How are users applying smartphone apps for remote monitoring and self-management of diabetes in Denmark?

- A study of users' perceptions and preferences of apps for diabetes to examine whether apps can enhance adherence to remote monitoring and self-management of diabetes, hence behavior change.

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Foreword

This master project is prepared by me, Rejane Pires De Pádua Nielsen, student of the education 'Master of Information Technology in Health Informatics, at Aalborg University. The overall frame for the project is, according to the curriculum, 'Health Informatics in a design and/or implementation perspective'. My project deals with the opportunities and challenges of the smartphone app technology as a potential tool to enhance adherence to remote monitoring and self-management of diabetes.

I would like to thank my family for their patience during a tough and long journey, when I have had no time them. I faced a lot of challenges with my project which meant that I lost half a year that I could have worked quietly towards the goal. I had to start all over again with the project work with a lot of time spent on concentrated literature search and review in February and March months. After that, I started to write first in the end of March until the very beginning of June to the last day before the deadline to deliver the project.

I would also like to thank people that answered the survey on facebook; the endocrinologist from the Danish Endocrinologist Association who answered the interview; the consultant in MedCom who have been very patient in his response to an e-mail interview about some clarifications on the 'Common Chronic Data Set', and my advisor for his valuable input to this project.

Finally, I thank my employer, especially my manager, who made it possible for me to take this challenge.

Abstract

Mål: Målet for denne projekt var at se på, hvordan brugerne i Danmark opfatter smartphone app-teknologien, deres præferencer med hensyn til funktioner og værktøjer for hjemmemonitorering og egenomsorg af diabetes kontrol, hvorvidt teknologien kan øge overholdelse af hjemmemonitorering af diabetes og fremme adfærdsændring for at forbedre livsstil. Jeg kiggede også på de sundhedsprofessionelles mening om teknologien.

Metoder: De empirik data var sammensat af et spørgeskema og en skriftlig struktureret interview. I spørgeskemaet og i interviewet, blev respondenterne præsenteret med spørgsmål vedrørende funktioner og værktøjer i teknologien, spørgsmål relateret til forholdet mellem patient og sundhedsprofessionelle, etiske, juridiske - herunder sikkerhedsspørgsmål, og organisatoriske spørgsmål.

Resultater: De fleste af de adspurgte i spørgeskemaet er positive over teknologien, de udtrykker ønske om at engagere deres læger i deres diabetes kontrol i en kombination af digital og personlig kontakt, de er tilfredse med nogle af de funktioner og værktøjer af teknologien og utilfredse med andre. De føler sig motiveret til at ændre deres livsstil med deres læge engagement og de mener, at teknologien kan bidrage til dette. Den interviewede sundhesprofessionels mening er i overensstemmelse med brugernes forventninger.

Konklusion: Det er blevet bevist, at teknologien kan øge overholdelse af monitorering og egenomsorg af diabetes, på betingelse af, at etiske, juridiske, organisatoriske og tekniske aspekter er på plads for at teknologien kan betragtes som stabilt. Der kan dog stadig være mange forskellige opfattelser af teknologi blandt de mange forskellige aktører i sundhedssektoren.

Nøgleord: smartphone app teknologi, kontekst-afhængig, ubiquity, pervasive computing, hjemmemonitorering, egenomsorg, diabetesbehandling.

Reader's guide

The central topic of this research is the smartphone app technology for remote monitoring and self-management of diabetes.

Chapter 2, 3	Introduces the context of the problem with topics that are relevant for evaluation of the smartphone app technology for diabetes care.
Chapter 4	Possibilities of the technology as a new interventional method.
Chapter 5	The challenges that the technology brings to ethics, legal, healthcare organizations, and the technical challenges of the technology.
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Definition of terms

Besides the below, other terms are explained in the text of this research.

Wi-Fi
WI-Fi is a popular technology that allows an electronic device to exchange data wirelessly (using radio waves) over a computer network, including high-speed Internet connections
Wikipedia: http://en.wikipedia.org/wiki/Wi-Fi (accessed 20-may-2013)

Apps
The term is an abbreviation for "application" in the IT community and became popular for mobile applications in smartphones and tablets. Application software is all the computer software that causes a computer to perform useful tasks (compare with Computer viruses) beyond the running of the computer itself. A specific instance of such software is called a software application, application or app. The term is used to contrast such software with system software, which manages and integrates a computer's capabilities but does not directly perform tasks that benefit the user. The system software serves the application, which in turn serves the user.
http://en.wikipedia.org/wiki/Application_software
(accessed 02-june-2013)

NFC
Near field communication, abbreviated as NFC, is a form of contactless communication between devices like smartphones or tablets. Contactless communication allows a user to wave the smartphone over a NFC compatible device to send information without needing to touch the devices together or go through multiple steps setting up a connection. NFC can be used to payments via credit cards. http://www.nearfieldcommunication.org/how-it-works.html (accessed 2-june-2013)

Ethernet
It is a family of computer networking technologies for local area networks (LANs). Since then Ethernet technology has evolved to meet new bandwidth and market requirements. In addition to computers, Ethernet is now used to interconnect appliances and other personal devices.
http://en.wikipedia.org/wiki/Ethernet#cite_note-27 (accessed 02-june-2013)

Smartphone and Operating Systems
A smartphone is a mobile phone built on a mobile operating system, with more advanced computing capability and connectivity than a feature phone (mobile phone). iOS (previously iPhone OS) is a mobile operating system developed and distributed by Apple Inc. The mobile operating systems (OS) used by modern smartphones include Google's Android, Apple's iOS, Nokia's Symbian, RIM's BlackBerry OS, Samsung's Bada, Microsoft's Windows Phone, Hewlett-Packard's webOS, and embedded Linux . Such operating systems can be installed on many different phone models, and typically each device can receive multiple OS software updates over its lifetime.
http://en.wikipedia.org/wiki/Smartphone (accessed 02-june-2013)

Mobile phone (cellular)
A mobile phone is a device that can make and receive telephone calls over a radio link while moving around a wide geographic area. It does so by connecting to a cellular network provided by a mobile phone operator, allowing access to the public telephone network.
http://en.wikipedia.org/wiki/Mobile_phone (accessed 02-june-2013)

GPS
The Global Positioning System (GPS) is a space-based satellite navigation system that provides location and time information in all weather conditions, anywhere on or near the Earth where there is an unobstructed line of sight to four or more GPS satellites.
http://en.wikipedia.org/wiki/GPS (accessed 02-june-2013)

Bluetooth
Bluetooth is a wireless technology standard for exchanging data over short distances (using short-wavelength radio transmissions in the ISM band from 2400–2480 MHz) from fixed and mobile devices, creating personal area networks (PANs) with high levels of security.
http://en.wikipedia.org/wiki/Bluetooth (accessed 02-june-2013)

Welfare technology
Concept welfare technology is an umbrella concept that covers more than one technological solution and intelligent systems. Welfare technologies are also services enabled by technology that are economic saving and helps to improve the quality people. DS – Dansk Standard:
http://www.ds.dk/da/standardisering/fagomraader/velfaerdsteknologi/hvad-er-velfaerdsteknologi (accessed 30-may-2013)

IT & Telestyrelsen
National IT and Telecom Agency. It worked to increase IT security and to promote citizens' use of IT and to support the development of Danish telecommunications industry and to ensure public communication and information. The current government closed the agency in October 2011 and its operations were divided between the Business and Growth Ministry of Defence, the Ministry of Finance and Economy and the Ministry of Interior.
http://www.denstoredanske.dk/Samfund%2c_jura_og_politik/ (accessed 01-june-2013)

Mobile interventions
I did not find a specific definition for the term, though in the literature review, many authors use the term to express the use of technology such as mobile phones in clinical studies or programmes. See also m-Health.

Telehealth
KL's definition of telehealth: "*Telehealth is the use of information and communication technologies to support preventive, treatment or rehabilitation activities over distance*." (1)

m-Health, e-Health
m-Health (also written as m-health or mobile health) is a term used for the practice of medicine and public health, supported by mobile devices. The term is most commonly used in reference to using mobile communication devices, such as mobile phones, tablet computers and PDAs, for health services and information, but also to affect emotional states. The mHealth field has emerged as a sub-segment of eHealth, the use of information and communication technology (ICT), such as computers, mobile phones, communications satellite, patient monitors, etc., for health services and information. mHealth applications include the use of mobile devices in collecting community and clinical health data, delivery of healthcare information to practitioners, researchers, and patients, real-time monitoring of patient vital signs, and direct provision of care (via mobile telemedicine).
http://en.wikipedia.org/wiki/MHealth (accessed 30-april-2013)

HCP
Health care professional (HCP) are persons who have special education on health care and who are directly related to provision of health care services, such as physicians (general practitioners and specialists), nurses, therapists, technicians, emergency medical service personnel, dental personnel, among others. In this research, i refer to HCPs as the general class of health workers, but mainly doctors and nurses, depending of the situation.
http://definitions.uslegal.com/h/health-care-personnel-hcp/ (accessed 29-june-2013)

Division of labour in healthcare sector in Denmark
It is the politicians, national, regional and municipal, which sets the framework for health and how it should be developed. The regions are responsible for the operation of hospitals and through agreements and contracts with general practice. The municipalities are responsible for preventative and better public health services, and it is the National Board of Health that provides the scientific framework for health work in Denmark.
http://www.sst.dk/Om%20styrelsen/Maal_og_opgaver.aspx (accessed 28-mar-2013)

1. Introduction

1.1 Reason for choice of topic

I decided to choose the topic 'smartphone apps for diabetes' because I am interested in understand the app phenomenon combined with the global pandemic of diabetes and its consequences for users and healthcare sector.

I made a literature review in order to get insights to potential topics for this research. The review revealed that, to date, it is still unknown what users are applying their apps for and what their perceptions and preferences are.

I wondered how users in Denmark are applying their apps, how they perceive the medical apps available on the market and whether and how they are using apps in conjunction to monitoring and management of diabetes.

In the overall, I am interested in understand the possibilities and challenges that the smartphone app technology brings to users and healthcare in Denmark.

2. Delimitation of the problem

The app technology is a phenomenon itself, though there is a need to know which topics can be relevant to define of the context of the problem and its analysis. I made a literature review in order to learn about relevant topics related to the smartphone app technology.

On the basis of the findings in the literature review, I establish the context of the problem in terms of possibilities and challenges with description of the topics that are dominant in the area: ethics, legal, healthcare organizations and the smartphone app technology. These are the aspects I will focus on in this research.

The literature review findings serve as evidence of what is already known and what is unknown about the topic, which gives me the basis to explore the aspects around the technology and attempt to explain my own findings to support the research question.

In order to get better understand about some processes in the Danish healthcare, I interviewed a consultant from MedCom about an ongoing project on the 'Common Chronic Data Set'. I will refer to this interview later.

3. Context of the problem

3.1 Chronic illness

The world is facing an increasing number of people with chronic illness. This poses enormous socio-economic challenges for the healthcare sector in many countries. Chronic illness has been the cause of death in recent years; there were 36 million deaths globally in 2008. This number will continue to increase globally by 15% between 2010 and 2020, according to the World Health Organization (WHO).(2,3)

According to a report by the Organization for Economic Cooperation and Development (OECD), chronic illnesses – also called non-communicable diseases, are diabetes, cancer, cardiovascular disease, osteoporosis, musculoskeletal disorders, asthma and allergies, Chronic Obstructive Pulmonary Disease (COPD), and mental disorders.(4)

Tobacco, food habits and lack of physical exercise can lead to obesity, which is considered a lifestyle disease that increases the risk of death, according to OECD.(4) Ageing has a direct impact on chronic illness. In Europe, the increasing number of elderly people has raised concerning about chronic illness and the impact caused on the healthcare sector and economy of a society. Though ageing is not alone the cause of chronic disorders; lifestyle can lead both the young and the elderly to chronic illness. Chronic illness due to lifestyle can lead to, among others, hypertension, cardiovascular disease and diabetes.

Though the older the population, the bigger are the chances for a high number of chronic ill people, which in turn will require more healthcare resources. As a consequence, few will be the number of people to contribute to productivity in society. This is a point of disequilibrium that requires new technological solutions to cope with the increasing demand of resources, both human and economic, posed to the healthcare sector worldwide.

In Denmark it is estimated that up to 1.8 million of the population are chronic ill, according to KMD.(5) The number of people over 65 will increase from 16% to 25% by 2040, according to predictions by Danmark Statistik.(6) Chronic ill patients require a lot of health resources; their disease condition is prolonged and requires treatment, monitoring, and coordination among healthcare professionals.

3.2 Diabetes

Diabetes is among the chronic illness that can lead to death. OECD reports show that type 2 diabetes is increasingly in development worldwide and will explode by 2030.(4,7) It is well known that tobacco smoking, physical inactivity, and mainly obesity are factors that increases the chance of being diagnosed with type 2 diabetes and therefore, the risk of death.

Predictions by the International Diabetes Federation (IDF) show that the number of adults with diabetes is expected to rise from 285 million (2010) to 439 million by 2030 globally.(8) Type 2 diabetes (T2D) is a typical lifestyle disease which brings many sequels. These sequels are complications that can affect heart, blood vessels, nerves, eyes, and kidney.

In Denmark, the Diabetes Association reports that, to date, about 306,638 of the population are diagnosed with diabetes, which means that the number has doubled in the last 10 years. Type 2 diabetes represents 80% of the diagnosed population. 200,000 people do not know they have diabetes, and in 2025 the number of diabetics can reach up to 600,000. This estimate does not include the more than 200,000 people currently undiagnosed.(9)

Expenses with diabetes cost the Danish government 86 million Danish crowns daily. It is also estimated that, about 750,000 of the population have "pre-diabetes" (precursors to type 2-diabetes).(9) Diabetes (both type 1 and 2) control relies on constant monitoring of blood glucose and improvement of quality of life; i.e. medication, food and physical activity.

3.3 Pressure on new intervention methods

The increasing development of chronic disorders, and mainly type 2 Diabetes, demands huge efforts from the healthcare sector and puts a great pressure on society. As the healthcare sector cannot afford not to empower users and patients, telemedicine solutions can be the best approaches. Later in section 'empowerment' I will explain and discuss the term.

In order to respond to this pressure, healthcare authorities must be able to offer new intervention methods. The situation requires sustainable solutions that both reduce the financial pressure on public resources, facilitates workflows across the healthcare sector, and benefit patients with effective prevention and treatment methods.

4. Possibilities

4.1 Welfare technologies

Telemedicine as an intervention method

In the draft outline of the National Strategy for Telemedicine, the National Board of Health (Sundhedsstyrelsen) recommended a patient-centered healthcare; i.e. an alignment of task distribution, communication and collaboration between municipalities and regions, including general practice and hospitals. The draft outline points to these three actors (municipality, region, and general practice) as the overall responsible for the patient's trajectory in healthcare. (10)

What is then telemedicine? There are different definitions of the term 'telemedicine'. MedCom define it as:

> *"Telemedicin omhandler de situationer, hvor en sundhedsydelse kan leveres over større eller mindre afstande ved hjælp af informations- og kommunikationsteknologi, herunder til understøttelse af diagnosticering, behandling, forebyggelse, forskning og uddannelse. Hjemmemonitorering dækker over de løsninger, hvor den telemedicinske ydelse leveres til patientens eget hjem."* (MedCom, 2011) (11)

MedCom is a cooperative work between health authorities, public organizations and private companies connected to the Danish healthcare sector. MedCom stands for the development and testing, deployment and quality assurance of electronic communication and information in the healthcare sector with a view to supporting the patient care.

The central point in the National Strategy for Telemedicine is to bring coherence to the patient trajectory within the healthcare sector. A coherent patient-centered process places great demands on cooperation, division of work between the involved actors, and requires interdisciplinary problem solving among the involved actors (municipality,

hospitals, and general practice) in order to succeed.

This new form of organization involves a risk of loss of information, clarity, and continuity, thus quality, as it has been the responsibility of the general practitioner (GP) to be the point of access to healthcare in Denmark.

In the latest 10 years, telemedicine became a focus area in Denmark and many pilot projects were initiated and successful intervention methods were deployed or are about to be implemented; for instance: video consultations, home monitoring, online social networks of patients, virtual training, the chronic journal, baby suitcases to maternal parents, monitoring of diabetic foot ulcers and ethical guidelines for health technology, among many others. All projects within telemedicine can be seen at patient@home.(12)

Patient home is the Danish largest organisation working on welfare technological research and innovation projects with focus on new technologies for rehabilitation and monitoring of the Danish Public health. The organisation is based on interdisciplinary cooperation between public and private sectors and involves professionals, patients, companies and research institutions.

A survey by KMD shows that more than 50% of the chronic ill population in Denmark is ready to new technologies. The survey results show also that chronic ill people are willing to use telemedicine to control their disease; they believe that technology will reduce their visits to the doctor, and they expect technological solutions from the healthcare sector.(5)

The introduction of technology makes great demands on communication between patient and healthcare professionals (HCPs), but not least, the healthcare sector as a whole. On one hand, there is a need to include patients. These are now taking a central role in the healthcare scenario. On the other hand, new technology implies that chronically ill patients are expected to take their own responsibility (empowerment) to monitor their disease. That can be achieved by use of technologies.

The pandemic of diabetes is a great opportunity for new technologies to deliver tools to remote monitoring and self-management of diabetes through mobile interventions.

Many studies have showed positive results of mobile interventions with significant potential to improvements in diabetes care.(13-20) These interventions can either be through mobile cell phones, smartphones, Internet, web-based programs, among others, but all showing chances of mobile interventions to address symptoms and behaviour change that can lead to better adherence to treatment and control of chronic illness such as diabetes.

The Municipalities' Association Telehealth Strategy

In Denmark, the Municipalities' Association (Kommunernes Landsforening – KL) made public in April 2013 a proposal for better use of emerging technologies; the Telehealth Strategy. This initiative is not only for the municipalities' services, but it is intended to involve other healthcare professionals (hospitals and general practitioners), where there is a need for cooperation and coordination in the patient care. This can be good news for the smartphone app technology.(1)

The strategy is based on a paradigm shift from focusing on the citizens' health rather on their illnesses. The overall goals of the telehealth strategy are intended to enable the citizen to continue to live their daily lives with the disease and disability, provide independence (mobility), trust, security and support prevention, treatment and rehabilitation of citizens in and around their home.((1) p.3)

According to KL, emerging technologies such as video conferencing and smart devices can support all types of services provided by the municipalities. KL's telehealth strategy is inspired by telemedicine projects, such as: virtual acute place in Horsens; KOL project 'Telecare Nord' in Aalborg, where 11 municipalities are participating; Lyngby-Taarbæk's project 'Epitalet' to patients that come home after hospitalization, a project between Copenhagen Municipality and Copenhagen University on a 3D rehabilitation platform, Skype project – an IT-based cognitive behaviour therapy via PC with touch screen and embedded features as TV, radio and news. (1) p.13-15)

In addition, it is also based on previous and current projects on apps, at international and national level, such as 'Apps for Healthy Kids' in USA, apps to angst treatment (ADHD) in Sweden, and in Denmark the Social Agency (Socialstyrelsen) is driving a pilot on apps to children and young people with autism and ADHD. ((1) p.11-13)

One of the conditions for the technology to be implemented is to reach as many people as possible and that it is user-friendly. Smart devices and apps can be an easy way to approach implementation, because in the telehealth strategy, technologies must be built into solutions in the citizens' already existent IT devices (e.g. smartphones and tablets). The technology becomes an extension of people's own IT habits, i.e. context-sensitivity. This forces suppliers to develop solutions on already standardized products. One of the advantages of using the citizens' existent IT devices is a significant reduction of costs for the municipalities. ((1) p.5)

One of the visions of the strategy is to benefit the municipalities' employees with the comprehension that telehealth provides a more coherent healthsector, an easier access to specialized healthcare skills and that it will bring new skills for the employees as they will work with technology in cooperation with other healthcare professionals. ((1) p.4)

4.2 Applications (apps) for smartphone

Within the field of telemedicine solutions, the advent of smart devices, such as smartphones, along with applications (apps), the health scenario has changed dramatically and quickly. New concepts have emerged or became more evident, just to mention a few: mHealth, e-Health, telehealth, health apps, medical apps, participatory healthcare, and Consumer Health Informatics (CHI) are key words within the domain of Information Communication Technology (ICT) and healthcare.

