Design of an Internet-Based Disease Management System for Chronic Heart Failure

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CHALMERS UNIVERSITY OF TECHNOLOGY
Göteborg, Sweden
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by

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Front cover: Schematic image of the system overview. Further information can be found in chapter 3.
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I may not have gone where I intended to go, but I think I have ended up where I intended to be.

–Douglas Adams

To
Abstract

Chronic diseases are one of the most challenging health problems in the world, and their burden on society is increasing. Managing these diseases using eHealth solutions could prove very beneficial, both in terms of economic costs and quality of life for patients. However, reaching these goals require knowledge in how to create distributed disease management systems for chronic diseases.

In the project Care@Distance the aim is to acquire knowledge on how to use eHealth in order to improve treatment compliance in chronic diseases, improve possibilities for personalized care, alert about deteriorating health on an individual patient level, obtain acceptance among users (both care providers and patients), and finally introduce eHealth-based disease management systems into standard treatment procedures. This thesis covers one of these aims; designing for acceptance among users, mainly patients, but also care personnel. As a first step, the user group has been limited to only include patients with chronic heart failure, and the nurses connected to them. However, expanding general findings and experiences to other disorders should not cause any difficulties.

Both the design process and the evaluation of two prototype systems will be covered in this thesis. The intention of the prototype systems was not to create a technically advanced and innovative system, but to produce a tool for attaining new knowledge about the issues related to introduction of eHealth-based disease management systems in Swedish health care. Both systems are described, the evaluations of the first prototype system are presented, and the results are discussed.

Two patient related evaluations and one nurse survey have been performed, and the results indicate that the simple prototype system could be possible to transform into a solution suitable for use in the home of patients. Both the patient evaluations and the nurse survey also give insight into important issues to consider when designing an eHealth-based disease management system for chronic diseases. Especially important is the knowledge that one of the largest challenges will be handling of the information overflow related to regular collection of patient data.

Future work includes evaluation and development of the second prototype system. The development of the prototype includes decision support for managing large amounts of patient data, and also increasing mobility of the system. Furthermore, additional measurement methods could be included in the prototype system in order to include special cases of patients, or other disorders.

Keywords: eHealth, health informatics, telemedicine, home monitoring, disease management, chronic diseases, heart failure, internet, web-based, treatment compliance.
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My beloved family, my mother and father, my grandmothers. You have brought me to this point, I couldn’t have done this without you.

To Tefnut, for your unconditional love, and always warming my bed.
## Abbreviations and Acronyms

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<tr>
<td>ACE</td>
<td>Angiotensin-Converting Enzyme</td>
</tr>
<tr>
<td>ADSL</td>
<td>Asymmetric Digital Subscriber Line</td>
</tr>
<tr>
<td>AMI</td>
<td>Acute Myocardial Infarction (&quot;heart attack&quot;)</td>
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<tr>
<td>CHF</td>
<td>Chronic (or Congestive) Heart Failure</td>
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<tr>
<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<tr>
<td>CTH</td>
<td>Chalmers Tekniska Högskola (Chalmers University of Technology)</td>
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<tr>
<td>CVD</td>
<td>Cardiovascular Disease</td>
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<td>DAGA</td>
<td>CHF clinic at SU/Ostra</td>
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<td>EBI</td>
<td>Electrical Bioimpedance</td>
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<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
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<td>EDV</td>
<td>End Diastolic Volume</td>
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<tr>
<td>E-R</td>
<td>Entity-Relationship</td>
</tr>
<tr>
<td>GPRS</td>
<td>General Packet Radio Service</td>
</tr>
<tr>
<td>ICD</td>
<td>Implantable Cardioverter Defibrillator</td>
</tr>
<tr>
<td>ICT</td>
<td>Information and Communication Technology</td>
</tr>
<tr>
<td>MD5</td>
<td>Message-Digest algorithm 5</td>
</tr>
<tr>
<td>NST</td>
<td>Nasjonalt Senter for Telemedisin (Norwegian Center for Telemedicine)</td>
</tr>
<tr>
<td>NYHA</td>
<td>New York Heart Association</td>
</tr>
<tr>
<td>SSL</td>
<td>Secure Sockets Layer</td>
</tr>
<tr>
<td>SQL</td>
<td>Structured Query Language</td>
</tr>
<tr>
<td>SU/Ostra</td>
<td>Sahlgrenska University hospital – Östra hospital</td>
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<td>TLS</td>
<td>Transport Layer Security</td>
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<tr>
<td>UMTS</td>
<td>Universal Mobile Telecommunications System</td>
</tr>
<tr>
<td>VPN</td>
<td>Virtual Private Network</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>VINNOVA</td>
<td>Verket för Innovationssystem (Swedish Governmental Agency for Innovation Systems)</td>
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Conference Appearances

The work presented in this thesis has been presented at the following conferences. Conference abstracts have been published for all conferences, except EMBC 2008 where a full conference paper is available.


Medicintechnikdagarna, 2-3 October 2007, Örebro, Sweden. *Care@Distance - Disease Management för hjärtsviktpatienter i hemmet*, A. Gund, B. A. Sjöqvist, K. Lindecrantz, I. Ekman.


Svenska Läkaresällskapets Rikstämman, 29 November - 1 December, 2006, Gothenburg, Sweden. *Care@Distance - IT-baserad hemvård av hjärtsviktspatienter*, A. Gund, B. A. Sjöqvist, K. Lindecrantz, I. Ekman.

Medicintechnikdagarna, 3-4 October 2006, Uppsala, Sweden. *Care@Distance, Home Monitoring System for Patients with Congestive Heart Failure*, A. Gund, B. A. Sjöqvist, K. Lindecrantz, I. Ekman.
Introduction

This licentiate thesis will cover parts of the project Care@Distance, which aims to attain knowledge in the area of disease management of chronic diseases. Disease management using eHealth solutions have the possibility to, among other things, improve quality of life for patients and reduce health care costs on the society. However, there are many obstacles preventing new applications from surviving all the way from idea to finished product.

1.1 eHealth, Medical Informatics and Telehealth

The area of medical informatics is fast growing, and large investments are made in information and communication technology (ICT) in health care. For readers not introduced to the field, the different terms associated with it might be confusing. Medical informatics can be seen as a combination of health care with computer science and information science. Telehealth relates to communication technology for health related purposes, and is often used for delivery of health services on a distance, through e.g. tele-consultation or robotic surgery. However, large distances are not necessary, it could just as well be communication within the same room.

A commonly used term today is eHealth, often referring to a combination of different areas, including medical informatics and telehealth [1]. Several different definitions exist, where one of the most well cited is by Gunther Eysenbach, published in the Journal of Medical Internet Research in 2001. There Eysenbach states that:

\[
\text{e-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using}\]

1
In short, one could define eHealth as the use of ICT in health care. This very broad definition partly explains why this area attracts so much attention. Included are applications and services such as electronic patient records, electronic prescriptions, remote monitoring of patients, systems for health care organization, medical education, imaging systems, robotic surgery, smart homes, etc.

1.2 Chronic Diseases

Chronic diseases\(^1\) account for approximately 60 % of all deaths, world wide \([3]\). Among them the largest groups are cardiovascular diseases (CVD, 30 % of all deaths), cancer (13 %), chronic respiratory diseases (7 %), and diabetes (2 %). Ischemic heart disease (reduced oxygen supply to the heart) is the most common cause of death in the world, and it alone causes as many deaths as all types of cancer together \([4]\). Since only 20 % of all deaths due to chronic diseases occur in high income countries \([3]\), it can be interesting to take a deeper look at these numbers in the western world. Taking the European region\(^2\) as an example, chronic diseases account for approximately 86 % of all deaths; CVD 51 %, cancer 19 %, respiratory diseases 4 %, and diabetes 1 % \([4]\). In the USA and Canada the numbers are similar with about 88 % of all deaths being due to chronic diseases; CVD 38 %, cancer 23 %, respiratory diseases 8 %, and diabetes 3 % \([4]\). In fact, this pattern can be seen in most regions of the world, except in very low income regions where the group “communicable diseases, maternal and perinatal conditions, and nutritional deficiencies” is the major cause of death \([3]\).

Although chronic diseases not only affect elderly people, elderly are highly over represented as about 77 % of all deaths due to chronic diseases, world wide, occur in the age group 60 year of age and older \([3]\). Moreover, in the USA it is approximated that over 80 % of the population over 65 years of age suffer from one or more chronic diseases \([5]\), and more than 60 % has two or more \([6]\). In Sweden 17.5 % of the population is 65 years of age or more and, as in the rest of the world, the amount of elderly is increasing \([7]\). Considering that the demographics of the world are changing rapidly, age related disorders will become a large problem in the near future. The baby-boom generation of the 1940’s will soon reach retirement age, putting higher demands on the health care for the elderly.

In the USA about 80 % of the health care costs are due to chronic diseases \([6]\), \([8]\), and people with chronic diseases represents five times higher costs than those without \([8]\). The total cost for CVD alone was in 2005 approximately $394 billion (including production lost due to morbidity and mortality) \([8]\). For cancer the cost in 2005 was $210 billion, and in 2002 the cost for diabetes was $132 billion \([8]\). For comparison, in 2003 the total cost for CVD in the EU was about €169 (€105 billion in health care costs, the rest production loss due to

---

\(^1\) As defined by the World Health Organization (WHO); includes all cardiovascular diseases, e.g. stroke, ischemic heart disease, heart failure, etc. \([3]\)

\(^2\) The countries included in the “European region” are defined by WHO \([3]\)
morbidity and mortality, and informal care), with Germany and the UK in the top with €54 billion and €37 billion respectively [9]. Sweden spent an estimated €5 billion in total costs on CVD, of which almost €3 billion were health care costs, representing 11.6% of the total health care expenditures [9].

1.3 Related Work

Chronic disease management is a large field, and there are many ongoing projects intending to solve the problem with this growing patient group. When searching in scientific databases for projects on systems and solutions for monitoring and management of chronically ill patients, one will easily be overwhelmed with information. The projects span from construction of small parts of monitoring systems, such as sensors for physiological data acquisition, to full systems involving everything from sensors to integration with hospital information systems (HIS), programs improving care by educating patients about their diseases, and so called smart homes. In order to give an insight into the field a very small selection of projects will be introduced in this section.

