Remote monitoring for patients with implanted defibrillators

Technology evaluation and broader regulatory framework

KCE reports 136C

Belgian Health Care Knowledge Centre
Federaal Kenniscentrum voor de Gezondheidszorg
Centre fédéral d'expertise des soins de santé
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Executive summary

OBJECTIVES

The objectives of this report were twofold:

- to describe the technology of remote monitoring systems specifically for Implantable Cardioverter Defibrillators (ICDs) whilst providing a systematic review of the available evidence on the clinical effectiveness and cost-effectiveness;
- to identify organisational, reimbursement and legal hurdles for the implementation of remote monitoring. This was done in a broader sense, i.e. irrespective of being related to ICDs.

The combination of these two aims has led to an extensive report that is also intended to be used as a reference document.

THE DISEASE

Individuals at high risk for sudden cardiac death are often treated by implanting an ICD. Patients receiving those devices are ranging from those with an increased primary risk for cardiac arrest and no or only mild symptoms, to patients with advanced degrees of symptomatic heart failure. The latter group needs much more medical attention, apart from controlling the well-functioning of their ICD. However, both groups are dependent on the correct functioning of their ICD-system for surviving an episode of cardiac arrest.

THE DEVICES

ICDs are implantable, battery-powered, programmable electronic medical devices capable of monitoring the heart rhythm and delivering anti-tachycardia pacing (ATP), cardioversion and/or electric shock to restore normal rhythm when a life-threatening arrhythmia is detected. An ICD system consists of two main parts: the defibrillator and the leads with electrodes and shocking coils.

Patients with severe heart failure are sometimes treated with an implanted cardiac resynchronisation therapy device (CRT). These CRT devices can be incorporated in a standard ICD and is then denoted as a 'CRT-D'. This report deals with both the remote monitoring of ICDs and CRT-Ds. For ease of reading we will use the term ICD to designate both types of devices.

Device longevity of ICDs has been gradually extended with advances in battery technology. ICDs now last from 5 to 8 years before replacement is required. The price of an ICD has been decreasing over time but large price differences are seen between countries.

IN-CLINIC FOLLOW-UP OF PATIENTS AND DEVICES

ICDs are complex pieces of electronics that interact directly with the patient. Therefore, regular follow-up of both patient and device is recommended. This follow-up, which is performed in Belgium within the framework of the cardiac care programmes (E), covers both the functioning of the device and the condition of the patient. Guidelines recommend several follow-up schedules, adapted to device type, time elapsed since implantation and patient general health condition. On top of this, unscheduled follow-ups may be necessary because of device alerts or for clinical reasons.

PRINCIPLES OF REMOTE MONITORING

One of the expressed goals of introducing remote monitoring technology for ICDs is to reduce the number of in-clinic follow-ups needed. This might offer advantages in terms of less workload for health care personnel and less patient travelling. Additionally, remote monitoring can be used to monitor system integrity, to alert on tachyarrhythmia episodes and potentially for remote disease management of underlying conditions and co-morbidities, such as atrial fibrillation and congestive heart failure.

In this report we will mostly use the generic term of remote monitoring but this term actually covers three different practical concepts:

- remote monitoring (strictu sensu): transmission of device data on a regular (daily, weekly) basis with an automatic alerting system allowing the physician to be informed on a regular basis of any pre-defined events;
- remote follow-up: transmission of device data at a pre-specified moment in order to replace an in-clinic follow-up or to prepare one;
- remote disease management: transmission of device data to remotely measure clinical parameters in order to warn about, prevent, anticipate or minimise a medical condition and/or to modulate therapy.

TECHNOLOGY OF REMOTE MONITORING

All ICDs can be interrogated and reprogrammed during an in-clinic visit, but most current ICDs also have the potential to be remotely monitored. In recent years, major ICD manufacturers started to offer remote monitoring systems that allow communicating data from the device to the implanting physician and referring colleague physicians.

In practice, remote monitoring occurs in several steps.

- First, data from the device is communicated to a monitor in the patient's immediate vicinity through a magnetic induction system or through radio frequency. Depending upon the system used, transmission can occur automatically when episodes of arrhythmia are detected (device-initiated transmission), on a regular basis (daily or weekly monitor-initiated remote monitoring), or at pre-scheduled moments (physician-initiated remote follow-up) and in some cases even patient-initiated.
- Next, the data is transmitted over a mobile or fixed telephone line to a central database server. The treating physician(s) has secured access to the data of the devices under his supervision.
- The physician(s) can also be alerted about specific urgent events by e-mail, SMS, fax or phone messages. The triage system and the kind of events triggering alerts can be customised and may therefore aid with the organisation of the workflow at the follow-up clinic.

