Master's Thesis

The awareness of the healthcare professionals regarding the difference between medical and consumer devices

In cooperation with Clinipower and Heart2Save

MSc in Business Administration and Innovation in Healthcare

Copenhagen Business School

Anna Näveri, 124871 & Johanna Pasanen, 125254

Supervisor: Till Winkler

Co-supervisor: Lisbeth Kjellberg

Date of submission: 14.01.2021

Number of pages: 97

Number of characters (incl. spaces): 149 970

Abstract

If left untreated, the issues with heart rate, such as atrial fibrillation might lead to a stroke. This is why more and more preventive digital treatment methods for the consumers to use at home are becoming available on the markets, such as Heart2Save's AiVoni device, which is a regulated medical device designed for consumers to use. These medical devices can be used by both – the consumers at home and the medical professionals in clinical settings as a tool in diagnostics process. Due to this, it might be difficult for a healthcare professional to keep their knowledge about the new devices up to date and be aware of whether a device is regulated and can be used as a part of the diagnostic or treatment process. This thesis studies whether the healthcare professionals are aware of the difference between medical and consumer devices sold in consumer markets and whether the division of responsibility if something goes wrong whilst using a medical device is clear for them. The qualitative study the thesis consists of 9 interviews with healthcare professionals working in different parts of Finland.

The results suggest that the knowledge of the professionals could be improved as it was seen from the results that the difference is not always clear for the professionals. Also, the lines of responsibility are not clear either which means that awareness about the topic should be improved. Through these findings it can be seen that the healthcare professionals might benefit from training in order to be able to use the new tools more efficiently in their day-to-day job.

Keywords: medical devices, healthcare professionals' responsibility, new medical technologies, atrial fibrillation

Table of contents

1. Introduction

Multiple trends are affecting healthcare nowadays; the population is aging, there is a need for more healthcare personnel to respond to the increasing demand, and more and more people are having chronic conditions (Topol, 2019). All of these, and also other trends affecting healthcare have one common factor - more resources and new technologies will be needed, even if they are not always available. To be able to handle the constantly increased demand of healthcare, there is more and more demand for new innovations. They do not make the system only more cost effective, but may also increase the quality of healthcare, and diagnostic services (Topol, 2019).

Traditionally the healthcare professionals are responsible for the decisions they make in regard to the treatment of their patients (Holm, 2011). However, as the number of new healthcare technologies that are used daily as tools to diagnose and treat patients increases, so does the importance for the healthcare professionals to understand what is on their responsibility and accountability and what is not (Winfield & Jirotka, 2018). Reddy et al. (2019) notes that with current regulations, the lines of responsibilities are not always clear to people who work with technological tools that are used when treating patients. Due to this, the new Medical Device Regulation (MDR) provides clear guidance as it states that the manufacturer is responsible, when using devices that use algorithms or artificial intelligence to diagnose or treat a patient and the device is used as intended.

One of the conditions that increase when people live longer, is stroke. For example, if the number of stroke cases could be prevented, it could increase the quality of life of many patients, and decrease the costs (Stevens et al., 2017). One way of doing this is by offering new preventive digital treatment methods as a part of the care

chain, such as Heart2Save's AiVoni product (Heart2Save, n.d.) which is able to detect stroke from its user, or Apple Watch 6, that is able do to the same (Apple, n.d.) As the amount of medically regulated devices and algorithms is increasing, also more regulation is needed - this is important to ensure new solutions safety, and that they can be used as intended.

The consumer markets within the healthcare related products are revolutionizing in upcoming years, as the amount of the medically regulated devices that consumers themselves can buy as easily as normal, non-regulated consumer products, is increasing. These devices can also be used as part of the diagnostic or treatment process. This can lead to misunderstandings among healthcare professionals, if the professionals are not aware how to differentiate regulated and non-regulated devices, as medical technology has been traditionally sold and used mostly in healthcare surroundings, such as in hospitals or in clinics (Quinn et al., 2013). Unconsciousness can also mean that many new innovations do not get into the hospital or other healthcare environment to advance the treatment process, even though both healthcare professionals and patients would benefit from it. Also, if medically regulated devices sold in consumer markets do not work as intended, who is responsible: is it the physician who made the diagnosis with the help of the device, or is it the manufacturer?

This thesis aims to research if the division of responsibility is clear for the people who work in the healthcare industry in Finland, and if they know how to differentiate the medically regulated device from the unregulated one. Based on the background research made for the thesis about the subject, the previous research of the topic is minimal or non-existent. This presents an issue, as the market of medical devices and softwares has increased as more and more new solutions become available. How the potential of new technology can be utilized, if the actual users

are not sure that devices can be used as a part of the treatment process or are afraid of using them as they are not sure who is responsible if the patient is misdiagnosed.

1.2. Market and Company Background

In 2017, the size of the medical technology market in Europe according to MedTech Europe (2019) was approximately 115 billion euros, which makes it the second largest medical technology market after the United States. There are currently over 500 000 medical devices and 27 000 medical technology companies in Europe. The number is estimated to continue to grow in the future (MedTech Europe, 2019). It has also been predicted that the cardiology and heart disease diagnostics will have the second largest share of the medical devices after in vitro diagnostics (EvaluatePharma, 2018).

In line with global trends, the Finnish medical and wellness industry has been steadily growing for the past 20 years and is now one of the fastest growing industries in Finland (Healthtech Finland, 2019). According to the yearly report of Healthtech Finland (2019), the medical technology export was worth 2.3 billion euros in 2018 with an annual growth of 3.4 % compared to 2017. Medical devices have the largest, 71 % share of the total exports of all medical technologies.

One of the companies that work in the medical technology industry in Finland is Heart2Save, which the thesis was decided to make in collaboration with. Heart2Save was founded in 2015 in Kuopio, Finland. The idea behind Heart2Save is to provide an easy-to-use tool for both patients and doctors, to detect arrhythmia before further complications arise.

Heart2Save has developed CE-marked (Q1/2020) class IIa medical device, AiVoni product, which aims to prevent stroke by detecting atrial fibrillation. Atrial fibrillation, if untreated, causes death or disability in ⅔ cases. ⅓ of the cases returns back to normal life after the stroke (Stevens et al., 2017).

The AiVoni product is a handheld medical device, aiming to measure a user's electrocardiogram (ECG). It consists of an algorithm which is able to detect atrial fibrillation by measuring heart rate with Suunto Movesense sensor. After the measurement, the algorithm provides the analysis of ECG to customers via app. The results can also be used by healthcare professionals. Traditionally, atrial fibrillation has been hard to detect in some cases, e.g., it may not occur when ECG measuring is done in the clinical setting, but the patient is still having dangerous arrhythmia without symptoms. With AiVoni product, the diagnosis process will be transformed from clinical settings to homecare, which increases the quality of care by making arrhythmia detection easy and accurate and decreases overall costs (Heart2Save, n.d.).

1.3. Problem definition and statement

The thesis was made in cooperation with Finnish consultancy company Clinipower and Heart2Save. The CEO of Clinipower, Maija Laukkanen has been working with healthcare professionals over a decade and has noticed that the amount of medically regulated devices used in healthcare have been increasing, but the knowledge about the subject among professionals working in the field is not always up to date. Clinipower and Heart2Save aimed to gain more insights about the current market situation and the overall awareness of professionals. Clinipower was interested in a more general overview, and Heart2Save wanted to know about possible competitors

and the overall landscape at the market. Also, innovation adoption was partial interest.

The market has changed rapidly; usually devices available in consumer markets are not targeted for diagnosing or treatment purposes, such as fitness watches and heart rate sensor belts. Of course, there has been for example blood pressure meters available for consumers to buy, but the number of medical devices available to consumers has been rather moderate. Within the last years, new medically regulated devices have increasingly started to enter the consumer markets and can be used more and more as part of the diagnosing and treatment process.

As some of the new regulated devices, e.g., portable heart rate measuring devices embedded with algorithms, or continuous glucose monitoring technologies are nowadays offered in consumer markets, this may be confusing to healthcare professionals. The reason for this is that they might not be aware that the medically regulated devices are also available for the consumers to buy from the regular stores, as they have been traditionally purchased by hospital or healthcare centre purchasing boards and used only in healthcare environments. During the interview phase it was also noticed that professionals usually just assume the devices are regulated but are not really aware how to be sure about it; traditionally the buying person or purchasing board has been responsible for ensuring that the purchased goods are regulated. Laukkanen has also noticed that the amount of knowledge of the purchasing body really varies in Finland, which is worrisome as they have been traditionally responsible for purchasing regulatorily approved devices.

If the difference between medical and consumer devices, especially when measuring heart rate, is not always clear for doctors or other healthcare

professionals, or purchasing professionals, how can they recommend or purchase the new technology to be used as a part of the treatment process? Laukkanen also states that as the regulated devices are nowadays sold more and more in consumer markets, it can be really confusing to doctors, whether or not the results from the devices can be used in a clinical setting. The other thing that might be confusing is responsibility - if a consumer buys a regulated medical device from the consumer market, who is responsible if the device does not work as intended?

Problem statement

Based on discussions with other healthcare professionals and industry representatives, Laukkanen has identified the possible unawareness of the differences between consumer and medical devices. The responsibility division may hinder especially multiple start-up companies and other new player's market entry, including Heart2Save, whose solution is used as an example through the thesis. The problem arises especially if the companies are aiming to sell their products straight for the hospital districts or individual hospitals or clinics or aiming to international markets at some point. World Health Organization (2010) also states that traditionally there has been an asymmetry between physical and patient when deciding the treatment methods. Therefore, if the professionals are not familiar enough with the new device, they rather hinder than facilitate the implementation process of innovation.

Within this thesis the researchers have decided to look into the real-life opinions of healthcare professionals; how they see the difference between consumer and medical devices, and how they see that the responsibility is divided between the healthcare professional and the manufacturer of the device, when it is used for diagnosing purposes.

Although European Union's and local legislation provide regulations on this issue, in day-to-day life people may expect, think and assume differently. The new Medical Device Regulation entered into force in May 2020 with an aim to clarify the legislation regarding the medical devices. Although the MDR came into force in all European countries, it must be kept in mind that findings of this thesis are not necessarily applicable other countries than Finland, as the selected interviewees are Finnish. Therefore, the two main objectives of the study are, firstly, to find out how the Finnish healthcare professionals understand the difference between consumer and medical devices and secondly, how aware they are about their responsibility when using these new technological tools in their everyday work.

To help Heart2Save and Clinipower to gain a better understanding of the main problem statement, the following research question and sub-questions have been formulated:

How the healthcare professionals understand

1) Difference between medical and consumer devices which are sold in consumer markets?
2) The division of responsibility between professional and manufacturer, when using the medical device sold in consumer markets? I.e., situation where the device does not work as intended?

To answer this question in detail, it will be necessary to consider the following sub-questions:

- What regulations affect medical devices, and how does it differ from the regulation affecting the consumer devices?
- How the healthcare innovations are diffused in the healthcare environment and what are the main barriers?

1.4. Delimitation

The authors of this thesis have decided to research this specific topic, because there is limited information and research of the subject available in Finland. The aim was also to improve awareness of the subject, especially as the number of medical devices sold in consumer markets is increasing, and therefore the importance of the subject becoming significant.

There were also several delimitations when considering the objectives of the study. As the number of the interviewees is limited, the thesis may not offer a complete picture of the subject. The study also focuses mostly on heart rate measuring devices, and nevertheless other devices are mentioned, the results may not be applicable to all kinds of devices. The objectives were also scoped only to certain topics that new Medical Device Regulation affects.

As the authors noticed that there is common unawareness on the researched topic, the following research question delimitations were set. The further research about medical technology marketing was decided to be left off, as it does not seem to be relevant for the thesis aims. Also, more detailed inspection on customer device legislation and regulation were excluded, to prevent the thesis to be too wide.

The scope population of the study was especially healthcare and other professionals, who are working in the position that faces the stated problem. This study aims to provide information also to other stakeholders working in healthcare, e.g., those in administrative positions, or working with the device purchase process, to be informed about the current level of knowledge regarding the research subjects. The study was conducted in Finland, so the results might not be generalized into other countries.

1.5. Structure of the thesis

The thesis will be divided into six chapters: introduction, theoretical background, methodology, empirical results, discussion and conclusion, respectively.

Firstly, there will be an introduction to the topic, and a description of the case company and the market. After that the studied research questions, the problem statement and the delimitations of the study will be introduced.

Secondly, the thesis will aim to provide a solid theoretical background by including a thorough description of the medical and consumer devices. It will provide an insight into the differences between these devices, and their intended purpose. The following sections will include the differences in regulation in accordance with CE mark, ISO certification, and data privacy of these devices. In addition, the innovation process of the medical devices, and the possible responsibility issues will be considered in the theoretical background.

Thirdly, the thesis will present the data acquisition process of the thesis. The relevant methodology that will be used to perform the qualitative research for the

study will be introduced. It is reasoned thoroughly and chosen research methods will be presented. In addition, analyzing, transcription and coding methods will be presented.

Fourthly, the empirical results section will provide an introduction to the interviews that were conducted. In addition, the main findings are presented before a thorough analysis in the discussion section.

Fifthly, the discussion will include a thorough analysis of the results and elaborate on the results. It will analyse the results and link them to the theoretical background in order to provide a solid conclusion of the results. The discussion will also introduce the limitations of the thesis and the suggestions for further research.

Finally, the last part of the thesis will be the conclusion. It will highlight the most important research findings and conclude the research.

2. Theoretical background

2.1. Medical and consumer devices

Quinn et al. (2013) points out that traditionally the healthcare professionals have been in charge of the purchase decisions of the medical devices. However, nowadays more and more medical devices can be found on consumer markets, and this makes it possible for consumers to buy the medical devices themselves. Therefore, the intended purpose needs to be stated in medical devices, so that the consumers and healthcare professionals can understand which devices can be used for e.g. diagnostics and which cannot (Quinn et al., 2013). This section aims to clarify the main differences between medical and consumer devices and their intended use.

2.1.1. Medical devices

MedTech Europe (2019), describes medical technologies as the products and services that are used for saving and improving people's lives. All medical technologies need to be regulated as they are used for the prevention, diagnostics and treatment of patients. Medical technologies can be divided into two categories:

1) medical devices (MD), such as software, appliances or instruments, which are intended to be used for medical purposes (EU MDR 2017/745). These can be used either by consumers, or by healthcare professionals.

2) digital health, or wellness technologies (MedTech Europe, 2019), which consumers can use by themselves without professional medical assistance to

measure their overall wellbeing, e.g., new smart watches. These are unregulated, and traditionally not intended to be used as a part of the treatment.

The EU considers a product to be a medical device, and subject to regulation, if it meets the definition of a medical device per Medical Device Regulation (MDR) 2017/745. On MDR 'medical device' means an instrument, apparatus, appliance, software, implant, reagent, material or other article, which is intended by the manufacturer to be used alone or in combination for human beings for medical purposes. Examples of the medical devices are X-ray scanners and dentures to hip joints. Also in vitro diagnostic products are considered as medical devices, but the further review of the legislation that applies to them is out of the scope of the thesis. Medical devices have an important, often crucial role in different medical and treatment purposes. On MDR these purposes are defined as following:

- Diagnosing, preventing, monitoring, predicting, prognosing, treating or alleviating a disease
- Diagnosing, monitoring, treating, alleviating or compensating for an injury or disability
- Investigating, replacing or modificating the anatomy, or a physiological or pathological process or state
- Providing information by means of in vitro examination

Also, devices which support or control of conception, or are meant for disinfection, sterilisation or cleaning of devices are also deemed to be medical devices (MDR 2017/745).

All medical devices must carry a CE mark in order to comply with the MDR. These requirements increase the costs of the development process as e.g. the application process of a CE mark tends to be quite slow (Piester & Rosager, 2017).

The MDR states that the main differences between medical and consumer devices include reporting a situation if a device fails, the clinical evaluation process and language requirements in documentation (EU MDR 2017/745).

It is stated in the MDR that the main differences between medical and consumer devices are the following:

Failure of a device

If a medical device fails to work as intended, the reporting process has to be thorough and documented in a correct way that is described in the MDR article 14. This process and documentation of it will be described in detail in this thesis later when discussing the regulations that affect the medical devices. When using a consumer device, there is no such process, but usually there is also no need, as these devices are not meant for treatment purposes.

The clinical evaluation process

The clinical evaluation under the MDR shall be based on a critical evaluation of the scientific literature on the subject, a critical evaluation of the results of all available clinical trials and a consideration of currently available alternative treatment options. Article 61 in the MDR describes that the manufacturer needs to specify and justify the level of clinical evaluation that is necessary for a medical device to demonstrate compliance with the relevant general safety and performance requirements. The clinical evaluation needs to take into account the intended use of

the device and the clinical evaluation process shall be designed, performed and documented accordingly to the MDR.

Language requirements

In addition, it is stated in the new MDR that the documents and other information has to be translated to the official language determined by the Member State concerned. For example, in Finland the material needs to be produced in Finnish and Swedish. The documents may include:

- Information supplied with the device such as user manual
- Information supplied with the implanted device
- The declaration of conformity and the certificate drawn up by the notified body
- The application for naming the notified body
- The information and documentation to be provided to the authority to demonstrate the conformity of the device
- General safety announcements of a device
- Clinical evaluation overview (EU MDR 2017/745).

2.1.2. Consumer devices

The consumer devices are used for different purposes, focusing more on people's wellness. Consumer devices are most commonly used in the form of self-tracking devices, such as smart wearables (e.g. watches, belts, bracelets) that are wireless sensor-equipped devices, designed to be worn continuously and used in sync with an application (Cheng & Mitomo, 2017). These solutions help people to track their own health and performance (Hoyt & Yoshihashi, 2014). These devices are also targeted to consumers, who can use devices to measure information such as their

locations, environments, movements, and vital signs (Cheng & Mitomo, 2017; Sjöklint & Constantiou, 2015).

The major difference between the medical device and wellness technology market is that the medical devices are used to prevent, diagnose and treat the patients and they need to be regulated. The consumer devices cannot be used to treat a patient and they do not have to be regulated in order to be sold in consumer markets (EU MDR 2017/745). From the market point of view, Piester and Rosager (2017) also point out that the biggest advantage of non-regulated devices is that it usually fastens the market introduction, and therefore initial learnings and revenue to fund for the future activities. This is because the classified devices come with more strict requirements to demonstrate the device's safety, effectiveness and performance (Piester & Rosager, 2017).

As the consumer devices are not used as medical tools, also the responsibility is seen differently as the responsibility of a device transfers to the consumer when they have acquired the physical possession of the good, EU Directive 2011/83/EU, (European Parliament & Council of European Union, 2011). The Finnish Competition and Consumer Authority (2020) states that after purchasing a consumer product, the consumer is in charge of using it correctly and complying with the given instructions and using the product as intended. If the product is not used as intended, the consumer is responsible for the harm it may cause (Consumer Protection Act 38/1978, 2020). However, an exception appears, if the product is flawed, the Directive 85/374/EEC (1985) of European Union states that if the product has been faulty, the producer shall be responsible for the damage caused by the product (European Union, 1986).

2.2. Regulation affecting medical and consumer devices

Piester and Rosager (2017) have noted that when developing healthcare technologies such as medical devices, legislation has a significant role. Legislation and regulations need to be taken care of as a part of the development process, and there is also need to comply with post-launch requirements. Stricter legislation and requirements are mandatory for medical devices, as they ensure users safety whenever the devices are used (Piester & Rosager, 2017).

2.2.1. Medical Device Regulation

The new MD- and IVD regulations overruled the old regulations 90/385/ETY on active implanted devices, 93/42/ETY on medical devices and 98/79/EY on in-vitro diagnostics in the EU. For the old directives 90/385/ETY and 93/42/ETY the termination date was 26.05.2020 and for 98/79/EY it will be 26.05.2022 (EU MDR 2017/745).