The city of Troms in northern Norway has a 20 year history of working with telemedicine solutions [10]. Starting as a department of telemedicine in 1987, a center called Norwegian Center for Telemedicine (NST) was established in 1993, and in 2002 it was designated as a WHO Collaborating Center for Telemedicine. NST offers consultation in the areas surrounding telemedicine and eHealth, as well as education at Master’s level. NST also conduct their own research projects, and examples of these projects are MyHealthService [11] which deals with managing chronically ill patients by use of their own TVs, a system for improving out of hospital blood glucose measurements for diabetes patients [12], and a telemedicine solution for home-dialysis for people with kidney failure [13].

During 2003-2007 the Swedish Governmental Agency for Innovation Systems (VINNOVA) ran a program called “IT in Home Healthcare” [14]. In this program, funded by VINNOVA and the Knowledge Foundation (KK-stiftelsen), 22 projects were included, all of them related to care in the home. The projects include development of systems for management of CVD, stroke rehabilitation, chronic pain in palliative care, eating disorders, psychological and cognitive disorders, diabetes and tools for home care assistance. Many of the systems in the projects are adaptable for many different chronic diseases.

Better Breathing [15] is a project intended to improve care for patients with chronic obstructive pulmonary disease (COPD) using ICT tools, both at home and in the hospital. The project addresses home monitoring, home rehabilitation, web communities for communication between patients and care giver, and self management education tools. Co-coordinated by the Danish Region Syddanmark and MedCom International in Denmark, this EU-funded project is a collaboration between the UK, Spain, Italy, Norway and Denmark.

Another way of seeing how the area of health informatics is influencing the health care is to look at national health ICT programs. As one example, in 2004 the Department of Health in England announced the allocation of £80 million through the Prevention Technology Grant. The purpose of the grant is to meet
the demands of the aging population by means of telecare solutions.

**Company Driven Projects and Commercial Products**

It is not only research groups and governments that are interested in disease management of chronic diseases. Many companies have also noticed the potential market. Below are few examples of company driven projects and commercial products already on the market.

Within the area of CVD management the European Commission funded project MyHeart, in which Philips plays a big role, is one of largest with a budget of approximately €35 million [16]. The project, which began in 2004 [17] and will continue until the end of 2008 [16], involves 33 partners in 10 countries [16]. Their applications include systems for dealing with physical activity, nutrition, sleep and relaxation, stress, and diagnosis and prevention [18].

The American company Health Hero Networks Inc. [19] has developed a complete system for health care management of patients with various chronic diseases. Their system consists of a home system called the Health Buddy, with which the patients interact by answering questions and transmitting physiological data, and an internet based decision support tool through which the health care personnel can access information about the patients. A development tool for modifying the Health Buddy is also available.

A similar system is available from the UK based company Docobo [20]. Their doc@HOME solution gives health care providers a tool for monitoring chronically ill patients in their homes using a either combination of web-based solutions together with medical equipment and patients’ personal mobile phones, or Docobo’s own tool HealthHUB. The HealthHUB is a small handheld device for monitoring patient’s conditions, by using built in or external sensor equipment, and by asking health related questions.

**1.4 Considerations on Design and Clinical Introduction**

One of the major challenges when developing medical applications today is not the technology itself, but rather introduction and acceptance, both clinical and user, of the products and solutions. The time from idea to finished product is long, and many solutions fail along the way. If a new medical method or application is to be successful, cooperation with the future users, i.e. nurses, physicians, administrators, etc., is crucial. One has to remember for whom the solution is being designed, and what problems it is addressing. As an engineer it is easy to get “lost” in new and advanced technology, but it is not always the most technically advanced solutions that give the best overall results. Cooperation with medical staff also opens a window of opportunity; to perform tests in clinical environments, to get access to test patients, to get constructive feedback during the development process, and to get clinical assistance in introducing the finished product in the clinic.

Another key factor is proof of concept, i.e. showing that the new product is beneficial to e.g. the quality of life for the patients, the economy, or the
work load for the staff. For this, testing and validation is necessary. During
the development phase, several prototypes may be needed in order to show
the benefits of the new solution. These prototypes do not have to be finished
products; it is often better to keep it simple at start and then add more advanced
features, stepwise governed by acceptance and clinical needs. A less advanced
solution may be accepted more easily by the users. It will also be easier to
change the design concept if it proves to be non-beneficial. Once the simple
prototype has been tested and accepted, new features and ideas from e.g. users
can be added to improve the functionality of the product. Within the scope of
this project the intention, at this stage, is therefore not to create a technical
advanced medical solution, but rather to design a system which can be accepted
in the daily routines, by both care personnel as well as patients. With help from
these users the system can then be developed further.

The patient group is another important issue. Sometimes medical technology
solutions tend to focus on making their product usable for all patients in a certain
patient group. The result may be quite complicated products where a great deal
of time has been put into making sure everyone can use it. In this project,
however, the idea is to make the system work on the large majority of patients
and, at least in the beginning, overlook the special cases. All these issues have
been taken into consideration during the project described in this thesis.

1.5 Research Objectives

The goal of this project is to acquire knowledge on how to design and implement
eHealth applications in order to:

- improve treatment compliance in chronic diseases.
- improve possibilities for personalized care.
- alert about deteriorating health on an individual patient level.
- obtain acceptance among users, both care providers and patients.
- introduce disease management systems into standard treatment proce-
dures.

In this thesis focus is on the fourth item; finding out which design solutions
are preferable in order to get acceptance among both health care personnel and
patients. A first step in achieving this goal has been to develop a prototype
system for disease management of chronic diseases. Because of the reasons men-
tioned in section 1.4, the technology in the prototype system has been kept on
a rather basic level. It is not the technology which is the main concern; it is the
acceptance with the users, both patients and medical staff.

Certain limitations have been set in order to make reaching the goal feasible
within the scope of the project. First, focus is to reach the large population of
patients, and not special cases. Not all patients are required to have advanced
health care; the large masses can often be managed with simpler measures. By
initially focusing on these groups, costs on the society could be greatly reduced
since not all patients need advanced equipment at home. Of course, this not hinder the future development of a more advanced system for the smaller groups of special cases.

Second, the patient group has been restricted to chronic heart failure (CHF) patients. This group of patient is a of significant number in the western world society, and there is much room for improvements in the care given to them. Many of the patients with CHF are often well enough to take care of themselves for a long time during their illness, and it is on these patients that this project focuses. The hope is that patients who are well enough to live a normal life should stay that way for as long as possible. Moreover, the research group involved in this project has good connections with medical staff at a heart failure day clinic (called the DAGA-clinic) at Sahlgrenska university hospital – Östra hospital (SU/Östra), in Gothenburg, Sweden.

The aim of this thesis is therefore to assess the usability of a simple disease management system, designed for heart failure patients in a home environment. Two versions of prototypes have been developed, and one of them has been evaluated in surveys and a small scale trial.
Background

Cardiovascular diseases (CVD) is, according to the World Health Organization (WHO), the number one cause of death in the world. Chronic heart failure (CHF), also called congestive heart failure or simply heart failure, is a condition which belongs to this category. An estimated 5 million people in USA (~2.3% of the population) [21], and about 250 000 people in Sweden (~2.7% of the population) [22], suffer from this condition. Studies have shown that treatment compliance is low in this group of patients [23], [24], [25], which opens up the possibility to improve the care given to them by disease management.

2.1 Physiology and Pathology of CHF

The heart is, together with the circulatory system, responsible for distributing blood throughout the body. Figure 2.1 shows a cross section of a heart. De-oxygenized blood enters the right atrium through the superior vena cava, and then flows into the right ventricle. As the right ventricle contracts the blood is pushed through the pulmonary artery into the lungs where oxygen is once again collected. From the lungs the oxygenized blood runs through the pulmonary veins into the left atrium, and then into the left ventricle. The left ventricle, which is the strongest part of the heart, pushes the blood out into the body.

CHF is not a disease but rather a condition, described by a series of symptoms and signs, leading to a reduced pumping ability of the heart [26]. The European Society of Cardiology defines heart failure according to three criteria, seen in table 2.1, where I and II are required criteria. A common cause of CHF is acute myocardial infarction (AMI), or “heart attack” in common speech. This is one of the ischemic heart diseases which, as previously mentioned in section 1.2, is one of the largest causes of death in the world. In Sweden in 2003, more than 38 000 people suffered from AMI in at least one occasion [27].

There are two different types of CHF: diastolic and systolic dysfunction. In diastolic dysfunction the compliance of the ventricles of the heart is decreased,
CHAPTER 2. BACKGROUND

Figure 2.1: Cross section sketch of the human heart.

Table 2.1: Definition of Heart Failure according to European Society of Cardiology. Quoted from "Guidelines for the diagnosis and treatment of chronic heart failure: executive summary (update 2005)" [23]

| I | Symptoms of heart failure (at rest or during exercise) and |
| II | Objective evidence (preferably by echo cardiography) of cardiac dysfunction (systolic and/or diastolic) (at rest) and (in cases where the diagnosis is in doubt) and |
| III | Response to treatment directed towards heart failure |

leading to a lowered end-diastolic volume (EDV\textsuperscript{1}). A lowered EDV results in less blood being pumped out into the body at each heart beat (stroke volume). In systolic dysfunction the contractibility of the heart is instead reduced, due to damage of the cells of the heart. Here the heart is unable to eject all blood from the ventricle, resulting in a lowered stroke volume.

Both conditions result in the same thing: reduced stroke volume. The body tries to compensate for this, by e.g. increasing the heart rate, leading to increased blood pressure and increased interstitial fluid, so called edema. Depending on if the right or the left side of the heart is affected, the edema can be situated in the peripheral system (right side), or in the pulmonary system (left side). Edema in the peripheral system usually leads to swelling of limbs, e.g. legs and feet, while edema in the pulmonary system leads to water accumulation in the lungs. Decreased stroke volume also results in an increased blood pressure, forcing the heart to work harder. This in turn leads to a worsening of the condition, and

\textsuperscript{1}EDV is the volume of blood a ventricle right before ventricular contraction
finally a complete loss of cardiac function.

The severity of CHF has been divided into four different classes by the New York Heart Association (NYHA), as seen in table 2.2. NYHA I is the least severe case where there are hardly any signs or symptoms, and NYHA IV is the most severe.