As showed in scientifical literature, the smartphone app technology has the great potential to explore the healthcare sector. A few other studies show that smartphone apps can deliver effective tools for monitoring, education, guidance and interaction between patient and Healthcare Professionals (HCP).(15,21-26)

Smartphone apps allow us real time data information for monitoring and management of our health condition or disease at any time, everywhere. Since the first app came to the market, more and more consumers are downloading apps. By the time I started this research project, 40 billion apps were downloaded in half 2012, excluding re-download and updates. To date, according to current report from App Store Library; the actual number is now 50 billion apps.(27,28) It seems that healthcare is going mobile.

Smartphone app technology can change healthcare deliverables. Smartphone health apps are considered as promising tools to evidence-based healthcare in the future, as indicated in literature review. They can deliver real time, context-based interventions through features and tools that can enhance change behaviour. In a study of 146 publications, it has been proved the value of technology applications in the improvement of health outcomes and that technology helps to diminish the social disparities within healthcare.(20) Social disparity is connected to income and access to technology, but also about reaching those that never or rarely go to the doctor.

Context-sensitivity

Today, there are thousands of smartphone apps to monitoring and self-management of diabetes that work in real time access to information. One can check his/her health status on the go; i.e. everywhere, at any time. This is the context-sensitivity that enables decisions in the moment they are needed, according to the user's age, work and social life, culture, and geographic placement. The technology can contribute to healthcare by reaching patients that do not adhere to the disease management and control and those that are under the risk of developing the disease.

The smartphone app technology reflects the users' and patients' lives in terms of their own context. It can empower them with features and tools to remote monitoring and self-management of health condition or disease according to their daily life.

Features

The features are, among others, chat via short message service (SMS), e-mail connectivity, social networking, Wi-Fi (transmission of data wirelessly) connectivity with which allows transfer content, use of maps and navigation to search location (GPS), to edit and send documents, video and photo camera, and the ability of the technology to engage other devices (apps and smartphones) or even other systems.(29)

Tools

As in Dennison et al (30), tools can be understood the ways features can be used and combined to promote changes in disease control. The smartphone features provide tools that can motivate behavior change which can be:

Goal setting and feedback: physical activities and weight-loss which can be done through advice, games, tips and information, HCP's feedback by message (SMS) or by e-mail.
Reminders: to take medication, to measure BG, to food intake, to make physical exercise, for coaching and educational programs such as self-management programs (SMS), patient-HCP involvement.
Context-sensitivity: to show where you are, to trigger an alert to family members or friends showing your location, to enable to take measures where you are; i.e. at work, at home, anywhere and when it is needed.
Social networking: to show your progress and share it with a group, to discuss any topics about the disease, to share experiences and feelings about the disease, about a technology or a product, to share everyday life events at social network groups on facebook or on educational websites.

Despite the great possibilities and opportunities showed in scientifical literature, national and international reported experiences, and the Danish initiative of implementing smartphone apps in the municipalities, there are still many challenges to overcome, such as ethics, legal and organizational issues. Many questions on how the smartphone app technology interventions will impact users and healthcare sector are still unanswered.

5. Challenges

5.1 Ethics

Smartphone apps give users and patients new possibilities of involving in their self-management of health condition or diabetes beyond the conventional clinical setting boundaries that we are used to. The smartphone app technology provides real time information; i.e. the possibility of taking action when and where it is needed, in the context of the patient in opposition of being at the doctor's office.

While users or patients are expecting more from the healthcare sector – as showed in the KMD report, users in Denmark are expecting more mobility(5), healthcare authorities expect users and patients to take the responsibility of their own health condition and control of disease. In this sense, we are expected to be empowered. What are then the ethical dilemmas that app technology can bring to the healthcare scenario?

Ethics is about obligations and rules in a society. These can be either written or unwritten, whereas ethical dilemmas are characterized by norms and values of each individual; i.e. the right and wrong, the good and bad in relation to ours and others' values. Birkler mentions the following in *Etik i Sundhedsvæsenet* about ethical dilemmas:

"The ethical dilemma – The difficult conflict of values at which a single choice must be done between several alternative courses of action. An election whose outcome will have consequences for other people." (Birkler, 2011, p. 21)

The ethical dilemmas that new technologies can bring to the healthcare scenario are, among others, those related to the patients' autonomy versus the HCPs' paternalism. This can interfere in the relationship patient-HCP and impact the choice of treatment or control of the disease. It characterizes an ethical dilemma because users are downloading health apps and, probably, making their own decisions according to their context and preferences to monitoring and self-management of diabetes, in opposition to the paternalistic view of HCPs in relation to what they consider the best choice for the patient.

Autonomy and paternalism are concepts related to ethics. Autonomy is the right to make own decisions, whereas paternalism has three dimensions: HCPs take over patient's autonomy, HCPs handle against the patient's wish, or patient and HCP share the responsibility of the decisions.

For instance, if a patient, conscious of his actions, takes his blood glucose measurements and transfers them through a smartphone app. The app suggests the insulin dosing to be taken. This handling was entirely done without the HCP's advice, i.e. autonomy. In the conventional clinical setting, HCPs advise their patients on how to measure and take medication accordingly, based on the medical history of their patients and on the HCP's knowledge. This decision is characterized as paternalistic and can be of one of the forms described above.

One danger of running into ethical issues with implementation of smart devices and apps in healthcare is the patient's perception of feeling isolated if no personal contact with any HCP.(1) (p. 20). Other ethical aspect that emerges from the smartphone app technology is the involvement of pharmaceutical industries on the app market. There can be discussions on whether apps developed by pharmaceutical industries constitute ethical issues due to conflict of interest, as these kinds of apps could only be focusing on marketing interests. An app from a pharmaceutical industry could have being designed and market to be used only with its own products.(31)

5.1.2 Empowerment

Telemedicine opens new opportunities to engage and involve patients in their own treatment and monitoring of disease. In general, 'empowerment' means a shift in the patient role from passive to active in order to obtain a greater insight to his own health condition or disease and take responsibility of his life towards a better quality of life. Empowerment involves ethical dilemmas in the patient-HCP relationship.

There are many discussions about the definition of patient empowerment. Patients are heterogeneous as people and in their health condition. HCPs may attribute different meanings to the term 'empowerment'. With the advent of new technologies, new concepts have emerged and with them new ways of looking at patients and empowerment.

Birkler and Dahl come up with the concept "the digital patient" (32) as a reflection of the effect that the digital media has on everyday life. In the book, a patient can also be expressed as a citizen or a client. The digital patient is an expression which shows that as citizens and patients, we all leave digital traces in our contact with healthcare, which in turn will be converted into digital systems.

Data on the digital patient could emerge in different places at the same time, even if the patient is dead, as well as the patient could be at many places or nowhere at the same time, considering that the patient's identity in the digital environment is related to the connection with one or several computers through the Internet.

Birkler and Dahl explain how a citizen becomes a digital patient and how it is expressed. In my interpretation, the transition between being a citizen to being a patient is

determined by the moment that patient information and communication is registered into healthcare systems, such as Electronic Health Records (EHR) or in the GP's IT system. Considering that the smartphone app technology does not synchronize with any healthcare systems in Denmark, there is no digital patient in this sense.

Looking at the digitalising of patient information, it is important to point to another concept that has become very popular: "participatory healthcare". This means that users and patients have become more active in relation to managing their health condition or disease by accessing health information on the Internet, making decisions based on the information obtained or in conjunction with their doctors, discussing the disease in social networks of patients, downloading medical apps, and in many other ways. Therefore, they are practicing participatory healthcare.

How patient empowerment takes place between the digital patient and participatory healthcare? Will patient empowerment be seen from patients' perspective or limited to organizational, clinical and economic factors?

The last concept can help to understand and maybe cover the gap expressed in the questions above. This is the "the digital health continuum", developed by Boye.(33)

According to Boye, the citizen has the possibility to be a "co-producer" of health, which results in a strongly empowered patient in what he calls the Co-production of health (Cph). Cph is a service model that addresses the point of access to information from the individual level as a citizen to the patient level, as showed in the table below.

Lifestyle	Prevention Ambient Assisted Living	Chronic Disease Management	Telemedicine	Hospital
100% Citizen ⟷ **100% Patient**				

Table 1: The digital health continuum
Adapt from: The digital health continuum. Boye, N. Co-production of Health Enabled by Next Generation Personal Health Systems. IOS Press. 2012

The model proposes a way of organizing health data that would run parallel to the conventional provider-centered model. Cph focuses on personalised, context-aware communication and smartphone is one of the devices that could allow users to access data. The Electronic Health Record (EHR) would be the central point of access, which in turn would filter information to the Personal Healthcare Record (PHR). Citizens and patients will be empowered with the *responsibility* of their health as owners of the disease and with the *response ability* for living with this health condition.

The fundamental idea of the Cph is the knowledge transfer based on data collected from the citizen to the provider-centered model (the conventional healthcare model) and from the provider back to citizens or patients, given that clinical data is filtered and then made appropriate to individual level of understanding. A barrier that could limit the Cph implementation is the need of advanced computer modelling systems.

Taking the HCPs into the empowerment scenario and seeing it from the patients' perspective, not all HCPs seem to be ready to work in cooperation with them.(34) Two studies on patient empowerment in diabetes with focus on HCPs experiences show that HCPs are still struggling with the term 'empowerment' and with what extent their practice is in consistency with empowerment principles. The main barriers found in these studies are related to the level of autonomy patients may have in making own choices, lack of resources (tools and techniques) and time to HCPs train themselves in empowerment, and difficulties in implementing empowerment in the daily clinical practice.(35,36)

These findings go hand in hand with the fact that more and more users and patients are prone to empower themselves with use of technology. Users and patients seem to be practicing participatory healthcare by looking for information on the Internet, discussing their health condition and disease in social networks of patients and by using new technologies such as apps to own control and monitoring of disease. In this sense, the app technology can be both a possibility to users and patients, but an extra barrier for HCPs to train themselves in empowerment and thereafter empower their patients.

5.2 Legal

Legal issues are one of the biggest barriers for emerging technologies. The more consumers are downloading smartphone apps to own monitoring and control of health condition and disease control, the bigger is the need for regulation. Transmission of information from one device to another can involve breach of confidentiality.

Besides smartphone, there are lots of smart devices available on the market and many of these are becoming trendy among consumers. As an example, wearable wireless devices which are gadgets to health monitoring to be used in clothes or worn on the body. These 'wearables' are embedded with apps that can turn to diagnostic devices. Just to name a few: an electrocardiogram monitor (Heart-EKG) and AliveCor heart monitoring, and iBGStar.(37)

iBGStar is a glucometer that integrates with the iPhone via a sensor. It is about to be approved by the Food and Drug Application (FDA) in the US, as well as the device is the only one until now approved to use in Europe.(21) iBGStar is developed by the pharmaceutical industry Sanofi.

There is a need for definition of smart devices (smartphones and wearable wireless devices such as sensors) that can be risky for privacy and security of information. Safety and security emerge as central topics with the use of new technologies in healthcare. In this respect, it calls for guidelines and regulation, certification, and peer review by health professionals. Innovation occurs much faster and regulation does not seem to follow it on the same way. Despite safety and security risks, some experts mean that too much regulation can undermine innovation.(31)

5.2.1 Safety - Human factors

Smartphone apps are being target to consumers; i.e. laypeople. There are still thousands of apps available on the market without any safety evaluation.(31)

As mentioned previously, many articles have showed positive outcomes of mobile interventions, though many of the same articles and other studies also address questions regarding lack of clinical documentation, moderate or limited evidence of effects, adherence to diabetes control, and the impact of smartphone apps in diabetes

interventions. It is important to stress that the discussions depend on the type and purpose of the studies, for instance, if interventional or non-interventional, systematic review, etc.(18,22,24,38)

Most of the findings reported in these studies are either directly related to indicators of effects of diabetes control, for instance, blood glucose control, adherence to medicine, physical activity, or to the outcomes of the design of apps interventions such as text messaging, alerts, though all impact safety and security with the use of technology.

Smartphone apps that provide the possibility of user input that in turn generates medication dosing or even a diagnosis can be dangerous, unethical and illegal. Who is legally responsible if an individual's handling leads to death? Consumers are downloading apps without any guidance, without knowing whether the app is safe and whether and how it can harm or even worse their health condition.

Safety and quality could enhance the development of evidence-based medical apps, but still very little is known about which danger medical apps can expose users and patients to. The lack of involvement of medical professionals in design and development of medical apps is another issue. Once there is no proof of reliability and accuracy, the consequences for the safety of users and patients remains unknown.(19,31,39)

Today, anyone can download medical apps that can be used to support diagnosis and management of diseases; i.e. apps that allow manual user input that generates a diagnosis of a disease or a health condition, for instance apps that track pregnancy, monitor mood, wellbeing, and sleep habits. Some websites provide medical professionals comments on medical apps, though it is not a replacement for assessment of any potential danger. These comments are more based in usability, design and control of content than safety assessment of apps.(31)

Lack of guidance and educational tools about the use of the apps can lead to unsafe and inappropriate use, resulting in unreliable outcomes. Any apps that allow user input can generate results that are prone to error, as humans are prone to errors.(40)

5.2.2 Security

Privacy and security are the main challenges to keep and ensure any health or personal information. Transmission of data through technologies such as smartphone app might need to be encrypted and authenticated. This is a main concern with smartphones. They enable other smart devices and apps to collect, store and track large amounts of data either for the developer to improvement of the technology or for further processing, which can be unknown. This is due to cloud computing.

Hurwitz defines 'cloud' (p.33) as follows:

> *"The **cloud** itself is a set of hardware, networks, storage, services, and interfaces that enable the delivery of computing as a service. Cloud services include the delivery of software, infrastructure, and storage over the Internet (either as separate components or a complete platform) based on the demand."*

The '*cloud computing'* enables connection to several network interfaces such as Bluetooth, Wi-Fi, NFC, and Ethernet.(41,42) This is called 'ubiquitous and pervasive computing' and it makes possible for smart devices to access other devices, apps and data anywhere, at any time, as long as there is connection to the Internet. This is the reason why smartphones have the potential to explore and add value to healthcare. Given their mobile and contextual-aware computing nature, it allows users to access and manage their health condition according to their life context. Facebook and LinkedIn are examples cited by Hurwitz as cloud services.

At the same time that the cloud computing plays a vital role in allowing real time access to data providing mobility to individuals, the disconnection to the Internet can result in loss of data or at the data is stored in the 'cloud environment', which can be completely unknown. This is when legal and security affairs matter; i.e. when the smart device results in possible breach of confidentiality of personal data. In the use of their smartphones, many consumers can engage other devices without being aware of it. Data transmitted from a smartphone app can be processed around the earth, reprocessed, stored and copied while consumers are unaware of it.(43)

According to the Independent European Advisory Body on Data Protection and Privacy (43), the main risks that can impact users is lack of awareness about the cloud computing features embedded in apps; lack of consent from users before and after processing of information; and poor security measures. Another main concern that affects users' security of personal data is the lack of approval of apps by governmental agencies, lack of a certification from health authorities or even by clinicians' organisations. Safety and security are fundamental aspects of mobile interventions, especially for smartphone health apps. The lack of safety and security can undermine any program on health and disease management at individual or governmental level, as well as impede the technology to be implemented in clinical settings.

Despite the lack of clinical evidence or discussions on whether there is evidence of outcomes in smartphone interventions, in Sarasohn-Kahn's research on how smartphones are changing the healthcare, it is showed that, for severe chronic ill patients their health condition is more important than privacy.((24) p.15)

5.2.3 Regulation

In the US

Mobile health (mHealth) poses challenges to governmental regulation and health authorities. In the US, the FDA has changed its definition of devices in order to incorporate mobile devices as apps. These are now under regulation for medical device and a draft guideline is being created. There has been proposed the creation of certification granted either by a governmental or health authorities to ensure medical apps devices are safe and reliable.(44)

In Europe

The independent European advisory body proposed in February, 2013 an extension of the EU legal framework for the Data Protection Directive (95/46/EC) to regulation of apps on smart devices.(43) The work resulted in the 'Opinion 02/2013 on apps on smart devices'. In addition, the opinion refers to the ePrivacy Directive (2002/58/EC) and its last revision in 2009, with a set of standards for all parties wishing to store or access information in the devices of users within EU. The standards apply to: app developers (including app owners), manufacturers of Operating Systems and device, app stores, and other third parties involved in the processing of personal data.

The overall standards cover the involved parties' legal responsibility grounded in the following aspects: consent prior, during the use and after installation and processing of personal data; obligation to inform and request consent for any app processing data and the type of data; continuous security measures on the design of apps and proactive notification to users about any possible breach of confidentiality; inclusion of audit trails allowing end user to be able to track if and which app access data on their devices; and special attention to children to which a parental consent must be in place.

This regulation can result in the need of changes in the design and development of apps and smart devices.

In Denmark

It is the Personal Data Law (*Persondatalov*) that regulates the scope of personal information and when and how personal information must be treated. In general the law applies to electronic handling of personal information, but also manual handling of information registries. Person information is treated into three types: sensitive, information on others private affairs, and non-sensitive information.(45)

If any personal information is handled through a smartphone app, it can fit in all of the three types, depending on the information. Any intend of processing personal information must be report to Datatilsynet, the Danish authority in charge of supervision that the Personal Data Low is complied with, through guidance and counselling. All individuals have the right to access their registered information or even of others, right to obtain information about the collection of information, and right to withdraw inaccurate information. There is though a set of conditions and exceptions.(45)

IT and Telestyrelsen published in 2011 a guide on cloud computing in order to clarify the definition of 'personal data' as being any information relating to a person or able to identify a person, for example, an IP address. The guide sets also a legal framework for use of personal information and any contractual relations subjected to the Danish Laws.(46)

Standards for common data on chronic ill patients

The National Board of Health 'Sundhedsstyrelsen' recommended through the National Strategy for Telemedicine, the development of a model for disease management programs for chronic illnesses.(10) As a result of that, MedCom has started on the project Common Chronic Data (*Fælles Kroniker Data*) for development of a common platform on chronic ill patients with the aim to implement IT tools that support the coordination of the patient-centered care across the healthcare sector.(47) The product of the project is the National Standards for sharing chronic patients' data across the healthcare sector. The data will be pulled out from systems such as the Common Medication Card (FMK) and P-journal.

