the research questions.

- What main factors influence the adoption of a CTG telemonitoring solution on a global market?

On a social system level, the rules and regulations that the product will have to comply with will affect the diffusion of the product greatly. It being a medical product with clinical value is essential for it to be able to be offered as B2B. The clinical value of the product is not of same importance if it would only be introduced within the consumer goods market. Thus, the application possibilities is affected by the government and rules and regulations. Complex and slow-to-change policies affects the healthtech adoption in general. The readiness of the industry will also affect the adoption of the product. For example, reimbursement systems not being in place for telemonitoring solutions have a big impact on its application possibilities and how such a system as a whole can be designed and offered to different markets. This is not affecting the adoption of a CTG telemonitoring solution if it is not considered to be a medical device. How well the solution integrates with existing values and norms in the social system will affect the diffusion of the product regardless of the business model it is offered through. One influential factor is the Covid-19 pandemic, as the crisis has led to other widespread needs and values emerging, both in the healthcare industry and on an individual level. However, connected to the existing values and norms of pregnant women, the adoption of the product as a consumer product will be affected by women's demand and willingness for making active care choices. The digital transformation of industries and digitalization in all parts of society, will have an impact on the adoption of a CTG telemonitoring solution. This is true regardless of the target group. However, the adoption decision, if offered as B2C, will be affected by women's desire to monitor, collect data and interest in technologies in general. In addition, which patients that technically will be able to use the product, will affect the adoption of it as the benefits are greater with a bigger target group.

It is clear that how the product is communicated and offered to pregnant women is imperative for it being adopted, as this is connected to the ability to reduce uncertainties. The marketing of the product will play a critical role for the successful implementation of the product, if it is offered as B2C, as it will highly affect users perception on benefits connected to adoption. The uncertainties and risks are bigger if the product is offered as B2C, as the novelty of the product is greater for pregnant women due to

the medical nature of the product. Also, one critical factor if the solution is offered to pregnant women directly, is their ability to understand the benefits of adopting the product. Due to the nature of the product and its novelty, the personal benefits and value of the product is not as intuitive as compared to other consumer products. The value of the product will be set against its price, thus, the price is one of the most influential factors for the adoption decision. Connected to the price, the values and norms of paying for health care will affect the adoption of the product as it is directly connected to customers willingness to pay. A part in customers willingness to pay is their socioeconomic status, thus the adoption is additionally being negatively influenced by a lower socioeconomic status if offered as B2C.

If the product is offered as B2B, the benefits of the product is completely different as the customer is not the end user. If the adoption requires additional products to be acquired to be able to use the product or use existing technologies such as smartphones and Wi-Fi, will have an effect on the adoption for both business model offerings but mostly for B2C. Thus, the infrastructure in a country will have an influence. The GDP and AIC of a country will be influential as well. In addition, a factor influencing the adoption of a CTG telemonitoring solution that is offered directly to its end users, is how well it can be integrated with existing care. The main perceived risk for B2B could be argued to be costs, as adopting the product would mean initial investment costs, and the benefits versus cost will be a trade-off affecting the investment decision. The initial cost of investing in the product will affect the adoption decision, even if it would result in future cost benefits. The main factor of the solution being adopted if offered as B2B is that the product will need to be a medical device compliant with rules and regulations. In addition, the adoption will also be affected by the products clinical value and by the possibility to see its benefits for both patients and for the organization itself. Industry trends and digital transformation of the industry will also affect the diffusion of the product if it is offered via B2B. In addition, whether or not there is a set way or idea on what antenatal care is and should look like in the healthcare sector and in individual hospitals, as well as guidelines on antenatal care and the use of CTG, will affect the adoption in the case of B2B.

- When taking influential factors for adoption into account, is there a market opportunity for a CTG telemonitoring solution on one promising market within the OECD?

The most prominent determinants for the USA for CTG telemonitoring solutions are the firm strategy, structure and rivalry as well as the demand conditions. The strong culture of the USA as the home base for leading sophisticated technologies within the consumer goods market, with the combination of a demand on both the individual and societal level for changes within the existing healthcare systems, are two strong determinants when combined. They would however not be successful contributors to the overall potentials and challenges for the market opportunity attractiveness for application 4, without addition of both basic and advanced factor conditions as well as supporting industries and constructive governmental interaction.

The following section will synthesise the analysis originating from the application of Porter's Diamond Model combined with parts of the MON into a proposition of the market opportunity for application 4 of a CTG telemonitoring solution in the USA. This is analyzed to see if the potentials and challenges of application 4 can be met by the contextualized climate of the USA. The influential factors for adoption presented above will be taken into account throughout the prediction of the market opportunity.

The compelling reason to buy the solution is generally stated to be of high value for its attractiveness on the market. For a CTG telemonitoring solution, the unsatisfied unmet need to be able to make active care choices, monitor and collect data, are demand conditions that will influence the adoption of the application strongly. The USA have strong demand conditions from the end user side in a desire for replacing some of their appointments by being able to monitor from home. The private care setting in the USA will further be an enabler for patient-centric care, since the private care setting can offer more tailored solutions if patients are willing to pay for them. Moreover, the USA as a nation that is traditionally competitive in the MedTech industry and the Software industry has created intense rivalry, but also a sophisticated customer demand for IoMT solutions. The Apple Watch as a premium monitoring device is one example where advanced customer needs have set the scene for the product quality. However, sophisticated buyers will, as Porter stated "not translate into advanced products". The demand conditions are only exerting pressure on firm strategy and structure, as well as on related and supporting industries to be highly competitive. The link to related and supporting industries is of high value for the success between customer demand and product development. The USA has well developed clusters in the area of

IoT device development. The amount of university research and attractive international skill set, as well as knowledge commercialization, is an example of where the industry determinant has been turned into an advanced factor condition, important for the possibility to present an effective solution that is better than current solutions on the market. However, a negative demand condition that needs to be taken into account is the reflection around if American women need to be convinced that home care is safe.

The market volume parameter will affect the attractiveness of the solution. The early adopters of the solution are to a big extent situated in cities. The national advantage of geographically dense areas in the form of cities in the USA, is a prerequisite for application 4 to be introduced to the right customer group, while still gaining market volume. The possibility to further offer the solution to women with long distances to their medical centre, as later adopter categories, gives an opportunity for major market growth. The offering would be possible when the product has diffused on the market to some extent and reached a high reliability after initial testings, This, while still operating in the same country under the same rules depicted by the government. The market volume is however limited by the potential user group being restricted, as the technology lacks effectiveness for black women and women with larger body types. The main issue here to address is importantly *not* the market volume. The concern is the internalized racism and discrimination the technology plays a part in, when adapting to white physical standards and stereotypes of the female body. Rather than excluding groups from a market volume potential, the technological inclusion is a pressing matter to take into account in the product development phase. Ethically, the USA is a good place for introduction since the demand for development will be high due to their diverse population. Moreover, the USA has a selective factor disadvantage of increasing costs in the existing healthcare setting, in combination with an aging population and declining fertility rate (which will further complicate the increased age scenario). The pressure on the current care setting as a negative factor condition for B2B offerings is accelerating the need for upgrading of competitive advantage, to meet care demands in other ways. Consequently, the demand for new market solutions is emerging where patients themselves can take active care choices, through B2C offerings, to avoid waiting times and reduction of quality in the health care setting. Application 4 fits well into these needs, since it can be introduced both in relation to existing care settings and on new emerging markets.

The economic viability influence the attractiveness of application 4. Customer's willingness to pay for the solution is influenced by how well it is integrated with existing values and norms in the USA. Since a combination of private and public care is well established in the USA, as well as an existing expectancy for individuals to pay for their own health care insurance, there is a willingness to pay for health care in general. The customer's ability to pay will be influenced by the possibility to get reimbursement. This is directly affected by the support from related industries, in this case insurance companies, as well as the FDA approval as a medical device from the government. The willingness to pay for a CTG telemonitoring solution for early adopters in the USA is not very high, and the margins would be critical. However, their willingness to pay is affected by the products level of diffusion, and having people around using and recommending the product is connected to a higher willingness to pay. Moreover, the willingness to pay is affected by the users' socioeconomic status. The AIC and GDP are therefore relevant factor conditions to take into account when evaluating possible markets to implement the product on. As a country within the OECD, the USA have a customer base with high willingness to pay. The customer stickiness for application 4 is dependent on women conceiving multiple times. However, first-time parents are a prominent customer segment due to their nature of being more worried than parents that have experienced several pregnancies. Therefore, the declining fertility rate in the USA is not seen as a major weakness for it to be a suitable country to implement a CTG telemonitoring solution in.

Implementation obstacles in the USA will highly affect the challenges connected to the introduction of application 4 on the American market. The funding challenge is major for companies in any nation, since the costs of getting the device medically approved and to develop a working system that is integrated with the current healthcare setting are high. The government plays a large role in shaping the academic ground in regards to knowledge commercialization, in synergy with supporting industries. A knowledgeable academic setting such as highly ranked and specialized universities, contribute to attracting human skill sets. This in turn accelerates the advanced factor conditions of professional managers and engineers found in the firm. These factors are needed for efficient product development that passes the requirements of integration to existing care. The introduction of the FHIR standard is additionally one example of how the nation's government is acting as a catalyst for IoMT devices to work in current, as well as newly formed, healthcare settings. This is an indication that the American government moreover acknowledges

the need for adjustments in the healthcare industry to cater for new innovative solutions. The USA as a nation is moreover characterised by funding opportunities and in this matter it is a perfect nation for young ventures to gain competitive advantage in without private initial investments or need for organic growth.

The time to revenue is a crucial aspect to lower the challenges connected to the market introduction of application 4. The American government has shaped a context in which the requirements to get an approval of clinical value with a FDA certification are high. Consequently, the time needed to develop compliant, high quality medical products is challenged. Certification can however be given in a short time frame with enough capital investment. The market for IoMT is growing quickly, but the overall healthcare industry is characterized by slow transformations. The USA is investing in a transformation of their health care structures, to be more digitized and compliant with preventive care and data-driven decisions. It is however a radical transformation and the market is not currently ready to utilize the full potential of application 4. Despite this, the solution would be viable considering the demand aspects, willingness to pay for health care and the product readiness. Consequently, the time between product and market readiness would be low if introducing it in the USA. The sale cycle is, as previously stated, quite long considering it being a B2C offering. However, if marketed properly in terms of uncertainties being effectively reduced and users being able to understand the benefits and value of the product quickly, there is a potential for a shorter sale cycle. For example, if the product is bought only based on it reducing travel times, then the buying decision will most likely be shorter compared to if it is bought as an addition to the existing health care. This because the user will have to be better informed about the solution's medical value in that case.

