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**The Reality of Home Remote Patient Monitoring: a  
Thesis on the Nature, Dynamics and Effects of  
Telehealth**

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Juan Jesús Adriano Morán

**A Thesis Submitted for the Degree of Doctor of Philosophy (PhD)  
in Health Informatics**

City University London  
Centre for Health Informatics

**April 2012**

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## **DECLARATION**

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## **ABSTRACT**

Chronic diseases are very complex conditions in which two or more disease processes may coexist. Managing patients with chronic conditions represents a major challenge to public health, since eighty per cent of GP consultations are related to these groups. Furthermore, five per cent of them represent roughly forty two per cent of the total acute day bed occupancy.

Nowadays, the tendency is to bring patients from high levels of care to primary care and home settings. In this scenario, telehealth is one of the methods that can be used to improve and provide access to remote patient monitoring at home. This is important for patients with chronic diseases as it can help to recognise any signs of deterioration, provide health education and support management of their condition.

Potentially, telehealth can reduce deaths, emergency visits, A&E visits, elective admissions, bed stays and costs. This can be done by designing and implementing telehealth interventions that help reduce unnecessary referrals to specialised services and monitor patients remotely at home. However, there is not a unique framework for designing telehealth interventions. In order to design a robust, accurate and reliable telehealth intervention, a number of important factors have to be taken into account.

A review of three systematic reviews, and an in-depth investigation of a case study based on an EU funded project, were used to gather the evidence for telehealth interventions. These were used to identify the main components of the framework proposed. The investigation focused primarily on home monitoring for patients with diabetes, asthma, hypertension and COPD. We concluded that factors such as usability, safe intervention, patients' individual requirements, training, safe interventions, ease of use, data integration, development of procedures and allocation of appropriate staff are important components that need to be considered in order to satisfy a robust framework.

## KEY TO ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
BG	Blood Glucose
BMI	Body Mass Index
BP	Blood Pressure
CfH	Connecting for Health
COPD	Chronic Obstructive Pulmonary Disease
CSV	Comma Separated Values
DH	Department of Health
ECG	Electrocardiogram
EU	European Union
FAO	Food and Agriculture Organisation
FEV	Force Expiratory Volume
FVC	Forced Vital Capacity
GDP	Gross Domestic Product
GINA	Global Initiative for Asthma
GP	General Practitioner
HCI	Human Computer Interaction
ICT	Information and Communication Technologies
MBP	Mean Blood Pressure
NS	Non Stated
PDA	Personal Digital Assistant
PEF	Peak Expiratory Flow
PFR	Peak Flow Rate
QoL	Quality of Life
RCT	Randomised Control Trial
REALITY	Representative Evaluation of Evolving Remote Home-Based Patient Monitoring Delivery
SD	Standard Deviation
WHO	World Health Organisation
WSD	Whole System Demonstrator

# Chapter 1. Introduction

## 1.1 Background

Last decade, around six hundred million people represented the total ageing population in the world, and it has been predicted to rise to around two billion by 2050 (WHO, 2003). As three leading causes of diseases in adults aged 60 years and over are: (1) ischemic heart disease, (2) cerebrovascular disease, and (3) chronic obstructive pulmonary disease, the ageing population is more likely to suffer chronic and degenerative illnesses (WHO, 2003).

In the case of the UK, seventeen and a half million people live with a chronic disease, such as diabetes, asthma, or arthritis (DH, 2005a). Roughly 80% of GP consultations are related to chronic diseases, and around 5% of inpatients with chronic conditions (very high intensive users) constitute 42% of all acute bed-day occupancy (DH, 2004). Numbers in the rest of the world are not much better. Global estimations predict that by 2020, approximately 75% of all worldwide deaths will be as a consequence of chronic diseases (WHO/FAO, 2003).

In 2002, Derek Wanless (Wanless, 2002) explored future health trends and resources in terms of staff, equipment, and other technologies needed by the NHS to satisfy the health care demand by 2022. For this, a model was developed under three scenarios: “slow uptake”, “solid progress”, and “fully engaged”. The model predicted that, in the best of the cases (fully engaged), total health spending might increase from 7.7 to 10.6 percent of Gross Domestic Product (GDP); in the worst case scenario this would be up to 12.5 percent of GDP.

One can conclude from his report that, on the one hand, morbidity plays an important role in health care expenditure in England (likely to be similar in other countries). On the other hand, there is a need of increasing or optimising resources on the supply side to avoid any eventual collapse of the healthcare system.

It has been argued that access and consumption of technologies in everyday life may not only represent improvements to the quality of life, but also progress towards equity in contemporary societies. To avoid social segregation, a minimum

set of affordable products and services must be universally accessible and regulated by the state and local governments.

Emerging or enhanced Information and Communication Technologies (ICT) are acknowledged to have the potential of being adopted by a significant number of healthcare systems across the world and be critical for service modernisation. In recent years, the global tendency has been to consider ICT a key service for future delivery of care. This is related:

- First, to the latent worry and assumption that upcoming demand for health care is likely to be increased as a direct effect of the growing of the elderly population. In particular, the non disease-free groups and other particular health consumers living with long term conditions in whom disease management is often both complex and resource consuming.
- Second, to the fact that health workforce is currently limited; predictions state that this may remain in the same way.
- Finally, to the need for increasing health expenditure and optimising resources on the supply side. As stated above, by 2020, it has been predicted that the total health spending in the UK would increase up to 12.5 % of GDP in the worst case scenario.

Uncertainty of being able to meet and satisfy future demands has made institutions like the Department of Health (DH) to look at a range of alternatives for finding methods that not only satisfy but also help to provide and improve access to health and social care anywhere. Some of these choices fall within the domain of telehealth and telecare. By 2010, it was expected that home based monitoring systems would play an important role in the management of patients with chronic diseases (DH, 2002). Recently, the Department of Health (DH, 2012) has announced that at least 3 million people living with long term conditions and social care needs could benefit from the use of telehealth and telecare services over the next five years. This announcement was based on the early findings published by Whole System Demonstrator (WSD) programme (DH, 2011), the largest RCT of telehealth and telecare in the UK. The WSD indicated that telehealth can reduce deaths by 45%, emergency visits by 20%, A&E visits by 15%, elective admissions and bed stays by 14% and tariff cost by 8% (DH, 2011). These findings confirmed the expectations of many enthusiastic people, but are strongly questioned due to the lack of full results (McCartney, 2012).

## **1.2 Research problem and motivations**

Efforts have been made in telehealth research. This has generated roughly 6000 publications between 1964 and 2003, and ranks the UK after the USA in the second position of published papers on this field (Moser et al., 2004; Demiris and Tao, 2005). However, in spite of the considerable amount of research done, the survival of telehealth and telecare projects in the long term is very low. Furthermore, evidence of benefits is still scarce.

As observed by Hailey et al. (Hailey et al., 2002; Hailey et al., 2004), good quality studies are limited and insufficient. This is also confirmed by a similar study which concluded that there is little evidence about cost effectiveness (Whitten et al., 2002). In the organisational part, Aas (2002) has remarked on the lack of analysis of organisational changes as a consequence of telemedicine implementation. Such changes are important to be studied because they may have side effects in healthcare organisations. For example, the implementation of telemedicine and telecare could interfere with other activities of health providers, increment workload, and promote resistance to adoption.

In an effort to demonstrate the effects of telecare on frail elderly patients, a research group (Bayer et al., 2007) implemented a System Dynamics (SD) model. Their simulations showed that the impact of telecare would be minimal in the short term and, in the best of the cases, it could take up to 20 years to achieve a significant reduction in the demand for institutional care provided to the frail patient supported by telecare.

For successful design and implementation of telehealth and telecare services, many feasibility, observational, clinical and evaluation studies have been carried out in the past. Traditionally, these projects are implemented to capture organisational changes, direct benefits and economic implications caused by the adoption of such systems into the healthcare practice. However, because of the complexity involved, clinical effectiveness and evidence based practice are rarely or superficially investigated.

Besides, healthcare systems are usually messy and complex in nature. They involve different professions, divisions, and specialisations working together with the purpose of providing health services to patients and public in general. Issues in these organisations may be difficult to understand and interpret without a clear

notion of what is important to address. Others may be hard to decipher because of the complexity that they involve. Establishing a good framework for service design can help to make clear the relationships between the different components of a system and reduce its complexity. There is still room for research to be done and to get the evidence that proves what works best.

### **1.3 Hypothesis**

Ill-defined projects, technology-driven approaches, and lack of complex system understanding seem to be the factors that lead non-satisfactory telehealth implementations. Additionally, it is unknown the effects of patients' demographics on telehealth performance. Therefore, an investigations focusing on patient performance and effectiveness should help to develop a practical framework for the correct analysis, design, development, implementation and evaluation of telehealth services.

### **1.4 Aim and Objectives**

Considering the situation described above, the aim of this research is to develop a framework applicable to a broad spectrum of telehealth interventions for patients with long term conditions.

The specific objectives for the present work are:

- to provide a comprehensive review of literature on telehealth.
- to identify the most effective telehealth interventions in the cases of diabetes, asthma, chronic obstructive pulmonary disease and hypertension.
- to investigate any relationship between demographics, socio-economic status and patient's performance on telehealth.
- to evaluate the clinical effectiveness of a telehealth intervention
- to summarise findings and make recommendations.

### **1.5 Content**

The remainder of this thesis consists of the following chapters:

**Chapter 2**, introduces the subject using a number of definitions, such as telemedicine, telehealth, telecare and eHealth. It also justifies the need for telehealth systems in healthcare.

**Chapter 3**, reports the findings and presents the summaries of the telehealth studies extracted from three systematic reviews by gathering the best available evidence on telehealth interventions, specifically in home monitoring for patients who have diabetes, asthma, hypertension, and COPD. The review was focused mainly on studies that were comparable to a case study “The REALITY project”. In this chapter some important limitations were found in the evidence reviewed.

**Chapter 4**, is the introduction of our case study “The REALITY project”, an EU funded project in which UK, Estonia and Portugal were involved. In here clinical and demographic circumstances found among patients are summarised. It was concluded that in order to facilitate a more user centred approach, demographic characteristics must be considered in the design and implementation of the treatment intervention.

In **Chapter 5**, the association between patients’ demographics and their performance during the project are investigated. For this, a series of cross-tabulations and statistical tests for association were carried out, and it was found that the demographics of patients influences uptake of telehealth.

Results generated by the clinical outcomes collected from our case study are analysed in **chapter 6**, and a brief discussion about clinical effectiveness is given.

Study and main findings are summarised in **chapter 7**, limitations outlined and a series of recommendations made according to the research findings.

Finally in **chapter 8**, research contributions, review of the aim and objectives; and future research necessary to help overcome the current limitations of this research are summarised.

## **Chapter 2. Literature review**

### **2.1 Introduction**

Telehealth has been around for decades or even centuries. Its history can be traced back to the transmission of disease information, such as bubonic plague through heliograph or bonfires in Europe, and the use of telegraph for ordering medical supplies during the USA civil war (Zundel, 1996). However, it was not until the end of the Cold War and the conclusion of the 'space race' between the United States and the ex-Soviet Union that formal telemedicine programs began in earnest, mainly in the USA (Rinde and Balteskard, 2002).

The National Aeronautics and Space Administration (NASA), one of the pioneers of the telemedicine research (Nicogossian et al., 2004), has made important contributions to this field since the first attempts to put a man in space, when remote monitoring of the astronaut's health status was required. Currently, several technologies for telemedicine are commercially available and the rapid advance of telecommunications creates the opportunity to transmit not just bio-signals, but also documents, images, audio, and video via regular phone lines.

This chapter starts with an overview of definitions. Then, the chapter moves to examine why we need telehealth and ends with a discussion on aspects for adoption.

### **2.2 Definitions**

Agreements on terminology are required and probably will create intensive debates among researchers, professional bodies, and funding organisations. However, that should not distract their (or our) attention from other more important issues attached to telehealth and telecare. After all, new terms in the "tele" and "e" healthcare field may emerge as more innovative and sophisticated technologies appear in the future. Besides, a lack of universal definitions may be reflecting the inherent complexity and dynamic changes involved in these relatively new disciplines.

### **2.2.1 Telemedicine**

Etymologically speaking, telemedicine means medicine at a distance. It comes from the Greek -τελε - tele (far away, far off, at a distance) and the Latin medicina (medicine). The term was applied for the first time in the 1970s (Moore, 1999), and linked to the provision of medical services using ICT for remote delivery of care. This delivery, by definition, has often implied the intervention of a doctor on either side of the healthcare facility.

Commonly, telemedicine services are associated with the name of the medical speciality in matter. For example:

- Teleradiology, digital transmission of radiographs and other images to radiologists for interpretation and supervision.
- Telepathology, digital transmission of pathological details of samples to correspondent specialists for diagnostic.
- Teledermatology, examination of skin abnormalities by transmission of digital pictures to dermatologists.

Thus, semantically speaking, adding the prefix “tele” to a specific medical speciality can be generally referred to as telemedicine.

It is believed that telemedicine could become crucial as an alternative way of practicing medicine, for example, where limitations in face to face communications persist between patients living remotely, while medical specialists live, generally, in urban areas. However, currently, there is not a universal definition accepted by all its promoters.

For instance, the American Telemedicine Association (ATA) refers to telemedicine as “the use of medical information exchanged from one site to another via electronic communications to improve patients' health status”. Similarly, Nagendran et al. (2000) describe it as “medical practice at a distance, where the transmission of information and data related to the diagnostic and treatment of, as well as education about, medical conditions occur via electronic communication networks”. Darkins and Cary (2000) make evident the lack of consensus, and approach the issue suggesting the adoption of definitions already available in the literature. They argue that defining telemedicine is a matter of individual preference, and recommend the use of the word “telehealth” instead, as a more appropriate term.

The existence of several definitions can cause confusion and make telemedicine difficult to interpret (or to interpret in many different ways), including policy makers perceiving the implementation of EPR as telemedicine. Consequently, a concise and effective description is needed to resolve any ambiguity.

In this sense, Richard Wootton (Wootton, 2001) argues that telemedicine is “any medical activity involving an element of distance”. His conception is simple, concise, and comprehensive. He implicitly includes the use of technology, since non face to face communication processes currently involves any form of ICT, but at the same time, he leaves technology lying, perhaps intentionally, on a secondary plane. That opens the opportunity of perceiving telemedicine in a more clinical or patient-centred context.

### **2.2.2 Telehealth**

A broader expression, which covers a whole range of healthcare professionals, has been introduced in the literature over the past few decades. Bashshur (2000) argues that this term, telehealth, started to circulate in the late 1970s.

Literally, the term means delivery of health at distance. Such delivery can be set for clinical, administrative, educational, and other purposes. Therefore, the range of healthcare professionals who participate in telehealth, or telehealthcare, includes not just doctors, but also nurses, psychologists, paramedics, medical social workers, and so on.

Several telehealth definitions abound. To avoid citing all of them, we follow the approach by Darkins and Cary (2000), which proposes to embrace one of the descriptions already available in the literature. For this purpose, the latest definition published by Finch and colleagues is adopted below.

“Telehealthcare refers to a wider and more diffuse set of systems often employing nurses, that develops and delivers advice and treatment management, where participants are geographically separated.” (Finch et al., 2006)

Their definition covers two important aspects. First, they describe telehealth as a set of systems. This is an advantage, because thinking in terms of systems may be necessary for success implementation of telehealth. Second, they reveal one of the most common healthcare professionals truly involved in telehealth. It is

important to identify the role that nurses may be playing in telehealth because evidence shows that health workforce, particularly doctors, may refuse to accept its implementation (Tanriverdi and Iacono, 1998; Lapointe et al., 2002).

### **2.2.3 Telecare**

Telecare implies the delivery of either health or social care (or both) usually at home. Internationally, it is also known as telehomecare, home telehealth, or home based ehealth (Koch, 2005). Although several definitions of telecare abound, in the UK, telecare refers to the idea of enabling people to remain independent in their own homes by the use of sensors, alarms and monitoring devices to support the individual or their carers.

Telecare can be classified into three major categories (Barlow et al., 2004): safety and security monitoring (bath overflowing, gas left on, door unlocked), personal monitoring (physiological signs and activities of daily living), and information and communication (health advice through the phone, internet, or digital interactive TV).

Since the philosophy of telecare is to support independent living, especially for those who are vulnerable, the home environment becomes the usual care scenario. It is distinguished by the need of active commitment of patients (or people to be supported) in the adoption of telecare technology, and in handling self-management for their own care.

One could think of telecare as telehealth systems that are applied outside of healthcare facilities. Nevertheless, the purpose of telecare is not just to help patients, but also other people who are not necessarily ill, but suffer from any physical or mental impairment. In those cases, it is required that health and social carers work together as a multidisciplinary team.

### **2.2.4 eHealth**

It is most likely that the word electronic health or eHealth had been introduced into the “e-world” vocabulary (e-commerce, e-business, e-economics, e-consultancy, etc.) by industrial leaders and marketing people in the late 1990s (Eysenbach, 2001). Currently, the term has been adopted by scientific communities, governments, medical suppliers, and others.

eHealth involves more than just the attempt to explore electronic commerce into the healthcare field. Practically, it includes any lifestyle information and health application based on the internet. It also includes telemedicine and telecare (Wyatt and Liu, 2002).

At the present time, there is no single definition of eHealth and, most likely, there will not be one soon. A systematic review of eHealth published definitions (Oh et al., 2005), reported 51 different meanings of the term. Most of them included the words: health and technology as common denominators, and a combination of the words: commerce, activities, stakeholders, outcomes, places, and perspectives. Despite the lack of agreement, this term is widespread in industry and academia, and in clinical, finance, legal, educational, and health related journals (Pagliari et al., 2005).

Although difficult to define, in the simplistic way, one could think of eHealth in terms of digital information, the use of internet, and the health care context. However a more complete definition is given below:

“eHealth 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 information and communication technology.” (Eysenbach, 2001)

This definition has been proven to be the one most often cited on the internet (Oh et al., 2005), and is thus the definition adopted in this research.

In summary, first, we have emphasised the importance of terminology and have suggested the adoption of standard definitions for the terms telemedicine, telehealth, telecare, and eHealth. It is not easy to give a unique definition for each of them; however, it is clear that these terms have been commonly used for describing a non traditional approach to the remote delivery of care.

Second, although, the use of some of those expressions are considered “more politically correct” (Wootton, 2001), after eHealth (google.co.uk 31/5/2012;

eHealth: about 23,300,000 results), telemedicine (google.co.uk 31/5/201; telemedicine: about 5,550,000) seems to be one of the preferred terms to express this concept. This can be demonstrated by Googling “telemedicine”, which returns the largest number of results in comparison to the other terms discussed in this chapter.

Third, in any case, the correct use of one term over the others does not necessarily influence or affect the other issues (e.g., technological, organisational, legal, cultural, and ethical) related to these fields.

Finally, it can be concluded that telemedicine, telehealth, and telecare are subsets of eHealth.

### **2.3. Why do we need telehealth?**

Traditionally, telehealth has been seen as a way of enhancing healthcare systems. Ideally, it is expected that it will help to enable, not just equal access to healthcare for underserved populations, but also to enable people to remain living independently and to support them in their own homes. Concurrently, by introducing these unconventional health services, it is expected that healthcare systems will become more efficient through better use of the existing workforce and other resources. Decreasing waiting lists and costs (or at least, reduction in some health expenditure) are expected as a result of relocating patients from secondary and tertiary care to primary care and home settings.

In recent years, telemedicine, and more specifically telehealth, have been considered key services for the future delivery of health care. This is most likely related to concerns about potential increases in health demand as a consequence of:

- growing of an ageing population,
- management of complex diseases, and chronic conditions, that are often resource consuming, and
- workforce limitations to meet such demands.

However, the integration of new healthcare services based on ICT systems have been shown not to be an easy task.

### **2.3.1 Life expectancy**

Life expectancy is the period of time (in years) that a given person is expected to live. This can be referred “at birth” or at any time of interest. Life expectancy has been increasing relatively rapidly, particularly over the last fifty years worldwide. In medieval England, for example, life expectancy used to be between 32 to 35 years (Raleigh, 1999), whereas currently it is estimated to be around 80 years<sup>1</sup>.

The achievements of general increase in life expectancy worldwide can be attributed to global modernisation, access and better quality of resources such as water and food (Besley and Kudamatsu, 2006), improvement in education (Meara et al., 2008), and advances and production of new medical technologies (Kleinke, 2001) such as development of antibiotics, vaccinations, nutritional products, and electronic devices for diagnostic and medical treatment. Such achievements have had a direct impact on life expectancy at birth and have contributed to the increase in the population aged 60 years and over. However, this trend is not necessarily present in all over the world. Low life expectancy levels are still present in some developing countries, and has dramatically decreased as a consequence of dreadful diseases such as AIDS and malaria (Azémar and Desbordes, 2009).

### **2.3.2 Health demand and future issues in health and social care**

Ros and Drzymala (2002) argued that factors that affect or may change health demand are:

- Size and age composition of population,
- Changes in disease incidence and emerging new diseases,
- Geographic distribution,
- Education,
- Literacy levels,
- Individual income and wealth,
- New technologies, treatments, and tests,
- Increases in life expectancy, and
- More informed population

Ros and Drzymala have observed that increases in life expectancy will contribute to the demand for doctors in the future, and therefore, changes in the human

---

<sup>1</sup> <http://www.statistics.gov.uk/hub/population/deaths/life-expectancies/> [Accessed 3 March 2012]

longevity may compromise health systems in the world. This is because an ageing population tends to require more health services as they are more likely to suffer from chronic and degenerative conditions, as previously mentioned in chapter 1. Chronic diseases are “diseases of long duration and generally slow progression” (WHO, 2012). This therefore represents a major challenge to public health.

Estimations of people living with a long term condition such as diabetes, asthma, and arthritis are high (17.5 millions in the UK). Furthermore, 80% of total GP consultations are related to these chronic disease groups, and 5% of them represent roughly 42% of the total acute bed day occupancy (DH, 2004; DH, 2005b).

In the UK (Wittenberg et al., 2004), it is expected that the number of people over 65 years will rise from 9.3 to 16 million, and number of people over 85 years increase from 1.1 to 4 million by 2051. By 2020, population with long term conditions is expected to increase to 2.1 million (from 18.5 to 20.6 million).

In the social care arena, places in residential care homes, nursing homes and hospitals will need to rise by 150%. The number of home care hours will need to increase by around 137%, and, to satisfy such demand, the social care workforce will need to be more than double by 2051 (Wittenberg et al., 2004).

### **2.3.3 Benefits and factors of success**

Telehealth systems should satisfy patients’ needs. At the same time, it is expected that the use of such systems will help to enhance existing service delivery while relieving some of the pressure on services. Preliminary studies have shown multiple benefits in the utilisation of telemedicine. Such benefits can be grouped in six main categories (Hjelm, 2005): (1) improved access to information, (2) provision of care not previously deliverable, (3) improved access to services and increasing care delivery, (4) improved professional education, (5) quality control of screening programmes and (6) reduced health care cost.

A systematic review has shown effectiveness when telehealth was used in areas such as diabetes, mental health, risk pregnancy monitoring, heart failure, and cardiac diseases (Bensink et al., 2006a). However, positive outcomes are not enough to guarantee adoption if telehealth cannot demonstrate other elements of

success. Therefore, it is sensible to establish which factors of success or failure should be accepted as valid before performing any evaluation of telehealth. Yet, doing this can be very complex and several key points need to be taken into account.

For instance, Wootton and Herbert (2001) maintain that the appropriate indicators for measuring telemedicine factors are cost and quality of care. Table 2.1 illustrates the factors they commonly associate with success.

Table 2.1. Factors for success in telemedicine (Wootton and Hebert, 2001).

Factor	Quality metric	Cost metric
Routine operation	✓	✓
Successful outcomes	✓	
Mainly clinical activity	✓	
Sustainable operation	✓	✓
Cost-effectiveness		✓
Adequate financing		✓
High activity levels	✓	✓
Acceptance by clinicians	✓	
Improved access to health-care	✓	
Avoidance of travel		✓

Once success is defined, the next step is to understand how to achieve it. Researchers, in several research areas, have concluded that success may depend on the stakeholders and their views. For example, Checkland and Scholes (1990) pointed out the importance of *Weltanschauung*, a German word that means “the view of the world and human life”, when dealing with soft problems. Vos (2003) remarks on the need of identifying stakeholders since they can influence organisational behaviours. She cited a classification of stakeholders based on three main elements: power, urgency, and legitimacy (fig. 2.1), and proposed the use of critical systems heuristics, a modelling methodology, for the identification of stakeholders. Heriksen et al. (2005) used the stakeholder theory for telemedicine evaluation, and argued that without the inclusion of stakeholders in project planning, implementation of new eHealth services would not succeed.

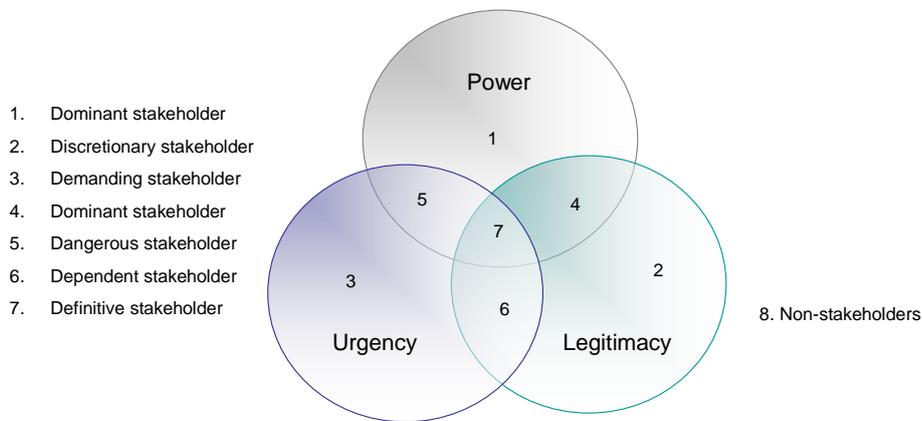


Figure 2.1. Classes of stakeholders (as cited by Vos (2003)).

Success may also depend on the decision of the scale at which a system or subsystem is going to be evaluated (e.g. individual, managerial, or organisational level). Flood and Carson (1993) refer to this scale as “level of resolution” and the decision of the scale as “system in focus”. For instance, Herber et al. (2002) proposed an evaluation framework in both levels of resolution: individual and organisational level (see fig. 2.2).

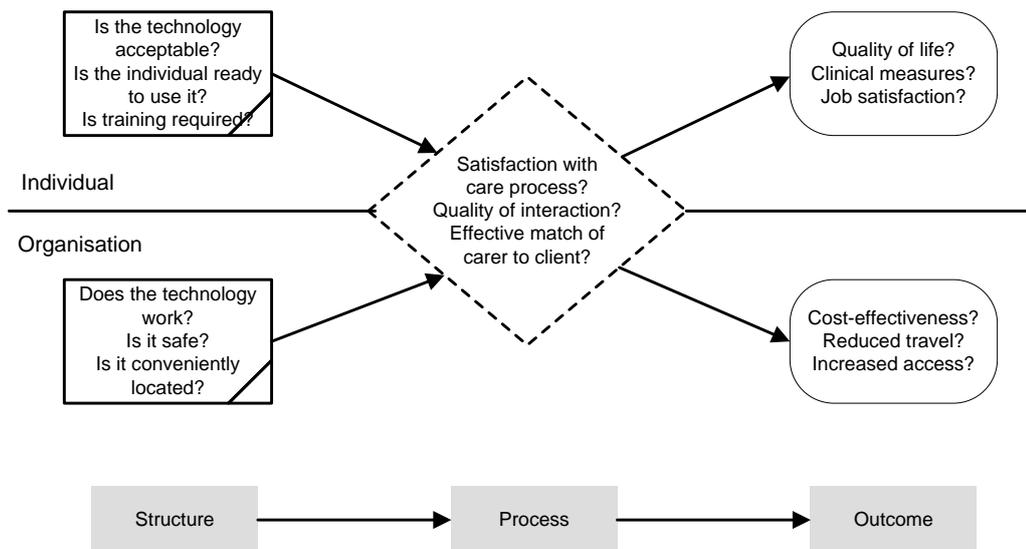


Figure 2.2. Framework for telehealth applications (Hebert et al., 2002).

As can be seen, telehealth success is multifactorial. Therefore an appropriate evaluation framework is likely to be the most valuable way to assess success.

## **2.4 Adoption considerations**

Omitting financial and technology considerations, the major aspects to be considered for adoption of telehealth can be summarised as:

- People
- Organisational context
- Evaluation

### **2.4.1 People**

Previous studies have shown that people's attitudes, expectations, perspectives, needs, and roles are determinant in the adoption of ICT (Rigby and Robins, 1997; Hu et al., 2000; Lahdenpera and Kyngas, 2000; Lehoux et al., 2002; Gagnon et al., 2003; Hibbert et al., 2003; Levy et al., 2003; Stronge et al., 2007). It is also important to bear in mind how people are going to be interacting with technology in order to avoid obtrusiveness (Hensel et al., 2006). Therefore, it is imperative to identify and consider all of the key players in telehealth to guarantee the success of the service.

In a telehealth system, stakeholders can range from patients to doctors, nurses, healthcare assistants, patients' relatives, technology providers, and other healthcare professionals. They usually have different needs, expectations, and priorities. Understanding, determining, and satisfying them, should ensure, if not success, at least effective communication in the care practice. Three major groups are under discussion below.

#### **2.4.1.1 Doctors and other healthcare professionals**

As a whole, telehealth, and also telecare, can be "attractive" choices for delivery of health care and ways of workforce preservation in rural areas (Isles, 2001). However, it has been suggested that the health workforce, particularly doctors, may resist ICT adoption if they perceive any loss of autonomy, status, or change in their role as practitioners (Tanriverdi and Iacono, 1998; Hu et al., 2000; Lapointe et al., 2002). Furthermore, it is unknown how compatible telehealth will be with the physician's clinical routines (Lehoux et al., 2002). Thus, in order to match managerial needs with the health professional ones, health workers should

be involved in early stages of telehealth implementation. Otherwise, disagreements could provoke implementation of new telehealth policies to fail.

#### 2.4.1.2 Patients

Patients are also stakeholders that play an active role in the acceptance of telehealth. Their expectations about living independently, especially in the group of older adults, are high and make telehealth very attractive. So far, the attitude of older people to telehealth has been reported positively (Levy et al., 2003). However, as suggested by Lahdenperä and Kyngäs (2000) if the patient feels that a telehealth service would detriment rather than benefit his or her treatment, then, the technology should not be used. For these reasons, considering the patient's perspective for implementing telehealth should ensure that their needs are met.

#### 2.4.1.3 Relatives

Last but not least, special attention should be given to a patient's relatives since they play an important role in the provision of care. In recent studies, relatives have been actively involved in the telehealth process, especially for providing psychological support. Evidence shows that their opinion about telehealth has been overall positive (Sävenstedt et al., 2003; Bensink et al., 2006b; Engström et al., 2006).

### **2.4.2 Organisational context**

“Many implementation difficulties relate more to the organizational and structural conditions within which telecare is deployed than the technology itself...The service redesign implications of telecare – including associated organizational and cultural issues – need to be addressed and a better understanding of the systemic effects of telecare over time is required.” (Barlow et al., 2005)

“When IT is implemented, high failure rates may be related to individual and organisational factor...At its present volume, telemedicine generally fitted well into daily work routines. In the future...it may be necessary to distribute the telemedicine activity...[and] to limit the length of sessions and to plan breaks during sessions” (Aas, 2001).

Understanding that the relation between cause and effect is often separated in time and space should help decision makers to prevent unintended organisational

consequences. Therefore, the field of eHealth requires some reasonable guidelines that help to identify and prevent or reduce organisational issues.

In the managerial world, responses may be the consequences of the introduction of new policies, technologies, and work procedures (stimuli) in organisations. These stimuli may or may not provoke any organisational response. But, in case they do, appropriate evaluation frameworks are required to observe those effects. However, little work has been carried out in developing organisational models for telehealth.

Organisational change theories have been proposed to evaluate alterations in the state of organisations. Stickland (2002) cites and summarises such theories in three perspectives:

- Organisational level
- Group level
- Individual level

According to Stickland, analysis of the changes at organisational level firstly implies a look at the organisation and its components (subsystems) as well as the interactions among them, and secondly, a look at the subsystem interactions with their external environment. This perspective allows analysis at the macro level, e.g., “changes in culture, corporate structure or high level business process” (Stickland, 2002).

At the group level, as its name implies, it is focused on the group and team behaviour. Values, norms, and roles are involved in the change, which is seen as an expression of interactions, conflicts and relationships among groups. This perspective deals with the social and psychological aspects of organisations.

Finally, the individual level concentrates on understanding individual needs and motivations which can help to prevent or minimise possible areas of resistance to change, and at the same time, to identify how to deal with them. “Emancipation, participation and ownership are considered key concepts to understanding effective change management” (Stickland, 2002).

Organisational structures define the way in which organisations operate and perform. In order for telehealth to perform well, it is required to be “needs-driven”

rather than being driven by technology (Brebner et al., 2005). There is also a need for having enough finance and well established policies, procedures, protocols, and work practice as well as to provide patients and staff training. During implementation of new ways of delivering care, such as telehealth, special attention should be given to time spent with patients (McIntosh et al., 2003), where doctors and other healthcare providers may be already exhausted (Morrison and Smith, 2000). This can create additional strain. In these types of cases, telehealth may create conflicts rather than satisfying demand (Oldham, 1999).

### **2.4.3 Evaluation**

From this point of view, evaluation has to show positive clinical outcomes as well as proper economical analyses. One could say that this is the “Achilles’ heel” of telehealth. Clinical and economic analysis led this issue.

In clinical evaluation, the Randomised Controlled Trial (RCT) is the gold standard. Unfortunately, the majority of research trials omit this standard. From the economic evaluation side sustainability has to be shown.

Problems on evaluation can be summarised from Whetton (2005):

- Weak study design
- Insufficient or inadequate data
- Focus on pilot projects and short perspective
- Lack of information on broad health outcome
- Emphasis on qualitative user satisfaction
- Problems with the measurement of cost
- Focus on descriptive rather than analytical evaluation criteria
- Few comparisons of telemedicine with conventional service delivery

Rapidly evolving technologies present additional problems for evaluation. As new technologies become available in healthcare, standard evaluation methods used in the past may be no longer applicable or appropriate. For example, clinical trials are usually dependent on a specific fixed technology. This can lead to a clinical trial that is in the verge of being technologically obsolete before it is even completed. Therefore, it is important to respond appropriately to such new technologies. Firstly, by identifying them through horizon scanning (word of mouth, published reports and the World Wide Web) and collective scanning

(regular meetings and surveys of sentinel groups of experts) (Stevens et al., 1999). Secondly, by designing evaluation methods that take into account the evolution of technology, techniques, and additional information that routinely occurs. A good example of these methods comes from Lilford et al. (2000) who have suggested the use of “tracker trials”, a flexible method which allows different new treatments to be compared and evaluated. This method can be used for rapid detection of treatments that perform poorly or are potentially dangerous, to reject unpromising new treatments, and to provide maximum information as to which treatments are best (Lilford et al., 2000).

According to Friedman and Wyatt (2006) evaluation “describes a range of data-collection activities designed to answer questions ranging from the casual...to the more focused...”. They argue that reasons for performing evaluations in the “biomedical informatics field” are related to promotional, scholarly, pragmatic, ethical, and medico-legal circumstances. The idea of performing evaluations is to study the collection, processing, and communication of information related to health care, research, or health education.

Telehealth evaluation should be created for the purpose of systematically documenting, collecting, and analysing in detail any evidence that answers questions concerning “the benefits and costs of alternative modalities and various dynamic combinations and configurations of technology, human resources and health applications” (Bashshur et al., 2005). Bashshur et al. argue that an agenda for programme evaluation in health care usually combines two components: “scientific requirements” (robust research design, reliable and valid measurement, and rigorous methods for collection and data analysis) and “political realities” (priorities of public policy and funding agencies and process of allocating research fund). According to them, these components are usually incompatible and part of the basic issues in evaluation.

In fact, success may be influenced by political conditions, which are needed for starting any telehealth initiatives, but not totally necessary to guarantee success. Nevertheless, it is better to bear in mind that some political circumstances, e.g. governmental transitions, may provoke the failure of telemedicine implementation (Urtubey and Petrich, 2002).

Complexity seems to be inherent to healthcare and telehealth interventions (Finch et al., 2003; Campbell et al., 2007). That may explain why clinical evidence and cost-effectiveness studies are limited in telehealth and telecare. This has been highlighted by Aoki et al. (2003) who reviewed a hundred and four articles to investigate telehealth evaluation studies. They found that sixty four percent of evaluations were descriptive or “ad hoc”, twenty seven percent employed a statistical analysis, and eight percent performed cost analysis. They concluded that evaluation of telemedicine might require cooperation of multiple disciplines and methodologies. Bashshur et al (2005) also discussed the level of complexity that is inherent to health programme evaluation and classified it in two types: the ones concerned with testing efficacy, effectiveness and safety of new medical technology and the ones related to assessment of performance and achievements in terms of stated goals and objectives.

However, one of the basic problems of telehealth evaluation, as observed by Harrison et al. (2002), seems to lie mostly in “conducting an evaluation before a particular technique has become stable and accepted into daily routine”. Another problem is present when pilot projects rely on volunteers or enthusiasts (Hebert, 2001). Consequently, the use of a suitable methodology or framework for dealing with the evaluation of telehealth systems is required.

Carson et al. (1998), and Cramp and Carson (2000) suggest the use of System Methodology for dealing with such complex issues. Other researchers such as Campbell et al. (2007) also pointed out the need for modelling during evaluation of complex interventions.

## **2.5 Summary**

In this chapter, it has been noted that technology is not the most important element of a telehealth system. Telehealth embraces human resources and health applications embedded in an organisation (Bashshur et al., 2005). Technology is a tool for enhancing the delivery of health care, but not the whole solution.

Success of telehealth can be seen from many stakeholder perspectives and at different levels of resolution. Thus, it is important to define what tools can be acceptable for measuring success.

Evaluating the promises of telehealth requires looking into the patient's health status, the relationships among stakeholders, and the interaction with technology. There is no doubt that telehealth has the potential to bring enormous benefits. However, to do so, it will definitely require changes in both the way healthcare organisations are currently set up, and the way in which patients are traditionally involved in their own disease management.

## **Chapter 3. What the evidence says?**

### **3.1 Introduction**

A search for research papers was conducted in order to gather the best available evidence on telehealth interventions, specifically in home monitoring for patients who have diabetes, asthma, hypertension, and chronic obstructive pulmonary disease (COPD). The review was focused mainly on studies that were comparable to the REALITY project (REALITY Consortium, 2005b).

This chapter reports the findings and presents the summaries of the telehealth studies extracted from three systematic reviews.