The *National Sundheds IT* – NSI is one of partners working in cooperation with MedCom. Its role is to set the technical infrastructure for a reference-architecture and standards to the collection of health data from citizens. This will allow communication and reuse of both IT systems and data, and consequently reduction of costs of telemedicine solutions.(47)

The reference-architecture is based on collection of health data from citizens. This represents a paradigm shift from health data collected by HCPs to collection at the individual level as in the Cph model. All data will be stored in repositories where HCPs can access relevant information to the treatment of the patient.

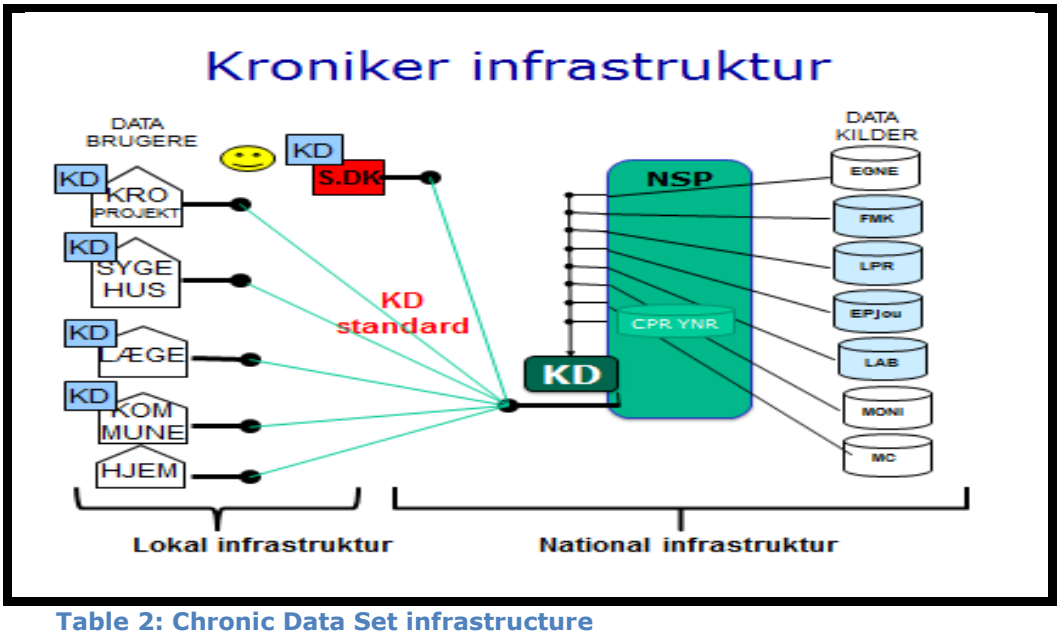

Table 2: Chronic Data Set infrastructure

Fælles Kroniker Data (KD), et udkast der skal godkendes af National Sundheds-IT (NSI). (47)

There will be three types of reference-architectures: the first, describing general architectural requirements such as information about security to be used anywhere in health care; the second, defining architecture requirements and appropriate technological solutions such as a description of how web services should be developed and applied; and the third, a specific business area indentifying principles and guidelines for the specific IT solutions, such as sharing of documents and photos.

The standards for communication and use of health data by use of technology addresses the health professionals' responsibilities and their IT systems must be in compliance with the following paragraph of the Danish law '*Bekendtgørelse om standarder for it-anvendelsen i sundhedsvæsenet*' (48):

> *"**§ 2.** Staten, regioner, kommuner, private sygehuse og klinikker m.v., herunder praktiserende sundhedspersoner, er forpligtet til at sikre, at deres it-systemer anvender de standarder for it-anvendelse i sundhedsvæsenet, som er godkendt af NSI efter reglerne i denne bekendtgørelse."*

The document 'Reference-architecture for collection of health data from citizens' is not yet approved, but under public consultation at *Høringsportalen* since April 30, 2013.

In the model developed for the project, it is assumed that the chronic patients are in great extent treated in the primary care through planning and coordination of activities between general practice, municipalities and hospital. The Common Chronic Data is expected to be the way to ensure effective cooperation and a common understanding of the plans for treatment and preventive efforts to chronic ill patients.

In an e-mail interview with a consultant from MedCom, I had the chance to better understand the work of MedCom and how patients and healthcare professionals can engage in the treatment of chronic illness by use of technology, which I attempted to explain below. The interview can be seen in the 'appendices' section.

Hospitals transfer data from Electronic Health Records (EHR) to a central database, which is presented as web browser as e-journal via sundhed.dk. Today, citizens and general practitioners have access to health data on e-journal. GPs will have access to the Common Data Set and therefore a better overview of patients' data through P-journal.

P-journal stands for practice journal and it will include the data content in the Danish General Practice Database – the Sentinel.

All the collected data will be stored in the Chronic Data Set web service (*Kroniker Datasættet webservice*) and from there the involved actors can pull the data set with view in the health journal through the web site sundhed.dk. The new thing is that the chronic data set will be available for patients, not only for viewing, but also for entry of their own data through a digital diary: "My diary". It will be possible for patients to enter contact information e.g. telephone number, email address, family's contact information and the patient's personal goals. The access to the diary will be either through sundhed.dk or web service entry, where users' IT system retrieves the Chronic Data web service structured in the national service platforms and displays it on their own browser.

In my understanding, this signalises a huge step towards patient's access to information on a deeper level than just seeing medication and consultation, but also the opportunity to influence and take responsibility of the disease control and monitoring in conjunction to the HCP assistance. MedCom's Chronic Data Set can be compared to and directs one's thoughts to the Personal Healthcare (PHC). There have been many international research projects, including Denmark, to chronic ill patients' access to health data either through Internet portals or via PHC.(49) The PHC has though not yet succeeded in Denmark.

Another similar experience is the 'Shared Care platform' for chronic ill patients in the Region South in Denmark. The project started in 2011 and is still on pilot phase. The aim is to develop a share platform across the healthcare sector for use by healthcare professionals that have share responsibilities in treatment of patients with chronic illness.

According to the project description:

> "…. *the platform is intend to promote knowledge sharing and communication between the parties, creating an overall picture of the coherent patient care, creating the best possible decision for an effective and coordinated treatment strategy for each patient, increasing the quality of care and optimize resource deployment*."(50)

The pilot is to support programs for patients with chronic heart disease and is planned to be extended to other areas as COPD and diabetes. The platform must be able to support mobile applications via smartphones as iPhone, Android, Symian or Windows. Patients will have access to own treatment data through the Internet, which could be in a view such as sundhed.dk or similar to the MedCom description for the Common Chronic Data.

The Common Chronic Data opens the door for implementation of the smartphone app technology in healthcare settings. The Shared Care Platform is the first initiative in the Danish healthcare, where citizens and patients will have access to their own health data and be able to enter data by use of smartphones. ((50)) p. 6)

It is interesting to see, after evaluation of the project, the benefits and challenges for patients and for the healthcare professionals involved and their perceptions about the technology and any conflicts that might happen with the need for coordination of the clinical work. Equally will be the chance to see whether and how emerging technologies poses technical challenges with regards to integration with other IT systems and to ethical, safety and security aspects.

5.3 Healthcare organizations

Introduction of technology in healthcare settings means that chronically ill patients are faced with a great responsibility to monitor their disease using devices that collect, measure and can transmit their measurements to HCPs. This can lead to organizational challenges for general practitioners if they are the ones to receive, coordinate and distribute data and knowledge on chronic illness across the healthcare sector, but also with patients moving between practitioner, municipality and hospital.

The Common Chronic Data infrastructure can enable the use of the smartphone app in clinical settings in the future. Many of the telemedicine solutions already tested do not integrate with the municipalities IT-systems, which means that health professionals have to seek information on patients in many different systems. It is the so-called 'independent islands'. (1)

Despite the current initiatives, ethical, legal and organisational issues are not solved yet, though they have been addressed. There is still a distance between addressing these issues and achieving the expected results. Aspects not directly addressed in the KL's Telehealth Strategy is the clinical evidence of pilot telemedicine interventions and the challenging nature of smartphone apps as ubiquitous, pervasive computing features. This can impact GPs directly because they have their own independent IT systems.

Another aspect is the transition from the current conventional healthcare setting to the point of digital healthcare continuum as in the CpH's proposal. As it is today, the conventional healthcare seems to be incongruent with the smartphone app's context-sensitivity characteristic and real time environment and with patients' expectations for more mobility.

Organizational issues that can derive from the smartphone app technology can be changes in the general practitioners' workflow, without mention HCPs in the municipalities and hospitals and the coordinated workflow among them. Based on the findings in literature review, I identify a need to understand how far consumers and patients are willing to go for a participatory healthcare in the monitoring and self-management of their disease, as well as a need to examine how HCPs will respond to the patients' technological demands and the impact on their daily work with new information coming from smartphone apps into their systems.

Physicians constitute a strong group of specialised professionals, the so-called '*primadonnas'*, where the profession is a call not a work.(51) They have the power to seek control and influence on organizational decisions and on innovations that can impact their work. Primadonnas can be a challenge for organizational and change management with implementation of new technologies. In the case of GPs, they would constitute a challenge with regards to reach agreements with the Danish Regions – 'Danske Regioner'.

Knowledge of chronic illness – Whose responsibility is it?

In the Danish model, the GP is the gatekeeper - the first point of contact of the patient with the healthcare services. Following the National Board of Health's decisions on a

patient-centered care for chronic ill patients, the Danske Regioner came up with concrete proposals on a vision for a coherent and economically viable healthcare system. The aim is a new and stronger cooperation between regions, municipalities and general practice.

According to Danske Regioner's *vision* (52) : "*the general practice must continue to be the gatekeeper of healthcare services. And there is a need to strengthen the general practice as the access to healthcare.*" As coordinator for the whole patient pathway, general practice accounts for 80 percent of patients diagnosed with diabetes and 20 percent of referrals to specialists and hospitals. Danske Regioner mentions also in its vision, already back in 2007, the need for reforms to equip the general practice to the many challenges facing the Danish healthcare.

As it is today, GPs must be able to capture chronic ill patients in their record systems and take the 'datafangst' in use, according to the GP's agreement with Danske Regioner on the framework for general practice, § 98 Data capture, Stk. 1.

Datafangst is a data acquisition module designed to collect data as they are produced, - regardless of the medical system used by the GP. The data is related to medicine service codes, laboratory data and ICPC codes. In this sense, it creates a standardized independent database – the 'Sentinel' database.

ICPC stands for the international classification for general practice and it is related to COPD: asthma, chronic musculoskeletal disorders, osteoporosis, cardiovascular disease, cancer, diabetes and non-psychotic mental disorders.

With smartphone apps about to be implemented in clinical settings, it could be another burden to GPs, but also for the entire healthcare sector with regards to coordination and knowledge of chronic illness data. As pointed in the literature review, the HCPs' perception of the smartphone app is unknown, as well as it is unknown how users in Denmark are monitoring and self-managing diabetes through health apps and whether they share health data with their doctors.

Conflicts among healthcare professional

Currently, the agreement between the Danske Regioner and the GPs is about to collapse due to conflicts of power. The *Danske Regioner* proposed a new framework for the general practicing, which in the GPs' eyes, means control over their work as independent

health professionals. (53) The results of this conflict are still unknown as both parties are still negotiating their conditions.

In a report by Ballegaard et al in 2012 for KORA, the 'National Institut for Kommuner og Regioners Analyse og Forskning' (54), central organizational challenges were identified in relation to telemedicine projects on COPD in three hospitals in Denmark. New roles were identified when evaluating the patients' and HCPs' perspective, the interaction of these two groups with the use of technology, but also the relationship among the HCPs involved in the coordination of the patient care. The aim of the project was to learn how technology is being used and to identify the factors that affect the process from and after implementation.

Ballegaard et al ((54) p. 49) introduces the term *diagnostic actor'* to define the expectations to the home patient participant in a self-care remote monitoring by use of technology. The patient is supposed to be able to diagnose and evaluate symptoms in his own body and be able to react either by treating himself or by contacting a healthcare professional. This expectation is built on the principle that the patient has certain knowledge about his disease and he can recognize symptoms. Patients act differently to different situations as diagnostic actors. Technological interventions can help patients to learn about their disease. Though, patients do not always may take the appropriate actions. Besides, it implies that patients must make their own decisions that may not be coherent to the HCPs' recommendations.

One observation about the 'diagnostic actors' is the risk of ethical dilemmas. Patients are attributed the responsibility of taking action on their own and the information and responsibility about their health data is split among different relevant social groups.

One of the consequences of patients being diagnostic actors is immediately reflected in the work of HCPs. The remote monitoring of the chronic diseases via telemedicine solutions requires coordination and constant negotiation of responsibilities for the treatment among the involved healthcare professionals in hospitals, municipalities and general practitioners.

This creates tension among HCPs. A patient usually refers to his own doctor, the GP, but in case of hospitalization, the hospital has the most current knowledge about the patient condition, whereas the home monitoring is done by a hospital nurse according to recommendations by hospital's doctors and specialists. In situations where the municipalities are involved in the home monitoring, there will be even more actors contributing to add more uncertainties and more demands to the home patient care process. It is the 'gray zone' of tensions and conflicts demanding continuous negotiation among these actors about communication, coordination and responsibility split, as showed in Ballegaard et al. ((54) p. 60).

Another spectrum of the problem is the workflow of these HCPs. As they operate in different instances of the healthcare sector; they have their own IT systems which do not communicate with each other. The result of this is the register of patient data in many different systems, risk of inconsistence information, and the risk of loss of data.

5.4 Technology: Smartphone app

As described previously, the smartphone app technology is a potential tool to healthcare. For this reason, it can be a promising approach to diabetes self-management as it can empower users and patients to monitor and control the disease. Smartphone apps have also the potential to exploit the healthcare sector as a telemedicine alternative among the existent ones in current use.

One of the main challenges of the smartphone app technology is the lack of evidence in clinical interventions. (19,31) In order to be used in clinical settings, it is crucial that the technology can deliver features and tools that promote behaviour change to enhance treatment or medication adherence, instead of just being stand-alone s.

Some studies have already addressed and documented the feasibility and usability of mobile interventions and smartphones apps to diabetes care (15,21,26,55,56). Despite the proof of the effectiveness of the technology, there is still a need for studies that address clinical evidence of efficacy with clear criteria on how to improve diabetes control by use of technology.(23)

In Health Technology Assessments (HTA), efficacy and effectiveness are defined as such, according to Nøhr (57): "*Efficacy is the probability of benefit to individuals in a defined population by use of a health technology in a given medical problem under ideal circumstances."* In this case, it could be young patients applying smartphone medical apps for obesity prevention, and with that prevention of diabetes type 2.

Effectiveness is defined as: "*The probability of benefit to the entire population of the use of medical technology in a given medical problem during everyday circumstances.",* which I interpret as: once the efficacy of the smartphone app technology has been assessed for that specific purpose, then it would be followed by the assessment of extension of the use of the technology for other populations than diabetics, for instance other chronic ill patients.

The lack of clinical evidence of mobile interventions' efficacy leads to several discussions about the lack of behaviour theory constructs in the design of apps.(30,58-60) Features and tools in smartphone apps can become useless if there is no engagement to motivate patients to mobile interventions for monitoring and self-management of chronic diseases. Feedback, especially tailored feedback, has been proven an important element in problem solving and therefore motivation to change.(39)

Motivation can be addressed through educational websites, social networking, and synchronization of the technology with other devices including with the HCP system, guidelines, and individual tailoring. Triggers are essential to motivate and keep behaviour change. Triggers can be as alerts, planning, goal setting and data reporting such as log-ins and uploads to document engagement. Behaviour change leading to better health outcomes through cell phone interventions via voice or text message service has been documented in clinical settings.(18)

One of the explanations for the lack of behaviour theory constructs in apps is due to the lack involvement of medical professionals and experts in behaviour theory, and due to the fact that apps are developed and designed by technicians, whose majority has no knowledge about health behaviour theory.(58,59,61,62)

And finally, the ubiquitous and pervasive nature of the smartphone app technology is at the same time an opportunity and a challenge itself. It requires compliance with ethical, legal and organizational aspects in the case of implementation in healthcare settings. In order to meet these challenges, the technology might need to change. It could require improvement of existent tools and features or development of new ones for the technology to be able to provide evidence-based mobile interventions in diabetes care.

Some examples could be the addition of behaviour theory constructs in the design of the technology to allow motivation to change, to address security issues by adding requests for consent for the device or app to collect and share information or notifications about a device being able to engage other devices – as suggested by the European Advisory Board (43), guidance on how the app works and technical support, integration with other devices and systems including websites, by involvement of health professionals in design and development of smartphones and apps – just to mention a few.

6. Delimitation of the research topic

In this master project, I will focus on the themes described in the context of the problem, i.e. ethics, legal, healthcare organizations in relation to the smartphone app technology for the remote monitoring and self-management of diabetes for users and in the healthcare sector in Denmark.

I decided to work with diabetes in general, not making any distinctions of types (T1, T2 or pre-diabetes). I choose to refer to users as a general term, though 'users' can be citizens, consumers or patients.

Any reference to organizational issues will be done on the basis of input from literature review, users' input to survey and interview with an endocrinologist from the Danish Endocrinological Association.

As mentioned previously, the context of the problem clearly defines the possibilities and challenges that the smartphone app technology brings to healthcare. Currently in

Denmark, there are many telemedicine pilot projects in order to respond to the demographic and economic pressure. Elderly people are more prone to develop chronic diseases and the healthcare has neither the economical nor the human resources to cope with this situation. Therefore, there is a need to investigate the implementation of new initiatives that can help to diminish the problem. One of the solutions is telemedicine through new technologies, and the smartphone app could be one of them.

As a new phenomenon and emerging technology, very little is known about the smartphone app technology, about how users are applying it and about the HPCs' meanings about the technology. There are very few scientifical articles available about these topics and not all aspects of the use and evidence of the outcomes of the technology for either consumers or for patients and in clinical settings have been evaluated yet.

The context of the problem has helped to enlighten potential aspects still not yet researched and this brings me to my research question.

7. Research question

How are users applying smartphone apps for remote monitoring and self-management of diabetes in Denmark?

- A study of users' perceptions and preferences of apps for diabetes to examine whether apps can enhance adherence to remote monitoring and self-management of diabetes, hence behavior change.

I work with the hypothesis that users in Denmark are using smartphone health apps. Then I will look specifically at the following sub-questions:

- How are users applying apps in conjunction to monitoring and self-management of diabetes?
- What are users' perceptions and preferences of smartphones apps for diabetes?
- Can the smartphone app technology be used as a tool to enhance adherence to remote monitoring and self-management of diabetes and hence behaviour change?

