Technology Ready to be Launched, but is there a Payer? Challenges for Implemeting eHealth in Sweden

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Abstract. The development of a sustainable, high-quality, affordable health care is today a high priority for many actors in the society. This is to ensure that we will continue to afford to care for the growing portion of elderly in our population. One solution is to enable the individual's power over her own health or illness, and participation in her own care. There are evidently opportunities with the rapid development of eHealth and wearable sensors. Tracking and measuring vital data can help to keep people out of the hospital. Loads of data is generated to help us understand disease, to provide us with early diagnostics and warnings. It is providing us with possibilities to collect and capture the true health status of individuals. Successful technologies demonstrate savings, acceptance among users and improved access to healthcare. But there are also challenges. Implementing new technologies in health care is difficult. Researchers from around the world are reporting on similar problems, such as reimbursement, interoperability, usability and regulatory issues. This paper will discuss a few of these implementation challenges as well as a few of the efforts in meeting them. To conclude, eHealth solutions can contribute to patient empowerment and a sustainable health care. Our assumption is however, that as long as we do not face the implementation challenges and invest in overcoming the pressing obstacles, society will not be able, or willing, to pay for the solutions.

Keywords. Implementation, eHealth, patient empowerment, sustainable health care

Introduction

The second half of the last century presented an ageing population in Europe due to low levels of fertility and lower mortality rates among the elderly. By 2060, most of the countries are expected to have a proportion of oldest-old of more than 10%, as compared to the 1-2 % a hundred years ago [1].

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With that said, it is easy to grasp the great challenge that the global health care sector is facing over the coming three decades, with an increasing share of elderly having to be cared for by a decreasing number of producers [2]. Three-quarters of the European population live in countries with fertility below the replacement level [3]. The aging portion of the population has a growing need for health care and, simultaneously, the percentage of the population of working age (ages 15-64) is decreasing, thus reducing the ability to finance health care. In 2010, for every person aged 65 or older, there were about four persons of working age for each person of retirement age and above (ages 65+) but in 2050, the ratio is expected to be less than two to one.

In many countries worldwide, the growth in health care expenditure is exceeding the growth in GNP, a trend that obviously must be broken. At the same time, we have benefitted from promising advancements in diagnostic and therapeutic possibilities, but to an increased cost. As we see changes of the demographic landscape of countries worldwide with a subsequent increased pressure on healthcare and social services, the need to develop a sustainable, high-quality, affordable health care becomes crucial.

One opportunity to tune the direction of the development towards a sustainable, high-quality health care is to enable the individual's power over her own health or illness, and participation in her own care. As in other areas of our lives, technology plays an increasingly important part also in health and care aspects. It provides us with efficient, reliable tools for e.g. communication, transport and safety. Technological breakthroughs present tools for patient self-care and empowerment, and for efficient care routines. For the frail elderly or for people suffering from chronic conditions, medical technology and digital health can offer solutions for an independent and active life of high quality [4-6]. Patient- or caregiver-initiated development of mHealth solutions, such as online diaries, online software, etc., coupled with code-free development software platforms are creating an open and integrated market for, and reducing the cost for, novel mHealth tools [7].

Numerous declarations, agendas and plans from the European Commission from 2000 and onwards underscore how the rising demands for health care services can be met by harnessing the potential of Information and Communication Technology (ICT). The so-called Personal Health System is by Codagnone [8] and others mentioned as one of the main pillars of the eHealth policy and research agenda, as it envisions how ICT can be used in health care; offering continuous, quality controlled, and personalized health services to empowered individuals regardless of location. A Personal Health System can include a myriad of applications; wearables, biosensors, micro- and nano-systems, signal processing, feedback loops, etc. A Personal Health System may appear under many names, such as telemedicine, tele-health, home health monitoring, etc., but for the purpose of the present research project, the term eHealth system will be utilized.

