

Trinity College Dublin  
Centre for Health Informatics  
Department of Computer Science

**M.Sc. in Health Informatics**

**The challenges in implementing Remote Cardiac Patient  
Monitoring Solutions**

by

Fergal Kearns - 06136443

University of Dublin  
Trinity College

## **Declaration**

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university.

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## **Research Declaration**

Research ethics approval was granted by the School of Computer Science and Statistics for the patient interview component of the research described herein. The research involving the participation of professionals commenced after submission of an application for ethics approval, but before that process concluded. As retrospective ethics approval is not possible, I do not have an endorsement that this component of the study conforms to the ethical standards or good research practise guidelines of Trinity College Dublin.

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## **Abbreviations**

AARP - American Association of Retired Persons

AHA – American Heart Association

AHIMA – American Health Information Management Association

ARPU – Average Revenue Per User

CE - *Conformité Européenne*

CEN - Comité Européen de Normalisation

CENELEC - European Committee for Electrotechnical Standardization

COCIR - European Coordination Committee of the Radiological Electromedical and Healthcare IT Industry

CIS – Clinical Information Systems

CSO – Central Statistics Office

ECG – Electrocardiogram

ETSI - European Telecommunications Standards Institute

EU – European Union

GPRS - General Packet Radio Service

GSM – Groupe Spécial Mobile (now Global System for Mobile communication)

GSMA - Global System for Mobile communication Association

HIPAA - Health Insurance Portability and Accountability Act

HL7 – Health Level 7

HSE – Health Service Executive

HSPA – High Speed Packet Access

ICD – Implantable Cardioverter Defibrillators

ICT – Information & Communications Technology

IEGM - Intra cardiac electrogram

IHF – Irish Heart Foundation

IT – Information Technology

MHz – Megahertz

MQTT - Message Queuing Telemetry Transport

NHSC - National Horizon Scanning Centre

PSTN - Public Switched Telephone Network

RM – Remote Monitoring

SCD – Sudden Cardiac Death



SMS - Short Message Service

TTM - Trans Telephonic Monitoring

UMTS - Universal Mobile Telecommunications System

VF – Ventricular Fibrillation

VHI – Voluntary Health Insurance

VT - Ventricular Tachycardia

## **Abstract**

In western countries, heart disease is still the main cause of premature death and almost two thirds of cardiac deaths occur outside of hospital. Aging populations and the increased burden of chronic illness are escalating pressures on healthcare systems. In this type of environment solutions are required that can assist in managing increasing numbers of patients at a reduced cost while increasing the quality of care. It is clear too that methods and solutions are required to reduce the length of time between cardiac events and their treatment. eHealth solutions like remote monitoring technology offer one such solution. This dissertation seeks to examine some of the current remote cardiac patient monitoring solutions with a particular focus on those that manage the monitoring of cardiac patients who have been fitted with Implantable Cardioverter Defibrillators (ICD).

As part of the research effort interviews were conducted with experts in the field of mobile communications, information technology and medical devices. In order to understand the perspective of the ultimate users of these solutions, interviews were also conducted with a patient who has been implanted with a cardiac device, with the head of a relevant Patient Support Group and also with medical personnel working in the cardiac care arena.

The work examined and assessed the key challenges in this area particularly those in relation to the adoption of these technologies by patients and medical personnel alike. The work also established that the key challenges in relation to adoption, technologies and technology standards being used, the cost and reimbursement question and the legal and ethical issues still remain despite significant progress.

# 1 Introduction

‘Hackers find security holes in defibrillators’

(IBM, 2008)

As one IBM Security Analyst remarked in response to the above headline, ‘here’s a new twist on the phrase heart attack’ Researchers from the University of Massachusetts have discovered that the software in electric heart monitors can be hacked to collect private patient information or even deliver powerful electric shocks (IBM, 2008).

According to the same article, the researchers used a personal computer, a wireless radio, an oscilloscope, some antennas, and free software to hack into the software managing an implantable cardioverter defibrillator (ICD) and by gaining access to the device, the researchers ‘were able to disrupt its operation and even use it to administer a powerful shock that is said to feel like a kick to the chest’ (IBM, 2008).

Security risks such as the one described above are just one of many challenges posed to the successful and safe implementation of remote cardiac patient monitoring solutions.

This dissertation will explore the potential use of remote monitoring technology in delivering on the remote monitoring of patients with serious coronary conditions and the challenges to their implementation and use.

Remote health monitoring solutions fall under the category of ‘eHealth’ (or electronic health). eHealth is an ‘overarching term that is used to describe the application of information and communications technologies in the health sector’ (OMF, 2008).

The work will also look at the use of mobile technology in this area. This is known as mobile health or ‘mhealth’. mhealth has been defined as ‘the use of PDAs, tablet computers, subnotebooks, smart phones, wireless networks, mobile hardware peripherals, and all related software for healthcare’ (AIHMA, 2003).

This work will also seek to focus on cardiac patients who have been fitted with Implantable Cardioverter Defibrillators (ICDs) and the transmission and monitoring of the data produced by these devices. (An ICD is a device commonly used to treat patients who have experienced a potentially dangerous ventricular arrhythmia. These devices continuously monitor the heartbeat and automatically deliver a small electrical shock to the heart if a sustained rapid heart rhythm occurs (Johns Hopkins, 2007).

These solutions have much to offer patients and clinicians alike as using 'technologies to remotely monitor patients has many potential benefits, not the least of which is the improvement in quality of life which patients experience when they are in their home environment rather than a hospital' (Kirsch et al., 2007).

The other benefits of such systems include

- 'enablement of better utilization of limited healthcare resources (e.g. physician specialists)'
- 'a reduction in the hardships (physical and economic) associated with travel (for patients or physicians)'
- 'enablement of early diagnosis, intervention, and treatment in certain events'

(Chu, Ganz, 2005)

'By diminishing the frequency of clinic visits, remote monitoring may reduce health care costs and patients' inconvenience' (Reynolds et al., 2006). This has increasing importance given that people are living longer and health care costs are rising and, 'as older people begin to make up an increasing percentage of the world's population, caring for them is becoming more and more challenging' (Enterprise Ireland, 2007).

### **Research Question**

The Research questions can be defined as follows; what are the challenges associated with the implementation of remote monitoring systems for cardiac patients (particularly those with ICDs)?

## **Research Overview**

The Literature Review was used to identify the set of issues and challenges in this area as identified by other academic and commercial studies. These outputs were then grouped by relevant stakeholder i.e. the group or individual impacted. In addition the literature review assisted in identifying the key questions for stakeholders for the research phase to be used to support or disprove current analysis.

The questions were then sorted into their relevant area for inclusion in the pre-defined questionnaires to be used for the more structured interviews. Interview targets were selected, interviews arranged and conducted and the data was again clustered by groups and categories for the research analysis stage.

In this thesis a flexible design was employed so as to allow data collection to develop as new interviewees were identified (as the result, for example, of a previous interview) and access to new materials subsequently arose.

## **Outline of Dissertation**

Chapter 2 comprises a Literature Review of the state of the art and latest research on eHealth, mHealth, remote monitoring solutions and the challenges to implementing such systems.

Chapter 3 describes the research methodology and outlines the research approach adopted for this thesis and the research processes used.

Chapter 4 outlines the detail of the research primarily documenting the output of the research interviews with experts in this field.

Chapter 5 comprises an evaluation and discussion of the research data and the work closes with a Conclusions and future work section in Chapter 6.

## 2 Literature Review

‘A literature review surveys scholarly articles, books and other sources (e.g. dissertations, conference proceedings) relevant to a particular issue, area of research, or theory...the purpose is to offer an overview of significant literature published on a topic’(UCSC, 2005).

This literature review therefore seeks to ascertain the current state of the art with regard to ‘eHealth’ solutions that employ remote monitoring in the cardiac care of patients, particularly those patients who have been fitted with ICDs, and the potential for ‘mHealth’ solutions in this area. It will also outline the challenges to implementing these solutions and how the latest literature perceives progress in this area, particularly over the last decade.

The review will look at some of the drivers that exist for such technologies and for eHealth generally and the benefits that can be derived by their adoption. It will also examine some of the commercially available solutions and assess their effectiveness in fulfilling the stated requirements of such systems.

A wide variety of academic and industry journals were consulted for this review. The author did note however that many of the papers reviewed were written with the support of some of the device manufacturers and therefore not all analysis could be described as fully independent. (See Appendix F for notes on these conflicts of interest).

## 2.1 Remote Patient Monitoring

### 2.1.1 Introduction

‘Healthcare is in crisis’.  
(IBM, 2008)

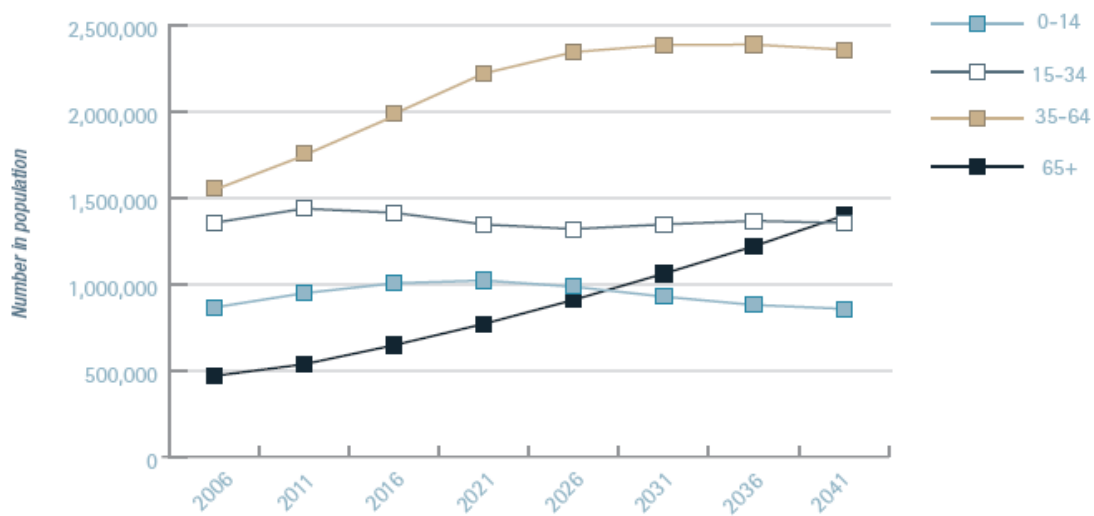
The IBM report ‘Healthcare 2015’ supports this statement by arguing that healthcare costs are rising rapidly, quality in healthcare is poor or inconsistent and that a new environment is emerging that is dominated by the pulls of ‘globalization, consumerism, demographic shifts, the increased burden of disease, and expensive new technologies and treatments’. (See also Table 2.1)

Some Healthcare Statistics
‘The United States spends 22 percent more than second-ranked Luxembourg, 49 percent more than third-ranked Switzerland on healthcare per capita, and 2.4 times the average of the other OECD countries. Yet, the World Health Organization ranks it 37th in overall health system performance’.
‘In Ontario, Canada’s most populous province, healthcare will account for 50 percent of governmental spending by 2011, two-thirds by 2017, and 100 percent by 2026’.
‘In China, 39 percent of the rural population and 36 percent of urban population cannot afford professional medical treatment despite the success of the country’s economic and social reforms over the past 25 years’.

Table 1.1 - Some Healthcare Statistics – IBM Healthcare 2015

Due to the growing aging population and the increasing number of people suffering from chronic illness, ‘over 50 per cent of hospital beds across Europe are estimated to be occupied by patients with chronic illness that require continuous monitoring’ in healthcare facilities. (Frost & Sullivan, 2005)

Population ageing is evident too in the current population composition in Ireland. While the ‘proportion of persons 65 years and over, currently at 10.9%, is relatively low compared to other countries the number of persons in this age group has increased by 33.2% between 1979 and 2008 and is projected to increase by a further 88.7% to approximately 908,800 persons by 2026’. (HSE, 2008) See also Figure 2.1



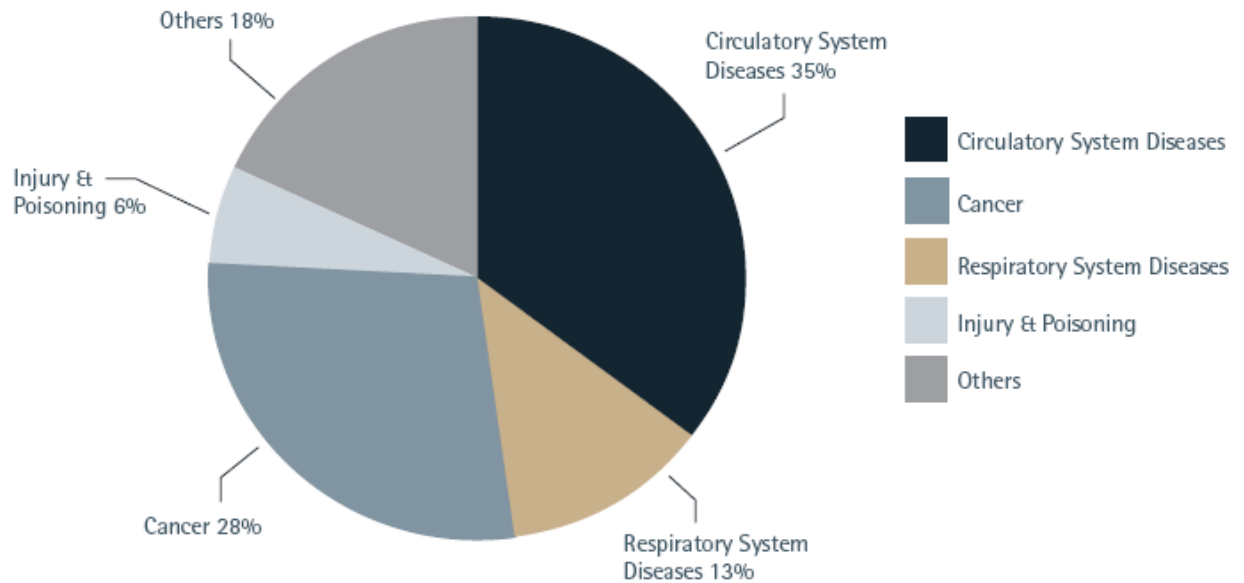
Source: Population and Labour Force Projections 2011-2041, CSO

Figure 2.1 Projected population changes (M2F2) by age group in Ireland, 2006 – 2041 (HSE, 2008)

According to Rubel et al. (2005), heart disease is still the main cause of premature death in western countries with almost two thirds of cardiac deaths occurring outside of hospitals indicating that the earlier treatment is given the better. New methods and solutions are therefore required to reduce the length of time between cardiac events and their treatment (Rubel et al. 2005).

Circulatory disease is ‘also the most common cause of death in Ireland, accounting for over one third (35%) of all deaths’ and ‘it is also a major cause of illness, accounting for 14.6% of all bed days used in acute hospitals’ (HSE, 2008). (See also Figure 2.2.)





Source: Vital Statistics, CSO.

Figure 2.2 Principal causes of death in Ireland, 2007

In its 2008 document ‘Priorities for Improving the Health & Wellbeing of the Population of Ireland’ the HSE have highlighted that it is ‘necessary to shift the balance from hospital to primary care - the major burden of illness and the main demand on services, are derived from chronic illnesses that can be...managed in primary care settings’.

In this type of environment solutions are required that can assist in managing increasing numbers of patients outside of the acute hospital sector, at a reduced cost while increasing the quality of care. One way of addressing some of these challenges in healthcare is through the provision of mobile or remote facilities for patient management. The literature variously describes this trend as the use of eHealth, ‘pervasive healthcare’ (Varshney, 2005) or ‘taking healthcare home’ (Frost & Sullivan, 2005). Varshney (2005) defines pervasive healthcare as ‘healthcare to anyone, anytime, and anywhere by removing location, time and other restraints while increasing both the coverage and the quality of healthcare’. Frost & Sullivan (2005) use the term ‘taking healthcare home’ when describing solutions like remote patient monitoring systems and trends in managing and caring for people with chronic illness. Information and communication technology (ICT) and remote patient monitoring is ‘likely to vastly alter the approach to healthcare delivery in the future’ (Frost & Sullivan, 2005).

In 2005, Varshney outlined some of the requirements of 'pervasive healthcare', they include:

- Appropriate levels of security through encryption, authentication, and access control to protect healthcare information and in turn appropriate levels of privacy and the ability to support patient anonymity
- Usable, reliable and mobile or wearable patient devices
- Usable, reliable, dynamic and available infrastructure with sufficient capacity and failover capability
- Business models that can bear the initial investment costs and secure the potential cost savings
- Solutions to the challenges faced by healthcare managers in relation to system adoption, training, regulatory and payment issues

Istepanian (2003) identified a number of key factors that could assist the with rollout of telemedicine solutions and they included:

- Adopting healthcare technology strategies that embrace mobile technologies
- Investment from central Government to fund pilot mobile health systems
- Funding for comprehensive feasibility studies (Istepanian was asserting that much work in this area was being left to 'enthusiasts')
- Create a greater awareness amongst key stakeholders in the health system of the advances in eHealth and mHealth
- Clarification of the legal and ethical issues

It is evident from the work of both authors that the key issues and challenges would appear to come from a number domains; Technology, Security, Cost, Adoption and Legal.

Technology will need to be robust, secure and interoperable. Solutions will need to be financed and shown to have demonstrable financial benefits. Barriers to adoption by both patients and medical personnel will need to be overcome as will any legal and ethical issues associated with maintaining and transmitting potentially confidential or sensitive information.

### **2.1.2 Remote Monitoring Technology**

Like many of the concepts at work in the Services sector remote monitoring has its roots in manufacturing. Baxter and De Jesus (2006) identified a combination of factors that have led to the latest form of predictive maintenance in industrial settings, that is, remote monitoring. New technologies and the internet have enabled automatic data collection and remote analysis and this method reduces expensive cumbersome manual data collection. Web access also means that data can be accessed from virtually any location at any time. They state that the key element of the shift to remote monitoring has been the development of wireless technology solutions.

In their 2006 paper 'Remote machine monitoring – a developing industry' Baxter and De Jesus outline some of the reasons to move to remote monitoring models using wireless technology:

- Ability to gather data from previously inaccessible areas
- Automated data gathering at any time regardless of location and to increase the frequency of monitoring and gathering of data
- Ability to collect more detailed information
- Ability to set accurate alarms

Many such remote monitoring processes and concepts have benefits for patients and medical personnel alike in the healthcare arena. The ability to gather detailed patient data from locations other than a hospital or clinic at any time is already proving beneficial for patients with chronic illness. There are already a number of systems in operation that facilitate this 'any time, any where' transfer of patient data for review by medical personnel.

One such example is the 'LifeStat' Remote Monitoring and Health Management service (a joint venture between Canadian company SaskTel and Alcatel-Lucent). This is a system for the management of diabetes and hypertension. The system records and transfers daily blood glucose and blood pressure readings automatically, creating reports that can be viewed online by patients, caregivers and health professionals (LifeStat, 2008).

Remote monitoring can also yield benefit for patients particularly for the remote interrogation of medical devices. The next section examines the use of remote monitoring for one such medical device; the Implantable Cardioverter Defibrillator or ICD.

### **2.1.3 Remote Monitoring Implantable Cardioverter Defibrillators (ICDs)**

‘95% of people with an ICD will survive an episode of sudden cardiac arrest’

(Boston Scientific, 2008).

#### **Background**

According to Reynolds et al. (2006) trans telephonic monitoring (TTM) was first introduced in the early 1970s to monitor the durability of pacemakers and the method was identified as a useful way of monitoring all the basic function of those systems; ‘particularly in the early era of pacemaker development when both lead and pulse generator longevities were unpredictable’ In subsequent years the method came to be used as a diagnostic tool for the identification of both device problems (like lead malfunction) and medical issues (like arrhythmias), and eventually the concept was adapted for use with ICDs (Reynolds et al. 2006).