7.1 Aim of this research

I wish with this master project to look at the users' perceptions and preferences of the technology and whether health apps can enhance adherence to remote monitoring of diabetes. I will also look at HCPs' perspective to the technology based on the users' perspectives and to the HCPs meanings about the technology in relation to their clinical workflow.

I will seek to proof whether the app technology can be considered a solution to both enhancement of diabetes treatment and therefore as a tool to promote life style changes in the users' behaviour as autonomous persons in charge of their health condition or disease control.

8. Research Design

Hermeneutical-phenomenological paradigm

The theme of this research is within the hermeneutical-phenomenological paradigm.

I am interested in understanding and interpreting by looking at the users' and HCPs' meanings about the smartphone app technology in healthcare. I look at potential possibilities and challenges that may impact the interaction between users and technology for diabetes control.

All empiric data will be analysed based on hermeneutics and phenomenology. Both are social subjectivist paradigms where meanings are subjectively created, as in Berthon et al. 2002, mentioned in Croucher. (63) In this sense, I seek to understand human experiences with the purpose of describing them and trying to capture the essences of the empirical data. As defined by the work of Klein and Heidegger, it is a holistic approach of the interaction of humans with an artefact and the context of these interactions, which cannot be seen separate. (63) In this sense, my approach is hybrid; i.e. a mix of explorative and explanative in order to work on a systematic reflection of the users'

consciousness as a result of their experiences with, judgments and perceptions of the phenomenon in the given context of this research.

9. Methods

Triangulation: Qualitative and quantitative methods

Triangulation is the use of one or more methods or theories in a research to verify results of data collection on the same phenomenon. It is a cross verification that can be through qualitative and quantitative methods. The purpose of triangulation is to determine the generalization, validity and reliability of data.(64)

I applied literature review as a qualitative method in order to identify potential issues relevant to the context of the problem and to support the research question. A literature review is a process of studying what is already written or known on a specific topic. Literature review is considered a qualitative research process, unless it is a systematic review, where the focus is on an extensive amount of articles dealing with a specific topic.(65)

In order to obtain a sample of the users' perspectives to smartphone apps in conjunction to diabetes, I chose to apply a survey as a quantitative method. Quantitative methods can be applied when a sample of the population is needed in order to achieve comprehensive and representative information about a problem. Quantitative methods such as a survey have the purpose of testing hypothesis and theories.(65)

I chose also to apply another qualitative method: a structured written interview with a healthcare professional in the attempt to confirm or discard the survey findings by triangulating one method with another. The appropriate approach to understand users' experiences, judgments and meaning is a qualitative method, which is often characterized as being interview-based.(65)

I interviewed a consultant in MedCom in order to explore the potential of the smartphone app technology in the healthcare sector in Denmark and to get a better understand of the technical aspects of the Danish healthcare IT infrastructure and systems. I will not consider this interview in the analysis of empirical data because I used it in the context of the problem.

Finally, I decided to use one last qualitative method to the analysis of the results: the MAST model. I considered MAST a qualitative method because it looks at effectiveness and contribution to quality of care of telemedicine solutions through a holistic view via multidisciplinary aspects.

9.1 Literature review

Aim

The purpose of the literature review was not to make an exhaustive review, but rather as comprehensive approach to get insights about the topic I chose in order to identify relevant themes that served as evidence of what is already known and what is unknown about the topic. Another purpose of the literature review was to support the establishment of the context of the problem and the argumentation of the research question.

Strategy

The first step in searching for literature is to define the parameters for what one wants to know. Once the topic is clear, it is necessary to systematize the search, otherwise the findings will be either too broad or too narrow.(66)

My overall strategy was to look for the combination of term 'smartphone apps and diabetes'. As the smartphone app is a new technology and the combination of words gave different results than expected, it was important to create parameters to conduct a more specific search. The rationale for doing so is to set focus and establish the relevance of the expected findings. A way of doing this is creating inclusion and exclusion criteria.

Inclusion criteria – Articles about diabetes including mobile interventions, smartphone, apps, smart devices, empowerment, m-Health, e-Health, patients' and HCPs' perspectives.

Exclusion criteria – Articles containing the word 'mobile cell phone', studies referring to PDA devices only, and those containing other chronic illnesses than diabetes. Though the app phenomenon is still new and there are very few studies about the topic. Most of the studies found on diabetes are based on cellular phones, rather than on smartphone apps, then I had to include some of these studies as they address many of the questions relevant to my research topic.

Besides the literature review, I also made use of the reference lists of some articles in order to get a deeper insight to specific topics. I conducted my search in different periods of time and refined the search parameters according to the findings.

I used different databases by doing a cross search in the Novo Nordisk's online Library. The search was conducted in several databases, search engines and journals, among others PubMed, Embase, Biosis, Scopus, Cinahl, Cochrane, Google Scholar, and at databases of individual scientific journals.

Search terms were as an example: smartphone devices, smartphone apps, android, mobile devices, app, e-health, m-health, patient and empowerment, diabetes interventions, diabetes and telemedicine, patient satisfaction, users' perceptions, consumer's perceptions, HCPs' perceptions, behaviour change, ICT and decision models, health technology assessments, etc., either as individual terms or combined with Boolean operators.

This operator means simply the association of key terms and words that can be linked or excluded by use of AND, IN, OR, NOT and others.

Language – The preferred language was English. It was difficult to find articles published in Danish for the terms or topics I was looking for.

Data of publication – For search about app, smartphone, android, cloud computing and similar or combined with studies about diabetes and mobile interventions, I chose the most recent articles. My timeframe was 2009-2013. For other terms such as empowerment, diabetes in general, articles with definition of terms and concepts, reports, and similar, the timeframe was broader, though my general strategy was to choose the most recent knowledge.

Results – I identified about 140 potential articles. After a screening to select the most relevant, the articles were checked against my inclusion/exclusion criteria and thereafter ordered according to themes; e.g. chronic illness, diabetes, smartphone app technology, patient empowerment, ethics, safety and security, regulations, health care professionals, health technology assessment. These were further refined and I ended-up with ethics, legal, organization and smartphone app technology as the elements for the context of the problem.

Limitations – Given the many different nomenclatures and terms to refer to health technology, mobile interventions with smartphone apps and similar combined with diabetes, I cannot state that my search identified every relevant article. The lack of articles in Danish language or referring direct to the topic of my study was also a limitation. In this sense, my search was comprehensive and not exhaustive.

The interpretation of the results can be seen in the 'context of the problem'.

9.2 Survey

Aim

The aim of the survey was to collect a sample of the population that uses smartphone health apps to diabetes control in Denmark. Primarily, the survey results can confirm or discard the hypothesis that users are applying the technology in Denmark. Then, it answers the sub-question 1 about how users are applying smartphone apps and the sub-question 2 about the users' perceptions and preferences.

Through literature review, I found out that there is a need to know how users are applying smartphone apps for, especially medical apps to monitoring and control of chronic illness. Furthermore, the literature shows the users' readiness to new technologies and the increasing amount of downloads of medical apps in apps stores.

Setting up the survey

It is necessary to follow some steps to the setup of the survey.(65) I use the steps that are in the scope of this research:

Determine the target group – The target group is composed of the following social networks of patients on facebook: Patienforeningen in Denmark, Hovedstadens Netværksgruppe for Voksne med Type 1 Diabetes, Diabetes Produkter Type 1 og Type 2, Diabetesforeningen, and local Diabetesforeningen i Odense and Fredensborg.

Selection of population – I used a systematic selection strategy. This type of selection is appropriate to ensure a representative sample of the target group, in this case, diabetic population.

Inclusion criteria – The delimitation of the population was defined as people between 18 to 80 years old, both inclusive.

Exclusion criteria – The population excluded is minors (children and teenagers) and people above 80.

Determine themes and problem(s) – The theme is 'Smartphone apps to remote monitoring and self-management of diabetes'. The identified problems were related to the following subtopics: usability, apps' features, tools for enhancement of behaviour change, safety, security, ethics, patient-HCP interaction, and the overall meaning about app technology.

Design and data collection – I chose to work with a nominal scale, where there is no rank order, because it would not make any sense to the type of information I was looking for. Nominal scale is typically used for background information, but also where the respondents have more answers as a response list.(65)

It gives meaning to work with variation of questions and response categories in order to force the respondents to read the questions with the intention to give the right answer. Furthermore, the survey was created as a combination of open and close questions. The survey questions cover the following dimensions: attitude questions (behaviour dimension), actual questions (time dimension), and combined answers (response dimension). In total there were 18 questions, 2 out of these were demographic questions. The survey was constructed in English and translated to Danish.

The sequence of the questions was controlled designed, so that the respondents could not jump to the next without answering the current question.

Determine the method – The method applied in the survey is the internet-based, i.e. an e-survey in order to meet the users where they are: on social networks of patients on facebook, sharing experiences with other people with the same problem. The survey could be responded either via PC or a smartphone device.

Test of the survey

It is important to validate a survey before it is sent out to the target group. One way of validating my survey would be to interview one of the users in my target population. The purpose of the validation is to ensure that the survey serves its purpose. Due to limitation of time and in order to avoid any bias prior to the survey launch, I decided to test it with people I know. I asked them to check if the content was clear and the navigation was easy, and if they found anything that could be improved. The test was sent to seven persons and I received a positive feedback.

Implementation

After the test, I launched the survey on facebook and it was available for the respondents for seven days. The advantage of an e-survey is the ability of being able to track the number of responses and to analyze them as they come.

9.3 Interview

Interview with a Medical Director and member of the Danish Endocrinological Association

Aim

I intended with the interview to look at whether HCPs have interest in engage themselves in the patients' monitoring and self-management of diabetes by use of the technology and whether their meanings are congruent with the users' expectations showed in the survey. Knowing the HCPs meanings, I intend to be able to reflect on the impact of the smartphone app technology to healthcare organizations, and specifically to the HCPs' clinical settings.

Structured written interview

I decided to analyse the interview results using SCOT analysis, where I also refer to the survey results analysed through the Mast model, and to findings in literature review about HCPs' perspective. I will attempt to understand the HCPs' meanings of the technology in and the impacts on organizational aspects that were not addressed in the survey.

Due to time and resources limitation, it was only possible to interview one HCP. This means that I cannot claim that the interviewee's meanings are representative for all HCPs, nor for all the group of endocrinologists in Denmark.

It was not possible to interview the HCP personally; thus I had to choose to work on a structured written interview. This type of interview is often known as hypothesis tester. ((65) p. 71) In this case, users' assumptions (as I interpreted in the survey results) that, their HCPs might not be interested in engaging themselves in the users' diabetes control by use of the technology.

The interview has an explorative character as I am interested in getting knowledge about an 'unknown' area; i.e. the HCPs' meanings about a new phenomenon – the smartphone app technology. ((65) p. 72)

Interview Guide

The purpose of the interview guide is to define the themes and their order of sequence in the interview questions. Structured interviews require an interview guide with clear and pre-defined questions, which i turn allows a structured and logic analysis of the responses. I had my topics (i.e. themes) pre-defined already in the context of the problem. I prepared the interview with the same themes: ethics and empowerment, organizational issues, safety security and legal aspects, and the smartphone app technology. The interview guide was, then, also adapted to the MAST model.

All the questions in the interview are related to behaviour, meanings and values. These types of questions reveal the interviewee's interpretation of others actions, wishes and opinions. ((65) p. 75)

An important aspect that needs to be stressed is that the interview guide became the interview itself, because I performed a written and not a personal interview. I did not pilot the interview due to limitation of time, though I believed I had strong evidence in my arguments and questions which were based on the literature review and survey findings.

9.4 MAST model

I chose MAST because it is a multidisciplinary model that, through a holistic, view covers all topics raised in the context of the problem, and because I believe it can contribute to enrich the discussions about assessment of emerging technologies in healthcare such as smartphone app. Another reason is due to the fact that current HTA models have been criticized for not enable their validation quantitatively as most of the telemedicine initiatives are pilot project experiments in specific contexts, which limits comparison of experiences and deployment of technology in a broader extend.(67)

MAST stands for Model for Assessment of Telemedicine Applications. MAST is a framework, a standardized method for evaluating telemedicine solutions. It is a multidisciplinary approach because it looks at medical, social, economic and ethical aspects of using a given technology.(68) The method was developed with the European Commission support and it is based on European experiences with telemedicine and with the Scandinavian

expertise in telemedicine projects in Denmark and Norway through MedCom and Norwegian Centre for Integrated Care and Telemedicine.(69) The model is being recommended for assessment of effects and impact of telemedicine solutions within the European Union.

As showed in Kidholm ((68) p. 44), the biggest barriers for telemedicine are: the lack of evidence as the technological applications are still new in the healthcare field (despite many scientifical articles have claimed telemedicine outcomes), a questionable quality of telemedicine studies, and the fact that telemedicine faces competition with other solutions, which could be a preference for conventional solutions already existent in the healthcare sector.

MAST provides a systematic way of evaluating and ensuring that the technologies available are effective, safe and economically viable. MAST aims to assess telemedicine solutions with focus on decision makers, but also for developers and designers of telemedicine solutions as they can be oriented about the impact of the technology solutions on treatment of patients.

MAST model

Preceding considerations

- Purpose of the telemedicine applications
- Relevant alternatives?
- International, national, regional or local level of assessment?

Multidisciplinary assessment

1. Health problem and characteristics of the applications
2. Safety
3. Clinical effectiveness
4. Patient perspectives
5. Economic aspects
6. Organizational aspects
7. Socio-cultural, ethical and legal aspects

Transferability assessment

-Cross border

-Scalability

-Generalizability

Table 3: MAST model
Adapted from: Kidholm, K., et al. A model for assessment of telemedicine applications: MAST. International Journal of Technology Assessment in Health Care, 28:1 (2012), 44-51.

MAST consists of three steps where a series of questions that guide and show directions on what to ask. The framework has a structure of aspects and these must be followed.

The first step: It is a preliminary assessment with considerations on whether the assessment is relevant and in which the supplier/developer of the given technology makes clarifications about technology.
Question:
Is the technology sufficiently matured, tested, and what the legal and economic conditions the technology presents.

The second step: It is the multidisciplinary assessment to describe the outcomes of the telemedicine application in seven domains.
1. Health Problems and features of technology: What kind of health problem does the solution address? How big is the problem? Are the current choices available? What kind of technology you think can solve the health problem?
2. Patient Safety: Is the technology's performance satisfactory? Is it safe for patients and healthcare professionals?
3. Clinical efficacy: What are the effects on patient health and disease? Does it reduce mortality and increase health-related quality of life? What is the behavioural outcome and impact on health services?
4. The patient's perspective/experience: What is the patient's and family's perception of the technology's performance? Are they satisfied and accept the solution? Do they understand the information they receive? Can they use the solution correctly?
5. Economic aspects: What are the health economic impacts (cost versus effect)? What is the business case (costs versus revenues)?
6. Organizational aspects? : Does the technology require a new organization of the treatment? Does the implementation of the solution mean changes in the organization and between organizations (process, structure, culture and management)? What is the staff meaning about these changes?
7. Socio-cultural, ethical and legal aspects: Are there possibilities of equal access to treatment? Does it alter the doctor-patient relationship? Does the technology changes the patient perception of his illness and its own role?

The third and last step: The description of the outcomes.
Are the results valid for a small and narrow group or can it be scaled up and used for another groups of patients and in other countries?

On the basis of the context of the problem in this research, I chose to focus on the following topics in the analysis of the survey results:

- Health problem and characteristics of the applications
- Safety
- Patient perspectives
- Organizational aspects
- Socio-cultural, ethical and legal aspects

Delimitations for the use of the MAST model:

I will use the MAST model as inspiration to approach the analysis of empirical data in the survey. My intention is neither to explore all topics in depth, nor address all questions. I will rather place my interpretation of the impacts of the smartphone app technology within the context of diabetes control in contrast to the following aspects stressed in the context of the problem: ethics, legal and healthcare organizations.

10. Theoretical framework

My theoretical approach to this research is within the field of constructivism. In constructivism there is not only one truth, but several. The world is constantly changing and it is seen from a social-psychological perspective. The reality is dependent on time, place, and context. In this project I work with individuals and their interactions with the world. The interactions can be with material and non-material s and the product of these interactions generate constructions of 'subjective' meanings in a specific context. These meanings are subjective in the sense that they are bound to the individual's consciousness.(70)

I chose constructivism because I find it in line with my research question, where I seek to understand and interpret how the users' perceptions and preferences contribute to the

construction of smartphone app technology. In addition, the constructivist approach takes into consideration the social context of the problem, which I considered very appropriate to my topic as it helps to find and understand the several truths of the actors involved through different perspectives in a given context.

I can summarize it by stating that: around any information system (IS) there are people, their human subjectivity, and their social contexts; without these there is no construction of technology, which is expressed by Gremy as (71):

> " *'Peopleware' is everywhere in the different steps of conception, realisation, and evaluation of a health information system."*

10.1 Theory

10.1.1 Social Construction of Technology – SCOT

Social Construction of Technology (SCOT) is a theory within the field of social constructivism. It was developed by Trevor J. Pinchi and Weibe E. Bijker in 1987.(72) SCOT is a theory then can be used to understand the relationships between technology, technological development, and social contexts.

The fundamental feature of SCOT is that the technological and the social cannot be separated. Technology is only what it is in relation to particular social groups, as these can impact technology design. Social groups determine whether the technology will stabilize in a given context through the group's meaning, emphasis, and opinions of the technology. There can though be different opinions about technology. Who uses technology and who avoids it? SCOT calls this concept social-constructivism. A social group can be both a group of people at the workplace or for example an organization.

SCOT does not see technology as a linear development where technology has a pre-defined start direction to where it develops from. In SCOT, technology is a multidirectional development, where multiple versions of the same technologies are competing with each other. The social group or social context determines which technology will survive the others. A linear development can only be achieved if one looks to development retrospectively and avoids the technological failures and focus on the successes. Technological failures are just as important as the successes and must be

seen from a historical perspective. This is called in SCOT *symmetry* – Failure and success have equal importance in analysis of technology development.

Core concepts in SCOT:

Relevant social groups – They are users of a given technology that in groups share or have opposite interpretations of the technology. The technology itself is a construction of social groups or actors that, with their similar or divergent perceptions, shape the technology in different ways.

Interpretative flexibility – It means that various social groups have different interpretations of a technology. Alternative interpretations give insights of possibilities to problem solving to several aspects such as design, features, purpose, etc. From a retrospective view, many technologies in use today are taken as stable, tough they have been subject of controversies among different groups or actors.

Stability or closure – When the controversies among groups and users no longer take place, the technology is considered stable. Users and groups see the problem as being solved and any needs diminish. This does not mean that the problem is solved, but perceived as solved by relevant social groups as such; i.e. closure is a social construction. In this case it is called *rhetorical closure*.

Another way of reaching technology stability or closure is a *redefinition of the problem*, which can be a change in focus by creating a new problem. For instance, in Pinch's and Bijker's example of the bicycle development; the air tires were considered aesthetically ugly, but they solved the speed problem. Closure is though not permanent as new social groups can reintroduce new interpretation flexibility causing a new debate, which calls for solutions that can lead to stability or closure.