The health care sector is shifting its' focus from disease management to that of health management. And eHealth solutions are assumed to be the tool that can enable "the shifting from the traditional hospital-centered and reactive health care delivery model toward a person-centered and preventive one" [9], i.e. a patient empowerment tool. Patients are monitored in the home setting and are communicating with their healthcare providers and the healthcare system as a whole in completely new ways.

In 2009, the Swedish Presidency of the EU presented a study by Gartner [10] from six EU member states on eHealth that demonstrated the significant potential for health

care improvement using eHealth as a catalyst. Additionally, levels of technical know-how among the population are growing overall and the potential for playing an active part in an on-going course of treatment or monitoring has increased. The data generated from health management can, together with Sweden's national quality registers and high quality bio-banks, present valuable sources in the big data revolution where the analysis of massive amounts of data that can help keep people healthy [11, 12]. The developer of these tools, the medical device R&D community, thus has a critical role in the generation of better health outcomes and value to patients and providers [5, 13].

Sweden has a proud tradition of developing innovative medical technology solutions: Swedish innovations such as the implantable pacemaker, stereotactic radiosurgery with the gamma knife, the use of ultrasound for medical diagnostics, the incubator and the first practical dialysis machine have all increased the ability for healthcare to save, prolong and improve the quality of life of many. The foundation behind these success stories has been a fruitful collaboration between academia, industry, the health care sector and patients, a collaboration that ensures a need-driven, patient-centered technology development as well as an up-to-date modern health care.

Swedish health care is facing something of a paradigm shift. There are many policy activities on an international level as well as on the national/regional levels to enable/facilitate safe and efficient tools for patients to take their care into their own hands or, at least, to partake in their own care. Examples are the revision of the medical device directives, new collaboration rules prescribing how publicly funded health care providers should relate to their suppliers, introduction of guidelines for development of software as medical devices, etc. A recent study on policy translation has highlighted the importance of taking into account the process of translating policy through the levels of the health care system [14].

All in all, the challenge for the future will be to enhance the possibilities for the patient's participation in their own care, to offer patient-centered care with individualized solutions that are "based on respect for every patient's self-determination and integrity in which the treatment, as far as possible, is planned and implemented in consultation with patients and their relatives" [15].

1. Implementation Challenges for eHealth Solutions in Swedish Health Care

Even if technological innovations in health care are viewed as tools to achieve patient empowerment and cost savings while improving patient care, the implementation of clinical research results is deficient [16, 17]. Implementation is defined here as the process where an activity or a program is put in practice [18]. It is estimated that it takes in general 17 years for new knowledge to be implemented [19]. The implementation will encounter obstacles related to the specific context of the health care system [16, 20], such as conservative mentality, organizational and professional resistance, innovation-unfriendly accounting systems, complex purchasing procedures, lack of motivation and of accountability. To address the gap between R&D and actual use in routine care, health care researchers have focused on the role of the practitioners [21], on clinical and organizational barriers [22], on economic barriers [23] and on the features of the innovation itself [24]. The importance of the surrounding society and the impact of economic, social and political variables have also been acknowledged [25].

The health care system is obviously complex, characterized by multifaceted and contrasting forces acting on many different levels, and different clinics exhibit local

variations in how they relate to new technical applications [26, 27]. This may unfortunately result in patients not receiving care that utilizes the technological solutions and innovations shown to be of value to them. The question the present paper wants to highlight is therefore:

Why are not eHealth technologies that, in a clinical testing situation enable patient empowerment, implemented in routine care?

This paper will discuss a few of the implementation challenges as well as a few of the efforts in meeting them. One assumption is that as long as we do not meet these challenges, society will not be able and/or willing to pay for the solutions. We have identified specific issues of importance to meet the challenges and these issues are listed below. Our list is not exhaustive, but rather selected from an industry perspective.

The issues are structured in a frame of critical topics provided by Schartinger et al [16]; namely *Social acceptance, Service System, Research and technological development of eHealth systems and Framework conditions* (see Table 1). Some of the specific issues may fit under more than one critical topic and the suggested division may be debated.

Table 1. Implementation issues discussed in the following sections.