#### **ICDs**

Implantable defibrillators ‘are used to treat abnormal heart rhythms which are a leading cause of preventable sudden death’ (IHF, 2007). Abnormal heart rhythms (or arrhythmias) occur where a heart rate is too fast, too slow or irregular and are caused by problems with the heart’s electrical system. There are a number of arrhythmias types; the term bradycardia describes a heart rate that’s too slow (less than 60 beats per minute), Tachycardia usually refers to a resting heart rate that’s too fast (more than 100 beats per minute). Severe Arrhythmias can lead to Ventricular fibrillation (or "V fib") – an extremely serious condition where the heart's lower chambers contract in a rapid, unsynchronized way. (AHA, 2009)

An ICD is a small metal covered electrical device that uses a battery-powered electronic circuit to monitor the rhythm of a patient’s heartbeat. When the device identifies an abnormal heart rhythm (or arrhythmia) it uses electrical impulses or shocks to restore normal rhythm in the heart. The ICD is small enough (approximately 5 cm in diameter) to be inserted under the skin usually near the patient’s shoulder area and electrode leads connect the device to the inside of the heart (IHF, 2007).

‘Patients with life-threatening arrhythmias who have not been fitted with an ICD are at high risk of sudden cardiac death’ and sudden death due to cardiac arrest affects 460,000 people each year in the United States (Boston Scientific, 2008).

ICDs have four major functions:

- ‘Sensing - the recognition of local atrial and ventricular electrogram signals’
- ‘Detection – the classification of sensed signals according to programmable heart rate zones’
- ‘Provision of therapy - to terminate ventricular tachycardia (VT) or ventricular fibrillation (VF)’
- ‘Pacing - for bradycardia and/or cardiac resynchronization therapy’.

(Stevenson et. al, 2004)

‘Appropriate and inappropriate therapies of implantable cardioverter defibrillators have a major impact on morbidity and quality of life in ICD recipients’ (Reynolds et al. 2006).

### **ICD Prevalence**

The rate of implantable cardioverter defibrillator (ICD) implantation has increased as ‘primary and secondary prevention trials have relatively consistently shown significant improvement in mortality and morbidity’ (Reynolds et al. 2006).

While it is difficult to assess accurately the most recent figures for the numbers of remotely monitored ICDs in use today some information is available.

According to Stevenson et al. in 2004 more than 100 000 ICDs were being implanted annually in the United States alone. Also in 2004 there were 2,337 ICDs implanted in the UK (NHSC, 2006) and Raatikainen et al. (2008) stated that, in Western Europe, 160 ICDs per million inhabitants are being implanted annually.

It is estimated that there are now over 2000 people in Ireland implanted with ICDs (IHF, 2007). According to Jung et al. (2008) over 200,000 patients worldwide are now being managed using remote ICD monitoring systems for the detection of either device issues or the latest patient physiological status.

Given that, as stated in the introduction, 95% of people with an ICD will survive an episode of sudden cardiac arrest and the ability of remote monitoring to provide almost instant communication of events; this has many positive implications for cardiac patients.

### **ICD Follow ups**

According to international guidelines, patients with ICDs should attend their cardiac clinic for a follow up review at 3-month intervals, ‘depending on the device model and the patient’s clinical status’ (Raatikainen et al. 2008). As many patients would also need to attend their clinic outside of their normal schedule this places quite a burden on ICD recipients. ‘Remote monitoring systems can substitute for routine follow-up visits and/or deliver continuous diagnostic and device status information’ (Reynolds et al. 2006). This therefore has the potential to reduce the need for attendance in person, an obvious benefit particularly for patients who may have to travel long distances for ICD follow up reviews.

### **Requirements of an ICD Monitoring System**

Jung et al. (2008) outlined the fundamental requirements of a remote ICD monitoring system. They state that these systems should have a positive impact on the quality of medical care and patients’ quality of life by:

- ‘allowing the early detection of arrhythmias, abnormal device functions, or changes in patients’ clinical status well ahead of scheduled follow-up’
- ‘helping in the design of individualized follow-up schedules to optimize the management of patients with frequent arrhythmias or technical complications, and reduce the cost and workload imposed by uncomplicated patients in stable clinical condition’
- ‘providing patients with the highest level of assurance that the implanted device functions properly and with the advantage of fewer regular, uneventful clinical visits’

(Jung et al 2008)

## 2.1.4 Remote ICD Monitoring in practice

In their simplest form all the available remote ICD monitoring solutions work in a 3 stage process – see Figure 2.1.



Figure 2.1 - The simplest model – (Biotronik, 2009)

- Data is transmitted from the ICD to a patient device
- Data is then transferred from that device to a central database
- Action by clinician based on the data

According to a National Horizon Scanning Centre (University of Birmingham) study conducted in 2006 there are just four systems available for the remote monitoring and/or interrogation of implantable devices. They are German device maker Biotronik's 'Cardiomessenger' service, Medtronic's 'CareLink' software, Boston Scientific's 'Latitude' System and the 'Housecall' System from St Jude Medical who are all U.S. based (NHSC, 2006).

(See Appendix D for more detail on these organisations).

The main differences between the various monitoring systems relate to 'the frequency of data transmission and report generation, type of reports generated, degree of patient involvement required for successful transmissions, sensor technologies, and mobility offered to the patient and transmitter' (Jung et al. 2008).

Following device programming during an out-patient visit all four solutions do however all work in a very similar way; as illustrated in Figure 2.1 data is transmitted from the ICD to a patient device, it is then transferred from that device to a central database where action is subsequently taken by medical personnel based on the data presented.



## Stage 1 – ICD Transmission

A small, integrated antenna in the ICD sends medical and technical information to a patient monitoring and communication device. The type of information is dependent on what the clinician has programmed for but the data would usually include information on device functions and several clinical elements including the following:

- clinically relevant changes like Arrhythmias that have occurred;
- Intra cardiac electrogram (IEGM) history
- Therapies (paces/shocks) delivered by the implant;
- implant's battery status;
- the status of the leads.
- general device status

(Jung et al., 2008)

(For a device specific example of programmable event triggers see Appendix C).

While all systems effectively produce the same data as would be gained from a normal follow up, the Biotronik system however uses 'daily automatic device-initiated transmission of the above mentioned subset of data, i.e., less data with a much higher frequency compared to the standard in-office follow-up' (Brugada, 2006).

## Stage 2 - Monitoring System

The patient monitoring and communication device then transmits this event data either on a daily basis, at fixed time intervals, or immediately upon the occurrence of a clinically relevant event (Jung et al. 2008). The Medtronic, Latitude and St Jude Medical variants all use a monitoring and communications device in the patient's home though patients can travel once they have access to a standard analogue phone line (Internet access is not required) (Medtronic, 2008 – see also Table 2.1).

With the Biotronik device data transmission is automatic and does not require patient initiation but the largest difference between this product and the other three is the method of transmission - the Biotronik device uses mobile telecommunications to send patient data back for analysis (Biotonik, 2009).

In the US, both the 'CareLink' and 'Latitude' systems offer the choice of 'active' or 'patient initiated' monitoring. Active Monitoring uses a wireless device to automatically collect data from the implanted device, whereas patient-Initiated monitoring uses a "wand" that the patient uses to check the device (Boston Scientific, 2008 – see also Table 2.1).

### Stage 3 - Data Analysis

The third stage in the process is where medical personnel review and assess the transmitted data. This provides the reviewer with an overview of a patient's progress during treatment, it also allows medical personnel to detect any changes in a patient's physical status in a timely manner and to adjust the ICD accordingly and the accumulation of data over time allows medical staff to also view a patient's historical trends (Jung et al. 2008). With the Medtronic system patients also have some limited access to their own data (Jung et al. 2008). One of the key differences with the St Jude Medical system is that it can operate in real time for consultations with a medical professional. (St Jude Medical, 2009).

## System Comparison

Parameter	Biotronik: Home Monitoring	Medtronic: Carelink Network	Boston Scientific: Latitude	St. Jude House Call Plus
FDA approval (year)	2001	2005	2006	2007
Name(s)	CardioMessenger	PatientLook, SentryCheck	Latitude Communicator	HouseCall Plus
Characteristic	Portable, simple	Stationary, simple	Stationary, interactive:	Stationary, voice interaction
Home telemetry				
USA	MICS	MICS, wand	Wireless, wand	MICS
EU, rest of world	MICS	Wand	Not available	Wand
Wireless products <sup>a</sup>	All products	ICD, CRT-D	All products	ICD, CRT-D
Patient reminder for manual transmission	Automatic only	None	Yes	None
Patient trigger to take action <sup>b</sup>	CardioMessenger call-back light	Audio	Audio	Vibration
Long-range telemetry	4-band GSM, GPRS mobile, landline	Landline	Landline	Landline
Caregiver interaction during transmission	No	No (wireless), Yes (wand)	No (wireless), Yes (wand)	Yes
Transmission	Daily FU, event messages (automatic)	Scheduled FU, event messages (patient initiated)	Scheduled FU, event messages (patient initiated)	Patient initiated (manual)
Information channels by events	Fax, E-mail, text message	E-mail, text message	Fax, phone	Fax, internet, EMR
Early detection	<24 h (all event types)	<24 h (some event types)	<24 h (some event types)	n.a.
Data storage	Long-term	Long-term	Long-term	Long-term
Interface with EMR	HL7	HL7, some EMR	HL7	HL7, some EMR
Data presentation	Event-based guidance	Event-based guidance	Traffic light-based guidance	Event-based guidance
IEGM or real-time Holter transmission	Event-triggered IEGM (up to 45 s)	Pacemaker Holter, 10 s IEGM strip on request	Pacemaker Holter	n.a.
Sensor	Heart failure Monitor	OptiVol (intrathoracic impedance), Cardiac compass	Weight, blood pressure, symptoms, pacemaker statistics	Pacemaker statistics, surface ECG
Cognitive interpretation	Physician	Raytel partnership	Raytel partnership	Mednet, Raytel, PHTS partnership
Impact of daily monitoring on battery longevity	Low	High	High	n.a.

**Table 2.1** Remote patient management systems in 2008 (Jung et. al., 2008)

## **2.1.5 Benefits of Remote Monitoring ICDs**

The Literature identifies a number of significant benefits presented by the remote monitoring of ICDs including

- a direct medical benefit to the patient
- a reduced burden on the patient (in terms of travel, inconvenience etc.)
- a reduced cost burden on the patient
- a reduced cost burden on the healthcare system

### **2.1.5.1 Medical Benefits**

According to Raatikainen et al. (2008), recent studies of remote monitoring with automatic data transmission have been shown to improve the early detection of both device malfunction and serious arrhythmias.

Nielsen et al. (2008) study of remote monitoring data also discovered that it successfully allowed the monitoring of both ‘the frequency of arrhythmic events and therapeutic outcomes’. Benefits reported to date include

- ‘the discovery of clinically relevant but minimally symptomatic incessant VT in several cases’
- ‘detection of inadequate shock and anti-tachycardia pacing therapies because of sinus tachycardia’
- ‘supraventricular tachycardia or T-wave over-sensing’
- ‘tracking of the episodes of recurrent slow VT’
- ‘unfolding pro-arrhythmic effects of medications’
- ‘reassuring concerned patients that no VT or VF therapy was delivered’.

(Nielsen et al. 2008)

### 2.1.5.2 Patient Benefit

Raatikainen et al. (2008) contend that as remote monitoring reduces the requirement for unnecessary visits to hospitals/clinicians that this is likely 'to alleviate the anxiety of the patients as remote monitoring provides a prompt response to their concerns'. Res et al. (2006) concur and state that even if a patient does have to attend a clinician as a result of a remote monitoring initiated event then subsequent ICD programming should reduce further the risk of future events or device issues.

In their study of the Biotronik remote monitoring system Res et al. (2006) assert that despite the fact that many patients were elderly there was a high degree of acceptance to the technology. There were very few issues with regard to the ability to cope with the technology itself and 'a high or very high level of satisfaction with [the system] was claimed by 97% of our patients. Patients appreciated the fact that ventricular arrhythmias could be traced and followed, and that they could be summoned for treatment' (Res et al. 2006). Joseph et al. (2004) identified that after using remote monitoring system patients:

- were able to maintain their relationship with their clinician,
- saw that clinicians were able to give better informed advice over the phone as they had the same information that they previously could obtain only in person
- Found the system easy to learn (and to its full potential)
- Found the system less intrusive to their social lives
- indicated a high level of satisfaction with the ease of use of the system
- enjoyed the convenience, associated time saving and reliability of the system. (see Figure 2.2)
- Found that despite initial misgivings that they would lose contact with their doctor, they were in fact available as necessary

(Joseph et al. 2004)

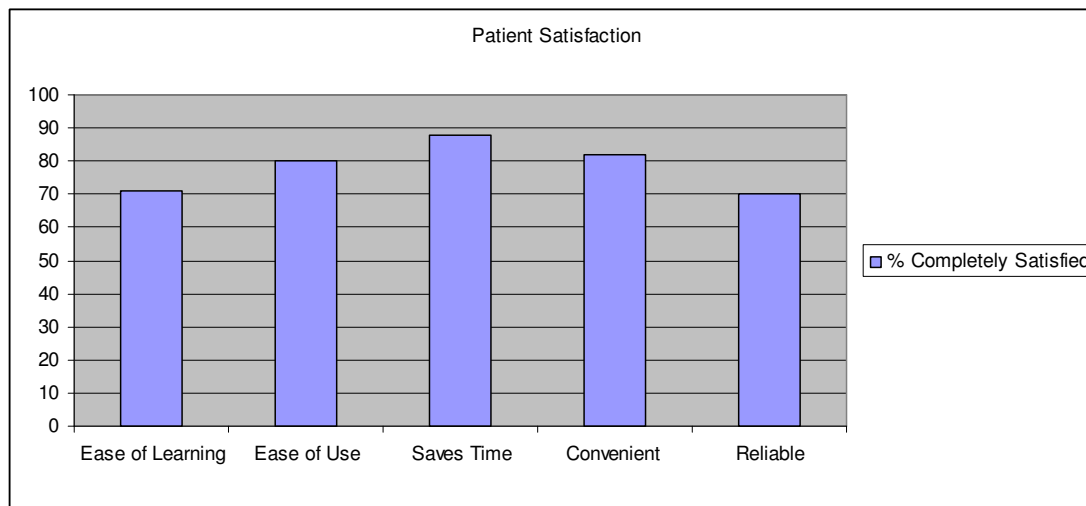


Figure 2.2 – Patient Satisfaction (Joseph et al. 2004)

While much of the literature highlighted the many positives for patient outcomes and usage one note of caution was sounded by Jung et al. (2008); ‘Some systems require that patient interact with the device and follow instructions to answer specific questions to more accurately assess changes in general health status. Whether patients will comply with this daily routine and support this robust remote data collection process remains to be determined’ (Jung et al. 2008).

### 2.1.5.3 Cost Savings benefit

There are number of studies describing cost saving as a significant benefit of remote monitoring of patients with ICDs. Much of the literature points to travel costs to and from hospitals as being a major proportion of the cost of ICD follow-up ‘therefore, the greatest cost benefit is expected among patients who live far away from the device clinic’ (Raatikainen et al. 2008). This is confirmed by Fauchier et al. (2005) who estimated that remote monitoring reduced the overall cost of ICD follow-up when the distance between home and the device clinic was greater than 100 km.

According to Heidbuchel et al. (2008) 160 ICDs per million inhabitants are implanted annually in Western Europe. On that basis ‘it can be calculated that if remote monitoring were to be applied to all the patients with new ICDs, the annual saving for the healthcare system would be 16–23 million euro’ (Heidbuchel et al. 2008).

A more recent study in 2008 by Raatikainen et al. re-asserted that remote monitoring offered a cost-effective solution to ICD follow-up. Their study followed 41 patients who had been previously fitted with ICDs, for a period of 9 months. 119 scheduled and 18 unscheduled data transmissions were performed. Remote monitoring required less time from patients and physicians to complete the follow-up when compared with normal visits. Substitution of two routine in-office visits during the study by remote monitoring reduced the overall cost of routine ICD follow-up by €523 per patient (or 41%). See Table 2.2.

	Standard follow up	Remote follow up	Savings €
Number of scheduled visits			
In-office visits	164	82	
Remote data transmission	0	82	
Direct cost	€	€	€
In-office visit fee	34,440	17,220	17 220
Remote monitoring	0.00	4510	-4510
Patient fee	3608	1804	1804
Indirect cost			
Travelling	12 195	6097	6097
Accommodation	40	20	20
Sickness allowance	1672	836	880
Total costs	51 955	30 487	21467
Total costs per patient	1267	743	523

**Table 2.2** - Comparison between the cost of standard and remote ICD follow-up (Raatikainen et al, 2008)

However, another clinician contends that ‘to justify adding the expense of remote monitoring to an already expensive therapy requires evidence of what utility is gained from the incremental expense’ (Marine, 2009).

Marine goes on to state that given that ICD leads have a 2% annual failure rate, one-third of which result in inappropriate shocks, and that remote monitoring can reduce this rate by 50%, there is therefore a cost of \$90,000 associated with preventing one case of inappropriate shocks.

There are two new studies occurring in 2009 which may yield higher quality data as to the costs and benefits of remote monitoring of ICDs. (It should be noted that these are manufacturer studies and therefore not necessarily independent validations).

The first is the 'TRUST' study which will assess 1000 randomly assigned patients (in a 1:2 ratio) to receive either usual follow-up or daily wireless remote monitoring with the Biotronik Home Monitoring system. This will run for 15 months and the results are expected mid to late 2009. The second is the 'CONNECT' study which involves an assessment of 2000 patients (in a 1:1 ratio between usual and remote follow up) on the Medtronic Carelink system. The results of that study are also expected in late 2009. (Marine, 2009)



## **2.1.6 Remote Monitoring using Mobile Technology**

Many industries now utilise remote monitoring technologies using wireless and mobile solutions. The simplest forms of remote monitoring applications use text messaging from a mobile phone over a GSM/UMTS network and these systems are designed to allow the unattended operation of equipment and the transmission of fault alarms as well as status information (Tel-me, 2005). (See also Appendix A).

The use of mobile technology in the remote monitoring of both people and systems has moved into the Health sector too and as Varshey (2005) points out, 'the role of wireless infrastructure in healthcare application is expected to become more prominent with an increasingly mobile society and the deployment of mobile and wireless networks'.

Mobile technology is already being used for the remote monitoring of some ICD patients. One of the commercially available systems discussed in Section 2.1.4, Biotronik's 'CardioMessenger' system, operates like a mobile phone and uses mobile technology to automatically forward the data gathered by the ICD (in an encrypted format) via a mobile network to a central database where the data is processed and forwarded to a secure internet site (Biotronik, 2009). In the event of a serious issue the medical contact 'is alerted via e-mail, text or fax while a light on the device advises the patient to immediately contact their clinician' (Biotronik, 2009).

By the end of September 2009 there were over 3.6 billion mobile devices active world-wide (GSMA, 2009) i.e. almost one device for every two people on the planet. Mobile phone penetration in Ireland is still rising and there were 103 mobile phones for every 100 people in the country in the second quarter of 2006 (CSO, 2007). Even in developed countries the use of mobiles has overtaken land lines. In Finland for example, there are currently 5.7 million mobile phones (108 per 100 inhabitants) and only 1.9 million analogue phone lines (Raatikainen et al. 2008).

Outside of ICD monitoring there are now many examples of medical solutions that enable medical personnel to remotely monitor and collect patient information (including real-time patient data like daily blood glucose or blood pressure readings) using the patient's own mobile phone - one such system is provided by T+ Medical in the UK (PRWeb, 2008).

## **2.2 Challenges to Implementation**

The Literature identifies many challenges to the successful implementation of remote monitoring systems in healthcare including

- Adoption (by both Patients and the medical community)
- Technology challenges and limitations
- Cost and Reimbursement issues
- Legal and Ethical challenges
- Standards issues

### **2.2.1 Adoption**

#### **2.2.1.1 Adoption by Patients**

As already described in Section 2.1 there is a high degree of acceptance among patients for new solutions in the area. However there are still some challenges to the future adoption of these technologies by cardiac patients.