<table>
<thead>
<tr>
<th>Class</th>
<th>Symptoms</th>
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<tbody>
<tr>
<td>I</td>
<td>No symptoms and no limitation in ordinary physical activity.</td>
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<tr>
<td>II</td>
<td>Mild symptoms and slight limitation during ordinary activity. Comfortable at rest.</td>
</tr>
<tr>
<td>III</td>
<td>Marked limitation in activity due to symptoms, even during less-than-ordinary activity. Comfortable only at rest.</td>
</tr>
<tr>
<td>IV</td>
<td>Severe limitations. Experiences symptoms even while at rest.</td>
</tr>
</tbody>
</table>

Table 2.2: Classification of heart failure according to New York Heart Association. Quoted from American Heart Association website. [28]

Symptoms of CHF varies between patients, but some of the most common are dyspnea (shortness of breath), edema, increased weight, fatigue (tiredness), high blood pressure and increased heart rate. Worsening of symptoms could be a sign of deteriorating health, thus important indicators for adjustment of treatment.

2.2 Treatment of CHF

The information in this section is attained from guidelines by the European Society of Cardiology from 2005 [23], unless cited otherwise.

CHF is to a large extent defined by present symptoms, and the reasons behind the condition can be many. Therefore, a first step in treating CHF is to treat the underlying causes. A non-pharmacological measurement is e.g. monitoring and managing weight changes. Large increase in weight can indicate water retention, while decrease in weight can mean a reduction in total body fat and lean body mass. Diet and exercise are important to consider, as is reduction in alcohol intake and smoking. When it comes to pharmacological measurements there are several drugs commonly used to treat CHF. Among them are diuretics, angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers, beta-blockers, aldosterone antagonists and cardiac glycosides. It is important to monitor the patient signs and symptoms when administrating new drugs or changing doses, since the response to the treatment is individual, and also depends on combination of the drugs. To tailor the optimal treatment for the individual patient is a sophisticated balancing act.

In some cases surgical measures can be motivated. This includes mitral valve surgery, and implantable devices such as pacemakers and defibrillators (ICD). As a last measure, heart transplantation could be considered. However, this should only be contemplated when the patient is at the end stage of CHF. Even
though heart replacement surgery can increase quality of life greatly, there are major risks with the procedure, including organ rejection and infection. The lack of donor hearts is also a major issue.

One reason behind worsening symptoms in CHF is low treatment compliance [23], [24], [25]. Patients with CHF tend to not follow the treatment they are prescribed, pharmacological and/or non-pharmacological. Regardless of reason behind deteriorating health, monitoring of signs and symptoms is crucial in order to correct treatment plan, or encourage compliance with the treatment. Using eHealth-solutions is one possible method of managing CHF on a regular basis, allowing for a fast detection of worsening conditions.

2.3 History of Care@Distance

Care@Distance started in 2001 as a master of science degree project in industrial design [29] at Umeå University, in collaboration with the health care IT-company Ortivus AB. In that project Sofia Jacobsson designed and created a non-functioning prototype showing a possible solution of a home monitoring system, as seen in figure 2.2.

The design study was followed by the building of a functioning prototype system in 2004. This was also a master of science thesis project, at Chalmers University of Technology (CTH) in Gothenburg, Sweden, by Robert Carlsson and Andreas Rudolfsson [30]. In 2005 the project was turned into a doctoral project at the Department of Signals and Systems at CTH. Since then, the prototype system has been developed further, and tested in both a survey and a small field trial, see chapter 4. Through a master of science thesis at CTH in 2007 by Linda Ivarsson [31], and with some help from external consultants, a second version of the prototype was developed.
2.3 HISTORY OF CARE@DISTANCE

Figure 2.2: Photograph of the non-functioning prototype designed by Sofia Jacobsson in her master thesis in 2001.
System Description

One of the major issues in constructing a system for monitoring patient vital signs, and other data, in a home environment is not, as one may think, the technical issues. It is more often the introduction and acceptance that stands in the way of a successful solution. In order to test whether an eHealth-based system for disease management is possible to introduce into the Swedish health care sector, a prototype system was developed. This chapter describes the technical details and design choices of the system, or rather systems, used in the project Care@Distance.

3.1 System Overview

The system used in the project is illustrated in figure 3.1. It consists of a home part, called the home terminal, and a care giver part, called the web portal. There is also a central database connected to the network.

In the home terminal, the patient uses a communication device such as a computer to access either a program or a web page, depending on the version of the system (see section 3.3 for further information), which will guide the patient through a measurement session. Each measurement session contains a number of measurements of physiological data and subjective health related questions. The measurement data, symbolized in the figure by a scale and a blood pressure monitor, is transferred to the computer, either by a local network such as Bluetooth®, or manually by the patient. After a completed session the data is transmitted through the internet to the central database. On the database the data of all patients is stored, along with other information, such as patient name, personal number (Swedish social security number), etc.

The health care personnel can access the data from the database through a web portal using a standard web browser. They can also administrate the patient system to suit individual patient needs. If requested, the system could also be accessed by patients’ families, and by patients themselves. More details on the web portal can be found in section 3.4.
3.2 Choice of Measurements and Questions

Through the home terminal, the patients will perform one or several measurements of physiological data, and answer questions regarding their subjective view on their health. Chosen physiological parameters are body weight, blood pressure, and pulse (to be added). Studies have shown that home measurements of both blood pressure and body weight can predict CVD events and hospitalization [32], [33], [34], and keeping track of changes in these parameters in heart failure patients can therefore be of great importance. Since heart failure to a great extent is defined and diagnosed by subjective symptoms, see table 2.1 and 2.2 in chapter 2, questions are asked regarding the patients perceived dyspnea and fatigue. The answers are given as numeric values between one and five, according to the Likert scale\(^1\). A guide is given to the patient to help answering the questions correctly, according to table 3.1. Monitoring symptoms can potentially both predict deteriorating health, and increase quality of life for the patient [36], [37], [38]. Both types of measurements and questions were chosen in cooperation with the specialist nurses at the DAGA-clinic at the SU/Ostra hospital. Table 3.2 gives a summary of the monitored parameters, together with which instrument or question that is used. More information about the medical measuring equipment can be found in section 3.6.1.

\(^1\)The Likert scale is a tool for measuring agreement with a statement, and is often used in questionnaires. It is described in an article from 1932 by Rensis Likert [35], hence the name Likert scale.
### Table 3.1: Guide to answering the subjective questions on symptoms.

<table>
<thead>
<tr>
<th>Value</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I am never out of breath or tired</td>
</tr>
<tr>
<td>2</td>
<td>When walking up a staircase</td>
</tr>
<tr>
<td>3</td>
<td>When walking on flat ground</td>
</tr>
<tr>
<td>4</td>
<td>When walking slowly on flat land or when showering or dressing</td>
</tr>
<tr>
<td>5</td>
<td>When at rest</td>
</tr>
</tbody>
</table>

**Table 3.2:** Physiological parameters and questions chosen to monitor, as well as the equipment and questions used.

<table>
<thead>
<tr>
<th>Physiological parameters</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body weight</td>
<td>Body weight scale (A&amp;D UC-321PBT)</td>
</tr>
<tr>
<td>Systolic blood pressure</td>
<td>Blood pressure monitor (A&amp;D UA-767PBT)</td>
</tr>
<tr>
<td>Diastolic blood pressure</td>
<td>Blood pressure monitor (A&amp;D UA-767PBT)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Subjective symptoms</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>How tired do you feel?</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>How out of breath do you feel?</td>
</tr>
</tbody>
</table>

### 3.3 Home Terminal

#### 3.3.1 First Prototype: Installed Program

The first prototype of the home terminal was initially designed and constructed in 2004 [30]. It consists of a tablet PC with an installed guidance program, which leads the patient through a measurement session. Through the guidance program, written in the programming language C#, data is collected. The collected data is stored on a local database before being transmitted to the main database through the internet. Data from the medical equipment is entered manually by the patient using a small numeric keyboard and the touch sensitive screen of the computer.

In order to assure that the patients do their measurements at approximately the same time every day, a measurement schedule containing one or several measurement sessions is set up. A patient can e.g. each day do blood pressure measurements and weight measurements some time between 9 and 10 am, and only weight measurements between 7 and 10 pm. The program starts automatically when it is time for a measurement session, and between sessions an image of a clock can be seen on the screen showing what time it is and at what time intervals the sessions occur, as seen in figure 3.2. If the patient should miss a session, e.g. due to waking up late, the patient choose to do an extra measurement session by pressing a button next to the clock.

In the design, considerations were taken to the age of the patients and their, to some extent, lack of computer experience. The buttons are large, as is the text size, and the colors are chosen to be soft and easy on the eye. At the same time as the contrast between background and text is high. Text is added to the buttons to emphasize their functions.
System Walkthrough

When it is time for a new measurement session, the program will automatically exit the clock mode, and enter the measurement mode. A start page, as in figure 3.3(a), will be visible where the patient can choose to start the session by clicking on the “start” button on the screen. If the patient has chosen to do an extra measurement, by clicking a button when in the clock mode, a “cancel” button will also be visible, as in figure 3.3(b). In the top left corner is a small button intended for administration, which is also visible when in the clock mode. If the patient should choose not to do a session the program will automatically exit the measurement mode and enter the clock mode again at the end of the scheduled time slot.

Once a measurement session is started, a list of the measurements that will be done and which forms, containing questions, should be filled out, is shown to the patient as in figure 3.4. Should the patient choose not to continue with the session there is always a possibility to end the session by clicking the arrow shaped button pointing to the left. The patient continues with the session by clicking the arrow shaped button pointing to the right. Both buttons have explaining text written on them to clarify their function.

Figures 3.5(a)–(c) show the measurement and question pages. Here the patient enters body weight, blood pressure (systolic and diastolic), and answers questions on experienced dyspnea and fatigue. The values are entered manually using a numeric keyboard. There are some limitations in which values are allowed to be entered, e.g. the values cannot be too large or too small. It is possible to go back and forth between measurements by clicking on the arrow shaped buttons.
Figure 3.3: Snapshot of the start screen, without (a) and with (b) having chosen to do an extra measurement.

Figure 3.4: The current session is described to the patient.
(a) Weight measurement.

(b) Blood pressure measurement.

(c) Question answered on a scale between 1 and 5.

Figure 3.5: Snapshots of the three different types of measurements in the program.
When all measurements are completed, a list of the results will be shown, as seen in figure 3.6, which gives the patient a possibility to confirm the data. The patient can at this stage still choose to go back and change certain values, or to end the session without saving the data. If the results are to the patient’s satisfaction, the square shaped button can be clicked, saving the results on the local database. Directly after this, the local database will synchronize with the main database, thereby allowing the health care personnel, if interested, to access the data shortly after each measurement session. Should the internet connection temporarily be down at the moment of synchronization, the data will be transmitted at the next session; no attempts to automatically transmit the data will be done in between measurement sessions.