Social acceptance	**Service systems**
• Users • Work processes	• Reimbursement models • Public Procurement
Research and technological development	**Framework conditions**
• Interoperability and standardization • Interpretation	• New competences/skills • Security and safety • Regulatory issues

1.1. Social Acceptance

The social acceptance of a new system is necessary for successful implementation. All stakeholders - patients, relatives, caregivers, payers, etc. - must see the benefit of the system. Even if levels of technical know-how among the population are growing overall, equity issues must be taken into account. The potential for playing an active part in an ongoing course of treatment or monitoring will only increase if the tool to do so suits the specific conditions of the user. Reflections on these user conditions, as well as on work processes and recipients are provided below.

1.1.1. Users

Numerous studies have shown that successful development of new products is highly dependent on a thorough understanding of customer needs, requirements and

preferences [28]. A study by Wadell [29] indicated that health care professionals are the chief external sources of innovation for medical technology companies. Meaningful use, or relative advantage, has shown to be the most important factor for the adoption of technology [24]. Thus, a healthy collaborative climate with patients and health care is essential in order to ensure the development of efficient and cost-efficient medical devices. Today, health care organizations have problems in even testing new technologies, as they cannot easily estimate the costs vs. benefits of possible necessary changes in work processes and methods or staff training. Also, the production and administration demands made on health care staff have increased with the consequence of fewer opportunities for participation in R&D projects with medical device companies. In an effort to mitigate this problem, new collaboration rules prescribing how publicly funded health care providers should relate to their suppliers was introduced in 2014 [30].

Furthermore, in a patient-centered care, the patient is expected to be involved in her own care process, which also means that the service provider is forced to deal with a more heterogeneous group of users, where everything from technical interest and family networks play into how services are received and perceived. Thus, caregivers and developers must have an understanding of the user. As a reflection on the apps produced today, J.C. Herz claimed in an issue of Wired that ”…young, healthy, highly educated, mostly male entrepreneurs are developing marginally useful apps and gadgets for people just like themselves” while it is actually people with two or more chronic diseases who make long-term commitment to measuring and tracking their health [31].

1.1.2. Work Processes

The introduction and integration of new medical technologies might necessitate new work processes, new infrastructures. In terms of eHealth solutions, the medical profession has often been somewhat resistant to the new technology, partially as a result of how technology shifts the power over the care process towards administrative staff and IT consultants [32]. In the case of much eHealth technology, more control shifts from health professionals to technology developers and technology platforms, and the knowledge of a patient's situation is spread out over several partners in the care process [33]. Regulatory arrangements designed to make health care more equitable and evidence-based, such as the national guidelines, also implies a shift of power over the care process from regional actors to more centralized functions of the health care system [34].

Nevertheless, a change in work routine within the health care sector may ultimately be necessary so as to reap the promised benefits from an innovative product and to create value for patients. A recent study by Schartinger et al [16] points to the need to understand the eHealth technologies as part of a service system where it is important to consider not only the specific ICT aspects, but also to understand how the technology fits into the care process and the organization as a whole.

1.2. Service Systems

Technology is today an integral part of both technical and organizational systems of patient care. Needless to say, the complexity of implementing eHealth systems requires

dialogues across the boundaries of not only medicine and technology, but also clinical practice, design and others.

The different stakeholders in the ecosystem of eHealth implementation are the health care sector, industry, the academic community, and administration and politics. These actors all need a tightened connection through effective meeting places and collaboration projects in order to grasp each other's goals, missions and challenges. As for health care, we need to for instance regard the boundaries between health care providers in the inpatient, outpatient and primary care. In addition, all stakeholders are strongly dependent on the existing reimbursement system and the public procurement process. Indeed, as for the industry actors, a study from Wadell [29] indicated that service public procurement and the reimbursement system were the most critical challenges that innovative medical device companies faced.