### **3.2 Aim**

We reviewed a number of pieces of evidence available for home telehealth systems with the aim of determining clinical effectiveness and to find the best models for telehealth implementation. In order to achieve this aim, we analysed the existing systematic reviews considered to synthesise the best interventions available, and reviewed their primary studies in the case of diabetes, asthma, hypertension, and COPD.

### **3.3 Search strategy**

A literature search was performed for identifying systematic reviews in home telehealth published between January 2000 and July 2007. To find out the relevant reviews, this study was conducted using the databases: PubMed, the Cochrane Library and ISI Web of Knowledge. Search keywords applied for extraction of reviews were: systematic AND review AND (telemedicine OR telecare OR telehealth OR telemonitoring OR telehome) AND home AND (outcome OR evidence or benefits) NOT (smart OR alarm).

This strategy found 18 items in PubMed, 0 items in the Cochrane Library and 15 items in ISI Web of Knowledge. After exclusion of 14 duplicated records, a total of 19 articles were identified among the 3 databases. From these titles, 9 articles were judged to be potentially relevant and corresponding abstracts were retrieved online. Only 3 articles were downloaded for closer inspection and full text review.

### **3.4 Inclusion criteria (systematic review)**

A systematic review was selected when the study:

- was written in English;
- was described in detail to assess the type of telehealth interventions included;
- attempted to show any evidence of clinical benefits; and
- included cases with participants who were treated for asthma, diabetes, hypertension, or COPD.

### **3.5 Exclusion criteria (systematic review)**

Systematic reviews were excluded when:

- technology, education or economic impact was the main reason for performing such study;
- the majority of primary studies within the review were not related to home telehealth or already covered in a more recent revision.

## **3.6 Results**

### **3.6.1 Primary study extraction and synthesis**

Three systematic reviews met the inclusion criteria (Bensink et al., 2006a; Barlow et al., 2007; Pare et al., 2007). Mark Bensink kindly provided a full electronic reference of papers reviewed via email. In the case of the review by Barlow et al., the URL <http://www.cat.csip.org.uk/index.cfm?pid=433> was used to contain the complete details of references; however, access to the URL is no longer available. Pare et al. cited all the primary studies in their original paper. Search terms, inclusion criteria and exclusion criteria of the 3 systematic reviews selected are shown in table 3.1.

Table 3.1. Comparison of search terms, inclusion and exclusion criteria.

	Bensink et al. (2006a)	Barlow et al. (2007)	Pare et al. (2007)
Search terms	<p>1. Telehomecare OR tele-homecare</p> <p>2. Telemedicine OR remote consultation OR online health OR on-line health OR telepathology OR telepathology OR telehealth OR teleHealth OR eHealth OR ehealth OR telecare OR telecare OR teledermatology OR tele-dermatology OR telepsychiatry OR telepsychiatry OR telesurgery OR tele-surgery OR teleconsult* OR tele-consult* OR telecardiology OR telecardiology OR teleophthalmology OR teleophthalmology OR teleoncology OR teleoncology OR teleradiology OR tele-radiology OR teleneurology OR tele-neurology OR telemental health OR tele-mental health OR teleradiology OR tele-radiology OR e-mental health OR telemetry OR telegeriatric* OR telegeriatric* OR teledialysis OR tele-dialysis OR telerehabilitation OR tele-rehabilitation.</p> <p><sup>2</sup></p>	<p>Telecare, telemedicine, telehealth, telehomecare, ehealth, telephone monitoring, alerts, telephone support, telesecurity, community alarm, teleconsultation, teleconference, call centre, telecommunication s, prevention, health-care delivery, frail elderly, long-term conditions, chronic condition, chronic care, heart failure, asthma, diabetes, depression, dementia, arthritis, stroke, hypertension, COPD, systematic review, randomized trial, names of key researchers</p>	<p>Telemonitoring, telecare, telemedicine, telematics, telehealth, and telehomecare in conjunction with diabetes, hypertension, blood pressure, pulmonary diseases/conditions, asthma, respiratory diseases/ conditions, cardiac diseases/ conditions, and heart failure.</p>
Inclusion criteria	<p>1. Studies that reported outcomes in terms of administrative changes, patient management decisions, patient outcomes, caregiver outcomes, economic impact, or social impact on patients.</p>	<p>1. Examined home-based telehealth services.</p> <p>2. Included telehealth as a core component, not merely one intervention among</p>	<p>1. Have an experimental design involving direct data collection from patients with any of the four considered</p>

<sup>2</sup> 3. Home\* OR home-care OR home health care\* OR home nursing\* OR home care agencies OR home care services\* OR home dialysis OR home health agencies OR home monitoring OR rehabilitation OR home visits OR homebound patients OR homebound persons OR self help devices OR self administration OR self care OR self evaluation OR self help OR self medication

4. Cost OR cost-effectiveness OR economic\* OR cost analysis OR budget OR financial OR health care costs OR cost-benefit analysis OR cost of illness OR cost description OR cost minimization analysis OR cost-utility analysis

5. Teleeducation OR tele-education OR teleteaching OR tele-teaching OR telelearning OR tele-learning

6. 2 AND 3

7. 1 AND 4

8. 2 AND 3 AND 4

9. 3 AND 5

		<p>many.</p> <ol style="list-style-type: none"> <li>3. Included information about individual or system wide effects.</li> <li>4. Included frail elderly people or adults of any age with long-term conditions.</li> <li>5. Comprised randomized trials of any size or observational studies with at least 80 participants.</li> </ol>	<p>chronic diseases,</p> <ol style="list-style-type: none"> <li>2. Be published in the English language and appear in peer-reviewed journals, and</li> <li>3. Documented telemonitoring effects.</li> </ol>
Exclusion criteria	<ol style="list-style-type: none"> <li>1. References without abstracts were excluded.</li> <li>2. Where duplicate publications were identified, i.e. papers reporting results on the same set of patient data in different journals or papers reporting preliminary results of a research project where a subsequent paper reported the full project results, the most comprehensive publication was selected for review.</li> </ol>	<ol style="list-style-type: none"> <li>1. Reviews, purely descriptive studies and those which focused only on implementation issues or satisfaction.</li> <li>2. Had insufficient methodological detail, focused on residential homes, prisons or other institutions, or</li> <li>3. Focused on terminal conditions.</li> </ol>	<ol style="list-style-type: none"> <li>1. Conference and poster abstracts, which do not present detailed studies</li> <li>2. General reviews, articles that focused on multipathology groups of patients, or did not involve telemonitoring experiments and timely transmission of data.</li> <li>3. Publications that focused on pregnant women, patients on dialysis, AIDS/HIV patients</li> <li>4. other locations than home (e.g., prisons)</li> </ol>

After collecting references, all primary studies covering diabetes, hypertension, asthma and COPD were identified and searched for. Articles were obtained and read by a single researcher (JA). After exclusion of duplicated records, a total of 67 articles were obtained: 37 (55%) related to diabetes, 16 (24%) in hypertension, 10 (15%) in asthma and 4 (6%) in COPD.

For each primary study, data were extracted according to the following categories: general study characteristics, patient characteristics, and PICO model. A complete list of items included in every category is displayed in table 3.2.

Table 3.2. Information extracted by category.

<b>Category</b>	<b>items</b>
I. General study characteristics:	<ul style="list-style-type: none"> <li>• first author</li> <li>• year</li> <li>• country of origin</li> <li>• objective</li> </ul>
II. Patient characteristics:	<ul style="list-style-type: none"> <li>• total sample size</li> <li>• age</li> <li>• gender</li> <li>• disease duration</li> <li>• interventions time</li> </ul>
III. PICO model:	<ul style="list-style-type: none"> <li>• population</li> <li>• intervention</li> <li>• comparison (control group)</li> <li>• outcome</li> </ul>

The studies were grouped by disease conditions and synthesised information is reported in sections 3.6.2, 3.6.3, 3.6.4 and 3.6.5 according to the items in table 3.2. When available, continuous data (measurement of a numerical quantity) were extracted, analysed and directly plotted for quantifying the clinical effects using meta-analysis.

### **3.6.2 Diabetes publications**

**Author/Year:** Ahring et al. (1992)

**Country:** Canada

**Study objective:** to assess if care accessibility by modem improved diabetes control.

**Total participants:** 42

**Age<sub>avg</sub> (yrs):** 41.4

**Gender (% male):** 47.1

**Disease duration (yrs):** 11.5

**Intervention time (months):** 3

**Population:** diabetic patients with insulin dependency.

**Intervention:** 22 patients were provided with glucometers and telephone modems to monitor and send data once a week. Patients were contacted by telephone for insulin adjustments and food intake.

**Control:** 20 patients collected glucose readings 5 times/day twice at week and kept their data in a diary or in the glucometer's memory.

**Outcome:** researches reported that a better control of HbA1c was observed in the intervention group.

**Author/Year:** Albisser et al. (1996)

**Country:** USA

**Study objective:** to design and evaluate an electronic system that facilitates improvement in blood glucose control.

**Total participants:** 204

**Age<sub>avg</sub> (yrs):** NS

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** 12

**Population:** Patients with diabetes type 1 and 2.

**Intervention:** Patients collected blood glucose, crisis events, lifestyle factor, and medication data. A touch-tone phone was used to transmit data to an electronic information system. A nurse supported the patients (medication adjustments and pertinent feedback) and a doctor reviewed printed reports on a weekly basis.

**Control:** Patients not actively using the system.

**Outcome:** researchers reported that HbA1c improvements in the intervention group were statistically significant.

**Author/Year:** Bellazi et al. (2002)

**Country:** Italy

**Study objective:** to design, develop and evaluate a telehealth system for diabetes management.

**Total participants:** 12

**Age<sub>avg</sub> (yrs):** 35

**Gender (% male):** 54

**Disease duration (yrs):** NS

**Intervention time (months):** 18

**Population:** 12 patients recruited in 4 medical centres (Italy, Spain and Finland).

**Intervention:** patients were provided with monitors to collect and send blood glucose data to a database in a hospital. The system assisted physicians in the definition of basal insulin regimen.

**Control:** no control group.

**Outcome:** researchers found that there was not a significant reduction in HbA1c but there was a significant reduction in insulin requirement.

**Author/Year:** Bergenstal et al. (2005)

**Country:** USA

**Study objective:** to evaluate the impact of transferring blood glucose information via modem.

**Total participants:** 47

**Age<sub>avg</sub> (yrs):** 44

**Gender (% male):** 38

**Disease duration (yrs):** NS

**Intervention time (months):** 1

**Population:** patients with diabetes type 1 and 2.

**Intervention:** 24 patients were provided with a blood glucose meter. Data were sent to a fax machine using a modem at least once a week.

**Control:** 23 patients collected blood glucose data in a booklet and reported results by telephone.

**Outcome:** researchers reported that similar improvements in HbA1c were found among groups. Data reported by telephone had 6% error (0% error by modem).

**Author/Year:** Biermann et al. (2000)

**Country:** Germany

**Study objective:** to assess the impact of a telehealth system in terms of clinical outcomes, economical savings and patient satisfaction.

**Total participants:** 46

**Age<sub>avg</sub> (yrs):** 30.5

**Gender (% male):** NS

**Disease duration (yrs):** 9

**Intervention time (months):** 8

**Population:** patients with diabetes type 1.

**Intervention:** 30 patients were provided with a blood glucose meter connected to a modem to transmit data from home to a diabetes centre every 1 to 3 weeks.

**Control:** 16 patients were in conventional outpatient care with personal visits.

**Outcome:** researchers reported that similar improvements in HbA1c were found with no significant difference between the groups.

**Author/Year:** Biermann et al. (2002)

**Country:** Germany

**Study objective:** to find out if there were any time and cost savings by using telehealth.

**Total participants:** 43

**Age<sub>avg</sub> (yrs):** 30

**Gender (% male):** NS

**Disease duration (yrs):** 9.8

**Intervention time (months):** 8

**Population:** diabetic patients with insulin dependency.

**Intervention:** 27 patients measured their blood glucose and transmitted their values by modem before visits or personal consultations for at least every 2 weeks. Advice for insulin adjustment was provided by phone.

**Control:** 16 patients received conventional care. All patients had diabetes training for dose adaptation.

**Outcome:** researchers reported that HbA1c improved in the intervention group but was not significantly better than in the control group. Telehealth could help to save time and cost.

**Author/Year:** Billard et al. (1991)

**Country:** France

**Study objective:** to study the use and effects of transmitting self monitoring BG to a central database for glucose monitoring.

**Total participants:** 22

**Age<sub>avg</sub> (yrs):** 32

**Gender (% male):** 36

**Disease duration (yrs):** 13

**Intervention time (months):** 3

**Population:** diabetic patients with insulin dependency.

**Intervention:** 11 patients were provided with glucometers. Data were sent to a central database throughout a telephone network by a minitel terminal. Patients could use their system on demand.

**Control:** 11 patients were provided with glucometers and data were recorded in booklets.

**Outcome:** researchers reported that self monitoring of BG was feasible and metabolic control improved slightly.

**Author/Year:** Chase et al. (2003)

**Country:** USA

**Study objective:** to determine the impact of modem transmission when used instead of clinical visits.

**Total participants:** 70

**Age<sub>avg</sub> (yrs):** 17

**Gender (% male):** 47

**Disease duration (yrs):** 7.9

**Intervention time (months):** 6

**Population:** adolescent patients with diabetes type 1.

**Intervention:** 35 patients had 2 clinic visits (0 and 6 months) and transmitted blood glucose data every 2 weeks via modem. A nurse reviewed data and called patients to provide feedback and made treatment changes if needed.

**Control:** 35 patients had 3 clinic visits (at 0, 3, and 6 months) with the option of sending blood glucose data to a clinic through telephone or fax as desired.

**Outcome:** researchers found that HbA1c decreased in both groups with not statistically significant difference.

**Author/Year:** Chumbler et al. (2005a)

**Country:** USA

**Study objective:** to assess the effect of 2 different telehealth monitoring intensities for veterans.

**Total participants:** 395

**Age<sub>avg</sub> (yrs):** 66.5

**Gender (% male):** 97.5

**Disease duration (yrs):** NS

**Intervention time**

**(months):** 12

**Population:** patients with diabetes who had complex medication conditions and high risk factors for healthcare utilisation.

**Intervention:** one group of patients was monitored weekly for aggressive wound management to promote healing. Patients (or caregivers) took pictures of their wounds and mailed them to a care coordinator who decided if patients required further evaluation.

**Control:** the other group was monitored daily using handheld devices, telemonitors and videophones. A care coordinator monitored patient's symptoms and needs related to chronic disease management. This was not a control group.

**Outcome:** researchers found that there were not significant differences in the clinical outcomes between groups. However, hospital admissions and number of bed days of care decreased in the daily monitoring group.

**Author/Year:** Chumblor et al. (2005b)

**Country:** USA

**Study objective:** to examine the effectiveness of a telehealth programme.

**Total participants:** 800

**Age<sub>avg</sub> (yrs):** 64.8

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** 12

**Population:** diabetic patients at risk

**Intervention:** 400 patients were provided with telehealth technology, that was used for answering questions related to their health status and monitor their BG. Data were received daily by a coordinator who called patients for follow up, if needed.

**Control:** 400 patients with diabetes did not received the care coordination and telehealth.

**Outcome:** researchers reported that there was a significant increase of demand in primary care visits in the intervention group which prevented health deterioration.

**Author/Year:** Dansky et al. (2001)

**Country:** USA

**Study objective:** to assess the effects of telehealth and evaluate its financial cost.

**Total participants:** 171

**Age<sub>avg</sub> (yrs):** 74.5

**Gender (% male):** 27

**Disease duration (yrs):** NS

**Intervention time (months):** NS.

**Population:** diabetic patients referred to nursing care.

**Intervention:** 86 patients received video-visits in addition to nursing visits.

**Control:** 85 patients received only nursing visits.

**Outcome:** researchers reported that the total cost per patient in the intervention group, including hospitalisation, was lower than in the control group.

**Author/Year:** Edmonds et al. (1998)

**Country:** Canada

**Study objective:** to determine if a telephone call would be an acceptable method for communicating results of blood glucose to a central database.

**Total participants:** 35

**Age<sub>avg</sub> (yrs):** NS

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** 6

**Population:** patients with diabetes type 1.

**Intervention:** patients were provided with a 350 vista telephone to record and send BG data to a clinical database in daily basis.

**Control:** NS.

**Outcome:** researchers concluded that the study confirmed feasibility and acceptability of the telephone system.

**Author/Year:** Farmer et al. (2005)

**Country:** UK

**Study objective:** to determine whether a mobile phone based system can improve glycaemic control.

**Total participants:** 93

**Age<sub>avg</sub> (yrs):** 24

**Gender (% male):** 59

**Disease duration (yrs):** 12.5

**Intervention time (months):** 9

**Population:** Young patients with diabetes type 1.

**Intervention:** 47 patients were provided with a blood glucose monitor connected to a mobile phone for recording blood glucose, insulin dose, food intake, and activity levels. Results were automatically transmitted to a central server. A diabetes specialist nurse checked the readings fortnightly and provided advice and counselling.

**Control:** 46 patients were provided with the same system as the intervention group. Data were sent to the same central server but were not available to the nurse.

**Outcome:** researchers reported that difference in change in HbA1c between groups was not statistically significant. Telehealth is feasible and acceptable to patients but did not improve glycaemic control.

**Author/Year:** Gómez et al. (2002)

**Country:** Spain

**Study objective:** to evaluate a telehealth system as a tool for intensive management.

**Total participants:** 10

**Age<sub>avg</sub> (yrs):** NS

**Gender (% male):** NS

**Disease duration (yrs):** 13.8

**Intervention time (months):** 6

**Population:** patients with diabetes type 2.

**Intervention:** patients were provided with a blood glucose system and asked to send the data to doctors. Doctors analysed the data and provided feedback within 24 hours.

**Control:** Patients used a BG meter and registered the data in a logbook.

**Outcome:** researchers found that there was a trend towards HbA1c improvement with no incidence in the number of hypoglycaemias.

**Author/Year:** Howells et al. (2002)

**Country:** UK

**Study objective:** to evaluate self management in young patients

**Total participants:** 79

**Age<sub>avg</sub> (yrs):** 16.5

**Gender (% male):** 50

**Disease duration (yrs):** 6.7

**Intervention time (months):** 12

**Population:** Young patients with diabetes type 1.

**Intervention:** 25 patients received telephone calls (negotiated telephone support); to be assisted in problem solving every 2 to 3 weeks.

**Control:** 28 patients received routine care management (regular attendance in clinic, standard advice and education, and support by telephone).

**Outcome:** researchers reported that the intervention group did not improve their glycaemic control in comparison with the control group, but telephone conversations were appreciated and psychological measures improved.

**Author/Year:** Kim and Oh (2003)

**Country:** South Korea

**Study objective:** To research the effect of nurse telephone calls on HbA1c levels and adherence.

**Total participants:** 50

**Age<sub>avg</sub> (yrs):** 60

**Gender (% male):** 30

**Disease duration (yrs):** 14

**Intervention time (months):** 3

**Population:** type 2 diabetic patients.

**Intervention:** 20 patients received weekly telephone calls for education, reinforcing of diet and exercise, medication adjustments and blood glucose monitoring.

**Control:** 16 patients were in routine care (visiting a physician every 3 months).

**Outcome:** researchers reported that a significant difference was found in HbA1c between the intervention and control group. The intervention group also showed greater adherence to diet and blood glucose monitoring.

**Author/Year:** Kirkman et al. (1994)

**Country:** USA

**Study objective:** to study if a telehealth intervention designed to improve glycaemic control improved coronary high risk factors with non-insulin dependent patients.

**Total participants:** 275

**Age<sub>avg</sub> (yrs):** 63.7

**Gender (% male):** 99

**Disease duration (yrs):** NS

**Intervention time (months):** 12

**Population:** patients with non-insulin dependent diabetes.

**Intervention:** 204 patients received telephone calls at least once a month to encourage medical regimen compliance and behavioural changes, and to facilitate dietitian or smoking cessation clinic referrals.

**Control:** 71 patients receive usual care but not telephone calls.

**Outcome:** researchers reported that no significant changes were found in adherence to diet, exercise, weight lost nor score for any serum lipid measurement.

**Author/Year:** Kruger et al. (2003)

**Country:** USA

**Study objective:** to determine if transmission of blood glucose data by pregnant woman provided faster communication of results and increased clinic work flow.

**Total participants:** 72

**Age<sub>avg</sub> (yrs):** 31

**Gender (% male):** 0

**Disease duration (yrs):** NS

**Intervention time (months):** 1.5

**Population:** pregnant patients diagnosed with gestational diabetes.

**Intervention:** patients were provided with a blood glucose system to transmit data on a weekly basis. The system included an interface modem. Nursing staff reviewed data and provided feedback by telephone each time data were received at the clinic.

**Control:** patients transmitted blood glucose data over the telephone.

**Outcome:** researchers reported that no significant differences in telephone consultation time, clinic workflow, efficiency or accuracy were found between groups.

**Author/Year:** Lavery et al. (2004)

**Country:** USA

**Study objective:** to assess the effectiveness of home monitoring of foot skin temperature to prevent ulcerations.

**Total participants:** 85

**Age<sub>avg</sub> (yrs):** 55

**Gender (% male):** 50

**Disease duration (yrs):** 14

**Intervention time (months):** 6

**Population:** diabetic patients with diabetic foot risk category 2 and 3.

**Intervention:** 44 patients were provided with handheld infrared skin thermometers to measure their temperature on the sole of their foot in mornings and evenings. When temperatures were elevated, patients were instructed to reduce their activity and contact a nurse.

**Control:** 41 patients received therapeutic footwear, diabetic foot education and foot evaluation from a podiatrist every 10 to 12 weeks. Patients in the intervention group also received this usual care.

**Outcome:** researchers reported that the intervention group showed significantly evidence of fewer diabetic foot complications. The intervention group showed to be 10 times more likely to develop complications.

**Author/Year:** Liesenfield et al. (2000)

**Country:** Germany

**Study objective:** to evaluate the influence of a telehealth programme on glycaemic control.

**Total participants:** 61

**Age<sub>avg</sub> (yrs):** 13

**Gender (% male):** 59

**Disease duration (yrs):** 5.5

**Intervention time (months):** 5

**Population:** children and adolescent patients with diabetes type 1.

**Intervention:** patients were provided with blood glucose meters and PDAs with integrated modem for daily collection of data (blood glucose, insulin doses, meal an exercise). Data were sent and automatically stored into a hospital database.

**Control:** no comparison group.

**Outcome:** researchers found that HbA1c improvements were statistically significant after the intervention. There was also a reduction of hypoglycaemic events.

**Author/Year:** Marrero et al. (1995)

**Country:** USA

**Study objective:** to assess the efficacy of using a telehealth system to assist paediatric patients.

**Total participants:** 106

**Age<sub>avg</sub> (yrs):** 13.3

**Gender (% male):** 59.4

**Disease duration (yrs):** 6

**Intervention time (months):** 12

**Population:** paediatric patients with type 1 diabetes.

**Intervention:** 52 patients transmitted blood glucose data to a hospital every 2 weeks, where a nurse reviewed them and telephoned patients to discuss regimen adjustments.

**Control:** 54 patients received usual care (visiting every 3 months to a clinic and care provided by a multidisciplinary team).

**Outcome:** researchers reported that no significant differences were found between groups for metabolic control, rates for hospitalisation or A & E admissions, psychological status, general family functioning, quality of life nor parent-child responsibility.

**Author/Year:** Meneghihi et al. (1998)

**Country:** USA

**Study objective:** to assess the usage and safety of an electronic system designed to facilitate glycaemic control.

**Total participants:** 184

**Age<sub>avg</sub> (yrs):** NS

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** 12

**Population:** patients with complicated and difficult to manage diabetes.

**Intervention:** patients were asked to report daily blood glucose levels, hypoglycaemic symptoms and life style events to an electronic case manager using a touch tone telephone. Diabetes crises were identified by the electronic system and immediately flagged.

**Control:** no control group.

**Outcome:** researchers found that patients showed a significant reduction of diabetes crisis. There was also a significant reduction in HbA1c.

**Author/Year:** Montori et al. (2004)

**Country:** USA

**Study objective:** to determine the efficacy of telehealth to support intensive insulin therapy.

**Total participants:** 31

**Age<sub>avg</sub> (yrs):** 43

**Gender (% male):** 32

**Disease duration (yrs):** 17

**Intervention time (months):** 6

**Population:** patients with diabetes type 1 and inadequate glycaemic control.

**Intervention:** 16 patients were provided with blood glucose meter and an interface modem to monitor blood glucose 4 times per day and transmit data every 2 weeks. Patients received feedback from a nurse 24 hours after data transmission.

**Control:** 15 patients were provided with the same system but did not receive nurse feedback unless they contacted her.

**Outcome:** researchers reported that improvements in adherence to self monitoring and glycaemic control were observed in both groups. Telehealth has a small impact on glycaemic control.

**Author/Year:** Oh et al. (2003)

**Country:** South Korea

**Study objective:** to research the effect of telephone calls on glycaemic control and BMI

**Total participants:** 50

**Age<sub>avg</sub> (yrs):** 60

**Gender (% male):** 36

**Disease duration (yrs):** 26

**Intervention time (months):** 3

**Population:** type 2 diabetes patients.

**Intervention:** 25 patients received weekly telephone calls for education, reinforcing on diet and exercise, medication adjustments and blood glucose monitoring.

**Control:** 25 patients were in routine care (visiting a physician every 3 months).

**Outcome:** researchers reported that a significant change was found in the improvement of HbA1c in the intervention group, but there were no significance differences observed in the BMI between the 2 groups.

**Author/Year:** Piette et al. (2000a)

**Country:** USA

**Study objective:** to evaluate the impact of telehealth among low income patients.

**Total participants:** 248

**Age<sub>avg</sub> (yrs):** 54.5

**Gender (% male):** 41.1

**Disease duration (yrs):** NS

**Intervention time (months):** 12

**Population:** English and Spanish speaking patients with diabetes.

**Intervention:** patients received automated calls for reporting health and self care information, receiving education, and appointment reminders every 2 weeks and nurse telephone follow ups in addition to usual care.

**Control:** patients received usual care with no contact to the automatic system or nurse follow ups.

**Outcome:** researchers found that the intervention group reported fewer symptoms of depression and days in bed, and greater efficacy to conduct daily activities.

**Author/Year:** Piette et al. (2000b)

**Country:** USA

**Study objective:** to evaluate the effect of automated calls and nurse follow ups.

**Total participants:** 280

**Age<sub>avg</sub> (yrs):** 54.5

**Gender (% male):** 41.5

**Disease duration (yrs):** NS

**Intervention time (months):** 12

**Population:** patients with diabetes who spoke English or Spanish.

**Intervention:** 124 patients received bi-weekly automated assessment and self care education calls with nurse follow ups. Patients used the system for reporting BG levels.

**Control:** usual care and some follow ups.

**Outcome:** researchers found that the intervention group reported better glycaemic control, lower HbA1c levels, and better weight monitoring.

**Author/Year:** Piette et al. (2001)

**Country:** USA

**Study objective:** to evaluate automated telephone disease management for improving diabetes treatment.

**Total participants:** 272

**Age<sub>avg</sub> (yrs):** 60.5

**Gender (% male):** 71

**Disease duration (yrs):** NS

**Intervention time (months):** 12

**Population:** diabetic patients using hypoglycaemic medications.

**Intervention:** 146 patients received biweekly automated telephone calls for health assessment and self care education calls, and telephone nurse follow ups.

**Control:** 146 patients received usual care.

**Outcome:** researchers reported that no significant changes were found in the improvement of HbA1c between groups. However the intervention group reported

fewer symptoms of poor glycaemic control and increased their satisfaction with care.

**Author/Year:** Shea et al. (2006)

**Country:** USA

**Study objective:** to conduct a randomised controlled trial comparing telehealth case management to usual care and to measure the intervention effects.

**Total participants:** 1665

**Age<sub>avg</sub> (yrs):** NS

**Gender (% male):** 37

**Disease duration (yrs):** NS

**Intervention time (months):** 12

**Population:** patients with diabetes aged 55 or older and treated with diet, oral hypoglycaemic agent or insulin.

**Intervention:** patients received a home telehealth unit consisting on a web enabled computer with modem connection to an existing telephone line. The unit provided videoconferencing, remote monitoring (glucose and blood pressure), dial up internet access and access to an educational website. A nurse case manager interacted through videoconferencing with the patients. Notes were supervised by a diabetologist and when a change in management was suggested, the primary care doctor was contacted by email, fax, letter o telephone.

**Control:** patients remained under the care of their primary care providers.

**Outcome:** researchers reported that after 1 year of follow up, mean HbA1c level decreased in the intervention group from 7.35% to 6.97% and in the control group from 7.42% to 7.17%.

**Author/Year:** Shultz et al. (1992)

**Country:** USA

**Study objective:** to test the importance of transferring home monitoring information to health care providers.

**Total participants:** 30

**Age<sub>avg</sub> (yrs):** NS

**Gender (% male):** 85

**Disease duration (yrs):** NS

**Intervention time (months):** 18

**Population:** diabetic patients using insulin.

**Intervention:** patients collected their blood glucose measurements twice daily and transferred them weekly to a laboratory via modem.

**Control:** patients used a handwritten diary to record blood glucose data.

**Outcome:** researchers reported that a significant change was found in the improvement of HbA1c in the intervention group.

**Author/Year:** Thompson et al. (1999)

**Country:** Canada

**Study objective:** to investigate if insulin adjustment by telephone led to a better glucose control.

**Total participants:** 46

**Age<sub>avg</sub> (yrs):** 48.75

**Gender (% male):** 48

**Disease duration (yrs):** 17

**Intervention time (months):** 6

**Population:** Diabetes patients (type 1 and 2) with poor glucose control.

**Intervention:** Patients were provided with insulin, blood glucose meters and strip. They received regular telephone calls (average 3 per week) by a diabetes nurse educator for insulin adjustments and advice.

**Control:** Patients received usual care (visiting their physician every 3 months and education through a diabetes educator).

**Outcome:** researchers found that insulin adjustments improved glucose control in the intervention group.

**Author/Year:** Tsang et al. (2001)

**Country:** Hong Kong

**Study objective:** to assess the impact of monitoring systems on glycaemic control and patient's acceptance.

**Total participants:** 19

**Age<sub>avg</sub> (yrs):** 32.5

**Gender (% male):** 63

**Disease duration (yrs):** 8.5

**Intervention time (months):** 6

**Population:** diabetic patients.

**Intervention:** 10 patients stored data about their food intake and blood glucose in a handheld device and sent them to a computer system twice a week. Data were analysed automatically by the system and sent back to the handheld device.

**Control:** 9 patients had conventional care (follow up consultations with a diabetes team).

**Outcome:** researchers reported that a significant change was found in the improvement of HbA1c in the intervention group.

**Author/Year:** Vahatalo et al. (2004)

**Country:** Finland

**Study objective:** to evaluate the impact of transmission of blood glucose data by mobile phones.

**Total participants:** 203

**Age<sub>avg</sub> (yrs):** 43

**Gender (% male):** 56

**Disease duration (yrs):** NS

**Intervention time (months):** 12

**Population:** patients with diabetes type 1.

**Intervention:** patients were provided with a mobile phone to transfer blood glucose data to a database. Physicians monitored results weekly and sent text messages to patients with instructions.

**Control:** patients continued with normal visits to their physician every 3 to 4 months.

**Outcome:** researchers found that there was not a significant difference in HbA1c between groups

**Author/Year:** Weinberger et al. (1995)

**Country:** USA

**Study objective:** to examine the impact of nurse intervention by telephone non insulin dependent patients.

**Total participants:** 275

**Age<sub>avg</sub> (yrs):** 64

**Gender (% male):** 99

**Disease duration (yrs):** 14

**Intervention time (months):** 12

**Population:** patients with diabetes type 2.

**Intervention:** 204 patients received telephone calls on monthly basis for monitoring their health status, educational purposes, facilitating compliance and access to primary care.

**Control:** 71 patients received usual care (visiting a physician every 3 to 4 months).

**Outcome:** researchers reported that a significant change was not found in the improvement of QoL and HbA1c between groups.

**Author/Year:** Welch et al. (2003)

**Country:** USA

**Study objective:** to assess the clinical impact of transferring blood glucose information via modem and educator phone calls.

**Total participants:** 52

**Age<sub>avg</sub> (yrs):** 41.3

**Gender (% male):** 36

**Disease duration (yrs):** 21.6

**Intervention time (months):** 12

**Population:** patients with diabetes type 1, poorly controlled.

**Intervention:** 26 patients were provided with a modem equipped blood glucose meter system to monitor and send data. Patients received diabetes educator phone calls for making any adjustment to insulin every 2 weeks.

**Control:** 26 patients received usual care.

**Outcome:** researchers reported that HbA1c improvements in the intervention group were statistically significant.

**Author/Year:** Whitlock et al. (2000)

**Country:** USA

**Study objective:** to study the impact of telehealth on diabetic management.

**Total participants:** 28

**Age<sub>avg</sub> (yrs):** 63

**Gender (% male):** 39

**Intervention time (months):** 3

**Population:** patients with diabetes type 2.

**Intervention:** 15 patients received video calls from a nurse for reviewing patient's blood glucose, weight, and blood pressure once at week.

**Control:** 13 patients received usual care.

**Outcome:** researchers reported that significant changes were found in the improvement of HbA1c and weight reduction.

**Author/Year:** Wojcicki et al. (2001)

**Country:** Poland

**Study objective:** to evaluate the therapeutic effectiveness of telehealth for treatment of pregnant woman with diabetes type 1.

**Total participants:** 32

**Age<sub>avg</sub> (yrs):** 26

**Gender (% male):** 0

**Disease duration (yrs):** 8.8

**Intervention time (months):** 36

**Population:** pregnant woman with diabetes type 1.

**Intervention:** 17 patients were provided with a blood glucose meter. Readings were sent automatically to a database every night, a diabetologist reviewed them the morning after, and called the patient to modify her treatment if necessary.

**Control:** 15 patients received clinical examinations every 3 weeks.

**Outcome:** researchers found that general assessment showed better glycaemic control for the intervention group (based on mean blood glucose). However results were not statistically significant.

**Author/Year:** Young et al. (2005)

**Country:** UK

**Study objective:** to determine the impact of telephone calls by nonmedical staff supported by a software programme for glycaemic control.

**Total participants:** 591

**Age<sub>avg</sub> (yrs):** 67

**Gender (% male):** 58

**Disease duration (yrs):** 6

**Intervention time (months):** 12

**Population:** Patients with diabetes type 2.

**Intervention:** 394 patients received telephone calls according to a protocol based on their last HbA1c level.

**Control:** 197 patients received usual care (life style advice, drug treatment, continuing education programme and local guidelines).

**Outcome:** researchers reported that a reduction of 1% of HbA1c was not achieved.

### 3.6.3 Asthma publications

**Author/Year:** Bruderman and Abboud (1997)

**Country:** Israel

**Study objective:** to describe a new telehealth system and to assess the ability of the system to detect early signs of asthmatic deterioration.

**Total participants:** 30

**Age<sub>avg</sub> (yrs):** 53

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** NS

**Population:** 39 patients with moderate to severe asthma.

**Intervention:** patients were provided with a spirometer to transmit pulmonary function test to a medical centre by placing a telephone handset on the spirophone speaker.

**Control:** no control group.

**Outcome:** researchers reported that in 49% of patients were possible to detect early signs of deterioration.

**Author/Year:** Chan et al. (2003)

**Country:** USA

**Study objective:** to study the adherence and disease control associated with the use of a “store and forward” monitoring system for paediatric asthma patients.

**Total participants:** 10

**Age<sub>avg</sub> (yrs):** 8

**Gender (% male):** 50

**Disease duration (yrs):** NS

**Intervention time (months):** 6

**Population:** paediatric patients with persistent asthma.

**Intervention:** patients were provided with a computer system which included a video camera, a microphone and access to internet. A video of patients using the peak flow meter and inhalers was recorded twice at week. Videos and electronic diaries were sent to a case manager who reviewed them and emailed patients with his assessment. Education was provided online.

**Control:** patients received education from the case manager during scheduled asthma visits.

**Outcome:** researchers found that there was not difference in outcomes between the intervention and control group.

**Author/Year:** Farzanfar et al. (2004)

**Country:** USA

**Study objective:** to investigate to what extent interviews provide effective tools for usability testing of telehealth systems.

**Total participants:** 5

**Age<sub>avg</sub> (yrs):** NS

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** 0.5

**Population:** patients with asthma.

**Intervention:** 5 patients were trained in how to perform spirometry measurements and use a personal digital assistant (PDA). Patients performed regular lung function testing and answered clinical status questionnaire in the PDA. Patients received automatically messages via the PDA. Patients received a follow up telephone interview at the end of a 2 week period.

**Control:** no control group.

**Outcome:** researchers reported that patients tended to evaluate the telehealth system on how it fit into their everyday lives and personal preferences.

**Author/Year:** Finkelstein et al. (2000)

**Country:** USA

**Study objective:** to asses the validity of spirometry self-testing and to evaluate the acceptance of telecare system by asthmatic patients.

**Total participants:** 31

**Age<sub>avg</sub> (yrs):** 42

**Gender (% male):** NS

**Disease duration (yrs):** 19

**Intervention time (months):** 0.75

**Population:** 31 patients with asthma.

**Intervention:** patients were provided with a spirometer which was connected to a PDA for data transmission. They were trained and performed spirometries on a daily basis. The system automatically transmitted results, symptoms and patient's notes to a medical centre. Patients were evaluated on their ability to perform a self-testing spirometry by a medical professional by the end of the third week.

**Control:** no control group.

**Outcome:** researchers reported that there was not significant difference between unsupervised and supervised spirometry self-testing. Variability of FVC, FEV and PEF in the study was similar to other comparable studies.

**Author/Year:** Guendelman et al. (2004)

**Country:** USA

**Study objective:** to study the effectiveness of a novel technology for self management of children with asthma in decreasing frequency of control problems and hospitalisations.

**Total participants:** 134

**Age<sub>avg</sub> (yrs):** 12

**Gender (% male):** 58

**Disease duration (yrs):** NS

**Intervention time (months):** 3

**Population:** children with persistent or out of control asthma.

**Intervention:** 66 patients received training on how to carry out peak flow reading, use medications, and make use of a handheld device programmed for recording asthma symptoms, PFR, functional status, medications and health service utilisation. Patients were asked to use the device once a day. The device transmitted data to a nurse coordinator through a secure website.

**Control:** 68 patients used a diary for tracking symptoms. All patients, including those in the intervention groups, were asked to return for 2 follow up visits at 6 and 12 weeks.

**Outcome:** researchers concluded that both groups reported a decrease in the number of control problems at the end of study (12 weeks). However at 6 weeks, the intervention group had a significantly lower mean number of control problems (2 with a SD of 1.6) in comparison to the control group (2.7 with a SD of 1.6). There was a significant short term impact.