The new MDR (EU MDR 2017/745) article 10 regulates the general obligations of manufacturers. When the manufacturer is producing a medical device available on the market, or putting them into service, they need to ensure that they are designed and manufactured as it is stated in the regulation. (EU MDR 2017/745). When discussing requirements on medical devices on EEA, there are also other regulations than CE-mark applied. As medical devices are expected to be safe and to incorporate the latest science and manufacturing technology, EU recently updated the rules on the safety and performance of medical devices (European Commission, n.d.-d):

- EU 2017/746 on in vitro diagnostic devices
- EU 2017/745 on medical devices

The new directives entered into force on 25 May 2017 and were fully applicable in May 2020 for medical devices and will be fully applicable May 2022 for in vitro diagnostic devices (European Commission, n.d. -d). When European Commission (2019) made proposals as the new regulations, the aim was to ensure high protection for customers when using medical devices, and also support innovations - the commission wanted to restore patients, consumers and clinical professionals' confidence in medical devices, after the issues with e.g. breast implants in France.

The new regulations aim to following (European Commission, 2019a)

- Increase clinical investigation requirements and manage risk to ensure patient safety
- Reinforce surveillance and management of the entire MD and IVD life cycle
- Improve transparency and traceability
- Reduce ambiguity with clear classifications and definitions

Especially patients benefit from the new MDR. This is the result of the increased safety requirements and performance of devices, which means more information, surveillance and transparency of the medical devices. There are also improvements for healthcare professionals and health institutions: this is because of improved transparency on clinical and vigilance data through EUDAMED. Also the roles and responsibilities for authorised representatives, importers and distributors were clarified and reinforced. This was to ensure the legal compliance of devices on the EEA market. The value of CE marked devices also strengthened, as new regulations

reflect better scientific and technological advancements (European Commission, 2019a).

New features in the MDR include the Unique Device Identifier (UDI), European Database on Medical Devices (EUDAMED), an implant card for patients with information on implanted medical devices, and stricter pre-market control for high-risk devices (European Commission, 2019b).

The changes are significant, and the guidelines for doing public procurement have been strengthened. Before the medical device may enter the market, it needs to comply with safety and performance requirements, which are clarified on new MDR (EU MDR 2017/745). Also, before the new MDR there has not been a comprehensive EU database on medical devices, or device traceability systems with unique identification codes, so the directive-compliance has been hard to detect.

In order to make detecting the directive compliance easier, European Database on Medical Devices (EUDAMED) was introduced in the MDR. EUDAMED is the common database for medical devices: it contains information for registration, collaboration, notification and dissemination. EUDAMED will be implemented in 2022 for medical and in-vitro medical devices. EUDAMED will contain different modules for example on actors, UDI & devices and notified bodies & certificates (European Commission, n.d.-c). Sometimes it is also specified on public procurement that the manufacturer must attach the manufacturer's declaration of conformity, which specifies CE-mark and intended use. With the new MDR it is the responsibility of the manufacturers and distributors to ensure that the device is directive-compliant, and the buyer does not have the whole responsibility. Manufacturer e.g., must draw up a declaration of conformity, which states that

requirements laid out in the regulation has been completed in respect of the device covered by that declaration of conformity (EU MDR 2017/745).

The Unique Device Identification System (UDI) is a new addition to the MDR. It aims to facilitate easier traceability and monitoring of medical devices. UDI is a unique series of characters assigned to a medical device which allows the unambiguous identification of a device (EU MDR 2017/745). Economic operators shall be able to identify the following to the competent authority:

(a) any economic operator to whom they have directly supplied a device;

(b) any economic operator who has directly supplied them with a device;

(c) any health institution or healthcare professional to which they have directly supplied a device (EU MDR 2017/745).

Product's UDI consists of two parts:

1. UDI device identifier (UDI-DI), specific to a manufacturer and a device, providing access to the information, and
2. UDI production identifier (UDI-PI), that identifies the unit of device production and, if applicable, the packaged devices (European Commission, 2019b).

It is stated in MDR that all medical devices need to have UDI and the European Commission has currently named four entities that can assign UDI to a device. The manufacturer of a device is responsible for complying with all UDI related requirements before placing the device to the market (European Commission, 2019b).

Another new feature in MDR is the implant card which provides information to patients about their implanted device. The implant card needs to be provided at the same time with the device and has to contain information about identification of the device, warnings, lifetime of the device and instructions about the safe use of the device (EU MDR 2017/745). Besides the mentioned changes, the MDR aims to enhance the competition in healthcare markets. To make the environment more patient friendly, it provides new and clear guidance about financial mechanisms that ensure that patients will be compensated in the case of defective products (European Commission, 2019a).

It is stated in the MDR that the medical devices can be used by the healthcare professionals, or individuals (consumers) without medical training. If the medical device is designed to be used without medical education, it should be specified on the manual. Term ‘user’ in the MDR refers to the healthcare professional or lay person who uses a medical device, where ‘lay person’ means an individual who does not have formal education in a relevant field of healthcare or medical discipline.

The user has responsibilities when using the medical device. The MDR Chapter II lays out the general obligations of the economic operators (manufacturer, an authorised representative, an importer or a distributor) and instructions that the users are highly encouraged to follow to ensure the safe use of the medical devices. The MDR states that the users need to inform the economic operator in case of incidents e.g., if the device does not work as intended or causes significant risk to a subject of treatment. By this way the safety of the patients is ensured, as the economic operator can withdraw the device from the market if necessary (EU MDR 2017/745).

The Chapter III in the MDR states that all the Member States should encourage or even require the healthcare professionals to store and keep, preferably electronically, the UDI of the devices which they have been supplied with. In addition, it is stated in Chapter I of the Annex I that as each device shall be accompanied with the information needed to use the device properly, also the user needs to make sure that he/she has the technical knowledge, experience, education or training in order to use a particular device in a correct way (EU MDR 2017/745). If a medical device is designed to be used by a lay person (the consumer), the similar responsibilities apply to them.

Chapter II in Annex I lists the requirements regarding the design and manufacture. It is important that if a device is designed to be used by a lay person, it shall be designed and manufactured in such a way that the device performs appropriately for their intended purpose, taking into account the skills and the means available to lay persons. It is the user's responsibility to make sure that he/she has the technical knowledge, experience, education or training, in order to use a particular device as intended and in accordance with the instructions. Also, as the reporting of a faulty device can be made by a user, the lay person shall report to the economic operator in question if the device does not work as intended so that the corrective actions can be taken (EU MDR 2017/745).

2.2.2. Intended use

The intended purpose definition has a central role in the new MDR. The MDR states that defining the intended purpose of any future planned device is the beginning of all decisions, whether the device is medical or not. "The intended purpose means the use for which a device is intended according to the data supplied by the

manufacturer" (Article 2 (12) EU MDR 2017/745) Intended use aims to describe three aspects (EU MDR 2017/745):

1) Confirmation, or not, of whether the product being considered fits the definition of a "medical device" and comply with the regulatory framework, or not.
2) The basis for the classification of planned devices into one of the four classes of device, as Article 51 requires.
3) Core text needed for the future labeling, instructions, promotional or sales materials, the clinical evaluation and technical documentation. Technical documentation defines medical devices intended purpose and intended users, which need to be defined as a part of the device's description and specification (EU MDR 2017/745).

When starting to define the intended purpose, the promotion of the product needs to be considered. The manufacturer should decide who, and with what the product will be messaged to potential consumers. Intended purpose describes intended medical use, not the product features and specifications. The best way to compose intended purpose is by a medical professional, who knows the medical writing. Intended user groups, medical professionals or patients need to be taken into account in writing, and suitable medical language should be used (EU MDR 2017/745).

2.2.3. CE mark

European Commission (n.d.-a) describes CE mark as a certification mark: by using the CE mark, the manufacturer declares that the product meets all the legal requirements on safety, health and environmental protection. The mark also makes

the competition more fair in European Economic Area (EEA), as it holds all companies accountable on the same rules (European Commission, n.d.-a).

CE marked products can be sold through Europe, and they are part of the EU's harmonisation legislation. CE mark appears on many products traded in the EEA, not only the medical devices; it can be found for example teddy bears, or on TVs. If the CE marking is required, the product needs to have it before the product can be placed to the market. In addition, it is forbidden to affix CE marks to products that do not require it. Marking benefits both businesses and consumers. Firstly, the businesses know that CE marked products can be traded in the EEA without restrictions. Secondly, the consumers have the same level of health, safety, and environmental requirements through the entire EEA (European Commission, n.d.-a).

Medical devices that are regulated by MDR need to have CE-mark, which needs to be affixed to the device prior to placing it on the market. CE-mark needs to be affixed to the medical device so that it is visible, easily readable and permanent, or if that is not possible, to the packaging. CE-mark needs to be present in every manual and sales package of the product. If medical devices are subject to other legislation that also regulates on affixing the CE-mark, CE-mark declares that devices comply also the requirements set out in that other legislation (EU MDR 2017/745).

Devices also need to comply with common specifications. Common specifications mean European standards that are adopted on the basis of a request from the Commission for the application of Union harmonization legislation. Manufacturers need to comply with these specifications, unless they can adequately justify the

introduction of solutions providing at least equivalent levels of safety and performance. These requirements are stated in EU MDR Article 9 (EU MDR 2017/745).

The notified bodies are organizations designated by the EU countries that can perform conformity assessments of products. EU controls and keeps an updated list of qualified notified bodies that can be used for product assessments (European Commission, n.d.-e). Depending on the risk class of the product or device, different conformity assessment procedures are used. For class I medical devices, the conformity assessment is based on the manufacturer's own assessment, whereas in classes II a, II b and III the conformity assessment is always carried out by a notified body (European Commission, n.d.-e). In order to be placed on the market, the product has to meet all the legislative requirements, pass the tests and inspections in conformity assessment (European Commission, n.d.-f). On the assessment process the product itself, the production process or the quality control can be evaluated. After the successful assessment, manufacturers can draw up the manufacturer's declaration of conformity, and affix CE marking to the product (EU MDR 2017/745).

Classification system has partly changed in the new MDR: e.g. a new classification system which is applied to software, tends to raise multiple software to higher risk class. Also, when a device is classified as class III implanted device, or class II active device that is intended to administer and/or remove a medicinal product, the notified body is obligated to request that a panel of experts nominated by the Commission goes through the raport addressing the clinical validation. Based on validation results the panel decides whether the scientific statement is given. The statement of the panel of experts is not binding, but the notified body needs to take it into consideration. Justification for dissenting opinion will be publicly available on EUDAMED (EU MDR 2017/745).

However, the article 14 in MDR states that if the importer or distributor has a reason to believe that a device is not in conformity with the requirements of the regulation, it shall not make the device available on the market. If the device is not in conformity with the regulation, the manufacturer and, where applicable, the manufacturer's authorised representative and the importer needs to be immediately informed. If the distributor considers or has reason to believe that the device presents a serious risk or the device is falsified, it shall also immediately inform the competent authorities of the Member States which it is established (EU MDR 2017/745).

2.2.4. ISO certification

The International Organization for Standards (ISO) provides international standards. ISO sets specifications and guidelines to ensure that materials, products and processes are fit for their purpose, and that the consumers can rely on their products to be safe (The International Organizational for Standards, n.d.-c).

Piester & Rosager (2017) note that the ISO certification is the first “need to have” pre-launch activity for gaining market access. This underlines the importance of the certificate. The ISO certificate can be either a product certification or a quality management system certification, depending on a business. Most MedTech companies tend to go for the quality management system certification, the ISO 13485 standard (Piester & Rosager, 2017). ISO (n.d.-a) describes the quality management as a way how an organization directs and controls activities related, either directly or indirectly, to achieve its intended results.

The ISO 13485 standard works as an overall standard for MedTech products to show compliance in many countries. Depending on the innovation, also additional ISO standards can be applied to medical devices, depending on a case (Piester & Rosager, 2017). The ISO 13485 specifies the requirements for the quality management system: the company needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements (The International Organizational for Standards, n.d.-b). It is also important to acknowledge that the ISO 13485 standard provides guidance on processes as it is a process-based standard, not a product-based (ISO, 2017).

In order to be ISO 13485 certified, an organization has to:

1. follow to the implementation guidelines of the standard and
2. a certified body needs to audit the performance of an organization by following the latest ISO 13485 standard

Only if the organization passes the auditing process, the certificate can be guaranteed (The International Organizational for Standards, n.d.-b). However, it is important to note that the MDR does not state that the medical device needs to be ISO 13485 certified, but the compliance with ISO 13485:2016 will help with complying with the MDR as they are similar (Speer, 2019). In addition, meeting the requirements in ISO 13485 is an important step towards the company gaining a CE mark for the product (Piester & Rosager, 2017).

Piester & Rosager (2017) note that risk management is an essential part of the quality management system, and most often the ISO 14971 standard is used. ISO 14971 intends to assist manufacturers of medical devices to identify the hazards associated with the medical device, to estimate and evaluate the associated risks, to

control these risks, and to monitor the effectiveness of the controls (The International Organizational for Standards, n.d.-a).

The MDR (Article 10 (2) EU MDR 2017/745) states that the "Manufacturers shall establish, document, implement and maintain a system for risk management". The risk management process needs to be understood as a continuous iterative process throughout the entire lifecycle of a device and it needs to be updated systematically. When carrying out the risk management process, the manufacturer shall:

(a) establish and document a risk management plan for each device;

(b) identify and analyse the known and foreseeable hazards associated with each device;

(c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;

(d) eliminate or control the risks referred to in point (e) in accordance with the requirements of Section 4;

(e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and

(f) based on the evaluation of the impact of the information referred to in point (e), if necessary, amend control measures in line with the requirements of Section 4 (Article 10 (2), EU MDR 2017/745).

However, the MDR does not explicitly state that the ISO 14971 standard needs to be followed, as it would not allow other risk management to be used or developed.

2.2.5. Marketing regulations

The marketing of medical devices has to follow the standards laid out in the MDR (EU MDR 2017/745). It is stated in the MDR that it is prohibited to use text, names, trademarks, pictures and figurative or other signs that may be misleading for the users or patients when marketing the medical devices. MDR lists the following claims misleading about medical devices, and they are prohibited to be used when marketing:

A. Ascribing functions and properties to the device which the device does not have;
B. Creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;
C. Failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;
D. Suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out (Article 7, EU MDR 2017/745).

The General Data Protection Regulation (GDPR) regulates the data that consumer heart measuring devices produce (EU GDPR 2016/679). For example, again in the United States the Food and Drug Administration (FDA) (2016) has created more specific standards that apply only to general wellness consumer devices and how they can be marketed. FDA (2016) states that a device is classified as a general wellness device (consumer device) if it meets the following two factors; 1) the device is intended for only general wellness use and 2) the device presents a low risk to the safety of users and other persons. In addition, the general wellness devices can then be divided into two categories depending on the intended purpose:

1. The intended purpose relates to maintaining or encouraging a general state of healthy activity or

2. The intended purpose relates to the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions where it is well understood and accepted that healthy lifestyle choices play an important role in health outcomes (Food and Drug Administration, 2016).

The devices that belong to category 1 cannot be marketed by making a reference to certain disease or condition, whereas the devices that belong to category 2 can be marketed by making a reference to certain disease or condition. In addition, the consumer devices, at any circumstances cannot be marketed as a medical device, as they do not meet the legal requirements (Food and Drug Administration, 2016).

2.2.6. Regulations on data security and privacy

Webb & Dayal (2017) state that as the healthcare sector is becoming more and more digitized, the importance of cybersecurity has increased. Even though technological progress has benefited healthcare, it has also created new risks. All stakeholders have a shared responsibility to ensure data privacy and cybersecurity threats that may affect medical, or other relevant devices. Healthcare providers and manufacturers should consider identification, detection and prevention of possible risks, on both pre-market and post-market stages. Also end users and medical professionals should be aware of cybersecurity risks, and awareness should be practiced. To be effectively protected, all stakeholders need to collaborate (Webb & Dayal, 2017). For digital healthcare technologies, it is vitally important that the underlying data is a subject to resilient, transparent, robust and legally enforceable data governance structures, policies and practices (Topol, 2019).

As many of the medical devices interface with other equipment and hospital information systems, the complexity of these makes them prone to security risks and threats. These risks include e.g., degraded performance of the medical device compromising patient safety, effectiveness and the security of the IT network. One way to manage the risk is through standardization (ISO, n.d.). The International Electrotechnical Commission (IEC) has created a standard IEC 80001-1:2010, which addresses the possible risks associated when incorporating medical devices into IT-networks. The purpose of the standard is to apply the risk management to these medical devices to ensure the safety, effectiveness and data and system security. It also defines the roles, responsibilities and activities that are needed for the risk management of these devices (ISO - IEC 80001-1:2010). Also cybersecurity risks related to these devices are more and more acknowledged. Wireless technologies can be vulnerable to attacks and expose patient data or devices itself to hackers. All healthcare stakeholders should understand, and mitigate cybersecurity risks, including patients and other end users, different healthcare facilities and providers and medical device manufacturers (Webb & Dayal, 2017).

The amount of medical devices that use wireless technology is already widespread. Also the healthcare entrepreneurs have started investing increasingly in apps and devices that have the capability to store and transmit high levels of patient data for improved healthcare services (Webb & Dayal, 2017). This is one of the reasons that e.g., FDA has actively considered the issue of cybersecurity on medical devices (Food and Drug Administration, 2020). In Europe, the two new regulations on medical devices 2017/745 (MDR) and 2017/746 (IVDR) also aim to consider cybersecurity threats. New regulations lay down new security requirements and aim to ensure that devices placed in the EU are able to face cybersecurity risks (Medical Device Coordination Group, 2019).

Other legislative acts that are important to the cybersecurity of medical devices, or to deal with protecting or processing personal data stored in those devices, are NIS Directive and GDPR (EU GDPR, 2016/679). NIS Directive boosts the EU's overall cybersecurity level by increasing preparedness, increasing cooperation among countries, and strengthening the culture of security across sectors. GDPR regulates processing of the EU citizens personal data by an individual, company or an organisation. Personal data is any information that might be identified, or identifiable to any living individual. On a worldwide level, the Medical Device Cybersecurity Guide by Working Group of the International Device Regulators Forum (IMDRF) are guiding the work on a high level (Medical Device Coordination Group, 2019).

Examples for possible risks vary, and the spectrum of potentially exposed devices is broad. For example, both the EU Commission and FDA in the US have raised awareness of the possibility that unauthorised users gain remote access to e.g., infusion pump systems, or that there are potential vulnerabilities in implantable cardiac defibrillators (Webb & Dayal, 2017). These risks do not surprise people who develop software, as it is commonly known that people make mistakes when writing source code and an error free software is highly impossible. Usually, the same features that expose medical devices for possible cybersecurity threats also improve healthcare and increase the ability of providers to treat patients more effectively (Webb & Dayal, 2017).

Both the EU Commission and FDA in the US have stated the importance of cybersecurity (Food and Drug Administration, 2020; Medical Device Coordination Group, 2019). There are requirements with pre-market and post-market aspects. Cybersecurity is shared responsibility: from pre-market until the end of the utilisation, all stakeholders have many, continuing obligations to maintain the

barriers against possible threats (Food and Drug Administration, 2020; Medical Device Coordination Group, 2019). In the EU, comprehensive cybersecurity requirements are stated in Annex I of the Medical Device Regulations, dealing with pre-market and post-market aspects.