Regardless of if the data has been sent to the main database or not the clock will again appear, showing the current time and the scheduled sessions, as in figure 3.2.

### 3.3.2 Second Prototype: Web-based

Today more and more systems are becoming web-based. One example is banking systems, where many people today handle their financial errands over the internet. There are a number of reasons why it in this project was chosen to discard the installed software used in the first prototype, discussed in section 3.3.1, in favor of a completely web-based system.

The first reason is the mobility of the system. In the first prototype the patients have to take the computer with them when leaving the home, e.g. when going on vacation. There also needs to be a possibility to connect that computer to internet at the new location. In a web-based solution the patient still need access to a computer and an internet connection, but they can transmit their measurements using any computer, e.g. in a local library or at an internet cafe. There is also no need to install anything, such as a database and a program as in the first prototype, on the computer.

A second reason is the cost of the system. A tablet PC, as the one used in the first prototype, is quite expensive, and one could easily question the motivation behind such a cost considering the constant cut backs in health care budgets. The
limited resources of this research project is also a reason for lowering the costs of the prototype system. If costs can be reduced the number of participating patients in trials can be increased.

The third reason is connected to the high usage of computers and internet in the Swedish society. Almost 30% of the Swedish population between 65 and 74 years of age use internet in their home at least once a week, and 46% of them have access to internet in their home [39]. Looking at the future group of patients, those who today are in the age range 55 to 64 years, 54% use internet each week, and 76% have internet at home [39]. As more and more people use internet in their homes, the possibility to used web-based interfaces increases.

Finally, utilizing web-based technology opens up for the possibility of using other types of communication devices than PCs. For example, so called “smart phones” (advanced mobile phones) could be used for further mobility of the patient and care provider. This also provides the patients with the choice to use the equipment best suited for their individual needs, thereby making the solution more personalized.

The second prototype was developed in 2007 as part of a master of science thesis project [31]. It is written in the scripting language PHP (PHP: Hypertext Preprocessor), which is a free, open source language often used for web applications [40]. Moreover, it is platform independent, meaning it can be used by any computer. The possibility to make dynamic web applications is also an advantage, making it easy to add new types of measurements. All this makes PHP suitable for a research prototype [40]. Details on the technical parts of the application can be found in the master thesis report [31].

Except for a few changes the design of the second prototype is similar to the first prototype. One important difference is that the patients need to log in and out of the second prototype system. When at home the patient can choose not to log out, making the application similar to the first prototype with a clock showing the times of the sessions. If at a different computer, however, there is a need to log out of the application to ensure that no one else enters information. Figures 3.7–3.9 show snapshots of the web-based second prototype.

As can be seen in figures 3.7–3.9, the design of the second prototype is very similar to the first prototype in figures 3.2–3.6. However, there are some differences. The questions are no longer answered using a gliding scale. Instead so called radio buttons are used as can be seen in figure 3.8(b). Help buttons have been added to some pages (measurement and question pages, clock page and log in page) in case the patient needs further guidance. Another feature in the application, not seen in the figures, is error messages. Whenever a patient does something not allowed, text appears in red color informing the patient what was done incorrectly and how to solve it. Also, when a patient tries to continue in the application without entering a value, red text appears asking if the patient does not want to answer the question. This is to ensure that the patient has not accidently pressed the button twice.
3.3 HOME TERMINAL

(a) Welcome page.

(b) Session description.

(c) Weight measurement.

Figure 3.7: Snapshots of the pages in the web-based, second prototype; welcome page (a), description of the current session (b) and weight measurement view (c).
CHAPTER 3. SYSTEM DESCRIPTION

(a) Blood pressure measurement.

(b) Question answered on a scale between 1 and 5.

(c) Review of results.

Figure 3.8: Snapshots of the pages in the web-based, second prototype; blood pressure view (a), example of question view (b) and review of session results (c).
3.3 HOME TERMINAL

Figure 3.9: Snapshots of the pages in the web-based, second prototype; page confirming finished session (a), clock mode (b) and log in page (c).
3.4 Web Portal

3.4.1 First Version

In the 2004 master thesis, not only the first prototype of the home terminal was created, as described in section 3.3.1, but also a first version of a web portal intended for the health care personnel [30]. This first web portal prototype was constructed in asp.net. Technical details can be found in the master thesis report [30]. Since certain key functions were missing from this first prototype it was decided to create a new version before testing the complete system in a larger trial, and the functions of this web portal will not be further described in this thesis.

3.4.2 Second Version

The second version of the web portal was designed and constructed in 2008. Ruby on Rails [41], which is a free open source framework using the script language Ruby, was used for the creation of this web application. Figures 3.10–3.12 show snapshots from the user pages, where the health care personnel can log in, search for patients, view patient information and data, and schedule measurement sessions. The web portal uses role based log in, meaning that depending on the user level (patient, nurse or administrator), different amount of information can be accessed through the web portal. For example, patients may only be allowed to examine their own data, while nurses could be allowed to see all patients’ data, as well as perform certain administrative tasks. Figures 3.13 and 3.14 show snapshots from the administration pages. These are only accessible to persons with an administration role stored in the database.

The web portal was designed using experiences gained in a survey with heart failure nurses in the DAGA-clinic, see section 4.2. After logging in to the web portal, the user will be able to search for a patient, figure 3.11(a). It is not possible to continue until a patient has been chosen. The user can search by entering complete information, or by supplying part of information, such as the first letter in the name. Because of patient security and integrity issues no patient related information, such as personal number or address, will be stored in the system at this time. The amount of information to search from is therefore limited, but it is possible to extend the search functions at a later time. In this page the user can also choose to add a new patient.

Once a patient has been chosen, the user can choose between a number of different pages. The available pages in the web portal are shown as “tabs” in the top of the window, and by clicking a tab the chosen page will appear. In the page “patient info”, figure 3.11(b), the user can see and edit patient information, such as name.

The most interesting page is the “patient data” page, figure 3.12(a), where the user can see the measurement values and the answers to the questions that the chosen patient has supplied from the home terminal. Patient data is shown as graphs with different colors in order to give a quick overview of the condition of the patient. It is possible to see all values, or only pick some values to look at. A cursor is available for more detailed information on each measurement.
3.4. WEB PORTAL

The user can also zoom in on certain values in the graph.

In the “schedule” page, figure 3.12(b), the user can create and edit measurement sessions for the patient. Using the “search patient” link next to the tabs, the user can go back to the patient search function and pick a new patient. The possibility to log out is always present.

Through the administrator pages, the user sees a similar view, with several tabs representing different pages. The “user” page, figure 3.13(a), allows for adding, editing and removing users. In the “instrument/measuring types”, figure 3.13(b), the user can add and remove measurement types (such as weight and blood pressure). This is also where help and information text for the measurement is created. The last tab is the “forms” page, figure 3.14(a), and here new forms, containing questions, can be created. By clicking on the name of a form it becomes possible to add and remove questions to that form, figure 3.14(b).

Figure 3.10: Snapshot of the log in page of the user pages, in the second prototype of the web portal.
Figure 3.11: Snapshots of the user pages, in the second prototype of the web portal; searching for patients (a) and viewing patient information (b).
Figure 3.12: Snapshots of the user pages, in the second prototype of the web portal; examining patient data (a) and editing schedules (b).
CHAPTER 3. SYSTEM DESCRIPTION

Figure 3.13: Snapshots of the administration pages, in the second prototype of the web portal; administrating user information (a) and measurements (b).
3.4. WEB PORTAL

(a) Editing forms.

(b) Administrating questions.

Figure 3.14: Snapshots of the administration pages, in the second prototype of the web portal; editing forms (a) and questions (b).
3.5 Database

There are two main database versions for storing patient information and data, depending on which prototype version of the web portal is considered. The first database was constructed along with the first prototype system in 2004, while the second version was constructed during the design and construction of the second web portal prototype. When designing the second database entity-relationship (E-R) diagrams, and functional dependencies tested with Boyce-Codd normal form, were used to create and assess the database. E-R diagram and functional dependencies for the second database can be found in appendix A. The databases are designed to contain information regarding both patients and personnel.

For managing both databases, the database management system used was Microsoft SQL Server 2005. This system uses basic structured query language (SQL) code for creating and managing databases in a simple and effective way. There are both advantages and disadvantages with using Microsoft SQL Server, and one may argue that the licence costs are too large for a prototype system. However, Microsoft products are commonly used in medical applications today, and support is easily acquired whenever technical issues occur. Moreover, Microsoft has through msln academic alliance made an agreement with CTH to use a selection of their software, including SQL Sever 2005, for research and educational needs at no additional cost. If the prototypes are to be commercialized the choice of database management software needs to be reassessed.

3.6 Hardware

3.6.1 Medical Equipment

Each system includes one blood pressure monitor (UA-767PBT) and one personal body weight scale (UC-321PBT) from A&D Medical. Both equipment have integrated Bluetooth®, although this is not implemented within the scope of this project. The scale is started by pushing a button on the front side of the scale, and the weight is obtained by stepping onto the scale and waiting until the value appears on a display. The cuff of the blood pressure monitor is applied on the upper arm, and the measurement is started by pressing a button on the monitor. Inflation of the cuff will be automatic, and after a correct measurement the monitor displays upper (systolic) and lower (diastolic) blood pressure, as well as the pulse.

3.6.2 Communication Equipment

In the first prototype system, see section 3.3.1, a FujitsuSiemens Lifebook P1510 tablet PC with a touch sensitive 8.9" screen is used for communication between the patients and the main database. The operating system is Microsoft Windows XP Tablet PC edition. Patients enter results from measurements through a small numeric keyboard connected to the computer by USB, and answers questions by pressing the screen with their fingers. Installed on the computers, apart from the system software, is a Microsoft SQL 2005 database with the same set of tables as in the main database, and .net 2.0.
Access to internet is through a fixed connection, e.g. ADSL. Connection through a wireless system such as UMTS (3G) or GPRS is also possible, but was not utilized in this project due to difficulties with wireless internet provider used in the project. Every 24 hours, the wireless internet software closed the internet connection, meaning that the patient would have to reconnect every day. It was decided that this was not an option considering the technical experience of most patients.

The server used for the main databases is a Dell Optiplex GX 620 PC with Microsoft SQL Server 2005. This is an ordinary PC, which works well for small trials as the ones within the scope of this thesis. However, for larger trials a computer better suited for server use should be considered. All web applications for the second prototype are also stored on this server.