Technological frames – In SCOT, social groups, interpretative flexibility and stability/closure must be complemented with technological frames. These frames are the basis for SCOT as a theory on development of technology and must not be confused with a set of empirical studies, but a set of elements that together influence the relevant social groups' attribution of meaning to technical s and thus, leading to construction of technology.

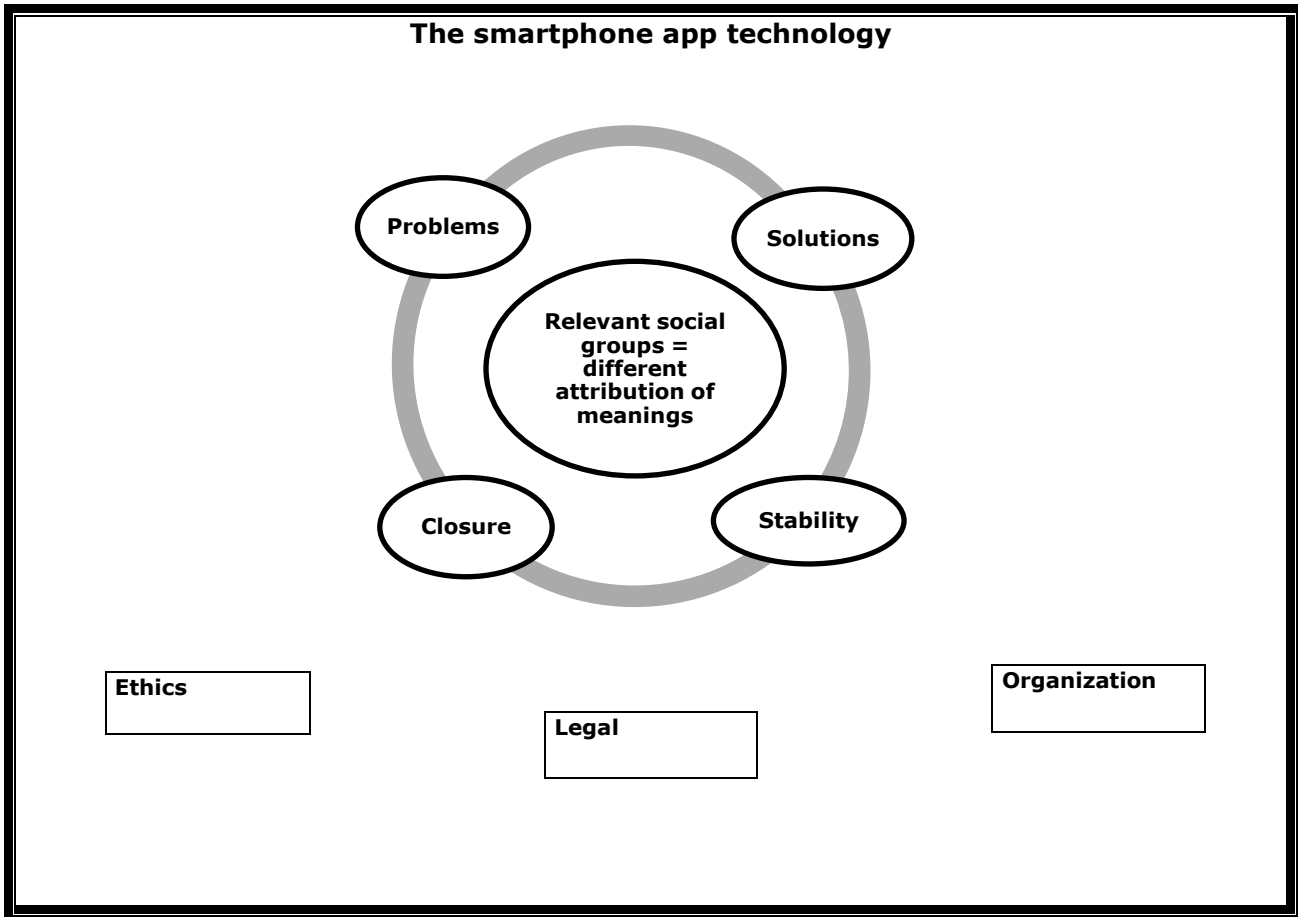

Table 4: SCOT's construction of technology
Construction of technology adapted to this research, inspired by technological frames in SCOT.

Aim

Inspired by SCOT, I will apply the above technological frame as theoretical analysis of unit in order to understand, interpret and be able to explain how users and HCPs perceive and shape the smartphone app as a technology within the context of healthcare scenario. Technological frames show possibilities and challenges of a given technology in a given context. The overall elements for the analysis of results are ethics, legal and organizational issues in relation to the technology.

Strategy

I intend to cross the results of the survey and interview worked through the MAST model in the SCOT analysis in order to confirm or discard any similarities. I will focus on equal and different opinions to the same and different problems that can be related to needs and concerns about the technology.

I do not intend to analyse any organizational issues in depth, but only those I identified most relevant in relation to the impact the smartphone app technology could have if deployed in clinical settings.

11. Results and analysis

11.1 Survey

MAST

I will apply the MAST model to present the survey results. I will focus on the multidisciplinary assessment section of the MAST model as inspiration to answer questions related to the health problem, safety, patient perspectives, organizational, and socio-cultural, ethical and legal aspects.

The MAST model is used to assessment of technology that is evaluated in order to see whether there is a potential to implementation or not. The smartphone app technology is still a new phenomenon and has not yet been evaluated in Denmark as other competing telemedicine solutions.

I will adapt my findings so that they match in some way the MAST framework. This is not intended to be an exhaustive comparison. I will omit some of the guided questions of the MAST model, though all questions I considered relevant to the survey and possible to answer will be addressed accordingly. I will compare the results of the survey with the results of the interview and complement the analysis with the organizational aspects that were not addressed in the survey.

I decided to order and classify the survey results in terms of *consensus* and *controversies* in order to give a clear overview and alignment of the findings when applying SCOT's theoretical concepts in the analysis. I consider a consensus when the rating is higher than 50% and a controversy any ratings that are close to each other.

MAST

To the first question on the MAST model about the technology:

Is the technology sufficiently matured, tested, and what the legal and economic conditions the technology presents?

The smartphone app technology is still new, though I interpret it as being on a diffusion phase as the technology has been adopted worldwide by many users. Though in clinical settings, it would be in innovation phase. Concerning the degree of maturity and testing, as pointed before, it is difficult to affirm due to the lack of clinical evidence of mobile interventions to diabetes care and due to a very few scientifical articles about clinical interventions with smartphone apps, together with uncertainties related to the quality of the results in diabetes care, as pointed in literature review. The clinical evidence is though not in focus in this research. The legal aspects have already been addressed in many scientifical articles; politicians and health authorities have already started taking initiatives. The economic aspects are not in scope of this research either, though consumers are financing the device and applications themselves. Referring to the Municipality's Telehealth Strategy, it is clear that health authorities expect us to continue to finance the costs with devices and Internet connection.

The overview of the responses as is follows:

There were 71 views to the survey. The total of respondents is 42, of which 24 are full answers and 18 incomplete answers. The frequency for age and gender of respondents (completed answers only) can be seen in the tables below:

	Total	
Hvor gammel er du?	**Procent**	**Antal**
18-30	13%	3
31-40	29%	7
41-50	33%	8
51-60	25%	6
61-70	0%	0
71-80	0%	0
Total	**100%**	**24**

Table 5: Survey frequency of age

	Total	
Jeg er:	**Procent**	**Antal**
Mand	46%	11
Kvinde	54%	13
Andet	0%	0
Total	**100%**	**24**

Table 6: Survey frequency of gender

The health problem

What kind of health problem the solution addresses?

The overall aspect of the problem is the adherence to remote monitoring and control of self-management and whether the app technology can deliver tools that contribute to solve this problem.

How big is the problem?

The increasing number of chronic ill patients and the lack of financial and human resources is a huge problem for the healthcare sector. There is a need for new intervention methods such as telemedicine as a solution to the problem.

Are current choices available?

The current choices available within telemedicine are video consultations, home monitoring, online patient network, virtual training, and the chronic journal, as mentioned before. These are competing with the smartphone app technology in case of it being evaluated to be deployed in clinical settings. Other choices are the already existent solutions such as the conventional diabetes control at the GP's clinic or rehabilitation programmes in the municipalities without use of technology.

What kind of technology you think can solve the problem?

The smartphone app technology has the potential to solve the problem as it is context-sensitivity, it provides real time access to information, it can be embedded with features and tools for monitoring and education of patients, and it can allow interactions between patients and HCPs.

One main issue with the smartphone app technology is its pervasive computing nature, which can result in problems of breach of confidentiality of personal information, constituting a barrier in healthcare as health data is considered sensitive information. Another problem is the integration of the technology with the existent IT systems in healthcare sector.

As showed in the survey, health apps are being used for different purposes in Denmark according to question 1. Carbohydrate measurement is the main purpose for the majority of the users. This is one of the indicators of diabetes control.

1. Du bruger din smartphone sundheds-app (s) til måling eller kontrol af:	
Blodsukker (*Blood Glucose - BG*)	17%
Blodtryk kontrol	13%
BMI (Body Mass Index)	8%
Insulin eller medicin indtag	21%
Kulhydrat	75%
Kolesterol	0%
Dagbog af medicin indtagelse	13%
Dagbog af hypoglykæmi	13%
Fysisk aktivitet	13%
Andet	33%

Concerning the frequency of usability of apps, there is a *controversy* among users as the highest ratings are very close, though they are in contradiction with each other as showed in question 2. '*En gang imellem*' can mean many things.

2. Hvor ofte bruger du denne / disse?	
En gang dagligt	13%
Flere gange dagligt	38%
En gang imellem	33%
ofte	0%
Aldrig	17%

Characteristics of the app technology

To questions related to apps' features and tools, the survey reveals that there is a *consensus* among the users that: a) either features or tools are not embedded in their apps or b) they are neither relevant or not of their interest, as showed in questions 3 and 14. Though in question 4, there is a clear *controversy*.

3. Din app kan overføre data automatisk fra f. eks. en BG apparat til din smartphone sundheds- app, og det sker ved:	
Sensor	0%
PDF eller Excel fil	8%
e-mail	0%
Alle af de ovennænte	0%
Ingen af ovennævnte	92%

4. Kan du sende dine målinger fra din sundheds-app til din læges e-mail og diskutere dem med lægen derefter?	
Ja	13%
Nej	38%
Ved ikke	17%
Ikke relevant	33%

14. Har du en påmindelse (advarsel) service i din sundheds-app til at minde dig om, fx at måle dit blodsukker, blodtryk, medicin indtag eller andet?	
Ja, det har jeg og jeg bruger det	8%
Ja, men jeg bruger det ikke	17%
Nej, men jeg ville gerne have det	17%
Nej, og jeg er ikke interesseret	58%

Socio-cultural aspects and empowerment

Are there possibilities of equal access to treatment?

As showed in question 1, 75% of the users are applying smartphone apps to diabetes control. This could mean that patients are empowering themselves by use of technology, which can lead to rich possibilities of equal treatment.

Does the technology alter the doctor-patient relationship?

According to the survey findings, there is a *consensus* among the users on their wish towards a participatory healthcare, where they share their measures and their monitoring and self-management of diabetes with their doctors, as showed in questions 5 and 10.

5. Vil du føle dig tryg, hvis din læge kunne anbefale dig pålidelige og sikre sundheds-apps?	
Ja	75%
Nej	0%
ed ikke	8%
Ikke relevant	17%

10. Du har sendt dine smartphone sundheds-apps målinger til lægen via e-mail. Ville du så gerne modtage en tilbagemelding om dit fremskridt?	
Ja	75%
Nej	4%
Ikke relevant	21%

Social networking can be a powerful tool for patient education, which in turn could contribute to the doctor-patient relationship, though there is a *controversy* among users as not all respondents are interested, as showed in question 6.

6. Kan din sundheds-app integrere med et websted eller sociale medier, hvor du kan lære mere om din helbredstilstand eller om diabetes?	
Ja, og jeg bruger det	13%
Ja, men jeg bruger det ikke	8%
Nej, men jeg vil gerne det	42%
Nej, jeg er ikke interesseret	38%

Does the technology changes the patient perception of his illness and its own role?
As showed in question 12, it is clear *consensus* as the majority of the respondents feel motivated to change their life style with the engagement of their doctors, hence behavior change.

12. Tror du, at med lægens feedback og vejledning, du ville føle dig mere motiverede til at ændre eller forbedre din livsstil eller helbredstilstand?	
Ja	63%
Nej	4%
Ikke relevant	33%

Safety, security, ethical, and legal aspects

Is the technology's performance satisfactory?
There is a general *consensus* among the users in questions 5, 8, and 15 in the way they perceive the technology performance. They would feel safe if recommended reliable apps by their HCP and would not be concerned about any malfunctioning that could lead to breach of confidentiality on personal data, though they do not fully trust the technology in case of a diagnosis made by an app.

5. Vil du føle dig tryg, hvis din læge kunne anbefale dig pålidelige og sikre sundheds-apps?	
Ja	75%
Nej	0%
Ved ikke	8%
Ikke relevant	17%

8. Du har målt dit blod sukker, BMI, og fødeindtagelse og sendte disse til din læge via e-mail i din app. E-mailen blev ikke leveret. Bliver du bekymret for sikkerheden mht. dine personlige oplysninger?	
Ja	25%
Nej	63%
Jeg er ligeglad, min helbredstilstand er vigtigere.	13%

15. Mange sundheds-apps i dag kan diagnosticere en helbredstilstand eller sygdom. Vil du have tillid til en diagnose lavet af en smartphone sundheds-app?	
Ja	25%
Nej	58%
Altid	0%
Aldrig	17%

Is the technology safe for patients and healthcare professionals?

In question 7, 50% of the users would trust the technology with regards to safety in automatic suggestion of insulin dosing, though it does not represent the majority of the users as 38% of the respondents do not trust the technology. It is a *controversy*. HCPs were not included in the survey; therefore it is unknown which safety issues would be connected to them.

7. Du overfører data fra et BG apparat til din sundheds-app. Det data vil generere din insulin dosering. Ville du føle dig tryg med app-teknologi, selvom der ikke er en teknisk support, hvis der sker fejl?	
Ja, jeg vil have tillid til teknologien alligevel.	50%
Nej, jeg ville ikke stole på teknologien.	38%
Ved ikke	13%

Patients' perspectives

The patients' perspectives are identified in my survey as users' perceptions and preferences of the technology. As such these are described below:

Perception – In question 16, about the general perception of the app technology in the future as a replacement to control visits to the doctor's office, the opinion is equally divided; 33% answered yes and the same amount answered no. These results point to a clear *controversy* among users.

16. Tror du, at mange kontrolbesøg hos lægen vil i fremtiden blive erstattet af smartphone sundheds-apps?	
Ja	33%
Nej	33%
Ved Ikke	29%
Aldrig	4%

Preferences – The questions about preferences are connected to the communication between users and their HCPs by use of the smartphone features and tools that can enhance behavior change.

What is the patient's perception of the technology's performance? Are they satisfied and accept the solution?

In the overall, the findings show that the users have accepted the technology, they are satisfied with it, they have accepted it, and that they are willing to use the technology in combination with the HCP involvement. In questions 9 and 13 there is a *consensus* among users. An observation to question 9 is that, despite the major rating of 75%, no one knows (i.e. 0%) if the doctor is interest in digital contact. As they preferred a combination of digital and personal contact, I understand that it signalizes an expectation that their HCPs could be interested in being involved in their diabetes care by use of technology.

9. Foretrækker du digital (fjern) eller personlig kontakt med din læge til den daglige monitorering af din helbredstilstand eller sygdom?	
Digital	8%
Digital, men jeg ved ikke om min læge er interesseret	0%
Personlig	17%
En kombination af begge to	75%

13. Hvilken form for registrering af monitoreringen af din sygdom foretrækker du?	
Digital dagbog	63%
Papir dagbog	8%
En kombination af begge to	17%
Ingen	13%

In question 11 about the form of feedback from the doctor, there is a clear *controversy* as the opinion is divided.

11. Du modtager en tilbagemelding fra din læge. Foretrækker du, at det er et personligt eller automatisk svar?	
Personligt	38%
Automatisk	8%
En kombination af begge to	42%
Ikke relevant	13%

Open-ended questions

About the type(s) of apps used:

The Diabetesforeningen Kuldhydrat app appears to be the most used, followed by Endomondo. Diabetesforeningen Kuldhydrat app is mentioned 8 times, while Endomondo is mentioned 5 times. These findings reveal that most users are applying their apps to counting of calories in food, but also to track their physical activity. Food intake and physical together with medication are important indicators of diabetes control. Endomondo is a sport tracker app embedded with a GPS track running feature. Endomondo interacts directly with facebook and with Endomondo's web site news feed, where one can see its own performance and share it with others. Several users apply more than one app, each with a specific purpose, so that they supplement each other due to lack of integration.

11.2 Interview

In the survey results, it was revealed that users would like to share their measures and knowledge on diabetes control with their doctors. These findings have triggered my interest to know about the HCPs' perceptions on the use of smartphone app technology to diabetes care. And, as showed in the literature review, to date, there is no research on HCPs' meanings about the smartphone app technology to diabetes interventions.

The interview findings are inserted in the SCOT analysis. The entire interview can be seen in the 'appendices' section.

SCOT analysis

The following elements will be treated in this section:

- The technological object of study: smartphone app technology
- The relevant social groups: Users, HCPs and health authorities
- Interpretative flexibility: the meanings, judgments and opinions the group attribute to the technology
- The technological frame: the context of the problem

The technological object of study: smartphone app technology

As described previously in the section 'context of the problem', the smartphone app technology has the potential to deliver outcomes to diabetes care. The technology is congruent with the users' context and the desire for more mobility. Smartphone devices can be brought along everywhere, at any time, which is relevant to the monitoring and self-management of diabetes. In comparison with the conventional clinical setting as it is today, the smartphone app technology could deliver tools for remote monitoring and self-management of diabetes, which also could enhance users' and patients' adherence to control of the disease through behaviour change.

The smartphone app technology is a new phenomenon, but it has already been adopted by users worldwide, including Denmark. The overall results of the survey show that all the respondents apply smartphone health apps to diabetes control to many different purposes as well as they apply different types of apps.

In order to be implemented in healthcare, a new technology must comply with technical, legal and security requirements. In SCOT, what takes for a technology to be considered stable and hence be implemented and used is defined by the *technological frames*; i.e. the set of elements that together attribute meaning to the technical and leads to the construction of technology.

The relevant social groups: Users, HCPs, health authorities

As there was no distinction among in the survey to the different social networks of patients on facebook, I will take all network groups as the relevant social group for all diabetic network groups. This relevant social group is represented by users, which also represent patients.

There is also a need to refer to HCPs as a relevant social group. Only one HCP was involved in this research through a written structured interview. If the smartphone app technology was to be implemented in clinical settings today, HCPs could be the first in healthcare organizations to be impacted by the technology, and they would, in turn, impact the technology by using it or avoiding using it. I am aware that only one actor in the HCPs relevant social group is not representative for the entire group, but I will take the

interview as basis for my interpretation, by which I will try to draw conclusions that may be applicable for HCPs in general as a relevant social group.