One risk area is that patients fail to follow the exact requirements of their treatment or the management of their system. ‘Some systems require that patient interact with the device and follow instructions to answer specific questions to more accurately assess changes in general health status. Whether patients will comply with this daily routine and support this robust remote data collection process remains to be determined’ (Jung et al. 2008). Nielsen et al. (2008) assert that in order to avoid setbacks because of in compliance, patients should preferably play no active role in the monitoring process. Currently only one commercially available system offers fully automated remote monitoring capabilities although that facility will probably be included in future developments by the other manufacturers (Jung et al. 2008).

Another challenge is being driven by the increasing prevalence of mobile phones and their use as a substitute for land lines and thus a steady reduction in land line usage.

However, of the four commercially available technologies for the remote monitoring of patients with ICDs, only one is mobile. (The Biotronik device is fully portable and so regardless of patient location information can be transferred and received (Biotronik. 2008)).

Raatkainen et al. (2008) identified the lack of mobility as being a specific weakness of the Medtronic system with regard to clinical usability. 'The main problem of the present CareLink network is that device data must be transmitted via a standard analogue phone line. Thus, it is not surprising that presently ~50% of the patients in our hospital district cannot use the system. Therefore, a system that can send data automatically via a mobile phone network would be a more attractive alternative' (Raatkainen et al. 2008)

Schoenfeld et al. (2005) ask to what extent remote monitoring of ICDs will 'fit' into any individual patient's follow-up program, and what are the indications for its usage? They state that this will reflect a variety of issues, including 'proximity of the patient to the follow-up centre, costs, and both the acuity and stability of the patient's medical condition. More frequent monitoring may be required immediately following an implant and also as the device approaches its end of service life.'

### **2.2.1.2 Adoption by Medical Personnel**

While the literature points to some major benefits to clinicians for the use of remote monitoring systems there are also some drawbacks highlighted particularly with regard to the fact that the number of ICD recipients is on the increase and 'more complex devices are leading to rapidly increasing workload for the follow-up of these patients in specialized centres' (Heidbuchel et al. 2008)

Res et al. (2006) suggest that implementation of these types of solutions 'may allow the treatment of three times the number of patients compared to the standard care approach'. This correspondingly means an increase in automated notifications resulting in additional 'burden to the physician, nursing, and technical personnel' (Nielsen et al. 2008) and 'checking daily reports will require investments in [additional] infrastructure, personnel, and training (Heidbuchel et al. 2008).

However, Raatikainen et al. (2008) see remote monitoring as giving clinicians extra time to spend with patients with critical conditions and better 'ensuring medical efficiency, and better overall patient management, which is expected to reduce the cost of the treatment even further'.

Istepanian (2003) identified that another challenge for clinicians in future would be the increased expectation of patients for their care. He suggests that because of easier access to information 'the pre-eminence of the physician will be challenged'.

According to Wireless Healthcare (2005) the key barrier to adoption of many ehealth systems may well be the medical community's resistance to change as 'nurses, clinicians and consultants are concerned that automation will impact on their careers and lead to job losses'. The report suggests these fears may well be justified as governments seek ways to tackle spiraling healthcare costs.

In summary a number of key challenges emerge as to the ability and willingness of medical personnel to adopt to such technologies including cultural issues, fears around increased, or paradoxically, reduced workload and concerns around future job security.

## 2.2.2 Technology challenges and limitations

Reliable, fast and fully redundant networks are critical to the success of any wireless service and Varshney (2005) states that wireless health monitoring will require systems that work even where there are:

- Networks outages: when base stations, mobile devices, or databases experience failure
- Coverage limitations: when mobile networks experience coverage issues
- Intermittent access: when a device is unable to access a network continuously (systems should be fully redundant and with an ability to change to a different network if required)

‘We are defending against a denial-of-service attack, and will update status again shortly’. (Twitter.com, 2009)

As this most recent example shows, internet availability is increasingly under threat from ‘Denial of Service’ attacks and, while mobile phone networks are increasingly reliable they are still susceptible to external and internal events that can and do impact coverage and availability.

A ‘Denial of Service’ is ‘an attack on a system (typically a server or a network) that aims to crash, block or overload the system and thereby deny its services to others’ (Cryer, 2009). Given that many remote monitoring solutions use the Internet to allow medical personnel analyse patient information these types of attacks do present a threat to both the system itself and to patient safety.

Telefonica O2 Ireland has stated that their network covers 99.6% of the population and 95% of the country (O2, 2009) and though comprehensive there are still obvious gaps. In the author’s time as an employee of O2 (1997 – 2008) complete network outages were rare occurrences but did happen on occasion due to significant weather events, industrial accidents and server failures.

Chu & Ganz (2000) highlight a risk with some 3G access links and state that they can be subject to fluctuations in rates of data transfer e.g. Verizon code division multiple access (CDMA) wireless data service, provides data rates of up to 153Kbps but the actual throughput is fluctuant with an average throughput of around 70Kbps. They suggest that the implementation of mobile telemedicine systems over such a network require 'special considerations' (Chu & Ganz, 2000)

### **2.2.3 Technical Limitations**

Both Brugada (2006) and Raatkinen et al. (2008) highlight that none of the systems currently commercially available allows for remote device programming.

In the case of a requirement for re-programming of the device, the only option is to attend a physician in person. Jung et al. (2008) suggest that it is unlikely that this type of functionality will become available in the foreseeable future primarily because of regulatory issues.

That view is shared by Schoenfeld et al. (2005) who state that the reprogramming of ICDs remotely 'has additional caveats, both technical and ethical, that need to be addressed before widespread implementation will be possible'.

### **2.2.4 Reimbursement**

'Ultimately, one of the major factors dictating a more universal adoption of the technology may well be that of cost, i.e., who pays for it?' (Schoenfeld et al. 2005)

According to Jung et al. (2008) 'slow progress in confirming the clinical benefits of remote monitoring is limiting appropriate reimbursement in many countries' but that where reimbursement is the norm there is greater utilisation of the technology.

'Currently, European governments do not reimburse remote monitoring of patients and this acts as the most important challenge that is facing the European remote patient monitoring market' (Frost & Sullivan, 2005).

Jung et al. (2008) broadly concur by stating that while most state Medicaid programs in the U.S. offer some reimbursement for telemedicine services, across Europe only one country, Germany, reimburses for remote monitoring at a similar rate to the normal method (and there is currently no constraint to the number of remote interrogations that the medical practitioner can seek). Neither the UK nor France offers reimbursement for remote monitoring and ‘generally, the reimbursement for remote monitoring of implanted devices in the European Union is very limited, which might slow its adoption in other parts of the world’ (Jung et al. 2008).

### **2.2.5 Legal & Ethical Issues**

Data privacy is always a concern particularly where confidential or sensitive information is being managed. Schoenfeld et al. (2005) pose a number of questions in this area including

- ‘who should be allowed to access data obtained from remote monitoring?’
- ‘who is “qualified” to access this data and who should be allowed to: the physician, allied professional, field representative, patient, third parties?’
- ‘Should a patient be empowered to review all data via the Internet, or should limits be set (e.g., patient can only query battery status and confirm device discharges)?’

(Schoenfeld et al. 2005)

Jung et al. (2008) raise some legal issues and ask who has the legal responsibility when an alert regarding, for example, a serious device issue is made. If a patient sends data that is not viewed or acted upon in a timely manner then ‘who is responsible, particularly if a poor outcome arises from delayed interrogation?’ (Schoenfeld et al. 2005) Data transferred using these solutions become ‘part of the medical records and obligates the caregiver to take action. Guidelines need to be issued, which spell out at which intervals the remote data need to be reviewed and documented’ (Jung et al. 2008)

Singh (2006) suggests that there are ‘several potential points during data transmission in telemedicine (and even the nature and setting of telemedicine itself), which makes it a likely candidate for HIPAA (Health Insurance Portability and Accountability Act) violation’. (HIPAA is a 1996 U.S. Act of Congress which includes provisions to address the security and privacy of health data (Varshney, 2005)).

Jung et al. (2008) suggest that patients need to understand the constraints of remote monitoring processes and systems and should be informed that even though their status is checked regularly (and despite the use of alarm-type functionality) these are *not* emergency systems.

As Nielsen et al. (2008) describe, while remote monitoring does indeed shorten the reaction time of medical staff to events, that the estimated average duration between an event occurring and notification to a doctor was approximately 12 hours.

#### Data Protection

According to the Irish Data Protection Commissioner, the confidentiality of patient records ‘forms part of the ancient Hippocratic Oath, and is central to the ethical tradition of medicine and health care and that this tradition of confidentiality is in line with the requirements of the Data Protection Acts 1988 & 2003’. These acts state that personal data must be obtained ‘for a specified purpose, and must not be disclosed to any third party except in a manner compatible with that purpose’ (DPC, 2009). However the Data Protection Commissioner recommends some additional effort in this sector that, to date, has not been completed. They state that it would be ‘preferable for comprehensive and carefully thought-through guidelines to be designed by the appropriate representative bodies in this sector, by way of statutory codes of practice’ (DPC, 2009).



### 2.2.5.1 Safety Issues

As already described in the introduction there is a risk to patient safety as a result of potential hacking attack. As shown in the introduction to this work, implantable cardioverter defibrillators are potentially ‘susceptible to malicious attacks that violate the privacy of patient information and medical telemetry, and also may experience malicious alteration to the integrity of information or state, including patient data and therapy settings for when and how shocks are administered’ (Halperin et al. 2008). Brugada (2006) identified a number of safety concerns or risks following his study of one remote monitoring device. They included

- a failure to detect a number of cases where lead dislodgement had occurred
- an issue where symptoms or problems are reported by the patient but are not mirrored by any indicators in the remote monitoring data
- the risk of delays in identifying new or worsened conditions if a patient is seen less often

(Brugada, 2006)

It should be noted though that the system examined by Brugada is now obsolete however; it does remain an area of potential concern.

Another safety issue was identified during a study conducted at the University of Heidelberg of 240 patients implanted with ICD devices that had patient-alert features; a total of 22 serious complications (requiring either reprogramming or device/lead replacement) were seen, only 14 of which were identified through a patient alert (Becker et al. 2004).

## 2.2.6 Standards, Licensing & Regulation

According to a 2005 Frost & Sullivan report ‘the European Union currently has a very fragmented healthcare system and standardisation and the implementation of a common code for remote monitoring is a major factor, which needs to be addressed’.

eHealth-INTEROP (a sub-group of the European Standardisation Organisations alliance) recently published a report ‘warning of gaps and overlaps in ehealth standards’ and they identified one of the major risks of not having robust standards by stating that ‘despite implementers’ and users’ expectations a standard fails to address all the aspects necessary for implementation – so a ‘local’ solution is produced, leading to a lack of interoperability... implementations of the same combination of standards with different approaches to linking them results in incompatibilities and non-interoperability’ (eHealthEurope, 2009).

Interoperability has been defined as ‘the ability of a network to coordinate and communicate with other networks, such as two systems based on different protocols or technologies’ (Openmarket, 2009)

Robust standards and systems interoperability will be crucial to the success of developments in eHealth.

According to a report commissioned by the Continue Health Alliance in 2008, a number of different types of interoperability must be achieved to support remote patient management and examples of the connections that must be made to transmit patient information include:

- ‘Connecting devices that collect data, such as a home monitoring station’
- ‘Transporting data collected remotely to a central repository’
- ‘Sharing data from a central repository with care providers’
- ‘Incorporating data from a central repository into information systems, such as electronic health records, maintained by care providers’.

(HealthPolicyR&D, 2008)

There are many standards organisations working in the area of ehealth. They include:

- ‘CEN - The European Committee for Standardization, founded in 1961 by the national standards bodies in the European Economic Community and EFTA. The scope of CEN standards work is very broad; effectively it covers by default all areas not addressed by the more specific scopes of CENELEC and ETSI’.
- ‘CENELEC - The European Committee for Electrotechnical Standardization, is a technical organisation composed of the National Electro technical Committees of 30 European countries whose scope is to prepare electro technical standards for electrical and electronic goods and services including eHealth’
- ‘ETSI - The European Telecommunications Standards Institute (ETSI) defines electronic communication standards for products and processes, including protocols and testing, in information & communication technology (ICT)’.
- ‘CDISC - Clinical Data Interchange Standards Consortium is a global organisation that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata’.
- ‘IHTSDO - The International Health Terminology Standards Development Organisation, which owns and administers the rights to SNOMED CT and other health terminologies’.
- ‘ISO (International Organization for Standardization) is the world largest standards developing organisation. They are involved in the development of ISO standards and deliverables that adapt their generic management system to specific sectors or aspects including Medical devices’.

(eHealth-INTEROP, 2009)

Another standards body working in the area of remote cardiac monitoring is OpenECG. OpenECG's objective is to 'promote the consistent use of format and communication standards for computerised ECGs and to pave the way towards developing similar standards for stress ECG, Holter ECG, and real-time monitoring and OpenECG plans to bring the SCP-ECG (Standard Communications Protocol for Computer-Assisted Electrocardiography) to life by supporting specific implementations and applications' (OpenECG, 2009).

Of particular interest to this study though is the work of the following standards organisations; the IHE, Continua, HL7, IEEE and WS-I.

The goal of Integrating the Healthcare Enterprise (IHE) is to 'improve the quality, efficiency and safety of clinical care by making relevant health information conveniently accessible to patients and authorized care providers. IHE brings together users and developers of healthcare information technology (HIT) in an annually recurring four-step process' (IHE, 2009). The process is as follows:

1. 'Clinical and technical experts define critical use cases for information sharing'.
2. 'Technical experts create detailed specifications for communication among systems to address these use cases, selecting and optimizing established standards'.
3. 'Industry implements these specifications called IHE Profiles in HIT systems'.
4. 'IHE tests vendors' systems at carefully planned and supervised events called Connectathons'

(IHE, 2009)

The Continua Health Alliance is a 'membership organisation with around 160 members, a majority of whom are product manufacturers. Their Version 1 Guidelines combine healthcare informatics data standards with consumer electronic technologies and this integration provides the specifications necessary to enable connectivity across a wide variety of personal telehealth devices and services. The Version One standards for devices include the Bluetooth Health Device Profile (HDP)' (eHealth-INTEROP, 2009) a standard that could be beneficial to future remote monitoring development.

HL7 (Health Level 7) is a 'US-headquartered standards organisation, based on individual or corporate membership' (eHealth-INTEROP, 2009). Health Level Seven (HL7) refers

to the standards for the ‘exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services’ (HL7, 2009)

IEEE is ‘one of the world's largest professional associations for the advancement of technology with in excess of 375,000 members.. IEEE are engaged in a number of activities of specific relevance to eHealth one of which is the 11073 standard concerned with medical and personal health device communications’ (eHealth-INTEROP, 2009).

The Web Services Interoperability Organization (WS-I) is an ‘open industry organization chartered to establish Best Practices for Web services interoperability, for selected groups of Web services standards, across platforms, operating systems and programming languages’ (WSI, 2009).

The reason for the significance of this list is that in August 2009, just as this work was completing, a major announcement was made by Continua and IHE where they formally agreed to ‘a single set of content, transport, and vocabulary standards that work for all devices - home-based and hospital-based, simple and complex. This means that the industry is free to innovate and regardless of the devices created, they will be interoperable’ (Healthcare ITNews, 2009). The standards chosen were:

‘Content - HL7 v2.6 messages using IHE PCD-01’

‘Vocabulary - Constrained to IEEE/ISO 11073-20601/11073-104xx nomenclature’

‘Transport - Web Services transport based on WS-I Basic Profile’

(Healthcare ITNews, 2009).

These two organizations believe that this development ‘accelerates the deployment of convenient and reliable home-based health monitoring and care, and facilitates many other forms of remote monitoring as well. It makes it possible for vendors of Medical Devices and Personal Health Devices to efficiently send patient data to the Personal and Electronic Health Records vendors using a single unified interoperability standard’ (Healthcare ITNews, 2009).

### 2.2.6.1 Standards for Monitoring ICDs

As Table 2.1 showed all the available remote monitoring solutions for ICDs use the same standards - the MICS standard is used for the transmission of telemetry data to the monitoring device and the HL7 standard (already discussed) for interfacing back into IT systems.

The 402-405 MHz Medical Implant Communications Service (MICS) band is the 'dedicated radio frequency (RF) communication system linking implanted electronic medical devices and their programming and monitoring systems. The 402-405 MHz band is well suited for in-body communication networks due to its international availability, compatibility with the incumbent users of the band (weather balloons) and signal propagation characteristics of the human body which has relatively low attenuation at these frequencies' (ECN, 2009).

However, it is important to note the proprietary nature of the current remote monitoring systems for ICDs and that despite similar standards the systems are still not fully interoperable, each system can only be used with devices manufactured by the same company (Schoenfeld et al. 2005). This poses some issues for clinicians and Schoenfeld et al. (2005) pose the following question 'Are physicians who follow ICDs then required to purchase and/or contract out remote-monitoring systems for all manufacturers that they utilize, or limit the choice of manufacturer to a specific ICD and/or monitoring system?' They ask 'how, if at all, to universalize remote monitoring' while Nielsen et al. (2008) adds that, 'at the dawn of the era of evolving medical records, there are appeals to establish common approaches to transmission and storage of data generated by ICDs of different manufacturers'.

Complications exist too internationally so for example in Europe, 'only the 'wand' versions are available for the Medtronic ICD monitoring system as the wireless 914-MHz frequency bandwidth used in their 'active' monitoring solution is not approved for medical device implants outside the USA' (Jung et al. 2008).

### **2.2.6.2 Licensing & Regulatory Structures**

All medical devices in use in Ireland and the EU must carry the CE mark (IMB, 2008). The European Union Medical Devices Directives sets out ‘the essential requirements to ensure that a medical device will not compromise the health and safety of the patient, user or any other person, and that any risks associated with the device are compatible with patient health and protection’ (NSAI, 2009). CE marking on a medical device is a ‘manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation’ which then allows the product to be freely placed on the market within the EU (NSAI, 2009).

The ‘Competent Authority’ in Ireland for the regulation of medical products in Ireland is the Irish Medicines Board (IMB) (NSAI, 2009). The IMB also ‘regulates clinical trials, as well as having a role in the monitoring and inspecting of products on the market to ensure their safety and efficacy’ (IMB, 2009).

The EU Directive 2007/47/EC, published in September 2007, amends the current Medical Devices Directive (93/42/EEC), the Active Implantable Medical Devices Directive (90/385/EEC) and the Biocides Directive (98/8/EC), and comes into effect from 21st March 2010. This new directive includes a significant change with the advent of specific definitions for clinical data which may place additional requirements on manufacturers of medical devices (IMB, 2009).

## 2.3 Review Conclusions

In 2003, Istepanian documented the contemporary limitations of Wireless Technologies for mHealth as follows:

- The lack of a operational compatibility between systems
- The high cost of communications
- The limited data transfer rate of the current mobile systems (around 9.6 Kilobits per second).
- The limited availability of the mobile internet and its bandwidth limitations.
- Healthcare is a very complex sector and change is a challenge
- The potential impact to medical personnel as a result of the organizational changes required implementing and realising the benefit of mHealth solutions e.g. losing/gaining power, economic impacts on systems and personnel etc.
- Payment for mHealth is uncertain and there is a lack of evidence for mHealth's savings potential.
- There is a lack of incentive for busy medical staff to utilise mHealth as it is seen as something else they will not be paid for
- Current telemedicine equipment can sometimes be difficult to use.
- There is a lack of integration between mobile telemedicine systems and other information systems e.g. ordering systems, medical records etc.

The review of the Literature since 2003 would appear to indicate that little has changed on the majority of these points in the intervening period with the notable exception of data transfer rates which have increased beyond 10 times the 2003 capability described above. Many European networks now deploy HSPA solutions to deliver wireless data. HSPA (High Speed Packet Access) 'is a 3G protocol that allows users to transfer data at a rate of at least 1.4 and possibly as high as 14.4 Megabits per second (Mbps) with peak uplink speeds of up to 5.7Mbps' (GSMA, 2009)

However, technical challenges remain particularly with the lack of standardisation in systems. (Istepanian omits one other key area of concern raised in the Literature and that is the legal and ethical issues associated with eHealth and mHealth).