1.2.1. Reimbursement Models

eHealth solutions create favorable conditions to keep patients away from an expensive medical care. This implies, in the current system, a reduced income for the caregiver who will lose a care episode. Ultimately, this leads to a diminished incentive to implement a solution, which, at least in the short term, decreases revenues. We can of course assume the interests of society and the health care sector to be the same: a healthy population and the best possible care at a reasonable cost. Since the financing models of the health care sector do not seem to incentivize offering the best possible care for patients, we need alternative reimbursement models. Thus, new technologies that enable new processes in health care often also create a need for development of new business models as well as rethinking the existing models for reimbursement.

That said, the spring of 2014 was marked by the start of several pilot projects focusing on changing the reimbursement models in a number of different diagnostic areas, in some selected hospitals; models that are based on the patient value created [35]. *Sveus*, a national collaboration for value-based reimbursement in health care, are leading these pilots. A focus on a *Value Based Health Care* will help to keep a patient perspective in health care development and to clarify the relation between quality of patient care and cost efficiency for society. The overall goal in a Value based health care is to achieve high-quality health care and value for patients in a cost efficient manner.

Additionally, the Board for Pharmaceutical Benefits (TLV) was in 2012 commissioned by the Swedish Government to conduct health technology assessments of medical devices. The aim is to produce assessments to aid health care decision makers whether to introduce new methods and in procurement processes.

In the case of apps, alternative funding models may of course be emerging. It is of course possible that 1) the user (patient) pays for whatever app she feels is needed or 2) the insurance companies pays for gadgets that reduce their costs, 3) companies pay for gadgets that motivates a user to pay for related services and 4) the Government pays for scientifically proven methods and technologies that increase public health.

Investments in technology enabling more efficient and successful treatment, monitoring and diagnose will provide savings and benefits for the individual, society and the health care system as a whole, an initial investment has to be made and it may be some time before the potential benefits appear. This is why the implementation of Value-Based Health Care is crucial to ensure that investments in new health care solutions are based on the common interests of society and the health care sector. The

key word here is *Value*. When goods or services can demonstrate patient benefit then there will be an incentive to purchase. What is required is an open process based on common sense, validation and an evaluation of prioritized public health needs. When the economic interests of the individual and society are matched, it is reasonable to assume that the same will be true for the health care sector's priorities. Barriers to rational choices of a medical device include a lack of health economic consideration and insufficient product information.

1.2.2. Public Procurement

Procurement processes for innovations providing changes in health care is often long and expensive one for the companies involved. Clinicians taking part as experts in studies on new technologies or procurement committees are greatly needed and poorly rewarded. They play a crucial and yet unappreciated role in the process, often involving extra efforts on their spare time.

Public procurement in health care in Sweden is conducted by the municipalities, regions and county councils. Some research has questioned the public procurement system as a tool for innovation, but rather accused it to be an innovation obstacle [36]. Lately however, the public procurement directives for the public health care system are attaching greater importance to the function-oriented and innovation-friendly procurement procedures. A number of programs and pilot cases are carried out to gain experiences on how the procurement process should be designed for innovation promotion.

The possibility to conduct innovation procurement is still a largely unknown territory, but may provide opportunities for improved collaboration between the health care sector and the industry. This will be of utmost importance for patients and health care in order to be able to benefit from all the advantages of new technology - for patients and relatives to have access to the latest, most efficient medical devices.

1.3. Research and Technological Development of eHealth Systems

In order to counter a fragmented market we need international standards for interoperability. As in the telecom market, international standards will be the basis for a global distribution of products and services. International standards are also a condition for an open system in which suppliers in competition can offer patients and healthcare a variety of products and services.

Furthermore, the wealth of data collected in the eHealth era will have to be put to use. Data alone won't do it; in order to generate value this data must be analyzed and interpreted and, ultimately, translated into knowledge and action.