When considering the role of manufacturers, in the pre-market stage it is important to address cybersecurity vulnerabilities during the design and development of the medical device. Safety, security and effectiveness are critical aspects in the design of security mechanisms. This is why these aspects need to be considered, and there are clear requirements for manufacturers from an early stage of development, continuing throughout the entire life cycle. On pre-market stage, the following activities are taken in the EU (Medical Device Coordination Group, 2019):

- Secure design
- Risk management
- Establish risk control measures
- Validation, verification, risk assessment and benefit risk analysis
- Technical documentation
- Conformity assessment
- Establish a post market surveillance plan and system
- Clinical evaluation process

On post-market stage, FDA (2016) has stated that it is important to implement the "Identify, Protect, Detective, Respond and Recover" strategy. EU aims to similar outcome, and the post market activities include following (Medical Device Coordination Group, 2019):

- Risk management
- Modifying risk control measures, making corrective actions and patches
- Validation, verification, risk assessment and benefit risk analysis

- Maintain and update a post-market surveillance plan and surveillance system
- Reporting trends
- Analysis of serious incidents
- Post-market surveillance report
- Periodic safety update report
- Updated technical documentation
- Inform the electronic system on vigilance

Webb and Dayal (2017) point out that also patients, end users and medical practitioners have their role to maintain cybersecurity. Webb and Dayal use the term "cyber hygiene", which can mean anything from checking the cybersecurity standards of medical devices and installing updates or check patches that the manufacturer has released. Medical professionals have confidentiality obligations, so they are legally required to ensure the privacy of sensitive patient information (World Health Organization, 2010b). Therapeutic Goods Administration (2019) also suggests that to ensure cyber safety, owners should e.g. disconnect unused devices, maintain physical and logical security and remove medical devices from untrusted systems. Webb and Dayal (2017) also state that the extent of controls are dependent on the context, and who will be exploiting potential vulnerabilities.

2.3. Innovation process in medical devices

2.3.1. Different types of innovation

Innovation as a term provides a myriad of descriptions and Goffin & Mitchell (2017) and has noted that the term innovation is described differently by everyone. OECD (n.d.) provides a one definition of innovation: "An innovation is the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations."

A common misconception about innovation is that it needs to be something completely new, which is false as some of the cases the innovation originates from already existing products or innovations and whereas some innovations are completely new (Goffin & Mitchell, 2017). Goffin & Mitchell (2017) also point out that there is no generally accepted terminology on how the innovations can be differentiated from each other; the theory by Kalbach (2012) is used in this thesis, as it is widely known and accepted. To make the distinction between different kinds of innovations easier, innovations can be divided into zones as Kalbach (2012) describes them. These innovation zones describe more accurately the nature of innovation and can better guide innovation efforts as each of the zones has a different purpose and requires a different strategy (Kalbach, 2012).

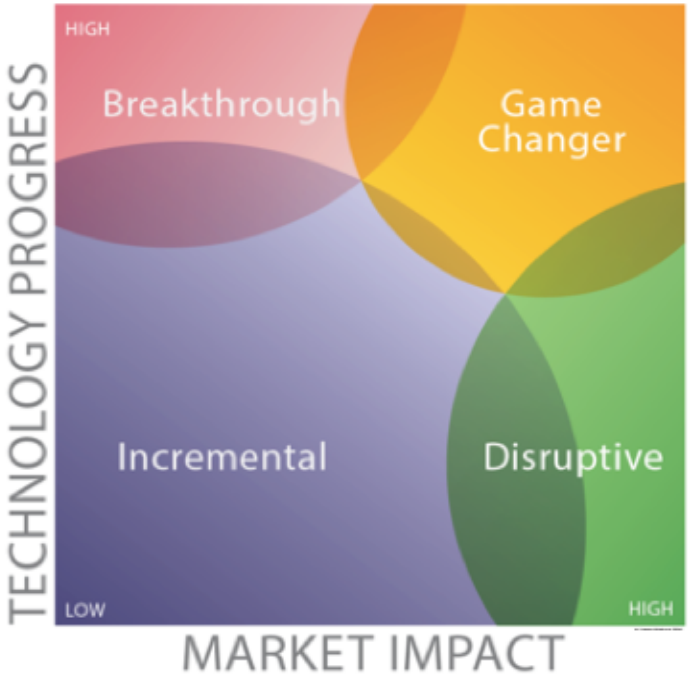

Figure 1. 2-dimensional picture of innovation. Reprinted from Clarifying Innovation: Four Zones of Innovation, by J. Kalbach, 2012.

Source: https://experiencinginformation.com/2012/06/03/clarifying-innovation-four-zones-of-innovation/.

The model is 2-dimensional. Y-axis represents technological progress that innovation represents. If its position is high in the y-axis, the innovation has more improved capabilities, services and products. X-axis shows the impact that innovation has on the market, also from low to high. The higher position indicates new business models or reaching previously unserved target groups.

The Kalbach's (2012) model has four distinct **zones of innovation**:

- **Incremental** innovations: innovation brings modest changes to existing products and services. These improvements keep a business competitive. They can be described as new product features and improvements in service.
- **Breakthrough** innovations: large technological advances that remodel readily existing products or services ahead of competitors. Breakthrough innovations are often produced by research and development labs (R&D), which aim for the next patentable formula, device or technology.
- **Disruptive** innovations bring completely different value propositions than there has been previously.
- **Game-changing** innovations have capability to transform markets, or even societies. These innovations have a radical impact on how human behaviour, thinking and feeling in some way.

2.3.2. Innovation diffusion

WHO (2010) states that innovation diffusion is conceptualized differently in different fields, but means things such as implementing, adopting or disseminating innovation. Also, innovation spreading mechanisms are different. They can be either passively adopted by individuals or organisations, or there can be active attempts trying to influence the rate and success of adoption (Greenhalgh et al., 2007). Fitzgerald et al. (2002) have researched the subject especially in the healthcare environment, and point out that in the healthcare environment medical professionals are strongly positioned when adopting innovation, and the effect is even stronger at the local level. The inter-professional alliances and networks may either facilitate or inhibit the innovation diffusion process (Fitzgerald et al., 2002). Rogers (1995) and Hopkins (2004) reveal other factors affecting on innovation adoption of people in general: utility of the innovation, disruptions that it can cause to existing habits, personal and/or social values, social status of opinion leaders and

whether the individuals are tolerant or resistant towards the innovation (Hopkins, 2004; Rogers, 1995).

Also other things may affect innovation implementation especially in healthcare. New innovations are sensitive to changes especially in terms of financing and delivering of healthcare, as the level of reimbursement of the innovation may vary (Piester & Rosager, 2017). Social forces and different accidents can also shape the new technology: robust evidence, such as clinical evidence or scientific research may confirm or reject the need for innovation, but diffusion depends on the context (World Health Organization, 2010a). In general, the diffusion can also be affected by broader context: stakeholders' interests, the political climate, and public expectations (Nahta & Esteva, 2007).

When considering innovation diffusion in healthcare, exploring the technological development is especially challenging for several reasons (World Health Organization, 2010a).

1) Emotional factors are closely connected to the concept of health and illness. Also for example politicians usually commit to provide the latest advances in medicine. This causes the innovation process to be different than in other fields.
2) New medical technologies promise for better health and improved quality of life - this is usually associated with higher cost of services. The decision-makers often have to prioritize, as resources are scarce and there are continuous attempts to reduce costs. This results in some technologies to diffuse, whereas others do not.
3) When integrating technologies with clinical validity, they often fail to integrate into medical use, and patients do not benefit from scientific progress (Lang, Wyer, & Haynes, 2007).

When defining the innovation diffusion process in general, Geljins and Rosenberg (1994)describe it as a linear process. Firstly, a group of scientists develop an idea, which then moves in a linear trajectory from the laboratory to animal models, to applied research, to select populations, to manufacturing and marketing, and finally to adoption and use (Gelijns & Rosenberg, 1994). Some innovations may follow this kind of linear progression, but technologies in medicine can be diffused in the contrary way. The innovative technology can be adopted in a more non-linear, dynamic pattern, depending on multiple factors. These factors may originate from the technology itself, from the context which within the technology will be used, or from the interaction between these two (Meyer & Goes, 1988).

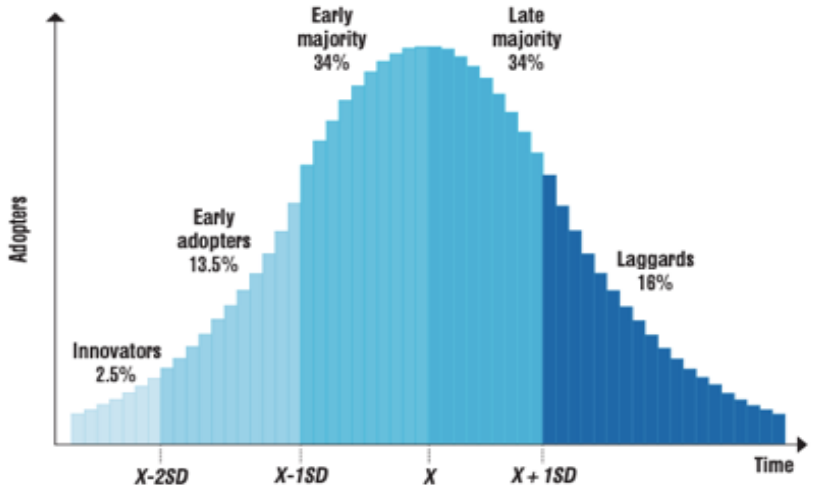

Figure 2. Distribution of new adopters of an innovation against time. Reprinted from *Diffusion of Innovations in Health Service Organisations: A Systematic Literature Review* (p. 101), by T. Greenhalg et al, 2005, Blackwell Publishing Ltd.

Greenhalgh et al., (2007) also explain that when examining an innovation adoption within a defined population, there can be identified several sub-populations with different willingness and ability to adopt. Populations which are more than two standard deviations earlier than mean in the innovation adoption curve, are called ‘innovators’, comprising 2.5 % of the population. Next comes the group of ‘early adopters’ comprising 13.5 % of the population. On both sides of the mean, there are ‘early majority’ and ‘late majority’ respectively 34 % each. The last group, beyond one standard deviation from the mean, are called ‘laggards - 16 % of population (Figure 2).

The purpose of the model introduced above is to describe how adopters of innovation increases over time and predict the diffusion process. In the product innovation context these graphs forecast first-purchase sales of innovations where the number of adopters defines the unit sales of the product, and therefore also the growth (Mahajan, Muller, & Bass, 1990).

Opinion leaders are important in innovation adoption. They are able to influence others, and facilitate idea spreading among individuals through imitation (Greenhalgh et al., 2007). Rogers (1995) also states that opinion leaders are especially important in the early adoption stage, if there is any intention to diffuse any innovation, there is a need to convince the opinion leaders first. Convincing may happen through interlim ties, such as exchanges about the innovation with peers, or through mass media and persuasion - the latter is less effective. Opinion leaders are seen as more trusted channels to deal with resistance towards new ideas, and they may also influence strong attitudes (Rogers, 1995). Opinion leaders are seen as important, especially in the healthcare environment.

Linear model of innovation diffusion has also been criticised. Fitzgerald et al., (2002) present that the innovation decision process is not only accepted or rejected, as this does not explain why the knowledge or evidence related to innovation is accepted or rejected. Usually in health policy on many conditions there are more than one science based optimal solution (Fitzgerald et al., 2002). Consoli et al., (2009) state that diffusion is a more complex, and dynamic process as it may solve problem sequences, rather than individual problems. Innovation may also generate challenges for the pre-existing processes and practices, as they may have disruptive or destabilizing effects on them (Consoli et al., 2009).

WHO (2010) also states that medical devices do not exist in a vacuum: they are always part of a broader context. Every time a new device, treatment or procedure is introduced, this innovation is influenced by multiple interests of the involved stakeholders. For example, traditional practices and attitudes may affect innovation implementation. There is rarely agreement for an only one optimal solution amongst the professionals, and professionals adapt innovations in different phases. As a consequence, only a single new solution is not likely to be implemented. Also interpretations and priorities among those who adopt an innovation effect on innovation diffusion, so users have an active role in spreading innovation (World Health Organization, 2010a).

2.3.3. Barriers to innovation

When discussing about barriers that may affect for innovation of medical devices, WHO (2010) defines it as following

- Limited staff training how to use new devices
- Hostility on the part of established medical practice
- Reluctance to admit the need for skill upgrade

- Reimbursement
- Regulations

As in some of the equipment is getting increasingly complex, it is essential to train the staff to use the new devices. For example, Topol (2019) and WHO (2010) have addressed this issue and its importance on different healthcare systems.

Technical skills on how to operate equipment form is an essential part of its effective use, the lack of these skills may also present a barrier on technology diffusion. If the training of the staff is limited, on one hand it may cause a higher risk of incidents and complications, and also hinder the diffusion of innovation. With highly educated specialists, "brain leak" is possible: it describes a situation where educated workers emigrate elsewhere. To prevent this happening, the amount of education needs to be ensured WHO (2010). The role of physicians when using new technologies has also been criticised: Blume (1992) points out that from physician's perspective, inventing technologies that need highly specialized medical expertise to operate, physicians may also secure a role for themselves.

Piester & Rosager (2017) also name the conservativeness of the healthcare market as one of the potential market barriers. Healthcare market is known to be usually conservative when introducing new treatments; doctors do not want to take new innovations too soon because of possible safety issues, but not too late as it can be bad for one's career and patients. Especially game-changing innovations can be hard to implement in the healthcare system, as identifying the right business model can be tough. Also, correlation between revenue and size of the innovation is not straightforward: sometimes game changer innovations create less, or the same revenue as smaller, incremental innovations (Piester & Rosager, 2017).

On European Union, some countries have insurance-based healthcare systems. When introducing new medical technology, possible compensation should be taken into account: if the new medical technology is not part of statutory healthcare, it can cause a problem. This problem arises especially with innovations, if the innovation is not yet included in the reimbursable catalogue of benefits, or if there is uncertainty whether or not the innovation should be included or excluded from the mainstream care package. If the new innovation is not integrated with compensated diagnosis-related groups, it will not be reimbursed under this system WHO (2010).

3. Methodology

The qualitative interview is an irreplaceable way to explore how subjects experience and understand their world. It provides a unique access to the lived world of the subjects, who are able to describe in their own words their activities, experiences and opinions as precisely as possible (Kvale, 2007).

Van Aken et al. (2012) have noted that qualitative research methods are particularly important if the aim of the study is to research people, groups, organizations and societies. For example, if the research aim is to study how an individual interprets their own situation or experiences. It is also important to determine the *unit of analysis* before starting to collect the data. The unit of analysis is the type of object that is the focus of interest. The four most common unit of analysis are:

- Orders and projects
- Events, incidents, decisions and interactions
- Organizational units (such as individuals, teams or departments)
- Business processes or organizational systems (van Aken et al., 2012).

As the research in this thesis is qualitative and carried out by having one-to-one interviews with medical professionals and people who work closely with medical devices, the unit of analysis chosen for the thesis is organizational units. When using the organizational units as a unit of analysis, the opinions and experiences of individual employees can be compared and studied (van Aken et al., 2012).

3.1. Data Acquisition

3.1.1. The interview process

The following process was chosen when designing the interviews and the study (Kvale, 2011).

1. Thematizing the interview. Define the purpose of an investigation and conception prior to starting the interviews. The questions why, what and how are posed.
    - Clarify the purpose of the study
    - Obtain a pre-knowledge of the investigated subject, and
    - Become familiar with different techniques of interviewing and analyzing; to decide which to apply to obtain the intended knowledge.

1. Designing. The stage aims to plan the design of the study before interviewing, to obtain the intended knowledge.
2. Interviewing based on interview guide, still keeping the reflective approach and interpersonal relations in mind.
3. Transcribing. This stage prepares the interview material for analysis.
4. Analyzing. Deciding the appropriate analysis method for the interviews, based on the interviews, the purpose and the topic of investigation.
5. Verifying. Check if the results are valid, reliable and generalizable. Also evaluates whether or not the study investigates what is intended to be investigated.
6. Report. Communicate the findings and applied methods in a clearly readable form that follows scientific criteria, taking the ethical considerations into account.

As Kvale (2011) states that the researcher will become wiser throughout the study, this thesis aims to verify the results during all stages, but especially when reporting the final results.

3.1.2. Research methods

This study focuses on specific theme; to examine how the healthcare professionals, and people who work close to the field, understand

1) the division of responsibility between the professional and manufacturer, when using medical devices
2) The overall difference between medical and consumer devices

To answer these questions in detail, it will be necessary to consider the following sub-questions:

- What regulations affect medical devices, and how does it differ from the regulation affecting the consumer devices?
- How the healthcare innovations are diffused in the healthcare environment and what are the main barriers?

Multiple ways to collect data in qualitative research exists. The most common ones are interviews, observations, case studies and ethnographic (Sharan & Tisdell, 2015). Interviews, specifically one-to-one interviews, are the most used way of conducting interviews in qualitative research (Ryan et al., 2009). The interviews will be conducted as one-to-one interviews as they enable more in-depth and

personal responses from the participants, as this kind of interviewing method is described to be more intimate to the interview subjects (Ryan et al., 2009).

Ryan et al., (2009) have studied the nature of qualitative interviews and notes that the interview technique is chosen in accordance with the researched topic. The interview techniques differ from each other by how the interview is structured. The qualitative interview types are divided into three categories depending on how the interviews are structured:

1. Structured interviews with pre-structured questions, that do not leave room for veering the topic in question. All the interviews must have the same number of questions presented in the same order.

2. Semi-structured interviews which consist of predetermined topics but leave room for spontaneous questioning through open-ended questions.

3. Unstandardized interviews, which do not include any specific framework or questioning. The interviewer asks broad, open-ended questions and the direction the interview takes depends on the interviewee's answers (Ryan et al., 2009).

In this thesis the semi-structured interviews are conducted. Semi-structured interviews were chosen because they are the most flexible type of interviews, leaving more room for the interviewees to reflect on their own experiences. In semi-structured interviews, the topics are predetermined, but often open-ended questions are used which allows the exploration of spontaneous issues (Ryan et al., 2009). Kvale (2011) also states that in semi-structured interviews there are neither strictly structured standard questions, nor entirely 'non-directive'. The used questions are mostly open because this enables the interview to focus on the topic of research. It also makes it possible for the subjects to bring up the dimensions they find important. The interviewer's role is to lead the subject towards certain themes, but not to specific opinions (Kvale, 2011).

Kvale (2011) highlights that when conducting an interview, the importance of the interviewer's role needs to be emphasized, as the interviewer works as the research tool. The interviewer must show interest, understanding and respect towards what the subject says, and also be clear about what he or she wants to know. It is important for the interviewer to be an active listener and to react accordingly to the answers, e.g., present second questions or give space to the subject if necessary. This makes the interview situation as comfortable for the subject as possible.

The number of interview respondents can be argued, and Kvale (2011) describes that there is no universal number of interviews that a research needs to have. More important is that the problem statement of a research can be answered with the results gained from the interviews. However, Kvale (2011) describes that on average 15 ± 10 interviewees should be enough. Bourdieu, on the other hand, believes that one informant is enough, as long as it is the right one (Øye, Sørensen, & Glasdam, 2015). Within the framework set for this thesis, it has been decided to interview 8-12 professionals, who are thought to provide enough information to answer the problem statement of the thesis.

In order to get most out of the interviews, the interview guide is formed prior to the interviews. An interview guide is a script that structures the interview; it can be more or less tight. In a semi-structured interview, the guide includes the outline of covered topics, with suggested questions (Kvale, 2011). The interview guide enables the researchers to focus on a specific field of interest. It also facilitates openness and conscious naivety towards the interviewee's individual perceptions and interpretations of the given interview questions. This way it is also easier to find what the interviewees find important to tell (Kvale & Brinkmann, 2009).

Interview questions are formed out of research questions, preferably keeping the later analysis, verification and reporting in mind. The questions should be brief and simple. (Kvale, 2011). The interview may start with a few entry questions, which reflect the key issues that the interviewees may have and gives an overall picture about the interviewees' thoughts about the subject. There is also a good opportunity to ask more detailed questions to gather more detailed information (Kvale, 2011).