**Author/Year:** Kokubu et al. (1999)

**Country:** Japan

**Study objective:** to study the effectiveness of a new telehealth system in reducing frequency of hospitalisation.

**Total participants:** 66

**Age<sub>avg</sub> (yrs):** 49

**Gender (% male):** 41

**Disease duration (yrs):** 17

**Intervention time (months):** 6

**Population:** asthmatic patients at high risk for hospitalisation.

**Intervention:** 32 patients performed daily peak flow (PEF) monitoring and transmitted measurements via modem to a database. A nurse provided regular follow ups to patients (under supervision of a physician) via telephone.

**Control:** 34 patients monitored PEF and registered values in a diary at least twice a day. They had an outpatient visit every month.

**Outcome:** researchers found that there was a significant reduction in hospitalisations (83%,  $p=0.01$ ) in the intervention group vs. the control group. PEF and symptoms also improved in the control group.

**Author/Year:** Ostojic et al. (2005)

**Country:** Croatia

**Study objective:** to evaluate the feasibility of monitoring patients by mobile phone text messages and to determine its impact on asthma control.

**Total participants:** 16

**Age<sub>avg</sub> (yrs):** 25

**Gender (% male):** 57

**Disease duration (yrs):** NS

**Intervention time (months):** 4

**Population:** patients with moderate persistent asthma.

**Intervention:** 8 patients received a mini Wright and instructions to send their PEF results via text messages, on a daily basis, to a mobile telephone connected to a computer in a hospital. Patients received weekly instructions by text messages on adjustment of therapy and follow-up.

**Control:** 8 patients received a mini Wright and were asked to register PEF measurements, medication use and symptoms in a paper diary.

**Outcome:** researchers found that there was a significant change in reduction of PEF variability ( $p=0.049$ ) in the control group ( $16.2 \pm 6.93$ ) vs. ( $27.24 \pm 10.01$ ) and slightly but not significant improvement in  $FEV_1$ .

**Author/Year:** Rasmussen et al. (2005)

**Country:** Denmark

**Study objective:** to explore the effects of using an internet based monitoring tool in comparison with conventional asthma treatment.

**Total participants:** 300

**Age<sub>avg</sub> (yrs):** 30

**Gender (% male):** 37

**Disease duration (yrs):** NS

**Intervention time (months):** 6

**Population:** patients with asthma.

**Intervention:** 100 patients used an internet tool which included an electronic diary, an action plan and a decision support system. They were given a peak flow meter and encouraged to use the system daily. A doctor contacted patients by email or telephone to adjust treatment.

**Control:** 100 patients were sent to a specialist who taught patients how to adjust their medications. They were provided with a peak flow and an action plan. Another 100 patients were asked to contact their GP who decided, based on guidelines, their drug treatment.

**Outcome:** researchers found that there was a significant improvement of symptoms, quality of life and lung function between the intervention group vs. specialist group and the intervention group vs. the GP group.

**Author/Year:** Ryan et al. (2005)

**Country:** UK

**Study objective:** to evaluate patient's compliance when using an electronic peak flow.

**Total participants:** 91

**Age<sub>avg</sub> (yrs):** NS

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** 9

**Population:** patients with stable asthma between 12 to 55 years who required treatment with steroids and bronchodilators.

**Intervention:** 91 patients were provided with a handheld peak flow meter which was connected to a mobile phone. Patients were asked to monitor peak flow in the mornings and evenings and transmitted the readings to a server. Immediate feedback was sent back to the mobile in a form of trend analysis.

**Control:** no control group (observational study).

**Outcome:** researchers found that there was a high level of compliance in 64% patients. However, there was a poor compliance for reasons that were not identified.

**Author/Year:** Steel et al. (2002)

**Country:** UK

**Study objective:** to evaluate the feasibility of using an asthma monitoring system at home.

**Total participants:** 33

**Age<sub>avg</sub> (yrs):** 34

**Gender (% male):** 43

**Disease duration (yrs):** NS

**Intervention time (months):** 0.5

**Population:** patients admitted with acute asthma between 17 and 50 years.

**Intervention:** 33 patients were provided with an asthma monitor and a modem to monitor daily their asthma for 2 weeks from home. A nurse reviewed the data every day and contacted patients whether a clinical intervention was required, or if patients failed to transmit data.

**Control:** no control group.

**Outcome:** researchers reported that remote monitoring at home is feasible. Compliance with the use of the system was acceptable: 80% for monitoring and 52% for modem transmission.

#### **3.6.4 Chronic obstructive pulmonary disease (COPD) publications**

**Author/Year:** Dale et al. (2003)

**Country:** UK

**Study objective:** to conduct a telehealth pilot study for patients with COPD.

**Total participants:** 55

**Age<sub>avg</sub> (yrs):** NS

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** 3

**Population:** patients with COPD.

**Intervention:** 55 patients were provided with a pulse oximeter and a weight monitoring device. A nurse called patients every day to ask questions and capturing patients' responses into decision support software. A day-to-day assessment, reassurance, advice and education was offered.

**Control:** no control group.

**Outcome:** researchers reported that the system shown capability of diagnosing sleep apnoea syndrome and therefore, reduce the rate of hospital admissions (50%).

**Author/Year:** Pare et al. (2006)

**Country:** Canada

**Study objective:** to present the findings of an economic analysis of a telehealth programme for patients with COPD.

**Total participants:** 30

**Age<sub>avg</sub> (yrs):** 70

**Gender (% male):** 57

**Disease duration (yrs):** NS

**Intervention time (months):** 6

**Population:** patients with COPD that required frequent home visits.

**Intervention:** 20 patients received a web phone with an integrated touch screen and modem. Patients' were trained for collecting and sending peak flow measurements, symptoms and medications over the internet. Data were reviewed by a nurse on a daily basis and patient received an automatic response by the device or a call from the nurse.

**Control:** 10 patients received usual care ((home visits).

**Outcome:** researchers found that the telehealth programme caused savings reducing hospitalisations rates and less home visits. Overall net savings were found to be 15%.

**Author/Year:** Ries et al. (2003)

**Country:** USA

**Study objective:** to evaluate a telephone based programme after pulmonary rehabilitation in patients with chronic lung disease.

**Total participants:** 164

**Age<sub>avg</sub> (yrs):** 67

**Gender (% male):** 54

**Disease duration (yrs):** NS

**Intervention time (months):** 24

**Population:** patient with chronic lung disease.

**Intervention:** 83 patients received a maintenance intervention which consisted in weekly telephone calls for verifying compliance with the care plan and recent health problems. Staff provided advice and assistance to patients when needed.

Patients also received monthly reinforcing sessions designed to review the information that was taught, re-evaluate treatment programmes and provide encouragement.

**Control:** 81 received standard care, which included a referral back to primary care for continuous medical care, and a letter indicating the recommended home care rehabilitation programme.

**Outcome:** researchers found that there was not significant difference between groups at the end of the study. However, some short term modest improvements were noticed before the first year in terms of exercise tolerance and overall health status with a reduction in hospital days.

**Author/Year:** Wong et al. (2005)

**Country:** Hong Kong

**Study objective:** to determine if a nurse telephone programme can increase patients' self-efficacy in patients with COPD.

**Total participants:** 60

**Age<sub>avg</sub> (yrs):** 74

**Gender (% male):** 78

**Disease duration (yrs):** 7

**Intervention time (months):** 0.75

**Population:** patients with COPD.

**Intervention:** 30 patients were provided with educational and supportive telephone follow-ups by a nurse. The patients received 2 calls on days 3-7 and 14-20 for (i) assessment of patient's clinical status and use of self-efficacy scale, (ii) patient management consisted in performance, verbal persuasion and emotional arousal, and (iii) evaluation with appropriate referral.

**Control:** 30 patients received routine care without phone calls.

**Outcome:** researchers reported that patients in the intervention group had some relatively higher score for some dimensions of the Chinese self-efficacy scale questionnaire (physical exertion and weather). A significant difference between groups in total scores was observed.

### 3.6.5 Hypertension publications

**Author/Year:** Aris et al. (2001)

**Country:** Malaysia

**Study objective:** to develop a blood pressure monitor system for patient with hypertension.

**Total participants:** 4

**Age<sub>avg</sub> (yrs):** 28

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** NS

**Population:** subjects aged 24 to 30 years old.

**Intervention:** subjects were provided with a device and asked to measure their blood pressure at home using the monitor. Measurements were sent to a database via the internet. Access to data were possible through a website.

**Control:** no control group.

**Outcome:** researchers reported that blood pressure readings rest within 3% error. The system was reported easy to use.

**Author/Year:** Artinian et al. (2001)

**Country:** USA

**Study objective:** to test improvements in blood pressure groups with telehealth and community based monitoring vs. usual care.

**Total participants:** 26

**Age<sub>avg</sub> (yrs):** 59

**Gender (% male):** 12

**Disease duration (yrs):** NS

**Intervention time (months):** 3

**Population:** adult patients with hypertension.

**Intervention:** 6 patients were provided with blood pressure monitors and asked to measure their blood pressure 3 times a week. Data were sent every Friday through a modem interface by telephone. Every Monday, patients received a phone call from a nurse to provide feedback and counselling.

**Control:** 9 patients received usual care. Other 6 patients were assigned to a community nurse that runs a blood pressure monitoring group.

**Outcome:** researchers found that there was not any significant change between the intervention group and the community based group. However, blood pressure

improved in both groups, whereas, the usual group did not show any improvement.

**Author/Year:** Bertera and Bertera (1981)

**Country:** USA

**Study objective:** to answer whether telephone counselling is as effective as face to face counselling, and whether is cost-effective.

**Total participants:** 40

**Age<sub>avg</sub> (yrs):** 53

**Gender (% male):** NS

**Disease duration (yrs):** 2.6

**Intervention time (months):** 6

**Population:** patients with a history of high blood pressure.

**Intervention:** 10 patients received regular counselling by telephone every 3 weeks.

**Control:** 10 patients received face to face counselling every 3 weeks and 20 patients received usual care.

**Outcome:** researchers reported that similar improvements in blood pressure control were found between the intervention group and the face to face counselling group.

**Author/Year:** Bondmass et al. (2000)

**Country:** USA

**Study objective:** to determine the effect of telehealth monitoring on achievement of blood pressure control.

**Total participants:** 33

**Age<sub>avg</sub> (yrs):** 52

**Gender (% male):** 30

**Disease duration (yrs):** NS

**Intervention time (months):** 3

**Population:** African American with uncontrolled blood pressure despite drug treatment.

**Intervention:** patients were provided with a monitor to measure their blood pressure once or twice a day. Data were sent automatically by the monitor to a medical centre on a daily basis. Patients received education and medication adjustment over the phone.

**Control:** no control group.

**Outcome:** researchers reported that compliance was achieved in 88% of patients. A significant decrease in both mean systolic (154 to 141 mmHg) and diastolic (90 to 83 mmHg) BP was observed.

**Author/Year:** Friedman et al. (1996)

**Country:** USA

**Study objective:** to assess the effects of a telehealth intervention (monitoring and counselling) on patient adherence and blood pressure control.

**Total participants:** 267

**Age<sub>avg</sub> (yrs):** 77

**Gender (% male):** 23

**Disease duration (yrs):** NS

**Intervention time (months):** 6

**Population:** patients with hypertension.

**Intervention:** 133 patients were provided with an automatic monitor to measure their blood pressure. They reported blood pressure values to a computer system using their telephone keypad on a weekly basis. The system asked questions about the patient's status and gave feedback to promote adherence to treatment.

**Control:** 134 patients receive usual care.

**Outcome:** researchers reported that there was not a significant difference in adherence between intervention and control group, but mean diastolic blood pressure decreased more in the intervention group as medication adherence improved.

**Author/Year:** Menard et al. (1996)

**Country:** France

**Study objective:** to study the feasibility of sending self measurements from home to a doctor's computer.

**Total participants:** 96

**Age<sub>avg</sub> (yrs):** NS

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** NS

**Population:** patients with hypertension.

**Intervention:** patients were provided with a blood pressure monitor and asked to perform 3 consecutive measurements in the mornings and in the evenings. Data

were sent automatically to a computer server or a PC in the doctor's office. Information was available in tabular or graphical form.

**Control:** no control group.

**Outcome:** researchers reported that self monitoring was possible. Variability of blood pressure under controlled conditions was demonstrated, which suggested that BP taken at a doctor's office should not be used as a standard for hypertension management.

**Author/Year:** Mengden et al. (2004)

**Country:** Germany

**Study objective:** to explore the feasibility of using telehealth in patients with uncontrolled hypertension treated with olmesartan medoxomil.

**Total participants:** 53

**Age<sub>avg</sub> (yrs):** 58

**Gender (% male):** 55

**Disease duration (yrs):** 6

**Intervention time (months):** 3

**Population:** patients with untreated or uncontrolled hypertension.

**Intervention:** patients were provided with a blood pressure monitor and asked to take their blood pressure at least twice a day. Data were automatically sent to a service centre every fortnight. Patients were prescribed with olmesartan medoxomil for 12 weeks.

**Control:** no control group.

**Outcome:** researchers concluded that telehealth allowed early identification of patients who responded to olmesartan medoxomil. Monitoring compliance declined towards the end of the study.

**Author/Year:** Moller et al. (2003)

**Country:** Denmark

**Study objective:** to compare accuracy between clinic blood pressure and home measurements in treated hypertensive patients.

**Total participants:** 362

**Age<sub>avg</sub> (yrs):** 58

**Gender (% male):** 50

**Disease duration (yrs):** NS

**Intervention time (months):** NS

**Population:** patients with hypertension.

**Intervention:** patients were provided with a BP monitor and a modem interface for automatic transmission of data to a server in a hospital. Measurements were taken 4 times a day.

**Control:** clinic blood pressure was taken at a doctor's office with a mercury sphygmomanometer. Ambulatory blood pressure was measured by an automatic device every 15 min from mornings to evenings and every 30 minutes at nights.

**Outcome:** researchers concluded that patients can accurately measure their blood pressure at home. Progressive accuracy improvement was observed on the 5th day. Blood pressure accuracy was higher at home than at the clinic.

**Author/Year:** Naef et al. (1998)

**Country:** USA

**Study objective:** to determine whether automated measurements of blood pressure was reliable for pregnant woman with hypertension.

**Total participants:** 7

**Age<sub>avg</sub> (yrs):** NS

**Gender (% male):** 100

**Disease duration (yrs):** NS

**Intervention time (months):** 3

**Population:** pregnant woman with chronic hypertension.

**Intervention:** 7 patients were provided with blood pressure monitors to take their blood pressure and pulse 4 times a day and transfer the data by telephone once a day. Printed reports were sent to a physician.

**Control:** no control group.

**Outcome:** researchers explained that mean blood pressure measurements at home were compared with values obtained in the clinic when patients had their prenatal visit every 2 weeks. The device was reported easy to use and measurements correlated well.

**Author/Year:** Nakajima et al. (2006)

**Country:** Japan

**Study objective:** to report the development of a low cost BP monitoring system.

**Total participants:** 10

**Age<sub>avg</sub> (yrs):** NS

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** NS

**Population:** elderly volunteers.

**Intervention:** a wrist cuff BP monitor was provided to volunteers. BP was measured twice a day. Data were sent in a CSV file via internet to researchers.

**Control:** no control group.

**Outcome:** researchers reported that the system was easy to use and implementation was of low cost.

**Author/Year:** Nakamoto et al. (2004)

**Country:** Japan

**Study objective:** to develop a telehealth system based on mobile phones and internet website to monitor BP in patients on continuous ambulatory peritoneal dialysis.

**Total participants:** 20

**Age<sub>avg</sub> (yrs):** 44

**Gender (% male):** 60

**Disease duration (yrs):** NS

**Intervention time (months):** 3

**Population:** patients with hypertension in whom continuous ambulatory peritoneal dialysis were carried out.

**Intervention:** patients were provided with a BP monitor and asked to measure their BP twice a day. Data were transferred to a mobile phone and then sent to a server. Patients were able to access their data using a mobile phone or a website.

**Control:** no control group.

**Outcome:** researchers found that blood pressure measurements in outpatient clinics were higher than the measurements at home. The systems helped to determine patients with "white coat" hypertension.

**Author/Year:** Port et al. (2003)

**Country:** Estonia

**Study objective:** to study if self reported drug administration and self monitoring is useful for treatment adjustment.

**Total participants:** 50

**Age<sub>avg</sub> (yrs):** 52

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** 12

**Population:** patients with essential mild to moderate hypertension.

**Intervention:** patients were provided with a blood pressure monitor and a data collection device (handheld), and asked to measure their blood pressure twice a day. They entered blood pressure values, daily symptoms, stress level, and collected ECG into the handheld which sent data to a server. Data were accessed by doctors via internet.

**Control:** no control group.

**Outcome:** researchers found that 3 groups emerged: a group whose blood pressure (BP) decreased (16), one that showed no change (21) and another group whose BP increased (13). This study revealed different patterns of compliance and effectiveness.

**Author/Year:** Port et al. (2005)

**Country:** Estonia

**Study objective:** to evaluate self monitoring using a telecare system.

**Total participants:** 43

**Age<sub>avg</sub> (yrs):** 52

**Gender (% male):** 60

**Disease duration (yrs):** NS

**Intervention time (months):** 12

**Population:** patients with moderately hypertension.

**Intervention:** patients used a blood pressure monitor and a data collection unit for storing and transmitting data (sleep quality, BP, weight and ECG) to a central server. Doctors accessed the data by a secure internet connection.

**Control:** no control group.

**Outcome:** researchers found 2 phases of usage: "initial enthusiasm" and "personal convenience". 3 patient groups were identified: one with an increasing blood pressure trend, another with decreasing blood pressure trend and the third with no consistency.

**Author/Year:** Rogers et al. (2001)

**Country:** USA

**Study objective:** to find out the efficacy of a telehealth service in reducing blood pressure.

**Total participants:** 121

**Age<sub>avg</sub> (yrs):** 53

**Gender (% male):** NS

**Disease duration (yrs):** 2.5

**Intervention time (months):** 2

**Population:** patients with essential hypertension under evaluation for a change in drug therapy.

**Intervention:** 60 patients were provided with a blood pressure monitor that transmitted data over analogue telephone line. They were asked to monitor their blood pressure at least 3 times per week. Data from the monitor were sent automatically to a centre where reports that included mean systolic and diastolic blood pressure, and heart rate were created. Patients and doctors received the reports on a weekly basis. If elevated blood pressure was detected, the patient received a phone call from the doctor in order to adjust its antihypertensive medications.

**Control:** 61 patients received usual care according to Joint National Committee on Prevention, Detection, and Treatment of High Blood Pressure in the USA.

**Outcome:** researchers found that there was a significant difference in blood pressure between the intervention group and control group. Decrease of mean, diastolic and systolic blood pressure (2.8, 2, 4.9 mmHg respectively) were found in the intervention group vs. increase of mean and diastolic pressure (1.3 and 2.1 mmHg) and decrease in systolic pressure (0.1 mmHg) in the control group.

**Author/Year:** Rogers et al. (2002)

**Country:** USA

**Study objective:** to assess the efficacy of a telehealth service for the diagnosis of hypertension.

**Total participants:** 74

**Age<sub>avg</sub> (yrs):** 56

**Gender (% male):** 49

**Disease duration (yrs):** NS

**Intervention time (months):** 0.25

**Population:** patients with suspected essential hypertension.

**Intervention:** 37 patients used a BP monitor 3 times before having breakfast and 3 times before going to bed every day. The monitor automatically transmitted the data to a central computer that printed summary reports on a weekly basis. The report included tabular as well as graphic formats of systolic and diastolic blood pressure and was faxed to patient's doctor and patient (sent by post).

**Control:** 37 patients were followed up by doctors (as specified by national American guidelines) and considered to have essential hypertension if the doctor recorded the diagnosis or if the patients began antihypertensive therapy.

**Outcome:** researchers reported that detection of essential hypertension improved in the intervention group (64%) in comparison to detection in the control group (26%).

**Author/Year:** Roth et al. (1999)

**Country:** Israel

**Study objective:** to study if there is any “white coat” effect in a telehealth programme.

**Total participants:** 30

**Age<sub>avg</sub> (yrs):** 59

**Gender (% male):** NS

**Disease duration (yrs):** NS

**Intervention time (months):** 0.5

**Population:** Patients with hypertension treated at least for 1 yr with medications, 10 with  $\beta$  blockers (group b) and 10 with other antihypertensive medication (group c).

**Intervention:** 20 patients received a monitor for automatic transmission of BP readings. Patients were asked to take 2 sets (3 measurements) of BP. One set was sent automatically by telephone to a data centre and analysed by a nurse who contacted patients if the readings were not within the expected range. The other set was entered on a form and mailed to the centre at the end of the study.

**Control:** 10 normotensive participants (group a) with no cardiovascular condition or other disease received a BP monitor and performed the same 2 sets.

**Outcome:** researchers found that no blood pressure difference was observed among data sets with the same group. White coat effect was not present in this telehealth programme.

### 3.7 Discussion

#### 3.7.1 Diabetes

Mixed evidence for impact on clinical outcomes was found. In the case of diabetes, only Chumbler et al. (2005b) and Shea et al. (2006) had a large number of participants (800 and 1665, respectively) and both studies were randomised

controlled trials (RCT). These studies lasted for about 12 months, and reported significant statistical improvement in HbA1c. The study by Chumbler et al. (2005b) enabled patients to answer questions and monitor their blood glucose daily. A care coordinator called patients if it was needed and performed a follow up. In the case of Shea et al. (2006), a more complex technology was used including a computer with modem that provided videoconferencing, remote monitoring, dial up internet access and access to an educational website. In this case a nurse interacted with patients by videoconferencing under the supervision of a diabetologist.

Nine studies in diabetes had more than 200 participants and less than 800 (Kirkman et al., 1994; Weinberger et al., 1995; Albisser et al., 1996; Piette et al., 2000a; Piette et al., 2000b; Piette et al., 2001; Vähätalo et al., 2004; Chumbler et al., 2005a; Young et al., 2005). However, only Piette et al. (2000a), Piette et al. (2000b) and Albisser et al. (1996) reported positive or improvement effects. The intervention duration for these 3 studies was 12 months. The study design was declared to be RCT for both, Piette et al. (2000a) and Piette et al. (2000b).

The remaining diabetes studies (in total 26) range from 10 participants (Gómez et al., 2002) to 186 participants (Meneghini et al., 1998). Interestingly, 18 studies out of the 26 had less than 50 participants, in which half of them (8/16) reported positive findings or improvement effects (Ahring et al., 1992; Shultz et al., 1992; Edmonds et al., 1998; Thompson et al., 1999; Whitlock et al., 2000; Tsang et al., 2001; Oh et al., 2003; Welch et al., 2003).

In 22 out of the 37 studies enough HbA1c clinical data were found in order to analyse the effect of the intervention via meta-analysis. Meta-analysis is a statistical approach for combining data from multiple independent studies. The approach is typically used in areas of evidence based medicine and helps to explore conditions under which clinical effects occur. Figure 3.1 shows the results of meta-analysis assuming a fixed effect. On this model, the approach assumes no heterogeneity<sup>3</sup> between results of the 22 telehealth studies and estimated a common underlying treatment effect of -0.24 (-0.33, -0.15) with a 95% confidence interval. However, the value of  $I^2$  (70.7) indicated high heterogeneity; therefore,

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<sup>3</sup> Heterogeneity in meta-analysis refers to the variation in study outcomes between studies. The  $I^2$  index describes the percentage of variation across studies that is due to heterogeneity rather than chance (Higgins and Thompson, 2002).

the true effect size cannot be interpreted as a common true value since the  $I^2$  index indicated inconsistency within the results in the studies.

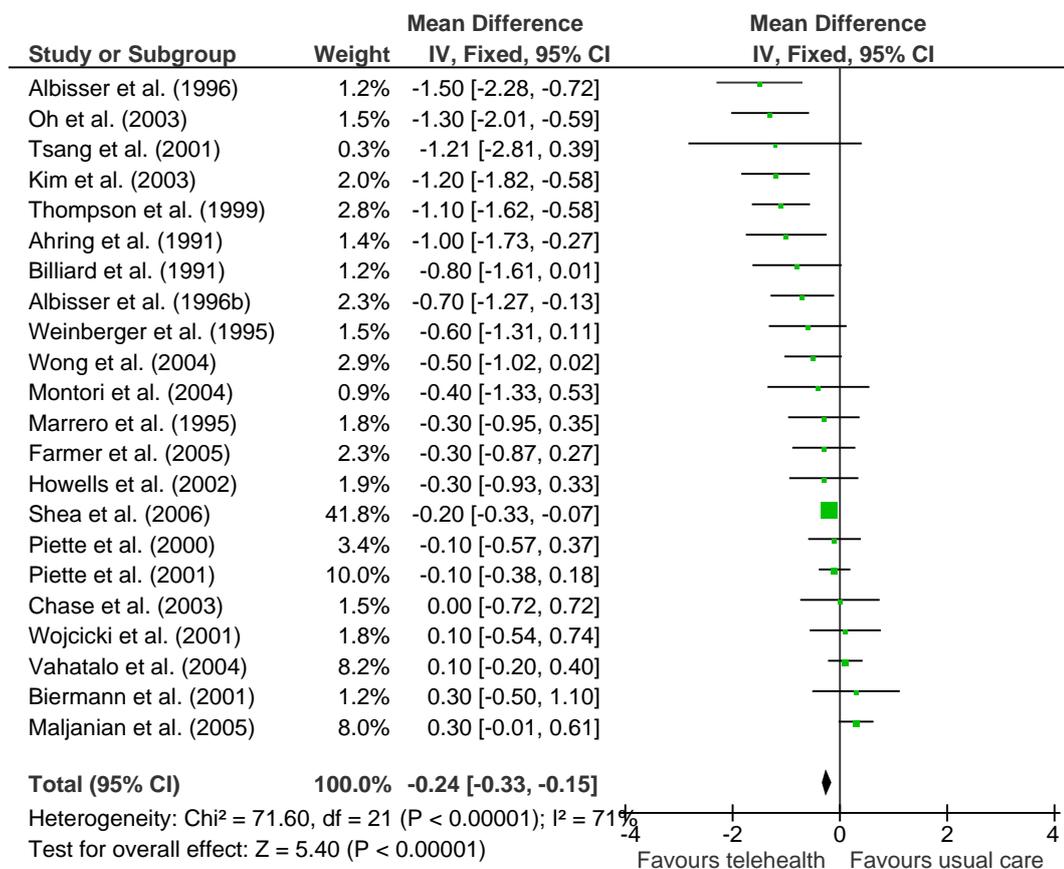


Figure 3.1. Forest plot of 22 telehealth studies assuming a fixed effect model.

Causes of heterogeneity have been investigated before. Glasziou (2002) attributed variations in studies due to the patient or the disease group, the intervention timing or intensity, other treatments that the patient received and the outcome of measurement and timing. Other factors can be associated to the quality of the design and conduction of the study, the extent of compliance with the intervention and the accuracy of the outcome measures (Glasziou and Sanders, 2002).

In a similar meta-analysis that included 8 studies in diabetes, Montori et al.(2004) found that telehealth intervention was not significantly different from usual care. They found that HbA1c pooled effect changed from baseline 0.2 (-0.2, 0.6) with a 95% confidence interval. They were not able to explain heterogeneity. Our meta-analysis and Montori's suggest that because of the complexity of interventions, heterogeneity is common in telehealth and it should be expected.

For the reasons above, a second model that fitted better with the data were considered. A random effects model is shown in fig. 3.2. The results show that the effects being estimated in the different studies are not identical, but follow some kind of distribution. A statistical significant ( $p < 0.0001$ ) overall effect lay on  $-0.41$  ( $-0.61, -0.22$ ) with a 95% confidence interval. Although the pooled effect was statistically significant, it remained as a question whether the association is clinically significant. The effect value of this finding is similar to the one reported by Polisen et al. (2009). They found that home telehealth monitoring had a positive effect by decreasing HbA1c, and their meta-analysis estimated a weighed mean difference effect of  $-0.21$  ( $-0.35, -0.08$ ) with 95% confidence interval (Polisen et al., 2009).

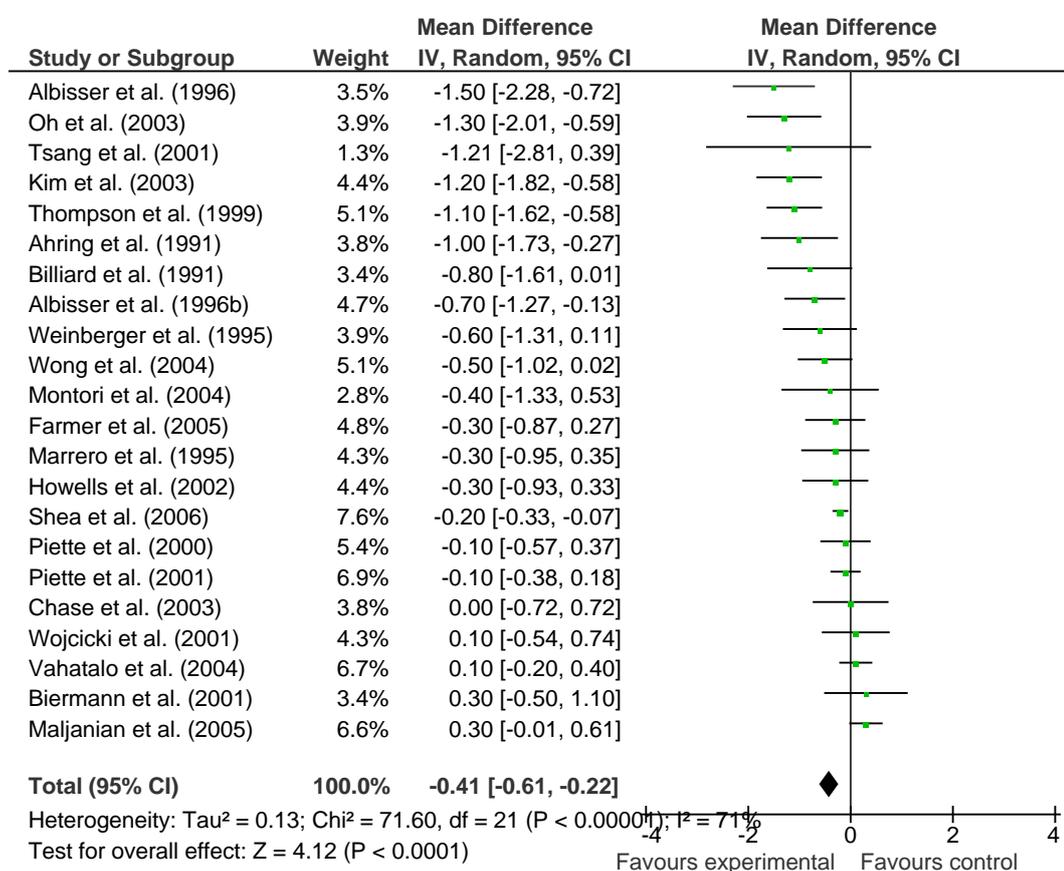


Figure 3.2. Forest plot of 22 telehealth studies assuming a random effects model.

By grouping the studies together in the Forest plot (fig. 3.2), several aspects can be explored:

- It can be easily seen which studies had a positive effect in favour of telehealth (the ones on the left) and which had no effects to telehealth (the ones on the right).

- Significant positive effects can be identified by finding those studies with confidence intervals on the left side of the no-effect line (Ahring et al., 1992; Albisser et al., 1996; Thompson et al., 1999; Kim and Oh, 2003; Oh et al., 2003; Shea et al., 2006).
- Significant effects favouring the control group can also be identified by finding those studies with confidence interval on the right side of the no-effect line. The closest example to this was: (Meneghini et al., 1998).
- Some studies showed positive effects in favour of telehealth but were not significant (Marrero et al., 1995; Piette et al., 2001; Tsang et al., 2001; Howells et al., 2002; Montori et al., 2004; Wittenberg et al., 2004; Wong et al., 2005).
- Some studies showed positive effects in favour of the control group but were not significant (Wojcicki et al., 2001; Vähätalo et al., 2004).

From the above, it can be concluded that the telehealth interventions that had better effects on reducing HbA1c were in the studies of Ahring et al. (1992), Albisser et al. (1996), Thompson et al. (1999), Oh et al. (2003), Kim and Oh (2003) and Shea et al. (2006). A common factor that these studies share was the contact with a health care provider, usually a nurse. These studies can be considered the best models for telehealth implementation, but only those of Albisser et al. (1996) and Shea et al. (2006) proved to be effective at 12 months. In general, home telehealth for diabetes management had positive effects, but the results must be interpreted with caution and as suggested by Polisena et al. (2009) further research, with a high methodological quality, is needed to demonstrate the potential clinical effectiveness of the telehealth intervention.

### **3.7.2 Asthma**

In terms of research concerned to asthma, only 2 medium size studies were found. Rasmussen et al. (2005) included 300 patients in their RCT study; the duration of the intervention was 6 months. On average the participants were young (mean age=30 yrs). The service was implemented using a computer for data transmission and electronic feedback. This study reported positive effects regarding asthma symptoms, quality of life and lung function. Rasmussen et al. found that fewer asthma symptoms were reported by patients in the intervention group. This group also reported better quality of life as well as better pulmonary function.

The other medium size study was that of Guendelman et al. (2004). Guendelman et al. reported some positive health changes in their study. The study included 134 children with an average age of 12 yrs. The intervention consisted in sending electronic questions to children through an interactive communication device for self-management. The questions were regarding asthma symptoms, peak flow rates, functional status and use of medications and health services. They found that the intervention group was less likely to experience peak expiratory flow readings that indicated a severe exacerbation or poor asthma control. Significant effects were found at 6 weeks, but after 12 weeks the effects were not statistically significant.

More positive results were reported in Ostojic et al. (2005) and in Kokubu (1999). But in Ryan et al. (2005), Farzanfar et al. (2004), Steel et al. (2002), Finkelstein et al. (2000) and Bruderman and Abboud (1997) the effectiveness of the telehealth intervention was difficult to evaluate. The main characteristics of the asthma studies are summarised in table 3.3. The majority of studies below (table 3.3) investigated the transmission of spirometry data via modem transmission or mobile technology with the aim of improving management and compliance with treatments. Most of the studies were pilot projects and feasibility studies. None of them were evaluated beyond 6 months. Even though some of these studies showed significant improvement in peak flow rates, reduction in the symptoms associated to asthma and improvements in quality of life, the results must be taken with caution because of the short term outcomes. These findings are aligned with a recent systematic review (McLean et al., 2010) in telehealth for asthma and a RCT study (Willems et al., 2008) . The review by McLean et al. (2010) included 21 studies and found that these types of interventions did not result in significant improvements from the quality of life point of view. Willems et al. (2008) also found not significant decrease in asthma symptoms nor medical consumption nor improved asthma-specific quality of life. Therefore, more research evaluating the effectiveness of asthma intervention in home monitoring is needed.

Table 3.3. Characteristics of the asthma studies found in the 3 systematic reviews.

Author	Number of participants	Age <sub>avg</sub> (yrs)	% Male	Disease duration (yrs)	Study duration (months)	Intervention type			
						Mobile phone intervention / follow up	Modem transmission & telephone counselling	Computer transmission & electronic feedback	Modem data transmission no feedback
Guendelman et al. (2004)	134	12	58	NS	3				X
Kokubu et al. (1999)	66	49	41	17	6		X		
Ostojic et al. (2005)	16	25	57	NS	4	X			
Rasmussen et al. (2005)	300	30	37	NS	6			X	
Ryan et al. (2005)	91	NS	NS	NS	9	X			
Steel et al. (2002)	33	34	43	NS	0.5		X		
Chan et al. (2003)	10	8	50	NS	6			X	
Farzanfar et al. (2004)	5	NS	NS	NS	0.5			X	
Finkelstein et al. (2000)	31	42	NS	19	0.75				X
Bruderman and Abbound (1997)	30	53	NS	NS	NS				X

NS= not stated

### 3.7.3 COPD

In the case of COPD, the only middle size study found was Ries et al (Ries et al., 2003). The study was a randomised controlled trial that included 172 patients. Half of the patients were assigned to the telehealth intervention which included weekly telephone contacts and monthly supervised reinforcement sessions. At 12 months of evaluation, exercise tolerance and overall health status were better in the intervention group, but no differences were found in pulmonary function, dyspnea, quality of life or health care use. Overall, the study indicated significant benefits in short term periods (8 weeks), but such benefits progressively disappeared.

The rest of studies were small trials and the interventions varied broadly in terms of study duration (see table 3.4).

Table 3.4. Summary of the main characteristics of the COPD studies.

Author	Total participants	Age <sub>avg</sub> (yrs)	Gender (% Male)	Disease duration (yrs)	Study duration	Intervention type and effect	
						Counselling & support by telephone	Computer transmission & electronic feedback
Ries et al. (2003)	164	67	54	NS	24	X	
Wong et al. (2005)	60	74	78	7	0.75	X	
Pare et al. (2006)	30	70	57	NS	6		X
Dale et al. (2003)	55	NS	NS	NS	3	X	

There was not sufficient evidence reported in the studies (Dale et al., 2003; Ries et al., 2003; Wong et al., 2005; Pare et al., 2006) that supported clinical benefits for COPD telehealth interventions. This is not a new finding. For instance, Bolton et al. (2011) examined the effectiveness of telemonitoring interventions for adult patients with COPD. They conducted a systematic review of studies that have addressed the effectiveness of telemonitoring practices for patients with COPD. In their review, Bolton et al. (2011) criticised that the studies were typically underpowered, had heterogeneous patient populations and had a lack of detailed intervention descriptions and a lack of the care processes that accompanied telemonitoring. They concluded that the benefits of telemonitoring for COPD has not yet been proven.

### 3.7.4 Hypertension

Finally, the relatively largest studies in hypertension were published by Montori et al. (2004) and Friedman et al. (1996). Montori et al. (2004) compared the accuracy of clinical blood pressure measurements with home telehealth blood

pressure (BP) measurements. For this, they recruited 362 patients. The researchers provided a blood pressure device with an interface for automatic transmission of BP data over analogue telephone lines. Patients had to take duplicate measurements four times a day for 5 consecutive days. Montori et al. (2004) found that telehealth home blood pressure provided a better prediction of BP than the conventional measurement in the clinic.

Friedman et al. (1996) evaluated the effect of patient monitoring and counselling on patient compliance to medications and BP control. They implemented a randomised controlled trial and recruited 267 patients for this purpose. The duration of the intervention was for 6 months and consisted in transmitting BP data over the phone using the touch-tone key pad. A computer based system conversed with patients in their homes using computer synthesised speech. During the conversation, patients reported their BP readings, their understanding of prescribed medication regimen, their adherence to medications, and any symptoms known to produce side effects. The computer system provided education and motivational counselling. Friedman et al. (1996) noticed a non significant trend towards a drop in systolic blood pressure which was limited to subjects who were not adherent to their medication regime at baseline. For these subjects the mean systolic BP dropped by 12.8mmHg in comparison to 0.9mmHg in the control group ( $p=0.09$ ). However, in the analysis of diastolic BP, the intervention group sustained a significant decrease of 5.2mmHg ( $p=0.02$ ).