There are several external risks that could contribute to challenge the market attractiveness of application 4. The estimate on the size of a challenge for a risk is however not rated only by its severity, but also by its probability of happening. The risk of future competitive threats exist. High quality requirements from governmental interaction will constitute a risk of trends neglecting the prioritization of clinical value from the firm strategy side, in order to lower the implementation time. The characteristic of the USA as a nation that fosters firm strategy reliant on short-term results pressed on by risk capital investors, will further enhance this societal risk. As a result, companies might aim for a new market where IoMT devices are not compliant with the healthcare setting and its standards of quality, as is seen as a trend today. As a consequence, MedTech companies might be challenged by a new type of competition, where the medical value of products is not of importance. In the light of the safety issues connected to overuse of the CTG technology, supervision from medical professionals has an important role in satisfying ethical requirements. The risk of competition for non-medical health devices might be avoided by the introduction of restricting rules on use of products that can have harmful effect if not used properly, as for example risk of radiation. Another competitive threat is the risk of substitute technologies being introduced, with the same value as using CTG. Meaning, products reducing worries and providing parents with information about the fetus well-being. Clusters containing large skills, such as in Silicon Valley, naturally creates rivalry. If the potential for one product is seen, competitors will try to tap into the same area.

Today, application 4 would not be compliant with all third party dependencies considering reimbursement, existing healthcare settings and guidelines. However, the trend for the USA is that the third parties involved are actively working towards making it easier for IoMT devices to be a part of the current care setting. The probability of the trend of enabling eHealth to be a part of the care setting in the future will turn, is seen as small since more efficient care would be a win-win situation.

The largest threat to adoption of a CTG telemonitoring solution in the USA is most likely if use of CTG would no longer be advised by related and supporting industries. Such as by medical professionals and the ACOG and NICHHD guidelines. Today, the USA has a strong influence with their guidelines on intrapartum use of CTG. However, the criticism towards the CTG technology not having clinical value, would strongly affect the attractiveness of the solution. Despite current research lifting new aspects, the healthcare industry is slow moving. New discoveries, that are not of a disruptive character, would most likely take up to ten years to be implemented in the current healthcare setting. The ethical aspect of commercializing a technology in the medical setting that lacks clinical value is however a major factor to take into account. Moreover, since a large part of the criticism lies in insufficient recommendations for antenatal use and interpretation from health care professionals, a solution with a specialized team on CTG readings would contribute to a higher clinical value than what can currently be offered in the traditional healthcare sector.

8

Discussion

The benefits of CTG telemonitoring solutions are evident and the range of people that could benefit from such solutions is broad. An ambition with this study was to contribute to the transformation of a technology, that would support the improvement of care for all, but especially for those that do not have access to appropriate care today. In an ideal world, application 4 could be introduced and adopted in countries where the benefits and value are greatest. This is not within OECD countries with a population with a high socioeconomic status. Women in these countries have in general already access to appropriate care. Thus, the technology would have biggest significance in countries where the antenatal care is lacking and a CTG telemonitoring solution would reduce maternal as well as neonatal mortality and morbidity. However, since the development of the solution requires monetary investments, it is economically beneficial to first introduce it to customers and users that have the economic ability to pay for it, in the early stages of adoption. If taking into account that the solution would be offered by a company looking at revenues and sales, the solution would need to be introduced to early adopters with strong purchasing power. By making something available to some, pressure is created, for example on hospitals, to further develop and offer the technology to other target groups resulting in a greater good.

New technologies have features that affect the adoption and diffusion process as people are prone to adopting solutions that fit with their existing behaviors. However, more knowledge is needed about the implications of innovations for the public as a whole, specific segments, governments and businesses. Thus, the consequences of the use of an innovation needs to be assessed. Diffusing a CTG telemonitoring solution by emphasizing its benefits and downplay the negative aspects can enhance the social acceptance of the innovation. However, as application 4 includes it being a medical device there are ethical concerns that should be considered when implementing the product. The initial impact of the solution does not necessarily reveal its long term effects. The technology can have indirect effects which could be greater than the solution itself. Such an outcome could be increased constrain on hospitals due to it creating more worries rather than less for those using the solution. This would be a complete opposite effect to the one motivating the solution. Therefore, application 4 with the aspect of the solution being offered to women without medical indications as well, could give rise to indirect negative outcomes.

The introduction of CTG as a home monitoring service will most likely further establish the technology in the norm of antenatal care services. The issue of the technology not being biologically suitable for every woman is however largely discriminating. As mentioned in section 3.2.2, the use of the technology on women with different ethnicity and body sizes will not only contribute to situations where no reading can be acquired. The use is further demonstrated to give rise to false positive readings for women with different skin color, and consequently interventions being made based on faulty information. While the majority of the US population is white, 23,7% are comprised of other skin colors (Bureau, 2019). Moreover, 42,4% were considered obese in the USA between 2017-2018 (and Prevention, 2021). There is consequently an ethical issue of introducing CTG telemonitoring on the US market, since a large part of the population will not be able to utilize its full effect. Or worst case, risks being subject to unnecessary C-sections or any other excessive intervention. The risk of false positive readings is not only an issue dependent on ethnic differences. As further mentioned in section 3.2.2, the uncertain clinical value of the CTG technology is problematic. However, part of the problem lies in general interpretation mistakes from healthcare professionals. Consequently, there is an evident potential for computerized CTG where interpretations are not based on the subjective perception from the individual care giver. The increased efficiency of a computerized decision maker would moreover contribute to less work load for healthcare professionals. On the other hand, as of today, there is still no computerized CTG algorithm that is fully satisfactory. Consequently, responsible technology development as well as experienced interpretation teams are key to avoid reading issues, as well as better fact-based guidelines for antenatal CTG specifically. Application 4 is a good alternative in this matter. An external team with the main job of performing CTG interpretation will most likely be less prone to make faulty observations, since they will gain experience and be provided training to perform well. The main care giver would then instead be able to focus on the overall health of the pregnant woman.

Another ethical issue with the CTG technology is the risk of too much radiation exposure if the device

is left to be handled directly by a pregnant woman. As seen in the customer interaction, many of the questioned women believe that they would feel an urge to monitor all the time if possible, to ensure that everything is well. They however also express that they would not use the device more than intended if they got clear instructions from an healthcare professional. Consequently, CTG telemonitoring providers should take the responsibility to introduce the device with user restrictions, limiting the risk of fetal damage. The safest way to ensure rightful use would be to introduce it in connection to existing healthcare systems, as for application 4. It would however also be an option to physically restrict the use for a non-medical solution. However, the possibility of potential customers buying multiply devices do exist in that case, as opposed to if the product use is connected to the user's medical records.

One major risk for the market introduction in the USA not included in the MON is the widespread compensation culture. As discussed, the CTG technology has drawbacks that ultimately can leave the user with quite substantial implications as a consequence of faulty health care decisions, such as a planned C-section. The introduction of a medical device as for application 4 is therefore linked with the risk of highly costly lawsuits, if the interpretation is of low quality or in the case of extensive use. As seen in section 4.2.2, the trend is inevitably moving towards more patient-centric care and availability of B2C IoMT devices. Even though the CTG telemonitoring solution is not intended for normal, low-risk pregnancies from a medical viewpoint, the urge to track and monitor our everyday lives is still putting pressure on further development.Therefore, it is important that companies take their moral responsibility in this inevitable transition, to assure that the value exceeds the risks for everyone.

8.1 Further Research

What has not been investigated in this thesis is to what extent application 4 would affect the existing healthcare setting. Furthermore, how the technology could risk exerting damage on the fetus if used extensively is not investigated either. These two topics are of great importance to look further into in future research, as they will largely affect the market opportunity of a CTG telemonitoring solution. Also, to be able to state with certainty that there is a market opportunity for application 4, further research will need to be carried out on a more detailed level. However, it can be stated that there *is* a market opportunity for the CTG telemonitoring solution on the US market. This does however not imply that the best market opportunity, among all OECD countries, is found in the USA. In order to investigate which country that has the most potential for this solution, further research will be needed.

9

Conclusion

This study has investigated what main factors influence the adoption of a CTG telemonitoring solution on a global market and if there is a market opportunity for one application on the US market. It can be concluded that several factors influence the adoption of a CTG telemonitoring solution. One of the main influential factors on adoption of connected medical technologies involve acceptance by both healthcare systems and individual healthcare professionals. For instance, the readiness of the industry is connected to reimbursement issues that affect the diffusion to a big extent. Digital transformation of other industries is also affecting the diffusion of the solution. In summary, from the analysis on aspects of diffusion, there are some factors that apply to the technology independent of how it is offered. The rules and regulations that the product will have to comply with will affect the diffusion of the product greatly and complex and slow-to-change policies affect healthtech adoption in general. The products clinical value, if using the product requires additional resources, and the infrastructure of countries are other identified influential factors. Also, the adoption will be affected by how well the product can be integrated with existing care and if there is a standard of antenatal care and guidelines for the use of CTG in general. However, it is evident that the main influential factors vary depending on the customer offer. Factors that will influence the adoption of a B2B solution will not be the same as for a B2C solution. A CTG telemonitoring solution offered as B2C is greatly affected by the price of the offering and customers' willingness to pay for health care, thus also customers' socioeconomic status. The adoption is influenced by how well the solution integrates with existing values and norms, where the Covid-19 pandemic has led to other widespread needs and values emerging. Customers willingness to make active care choices and their desire to monitor, collect data and technology interest in general, are other influential factors. Also, how the solution is communicated and offered will affect the diffusion, as it is connected to users ability to reduce uncertainties and their perception on the value and benefits of adopting the product. Finally, which users that technically will be able to use the product will affect the size of the potential target group and thus the diffusion of the product.

The USA has a favourable combination of determinants creating a dynamic and challenging home environment for introduction of CTG telemonitoring. The nation has for example the advantage of large talent pools as well as opportunities for funding and advanced customer needs forcing improvement, innovation and upgrading. The overall market potential is very high for a CTG telemonitoring solution, while the overall challenge is medium-high. There are high compelling reasons to buy, a super high market volume and a high economic viability for the solution. However, implementation obstacles are super high, time to revenue is low and the external risks are medium-high. Moreover, taking into consideration its many areas of application, it can be concluded that there is a market opportunity for a complete solution with connection to EHR and a local CTG interpretation team, in the US as a promising market. This answer does not however imply that it has the best market opportunity among all OECD countries and that the application has the biggest market opportunity out of the different solutions. It is evident that the market of connected medical devices is expanding and will continue to do so in the near future. Consequently, MedTech companies will be forced to develop new skill sets and take innovative responsible decisions as well as introduce cooperation between actors to remain competitive in a changing environment, going in a direction that can not be stopped.

If taking into account that the solution would be offered by a company looking at revenues and sales, the solution would need to be introduced to early adopters with strong purchasing power. However, the technology would contradictory be of largest significance in countries associated with lower socioeconomic status. The issue of the technology currently not being biologically suitable for every woman is moreover largely discriminating, and the uncertain clinical value of the CTG technology is problematic. These concerns need to be overcome by further research and development. In the light of the transition of healthcare systems towards patient-centric use of IoMT devices, involved actors have the opportunity to develop a CTG telemonitoring solution that is satisfying customer needs as well as releasing strain on current healthcare institutions and meet the lack of proper antenatal care. We hope that this thesis will emphasize the market opportunity and moral responsibility for a ethically viable application that, beyond contributing to cost-savings, presents a solution to the need for minimization of neonatal and maternal morbidity and mortality, globally.