One more group that is not included in this research in terms of empirical data is the Danske Regioner – representing the governmental health authorities, but I will try to make references to this group as it plays a vital role together with the above mentioned groups to shape the technology in healthcare settings.

Interpretative flexibility: the meanings, judgments and opinions the groups attribute to the technology

Looking at the overall results of the survey and interview, I decided to divide the attribution of meanings, judgments, and opinions to the technology as consensus and controversies, where I found it possible. The same was done in the MAST model for the survey. Thereafter, I divided consensus and controversies into successes and failures to better identify these with SCOT's concepts.

Users', HCPs', and health authorities' perceptions of the technology

Both users and HCPs have accepted and seem to be satisfied with the technology in general, despite the recognition of failures that need repair. These failures can be related to features and tools that might not be embedded in their devices or apps and/or lack of interest in some aspects of the technology that can be due to lack of integration with other devices and systems.

The open-ended questions in the survey show the overall users' meanings and judgements about positive and negative aspects of the smartphone app technology. When prompted with the question of the types of apps they use, 26 different types were listed. I consider it a successful factor as evidence that users are interested in the technology, though most users apply more than one app to complement each other.

"*… Pictures of food, easy to use, god speed, text-info, nutritional information, calculation of insulin doses, carbohydrate intake, data gathered in one place for later analysis and overview, calculation of amount of carbohydrates in the products, ideas for portion size, shows how long you spend on physical activities, how many calories you burn, it stores your routes so you can compete with yourself, you can see other paths and routes, can export all data to CSV format, interaction with other apps so you do not have to enter data - it happens automatically*."

In my interpretation, despite accept and adoption, users seem to attribute a meaning to the characteristics of the technology as a stand-alone technical artifact that needs to be combined with other artifacts due to lack of integration with other devices or systems. The technology seems to be unfinished. Here I focus on failures because it is where the technology might be considered unfinished, hence not yet stable. Below extracts from open-ended responses that support this argumentation:

"*... Ikke glad for: at appen ikke kan kommunikere med med insulinpumpen.*"

"*... At måleapparat ikke arbejder sammen med mobil/applikation.*"

"*... der mangler en masse fødevarer, ergo kan man ikke tjekke alt i app'en.*"

"*... At den ikke selv logger mit BG og Kulhydrat indtag når jeg taster dem ind i lommeregneren.*"

"*... Mangler dog flere fødevarer. Og andre apps på dansk.*"

"*... Måske mangelfuld på nogle områder sikkerheden.*"

"*... DÅRLIGT: / Nogen gange stopper app'en af sig selv og ens resultat ødelægges. Nogen gange er det grundet dårligt GPS signal andre gange??? I don't know :).*"

According to the concept of *symmetry* in SCOT, failures and successes have equal importance in analysis of technology development. In this sense, I interpret the users' perception of positive and negative aspects attributed to the smartphone app technology as symmetry. Successes contribute to acceptance and adoption of technology, as well as

failures contribute to improvements that call for solutions for the technology to be considered fully implemented and then obtain the status of *stable* or *closure*.

HCPs might share the same opinion as users with regards to successes and failures. In the interview, when asked about the risk of safety and security failures that can undermine the adoption of the technology in diabetes care and about the users' perceptions of these failures, the interviewed endocrinologist responded:

"I do not really think that it will undermine the adoption of technology – this kind of feedback from the users will only contribute to further improvement of the apps."

The general consensus about successes and failures:

Successes:

In the social-cultural aspects with regards to the patient-HCP relationship and the health problem, users are willing to involve their doctors in the remote monitoring and self-management of diabetes through use of the technology. They feel safe if recommended reliable apps by their doctors. The technology helps patients to change their perception of their illness and the importance of taking responsibility of their health condition. Users want to use the technology in conjunction with their doctors, meaning that the personal contact is not expected to be abolished. HCP engagement through guidance and feedback can improve the patient-HCP relationship and enhance motivation to behavior change. Though, no users know whether their HCPs are interested in digital contact, which can be due to lack of engagement or interest by the doctor.

When prompted with a question about his interest to patients' monitoring and self-management of diabetes, the endocrinologist responded:

"HCPs need to realize that patient-centered communication is important and need to modify their behavior towards this. Such changes take time."

The HCP also makes a positive reference to the patient-centered communication.

Contrary to the findings in scientifical articles about HCPs not being ready to empower patients and the users' perception as lack of interest by their doctors, it is proved to be the opposite. When asked about his meaning, the endocrinologist answers:

"In part, it is a management responsibility to allow HCPs to train in empowerment and understand the benefit of that – but in part it is also the responsibility of HCPs to show interest in development of their clinical and professional skills. If they do this, it may very well impact patients, in terms of improved satisfaction and confidence with the HCP."

I understand the 'management responsibility' term as a reference to organizational issues, which can mean time and resources to empower patients, but also the management's understanding of the benefits of empowerment and the support to the HCPs. This means that attributions to the technology can vary depending on the involved actors, their roles and tasks.

Until the smartphone app technology is not implemented in the conventional healthcare sector, it seems to be playing in favor of GPs, as they can interact with patients by use of the technology while keeping in control of the information.

Failures:

The meanings and judgments to the characteristics of the technology were expressed as such: the technology cannot synchronize with other devices and systems. There is not interest enough in using some types of features and tools. Users do not trust the technology fully; they would not trust a diagnosis made by a medical app.

When prompted with the problem of medical apps being downloaded without health professional guidance, the endocrinologist meaning is:

"Not yet a problem in our clinic. I think it is mainly a positive development, leading to more competent communication with the HCP."

In another question about his beliefs in the smartphone app technology as a potential tool to address the health problem, increasing the chances of the technology to be

implemented in healthcare sector as a telemedicine intervention, to which the endocrinologist responds:

"*Yes, I do. I recommend it to my patients*."

It reflects a *redefinition of the problem* by creating another problem that can be solved; the lack of available health professional guidance on apps stores can force patients to seek guidance with their doctors, which in turn will contribute to the patient-HCP relationship.

The general controversies about success and failures

Successes:

Users do not perceive the technology as a replacement for control visits to the doctor; they want a combination of personal and digital form of communication. Users' perception of security does not constitute a barrier for use of the technology, which I consider a success despite the controversy among the users: 50% of the respondents are not concerned about their security, while 38% are.

I asked the endocrinologist if he would believe that the technology can enhance remote monitoring and self-management of diabetes despite the issues related to safety, security and legal with the use of the technology:

"*Yes I do, anything that can make daily life easier has potential*."

The endocrinologist's meaning is congruent with the meaning of 50% of the respondents of the survey. For them, potential risks related to safety, security and legal aspects do not constitute motive enough to abandon the use of the technology to diabetes care. Though, not all users perceive it in the same way.

Failures:

Not all users find it relevant to send their measures to their doctors meaning that they do not agree to what extent they should involve their doctors in their diabetes control.

Not all users are interested in social media networking, especially on educational websites. Maybe due to the fact that diabetes type 2 is connected to life style; it can be too private to share with others. I asked the endocrinologist what the technology would represent in terms of his daily workflow if users started sending their data to his system:

"We already have patients sending mails with their glucose measurements, and it provides us with improved treatment options. Integrating an app in our system would improve this further."

Despite the technology not being able to integrate with the endocrinologist system, it seems that this problem was redefined by use of emails. This is a clear example of redefinition *of the problem* in response to what the technology is not yet able to solve. The problem itself is not solved, but perceived as such by the endocrinologist.

It also points to the fact that the technology is unfinished, as the users also perceive it when having to use more than one app. Having the clinical practice workflow in mind, implementation of new technologies, such as smartphone apps, can require collection and register of patient data, in this case, the need to transfer the information coming from the patient's app to the doctor's email system and from there to the clinical IT system or to the Sentinel database.

A different perspective to interpret the *redefinition of the problem* can be related to an alternative solution to the patient-centered healthcare. As in the 'digital health continuum' in the CpH model, data is collected from the citizens. By doing so, HCPs can collect health data coming from the patients' apps. This could be seen as a solution to the problem of data ownership as an instrument of control and without having to share the data with other health professionals.

Another argument that supports this interpretation is the fact that the smartphone app technology is not yet implemented in the healthcare sector as a telemedicine solution, but as pilot project. Any use outside this scope does not imply the responsibility of the GP to share information.

In SCOT, the technology itself is a construction of social groups. As it is today, the smartphone app technology seems to remain a stand-alone technical artifact. The consensus and controversies found in the analysis proof that relevant social groups with their similar or divergent perceptions of successes and failures shape the technology by practicing *interpretative flexibility*. As suggested in the endocrinologist statement above in receiving patient data from smartphone apps, it allows 'improved treatment options' that can lead to individualized care in opposition to or as an alternative solution to the patient-centered healthcare.

In one hand, in the conventional healthcare, health data must be standardized in order to be distributed across the health sector. On the other hand, patients are different with regards to their disease and context; this opens an opportunity to tailor remote and self-management of diabetic patients. The patient-centered care is in conflict with the tailored-care and it is a *controversy* that reflects the ongoing conflicts between GPs and Danske Regioner.

Another interesting finding is the users' lack of interest when prompted with reminders. I interpret this as what I have seen in scientifical literature as 'one-size-does-not-fit-all' with regards to apps' features and tools, meaning that users have different preferences. Seeing the app technology as it is developed until now (not with the intention of a linear development view), there is room for improvement toward an individualized design, where users can adapt to according to their personal preferences.

Young people might have different perceptions and preferences of the technology, and so adults and elderly people. The latter deserves special attention because most of the chronic ill patients are old of age. This group of people would need an app interface that is compliant to their needs, for instance, in the case of eye complications the icons must be large and the navigation easy. Other issue that might be considered is the language of the app, as pointed in the open-ended questions; the desire for more apps in Danish.

This could lead to a *redefinition of the problem*, defined in SCOT as a change in focus by the creation of a new problem. A redefinition of the problem does not mean that the problem is solved, but perceived by the actors as such. In this case, the technology gets the status of *rhetorical closure*.

The app technology is still a new phenomenon and more and more new apps are being developed and made available in apps stores. The chances for rhetorical closure are big, though; there will always be new relevant social groups that will practice *interpretative flexibility*, which calls for solutions for *stability* and *closure*. It is a cyclical process in the social construction of technology, as showed in table 3.

The technological frame: the context of the problem

According to SCOT, the technological frame is a set of elements that together influence relevant social groups' attribution of meaning to technical artifacts and this is what leads to construction of technology.

As described before, the context of the problem in this research is within the scope of ethics, legal, healthcare organizations and the smartphone app technology. As per SCOT's definition, the technology has a place for itself; it is the object of the study within a context. In this sense, the technology cannot be assessed alone, it is there to be used by relevant social groups in a given context and it is this interaction that promotes the social construction of technology. Besides that, empirical data alone cannot contribute to the construction of technology; data must be embedded in a context.

Ethics and empowerment

In the section 'context of the problem' I discussed ethical dilemmas that can occur in the interaction between patients and HCPs, and the term empowerment. In my interpretation of the survey analysis, despite the interest of the majority of the users to engage their HCPs in their monitoring and self-management of the disease, there is still a divergent opinion on what extent their HCPs should be involved or even involved. From the clinical side, as showed in the literature review, not all HCPs are ready to work in cooperation with patients; they question at what extent patients may have autonomy.

Though, I can discard the user's assumption that HCPs are not interested in interacting with their patients by use of technology. I am aware that it might not be representative for the entire groups of HCPs, but at least it is evidence based on the empirical data in this research.

If I had to make any conclusions about the HCPs' accept of the smartphone technology based on my literature review, I would have stated that HCPs would reject the technology as they would need to consider a change in their workflow in terms of time and resources to empower their patients. I can partially discard this conclusion, based on my empirical data, using the same argument as before about empowerment, provided by the interviewed HCP:

"In part, it is a management responsibility to allow HCPs to train in empowerment and understand the benefit of that – but in part it is also the responsibility of HCPs to show interest in development of their clinical and professional skills…."

Some of survey responses related to smartphone apps' features and tools point to certain lack of interest by users, to which a possible interpretation could be lack of integration of features and tools in one device and integration with educational websites and with the doctor's system. If the app technology does not comply with the users' desires to enhance empowerment, there will still be much *interpretative flexibility*.

Legal

The legal aspects comprehend safety and security. There is no proof of reliability and accuracy of the medical apps available on the market, as showed in literature review. Despite the majority of the users in the survey have responded that they would trust the technology even if there was a technical malfunctioning, the effects of relying on information generated from a smartphone app are still unknown. To date, there is no clinical evidence or assessments of potential danger that medical apps can cause to human beings, which can be due to the smartphone app technology being considered a stand-alone technical artifact applied by users with no guidance and no interaction with clinical IT systems.

The lack of safety and quality parameters and the lack of the involvement of medical professionals can represent both; barriers and possibilities for health professionals to influence development and design of medical apps.

The HCP's meaning is congruent with the findings in literature review, though he does not mention the health professional involvement in the development and design of safe and reliable medical apps:

"Apps must be developed by trustworthy and quality assured companies. Maybe some sort of certification would help."

When it comes to the pervasive nature of the smartphone app technology, it is a barrier itself that impacts users and collides directly with the security requirements necessary in clinical settings in healthcare sector.

As showed in the section 'regulation', there is a series of ongoing initiatives at international and national level to protect personal data for both; individuals and healthcare organizations. Rules are being drafted or already effective in order to regulate standards for the use of smart devices and apps, and to define requirements to protection of personal data. These points to several aspects of the cloud computing that have probably been object of *interpretative flexibility* among the involved relevant social groups working on regulations. The result of their interpretative flexibility might have led to the draft of the law; i.e. the *solution* to the problem and hence the possibility of the technology to get the status of stable and then of closure.

As these rules already became or are about to become effective, chances are big for relevant social groups to perceive the *problem solved,* due to the fact that there will be legal consequences if no compliance. Developers and owners of apps, manufacturers of Operating Systems and smart devices, app stores and any other third parties involved will be legally binding. And so will be HCPs with regards to their IT systems that must be compliant to the Danish law '*Bekendtgørelse om standarder for it-anvendelsen i sundhedsvæsenet*' (48).

Smartphones operates in cloud environment, this will keep politicians, health authorities, developers and designers busy trying to keep in track of any potential security risks that can lead to breach of confidentiality of personal data.

Healthcare organizations

The pressures for new intervention methods to deal with the increasing number of chronic ill patients and the response by the Danish health authorities to a patient-centered healthcare pose enormous challenges to healthcare organizations. Along with that, the advent of the smartphone app technology and the users' expectations to interact with their HCPs can mean an additional problem to the clinicians' workflow.

When asked on whether HCPs are interested in being the gatekeepers of information coming from the patients' apps and if they would make resistance to that, the interviewed HCP answered:

"There is always some resistance to change – but I also think there would be a lot of interest in such a new app. Depending on HCP personality."

I interpret it as the HCPs readiness to emerging technologies and to the challenges technology can pose to their workflow, but the benefits seem to be more interesting. The interviewee is a junior doctor. He showed much interest in the topics of the interview, which made me to think that young doctors are more open for new technologies. The doctor students of today represent the generation that live with the smartphone app technology in their everyday lives. They can be those that will play an important role and will have influence on implementation of new technologies in the 'tomorrow's healthcare'.

Along with changes in the clinicians' workflow, information produced by medical apps is not standardized as it is in the conventional healthcare. The work of data collection, distribution and coordination could mean a burden to the HCPs' workflow. Though, it is still unknown with regards to the smartphone app technology in clinical settings. The Shared Care Platform and the projects derived from the KL's telehealth strategy will provide new learning experiences about use of technology in healthcare.

Initiatives like the KL's telehealth show a *redefinition of the problem* as a way to provide *solutions* to the part of the healthcare the actors in the municipalities are in charge of. Though, this kind of redefinition may be in conflict with the coordination of the patient-centered care among other relevant social groups, as pointed in the KORA's report.

Looking at the ongoing conflicts between the government through the Danske Regioner and the GPs, there are many divergences among these groups. The most controversial points, according to these parties, are as follows: (53,73)

- GP – Danske Regioner will take control of the medical work in general practice
- Danske Regioner – There is no intention to take over control of the GPs work

- GP – The regions and municipalities will determine the relationship between GPs and patients
- Danske Regioner – GPs cannot determine how often they will be available for patients and they must provide core services such as consultation, treatment, home visits for their patients.

- GP – The new requirements for registration and documentation will be time-consuming and increase bureaucracy. GPs will have no influence.
- Danske Regioner – It will be a requirement for the individual practitioner to keep their knowledge updated and treat patients in accordance with updated knowledge and professional guidelines, especially for groups of patients with heart disease, diabetes, COPD, asthma or cancer. This is to ensure a consistent high quality, systematic follow-up and coherent patient treatment.

I will make a reference to the MAST model as inspiration to analyse the controversies among Danske Regioner and GPs. In MAST, the organizational aspects are evaluated through the following questions:

Does the technology require a new organization of the treatment? Does the implementation of the solution mean changes in the organization and between

organizations (process, structure, culture and management?) What is the staff meaning about these changes?

Both parties have controversial meanings concerning the coordination of the patient care. A patient-centered care, as proposed by the Danish health authorities, implies new ways of patient treatment and distribution of health data through standards for chronic ill patients, as seen before with the MedCom project 'Common Chronic Data'. This means that many HCPs from different instances in the healthcare will be involved at a certain point in the patient care.

A solution to the patient-centered care is use of technology, mainly within telemedicine, by which several actors will need to coordinate their work. The introduction of technology implies changes for the HCPs' workflow and may impact their IT systems directly in the case of GPs. This poses challenges to coordination and distribution of data among actors and systems and might generate frustrations with the technology.

As the first-point of access to healthcare, GPs have the control of patient data at that point of care and they may not be willing to share this information with other actors or relevant social groups in the healthcare sector. Another way of looking to the problem is the burden to the HCPs in order to keep their IT systems in compliance with the requirements of the coming NSI's reference-architecture and standards architecture for the healthcare sector.

The attribution of meanings judgments and opinions among actors or relevant social groups in healthcare sector may impact technology in different ways. As seen in Ballegaard et al ((54) p. 60), the patient-centered care seems to lead to tensions and uncertainties in the relationship among relevant social groups: HCPs from hospitals (doctors, specialists and nurses), HCPs from municipalities (physiotherapists, home nurses) and GPs. These groups are still discussing their roles and their responsibility with regards to communication, coordination and distribution of work with the use of technology in remote monitoring of patient care. Some of these relevant social groups

have also strong divergences with health authorities in relation to their clinical work, as seen in the conflict between GPs and Danske Regioner.

12. Conclusion

Conclusion of the SCOT analysis

In the survey results, I identify that there is no general consensus about all topics, but rather a division of opinions that all together ends up in a controversy. The consensus itself is not enough to consider the smartphone app technology stable because the aspects examined in the survey constitute parts of the technology, not the technology as a whole. The actors in the relevant social group of diabetic patients have still divergent meanings about similar and different parts of the technology. If there was either a general consensus about all topics or a general controversy about all topics, then the relevant social group would have reached a consensus. Though as showed in the analysis, the meanings, judgments and opinions in the relevant social group of users are divided.