In 11 out of the 16 hypertensive studies, the number of participants were less than 55 (Bertera and Bertera, 1981; Naef et al., 1998; Roth et al., 1999; Bondmass et al., 2000; Aris et al., 2001; Artinian et al., 2001; Port et al., 2003; Mengden et al., 2004; Nakamoto et al., 2004; Port et al., 2005; Nakajima et al., 2006). A mix of studies regarding BP monitoring, counselling diagnosis, compliance and cost demonstrated the heterogeneity of the studies reviewed. Furthermore, just a few of them were randomised controlled trials (Bertera and Bertera, 1981; Friedman et al., 1996; Artinian et al., 2001; Rogers et al., 2001; Rogers et al., 2002) and most of these were trials at small scale. These issues appear to be still valid. For instance, a recent study (Omboni and Guarda, 2011) evaluating the impact of telehome monitoring of blood pressure also suggested that because of the heterogeneity of published studies, more large scale and well design RCT studies are needed to demonstrate clinical effectiveness.

### **3.8 Summary**

This chapter identifies key research publications that addressed home monitoring in the management of diabetes, asthma, chronic obstructive pulmonary disease (COPD) and hypertension.

Some important limitations were found in the evidence produced by the majority of the studies published in these telehealth subjects. Most importantly, it was noticed that the majority of studies tended to measure only short term clinical outcomes, usually carrying out assessments at 6 months or less. Therefore, little is known about whether initially observed effects can be sustained over long periods of time. Furthermore, the studies varied considerably in terms of trial duration, disease duration, number of participants, age and intervention type.

It was also difficult to determine how much of the effects reported in these studies were due to telemonitoring as there are no study regimens and evaluation methods standardised. In addition to this, in the case of diabetes, the meta-analysis suggested that small studies tended to produce higher effect sizes.

Insufficient or incomplete sets of data made it difficult to establish which groups or subgroups and factors contributed to effectiveness in the case of asthma, COPD and hypertension. Therefore, no attempts were made for performing meta-analysis. As suggested before, further high quality research is needed to demonstrate the clinical effectiveness of such telehealth interventions.

The rapidity and scope of scientific studies and technological developments have led to new publications in telehealth that provide evidence that complements section 3.6. For instance, in terms of monitoring technology in heart failure, Maric et al. (2009) classified five groups of interventions: device based monitoring, telephone touch pad based telemonitoring, video consultation based, web site based monitoring and a combination of the previous telemonitoring modalities. A similar classification was also provided by Sutcliffe et al. (2011), who identified five categories of communication technologies to promote access and engagement of young patients with diabetes. Their classification included: video and teleconferencing, mobile telephony, telephone support, novel electronic communication and web based discussion boards. Although new communication technologies such as mobile telephony, social networks and Voice over Internet Protocol (VoIP) can potentially facilitate communication between healthcare

professionals and young patients with diabetes (or other chronic diseases), Sutcliffe et al. (2011) have found limited or no research involving these technologies in young populations. The lack of research may explain, in the current study, the telehealth results for this group, who may benefit from this, more sophisticated, technology.

In terms of effectiveness, the reported evidence is still limited and inconsistent with regard to the monitoring of heart failure, diabetes and asthma, COPD, diabetes and hypertension (Ekeland et al., 2010; Wootton, 2012). However, recent systematic reviews have found small but significant improvements in cases such as BP home telemonitoring (Bray et al., 2010; Agarwal et al., 2011). The gaps in the evidence for effectiveness suggest that more systematic reviews in home telehealth are required (Bahaadinbeigy et al., 2010).

## **Chapter 4. Demographic and clinical profiles**

### **4.1. Introduction**

In this section, we present the clinical and demographic circumstances found among patients who were enrolled in the REALITY project, a telehealth study involving three EU countries. This case study exemplifies a wide variability of conditions carried by those patients with chronic diseases who could potentially be in need of additional medical support and closer follow up by means of telehealth.

Understanding in isolation the complexity of a patient's medical conditions appears not to be enough for managing patients through telehealth. As will be discussed in later chapters, our case study shows that not all the clinically ill subjects exposed to telehealth may be able to use the service properly or to experience any clinical benefit. The reasons for that are unclear, but one explanation can be attributed to unmet patient needs. As a consequence of that, this chapter provides the starting point towards understanding those needs, recognising in the first place the chronically ill patient as a whole.

The figures appearing in this report are derived from data collected by the REALITY consortium financially supported from the European Union. Therefore, some of the information presented in this chapter was previously reported to the 5th Framework Program of R&D of the European Commission in 2005 (REALITY Consortium, 2005b). Yet, to compare and analyse the demographic composition of the recruited groups, we have extracted and reorganised the raw data that were originally collected in the electronic forms by the consortium.

### **4.2. REALITY background**

Between 2004 and 2005, more than 190 patients with different chronic diseases, from locations in the UK, Estonia and Portugal, took part in an EU-funded project called REALITY (representative evaluation of evolving remote home-based patient monitoring delivery – QLG7-CT-2002-02657). This was a telecare project implemented as a remote clinical monitoring service for the care of patients with chronic diseases staying at home. The project aimed to provide a socio-economic evaluation of a telecare service including the perspectives of patients, doctors and

healthcare managers. Four clinical partners based in: a GP practice (London), a University Hospital (Tartu), and two other Hospitals (Lisbon and Evora) recruited patients with diabetes and hypertension, asthma, heart conditions, and pulmonary diseases. Patients who met the criteria given in table 4.1 (REALITY Consortium, 2004) and agreed participation were recruited, trained and provided with medical devices based on the patients' primary health condition.

The project included a technical partner who provided a system designed for the management of patients with long term conditions. This consisted of a web service for doctors' interaction with both the data collected and their patients, and a handheld device for home data collection. On a regular basis, patients recorded their clinical and quality of life data using the handheld and other third party products such as glucometers, blood pressure monitors, peak flow meters and pulse oximeters. Subsequently, physiological measurements and health related data were sent automatically from local homes to a central server over standard phone lines. Using a PC, doctors were able to access the information collected by patients from their local healthcare facilities via the internet.

Table 4.1. Criteria for patient selection and method of recruitment.

	<b>London</b>	<b>Tartu</b>	<b>Lisbon</b>	<b>Evora</b>
<b>Inclusion criteria</b>	Patients with: <ul style="list-style-type: none"> <li>• Diabetes and hypertension</li> <li>• Bronchial asthma</li> <li>• Age: 25+</li> </ul>	Patients with: <ul style="list-style-type: none"> <li>• Chronic heart failure</li> </ul>	Patients with: <ul style="list-style-type: none"> <li>• Chronic respiratory failure</li> <li>• Long-term oxygen therapy and/or non-invasive ventilation</li> </ul>	Patient with: <ul style="list-style-type: none"> <li>• Bronchial asthma</li> <li>• Chronic respiratory failure</li> </ul> Patient or immediate carer/family able to read. Patient with severe or moderate disease category. Patient located close/far away from Evora. Only patients interested in the evaluation
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• Visually impaired</li> <li>• Patients who cannot read</li> <li>• Pregnant woman</li> <li>• Patients with no telephone line</li> </ul>	Not stated	<ul style="list-style-type: none"> <li>• Patient/family illiteracy</li> <li>• Patients with pacemaker</li> <li>• Patients with no telephone line</li> </ul>	<ul style="list-style-type: none"> <li>• Patients with no telephone line</li> </ul>
<b>Method of recruitment</b>	Local advertisement posters, flyers and leaflets	Not stated	Not stated	Not stated

To collect data and provide a comprehensive evaluation from the patients and doctors perspectives, the research consortium developed different electronic questionnaires (forms 1 to 4). Forms were distributed to patients or answered as

appropriate by clinical partners at 3 stages of the project: recruitment and training, interim visit and final visit (fig. 4.1).

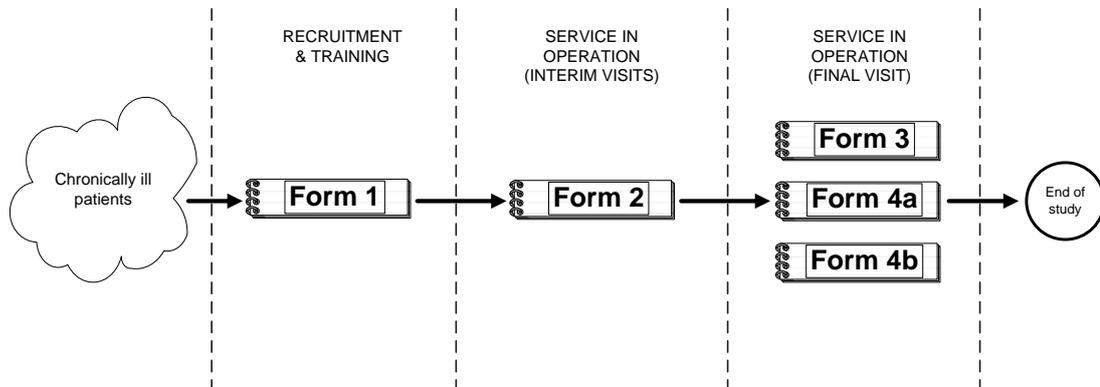


Figure 4.1. REALITY process and the stages at which the electronic forms were distributed for the project evaluation.

### 4.3. Patient's demographics

#### 4.3.1 Total patients per study site

A total of 193 cases were retrieved from the patients recruitment form:

- 62 patients in London
- 60 patients in Tartu
- 38 patients in Lisbon and
- 33 patients in Evora.

#### 4.3.2 Age distribution

As illustrated in fig. 4.2, the youngest patients were recruited in London and Tartu with an average age of 53.1 years (SD=15.5) and 55.5 years (SD=9.9) respectively. The mean age in Lisbon was 70.6 years (SD=9). Average age in Evora was 60.9 years (SD=14.3).

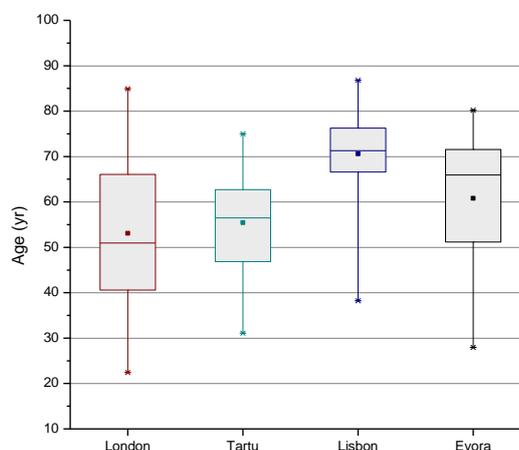


Figure 4.2. Box plot displaying the difference in age among the 4 sites.

To the Shapiro-Wilk normality test ( $W>0.05$ ), the participants' age in London, Tartu and Lisbon followed a normal distribution (elimination of an outlier was needed in Lisbon). Evora displayed a left skewed age distribution with a large proportion of recruited patients between 70 to 75 years old. The normality test suggests no recruitment preference for any specific (target) age group at least in 3 out of the 4 sites. It also suggests that genuine patient participation for telehealth studies can be achieved normally distributed by age, allowing an unbiased estimator of the population mean and possible generalisability of future local studies.

As indicated in table 4.2, 26.9% of the total participants were between 61-70 years old, followed by the groups 71 to 80 (23%), 41 to 50 (18.1%) and the 51 to 60 years old (17.6%). Only 3.1% of the total participants were younger than 31 years or older than 80. Almost 50% of the recruits in London were younger than 51 years. The majority of participants in Lisbon (92%) were older than 60 years. Tartu had almost equal proportion of participants in the intervals 41-50, 51-60 and 61-70 years. There was a significant association between the age of participants and the location of recruitment (Cramer's  $V=0.342$ ,  $p<0.001$ ).

Table 4.2. Distribution of age by class intervals.

Age:	Clinical site				Total
	London (n= 62)	Tartu (n=60)	Lisbon (n=38)	Evora (n=33)	
<= 30	8.1%			3.0%	3.1%
31 – 40	16.1%	5.0%	2.6%	9.1%	8.8%
41 – 50	24.2%	26.7%		12.1%	18.1%
51 – 60	12.9%	30.0%	5.3%	18.2%	17.6%
61 – 70	22.6%	30.0%	34.2%	21.2%	26.9%
71 – 80	12.9%	8.3%	47.4%	36.4%	22.3%
81+	3.2%		10.5%		3.1%
Total	100.0%	100.0%	100.0%	100.0%	100.0%

### 4.3.3 Gender

An equal proportion of male and female participants were recruited in the four clinical sites (see fig. 4.3). As a whole, there was no significant preference for participation in the trial by male (53.7%) or female (46.3%) subjects ( $\chi^2=1.032$ ,  $df=1$ ,  $p=0.310$ ).

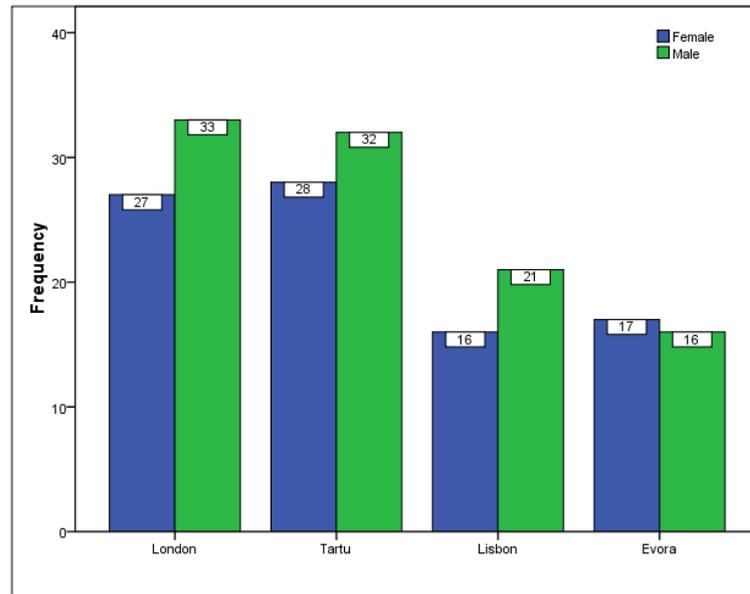


Figure 4.3. Gender distribution per clinical site.

### 4.3.4 Education level

The education level of participants by the four sites is shown in table 4.3. Tartu showed the highest proportion of adults who had completed either college (20%) or university (46.7%), followed by the group in London (16.9 and 28.8% respectively). Notably, Evora had the highest proportion of participants with no education at all. As a whole, 31% of the total participants declared to have completed high/secondary school. There was a strong association between education level and the location of recruitment (Cramer's  $V=0.505$ ,  $p<0.001$ ).

Table 4.3. Education level.

Education:	Clinical site				Total
	London (n = 59)	Tartu (n = 60)	Lisbon (n = 37)	Evora (n = 33)	
None	6.8%		2.7%	24.2%	6.9%
Primary School		5.0%	78.4%	39.4%	23.8%
High / Secondary School	47.5%	28.3%	18.9%	24.2%	31.7%
College	28.8%	20.0%			15.3%
University	16.9%	46.7%		12.1%	22.2%
Total	100.0%	100.0%	100.0%	100.0%	100.0%

n reports only the valid cases. Missing or not recorded answers: London= 3; Lisbon=1

### 4.3.5 Marital status

In total, 132 participants were married (70.2%), 30 were single (16%), 12 divorced (7.3%) and 14 widowed (7.4%). As illustrated by fig. 4.4, Tartu and Evora had the largest and almost equal proportion of married cases (78.3 and 78.8% respectively). The largest percentage of widowed participants was recorded in Lisbon (21.6%) whereas London had the largest proportion of singles (27.6%). A moderate but significant association was found between the participant's marital status and the clinical site (Cramer's  $V=0.223$ ,  $p=0.001$ ).

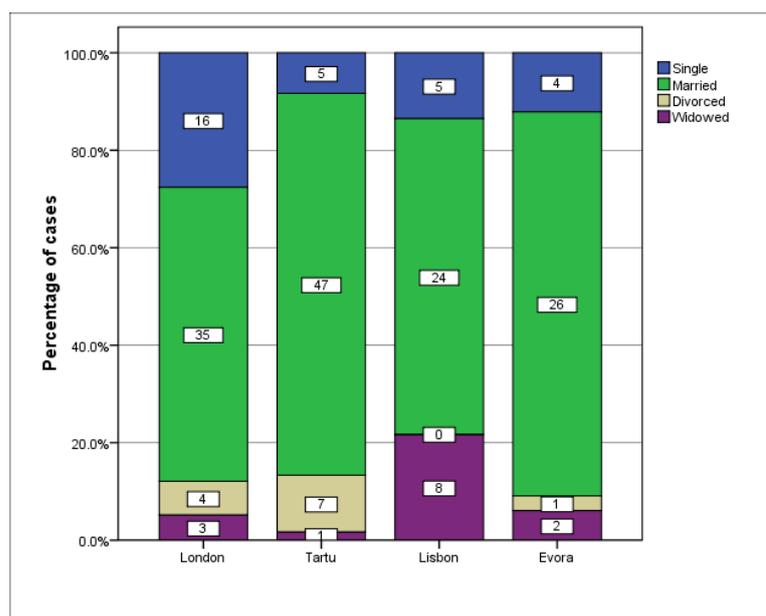


Figure 4.4. Marital status per clinical sites (5 cases missing).

### 4.3.6 Occupation

Altogether, manual labour accounted for the main current or most recent occupation (26.9%), followed by technical/administrative profession (22.9%) and service occupation (19.4%). For Tartu (see table 4.4), subjects were more likely to be in the category of technical/administrative profession or manager/highly trained profession, whereas subjects in London were either in the service occupation or seeking employment category. In Evora, more than 50% of the subjects reported to be manual labourers as well as one third of the subjects in Lisbon. A significant relationship was observed between occupation and the site of recruitment (Cramer's  $V=0.400$ ,  $p<0.001$ ).

Table 4.4. Current or most recent occupation.

Current or most recent occupation:	Clinical site				Total
	London (n=50)	Tartu (n=56)	Lisbon (n=36)	Evora (n=33)	
Manual labour	10.0%	21.4%	33.3%	54.5%	26.9%
Mid-level technical/administrative profession	12.0%	37.5%	19.4%	18.2%	22.9%
Seeking employment	18.0%	1.8%			5.7%
Senior manger / highly trained profession	8.0%	30.4%		12.1%	14.3%
Service occupation	36.0%	5.4%	25.0%	12.1%	19.4%
Skilled labour	16.0%	3.6%	22.2%	3.0%	10.9%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

n reports only the valid cases. Missing or not recorded answers: London=12; Tartu=4; Lisbon=1

### 4.3.7 Activity of retired patients

The total percentage of subjects inactive either as a result of illness or by choice is shown in fig. 4.5. Almost all subjects from Lisbon were inactive due to illness (33/36). Subjects from Evora were reported to be either active (14/33) or inactive due to illness (15/33). In Tartu, subjects were more likely to be inactive by choice (12/23) whereas in London subjects were more likely to be inactive due to illness (13/25). There was a significant association between being active or inactive and the clinical site (Cramer's  $V=0.463$ ,  $p<0.001$ ).

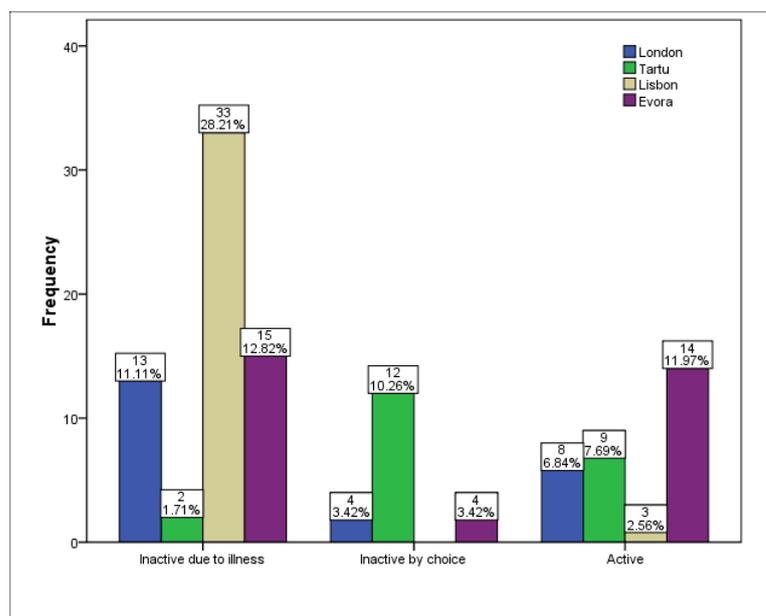


Figure 4.5. Activity if patient has reached retirement age.

### 4.3.8 Literacy in local language

As evident from fig. 4.6, all participants in Tartu were literate in the local language whereas a considerable proportion of participants (24.2%) in Evora were not literate. Less than 3% of the Lisbon and London groups were not literate (one

case in each site). There was an association between literacy in local language and the place of recruitment.

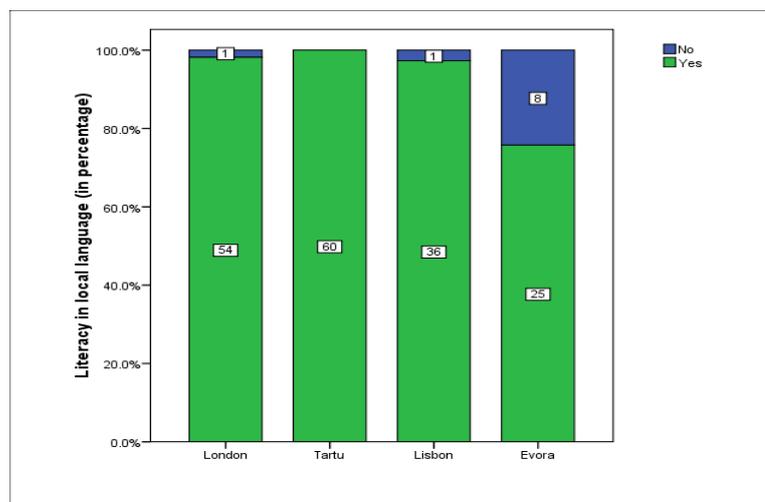


Figure 4.6. Percentage of literate participants per clinical site.

#### 4.3.9 Ethnicity

Patients in London were more likely to come from a cultural or ethnic minority group with a large participation of Black Afro Caribbeans. In Tartu, participants were predominantly White Caucasians with only one participant reporting coming from an unspecified background. The other two sites did not specify any ethnic minority background within their living areas. Further details can be consulted in table 4.5. There was a significant association between ethnicity and the clinical sites (Cramer's  $V = 0.597$ ,  $p < 0.001$ ).

Table 4.5. Ethnic Groups.

Ethnic group:	Clinical site				Total
	London (n=62)	Tartu (n=60)	Lisbon (n= 37)	Evora (n= 33)	
Asian: Indian	3.2%				1.0%
Asian: Pakistani	1.6%				0.5%
Black: Afro Carribbean	62.9%				20.3%
White: Caucasian	17.7%	98.3%		93.9%	52.6%
Other				3.0%	0.5%
Not specified	14.5%	1.7%	100.0%	3.0%	25.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

n reports only the valid cases. Missing or not recorded answers: Lisbon=1

#### 4.3.10 Location of the patient's home

Fig.4.7 shows the general location of the patient's home (only the valid cases) at each clinical site. As can be seen, all patients in London lived in the urban area. Patients in Tartu were living in different locations, but almost 80% of them lived in either the inner or the outer city. The majority of patients in Lisbon (65%) lived in

the outer city whereas in Evora, patients lived either in towns (55.5%) or rural areas (45.5%). There was a significant association between the location of patient's home and the clinical sites (Cramer's  $V=0.597$ ,  $p<0.001$ ).

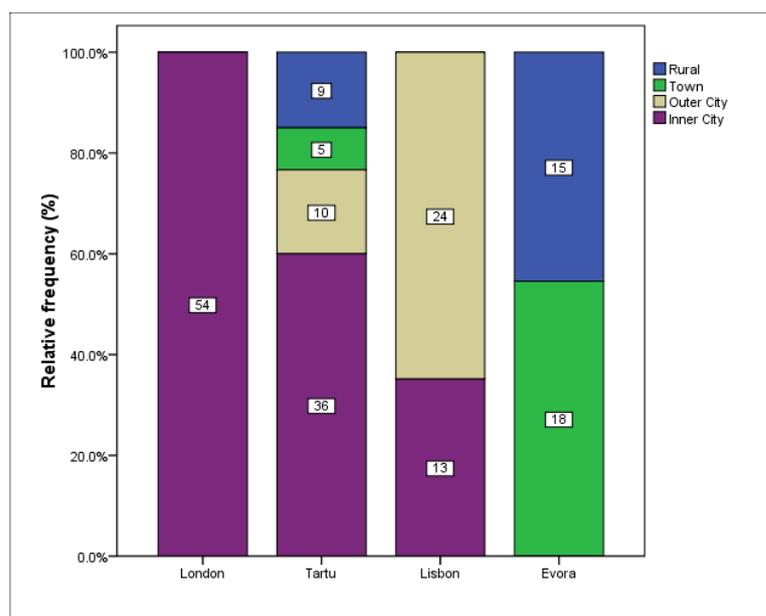


Figure 4.7. General location of patient's home.

#### 4.3.11 Household

The patient's status within the household is shown in table 4.6. At least 50% of all patients owned the property where they lived. Almost 30% of patients were an equal representative householder among people in the same property and 18% of patients were the main householder's partner. No association was found between the patient's status within the household and the clinical site (Cramer's  $V=0.148$ ,  $p=0.220$ ).

Table 4.6. Household status per clinical site.

	Clinical site				Total
	London (n=54)	Tartu (n=60)	Lisbon (n=35)	Evora (n=33)	
Patient's status within the household:					
Patient is the main householder	48.1%	60.0%	60.0%	39.4%	52.7%
Patient is the main householder's partner	16.7%	16.7%	8.6%	33.3%	18.1%
Patient is a representative householder (equal among people in the same house)	33.3%	23.3%	31.4%	27.3%	28.6%
Patient is representative of other patients in the care/nursing home or sheltered accommodation	1.9%				0.5%
Total	100.0%	100.0%	100.0%	100.0%	100.0%

n reports only the valid cases. Missing or not recorded answers: London=8; Lisbon=3

The majority of patients lived either with their partners (39%) or with family or friends (46%) in all sites. However, almost 20% of the patients in London and

Portugal lived alone. An association was found between with who the patient lived and the site of recruitment (Cramer's  $V=0.493$ ,  $p<0.001$ ).

#### 4.3.12 Main income of the household

Overall, 55% of patients stated that the main income of their households came from a monthly salary, followed by State benefits in 43% of all cases. Individually, as illustrated by fig. 4.8, Lisbon had the highest proportion of patients who were reliant on State benefits (almost 92%), whereas Tartu had the lowest proportion (13.5%) for the same category. There was an association between main income of the household and the clinical site (Cramer's  $V=0.344$ ,  $p<0.001$ ).

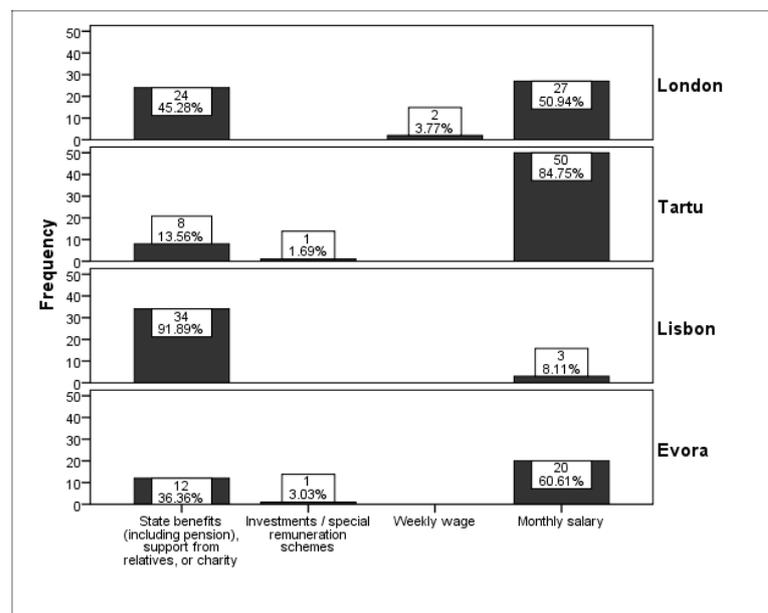


Figure 4.8. Main income of household.

#### 4.3.13 Living accommodation

In general, patients were more likely to declare reasonable conditions for their quality of living accommodation in 40% of the cases, followed by the category of good condition (33%) and reduced conditions (22%). Patients in Tartu rated "good condition" in 76.7% of the cases while majority of patients in Evora (45.5%) rated their accommodations condition as reduced. Patients in London and Lisbon rated their living accommodation as reasonable almost in 60% of the cases. Full details are listed in table 4.7. There was an association between the quality of living accommodation and the clinical site (Cramer's  $V= 0.426$ ,  $p<0.001$ ).

Table 4.7. Quality of living accommodation.

Quality of living accommodation:	Clinical site				Total
	London (n=51)	Tartu (n= 60)	Lisbon (n= 37)	Evora (n= 33)	
Inadequate conditions	5.9%		2.7%	3.0%	2.8%
Reduced conditions	25.5%		29.7%	45.5%	21.5%
Reasonable conditions	58.8%	18.3%	59.5%	27.3%	39.8%
Good conditions	9.8%	76.7%	5.4%	21.2%	33.1%
Very good conditions		5.0%	2.7%	3.0%	2.8%
Total	100.0%	100.0%	100.0%	100.0%	100.0%

n reports only the valid cases. Missing or not recorded answers: London=11; Lisbon=1

## 4.4 Existing services and support from carers

### 4.4.1 Access to local medical and social care services

There was a clear difference in the answers from patients living in London and Tartu in contrast to the ones living in Lisbon and Evora. As illustrated by fig. 4.9, patients living in Portugal were quite likely to have an existing care provision and access to local medical and social care service, whereas patients living in the UK and especially in Estonia were unlikely to have an existing care provision in place. There was a strong association between existing services and support from carers and the local sites (Cramer's  $V= 0.856$ ,  $p<0.001$ ).

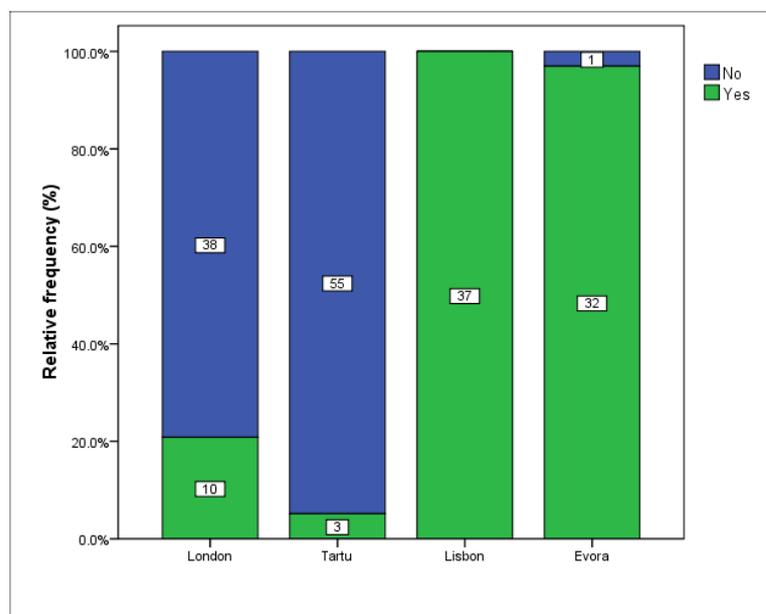


Figure 4.9. Existing care provision and access to local medical and social care services (only data for the valid cases are shown).

#### 4.4.2 Main carer had also any medical condition?

The proportion of answers including missing or not recorded data is displayed in fig. 4.10. Lisbon reported 18 cases (47%) where the main carer also had a medical condition, followed by 6 cases (18%) in Evora and 3 cases (5%) in London.

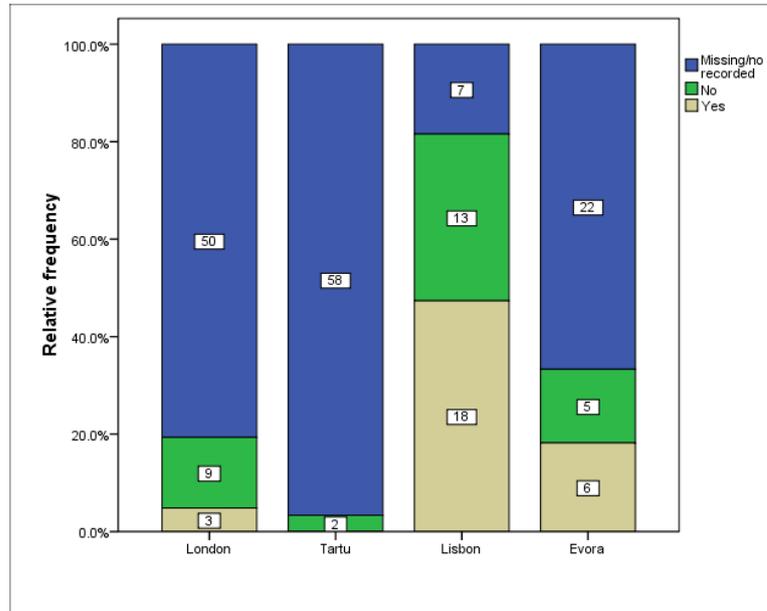


Figure 4.10. Cases reported where the main carer also had a medical condition.

#### 4.4.3. Carer's availability and level of support

In Lisbon, 18 patients were stated to have a carer available at home all day, 10 patients had a carer at home only at night and 7 patients had a carer that paid occasional visits. In London, a carer was available at home all day for 5 patients and a carer paid occasional visits to another 3. In Evora, 4 patients had a carer available at home only at nights. A large proportion of data was missing or not recorded for Tartu and London (see fig. 4.11 and 4.12).

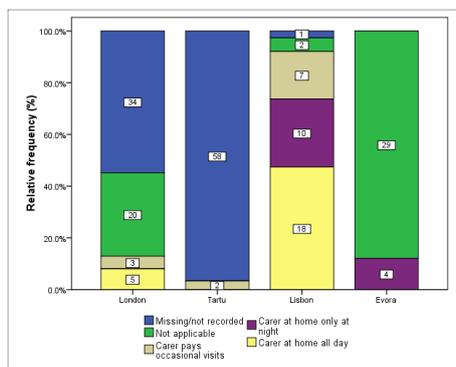


Figure 4.11. Carer's availability.

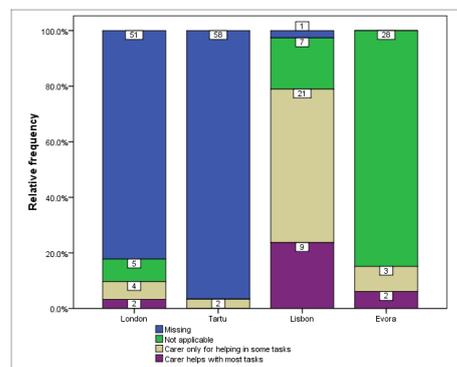


Figure 4.12. Carer's level of support.

Patients in Lisbon were more likely to depend on the support of their carers with 21 cases requiring a carer only for helping in some tasks and 9 cases requiring a carer for helping in most tasks. Five patients in Evora and six in London required either help in some tasks or help in most tasks. Only 2 cases in Tartu were declared to require support from a carer in some tasks.

#### 4.5 Baseline clinical conditions

The medical conditions reported by the 193 patients are presented below:

- London included 35 patients with diabetes and hypertension, and 27 patients with bronchial asthma;
- Tartu consisted of 19 patients with chronic heart failure and 41 patients with hypertension;
- Lisbon included 38 patients with chronic respiratory failure; and
- Evora consisted of 21 patients with bronchial asthma and 12 patients with chronic respiratory failure.

##### 4.5.1 Disease duration

Fig. 4.13 contains box plots for each independent disease in 3 out of the 4 sites (data were not available from Lisbon). The bottom of each box represents the 25th percentile and the top the 75th percentile of disease duration in years. Median values are represented for the line in the middle and mean years of diseases are shown in square dots. Additional information about the dispersion of data is shown by the whiskers (extreme values). As can be seen, mean and median disease duration varied significantly ( $F=4.06$ ,  $p=0.0007$ ) among the primary medical conditions in all clinical sites.

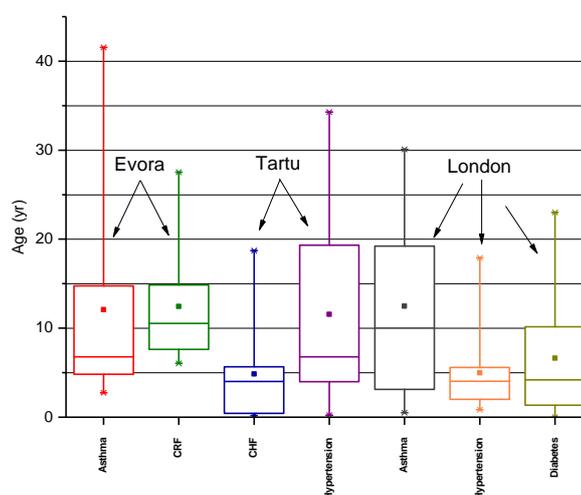


Figure 4.13. Distribution of patient's disease duration per site (no data available from Lisbon).

Patients with respiratory diseases (London and Evora) were the ones with greater median years of living with a medical condition since diagnosis (10.01yr, 10.55yr, and 6.92yr respectively), followed by those with hypertension in Tartu (6.78yr), and diabetes and hypertension in London (4.28yr and 4.13yr respectively). As a disease category, patients with chronic heart failure were the ones more recently diagnosed (3.99yr). Numerical details, including sample size, mean, standard deviation and median are displayed in table 4.8.

Table 4.8. Patient's disease duration.

Diagnosis	N	Mean(yr)	SD(yr)	Median(yr)
Asthma (Evora)	20	12.08	11.63	6.92
Chronic respiratory failure (CRF, Evora)	12	12.43	6.36	10.55
Chronic heart failure (CHF, Tartu)	19	4.85	5.52	3.99
Hypertension (Tartu)	57	11.55	10.92	6.78
Asthma (London)	26	12.48	10.09	10.01
Hypertension (London)	26	4.98	4.22	4.13
Diabetes (London)	32	6.62	6.37	4.28

#### 4.5.2 Aetiology

Causes or origin of disease for patients living in London were divided in two groups. Those related to diabetes and hypertension; 30/35 cases with diabetes type 2 and 1/35 cases with diabetes type 1 (4 cases not recorded) and for the same group 32/35 cases with hypertension (2 cases not recorded and 1 declaring not to have hypertension). The other group was the asthmatic patients who accounted for 27 cases. In terms of of asthma severity (GINA classification), 5/27 patients fell in the intermittent category (asymptomatic), 9/27 in the mild persistent (attacks might affect activity), 8/27 in the moderate persistent (attacks affected their activity) and 5/27 in the severe persistent category (limited physical activity).