The Literature does however broadly agree on the merits and many benefits, particularly for patients, of remote monitoring of ICDs. As Heidbuchel et al. (2008) conclude 'Remote monitoring may never replace completely the follow-up visits in a specialized electrophysiology clinic, but it certainly has the potential to safely lengthen the time interval between those visits'.

The Literature is however not so strident on the benefits to medical personnel of these types of systems. There does too appear to be differences of outlook on the cost/benefit equation. The Literature does seem to suggest that the lack of adequate reimbursement is preventing adoption of these types of technologies.

In summary, eHealth solutions like remote patient monitoring generally, and specifically for patients with ICDs, do offer significant benefit both to the patients themselves and to the wider healthcare system. However, many challenges still remain to the implementation of remote patient monitoring solutions in the healthcare system. It is clear too that mHealth offers much potential in this area especially with the current levels of mobile phone penetration and the successful deployment of mHealth solutions to date. However there are also many challenges remaining in that area.

There was little or no discussion of remote patient monitoring systems in the Irish health system and the research sections of this work will attempt to address this deficit.

### **3 Research Methodology**

‘Research is formalized curiosity. It is poking and prying with a purpose’.

Zora Neale Hurston (1942)

#### **3.1 Introduction**

The purpose of this chapter is to outline both the research types and methods evaluated and ultimately selected for this project. It describes the Research approach and design and outlines the process followed in the Research phase.

#### **3.2 Research Type**

The research methodology used in subsequent chapters primarily consists of Primary Research which the Yale University Library (2005) describes as ‘firsthand testimony or direct evidence concerning a topic under investigation’. It refers to original data gathered by the author.

This was supplemented by the addition of some secondary research that was previously unavailable to the author as it was only accessible with the permission of the relevant interviewees. (Secondary data consists of ‘data that has already been gathered by researchers, data published in statistical and other journals and information available from any published or unpublished source’ (Sekaran, 2003). This secondary research comprises of documents not generally available to the academic or general community as it derived from commercial sources.

#### **3.3 Research Methods**

Qualitative research can be described as ‘an inquiry process of understanding a social or human problem, based on building a complex, holistic picture, formed with words, reporting detailed views of informants, and conducted in a natural setting’ (Cresswell ,1994).

The term 'Qualitative Research' can also mean 'any type of research that produces findings not arrived at by statistical procedures or other means of quantification' (Strauss & Corbin, 1998) i.e. Quantitative Research.

Giacomini & Cook identified 4 essential aspects to Qualitative Analysis.

- 'the participant selection must be well reasoned and their inclusion must be relevant to the research question'.
- 'the data collection methods must be appropriate for the research objectives and setting'.
- 'the data collection process, which includes field observation, interviews, and document analysis, must be comprehensive enough to support rich and robust descriptions of the observed events'.
- 'the data must be appropriately analyzed and the findings adequately corroborated by using multiple sources of information'

(Giacomini & Cook, 2000)

This is the design chosen for the thesis.

This design consists of a series of formal interviews and a pre-defined question set. The idea of mailing questionnaires was considered but was discounted due to the traditionally low response rates to such requests – the 'response rate is almost always low (a 30% rate is quite acceptable)' (Sekaran, 2003).

### **3.4 Research Design**

#### **Research Process Method**

At the outset a Research Process was designed for use through the course of the thesis (see Table 3.2).

Research Process Phases	
Stage 1	Literature Review identifies issues/challenges
Stage 2	Issues and challenges clustered by groups and categories
Stage 3	Key questions extrapolated
Stage 4	Stakeholders identified
Stage 5	Appropriate and targeted Questionnaires designed
Stage 6	Interviews arranged and conducted
Stage 7	Responses/outputs categorised
Stage 8	Analysis of data

Table 3.2 - Research Process

The literature review was used to identify the set of issues and challenges in this area as identified by other academic and commercial studies. These outputs were then grouped by relevant stakeholder i.e. the group or individual impacted. In addition the literature review assisted in identifying the key questions for stakeholders for the Research Phase to be used to support or disprove current analysis.

The questions were then sorted into their relevant area for inclusion in the pre-defined Questionnaires to be used for the more structured Interviews. Interview targets were selected, interviews arranged and conducted and the data was again clustered by groups and categories for the research analysis stage. In this thesis a flexible design was employed so as to allow data collection to develop as new interviewees were identified as the result for example of a previous interview) and access to new materials subsequently arose.

## Interviews

In the context of academic research an interview is a technique for ‘acquiring spoken evidence from a knowledgeable informant in order to assist in answering a research question’ (O’Callaghan, 2009). Britten (1995) states that there are 3 types of interview;

1. Structured
2. Semi Structured
3. In depth

Type	Description
Structured Interviews	‘Consist of administering structured questionnaires and interviewers are trained to ask questions (mostly fixed choice) in a standardised manner’
Semi structured Interviews	‘Conducted on the basis of a loose structure consisting of open ended questions that define the area to be explored and from which the interviewer or interviewee may diverge in order to pursue an idea in more detail’.
In Depth Interviews	‘Less structured and may cover only one or two issues but in much greater detail. Further questions from the interviewer would be based on what the interviewee said and would consist mostly of clarification and probing for details’.

Table 3.3 – Interview Types (Britten, 1995)

Some authors (e.g. Callaghan, 2009) often describe the 3<sup>rd</sup> structure as ‘Unstructured’ however Britten argues that the term "unstructured" is misleading as ‘no interview is completely devoid of structure: if it were, there would be no guarantee that the data gathered would be appropriate to the research question’ (Britten, 1995).

In depth, formal and ‘face to face’ interviews have the advantage in that follow up questions can be asked and any clarification of ambiguity can be offered there and then.

The subject of healthcare can also be quite sensitive and formal interviews allow the handling of sensitivities in a delicate manner.

In order to allow for later comparison and analysis, similar questions will be asked of all of the interviewees and in a similar context.

### **Research matrix**

To support and manage this process a Research matrix was designed and created – see Appendix B.

### **Research Interviewee Selection**

Interviews were conducted with key personnel working in the IT, Telecommunications and Health sectors all of whom are vastly experienced in their respective fields. They included:

A Senior Telecoms Consultant with significant experience in telecommunications R&D.

A GSM Networks Consultant with a large mobile communications organisation.

A Senior Manager specialising in healthcare – IBM Ireland

A Healthcare Solutions Executive - IBM UK

A leading Technical Consultant in a large ICT Research facility

A Technical Consultant with an ICD manufacturer

A Senior (Country lead)) Manager in the medical device sector

A Senior Customer Support Manager in the medical device and supply sector

A leading Consultant Cardiologist

A Senior Manager (at National level) in the HSE

A Patient who has been implanted with an ICD

The head of a relevant Patient Support Group

All three representatives of the medical device sector had previously worked as medical technicians in the hospital sector thus were also able to provide perspective on that area.

## 4 Research

### 4.1 Introduction

This section reviews the results of the research interviews with the relevant experts in various stakeholder groups. The analysis is supplemented by research made available to the author by a number of the research subjects.

The first section looks at some of the drivers for remote monitoring applications in general and remote cardiac patient monitoring solutions in particular. This is followed by a case study of a recently developed system for the remote monitoring of patient heart status and also a review of some of the drivers for mhealth development from the perspective of the mobile telecommunications community.

The final section reviews the challenges to the wider implementation of remote patient monitoring under the key headings identified by the review of literature and subsequent research. These can be classified as follows

- Adoption by patients (which will also be illustrated by a Patient Case Study)
- Adoption by medical personnel
- Technology issues
- Cost and Reimbursement questions
- Standards issues
- Legal & ethical concerns

Note; the references in brackets below refer to the draft interview notes in Appendix H.

## 4.2 Remote Patient Monitoring

Remote cardiac patient monitoring is not a new concept to healthcare in Ireland. One consultant cardiologist spoken to recalled an early deployment of ‘Trans-telephonic monitoring’ some 30 years ago. This doctor was successfully monitoring a priest, who he had implanted with an artificial pacemaker, who was then working on the African missions. Weekly phone calls were used to record what has being described as ‘a series of [analogue] whistles down the phone’ to assess heart status (H6.3).

One former technician in the hospital sector, and currently a senior manager with one of the leading medical systems companies in Ireland, has observed an upsurge in the adoption of eHealth strategies and systems. This take up is being driven both by the hospitals and the HSE with both of these sections of the health service broadly supportive of eHealth and aware of the significant benefits that can be derived (H9.1).

eHealth initiatives like major implementations of new Clinical Information Systems (CIS) for the hospitals can, in addition to the core deliverable, also deliver upon some of the HSE’s key requirements for eHealth systems including

- the provision of timely and accurate benchmarking information. This allows the comparison of clinical outcomes across the service
- facilitating ease of clinical audit
- driving efficiency e.g. by effectively monitoring and recording the number of hospital ‘bed days’ – the number of days a patient spends in hospital

(H9.2)

The HSE’s strategy in support of a move to managing patients via the greater provision of local and comprehensive primary care facilities also lends itself to the increased use of eHealth and remote monitoring technologies (H9.3). The HSE are now engaged in building, equipping and staffing these centres which aim to treat more patients in the community and consequently ease the pressure on acute hospitals (H9.4). Technology and eHealth solutions like remote monitoring will play a large part in these initiatives.



One telecommunications consultant (formerly a senior business development manager in one of the larger European networks) interviewed for this work was recently involved in a worldwide initiative to identify potential revenue streams for the mobile telecommunications industry in the healthcare arena. He spoke on this and the other drivers for ‘mhealth’ from the mobile operator perspective.

The two largest mobile operators in Ireland, Telefonica O2 and Vodafone, are active in the mobile healthcare arena although it was noted that most of the activity is happening at a global rather than local level. Telefónica has a major Research & Development centre in Granada (Spain) which is focused on the healthcare sector and in the UK, Telefonica O2 UK have focused on ‘reminder’ applications like Hospital Appointment Reminders Messaging - the goal being to reduce the number of ‘no shows’ at hospitals which has long been a considerable wasted cost for healthcare facilities. Telefonica’s biggest competitor in Ireland, the Vodafone Group, also considers the healthcare sector to be an important focus area. For example, last year, Vodafone’s venture capital arm invested in T+ Medical, a UK-based company that has been developing applications in the remote monitoring services area (H4.1).

Market Driver	
Aging & illness trends	Demand exists for long term monitoring
Government funding	Incentives exist at local and EU level (current economic climate excepted)
Technology developments	New new sensor technologies (see case study), LTE etc.
Industry associations	Help form partnerships and approaches e.g. the standards work by the Continua Health Alliance
Competitive telecoms environment	Falling revenues require new revenue streams

Table 4.1 – The Drivers for ‘mHealth’ (H4.2)

Table 4.1 describes some of the drivers for mobile telecommunication companies to become involved in mHealth. The operators have long recognised the demographic trends in terms of population aging and chronic illness and see that the remote monitoring of patients in the home in order to reduce healthcare costs and burdens, as one of the key drivers for an expansion of mHealth markets (H4.3).

Technological advancements in the network arena mean that advanced solutions for mobile remote monitoring are now more viable. In Ireland for example, Telefonica O2 have, invested significantly in their 3G/EDGE network and have a rapidly growing customer base for mobile broadband services. These types of bearer networks make for real business opportunities in mHealth. The promise of even better technology should increase these opportunities. One such example is Long Term Evolution (LTE) which is the next step up from 3G/WCDMA & HSPA and promises data speeds of up to 100Mb/s downlink and 50Mb/s uplink (H4.5).

Another driver for operator interest in the mHealth sector is the promotion of these technologies by specialist industry associations like the European Centre for Connected Health and the Continua Alliance (who are looking at developing interoperability in mHealth and eHealth technology) (H4.4).

All of Ireland's mobile telecommunications companies operate in an extremely competitive market environment and all recently announced a decline in revenues. The monthly average revenue per user (ARPU) from Telefonica O2's mobile customers, for example, fell 7.9 per cent during the year to the end of June from €42.19 to €39.76. The operators are therefore seeking alternative revenue streams in markets with long term potential and mHealth is one such proposition (H4.2).

### 4.3 Remote Monitoring Systems Case Study

An interview with a senior manager in the healthcare division of IBM Ireland revealed the background, objectives and solution for a recent remote patient monitoring project - the 'HealthPhone'. In 2007, IBM Ireland in collaboration with Biancamed (a small Irish medical device company) and St. Vincent's Hospital in Dublin began the development of a mobile healthcare support system for patients suffering from a chronic illness and for the healthcare professionals caring for them. This case study successfully demonstrates both the benefits and challenges to remote and mobile patient monitoring.

The 'HealthPhone' project team saw the 'weakest link' in treating serious heart complaints as being the patient's self-reporting of symptoms i.e. that may not occur in an accurate or timely fashion. Simplified and automated ways of accessing and verifying physiological parameters could therefore improve health outcomes. Heart failure patients are prone to sudden deterioration in their conditions which can require emergency admission to hospital. The early detection of changes in weight, breathlessness, and changes in breathing patterns during sleep may give early indication of potential problems and therefore save hospitalization.

With the Healthphone solution a patient receives electronic weighing scales, a mobile phone and a 'sleep minder' monitoring device. The patient stands on electronic weighing scales and it automatically transmits the details through a mobile phone to a central Server. Biancamed have developed a sensor that can monitor breathing and heart rate without physical contact with the patient. There are therefore no electrodes involved in the process and the patient can be monitored from a distance. The 'sleep minder' monitoring device is placed beside the patient's bed and constantly monitors every breath and motion and automatically transmits the information through the mobile phone to a central Server.

The system then gathers the information from the two sources onto one application and uses health algorithms to analyse those signals to tell patients how well they slept, if they have any breathing issues or any sleeping issues. This allows multiple types of analytics to be applied on the integrated data to support the clinical decision making process and appropriate treatments can begin.

The central application allows cardiac care professionals to define an appropriate set of clinical rules to proactively track patient status and highlight any patients requiring attention. The system also provides dashboards for the quick summary of the status of an entire patient community and with option to drill down to individual patient information

As one patient testimonial from the trial phase of the project describes; ‘its not an intrusion – it is a great feeling of security because you know that people are picking this up right away whereas the old fashioned way, they don’t see it until you go and see them’. This ‘connected care in real time’ assists in terms of peace of mind for those patients being monitored (H7.2).

The system allows access to clinical data, including results from sensors, providing complete transparency between clinician and patient (something relatively uncommon in healthcare). The system can also provide simple tools, such as mobile reminders, to help patients proactively manage their healthcare.

As the solution is fully mobile it can travel with patients wherever they go and patients are therefore not tied to home as can be the case with some remote patient monitoring solutions.

Both Biancamed and IBM are members of the Continua Health Alliance and therefore designed the system with full consideration of the standards issue. The system is both HIPAA & HL7 compliant.

Despite the use of standard platforms there were still however a number of technology challenges with the ‘Healthphone’ system.

Some particular versions of Bluetooth firmware on certain Sony Ericsson handsets had stability issues during long connections. In addition, As GPRS is a cellular based technology the technicians found that the more connections sought in a given cell the more the chance of a dropped session. While there may be no data loss transmission times are impacted (H7.5).

## 4.4 Challenges to Implementation

There appears to be broad agreement on what constitutes the barriers and challenges to the implementation of remote patient monitoring.

The Continua Health Alliance, a non-profit, open industry coalition of over 200 healthcare and technology companies recently commissioned a report to look into the barriers to the rollout of remote chronic disease management in the United States. Figure 4.1 illustrates the challenge areas identifies by that study. While some are very specific to the healthcare environment in the United States it is interesting to note that this corresponds quite closely to the literature reviewed as part of the research for this work and also to the set of challenges identified by the mobile telecommunications companies in Section 4.4 above.

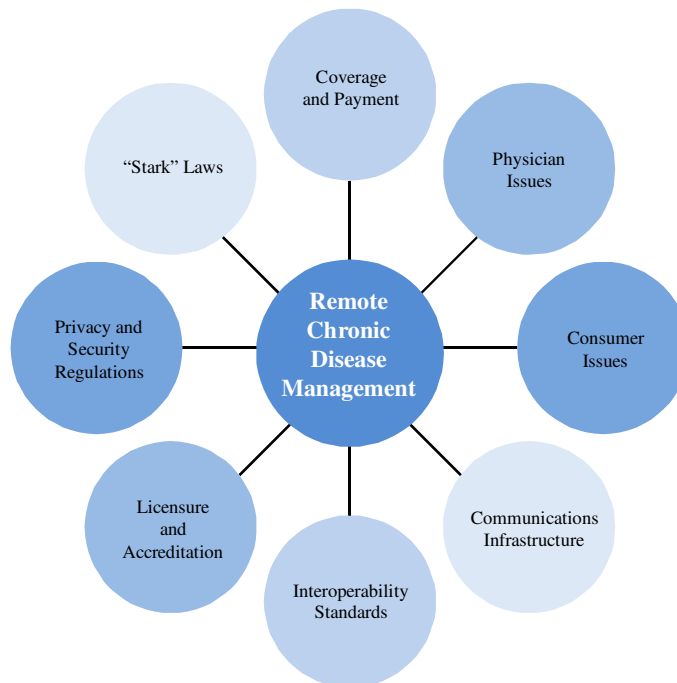


Figure 4.1 Implementation challenges in the U.S. (HealthPolicyR&D, 2008)

A similar list of challenges emerged from the discussion with representatives from the mobile communications sector. (see Table 4.2)

Barriers	
Adoption	Adoption by healthcare professionals may be slow
Patient-related concerns	moving care away from families
Technological	Some solutions are costly, may not be suitable
Security Concerns	Ensuring Data Privacy, risk of data loss
Cost	Capex, device and training costs are significant
Market, Product & Innovation Fragmentation	The many requirements in healthcare and the many choices of device, hardware and software

Table 4.2 – Telco challenges to implementing remote patient monitoring

The next sections will therefore describe the results of the interviews with key stakeholders like patients, medical personnel and people working in the ICT and medical device sectors.

## **4.4.1 Adoption**

Interviewees were asked for their perspectives on the two key areas with regard to the adoption of remote monitoring systems; adoption by medical personnel and adoption by patients.

### **4.4.1.1 Adoption by Medical Personnel**

According to Continua research the increased use of remote patient monitoring technology by medical personnel in the United States will depend on a number of factors, including how payment, workload, and liability concerns are addressed (HealthPolicyR&D, 2008). (The report also notes that most recent research estimates that only 10 percent of doctors in the U.S. currently use remote monitoring technology to manage their patients' conditions). Many of the interviewees spoken too for this work also highlighted the difficulties involved in getting medical personnel to adopt new technologies.

#### **Workload**

One of the first challenges identified was the fear that new technologies could add significantly to the workload of medical staff.

The threat of additional workload to already burdened departments emerged as a real risk to the future adoption of new technology. One consultant cardiologist highlighted the risk of additional workload for medical personnel. The requirement for daily transaction monitoring of multiple patients could add significantly to a doctor's schedule. Any system that was continuously monitoring patients would require even more effort to maintain (H6.4).

This consultant felt too that there was a very serious risk too that large volumes of data would generate a lot of 'noise' i.e. volumes of irrelevant information which could in turn either disguise potential issues or lead to inappropriate investigations (H6.5).

This analysis would appear to have parallels in the U.S. experience. As the Continua research describes it ‘a steady stream of biometric and health status data on patients with chronic disease could overwhelm a physician with too much information that may not be readily synthesized or acted upon’ (HealthPolicyR&D, 2008).

## **Motivation**

A number of interviewees addressed the question of motivation – i.e. what will move medical personnel to adopt and promote the use of remote cardiac patient monitoring.