\textbf{Figure 3.15:} Photograph of the first home terminal prototype, including the medical equipment, tablet PC and numeric keyboard.
System Evaluation

When designing any new product, system evaluation among its future users is a necessary part of the process. Without user interaction and comments the product might not be accepted once implemented in its real environment. This is especially true for products in the medical area where clinical acceptance, as well as change of behavior and practice, tends to be slow for new innovations and solutions. Contact has been upheld with heart failure specialist nurses at the DAGA-clinic at the SU/Ostra hospital, as well as with CHF patients, during the design process of the systems used in this project. Their views on the systems are of great importance if the prototype is to be accepted by patients in a larger trial.

Three evaluations have been performed in the scope of this thesis; one patient survey, one nurse survey and one small field trial. Two of the evaluations, the patient survey described in section 4.1 and the field pre-trial in section 4.3, were published in a conference paper from 2008 [42]. All three evaluations have also been presented at both national (Swedish) and international conferences in 2007 and 2008.

4.1 Patient Survey

The first home system prototype, see section 3.3.1, was designed during a master thesis, and was never tested by patients. Therefore, before starting the design of the second prototype, section 3.3.2, a small patient survey was completed in order to find the strengths and weaknesses of the existing prototype. The goal of the survey was to evaluate the design, usability and acceptance of such a system in the user group. This survey was completed together with two master of technology students at the department of computer science and engineering at CTH, and the results from the survey are published in a conference paper from 2008 [42]. The results have also been presented in several conferences during 2007 and 2008.

In February 2007, thirteen CHF patients were asked by nurses at the DAGA-clinic to participate in the survey during their regular visit. Three declined, and
ten were included in the survey. The home system prototype was demonstrated to each patient, and in some cases also their spouse. Both a nurse and a technician were present to answer any questions the patients might have during the demonstration and test.

After the demonstration the patients were asked to use the system once, including the measuring equipment if possible. Participating observation [43] was utilized during the test, meaning that the observer interacts with the test subject during the observation. Although participating observation may affect the outcome of the test, there are some advantages in this case. First, the observer was the same person as the one introducing the system, making it natural to continue the interaction during the test. It can also be difficult to master a system after only receiving one demonstration, compared to a real life setting where a more in depth education would be given. Second, in the setting of the test (nurse’s office) there is no place for the observer to “hide” from the test subject, and with a non-interacting observer in the room the test subject might feel uncomfortable.

Observation gave qualitative information about the system, and in order to get more quantitative information a questionnaire was given to the patients after the test. Questions were asked on background, usability (including learnability, flexibility and robustness), usability of the measurement equipment (when applicable), and finally a question regarding the patients interest of having such a system in their home. All questions were quantified, but the patients were given a possibility at the end of the questionnaire to write free text comments. The complete original questionnaire can be found in appendix B, and a summary in English is given in table 4.1.

4.1.1 Results from Patient Survey

The results from the questionnaire in the patient survey are presented in table 4.2, where it can be seen that the system was well received in the test group. Except from two patients giving very deviating answers, all patients gave the system very high scores in all categories. Unfortunately, only two patients wanted to try the blood pressure monitor, and only five tested the scale. It is therefore difficult to draw any conclusions on the usability of the measuring devices from the questionnaire. Two patients also gave free text comments; one wrote “if you live far away from Ostra H. [the hospital] it is good if you do not need to come as often”, and one simply wrote “diabetes diagram”. An interesting, and promising, result is that all patients answered that they could consider using the system in their homes daily.

From the observations, several additional results could be found. Six out of the ten test patients had difficulties managing the touch sensitive screen. The screen reacts better when tapping with a finger rather than pressing, which was not noted by the patients. Therefore many patients pressed very hard on the screen to get a reaction, and sometimes the computer interpreted this as two clicks instead of one. When answering the questions on dyspnea and fatigue, two patients wanted to press the keyboard instead of the screen, which was not possible in the first prototype. The numeric keyboard itself caused a few problems for five out of the ten patients. Many of them pressed more than one
<table>
<thead>
<tr>
<th>#</th>
<th>Field/Question</th>
<th>Answer type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sex</td>
<td>Male or Female</td>
</tr>
<tr>
<td>2</td>
<td>Age</td>
<td>Numeric</td>
</tr>
<tr>
<td>3</td>
<td>What is your previous computer experience</td>
<td>5 steps: “None” to “Very large”</td>
</tr>
</tbody>
</table>

**Usability**

<table>
<thead>
<tr>
<th>#</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Entering the blood pressure?</td>
</tr>
<tr>
<td>5</td>
<td>Entering the weight?</td>
</tr>
<tr>
<td>6</td>
<td>Answering the questions on tiredness and breathlessness?</td>
</tr>
<tr>
<td>7</td>
<td>Understanding the instructions?</td>
</tr>
<tr>
<td>8</td>
<td>Seeing the buttons on the screen?</td>
</tr>
<tr>
<td>9</td>
<td>Understanding what the buttons on the screen did?</td>
</tr>
<tr>
<td>10</td>
<td>Pressing the buttons on the screen?</td>
</tr>
<tr>
<td>11</td>
<td>Reading the text on the buttons on the screen?</td>
</tr>
</tbody>
</table>

**Design**

<table>
<thead>
<tr>
<th>#</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>Size of the text?</td>
</tr>
<tr>
<td>13</td>
<td>Size of the buttons on the screen?</td>
</tr>
</tbody>
</table>

Did you think that:

<table>
<thead>
<tr>
<th>#</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>The shape of the buttons on the screen increased your understanding of their function?</td>
</tr>
<tr>
<td>15</td>
<td>The color of the buttons on the screen was pleasant?</td>
</tr>
<tr>
<td>16</td>
<td>The color of the buttons on the screen was legible?</td>
</tr>
<tr>
<td>17</td>
<td>The color of the background was pleasant?</td>
</tr>
<tr>
<td>18</td>
<td>The color of the background was legible?</td>
</tr>
<tr>
<td>19</td>
<td>The combination of button color and background color was pleasant?</td>
</tr>
<tr>
<td>20</td>
<td>The combination of button color and background color made the buttons legible?</td>
</tr>
</tbody>
</table>

**Measuring equipment**

<table>
<thead>
<tr>
<th>#</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>Using the scale?</td>
</tr>
<tr>
<td>22</td>
<td>Reading the values on the scale?</td>
</tr>
<tr>
<td>23</td>
<td>Using the blood pressure monitor?</td>
</tr>
<tr>
<td>24</td>
<td>Reading the values on the blood pressure monitor?</td>
</tr>
<tr>
<td>25</td>
<td>Using the numeric keyboard?</td>
</tr>
</tbody>
</table>

**Other**

<table>
<thead>
<tr>
<th>#</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>26</td>
<td>Could You consider using this system daily?</td>
</tr>
<tr>
<td>27</td>
<td>Is there anything You would like to add?</td>
</tr>
</tbody>
</table>

“Yes”, “No”, “I do not know”, Free text

**Table 4.1:** Translation of questionnaire used in the patient survey.
key at the time due to the keys being too small, and one patient accidently pressed the “Num Lock” button causing the keyboard to function improperly.

As mentioned before, not many patients wanted to try the measuring equipment. Those five who tried the blood pressure monitor had difficulties both understanding how to apply it correctly, and tightening the cuff. This implies that better instructions are needed for this type of device, alternatively another type of device could be considered for home use. The scale did not seem to cause any problems for the two patients who tried it.

Many of the patients also gave suggestions on improvements of the system as they tested it. Pulse and blood sugar measurements were two suggestions, as was the possibility of using their own home computer instead of the tablet PC. Apart from suggestions from the patients, the nurses present at the test also had some comments. Among other things they mentioned that the font size might be too small in some instances, and that the instructions for the questions could be clarified. They also commented on the choice of measurements, and that certain values, such as pulse, could be useful for them to gather.

### Table 4.2: Results for questions number 1 to 26. Question 27 was free text comments.

<table>
<thead>
<tr>
<th>#</th>
<th>Mean</th>
<th>Median</th>
<th>Max</th>
<th>Min</th>
<th>No. of answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4 female and 6 male</td>
<td></td>
<td></td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>76.3</td>
<td>79</td>
<td>87</td>
<td>62</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>3.9</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>3.9</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>6</td>
<td>3.8</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>7</td>
<td>3.9</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>3.9</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>9</td>
<td>3.8</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>11</td>
<td>4</td>
<td>4.5</td>
<td>5</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>12</td>
<td>All answered “Good”</td>
<td></td>
<td></td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>13</td>
<td>All answered “Good”</td>
<td></td>
<td></td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>14</td>
<td>3.9</td>
<td>4</td>
<td>5</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>15</td>
<td>4.2</td>
<td>4</td>
<td>5</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>16</td>
<td>4</td>
<td>4</td>
<td>5</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>17</td>
<td>3.9</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>18</td>
<td>3.8</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>19</td>
<td>3.9</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>20</td>
<td>4</td>
<td>4</td>
<td>5</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>21</td>
<td>4.5</td>
<td>4.5</td>
<td>5</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>22</td>
<td>4.5</td>
<td>4.5</td>
<td>5</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>23</td>
<td>3.6</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>24</td>
<td>4.3</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>25</td>
<td>4.1</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>26</td>
<td>All answered “Yes”</td>
<td></td>
<td></td>
<td></td>
<td>10</td>
</tr>
</tbody>
</table>
Finally it could be worth mentioning that most of the patients handled the system very well, despite using it for the first time, and after only one demonstration. They had much more difficulties filling out the questionnaire. For example, one of the patients giving deviating answers, only answering 1 or 2 on each question, actually said that the system was very easy to use. Another patient who gave low ratings, claiming that the system was difficult, handled the system very well in practice.