In Tartu, 41 patients had hypertension and 19 patients had heart failure. Out of the 19 patients with heart failure, 16 also had a medical history of hypertension, 4 a history of cardiomiopathy, 2 a history of dyslipidemia, 2 a history of ischemic heart disease, and 1 a history of myocarditis.

In Lisbon, the origin of respiratory failure was related to chronic obstructive pulmonary disease (COPD) in 15/38 patients, to tuberculosis (TB) sequelae in 13/38 patients and in 10/38 to other origin. The respiratory function was classified as mixed for 13 patients, obstructive for 14 patients and restrictive for the last 11 patients.

Evora had 12 patients with respiratory failure for which their aetiology was related to COPD in 9 cases, lung fibrosis in 2 and TB sequelae in 1 patient. There were also, 21 patients with bronchial asthma. In terms of the severity of disease (GINA classification for those with asthma) 12/21 patients were classified as moderate persistent (attacks affected their activity) and 9/21 as severe persistent (limited physical activity). For those patients with respiratory failure, their respiratory function condition were classified in 6/12 cases as obstructive, in 3/12 as restrictive and in the last 3/12 cases as mixed.

#### **4.5.3 Disease related symptoms and special therapies use at home**

Out of the 35 patients with diabetes, 12 patients had a history of retinopathy, 8 patients a history of nephropathy and 1 patient had diabetic foot ulceration. For their diabetes control, 18/35 patients required oral drugs, 8/35 patients needed diet and oral drugs, 4/35 patients required insulin and only 1/35 required diet (4 cases were missing).

In Tartu, 2/60 patients had a history of previous myocardial infarction, 32/60 patients had symptoms of dyspnoea (shortness of breath), 20/60 had symptoms of peripheral oedema (soft tissue swelling due to the accumulation of fluid in the limbs), 48/60 had symptoms of fatigue. For those patients with heart failure, 7/19 reported no symptoms and no limitations in ordinary physical activity, and 11/19 had mild symptoms of shortness of breath and slight limitation during ordinary activities.

Table 4.9 contains the characterisation of breathlessness for those patients with asthma or respiratory failure in London (27 cases), Lisbon (38) and Evora (33). As can be seen, 30% of the patients in Evora, 24% in Lisbon and 15% in London were breathless at rest or minimal effort. In London, the majority of patients (66.6%) were able to keep up with people of similar ages, but not on hills or stairs.

Table 4.9. Characterisation of breathlessness.

	Clinical site		
	London n (%)	Lisbon n (%)	Evora n (%)
Breathless only during asthmatic attacks	2(7.4)		11(33.3)
Persistent mild/moderate breathlessness	2(7.4)		6(18.1)
Breathless at rest or on minimal effort	4(14.8)	9(23.6)	10(30.3)
Able to walk about 100 yards (91m) on the level		19(50)	4(12.1)
Able to walk for 1 mile (1600m) on the level at own pace, unable to keep up with people of similar age		10(26.3)	2(6)
Able to keep with people of similar age but not on hills or stairs	18(66.6)		

\* 1 case missing

Almost 95% of patients in Lisbon (36/38) and 37% in Evora (12/33) needed oxygen therapy. In addition, 29/38 patients in Lisbon (76%) and 2/33 in Evora (6%) also required non invasive home ventilation.

#### 4.5.4 Comorbidity

In addition to the primary disease condition, the presence of other disorders was recorded. Note that for the categories of diabetes and hypertension some patients from London and Tartu have been excluded as shown in table 4.10 (see note a, b and c). In total, 68/193 cases had Cor pulmonale (35%), 19/158 patients had diabetes (12%), 43/101 patients had hypertension (46%), and 40/193 patients had coronary heart disease (21%).

Table 4.10. Comorbidities by clinical site.

		Clinical site				Total
		London	Tartu	Lisbon	Evora	
Cor Pulmonale	Yes	35	1	24	8	68
	No	26	59	14	25	124
	Missing	1				1
Diabetes	Yes	3 <sup>a</sup>	5	7	4	19
	No	24	55	31	29	139
Hypertension	Yes	4 <sup>b</sup>	0 <sup>c</sup>	25	14	43
	No	21	3	13	19	56
	Missing	2				2
Coronary Heart Disease	Yes	8	16	11	5	40
	No	50	44	26	28	148
	Missing	4		1		5

<sup>a, b</sup> 35 patients were not considered as their primary diagnostic were diabetes with hypertension

<sup>c</sup> 57 patients were not included as their primary diagnostic were hypertension

Pulmonary heart disease (Cor Pulmonale) was a condition predominant in the London (35/68) and Lisbon (24/68) site whereas hypertension was predominant in Lisbon (25/43) and Evora (14/43). Coronary heart diseases were more common in Tartu (16/40) and Lisbon (11/40).

In addition to table 4.10, 6 patients with diabetes reported to have a peripheral artery disease and 2 more chronic renal failures.

An association was found between the clinical sites and the presence of Cor Pulmonale (Cramer's  $V=0.546$ ,  $p<0.001$ ) as well as the presence of hypertension (Cramer's  $V= 0.404$ ,  $p<0.001$ ).

#### 4.5.5 Body Mass Index

According to their Body Mass Index (BMI, WHO classification<sup>4</sup>), a large proportion of patients in Tartu (53%), Evora (52%), London (42%) and Lisbon (29%) were obese (see fig. 4.14 for further details). Only a small proportion of cases fell in the normal weight category including an equal proportion of cases in Lisbon and Evora (21%), followed by 16% of cases in London and a tiny proportion in Evora (5%).

The mean BMI value for patients in London was  $30.25 \text{ kg/m}^2$  ( $SD=5.28$ ,  $n=55$ ), for Tartu  $31.01 \text{ kg/m}^2$  ( $SD=4.97$ ,  $n=58$ ), Lisbon  $28.94 \text{ kg/m}^2$  ( $SD=6.63$ ,  $n=36$ ) and in Evora  $29.45 \text{ kg/m}^2$  ( $SD=5.24$ ,  $n=33$ ). There was not a significant BMI difference among the groups ( $F=1.237$ ,  $df=3$ ,  $p=0.298$ ).

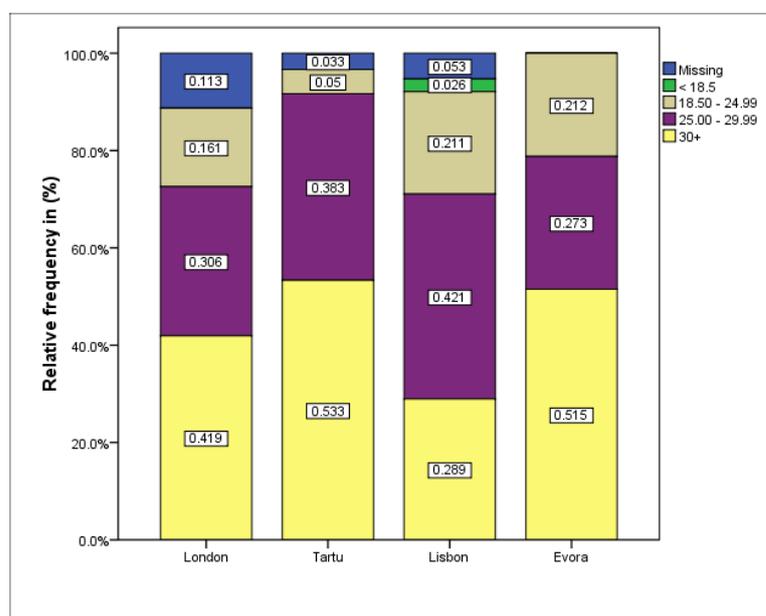


Figure 4.14. BMI in  $\text{kg/m}^2$ : underweight ( $<18.5$ ), normal ( $18.5-24.99$ ), overweight ( $25-29.99$ ) and obese ( $30+$ ).

<sup>4</sup> Available at: [http://apps.who.int/bmi/index.jsp?introPage=intro\\_3.html](http://apps.who.int/bmi/index.jsp?introPage=intro_3.html) [Accessed 17 February 2011]

### 4.5.6 Impairment

There were 4 types of disabilities consistently recorded at the clinical sites: hand movement, vision, hearing and cognitive impairments.

33% of patients in Evora, 27% of patients in London and 11% of patients in Lisbon reported finger or hand reduced movement. Notably, 100% of patients in Tartu had no hand problems (see fig. 4.15).

Patients reported either moderated or reduced vision in 45% of cases at Tartu, 36% at Evora, 27% at London and 5% at Lisbon. Evidence for this is shown in fig. 4.16.

Except for London (76%), as can be observed in fig. 4.17, the rest of the clinical sites reported at least in 91% of the cases normal hearing.

In relation to learning disabilities or memory problems, 58% of the cases in Lisbon and 42% of cases in Evora had cognitive problems (fig. 4.18).

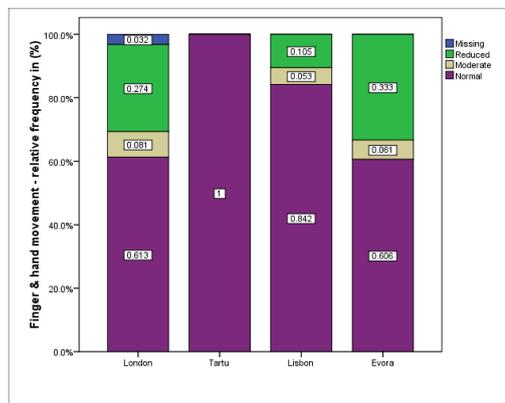


Figure 4.15. Hand movement impairment.

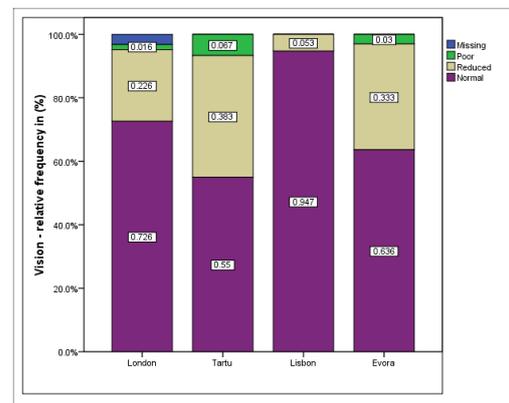


Figure 4.16. Vision impairment.

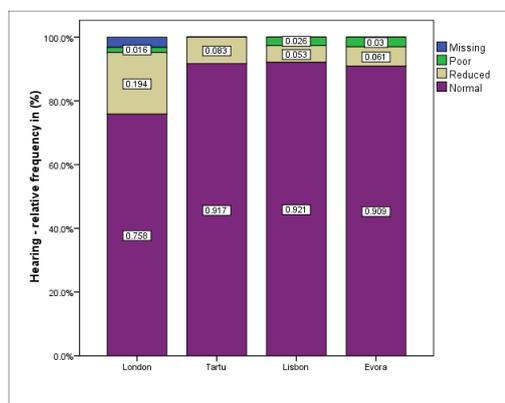


Figure 4.17. Hearing impairment.

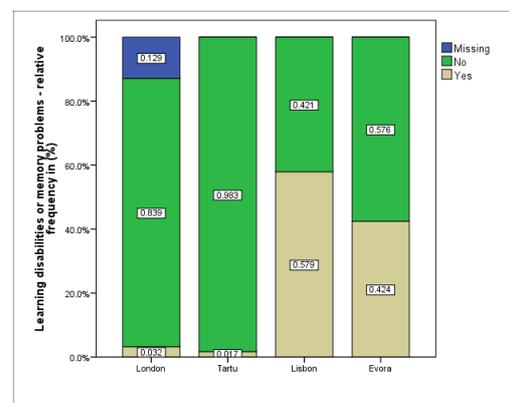


Figure 4.18. Learning disabilities or memory problems.

#### **4.6 Discussion**

At baseline, the characteristics of patients across the four clinical sites were found statistically significantly different (confirmed by Cramer's V test) with respect to age, education, marital status, occupation, activity, literacy, ethnicity, location, main income, living accommodation, access to social care, carer's availability and level of support. All differences, among and within the REALITY groups (clinical sites), reflect the situational context and complexity in which patients with long term conditions live. Such differences also represent a realistic scenario for which telehealth interventions must be designed and implemented. To ensure that these interventions are well-defined, good knowledge and understanding about the overall status of patients are required. Although, understanding patients' needs can be complex they should not be based solely on the patients' illness, but also based on other factors that surround the patients' way of living in which coping with long term conditions take place (Kelley, 2009; Lindsay and Vrijhoef, 2009).

Indeed, previous studies support the view that socio-economic and daily living conditions are important aspects that should be taken into account for design and evaluation of telehealth interventions. For example, in one study, Levy et al. (2003) found important associations between age, mobility status, home ownership, house type, household composition, quality of health service, and the presence of positive or negative attitudes to telehealth. In another study, Laviolette (2009) used "type of housing" as the criterion for interviewing a group of cardiac patients with the intention of investigating domestic use of space and participants' expectations to telecare. Finally, in a third study, Darkins et al. (2008) remarked on the importance of addressing "the complex biopsychosocial care needs of" patients. They criticised the fact that healthcare systems are inadequate adapted to deal with such needs and suggested the adoption of their approach for "marring health and social elements of care (Darkins et al., 2008).

Another important demographic aspect to be considered during the design of telehealth interventions is the users' age. Age-related changes can affect the requirements of telehealth (Stronge et al., 2007). For instance, telehealth services are in general linked with the care of older populations (typically 65yr old and over) since prevalence of long term conditions increases over time (Christensen et al., 2009). However, medical conditions such as diabetes and asthma are also manifested in younger age groups (see table 4.2) and thus the youngest groups could be supported by telehealth too. Nevertheless, for this to happen, a careful

evaluation of requirements is essential as older and younger generations tend to have different needs, interests, expectations and ways of interacting with technology (Weinschenk, 2008).

In relation to the use of complex technologies (small multi-functional electronic devices), Kang and Yoon (2008) have studied user behaviour differences between young adults (20 to 29yrs old) and middle-aged adults (46 to 59yrs old). They found that age affects the performance of users in terms of the frequency of errors made, the number of steps needed to perform a task, the frequency of repetitive actions with no meaningful outcomes, the success of physical operation methods, and the perception of an increase in workload. These findings may help to explain why some REALITY patients, especially the oldest, found themselves in real difficulty trying to work out how to use or carry out tasks with the technology supplied even after retraining.

For example, patient 4886 (75yr, female) decided to withdraw from the study even after additional training as she stated that the:

“Handheld unit is too difficult to use”.

Other patients found not the handheld unit complicated to operate but the measurement physiological devices as patients 8442 (75yr, male) and 8701 (72yr, male) commented:

“the oximeter, cables and connections were very difficult to use”.

In other cases, not only the patient (pt 8536, 71yr, female) but also the carers had similar issues in managing the devices as one of the clinicians in Portugal commented:

“patient and her family found the equipment too difficult to use”.

Thus, technology must be made not just available but also usable for older patients and their carers. On usability, Hawthorn (2000) has studied the implications of ageing and human computer interface design for older users. He reviewed the effects of age on users' relevant abilities and suggested that designers need to pay attention to visual, speech, and hearing impairments, as well as to psychomotor abilities, attention capacity, automated response, memory, learning, intelligence and expertise. Reasons for such considerations are related to the fact that sensory, motor and cognitive abilities tend to decline (Stronge et

al., 2007) with the process of ageing or as a consequence of some degenerative diseases. Reduction or deterioration of such abilities cannot just be ignored or put aside for future service design since evidence shows that impairment conditions are not rare among the chronically ill (see Section 4.5.6). In fact, visual impairments (45% of cases in Tartu, 36% in Evora, and 27% in London) and learning or memory disabilities (58% of cases in Lisbon and 42% in Evora) were commonly identified in the oldest REALITY groups.

In addition to Hawthorn's usability considerations, Kurniawan (2008) has suggested that mobile phones for older people need to be designed with the intention to minimise unintended user actions. Furthermore, safety considerations and haptic support should be also part of the user interface design. These considerations are important in telehealth. As people get older and sicker, health monitoring becomes more frequent in the community, which includes monitoring physical and emotional conditions (Gao and Koronios, 2010). Such monitoring applications need to be designed for users with different capabilities and needs, which include different levels of usability, due to the diversity in sensory, motor and cognitive abilities of people aged 50 or older (Lorenz and Oppermann, 2009). Although, we cannot quantify their direct impact, comments quoted below give indications that patients with learning disabilities and memory problems faced major limitations when they interacted with technology. Patient 8248 (76yr, female) expressed that:

“It was too much difficult to learn how to use the handheld unit”

Another similar example can be taken from the comment made by patient 6554 (76yr, male) who had decreased movement in his hands, reduced vision and reduced hearing, but no reported any learning disabilities or memory problems. He mentioned:

“I could not understand and remember how to use it”.

These couple of citations give indications that not only patients with cognitive impairment, but also other impairment groups found difficulties in how to use this particular technology. Similarly, a last quotation given by a Portuguese clinician in reference to his patient (patient 8112, 77yr, female), who in addition to cognitive impairment also had reduced vision:

“The patient found she had memory difficulties that interfere with the use of this equipment”

In fact, patient 8112 stayed for 50 days on the trial, a period in which she used the system for only 9 days (18% usage). As can be noticed from the citations above, all these patients required appropriate support that encouraged the use of their sensory, motor and cognitive capabilities in the best way so they could take care of themselves.

More conclusions about the importance of demographics for understanding patients' conditions, and therefore the requirements for telehealth, can be derived from the reports published by the Commission on Social Determinants of Health – WHO (WHO, 2008) and the Department of Economic and Social Affairs of the United Nations (DESA, 2009). These reports discussed the social determinants of health responsible for what is known as health inequalities. Such inequalities are usually measured in terms of socio-economic classes and unfortunately present everywhere, even in the wealthiest countries (HC, 2009). Factors such as lifestyle (smoking, nutrition, exercise among others), gender, ethnicity, education, employment, income, social status, disabilities, social support, physical environment and access to healthcare are all usually mentioned as health determinants (WHO, 2008; DESA, 2009; HC, 2009).

Not all the demographic characteristics may be equally important to be considered in a telehealth intervention. To explore their property values and impact on the use of technology, the REALITY's demographic data have been correlated with a selection of performance indicators from the evaluation forms. The results of the association between demographics and those indicators are presented in the next chapter.

#### **4.7 Summary**

Although complex and challenging, one of the first activities for a proper assessment of requirements is to recognise the actual user health needs, their socio-economic conditions and kind of support they need to receive at home. Sections above have provided a wide picture of the diverse characteristics among patients in the 4 clinical sites and shown some of the essential information needed to understand the contextual situation of the REALITY patients.

Some patients may not comply with monitoring (and treatments) if they do not understand the intervention or see it as appropriate to their particular circumstances; especially if technology is complex or difficult to use. To facilitate a more user centred approach for the design of telehealth interventions, demographic characteristics must therefore be considered in the design and implementation of the treatment intervention.

## **Chapter 5. Test for associations**

### **5.1 Introduction**

The previous chapter provided a description of the demographics and health characteristics of participants in REALITY. We have discussed earlier that the social and economic conditions are important factors to be considered in the design of interventions for telehealth. As shown in chapter 4, some of the oldest patients found it difficult to use the devices provided even after additional training. To investigate whether there was any association between patients' demographics and their performance during the project, we carried out a series of cross tabulations and statistical tests for association.

The purpose of this chapter is to present the findings of associations between demographics and a selection of items collected at the interim visit.

### **5.2 Measures**

A number of questions and their respective answers collected from the REALITY's Form 1 (Patient recruitment) and Form 2 (record of patient's progress at a clinical visit) were selected. Specifically, from Form 2, we retrieved questions from the following subdivisions:

1. Patient's understanding, skills and home support
2. Decisions and actions
3. Actions for continuing patients
4. Additional training

In the following subsections, we show details of the items and the summary of data retrieved.

#### **5.2.1 Patient's understanding, skills and home support.**

The original assessment of this subdivision was measured by a 9-item questionnaire. However, for the final analysis of association, 2 questions that were not considered relevant for the assessment of patient performance were eliminated. The final 7-item questionnaire included:

- Q1. "Understanding of the booklet, and other support material, and how to use them",
- Q2. "Understanding about the technical support help line and how to use it",
- Q3. "Skills in the use of the handheld unit and its built in sensors",
- Q4. "Skills to use other (third party) measurement equipment and sensors",
- Q5. "Skills to link the handheld unit to the telephone line and send data",
- Q6. "Skills to access and understand guidance messages sent by clinicians via the handheld unit", and
- Q7. "The patient finds encouragement from family and friends to use the service"

As illustrated by fig. 5.1, patients were more likely to have either a reasonable (40%) or good understanding (34%) of the material printed and how to use it, whereas 15% of the responding patients (25/193) were stated to have a poor understanding.

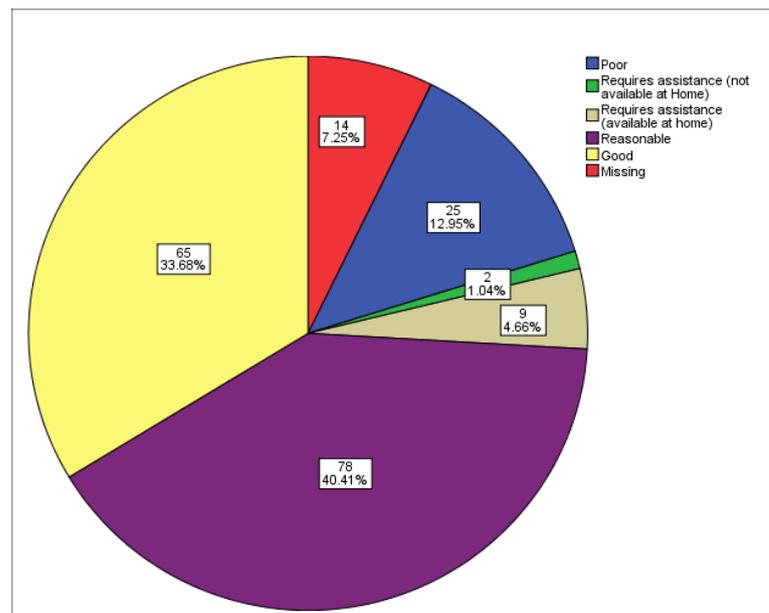


Figure 5.1. Q1.Understanding of the booklet, other support material and how to use them.

One hundred and thirteen of the 193 responding patients (59%) had a reasonable understanding about the technical support line, 18% a good understanding (35/193) and only 10% of them (20/193) stated to have a poor understanding. Further details for this item are shown below (fig. 5.2).

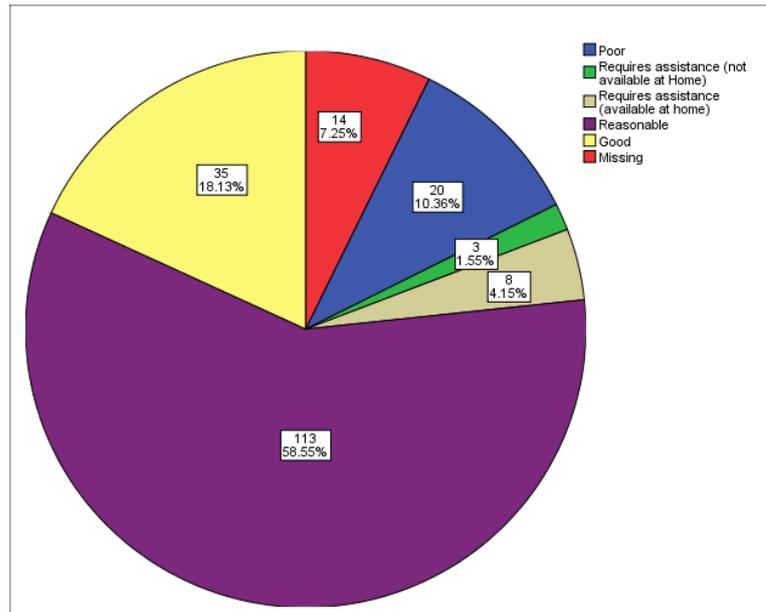


Figure 5.2. Q2.Understanding about the technical support help line and how to use it.

In respect to the skills in the use of the handheld unit and its built in sensors (fig. 5.3), 44% of the responding patients (84/193) were stated to have reasonable skills to use the handheld device and sensors, whereas 20% of them (39/193) were stated to have poor skills.

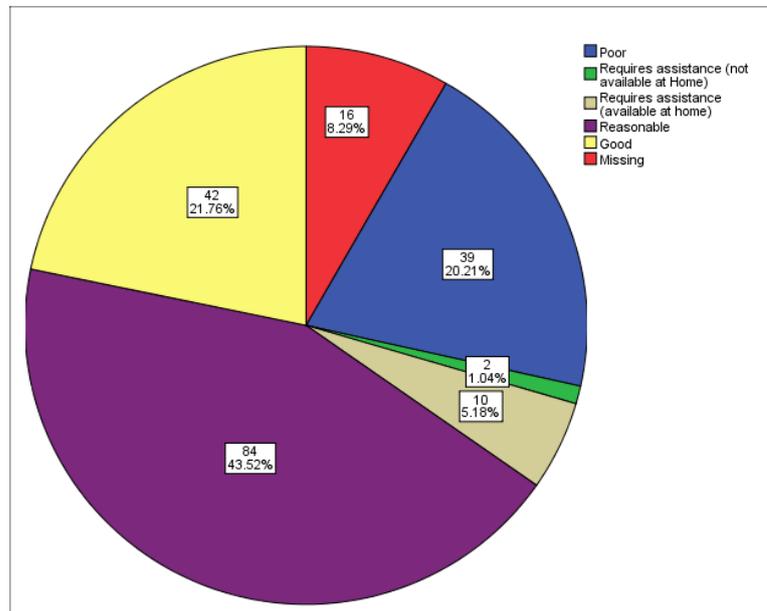


Figure 5.3. Q3.Skills in the use of the handheld unit and its built in sensors.

In relation to third party equipment and sensors (fig. 5.4), patients were more likely to have either reasonable (44%) or good (28%) skills to use the third party devices and sensors.

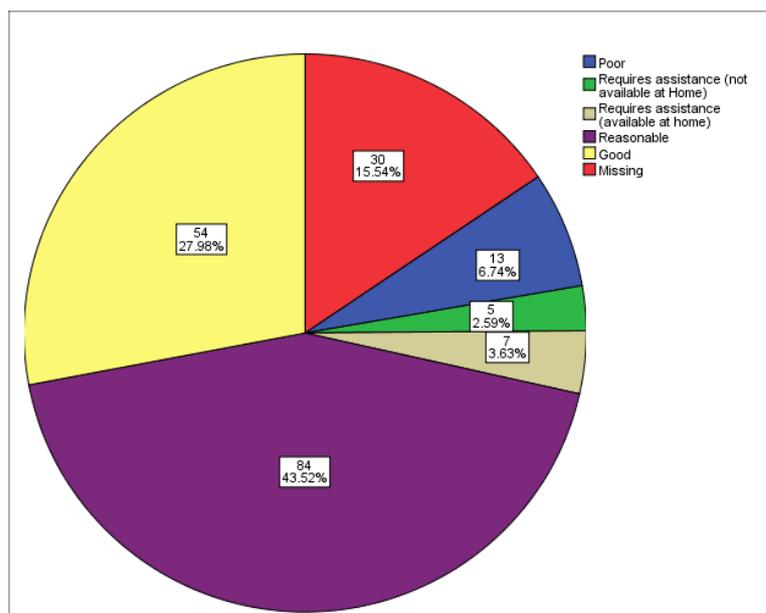


Figure 5.4. Q4.Skills to use other (third party) measurement equipment and sensors.

Patients were more likely to have either good (37%) or reasonable (35%) skills to link the handheld device to the telephone line and send data, whereas 11% of the total responding patients (21/193) had poor skills. Further details can be seen in fig. 5.5.

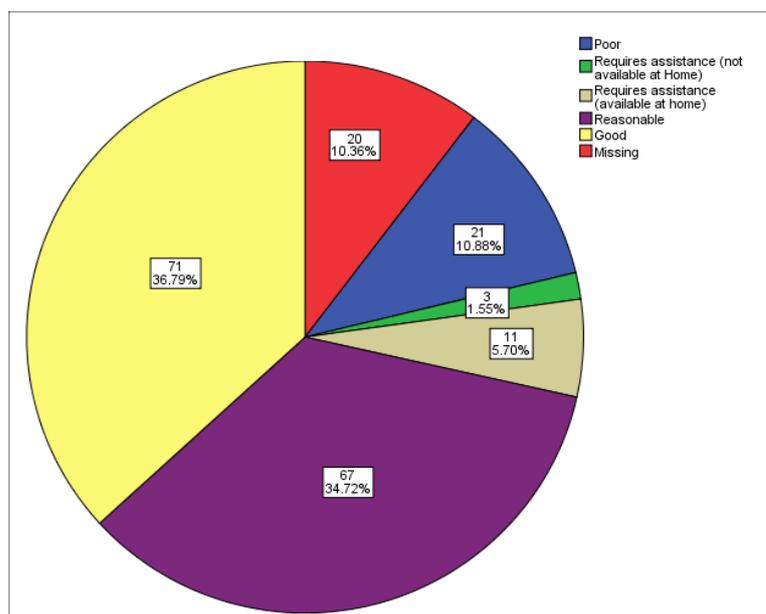


Figure 5.5. Q5.Skills to link the handheld unit to the telephone line and send data.

In relation to guidance messages sent by clinicians via the handheld unit (fig. 5.6), almost equal proportions of patients had reasonable (34%, 65/193) or good (31%, 60/193) skills to access and understand the message sent by the clinicians.

However, at least 17% (33/193) of the total participants had poor skills to manage the messages.

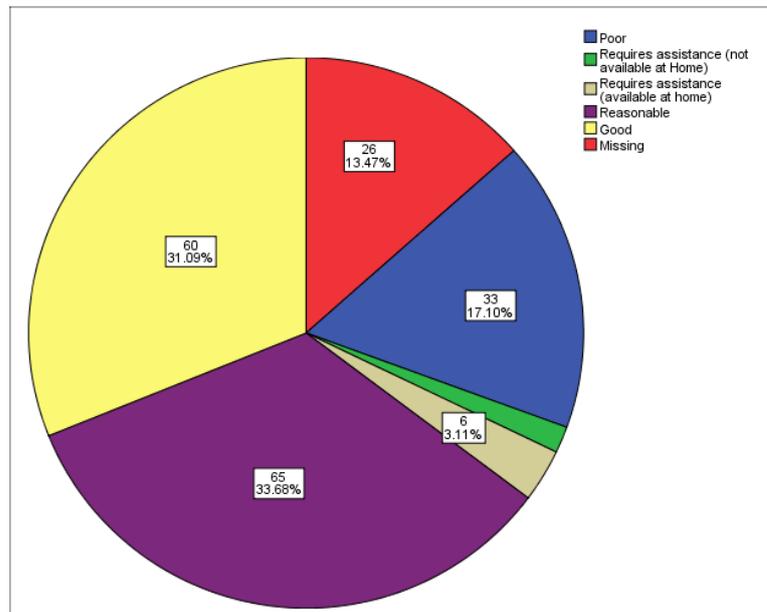


Figure 5.6. Q6.Skills to access and understand guidance messages sent by clinicians via the handheld unit.

In relation to support from relatives and friends (fig. 5.7), 40% (77/193) of the total responding patients found unnecessary the encouragement from their family and friends to use the services, whereas 32% of the total participants (62/193) found encouragement from relatives helpful. Ten percent (20/193) of responses were missing.

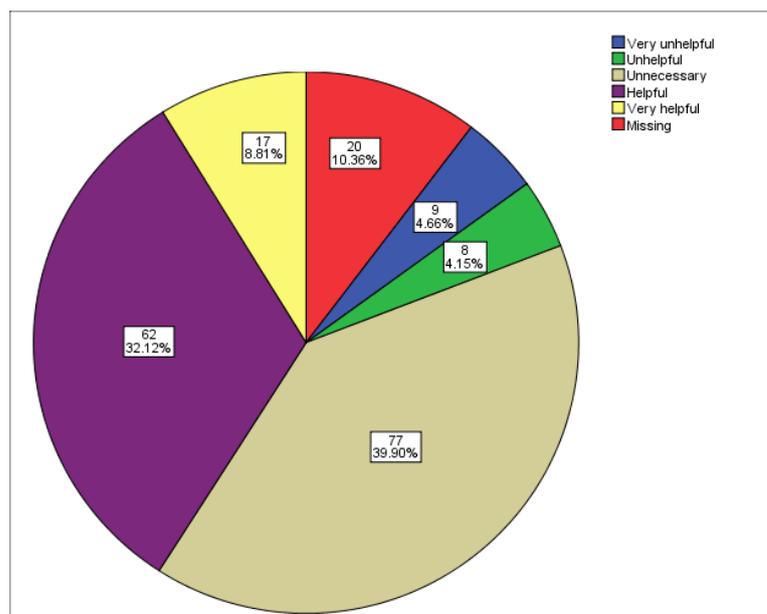


Figure 5.7. Q7.The patient finds encouragement from family and friends to use the service.

### 5.2.2 Decisions and actions

A single item measured whether patients were able to continue with the telehealth service and under what conditions (if any). The item was Q8: “Decision to proceed” (1 = “Patient withdrawn from the programme by clinicians”, 2 = “Patient decided to withdraw from the programme”, 3 = “Further training required before the patient continues to use any part of the service independently”, 4 = “Patient allowed to proceed with special monitoring of data quality by clinicians”, and 5 = “Patient allowed to proceed without additional precautions”). Summary details of this item are shown in fig. 5.8.

Sixty two out of the 193 patients (32%) were allowed to proceed without additional precautions at the interim visit, whereas 25% (49/193) were allowed to proceed with special monitoring of data quality. At this point, 20% of the total recruits decided to withdraw from the service (see fig. 5.8).

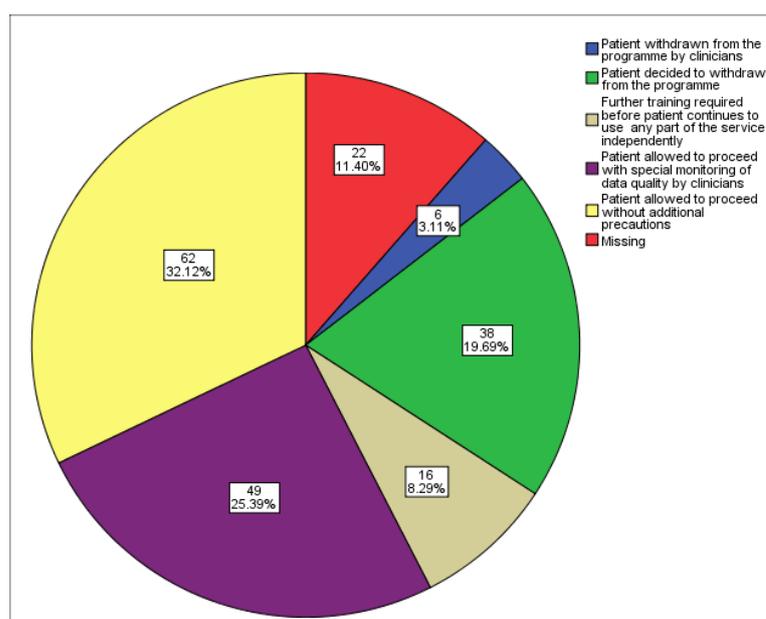


Figure 5.8. Q8.Decision to proceed.

### 5.2.3 Actions for continuing patients

Actions included the replacement of selected equipment. The 2-item questionnaire version included Q9: “Replacement of handheld unit + accessories” and Q10: “Replacement of third party devices” (1 = “Not required”, 2 = “Yes”).

Officially, there was a need to replace the handheld device in at least 12% of the cases (23/193), but 16% of responses (31/193) were missing for this item (fig. 5.9).

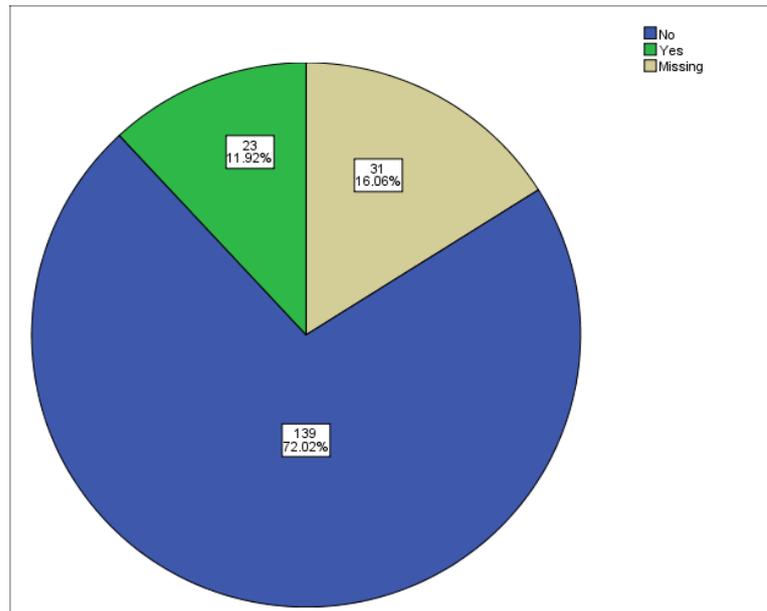


Figure 5.9. Q9.Replacement of handheld unit + accessories.

As shown by fig. 5.10, the majority of participants (75%) did not need replacement of third party devices. However, an important proportion of data (22%) was missed for this item.

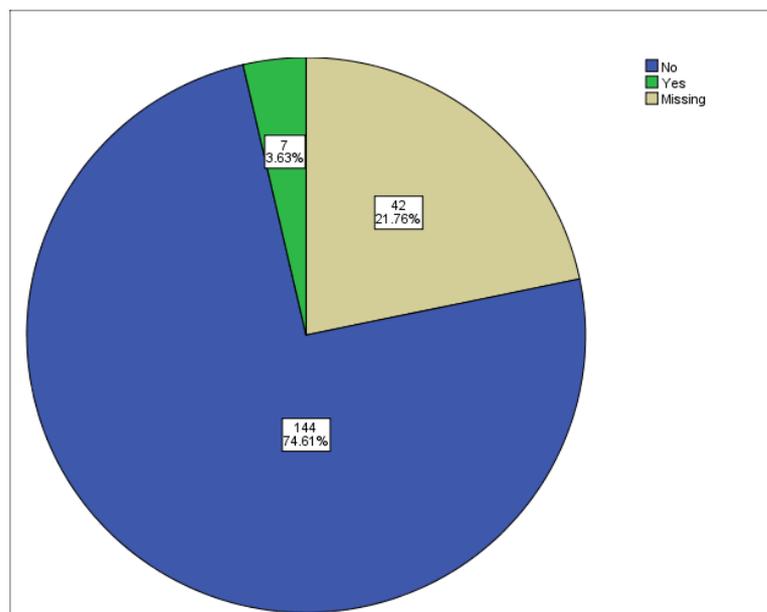


Figure 5.10. Q10.Replacement of third party devices.