The interview guide is based on the theory of the thesis and the problem statement. The used questions were also revised by gatekeepers, in order they to be as technically qualified and unbiased as possible. This is important as the area of the study is quite specific; as Kvale (2011) states, the kind of knowledge produced in the interview depends to a great extent on the wording of the questions.

3.1.3. Ethical considerations

Kvale (2011) states that ethical issues remain present throughout the whole research process. Potential ethical considerations should be taken into account from the beginning until the end of the research process. Interviews are saturated with moral and ethical issues: especially ethical problems arise particularly because of researching private lives and placing the results in the public. The ethical issues are present in all of the seven research stages:

1. Thematizing. The purpose of an interview study should be considered with regard to improvement of the human situation investigated.
2. Designing. Ethical issues of design involve obtaining the subjects' informed consent to participate in the study, securing confidentiality, and considering the possible consequences of the study for the subjects.

3. Interview situation. The consequences of the interview interaction for the subjects need to be taken into account, i.e. stress during the interview and changes in self-understanding.
4. Transcription. The confidentiality of the interviewees needs to be protected. There is also the question of whether a transcribed text is loyal to the interviewee's oral statements.
5. Analysis. Ethical issues in analysis involve the question of how penetratingly the interviews can be analyzed and of whether the subjects should have a say in how their statements are interpreted.
6. Verification. It is the researcher's ethical responsibility to report knowledge that is as secured and verified as possible. This involves the issue of how critically an interviewee may be questioned.
7. Reporting. There is again the issue of confidentiality when reporting private interviews in public, and of consequences of the published report for the interviewees and for the groups they belong to (Kvale, 2011).

It is also underlined that the professional ethical codes serve as contexts for reflection on the specific ethical decisions throughout the research study. These ethical codes are the ethical guidelines of the research, which are important to be defined from the beginning of the research. The most important guidelines to concern when doing research are the subjects' informed consent to participate in the study, confidentiality of the subjects, consequences of participation in the research project and the researcher's role in the study (Kvale, 2011).

It is important that the interviewed individual is well enough informed about the interview before conducting it. The informed consent entails to inform the research subjects about the overall purpose of the research and the main features of the research. The possible risks and benefits for participating in the study need also to

be stated in informed consent. It also needs to include information that the participation is fully voluntary and that the subject can withdraw from the study anytime as well as who will have access to the transcription of the interview (Kvale, 2011).

The confidentiality also possesses another important issue which needs to be considered. Confidentiality means that the subject of the interview cannot be identified. It is important to make clear who will have access to the interview after it has been conducted and transcribed and whether the interviewed individual will remain anonymous or if the name is publicized (Kvale, 2011).

The consequences of an interview are important to be weighted, as the ethical principle of beneficence states that the risk of harm to a subject should be the least possible. This means that the importance of knowledge gained should be greater than the risk of harm caused to the subject of the interview. It is also important for the interviewer not to take advantage of the intimate situation of interviewing and lead the interviewed individual to disclose any information the subject may later regret. This is when the integrity of a researcher becomes important. With the person who interviews being the instrument of interview research, ethical decisions in an interview project to a large extent come to rest on the integrity of the interviewer as a person such as his or her knowledge, experience, honesty and fairness (Kvale, 2011).

3.2. Data Analysis

Kvale (2011) emphasizes the importance of analyzing interviews as it is a crucial aspect to consider from the beginning of the research as well as during when

conducting the interviews. The method of analysis is important to be decided before the interviews, as after conducting and transcribing them it will be too late. Also, the amount of data gathered from the interviews can be too much to handle in a meaningful way for a single researcher.

There are various ways for conducting data analysis. The used methods are explained in more detail in this chapter, but their overall purpose is to identify common patterns within the responses of the interviewees, and analyze them in order to achieve the aims and objectives of the research.

3.2.1. Transcription

Whereas the quality of interviewing is often discussed, the quality of transcription is not usually addressed in the research of qualitative literature. Either way, transcription is still important: it is an interpretative process, which reveals the differences between oral speech and written texts and contains a series of practical and principal issues (Kvale, 2011).

Transcription translates the direct face-to-face conversation into a written form, and it becomes abstracted, and also tends to be regarded as the solid bottom empirical data of the interview project. The transcription process needs to be careful, as oral speech and written text entail completely different language games, and according to Ong (1982) also different cultures.

Interviews are usually recorded for later transcription; it can be done as audiotape reporting, videotape reporting, note-taking and remembering. Recording enables the interviewer to fully concentrate on the topic, and dynamics of the interview

(Kvale, 2011). For the thesis audiotape reporting, note-taking and remembering will be used. Audiotapes will be recorded directly to a computer, to make the latter transcription and analysis process easier. As Kvale (2011) also states, sometimes note-taking during the interview will be distracting and interrupt the free flow of conversation - this is why the possible notes will be written shortly after each interview.

Transcribing the interview is described in itself as an initial analysis. Sometimes it is also a tiresome and stressful job (Kvale, 2011). To make researchers of the thesis equally familiar with the transcribing process, the transcriptions will be divided equally. Kvale (2011) also states that by transcribing the interviews, the researchers may also remember more detailed social and emotional details of the interview situation. This is important, as sometimes for example language usage and things, that are not said, are actually important. Kvale (2011) also suggests that instead of transcribing the interviews verbatim word by word, i.e. retaining frequent repetitions, noting 'mh'-s and the like are left of, the conversations can be written into a more formal, written style. However, it is possible to deviate from this if it is essential for interpreting the transcription. As in the thesis there are two people included in the transcription process, the use of more formal written style is commonly agreed.

As a part of the transcription process, constant comparison analysis techniques will be used. This way development of knowledge will be ensured. After the first interview is conducted, researchers sit and go through the transcription. Then the analysis will be done by breaking the interview into themes. At this stage the analysis acts as an extra preparation before the next interview; the researchers evaluate their question technique, and the direction of questioning. The process goes through the rest of the interviews, if needed. This way the interviewers understand as many angles and sub-themes as possible from the selected theme, and

understand what is significant, and whatnot. Finally, these findings will be presented, even if contradicting with each other (Khan, 2020).

To facilitate the structuring and analysing of transcriptions, the computer program NVIVO will be used. Kvale (2011) also states that the programs are aids to structuring the interview material for further analysis, as they allow operations such as coding and categorization of the interview statements. In the analysis of the thesis the relevant passages will be coded, which makes later retrieving and inspecting process easier.

3.2.2. Analyzing

Saunders et al. (2007) state that the two most common approaches to research are deductive and inductive. Deductive approach starts with a theory from which hypotheses are formed and the final conclusion follows logically from the tested hypotheses. The deductive approach moves from more general to more specific. In the inductive approach the theories are built up and sought from the gathered data. The inductive approach moves from more specific to more general (Saunders et al., 2007).

The analysis for the thesis was constructed by using an inductive approach as it allows the researchers to explore the interviews more thoroughly and to develop theories while reading the interviews.

Different methods for analyzing the interviews exist. Most commonly used method is to focus either on analyzing the content of the interviews or the language of the interviews. Meaning and language are often interwoven. When doing interview analysis in practice, the focus on meaning differs considerably from focusing on

language. The methods that focus on meaning can be used to analyze what is said in the interviews, whereas the methods that focus on language focus more on metaphors and interpreting the meaning beyond what is said. As this thesis aims to analyze the experiences of the interviewees, the method which analyzes the meaning found in the text will be used.

According to Kvale (2011) there are three methods that focus on meaning: the meaning coding, meaning condensation and meaning interpretation.

1. Meaning coding or categorizing (content analysis)
2. Meaning condensation
3. Meaning interpretation

The first one, meaning coding or categorization attaches one or more keywords to a text segment, in order to permit later identification of a statement. Content analysis is dividing the text first into smaller parts then coding the text with relevant codes that describe the text and then categorizing a text's meaning into categories, which enables quantifying how often specific themes are addressed in a text. This way the frequency of themes can be compared and correlated with other measures. By categorization, the meaning of long interview statements is reduced to a few simple categories, which makes the interpretation of results easier and more efficient. The categories can be developed either before the interview, or they can arise during an interview (Kvale, 2011).

The second one, meaning condensation, in which longer statements are compressed into shorter statements, so the main sense of what is said is rephrased in a few words. Meaning condensation shortens the interview texts, and helps to explain the main themes from the answers (Kvale, 2011).

Last one, meaning interpretation, is where the researcher interprets the answers to work out the text's structures and relations. This method often leads to more deep and critical interpretations of the text. Compared to other methods, meaning interpretation tends to lead expansion of the text, rather than shortening (Kvale, 2011).

As the thesis will be a qualitative research based on interviews that were recorded, the content analysis method is used to analyze the findings. Content analysis was chosen, as it is described to be a systematic examination of communicative material, which in this case is transcribed interviews. The most essential thing in content analysis is that the communicative material needs to be fixed or recorded in some form (Mayring, 2004).

The different themes will be coded, categorized, and finally clustered around specific research questions. The final aim is to start to see clearly the repetitions and overlappings on stories that interviewees tell, and also different styles on how interviewees describe things. After this the gathered stories will be interpreted, and information will be passed to the audience; the final aim to construct a complete story of findings, classified under different themes.

3.2.3. Coding (content analysis)

As the content analysis was chosen as the form of analysis, the analysis process started by carefully transcribing each interview and then translating them into English. After transcribing them, the researchers read and discussed all of the interviews to get an overall image of the respondents' answers. After having a good

understanding of all of the interviews the interviews were condensed into smaller sections which still preserved the core meaning of each answer. The condensed units were then transferred to MS Excel so that it was easier to compare the different interviews with each other. Also, the condensation helped the researchers to think and create categories which were later used in the next step, which was coding the interviews with the help of NVIVO.

All the interviews were uploaded to NVIVO and relevant categories ("nodes") were created before starting the coding process, but few categories also rose from the text during the coding process. The categories were created so that they aimed to provide answers to the research questions. The categories aimed to compare the different interviewees e.g., in terms of attitudes, experiences, knowledge and feelings towards the medical devices.

After creating the suitable categories, all of the interviews were coded one at a time and all the interviews were coded twice. Most of the coding was done at the first coding round, but also some new text pieces were coded during the second round of coding. By doing the coding twice it was ensured that none of the crucial information was left behind.

After coding the interviews, the results under the nodes and the nodes itself were analyzed carefully in the light of the research questions. This was done to get a clear image of which results would be the most beneficial to answer which research question. The results were then decided to analyzed in five categories which were attitudes/experiences, regulations, responsibility, trust and data protection, as by using these categories, it was possible to get answers to the two main research questions. The results of the analysis will follow in the next chapter.

4. Empirical results

In this part of the thesis, the main findings and other relevant results are analyzed. Firstly, a short introduction to the interviews is included to provide a context of the chosen interviewees. Then, the analysis of the results is done in sequence by processing the first research question and then analyzing the relevant interview answers. Same procedure is done for the second research question.

4.1. Introduction to the interviews

In total 9 interviews were conducted for the thesis. The interviews were conducted in the Health Centre of Nokia (4 interviews), the Finnish Heart Association (3 interviews) and with cardiology specialists (2 interviews). The interviewees were chosen based on their knowledge of the topic and were accessed through gatekeepers. All the professionals interviewed worked within healthcare, but in different roles in various organizations which was important in order to see the differences in knowledge between different organizations. In addition, the interviewees were based on different cities to gain a wider view of the topic and how it differs amongst different parts of Finland.

Full transcriptions of the interviews can be found from the appendix at the end of the thesis.

Interview 1 (HA-K)	Finnish Heart Association representative in Kuopio
Interview 2 (HA-J1)	Finnish Heart Association representative in Jyväskylä
Interview 3 (HA- J2)	Finnish Heart Association representative in Jyväskylä
Interview 4 (C-C)	Cardiology Specialist (Capital region area)
Interview 5 (C-EF)	Cardiology Specialist (Eastern Finland)
Interview 6 (N1)	Nurse of Nokia Health Centre
Interview 7 (N2)	Nurse of Nokia Health Centre
Interview 8 (N3)	Nurse of Nokia Health Centre
Interview 9 (N4)	Nurse of Nokia Health Centre

Table 1. List of interview subjects for the thesis.

The interviews were conducted anonymously as recognizing the respondents from the interviews was not necessary when interpreting the results. The interviews were held remotely due to the Covid-19 situation. The original language for the conducted interviews were Finnish which were translated into English whilst transcribing them. In addition, interviewees were asked for permission for recording, if the permission was not given, the interview was not recorded and only notes were taken.

4.1.1. Cardiology Specialists

The cardiology specialists were chosen to be interviewed due to their excessive knowledge on the topic. In addition, two specialists from different cities were chosen to compare the differences between the capital region and the region of Eastern Finland, working in University Hospitals and in the private healthcare sector. Interviewed cardiology specialists used multiple different medical devices as a part of their work, but within the thesis we only include externally used (in-vitro excluded) devices, which are used outside of the hospital.

4.1.2. Finnish Heart Association

The Finnish Heart Association works closely with patients who suffer from cardiac conditions and provides support and information for them. The association also aims to spread information and promote a healthy lifestyle for people to avoid heart conditions (Sydän.fi, n.d.). The Heart Association is divided into local districts which are all independent units in charge of their own activities. These districts provide information and different services to people with cardiac conditions (e.g., measure blood pressure and heart rate) and sometimes try out new devices in order to spread awareness of those. In this thesis, people with experience of using Heart2Save's device were interviewed and their user experience and knowledge of that and similar medical devices was studied.

4.1.3. Nurses of Nokia Health Centre

The Health Centre of Nokia was chosen to be interviewed on this thesis based on their knowledge of the newer kind of medical devices. The professionals were chosen from the same department as it was known that the unit currently used multiple different medical devices to treat the patients; within the thesis we mostly focus on devices used for heart monitoring.

4.2. Main findings

This section aims to describe the main findings of the thesis. First, we describe the devices that professionals mentioned during the interviews, and which are currently used in the places where interviewees work, and the attitude towards these used devices. Secondly, we aim to respond to the first of the main research questions; how the healthcare professionals understand the difference between medical and consumer devices which are sold in consumer markets. Also, the second question will be analyzed and discussed: what is the division of responsibility between professional and manufacturer, when using the medical device sold in consumer markets?

The section also goes through both sub-questions: professionals' viewpoint for the question “what regulations affect medical devices, and how does it differ from the regulation affecting the consumer devices?” and key findings from the interviews related to the other sub-question: how the healthcare innovations are diffused in the healthcare environment and what are the main barriers?

During the interviews questions about data protection and overall trust about the devices were asked.

4.2.1. Attitudes/experiences about currently used devices

9 healthcare professionals were interviewed in total, both doctors and nurses. All of the interviewees were working with new medical devices, and most of them with ones related to arrhythmia detection. Through the conducted interviews we noticed that in different places professionals use different devices.

In Nokia Health Centre, for arrhythmia detection the most used device was Zenicor, but there were also other new devices in use, e.g., device used for sleep apnea detection, PoC tests, fast HP and CRP test, and possibility to start testing with device used for wound pressure treatment, and new kind of drop counters. The attitudes towards new medical devices were mostly good within the unit;

"Pretty good experiences from using Zenicor, easy to use." (N2, R. 628).

"Overall, I feel that the medical devices currently in use are easy to use and useful." (N1, R. 532-533).

"Ok experiences of different devices, sometimes some issues with their usage or they do not work. Also, some people are not able to use them correctly, both nurses and patients." (N4, R. 791-793).

Cardiologists were interviewed in two major cities in Finland. Both professionals work in University Hospitals, and the other Cardiologist also within the private sector.

The cardiology specialist working in a non-capital region did not remember the names of the used devices, but "*It is a Holter examination where the heart rhythm is tracked for 24 hours. The device is difficult to use, does not give reliable data, as sometimes the sensors do not stick to the skin properly. The EKG sensors might also cause irritation on skin. Used only for 24 hours, it might not be enough as sometimes arrhythmias do not appear within 24 hours. For longer surveillance the box type device is given, you put your fingers there and it registers it. The surveillance can also be done within the department, both neurology and cardiology, and the longer patients stay, more cases can be found. There are also invasive devices for rhythm surveillance - not installed for possible atrial fibrillation but can be found as a side product of use."* (C-EF, R. 406-423).

The box device was also described to be too big, and the patient needs a backpack to carry it. Same cardiology specialist also mentioned that *"The devices that are currently in use are pretty rudimentary if compared to the devices that currently exist in the markets." (C-EF, R. 443-444).*

The cardiology specialist has noticed difficulties on adoption and hoped the process to change: *"There are a lot of devices with great technology, but they can't be used in the hospitals or wards because of the strict regulations. It takes a long time to get better devices and it should be easier to detect the rhythm both at home and at the wards. There has been a lot of conversation about the devices in the wards, but people are against especially unregulated devices, also some of the staff are unwilling to use new devices. If there will be a lot of devices in the markets that can register data, there needs to be a lot of discussions with other doctors as they will have to figure out whether the symptom is real and what it actually is."* (C-EF, R. 444-454).

The Cardiology specialist working in the capital region said that the most used device is the Zenicor device when detecting arrhythmia. Besides using Zenicor, the cardiologist mentioned also other new medical devices; *"These new kinds of devices are still kind of rare so mostly holters (interviewee refers to Zenicor device) and then some devices that patients have found themselves. I have had patients that have found Beat2Phone and the newest Apple watch, which has the possibility to register data when seizure hits."* (C-C, R. 329-332). The cardiology specialist also used these devices as a helping tool for diagnosing the patient *"I have noticed that Beat2Phone and the newest Apple watch give reliable and good quality data from where a doctor can diagnose the arrhythmia already. If a patient has been thinking about buying an Apple watch, I might recommend that but in most of the cases the patients are already aware that the watch has this kind of feature."* (C-C, R. 341-345).

When conducting the interviews within Finnish Heart Association, the interviewed nurses had experiences only with Heart2Save's AiVoni product besides more traditional devices and methods. *"I have now had the device from Heart2Save for a while in use, it is the only newer kind of device to measure atrial fibrillation, no other devices are being used so no experience from other devices."* (HA-J1, R. 126-128). In Finnish Heart Association, the attitudes towards devices were positive *"Overall good experiences with Heart2Save's device, and people have shown interest towards the device."* (HA-K, R. 25-26).

RQ1: How do healthcare professionals understand the difference between medical and consumer devices which are sold in consumer markets?

One of the main research questions was to understand how the medical professionals understand the difference between medical and consumer devices, which are sold in consumer markets. When interviews were conducted in Nokia, half of the interviewed could tell what the difference between medical and consumer device is, and what kind of regulation effects on those;

"*I think that a medical device needs to be approved by FIMEA and that they are always CE certified. Consumer devices are not regulated and are sold at regular stores for consumers."* (N3, R. 766-768).

"Valvira and FIMEA regulate medical devices and they need to be CE certified. Consumer devices can be bought anywhere e.g. Lidl and the buyer can be a regular consumer." (N4, R. 837-839).

The medical personnel who could not tell the difference, assumed for example that the devices are always used only in hospital settings.

"*I am not entirely sure, but a medical device is a device that is used by nurses and doctors at a hospital setting. Consumer devices consumers can use at home by themselves."* (N1, 595-597).

"I can't really tell, it might be so that consumers can buy consumer devices from regular stores, I probably have heard what the difference is but don't remember anymore" (N2, R. 692-694).

Similar findings were found when nurses in the Heart Association were interviewed. Two of them stated that medical devices can be used as a part of diagnostics, consumer devices not; still the nurses did not mention the visible CE-mark or other requirements. One nurse could say right answer; *"[...] needs to have a CE-mark which usually indicates a lot of testing is needed. Also, the process of*

getting the product registered as a medical device is long so it needs to be well tested and inspected which increases the reliability. [...] Jäntti (Founder of Hear2Save) given lectures about the topic"(HA-K, R. 75-78, R. 110).