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A

Members of OECD

The list of included OECD in the report are listed in Table A.1.

Table A.1: Overview of the 37 OECD member countries as for 2021

OECD-Country
Australia
Austria
Belgium
Canada
Chile
Colombia
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Iceland
Ireland
Israel
Italy
Japan
Korea
Latvia
Lithuania
Luxembourg
Mexico
Netherlands
New Zealand
Norway
Poland
Portugal
Slovak Republic
Slovenia
Spain
Sweden
Switzerland
Turkey
United Kingdom
United States

B

Descriptions of Screening Criteria

An overview of the descriptions of each criteria included in the screening is presented below.

The descriptions are yet to be written.

1. Low birth weight - measured in % of total live births.
2. Mean age of women at childbirth - measured in years
3. Complications of pregnancy, childbirth and the puerperium (Maternal mortality)- measured in Deaths per 100 000 females (standardised rates).
4. Complications of pregnancy in the antenatal period (Hospitalization of pregnant women) - measured in days that women are being hospitalized.
5. Fertility - measured in children per women aged 15 to 49 years old
6. Women population aged 15-49 years old (Fertile (15-49 y/o) women population) - measured in the number of people.
7. Gross domestic product (GDP) - measured per capita, US$ purchasing power parity
8. Actual individual consumption (AIC) - measured in a price index of (2015=100).
9. Households with Internet access at home - measured in percentage of all households.
10. Computed Tomography scanners, total (Medical Technology access) - measured per million population.
11. Digital Services trade restrictions - measured as the Service Trade Restrictions Index (STRI) with a value from 0 to 1, where complete openness to trade gives a value of 0, and the opposite 1.

C

Screening Analysis: Three Scenarios

An overview of the three included scenario in the report are listed in Table C.1, C.2 and C.3. The markings in yellow are the factors that are varied in the different scenarios.

C.1 Scenario One

In scenario 1, seen in Table C.1 the rating for potential and actual sum of pregnancy related issues is set to medium, with accompanying weights.

Table C.1: Overview of the rankings for scenario one

Aspect	Potential and actual sum of pregnancy related issues				Fertile women population and amount of births		Economic status		Technology diffusion		Trade barriers for digital services
Rating	Medium				Medium-high		High		High		Medium-low
Variable	Low birthweight	Mean age of women at childbirth	Maternal mortality	Hospitalization of pregnant women	Fertility	Fertile (15-49 y/o) women population	GDP	AIC	Household internet access	Medical Technology access	Digital Services trade restrictions
Measure	% of total live births	Years	Deaths per 100 000 females	Days of being hopsitalized	Children per women aged 15 to 49 years old	Number of people	/capita, US$ purchasing power parity	Price index (2015=100)	Percentage	Per million population	Indicator STRI
Weight (1-5)	**3**	**4**	**2**	**3**	4	4	5	5	5	4	3
Effect (1/-1)	1	1	1	1	1	1	1	1	1	1	-1

C.2 Scenario Two

In scenario 2, seen in Table C.2 the rating for potential and actual sum of pregnancy related issues is set to low, with accompanying weights.

Table C.2: Overview of the rankings for scenario two

Aspect	Potential and actual sum of pregnancy related issues				Fertile women population and amount of births		Economic status		Technology diffusion		Trade barriers for digital services
Rating	Low				Medium-high		High		High		Medium-low
Variable	Low birthweight	Mean age of women at childbirth	Maternal mortality	Hospitalization of pregnant women	Fertility	Fertile (15-49 y/o) women population	GDP	AIC	Household internet access	Medical Technology access	Digital Services trade restrictions
Measure	% of total live births	Years	Deaths per 100 000 females	Days of being hopsitalized	Children per women aged 15 to 49 years old	Number of people	/capita, US$ purchasing power parity	Price index (2015=100)	Percentage	Per million population	Indicator STRI
Weight (1-5)	**1**	**1**	**1**	**1**	4	4	5	5	5	4	3
Effect (1/-1)	1	1	1	1	1	1	1	1	1	1	-1

C.3 Scenario Three

In scenario 3, seen in Table C.3 the rating for potential and actual sum of pregnancy related issues is set to high, with accompanying weights.

Table C.3: Overview of the rankings for scenario three

Aspect	Potential and actual sum of pregnancy related issues				Fertile women population and amount of births		Economic status		Technology diffusion		Trade barriers for digital services
Rating	High				Medium-high		High		High		Medium-low
Variable	Low birthweight	Mean age of women at childbirth	Maternal mortality	Hospitalization of pregnant women	Fertility	Fertile (15-49 y/o) women population	GDP	AIC	Household internet access	Medical Technology access	Digital Services trade restrictions
Measure	% of total live births	Years	Deaths per 100 000 females	Days of being hopsitalized	Children per women aged 15 to 49 years old	Number of people	/capita, US$ purchasing power parity	Price index (2015=100)	Percentage	Per million population	Indicator STRI
Weight (1-5)	**5**	**5**	**5**	**5**	4	4	5	5	5	4	3
Effect (1/-1)	1	1	1	1	1	1	1	1	1	1	-1

D

Screening Analysis: Final Ranking

In Table D.1 the ranking points can be seen for the three scenarios. Each scenario is sorted by points in a descending manner. For scenario one, the ten highest ranked countries were coloured petrol blue, and that colour remained in ranking two and three. It is therefore possible to see how countries change ranking score.

Table D.1: Overview of the ranking for the three scenarios, with the total points given for each scenario.

Nr.	Country	Sc. 1		Country	Sc. 2		Country	Sc. 3
1	United States	110,37		United States	86,16		United States	134,19
2	Japan	109,27		Luxembourg	81,47		Japan	132,02
3	Luxembourg	108,67		Japan	79,50		Luxembourg	129,15
4	Switzerland	102,05		Turkey	76,78		Switzerland	123,43
5	Korea	99,36		Norway	74,83		Korea	122,61
6	Turkey	98,13		Switzerland	73,64		Turkey	118,88
7	Germany	97,46		Australia	72,87		Germany	117,17
8	Norway	95,38		Germany	71,88		France	116,75
9	Australia	95,33		United Kingdom	71,52		Italy	112,93
10	France	94,81		Denmark	69,65		Australia	112,05
11	United Kingdom	92,31		Ireland	69,43		Norway	110,29
12	Ireland	91,74		Netherlands	68,91		Czech Republic	110,11
13	Italy	91,42		Korea	68,81		Hungary	110,08
14	Netherlands	91,14		France	67,64		Slovak Republic	108,39
15	Denmark	90,00		Sweden	67,13		United Kingdom	108,34
16	Czech Republic	89,14		Iceland	66,21		Belgium	107,49
17	Belgium	88,76		Canada	65,83		Portugal	107,40
18	Spain	87,31		Estonia	65,63		Israel	107,18
19	Israel	87,05		Belgium	64,80		Netherlands	107,00
20	Canada	86,71		Austria	63,92		Spain	106,77
21	Hungary	86,66		Czech Republic	63,16		Ireland	106,40
22	Austria	85,88		Finland	63,11		Denmark	104,41
23	Sweden	85,86		Italy	62,74		Greece	104,28
24	Slovak Republic	85,27		Israel	62,13		Slovenia	102,50
25	Estonia	85,08		Lithuania	60,75		Austria	102,45
26	Portugal	84,92		Spain	60,59		Canada	102,22
27	Finland	83,32		Hungary	59,38		Estonia	100,84
28	Iceland	83,03		Latvia	59,26		Latvia	100,28
29	Slovenia	82,34		Slovak Republic	58,96		Colombia	98,71
30	Greece	81,98		New Zealand	58,70		Sweden	98,44
31	Lithuania	80,52		Mexico	58,07		Finland	98,13
32	Latvia	80,22		Slovenia	57,34		Lithuania	96,65
33	New Zealand	79,28		Portugal	56,74		New Zealand	95,42
34	Mexico	73,05		Greece	53,43		Iceland	94,59
35	Poland	73,05		Chile	51,09		Mexico	93,30
36	Chile	71,45		Poland	50,93		Chile	91,34
37	Colombia	67,62		Colombia	44,53		Poland	90,95

E

OECD-Data Input

E.1 Low Birth Weight

Table E.1: Overview of data for low birth weight

Low birthweight	Year	2015	2016	2017	2018	2019	Average value
Country							
Australia		6,50	6,50	6,70	..	..	6,57
Austria		6,50	6,40	6,40	6,20	..	6,38
Belgium		6,80	6,70	..	..	..	6,75
Canada		6,30	6,40	6,50	6,50	..	6,43
Chile		6,30	6,30	6,70	..	..	6,43
Colombia		10,00	..	..	..	..	10,00
Czech Republic		7,80	7,50	7,40	6,90	..	7,40
Denmark		5,00	5,00	4,90	4,80	..	4,93
Estonia		4,20	4,10	4,20	4,10	..	4,15
Finland		4,20	4,10	4,20	4,10	..	4,15
France		7,60	7,50	7,60	..	..	7,57
Germany		..	..	..	..	..	.. ..
Greece		9,20	9,40	9,30	9,60	..	9,38
Hungary		8,60	8,50	8,30	8,50	..	8,48
Iceland		4,40	4,40	3,80	3,60	4,40	4,12
Ireland		5,60	5,60	5,70	5,70	..	5,65
Israel		8,00	7,70	7,70	7,40	..	7,70
Italy		7,40	7,40	7,40	7,30	..	7,38
Japan		9,50	9,40	9,40	9,40	..	9,43
Korea		5,70	5,90	6,20	6,20	..	6,00
Lithuania		4,50	4,50	4,90	4,60	..	4,63
Latvia		4,50	4,30	4,40	4,30	..	4,38
Luxembourg		6,30	6,90	6,30	6,20	..	6,43
Mexico		5,80	5,90	6,00	6,90	..	6,15
Netherlands		6,00	5,80	5,90	5,80	..	5,88
New Zealand		5,90	5,90	6,00	6,00	..	5,95
Norway		4,50	4,70	4,60	4,50	..	4,58
Poland		5,80	5,80	5,70	5,50	..	5,70
Portugal		8,90	8,70	8,90	9,00	..	8,88
Slovak Republic		7,70	7,50	7,50	7,30	7,50	7,50
Slovenia		6,40	6,60	6,60	6,30	..	6,48
Spain		7,90	7,80	7,80	7,70	..	7,80
Sweden		4,40	4,50	4,40	4,20	..	4,38
Switzerland		6,50	6,60	6,40	6,50	..	6,50
Turkey		8,60	8,30	8,10	7,60	..	8,15
United Kingdom		6,90	6,90	6,90	6,90	..	6,90
United States		8,10	8,20	8,30	8,30	..	8,23