### 5.2.4 Additional training

The need for retraining was evaluated by 6 items in the following areas:

Q11. "Measurement using handheld/accessories",

Q12. "Measurement using third party devices",

Q13. "Transfer of data using telephone line",

Q14. "Completion of EQ5D questionnaire",

Q15. "Use of messages from clinician" and

Q16. "Use of telephone help line".

Fig. 5.11 shows that a large proportion of patients (48%, 92/193) required retraining in how to use the handheld device and its accessories.

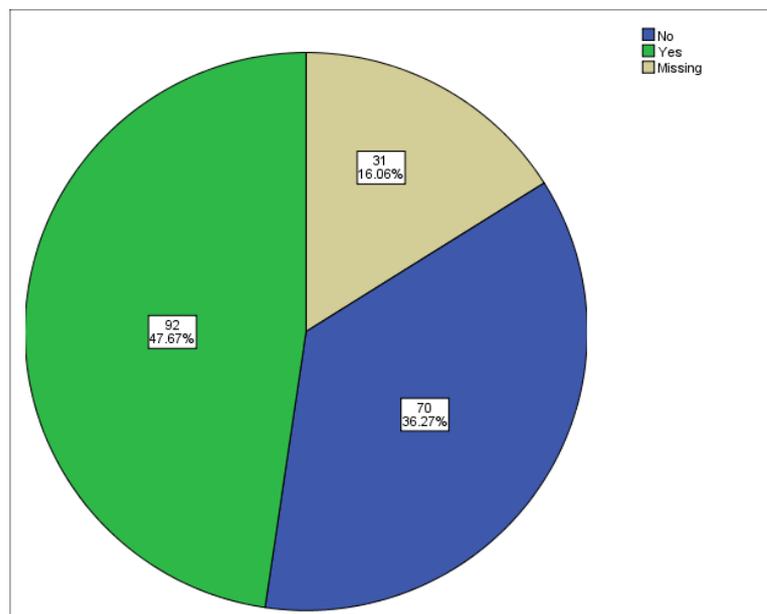


Figure 5.11. Q11.Measurement using handheld/accessories.

Only 20% of the patients (39/193) required retraining in the use of third party devices (fig. 5.12).

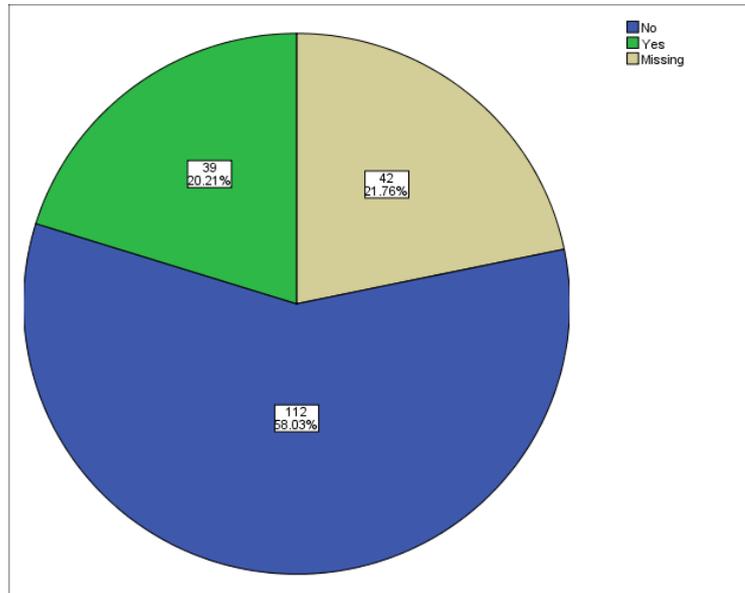


Figure 5.12. Q12.Measurement using third party devices.

Additional training for transferring data using a telephone line was required in 31% of the total cases (fig. 5.13).

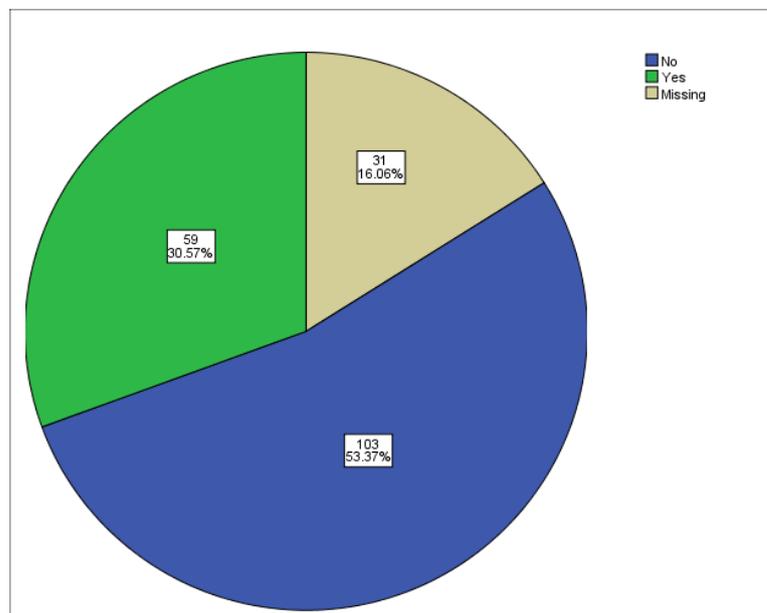


Figure 5.13. Q13.Transfer of data using telephone line.

As can be seen from fig. 5.14, 73 out of the 193 patients (38%) required retraining in the completion of the EQ5D questionnaire.

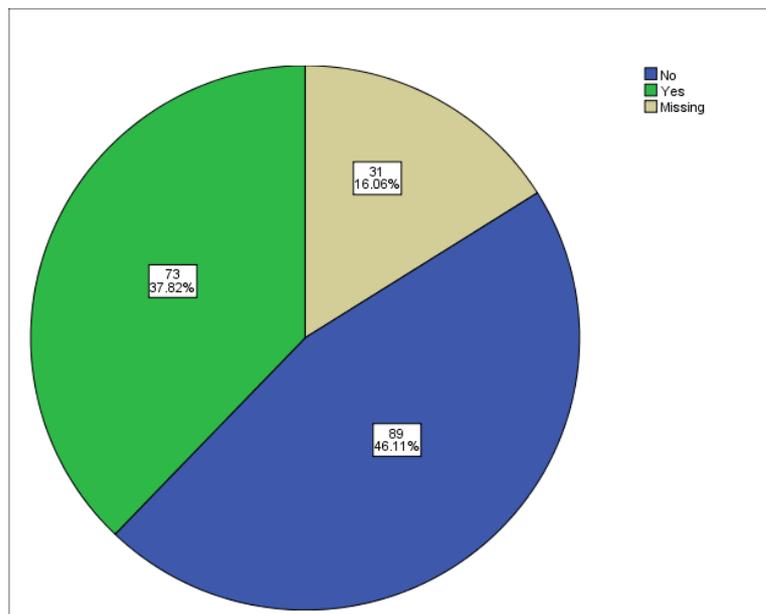


Figure 5.14. Q14.Completion of EQ5D questionnaire.

A large proportion of patients (48%, 92/193) required retraining in how to use messages from clinicians (see fig. 5.15).

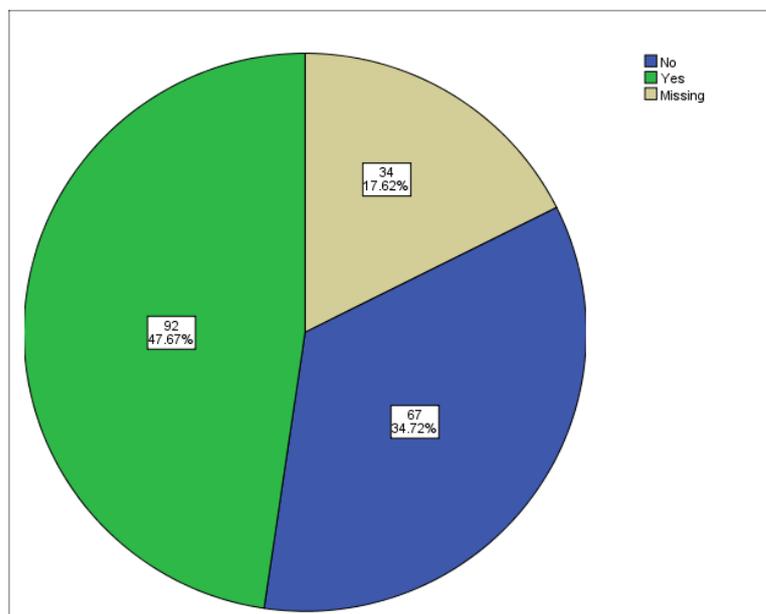


Figure 5.15. Q15.Use of messages from clinician.

Additional training in the use of the telephone help line was required in 22% (43/193) of the cases (fig. 5.16).

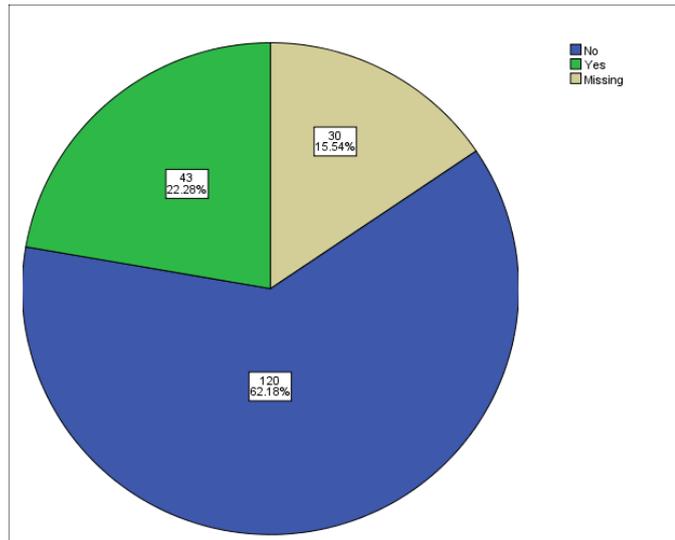


Figure 5.16. Q16.Use of telephone help line.

### 5.3 Statistical analysis

A method based on a joint frequency distribution that establishes an interdependent relationship between two variables displayed in a table known as cross tabulation or contingency table was used. However, different statistical approaches can be used to explore the association between two variables on a frequency table. According to Macnabb (2008) the selection of an appropriate nonparametric relationship test depends on the type of variable (eg. nominal, ordinal, etc.) and the shape of tables (square or rectangular). Kendall's tau-c and Cramer's V test were selected to compare the dependent variables (Q1 to Q16) with the independent demographic variables (eg. age, gender, marital status, etc) and to find any possible relationship, known as measurement of association.

Kendall's tau-c test is a statistical technique used when both variables in the contingency table are ordinal and the size of the table is rectangular (M x N), i.e. when the number of rows and columns are not the same. This is a symmetric measurement which can take any value from -1 to +1. It provides both the direction (positive or negative) and strength of the association.

Cramer's V is a test that computes a nonparametric correlation coefficient number that ranges from 0 to 1. A "0" value means no relationship and "1" value represents a perfect relationship. The test is appropriate when at least one of the variables is nominal (regardless of the table size). Since nominal variables have no direction, this test only determines the strength and not the direction of a relationship.

Coefficient index values over 0.5 are usually rare. For that reason we followed the guideline described by Healey (2009) in table 5.1. The table presents only estimate values for interpreting strengths of correlations.

Table 5.1. The relationship between the value of nominal level measures of association and the strength of the relationship (general guidelines only) (Healey, 2009)

Absolute value	Strength of relationship
Less than 0.1	Weak
Between 0.11 and 0.3	Moderate
Greater than 0.3	Strong

To compare variables to one another and look for a relationship between them, we selected all the socio-economic factors and support at home items already presented in Chapter 4. Every demographic item was considered an independent variable for the construction of contingency tables. Thus, the independent variables were: age, gender, marital status, education, occupation, activity if retired, literacy, ethnicity, location, quality of accommodation, care provision, care availability and care support.

#### 5.4. Results and discussion

An example of a cross tabulation is shown in table 5.2. The joint frequency distributions of cases are omitted since showing all tables (182 in total) was impractical. Instead, the statistical measures of association were summarised from SPSS (table 5.3) and made available in the following subsections.

Table 5.2. Cross tabulation of the understanding of the booklet, other support material and how to use them \* Age.

	Age							Total
	<= 30	31 - 40	41 - 50	51 - 60	61 - 70	71 - 80	81+	
Understanding of the booklet, other support material and how to use them								
Poor	0	0	1	1	4	14	5	25
Requires assistance (not available at Home)	0	0	0	0	0	2	0	2
Requires assistance (available at home)	0	0	0	0	2	7	0	9
Reasonable	0	6	16	14	27	14	1	78
Good	5	7	15	17	17	4	0	65
Total	5	13	32	32	50	41	6	179

Table 5.3. Measure of association for the understanding of the booklet, other support material and how to use them \* Age.

		Value	Approx. Sig.
Nominal by Nominal	Phi	.712	.000
	Cramer's V	.356	.000
Ordinal by Ordinal	Kendall's tau-c	-.408	.000
N of Valid Cases		179	

#### 5.4.1 Age

Except for Q7, Q9, Q10 and Q15, there were significant associations ( $p < 0.05$ ) between age and the rest of the items in table 5.4. In total 12 out of the 16 items (75%) were statistically significant and the majority of the relationships were found to be from moderate to strong (see table 5.1 for classification). The correlation with highest coefficient of association existed between age and the evaluation for retraining in “measurement using third party devices” ( $V=0.48$ ) and “measurement using handheld/accessories” ( $V=0.456$ ). Significant negative associations were found from Q1 to Q6, and Q8. The lowest, but significant measurement of association were found in Q8 ( $\text{tau-c}=-0.201$ ), Q15 ( $V=0.28$ ) and Q16 ( $V=0.288$ ). The negative values (Q1-Q8) reveal that as patients get older their understanding and skills get poorer.

Table 5.4. Association between age and 16 items extracted from the patient's progress at a clinical visit.

Association between age and:	N valid in %	Measure of Association	Value	$p$
Q1. Understanding of the booklet, other support material and how to use them	92.70	tau-c	-0.408	0.000
Q2. Understanding about the technical support help line and how to use it	92.70	tau-c	-0.335	0.000
Q3. Skills in the use of the handheld unit and its built in sensors	91.70	tau-c	-0.385	0.000
Q4. Skills to use other(third party) measurement equipment and sensors	84.50	tau-c	-0.293	0.000
Q5. Skills to link the handheld unit to the telephone line and send data	89.60	tau-c	-0.324	0.000
Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	86.50	tau-c	-0.306	0.000
Q7. The patient finds encouragement from family and friends to use the service	89.60	tau-c	-0.043	0.487
Q8. Decision to proceed	88.60	tau-c	-0.201	0.001
Q9. Replacement of handheld unit + accessories	83.90	V	0.176	0.541
Q10. Replacement of third party devices	78.20	V	0.213	0.334
Q11. Measurement using handheld/accessories	83.90	V	0.456	0.000
Q12. Measurement using third party devices	78.20	V	0.48	0.000
Q13. Transfer of data using telephone line	83.90	V	0.371	0.001
Q14. Completion of EQ5D questionnaire	83.90	V	0.359	0.002
Q15. Use of messages from clinician	82.40	V	0.28	0.052
Q16. Use of telephone help line	84.50	V	0.288	0.035

$N_{\text{total}} = 193$ ; Kendall's tau-c = tau-c ; Cramer's V = V

### 5.4.2 Gender

No significant relationship was found between gender and the items in table 5.5. The only item that got close enough to be considered significant (but is not) was the “measurement using handheld/accessories” (Q11,  $p=0.059$ ). This finding reveals no association between gender and the patients’ understanding nor skills needed to use the service, nor the need for additional training.

Table 5.5. Association between gender and 16 items extracted from the patient's progress at a clinical visit.

Association between gender and:	N valid in %	Measure of Association	Value	P
Q1. Understanding of the booklet, other support material and how to use them	91.2	V	0.066	0.942
Q2. Understanding about the technical support help line and how to use it	91.2	V	0.133	0.538
Q3. Skills in the use of the handheld unit and its built in sensors	90.2	V	0.219	0.079
Q4. Skills to use other(third party) measurement equipment and sensors	83.4	V	0.136	0.559
Q5. Skills to link the handheld unit to the telephone line and send data	88.1	V	0.086	0.868
Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	85	V	0.145	0.483
Q7. The patient finds encouragement from family and friends to use the service	88.1	V	0.22	0.083
Q8. Decision to proceed	87	V	0.194	0.177
Q9. Replacement of handheld unit + accessories	82.4	V	0.036	0.654
Q10. Replacement of third party devices	77.2	V	0.076	0.353
Q11. Measurement using handheld/accessories	82.4	V	0.15	0.059
Q12. Measurement using third party devices	77.2	V	0.127	0.123
Q13. Transfer of data using telephone line	82.4	V	0.085	0.283
Q14. Completion of EQ5D questionnaire	82.4	V	0.037	0.641
Q15. Use of messages from clinician	80.8	V	0.098	0.221
Q16. Use of telephone help line	82.9	V	0.022	0.784

N<sub>total</sub> = 193; Cramer's V = V

### 5.4.3 Marital status

Only 4 out of the 16 items (25%) can be associated to marital status. “Understanding of the booklet, other support material and how to use them” ( $p=0.034$ ), “understanding about the technical support help line and how to use it” ( $p<0.001$ ), “skills to use of the handheld unit and its built in sensors” ( $p=0.019$ ) and “the patient finds encouragement from family and friends to use the service” ( $p=0.004$ ). As can be seen from table 5.6, the coefficient of association ranged from 0.207 to 0.272 and the strength of association for the 4 items (Q1, Q2, Q3 and Q7) was moderate.

Table 5.6. Association between marital status and 16 items extracted from the patient's progress at a clinical visit.

Association between marital status and:	N valid in %	Measure of Association	Value	P
Q1. Understanding of the booklet, other support material and how to use them	90.2	V	0.207	0.034
Q2. Understanding about the technical support help line and how to use it	90.2	V	0.272	0.000
Q3. Skills in the use of the handheld unit and its built in sensors	89.1	V	0.217	0.019
Q4. Skills to use other(third party) measurement equipment and sensors	82.4	V	0.2	0.089

Q5. Skills to link the handheld unit to the telephone line and send data	87	V	0.178	0.194
Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	84.5	V	0.154	0.477
Q7. The patient finds encouragement from family and friends to use the service	87.6	V	0.239	0.004
Q8. Decision to proceed	86	V	0.112	0.903
Q9. Replacement of handheld unit + accessories	81.3	V	0.149	0.321
Q10. Replacement of third party devices	76.2	V	0.132	0.464
Q11. Measurement using handheld/accessories	81.9	V	0.185	0.145
Q12. Measurement using third party devices	76.2	V	0.161	0.281
Q13. Transfer of data using telephone line	81.3	V	0.178	0.175
Q14. Completion of EQ5D questionnaire	81.3	V	0.157	0.276
Q15. Use of messages from clinician	79.8	V	0.139	0.398
Q16. Use of telephone help line	81.9	V	0.129	0.449

$N_{\text{total}} = 193$ ; Cramer's  $V = V$ ;  $p$  values  $< 0.001$  are reported as 0.000

#### 5.4.4 Education

There was a significant association between education and 14 of the 16 items (88%) except for “the patient finds encouragement from family and friends to use the service” and the need for “replacement of handheld unit + accessories” (see table 5.7). The correlation with the highest coefficients existed between education and the need for additional training in the item of “measurement using third party devices” ( $V=0.517$ ), followed by “completion of EQ5D questionnaire” ( $V=0.488$ ) and “measurement using handheld/accessories” ( $V=0.414$ ). Strong measurements of associations were found for items Q1, Q4-Q6, and Q10-Q15, whereas moderate associations were found for Q2, Q3, Q8 and Q16. The positive association from Q1 to Q8 indicates that as the level of education goes higher, the understanding and skills needed to use the service get better.

Table 5.7. Association between education and 16 items extracted from the patient's progress at a clinical visit.

Association between education and:	N valid in %	Measure of Association	Value	P
Q1. Understanding of the booklet, other support material and how to use them	90.7	tau-c	0.349	0.000
Q2. Understanding about the technical support help line and how to use it	90.7	tau-c	0.278	0.000
Q3. Skills in the use of the handheld unit and its built in sensors	89.6	tau-c	0.236	0.000
Q4. Skills to use other(third party) measurement equipment and sensors	82.9	tau-c	0.355	0.000
Q5. Skills to link the handheld unit to the telephone line and send data	87.6	tau-c	0.336	0.000
Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	84.5	tau-c	0.356	0.000
Q7. The patient finds encouragement from family and friends to use the service	87.6	tau-c	0.034	0.587
Q8. Decision to proceed	86.5	tau-c	0.235	0.000
Q9. Replacement of handheld unit + accessories	81.9	V	0.068	0.948
Q10. Replacement of third party devices	76.7	V	0.388	0.000
Q11. Measurement using handheld/accessories	81.9	V	0.414	0.000
Q12. Measurement using third party devices	76.7	V	0.517	0.000
Q13. Transfer of data using telephone line	81.9	V	0.388	0.000
Q14. Completion of EQ5D questionnaire	81.9	V	0.488	0.000
Q15. Use of messages from clinician	80.3	V	0.372	0.000
Q16. Use of telephone help line	82.4	V	0.255	0.035

$N_{\text{total}} = 193$ ; Kendall's tau-c = tau-c ; Cramer's  $V = V$ ;  $p$  values  $< 0.001$  are reported as 0.000

#### 5.4.5. Current or most recent occupation

There were 12 items (12/16, 75%) associated with the most recent activity in which the participants were engaged. Except for items Q8-Q10 and Q16, the rest of items were significant correlated to the most recent occupation (see table 5.8). The highest measurement of associations were found in the subsections for additional training in items “measurement using third party devices” (Q12,  $V=0.358$ ), “measurement using handheld/accessories” (Q11,  $V=0.347$ ), “Completion of EQ5D questionnaire” (Q14,  $V=0.31$ ) and “transfer of data using telephone line” (Q13,  $V=0.308$ ). Strong relationships were only found in items Q11-Q14 ( $V>0.3$ ), the rest of significant association were classified as moderate for Q1-Q7, and Q15.

Table 5.8. Association between occupation and 16 items extracted from the patient's progress at a clinical visit.

Association between current or most recent occupation and:	N valid in %	Measure of Association	Value	$p$
Q1. Understanding of the booklet, other support material and how to use them	84.5	V	0.262	0.001
Q2. Understanding about the technical support help line and how to use it	84.5	V	0.267	0.001
Q3. Skills in the use of the handheld unit and its built in sensors	83.4	V	0.247	0.006
Q4. Skills to use other(third party) measurement equipment and sensors	76.7	V	0.251	0.01
Q5. Skills to link the handheld unit to the telephone line and send data	81.3	V	0.246	0.009
Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	78.8	V	0.286	0.000
Q7. The patient finds encouragement from family and friends to use the service	81.3	V	0.224	0.05
Q8. Decision to proceed	80.8	V	0.178	0.466
Q9. Replacement of handheld unit + accessories	77.2	V	0.159	0.586
Q10. Replacement of third party devices	72	V	0.263	0.086
Q11. Measurement using handheld/accessories	77.7	V	0.347	0.003
Q12. Measurement using third party devices	72	V	0.358	0.003
Q13. Transfer of data using telephone line	77.2	V	0.308	0.015
Q14. Completion of EQ5D questionnaire	77.2	V	0.31	0.014
Q15. Use of messages from clinician	75.6	V	0.298	0.023
Q16. Use of telephone help line	77.7	V	0.239	0.128

$N_{total} = 193$ ; Cramer's  $V = V$ ;  $p$  values  $< 0.001$  are reported as 0.000

#### 5.4.6. Activity if retired

Only 4 items (25%) in table 5.9 can be significantly associated to the patient's activity. Two items have strong associations “Measurement using third party devices” (Q12,  $V=0.492$ ) and “the patient finds encouragement from family and friends to use the service” (Q7,  $V=0.305$ ). The other 2 associations “understanding of the booklet, other support material and how to use them” (Q1,  $V=0.273$ ) and “transfer of data using telephone line” (Q13,  $V=0.248$ ) were significantly moderate.

Table 5.9. Association between activity if retired and 16 items extracted from the patient's progress at a clinical visit.

Association between activity and:	N valid in %	Measure of Association	Value	P
Q1. Understanding of the booklet, other support material and how to use them	59.1	V	0.273	0.03
Q2. Understanding about the technical support help line and how to use it	59.1	V	0.23	0.147
Q3. Skills in the use of the handheld unit and its built in sensors	58	V	0.192	0.412
Q4. Skills to use other(third party) measurement equipment and sensors	51.3	V	0.208	0.381
Q5. Skills to link the handheld unit to the telephone line and send data	56	V	0.231	0.172
Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	53.4	V	0.222	0.252
Q7. The patient finds encouragement from family and friends to use the service	56.5	V	0.305	0.009
Q8. Decision to proceed	57	V	0.209	0.296
Q9. Replacement of handheld unit + accessories	51.8	V	0.126	0.45
Q10. Replacement of third party devices	46.6	V	0.187	0.207
Q11. Measurement using handheld/accessories	51.8	V	0.213	0.103
Q12. Measurement using third party devices	47.2	V	0.492	0.000
Q13. Transfer of data using telephone line	52.3	V	0.248	0.044
Q14. Completion of EQ5D questionnaire	52.3	V	0.178	0.202
Q15. Use of messages from clinician	50.8	V	0.21	0.116
Q16. Use of telephone help line	53.4	V	0.12	0.475

N<sub>total</sub> = 193; Cramer's V = V; p values < 0.001 are reported as 0.000

#### 5.4.7 Literacy in local language

Nine out of the 16 items (56%) were found significantly associated to literacy in local language (table 5.10). Strong associations were found between literacy and items Q1 (V=0.715), Q2 (V=0.702), Q3 (V=0.738), Q4 (V=0.558), Q5 (V=0.788), Q6 (V=0.704), Q7 (V=0.46) and Q10 (V=0.4). A moderate association was found in Q12 (V=0.233). The rest of items were not statistically significant.

Table 5.10. Association between literacy and 16 items extracted from the patient's progress at a clinical visit.

Association between literacy and:	N valid in %	Measure of Association	Value	P
Q1. Understanding of the booklet, other support material and how to use them	89.1	V	0.715	0.000
Q2. Understanding about the technical support help line and how to use it	89.1	V	0.702	0.000
Q3. Skills in the use of the handheld unit and its built in sensors	88.1	V	0.738	0.000
Q4. Skills to use other(third party) measurement equipment and sensors	81.3	V	0.558	0.000
Q5. Skills to link the handheld unit to the telephone line and send data	86	V	0.788	0.000
Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	82.9	V	0.704	0.000
Q7. The patient finds encouragement from family and friends to use the service	86	V	0.46	0.000
Q8. Decision to proceed	84.5	V	0.135	0.562
Q9. Replacement of handheld unit + accessories	80.8	V	0.067	0.401
Q10. Replacement of third party devices	75.6	V	0.4	0.000
Q11. Measurement using handheld/accessories	81.3	V	0.144	0.071
Q12. Measurement using third party devices	76.2	V	0.233	0.005
Q13. Transfer of data using telephone line	81.3	V	0.13	0.104
Q14. Completion of EQ5D questionnaire	81.3	V	0.142	0.076
Q15. Use of messages from clinician	79.8	V	0.123	0.126
Q16. Use of telephone help line	81.9	V	0.08	0.313

N<sub>total</sub> = 193; Cramer's V = V; p values < 0.001 are reported as 0.000

### 5.4.8 Ethnicity

Half of items (8/16) in table 5.11 were significantly associated with the patients' ethnicity. The association with the highest coefficient existed between ethnicity and "understanding about the technical support help line and how to use it" (Q2,  $V=0.392$ ). Moderate significant association were found in Q3 ( $V=0.268$ ), Q4 (0.247), Q8 ( $V=0.236$ ), Q11 ( $V=0.212$ ), Q14 ( $V=0.252$ ) and Q15 (0.292) and strong associations in Q2 ( $V=0.392$ ) and Q7 ( $V=0.329$ ). The rest of items were not statistically significant.

Table 5.11. Association between ethnicity minority and 16 items extracted from the patient's progress at a clinical visit.

Association between ethnic minority and:	N valid in %	Measure of Association	Value	P
Q1. Understanding of the booklet, other support material and how to use them	89.1	V	0.227	0.064
Q2. Understanding about the technical support help line and how to use it	89.1	V	0.392	0.000
Q3. Skills in the use of the handheld unit and its built in sensors	88.1	V	0.268	0.016
Q4. Skills to use other(third party) measurement equipment and sensors	81.3	V	0.247	0.049
Q5. Skills to link the handheld unit to the telephone line and send data	86	V	0.238	0.052
Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	82.9	V	0.129	0.614
Q7. The patient finds encouragement from family and friends to use the service	86	V	0.329	0.001
Q8. Decision to proceed	84.5	V	0.236	0.06
Q9. Replacement of handheld unit + accessories	80.8	V	0.116	0.146
Q10. Replacement of third party devices	75.6	V	0.038	0.645
Q11. Measurement using handheld/accessories	81.3	V	0.212	0.008
Q12. Measurement using third party devices	76.2	V	0.039	0.64
Q13. Transfer of data using telephone line	81.3	V	0.002	0.981
Q14. Completion of EQ5D questionnaire	81.3	V	0.252	0.002
Q15. Use of messages from clinician	79.8	V	0.292	0.000
Q16. Use of telephone help line	81.9	V	0.116	0.146

$N_{total} = 193$ ; Cramer's  $V = V$ ;  $p$  values  $< 0.001$  are reported as 0.000

### 5.4.9 General location of patient home

Moderate significant associations were found between location of the patient's home and 10 out of the 16 items (62%) in table 5.12. The association with the highest coefficient existed between location and "completion of EQ5D questionnaire" (Q14,  $V=0.282$ ). The other moderate significant associations were found in Q1 ( $V=0.129$ ), Q2 ( $V=0.19$ ), Q3 ( $V=0.162$ ), Q4 ( $V=0.252$ ), Q5 ( $V=0.134$ ), Q8 ( $V=0.222$ ), Q9 ( $V=0.26$ ), Q12 ( $V=0.244$ ) and Q15 ( $V=0.266$ ).

Table 5.12. Association between location and 16 items extracted from the patient's progress at a clinical visit.

Association between location and:	N valid in %	Measure of Association	Value	P
Q1. Understanding of the booklet, other support material and how to use them	88.6	tau-c	0.129	0.012
Q2. Understanding about the technical support help line and how to use it	88.6	tau-c	0.19	0.000
Q3. Skills in the use of the handheld unit and its built in sensors	87.6	tau-c	0.162	0.004
Q4. Skills to use other(third party) measurement equipment and sensors	80.8	tau-c	0.252	0.000
Q5. Skills to link the handheld unit to the telephone line and send data	85.5	tau-c	0.134	0.024

Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	82.4	tau-c	0.094	0.114
Q7. The patient finds encouragement from family and friends to use the service	85.5	tau-c	-0.074	0.208
Q8. Decision to proceed	84.5	V	0.222	0.019
Q9. Replacement of handheld unit + accessories	80.3	V	0.26	0.015
Q10. Replacement of third party devices	75.1	V	0.211	0.091
Q11. Measurement using handheld/accessories	80.8	V	0.143	0.36
Q12. Measurement using third party devices	75.6	V	0.244	0.033
Q13. Transfer of data using telephone line	80.8	V	0.141	0.379
Q14. Completion of EQ5D questionnaire	80.8	V	0.282	0.006
Q15. Use of messages from clinician	79.3	V	0.266	0.013
Q16. Use of telephone help line	81.3	V	0.092	0.721

$N_{total} = 193$ ; Kendall's tau-c = tau-c ; Cramer's V = V;  $p$  values < 0.001 are reported as 0.000

#### 5.4.10 Quality of living accommodation

Except for “replacement of handheld unit + accessories” and “use of messages from clinician”, there were statistically significant associations between quality of living accommodation and the rest of items (14/16, 88%) in table 5.13. The association of measurement with the highest coefficient and strongest association existed between accommodation and “transfer of data using telephone line” (Q13,  $V=0.41$ ) followed by “use of telephone help line” (Q16,  $V=0.341$ ) and “replacement of third party devices” (Q10,  $V=0.305$ ). The rest of the significant associations (Q1- Q8, Q11, Q12, and Q14) were moderate.

Table 5.13. Association between quality of living accommodation and 16 items extracted from the patient's progress at a clinical visit.

Association between quality of living accommodation and:	N valid in %	Measure of Association	Value	P
Q1. Understanding of the booklet, other support material and how to use them	87	tau-c	0.255	0.000
Q2. Understanding about the technical support help line and how to use it	87	tau-c	0.159	0.002
Q3. Skills in the use of the handheld unit and its built in sensors	86	tau-c	0.122	0.03
Q4. Skills to use other(third party) measurement equipment and sensors	79.3	tau-c	0.209	0.000
Q5. Skills to link the handheld unit to the telephone line and send data	83.9	tau-c	0.29	0.000
Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	80.8	tau-c	0.283	0.000
Q7. The patient finds encouragement from family and friends to use the service	83.9	tau-c	0.142	0.02
Q8. Decision to proceed	82.9	tau-c	0.189	0.002
Q9. Replacement of handheld unit + accessories	78.8	V	0.149	0.498
Q10. Replacement of third party devices	73.6	V	0.305	0.01
Q11. Measurement using handheld/accessories	79.3	V	0.288	0.013
Q12. Measurement using third party devices	74.1	V	0.38	0.000
Q13. Transfer of data using telephone line	79.3	V	0.41	0.000
Q14. Completion of EQ5D questionnaire	79.3	V	0.273	0.023
Q15. Use of messages from clinician	77.7	V	0.144	0.541
Q16. Use of telephone help line	79.8	V	0.341	0.001

$N_{total} = 193$ ; Kendall's tau-c = tau-c ; Cramer's V = V;  $p$  values < 0.001 are reported as 0.000

#### 5.4.11 The patient has existing care provision and access local medical and social care

Fifteen out of the 16 items (94%) in table 5.14 were significant associated with the existing of care provision. The association of measurement with the highest coefficient was between existing of care provision and “decision to proceed” (Q8,  $V=0.618$ ) followed by “skills to use other (third party) measurement equipment and sensors” (Q4,  $V=0.516$ ), “measurement using third party devices” (Q12,  $V=0.511$ ) and “completion of EQ5D questionnaire” (Q14,  $V=0.508$ ). The other items that had a strong relationship with care provision were Q1 & Q2, Q5-Q7, Q11, Q13 and Q15. Moderate association were found in Q3 ( $V=0.285$ ), Q10 ( $V=0.195$ ) and Q16 ( $V=0.211$ ).

Table 5.14. Association between care provision and 16 items extracted from the patient's progress at a clinical visit.

Association between care provision and:	N valid in %	Measure of Association	Value	P
Q1. Understanding of the booklet, other support material and how to use them	85	V	0.426	0.000
Q2. Understanding about the technical support help line and how to use it	85	V	0.475	0.000
Q3. Skills in the use of the handheld unit and its built in sensors	83.9	V	0.285	0.011
Q4. Skills to use other(third party) measurement equipment and sensors	77.2	V	0.516	0.000
Q5. Skills to link the handheld unit to the telephone line and send data	81.9	V	0.408	0.000
Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	78.8	V	0.377	0.000
Q7. The patient finds encouragement from family and friends to use the service	81.9	V	0.389	0.000
Q8. Decision to proceed	81.3	V	0.618	0.000
Q9. Replacement of handheld unit + accessories	77.7	V	0.016	0.848
Q10. Replacement of third party devices	72.5	V	0.195	0.021
Q11. Measurement using handheld/accessories	78.2	V	0.324	0.000
Q12. Measurement using third party devices	73.1	V	0.511	0.000
Q13. Transfer of data using telephone line	78.2	V	0.435	0.000
Q14. Completion of EQ5D questionnaire	78.2	V	0.508	0.000
Q15. Use of messages from clinician	76.7	V	0.33	0.000
Q16. Use of telephone help line	78.8	V	0.211	0.009

$N_{\text{total}} = 193$ ; Cramer's  $V = V$ ;  $p$  values  $< 0.001$  are reported as 0.000

#### 5.4.12 Carer's availability

Only 2 out of the 16 items (13%) in table 5.15 were significantly associated with carer's availability. There were strong associations between carer's availability and “replacement of third party devices” (Q10,  $V=0.468$ ,  $p=0.042$ ), and “use of telephone help line” (Q16,  $V=0.405$ ,  $p=0.034$ ). The rest of items were not statically significant.

Table 5.15. Association between carer's availability and 16 items extracted from the patient's progress at a clinical visit.

Association between carer's availability and:	N valid in %	Measure of Association	Value	P
Q1. Understanding of the booklet, other support material and how to use them	95.9	tau-c	0.117	0.389
Q2. Understanding about the technical support help line and how to use it	95.9	tau-c	0.201	0.117
Q3. Skills in the use of the handheld unit and its built in sensors	93.9	tau-c	0.198	0.12
Q4. Skills to use other(third party) measurement equipment and sensors	69.4	tau-c	0.075	0.628
Q5. Skills to link the handheld unit to the telephone line and send data	87.8	tau-c	0.096	0.476
Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	83.7	tau-c	0.22	0.096
Q7. The patient finds encouragement from family and friends to use the service	87.8	tau-c	0.006	0.963
Q8. Decision to proceed	95.9	tau-c	0.14	0.301
Q9. Replacement of handheld unit + accessories	79.6	V	0.088	0.861
Q10. Replacement of third party devices	59.2	V	0.468	0.042
Q11. Measurement using handheld/accessories	81.6	V	0.361	0.074
Q12. Measurement using third party devices	61.2	V	0.249	0.394
Q13. Transfer of data using telephone line	81.6	V	0.354	0.081
Q14. Completion of EQ5D questionnaire	81.6	V	0.248	0.294
Q15. Use of messages from clinician	77.6	V	0.371	0.073
Q16. Use of telephone help line	83.7	V	0.405	0.034

N<sub>total</sub> = 49; Kendall's tau-c = tau-c ; Cramer's V = V

#### 5.4.13 Carer's level of support

Only 1 item (1/16, 6%) was significantly associated with carer's level of support: "measurement using handheld/accessories" (Q11, V=0.369,  $p=0.029$ ). The associations in the rest of items in table 5.16 were not statistically significant.