Then, I conclude that it is more appropriate to consider the overall analysis as a *controversy* among the relevant social group of users, which is in SCOT is referred as *interpretative flexibility.* Though, when comparing both groups: the relevant social group of users and the relevant social group of HCPs, I identify the HCP's meanings in the interview congruent with the users' expectations.

Controversies are alternative interpretations that actors and relevant social groups use to the social construction of technology. Controversies lead to insights to possibilities that can solve the problem. The different points of view can provide feedback to a better design, improvement of features and tools, and the use of the technology to a different purpose than the one in current use. In order to be fully accepted and used as a telemedicine solution in the healthcare sector in Denmark, the needs and desires of users and healthcare professionals must be taken into consideration.

According to SCOT, only when the controversies among actors in a relevant social group or among relevant social groups cease, the technology is considered stable and gets the status of closure. The interpretative flexibility will be followed by stability or closure, if and when the controversies no longer take place.

Looking at the experiences from the three hospitals reported by Ballegaard, in the KORA report, and at the ongoing conflict between GPs and Danske Regioner, relevant social groups have still many different perceptions and solutions to the problem – the patient care by use of technology. As long as these controversies are still taking place, the technology can be considered neither stable nor get the status of closure.

Conclusion of the research question

In order to be able to answer the research question, I reviewed my empirical data (survey and interview) in relation to the three sub-questions analyzed through the MAST model and SCOT theory to cover existent issues related to the smartphone app technology in diabetes control. From this, I conclude on my research question, which is as follows:

How are users applying smartphone apps for remote monitoring and self-management of diabetes in Denmark?

- A study of users' perceptions and preferences of apps for diabetes to examine whether apps can enhance adherence to remote monitoring and self-management of diabetes, hence change behavior.

I had a hypothesis that users are already applying smartphone health apps in Denmark, though I need to confirm or discard it, which I did through the survey.

- How are users applying apps in conjunction to monitoring and self-management of diabetes?

The survey results confirm my hypothesis and answer the first sub-question. Users in Denmark are applying smartphone health apps to the monitoring and self-management of diabetes. They apply different apps and use them for different purposes in their diabetes control, though most of the users use it for carbohydrate measures, which is one of the indicators of diabetes control related to food intake.

- What are users' perceptions and preferences of smartphones apps for diabetes?

The general perception is very positive, both users and the interviewed HCP have adopted and accepted the technology. It indicates that users have incorporated the technology into their daily life. The mobility that smartphone app technology provides seems to be congruent with the users' life context.

Users are both satisfied with some of the technology's features and tools and they expect to be able to engage their doctors in their diabetes control through use of the technology. Most of the users prefer a combination of both: the use of the technology and personal contact with their doctors. Safety and security do not prevent users and the HCP to use the technology.

On the other side, many users pointed to a series of negative aspects which the technology does not address. These are lack of integration with other devices, hereby the BG meter, with the doctor's IT system, and with websites. The lack of synchronization causes the users to have to apply more than one app, which in turn seems to give them the impression that the technology is unfinished as a stand-alone artifact, as they prefer 'all-in-one-place'.

Not all users are glad for alert functions that could prompt them with reminders to medication or food intake or anything else. It reveals the need for certain degree of autonomy in the diabetes control and for more individualized options, as users are different as persons and patients. HCPs may share the same perception; in the interaction with the patient, they can provide improved treatments to each individual

according to the health condition or disease, age and socio-cultural context. The users' needs and desires point to improvements to the development and design of smartphone apps.

- Can the smartphone app technology be used as a tool to enhance adherence to remote monitoring and self-management of diabetes and hence behaviour change?

Both users and the HCP seem to be confident with the technology and they believe that it can be used as a tool to enhance diabetes control. Users feel motivate and therefore they believe that with their doctor's engagement, they could change or improve their life style or health condition. Despite their beliefs, users would not trust the technology when it comes to diagnosis of health conditions generated from apps. Nor they believe that the technology is a replacement for the doctor.

I conclude that the smartphone app technology can enhance adherence to remote monitoring and self-management of diabetes, and that the technology can promote behaviour change, as long as the HCP is engaged in the diabetes control through use of the technology and by personal contact, and given the following observations:

1. The technology is applied informally by users without HCP involvement. It is not formally implemented in the healthcare sector yet, only through pilot projects. In order to ensure enhancement of adherence to diabetes control, there is a need to develop a model for treatment or a program where patients and HCP can interact mediated by technology, so that none of the parts are left alone, but rather integrated with each other.

2. The technology must address technical aspects such lack of integration and synchronization with other devices and systems in order to enable mediation between patients and HCPC for the monitoring and enhancement of diabetes control, instead of being a stand-alone artifact.

3. There is a need for implementation of behaviour theory constructs in the development and design of smartphone apps. Without this, features and tools will neither address nor enable assessments on important aspects that promote behaviour change and adherence to diabetes control, such as goal setting, feedback, social networking, and reminders.

4. Different groups of HCPs may perceive the technology in different ways and not all may consider it in consistency with their workflows and with the interactions among the different actors in the healthcare sector. Therefore, the technology can be considered inappropriate to enhancement of remote diabetes control.

According to Jacobsen and Thorsvik, technology changes faster than organizations.(74) In this sense, the smartphone app technology can achieve some of the required and expected changes showed in this research and make them outdated; i.e. solved or perceived as such, while organizational changes take much longer.

13. Discussions

About use of theory

SCOT analysis proved to be suitable to indentify the different interpretations of relevant social groups about the smartphone app technology to diabetes care. It has also helped to evaluate the status of the technology in terms of its technical characteristics and in relation to the technological framework, where several aspects are set in context. In this sense, the theory served its purpose. With SCOT, I was able to cover all important aspects raised in the context, enabling me to answer my research question.

I had no intention to refer to any organizational theories; my focus was primarily on users not organizations. Though, I learned later, in the analysis of aspects related to technological and organizational changes, that SCOT does not address enough how organizational aspects affect the relevant social groups of healthcare professionals.

Instead, to cover the aspects not found in SCOT, I decided to get knowledge of organizational issues by referring to the KORA's report. This was not intended to be a replacement of any theory, but rather as a complementary approach to understand how different relevant social groups shape technology and decide who will use it and who will avoid it.

I made also a short reference to the role of healthcare professionals as 'primadonnas', in the attempt to predict how these professionals can react to technological changes in healthcare organizations.

What I could have done differently

After literature review, I knew from the beginning which the main aspects related to the topic would be; this facilitated the setup of the context of the problem by themes. Later in the process, I found the MAST model, but late enough that I could not manage to set up the survey with the same structure of themes. The survey was already done and launched. I had a clear intention of what I wanted to ask the users and had even a structure; though it was not organized in the same way as in MAST, which I would use to the analysis. It resulted in a lot of work and time spent on it.

I would like to have had the opportunity to interview at least two HCPs; a specialist, which I succeeded in the last moment, and then a general practitioner, which was not possible. I believe that general practitioner's perspective would enrich this research, mainly because they have a central role in the care of chronic ill patients. This is a gap that I unfortunately could not cover.

Another gap was the impossibility to interview at least one patient. This would have given different insights to the survey findings that I could confirm or discard. I am aware of it, but was limited by time and resources to do so.

I could have applied organizational theories like Mintzberg to understand the complexity of healthcare organizations as professional bureaucracies and the conflicts and negotiations among the actors. This would have helped to understand better how healthcare professionals would react to the smartphone app technology in clinical settings and the attribution of meanings that would come up from experienced and young doctors. I found it difficult to relate theoretical knowledge to practical experience within healthcare. If I have had more time to write this project, I would have used Mintzberg.

One last theory I was very interested in is behavioural theory. I had no intention of exploring a psychological side of the problem; but the theory is definitely important to understand how motivation is created through the many actions individuals take in the remote and self-management of diabetes with the use of features and tools in the smartphone app technology.

About methods and bias

Generalizability

The research methods used, despite valuable findings, do not give basis for firm conclusions that can be generalized to the entire population of diabetic patients in Denmark. The same applies to the HCPs with regards to the interview findings. The main challenge I have learned is that methods such as survey and interview required a reasonable time frame that allows finding the right respondents.

I mean I found the right respondents to the survey, though the number of respondents is not representative, which limits the possibility to apply the knowledge I learned through the findings to a broader population. One problem connected to the online survey and to the written interview compared to personal data collection is the limitation of the researcher to judge the quality of the responses.

The MAST model focuses on decision makers, developers and designers of telemedicine solutions. If organizational aspects were treated in depth, there would be more valuable evaluations and learning from pilot experiences that could contribute to understand how technology affects organization and how the involved actors perceive and shape technology. Leaving these aspects untreated can lead to a technology that might not be used or only partially used.

Validity

I validate the survey findings with the interview by doing triangulation of methods. The same was done when using the MAST model to analyse the survey results, as the MAST is a qualitative method. Triangulation is the most important way to validate qualitative researches. ((75) p. 49)

I would have obtained a more consistent validity if I could have had the chance to interview one of the respondents of the survey and one general practitioner. This would allow me to draw more valid conclusions as a complement and support to the findings.

According to Alston et al ((76) p. 47), the best way of ensuring validity is to check and ensure that you are measuring what you intended to measure or evaluate. Are there any validity, then you can draw valid conclusions. In this sense, my conclusions are valid.

External validity

Looking at the survey, I made an attempt to obtain external validity by selecting a group of people that could represent an entire population. The results do not give arguments to claim that they are representative for an entire population due to the low number of responses.

Internal validity

I obtained a high internal validity in the survey, as I had an hypothesis to the research questions that users in Denmark are applying smartphone health apps to diabetes control. This was confirmed in the results. I do not consider any bias in the survey and in the interview, as I had no contact with the respondents other than introducing myself.

One bias that might have happened is my own interpretation and analysis of the results. As this research is based on a hermeneutical-phenomenological paradigm, in my attempt to understand, interpret and explain the users' subjective meanings about the technologic, I tried to be as neutral as possible, though I cannot guarantee a completely neutrality when analyzing the results.

In a study where you can explain the findings through hypothesis, it will provide internal validity. In a high internal validity, it is important to have a good control of possible bias. ((76) p. 79)

Reliability

I am confident that the same result could be found if the survey was launched to the same population and with the same premises and basis. Reliability is present when you get the same result in an identical environment, when a measurement or test shall be repeated on the same premise and basis. ((76)) p. 80). Though, with regards to the interview, I

assume there would be a low reliability as I interviewed one single person who gave his personal meaning about the topics he was asked about. Interviewing another person with the same profession and in the same environment is not enough to add reliability to this research. People are different and have different meanings.

14. Perspective

This research points to some aspects of the technology that needs further investigation and discussion. One of those is a model for the smartphone app technology to be deployed in clinical settings. The Shared Care Platform project will provide new experience on both the model used for telemedicine through smartphone technology and on HCPs perspectives to the patient-centered care. An evaluation of the project can result in fruitful discussions about interaction among HCPs by use of technology in contrast with the experiences reported in KORA.

Similar evaluation can be done on the basis of the projects derived from the KL's telehealth strategy which can be compared to both the Shared Care Platform and KORA. In this sense, there will be possibilities to see whether and how patients and HCPs perceive the technology and the coordination of the patient-centered care, and whether they change their perceptions.

The Shared Care Platform will also provide knowledge about how ethical, safety and security issues will be handled in regards to introduction of smartphone apps in telemedicine programs.

Another possibility with upcoming projects involving actors across the health sector is to see how apps used in telemedicine intervention programmes in Denmark are behaviour-theory constructed in order to evaluate not only the technology, but whether and how it addresses motivational tools that can enhance behaviour change. This could provide valuable lessons on how to design mobile interventions in clinical settings.

15. List of tables

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APPLIED REFERENCE SYSTEM: VANCOUVER

17. Appendices

Appendix 1 – Survey layout launched on facebook

Introduktion

Mobile Health (mHealth): Brugerundersøgelse af sundheds-apps (applikationer) til smartphones for monitorering og kontrol af diabetes.

Flere og flere forbrugere downloader sundheds-apps til egen monitorering og kontrol af helbredstilstand eller kronisk sygdom, såsom diabetes. Der er en enorm mængde af sundhedsmæssige apps tilgængelige i apps stores (Apple, Android, Windows). Dette kan gøre det ganske vanskeligt at træffe en beslutning. Ifølge videnskabelig litteratur er det stadig lidt der kendes til om, hvordan forbrugerne anvender deres sundheds-apps i dag.

Jeg er master studerende i Sundhedsinformatik på Aalborg Universitet og vil gerne lære mere om forbrugernes anvendelse af og opfattelser om sundheds- apps til monitorering og kontrol af diabetes. Undersøgelsen er 100% anonym.

BEMÆRK, VENLIGST, AT denne undersøgelse er begrænset til alle der anvender sundheds- apps til smartphones for diabetes (type 1, 2 eller prædiabetes). Den dækker hverken mobiltelefoner uden integration til internettet eller iPad.

Det tager ca. 5-8 min at besvare på spørsmålene!

1. Hvor gammel er du?

(Angiv kun ét svar)

18-30	31-40	41-50	51-60	61-70	71-80
❑	❑	❑	❑	❑	❑

2. Jeg er:

(Angiv kun ét svar)

Mand	Kvinde	Andet
❑	❑	❑

3. Du bruger din smartphone sundheds-app til måling eller kontrol af:

(Angiv gerne flere svar)

❑ Blodsukker (Blood Glucose - BG)

- ❑ Blodtryk control
- ❑ BMI (Body Mass Index)
- ❑ Insulin eller medicin indtag
- ❑ Kulhydrat
- ❑ Kolesterol
- ❑ Dagbog af medicin indtagelse
- ❑ Dagbog af hypoglykæmi
- ❑ Fysisk aktivitet
- ❑ Andet

4. Hvor ofte bruger du denne/disse?

(Angiv kun ét svar)

En gang dagligt	Flere gange dagligt	En gang imellem	ofte	Aldrig
❑	❑	❑	❑	❑

5. Hvilke slags sundheds-apps bruger du? Nævn, venglist, mindst én.

_ _

6. Nævn, venligst, én ting, som du er meget glad for i din app og én ting, som du ikke er særlig glad for.

_ _

7. Din app kan overføre data automatisk fra f. eks. et BG apparat til din smartphone sundheds- app, og det sker ved:

(Angiv gerne flere svar) (Vælg 1-2 svaralternativer)

- ❑ Sensor
- ❑ PDF eller Excel fil
- ❑ e-mail
- ❑ Alle af de ovennævnte
- ❑ Ingen af de ovennævnte

8. Kan du sende dine målinger fra din sundheds-app til din læges e-mail og diskutere dem med lægen derefter? (Angiv kun ét svar)

Ja	Nej	Ved ikke	Ikke relevant
❑	❑	❑	❑

9. Vil du føle dig tryg, hvis din læge kunne anbefale dig pålidelige og sikre sundheds-apps?

(Angiv kun ét svar)

Ja	Nej	Ved ikke	Ikke relevant
❑	❑	❑	❑

10. Kan din sundheds-app integrere med et websted eller sociale medier, hvor du kan lære mere om din helbredstilstand eller om diabetes?(Angiv kun ét svar)

Ja, og jeg bruger det	Ja, men jeg bruger det ikke	Nej, men jeg vil gerne det	Nej, jeg er ikke interesseret
❑	❑	❑	❑

11. Du overfører data fra et BG apparat til din sundheds-app. Det data vil generere din insulin dosering. Ville du føle dig tryg med app-teknologien, selvom der ikke er teknisk support, hvis der sker fejl? (Angiv kun ét svar)

Ja, jeg vil have tillid til teknologien alligevel.	Nej, jeg ville ikke stole på teknologien.	Ved ikke
❑	❑	❑

12. Du har målt dit blod sukker, BMI, og fødeindtagelse og sendt disse til din læge via e-mail i din app. E-mailen blev ikke leveret. Bliver du bekymret for sikkerheden mht. dine personlige oplysninger? (Angiv kun ét svar)

Ja	Nej	Min helbredstilstand er vigtigere.
❑	❑	❑

13. Foretrækker du digital (fjern) eller personlig kontakt med din læge til den daglige monitorering af din helbredstilstand eller sygdom? (Angiv kun ét svar)

Digital	Digital, men jeg ved ikke om min læge er interesseret	Personlig	En kombination af begge to
❑	❑	❑	❑

14. Du har sendt dine smartphone sundheds-apps målinger til lægen via e-mail. Ville du så gerne modtage en tilbagemelding om dit fremskridt? (Angiv kun ét svar)

Ja	Nej	Ikke relevant
❑	❑	❑

15. Du modtager en tilbagemelding fra din læge. Foretrækker du, at det er et personligt eller et automatisk svar? (Angiv kun ét svar)

Personligt	Automatisk (f. eks SMS)	En kombination af begge to	Ikke relevant
❑	❑	❑	❑

16. Tror du, at med lægens feedback og vejledning, du ville føle dig mere motiveret til at ændre eller forbedre din livsstil eller helbredstilstand? (Angiv kun ét svar)

Ja	Nej	Ved ikke
❑	❑	❑

17. Hvilken form for registrering af monitoreringen af din sygdom foretrækker du? (Angiv kun ét svar)

Digital dagbog	Papir dagbog	En kombination af begge to	Ingen
❑	❑	❑	❑

18. Er der en påmindelse (advarsel) service i din sundheds-app til at minde dig om, fx at måle dit blodsukker, blodtryk, medicin indtag eller andet? (Angiv kun ét svar)

Ja, det er der og jeg bruger det	Ja, men jeg bruger det ikke	Nej, men jeg ville gerne have det	Nej, og jeg er ikke interesseret
❑	❑	❑	❑

19. Mange sundheds-apps i dag kan diagnosticere en helbredstilstand eller sygdom. Vil du have tillid til en diagnose stillet af en smartphone sundheds-app? (Angiv kun ét svar)

Ja	Nej	Altid	Aldrig
❑	❑	❑	❑

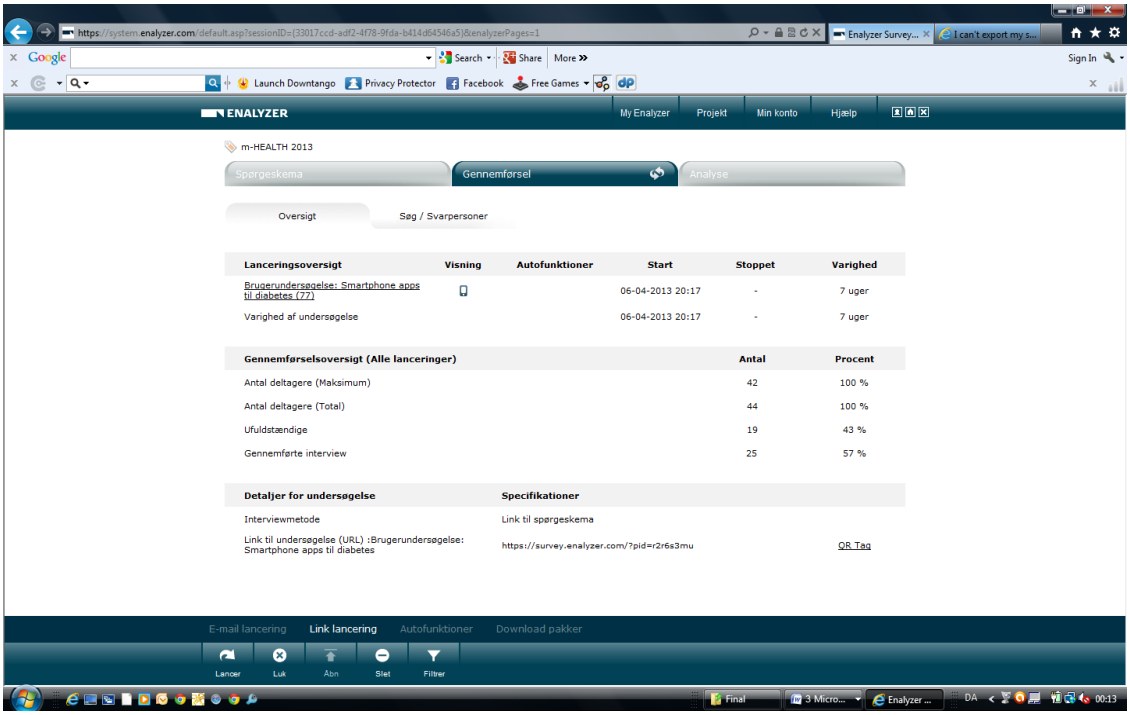
20. Tror du, at mange kontrolbesøg hos lægen i fremtiden vil blive erstattet af smartphone sundheds-apps? (Angiv kun ét svar)

Ja	Nej	Ved ikke	Aldrig
❑	❑	❑	❑

Tak for din besvarelse! Dit bidrag er af stor betydning for forskning i samspillet mellem mennesker og teknologi, specielt med hensyn til hvordan forbrugere anvender og opfatter sundheds applikationer til smartphones for monitorering af diabetes.