When the cardiology specialists were interviewed, the other one could not tell the right answer, and the other did not mentioned CE-mark; *"Medical devices should always pass some tests and go through a certain process to get accepted and certified to be used as a part of the diagnostics process."* (C-C, R. 396-397).

The interviews show that the medical professionals understand the difference roughly, and only some can mention that CE-mark is required for the certified device. The knowledge varies between the study participants.

RQ2: The division of responsibility between professional and manufacturer, when using the medical device sold in consumer markets? I.e., situation where the device does not work as intended?

When the professionals were asked how they understand the division of responsibility between professional and manufacturer, when using the medical device sold in consumer markets, in Nokia the interviewees think that it depends on a situation who is responsible. In some situations, it can be a nurse, and in some patients, as for example in following situations:

"Difficult question as it depends a lot what kind of mistake is in question, cause at any point a mistake can happen. Depends also when the mistake happens, e.g., a nurse can install the device in a faulty way or give wrong instructions. It can also

be that the patient uses the device in a wrong way. I think it depends on the situation who is responsible." (N1, R. 580-584).

Some nurses also could tell that the responsibility is also manufacturers, so they had right knowledge about the subject.

"If I have made a mistake when giving instructions about the device or e.g., given already used batteries, then I consider it to be my fault. But if it is something bigger such as the device just does not work, then the manufacturer should be in charge. Also, when sending out the data forward, something can go wrong. Difficult topic as it is hard to say who is responsible." (N2, R. 676-680).

"I would first check if the mistake in question happened due to my own behavior (e.g., would do a test again etc.). If the device would still claim a mistake has happened or would give an error code, then would probably try to contact the manufacturer." (N3, R. 752-755).

"Hard to say, the device needs to be calibrated and maintained, I think that the manufacturer is responsible for the mistake. Also, it is important that the person using the device understands how it works and the instructions." (N4, R. 824-826).

When interviewing professionals working in Finnish Heart Association, they used only one device (Heart2Save AiVoni) compared to Nokia, where multiple devices were used. Therefore, in Nokia the experiences were referring to multiple devices and their user experiences, and in Finnish Heart Association just AiVoni product. Within Finnish Heart Association, all the interviewees recommended tested people to go to see a doctor, in case the AiVoni diagnosed potential arrhythmia, and also if they were otherwise feeling unwell.

"In general people often tend to get scared if the device shows atrial fibrillation but they actually do not have it. It is important that people are guided to see a doctor if they feel unwell or if the device shows that there is some atrial fibrillation or arrhythmia. Important that people are not left alone in these cases." (HA-K, R. 91-94).

"In general, I encourage people to trust their gut feeling; if they feel unwell, they should go to see a doctor rather than just trust the device. Also, knowing how to feel out the pulse is important as trying that is essential." (HA-K, R. 96-98).

"Firstly, I think that it is important that the person who does the measurement knows well how to use the device so that the measurement is done correctly. But also, if a device makes a mistake, it is important that then the manufacturer is informed that there has been an issue with the device." (HA-J1, R. 189-192).

"We always forward patients to see a healthcare professional, so if there is a case where we get a false positive, we might direct the patient to a healthcare professional for nothing, but I don't really know if it is really that bad of a thing. But as we can't diagnose the patients, and they just decide to come to get themselves measured randomly e.g. while doing their groceries, we always emphasize for them that it is the current situation and tell them to go to see a healthcare professional immediately, not in two days or in a week. It is crucial for the patients to go directly from the measuring spot to the health station or a hospital, because the atrial fibrillation is ongoing. The issue is that we do not know whether the patient ever went to see a doctor, so I would say it is the patient's responsibility to go and see a medical professional." (HA-J2, R. 296-306).

When the cardiology specialists were interviewed, the other interviewed said that *"the doctors are responsible for reading the results and data in a correct way."* (C-EF, R. 496). The other cardiology specialist commented that *"All kinds of devices can always have technical issues, and nothing really can be done about that.*

Usually, the issues that appear with these kinds of devices have something to do with skin contact and it is also very important to have good instructions on how to use these devices and make sure that the skin is not greasy etc." (C-C, R. 380-384). None of them mentioned the manufacturer's responsibility.

4.2.2. Data protection

When asking about the data protection and whether the interviewees thought that it has been taken into consideration. The nurses working at Nokia Health Centre were aware of data protection, but it seemed that they had doubts whether all of the devices they use take it into account.

"Difficult to say, in some devices we put all the patient's personal data into a device which might be a bit of an issue. But the newer devices might not have these issues, or it is taken into account?" (N1, R. 589-591).

"In sleep polygraphy we can't put a patient's name, social security number or birth date into the device, it creates codes for each patient. In Zenicor we put all the patients' information to the device. There could be always someone who could hack the devices which might cause a problem." (N2, R. 685-688).

"I think that in most cases yes, data protection is considered. However, the beginning of social security number is needed in some cases, but it is hard to identify people based on that." (N3, R. 760-762).

All the representatives of the Heart Association were very aware of data protection and thought that it is well taken into consideration when using the device (Heart2Save's AiVoni).

"*People get an anonymous personal number from the device how they can identify their results, so no names or other personal information is written, and the results are sent into their email. The security of the email could be an issue, but on the other hand, also a lot of other personal information is sent to email."* (HA-K, R. 103-106).

"The device does not collect any personal information about the customer, everything is anonymous, so I think that yes, the data protection is taken into consideration with this device." (HA-J1, R. 197-199).

"Yes, I do think the data privacy is considered as we do not process any information. We just print and give them the pdf results. In our case we do not see or ask any information about the patients." (HA-J2, 311-313).

When interviewing the cardiology specialists, the one working in capital region emphasized the importance of health over data protection "*Hard to tell really, but in general the person's own health should be more important than the fact that someone can access this info. It might be a bit different if the patient is someone who is economically or politically important. But I still think health should come first*." (C-C, R. 389-392). The Cardiologists in Eastern Finland noted that the age of devices might also come in the way of data protection "*Interesting question. How is it possible to pay attention to these things when the devices in use are really antique? Also, it kind of depends how they read the data in the hospitals, it is important to pay attention to data protection there." (C-EF, R. 501-503).*

4.2.3. Trust

When asking about whether people trust the medical devices they have used, in the clinical setting (Nokia Health Centre and Cardiologists) people seemed to trust the devices but were also a bit critical towards them.

"*Yes, I do trust these devices, as they have needed to be tested and certificated before use. However, I tend to be a little critical towards new devices."* (N1, R. 575-576).

It was also noted that they have to trust the devices and they need to be taken care of properly in order to work.

"We don't really have any other option than to trust, so yes." (N2, R. 672).

"*I trust the devices if they are properly calibrated and taken care of."* (N4, 820).

"Yes, I do trust them if they can give out data that is of a good quality." (C-C, R. 376).

The interviewees from the Heart Association felt that they can trust Heart2Save's device, however, again the experiences were based only using one device to which they have gotten proper training from the founder of Heart2Save.

"I think the device is reliable as these kinds of devices have to go through thorough inspection and tests before it can be used. Even needs to have a CE-mark which usually indicates a lot of testing is needed. Also, the process of getting the product registered as a medical device is long so it needs to be well tested and inspected which increases the reliability." (HA-K, R. 74-78).

"Yes, I feel that it (Heart2Save's device) is reliable […] e.g., if the device has shown especially low heart rate, the customer has agreed that to be the case or if the device

has measured that the customer has had extra heart beats then the customer has agreed, so it seems to be very accurate and reliable." (HA-J1, R. 180-185).

"So yes, I do trust the device and always forward the patient forward if it shows something out of the normal, as in the end, it is the healthcare professionals' task to diagnose the patient." (HA-J2, R. 290-292).

In relation to trust, when asking about the criteria when choosing devices that the professionals may suggest to their patients, reliability was mentioned a few times. It was seen very important that the device in use is reliable, otherwise the professionals do not benefit from using the device.

"It needs to produce data that is reliable and of good quality so that a physician can make a diagnosis based on that." (C-C, R. 354-355).

"We screen people at events and guide people to use the devices, so it is important that the devices are easy and fast to use and reliable." (HA-J1, R. 150-151).

"[…] the device needs to be cost efficient and reliable." (N1, R. 548-549).

5. Discussion

The thesis studied how the healthcare professional understood the difference between medical and consumer devices, and whether the division of responsibility between the professional and manufacturer was clear to healthcare professionals. The following chapter will discuss the findings of RQ1 and RQ2 respectively and apply the theoretical framework into the results.

In the healthcare field it is traditional that there has been an information asymmetry between physician and patient. This has given hospital professionals power to determine the demand for healthcare tools and services. New innovations may outmode the traditional model as they enable patients to be more active participants regarding the decisions about their own health and care, and through it access to the newest services. However, there is still time before complete revolution: hospital professionals, especially physicians, are still mostly responsible for the innovation adoption process, and have the power to facilitate or block innovation (WHO, 2010).

This could also be seen when a capital region cardiologist was interviewed; if it was thought that some new device could potentially be used as a part of the treatment, it was used. Usually there is more than one individual physician making decisions; when a cardiologist was interviewed from Eastern Finland region, from the interviews could be noticed that even one doctor would like to use new devices, it does not happen if most of the others resist the idea. Also, when Nokia and Heart association nurses were interviewed, the used new medical devices always seemed to go from up to down; in one case the nurse has suggested taking the new device

into use. Unfortunately, the amount of interviewed professionals were quite limited, so it is hard to say whether or not those will fit for the whole population.

5.1. Research question 1

How the healthcare professionals understand the difference between medical and consumer devices which are sold in consumer markets

5.1.1. Regulations

As it has been stated by Piester and Rosager (2017) that when developing healthcare technologies such as medical devices, legislation has a significant role. When looking at the interview results, the knowledge about regulatory requirements among the healthcare professionals could be improved. The overall results on the knowledge of healthcare professional's on regulations varied; some of them were able to tell the difference well, whereas others were not sure. Out of 9 interviews 4 people could tell the difference, where 5 people were not aware of the difference. However, almost in all of the cases the participants were able to tell the difference roughly.

Quinn et al., 2013 stated that medical technologies have been traditionally sold and used mostly in healthcare surroundings, such as in hospitals or in clinics. This can lead to misunderstandings among healthcare professionals, if the professionals are not aware how to differentiate regulated and non-regulated devices and the patients or customers purchase them from somewhere by themselves. This was also noted in the interviews as it was thought that medical devices are only used by healthcare

professionals and none of the participants mentioned the possibility of regular consumers buying the medical devices.

Also, if medical professionals are not trained about the regulation requirements and how they are shown in the device, this may potentially cause dangerous situations within the healthcare if devices are used for wrong purposes or in a wrong way. Currently it seems that the responsibility for device purchase is on the purchase department, and also the "the knowledge about the subject may vary" (CEO of Clinipower, Maija Laukkanen).

The new medical devices could increase the efficiency of the healthcare industry and increase the quality of care which are important aspects as the demand for healthcare increases (Topol, 2019). In order to utilize the full potential of the medical devices (e.g., in the diagnostic process), understanding the difference between the medical and consumer devices should be emphasized more e.g., through training. With the current situation it might be unclear for the professionals whether a device can be used as a part of the diagnostic or treatment process, which might cause that the devices and their data will not be used. As the number of different devices are constantly rising within the healthcare sector, it becomes more crucial that purchase bodies know what they are buying, and healthcare professionals know what type of devices they are using. Maybe this will not be a problem within the bigger hospital districts, but in smaller hospitals and healthcare clinics should also be covered.

5.2. Research question 2

The division of responsibility between professional and manufacturer, when using the medical device sold in consumer markets? I.e. situation where the device does not work as intended?

5.2.1. Responsibility

As the number of new healthcare technologies that are used as tools to diagnose and treat patients increases, understanding the division of responsibility becomes increasingly important (Winfield and Jirotka, 2018). It has been noted that with the previous regulations, the lines of responsibilities are not always clear to people who work with newer kinds of medical devices (Reddy et al., 2018).

Understanding the difference when viewing who is responsible if something goes wrong while using a device is crucial. The MDR (EU MDR 2017/745) states that if something is to go wrong whilst using a medical device, the manufacturer of the device is responsible for the mistake, whereas in consumer devices the consumer is in charge if something goes wrong. This might present an issue if the knowledge about the difference between medical and consumer devices is not up to date as the healthcare professionals might potentially take the blame for e.g., diagnosing the patient wrong even though the manufacturer is responsible for the wrong diagnosis, if the device does not work as intended. This is in line with the results as many of the interviewees suggested that it is the user's responsibility if the device makes a mistake.

The results from the interviews showed that 3 people were able to name the manufacturer as responsible if something would go wrong. Other suggestions were the person using the device (doctor, nurse or representative of Heart Association), or the patient and it was also reported to be dependent on the case who is responsible. As here we are not evaluating e.g., AI diagnostic tools, or other kinds of diagnostic support devices than those mentioned within the thesis, it is hard to say whether these results will apply to other devices as well. Also here the interviewees did not use the device as an only way for diagnosing the patient, doctor is always a part of the process.

In accordance with the responsibility, the MDR also states that it is the user's responsibility to make sure that he/she has the technical knowledge, experience, education or training, in order to use a particular device as intended and in accordance with the instructions, which was also stated in the interviews as it was emphasized that the person using the device needs to understand how the device works.

5.2.2. Data protection

Webb & Dayal (2017) state that as the healthcare sector is becoming more and more digitized, the importance of cybersecurity has increased. Even though technological progress has benefited healthcare, it has also created new risks, and this is why the knowledge about the data protection was also considered to be an interesting topic to cover during the interview process. The new kind of medical devices process a lot of data and with new technologies it is a possibility that a patient's personal information could be leaked if the device does not work as intended. The MDR, IVDR and GDPR aim to tackle the possible challenges that might appear when

using devices that process personal information. These regulations need to be considered in new devices, but if they are taken into consideration in old devices might be a bit questionable.

When asking the interviewees whether they thought that the data protection was considered in devices they use, the personnel working at Nokia seemed to be aware of the concept of data protection, however whether the data protection was considered in the devices, was a bit questionable as some of the devices needed patient's personal information to be put into the device. Especially with Zenicor, the patient's personal information was added to a device which might possess a risk if a data leak would happen and it also might violate the GDPR.

Another possible issue was seen to be the old devices which was pointed out by the Cardiologist at Kuopio, as it is a possibility that the data protection has not been taken into account whilst designing the device. The representatives of Heart Association were all sure that the data protection has been taken into account when using Heart2Save's device as they knew well how the device works and have gotten lectures from the founder of Heart2Save.

Interestingly, only one interviewee noted that a person's health should come first before worrying about data protection.

5.2.3. Trust

As Charisi et al. (2017) stated, the healthcare professionals need to be able to trust the decisions that the device makes. In order for the healthcare professionals to be willing to use the device, the reliability of the devices need to be considered.

When asking the interviewees whether they trusted the devices they have used, the overall opinion was that people seemed to trust the devices. The representatives from Heart Association had positive responses when looking at whether they trust the devices. This can be due to multiple reasons; they have gotten good training on how to use the device and also gotten instructions on what to do if something does not work. Also, they all had experiences on using one particular device, compared to people working in a clinical setting who used multiple different devices. In addition, they have had time to try out the device properly and they knew well how it works.

When looking at the clinical setting, the quality of data and the device was an important factor, it was also mentioned that as long as the devices work properly and are maintained the right way, they trust the devices. It was also noted that they have no other option than to trust the devices. People working in clinical settings had experience of working with multiple different devices, which all worked differently, and the training seemed not to be as thorough as compared to the training the Heart Association representatives had gotten with Heart2Save's device. People also seemed to be a slightly more critical towards trusting the devices.

It was also noted that when choosing the devices, the professionals use, one of the main criteria for choosing a device was trust. They need to be able to trust the device to use it. This is intertwined with regulations as well – as the regulated medical

devices need to pass tests and be certified by authorities, it was seen that the medical devices are trustworthy and reliable by the professionals.

5.3. Results in relation to theories

5.3.1. Different types of innovation

The new innovation can be divided into 4 categories by Kalbach (2012), which are: Breakthrough, Game changer, Incremental and Disruptive. If we compare the mentioned devices during the conducted interviews for the Kalbach's (2012) four-zone innovation model, the findings could position as follows;

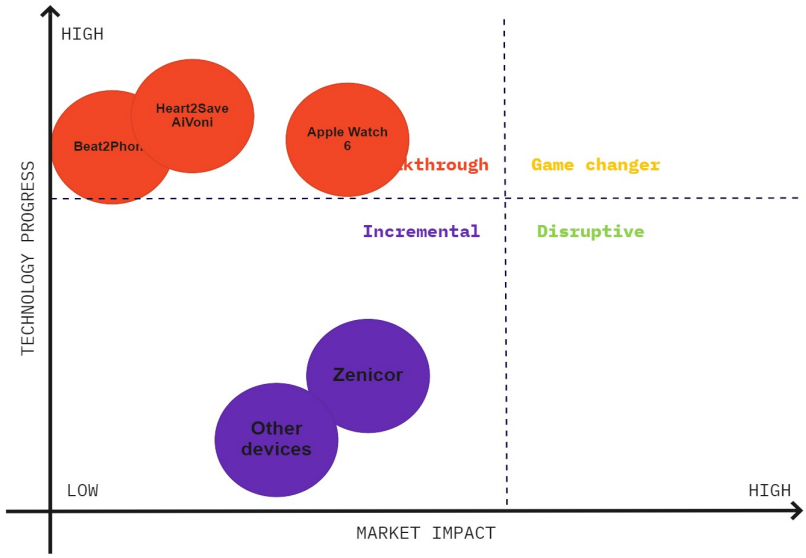

Figure 3. The four-zone innovation model, case Heart2Save.

Source: Author's own interpretation

When Heart2Save's AiVoni product is compared to Kalbach's (2012) model, it positions as "breakthrough" innovation – there is a large technological advancement when compared to existing products, and it contains a patentable function, as there is an algorithm embedded into the solution. Also, Apple Watch and Beat2Phone can both be described to be breakthrough innovations, as they also contain large technological advancements, and are both produced by research and development labs. Both solutions are also CE-marked (Apple, n.d.; VitalSignum, n.d.).

Zenicor devices were also mentioned during the interviews. It could be described as an incremental innovation as it brings modest changes to existing products. The Holter recording has existed for a long time, but the improvement for a patient is that the device can be easily carried with the patient, instead that the recording would be done in the hospital. As this device already exists in the Finnish healthcare market, its market impact could be described to be higher than AiVoni, as that product is not yet introduced to the market. Also, the AiVoni device's size is smaller than the products currently used. When Zenicor is compared to Apple watch or Beat2Phone's solution, based on the interviews it can be also said that Zenicor's market impact is also higher than these solutions, but as the number of interviewed professionals is very limited, this cannot be stated as the truth. Also, other devices were mentioned during the interviews (names were not mentioned) which can be described as incremental innovation, if they are compared to the traditional hospital Holter monitoring (patient stays in the hospital).

The results show that even some new innovations are in use within the interviewed healthcare units, the amount is still rather small. Also, if the innovation is breakthrough (Apple Watch 6, AiVoni) there seemed still to be rare within healthcare settings.

5.3.2. Innovation diffusion

In general, based on the conducted interviews it can be said that new medical devices are just arriving into healthcare settings. When people in different parts in Finland, all working in various positions and different units were interviewed, they seemed to not have used, or currently use too many of these kinds of new medical devices. Also the interviewers got the overall feeling that neither the devices nor their adoption process (for nurses the devices seemed to come from upper decision making bodies) were not too familiar for the interviewed professionals.