E.2 Mean Age of Women at Childbirth

Table E.2: Overview of data for mean age of women at childbirth

Mean age	Year	2013	2014	2015	2016	2017	Average value
Country							
Australia		30,60	30,70	30,80	..	..	30,70
Austria		30,30	30,40	30,60	30,60	30,70	30,52
Belgium		30,20	30,30	30,40	30,50	30,60	30,40
Canada		30,40	30,50	30,70	30,80	..	30,60
Chile		28,30	28,50	..	..	..	28,40
Colombia		25,90	26,00	..	..	..	25,95
Czech Republic		29,90	29,90	30,00	30,00	30,00	29,96
Denmark		30,80	30,90	31,00	31,00	31,10	30,96
Estonia		29,50	29,60	29,90	30,20	30,40	29,92
Finland		30,50	30,50	30,60	30,80	30,90	30,66
France		30,20	30,30	30,40	30,50	30,60	30,40
Germany		30,80	30,90	30,90	30,90	31,00	30,90
Greece		30,90	31,10	31,30	31,30	31,40	31,20
Hungary		29,50	29,50	29,60	29,60	29,80	29,60
Iceland		30,40	30,20	30,30	30,60	30,60	30,42
Ireland		31,70	31,80	31,90	32,10	32,10	31,92
Israel		..	30,40	30,50	30,40	30,40	30,43
Italy		31,50	31,50	31,70	31,80	31,90	31,68
Japan		31,60	31,70	31,80	31,90	32,00	31,80
Korea		31,80	32,00	32,20	32,40	32,60	32,20
Lithuania		29,20	29,40	29,50	29,70	29,80	29,52
Latvia		29,00	29,20	29,40	29,60	29,70	29,38
Luxembourg		31,30	31,40	31,50	31,70	31,90	31,56
Mexico		26,50	26,60	..	..	..	26,55
Netherlands		31,00	31,10	31,20	31,30	31,40	31,20
New Zealand		29,90	30,10	30,20	30,40	..	30,15
Norway		30,50	30,60	30,70	30,80	31,00	30,72
Poland		29,00	29,10	29,20	29,40	29,50	29,24
Portugal		30,40	30,70	30,90	31,10	31,20	30,86
Slovak Republic		28,80	28,80	28,80	28,80	28,80	28,80
Slovenia		30,10	30,20	30,20	30,30	30,30	30,22
Spain		31,70	31,80	31,90	32,00	32,10	31,90
Sweden		30,90	31,00	31,00	31,10	31,10	31,02
Switzerland		31,60	31,80	31,80	31,90	31,90	31,80
Turkey		28,30	28,40	28,60	28,60	..	28,48
United Kingdom		30,00	30,20	30,30	30,40	30,50	30,28
United States		28,80	29,00	29,10	..	..	28,97

E.3 Maternal Mortality

Table E.3: Overview of data for Maternal mortality

Maternal mortality	Year	2013	2014	2015	2016	2017	Average value
Country							
Australia		30,60	30,70	30,80	..	..	30,70
Austria		30,30	30,40	30,60	30,60	30,70	30,52
Belgium		30,20	30,30	30,40	30,50	30,60	30,40
Canada		30,40	30,50	30,70	30,80	..	30,60
Chile		28,30	28,50	..	..	..	28,40
Colombia		25,90	26,00	..	..	..	25,95
Czech Republic		29,90	29,90	30,00	30,00	30,00	29,96
Denmark		30,80	30,90	31,00	31,00	31,10	30,96
Estonia		29,50	29,60	29,90	30,20	30,40	29,92
Finland		30,50	30,50	30,60	30,80	30,90	30,66
France		30,20	30,30	30,40	30,50	30,60	30,40
Germany		30,80	30,90	30,90	30,90	31,00	30,90
Greece		30,90	31,10	31,30	31,30	31,40	31,20
Hungary		29,50	29,50	29,60	29,60	29,80	29,60
Iceland		30,40	30,20	30,30	30,60	30,60	30,42
Ireland		31,70	31,80	31,90	32,10	32,10	31,92
Israel		..	30,40	30,50	30,40	30,40	30,43
Italy		31,50	31,50	31,70	31,80	31,90	31,68
Japan		31,60	31,70	31,80	31,90	32,00	31,80
Korea		31,80	32,00	32,20	32,40	32,60	32,20
Lithuania		29,20	29,40	29,50	29,70	29,80	29,52
Latvia		29,00	29,20	29,40	29,60	29,70	29,38
Luxembourg		31,30	31,40	31,50	31,70	31,90	31,56
Mexico		26,50	26,60	..	..	..	26,55
Netherlands		31,00	31,10	31,20	31,30	31,40	31,20
New Zealand		29,90	30,10	30,20	30,40	..	30,15
Norway		30,50	30,60	30,70	30,80	31,00	30,72
Poland		29,00	29,10	29,20	29,40	29,50	29,24
Portugal		30,40	30,70	30,90	31,10	31,20	30,86
Slovak Republic		28,80	28,80	28,80	28,80	28,80	28,80
Slovenia		30,10	30,20	30,20	30,30	30,30	30,22
Spain		31,70	31,80	31,90	32,00	32,10	31,90
Sweden		30,90	31,00	31,00	31,10	31,10	31,02
Switzerland		31,60	31,80	31,80	31,90	31,90	31,80
Turkey		28,30	28,40	28,60	28,60	..	28,48
United Kingdom		30,00	30,20	30,30	30,40	30,50	30,28
United States		28,80	29,00	29,10	..	..	28,97

E.4 Hospitalization of Pregnant Women

Table E.4: Overview of data for hospitalization of pregnant women

Hospitalization	Year	2015	2016	2017	2018	2019	Average value
Country							
Australia		3,40	3,30	3,30	..	..	3,33
Austria		3,20	3,10	3,00	3,10	..	3,10
Belgium		..	3,90	3,80	3,80	..	3,83
Canada		2,60	2,50	2,50	2,50	..	2,53
Chile		3,60	3,60	3,70	3,70	..	3,65
Colombia		..	..	..	..	..	.. ..
Czech Republic		4,80	4,80	4,80	4,60	..	4,75
Denmark		2,90	2,90	..	..	..	2,90
Estonia		..	..	..	..	..	.. ..
Finland		3,60	3,50	3,40	3,50	..	3,50
France		4,80	4,70	4,70	4,70	..	4,73
Germany		4,40	4,30	4,20	..	..	4,30
Greece		..	..	..	..	..	.. ..
Hungary		4,80	4,80	4,90	4,80	..	4,83
Iceland		..	2,30	2,30	..	..	2,30
Ireland		2,50	2,60	2,70	2,70	..	2,63
Israel		3,60	3,60	3,60	3,50	..	3,58
Italy		4,50	4,50	4,50	4,50	..	4,50
Japan		..	..	..	..	..	.. ..
Korea		5,60	5,50	5,60	5,50	..	5,55
Lithuania		4,20	4,10	3,70	3,60	..	3,90
Latvia		4,40	4,10	4,10	3,90	..	4,13
Luxembourg		4,50	4,40	..	..	..	4,45
Mexico		2,40	2,20	2,30	2,40	..	2,33
Netherlands		3,00	3,00	3,00	2,90	..	2,98
New Zealand		2,90	3,00	3,00	..	..	2,97
Norway		3,90	3,80	3,60	2,80	2,80	3,38
Poland		4,80	4,70	4,70	4,60	..	4,70
Portugal		4,10	..	..	3,90	..	4,00
Slovak Republic		5,90	5,70	5,70	5,50	..	5,70
Slovenia		4,50	4,60	4,50	4,60	..	4,55
Spain		3,10	3,20	3,20	3,30	..	3,20
Sweden		2,50	2,40	2,60	2,50	..	2,50
Switzerland		4,90	4,70	4,70	4,60	..	4,73
Turkey		2,90	3,00	3,10	3,10	..	3,03
United Kingdom		2,50	2,40	..	2,40	..	2,43
United States		..	..	..	..	..	.. ..

E.5 Fertility

Table E.5: Overview of data for fertility

Fertility	Year	2015	2016	2017	2018	2019	Average value
Country							
Australia		1,79	1,79	1,74	1,74	..	1,77
Austria		1,49	1,53	1,52	1,48	..	1,51
Belgium		1,69	1,67	1,64	1,61	..	1,65
Canada		1,56	1,54	1,50	1,50	..	1,53
Chile		1,75	1,71	1,68	1,65	..	1,70
Colombia		1,86	1,84	1,83	1,81	..	1,84
Czech Republic		1,57	1,63	1,69	1,71	..	1,65
Denmark		1,71	1,79	1,75	1,73	1,70	1,74
Estonia		1,58	1,60	1,59	1,67	..	1,61
Finland		1,65	1,57	1,49	1,41	..	1,53
France		1,93	1,89	1,86	1,84	1,84	1,87
Germany		1,50	1,59	1,57	1,57	..	1,56
Greece		1,33	1,38	1,35	1,35	..	1,35
Hungary		1,44	1,49	1,49	1,49	..	1,48
Iceland		1,81	1,75	1,71	1,71	..	1,75
Ireland		1,85	1,82	1,78	1,75	..	1,80
Israel		3,09	3,11	3,11	3,09	..	3,10
Italy		1,35	1,34	1,32	1,29	..	1,33
Japan		1,45	1,44	1,43	1,42	..	1,44
Korea		1,24	1,17	1,05	0,98	0,92	1,07
Lithuania		1,70	1,69	1,63	1,63	..	1,66
Latvia		1,70	1,74	1,69	1,60	..	1,68
Luxembourg		1,47	1,41	1,39	1,38	..	1,41
Mexico		2,22	2,19	2,16	2,13	..	2,18
Netherlands		1,66	1,66	1,62	1,59	..	1,63
New Zealand		2,00	1,89	1,84	1,74	1,75	1,84
Norway		1,73	1,71	1,62	1,56	1,53	1,63
Poland		1,29	1,36	1,45	1,44	..	1,39
Portugal		1,30	1,36	1,37	1,41	..	1,36
Slovak Republic		1,40	1,48	1,52	1,54	..	1,49
Slovenia		1,57	1,58	1,62	1,61	..	1,60
Spain		1,33	1,34	1,31	1,26	..	1,31
Sweden		1,85	1,85	1,78	1,75	1,70	1,79
Switzerland		1,54	1,54	1,52	1,52	..	1,53
Turkey		2,15	2,11	2,07	1,99	..	2,08
United Kingdom		1,80	1,79	1,74	1,68	..	1,75
United States		1,84	1,82	1,77	1,73	..	1,79