This case simply illustrates the challenges in this area; a number of years ago one of the medical device companies attempted to introduce some new and potentially beneficial technology (for use in the treatment of angina and heart failure) to one of the larger Dublin hospitals. The medical device company concerned were convinced that clinical experience and clinical studies had successfully demonstrated that this type of treatment did help to alleviate symptoms of heart failure. Their research showed that cardiac nurses were also convinced of the benefits of such therapy. However, the company were completely unable to get any interest in this product from the key stakeholders in the cardiac units of the major hospitals. The reasons for this were unclear however the company could only conclude that there was little or no motivation for cardiac care management and staff to adopt this type of technology as, quite simply, ‘there was nothing in it for them’ (H9.10).

The issue of reluctance on the part of some consultants, technicians and hospital management to adopt new technologies was a common theme. Some interviewees felt that this was simply down to the fact that these new developments were being perceived by medical practitioners as either new work practices (for which they will not be paid) or new technologies that could possibly reduce earning potential. As one interviewee put it ‘consultants, for example, are business people and therefore may not look favourably on anything that threatens their business’ (H2.9). Another interviewee suggested that the fact that there were significant benefits to patients with technologies like remote monitoring would not necessarily be a priority or driver in the minds of health sector personnel as compared with for example, issues of cost and workload (H9.11).



A more cynical interpretation emerged in two separate discussions. Some new technologies may not generate an opportunity for regular contacts between the supplier and the hospital thus limiting the opportunity for client relationship management activities like the provision of samples, promotional materials and entertainment (H9.12). (This particular issue is not peculiar to the health sector).

The adoption of new technologies by the medical community may also be hindered by concerns around liability as direct responsibilities, and to a certain extent control, are seemingly removed by the technology.

## **Culture**

There are three different types of hospital in Ireland all with varying cultural, structural and governance differences. They are as follows the:

- HSE or ‘Statutory’ hospitals, owned and funded by the Health Service Executive
- Voluntary public hospitals, often owned by private organizations (primarily the Catholic Church) and funded and governed by the Department of Health and Children,
- Private hospitals, which do not receive funding from government and have their own Board and Management structures

(H9.14)

Broadly speaking the Voluntary hospitals would appear to be the more innovative and consultant-lead whereas the ‘Statutory’ hospitals have governance models that pay more attention to ‘cost/benefit’ analysis.

The consultant-lead approach was the method that, for example, led to the first heart transplant and lung transplant operations in Ireland. Both approaches have their advantages and disadvantages. A consultant-lead approach can sometimes lead to the adoption of leading edge technologies which though successful may not actually be financially viable. On the other hand a more cautious approach based on financial considerations alone may mean higher mortality rates that would otherwise have been the case (H9.15).

There are many examples of conflicting cultural issues at work in the Irish healthcare system and attempts at integration have not always had a high degree of success.

One interviewee noted for example that despite there just being one Tallaght Hospital the organisation appears to retain the various cultural differences that existed prior to its creation. This can even be seen in the name of hospital – ‘The Adelaide and Meath Hospital, Incorporating the National Children's Hospital’. The 'them and us' culture that can occasionally exist in the health service i.e. between the hospital sector and the HSE is also seen as a major barrier to the future development of cohesive approaches to new developments and new technologies for healthcare (H9.16).

Expressions like ‘highly political organisation’, ‘everyone is protective of their position’ and ‘the culture and structures work against the objectives’ were common descriptions of both the HSE and the hospitals in many of the interviews though a number of people did point out that these descriptions are most definitely not unique to the health system (H2.9).

When describing the willingness of health systems to adopt new technologies some of the phrases used included. ‘people in here have a fear of change’, ‘there is a fear of embracing new technologies’, ‘change is difficult’, ‘this aversion to change is cultural in this community’, ‘some people are at an age where change is not easy’ (H2.5 & H10.4). Again though, it must be pointed out that these descriptions of people and organisations are not uncommon outside of the health sector either.

## **Staffing**

The availability of adequate resources in terms of skilled personnel has the potential to become a barrier to the adoption of new eHealth and mHealth technologies. Should the adoption of a new remote monitoring solution require additional staff of, for example, a specialty nature then it is highly unlikely to proceed particularly in the current economic environment (H9.6).

A shortage of consultant cardiologists may also be a challenge. As the head of one of the Patient Support Groups working in this area highlighted; Ireland has approximately 12 consultant cardiologists per million people, compared with the EU average of 35 per million (H5.1).

In May 2009 the Health Service Executive introduced a staff recruitment embargo and this remains in place at the time of writing.

The mobile telecommunications organisations recognise some of the risks to the adoption of mHealth systems by healthcare professionals. One in particular was highlighted and concerned the perception of ‘technophobia’ and/or an unwillingness to learn new technology in some areas of the health system (H4.14). The operators see the way to overcome this reluctance is to ensure that systems are relatively easy to use, reliable and have been successfully and comprehensively shown to be a success in e.g. clinical trials (H4.15).

### **ICD Monitoring**

The next question concerned the means by which remote ICD monitoring services were being adopted in the hospitals currently.

The choice of ICD and in turn any remote monitoring potential is currently a matter of the preference of the relevant cardiac consultant or, on occasion, cardiac technician. The adoption of any particular device or service also varies from hospital to hospital. At present nothing is mandated or imposed or chosen in advance (H2.1).

According to the head of one of the ICD suppliers, many cardiac consultants trained in the United States and may therefore have become familiar with a particular device type or model during that time. When their training has completed and they return to Ireland to take up a position here they often bring their preference for a remote monitoring system with them (H2.2).

The decision as to which device type is to be implanted and, potentially remotely monitored does not always appear to be based on the patient's circumstance as, for example, it has happened that a patient without a landline at home was fitted with a device that can only be remotely monitored using the PSTN or 'landline' network. There is also a risk that a patient may be given a model that uses the mobile network for remote monitoring but that patient resides in an area that has poor or negligible mobile phone coverage (H2.3).

#### **4.4.1.2 Adoption by Patients**

In order to assess the patient perspective of this subject a number of detailed interviews were conducted with a patient who had been implanted with an ICD. The results of the interview were subsequently collated into a case study to look at the potential challenges to patient adoption of remote monitoring technology.

##### **Patient Case Study**

The patient is a 67 year old female from Dublin. The patient suffered a myocardial infarction in October 2001 and was subsequently diagnosed with cardiac arrhythmia and cardiomyopathy. In December 2001 the patient was fitted with an Implantable Cardioverter Defibrillator (ICD). This ICD did feature a pacemaker facility but this was not activated. Since implantation the device has delivered therapy ('shocked') on at least 3 occasions (all occurred in 2003). The implanted device is a Medtronic, Model 6947 Implantable Cardioverter Defibrillator. All treatment and subsequent care took place in St James' Hospital, Dublin. (St. James' hospital delivers health treatment, care and diagnostic services 'at catchment, regional, super-regional and national levels. Its service remit ranges in complexity from secondary to tertiary level. (SJH, 2009))

At the beginning of the treatment it was recommended to the patient that the interval between follow ups for reading the device and assessing any required changes was every 3 months. (This is in line with International standards). In recent times however the patient has attended the cardiac clinic as often as every 6 weeks (equating to over 8 visits a year).

The patient resides approximately 8 miles from the hospital. However, the hospital is located in Dublin city centre and so travel times of 1 hour each way would not be exceptional, stretching to one and a half hours in heavy peak-time traffic.

Appointments outside of the normal follow up regime would occur, on average, twice annually. These are usually occasions where a GP visit has resulted in a referral to the hospital. In this case the patient's GP has been successful in securing appointments directly with the cardiac clinic.

The hospital would assert though that presentation at Accident & Emergency (A&E) would be the appropriate route for admission for assessments that occur in a perceived emergency situation or outside of the normal follow-up regime.

The patient expressed an unwillingness to follow such a route given their perception of the A&E environment as being a very uncomfortable place to be. Previous A&E visits (although not directly related to the cardiac condition) have resulted in a very poor experience often featuring long waits in a crowded waiting room. The A&E department appeared to the patient to be short staffed and the waiting areas often populated by abusive persons (themselves often substance abusers). The patient described conditions in one particular Dublin hospital (not their treating hospital) as 'akin to 3<sup>rd</sup> World'.

On the other hand the patient has observed that people with cardiac conditions do appear to get through this system faster than others. Nevertheless, the patient expressed the view that they would dread having to experience A&E as a result of any cardiac episode.

### **Device History**

After 5 years the first device gave warning of a low battery during a normal scheduled follow up session (during which a battery check is performed in addition the review of clinical data). This new device was replaced and successfully tested on the day of implantation but it later emerged that the replacement device had suffered a complete failure at some point unknown after the initial test. The problem was not picked up until almost one month later. The patient felt that a remote monitoring solution would have picked this up far sooner.

## **Awareness of Remote Monitoring Systems**

At no point prior to fitting of the ICD was the patient offered any options with regard to remote monitoring for the device.

None of the literature presented to the patient made mention of such an option nor was it ever mentioned by any of the clinical care staff in the hospital at that time. In addition, at no point in the 8 years since implantation has the patient been informed of any developments in the ICD area (including with regard to remote monitoring options). Up until 2007 the patient attended meetings of two of the relevant Patient Support Groups for people with these conditions (both associated with the Irish Heart Foundation) - the Implantable Cardioverter Defibrillator Support Group and the Cardiomyopathy Support Group. At no point during any of these contacts was there discussion of remote monitoring options for ICDs. (Subsequent examination of some of the Patient newsletters and other materials would appear to confirm this).

However, the patient did highlight the fact that these support groups are family oriented and not specifically seeking to address deficiencies/options in treatment or to act as lobbyists in this area.

When asked if they had ever heard at all of such remote monitoring systems the patient had heard of the facility as part of a pilot project in England. The patient heard of this via the medium of television on a UK documentary programme.

When asked if they would consider using such a system were it to be made available the patient was emphatic in their reply – yes, without hesitation.

Given the patients stated fear of having to present at an Accident & Emergency department it is unsurprising that they would immediately express a great interest in a system that could potentially reduce the need for attendance there.

As the patient gets older travel becomes an ever increasing burden especially as the medical condition itself exacerbates tiredness particularly in warm travelling conditions.

The patient saw the benefits of such systems in not just the monitoring of heart rhythm and the potential that may have to provide indications of future events but also in the actual status of the device and its leads etc.

This ability to have the device status monitored rated quite high in the benefits area. One major reason for that was that on one occasion the patient's ICD suffered a complete failure and they were quite unaware of this fact for over 3 weeks. During that time they were visiting a very remote location in the west of Ireland, quite a considerable distance from any available cardiac care. Had there been a cardiac event during that sojourn it could potentially have been extremely serious. Remote monitoring however could have immediately picked up on such a threat through its processing of device status information. Given the remote location and the lack of landline connections a mobile device would potentially have offered more security. However, it is also interesting to note that the coverage of one of the larger mobile telecommunication companies in this particular area is very poor.

This type of episode has resulted in increased anxiety which again could be eased by the utilisation of remote monitoring system

### **Usage and Acceptance**

The patient is both highly computer literate and a mobile phone user for many years. Using the materials made available by the interviewer they did not envisage any issues with adapting to using a remote monitoring system. While the technology itself holds no fear for the patient there was however wariness with regard to the reliability of some of some of technologies that makes up these systems. For example, the patient is aware that a state of the art broadband internet connection provided by one of the leading telecommunications companies to her home has often failed to work either completely or with reduced availability of service.

It was interesting to note though that the patient had no such fears around the medical device aspects of remote monitoring systems.

(This may be related to some findings in this work about patient acceptance and compliance. As the head of one of the relevant patient support groups working in this area confirmed, patients do generally trust their systems (or medication) and are generally very good at following instructions closely).

### **Other Patient issues**

One of the key patient-related challenges identified by mobile communications researchers was the fact that some of the more technical remote monitoring technologies may well require additional training and support for patients (H4.8). Patients may also be resistant to new systems or in the case of aging, infirm or chronically ill there is a risk that equipment could become damaged or lost due to unfamiliarity with such technology, a point echoed by the ICT research sector interviewee (H1.5).

One interesting patient-related challenge uncovered by telecoms researchers in this area is the risk that there may be a decline in patient care and ‘well being’ following the implementation of a remote monitoring system. They see that a lack of ‘in person’ human contact, which may result from a monitoring system stating that the patient is not in any danger or at risk, could have an adverse psychological impact on patients. They also highlight some research that stated that there may be a trend in family members removing themselves from care situations as they feel that these systems have addressed any needs in that regard (H4.8).

Individuals interviewed from the device sector did not generally feel that usability for patients was an issue. As one of their representatives described, the system is designed to work ‘out of the box’ with little or no patient interaction. However, it was pointed out that some induction type training is necessary and the risk is that this does not happen (H2.11).

The critical time for the patient is the demonstration that takes place just before the patient goes home. However, experience has shown that in busy cardiac units with patients also anxious to leave this does not always happen. There is a risk that the benefits of such a system would not be realised if the basic set up was not performed correctly (H2.11).



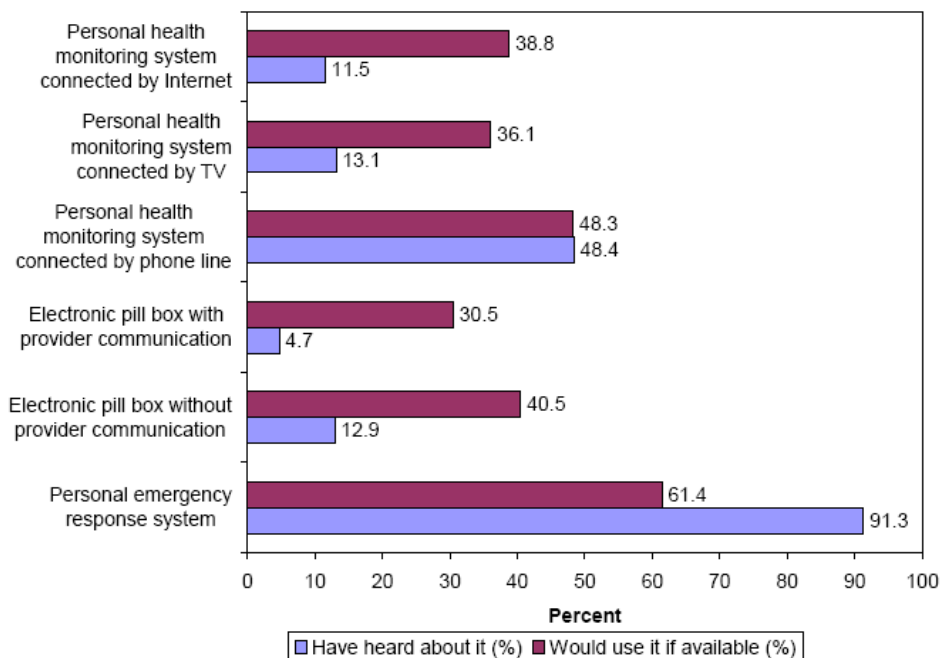
## ‘Continua Patient’ Research

Research commissioned by the Continua Health Alliance in 2008 identified a number of factors in broadening patient adoption; ‘to achieve widespread use, patients must accept, use, and trust remote monitoring devices and remote patient management strategies’ (HealthPolicyR&D, 2008). AARP Foundation research recently cited by Continua surveyed adults in the United States over age 65 on their awareness of, and their willingness to use, new remote monitoring technology.

The study suggested that there was a growing awareness of new technology and a willingness to use it but quite a number of fears and concerns still existed.

## Awareness

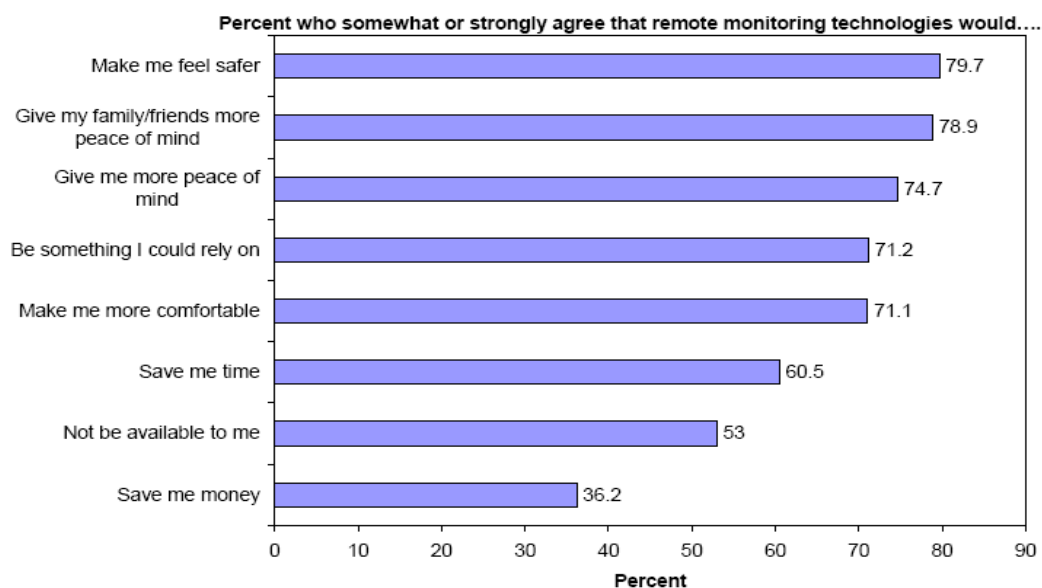
While the knowledge of the concept of remote monitoring was quite high (note the awareness for personal emergency response systems) it was also notable though that awareness for e.g. systems connected via the internet was quite low. (See Figure 4.2)



Source: Barrett, LL. 2008. Healthy @ Home. AARP Foundation.

Figure 4.2 - Knowledge of remote monitoring technologies (Barrett, 2008)

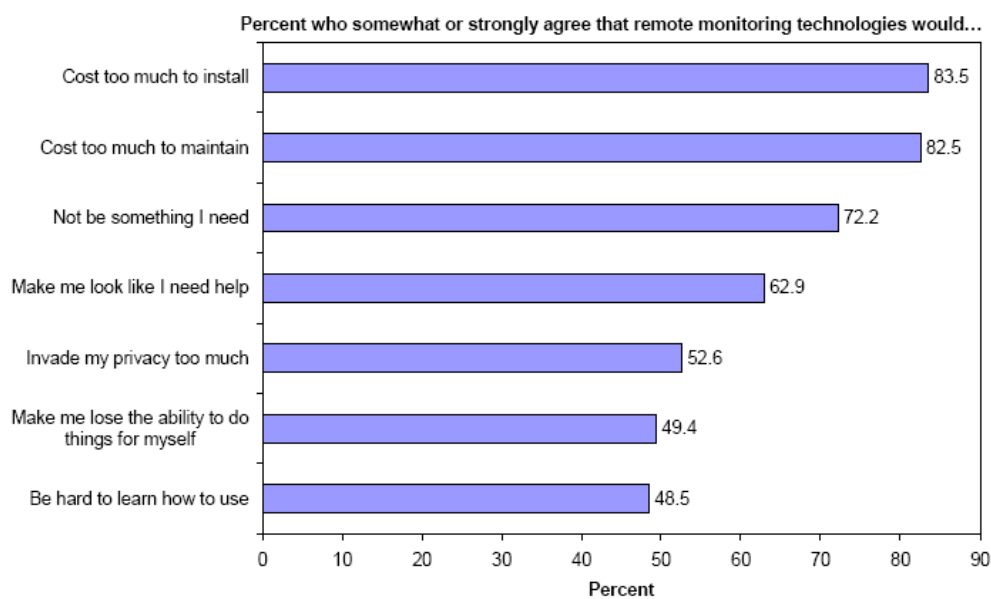
Those surveyed did however see these technologies as potentially making them feel safer and offering ‘peace of mind’ to both them and their families. (See Figure 4.3 below)



Source: Barrett, LL. 2008. Healthy @ Home. AARP Foundation.

Figure 4.3 - Benefits of remote monitoring technologies (Barrett, 2008)

However, the potential costs relating to any new remote monitoring technology were a fear for more than three quarters of those surveyed (see Figure 4.4 below). The ‘usability’ of technology was also a major issue especially for patients who were perhaps more frail or suffering disabilities and who would find some technology a challenge.