Table 5.16. Association between carer's level of support and 16 items extracted from the patient's progress at a clinical visit.

Association between carer's level of support and:	N valid in %	Measure of Association	Value	P
Q1. Understanding of the booklet, other support material and how to use them	95.3	V	0.194	0.82
Q2. Understanding about the technical support help line and how to use it	95.3	V	0.452	0.078
Q3. Skills in the use of the handheld unit and its built in sensors	93	V	0.315	0.411
Q4. Skills to use other(third party) measurement equipment and sensors	67.4	V	0.435	0.241
Q5. Skills to link the handheld unit to the telephone line and send data	86	V	0.139	0.95
Q6. Skills to access and understand guidance messages sent by clinicians via the handheld unit	83.7	V	0.444	0.131
Q7. The patient finds encouragement from family and friends to use the service	86	V	0.352	0.332
Q8. Decision to proceed	95.3	V	0.305	0.433
Q9. Replacement of handheld unit + accessories	79.1	V	0.268	0.118
Q10. Replacement of third party devices	58.1	V	0.253	0.205
Q11. Measurement using handheld/accessories	81.4	V	0.369	0.029
Q12. Measurement using third party devices	60.5	V	0.015	0.94
Q13. Transfer of data using telephone line	81.4	V	0.076	0.652
Q14. Completion of EQ5D questionnaire	81.4	V	0.019	0.908
Q15. Use of messages from clinician	76.7	V	0.182	0.297
Q16. Use of telephone help line	83.7	V	0.229	0.169

N<sub>total</sub> = 43; Cramer's V = V

## 5.5 Summary

The results presented in this chapter showed a consistent degree of association between the demographics variables (13 independent variables in total) and the dependent variables (Q1 to Q16) which were extracted from the evaluation of patients' progress using the telehealth service.

Tables 5.4 to 5.16 show that at least 50% of the dependent variables were associated with an important proportion of the independent variables except in the case of marital status, activity if retired, carers availability, carers level of support and gender. In line with the classification of strength in table 5.1, the largest number of strong relationships was found in the following order:

1. Existing care provision and access local medical and social care (11/16, 69%)
2. Education (10/16, 63%)
3. General location of patient's home (10/16, 63%)
4. Age (9/16, 56%)
5. Literacy in local language (8/16, 50%)
6. Quality of living accommodation (4/16, 25%)
7. Current or most recent occupation (4/16, 25%)
8. Marital status (4/16, 25%)
9. Ethnicity (2/16, 13%)
10. Activity if retired (2/16, 13%)
11. Carers availability (2/16, 13%)
12. Carer level of support (2/16, 13%)
13. Gender (0/16, 0%)

Based on the ranking and strength of the relationship, we considered that at least the first five conditions listed above were important factors influencing the adoption of the service. In general, the patients who had already existing care provision and access to local medical and social care had also poor understanding and poor skills in the use of the telehealth service which included the utilisation of telehealth units, some sensors and other third party measurement equipment. These patients also required additional training for the correct operation of the telehealth units and for the completion of EQ5D questionnaires as well as for the use of messages from clinicians.

The level of the patient's education also appeared to play an important role in the adoption of service. Patients with the lowest level of education were more likely to

require additional help and further training before they were able to continue using any part of the service independently. For them, it was more complicated to learn how to use the devices effectively. They were allowed often to proceed with the service with special monitoring of data quality by the clinicians.

In terms of the location, patients that lived in inner cities had better skills and understanding in how to use the technology, access the clinical data and to retrieve messages sent by the clinical staff. They were more likely to be allowed to proceed with no additional precautions during the interim visit. Difficulties with the technology were rare in this group.

The performance of patients using the service also differed between different age groups. That can be probably explained by the effects of the natural ageing process and the fact that the oldest participants were sicker than the youngest. In general, the patients in the group of 60 year old and over required more assistance as they had poorer skills and understanding of the service. They were also more likely to withdraw from the service and to be retrained. In most of cases, they considered that learning to use the equipment was very difficult.

Patients lacking literacy in the local language were more likely to require additional help and further training before they continued to use independently any part of the service. It was also noticed that the replacement of third party devices were significantly higher in this group. Without literacy skills, the ability to solve problems and to use telehealth technology are not the only concerns. Low literacy is also associated with several poor health outcomes (DeWalt et al., 2004). Therefore, better understanding between general literacy, health literacy and information technologies are required for patients to be effectively engaged in telehealth interventions.

In summary, the mechanisms through which the economic and social conditions of patients influenced the telehealth service seem to be multiple. More research needs to be done to fully understand the underlying mechanisms that determine performance and adoption of telehealth interventions. However, this chapter has shown that the demographics of patients influences uptake of telehealth. Therefore, socio-economic conditions must be considered during the design and implementation of telehealth services.

## **Chapter 6. Clinical outcomes**

### **6.1 Introduction**

This chapter briefly introduces the concept of clinical effectiveness. The following main discussion is centred on the analysis of results generated by the clinical outcomes collected from the REALITY case study.

### **6.2 Clinical effectiveness**

The Department of Health has defined clinical effectiveness as “the application of the best knowledge, derived from research, clinical experience and patient preferences to achieve optimum processes and outcomes of care for patients. The process involves a framework of informing, changing and monitoring practice”(NHS Executive, 1996).

Clinical effectiveness provides an opportunity for healthcare providers to understand what really works the clinical practice. To find out the clinical effectiveness of an intervention, a number of medical and health care procedures are being put in place, in order that a desired effect can be reproduced and that the beneficial changes of the given intervention can be measured. Nowadays, the best way of evaluating the effectiveness of an intervention is through clinical trials and systematic reviews. These studies usually provide robust, consistent and systematic evidence. Historically, some entities have been better positioned than others to produce and access good quality evidence that supports the use of specific interventions for prevention, treatment or rehabilitation. According to Jacobson (2007) in the USA the majority of the clinical effectiveness studies came from academic research (58%); private institutions (30%); pharmaceutical companies (7%) and government (5%).

Improving healthcare services using the best evidence available for health and social care has been a key component of the UK Government’s strategy led by the National Institute for Clinical Excellence (NICE), nevertheless, this is not the only institution concerned with clinical standards. Other groups have been established with the aim to carry out national audits, produce evidence on clinical and cost effectiveness and develop evidence based guidelines; for instance, that is the case of the Clinical Effectiveness Unit (CEU) of the the Royal College of

Surgeons (RCS), the Clinical Effectiveness and Evaluation Unit (CEEU) at the Royal College of Physicians and the Centre for Reviews and Dissemination at University of York among others.

In practice, a series of conditions need to be met in order to make a clinical effectiveness study useful. Such conditions must include relevant research in the clinical area of interest, methods to translate the research into practice, methods to monitor changes in the outcomes, and clinicians prepared to consider change to practice (Cape, 2000). Without meeting these conditions, a mismatch between the available research evidence and the current clinical practice can happen. Unfortunately, it is not rare that mismatches can occur due to the lack of research funding, lack of interest from particular practitioner groups and the complexity of the intervention.

### **6.3 Effectiveness of telehealth**

In recent years, there has been an increasing interest in the implementation of telehealth services for managing patients with long term conditions. These services are considered to be important because in ageing societies it is expected that people can live independently in their own homes by providing access to appropriate home services and technologies.

As a consequence, several research and evaluation studies have investigated the effectiveness of telehealth. In doing so, the majority of studies used multiple measures which in some cases can be difficult to interpret (Bergmo, 2009). These measures varied from diagnostic accuracy, blood glucose levels, anxiety and depression levels, physical capacity and health-related quality of life (HRQL) to life-years gained (LYG) and quality-adjusted life-years (QALYs).

Although in some cases research has demonstrated the benefits of telehealth, it is still common to find in the published literature limited and inconsistent levels of evidence supporting the effectiveness of telehealth (Ekeland et al., 2010). Therefore, more evidence is needed with larger clinical trials, proper study quality and scientific rigour (Bensink et al., 2006a).

## 6.4 Results

Amongst the measures collected at baseline and at the end of the REALITY project, we collected clinical data such as peak expiratory flow, blood pressure and haemoglobin A1c (HbA1c). With such data, a before and after clinical evaluation was conducted using paired samples t-tests.

The results presented below rely on the data collected at recruitment (pre-study) and final clinical visit (post-study).

**Lisbon.** A paired samples t-test was conducted to compare the peak expiratory flow (PEF) value in patients from Lisbon, before and after the telehealth intervention (fig. 6.1).

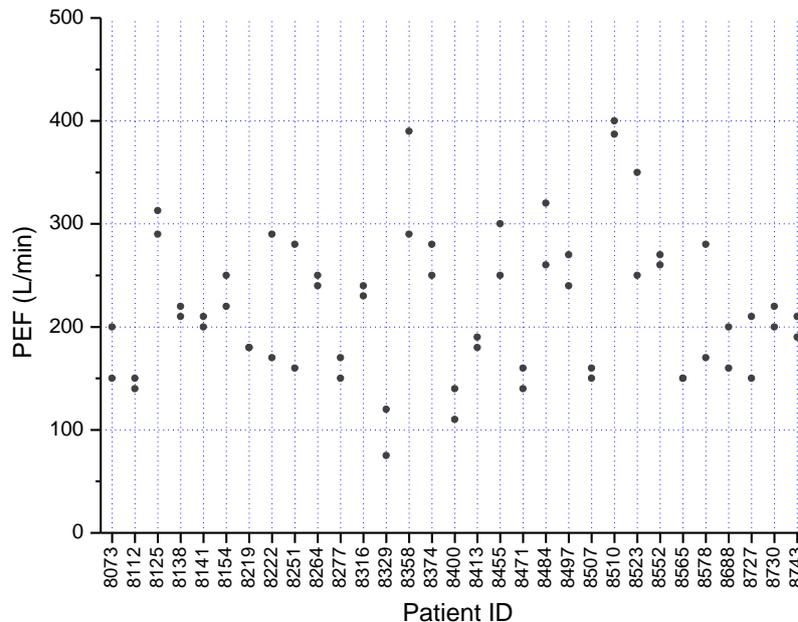


Figure 6.1. Initial and final peak expiratory flow values of 31 patients: paired comparison.

There was not a significant difference between the mean PEF values for pre ( $M_1=216.13$ ,  $SD_1=64.17$ ) and post-study ( $M_2=221.77$ ,  $SD_2=76.08$ ) among patients at the Lisbon clinical site;  $t(30)=-0.599$ ,  $p=0.553$ . This result confirms that the intervention did not have any effect on the primary outcome variable.

**Evora.** Similarly, the differences between the PEF values pre and post intervention (fig. 6.2) for the group at Evora were tested by the paired samples t test. No significant difference was found between the mean PEF values for pre ( $M_1=382.5$ ,  $SD_1=136.26$ ) and post ( $M_2=381.5$ ,  $SD_2=130.51$ ) telehealth

intervention;  $t(19)=0.071$ ,  $p=0.944$ . Specifically, this result shows that the patients' ability to breathe out air did not also improve for patients at Evora.

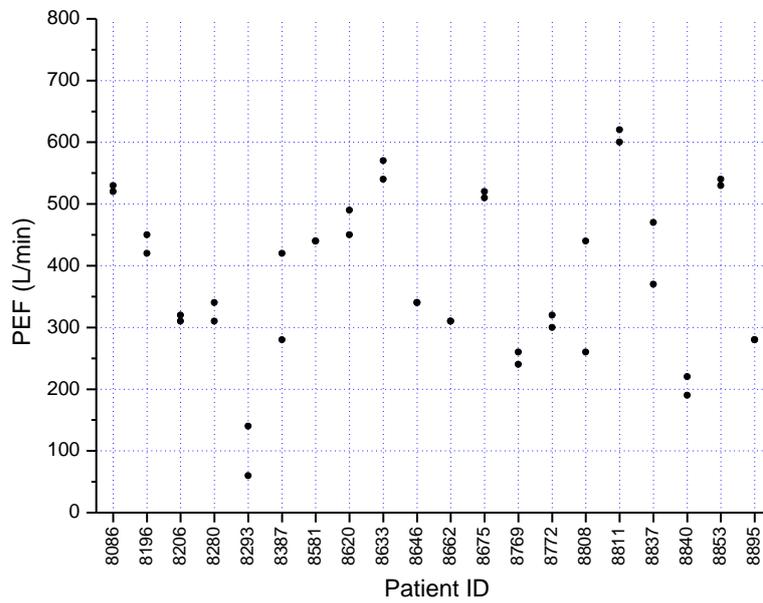


Figure 6.2. Initial and final peak expiratory flow values of 20 patients: paired comparison.

**Lisbon.** The difference between mean blood pressure (MBP) values before and after the intervention (fig. 6.3) was tested by using paired t test.

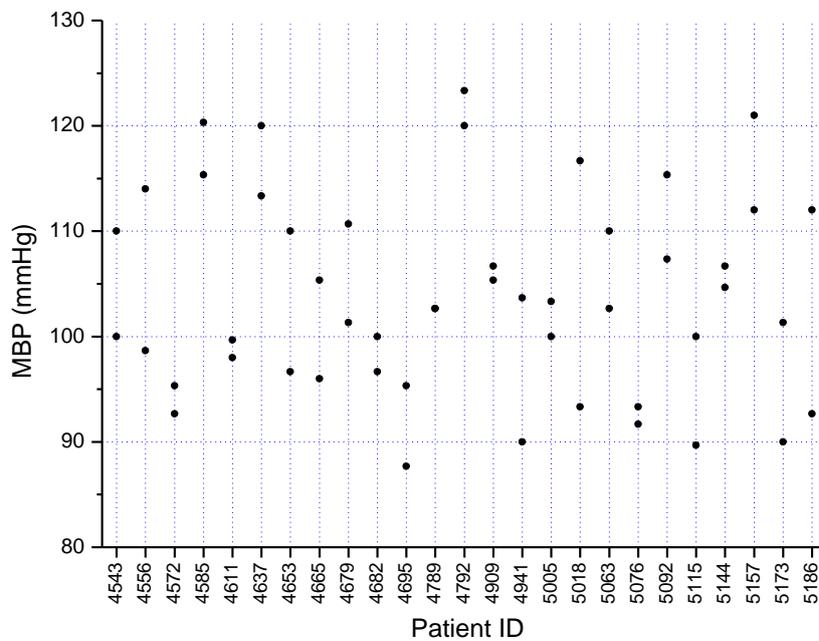


Figure 6.3. Initial and final mean blood pressure values of 25 patients: paired comparison.

The paired t test results showed no significant differences between MBP at baseline ( $M_1=103.86$ ,  $SD_1=10.654$ ) and final clinical visit ( $M_2=103.93$ ,  $SD_2=8.216$ );  $t(24)=-0.033$ ,  $p=0.973$ . For patients at Tartu, the mean blood pressure did not improve as a consequence of the telehealth intervention.

**London.** The difference between the initial haemoglobin A1c (HbA1c) values and the values after the last clinical visit (fig. 6.4) was determined using paired student's t-tests.

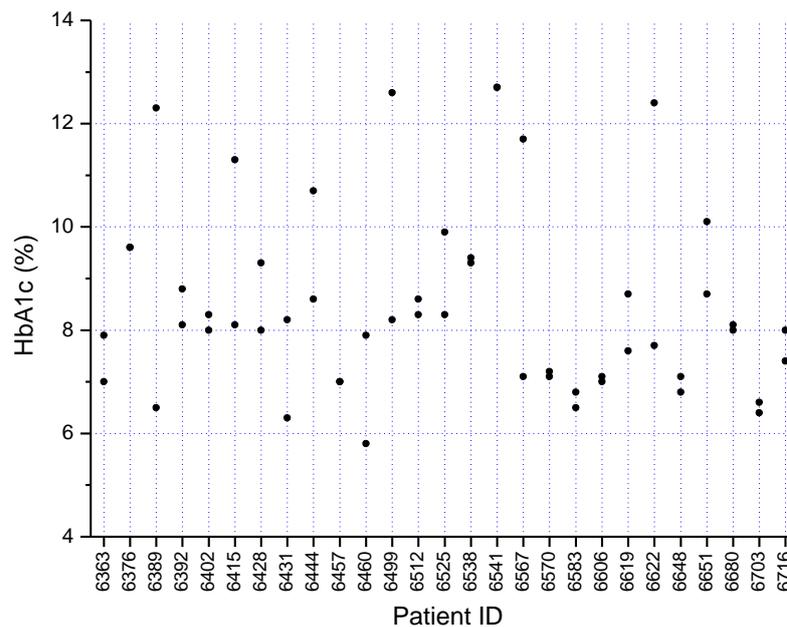


Figure 6.4. Initial and final haemoglobin A1c values of 27 patients: paired comparison.

There was not a significant difference between the mean HbA1c level for pre ( $M_1=8.34$ ,  $SD_1=1.890$ ) and post-study ( $M_2= 8.63$ ,  $SD_2=1.725$ );  $t(26)=-0.681$ ,  $p=0.501$ . The mean HbA1c difference did not show any improvement in the metabolic control for patients with diabetes.

For this site, it was also tested the difference between mean blood pressures (MBP) values before and after the intervention (fig. 6.5) by using paired t test.

There was not significant differences between MBP at baseline ( $M_1=104.18$ ,  $SD_1=9.817$ ) and final clinical visit ( $M_2=100.01$ ,  $SD_2=9.294$ );  $t(30)=-1.972$ ,  $p=0.057$ . For patients with hypertension, the mean blood pressure did not improve as a consequence of the telehealth intervention.

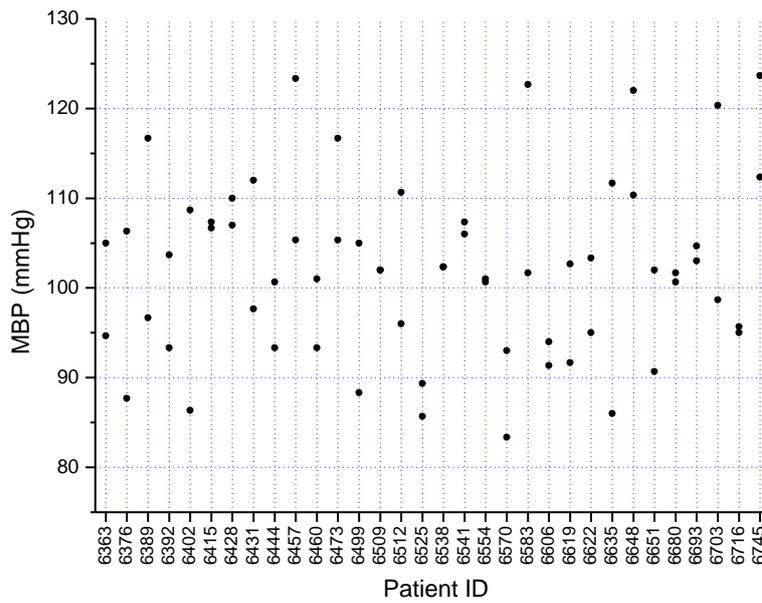


Figure 6.5. Initial and final mean blood pressure values of 32 patients: paired comparison.

Finally, the differences between the PEF values pre and post intervention (fig.6.6) for asthmatic patients in London were tested by the paired samples t test. No significant difference was found between the mean PEF values for pre ( $M_1=335.92$ ,  $SD_1=147.908$ ) and post ( $M_2=379.92$ ,  $SD_2=136.291$ ) telehealth intervention;  $t(12)=-1.389$ ,  $p=0.189$ . The regular monitoring of PEF did not lead to significant improvement in asthma patients.

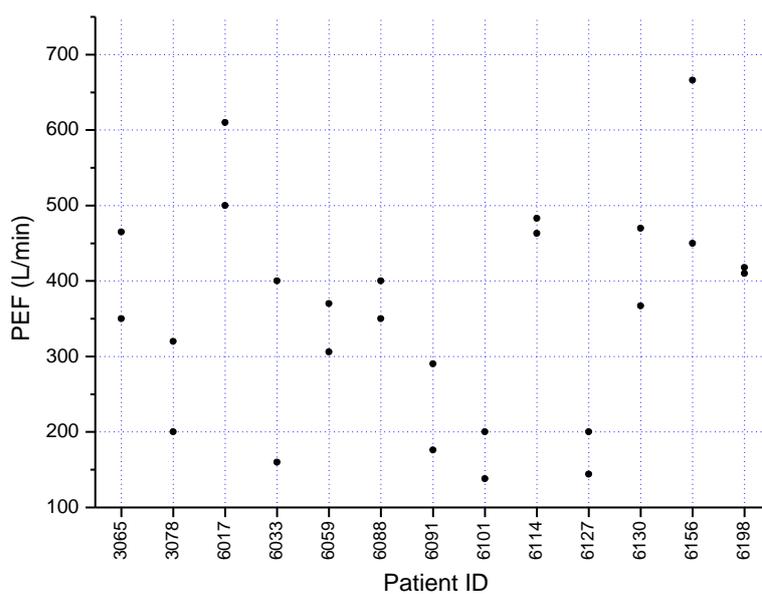


Figure 6.6. Initial and final peak expiratory flow values of 13 patients: paired comparison.

## 6.5 Discussion and conclusions

Overall, there were no significant differences in the pre and post- test of the primary outcomes for any of the four clinical sites. These statistical results indicate no clinical improvements after the telehealth intervention. The results are a challenge to interpret but not necessarily atypical. For instance, in a telehealth randomised controlled trial of 123 young patients with diabetes type 1, Nunn et al. (2006) found that the mean HbA1c level did not change (no significant difference) between the treatment and control group after 7 months of intervention. In another diabetes study, Farmer et al. (2005) found no significant difference in HbA1c changes between the telehealth and control groups at either 4 or 9 months of evaluation. Similarly, in a year long telehealth monitoring study in children with asthma Deschildre et al. (2012) found no significant changes between the control and intervention group for lung function. In the same context, Ostojic et al. (2005) found no significant difference in the PEF values between the telehealth group (short message service) and the control group for the 16-week randomised controlled study. Finally, in the case of hypertension, a videoconferencing system for the treatment of patients with hypertension was studied (Nilsson et al., 2009). Nilsson et al. (2009) found no significant difference in systolic and diastolic blood pressure between the intervention group and control group after 21 months.

The interpretation of the t-test results and the above studies suggests that there is insufficient clinical evidence to support the use of telehealth for home monitoring of patients with diabetes, asthma, COPD and hypertension. However, as pointed out by Stoltz et al. (2009) "Insufficient evidence of effectiveness is not evidence of no effectiveness". We already discussed in section 3.8 that the problem of evidence can be related to the difficulty of evaluating these types of complex interventions in short trials with small and heterogeneous groups in which the intervention type varies. Furthermore, the statistical analysis of aggregated data may be inadequate for showing individual cases in which the intervention has worked.

For instance, in fig. 6.5 we observed improvements in the mean blood pressure (MBP) for patients 6402 and 6635, who showed a reduction of MBP from 110 mmHg to 88 mmHg approximately. In the same way, a drop of at least 5% (from 12% to 7%) in HbA1c was observed in patients 6389 and 6567 (see fig. 6.4); and improvements of peak expiratory flow (more than 100 L/min) were observed in patients 8358 (fig. 6.1) and 8808 (fig. 6.2). All these observations are based on

baseline and final values, but some other examples with full data collection have been previously reported (REALITY Consortium, 2005a). In fact, data collection of MBP for patient ID 6457 (62 years old, male, diabetic with hypertension) have been plotted in fig. 6.7; noticeable changes and gradual improvements in MBP can be seen over time (see tracked mean line).

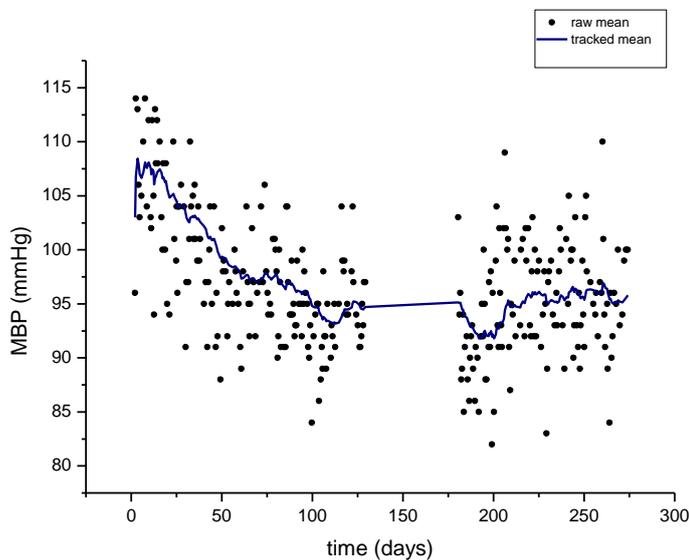


Figure 6.7. Improvement of mean blood pressure over time for patient 6457 (REALITY Consortium, 2005a). Demographics: 62, male, divorced, education level college, profession senior manager/highly trained profession, literate in local language, Afro Caribbean, living alone in inner city, he is the main householder, depends on monthly salary, accommodation in reasonable conditions.

Another real example of what can be achieved with a telehealth intervention is shown in fig. 6.8. On this figure, progressive improvements in the peak expiratory flow for a 61 years old male patient with chronic respiratory condition can be observed.

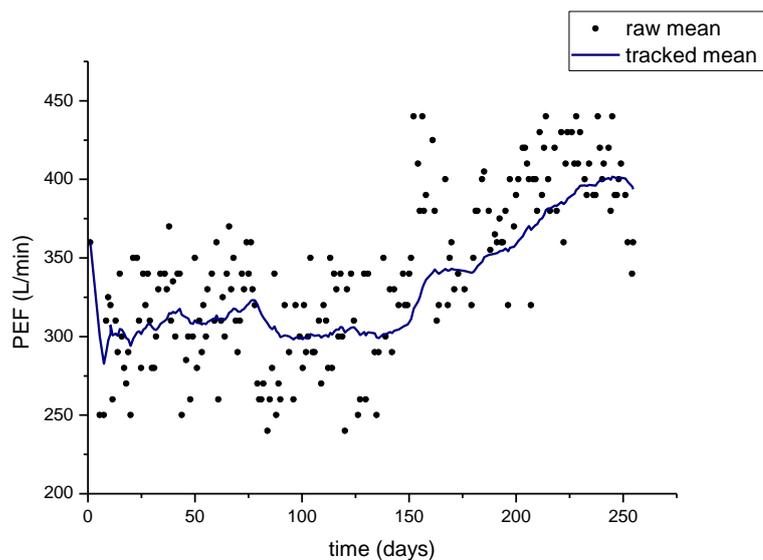


Figure 6.8. Changes of peak expiratory flow over time for patient 8138 (REALITY Consortium, 2005a). Demographics: 61yrs old, male, single, education primary school, profession skilled labour, active, literate in local language, living outer city with family/friends on state benefits, living accommodation reasonable conditions, carer at home only at night.

The fact that we could not find improvement in clinical outcomes does not mean that telehealth cannot offer any benefit. In fact, despite the discouraging findings already mentioned, new evidence from the world's largest research trial regarding the effect of telehealth and telecare has demonstrated promising results. As stated in section 1.1, the WSD programme findings showed that if used correctly, telehealth can reduce deaths by 45%, emergency visits by 20%, A&E visits by 15%, elective admissions and bed stays by 14% and tariff cost by 8% (DH, 2011). The full results on the use of secondary care and mortality have recently been published by Steventon et al. (2012). Interestingly, Steventon et al. (2012) discussed that service utilisation did not necessarily correlate with health status, and they recommended that multidimensional analysis is required for the assessment of the intervention.

The assessment of clinical effectiveness for the WSD trial was proposed by looking at improvement in quality of life, well being, self care, and carer burden (Bower et al., 2011). Data were available from 98% of participants (Steventon et al., 2012). In our case study, we have chosen the clinical measures for those persistent patients whose paired data were available (less than 50%), which as a result may have had a negative impact on the statistical results.

In conclusion, some individual cases have shown improvements in their health outcomes, as it can be observed in figures 6.7 and 6.8. However, in general, it was evident that through our case study we were not able to find any conclusive clinical evidence that supports whether these kind of interventions work. These discouraging findings are consistent with the results of other telehealth studies (Farmer et al., 2005; Ostojic et al., 2005; Nunn et al., 2006; Nilsson et al., 2009; Deschildre et al., 2012). However, this interpretation requires us to consider that, overall, detectable changes in patients' health status were rare. This can be associated with the fact that almost half of the cohorts in London and Tartu withdrew, which created considerable gaps in the intended daily and weekly clinical collection of data, and loss of statistical power as a result. This was also due to the fact that retraining needs were not detected in time and equipment problems were often experienced, which subsequently led to discouraging patients in using the equipment, particularly in the Lisbon group. In some other cases, patients were too sick to use the equipment. To avoid similar findings as presented in section 6.4, future studies that aim to demonstrate the clinical effectiveness of telehealth interventions should include:

- close patient follow-up,
- observations on severity of disease,
- early detection of retraining needs, and
- mature technology that has been in use long enough so that most of its initial faults have been removed or reduced.

## Chapter 7. Discussion and recommendations

### 7.1 Introduction

Each chapter is discussed separately, limitations of this research are outlined, and recommendations are made in order to design a framework for telehealth interventions.

### 7.2 Overview

We have already argued in chapter 1 that the access and consumption of technologies in everyday life represents improvements to the quality of life and also progress towards equity in our societies. For this reason, the global tendency has been to consider telehealth as a key service for future delivery of care. It promises lowering the cost of care, improving quality, and mitigating provider shortages, making it attractive as a clinical tool (Speedie et al., 2008). However, the evidence in chapter 3 and chapter 6 shows that telehealth interventions do not work in every case. Therefore, fundamental questions about how we should design, understand and implement new healthcare services based on ICT are raised.

Often, organisational and cultural issues are mentioned as fundamental to the failure of telehealth (Barlow et al., 2005). Telehealth may still fail if success depends on behaviour and organisational change, even if the evidence shows reduction in cost and utilisation. For that reason, it is important to understand what causes organisational changes.

Researchers have classified types of stimuli affecting organisations and their respective responses (Feibleman and Friend, 1945). Understanding these phenomena may be a real challenge, especially given the fact that, as we have seen in Section 3.7, telehealth interventions may, or may not, generate clinical effects.

Feibleman and Friend (1945) classified stimuli in (see fig. 7.1):

- Negligible;
- Destructive;
- Effective.

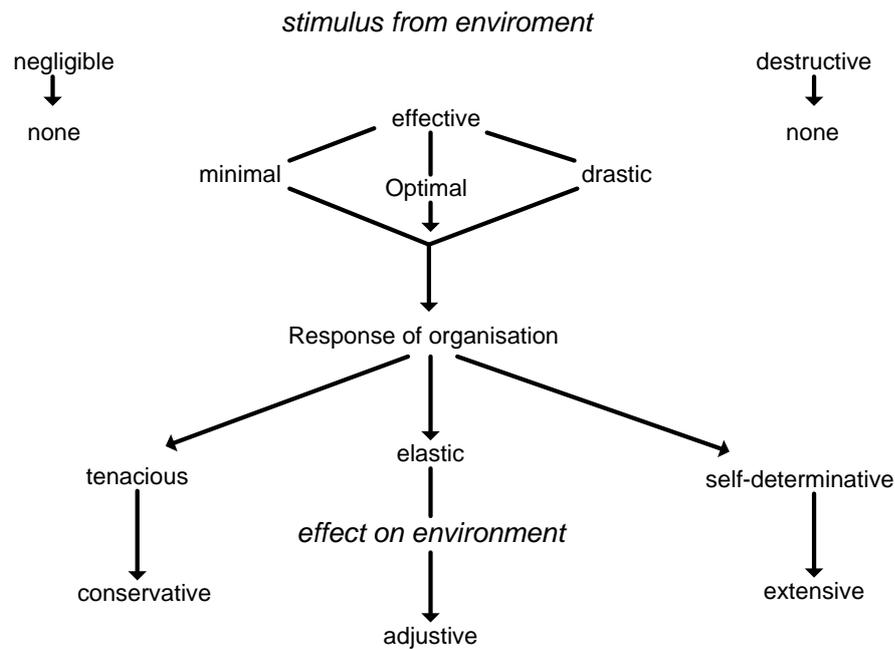


Figure 7.1. Stimuli to and responses from organisations (Feibleman and Friend, 1945).

A negligible stimulus is the one that does not trigger any organisational reaction. That is because it is below a threshold. A destructive stimulus, as the negligible, generates no response, but destroys the organisation; this stimulus can be excessively strong. Contrary to negligible and destructive stimuli, an effective stimulus is the kind that triggers a response in the system. This last stimulus is the one that interests us.

Effective stimuli can be divided into three types (Feibleman and Friend, 1945): minimal, optimal and drastic. A minimal stimulus, as its name implies, is the minimum stimulus needed for exceeding the threshold and subsequently generation of a response. An optimal stimulus is considered the best for triggering change, whereas a drastic stimulus is on the boundaries of destructive stimuli.

Given an effective stimulus, the behaviour or organisational response may be one of the three following forms (Feibleman and Friend, 1945):

- Tenacious, a response that tends to conserve its original organisational state. As a mechanism of defence, it generates resistance to change.
- Elastic, a response capable of adopting a new state while the stimulus remains, but returning to its initial organisational state once the stimulus ceases.
- Self-determinative, a response that allows change, adapting elements of the stimulus and transforming them to suit itself.

It is not uncommon that people resist change when they perceive it as a threat. In general, resistance to change is a factor of concern in telehealth (Debnath, 2004; Hebert et al., 2006; Jones et al., 2006; Lee et al., 2011). Resistance can also be present when the burden of treatment for patients with complex illnesses reduces their capacity to collaborate in their own care (May et al., 2009). To overcome this issue, May et al. (2009) suggested that we need to implement minimally disruptive structures for effective treatment and service provision.

Essentially, clinical trials and pilot projects are implemented to demonstrate and evaluate the feasibility of studies before establishing operations on a large scale. The effects of pilot projects and research trials can be considered to be of the type of elastic response due to their temporary nature, as they seldom move from such stages to routine service delivery.

To avoid tenacious and elastic responses and move telehealth into the mainstream of medical practice as a self-determinative response, effective health care processes are needed in place before any changes are attempted (Jennett et al., 2005). Also, good acceptance and satisfaction are required from health care professionals, patients, caregivers, and other users, as well as solving any issues related to staff, skills, learning and training needs (Zanaboni and Lettieri, 2011). Definition of leadership, roles and responsibilities need to take place and be communicated among health care staff. Beyond the boundaries of the organisation, collaboration, cooperation, partnership and networks with other health care providers and stakeholders are also required (Zanaboni and Lettieri, 2011).

But, before telehealth can occur routinely, a number of processes have to be put in place (Jennett et al., 2005). One important element that needs to be considered is the collection of information that will be sent to a healthcare provider. From section 3.6, we already know that the information that needs to be transmitted within a telehealth system depends on the patient's specific disease. This can be divided in to:

- Physiological data (blood pressure, glucose, ECG, peak flow, oxygen saturation, among others),
- Health-related data (sleeping quality, quality of life (QoL), weight, symptoms, medication taken, daily stress, etc),
- Text data (patient id, automatic reports, and text messages to patients)

- Audio (voice, electronic stethoscope, etc),
- Video (images in real time),
- Others (still images).

From section 3.6, we also know that in telehealth patients are supported by some biomedical technologies, which enable the acquisition, displaying, and coding of clinical and health-related information (the message). The information travels from and through the telecommunication system available at the patient's home, to a healthcare facility (either directly or indirectly) where a healthcare provider with the support of some technologies (ICTs) stores, decodes, displays, and interprets the information sent. In their workplace, the healthcare provider can have further discussion with other colleagues or carers before decision making and other support (feedback) takes place. This description makes information an important component of the care practice in telehealth.

However the process of collecting useful information requires different actions from stakeholders and can be very complex. As a rule of thumb, the more information, the more difficult and time consuming it is to obtain useful medical information. Usefulness of medical information can be expressed by the equation (Shaughnessy et al., 1994):

$$\text{Usefulness of medical information} = \frac{\text{relevance} \times \text{validity}}{\text{work}}$$

where:

- relevance means that information has to be relevant to everyday practice;
- validity implies that information has to be correct; and
- work denotes that medical information must require to be obtained with fairly little work.

Therefore, gathering relevant and valid information should be part of the information design. From all the information created in healthcare, the fraction of the total number of transactions that implies interpersonal interaction, e.g. face to face conversations, telephone calls, letters, faxes, and emails, is known as "the communication space" (Coiera, 2006). Coiera (2006) argued that such communication space in clinical settings tends to be interruption-driven (multiple interruptions by clinical colleagues and others, either face to face or through call events), contain deficiencies in its communication systems, and result in poor practice (Coiera and Tombs, 1998; Coiera, 2006).

In the REALITY case study, some indications of poor communication and information design were found. As one of the clinicians (PG) from the London site commented at the end of the study:

“Problems with the handheld units, not as user friendly or clear as originally stated. Lots of technical issues and feedback form website were extremely poor. At times it appeared to just be a data gathering exercise”

Another clinician (IM) from Portugal was also disappointed with the system:

“I have not enough time to analyse data; I expected the results from oximeter could be more useful; I also expected to have more efficient technical support”

One more clinician (SW) commented:

“[there were] Problems with the handheld units, not linked to the clinical system so it seemed isolated. Data overload as a result”

Clinicians found it difficult to understand the status of their patients and make any decisions as there was too much information to deal with. One question that still needs to be answered is whether they really needed or wanted to have access to all of the data generated by telemonitoring.

### **7.3 Main findings**

The purpose of this research was to develop a generic framework that is applicable to a broad spectrum of telehealth interventions for patients with long term conditions. In order to accomplish the aim of this research, we systematically first looked at the evidence available for home telehealth interventions focused on diabetes, hypertension, COPD and asthma. This was done to determine the clinical effectiveness of the studies and to find the best models for telehealth implementation. Secondly, we looked at the profiles of patients from a real case study since we argued that other factors such as socio-economic and living conditions are important determinants to be considered for appropriate service implementation. Then, we tested whether there was a statistical relationship between demographics and the performance of patients during the telehealth case study. Finally, we performed a series of tests to evaluate the effectiveness of the telehealth case study. The main findings are summarised below.

### 7.3.1 What the evidence says (Chapter 3)

Mixed evidence was found regarding the effects of home telehealth on clinical outcomes. The evidence found reflects the variability of studies and the lack of standards for these types of interventions. The small sample size and inadequate length of the intervention (typically less than 6 months) for most of the studies included in this review limited our results. On the one hand, sample size is important because of its effect on the probability that a statistical test will indicate a significant difference when there truly is one (Eng, 2003). On the other hand, a change in a clinical outcome can be attributed to a temporal effect (due to changes over time) that not necessarily have to be related to the intervention (Nelson, 2011). For instance, we found temporal improvements in some patients from the REALITY project. Fig. 48 shows a reduction in the blood glucose levels (elastic response) of patient ID 6460 from day 50 to day 100. The improvement was not sustained in the long term and by the end of the study blood glucose level went back to its initial state. For this reason, the length of interventions in telehealth should be sufficient to determine temporary and long term effects.