E.6 Fertile (15-49 y/o) Female Population

Table E.6: Overview of data for fertile (15-49 y/o) female population

Population	Year	2014	2015	2016	2017	2018	Average value
Country							
Australia		5654358	5722799	5801256	5892553	5970371	5808267
Austria		1996074	1992594	1994347	1984376	1971035	1987685
Belgium		2505104	2500133	2496739	2493803	2493690	2497894
Canada		8228740	8189075	8214746	8278227	8377717	8257701
Chile		4633341	4648855	4668739	4710725	4781104	4688553
Colombia		12537111	12628621	12713201	12795639	12877806	12710476
Czech Republic		2437301	2414152	2395539	2379747	2369520	2399252
Denmark		1261195	1262523	1264186	1263353	1263651	1262982
Estonia		293910	291279	289255	287127	285792	289473
Finland		1156166	1151693	1146891	1142081	1137627	1146892
France		14645314	14596923	14550931	14505734	14459348	14551650
Germany		17538189	17450192	17357906	17205729	17065424	17323488
Greece		2483931	2445096	2407002	2370074	2332408	2407702
Hungary		2303676	2289104	2272144	2252838	2232274	2270007
Iceland		77477	77798	78382	79792	81938	79077
Ireland		1153719	1156432	1160498	1168478	1180573	1163940
Israel		1929566	1962415	1996136	2031100	2060497	1995943
Italy		13458566	13262917	13052617	12841926	12638216	13050848
Japan		26299127	26106605	26012587	25730459	25433450	25916446
Korea		12858689	12758608	12651810	12506104	12334775	12621997
Lithuania		676768	662193	643028	619664	600342	640399
Latvia		449736	439601	429936	420405	411939	430323
Luxembourg		137529	140451	143609	146454	148811	143371
Mexico		32872536	33201065	33508169	33793726	34059608	33487021
Netherlands		3779722	3768700	3766897	3770845	3777110	3772655
New Zealand		1073140	1090280	1112860	1135090	1153760	1113026
Norway		1189481	1197248	1201907	1204376	1205759	1199754
Poland		9284025	9221609	9158262	9097121	9032889	9158781
Portugal		2404756	2374968	2345675	2318011	2297403	2348163
Slovak Republic		1341478	1329384	1317468	1306044	1295791	1318033
Slovenia		456811	450224	443390	436478	430225	443426
Spain		10885691	10729271	10607795	10511434	10470773	10640993
Sweden		2143951	2147166	2156788	2172310	2188557	2161754
Switzerland		1923091	1927625	1929749	1927707	1923274	1926289
Turkey		20451114	20581468	20763594	21000029	21222525	20803746
United Kingdom		14975471	14949580	14908152	14839556	14793311	14893214
United States		73771705	73917955	74178115	74398030	74654838	74184129

E.7 Gross Domestic Product (GDP)

Table E.7: Overview of data for annual gross domestic product (GDP)

GDP	Year	2015	2016	2017	2018	2019	Average value
Country							
Australia		47305	50284	51297	53723	54764	51475
Austria		49879	52633	54637	56871	58731	54550
Belgium		46213	48609	50725	52250	53746	50309
Canada		44671	46481	48634	50078	50967	48166
Chile		22685	22762	23730	24736	24985	23780
Colombia		13699	13787	14203	14892	15520	14420
Czech Republic		33691	35877	38490	40389	42242	38138
Denmark		49059	51971	55065	57218	59266	54516
Estonia		29397	31232	33821	36358	38462	33854
Finland		42509	44930	47481	49373	50568	46972
France		40861	42920	44784	46455	47868	44578
Germany		47684	50564	53012	54457	55795	52302
Greece		26903	27823	29089	30354	31134	29061
Hungary		26668	27700	29529	31579	33787	29852
Iceland		48854	53025	55562	57742	59061	54849
Ireland		69056	71922	78128	84460	90562	78826
Israel		35437	37844	38967	40261	..	38127
Italy		36909	39923	41785	42816	43901	41067
Japan		40411	39990	40885	41364	42477	41025
Korea		37908	39546	40934	42113	43445	40789
Lithuania		28824	30925	33821	35832	38227	33526
Latvia		24831	26405	28489	30645	31987	28471
Luxembourg		103751	110376	112823	116787	119862	112720
Mexico		18362	19412	19913	20537	20640	19773
Netherlands		50302	52283	55348	57565	59636	55027
New Zealand		37613	40120	41741	42814	43873	41232
Norway		60385	58934	62941	67640	69426	63865
Poland		26856	28284	30153	31834	33747	30175
Portugal		29669	31605	33086	34341	35961	32932
Slovak Republic		29924	29652	30907	32575	33937	31399
Slovenia		31637	33868	36651	38749	40172	36215
Spain		34913	37282	39576	40483	41903	38831
Sweden		48975	50434	52693	53808	55095	52201
Switzerland		63939	65720	67139	69358	70770	67385
Turkey		25727	26510	28209	28455	28493	27479
United Kingdom		42518	44163	45975	46956	48226	45568
United States		56840	57952	60062	62997	65281	60626

E.8 Actual Individual Consumption (AIC)

Table E.8: Overview of data for actual individual consumption (AIC)

AIC	Year	2015	2016	2017	2018	2019	Average value
Country							
Australia		100,00	101,00	102,50	104,40	..	101,98
Austria		100,00	101,50	103,50	105,70	107,60	103,66
Belgium		100,00	101,30	103,40	105,50	107,10	103,46
Canada		100,00	100,80	102,10	103,90	105,90	102,54
Chile		100,00	103,60	..	..	..	101,80
Colombia		100,00	106,40	110,40	114,20	..	107,75
Czech Republic		100,00	100,70	103,40	106,50	110,40	104,20
Denmark		100,00	100,30	101,60	102,80	103,80	101,70
Estonia		100,00	101,40	105,40	110,20	113,80	106,16
Finland		100,00	99,90	100,60	101,90	103,40	101,16
France		100,00	100,10	100,90	102,20	103,10	101,26
Germany		100,00	100,70	102,10	103,70	105,30	102,36
Greece		100,00	99,20	99,80	100,30	101,00	100,06
Hungary		100,00	100,80	104,30	108,00	112,30	105,08
Iceland		100,00	101,80	102,00	105,70	110,10	103,92
Ireland		100,00	100,40	101,80	103,90	105,60	102,34
Israel		100,00	99,70	100,20	101,50	..	100,35
Italy		100,00	100,20	101,20	102,30	102,80	101,30
Japan		100,00	99,50	99,70	100,10	..	99,83
Korea		100,00	101,20	103,20	..	..	101,47
Lithuania		100,00	101,30	105,30	108,90	112,10	105,52
Latvia		100,00	101,10	104,00	107,10	110,20	104,48
Luxembourg		100,00	100,50	102,40	104,90	107,40	103,04
Mexico		100,00	104,40	109,60	114,00	..	107,00
Netherlands		100,00	100,30	101,80	104,10	107,20	102,68
New Zealand		100,00	101,10	102,70	104,50	..	102,08
Norway		100,00	102,80	105,10	107,70	110,40	105,20
Poland		100,00	99,80	101,90	103,70	105,80	102,24
Portugal		100,00	101,10	102,90	104,30	105,50	102,76
Slovak Republic		100,00	99,80	101,50	103,80	106,50	102,32
Slovenia		100,00	99,90	101,80	104,20	106,40	102,46
Spain		100,00	100,20	101,70	103,10	..	101,25
Sweden		100,00	101,40	103,80	106,70	109,20	104,22
Switzerland		100,00	99,90	100,50	101,60	..	100,50
Turkey		100,00	106,80	118,30	136,10	..	115,30
United Kingdom		100,00	101,40	102,70	105,30	106,80	103,24
United States		100,00	100,90	102,80	105,10	..	102,20

E.9 Households With Internet Access (ICT) at Home

Table E.9: Overview of data for households with internet access at home (ICT access)

ICT access	Year	2016	2017	2018	2019	2020	Average value
Country							
Australia		86,11	..	..	..	..	86,11
Austria		85,09	88,79	88,78	89,91	90,24	88,56
Belgium		84,79	85,97	87,27	89,73	90,86	87,72
Chili		79,30	87,54	..	..	..	83,42
Colombia		45,75	..	52,66	..	..	49,21
Czech Republic		81,65	83,24	86,36	87,00	88,02	85,25
Denmark		94,34	97,00	92,66	95,43	95,27	94,94
Estonia		86,19	88,27	90,47	90,43	89,98	89,07
Finland		91,95	94,42	94,28	94,36	96,00	94,20
France		85,87	86,41	88,56	90,17	..	87,76
Germany		92,14	92,86	94,39	94,83	95,80	94,00
Greece		69,13	70,96	76,49	78,54	80,38	75,10
Hungary		79,18	82,35	83,31	86,20	87,63	83,74
Iceland		..	97,86	99,18	97,70	98,48	98,31
Ireland		86,91	88,37	89,11	90,59	91,82	89,36
Israel		75,37	74,06	..	..	..	74,72
Italy		78,51	81,02	84,34	85,17	..	82,26
Korea		99,19	99,50	99,48	99,69	..	99,47
Latvia		77,34	78,61	81,58	85,45	89,73	82,54
Lithuania		71,75	74,97	78,38	81,52	82,13	77,75
Luxembourg		97,04	97,23	92,99	95,20	93,57	95,20
Mexico		47,02	50,92	52,86	56,36	..	51,79
Netherlands		96,66	98,23	98,00	98,41	96,95	97,65
Norway		97,05	96,65	96,01	98,38	96,20	96,86
Poland		80,45	81,88	84,19	86,75	90,38	84,73
Portugal		74,05	76,94	79,43	80,94	84,49	79,17
Slovak Republic		80,52	81,33	80,84	82,19	85,78	82,13
Slovenia		78,42	81,74	86,68	88,96	89,97	85,16
Spain		81,93	83,39	86,36	91,44	95,38	87,70
Sweden		93,80	94,73	93,42	96,06	93,94	94,39
Switzerland		..	93,06	..	95,51	..	94,28
Turkey		76,34	80,74	83,79	88,30	90,73	83,98
United Kingdom		93,48	93,99	94,85	95,85	97,30	95,10
United States		..	77,97	..	79,88	..	78,93

E.10 Medical Technology Access

Table E.10: Overview of data for medical technology access

Medical technology access	Year	2015	2016	2017	2018	2019	Average value
Country							
Australia		59,54	63,00	64,34	67,29	70,25	64,88
Austria		28,93	29,07	28,64	28,84	..	28,87
Belgium		23,59	23,92	23,82	23,89	23,74	23,79
Canada		15,07	..	15,35	..	14,82	15,08
Chile		..	..	24,21	..	..	24,21
Colombia		1,02	1,19	1,24	1,30	..	1,19
Czech Republic		16,12	15,52	15,76	16,09	..	15,87
Denmark		37,65	39,11	39,72	39,70	40,65	39,37
Estonia		16,72	17,48	18,22	18,91	..	17,83
Finland		21,53	24,20	24,51	16,50	..	21,69
France		16,57	16,95	17,36	17,68	18,24	17,36
Germany		35,09	35,17	35,13	..	..	35,13
Greece		36,13	35,91	34,22	40,62	..	36,72
Hungary		8,43	8,86	9,19	9,41	..	8,97
Iceland		39,30	38,76	43,68	48,20	47,62	43,51
Ireland		17,65	17,24	19,14	20,34	21,41	19,16
Israel		9,67	9,60	9,53	9,57	..	9,59
Italy		33,31	34,29	34,57	35,12	..	34,32
Japan		..	..	111,49	..	..	111,49
Korea		37,03	37,80	38,18	38,56	..	37,89
Lithuania		21,00	23,01	23,33	24,27	26,48	23,62
Latvia		36,91	36,23	39,13	38,40	..	37,67
Luxembourg		17,56	17,14	16,77	16,45	16,13	16,81
Mexico		5,50	6,05	5,76	5,90	..	5,80
Netherlands		13,75	13,04	13,48	14,22	..	13,62
New Zealand		17,88	17,96	16,79	15,70	15,44	16,75
Norway		..	..	..	..	..	.. ..
Poland		17,16	17,33	16,88	18,14	..	17,38
Portugal		..	..	..	..	..	.. ..
Slovak Republic		17,88	17,31	17,28	18,36	..	17,71
Slovenia		13,08	14,04	15,00	15,91	18,26	15,26
Spain		18,02	18,31	18,65	19,12	..	18,53
Sweden		..	..	..	..	..	.. ..
Switzerland		37,67	38,93	39,28	39,70	..	38,90
Turkey		14,31	14,53	14,77	14,88	..	14,62
United Kingdom		..	..	..	..	..	.. ..
United States		41,01	41,88	42,74	44,55	44,94	43,02