1.3.1. Interpretation

Drawing on Schartinger's [16] definition, we describe an eHealth system as consisting of parts performing the following steps:

Step 1. Acquiring, monitoring and communicating physiological and other health-related data by ambient, wearable or in-body devices

Step 2. Intelligent processing of the acquired information (i.e. data analytics)

Step 3. Coupling it with expert medical knowledge and, in some cases, knowledge of social circumstances and living conditions

Step 4. Actions based on the processing of acquired information

As to the amount of data that will be generated (step 1) and transmitted from a system, there has to be a recipient. This recipient must be able to interpret the data or information (step 2) received and somehow to act as a transmitter (step 3) to trigger some type of action (step 4). All these steps will involve various stakeholders with different responsibilities. Some questions are then:

Step 1: We need quality assurance of data - a scientific approach to the collected data. *Who is responsible for the data quality?*

Step 2: Data must be translated into relevant information. *Where is data interpreted and by whom?* There may be possibilities with e.g. automatic interpretation using artificial intelligence.

Step 3: How do we interpret data such as ECG signals collected around the clock? We need to validate and correlate to the medical community knowledge. *Who will receive the information sent from a device?*

Step 4: One conflict arises with the Quantified Self movement, when it interprets the statistics itself. We must do this in collaboration with health care. The gadgets may not be mature enough today to monitor our health or illness without the interaction with someone who can translate the data to relevant information. Misinterpretation of data can cause unnecessary stress and, consequently, unneeded care visits.

1.3.2. Interoperability and Standardization

An interesting finding by Seto et al. 2009 [37] was that, back then, most online market applications were based on manual entry of data such as blood glucose levels and weight, while 62% of the applications used wireless automatic data acquisition. Wireless sensors are now widely available, but proprietary rights and vendor restrictions hinder their use in some commercial markets. Manual data input not only exposes the user to erroneous input, but it can also be a daunting task and may lower compliance.

This is an example of how standardization issues hamper the development and implementation of useful eHealth tools for patients and caregivers. There are, however, many on-going standardization initiatives. Several of these focus on *syntactic* and *semantic* interoperability (such as USB, IEEE, HL7, etc.). *Pragmatic* interoperability is the ability for ICT systems to work across health care providers and systems and this is today a prioritized subject for us. Two significant interoperability efforts are the *Continua Alliance* and *Integrating the Healthcare Enterprise* (IHE). The work in *Continua* entails promoting interoperability for devices and systems close to the patient, such as in the home care setting, and assures that data is transmitted reliably. *IHE* is instead primarily health care focused and ensures interoperability in transmitting data to the electronic health system.

Currently there is a proposal from the three largest regions in Sweden, together with industry, to connect to the Continua and IHE, as our neighboring countries in Scandinavia already have done. In practice this could mean that public procurement requirements may require Continua- and IHE-certification from producers. Inera has

been developing the National Service Platform, a so-called Enterprise Service Bus, which will facilitate integration between systems and services. The service platform acts as a hub and routes messages to the correct health or social care providers.

Additionally, a Healthcare Innovation Platform (HIP), with the purpose to develop process-related e-health services for citizens through open innovation, was recently launched. The platform offers developers, designers, and entrepreneurs access to tools that simplify the development of eHealth services for healthcare and citizens. It provides instructions and complete code (APIs) that meet the legal requirements that is a prerequisite for developing services with patient data. The HIP thereby represents the foundation or starting point for developing new solutions for Swedish eHealth.

Initiatives like Continua, IHE, the National Service Platform, and HIP are all crucial links in the chain from concept to actual patient benefits of eHealth solutions.

1.4. Framework Conditions

As mentioned, the complexity of the eHealth systems required to create beneficial health care outcomes creates a need for meeting arenas crossing the boundaries of medicine, technology, clinical practice, design and others. However, it also requires new competences. These competencies will in turn need to have the knowledge and understanding of the regulatory frameworks in order to develop products and services that both benefit patients and protect patient privacy.

1.4.1. New Competences/Skills

Health care services will in the future most likely not be provided by exclusively traditional caregivers. Those who have an insight into the needs of the health care sector are not always aware or do not always have access to the latest technologies. Conversely, technical researchers often lack an insight into the health care sector's problems and user needs. Thus, there is a need for closer collaboration, largely due to the increasing requirement for clinical evaluation of new methods in order to secure the clinical evidence required. New technologies may demand a different skill set among health care providers and patients. One question is how these new competences will be reimbursed [16].