CLINICAL EFFECTIVENESS AND SAFETY

The assessment of the literature was limited to the years 2006-2010 in order to ensure describing only current state of the art remote monitoring. Current evidence about the clinical efficacy, effectiveness, safety and patient acceptance of remote ICD monitoring is mainly based on small observational case series and expert opinion. Most clinical studies, both rare RCTs and observational studies, were performed on patients with no, or only mild symptoms. Therefore, results from these studies cannot be directly extrapolated to severe heart failure patients who are likely to need more direct and personal clinical attention.

Events detected

In all studies that considered both clinical events and device integrity, the majority of alerts were for clinical events and only a small proportion (around 5%) was for device integrity alerts. Most evidence in literature, though, is available for the detection of this infrequently occurring device malfunctioning. This can indeed be detected earlier when remote monitoring is added to regular follow-up. There is also limited evidence that specific patient events (mainly arrhythmias and inappropriate arrhythmia detections) are diagnosed earlier when remote monitoring is added to regular follow-up. Given adequate alert triage, the workload for both technical nurses and clinicians in electrophysiology centres appears to be limited, even with daily transmissions of data.

Safety of replacing some in-clinic follow-up by remote follow-up or remote monitoring

There is limited evidence indicating the safe replacement of some of the in-clinic follow-up visits by scheduled remote follow-up or regular remote monitoring for ICD patients with no, or only mild symptoms. There is however no evidence to enable extending these findings to more symptomatic congestive heart failure patients.

Patient outcomes

Very little evidence was found on important health outcomes (mortality, general health, health related quality of life, adverse events). Evidence on quality of life is currently perplexing: the only RCT that reported on quality of life reported lower health-related quality of life for the remote monitoring group.. However, evidence on quality of life from this small trial is not solid and should be reassessed by larger and better studies. Several major trials are ongoing implying that at least some of these conclusions may need to be revised in the future.

COST-EFFECTIVENESS

Due to the lack of clinical evidence, the economic literature is very inconclusive and the quality of the studies is low. The cost-effectiveness of remote monitoring for Belgium could not be investigated due to the lack of effectiveness data, the absence of cost data for the Belgian setting and a perceived general reluctance of care-givers to replace in-clinic follow-up by remote monitoring. By consequence, there is currently insufficient evidence to conclude on the cost-effectiveness and on the potential financial impact for the Belgian health care payer.

LEGAL ASPECTS

A wide range of legal issues such as the duty of professional secrecy and security aspects, professional and product liability, patients' rights, etc… are conditioning the implementation and successful functioning of a remote monitoring system, be it for ICDs or any other medical device alike.

There currently exists no regulatory framework specifically dealing with the issue of remote monitoring specifically. Both the EU and the local Belgian legal framework applicable to remote monitoring in general were investigated.

RELEVANT EU LEGISLATION

Although EU legislation does not address specifically eHealth systems and services, several Directives have a direct impact on telemonitoring applications.

- Processing of personal (health) data is mainly governed by the European Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- In the domain of liability, regulations are available in a fragmented way: objective liability of the producer of a defective product, liability of the data controller, liability of information system provider, etc… There is, however, no harmonised liability regime for professional liability for damage caused by healthcare services.
- Dispositions with regard to transparency and identification of suppliers, service providers and other consumers' (patients) protection rules for e-services are provided in several Directives.

DUTIES, RIGHTS AND RESPONSABILITIES OF THE DATA CONTROLLER, THE DATA PROCESSOR AND THE DATA SUBJECT

A number of duties, rights and responsibilities linked to the different roles (data controller, data processor, data subject) of intermediaries in the remote monitoring application are defined in EU data protection legislation and implemented in Belgian legislation (issued on 8 December 1992, hereinafter called as the Data Protection Law, DPL). The data controller must ensure that all obligations included in the DPL are respected. Prior to any data processing, the data controller needs to file a notification to the Belgian Privacy Commission, and must communicate several information elements to the patient, including the purpose(s) of the processing and the recipient(s) of the data. A contract between the parties involved, clarifying and defining their respective roles and responsibilities, is thus of an utmost importance.