4.2 Nurse Survey

When starting the design process of the second web portal prototype, see section 3.4.2, a small design study was performed at the DAGA-clinic. This study was performed at the same time as the patient survey mentioned in section 4.1. A paper prototype [44], see photograph in figure 4.1 and further description in section 4.2.1, representing a possible design of a future web portal was shown to three specialist nurses at the clinic. The nurses were asked to interact with the paper prototype, and meanwhile participating observation [43] was utilized. After the interaction, a semi-structured interview [45] was performed with each nurse asking questions regarding user friendliness, functionality and aesthetics, both on the paper prototype and medical systems in general. There were a separate set of questions for each page in the web portal paper prototype. The interviews took place in the nurses’ office rooms, and lasted approximately 30 minutes per nurse. The interview question template can be seen in appendix B. However, it should be kept in mind that being a semi-structured interview the template was only seen as a guide, and was not strictly followed. Notes were taken on the nurses’ answers. The survey has been presented at conferences during 2007.
4.2.1 Paper Prototype

A paper prototype [44] is an inexpensive and fast way of testing a new user interface in an early stage of a design process. There are different ways of making a paper prototype. For this survey a simple prototype made out of a combination of computer printed and hand drawn pieces of paper glued onto cardboard was used. Small pieces of colored plastic was used to highlight parts that the test person, in this case a nurse, selected. In order for the paper prototype to work optimally, the design needs to be well thought through before construction. For this, a method called hierarchical task analysis [46] was used. In this method, the functions of a product can be tested by analyzing the steps needed to complete a given task. It can be used for design as well as evaluation. However, for this survey it was only used in the design process.

The paper prototype used in this survey describes a web portal with four pages: “log in”-page, “patient”-page, “values”-page and “schedule”-page. On the “log in”-page the user can simply log in to the web portal. The “patient”-page lets the user search for patients and look at patient information, such as name, address, etc. Patient data is presented in graphs on the “values”-page. This was the most complicated page where the user can test several functions such as zooming, moving cursors and viewing different data sets. Lastly, the “schedule”-page, which was not tested in detail, showed a design suggestion of a system for scheduling times and measurements for patients.

4.2.2 Results from Nurse Survey

The interview began with a general question regarding the over all impression of the web portal. Two of the nurses considered the web portal simple to use, and used the word “foreseeable” to describe it. However, the third nurse thought that it would probably take some time to learn, as do all new systems. The more similar the web portal is to other systems they use, the easier it will be to learn.

Next, questions concerning the “patient”-page were asked. One nurse preferred to have one text box for name and one for personal number when searching for patients instead of a drop down list used to select which type of information to search for (e.g. personal number or last name). The other nurses did not mind the drop-down list. All three nurses would have liked to have the possibility to only write parts of the search, e.g. the first letter of the last name, or the first eight digits in the personal number. An idea was that only the patients that were connected to the nurse should be visible, but there should be a possibility to look at other nurses’ patients as well. However, patient data security and integrity has to be considered before implementing such a function. In the patient detail pop-up window the nurses thought it would be good if contact information of the patient’s relatives could be found. Also, the name of the button which opens the pop-up window should be changed from “detaljer” (eng. “details”) to “patientuppgifter” (eng. “patient information”).

The “value”-page was the most complicated, and the one where most time was spent during the interview. All three nurses found this page simple and effective. The possibility to study several different parameters, e.g weight and
blood pressure, at the same time was appreciated. One of the nurses claimed that
being able to compare values in this way was one of the major benefits of a system
like this, while another nurse had not considered this before. Values should be
connected to individual patients, i.e. only measurements and questions that the
patient measures should be visible. Having two axis in the graph, one for large
values and one for small values, did not seem to be a significant problem. The
nurses had different views on the introduced and calculated value “\( \Delta \)weight”,
which is the difference between the current data value and the mean of previous
data values. This calculated value gives an indication of changes in the weight
of the patient. One nurse found it unnecessary since they do this by hand.
Interestingly enough, this is the same reason that the other two nurses liked the
value; so that they did not have to calculate it by hand.

Lastly, the nurses were allowed to present any additional comments. One
nurse would like the possibility to add comments in the graph. This way certain
events, such as a change in treatment, could easily be connected to changes in
patient data.

4.3 Field Pre-Trial

Since the results from the patient survey, section 4.1, were promising, a longer
trial was completed in November-December of 2007. The aim of this trial was
not to get statistics on usability, cost efficiency, quality of life, or any other
parameter, but rather to see if a system like this is at all possible to implement
in a home setting. This was mainly done to prepare for a upcoming larger
trial with more patients over a longer period of time. Two patients, chosen
in cooperation with the heart failure nurses at the DAGA-clinic, were included
in the one month long pre-trial. The system tested in this trial was the first
prototype described in section 3.3.1. One nurse, responsible for both patients,
had access to the first version of the web portal. In that way she had access to
the patient data throughout the trial, but since the goal of the trial was not to
evaluate the web portal, this will not be discussed further.

At an initial meeting at the DAGA-clinic the system was demonstrated to
both patients, and the procedures of the trial were explained. The patients
had possibility to ask any questions they might have to either a technician or a
nurse during the meeting. Both patients agreed to have the complete prototype
system installed in their homes, and one of the patients also had an internet
connection installed since none was available before. Further instructions on the
system were given, both oral and written, during the installation of the system
in the homes of the patients. The patients were asked to direct any questions
regarding technical or functional issues about the system to the research group
at CTH during the trial, and any issues regarding their health to the nurses at
the DAGA-clinic as before.

After approximately one month of use, a semi-structured interview [45] was
performed at the home of each patient. Questions were asked regarding back-
ground, system functionality, design, and whether the patients had been to any
visits at the hospital during the trial. The interviews, which were 20 and 26
minutes long, were recorded, and full transcripts were written after the inter-
views. The results from the pre-trial are presented in a conference paper from 2008 [42], and were also presented at conferences during 2008.

4.3.1 Results from Field Pre-Trial

Starting with background information of the patients; both were over 65 years of age (69 and 79 years of age), retired, and living with a spouse. Both had children and grandchildren who, together with the spouse, were able to help with both health related as well as technical issues. They had both used computers in their work life, and one patient used computers and internet at home.

The results from the interviews of the patients indicate that the system works well in a home environment. Both patients were able to use the system as intended, and compliance with it was good. The extra session function was only utilized by one patient. No difficulties were noted on the tablet PC, including the touch sensitive screen and keyboard, which caused problems in the patient survey, see section 4.1. As for the medical equipment, the scale was well received by both patients, but the blood pressure monitor was problematic. One patient found the monitor painful and awkward, and the other patient needed technical support after the cuff had been twisted, thereby prohibiting the monitor from providing correct values.

Both patients were content with the user interface of the software. Size of text and buttons, as well as colors were satisfying. Whenever error occurred due to e.g. pressing buttons twice or entering incorrect values, the system reacted with appropriate error messages instructing the patients how to correct their mistakes.

Additional comments from the patients were that it seemed unnecessary to measure pulse (automatically done in the blood pressure monitor) and not entering it into the system. One patient, who was also diagnosed with type II diabetes mellitus, would like to document blood sugar values. An alarm system warning the nurses at the hospital of deteriorating health was also suggested.

During the trial one patient had been to a visit with the nurse at the DAGA-clinic. At that visit the nurse could examine the data collected during the trial and conclude that the treatment was working as intended, and no change in medication was necessary.
Chapter 5

Discussion

5.1 User Acceptance and Usability

In this thesis, the aim was to focus on one of the project goals for Care@Distance, namely how to design an eHealth-based disease management system for acceptance among health care providers and patients. For this, two prototype systems were created, and parts of them were evaluated.

The patient side of the system, called the home terminal, was designed in two different ways: one was a software program installed on a computer with a touch sensitive screen, and the other was a web-based solution enabling the patient to use any computer. There are advantages and disadvantages to both methods. In the first prototype the patient does not need to be very technologically advanced, because the key in designing it was simplicity. Anyone should be able to use it, no matter what computer experience they have. Both the patient survey and the small field trial indicate that there were no problems for patients with CHF to handle the first prototype system. Acceptance seemed very high as all patients in the survey answered that they could consider using the system on a daily basis, and the two patients in the small trial actually kept the system in their home even after the trial was over.

However, even if ten patients indicate in a survey that they could consider using a system similar to the first prototype regularly, it does not mean the same as actually using the system for a longer period of time. This is why the one month long trial was necessary, to give further insights. The two patients involved in the trial were chosen by the specialist nurses at the DAGA-clinic, and had volunteered as participants in the trial, which means they most likely had a positive attitude towards the system from the beginning. However, the results strongly indicates that an eHealth-based disease management system for CHF, designed for home use among the patients, is likely to be accepted by the patients.

Two major drawbacks for the first prototype are mobility and cost. The reason why one of the patients, involved in the home trial, finally returned the system was the inability to bring it to the summer vacation house. A mobile
system, using a wireless internet connection, could ensure that patients can keep the system with them at all times. If that patient had the possibility to access the system through a smart phone, a trip to the summer house would not have been a big issue.

The cost of the first prototype system, although less costly today, was also too high, both for this project and for health care. Allowing patients to use their own computers, or to supply them with less advanced communication equipment, reduces these costs considerably. Also, one should not forget that placing a system in a patient's home, with no other purpose than to monitor their health, could in itself be a burden. Even though the system is small, it still takes up room and needs to be connected both to the internet and to the power network. A PC in combination with a web-based application, as in the second prototype system, lets the patient perform other tasks with the computer when not transmitting data.

The web-based prototype used in this project was a natural evolution. An obvious drawback with a web-based solution is that the patients need to be more technologically advanced. Fear of technology, and maybe especially computers, is something that can be brought up in this context. However, other projects, e.g. the Action project [47], indicate that this may not be a big issue. Even if patients at first assume that they are unable to handle a computer they can, with the right education and support, soon become familiar with the system, as well as using the computer for other purposes. Other signs supporting the use of web-based solutions are the large amount of the population already using computers and internet in their homes, as discussed in section 3.3.2, as well as the next generation of patients being much more used to technology in general. One can also compare a solution for disease management to an internet bank system, where the users can handle their financial errands over the internet. This is very common in Sweden, as over 50% of the Swedish population used internet bank services at some time during the first quarter of 2007 [48].

All these arguments point towards a good possibility for acceptance of a web-based disease management system for chronically ill patients, not only CHF, at least considering the patient side of the system. Within the scope of this thesis the focus was on the usability and acceptance among the patient users, and not so much on the health care personnel. Although the nurses at the DAGA-clinic had a very positive attitude towards the web portal paper prototype, as well as the general idea of using the solution in their daily work routine, the survey presented in this thesis is not extensive enough to draw any conclusions on acceptance, usability and implementation among that group of users.

The results from the nurse survey are, however, not in anyway useless. Much experience was gained on design issues, which was applied when designing the second version of the web portal. Making the web portal resemble other systems used by the health care personnel seem to be an important issue. It can become troublesome and time consuming for the nurses switching between systems which are very different. Visual appearance and handling should be kept as similar to other systems as possible.