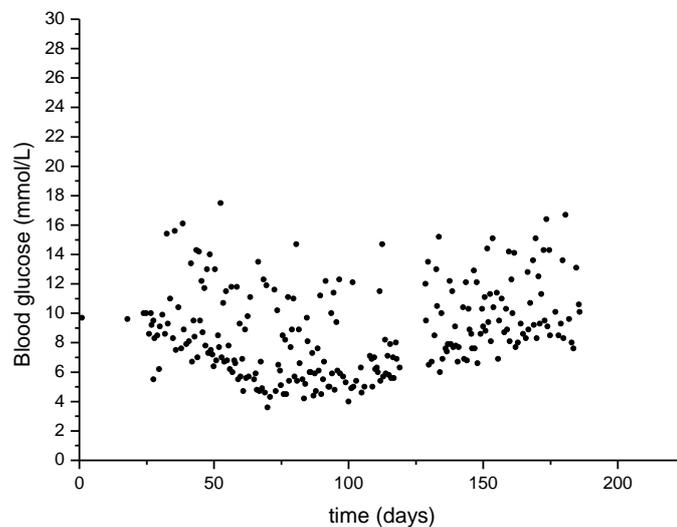


Figure 7.2. Changes of blood glucose over time (patient 6460).

It is important to note, that one of the findings during this review is the inconsistency in the way that primary outcomes were reported in telehealth studies (except for the diabetes studies). A lack of sufficient data to estimate final mean values and standard deviations, as well as lack of common outcome measures for the reviewed cases of asthma, hypertension and COPD, made it impossible to assess the effectiveness of such interventions by meta-analysis. In

order to facilitate research in telehealth, standardisation of interventions and outcome measures is needed (Ekeland et al., 2012).

Although meta-analysis is difficult to achieve, there is a current trend to utilise this statistical method for home telehealth research studies (DelliFraine and Dansky, 2008; Polisena et al., 2009; Polisena et al., 2010; Omboni and Guarda, 2011) since it is the only way to evaluate clinical effectiveness. In this research, we attempted to use meta-analysis to determine the best case studies with a quantitative approach. In the meta-analysis of diabetes studies, we found six studies with significant positive effects in favour of telehealth (Ahring et al., 1992; Albisser et al., 1996; Thompson et al., 1999; Kim and Oh, 2003; Oh et al., 2003; Shea et al., 2006). Some common factors were found among these studies. The study design was predominantly a randomised control trial, except in Albisser et al. (1992). In all interventions, patients were contacted at least once a week for education, counselling or medication adjustment and were supported by a nurse (except in Ahring et al., 1992). The technology at the patient's home was complex in Shea et al. (2006) who used web-based technology and videoconference, whereas, in the rest of studies a telephone based system was the technology available at home. In relation to patient characteristics, mean age of participants ranged from 41 to 60 years (unknown in Albisser et al., 1996) and mean duration of disease was greater than 11 years except in Shea et al. (2006) and in Albisser et al. (1996). These summarised the common factors that may be worth investigating in future research.

Furthermore, telehealth interventions involving nurses were mentioned at least in twenty diabetes papers (Kirkman et al., 1994; Marrero et al., 1995; Weinberger et al., 1995; Albisser et al., 1996; Thompson et al., 1999; Piette et al., 2000a; Piette et al., 2000b; Whitlock et al., 2000; Dansky et al., 2001; Piette et al., 2001; Chase et al., 2003; Kim and Oh, 2003; Kruger et al., 2003; Oh et al., 2003; Lavery et al., 2004; Montori et al., 2004; Bergenstal et al., 2005; Chumbler et al., 2005b; Farmer et al., 2005; Shea et al., 2006), in two asthma papers (Kokubu et al., 1999; Steel et al., 2002), in 3 hypertension studies (Roth et al., 1999; Bondmass et al., 2000; Artinian et al., 2001) and in three COPD papers (Dale et al., 2003; Wong et al., 2005; Pare et al., 2006). Whereas, interventions by doctors were less common in diabetes ((Billiard et al., 1991; Shultz et al., 1992; Meneghini et al., 1998; Biermann et al., 2000; Liesenfeld et al., 2000; Biermann et al., 2002; Gómez et al., 2002; Vähätalo et al., 2004) and more common in hypertension

studies (Friedman et al., 1996; Naef et al., 1998; Rogers et al., 2001; Rogers et al., 2002; Port et al., 2003; Mengden et al., 2004; Port et al., 2005). This shows a preference in having nurses in the frontline of telehealth as they can provide education, support, follow up and referral to other health professionals.

### **7.3.2 Demographics and clinical profiles (Chapter 4)**

This chapter explored the demographics and clinical conditions of individuals who participated in a telehealth EU project. Such conditions describe the general environment in which patients with chronic diseases need to cope with their medical conditions at home. From our analysis, we found statistically significant differences amongst the participants of the four clinical groups in terms of age, education, marital status, occupation, activity, literacy, ethnicity, location, main income, living accommodation, access to social care, carer's availability and level of support. We argued that each difference represents a different condition that needs to be taken into account during the telehealth intervention design (we tested that hypothesis in chapter 5). For instance, we found that half of the participants in London were less than 51 years old, a relatively young population likely to have their vision, hearing, psychomotor or cognitive abilities intact. No evidence was found that this group reported problems in using the technology. However, in the comments quoted from patients ID 8248, 6554, and 8112, in section 4.6, a tendency in reporting difficulties when using the technology was found. All these patients had in common one factor; they were older than 71 years. This shows that age can be an important factor when designing telehealth interventions.

There is not enough research done to determine the impact of socioeconomic variables on telehealth. None of the papers reviewed in chapter 3 discussed anything related to this matter. However, Or and Karsh (2009) have performed a systematic review of patient acceptance of consumer health information technology. They found in the majority of studies (with significant relationships) that age was negatively associated with acceptance. Or and Karsh also found that acceptance increased with higher education and that gender did not show any effect. Other socio-economic variables were examined in their study but inconclusive conclusions were found. These results may be not surprising, but they are important to be studied and evaluated. In our case study, it was found that Evora was the group with the poorest social and economical conditions: lower education, less skill (manual labour), less active, lower level of literacy, highest

proportion of people living in rural areas and reduced conditions in the quality of their living condition, whereas the group from Tartu had the best socio-economic conditions: higher education, highly trained professionals, inactive by choice, literate in the local language, less dependent on state benefits and having good quality of living accommodation. By looking at these findings one question remains, are socio-economic conditions a limiting factor when adopting telehealth?

In addition to the demographics factors, the treatment of chronic diseases can get more complicated in the presence of other medical conditions (DeBusk et al., 1999). In the REALITY project, patients with diabetes, hypertension, chronic heart failure, bronchial asthma and chronic respiratory failure were recruited. Apart from their primary disease conditions, it was found that patients also suffered from other medical conditions (comorbidities). Cases with pulmonary heart disease (68/193), hypertension (43/193), diabetes (19/193) and coronary heart disease (40/193) were recorded in the four clinical sites. It was also found that some patients from the diabetes group also had a history of retinopathy, nephropathy or foot ulceration (one case). In Tartu, patients also presented a history of myocardial infarction, symptoms of dyspnoea, peripheral oedema or symptoms of fatigue. A considerable proportion of the groups with asthma and respiratory failure were breathless at rest or minimal effort. The majority of the patients at Lisbon and a large proportion at Evora needed oxygen therapy. Notably, more than 70% of the patients were either overweight or obese, in whom a significant body mass index (BMI) difference was not found ( $F=1.237$ ,  $df=3$ ,  $p=0.298$ ) among the four clinical sites. This is an interesting finding, as the analysis showed that BMI was independent of the geographic location and of the primary disease condition. But it also indicated the need for obesity and weight control programmes in the intervention for patients with long term conditions. Under these scenarios, the challenge is to deliver appropriate telehealth interventions according to specific needs. Therefore, we need to consider not only the primary disease conditions, but also to consider comorbidities in the process of monitoring and treating patients (Gijzen et al., 2001).

Finally, daily life actions can be restricted by the presence of physical, sensory or mental impairments, which at the same time can affect the way patients interact with technology. The usability of telemonitoring devices especially for individuals with reduced mobility or cognitive impairment has been argued as a significant

problem (Hardisty et al., 2011). We found that finger and hand movement as well as limited vision were common in three out of the four REALITY sites. Hearing impairments were common in London, whereas learning disabilities and memory problems were common in Portugal. Some patients with learning disabilities and memory problems faced major limitations when they interacted with the handheld technology. Therefore, another factor to be considered in the design of telehealth intervention should include the specific needs of users with psychomotor, cognitive, and sensory disabilities. In this way, patients can have access to such interventions regardless of their disabilities or severity of their impairments. This is in line with the one of the design recommendations for sustainable medical informatics given by Ianculescu et al. (2012).

From what we observed in this chapter, the design of telehealth interventions needs to take into account four main factors: primary disease conditions, demographics and socio-economic status, comorbidities and other health related problems, and any other impairments.

### **7.3.3 Tests for associations (Chapter 5)**

In this chapter, we investigated the association between patient's demographics and patient's progress during a telehealth project. The progress was evaluated in four domains: (i) patient's understanding, skills and home support (Q1-Q7), (ii) decision to proceed with the telehealth service (Q8), (iii) actions for continuing patients (Q9-Q10) and (iv) evaluation of additional training (Q11-Q16). We found that more than half of the dependent variables (Q1-Q16) were associated with an important proportion of the demographic and socio-economic variables presented in chapter 4 (except for marital status, activity if retired, carer's availability, carer's level of supports and gender). These results provide significant evidence that support the theory that demographics and socio-economic variables can affect the patient's performance during a telehealth intervention. The strongest statistical examples include the existing care provision and access local medical and social care, education, general location of patient's home, age and literacy in local language. Notably, patients who had already access to local medical and social care were the ones with poorer understanding and skills in the use of the technology, also required retraining. In terms of level of education, it was found that higher education levels had a positive relationship with the understanding and skills needed for patients to use the service (the use of the handheld unit, help line, third party devices, etc.). It was also noticed that patients who lived in inner

cities had better skills and understanding in how to use the technology, access the clinical data and to retrieve messages sent by the clinical staff, and no additional precautions were imposed to this group. Finally, it was also found that older groups required more assistance, and were more likely to withdraw or required retraining.

We found weak, moderate and strong relationships among the demographics and socio-economic conditions in different proportions (section 5.4). The findings from this chapter support the idea that the performance of patients during a telehealth intervention can be associated with patients' living circumstances and other social conditions. As a hypothesis, it has been suggested before that "home telehealth monitoring would work most effectively for patients of higher socio-economic status" (Bonne et al., 2008). Our results show presence and strengths of some associations, but the mechanisms through which patients' demographics influenced the telehealth service seem to be multiple and more research needs to be done. However, the associations found have shown that the demographics of patients influences uptake of telehealth. Therefore, socio-economic conditions must be considered during the design and implementation of telehealth services.

#### **7.3.4 Clinical outcomes (Chapter 6)**

Paired samples t-tests were conducted to compare the peak expiratory flow (PEF) value in patients from Lisbon, Evora and London. Similarly, the difference between mean blood pressure (MBP) values before and after the intervention was tested by paired t test in patients from Tartu and London. Also any difference between HbA1c values before and after the last clinical visit in London was tested. None of the t-test results were statistically significant. These results indicated that there was not any effect in the patients' clinical outcomes at the end of the telehealth intervention. Similar results have also been found by Farmer et al. (2005), Ostojic et al. (2005), Nunn et al. (2006), Nilsson (2009) and Deschildre et al. (2012). However, the lack of statistical significance did not mean that individual patients had not experience any improvement. Patient 6457 and 8138 illustrated the kind of response it is expected from telehealth interventions.

We have previously tried to explain why this intervention did not work (REALITY Consortium, 2005b). Some real as opposed to ideal circumstances were found during the project. Although the motivational level at recruitment stage was high; 87% of the participants were either very interested (37%) or moderately interested

(50%), a few indifferent (4%) or reluctant (3%) and some did not know (6%), by the end of the project it was noticed that a large proportion of the patients in London (32/62) and Tartu (35/60) did not continue using the system (not more than 4 months) unlike patients from Lisbon (30/38) and Evora (22/35) who were the slightly more persistent. Reasons for lower service usage and withdrawals were not clear. As this was not anticipated, the evaluation forms did not have specific questions for explaining this behaviour (REALITY Consortium, 2005b). The four sites had some equipment problems (failure rate up to 24%) and it was reported (REALITY Consortium, 2005b) that delays and resolving equipment problems led to withdrawals. Some comments from patients related to technology and general aspects of the telehealth service are summarised in table 7.1. These comments are indicative of the overall situation that patients faced. Technical difficulties, lack of time, need for travel or relocation, family circumstances, and anxiety caused by the use of the technology were common explanations among the clinical sites.

Table 7.1. Patients' comments on technology and general usage [adopted from (REALITY Consortium, 2005b)].

	<b>Example explanations for withdrawals/gaps in home-data</b>	<b>What didn't work as well as expected?</b>
<b>London</b>	<ul style="list-style-type: none"> <li>* Recent diagnosis of cancer has overtaken.</li> <li>* My asthma got better therefore not use device any more.</li> <li>* I became sick so did not use it.</li> <li>* Not able to use device abroad.</li> <li>* Wanted to do it but I work shifts.</li> <li>* My husband died.</li> <li>* I do not have the time.</li> </ul>	<ul style="list-style-type: none"> <li>* Patient said too difficult.</li> <li>* Feedback was a problem, don't really know what I've entered.</li> <li>* Telephone support not helpful.</li> <li>* Problems with the telephone line</li> </ul>
<b>Tartu</b>	<ul style="list-style-type: none"> <li>* Patient travels a lot. Inconvenient to take the handheld unit with him.</li> <li>* Patient moved far away.</li> <li>* Health parameters are good and he doesn't need frequent monitoring anymore.</li> <li>* Lack of time.</li> </ul>	<ul style="list-style-type: none"> <li>* The handheld unit is too difficult to use.</li> <li>* Inconvenient to travel with the handheld unit, unnecessarily large and the battery lasts only some hours.</li> <li>* ECG registration too slow. Electrodes will not last.</li> <li>* Measurements take too much time.</li> <li>* Feedback - weekly report difficult to understand.</li> </ul>
<b>Lisbon</b>	<ul style="list-style-type: none"> <li>* Patient and family found the equipment too difficult to use.</li> <li>* No oximeter at home.</li> <li>* Patient was admitted in another hospital.</li> <li>* Child at home who could have an accident with the unit.</li> <li>* Found she Had memory difficulties that interfered</li> </ul>	<ul style="list-style-type: none"> <li>* Expected it would be easier.</li> <li>* Sending data to the hospital, particularly data from oximeter.</li> <li>* Connection with the oximeter.</li> <li>* Couldn't see the pictures and words on the screen.</li> </ul>

<b>Evora</b>	<ul style="list-style-type: none"> <li>* Patient and carer could never work with the oximeter.</li> <li>* Had family problems and thought this will bring more.</li> <li>* Patient's son died on a car accident.</li> <li>* When I feel good I don't remind the device.</li> <li>* Patient uses the device only at night. In the morning she is very busy.</li> <li>* Difficult to use device because I'm so depressed</li> </ul>	<ul style="list-style-type: none"> <li>* Device problems. Phone line problems.</li> <li>* Oximeter very difficult to use (the cables and connections).</li> </ul>
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While several conditions listed in table 7.1 were not the most ideal, patients from Portugal had the higher rate of persistency (they were also the sicker and older). Lisbon was the group who had the highest rate of persistence (30/38) among the four groups and felt more supported by the service while a large proportion of patients from Evora (22/35) also continued. Notably, the latter was the group with the poorest social and economical conditions: lower education, less skill (manual labour), less active, lower level of literacy, highest proportion of people living in rural areas and reporting reduced conditions in the quality of their living condition. These findings reinforce the idea that factors surrounding the patients' environment play an important role in telehealth.

#### **7.4 Limitations of the research**

Two specific limitations of the research are evident. First, the methods used to collect, collate and analyse the data from the REALITY project were not the most adequate. We had to obtain the data in the original form and reanalyse them. This was a time consuming process as data sets were incomplete and collected for other purposes than those of the present research and therefore not all the data collected were relevant.

However, the issues of collection, processing, analysis and use of telemonitoring data in research trials are not new (Ure and Hanley, 2011). Ure and Hanley (2011) argued four stages of the lifecycle of data that involve multiple transformations of data in which quality and validity need to be guaranteed: (1) data collection/generation by patients at home, (2) transmission and transformation (secure server), (3) de-encryption and decision support (call centre) and (4) interpretation and validation (health centre). Anomalies found at stages 1 and 2 of lifecycle and collection of questionnaires from the clinical sites raised questions about the validity of data, but due to the fact that system design

and data collection was not under control of the research team, imposing data quality were an important limitation. Even though we addressed some of these issues by detecting and correcting corrupt or inaccurate records from the original record sets, data processing was a relative limitation.

Second, the combination of the three systematic reviews (Bensink et al., 2006a; Barlow et al., 2007; Pare et al., 2007) did not take into account any new evidence coming from research after 2007 and made the results not exhaustive. However, “the evidence base for the value of telemedicine in managing chronic diseases is [still] on the whole weak and contradictory” (Wootton, 2012). Most importantly, due to the combination and nature of these systematic reviews we cannot neglect the heterogeneity of individual studies presented in chapter 3. Such heterogeneity explains some of the inconsistency in the results of the studies reviewed. In addition, lack of clinical data standards for interventions in the cases of asthma, COPD and hypertension made it impossible to evaluate the clinical effectiveness of these interventions.

## 7. 5 Recommendations

As cited by McLean et al. (2011), the essential steps of a telehealth intervention are as follows:

- **Step 1.** The patient provides some clinical data that give information about his/her health status (e.g. electrocardiography, oxygen saturation or glucose measurement).
- **Step 2.** Subsequently, the information is transferred electronically to a healthcare professional who can view it from his/her current location.
- **Step 3.** A clinical decision is made by the healthcare professional who can later provide treatment tailored according to the patient’s actual health status.

However, although in principle the procedure looks very simple, in fact implementation of the intervention can become complicated. For example, in step 1, clinical data provided by the patient may not be accurate enough since a number of mistakes can be made when taking clinical measurements; in step 2, some anomalies in the transmission of data can be present; in step 3, scheduling communications between the healthcare provider and the patient can be difficult. For all these reasons, a standardisation or quality criterion is needed in order to create a robust, accurate and reliable telehealth intervention framework. However,

it is unlikely that a unique framework will satisfy individual patient's needs since patient profiles vary not only from one medical condition to another but also within the same medical condition.

A series of recommendations that can be used by different stakeholders so they can take action in order to improve health care, quality of care and health information by means of telehealth have been made.

### **7.5.1 Patients' individual requirements**

As we discussed in chapter 4, primary disease conditions, demographics including socio-economic status, comorbidities, and any other impairment should be considered in the design of a telehealth intervention. Taking into account these considerations can encourage health care providers to be more flexible and help to acknowledge that patients are persons with unique personal histories and individual needs (Zandbelt et al., 2007). When health care providers focus on patients, their lives and health problems, they promote a patient centred approach. Adopting this approach recognises that patients vary in their knowledge, skills, psychological adaption and disease trajectory (Gambling and Long, 2010) and also recognises that a problem can be defined in terms of its physical, psychological and social components (Rolfe and Sanson-Fisher, 2002). The advantage of adopting a patient centred approach is that it motivates patients to assume an active and independent role in monitoring and treating their disease which leads to improved outcomes (Aschner et al., 2007).

### **7.5.2 Technology**

Technology chosen for telehealth interventions should be safe, easy to use and be able to integrate patient data into the electronic patient record (EPR) so an accurate clinical decision can be made and treatment tailored according to patients' needs.

**Safe intervention.** It is desirable that the operating conditions of any intervention remain under safe limits and free of hazards to support continuity of care. However, such conditions are not always satisfied, and when that happens, errors and clinical incidents may occur in healthcare settings. For example, during the REALITY project, one of the engineers (JP) raised the concern that there were some "points to potential problems in the web server logic; it was even possible, that the wrong data were shown to doctors..." The root of this problem was more

likely to be attributed to human and technical factors. Safe decision making requires access to high quality data and meaningful information that support data collection, aggregation, exchange, and retrieval from the point of care setting.

In the UK medical devices require regulatory approval. This approval is coordinated by the Medicines and Health Regulatory Authority (MHRA) which implements the European medical-device directives into UK law (Heneghan et al., 2011). Currently there are four medical devices regulations that place obligations on manufacturers to ensure that their devices are safe and fit for their intended purpose before they can obtain a CE marking (MHRA, 2011). The Statutory Instruments that are in place in the UK are: 2002 No. 618, 2003 No. 1697, 2007 No. 400 and 2008 No 2936 (MHRA, 2011). Although such instruments are in place, medical devices may still cause serious adverse effects in patients and contribute to additional healthcare costs (Heneghan et al., 2011). Therefore, safety must always be taken into account.

The risk in telehealth systems depends on a combination of type of users, circumstances of use, type of use, and nature of the system (Rigby et al., 2001). There is not a specific clinical risk guideline for telehealth, but Connecting for Health (CfH, 2009) has published guidance (DSCN 18/2009) related to the deployment and use of health software that can be used for identifying clinical hazards and controlling the risks of new systems. The process includes (CfH, 2009):

- “identification of current situation, requirements, scope, extent of change to the current situation, impact and expected benefits;
- creation of a clinical risk management plan;
- setting the requirements for and defining the competencies of personnel;
- clinical hazard identification;
- clinical risk analysis;
- clinical risk evaluation;
- clinical risk control;
- residual clinical risk acceptance;
- creation of clinical safety case report(s);
- post deployment monitoring and feedback to manufacturers; and
- review and maintenance of clinical risk management process”

The clinical risk management process listed above should be carried out by a multi-disciplinary group including clinicians, manufacturers and systems integrators. In addition to this process, a functional safety management system (Adriano et al., 2011) should be included to overcome any gaps unattended by DSCN 18/2009.

**Ease of use.** In terms of usability, patients from the case study consistently claimed that the handheld unit was difficult to use, travelling with the unit was inconvenient due to its large size, and the battery only lasted a few hours. Patients recommended that the buttons needed to be larger and displays made easy to read. Some even suggested that the third party devices (such as the blood pressure device) should be integrated within the handheld unit. The system should contemplate that some of the users may have a combination of impairments such as reduce vision, restricted mobility and poor memory. In order to overcome any type of usability problems, a full classification of usability requirements for home telehealth systems has been published by Jaspaljeet et al. (2010). This classification should help to prevent any individual or system limitations, so we recommend to follow their guidelines (Jaspaljeet et al., 2010):

- *Functionality*; (1) the system design should enable patients to interact with the system naturally; (2) language should not be a barrier for patients and the system should include multilanguage support; (3) scheduling should be implemented by useful reminders for monitoring sessions, medications and doctor appointments; (4) using interfaces that consist of just one screen and a few buttons should reduce computer anxiety; (5) the system should be customised according to the users' level of ability.
- *Understandability*; (6) patients need to understand how the system works as well as understand what is expected from them when using the system; (7) guided instructions in how to use the system should be provided.
- *Interface design*; (8) the system should be made readable (avoiding small font size and distracting context) and designed to accommodate users with visual problems; (9) more pictures than words should be used for presenting information; (10) the choice of colours should be appropriate to avoid distractions; (11) clear transition between screens should avoid confusion about where the users are in the system;
- *Operational support services*; (12) conduct tailored training programmes for reducing user's anxiety and improve self efficacy; (13) provide appropriate technical support and maintenance at home;

- *Reduce complexity*; (14) the system design should incorporate easy data entry to collect health information from the patient; (15) tasks should be simplified;
- *Feedback*; (16) the system should show the health status of the patient at an appropriate level of detail and terminology (17) graphical representation of health status should be used to visualise progress;
- *Non-functional requirements*; (18) the system should be stable, interoperate without interruption and provide reliable monitored values and (19) the system should support security and data confidentiality.

**Data integration into electronic patient records.** Ideally, all the data collected from the home telehealth intervention should be transmitted directly into the electronic patient record (EPR) available at the specific healthcare centre in order to provide an efficient patient centred care. Researchers have already demonstrated this feasibility of data capture from home monitoring devices into an electronic medical record (Shea et al., 2006). Integration between systems is important since the ability to exchange data with electronic medical records has been related to improvements in process outcomes for patients with chronic diseases (Dorr et al., 2007) and associated with success factors to control health care costs in the Veteran's Affairs home based primary care programme (Leftwich Beales and Edes, 2009). However, proper integration of telehealth data into electronic patient records is yet limited by the lack of standards in telehealth devices. Continua Health Alliance, a non profit organisation, has focused on interoperability aspects, designing guidelines to address the technical barriers of interoperability amongst multivendor systems (Wartena et al., 2009), but there are still technical and non technical challenges that need to be addressed (Wartena et al., 2010).

Continua has focused on the solution of three main barriers (Wartena et al., 2010):

- “Technical: design guidelines to support interoperable sensors, platforms and services and a logo and certification program to signify the promise of interoperability to the customer.
- Regulatory: work with regulatory agencies to safely and effectively manage diverse vendor solutions.

- Financial: work with leaders in the healthcare industries to develop new ways of addressing the costs of providing personal telehealth systems, such as new reimbursement models and co-pay solutions”.

Continua has focused their efforts of interoperability in the personal area networking (PAN) and local area networking (LAN) devices, an application hosting device (AHD), a wide area networking (WAN) device, and a health record (HR) device (Smart Personal Health, 2010). The interfaces are defined as the PAN, LAN, WAN, and x (electronic or personal) health record network (xHRN). At the PAN level, The Alliance has incorporated the IEEE 11073 communication standard and restricted its use to USB and Bluetooth to Continua Health Alliance Version 1 certificate (Wartena et al., 2010).

Continua Health Alliance came into existence to open up and provide guidelines for the ecosystem of connected medical devices that was starting to appear a few years ago, but its real job has been to ensure the integrity of data as it flows from the measuring device to the EPR (Hunn, 2010). Because a variety of EPRs exist in the healthcare domain, this makes difficult the exchange of information among different systems. Therefore, standard methods for systems to communicate such as Health Level 7 (HL7) (an international standard for the transmission of medical data) should also be considered as part of the system integration. There are other available standards that can be useful to improve the ability to access and exchange patient information, but that depends on the kind of EPR to be integrated or extended. That can be the case of the International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD10) or the Systematised Nomenclature of Medicine Clinical Terms SNOMED CT among others.

### **7.5.3 Training**

Patients should receive basic training and be evaluated on regular basis in order to become more competent in using the telehealth technology. Retraining should be expected since the evidence pointed out that training is often an important issue. In chapter 5, fig. 5.11 and 5.15 can be observed that almost half of the participants of our case study needed additional training (92/193) in how to use the handheld unit and use messages from clinicians. The need for additional training is not rare. For example, in order to identify work issues and difficulties, Sanderson and Attack (2004) conducted a qualitative study on 3 home telehealth

programmes. They found that "...patient training in the technology became a necessary but repetitive and sometimes unpleasant task for the nurses" (Sanderson and Atack, 2004). Similarly, Sandberg et al. (2009) noted that there is a "...call for additional, or perhaps ongoing, training and technology support for older adult patients involved in telehealth". In home blood pressure monitoring, clinicians have made their own observation stating that in order to achieve a more appropriate use of automated measuring devices, better patient training is needed (Parati et al., 2006).

Guidelines about evaluation for further training in telehealth were not found. This makes sense as each technology may have its own complexity. In chapter 4, the need for additional training by the minimum task a patient would need to perform was evaluated by:

- Measurement using the handheld/accessories,
- Measurement using third party devices,
- Transfer of data using telephone line,
- Completion of EQ5D questionnaire,
- Use of messages from clinician and
- Use of telephone helpline.

Lai et al. (2006) also identified a number of skills needed to use their telehealth system that included 5 tasks:

- Logging into the telehealth website;
- Reviewing monitoring data;
- Entering pedometer data;
- Sending messages to a provider;
- Reviewing messages from a provider.

From the above examples we recommend at least to evaluate 4 tasks:

- Measuring biomedical data
- Transferring data from the third party device (if any) to the telehealth unit
- Sending data from the telehealth unit to the healthcare facility
- Receiving data from health care providers

#### **7.5.4 Clinical intervention**

Clinical protocols should be developed for specific diseases and action limits should be defined. Also the purpose of the monitoring intervention should be

defined. Detection of slight changes in vital signs can alert health care providers to take actions before the health of the patient deteriorates. However, basic questions need to be answered such as how often the patient would send data or be monitored? Who takes responsibility for monitoring patients and making a phone call or home visit? When would the patient's doctor be contacted? What parameters would be monitored? What sort of decision support systems is needed to support care providers in automated tasks?

As any other new clinical intervention, telehealth interventions should be evaluated before being integrated in ordinary health care (Loane and Wootton, 2002). However, clinical effectiveness still needs to be demonstrated. It was argued before that patients' needs vary not only from one medical condition to another but also within the same medical condition. Variation of need can be observed in the Kaiser Permanente risk pyramid (fig. 7.3). In level 3, patients are with multiple and complex conditions (limited mobility). In level 2 patients are at high risk but can be managed at home. In level 1, patients are more stable and can be managed by self-care. Patients should be managed according to their chronic disease risk and the support provided should be according to that risk associated (Ham, 2010).

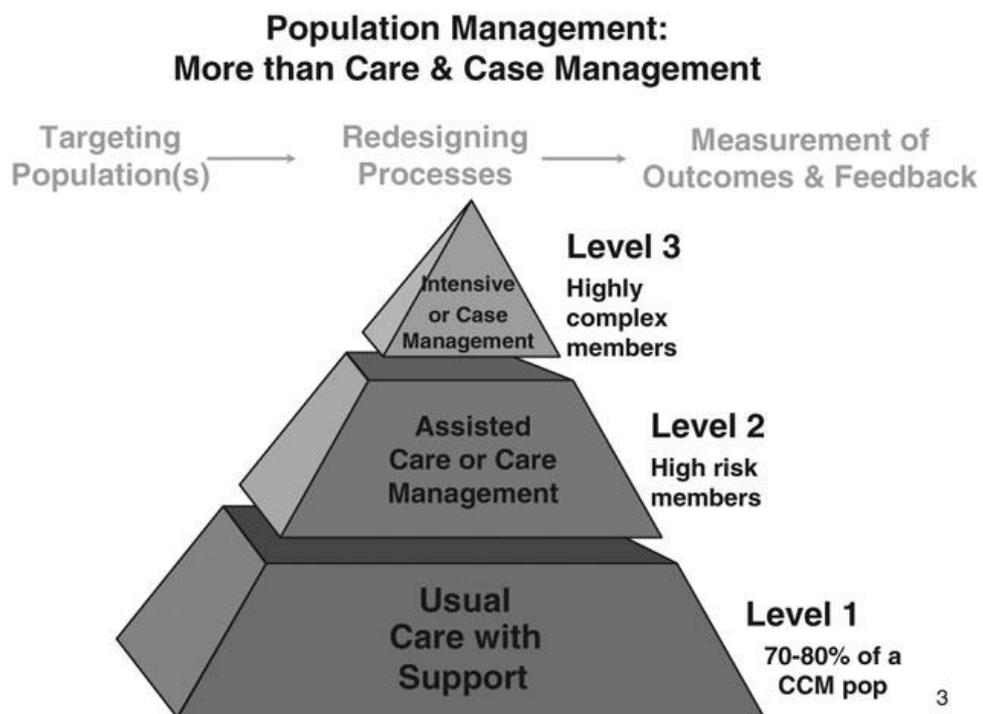


Figure 7.3. The Kaiser Permanente risk pyramid. Taken from (Ham, 2010).

Kaiser Permanente has shown that providing patients with on call home telehealth nurse by remote video technology was well accepted by patients, capable of maintaining quality of care, effective and save costs (Johnston et al., 2000).

Another conceptual model for disease management that has been proposed includes the following main features (Krumholz et al., 2006):

- Patient population
- Intervention recipient
- Intervention content
- Delivery personnel
- Method of communication
- Environment
- Clinical outcomes

The classification of disease management above should help to compare structures, process and outcome and promote uniformity in the design and conduct studies that look for validation of disease management strategies (Krumholz et al., 2006).

#### **7.5.5 Health care providers**

A group of different disciplines within the healthcare setting should be defined for specific telehealth interventions. As it was described in chapter 3, nurses, in preference, should be the intermediary healthcare providers between the patients and the consultant. They have begun to play unconventional roles in home telehealth, including installation of telehealth technology and training of patients (Starren et al., 2005).

#### **7.5.6 Clinical Effectiveness**

All the recommendations mentioned above have to be met before any attempt to demonstrate clinical effectiveness is made. At present, the most robust study design for evaluating effectiveness of a single intervention is randomised control trials (Chumbler et al., 2011).

Considering that there may be some participant withdrawals from future studies, as it happened in the REALITY project, and in order not to lose statistical power; an ample sample size should be sought. In addition to this, if the conditions allow it, the intervention should last more than 6 months (preferably 1 year or more).

Furthermore, in order to produce a meta-analysis, when reporting the results of these studies it is recommended to report as much data as possible, mainly mean values and standard deviations (if it is continuous data). It is also recommended that the use of common outcome measures within clinical studies be standardised.

## Chapter 8. Conclusions

### 8.1 Overview

In this chapter we summarise the research contributions, review the aim and objectives, and discuss the future research necessary to help overcome the current limitations of this research.

As has been shown in the profiles of the patients participating in the REALITY project (chapter 4), chronic diseases are very complex conditions in which two or more disease processes may coexist. For example, patients with diabetes can develop retinopathy, nephropathy, foot ulceration or a combination of them, and these complications can restrict patients' ability to do basic daily living activities. Therefore, managing patients with these conditions represents a major challenge to public health, since 80% of total GP consultations are related to these groups, and 5% of them represent roughly 42% of the total acute bed day occupancy (DH, 2004; DH, 2005b) as has been discussed in chapter 2.

Nowadays, the tendency is to bring patients from high levels of care to primary care and home settings. In this scenario, telehealth is one of the methods that can be used to improve and provide access to home remote patient monitoring – important in patients with chronic diseases as it can help to recognise any signs of deterioration, provide health education and support management of their condition.

Potentially, telehealth can reduce deaths, emergency visits, A&E visits, elective admissions and bed stays, and cost (Steventon et al., 2012). This can be done by designing and implementing proper telehealth interventions that reduce unnecessary visits to specialised healthcare services and monitor patients remotely at home. However, as shown in chapter 3, there is not a unique backbone for designing telehealth interventions. Designing and implementing telehealth interventions are not straightforward. According to Mair et al. (2012) the factors that promote or inhibit the implementation processes by which new health technologies and other complex interventions are routinely operational in everyday work are coherence (sense making work), cognitive participation (relationship work), collective action (enacting work) and reflexive monitoring

(appraisal work). In order to design a robust, accurate and reliable intervention a number of important factors that have been ignored in previous papers have to be taken into account. In addition to patient training, these factors include patients' individual requirements, technology to ensure safe interventions, ease of use, and data integration to electronic patient records, and clinical interventions such as development of procedures and allocation of staff appropriate to the corresponding health intervention. Without all these requirements in place a telehealth intervention is unlikely to show clinical effectiveness.

## **8.2 Summary of contributions**

The contributions of this research can be summarised as follows:

- Standardisation of common outcome measures to facilitate comparison among studies has been recommended.
- It has been demonstrated that meta-analysis can be used to determine from a quantitative approach the best case study in telehealth, for example, in the case of diabetes considered here.
- This research has provided an overall picture that telehealth interventions should be designed according to the patients' individual profiles and needs.
- Evidence that demographics and socio-economic variables can affect the patients' performance during a telehealth intervention has been provided. The strongest statistical examples include existing care provision and access to local medical and social care, age, education, general location of patient's home, and literacy in local language.
- A recommendation framework has been developed that includes the following components: patients' individual requirements, technology, training, clinical intervention, health care provider, and clinical effectiveness.

## **8.3 Review of the aim and objectives**

The aim of this research was to develop a framework applicable to a broad spectrum of telehealth interventions for patients with long term conditions. This has been achieved by meeting the following objectives:

*1. To provide a comprehensive review of literature on telehealth.* This has been reviewed and achieved in chapters 2 and 3. In chapter 2 some general topics such as definitions, life expectancy, health demand, benefits of telehealth, factors

of success and evaluation have been covered. In chapter 3, key research publications that addressed home monitoring in the management of diabetes, asthma, chronic obstructive pulmonary disease (COPD) and hypertension were identified.

*2. To identify the most effective telehealth interventions in the cases of diabetes, asthma, chronic obstructive pulmonary disease and hypertension.* 67 papers were identified and systematically reviewed in the cases of diabetes, hypertension, COPD and asthma and the main results were summarised using the PICO model for each paper. Additionally, we carried out a meta-analysis in the case of diabetes.

*3. To investigate any relationship between demographics, socio-economic status and patient's performance on telehealth.* Chapter 4 covered all the patient demographics from the case study (REALITY project) that was used for achieving this objective. In Chapter 5, the relationships between patients' demographics and performance were investigated. A set of indicators were selected from the case study data and test for associations were performed.

*4. To evaluate the clinical effectiveness of a telehealth intervention.* This has been achieved in two parts: chapter 3 and 6. In chapter 3, clinical effectiveness was evaluated by performing meta-analysis for the case of diabetes telehealth interventions, and in chapter 6, an evaluation of the case study was performed before and after by using a number of t-tests for different clinical sites.

*5. To summarise findings and make recommendations.* Summary of the findings and recommendations can be found in chapter 7. This chapter includes a number of recommendations made in order to achieve the aim of the study.

#### **8.4 Future research**

A number of recommendations have been made in order to carry out future work in this area of research:

1. The framework should be evaluated using real case scenarios and identify any flaws present within the recommendations.

2. The framework should be expanded by adding patients' privacy and confidentiality and legal aspects. These aspects are important concerns in any telehealth initiative since it has been reported as one of the sources of anxiety (Kidd et al., 2010).
3. Integration of home data collection with EPR systems is still an issue for a patient centred approach. More research is needed in this matter in order to satisfy the framework.
4. Further research needs to be done to fully understand the association between demographics and patient's performance.
5. A major limitation of the present research is the fact that the case study did not contain information on either staff characteristics or their behaviour regarding telehealth interventions. Further research should overcome this limitation and integrate that knowledge into the framework.
6. Due to the variations among the different telehealth interventions and the lack of reliable and sufficient data available in the literature, further research need to be done in order to guarantee that our framework recommendations can be generalised.

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