Source: Barrett, LL. 2008. Healthy @ Home. AARP Foundation.

Figure 4.4 Concerns about using remote monitoring technologies (Barrett, 2008)

These findings would appear to correspond quite closely with the results of the patient case study. The patient concerned had some knowledge of remote monitoring capability, was definitely interested in using such technology but was also wary of having to pay any additional cost toward such a system.

#### **4.4.2 Technology**

As the review of the Healthphone project revealed, despite the use of standard platforms there were still technology challenges with the 'Healthphone' system with regard to the software compatibility with GSM handsets and with coverage type issues for transferring data over the GPRS network. High availability of mobile network coverage will be critical to the success of remote mobile monitoring. While mobile network outages are relatively rare they do still occur.

On one occasion during the Research phase of this work the author was working from home in north County Dublin. For an extensive period there was no connection possible over a mobile broadband facility. Neither was there any voice communication available. The mobile network appeared to have suffered a failure impacting all voice and data communications in that area. Using the mobile broadband software an auto search of available networks in the area showed that both of the network operator's competitors' networks were fully operational but, as is standard, access to these was prohibited.

Subsequent investigation with the network provider concerned revealed that the outage was down to a hardware (multiplexer or mux) fault on the network requiring a replacement effort on two ends of the network. The fault resulted in an outage of just under 8 hours (from approximately 8.30 to 16.00) across north County Dublin. Coverage was either poor or non-existent from Malahide in the south as far north as Laytown and over as far as Ashbourne to the west. In other words a patient would have had to travel a minimum of 5 miles in any direction in order to return to coverage.

Should a patient have been in that situation there was the potential for at a minimum some added anxiety in that not only were they not being monitored they potentially had no immediate means of informing anyone that this was the case. While very infrequent these types of outages do still occur and are a potential risk to the patient's safety. As the patient case study revealed coverage issues have the potential to be a very serious risk to patient safety.

A leading member of the technical staff of one of Ireland's largest ICT R&D facilities (and a Ph.D. in Electronic and Electrical Engineering) has been monitoring the increase in research and development for the technology for remote and mobile health monitoring solutions. They noted that what many of the recently developed systems have in common is the fact that they are based on fairly simple 'number crunching' concepts with a limited range on what can be described. Remote monitoring of weight, blood glucose and blood pressure levels or even ECG data are relatively straightforward number-based and threshold alerting forms of remote patient monitoring (H1.3).

This means that medical personnel are not necessarily seeing the complete picture. Some researchers feel that there are risks associated with reviewing ECG data in isolation. So, for example, the situation arises where the instructions for remote ECG monitoring often ask the patient to also keep a diary of activity in an effort to get a more holistic view of their condition. Doctors need to understand what else is going on in the patient's life (H1.3). There are now many questions about the usefulness of only looking at one number and while it may be useful indicator of a patient's condition it may not provide enough information for an adequate assessment (H1.4).

Outside the area of remote monitoring for pacemakers or ICDs, which usually require little patient interaction, the challenges in the area of patient adoption begin to increase significantly. The challenge is to make any of the interactive features of these systems easy to use. Even presenting information can be difficult - how for example do you present information given the limitations of e.g. screen and keypad sizes on 'off the shelf' devices? How do you make interactive technology useable for the elderly, the infirm, people with physical disabilities, people with hearing or visual impairment? (H1.5).

The interviewee describes the next step for remote monitoring systems as requiring 'multi-modal' analysis in order to return a more complete picture of the patient's medical status. The question that then arises though is does this mean multiple applications may be required to effectively monitor patients remotely? (H1.6)

Three of the technical experts interviewed for this work all highlighted another technological barrier to future developments in this area. Very high power requirements are a feature of some wireless technologies (e.g. Bluetooth) in the mHealth area. These requirements are of concerns because of their potential impact on the battery life of medical devices. Battery life can be critical in medical devices especially in potentially life saving devices like ICDs. As one pointed out one of the objectives of ICD monitoring is to download and relay 'as much data as possible with the least amount of power drained' (H.2.10)

As the patient case study demonstrated battery replacement is not always straightforward and can even add additional risk or, at a minimum, inconvenience for patients. Some R&D projects in this area have foundered because the applications developed drew too much power from device batteries rendering them useless in a clinical environment (1.10).

It was noted that the telecoms research has shown that while new technologies are indeed emerging that are lower in power consumption the costs associated however remain high (4.19).

The next technology challenge concerns the appropriateness of the technology for individual patients.

The issue is that not all patients have landlines at home. Anecdotal evidence would suggest that some patients have been presented the capability for remote monitoring their ICD who actually only had a mobile phone at home whereas the solution required access to a landline. (That individual has to use a neighbour's phone to transmit data as per the schedule or as a result of an event). Conversely there is a risk that a patient will be offered and will take up a remote monitoring solution that uses mobile networks to transmit their data but they could potentially live in an area where network coverage was poor or even non-existent (H2.3).

One constantly recurring theme in interviews with both mobile telecommunications and medical device specialists was the topic of fragmentation. The mobile operators see both the mHealth market and mHealth technology development as especially fragmented and see this as the most significant impediment to the future success of deployments in the mobile healthcare arena. The mHealth market is still viewed as being relatively young. At a high level the mobile operators see different paces and levels of innovation (and the willingness to explore new technologies) in health systems. There are also a host of vendors and applications developers sometimes working in very specialist areas of expertise or with varying business models. This fragmentation of technological development is a major barrier to the achieving the types of economies of scale that the operators are used to or, at least, currently less than what they would need to develop further in this market (H4.9).

While basic applications like those based on the standard mobile functionality (i.e. voice and text) are relatively easy to implement the more complex applications may require a number of different platforms to be developed depending on the requirements of the healthcare provider. The capability to support a variety of high-end handsets and mobile devices and their associated application may become a burden for operators (H4.10).

While technical developments have been significant (with more to come) there is still a huge complexity in remote monitoring technology. Systems that require repeated and/or continuous access to any network, mobile or otherwise, have to be carefully managed so as to ensure there is no risk of system overload. Ultimately too there needs to be provisioning, rating and billing solutions and in the author's experience mobile billing is already convoluted enough without the addition of complex wireless and 4G systems (H4.16).

Another challenge for mobile operators in deploying mHealth solutions concerns the question of how these new systems integrate with existing and often incompatible systems or even if dependent systems actually exist e.g. centralised and integrated patient management systems (4.13).

### **4.4.3 Cost & Reimbursement**

The securing of project funding for mhealth systems like the Healthphone remains a significant challenge. That particular project struggled with gaining access to public funding for quite some time before they ultimately went to a private foundation for support (H7.4).

It was the view of a number of the private sector stakeholders that the complexity and slow pace of the public procurement process can and will hinder progress in this area (H2.8 & H7.8).

The Healthphone project team estimate that there are potential savings of somewhere in the regions of €8 million per annum were this system to be made widely available. As one ICT expert pointed out however that savings like these may well accrue to the hospital sector but that could come at a cost to the primary care sector (H7.7). This is a structural challenge that may well prove difficult to reconcile.

#### **Funding for ICD Monitoring**

Hospitals receive an annual budget allocation for the provision of ICDs and related cardiac services. From that allocation the hospitals decide which devices are required and would then generally source these from a number of different vendors (H9.5).

The cost of remote monitoring for ICDs does not appear to act as a barrier to adoption by either patients or medical facilities. The cost of the monitoring element of the system is usually built into the cost of the ICD itself which is in turn covered by both public and private insurance (H2.12).

The question of who pays for remote monitoring systems generally is obviously of great interest to the mobile operators. It is still unclear to them as to how much coverage, for example, health insurers will provide in this area. (As described above the coverage of ICD monitoring is occurring more by accident than design). However, even where insurers provide cover there may be a large demographic of older and lower income patients who may well have little or no private health insurance.



There is an increasing challenge for Governments worldwide, but particularly right now in Ireland, in providing finance for new health initiatives (H4.17).

High costs caused by the requirement for significant capital expenditure and capital outlay for 'high end' devices therefore remains a key barrier to implementing remote monitoring solutions as well as the additional cost associated with training, ongoing support and upgrades. Business process re-engineering costs and challenges plus any requirement to incentivize medical personnel may also have to be factored in. Finally, Insurance costs have to be considered in light of new systems and new risks (4.18).

During the patient case study the interviewee was asked for their view on the Cost/Payment topic. The patient has been treated to date primarily in the public health system though with many of the costs, including the cost of the patient's implanted device, borne by a private health insurance provider (VHI).

The patient expectation would be that the cost of any such system would be borne by the health insurer and did not express any interest in paying for such a system themselves

(A cursory check on the websites of the major Irish health insurers however reveals no information on coverage of remote monitoring).

#### 4.4.4 Legal & Ethical Issues

Research made available to the author from the Continua Alliance in the United States suggests that the remote management of patients ‘has the potential to introduce new sources of clinical information at all hours, with the expectation that physicians respond immediately’ (HealthPolicyR&D, 2008). They ask two key questions:

- ‘Do the data need to be monitored day and night?’
- ‘Will physicians be expected to act on possible evidence of a problem within minutes or hours?’

Given the potential for malpractice claims, the Alliance sees that the legal liability concerns of medical staff do still need to be addressed. Similar fears exist in Ireland.

The telecommunication interview highlighted that the fear of legal litigation and of becoming enmeshed in any complex legal or regulatory issues would be a major concern to mobile operators and is one of the reasons why a mobile operator would look to initially partner with an existing provider if possible (H4.20).

Unlike many of the other challenges in this area, legal and ethical issues were not however discussed in any great depth by many of the research interviewees. There appeared to be little or no awareness of the legal and ethical challenges to remote patient monitoring. There was perhaps even a reluctance to discuss depending on the stakeholder.

All the questions outlined in the review of the current data would therefore appear to remain open.

According to the Continua Health Alliance they include:

- A lack of a clearly defined legal framework outlining the legal and ethical responsibilities and liabilities of all the stakeholders; medical staff, network providers and device manufacturers.
- For global organisations the differing approaches depending on jurisdiction are also an obstacle to progress.

(HealthPolicyR&D, 2008).

One of the senior IBM managers spoken to (who is also actively involved in a number of industry coalitions) did however point out that the European Commission were now more active in supporting member states through their focus on three strategic sets of actions, one of which is ‘Bringing legal clarity’ (H8.8). (The other two are ‘Building confidence in and acceptance of telemedicine services’ and ‘Solving technical issues and facilitating market development’.)

Another challenge not often encountered by the telcos in other sectors is the requirement (usually) that medical applications or devices be tested for clinical use by a regulatory body. Like all regulatory impositions the operators see this as a barrier to the speedy rollout of mHealth solutions. The Irish mobile operators have not always had the best relationship with, for example, the Telecommunications Regulator – Comreg (H4.11). While healthcare specialists are seen as being well aware of the requirements in this area the mobile operators are extremely wary of additional, as they see it, impositions.

#### **4.4.5 Standards & Interoperability**

As the literature review has shown, a lack of standardisation can be a major barrier to successfully implementing healthcare solutions.

Interviews with both medical personnel and representatives of the device manufacturers confirmed that the ICD of a particular medical device provider can only be read by the device reader of that same provider. There is no standardisation and no such thing as a generic reader or programmer. The systems are proprietary which can necessitate the maintenance of a variety of readers and systems within the one care facility. Patients presenting with devices not supported by the hospital therefore cannot avail of remote monitoring facilities. (H9.7)

The application of appropriate standards for IT systems in the health setting has been and will continue to be a challenge. As the HSE manager pointed out, the hospitals are quite free to purchase new medical technology without specific reference to standardisation (H10.1). In addition it is difficult to impose standards without there being a basic integrated 'backbone' network for the health system, something that does not as yet exist (H10.2).

As a number of individuals described, typically the cardiac departments in Irish hospitals currently have a fragmented IT structure with a variety of IT systems (often for the same function) that vary from hospital to hospital. Even then, the repositories on which the remote monitoring information is collated and reviewed are not integrated into any other hospital system. Nor do appear to be any plans to do so (H2.17).

Despite the levels of standardisation and guidance provided by standards like HL7, systems integration can still pose difficulties and while not arduous they can still add integration effort to clinical information system-type projects. One reason for this that emerged in two separate discussions is that there are actually a number of differing variants with some standards including HL7 (H9.8 & H10.3).

As the Healthphone project demonstrated even when all the appropriate standards are put in place there can still be issues. The view of the team involved on that programme was that quite simply the interoperability challenge will always be there until 'plug and play' or seamless interoperability becomes the norm. There still remains quite a lot of uncertainty in this area as indicated by the questions posed by those in the telecommunication sector as to, for example, the exact classification of their systems.

As already described the European Union's key compliance requirements for standards in medical devices is the Medical Devices Directive. Individuals working in this area (like the IBM UK manager) are confident that the EU Medical Devices Directive should not become a burden or inhibitor to future development. He stated that this directive has in fact been re-drafted several times following consultations with many interested parties from the standards viewpoint including ETSI, CEN, CENELEC, COCIR and Continua and it is hoped that the final versions will not impose too many onerous conditions of suppliers of telemedicine and telehealth services (H8.4/5).

Many of the interviewees have indicated that they are encouraged by the progress that is being made in this area and are confident that the promotion and use of standardised solutions will be of huge benefit to the health sector

#### 4.4.6 Additional Challenges

‘HSE told to plan for up to €800m of spending cuts in 2010’

Irish Times headline, 20<sup>th</sup> August 2009

One additional and significant challenge emerged during the research phase and that concerns the domestic and global economic downturn. Indeed, since the interviews were completed one of the key interviewees was made redundant from their employment directly as a result of the changed economic circumstance. Budget cuts across all sectors of the economy will have major impacts on both operational and capital spending which may mean that opportunities to look at new and innovative solutions move down the priority list for both technology providers and healthcare systems.

Another challenge that emerged from the various discussions was the difficulty in raising awareness as to the advantages and benefits of new ehealth and mhealth technologies. One interviewee found that while the media may understandably be reluctant to promote commercial propositions it was difficult to engage them even on the benefits of the concept of remote patient monitoring (H2.19). Even within the health sector the levels of awareness of these types of technologies remains relatively poor. While it can be confirmed that all cardiac consultants in Ireland do know about remote monitoring systems (often through the efforts of the device sector to educate in this regard) the knowledge and understanding was described as ‘patchy’ with ignorance of the potential benefits commonplace across the health system (H2.4).

## 5 Evaluation

Both the review of the literature and the subsequent research interviews revealed a common set of challenges areas. There was quite a high level of consistency in the challenges identified by the various stakeholders.

They were in summary

- Adoption by patients
- Adoption by medical personnel
- Technology issues
- Cost and Reimbursement questions
- Standards issues
- Legal & ethical concerns

Some additional challenges were also highlighted with regard to the current economic climate.

The differences however arose on the extent to which these were real barriers to the future adoption of remote patient monitoring solutions. In addition some challenges not obvious from the literature were highlighted in discussion with the experts in this field.

As the patient case study showed it will be extremely difficult for patients to adopt or seek these solutions if they are not even aware that they exist. A wariness of technology remains, particularly in the older demographic, as does a fear of cost or in some cases, a complete unwillingness to pay for remote monitoring solutions. Overall though the patient adoption challenge closely mirrors the general understanding and none of the issues were viewed as insurmountable.

Workload and cultural issues dominated the discussions on the willingness or ability of medical personnel to utilise new remote monitoring technology. This is one challenge which appears greater than anything described in the literature to date and one which will perhaps require the most effort to overcome. It was also the one area that raised a genuine passion, possibly born of frustration, on the part of some stakeholders in the research interviews.

Of all the technology challenges discussed the network coverage risk was highlighted more than most and remains a significant challenge to the wider adoption of remote mobile monitoring as well as posing a potential threat to patient safety. Another recurring theme in this section was the topic of ‘fragmentation’. The fragmented technology structures in the healthcare systems and the fragmented nature of development and innovation rated highly for many of the stakeholders. The appropriate use of technology was an issue that was discussed often. The increasing move from landline to mobile phone usage can cause real difficulties for patients, medical staff and technology organisations.

While the topic of cost and reimbursement received much attention it was not rated as high a challenge as other areas. Funding for any system in any sector will always be a challenge though this has perhaps taken a turn for the worst in the current economic landscape. There was a common call though for the insurance companies to take a more active role in pushing new potentially cost saving technologies as does occur to some extent in the United States.

As the systems case study showed, even when systems are designed with appropriate and open standards there can still be problems. The key issue in the area of remote ICD monitoring was the proprietary nature of the systems and the fact that an ICD of a particular medical device provider can only be read by the device reader of that same provider which can necessitate the maintenance of a variety of readers and systems within the one care facility. Patients presenting with devices not supported by the hospital therefore cannot avail of remote monitoring facilities.



Systems interoperability remains a challenge but the general consensus was that this was getting better particularly through the efforts of the various industry and standards coalitions. The standards organisations were involved for example in drafting the new EU Medical Devices Directive and it is therefore hoped that standards do not become an imposition but actually assist and promote the development of emerging health technologies like remote patient monitoring. In addition, the announcement last month (August 2009) of an agreed single set of content, transport, and vocabulary standards for medical devices is to be particularly welcomed.

Legal & ethical concerns would appear to be one of the larger challenges identified particularly given the general lack of knowledge on the subject.

It is the author's view that the key challenge is in fact a question of demand. If remote monitoring is a way forward for healthcare with clear benefits for all the stakeholders where will the real demand for these solutions come from? The research has shown that many patients are unaware of options in this area, physicians and technology companies alike are extremely wary of them albeit for differing reasons, there is no coherent strategy at national level and there is a general and distinct lack of knowledge around the legal and ethical issues presented by these technologies.

#### Overcoming the challenges

While this work focused primarily on the challenges a number of people spoken to as part of the research did make many suggestions as to how some of these challenges can be overcome. (It should also be pointed out that many of the research interviewees highlighted the significant benefits of these technologies).

In order to address the issue of medical personnel workload one consultant cardiologist suggested it would be important that these systems target events as opposed to continuous telemetry. It was also important to ensure the correct selection of patients as subjects for monitoring. One potential approach would be to implant a temporary recorder for either triggered or continuous recording of heart data. A more informed decision could then be made as to the suitability of ongoing remote monitoring for that particular patient.

The increased use of systems that process data through some form of rules based system, and provide alerts when data is outside of a normal range, would assist medical personnel in managing additional workload. This type of 'exception reporting' method is already in use in some ICD monitoring systems. The latest Biotronik system, for example, offers a 'traffic light' view of records to allow for the rapid prioritisation of effort

The mobile operators believe that the best way to overcome the perceived reluctance of medical personnel to adopt new technology is to ensure that systems are relatively easy to use, reliable and have been successfully shown to be a success in e.g. clinical trials.

It is clear that in order to ensure system resilience and in turn patient safety, remote monitoring systems that utilise mobile networks for data transmission would need some type of national roaming agreement amongst the mobile telecommunications companies to address coverage issues in remote locations of the country.

Effective 'Change Management' programmes during the rollout of new technology would be of great benefit. As one research subject pointed out, to make a change you really need all the stakeholders on board - consultants, cardiac technicians (who seem to have a particularly busy workload) and nurses (who can often carry significant influence).

To aid the patient adoption of these systems more information could easily be made available through 'information days' and the simple distribution of material on these solutions. In the U.S.A. 'human factors' engineers are often used by medical technology companies to help develop systems that are suitable for all patients. Training and the availability of technical support would also be of great benefit in this area.

From the perspective of some in the medical device sector, remote monitoring is now seen as a differentiator between the available ICD systems. As one individual from the device sector explained, the ICD devices themselves are now almost generic in their make up with regard to their physical construction, the algorithms they use and the capability they offer. The key differentiator is now therefore on the

programming/monitoring side with regard to the systems and methods of patient monitoring. This fact may also help increase system adoption.