Persons accessing the personal health data need to be bound by a duty of professional secrecy or an equivalent contractual obligation. Both the data controller and the data processor have the obligation to take appropriate technical and organisational data protection measures against accidental or unlawful destruction, accidental loss, modification or unauthorised access or any other non authorised processing.

As for all health data, health data collected within the telemonitoring application can be shared between the treating physician, his/her (para)medical team and the referring physician if the addressee is also bound by the duty of professional secrecy, if the sharing of the confidential information is necessary to ensure continuity and quality of care and if the patient has given his explicit or tacit consent, or if the disclosure is at least in his/her best interest. The necessity of the intervention of ICT staff and other experts in the treatment of personal data of the patient requires considering them as "collaborators" of the health care professionals bound by the same confidentiality rules.

PATIENT RIGHTS AND DUTIES

The Belgian Patient's Rights Law (issued on 22 August 2002) defines several patients' rights that have a direct impact on the telemonitoring application.

Informed consent

Patients should receive all adapted and relevant information they need on the telemonitoring as a medical intervention and on the processing of their personal health data. The information given to the patient should include amongst others the identity of the different parties involved in the telemonitoring trajectory as well as their roles and responsibilities and the limitations and modalities of the telemonitoring system. Moreover, the patient should be informed on the fact that the service is currently not reimbursed and that it is not an emergency service.

It is unclear whether the physician would be legally obliged to inform the patient about the possibility of remote monitoring as an alternative or additional method of follow-up since there is no sound evidence on the clinical effectiveness.

For the telemonitoring application an integrated approach using a written consent containing information elements regarding data processing as well as the information linked to the telemonitoring as medical intervention is preferable.

Right to data access

The patient has a right of direct access to his or her own file including the data (or the derived results) revealed by the telemonitoring. He or she can request a copy of it, but has also the right to request correction or destruction of the data and the right to object to processing.

Right to freely choose a healthcare professional

Although patients can in principle freely choose a healthcare professional, in case of telemonitoring, however, this will not always be possible for the preview of the transmitted data or during on-guard duty.

Patient collaboration

The physicians need to respect the patient's rights as far as the patient collaborates in the patient-physician relationship.

LIABILITY ISSUES

Telemonitoring, not considered as the standard of care (yet)

As of today, there is no sufficient evidence on the clinical effectiveness of telemonitoring to consider it as the standard of care for the follow-up management of chronic patients suffering from heart diseases. Yet, in order to prevent defensive behaviour by physicians fearing liability, guidelines should be elaborated for physicians on how to deal with this emerging technology. The upcoming Belgian *'no-fault'* system does not solve the problems regarding the physicians' liability.

Contractual clauses and emergency systems

Contractual clauses stating that telemonitoring and alerts systems cannot be considered to be emergency systems even if they do function as emergency systems should be analysed with caution. Guidelines and corresponding service level agreements regarding the maximum response time for alerts and protocols regarding the assurance of continuity (who should organise the guards, status of the physician during on-guard time,…) are necessary to enhance medical and legal certainty for patients and physicians.

Industry Employed Allied Professionals

Industry Employed Allied Professionals (IEAPs) are professionals that are employed by industry with the aim to give technical council to the health professionals. IEAPs are legally authorised to provide technical expertise and advice regarding medical devices, but if they perform (technical) nursing activities, they could be sanctioned with fines and/or imprisonment. If a company systematically puts IEAPs at the disposal of physicians for free for assistance during surgery or during patient follow-up this could be considered as illegal according to the Belgian law on Pharmaceuticals.

Centralisation of liability

As telemonitoring implies the involvement of many players, particularly outside the hospital, the centralisation of liability at the hospital does not offer a proper solution.

Product liability

A producer is liable for damages caused by a defective product (for instance the decision-supporting software, the implanted device, the bedside monitor,...) as far as the affected party proves the existence of the product and the causal relation between the flaw in the product and the incurred damage. The affected person does not have to prove the producer's fault.

ORGANISATIONAL AND FINANCIAL ASPECTS OF REMOTE MONITORING OF ICD AND OTHER MEDICAL DEVICES

To date, no specific regulatory framework exists for remote monitoring in Belgium. Neither the telemonitoring equipment and supporting data processing services, nor the remote follow-up or monitoring by treating physicians are reimbursed by the compulsory health insurance. Companies mostly provide the service for free as part of their marketing policy for selling ICDs, but the systematic provision of this service for free might be illegal.

Some countries reimburse remote follow-up in the same way as in-clinic follow-up, but the monitoring equipment and supporting services are currently not reimbursed in most European countries.