1.4.2. Security and Safety

Medical apps of high quality can facilitate patient empowerment and provide relief for health care. There are, however, examples of products that do not assume responsibility for e.g. incorrect or delayed diagnoses. Here, collaboration with clinicians is vital in order to produce reliable data, information and advice (cf. also "step 3" in section 1.3.1). Moreover, privacy protection must be integrated in the design of eHealth systems from the onset.

Moreover, the rapid development in the mHealth area has unfortunately resulted in incidents such as transmission of medical information over non-secure mobile devices. Here, the intricate regulatory aspects need to be considered.

1.4.3. Regulatory Issues

What are the regulatory pathways a new device must take in order to fully function in the health care landscape? This question is extremely important. The control

organizations and traditional caregiving bodies of today are changing – we must make room for new individuals and new companies. Innovators, patients and caregivers developing their own software, as well as big players such as Google, Spotify and Apple must all adopt new regulations.

There are several laws that are important for companies that develop and/or sell medical devices in Sweden. These laws are primarily laws governing medical technology, environmental issues, procurement issues and contractual issues and are based on EU directives. Increased regulatory requirements for medical devices increase not only the cost, but also the need for testing/evidence and collaboration between different actors. Requirements differ vastly between countries and software products are no longer exempted from regulatory compliance.

An important event during 2014 was the revision of the medical device directive (MDD). Swedish Medtech, together with the European industry association Eucomed, are working to create an understanding among decision-makers for what is needed to maintain an innovative medical device industry sector, while naturally maintaining patient safety.

Furthermore, there is a new international guidance for software used as medical device adopted by the International Medical Device Regulators Forum (IMDRF). The guidance is aimed at manufacturers, regulators and users in order to shed light on the medical/clinical risks and challenges associated with the use of software in different contexts. The document describes, in addition to a harmonized terminology, a methodology for how software products with medicinal purposes can be divided into categories based on the intended use. It also provides recommendations on the considerations that a manufacturer should do, e.g. in terms of product development, use, clinical evaluation, and information security.

2. Conclusion

When the entire industrialized world faces challenges of a growing portion of elderly in our population, implementing eHealth solutions may very well be the solution we are looking for that will allow patients to take control of their own health as well as to be connected to and have the support from health care when needed.

While there are tremendous opportunities with the rapid development of eHealth and wearable sensors, there are also challenges; implementing new technologies in health care is difficult. Researchers from around the world are reporting on similar problems, such as reimbursement, interoperability, usability and regulatory issues. The present paper discusses a few of these as well as some of the efforts in meeting them. For a successful implementation of new eHealth technologies in health care we need to regard the following:

- *Users.* Developers need to have a thorough understanding of the users. Young entrepreneurs are today developing gadgets for the elderly.
- *Work Processes.* New technologies may necessitate new ways of doings things in the health care setting.
- *Reimbursement Models.* Who will pay for new technology? Especially when that technology may lead to revenue loss for the actor investing in it. How do we pay for health instead of care?

- *Public Procurement.* How can the procurement process open up for innovations?
- *Interoperability and Standardization* are key for a future eHealth landscape…
- *Interpretation* of the loads of data generated. Who will interpret data into information and knowledge?
- *New Competences/Skills* may be necessary to be able to utilize all the new technology.
- *Security and Safety* for safe data transmission and for privacy issues must be prioritized early in the development of new eHealth solutions.
- *Regulatory Issues.* What are the regulatory pathways a new device must take in order to fully function in the health care landscape? How should directives and regulations be outlined to promote innovation and safeguard patient safety?

In addition, innovation must include organizational and process innovation in health care as well as in administration and political leadership. After inventing new gadgets, we have to change peoples' minds and behavior. And that is harder.

In conclusion, eHealth solutions will contribute to patient empowerment and a sustainable health care. However, as long as we do not face the implementation challenges and invest in overcoming the pressing obstacles, society will not be able, or willing, to pay for the solutions.

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