Especially important is the knowledge gained that the nurses do not believe that the design is a big problem, but rather the handling of large amount of data. Looking at graphs of patient data works fine when managing one or two patients,
but when the number of patients becomes large the work load can increase to unacceptable levels. A system which becomes a burden instead of a helpful tool will not be used. This topic will be of great interest in the subsequent work of this project, and is further discussed in section 6.2.1.

5.2 Design Considerations

When designing the prototype systems the age of the patients was kept in mind. Most patients with heart failure are over 65 years of age, and many of them also have problems with sight and hearing. Therefore, all buttons and texts were large, and colors were chosen not only to be pleasant to look at, but also to give high contrast. In the second prototype, error messages have red text, making it more obvious that something needs the patient’s attention. There were comments from nurses during the ten patient survey that some text in the first home terminal prototype might be too small for some patients. This was hopefully corrected in the second prototype, and upcoming evaluations will verify if the text size is adequate.

Another design choice was to keep the amount of text displayed in the program at a low level. However, this could cause problems with poor instructions to the patients. The solution was to use a help button which the patients can press if they need further instructions. One way to further evolve this could be to also add visual and audible instructions, though e.g. video or animations. This could prove beneficial for the patients who also have visual or audial impairments.

In the first prototype home terminal a sliding scale was used for the patients to answer questions. While this might seem like an intuitive way to answer questions of this type (numeric answers, Likert scale), some patients in the survey found this confusing, since this was something that they were not used to. Although the two patients in the home trial did not have difficulties with this, the design choice for the second home terminal prototype was to use radio buttons instead. It is also quite common in other web-based applications to use radio buttons, and this is something that patients that are familiar with technology might find much more intuitive. The possibility to answer questions using the keyboard instead of clicking on the screen was also added after suggestions from the test patients in the survey.

Both the blood pressure monitor and the weight scale used in this project were equipped with Bluetooth®. This is, however, yet to be utilized in this project. The main reason was that the hardware was not accompanied by any software, and creating that software was not prioritized. Therefore, the system was evaluated using manual insertion of the data into the system using a small numeric keyboard. As it turned out, this caused no major difficulties for the two patients who used the system for a longer period of time. One conclusion that can be drawn from this is that simplifying a system in general is not always the most important task. Instead of underestimating the users, one can work with them to investigate where the real issues are, and spend time on those parts instead.
5.3 Technical Issues

During the evaluations of the first home terminal prototype some technical issues, which can be of interest to others working with similar systems, occurred. The initial intention during the planning of the small trial in a home setting was to use a mobile internet connection using UMTS (3G). This would enable the patient to take the system wherever they went, and it would also solve the problem with patients that did not have a fixed internet connections in their home. Before installing the system in the homes of the patients, tests were done in the homes of members of the project group. These test soon showed that each day the internet connection was lost, and a new one had to be established. The reason for this was that the software used disconnected every 24 hours, probably to ensure that the user had not forgotten to disconnect. Though this might be very good in normal personal use of the mobile internet connection, it was not good for the applications used in this trial.

Another major issue which occurred during both the ten patient survey as well as the small home trial was the difficulty using the blood pressure monitor. It became obvious that the cuff of the blood pressure monitor was difficult for the patients to apply without help. This was partly solved by first helping the patient applying the cuff correctly, and then asking them not to open the cuff up again. Instead they should slip the cuff on and off their arm. However, it turned out that the patient sometimes still opened the cuff, and when trying to put it back on, twisted the cuff. The result was an incorrect measurement, and sometimes no measurement value was attained at all. Although this problem may be a result of insufficient instructions, it can still be questionable if a blood pressure monitor with an upper arm cuff is a good solution for home use. Even if the blood pressure readings are much more reliable with an upper arm cuff than with a monitor applied to the wrist, the wrist type may still be a better choice in this case. This is, however, something that should be subject to further investigation.

One technical problem that sometimes occurred was that the numeric keyboard used to enter values in the system sometimes stopped functioning. The reason for this was obvious; the patients sometimes accidentally pressed the “Num Lock” button the keyboard. This resulted in that no numeric values appeared on the screen when pressing the buttons. Also, the buttons on the keyboard were quite small, and patients with large hands were observed to have some difficulties pressing only one button at a time. These problems might have been avoided by using an automatic transmission of the data instead.

5.4 Patient Security and Integrity

An important issue when working with medical solutions and applications is patient security and integrity. So far in this thesis, the question on how to handle patient data has not been raised. This is mainly due to the fact that the aim of the project not is to create a commercial medical product; the intention is to attain new knowledge, it is not product development.

However, it may still be of interest to discuss the issue in relation to eHealth-
based disease management systems. As with all systems connected to the internet, there is a great risk of security breaches. When combining internet-based applications with patient specific medical data, the demands on security becomes even greater. In the prototype used in this project, no patient related information, such as name or personal number, is currently stored on the database. Instead, each patient is identified using a identification key, and a list connecting each patient to its identification key is kept on the side. Also, both the web portal and the home terminal of the second prototype are password protected using MD5 cryptography. Unfortunately, securing the home terminal using passwords reduces the usability of the system since the patient have to remember their passwords.

There are several possibilities to increase the security in future prototype systems or commercial solutions. Virtual private networks (VPN) where a link, or “tunnel”, is created between two points on a network is one possible way to increase security, as VPN could be used to connect the patient’s computer to the server. Another possibility is using TLS (Transport Layer Security, successor to the SSL, Secure Sockets Layer, protocol), which is a protocol for creating encrypted links over the network. This is a very common security solution for internet applications today. Also, data security can be further increased by encrypting all data stored on the server, or elsewhere.
Chapter 6

Future Work

6.1 Further Evaluations

In the work covered by this thesis, three evaluations were performed. However, none of the evaluations are very large, and in order to get more reliable results from which conclusions can be drawn, larger trials are necessary. The two patient home trial was a preparation for a larger home trial. Therefore, the aim of that trial was not to get statistically significant results, but rather to see if the prototype was usable for CHF patients, and stable enough for a home environment. Also, the hope was to receive user feedback which could lead to suitable improvements to the second prototype. Based on the experiences gained from the evaluations of the first prototype, such as high costs and lack of mobility, the larger trials will only involve the second web-based prototype.

Another advantage of using the second prototype system is that the evaluation can also include health care personnel. By allowing the nurses connected to the test patients to participate in the trials, acceptance among the health care professionals can be investigated. Also, if the patients know that the data they transmit is being monitored, their attitude towards the system might be more positive. Moreover, when using the web portal regularly, and in realistic conditions, the nurses will be able to give better feedback on the usability of the system.

One of the goals of the project Care@Distance was to attain knowledge on how to improve treatment compliance in chronic conditions. A first step in achieving this goal could be to look at the treatment compliance in CHF patients, and see if the prototype system developed for this project has any effect, positive or negative. For this it would be necessary to include both test patients using the system in their homes, as well as a control group not using the system. A large amount of patients would be needed to get statistically significant results. It would also be imperative to investigate how to evaluate treatment compliance without affecting the results.
6.2 Development

6.2.1 Decision Support

Creating a system for monitoring chronically ill patients might very well be a good way of improving quality of life for the patients, and reducing the costs on society. However, information overflow is something that has to be considered for all disease management systems. The prototype systems developed for this project may work for small groups of patients, but what happens when the amount of patients increase? Even if examining the data of one or two patients is feasible, this will not be the case when the nurse has large amount of patients to watch over.

Displaying data in graphs was a design choice to give a swift overview of the condition of the patient, but one can hardly expect nurses to look at the data of every patient on a regular basis. Therefore, a decision support system needs to be developed. If all patients could be categorized into high or low risk on a daily basis, depending on individual criteria, it would be easier for the nurse to see which patient is in need of further attention. How this should be done is subject to further research, but a suggestion would be to use some type of classification or prediction, where individual data is weighted and compared to base line data for the patient. Cooperation with specialists in treatment of CHF, and other chronic diseases, will be necessary to get accurate thresholds.

6.2.2 Improvements and Additions

One of the choices made when designing the prototype systems was to only use rather simple physiological measurements, namely weight and blood pressure. More advanced measurements, such as electro cardiography (ECG) were rejected, partly due to being unpractical in a home environment, but also because of a limitation made early in the project. The limitation was to focus on the large parts of the patient group, and not on special cases. For most patients, monitoring simple data such as weight and blood pressure, in combination with health related subjective values, is enough. However, for some special cases of patients, more advanced measurements could be beneficial. Since the prototypes designed in this project are very dynamic it would be quite easy to include other types of measurements.

Except for ECG, one interesting measurement technique for monitoring of certain cases of CHF patients would be electrical bio-impedance (EBI). Using this technique information such as heart contractility, stroke volume, and breathing patterns could be collected. Changes in chest EBI could also indicate fluid being build up in the lungs, a problem present if certain cases of CHF.

However, if measuring EBI, or other more advanced techniques in need of electrodes, is to be feasible in a home environment, alternative types of sensors need to be considered. The patients cannot be expected to apply disposable electrodes as would be the case in a clinical environment. A possible solution could be “smart textiles” or “intelligent clothes”, where electrodes are woven or sewn into textile fabric which is then made into e.g. a sweater or a wrist band. Another possibility is to develop sensors that the patients hold in their hands,
stand on, or are built into chairs or beds.

Mobility was a key issue for moving focus from an installed software to a web-based solution. An evolution of this could be to design a prototype system which also works for mobile phones, or so called “smart phones”. This would increase mobility further for those patients who are familiar with this technology. Since the second prototype is web-based, a foundation for this is already in place. However, the security issues must be considered before field trials can be performed. Using a mobile internet connection would also increase mobility, even when using a PC. The issues regarding disconnections during the small field trial of the first home terminal prototype will not be as problematic with the second prototype as there is no longer a need to be connected 24 hours a day.

The limitation to only include CHF patients in the work of this thesis could of course be extended to also include other disorders. As mentioned before, the flexibility of the prototype system makes it very easy to include both other types of measurements, as well as disease specific questions. CHF patients often have a combination with types of afflictions, such as diabetes, sight or hearing impairments, or obesity, and since the system is patient specific, it can be adjusted to suit individual patient needs, making the care personalized.