Husk at afslutte ved at trykke på knappen "AFSLUT" for at undersøgelsen bliver gennemført.

Appendix 2 – Launch and overall of completed and uncompleted responses.



Appendix 3 – Open-ended questions & answers

Hvilke slags sundheds-apps bruger du? Nævn, venglist, mindst én.

- Diabetesforeningens kulhydrat app
- Bruger ikke nogen overhoved ;-)
- Diabetes og kulhydrattælling
- Clucool
- Endomondo / OnTrack
- Diabetesforeningens Kylhydrat tælling
- Diabtesforeningens,Shape UP,samt andre
- Xxxxxxxxx
- Jeg har ingen smartphone. Og klarer mig fint uden. Både med hensyn til Diabetes og andet.
- diabetes foreningens kulhydrater
- endomondo
- ingen
- dbees, endomondo, madlog, fitbit, jefit, withings
- endomondo / myfitnesspal / fitness pro
- Fitbit / Withings
- Diabetesfoteningens kulhydratudregner
- App om kulhydratindhold og Endomondo
- Diabetes foreningens app til kulhydrat.
- kulhydrattælling
- kulhydrattælling
- emondo, dog ikke sunhed, / men måler mine aktivteter, så jeg kan ser / hvormeget jeg har lavet og styre blodskukker
- Diabetes Diary (iphone app)
- Rapidcalc og shapeup
- Diabetes foreningens app til kulhydrattælling (Andriod), Carbs & Cals

Nævn, venligst, én ting, som du er meget glad for i din app og én ting, som du ikke er særlig glad for.

- Glad for: billeder af fødevarer, som også giver et indtryk af kulhydrater baseret på størrelse af fx et stykke rugbrød. App'en er nem og hurtig / Ikke så glad for: der mangler en masse fødevarer, ergo kan man ikke tjekke alt i app'en
- Det ved jeg ikke
- Glad for kombinationen af billede+tekstinfo om næringsindhold, ikke glad for den relativt begrænsede mængde madvarer
- Udregning af insulindosis i forhold til mit nuværende BG, mit mål BG og mit indtag af kulhydrater. / / At den ikke selv logger mit BG og Kulhydrat indtag når jeg taster dem ind i lommeregneren.
- Det er dejligt at have data samlet til senere analyse og overblik. At måleapparat ikke arbejder sammen med mobil/applikation
- Beregner den rette insulinmængde.
- At jeg kan finde ud af hvor meget kulhydrat der er i produkterne. Negativt: At der er mange ting man ikke kan finde. En app der kunne beregne kulhydrat ud af opskrift.
- Xxxxxx / Xxxxxx
- Jeg har ingen smartphone. Og klarer mig fint uden. Både med hensyn til Diabetes og andet.
- Den er god i en smal vending giver en idé om portionsstørrelse på flere ting. Jeg mangler dog mange fødevarer i registteret derfor benytter jeg også Ernæring som er ligeså mangelfuld
- GODT: / Jeg synes det er fedt at man kan se hvor lang tid man bruger på sin aktivitet, hvor mange kalorier man forbrænder. Den gemmer ens ruter og så kan man konkurrere lidt med sine tider samt at man kan se andres stier og ruter. / / DÅRLIGT: / Nogen gange stopper app'en af sig selv og ens resultat ødelægges. Nogen gange er det grundet dårligt GPS signal andre gange??? I don't know :)
- nothing
- dbees: kan exportere alle data til csv format. Kan ikke markere sport som årsag til blodsukker måling.
- samspillet mellem endomondo og myfitnesspal, som gør man ikke skal indtaste data fra endomondo, men det sker automatisk. / / hvis mit blodsukker apparat kunne overføre målinger direkte til en app på telefonen, så jeg kunne få en komplet app til alt omkring diabetes behandling, så ville det være perfekt.
- Alt foregår automatisk - registrering af vægt, skridttæller, søvnmønster / Jeg bruger det fordi det giver mig overblik, uden jeg skal gøre noget / Savner flere funktioner når man nu alligevel har en monitor på sig
- Tilgængelig gratis for alle. / Ubrugelig.
- Vareudvalget er begrænset. Der fåes mange oplysninger om motion, ikke kun diabetesrelevante, men relevante for alle
- Glad for kulhydrat og kalorietabel. Mangler dog flere fødevarer. Og andre apps på dansk.
- Kun glæde da der både er en masse billedkort og mulighed for egne kort. / / Måske mangelfuld på nogle områder
- sikkerheden
- ingen tinge
- Historical data to see how much insulin I took when eating the same meal from a restaurant.
- I rapidcalc får jeg god diabetesdagbok / Skulle gjerne sett statistikk siste 7, siste 14 osv
- glad for : at jeg kan lægge andre levnedsmidler ind i databasen. / / Ikke glad for : at appen ikke kan kommunikere med med insulinpumpen

Appendix 4 – Interview

INTRODUCTION

This interview is based on a survey that I launched in April 2013 on facebook to different network of diabetic patients, such as Patienforeningen in Denmark, Hovedstadens Netværksgruppe for Voksne med Type 1 Diabetes, Diabetes Produkter Type 1 and Type 2, Diabetesforeningen, and local Diabetesforeningen in Odense and Fredensborg.

The objective of this interview is to learn how healthcare professionals perceive the smartphone app technology and their meanings, judgments and opinions about the use of apps to diabetes control.

ABOUT YOU:

Name:

[redacted]

Profession:

MD

Job title: Junior doctor

Please feel free to add any other information you find relevant.

Please note your name will be kept anonymous in the thesis paper and in any other place where I mention this interview. I will refer to you with a code such as I-1 (Interviewee 1).

GUIDANCE

The interview is divided into 4 themes. To each theme there is a short introduction in order to clarify the context of the questions and facilitate your understanding. The introduction is either based on the survey findings or on scientifical articles. There are 10 questions in total. **Please insert your answers just below each question.**

I appreciate your input!

Theme 1: Ethics and empowerment

Patient-Healthcare Professional (HCP) relationship

In my survey the majority of the respondents pointed out that they would like to involve their HCPs in their remote monitoring and self-management of diabetes. Despite the users' interest, they do not know whether their doctors are even interested.

Question 1 – Do you believe that with the HCP involvement, patients would feel more motivated to change their life style and enhance diabetes control?
ANSWER: Yes

Scientifical articles about empowerment and chronic illness have showed that while patients can be empowered to a greater autonomy, not all HCPs are ready to work in cooperation with them. In the survey, there is a controversy among the users about to what extent their HCPs must be involved in the control of the disease.

Question 2 – Do you see this as a problem? Please explain.
ANSWER: HCPs need to realize that patient-centered communication is important and need to modify their behavior towards this. Such changes take time.

Another scientifical articles point to a lack of consensus among HCPs about the meaning and scope of the term 'empowerment' in clinical practice. Furthermore, HCPs claim that they do not have time and resources to train themselves in empowerment and thereafter empower their patients.

Question 3 – How do you think it can impact patients in the remote monitoring and self-management of diabetes?
ANSWER: In part, it is a management responsibility to allow HCPs to train in empowerment and understand the benefit of that – but in part it is also the responsibility of HCPs to show interest in development of their clinical and professional skills. If they do this, it may very well impact patients, in terms of improved satisfaction and confidence with the HCP.

Theme 2: Organizational issues

When asked if they would like to share their measures from their apps with their HCPs, 75% of the users responded yes. In another question, about their preference of form of contact with the HCP, if digital or personal, 75% of the users responded a combination of both.

As decided by Danish health authorities, among others Sundhedsstyrelsen, all data related to chronic ill patients have to be coordinated among all the involved actors in the healthcare sector ('den sammenhængende patient forløb mellem almen praksis, kommuner, hospitaler').

Because of the way the smartphone app technology is developed until today, it is not possible to send any data directly to the HCP system; i.e. to the system you use in your clinic. Besides that, the data from an app does not live up to the Danish standards for communication within and across the healthcare sector; therefore it cannot be transported among the different actors.

Question 4 – Having this in mind, and taking your perspective as a HCP, if it was possible today for the users to send you their data produced by a smartphone app and discuss it with you, how do you think it would impact the your daily workflow?

ANSWER: We already have patients sending mails with their glucose measurements, and it provides us with improved treatment options. Integrating an app in our system would improve this further.

Question 5 – Do you think that HCPs in general would make any resistance in being the gatekeepers of the patients' app data coming into their systems? Please explain.
ANSWER: There is always some resistance to change – but I also think there would be a lot of interest in such a new app. Depending on HCP personality.
Theme 3: Safety, security, and legal aspects

According to scientifical articles, the smartphone app technology is considered a promising tool to enhance diabetes control due to its real time and context-sensitivity access to information. One can check and control the health condition anywhere, at any time. Though there are still many aspects to be solved before the technology could be safely implemented in healthcare sector.

Many of the issues are connected to the pervasive computing nature of smart devices and apps, which means that a smartphone can engage other devices and capture data, even personal data, which can be used for different purposes, without the users been aware of it. Other issues are connected to input generated from apps, which can be dangerous, such as insulin dosing. To date, there is no proof of reliability and accuracy of many medical apps available on the market.

Question 6 – Despite the challenges described above, do you believe that smartphone apps can enhance the remote monitoring and self-management of diabetes? Please explain why.
ANSWER: Yes I do, anything that can make daily life easier has potential.

Question 7 – Many users at global plan, but also in Denmark, are downloading medical apps and using them without any health professional guidance and assistance, and without knowing what to do with the data these smartphone apps produce. Do you consider it a problem? At what extension is it a problem?
ANSWER: Not yet a problem in our clinic. I think it is mainly a positive development, leading to more competent communication with the HCP.

When transferring data from a BG meter to an app and the app would suggest the insulin dosing, 50% of the users responded that they would trust the technology anyway, even knowing that there is no technical support in case of failures.

Question 8 – What is your opinion about that?
ANSWER: Apps must be developed by trustworthy and quality assured companies. Maybe some sort of certification would help

Theme 4: The smartphone app features and tools

When asked on their preferences about types of apps they use, the Diabetesforeningen's app 'Kuldhydrat' was the most mentioned among the respondents, followed by Endomondo. Another interesting revelation was about positive and negative things about the apps (all types) the users apply, the following was pointed out:

Positive: Pictures of food, text-info, speed, ideas for portion size, nutritional information, calculation of carbohydrates in the products, how many calories you burn, and data gathered in one place.

Negative: Lack of lots of pictures of food, so you cannot check everything in one app, lack of integration between the BG meter with the app, lack of calculation of carbohydrate out of recipes, lack of integration with other systems such as e-mail and educational websites. All these result in the need of more than one app, which is annoying for most of the users.

Given the above input from the users in the survey, the smartphone app seems to be a 'stand-alone' and the risk of an app being downloaded, used once and twice and then being forgotten is big. Another issue related to that, as showed in scientifical articles, is the lack of involvement of health professionals in development and design of medical apps.

Question 9 – Do you believe that the lack of features and tools and their integration with other systems can undermine the adoption of the technology as a potential tool to adherence to monitoring and self-management of diabetes? Please explain.
ANSWER: I do not really think that it will undermine the adoption of technology – this kind of feedback from the users will only contribute to further improvement of the apps.

Question 10 – Do you believe that with the HCP engagement it would increase the chances for the smartphone app to be implemented in healthcare in Denmark as a telemedicine intervention method to remote monitoring and self-management of diabetes?
ANSWER: Yes I do. I recommend it to my patients.

THANK YOU!

Thanks a lot for the time spent on this interview. Your input is highly appreciated!

Best regards,
Rejane P. De P. Nielsen

Appendix – 4 Interview 2

Konsulent - Consultant at MedCom

Region of Southern Denmark/MedCom
Forskerparken 10 - 5230 Odense M - Denmark

Fra: Rejane Pires De Pádua Nielsen
Sendt: 17. april 2013 08:21
Til: [redacted]
Emne: RE: Om Fælles Kroniker Data (KD) ver 0

Hej Rejane,

Jeg svarer nede i din mail☺

VH

[redacted]
Konsulent - Consultant

Fra: Rejane Pires De Pádua Nielsen
Sendt: 10. april 2013 11:16
Til: [redacted]
Emne: Om Fælles Kroniker Data (KD) ver 0

Kære Casper

Jeg er master studerende på Aalborg Universitet og vil benytte mig af muligheden for at stille dig et par spørgsmål om 'borger indtastning' i journalen via en dagbog. Jeg har læst lidt i jeres materielle og er lidt i tvivl om det drejer sig om E-journal eller P-journal der er talt om. Kan du forklare det?

Hej Rejane,
Du refererer for det første til fælles kroniker data version 0. Vi har publiceret en ny version 1, som du kan finde her: http://www.medcom.dk/dwn5528.
Borgerindtastning er i dette MedCom projekt rettet mod at borgerne kan indtaste egne data (fx omkring kontaktoplysninger såsom telefon eller mail, kontaktinfo på pårørende, eller information om deres personlige mål). Du kan se mere i bilag 3 i V1. Det er i projektet meningen at selve indtastningen foregår via sundhed.dk. Det er også på denne side at borgeren får adgang til visning af alle data fra FKD.

Jeg arbejder på mit afslutningsprojekt om sundhed-apps via smartphone til selv-monitorering af diabetes. Jeg har også læst en del om 'personal health records' (PHR) eller "den vandrede journal for kronikere", og det lyder som om, det er noget af den slags I arbejder på. D.v.s. at give borgerne adgang til deres journal således at de har delvis indflydelse på kontrol og monitorering af sygdommen.

Ja, og nej. Vi i MedCom står for at lave standarder for kommunikationen imellem sektorerne, der dermed kan sikre at data kan transporteres frit mellem parter som understøtter/lever op til vore standarder. Vi gør dog nogle ting som netop fremmer PHR tankegangen. Bl.a. kan borgeren jo via e-journal hente data fra sygehuse omkring egne behandlinger. Vi giver dog ingen borgere direkte adgang til egne journaler. Journalerne er i det danske tilfælde driftet af hospitalet (EPJ), kommunen (EOJ), eller egen læge (Praksis systemer), der via samarbejder med leverandørerne nogle gange arbejder med borger adgang. For eksempel er Region Syddanmark i øjeblikket i gang med deres shared care projekt, hvor en specifik borgervisning er en del af løsningen.

Hvis du skulle kigge frem i tiden, vil du kunne sige, at vi om nogle år, kunne forestille os, at borgerne vil kunne have adgang til deres journal via en applikation (app)? Jeg tager selvfølgelig højde for etik, lov, sikkerhed mht til teknikken og personlige oplysninger, m.v.

Ja, det er selvfølgelig målet. Jeg tror dog realistisk set at der går længere tid (+ 2-3 år) før sådan noget er i drift (det er endnu ikke engang normalt at få en sms med påmindelse omkring behandling – så en app kan have lange udsigter). Der er dog andre veje:

- Sundhed.dk arbejder så vidt jeg er orienteret på en mobil adgang, hvilket vil give borgere adgang til data ad den vej.
- Der kører af og til EU og nationale projekter med sådanne objectives – så derigennem kan man sikkert godt komme til at se projektløsninger.
- Shared Care projektet arbejder vist nok også med mobil adgang for borgere.

Med alle de store skridt I har taget og fortsætter med, er vi ikke ved at bevæge os stille og roligt i den vej, hvor vi er mere mobile og kræver mere og mere af sundhedsvæsnet og vil en dag forventer at kunne have adgang til vores sundhedsdata og indtaste data via en app?

Jo, helt sikkert. Kravene øges konstant – og folk vil da forvente at kunne gøre sådan noget. Der er desværre en række barrierer som gør udviklingen langsom – især i og med at vi har med utroligt følsom data at gøre – data som kan bruges i behandlingsmæssigt øjemed. Det er derfor utroligt vigtigt at ting bliver godt gennemarbejdet og testet kvalitetsmæssigt (fx på måleudstyrets kvalitet i hjemmet og sikkerheden i transmission af data). I forhold til at indtaste data, så findes der allerede en række hjemmemonitoreringsudstyr som kan bruges uden aktiv indtastning – men som i stedet sender data via bluetooth. Se eventuelt på KIH projektet, på DREAMING projektet eller andre hjemmemonitoreringsprojekter.

Jeg vil understrege, at mit studie har INTET med Novo Nordisk at gøre. Jeg stiller dig de spørgsmål som studerende, men også som borger. Jeg synes, at det er vildt imponerende, det der sker mht til teknologi her i landet.

Helt fint…☺ Min far arbejder i Novo, så jeg er bestemt ikke bekymret;)

På forhånd mange tak.

Hilsen
Rejane

Borger indtastning
Borgeren indtaster selv via internettet følgende data i kroniker platformen:
- ***Datasegment 3. Pårørendes navn, adresse og telefon***
- ***Datasegment 4. Borgerens samtykke til at give adgang til kommune, læge og sygehus***
- ***Datasegment 5. Borgerens dagbog med egne oplevelser med sygdommen***
- ***Datasegment 15. Borgerens personlige mål for den fremtidige rehabilitering***

Det er derfor nødvendigt at kronikerplatformen giver mulighed for at indtaste de nævnte oplysninger på en sikker internet side. Borgerens internetadgang kan gives centralt via sundhed.dk eller via webadgange til lokale/regionale EPJ og EOJ journalsystemer.