Another way to sell the concept to patients and hospitals alike would be to highlight another potential benefit of remote patient monitoring that emerged in a discussion with one of the medical supply people. Any reduction in travel by patients to and from hospital has the added benefit of reducing their carbon footprint. Not alone do we live 'Green' conscious times but the public sector will come under increasing pressure to set targets in this area. It may also help to sell the concept itself

One way where demand for such solutions could rise would be if the health insurance companies to see the potential savings that could be achieved by for example a reduced requirement for 'follow up' Were the health insurers to actively advocate for the adoption of these technologies it is possible that both demand and awareness would increase.

Workarounds can be used to overcome challenges of standards and interoperability. Some device providers like Biotronik overcome the interoperability barrier by providing simple but effective interfacing abilities such the provision of a USB interface and the ability to easily generate standardised Adobe Acrobat (or .pdf) reports.

The formation of effective partnerships amongst the stakeholders may also assist in greater adoption. A common consensus emerging from all of the discussions with those in the information technology and communications sectors was a general 'wariness' of involvement in healthcare. One technical consultant's view was that while eager to venture into new markets the technology companies hear the word 'healthcare' and they sometimes equate it to risk and potential liability. Organisations are therefore being careful about moving into this area and are frequently seeking out potential partners already working in the sector who may have more experience of the risks involved. IBM for example, see themselves more as providing partnerships to bridge the gap between medical device companies and healthcare organizations. The mobile telecoms organisations also see partnerships as the way forward in this area.

In summary, many challenges still remain to the increased adoption of remote patient monitoring solutions. Many of the challenges identified though are far from insurmountable. The most challenging appear to stem from the culture of the health system, the increasing shift to mobile communications and the fragmented nature of developments in this area and these do represent a significant barrier to future progress.

As one of the technical consultants remarked however, 'it is still very early days with many of these technologies and it is important to remember where we are'.

There was no doubt though in the minds of all of the individuals consulted as part of this research effort – remote monitoring will become much more commonplace, it is a way forward for healthcare and it will certainly form an important part of patient care into the future.

## 6 Conclusions and future work

This chapter summarises the conclusions of this work, and identifies areas where further research is needed.

This research successfully addresses the research questions and objectives as described in Section 1.

The Research question was divided in to two parts, firstly, what are the challenges associated with the implementation of remote monitoring systems for cardiac patients (particularly those with ICDs)? Secondly, what is the potential of mobile technology in these systems and can mHealth help address both the challenges associated with remote monitoring systems and the challenges in the wider healthcare arena?

The work successfully outlined and reviewed the key challenges in this area. Through the provision of an appropriate case study and by gaining the perspective of the mobile telecommunications industry it is clear that mHealth has significant potential though many issues remain to be resolved.

The work has also highlighted the concerns and fears of the key stakeholders in this field and identified gaps in the knowledge.

There does appear to be a broad consensus as to what exactly the challenges are in this area. The differences arise in their seriousness.

The extent and depth of feeling as to the cultural issues at work in the Irish healthcare system seemed far greater than anything reflected in the review of experiences in the currently available literature The international experience reviewed and examined did not seem to highlight this particular challenge in anyway to the same extent as emerged in this work.

The work will be shared with all the interested parties in the various stakeholder groups in the hope that it comprises a contribution to the general body of knowledge and could assist future developments in this area.

Knowledge of the detail of the many challenges to the implementation of remote cardiac patient monitoring is the first step in overcoming them.

#### Limitations of the Research

While all those interviewed were experts in their various fields the sample size was still quite small. As always in human research there is a risk that particular agendas are at work which is understandable but on occasion it was difficult to know if it was an individual or an organisation who was really speaking.

As already indicated some of the the many of the research papers reviewed for this work were written with the support of some of the device manufacturers and therefore not all the analysis could be described as fully independent.

#### Future Work

Further research is most certainly required specifically into the potential legal and ethical issues surrounding this area as there appears to be a significant knowledge gap in evidence.

As this work focused primarily on the challenges to implementing remote patient monitoring more work is required on the effort required in overcoming these – some suggestions in this regard were described in the discussion but a more thorough examination would be of benefit.

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## 8 Appendices

### Appendix A- 101 Things To Do With A Mobile Phone In Healthcare'

1 Appointment Reminders (SMS)
2 Patient Support (SMS)
3 Medication Reminders (SMS)
4.Appointment booking
5 Medical Data On SIM Card
6 Patient Information For Relatives
7 Peer Support For Patients
8 Post Cardiac Surgery Support
9 Accessing Electronic Patient Records
10 Access To Dietary Information
11 ePrescribing
12 Patient Paging In Outpatient Clinics
13 Support For Alzheimer Patients
14 Support For Diabetes Sufferers
15 Clinical Trials
16 Support For Dementia Sufferers
17 Support During Rehabilitation
18 Support For The Deaf
19 Support For The Chronically Ill
20 Support For Addicts
21 Support For STD Sufferers
22 Baby Monitoring
23 Suicide Watch
24 Support For Children
25 Food Product Dietary Information

26 Allergy Alert Service For Asthmatics (SMS and GPS)
27 Doctor At Home
28 Self Diagnosis
29 Access To Electronic Patient Data For Overseas Travellers
30 Data Capture From Medical Instrumentation
31 Smart Card Applications
32 Monitoring For Asthma Sufferers
33 Blood Glucose Monitoring
34 Temperature Measurement
35 Weight Measurement
36 Medication Compliance Monitoring
37 Voice Pattern Analysis
38 Analysis Of Breath
39 Heart Rate Monitoring
40 Smart Homes For The Elderly
41 Patient Diaries For Clinical Trials
42 Collecting Data From Pacemakers
43 Fitness Monitoring
44 Real Time Patient Assessment
45 Sleep Monitoring
46 Collection Of Data From Wearable Sensors
47 Collection Of Data From Implanted Devices
48 Diabetes Monitoring In Chiropody
49 Detection Of Septic Episodes
50 Remote Antenatal Care
51 Telehealth Gateways
52 Patient Location

53 Pulse Oximetry
54 Personal Diagnosis
55 Early Detection Of Cardiological Syndromes
56 Appointment Scheduling
57 Accessing Electronic Patient Records
58 Diagnosis Support
59 Personal Attack Alarm Service
60 Clinician Identification
61 Asset Tracking (RFID)
62 Stock Control (RFID)
63 Patient Identification (RFID)
64 Dispensing Support
65 Locating Staff
66 Conferencing During Emergencies
67 Accessing Training Material
68 Accessing Laboratory Results
69 Blood Bank Support Services
70 Locating Blood Donors
71 Locating Organ Donors
72 Support For A&E
73 Tracking Surgical Instruments
74 Controlling Insulin Patches
75 Billing
76 Patient Consent
77 Drug Authenticity Verification (RFID)
78 Patient Entertainment And Communication
79 Patient Notes Dictation Systems
80 Tablet Computing



81 Linking Emergency Services To A&E
82 Access To X-ray Images
83 Skin Cancer Monitoring
84 Remote Consultation (Telemedicine)
85 Data Collection From Capsule Endoscopes
86 Conventional Endoscopes
87 Nutrition Coaching
88 Monitoring Wound Healing
89 Support For Neurosurgeons
90 Breast Cancer Screening
91 Context Sensitive Medicine
92 Disease Monitoring (epidemics)
93 Food Contamination Alerts
94 Environmental Contamination Alerts
95 MRSA Detector
96 Telecare In Rural Areas
97 Telecare In Developing Countries
98 A&E Field Support
99 Wireless Stethoscope
100 Support For Aids Sufferers
101 Call Centre Supported Health Services

(TheMobileHealthCrowd 2005)

## Appendix B – Research Matrix

Issues/Challenge		Stakeholders	Interview / Contacts	Resource Review	Interview Objectives
<b>Patient</b>					
	Acceptance	Patient A (Case Study)	Patient A	Materials issued to Patient	Challenges
	Usability				Benefits
	Confidence	Patient Support Groups	via Irish Heart Foundation	Materials issued to groups	Latest 'State of the Art'
	Physician contact			IBM research	
	'Fit' with treatment			Telco research	
	Availability				
<b>Medical</b>					
	Acceptance	Cardiac Specialists ->	Mater	Materials issued to Patient	Challenges
	Usability		St. Vincents	Materials used by Clinicians	Benefits
	Workload		HSE		Latest 'State of the Art'
<b>Technical</b>					
<i>including :</i>	Inter-operability	Device Vendors	Medtronic - contact X	Latest R&D Reports	Challenges
<i>Back-end Systems</i>	Standards (lack of)	IT Systems Vendors	IBM Ireland - contact X	Latest eHealth Strategies	Benefits
<i>Mobile Systems</i>	Bandwidth	Mobile Operators	Telco R&D	Case Studies	Latest 'State of the Art'
<i>Devices</i>	Availability	Systems Integrators	IBM Global	IBM Healthcare 2015	
<i>Communications</i>	Reliability		ICT R&D		
<i>Standards</i>			Biancamed / Biotronik etc.		
<i>Programming</i>					
<b>Legal/Regulatory</b>					
		Comreg ->	Telcos	Comreg Mandates	Challenges
	Data Security	Data Protection Commission	DPC	DPC guidance	Benefits
	Legal	Mobile Operators	ICT	Source materials	Latest 'State of the Art'
<b>Cost/Payment</b>					
	Who pays?	Private	ICT Sector contacts		Challenges
	Cost Benefits	Government	HSE - contact X	Strategy documents	Benefits
					Latest 'State of the Art'

## Appendix C - Table detailing event-triggers in a specific ICD

Category	Event trigger <sup>a</sup>
<b>Technical</b>	
Implant	ERI, EOS, backup mode, emergency pacing, VT/VF detection inactive, special implant status
Leads	RA/RV/LV pacing impedance outside specified range
	Daily shock path impedance (sub threshold) outside specified range
	Impedance of last shock outside specified range
	RA/RV/LV sensing amplitude below specified value
RV/LV pacing threshold rise above specified value	
Transmissions	No HM message received during specified number of days (4–14)
<b>Medical</b>	
Ventricular arrhythmia	VT1/VT2/VF detected
	Ineffective maximum energy shock
Atrial arrhythmia	Long episode detected
	Atrial monitoring episode detected
	SVT detected
Episode	Ventricular episodes
	Ventricular episode duration
	Ventricular monitoring episode
	Periodic IEGM
CRT	Percentage of CRT stimulation below specified value
Heart failure monitor <sup>b</sup>	Mean heart rate above specified limit (at rest and during 24 h)
	AF burden above specified value
	VES/h above specified value

*CRT* Cardiac resynchronization therapy, *CRT-D* CRT combined with implantable cardioverter defibrillator, *EOS* End of battery service life, *ERI* elective replacement time indicator, *IEGM* intracardiac electrogram, *HM* home monitoring, *LV* left ventricular, *RA* right atrial, *RV* right ventricular, *SVT* supraventricular arrhythmia, *VES* ventricular extrasystole, *VF* ventricular fibrillation, *VT* ventricular tachycardia

<sup>a</sup>Except for the “Implant” category, reporting of all other events can be disabled.

<sup>b</sup>The Heart Failure Monitor also includes trends of (1) patient activity measured by an activity pacemaker sensor, (2) percentage of CRT stimulation, (3) P-P variability. These data are processed at a central database, for possible alerts to the caregiver.

Home monitoring event-triggers in a Lumax 540 HF-T CRT-D

(Jung et al.2008).

## **Appendix D – Device Vendors**

### **Biotronik ‘Cardiomessenger & Home Monitoring’**

BIOTRONIK, Inc. sells, markets, and distributes cardiovascular products. The company was founded in 1963 and is headquartered in Lake Oswego, Oregon. (Linked In, 2009)

With the introduction of their first system, in 2001, Biotronik has pioneered the technology of remote IECED monitoring, with applications in over 50 countries (Jung et al. 2008)

The Biotronik Home Monitoring facility is available in all recently manufactured Biotronik ICD.

### **Medtronic ‘CareLink’**

Medtronic, Inc. engages in the development, manufacture, and marketing of medical devices worldwide. The company was founded in 1949 and is headquartered in Minneapolis, Minnesota. (Linked In, 2009)

### **Boston Scientific ‘Latitude’**

Boston Scientific Corporation engages in the development, manufacture, and marketing of medical devices that are used in various interventional medical specialties worldwide. The company was founded in 1979 and is headquartered in Natick, Massachusetts. (LinkedIn, 2009). Boston Scientific offer two different types of implantable cardiac devices that can be monitored remotely with the LATITUDE system: the implantable cardioverter defibrillator (ICD) and the cardiac resynchronization therapy defibrillator (CRT-D.) (Latitude, 2008)

### **St Jude Medical: Housecall Plus Remote Patient Monitoring system**

St. Jude Medical, Inc. designs, manufactures, and distributes cardiovascular medical devices and implantable neurostimulation devices worldwide. The company was founded in 1976 and is headquartered in St. Paul, Minnesota. (LinkedIn, 2009)

## Appendix E – Generic Questionnaire

### Introduction

I am currently undertaking a Masters (M.Sc.) in Health Informatics in Trinity College Dublin and I would be very interested in the perspective of the X sector (particularly X as one of the key players), for my Research.

In summary, my thesis seeks to explore the potential use of mobile technology in delivering on the Remote Monitoring of patients with serious coronary conditions and the challenges to the implementation and use of same. The paper will also seek to focus on cardiac patients who have been fitted with Implantable Cardioverter Defibrillators (ICDs) and the transmission and monitoring of the data produced by these devices.

I'm particularly interested in the challenges with these types of system including for example, Patient Acceptance, Clinician Workload, Technical obstacles, Cost/Reimbursement, Legal/Ethical issues etc. I am also interested in assessing the status of remote patient health management in Ireland generally.

All responses will be treated in confidence.

### Preliminaries

What developments/activities are you or your organisation involved in, in this arena?

#### Part 1 - General

1. In your experience, how widespread is the knowledge and use of remote health management technologies in the Irish health sector?
2. What remote monitoring technologies are currently used in the Irish Healthcare system?
3. What benefits do you perceive from these technologies? What risks?
4. What are the major barriers you see to greater adoption of remote monitoring technologies for health management?
5. Can you think of any steps that might address those challenges?
6. Do you have any other observations or thoughts about remote health management technologies or policies affecting their adoption?
7. Are there demonstration projects that show telemedicine's real savings potential?

#### Part 2 – Questions on the 'Challenge Areas'

In conversations with others and from reviewing the literature, I have identified a number of challenges to the successful adoption and implementation of remote patient health management technologies.

I have divided these into 5 major categories

- (i) Technology issues
- (ii) Legal and Ethical considerations
- (iii) Medical personnel concerns
- (iv) Patient concerns
- (v) Cost / Reimbursement

To what extent do you think the following issues and areas present a challenge to adoption of remote health management technologies?

**(i) Technology Issues**

1. What technical challenges do you see in the implementation of remote patient health managing technologies?

2. The Literature identified the following challenge areas - do you agree?

- a lack of communications infrastructure (e.g., broadband or wireless access)
- a lack of integration between telemedicine systems and other information systems e.g. ordering systems, medical records etc.
- a lack of accepted interoperability standards

**(ii) Legal/Ethical Challenges**

3. How are technological health solutions licensed in Ireland?

4. What are the key legal and ethical challenges to the greater deployment of remote monitoring health solutions?

5. Do you see any of the following issues as a barrier to the use of remote monitoring health solutions in Ireland?

- Compliance with Data Privacy and Security requirements
- Compliance with Legal and Ethical requirements
- Licensing
- the Regulatory environment

**(iii) Medical Personnel concerns**

6. What challenges do you see medical personnel facing with the deployment of remote patient health managing technologies?

7. The Literature identified the following challenge areas - do you agree?

- Workload - "There is a lack of incentive for busy specialists to practice mobile telemedicine because it is seen as yet another imposition for which they are not paid".
- Usability - The currently available telemedicine equipment can sometimes be difficult to handle.
- Power - Organizational changes implemented as a result of new systems may impact on how physicians and other staff members lose or gain power

**(iv) Patient concerns**

8. Are you aware of any issues with Patient ability to adopt, understand and use remote monitoring technology?

**(v) Cost and Reimbursement**

9. How is funding provided for such systems?

10. Is cost an issue i.e. are such systems prohibitively expensive to implement?

11. Is the availability of financial resources for new systems an issue?

## **Appendix F - Notes on Independence of the Literature**

Many of the papers reviewed were written with the support of some of the device manufacturers and therefore not all analysis could be described as fully independent.

For their paper ‘Remote Interrogation and Monitoring of Implantable Cardioverter Defibrillators’, Joseph et al. examined the St. Jude Medical - Housecall Plus system. While there was no declared conflict of interest acknowledgement was given to an employee of that vendor.

In the paper on ‘Potential role of remote monitoring for scheduled and unscheduled evaluations of patients with an implantable defibrillator’ Heidbüchel, et al., were not specific as to what systems were under consideration. There was however a declared conflict of interest as two of the authors were in receipt of unconditional research grants from Medtronic Inc. and Boston Scientific and one a member of the Physician Advisory Board of St Jude Medical and Coordinating Clinical Investigator of the Biotronik-sponsored EuroEco trial.

For their paper on ‘Remote monitoring of implantable cardioverter defibrillator patients: a safe, time-saving, and cost-effective means for follow-up’ Raatikainen et al. examined the Medtronic Carelink system. Funding to pay the Open Access publication charges for that article was provided by Medtronic Inc and there was a declared conflict of interest as two of the authors were employees of Medtronic Bakken Research Center B.V.

In the article ‘Automatic home monitoring of implantable cardioverter defibrillators’ Nielsen et al. (2008) examined the Biotronik Cardiomesenger & Home Monitoring system. Funding for Data collection was sponsored by a research grant from Biotronik GmbH & Co. KG, Berlin, Germany. There was also a declared conflict of interest as one of the authors was conducting research sponsored by Biotronik, one was a consultant of Biotronik and another a full-time employee. Two others were conducting research with the company.



## Appendix G – Research Types

There are two basic research types; Primary & Secondary.

According to University College Dublin’s Centre for Teaching & Learning most research ‘can be categorized as falling into one of two paradigms: viz. the Qualitative or the Quantitative’. The Qualitative ‘paradigm’ is concerned with subjective data. It relates to beliefs, attitudes and changing behaviour (UCD, 2006).

‘Quantitative research focuses on what can be measured and is concerned with objective data. Quantitative data is structured information in statistical form often obtained using a specific question set’. (UCD, 2006). The Centre go on to describe Qualitative and Quantitative research as offering ‘different ways of thinking about the world - and, hence, investigating it’. See also Table below.

	Qualitative Research	Quantitative Research
Also Known As	Interpretative / responsive	Positivist /hypothetico-deductive
Type of reasoning involved	(Usually) inductive	(Usually) deductive
Link with concepts	Identifies concepts	Uses identified concepts and investigates relationships
Action	Sometimes only describes a situation BUT in action-research openly intervenes	Tests relationships between concepts (the proposed theory) by looking for facts that support or deny the suggested relationship.
Outcome	Illuminates the situation to allow those involved in the hope that greater understanding will lead to improvement.	Accepts or rejects proposed theory
Approach to validity	Truth seen as context bound (socially constructed)	Truth seen as objective and universal

Qualitative and Quantitative Research (UCD, 2006)

## Appendix H – Draft Interview Notes

All interviews took place during July and August 2009.

All interview notes were handwritten and appear in their draft form below.

### 1. Research Interview Draft Notes – ICT R&D Consultant

**August 8<sup>th</sup> 2009 – TCD - 2pm to 3.30pm**

**Format: face to face**

Dr. X is a member of Technical Staff at Y. In 2005 she completed her Ph.D. in Electronic and Electrical Engineering from University College Dublin. Dr. has been monitoring the increase in research and development for remote and mobile health monitoring solutions

1.1 - More recent advances –an approach to development that attempts to avoid some of the risks with regard to standards and interoperability.

- use of 'off the shelf' monitoring technology which is often then Bluetooth enabled. -
- Applications run on standard mobile phones and in turn communicate with remote application servers.
- The server manages daily uploads and can issue standard SMS (text) alerts based on programmed thresholds.