Earlier it was mentioned that Fitzgerald et al. (2002) found out that medical professionals are strongly positioned when adopting innovation; also inter-professional alliances and networks may either facilitate or inhibit the innovation diffusion process (Fitzgerald et al., 2002). Also Roger (1995) and Hopkins (2004) stated that utility of the innovation, disruptions that it can cause to existing habits, social values, social status of opinion leaders and whether the individuals are tolerant or resistant towards the innovation affects innovation adoption. When analysing the innovation diffusion in terms of achieved interview results, those showed Fitzgerald et al. 's (2002), Roger's (1995) and Hopkins' (2004) points to be true;

"There are a lot of devices with great technology, but they can't be used in the hospitals or wards because of the strict regulations. It takes a long time to get better devices and it should be easier to detect the rhythm both at home and at the wards. There has been a lot of conversation about the devices in the wards, but people are against especially unregulated devices, and also some of the staff are unwilling to use new devices." (C-EF, R. 444-449).

From the previous quote (Cardiologist from Eastern Finland) it can be seen through the interviews that the professional network is able to hinder the adoption of the innovation, as Fitzgerald et al. 2002 have also noticed, even the innovation might be seen useful; if the professionals are resistant towards the innovation, it affects the adoption. Innovation can also cause disruptions to existing habits, so that may also be one hindering factor - in the interview it was also stated that some of the staff are unwilling to use the new devices, and these disruptions can be one reason behind that.

Interestingly, when comparing with the results obtained from a cardiologist working in the capital region, the cardiologist used Apple watch as a tool for the diagnostic process and sometimes even suggested that to the patients, whereas the cardiologist in Eastern Finland did not use any of these kind of new devices (besides the ones that the hospital has purchased to be used) and did not suggest them to the patients. This also indicates that there can be differences between different areas and hospitals.

In the first interview with a nurse (N1), it was mentioned that medical devices usually come from up to down; this was also highlighted during other interviews, although nurses were also able to suggest devices themselves if they knew suitable ones. The interviewee (N1) also mentioned the importance of peers on the device usage; if no one else has ever used the device, the adoption was considered more difficult; this also highlights Fitzgerald et al. 's (2002) point about the effect of inter-professional alliances or networks, which may facilitate or hinder the innovation. Through the interviews it was noticed that the overall attitudes towards new devices were positive, especially when they are noticed to be useful; despite these, there were also criticism towards completely new devices (not used by peers).

If peers have been using the new device, the utility of innovation within actual work can also be easier to prove, which facilitates the innovation adoption. This kind of attitude might also affect the individuals being tolerant or resistant towards the innovation, which further affects the adoption. This can be seen from the following caption;

"*I know that the final decisions which devices are used are made by the hospital management and that one of the main criteria is that the device needs to be cost efficient and reliable. At my last job I used a vacuum device for wound care and suggested to my superior here that it would be a great addition to have in this job as well and got the permission to start a trial to try it out. So, I think that in most cases it is important that someone already has used the device and knows how it works. I wouldn't recommend a device to a patient that I have never used or tried."* (N1, R. 547-553).

Cost-effectiveness was mentioned in a couple of interviews; this goes along with WHO (2010) observation "The decision-makers often have to prioritize, as resources are scarce and there are continuous attempts to reduce costs. This results in some technologies to diffuse, whereas others do not." As many hospitals and health centres (also the ones where interviews were conducted) already had existing technologies related to arrhythmia detection in use, new devices need to convince the relevant stakeholders also about their cost-effectiveness in order to be really diffused.

WHO (2010) also states that the clinical evidence is not always enough. This is in line with earlier remarks about innovation diffusion within this chapter, and also chapter about the innovation diffusion in the theoretical part. Also, Meyer & Goes (1988) state that the innovative technology adoption is sometimes non-linear,

dynamic pattern and dependent on multiple factors; within the healthcare environment this seems to be especially true.

Greenhalg et al. (2007) also describes that every time when examining innovation adoption within some population, several sub-populations can be identified; it happened also during these interviews. Cardiology specialists seemed to be more willing to adopt new innovations than other subgroups. They can in some cases possibly be described as “early adopters”. The reason for this might be that doctors usually decide about the patient treatment, and their opinion about the devices used from the treatment really counts (“opinion leaders”) and affects what will be implemented within the ward and what not. The cardiology specialists can also affect the patients, as in many cases they are trusted and will be the ones who decide about the patient care. For example, if a cardiology specialist from the capital region (Interview 4, C-C) mentions the apple watch, it can possibly facilitate the patient’s willingness to start using that new innovation.

Through the interviews it was noticed that in some cases nurses can also be “early adopters” of the innovation, as the Heart Association interviews prove. Clinicians are also usually seen as trusted channels. As the number of conducted interviews was quite low, this cannot really be said to suit a larger population. As they are not responsible for treatment decisions, this is probably not always the case within the hospital environment; depending about the hospital, they can also be part of the “late majority” or even “laggards”, as the hospital environment can be quite traditional, and staff may resist changes for the existing working habits. WHO (2010) also states that among the professionals there is rarely agreement for an only one optimal solution, and professionals adapt innovations in different phases; also as a consequence, only a single new solution is not likely to be implemented.

5.4. Limitations

As always in research, also this thesis had its limitations. The first limitation was the COVID-19 outbreak as the thesis was written during spring 2020. This caused the interviews to be changed and postponed a lot. In the beginning, it was aimed to conduct all the interviews at the same department so that the sample would consist of people working within the same unit. This did not become reality as it was not possible to get enough people from one unit to answer to the interviews due to the increasing amount of work the professionals faced due to COVID-19.

The second limitation was the small sample size. 9 interviews were conducted for the thesis. If the sample would have been bigger, the results could have shown more variation, or in certain cases maybe more similar opinions and the results could have been generalized better. We aimed to collect more data but as the situation with pandemic went in waves, it was not possible to reach as many people as we wished as accessing the healthcare personnel during a time like this proved to be challenging in Finland.

The third limitation was the lack of previous research within the topic. There was a limited amount of research conducted around the two main research questions; the division of responsibility when looking at new medical devices and whether the healthcare personnel understand the difference between medical and consumer devices. The topic should be researched more in the future as it deals with important existing issues that need to be emphasized more in order to make the healthcare sector more efficient and to fully utilize the potential the new devices can offer.

5.4.1. Further suggestions for research

As it was stated previously in the limitations, when the thesis was started, researchers did literature review about the subject and it was extremely hard to find any information about the topic, and this also affected the research. Either way, the topic is important - at some level the real knowledge about the researched subject, not only from the professional's viewpoint, but also by knowing purchasing bodies level of knowledge is surely beneficial when the amount of new medical devices will increase. Also, as more and more countries are trying to do new arrangements in the political field regarding the subject, such as ongoing SOTE-transformation in Finland, and many hospital districts are planning strategies to decrease the costs and increase the quality and effectiveness of care by involving an increasing the amount of digital services and devices in the use, researching this kind of topic is important.

When looking at the results of the thesis, it seemed that the results produced new knowledge about the field as it was noted that when the literature review was conducted, similar researchers about the topic were not found. This underlines the need for more research within the subject. The importance of the topic should be emphasized as the amount of new medical devices in consumer markets is rapidly increasing which requires the knowledge of the healthcare professionals to be up to date at all times. This thesis could provide a good framework on how to research the topic even further so that it would be possible to gain a proper view of the healthcare professionals' knowledge within the subject. Also, through more thorough research, it might be possible to pinpoint the weaknesses within the topic, e.g. lack of knowledge, and to find efficient ways to prevent and fix these kinds of issues.

6. Conclusion

As the amount of new preventive digital treatment methods and medical devices (such as Hear2Save's AiVoni) available on the markets increases steadily, so should the awareness within healthcare professionals. This research sought answers to how the healthcare professionals understand the difference between medical and consumer devices sold in consumer markets and whether the division of responsibility between the professional and manufacturer is clear if a mistake happens whilst using the device. Also, two other sub-question were studied in order to form a solid base for understanding the main questions. These sub-questions researched what kind of regulations affect the medical devices and how the medical devices differ from consumer devices in terms of innovation process and were answered through theories.

When studying the first research question from the interviews it was noticed that out of the 9 interviewees 4 could tell how these devices differ from each other. 5 were not able to tell the difference. However, almost in all of the cases the participants were able to tell the difference roughly. When looking at the interview results, the knowledge about regulatory requirements among the healthcare professionals could be improved. When starting the thesis process, this was the researchers' initial thought, and based on the research it seems to be true.

For the results there may be due to multiple reasons. As the medical devices that can be bought and used by both consumers and healthcare professionals are still rather new, it might be still confusing to the professionals whether they are able to use these devices as a part of the diagnostic process and what is the difference. Also, the knowledge of the devices was not particularly high amongst the participants as

none of the participants mentioned that medical devices could be used by consumers. This could be an indication that more training about the new devices is needed within the healthcare professionals.

When looking to the second research question, how the healthcare professionals understand the division of responsibility between professional and manufacturer, when using the medical device sold in consumer markets, the results from the interviews showed that 3 people were able to name the manufacturer as responsible if something would go wrong, which was only ⅓ of the respondents.

The finding indicates that more training about the devices is needed. The fact that the manufacturer is responsible if the device does not work as intended might be relieving information for the professionals as it would clarify that they are only responsible for their own actions, and not responsible for what the device shows or diagnoses if it does not work as intended. In light of this information, if people were more aware of how the responsibility is divided if something goes wrong, it could be possible that the healthcare professionals would use the devices more.

The research also included two sub-questions. The first sub-question aimed to find an answer to what regulations affect medical devices, and how does those differ from regulation affecting the consumer devices. The main finding was that for medical devices there were at least 2 affecting regulations and standards: Medical Device Regulation (EU MDR 2017/745), the ISO 13485 standard. As new medical devices also work more and more with data, there regulations about data security and privacy were also mentioned (NIS Directive and GDPR).

The second sub-question reviewed how the healthcare innovations are diffused in the healthcare environment, and what are the main barriers. The question was responded by firstly including theoretical frameworks in the research, which were further discussed and evaluated within the discussion chapter. When the Kalbach (2012) 4-zone innovation model was used to evaluate the results, three of the technologies mentioned during interviews (Apple Watch 6, Heart2Save AiVoni, Beat2Phone) were described as breakthrough technologies. Other mentioned technologies (Zenicor, other devices) were described as incremental innovation. Also Fitzgerald et al. (2002), Roger (1995) and Hopkins (2004) theories were evaluated, and they seemed to be mostly true when compared to research results.

Also, a question about data protection was involved, to see whether or not the healthcare professionals thought that the devices were safe to use. Everyone seemed to be aware about the concept, and mostly thought that the data protection was considered. This was mostly due the reason that personal / identifying information was not inserted to the device. With Zenicor some of the interviewees mentioned being unsure about data protection, as some personal information needed to be added on the device. Also, one interviewee said that the patient's health should be more important than data protection.

As the digital revolution is changing the healthcare industry and digital tools in medical devices that use artificial intelligence (AI) and machine learning (ML) are used increasingly in everyday work (Nebeker et al., 2019). Coeckelbergh (2019) emphasizes that the importance of understanding the issues with responsibility are crucial when using AI or ML as a part of decision-making (Coeckelbergh, 2019). Coeckelbergh (2019) underlines the question that needs to be asked when using AI as a tool when treating patients: who is responsible, if something is to go wrong while using these tools? This is one of the reasons the EU has decided to

develop MDR legislation even further; as the amount and variety of new technologies are increasing, there is a need for more comprehensive legislation about the subject. As there is not much research about the subject, in this thesis we decided also to look into responsibility issues.

The thesis aims to highlight that it is important for the professionals to understand how the healthcare professionals understand the difference between medical and consumer devices which are sold in consumer markets, and what is the division of responsibility when using these new medical devices. These topics are important, as these differences do not always seem to be clear for the people who are working with those devices. Surely this might not be the core knowledge needed for the professionals' everyday work, but as patient's safety needs always be ensured, it's still important - the medical professional shouldn't potentially take the blame, if the misdiagnosis is clearly a device's fault. Also, medical professionals are responsible for checking if the offered devices are suitable to be used in the healthcare settings.

Patient safety is one of the main concerns when taking new technologies into use. As newest advances in technology have been so significant, in terms of scale and pace, there has not always been enough time or opportunity to fully understand and evaluate their safety issues and overall performance. As the history of using software-driven and regulated medical technologies is not very long, there is not enough evidence and attention associated with dangers and safe use. There needs to be more patient research and safety training to address new risks, e.g., attention bias, where clinicians unquestioningly accept machine advice instead of validating it or maintaining vigilance. The safety of digital healthcare technologies needs to be ensured, otherwise there is a serious risk that the use might be harmful to patients (Topol 2019).

As the number of medical devices in use keeps increasing at a growing pace, so should the awareness of the professionals. Overall, the medical devices possess a great amount of yet unutilized potential that could tackle a myriad of existing challenges. However, before being fully able to unleash the potential of these devices, the professionals need to be more aware of the devices and their possibilities.

References

Aken, J. E. Van, & Bij, H. Van Der. (2012). *Problem Solving in Organizations*.

Apple Watch Series 6 - Apple (FI). (n.d.). Retrieved December 28, 2020, from https://www.apple.com/fi/apple-watch-series-6/

Blume, S. S. (1992). *Insight and Industry: On the Dynamics of Technological Change in Medicine*. Massachusetts: MIT Press. Retrieved from https://books.google.fi/books?hl=da&lr=&id=0Dhehc_2U9UC&oi=fnd&pg=PR9&dq=Blume+SS.+Insight+and+industry:+on+the+dynamics+of+technological+change+in+medicine.+Massachusetts,+Massachusetts+Institute+of+Technology+Press,+1992.&ots=uR2JFGqW6e&sig=ndVfVPLN6k_X

Cheng, J. W., & Mitomo, H. (2017). The underlying factors of the perceived usefulness of using smart wearable devices for disaster applications. *Telematics and Informatics*, *34*(2), 528–539. https://doi.org/10.1016/j.tele.2016.09.010

Coeckelbergh, M. (2019). Artificial Intelligence, Responsibility Attribution, and a Relational Justification of Explainability. *Science and Engineering Ethics*, *7*(0123456789). https://doi.org/10.1007/s11948-019-00146-8

Consoli, D., McMeekin, A., Metcalfe, J. S., Mina, A., & Ramlogan, R. (2009). The process of health care innovation: problem sequences, systems, and symbiosis. In *The Economics of New Health Technologies* (pp. 19–42). Oxford University Press. https://doi.org/10.1093/acprof:oso/9780199550685.003.0002

European Commission. (n.d.-a). CE marking | Internal Market, Industry, Entrepreneurship and SMEs. Retrieved January 9, 2020, from https://ec.europa.eu/growth/single-market/ce-marking_en

European Commission. (n.d.-b). Conformity assessment | Internal Market, Industry, Entrepreneurship and SMEs. Retrieved January 28, 2020, from

https://ec.europa.eu/growth/single-market/goods/building-blocks/conformity-assessment_en

European Commission. (n.d.-c). European database on medical devices (EUDAMED) | Internal Market, Industry, Entrepreneurship and SMEs. Retrieved January 13, 2020, from https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en

European Commission. (n.d.-d). New regulations | Internal Market, Industry, Entrepreneurship and SMEs. Retrieved January 9, 2020, from https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en

European Commission. (n.d.-e). Notified bodies | Internal Market, Industry, Entrepreneurship and SMEs. Retrieved January 27, 2020, from https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies_en

European Commission. (2019a). Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) Healthcare professionals and health institutions, 2588813.

European Commission. (2019b). Unique Device Identification System under the EU Medical Device Regulations 2017/745 and 2017/746, 6. Retrieved from https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system

European Parliament & Council of European Union. (2011). Directive 2011/83/eu of the European parliament and of the council. *Official Journal of the European Union*, *304*, 64–88. Retrieved from http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0064:0088:en:PDF

European Union. (1986). Product safety and product liability - An analysis of the EEC Council Directive of 25 July 1985 on the approximation of the laws,

regulations, and administrative provisions of the Member States concerning liability for defective products. *Journal of Consumer Policy*, *9*(2), 133–154. https://doi.org/10.1007/BF00380508

European Union. (2017). Regulation (EU) 2017/745 of the European Parliament and of the Council. *Hospital Practice (Office Ed.)*, *27*(4), 97–100, 103, 113. https://doi.org/10.1080/21548331.1992.11705401

European Union. (2018). Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation – GDPR). *International and European Labour Law*, *2014*(March 2014), 958–981. https://doi.org/10.5771/9783845266190-974

EvaluatePharma. (2018). World Preview 2018, Outlook to 2024, (11th Edition,June), 47. Retrieved from http://info.evaluategroup.com/rs/607-YGS-364/images/WP2018.pdf

Fitzgerald, L., Ferlie, E., Wood, M., & Hawkins, C. (2002). Interlocking interactions, the diffusion of innovations in health care, *55*(12), 1429–1449.

Food and Drug Administration. (2016). General Wellness: Policy for Low Risk Devices Draft Guidance for Industry and Food and Drug Administration staff. *U.S. Department of Health and Human Services Food*, 1–11.

Food and Drug Administration. (2020). Cybersecurity. Retrieved January 29, 2020, from https://www.fda.gov/medical-devices/digital-health/cybersecurity

Gelijns, A., & Rosenberg, N. (1994). The dynamics of technological change in medicine. *Health Affairs*. Project HOPE - The People-to-People Health Foundation, Inc. . https://doi.org/10.1377/hlthaff.13.3.28

Goffin, Mitchell (2017). Innovation Management: Effective Strategy and Implementation Retrieved December 29, 2020, from https://books.google.fi/books?hl=fi&lr=&id=NSKHDQAAQBAJ&oi=fnd&pg=PP1&dq=goffin+and+mitchell+(2017)+innovation+management+effectiv

e+strategy+and+implementation+3rd+edition&ots=KoqAPYn8l3&sig=uVxZ3SUqV2ufcC-GrBQuuz5Vy0g&redir_esc=y#v=onepage&q&f=false

Greenhalgh, T., Robert, G., Bate, P., Macfarlane, F., & Kyriakidou, O. (2007). *Diffusion of Innovations in Health Service Organisations: A Systematic Literature Review*. *Diffusion of Innovations in Health Service Organisations: A Systematic Literature Review*. Blackwell Publishing Ltd. https://doi.org/10.1002/9780470987407

Healthtech Finland. (2019). Terveyttä ja kasvua teknologialla Terveysteknologian vuosi 2019.

Heart2Save Oy. (n.d.). Retrieved December 28, 2020, from https://heart2save.com/?page_id=92

Holm, S. (2011). Final responsibility for treatment choice: The proper role of medical doctors? *Health Expectations*, *14*(2), 201–209. https://doi.org/10.1111/j.1369-7625.2011.00673.x

Hopkins, M. M. (2004). Technique-led technological change and the 'hidden research system' : genetic testing in the NHS.

Hoyt, R. E. ., & Yoshihashi, A. K. (2014). *Health Informatics Practical Guide for Healthcare and Information Technology Professionals. Lulu.com, Raleigh, 27.* Retrieved from https://www.scirp.org/(S(351jmbntvnsjt1aadkposzje))/reference/ReferencesPapers.aspx?ReferenceID=1744992

ISO - IEC 80001-1:2010 - Application of risk management for IT-networks incorporating medical devices — Part 1: Roles, responsibilities and activities. (n.d.). Retrieved December 28, 2020, from https://www.iso.org/standard/44863.html

ISO - Standards. (n.d.). Retrieved December 31, 2020, from https://www.iso.org/standards.html

Kalbach, J. (2012). Clarifying Innovation: Four Zones of Innovation.