6.3 Implementation and Introduction Procedures

Even if a disease management system is accepted by both health care personnel and patients, the problem with introduction and implementation into the daily routines still exist. Answers to questions such as interoperability, support, payment, etc. need to be found. If these issues are not resolved the systems run the risk of being rejected, regardless of their usability and acceptance.
Appendix A

Database Design

Functional Dependencies

People(patientId, fName, sName, userName, password, role)

Sessions(sessionId, startTime, endTime, patientId)
  patientId → People.patientId

Measurements(measurementId, measurementName, noAlternatives, helpText, helpImage, inputType)

MeasurementsInSession(sessionId, measurementId)
  sessionId → Session.sessionId
  measurementId → InstrumentMeasurements.measurementId

Limits(patientId, measurementId, lowerLimit, upperLimit)
  patientId → People.patientId
  measurementId → InstrumentMeasurements.measurementId

Answers(patientId, measurementId, answerDateTime, answerText, answerExtra, comment)
  patientId → People.patientId
  measurementId → Measurements.measurementId

InstrumentMeasurements(measurementId, infoText, unit, manual)
  measurementId → Measurements.measurementId

Questions(measurementId, questionText)
  measurementId → Measurements.measurementId

Forms(formId, formName)

QuestionsInForm (measurementId, formId)
  measurementId → Questions.measurementId
  formId → Form.formId

FormsInSession(sessionId, formId)
  sessionId → Session.sessionId
  formId → Form.formId
Entity-Relationship Diagram
Appendix B

Survey Questionnaire and Interview Protocols

In this appendix the questionnaires and interview protocols for the two surveys and the small home pre-trial will be given in their original format. As both interviews and questionnaires were in Swedish, this is also the language they are presented in here. A translation on the questionnaire is available, and can be found in table 4.1 in section 4.1.

B.1 Patient Survey Questionnaire

The questionnaire begins on the next page.
Care @ Distance

Tack för att Du medverkar i denna undersökning!
V.g. fyll i formuläret nedan enligt instruktioner. Beräknat tid att fylla i är 5 minuter

Bakgrund
V.g. fyll i det alternativ som passar bäst in med Dig:
1. Kön □ Man □ Kvinn
2. Ålder □
3. Vilken tidigare datorvana har du?
□ Ingen □ Liten □ Medel □ Stor □ Mycket stor

Användning av datorprogrammet
Fråga: Hur enkelt tyckte du det var att:
(1=mycket svårt, 2=lite svårt, 3=medel, 4=enkelt, 5=mycket enkelt)

4. Skriva in blodtrycket? □ □ □ □ □
5. Skriva in vikten? □ □ □ □ □
6. Svara på frågorna om trötthet och andfåddhet? □ □ □ □ □
7. Förstå instruktionerna? □ □ □ □ □
8. Se knapparna på bildskärmen? □ □ □ □ □
9. Förstå vad knapparna på bildskärmen gjorde? □ □ □ □ □
10. Trycka på knapparna på bildskärmen? □ □ □ □ □
11. Läsa texten på knapparna på bildskärmen? □ □ □ □ □
Utseendet på datorprogrammet

Fråga: Vad tyckte du om:

12. Storleken på texten?  □ Bra  □ Dålig  □ Vet ej

13. Storleken på knapparna på bildskärmen?  □ Bra  □ Dålig  □ Vet ej

Fråga: Tyckte Du att:
(1=inte alls, 2=lite, 3=mellan, 4=väl, 5=mycket väl)

14. Formen på knapparna på bildskärmen ökade förståelsen av deras funktion?
   □ 1 □ 2 □ 3 □ 4 □ 5

15. Färgen på knapparna på bildskärmen var behaglig att titta på?
   □ 1 □ 2 □ 3 □ 4 □ 5

16. Färgen på knapparna på bildskärmen var tydlig?
   □ 1 □ 2 □ 3 □ 4 □ 5

17. Färgen på bakgrunden var behaglig att titta på?
   □ 1 □ 2 □ 3 □ 4 □ 5

18. Färgen på bakgrunden var tydlig?
   □ 1 □ 2 □ 3 □ 4 □ 5

19. Kombinationen av knappfärg och bakgrundsfärg var behaglig att titta på?
   □ 1 □ 2 □ 3 □ 4 □ 5

20. Kombinationen av knappfärg och bakgrundsfärg gjorde knapparna tydliga?
   □ 1 □ 2 □ 3 □ 4 □ 5

Sida 2 av 3  Var god vänd -->
Mätutrustningen

Fråga: Hur lätt tyckte Du det var att:
(1=mycket svårt, 2=lite svårt, 3=medel, 4=enkelt, 5=mycket enkelt)

21. Använda vågen?

22. Läsa av värdena på vågen?

23. Använda blodtrycksmätaren?

24. Läsa av värdena på blodtrycksmätaren?

25. Använda nummerknapparna (tangentbordet)?

26. Skulle Du kunna tänka Dig att använda detta system dagligen.

Övriga kommentarer

27. Är det något övrigt Du vill tillägga?

Återigen, tack för Din medverkan! Dina åsikter kommer vara till stor nytta vid utvecklingen av detta system!

Mvh,

Anna, Eva Lina och Niklas

Care@Distance-projektet

Sida 3 av 3
B.2 Nurse Survey Interview Template

1. Bara kort, vad var ditt allmänna intryck av hemsidan?
   a. svårighetsgrad?
   b. utseende?

2. Vi skippar inloggningssidan, utan går direkt till Patient-sidan.
   a. Fanns det något satt du tyckte kändes intuitivt rätt för att välja patient?
   b. Efter att jag visat andra metoder, var det någon du tyckte verkade lättare?
   c. Vad tycker du om att få upp detaljer i ett “pop-up” fönster? Hade det varit bättre att se all information på patient-sidan?
   d. Är det något du saknar, tycker är överflödigt, eller vill ändra på i denna sida?

   a. Vi börjar med metoden att välja värden, vad tyckte du om den?
   b. Var det bra att kunna välja flera värden, och tyckte du det var ett bra sätt att göra det på?
   c. Var det bra värden som fanns representerade? Är △vikt en bra idé? Något annat du vill se?
   d. Om vi nu istället tittar på grafen, är det bra att få en stor graf som fyller nästan hela fönstret? Alternativet är att kanske ha fler funktioner.
   e. Exempel på andra sätt att visa värdena är i tabellform. Hade du föredragit detta framför att se numeriska värden som “cursor” i grafen?
   f. Vad tyckte du om att ha två axlar, en för stora värden (blodtryck och puls) och en för små värden (frågor, △vikt)? Kan du tänka ut en bättre representation?
   g. Är det något du saknar, tycker är onödigt, eller vill ändra på?

   a. Vad tyckte du var svårt/lätt med funktionerna på denna sida?
   b. Är det något du saknar, tycker är onödligt, eller vill ändra på?

5. Slutligen, är det några andra saker du saknar, tycker är onödiga, eller vill ändra på? Någon sida du “saknar”?

6. Är detta något du skulle använda i ditt arbete?
B.3 Field Trial Interview Template

Inledning

Tack så mycket för att jag får komma hit och göra denna intervju. Om det är ok med dig så kommer jag att spela in samtalen för att sedan kunna använda dina svar i min forskning. Du kommer givetvis att vara anonym, dvs. ditt namn kommer inte att finnas med någonstans. Många av de frågor jag ställer har vi redan pratat om, men jag kommer att ställa dem ändå för att få med dina svar i protokollet.

Jag kommer att börja med några frågor om din bakgrund. Sedan ställer jag lite frågor om det tekniska, och till sist lite om designen. Du får när som helst välja att inte svara på en fråga.

Har du några frågor eller funderingar innan jag sätter på bandspelaren? (Paus för frågor och reflektioner från patienten) Då börjar vi! Jag slår på bandspelaren nu.

Bakgrund

Först tänkte jag ställa lite frågor om dig och din hälsa.

1. Hur gammal är du?
2. Vilken är din högsta utbildning? (Realen, studenten, universitet)
3. Vad är din sysselsättning nu? (Pensionär)
4. Vad arbetade du med tidigare?
5. Har du någon erfarenhet av datorer innan detta?
   a. Hemma?
   b. På jobbet?
6. Har du någon hemma/i familjen/i närheten som kan hjälpa dig?
7. Hur ofta träffar du läkare?
8. Har du några andra sjukdomar förutom hjärtsvikt?

Funktioner/teknik

Nu tänkte jag fråga lite om datorn och mätutrustningen du haft hemma i drygt en månad.

1. Hur ofta har du gjort dina mätningar? (Två gånger, en gång om dagen, då och då)
2. Har du gjort blodtrycks-/viktmätningar varje gång? Om nej, varför inte?
3. Har du svarat på formulären varje gång? Om nej, varför inte?
4. Har du använt extramätningfunktionen? Om ja, varför?
5. Vad tyckte du om:
   a. Pekskärmen? (lätt/svårt att trycka)
   b. Tangentbordet? (små/lagom knappar, svårt/lätt att träffa rätt, förståelse)
   c. Blodtrycksmätaren?
   d. Vågen?

6. Stötte du på några problem under försöket?
   a. Vad för problem? (Datorn, mätutrustningen, Internetuppkopplingen)
   b. Hur löste du dem? (Ringde Anna, löste själv, fick hjälp på annat håll)

7. Vad tyckte du var svårast med systemet?

8. Hade du velat ändra något? Vad?

9. Hade du velat lägga till något? Vad?

Design

1. Vad tyckte du om färgerna? (Behagliga, otrevliga, otydliga, kontrast bra/dålig)

2. Vad tyckte du om teckenstorlek/färg?

3. Vad tyckte du om storleken på knappar, fönster och bilder?

4. Vad tyckte du om formen på knapparna?

Annan

1. Har du varit på undersökning på sjukhuset under försöket?
   a. Tittade sköterskorna på dina varden i datorn då?
   b. Om nej, varför inte?
   c. Om ja, vad tyckte du om det och vad tror du de tyckte om det?

Avslut

Då var jag klar med alla mina frågor! Jag stänger nu av bandspelaren. Denna intervju kommer att användas som bakgrund till ett större försök vi ska ta ut i vår med fler patienter. Den kommer ev. också att finnas med i konferensartiklar och i min licentiatuppsats som kommer ut nästa höst om allt går väl.

Om du vill får du gärna behålla systemet hemma. Jag skulle uppskatta det eftersom vi kan upptäcka fler brister då, och kan göra bättre förbättringar till nästa version.

Är det något du undrar över, eller vill tillägga? (Paus för patienten att reflektera) Då tackar jag för mig!
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Design Evaluation of a Home-Based Telecare System for Chronic Heart Failure Patients

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