E.11 Digital Services Trade Restrictions

Table E.11: Overview of data for Digital Services trade restrictions (STRI)

STRI	Year	2016	2017	2018	2019	2020	Average value
Country							
Australia		0,083	0,083	0,083	0,083	0,083	0,083
Austria		0,083	0,202	0,202	0,202	0,202	0,1782
Belgium		0,162	0,162	0,162	0,162	0,162	0,162
Canada		0,043	0,043	0,043	0,043	0,043	0,043
Chile		0,263	0,263	0,263	0,263	0,263	0,263
Colombia		0,299	0,299	0,299	0,299	0,299	0,299
Czech Republic		0,141	0,141	0,141	0,141	0,141	0,141
Denmark		0,104	0,104	0,104	0,104	0,104	0,104
Estonia		0,083	0,083	0,083	0,083	0,083	0,083
Finland		0,101	0,101	0,101	0,101	0,101	0,101
France		0,123	0,123	0,123	0,123	0,123	0,123
Germany		0,144	0,144	0,144	0,144	0,144	0,144
Greece		0,144	0,144	0,144	0,144	0,144	0,144
Hungary		0,166	0,166	0,166	0,166	0,166	0,166
Iceland		0,148	0,267	0,267	0,267	0,267	0,2432
Ireland		0,144	0,144	0,144	0,144	0,144	0,144
Israel		0,18	0,18	0,18	0,18	0,18	0,18
Italy		0,126	0,126	0,126	0,126	0,126	0,126
Japan		0,064	0,104	0,104	0,104	0,104	0,096
Korea		0,123	0,123	0,123	0,145	0,145	0,1318
Lithuania		0,104	0,104	0,104	0,104	0,104	0,104
Latvia		0,104	0,223	0,223	0,223	0,223	0,1992
Luxembourg		0,083	0,083	0,083	0,083	0,083	0,083
Mexico		0,101	0,101	0,101	0,101	0,101	0,101
Netherlands		0,104	0,104	0,104	0,104	0,104	0,104
New Zealand		0,18	0,18	0,18	0,18	0,18	0,18
Norway		0,083	0,083	0,061	0,061	0,061	0,0698
Poland		0,263	0,263	0,263	0,263	0,263	0,263
Portugal		0,145	0,145	0,145	0,145	0,145	0,145
Slovak Republic		0,101	0,101	0,101	0,101	0,141	0,109
Slovenia		0,083	0,083	0,242	0,242	0,242	0,1784
Spain		0,123	0,123	0,123	0,123	0,123	0,123
Sweden		0,144	0,144	0,144	0,144	0,144	0,144
Switzerland		0,083	0,083	0,083	0,083	0,083	0,083
Turkey		0,202	0,202	0,202	0,264	0,264	0,2268
United Kingdom		0,083	0,083	0,083	0,083	0,083	0,083
United States		0,083	0,083	0,083	0,083	0,083	0,083

F

User Survey

F.1 CTG Telemonitoring Solution

This survey will explore the insights from women in relation to pregnancy and cardiotocography (CTG) technology, used in the healthcare sector today for measuring the fetus heartbeat and contractions during the pregnancy. You might recognise the CTG from the picture below. It is

used most frequently during the third trimester and during labour. The two sensors are fastened on the stomach and the monitoring takes about 30 minutes. A telemonitoring solution would be connected to an app, which sends the information directly to a professional that interprets the data, and gets back to you promptly if there are any abnormalities or issues.

More about the survey: The academic research focus is on the possibility to offer CTG as a service

that can be used from home, connected to medical staff. For example to enable women living far away from hospitals equal healthcare, as well as minimising the times pregnant women attend healthcare facilities for monitoring purposes only. We who are doing this research are Lisa

Emanuelsson and Sara Kangefjärd, and it is the focus of our master thesis work in the field of engineering. We want to understand the view and opinions from women to contribute positively to the development, and are very happy for your help.

General questions

Q1. How old are you?
15-18
18-22
23-25
26-30
31-35
36-40
41-49
50+

Q2. Are you pregnant now?
Yes
No

Q2.1 –> If No –> Have you been pregnant before?
Yes
No

Q.2.2 –> If yes –> Has any of your pregnancies been considered high-risk* by yourself or a medical professional?

** High-risk can include anything that makes you or a medical professional think that you are at higher risk than a standard pregnancy, for example*

- *Advanced maternal age*

- *Lifestyle choices such as smoking cigarettes*
- *Maternal health problems such as high blood pressure, obesity, diabetes.*
- *Pregnancy complications and or a history of pregnancy complications such as premature birth and preeclampsia*

Yes
No
I don't know

Q2.3 –> If no on Q2 –> Are you planning on/trying to conceive in the near future?

Yes
No
I don't know

Q3. In what country do you live?

[List alternative including all countries]

Q3.1 In what type of area do you live?*
City
Town and semi-dense area
Rural area

**Degree of urbanization:*
Cities = have a population of at least 50,000 inhabitants
Towns and semi-dense areas = have a population of at least 5,000 inhabitants
Rural areas = less than 5,000 inhabitants

Q4. Have you heard about CTG (cardiotocography) before?

Yes
No
I don't know

Q4.1 –> If Yes –> Is it included in your health care routine provided in the months/weeks before childbirth?

Yes, it is included as a standard procedure in my health care without additional cost
Yes, it is offered as a service without an additional cost
Yes, it is offered as a service with an additional cost
No, it is neither included or offered as a service with an additional cost
I don't know
Not applicable (I am not or have not been pregnant)

Focused questions

For the following questions, please reply to them as if you were pregnant now, or refer back to your previous pregnancy.

.....

Investigating "Unmet need" (Why do you want to monitor?)

Q5. Do you think that you get enough information about your fetus's well-being at your appointments?

Yes, always
Yes, most of the time
Yes, sometimes
Seldom
No
I don't know

Q 5.1 –> If any answer except Yes, always –> In that case, what sort of information do you lack at your appointments? [Open question]

Q6. Do you feel worried that your child is not well between your scheduled appointments? Yes, always
Yes, most of the time
Yes, sometimes
No
I don't know

Q6.1 –> If any answer except No or I don't know –> Please try to specify why you are worried. [Open question]

.....

Investigating "Better than current solution"

Q7. Would you consider taking any active care choices based on other sources than from your medical professional (midwife/doctor)? Please motivate your answer. [Open question]

Q8. Would you consider using an app to track your fetus's well-being? Yes
No
I don't know

.....

Investigating "Effective solution"

Q9. Would it be beneficial to have regular (daily/weekly) updates about the fetus's heartbeat? Would you be willing to pay to get this update? [Open question]

Q10. Do you have any concerns in general about tracking information about your fetus? Yes
No
I don't know

Q10.1 –> If yes –> In that case, please specify what type of concerns you have: [Open question]

.....

Investigating "Business to customer investigation"

Q11. Would you consider paying for a service that diagnoses and informs that your fetus's heart is beating (with CTG-technology) while being at home? The diagnosis will be made by a healthcare professional, who will inform you personally and straight away if there are any abnormalities or issues.

This would be in addition to an potential CTG offered by your health care professional (midwife, doctor etc) Yes
No

I don't know

Q11.1 –> If no –> why not? [Open question]

Q11.2 –> If yes –> How much would you pay for this service?

**This sum is paid once per pregnancy. The cost includes renting the device, accessibility to the app and service for the relevant time of the pregnancy. The device would be sent to your home for the third trimester, and you would connect it to the app that sends the monitoring results to a medical center of telemonitoring.*

50-100 EUR
100-150 EUR
150-200 EUR
200-300 EUR
300-400 EUR
400-500 EUR
500-600 EUR
More than 600 EUR

Q11.3 At what price would you feel that the product is so expensive that it is not worth purchasing regardless of its good quality? [Open question]: EUR

.....

G

User Survey Replies

In the following appendix, the result from the closed and open ended questions from the user survey will be presented.

General questions

Q1. How old are you?

Table G.1: Question 1.

How old are you?	
23-25	1
26-30	16
31-35	11
36-40	7
41-49	3
Grand Total	**38**

Q2. Are you pregnant now?

Table G.2: Question 2.

Are you currently pregnant?	
Yes	10
No	28
Grand Total	**38**

Q2.1 –> If No –> Have you been pregnant before?

Table G.3: Question 2.1.

Have you been pregnant before?	
Yes	24
No	4
Grand Total	**28**

Q.2.2 –> If yes –> Has any of your pregnancies been considered high-risk* by yourself or a medical professional?

Table G.4: Question 2.2.

Has any of your pregnancies been considered high-risk* by yourself or a medical professional?	
Yes	14
No	18
I don't know	2
Grand Total	**34**

Q2.3 –> If no on Q2 –> Are you planning on/trying to conceive in the near future?

Table G.5: Question 2.3.

Are you planning on/trying to conceive in the near future?	
Yes	12
No	6
I don't know	2
Grand Total	**20**

Q3. In what country do you live?

Table G.6: Question 3.

In what country do you live?	
Australia	1
Canada	2
Pakistan	1
South Africa	**1**
Sweden	11
United Kingdom	**1**
United States (USA)	21
Grand Total	**38**

Q3.1 In what type of area do you live?*

Table G.7: Question 3.1.

In what type of area do you live?*	
City	19
Town and semi-dense area	13
Rural area	6
Grand Total	**38**

Q4. Have you heard about CTG (cardiotocography) before?

Table G.8: Q3

Have you heard about CTG (cardiotocography) before?	
Yes	27
No	7
I don't know	4
Grand Total	**38**

Q4.1 –> If Yes –> Is it included in your health care routine provided in the months/weeks before childbirth?

Is/was CTG included in your health care routine provided in the months/weeks before childbirth?	
Yes, it is/was included as a standard procedure in my health care without additional cost	5
Yes, it is/was offered as a service without additional cost	3
Yes, it is/was offered as a service for an additional cost	2
No, it is/was neither included or offered as a service with an additional cost	13
I don't know	2
Not applicable (I am not or have not been pregnant)	2
I don't know what CTG is	11
Grand Total	**38**

Investigating "Unmet need" (Why do you want to monitor?)

Q5. Do you think that you get enough information about your fetus's well-being at your appointments?

Q 5.1 –> If any answer except Yes, always –> In that case, what sort of information do you lack at your appointments?

Table G.9: Question 5.1.