Experiencing Information. Retrieved January 23, 2020, from https://experiencinginformation.com/2012/06/03/clarifying-innovation-four-zones-of-innovation/

Khan, S. (2020). Qualitative research: People, practices and phenomena. *Publications of the University of Eastern Finland. General Series, No 30*. Retrieved from https://epublications.uef.fi/pub/urn_isbn_978-952-61-3341-6/index_en.html

Kuluttajansuojalaki 38/1978 - Ajantasainen lainsäädäntö - FINLEX ®. (n.d.). Retrieved December 29, 2020, from https://finlex.fi/fi/laki/ajantasa/1978/19780038

Kvale, S. (2007). Conducting an interview. *Nursing Times*, *68*(16), 484–485. https://doi.org/10.7748/nr2000.07.7.4.75.c6132

Kvale, S. (2011). Planning An Interview Study. *Doing Interviews*, 34–50. https://doi.org/10.4135/9781849208963.n4

Kvale, S., & Brinkmann, S. (2009). *InterViews: Learning the craft of qualitative research interviewing, 2nd ed. InterViews: Learning the craft of qualitative research interviewing, 2nd ed.* Thousand Oaks, CA, US: Sage Publications, Inc.

Lang, E. S., Wyer, P. C., & Haynes, R. B. (2007). Knowledge Translation: Closing the Evidence-to-Practice Gap. *Annals of Emergency Medicine*, *49*(3), 355–363. https://doi.org/10.1016/j.annemergmed.2006.08.022

Mahajan, V., Muller, E., & Bass, F. M. (1990). New Product Diffusion Models in Marketing: A Review and Directions for Research. *Journal of Marketing*, *54*(1), 1–26. https://doi.org/10.2307/1252170

Mayring, P. (2004). Qualitative Content Analysis, 266–269. Retrieved from http://www.ghbook.ir/index.php?name&option=com_dbook&task=readonline&book_id=13629&page=108&chkhashk=03C706812F&Itemid=218&lang=fa&tmpl=component

Medical Device Coordination Group. (2019). *MDCG 2019-16 Guidance on Cybersecurity for medical devices*.

MedTech Europe. (2019). The European Medical Technology Industry – in figures 2019. *Hospital Progress*, *44*, 96–98.

Meyer, A. D., & Goes, J. B. (1988). Organizational assimilation of innovations: A multilevel contextual analysis. *Academy of Management Journal*, *31*(4), 897–923. https://doi.org/10.2307/256344

Nahta, R., & Esteva, F. J. (2007). Trastuzumab: Triumphs and tribulations. *Oncogene*, *26*(25), 3637–3643. https://doi.org/10.1038/sj.onc.1210379

Nebeker, C., Torous, J., & Bartlett Ellis, R. J. (2019). Building the case for actionable ethics in digital health research supported by artificial intelligence. *BMC Medicine*, *17*(1), 1–7. https://doi.org/10.1186/s12916-019-1377-7

OECD Glossary of Statistical Terms - Innovation Definition. (n.d.). Retrieved December 28, 2020, from https://stats.oecd.org/glossary/detail.asp?ID=6865

Ong, W. J. (1982). *Orality and literacy : the technologizing of the word*. London ; New York : Methuen: Routledge.

Øye, C., Sørensen, N. Ø., & Glasdam, S. (2015). Qualitative research ethics on the spot: Not only on the desktop. *Nursing Ethics*, *23*(4), 455–464. https://doi.org/10.1177/0969733014567023

Piester, C., Rosager, M. (2017). *MedTech Marketing*.

Quinn, P., Habbig, A. K., Mantovani, E., & De Hert, P. (2013). The Data protection and Medical Device Frameworks - Obstacles to the deployment of mHealth across Europe? *European Journal of Health Law*, *20*(2), 185–204. https://doi.org/10.1163/15718093-12341267

Reddy, S., Fox, J., & Purohit, M. P. (2019). Artificial intelligence-enabled healthcare delivery. *Journal of the Royal Society of Medicine*, *112*(1), 22–28. https://doi.org/10.1177/0141076818815510

Rogers, E. M. (1995). *Diffusion of innovations*. Retrieved from https://www.worldcat.org/title/diffusion-of-innovations/oclc/444656250

Ryan, F., Coughlan, M., & Cronin, P. (2009). Interviewing in qualitative research: The one-to-one interview. *International Journal of Therapy and Rehabilitation*, *16*(6), 309–314. https://doi.org/10.12968/ijtr.2009.16.6.42433

Saunders, M., Lewis, P., & Thornhill, A. (2007). *Research Methods for Business Students*.

Sharan B. Merriam, Elizabeth J. Tisdell - Google-kirjat. (n.d.). Qualitative Research: A Guide to Design and Implementation Retrieved December 31, 2020, from https://books.google.fi/books?hl=fi&lr=&id=JFN_BwAAQBAJ&oi=fnd&pg=PA137&dq=ways+to+gather+data+qualitative+research&ots=wOWYNO4G43&sig=MB7dDO4zno9BtcD7xHaNTLRaLmM&redir_esc=y#v=onepage&q=ways to gather data qualitative research&f=false

Sjöklint, Mimmi; Constantiou, Ioana; Trier, M. (2015). The Complexities of Self-Tracking - An Inquiry into User Reactions and Goal Attainment, 0–15.

Speer, J. (2019). The Essential Guide to Preparing Your QMS for the EU MDRT.

Stevens, E.; Emmett, E.; Wang, Y.; Wolfe, C. (2017). *The Burden of Stroke in Europe Report* (Vol. 53). https://doi.org/10.1017/CBO9781107415324.004

Sydän.fi - Tietoa sydänterveydestä ja hyvinvoinnista. (n.d.). Retrieved December 28, 2020, from https://sydan.fi/

The International Organizational for Standards. (n.d.-a). ISO - ISO 14971:2019 - Medical devices — Application of risk management to medical devices. Retrieved February 3, 2020, from https://www.iso.org/standard/72704.html

The International Organizational for Standards. (n.d.-b). ISO 13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes. Retrieved February 3, 2020, from https://www.iso.org/standard/59752.html

The International Organizational for Standards. (n.d.-c). The International Organization for Standards. Retrieved February 3, 2020, from https://www.iso.org/standards.html

Therapeutic Goods Administration (2019). Medical device cyber security information for users, (July), 1–54.

Topol, E. (2019). Preparing the healthcare workforce to deliver the digital future The Topol Review An independent report on behalf of the Secretary of State for Health and Social Care, (February), 102. Retrieved from https://topol.hee.nhs.uk/wp-content/uploads/HEE-Topol-Review-2019.pdf

VitalSignum | Buy Now. (n.d.). Retrieved December 13, 2020, from https://www.vitalsignum.com/en/buy-now/

Webb, T., & Dayal, S. (2017). Building the wall: Addressing cybersecurity risks in medical devices in the U.S.A. and Australia. *Computer Law and Security Review*, *33*(4), 559–563. https://doi.org/10.1016/j.clsr.2017.05.004

Winfield, A. F. T., & Jirotka, M. (2018). Ethical governance is essential to building trust in robotics and artificial intelligence systems. *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences*, *376*(2133). https://doi.org/10.1098/rsta.2018.0085

World Health Organization. (2010a). Medical devices : Managing the mismatch Barriers to innovation in the field of medical devices. *World Heath Organization*, 1–22. https://doi.org/WHO/HSS/EHT/DIM/10.6

World Health Organization. (2010b). Patients' rights. *WHO*.

Appendix

Interview 1, Finnish Heart Association representative of Heart District of Savo (Kuopio)

Q: Does the unit have new kinds of medical devices to measure patients in use currently? /Heart Association: What kind of devices have you used to track heart rate/arrhythmia?

A: Heart2Save's device has been in use in the heart district of Savo, we have here measured the heart rate of over 400 people in over 20 different events and pharmacies. We also had one fixed point where people could come and get their heart rate measured by Heart2Save's device. In general, there has been emerging interest towards the device. During the measuring period, 5 new cases were found who were not aware that they had atrial fibrillation.

Q: What kind of devices are planned to take into use? /Heart Association: What kind of knowledge do you have of these kinds of devices?

A: Besides Heart2Save's device, other medical devices from competitors have not been used. There has been one mobile application which has been used, but that was not classified as a medical device. We do also other measurements, such as measure blood pressure or heart rate.

Q: What kind of experiences do you have from these devices?

A: Overall good experiences with the Heart2Save's device and people have shown interest towards the device. We have been able to measure almost everyone, only a few times there were some small issues with e.g. bad connection or if the patients happened to have really dry skin. However, in these kinds of situations we have always been able to get help and support from Heart2Save's personnel and even most of these complicated cases were measured. In the end, there was only a few people who we were not able to measure.

We (the heart district of Savo) do not have the device in use currently. However, the plan is to buy one device during this year (2020). The aim is to offer the measurement of atrial fibrillation as a similar service as all the other measurements such as blood pressure.

Q: Do you suggest/recommend any devices for patients to use at home? /Heart Association: What kind of devices do you suggest/recommend people to use at home to track their heart rate/arrhythmia?

A: If a person asks about the devices that are meant for measuring atrial fibrillation, then we tell them about Heart2Save's device. It is the only device that we are aware of that can be used at home currently and have also gotten training on how to use it. If a person comes to measure their cholesterol levels, we usually do not tell them about the device but if a person comes for the measurement of atrial fibrillation/arrhythmia, then depending on a case, we might tell them. The traditional way is to feel out the pulse of a person and guide them how to do it themselves and then ask if they have had any abnormal feelings lately and if they have gone to a doctor for that issue.

Some people have heard about the Heart2Save's device, especially in the cases where they know they have atrial fibrillation and they know how it feels. In these cases, they have given out the contact information for Heart2Save.

There has been no contact from competitors, and there are not any other similar devices used currently.

Q: To whom you recommend the devices?

A: The people that are the most interested about the possibility to measure their atrial fibrillation at home are the ones that have been already diagnosed with a heart condition as they already know the abnormal feeling and recognize it. So, it is recommended for them mostly.

Q: How is the device given to a patient? (Process to guide the patient)

A: The plan is to have one Heart2Save's device at the measuring point so that people can come and do the measurement there, no plans to loan out or rent the device to people.

Q: Do you trust these kinds of devices?

A: I think the device is reliable as these kinds of devices have to go through thorough inspection and tests before it can be used. Even needs to have a CE-mark which usually indicates a lot of testing is needed. Also, the process of getting the

product registered as a medical device is long so it needs to be well tested and inspected which increases the reliability.

The connection issues e.g. at more rural areas can be seen as a risk, as then the device might not work as intended. But based on own experiences, the connection issues were rare.

The device is generally easy to use, but one possible risk could be when old people use the device because they might not be able to always use the device correctly. Training and guiding the elderly is important, and there could be even user support provided for the elderly.

Q: If a device makes a mistake, who is responsible for the mistake?

A: In general people often tend to get scared if the device shows atrial fibrillation but they actually do not have it. It is important that people are guided to see a doctor if they feel unwell or if the device shows that there is some atrial fibrillation or arrhythmia. Important that people are not left alone in these cases.

In general, I encourage people to trust their gut feeling; if they feel unwell, they should go to see a doctor rather than just trust the device. Also, knowing how to feel out the pulse is important as trying that is essential.

Q: Do you believe that data protection is considered when the devices process information?

A: People get an anonymous personal number from the device how they can identify their results, so no names or other personal information is written, and the results are sent into their email. The security of the email could be an issue, but on the other hand, also a lot of other personal information is sent to email.

Q: Do you know the difference between medical and consumer devices?

A: Heart2Save's founder has kept lectures about the device, which has increased the feeling about the reliability of the device. There are some devices for measuring the blood pressure that could also possibly detect atrial fibrillation, but those are mostly more suggestive, so those results are not probably as reliable and precise. There are a lot of people with atrial fibrillation and most of them are worried about it.

Interview 2, Finnish Heart Association representative of Heart District of Middle Finland (Jyväskylä)

Q: Does the unit have new kinds of medical devices to measure patients in use currently? /Heart Association: What kind of devices have you used to track heart rate/arrhythmia?

A: I have had devices to measure blood pressure, which can be used as a tool to detect atrial fibrillation as well. Firstly, I always suggest and guide people to feel out the pulse manually by hand. I have now had the device from Heart2Save for a while in use, it is the only newer kind of device to measure atrial fibrillation, no other devices are being used so no experience from other devices.

Q: What kind of devices are planned to take into use? /Heart Association: What kind of knowledge do you have of these kinds of devices?

A: I am aware that there are some apps which could be used in a similar way, but not used yet.

Q: Do you suggest/recommend any devices for patients to use at home? /Heart Association: What kind of devices do you suggest/recommend people to use at home to track their heart rate/arrhythmia?

A: Blood pressure monitors are in use, but often the heart rate tends to be a bit unreliable from those devices and those are firstly used to measure the blood pressure. I always ask if the customer has tried to feel out the pulse manually. Also, now that more people have heard about Heart2Save's device, so more people have started to ask if it is possible to buy it somewhere and if they can buy that to themselves. So, these three ways are used when discussing measuring their heart rate with customers.

Q: What kind of criteria do you use when choosing the devices?

A: We screen people at events and guide people to use the devices, so it is important that the devices are easy and fast to use and reliable. Many of the measuring events are held in stores and pharmacies with a lot of people so it is not possible to start putting heart rate monitors or other complicated devices on customers. Also, it is important that the customers do not need to make a lot of effort for the

measurement, e.g. take off their clothes in public so that they can maintain their privacy. We do not have any standardized process when thinking about the devices we use. We first test the device out and then think if it would be suitable for our use.

Q: To whom you recommend the devices?

A: We recommend the device for people who want to follow and see their own heart rate and who are interested in their heart health and also for the people who are in a risk group to have a heart condition and might benefit from the device. We also tell about the device almost always to people who have had atrial fibrillation or other issues with their heart. If we find or hear that someone has issues or concerns about their heart, we always direct them to a health station or hospital for further inspections. This goes also if we detect issues with blood pressure or when feeling the pulse manually, since it is always good to get it checked with a professional.

Q: How is the device given to a patient? (Process to guide the patient)

A: The customers do not use the devices on their own, there is always someone to guide and help with the use as it is part of the service. So, a nurse or a practical nurse is always present in the situation.

Q: Do you trust these kinds of devices?

A: Yes, I feel that it (Heart2Save's device) is reliable. When measuring and also when discussing with the patients about the results, they have always seemed to be correct, e.g. if the device has shown especially low heart rate, the customer has agreed that to be the case or if the device has measured that the customer has had extra heart beats then the customer has agreed, so it seems to be very accurate and reliable.

Q: If a device makes a mistake, who is responsible for the mistake?

A: Firstly, I think that it is important that the person who does the measurement knows well how to use the device so that the measurement is done correctly. But also, if a device makes a mistake, it is important that then the manufacturer is informed that there has been an issue with the device.

Q: Do you think that data protection is considered when the devices process information?

A: The device does not collect any personal information about the customer, everything is anonymous, so I think that yes, the data protection is taken into consideration with this device.

Q: Do you know what is the difference between medical and consumer devices?

A: Medical devices can be used as a tool for diagnosis and can be used in the healthcare setting. Also, Fimea tracks and has a register for these devices. Consumer devices can be used for tracking the information about the user, but it cannot be used for diagnostics.

Interview 3, Finnish Heart Association representative of Heart District of Middle Finland (Jyväskylä)

Q: Does the unit have new kinds of medical devices to measure patients in use currently? /Heart Association: What kind of devices have you used to track heart rate/arrhythmia?

A: For monitoring heart rate, mainly the device from Heart2Save has been used. We also always teach people how to measure their pulse manually, which is the most common used tool. In addition, sometimes a blood pressure monitor is used also for measuring the pulse.

Q: What kind of devices are planned to take into use? /Heart Association: What kind of knowledge do you have of these kinds of devices?

A: I have heard about Beat2Phone, have seen it few times but have not used it.

Q: What kind of experiences do you have from these devices?

A: All the experiences of the usage is based on Heart2Save's device. Overall I have had positive experiences about the device, thus have experienced few challenges while measuring: there has been connection issues few times with bluetooth, and also few issues with the internet connection. Also, it has taken a while to learn to measure the patient correctly and efficiently, e.g. placing the sensors to correct places etc.

Q: Do you suggest/recommend any devices for patients to use at home? /Heart Association: What kind of devices do you suggest/recommend people to use at home to track their heart rate/arrhythmia?

A: We always first teach people how to manually feel their pulse from their wrist. We usually also tell the patients that there are a few existing devices to measure their pulse, however we also note that the devices differ from each other e.g. by their quality. We tell the patients about the devices we know better and if needed also guide how to use them. Also, people are always guided to contact the health care professional if they feel that they have had some irregularities in their heart rate lately. We may tell about the devices but cannot directly recommend any certain device to a patient because it is against the ethical conduct of the Heart Association. However, they can always tell about the device without recommending them.

Q: What kind of criteria do you use when choosing the devices?

A: We get information about the new devices through the Heart Association, which informs about the new devices. It is very important that the devices need to be thoroughly researched and clinically assessed, currently I do not know if Beat2Phone and Heart2Save's have the CE-marking, I only know that it has been applied by Heart2Save but not sure if they have it yet. Also, it is not possible for the people that work with the patients to remember all the existing devices, so it is better just to learn a few devices and if the patients ask, maybe suggest those.

Q: To whom you recommend the devices?

A: We mention about feeling their own heart rate to everyone. Also, to almost everyone we tell about the devices available, because we aim to be as unbiased as possible towards everyone. We have also noticed that not only the elderly is interested in the device, but also younger people, especially men who play a lot of sports. In addition, maybe the older people are not as interested about the device, especially if they do not have a smartphone and they might be a bit more wary about these kinds of new technologies. But especially in these cases always feeling the pulse manually is very important.

Q: How is the device given to a patient? (Process to guide the patient)

A: We mostly just measure heart rate in different kinds of events and pharmacies, do not have a fixed measure spot at their office. For now, we have also had the device (Heart2Save) for the pilot testing and given feedback about it. During the

measuring situation I usually talk and guide the patient about what I am doing in detail so that the patient can learn at the same time how to use the device on their own.

Q: Do you trust these kinds of devices?

A: Basically yes. But in my case, I have had my share of the 5%, by which I mean that if the accuracy of a device is 95% in 5% of cases the device has not been measuring it correctly. But yes in a general level I do trust the device and it is a really good tool for us to use, e.g. if the device shows that there is atrial fibrillation, we always direct the patient to a health station or hospital, and there they can examine better, what kind of issue there is. So we are using the device as a criteria to forward people to care. Also, in most of the cases we will never know what was really wrong with the patient, unless we contact the patient again or ask them to contact us. We also always feel the pulse manually, if the device measures irregularities with the pulse. So yes, I do trust the device and always forward the patient forward if it shows something out of the normal, as in the end, it is the health care professionals' task to diagnose the patient.

Q: If a device makes a mistake, who is responsible for the mistake?

A: We always forward patients to see a healthcare professional, so if there is a case where we get a false positive, we might direct the patient to a healthcare professional for nothing, but I don't really know if it is really that bad of a thing. But as we can't diagnose the patients, and they just decide to come to get themselves measured randomly e.g. while doing their groceries, we always emphasize for them that it is the *current* situation and tell them to go to see a healthcare professional immediately, not in two days or in a week. It is crucial for the patients to go directly from the measuring spot to the health station or a hospital, because the atrial fibrillation is ongoing. The issue is that we do not know whether the patient ever went to see a doctor, so I would say it is the patient's responsibility to go and see a medical professional.

Q: Do you think that data protection is considered when the devices process information?

A: Yes, I do think the data privacy is considered as we do not process any information. We just print and give them the pdf results. In our case we do not see or ask any information about the patients.

Q: Do you know what is the difference between medical and consumer devices?

A: Well yes, a medical device is based on thorough research and it can be used to diagnose a patient. Anyone can buy a consumer device, and these can't be used to diagnose a patient.