1.2 - No great complexity in these constructs. The collation of data is straightforward and thresholds are set to aid management of the application. have in common is that they are based on fairly simple 'number crunching' concepts with a limited range on what can be described. Single measures like blood pressure, glucose levels, weight etc. are good examples

1.3 - Medical personnel are not seeing the complete picture. Some researchers feel that there are risks associated with reviewing ECG data in isolation. e.g. the situation arises where the instructions for remote ECG monitoring often ask the patient to also keep a diary of activity in an effort to get a holistic view. Doctors need to understand what else is going on in the patient's life.

1.4 - questions about the usefulness of only looking at one number and while it may be useful indicator of a patient's condition it may not provide enough information for an adequate assessment.

1.5 - Outside ICDs - challenge is to make any of the interactive features of these systems easy to use. presenting information can be difficult - limitations of e.g. screen and keypad sizes on 'off the shelf' devices? How do you make interactive technology useable for the elderly, people with disabilities etc

1.6 - Next step for remote monitoring systems as requiring 'multi-modal' analysis in order to return a more complete picture of the patient's medical status.

1.7 - Does this mean multiple applications required to effectively monitor patients remotely?

1.8 -As in US Were the health insurers to actively advocate for the adoption of these technologies it is possible that both demand and awareness would increase.

1.9 - Culture here - Loss of power will be fiercely resisted

1.10 – suitability of devices e.g. developed with poor battery life – have seen many developments fail on this issues alone

1.11 - it is still very early days with many of these technologies and it is important to remember where we are'.

## 2. Research Interview Draft Notes – Medical Device Sector

August 8<sup>th</sup> 2009 – Brooks Hotel – 10am to 12.30pm

### Format: face to face

X is Country Manager for Y Ireland and Z is a Technical Support Specialist for the same organisation. Like many of the individuals interviewed as part of the research effort to understand the perspectives of the medical device sector both had previously worked as cardiac technicians. This allowed for some interesting and varying perspectives and real insights into the challenges in implementing new technology solutions and indeed into the health system generally.

### Main issues

2.1 - choice of ICD a matter of the preference of cardiac consultant or, cardiac technician. The adoption of any particular device or service also varies from hospital to hospital. nothing is mandated or imposed or chosen in advance.

2.3 - many cardiac consultants trained in the United States bring their preference for a remote monitoring system home with them.

2.3 - decision as to which device type is to be implanted and, potentially remotely monitored does not always appear to be based on the patient's circumstance e.g. happened that a patient without a landline at home was fitted with a device that can only be remotely monitored using the landline. Risk that a patient may be given a model that uses the mobile network for remote monitoring but no coverage (story of Kerry neighbour...)

### Adoption – Medical personnel

2.4 - all cardiac consultants in Ireland do know about Remote Monitoring systems (often through the efforts of the device sector to educate in this regard) the knowledge and understanding is 'patchy' with ignorance of the potential benefits commonplace across the wider the cardiac arena.

2.5 Fear of change, fear of embracing new technologies

2.6 Lack of structure and accountability in world of cardiac technicians - all appear to work in different ways - Try Rollout using expert user - even this can be fraught with difficulty as the person may not be made available

2.7 - To make a change you really need all the stakeholders on board - consultants, cardiac technicians, (who seem to have a busy workload) and nurses who can often carry influence

2.8. - Procurement process sets up a pool or framework – not so efficient - possibly heading to centralised buying

2.9 HSE, consultants & hospital manager – cultural barriers

- massive cultural issue with structures
- everyone protective of their position
- political
- increased workload
- fragmentation (that term again)
- Consultants are business people first and foremost – nothing should threaten their position.

## Technical Challenges

### 2.10 As follows

- Battery life is key - and is improving
- Bluetooth could be a drain on battery
- As much data as possible with the least amount of power drained
- GPRS will automatically re-send
- Security - data encryption, some of the device manufacturers actually have hackers test their systems
- one identifier - not related to a patient (its a device id)
- N/W not liable ?

### Patient adoption

common barriers, like cost and usability,

### 2.11 Usability

For patients not an issue. As X described the system is designed to work 'out of the box' with little or no patient interaction. However, some induction type training is necessary and the risk is that this does not happen.

Critical time for the patient is the demonstration that takes place just before the patient goes home. This does not always happen - risk that the benefits would not be realised if the basic set up is not performed.

### 2.12 Cost

- built into the cost of the ICD itself

not prohibitively expensive however they are not cheap either - in fact they are more expensive in Ireland than they are anywhere else- something that the HSE should know?? price will come down

not currently a major impact to spending on devices however there are more cuts to come and at some point there will be a cap of some sort and cases are going to have to be prioritised

### Benefits

2.13 Mobility benefits – one very practical benefit highlighted - Allow return to work in that e.g. workers with equipment or near power etc. can easily check if there are potential issues

more access to more information has to be positive

2.14 Another potential benefit - reducing their carbon footprint

2.15 The device manufacturers struggle to sell the benefits (note IHF patient day)

### Licensing

2.16 CE if anything better than FDA ?

### Interoperability

2.17 cardiac departments in Irish hospitals currently have a fragmented IT structure with a variety of IT systems (often for the same function) that vary from hospital to hospital. repositories for rm data not integrated. no plans to do so.

- overcome this barrier by providing simple but effective interfacing abilities such the provision of a USB interface and the ability to easily generate standardised Adobe Acrobat (or .pdf) reports.

2.18 Nothing on medical devices directive

Other

2.19 Raising awareness even though the media is a major challenge. Little media interest even to concept (though they would be wary of commercial promotion) It is hoped that Patient awareness days may help

2.20 remote and mobile ICD monitoring is the way forward, it is going to happen

2.21 - Device manufacturers are working to assist with the issue of increased workload for cardiac personnel. E.g The latest Biotronik system offers a 'traffic light' system to allow for the rapid prioritisation of effort

2.22 - Could rise would be if the health insurance companies to see the potential savings that could be achieved by for example a reduced requirement for 'follow up' (note also R&D)

2.23 - remote monitoring a differentiator between the available ICD systems. As XX explained, the ICD devices themselves are now almost generic in physical construction, the algorithms they use and the capability. The key differentiator is now on the programming etc.

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### **3. Research Interview - A Patient (anonymous)**

**August 19<sup>th</sup> 2009 – Patient residence – 2pm to 6pm**

**Format: face to face**

Notes effectively as per Patient Case Study – lengthy interview presented opportunity to detail final version - see Chapter 4

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#### **4. Research Interviews – Draft Notes - Telecoms Sector - R&D expert/Telco consultant**

##### **Research Interview Draft Notes – ICT/R&D**

**July 20th 2009 – Telco Offices – 10am to 11.30am**

**Format: face to face**

X, independent consultant and formerly a senior engineer in Y's Research & Development division, has been monitoring the increased activity of the mobile telecommunications industry in the Healthcare arena.

XX, GSM Network Consultant with one of the largest mobile operators in Ireland.

X discussed latest research from Informa

Reference - Infoma, (2009) 'Mobile Healthcare: Markets and Trends for M-health Applications' Informa Telecoms & Media)

##### **4.1 – Background**

Telefonica O2 and Vodafone, are active in the Mobile Healthcare arena - mostly Global .  
Telefónica - major Research & Development centre in Granada (Spain) which is focused on the healthcare sector and supported by local government in Andalusia. Goals:

- 'Digital Hospital' Applications to assist medical personnel
- Telemedicine solutions.
- Remote storage and reading of x-rays.
- Emergency service platforms (primarily for the South American market)
- Remote rehabilitation services

In the UK, Telefonica O2 UK have focused on 'Reminder' applications like Hospital Appointment Reminders Messaging - the goal being to reduce the number of 'no shows'  
Vodafone invested in T+ Medical, Vodafone Foundation recently formed an alliance with the UN Foundation and the Rockefeller Foundation for the promotion of m-health in developing markets. (developed countries can learn from innovations in developing countries in mHealth and mobile communications generally).

##### **4.2 - What are the Drivers for mHealth?**

- Government Funding - Incentives exist at local and EU level
- Technological Innovation - New technologies facilitate involvement e.g. new Sensor technologies, LTE etc.
- Industry Associations - Help partnerships and approaches e.g. the Continua Alliance
- Competitive telecoms environment -Falling revenues require new revenue streams, telcos need to be leading edge
- Extremely competitive market environment falling ARPU €42.19 to €39.76

4.3 - Population aging and chronic illness - see that Remote Monitoring of patients in the home in order to reduce healthcare costs and burdens as key drivers for an expansion of mHealth markets. The operators see too that Governments and Private companies are investing more money in mHealth (current climate excepted).

4.4 – Industry orgs - European Centre for Connected Health, Continua Alliance (developing interoperability) and the Bluetooth Special Interest Group.

4.5 Technological advancements

Y have invested significantly in 3G/EDGE network and Mobile Broadband. Better technology should increase these opportunities. LTE – 4G - 100Mb/s downlink and 50Mb/s uplink.

### **What are the Challenges?**

4.6 - Complications in implementing mobile healthcare services within healthcare organizations that they may not have experienced in other Sectors

4.7 Slower (and more costly) process than it usually would as there are a host of additional considerations including:

- healthcare organisations cannot just stop what they are doing to facilitate the introduction of new systems
- there must be no interruption to existing service
- patient safety must be paramount
- services must work from 'Day 1' to ensure adoption
- real drivers and benefits must be visible also to ensure adoption

4.8 Patient-related Challenges

- training and support for patients or patients may be resistant to new systems
- equipment could become damaged or lost due to unfamiliarity with such technology.

Social challenge uncovered by Telecoms

- decline in Patient care and 'well being' following the implementation
- a lack of 'in person' human contact could have an adverse psychological impact on patients
- a trend in family members removing themselves from care situations as they feel that these systems have addressed any needs in that regard.

4.9 - Current market for mHealth quite complex. Fragmentation.- Mobile Operators see both the market and technology development as fragmented - most significant barrier. mHealth market is young. - different paces of innovation (and willingness) between Private and Public health systems. Many vendors/applications developers working in specialist areas of expertise or varying business models. This 'fragmentation of innovation' is a major barrier to achieving economies of scale that operators are used to or less than what they need

4.10 Voice and Text are easy - complex applications require a number of different platforms to be developed depending on the requirements. - Capability to support a variety of high-end handsets and mobile devices and their application may become a burden

4.11 - medical applications or devices have to be tested for clinical use by a Regulatory body. - - regulatory impositions the operators see this as a barrier to rollout of mHealth solutions. (not always the best relationship with Comreg).

4.12 - healthcare specialists well aware of the requirements in this area but Mobile operators are extremely wary of it all.

4.13 - question of how these new systems integrate with existing and often incompatible systems or even if dependent systems actually exist e.g. Patient Management Systems.

4.14 - risks to the adoption of mHealth systems by healthcare professionals.

- concerns over security of Patient data
- Concerns and fears surrounding electromagnetic interference (EMI).
- 'technophobia'

4.15 - ensure that systems are relatively easy to use, reliable and have been successfully and comprehensively shown to be a success in e.g. clinical trials.

4.16 - huge complexity in remote monitoring technology. Systems that require repeated and/or continuous access to the mobile network have to be managed to ensure no risk of system overload. Needs to be Provisioning, Rating and Billing etc. as well (not easy)

Who pays?

4.17 - It is still unclear

Some patients will have no insurance anyway (more US?)

A challenge for Governments worldwide, but particularly right now in Ireland, in providing finance for new health initiatives

4.18 - High Costs opex, capex, devices - key barrier to implementing remote monitoring solutions as well as additional cost for Training, ongoing support and upgrades. Business process re-engineering costs plus any requirement to incentivize.

4.19 – high power consumption is another tech challenge e.g. Bluetooth – new developments are emerging but cost is big concern here

4.20 – general wariness of healthcare – not understanding the standards, the complexities, fear of liability, The approach required would be to partner and risk-share

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## **5. Research Interviews – Draft Notes – Patient Support Group**

**August 18<sup>th</sup> 2009 – Lansdowne Hotel – 5.30pm to 6.30pm**

**Format: face to face**

List of key contacts provided

List of key web sites provided

Discussed Patient case study and general research

5.1 - highlighted major challenge - and that was major shortage of personnel in the key cardiac areas

Ireland continues to have a shortage of cardiologists (12 per million versus treble that for EU avg)

(and electro physiologists)

5.2 - Patient adoption

- patients generally good at following instructions “ stand on one leg in the rain and many would simply comply”

- Some Usability challenges (though none new)

5.3 New research required in remote ECG monitoring, its accuracy and effectiveness



## 6. Research Interview – Draft Notes – Consultant Cardiologist

July 21st 2009 – IHF Offices – 9am to 10am

Format: face to face

- 6.1 - remembered some initial patient resistance but this was quite a number of years ago
  - 6.2 - is totally in favour of the RM approach
  - 6.3 - TTM around for many years (indeed some 30 years ago Dr M was monitoring a priest in Africa TTM for Pacemaker – recording whistles down the phone
  - 6.4 – multiple daily transaction processing - workload a major issue –
  - 6.5 - 24 hr a lot of data could be time consuming - generate a lot of noise - major risks
  - 6.6 - Target events - Implant a recorder either triggered or continuous recording
  - 6.7 - No reason for not having one central Recording bank but - divorcing people who analyse - cardiac physiologists (was a shortage at one time)
  - 6.8 - Replacing outpatient visits Versus - continuous surveillance?
  - 6.9 - Real benefit monitoring people at risk - who may ultimately need devices
  - 6.10 - don't want continuously recorded data
  - 6.11 - Random hours records to assess e.g. burden of atrial fib
-

## 7. Research Interview – Draft Notes – IBM Ireland

July 24<sup>th</sup> 2009 – IBM – 4.30pm to 6.30pm

### Format: face to face

Interview with healthcare manager in IBM Ireland who was involved in the Healthphone Project

eHealth background - developments

7.1 Reviewed HealthPhone presentation and technical manuals (confidential) – use approved summary only

Note – approved summary is what is outlined on Pages 55 & 56

See Biancamed materials (confidential) – background only

Benefits

7.2 - User Adoption issue – very positive feedback from patient testimonial e.g. “; “Its not an intrusion – it is a great feeling of security because you know that people are picking this up right away whereas the old fashioned way, they don’t see it until you go and see them”.  
'connected care in real time' assists in terms of peace of mind

7.3 - potential 8m p.a. savings 60m overall

Challenges

7.4 - Cost - Funding – ended up went to a Private Foundation

7.5 - Phone - had to be that particular phone - couldn't be your normal one – technical issues SE

1. GPRS coverage
2. firmware issue

7.6 - Bluetooth Healthcare - possible use in future

7.7 Problem

Savings - Acute (hospital)

Cost - Primary (e.g. community, GP)

7.8 Public Procurement Process may hinder progress on these.

7.9 - question - was the mobile a medical device??

7.10 - legal queries Latest from EU on this - see IBM UK

## **8. Research Interview – Draft Notes – IBM UK**

**July 21st 2009 – 6pm to 7pm**

**Format: by phone**

Interviewee is a Senior Executive in the Healthcare arena for IBM UK & Ireland.

8.1 Access permissions given for Continua Health Alliance (industry coalition)

8.2 Reviewed US barriers – use Figure 4.1

8.3 Discussed Patient Adoption issues (suggested use AARP Research)

8.4 EU Medical Devices Directive, this has been re-drafted several times following consultations with interested parties (ETSI, CEN, CENELEC, COCIR, Continua etc)

8.5 “It is hoped that the final versions will not impose too many onerous conditions of suppliers of telemedicine and telehealth services”.

8.6 Seen (via COCIR) and it seemed to be mostly concerned with the safety of the devices and integrity of data generated, and how the data is subsequently processed.

8.7 Sure that the EU will try to not make this another inhibitor to market growth.

8.8 Reviewed the EU Communication on Telemedicine (copy given) especially

- Bringing legal clarity
- Building confidence in and acceptance of telemedicine services
- Solving technical issues and facilitating market development

8.9 The Communication gives some very specific recommendations and actions to help remove many of the current barriers to deployment.

## 9. Research Interview – Draft Notes – Medical Device & ICT company

July 24<sup>th</sup> 2009 – Company Offices – 5.30pm to 7.30pm

**Format: face to face**

X, a former technician in the hospital sector) and currently a Customer Support Manager with Y

9.1 - X has seen an upsurge in the adoption of eHealth strategies and systems driven both by the hospitals and the HSE with both sections of the health service broadly supportive of eHealth and aware of the significant benefits that can be derived.

9.2 - eHealth initiatives like Y's implementation of new Clinical Information Systems (CIS) for the ..... Care Unit can, in addition to the core deliverable, also deliver upon some of the HSE's key requirements for eHealth systems including

- Benchmarking information allows the comparison of outcomes across the service
- ease of clinical audit
- driving efficiency e.g. number of hospital 'bed days'
- number of days a patient spends in hospital

9.3 - The HSE's strategy in support of a move to supporting patients through the greater provision of local and comprehensive Primary care facilities also lends itself to an increased use of eHealth and remote monitoring technologies.

9.4 - Y, amongst others, are currently building, equipping and staffing these centres which aim to treat more patients via primary v acute

9.5 - Hospitals receive an annual budget allocation for the provision of ICDs and related cardiac services. From that allocation the hospitals decide which devices are required and would then generally source these from a number of different vendors.

9.6 Should the adoption of a new remote monitoring solution require additional staff then it is highly unlikely to proceed - a staff recruitment embargo

9.7 - The ICD of a particular medical device provider can only be read by the device reader of that same provider.

- no standardisation and no such thing as a generic reader.
- systems are proprietary which can necessitate the maintenance of variety of readers and systems
- Patients presenting with devices not supported by the hospital cannot avail of facilities.

9.8 - standards like HL7 systems integration can still pose difficulties and while not arduous they can still add integration effort to clinical information system projects. reason for this is that there are actually a number of differing variants with some standards including HL7. (NB. also mentioned by HSE)

9.9 - A number of years ago Y attempted to introduce some new and potentially beneficial technology to one of the larger Dublin hospitals.

9.10 – ZZ is a non-invasive, outpatient treatment for angina and heart failure that works by pumping blood to the heart at the appropriate point in the heart's cycle. X's company were convinced that this type of treatment did help to alleviate symptoms of heart failure. cardiac nurses also convinced of the benefits of such therapy but unable to get any interest in this product from consultants etc. Why?, was nothing in it for them.

9.11 - reluctance on the part of some consultants (or technicians) to adopt new technologies was a common theme. or new technologies that will reduce earning potential.". patient benefit – so what?

9.12 – no free lunches (NB emerged on other medical device discussion too)

9.13 - adoption of new technologies by the medical community may also be hindered by concerns around liability as direct responsibilities are seemingly removed by technology.

9.14 - different types of hospital in Ireland all with varying cultural, structural and governance differences. They are as follows the:

- HSE or 'Statutory' hospitals,
- Voluntary public hospitals,
- Private hospitals,

9.15 - Voluntary more innovative and consultant-lead whereas 'Statutory' pay more attention to 'cost/benefit' analysis. A consultant-lead approach was e.g. first heart transplant and lung transplant operations in Ireland. A consultant-lead approach can sometimes lead to the adoption of leading edge technologies but not financially viable, approach based on financial considerations alone may mean higher mortality rates

9.16 - Cultural e.g. Tallaght Hospital or 'them and us' culture that exists in the health service i.e. between the hospital sector and the HSE

9.17 - All medical devices in Ireland and the EU must carry the CE mark

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## **10. Research Interview – Draft Notes – HSE Manager (National-level)**

**September 8<sup>th</sup> 2009 – HSE National Offices – 2pm to 3pm**

**Format: face to face**

Interviewee discussed the HSE ICT Strategy. (Unfortunately meeting was very late for inclusion of more detail on what was a fascinating insight into that organisation).

- 10.1 hospitals are quite free to purchase new medical technology without reference
- 10.2 no basic integrated 'backbone' network for the health system
- 10.3 Yes, HL7 is a standard but within HL7 there a number of different versions
- 10.4 Change is difficult with many entrenched and powerful interest groups in the health sector
- 10.5 HSE still basically 8 orgs
- 10.6 New technologies like RM are inevitable