Do you think that you get enough information about your fetus's well-being at your appointments?	
If any answer except Yes, always –>In that case, what sort of information do you lack at your appointments?	
Yes, always	14
Yes, most of the time	7
Would want appointments more often	1
Few ultrasounds and few ctgs	1
Would have wanted do make more ultrasounds during the time I was pregnant.	1
I don't always get to see the fetus	1
I had very few ultrasounds so that's the only thing I feel like I lacked, seeing and checking in on baby. But honestly I try to be more holistic with prenatal care so I didn't opt for any ultrasounds that were optional.	1
I think we are often not trusted with full information (call if this happens, but then we'll tell you to monitor for something else); this causes more anxiety than if we were given more information from the beginning	1
None	1
Sometimes I didn't have enough time to ask all my questions.	1
Yes, sometimes	6
I would like to know more exactly how the baby is doing	1
-	1
Baby's movements	1
I have short cervix so I felt like that was what the focus was. I wanted to know if the fetus was measuring right, and doing what they should at each stage	1
I'm not sure. The appointments here are just checking heartbeat and fundal height and then you're sent on your way until the next month. Just seems lacking	1
Monitoring of some sort at each appointment	1
n/a	1
Seldom	2
I feel like if a patient is high risk(IC) at every apt they should be informed about the baby.eg. amniotic fluid, babies size etc.	1
Not sure but doesn't seem like it's very informative	1
No	4
I dont know	1
I want to be able to know that my baby is still alive and well at every appointment = more ultrasounds or possibility to listen to heartbeat at least	1

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Table G.9 – *Continued from previous page*

Do you think that you get enough information about your fetus's well-being at your appointments?	
If any answer except Yes, always –>In that case, what sort of information do you lack at your appointments?	
More ultrasounds to ensure baby is growing well, more frequent appointments for fetal heartbeat monitoring	1
Very little monitoring/assessment by community midwives. Under consultancy care received food monitoring from hospital but not joined up (three births at three different hospitals due to no free beds)	1
I don't know	3
Grand Total	**38**

Q6. Do you feel worried that your child is not well between your scheduled appointments?

Q6.1 –> If any answer except No or I don't know –> Please try to specify why you are worried.

Table G.10: Question 6.1.

Do you feel worried that your child is not well between your scheduled appointments?	
If any answer except No or I don't know –>Please try to specify why you are worried.	
Yes, always	3
I have had multiple misscarriages and never been able to keep a pregnancy longer than week 14	1
I've had a misscarriage that my body didnt notice. If for exempel ultrasound was made more frequently it would have been discovered a month earlier than it was.	1
When having decreased movements then you want to se/hear the baby so that you can feel calm	1
Yes, most of the time	3
I'm a NICU nurse and I know everything that can go wrong during a pregnancy. And one of my pregnancies was high risk and my child was born at 24 weeks.	1
Lack of information to calm anxiety about it all. I have no indication that everything is okay in between visits.	1
Worried the heart sudden Will stop	
Worried that something is going to happen and that I Will notice it when its to late	1
Yes, sometimes	18
-	1
If you have not felt the baby in a while. Unfortunately we know that many babies die in the stomach each year	
Advanced maternal age and previous miscarriage.	1
Anything really	1
Because I can't see them or check on them and I don't want them to die. If something happens in there there's nothing I can do.	1
Because I'm a mom! We worry if the baby is moving too much, not enough, if the baby has shifted position, is too big, too small....	1
Being a hyperemesis patient, not having a good nutrition worries about baby's health and heart beat	1
General worry about baby's wellbeing	1
I didn't have any way to monitor him other than counting kicks. It's easy for your mind to jump to worst case scenarios when you don't have any proof to quiet it	1
I had/have HG and therefore constantly worried that the baby isn't getting sufficient nutrients to grow well	1

Continued on next page

Table G.10 – *Continued from previous page*

Do you think that you get enough information about your fetus's well-being at your appointments?	
If any answer except Yes, always –>In that case, what sort of information do you lack at your appointments?	
I have had 13 pregnancies and only 5 living children so I have had alot of miscarriages and one stillbirth due to prolapsed cord. I always worry about a missed miscarriage because I have had that happen 4 times. Baby's heart stopped but I had no idea until my next appointment	1
I have had anterior placentas, so I don't normally feel much movement	1
I'm always aware/concerned about my own health and that of my loved ones, so I'd imagine I'd be the same with something as delicate as a pregnancy.	1
It's a no-news is good-news scenario at the beginning of pregnancy, and really that can be tough to be waiting	1
Just the unknown	1
Movement changes, general worry	1
The amount of weeks between ultrasounds and getting to listen to the heartbeats	1
When i cant feel her.	1
Worried that something is wrong, but the time between visits is too long to discover it in time.	1
Seldom	7
Concerns had been noted during an ultrasound, was waiting for follow up	1
I had bleeding; GD; irritable uterus	1
I had controlled gestational diabetes (controlled with diet and exercise so not considered high risk). Keeping my blood sugar in check for the health of my baby was what caused me to worry	1
My first Mc was due to IC which we figure out later. My 2nd MC we were focused on me cervix and not much the baby. when I went into early labor, the baby did not have much fluid but my water didn't break and they couldn't figure what happened.	1
Once in a while I'll have that back of the mind anxiety	1
Prior miscarriages	1
typical anxiety about baby's position in the final weeks of pregnancy	1
No	5
Grand Total	**38**

Investigating "Better than current solution"

Q7. Would you consider taking any active care choices based on other sources than from your medical professional (midwife/doctor)? Please motivate your answer.

Table G.11: Question 7.

Would you consider taking any active care choices based on other sources than from your medical professional (midwife/doctor)? Please motivate your answer.	
Yes	17
Home doppler would have been nice	1
I sought information on GD from a well-established group.	1
I would like a more regular health check for baby and myself having hyperemesis throughout pregnancy	1
Yes	1
I'm not sure exactly what the question is asking. but I did and do seek alternative sources for guidance and chose whichever I felt more confident and comfortable with.	1
Yes	1

Continued on next page

Table G.11 – *Continued from previous page*

Would you consider taking any active care choices based on other sources than from your medical professional (midwife/doctor)? Please motivate your answer.	
Ja absolut, tror mycket på holistisk hjälp	1
My midwife would be my first source of information. Second are medical journals and research. (I did extensive medical journal reading about diabetes medications and GDM)	1
Sure, but I would always run them by my CPM before doing them.	1
Yes	3
Yes	1
Yes, because I want to have the best picture of my own and my baby s health	1
Yes, I always do my own research.	1
Yes. Based on my own research/evidence/info from governing bodies (SOGCanada), my own instincts	1
Yes. I like to research.	1
Yes. I'd consider monitoring myself, if technology allowed me to do so,	1
Maybe	7
Depends on the source, and what the change was	1
Depends on what it is and the research behind it	1
I wouldn't if I thought it might be harmful to the baby	1
Maybe	1
Maybe. Would depend on what it was and what their experience/credentials we're and if there was any research to support it	1
only if they were recommended by sources/people I trust.	1
That depends on the source.	1
No	9
Information from others' personal experience would motivate me to explore possible issues and treatments with my doctor.	1
No	3
No - I stay away from doctor Google	1
No, I don't think so. I trust my doctor and she knows my specific information.	1
No, I trust my midwife and doctor	1
No. Why listen to uneducated peoole?	1
Not really. I researched key points that I was interested in (ie water birth) but I didn't want to overload with information and get confused.	1
I don't know	4
Dont understand the question	1
Don't know	1
I don't know	1
I don't know what that means. What is an "active care choice?"	1
Grand Total	**38**

Q8. Would you consider using an app to track your fetus's well-being?

Table G.12: Question 8

Would you consider using an app to track your fetus's well-being?	
Yes	29
I don't know	9
Grand Total	**38**

Investigating "Effective solution"

Q9. Would it be beneficial to have regular (daily/weekly) updates about the fetus's heartbeat? Would you be willing to pay to get this update?

Table G.13: Question 9

Would it be beneficial to have regular (daily/weekly) updates about the fetus's heartbeat? Would you be willing to pay to get this update?	
Absolutely, it would calm me down a lot as pregnant with a lot of miscarriages.	1
Both. Could give me more stress if i cant find the heart since it can be tricky sometimes.	1
Depending on the cost, yes.	1
Depends on how costly it is	1
Depends on price	1
Depends on the cost	1
I can't imagine this would be helpful after quickening. I would likely not pay for it	1
I heard baby's hearbeat once during my last pregnancy apart from at scheduled scans. It would certainly have been welcome and I would have been willing to pay (I bought a home monitor but was concerned about using it accurately and effects on the baby)	1
I think it could cause more worry if not being used properly or if there was an error with the device.	1
I think it might cause me anxiety to hyper focus on my baby's heartbeat through out the pregnancy.	1
I'm not sure. Before viability, it seems unnecessary.	1
Yes	1
Maube	1
Maybe	1
Maybe and probably not	1
No	1
No because It's not good to for the baby to do that every week/ daily	1
No. I think that pregnant mothers with no medial issues May over analyse and worry unnecessarily. Relax and enjoy it while being informed of the key issues to be conscious of such as preeclampsia symptoms, lower movements etc	1
No. I think too much information can be worrying, and you'll start to see patterns where there aren't any	1
Possibly	1
Potentially. There's a certain degree of trust that goes into making a baby. That being said, it would be cool to check in more often. I don't know that I would pay for it though.	1
Probably not, I think it would cause more stress. I live an hour and a half from the hospital, it may cause unnecessary trips if not completely accurate	1
probably, depending on cost, and how the pregnancy is. If it is an "average" pregnancy then I don't know if I would pay too much for it, as many others have gotten by without.	1
Well I am able to track with the fetal dopler. But yes.	1
Yes	7
Yes it would be beneficial, but it would depend on the cost and how high risk my pregnancy was.	1
Yes	1
Yes, but no, it isn't I wish about enough that I'd be willing to pay a significant amount	1
Yes, depending on the cost	1
Yes	1
Yes, if I were high risk. That information would be reassuring in that situation	1
Yes!!!	1
Grand Total	**38**

Q10. Do you have any concerns in general about tracking information about your fetus?

Q10.1 –> If yes –> In that case, please specify what type of concerns you have:

Table G.14: Question 10 and 10.1

Do you have any concerns in general about tracking information about your fetus?	
If yes –>In that case, please specify what type of concerns you have.	
Yes	**12**
Concerns about potential miscarriage	1
False information / poor readings causing undue stress	1
False sense of security that everything is ok.	1
Had an early MC before	1
Is it dangerous for baby	1
Kan användning av CTG så ofta påverka fostret?	1
Privacy	1
Prolonged exposure to dopplers isn't great for them, so I don't know if this would be either?	1
Technology, exposure to fetus, that the data is not always useful (pre viability) or requires professional interpretation.	1
The same concerns with home dopplers right now. User error leading to undue anxiety or sense of security.	1
The security and privacy of my medical information and my baby's medical information. Additionally, any adverse effects of using monitoring of that sort more frequently	1
Too much information without proper interpretation could lead to increased anxiety. Also standard privacy/data sharing concerns	1
No	**18**
I don't know	**8**
Grand Total	**38**

Investigating "Business to customer investigation"

Q11. Would you consider paying for a service that diagnoses and informs that your fetus's heart is beating (with CTG-technology) while being at home? The diagnosis will be made by a healthcare professional, who will inform you personally and straight away if there are any abnormalities or issues.