Interview 4, Cardiology Specialist, Capital region

Q: Does the unit have new kinds of medical devices to measure patients in use currently? /Heart Association: What kind of devices have you used to track heart rate/arrhythmia?

A: Every hospital has the ability to do Holter recording. I don't know for sure but also some of the hospitals use Zenicor symptom Holter, which is also used in Mehiläinen, Terveystalo and Meilahti at least. These new kinds of devices are still kind of rare so mostly Holters and then some devices that patients have found themselves. I have had patients that have found Beat2Phone and the newest Apple watch which has the possibility to register data when the seizure hits.

Q: Do you suggest/recommend any devices for patients to use at home? /Heart Association: What kind of devices do you suggest/recommend people to use at home to track their heart rate/arrhythmia?

A: The seizure-based arrhythmias need to be caught at the exact time they happen, so when a person is feeling the symptoms, it needs to be caught.

I have noticed that Beat2Phone and the newest Apple watch give reliable and good quality data from where a doctor can diagnose the arrhythmia already. If a patient has been thinking about buying an Apple watch, I might recommend that but in most of the cases the patients are already aware that the watch has this kind of feature.

The downside of using Beat2Phone is that it needs a heart rate belt to work, so in case a seizure happens, and a patient is not wearing a belt, it is already too late. So, the patient would need to wear the belt all the time, which might be difficult and uncomfortable. I have done diagnostics with the help of these two devices.

Q: What kind of criteria do you use when choosing the devices?

A: It needs to produce data that is reliable and of good quality so that a physician can make a diagnosis based on that. Also, needs to be user friendly, preferably small and easy to carry around. In light of these features, the Apple watch is convenient as you can carry it with you at all times.

Q: To whom you recommend the devices?

A: I take into consideration the patient and his/hers needs, as it is important to find out what is going on with the patients' health for their own sake. Experienced doctor who works a lot with arrhythmias can already deduct from the anamnesis if the patient needs extra measures to be taken and guess what kind of issue there might be. Of course, then the registering gives the final and most reliable results.

Q: How is the device given to a patient? (Process to guide the patient)

A: Zenicor is given out to patients to use it at home and it is based on the heart film's impedance which is given out to the laboratory to be analyzed. The device itself is used by the patient during the registering period and can be loaned out from the hospital. Then Apple watches etc. the patient needs to buy themselves.

Q: Do you trust these kinds of devices?

A: Yes, I do trust them if they can give out data that is of a good quality.

Q: If a device makes a mistake, who is responsible for the mistake?

A: All kinds of devices can always have technical issues, and nothing really can be done about that. Usually the issues that appear with these kinds of devices have something to do with skin contact and it is also very important to have good instructions on how to use these devices and make sure that the skin is not greasy etc.

Q: Do you think that data protection is considered when the devices process information?

A: Hard to tell really, but in general the person's own health should be more important than the fact that someone can access this info. It might be a bit different if the patient is someone who is economically or politically important. But I still think health should come first.

Q: Do you know what is the difference between medical and consumer devices?

A: Medical devices should always pass some tests and go through a certain process to get accepted and certified to be used as a part of the diagnostics process.

Interview 5, Cardiology Specialist, Eastern Finland

Q: Does the unit have new kinds of medical devices to measure patients in use currently? /Heart Association: What kind of devices have you used to track heart rate/arrhythmia?

A: I don't remember the name of the device, but the device needs to be asked from the clinical physiology department. It is a Holter examination where the heart rhythm is tracked for 24 hours and it needs to be carried around by the patient. The device is difficult to use and does not give reliable data as sometimes the sensors do not stick to the skin properly. The EKG sensors might also cause irritation on skin. As it is used only for 24 hours, it might not be enough as sometimes arrhythmias do not appear within 24 hours

Then there is this other device, also borrowed from the department of clinical physiology, the patients get a "box" where they put their fingers if they feel unwell and the box registers. These two I mentioned are the most common ones.

We also take patients in to monitor the ECG at the department. Most of the cases are atrial fibrillation, and also the neurology department can read those results (as atrial fibrillation and stroke are often intertwined, it is important that the neurologist can also read the results gotten from the ECG). It has taken a lot of work to train the neurologists also to read the ECG on a regular basis. We often tend to find the atrial fibrillation on patients that stay in the department – the longer they stay here, the more cases we find.

Then there are multiple devices from different companies that are invasive. Most of these devices are the size of a lighter, and the period for the registering is about 3 years. In these devices it is possible to enter certain algorithms to the device so that it will recognize if the heartbeat is above/below some limit or has longer breaks etc. so that the device will register these cases. These devices are not installed to detect atrial fibrillation, that can be found just as extra sometimes. When using the device and the reference heart rate is met and the device starts to register and the atrial fibrillation happens right at this time, then the device might also catch the atrial fibrillation.

Then also pacemakers: if the pacemaker is installed because of slow heart rate, then it can also detect atrial fibrillation. It recognizes pretty well the rhythm for atrial fibrillation, especially if it is a pacemaker that has an atrial and ventricular cord as

that is the most reliable combination. If it only has ventricular cord, they can detect the change in pace and a starting atrial fibrillation.

Q: What kind of experiences do you have from these devices?

A: The devices that are currently in use are pretty rudimentary if compared to the devices that currently exist in the markets. There are a lot of devices with great technology, but they can't be used in the hospitals or wards because of the strict regulations. It takes a long time to get better devices and it should be easier to detect the rhythm both at home and at the wards. There has been a lot of conversation about the devices in the wards, but people are against especially unregulated devices, also some of the staff are unwilling to use new devices.

If there will be a lot of devices in the markets that can register data, there needs to be a lot of discussions with other doctors as they will have to figure out whether the symptom is real and what it actually is. If the atrial fibrillation appears only a couple of times in a year, there will be no need for changes in medication.

Q: Do you suggest/recommend any devices for patients to use at home? /Heart Association: What kind of devices do you suggest/recommend people to use at home to track their heart rate/arrhythmia?

A: No one has ever asked, so I haven't suggested any.

Q: To whom you recommend the devices?

A: 24 hour long or longer Holter tracking for patients that feel dizzy, lose consciousness, feel arrythmias or if it is hard to detect whether the extra beats are atrial fibrillation or just random extra beats.

EKG long time registering to people that do not feel symptoms that often, so it is hard to detect the symptoms during the 24-hour period. The device is from stone age, and I am disappointed with the device – the technology and all feels like the first mobile phone, so it is outdated.

Q: How is the device given to a patient? (Process to guide the patient)

A: The patient will get the device from the department of clinical physiology; the cardiologists does not give the instructions on how to use it.

Q: Do you take the data from the devices into account when making diagnoses? In which cases?

A: The data from these devices is taken into account when diagnosing the patients. In a long time ECG registering a lot of difficult arrhythmias are found.

Q: Do you trust these kinds of devices?

A: In general, the Holter device is pretty reliable, however in some cases movement artifacts might appear, but it is still reliable.

When using the device for long term registering, it registers when the patient feels unwell, however the patient is in charge of measuring his/hers own heart rate, and the device is a big box that can be put into the backpack so it depends also on the patient.

Q: If a device makes a mistake, who is responsible for the mistake?

A: Doctors are responsible for reading the results and data in a correct way.

Q: Do you think that data protection is considered when the devices process information?

A: Interesting question. How is it possible to pay attention to these things when the devices in use are really antique? Also, it kind of depends how they read the data in the hospitals, it is important to pay attention to data protection there.

Q: Do you know what is the difference between medical and consumer devices?

A: Well at least the consumer devices do not have to battle with regulations.

Interview 6, Nurse at Nokia Health Centre, specialized in wound care

Q: Does the unit have new kinds of medical devices to measure patients in use currently? /Heart Association: What kind of devices have you used to track heart rate/arrhythmia?

A: Yes, we do have some devices in our unit. We have a device that is used for diagnosing sleep apnea, and also a device called Zenicor, which is used for diagnosing arrhythmias. Then we also do some tests here; we do the fast HP test as well as CRP tests in our unit. So I would say this department is pretty aware of medical devices and currently there are a lot of changes happening so in the future we will have even more specialized nurses in this department which also means that we will probably have even more devices that will be used in patient care. However, I am not part of the team that is responsible for the changes so don't know more about that.

The department is also starting a study about a device that is used for wound care, and if that is successful, the department will start using that device. The patients will borrow the device and use it at home.

Q: What kind of experiences do you have from these devices?

A: At my previous jobs I did not use any devices so when I started at Nokia, I needed to learn how to use different kinds of devices. Overall, I feel that the medical devices currently in use are easy to use and useful, however don't really work with Zenicor and others on a daily basis. I think that I have gotten good instructions on how to use them and that patients appreciate Zenicor because it is a small device and easy to take home.

Q: Do you suggest/recommend any devices for patients to use at home? /Heart Association: What kind of devices do you suggest/recommend people to use at home to track their heart rate/arrhythmia?

A: Sometimes yes, but in most of the cases the doctors make decisions whether the devices are used e.g. with arrhythmias.

Q: What kind of criteria do you use when choosing the devices?

A: I know that the final decisions which devices are used are made by the hospital management and that one of the main criteria is that the device needs to be cost efficient and reliable. At my last job I used a vacuum device for wound care and suggested to my superior in here that it would be a great addition to have in this job as well and got the permission to start a trial to try it out. So, I think that in most

cases it is important that someone already has used the device and knows how it works. I wouldn't recommend a device to a patient that I have never used or tried.

Q: To whom you recommend the devices?

A: I do not recommend the devices to everyone as it is important that the device is used in a correct way. I think that patients' age and overall health play an important part as in most cases the elderly people tend to have more issues with devices. Also the financial aspect to consider; no point of loaning out a device to person who doesn't know how to use it or doesn't have the intention to use the device - resources would go to waste. So it is important to consider what kind of patients the devices should be borrowed to.

Q: How is the device given to a patient? (Process to guide the patient)

A: The doctors assess the patients before deciding on if they need a certain device. Then we book an appointment where the device is given to the patient and we also give thorough instructions on how to use the device and when and how to return it. Also, an appointment is booked if the patient needs to hear about results from using a device, e.g. with Zenicor.

Q: Do you trust these kinds of devices?

A: Yes, I do trust these devices, as they have needed to be tested and certificated before use. However, I tend to be a little critical towards new devices.

Q: If a device makes a mistake, who is responsible for the mistake?

A: Difficult question as it depends a lot what kind of mistake is in question, cause at any point a mistake can happen. Depends also when the mistake happens, e.g. a nurse can install the device in a faulty way or give wrong instructions. It can also be that the patient uses the device in a wrong way. I think it depends on a situation who is responsible.

Q: Do you think that data protection is considered when the devices process information?

A: Difficult to say, in some devices we put all the patients personal data into a device which might be a bit of an issue. But the newer devices might not have this issues or it is taken into account?

Q: Do you know what is the difference between medical and consumer devices?

A: I am not entirely sure, but a medical device is a device that is used by nurses and doctors at a hospital setting. Consumer devices consumers can use at home by themselves.

Interview 7, Nurse at Nokia Health Centre

Q: Does the unit have new kinds of medical devices to measure patients in use currently? /Heart Association: What kind of devices have you used to track heart rate/arrhythmia?

A: Yes, we do have some devices, e.g. a device called Zenicor which we have gotten a few lately. Zenicor is used to register the heart rate, EKG. So, if a patient is feeling unwell and has some weird heart feelings, they put their thumbs to the device for about 20 seconds and it registers the heart film from there. The device then sends the registered film to TAYS (University hospital of Tampere) to be analyzed and everytime the patient feels unwell he/she should do it; they have the device for themselves for about 2 weeks. The device is pretty small and easy to carry around, it is about 5-7cm x 15cm and uses batteries.

Every now and then we get some new devices to our unit, e.g. we got 3 devices to measure sleep apnea. In this case also the patient takes the device home and sleeps with the device. Then they bring it back and the data is sent forward to be analyzed ja the device is cleaned for the next patient. We also use a device called ABI which is used for measuring veins to see how blocked they are.

Q: What kind of devices are planned to take into use? /Heart Association: What kind of knowledge do you have of these kinds of devices?

A: I have not heard about any new devices lately that would come to oyr unit. Firms often contact us and if the device is considered to be good, it just arrives at the unit.

Q: What kind of experiences do you have from these devices?

A: Pretty good experiences from using Zenicor, easy to use. Often patients who have issues with their heart are a bit concerned. Patients have liked the device and I think that it is a rewarding device also for the patients to use. For the nurse's perspective it is easy to use and has clear instructions and can be used for many patients. Also, pretty much everyone in the department can use it.

Q: Do you suggest/recommend any devices for patients to use at home? /Heart Association: What kind of devices do you suggest/recommend people to use at home to track their heart rate/arrhythmia?

A: In most of the cases when a patient comes to see a doctor/nurse and tells what is wrong, the physician suggests a suitable device. The final decision for using a device is done by a doctor. Sometimes the patients might suggest a device if they have heard of some good device.

Q: What kind of criteria do you use when choosing the devices?

A: Most commonly new devices are given for us, but in some cases if new devices and models appear, we can also try them out (e.g. ear lamp, they are pretty different actually). Usually when a device is new, we don't have that many options from where to choose but when more versions and models appear then we might get a chance to try them.

Usually people at a higher level decide about the new devices. The fanciest and newest devices come straight from the manufacturer as there are no other options.

Q: To whom you recommend the devices?

A: To patients with heart symptoms and they have to be able to use the device, mostly younger people who are about 40-50 years old can use.

Q: How is the device given to a patient? (Process to guide the patient)

A: The patient comes to see a doctor and the doctor makes the decision which device to use (e.g. Zenicor), then also a consultant nurse often comes to consult. Then the nurse checks when the device is available and books it for the patient and also books an appointment for the patient. During that appointment the patient will get instructions on how to use the device and how to return it. When the device is returned, the data is sent forward to be analyzed. Also, in the beginning the nurse

tells if the patient needs an appointment when the results come and some details about that.

Q: Do you trust these kinds of devices?

A: We don't really have any other option than to trust, so yes.

Q: If a device makes a mistake, who is responsible for the mistake?

A: If I have made a mistake when giving instructions about the device or e.g. given already used batteries, then I consider it to be my fault. But if it is something bigger such as the device just does not work, then the manufacturer should be in charge. Also, when sending out the data forward, something can go wrong. Difficult topic as it is hard to say who is responsible.

Q: Do you think that data protection is considered when the devices process information?

A: In sleep polygraphy we can't put patients name, social security number or birth date into the device, it creates codes for each patient. In Zenicor we put all the patients' information to the device. There could be always someone who could hack the devices which might cause a problem.

Q: Do you know what is the difference between medical and consumer devices?

A: I can't really tell, it might be so that consumers can buy consumer devices from regular stores, I probably have heard what the difference is but don't remember anymore.

Interview 8, Nurse at Nokia Health Centre, Paramedic

Q: Does the unit have new kinds of medical devices to measure patients in use currently? /Heart Association: What kind of devices have you used to track heart rate/arrhythmia?

A: We have some point of care tests in the unit that we can do. For example, in this department we have devices that can do leukocyte, potassium and sodium tests. We

got the devices to the unit during the summer of 2019 and there is also a device that can measure cardiac enzymes from a blood test.

Previously we had a separate laboratory that was in charge of examining the samples. However now that we moved to a different location, the unit got own devices to study the samples. We get the test results now faster but can do only a few different kinds of tests so the variety of tests is also more narrow.

Q: What kind of devices are planned to take into use? /Heart Association: What kind of knowledge do you have of these kinds of devices?

A: I have not heard that any new devices would be acquired in the near future.

I don't really know a lot about the devices. I can use the devices that are used in the unit and to which I have been trained for.

Q: What kind of experiences do you have from these devices?

A: Mostly positive; it makes the job faster and easier and feels also that patients like especially if they get the results back fast.

Q: Do you suggest/recommend any devices for patients to use at home? /Heart Association: What kind of devices do you suggest/recommend people to use at home to track their heart rate/arrhythmia?

A: Measuring the blood pressure I recommend pretty much to everyone besides children. Sometimes I also recommend people to follow the sugar level but in most of the cases the diabetic nurses are in charge of that.

We also get quite a few atrial fibrillation cases and for them I always recommends to feel out the pulse.

Q: What kind of criteria do you use when choosing the devices?

A: I always guide people to go and buy the medical device (e.g. blood pressure meter) from a reliable source (pharmacy). I don't recommend to buy them from regular stores, e.g. grocery stores or such.

Q: To whom you recommend the devices?

A: I recommend the devices (in this case blood pressure meter) for patients with hypertension, or to someone who has been feeling overall unwell.

We do not borrow the devices for the patients, used to do that but a lot of devices went missing.

Q: If a device makes a mistake, who is responsible for the mistake?

A: I would first check if the mistake in question happened due to my own behavior (e.g. would do a test again etc.). If the device would still claim a mistake has happened or would give an error code, then would probably try to contact the manufacturer.

Q: Do you think that data protection is considered when the devices process information?

A: I think that in most cases yes, data protection is considered. However, the beginning of social security number is needed in some cases but it is hard to identify people based on that.

Q: Do you know what is the difference between medical and consumer devices?

A: I think that a medical device needs to be approved by FIMEA and that they are always CE certified. Consumer devices are not regulated and are sold at regular stores for consumers.

Interview 9, Nurse at Nokia Health Centre

Q: Does the unit have new kinds of medical devices to measure patients in use currently? /Heart Association: What kind of devices have you used to track heart rate/arrhythmia?

A: Some devices in use in the department; e.g. fast crp, hematocrit, blood pressure meters, saturation devices and definitia monitors.

Q: What kind of devices are planned to take into use? /Heart Association: What kind of knowledge do you have of these kinds of devices?

A: I have suggested if it would be possible to order drop counters, however supervisors are in charge of the purchase decisions. I don't yet know from where the devices would be bought because I have only applied the permission from the budget to buy one.

Overall, I don't really have that much experience about devices, maybe new devices are used more in private hospitals and health centres.

Q: What kind of experiences do you have from these devices?

A: Overall ok experiences of different devices, sometimes some issues with their usage or they do not work. Also, some people are not able to use them correctly (both nurses and/or patients). The bigger issue however is that when a device does not work and needs to be sent out to be repaired which takes time. Not a big issue but happens every now and then.

Q: Do you suggest/recommend any devices for patients to use at home? /Heart Association: What kind of devices do you suggest/recommend people to use at home to track their heart rate/arrhythmia?

A: I recommend the devices to patients that would benefit from them, e.g. the sleep polygraphy device is given to patient to home to borrow overnight. Zenicor given to a patient for two weeks at a time. The specialized diabetic nurses recommend devices to diabetics also.

Q: What kind of criteria do you use when choosing the devices?

A: The decisions about the devices that are acquired are made based on need and price, in most of the cases if the treatment is faster and more efficient with a new device, we might buy that. Every now and then some tasks are transferred from special medical care units to basic medical centers so they can save resources in special units. Money plays a big role in these decisions.

Q: To whom you recommend the devices?

A: The recommended devices are decided based on the patient's needs.

Q: Do you trust these kinds of devices?

A: I trust the devices if they are properly calibrated and taken care of.

Q: If a device makes a mistake, who is responsible for the mistake?

A: Hard to say, the device needs to be calibrated and maintained, I think that the manufacturer is responsible for the mistake. Also, important that the person using the device understands how it works and the instructions.

Q: Do you think that data protection is considered when the devices process information?

A: In sleep polygraphy devices and Zenicor they need to insert their credentials multiple times, so the data is relatively well protected and hard to access. I think that data protection is considered in these devices.

Q: Do you know what is the difference between medical and consumer devices?

A: Valvira and FIMEA regulate medical devices and they need to be CE certified. Consumer devices can be bought anywhere e.g. Lidl and the buyer can be a regular consumer.