This would be in addition to an potential CTG offered by your health care professional (midwife, doctor etc)

Q11.1 –> If no –> why not?

Q11.2 –> If yes –> How much would you pay for this service?

Table G.15: Question 11, 11.1 and 11.2

Would you consider paying for a service that diagnoses and informs that your fetus's heart is beating (with CTG-technology) while being at home??	
If yes –>How much would you pay for this service?	
If no –>why not?	
Yes	**16**
50-100 EUR	5
100-150 EUR	5
150-200 EUR	2
200-300 EUR	4
I don't know	**13**

Continued on next page

Table G.15 – *Continued from previous page*

Would you consider paying for a service that diagnoses and informs that your fetus's heart is beating (with CTG-technology) while being at home?	
If yes –>How much would you pay for this service?	
If no –>why not?	
50-100 EUR	9
100-150 EUR	2
150-200 EUR	2
No	**9**
$0	1
Because if I was concerned about the baby enough to do that I'd want to see my obstetrician.	1
I don't see what benefit it would give me. If you notice a problem, does that mean I would have time to go to the ER? Are irregular heart beats fairly common and so I'd be getting notifications that would only increase anxiety for no reason?	1
I live in Canada and we don't pay for healthcare	1
I think it would cause more fear and possibly unnecessary interventions	1
I'm not interested	1
It's unnecessary and I think would just cause stress.	1
Part normal prenatal care with on/ midwife frequent home regulation could add undue stress if machine not used properly	1
Trust the body, it will be placed wrong and it will fail and give me more anxiety.	1
Grand Total	38

Q11.3 At what price would you feel that the product is so expensive that it is not worth purchasing regardless of its good quality?

Table G.16: Question 11.3.

At what price would you feel that the product is so expensive that it is not worth purchasing regardless of its good quality? (in EUR)	
30	1
50	1
150	1
200	1
300	1
400	1
425	1
500	1
1000	1
$350	1
200 euros	1
200 unless I had a very serious complication and at home monitoring would prevent a hospital stay or bed rest	1
200-300	1
201 EUR	1
300 or more	1
400-500 EUR	2
500+	1
500+ eur	1
500ur	1
Above 200 would be restrictive to many but it deoends on the quality of service	1
Dont know	1
I don't know euros	1

Continued on next page

Table G.16 – *Continued from previous page*

At what price would you feel that the product is so expensive that it is not worth purchasing regardless of its good quality? (in EUR)	
It would have to be on par with dopplers you can purchase.	1
No idea	1
Not sure	1
Over 200 euro	1
Over 330	1
Over 400	1
Grand Total	**29**

H

End User Interview Questionnaire

The following questions and topics were the basis for the end user interviews. They are not necessarily presented in a chronological order, due to the semi-structured character of the interviews.

Introduction on the subject, covering the following topics:

- Field of study, Industrial Engineering and Management
- Personal interest of health technologu and social sustainability
- Research project based on emerging trends for CTG home monitoring during pregnancy. Investigation of innovation criteria
- Neutral view, ok to express any feelings
- Understanding of the technology

Ask if the interviewee is consenting to the following discussion being video recorded.

Q. What are your initial thoughts after seeing the video?

Investigating "Trust case"

Q. If you would see this commercial promoting you to use CTG antenatally as a private service, meaning that it is not connected to your regular care given. It seems professional, well researched and is able to identify threats such as oxygen deficiency to your baby.

Q. Your midwife however has a negative opinion about. She wouldn't have the opinion that it was harmful to use, but rather unnecessary. Would you consider paying for this product?

Q. Would it make any difference if the product was offered through a medical professional (your midwife) or directly to you as a customer (for example via the internet or a pharmacy advertisement)?

Investigating "Job to be done: Control/reassurance/extra information"

Q. In what moments would you think about using this technology? Do you see yourself using it more regularly or a need to use it spontaneously (straight away if you get triggered by a specific feeling)

Q. In what situations do you think that you would use it spontaneously?

Q. What feelings do you feel when you monitor? (fun, reassuring etc)

Q. Do you think that you would use it more often than specified? For example if it was to be used once a week, would you feel urge to use it more often, to "double check" that everything is ok?

Investigating "Job to be done: Transport"

Pretend that: You were recommended by your midwife to monitor more often in your third trimester (every day, every other day, every week)

Q. Would it make a difference for you to do it from home or at the hospital setting? Both alternatives include a midwife who will look at your results in real-time and get back to you if there are any concerns.

Q. Would you consider using this product if it was only used to do additional check-ups than your regular and recommended meetings at the hospital?

Investigating "Job to be done: a positive experience/extra information (a cool feature or a connection to the fetus"

Q. Does it attract you to use the product if it has no clinical value, but it is not harmful either. Would you think it is a "fun/cool" thing to use?

(To be able to hear your baby's heartbeat and see how it changes when it is asleep etc. It could be comparable to the insights from a smart watch, a sleeping monitor, a training watch or something similar. Just for providing information)

Q. Do you think that it would give you connection with your baby?

Q. If yes, would it be a main reason for you to use it?

I

Industry Interview Questionnaire

The following questions and topics were the basis for the industry interviews. They are not necessarily presented in a chronological order, due to the semi-structured character of the interviews.

Introduction on the subject, covering the following topics:

- Field of study, Industrial Engineering and Management
- Personal interest of health technology and social sustainability
- Research project based on emerging trends for CTG home monitoring during pregnancy. Investigation of innovation criteria
- Neutral view, ok to express any feelings
- Understanding of the technology

Ask if the interviewee is consenting to the following discussion being video recorded.

Investigating "Diffusion Model of Innovation"

Q. What would you say is the relative advantage of the product you are offering?:

- In comparison to non invasive fetal ECG?
- In comparison to no use at all?

Q. compatibility (values, experiences and needs of the potential adopters?)

- Do you see different needs for the future?
- Different needs in different countries?

Q. Home care setting in the Netherlands? How important do you think it is for a successful implementation?

- Is there a difference in acceptance from hospitals in the Netherlands compared to other countries towards home monitoring technology?

Q. Is it hard for the woman to learn how to use it by herself for the first time trying it?

Q. As we understand it there is a discussion around antenatal CTG and the WHO has stopped recommending it. What is your thought around this?

Investigating "Market Opportunity Navigator"

Q. Did you consider releasing it as a product for private use?

Q. Do you see potential use for women that don't have high-risk pregnancies (b2c, b2b)?

Q. How did you decide to invest in this technology?

Q. Did you evaluate different ideas or solutions?

Q. What do you think is the compelling reason to buy?

Q. What do you think is the biggest challenge for the implementation for this product? (funding, data privacy, initial costs etc)

Q. Is there anything you see as a potential external risk? (such as large dependency on certain actors, changes in regulations etc)

Q. The readiness for connected medical devices in general seems low when it comes to regulations and support for example insurance companies and reimbursement models - what are your thoughts about this? Do you agree, what is your experience?

Investigating "Porter's Diamond Model"

Factor conditions (Advantages)

Q. Is it correct that the Netherlands is where you established yourselves first?

Q: Do you think there is something about the Netherlands that gives you a competitive advantage compared to other markets? for example academic research, specialized knowledge, a certain structure within the care sector that makes it favourable?

Q. What do you think are necessary parameters for this type of product to work on a market? eg. a decentralized care system etc.

Firm strategy structure and rivalry

Q. Is there anything special in how you are managing your organization internally that gives you a competitive advantage?

Q. Is there large competitiveness on the national market in this segment?

- If no, as a firm in general?
- If no, globally?

Q. Have you tried or considered introducing on any other markets? Why/why not?

Demand conditions

Q. What does the demand look like for this product? (home market/global)

Related and supporting industries

Q. Are you dependant/in contact with many businesses in the industry? Are there any cooperation? Are they global/national?

Q. Are there any missing segments/resources in the industry that hinders you from expanding? For example lack of labour force, suppliers, distribution etc.

Government

Q. Are you affected a lot by governmental steering?

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Medical Professionals Interview Questionnaire

The following questions and topics were the basis for the interview with a a gynaecologist and an obstetrician-medic that have been a part of the implementation of a remote CTG monitoring service at the medical centre they are working. The questions are not necessarily presented in a chronological order, due to the semi-structured character of the interview.

Introduction on the subject, covering the following topics:

- Field of study, Industrial Engineering and Management
- Personal interest of health technology and social sustainability
- Research project based on emerging trends for CTG home monitoring during pregnancy. Investigation of innovation criteria and implementation aspects
- Understanding of the technology

Ask if the interviewee is consenting to the following discussion being video recorded.

Investigating "Their experience"

Q. The story behind taking the initiative to use the home monitoring system and the accelerate use during Corona:

- Can you see an increased interest for the product during Corona?
- Is this something you would like to maintain, and see being maintained after the pandemic? Why/Why not?

Investigating "The technology/product"

Q. As we understand it there is a discussion around antenatal CTG and the WHO has stopped recommending it. What is your thought around this? (it not having clinical value)

- Has it affected the use of CTG during the antenatal period?

Q. Are women informed about antenatal CTG?

Q. Do you think women in general wish to make her own care choices?

Q. Do you think women are informed about different medical options/methods?

- Demanding certain care routines?
- Interested in the care she is given?

Q. Do you think there is a historical difference in women's attitude and patterns when it comes to care? More patient-centric?

Q. Is there a group of patients that are more interested or concerned about the care given to her?

Q. What types of worries do women carry in general?

Investigating "General worries about pregnancy "

Q. Do you think CTG telemonitoring would relieve any area of existing worries?

Investigating " How it works today: "

Q. Can the data collected during a woman's pregnancy be connected to upcoming pregnancies?

- How is the data stored?

Q. Today, is there any way for women to contact someone directly if she feels worried?

- How does it work today? Do women go to the emergency in the worst case, if they are worried?

Q. Is there any other collaboration, than with the product producer, to make the system work?

Q. How do you work to prevent overuse of the product? (mothers monitoring too much) Is it an issue?

Q. Is it hard for the woman to learn how to use the device by herself for the first time?

Q. What do you think are necessary parameters for this type of product to work on a market? eg. a decentralized care system etc.

Investigating "Future Potential"

Q. What do you think is the biggest challenge for the implementation for this product? (funding, data privacy, initial costs, resistance from employees etc) (perspective from you working in the hospital)

Q. How do you look at the future of this technology?

Q. Do you see a potential and future in this technology being offered to women without a medical condition?

- Do you think it is a product that should be offered to everyone or only to those with high-risk pregnancies?
- Being offered B2C or only doable through midwifes/doctors?

Q. Do you see any development potential for the product?

- Do you see a future where the process is more effective? Where you don't interpret the data?

Q. What issues and possibilities do you see with the product? (increased number of hospital visits e.g.)

Q. What do you think are or could be the biggest positive effects of using this product?

Q. What do you think are or could be the biggest negative effects of using this product?

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