Whenever reimbursement would be considered, remote follow-up (at scheduled moments) should be distinguished from remote monitoring (continuous or more regular transmission with a triage system), as the workload for physicians and allied personnel could be quite different.

In the case that alert systems with triage are used, timely reaction is mandatory. Since the number of alerts per day is rather limited, rotating on-guard systems between colleagues of the same specialty can be considered. The workload for the physician or other clinical personnel involved in telemonitoring depends on the frequency of data reviewing. Either dedicated time for the involved hospital personnel or the centralisation of data triage within a specialized centre (external or outsourced) are possible options to manage the workload.

The currently available systems and web applications differ significantly between manufacturers, which constitutes an important barrier for the implementation of remote monitoring, since most hospitals implant devices of more than one manufacturer. Furthermore, direct communication of the monitoring data to the centre's electronic health record system would be highly desirable.

DISCUSSION AND CONCLUSIONS

Remote monitoring of ICDs and other devices seems promising and attractive in theory, and the field is currently in constant evolution, with different approaches and solutions depending on the suppliers. There is currently very little evidence on direct patient benefits although the partial replacement of the in-clinic follow-up by remote monitoring seems reasonably safe in ICD patients with no, or only mild symptoms. Whether this is also feasible and safe in the Belgian context is not yet clearly established, and will undoubtedly depend on the organisational and financial framework that will be provided, and the availability of sufficiently detailed guidelines that orient clinicians to deal with this emerging technology.

A variety of new applications of remote monitoring will undoubtedly emerge in the near future. According to expert opinion these will relate to different medical domains including obviously cardiac monitoring, but also diabetes care, elderly care, remote monitoring of pregnancies at risk etc… The legal and organisational hurdles that are identified in this report need to be addressed. Hence, specific juridical guidance for the interpretation and application of the relevant legislation should be developed. Doing so, would prepare the healthcare system to deal in an effective manner with this emerging technology.

As long as benefits for the patient or the healthcare system are not clearly demonstrated, regular reimbursement for remote monitoring should remain out of scope. Even conditional reimbursement of remote monitoring irrespective of the medical application, should only be considered once there are sufficient indications of efficacy and safety, and needs imperatively to be accompanied by a system of additional pre-defined clinical evidence gathering. This could be integrated in a convention between the NIHDI (RIZIV/INAMI) and the centre performing the regular follow-up and/or the remote monitoring or remote follow-up. More in general, dissemination of an unproven, and, hence, even potentially inferior or harmful technology paid by the patient, private insurance or provided for free by the company, without due data collection and timely evaluation, seems hard to justify from an ethical point of view.

With the arrival of remote monitoring, the need to develop new financing mechanisms becomes evident. These should not only cover the reimbursement of care delivered at one specific moment and place, but also patient care and monitoring that occur remotely and over longer time periods.

RECOMMENDATIONS

GENERAL RECOMMENDATIONS FOR REMOTE MONITORING

- Although the existing legislation on data protection and security, professional secrecy, liability and patients' rights fully applies, remote monitoring covers a variety of specific situations in which solely a case-specific answer offers an appropriate solution. Hence, specific juridical guidance for the interpretation and application of the relevant legislation should be developed.
- In order to prevent defensive behaviour by physicians fearing liability, more detailed clinical guidelines should be elaborated on how to deal with this emerging technology.
- In general, in the absence of proven safety, effectiveness, and cost-effectiveness, a conditional reimbursement of remote monitoring applications could be considered once there are sufficient indications of efficacy and safety. Any conditional reimbursement should be accompanied with a rigorous system of registration with pre-defined research design and modalities and a re-evaluation within a few years. This could be integrated in a convention between NIHDI (RIZIV/INAMI) and the centre performing both regular follow-up, and remote monitoring or remote follow-up.

SPECIFIC RECOMMENDATIONS FOR REMOTE MONITORING OF ICDS

- Since there is currently insufficient evidence for relevant clinical benefits for the patient, nor for the cost-effectiveness of this technology, no reimbursement or other cost-coverage can be recommended at this stage.
- Because of significant implementation differences between the current remote monitoring systems for ICDs, no uniform approach to cost coverage or reimbursement should be decided.
- If the large ongoing trials would offer indications of relevant patient benefits or efficiency gains, a conditional reimbursement scheme might be considered with limited access and evidence collection on safety, quality of life and health outcomes. This should allow for further exploration to what extent follow-up visits can be effectively and safely reduced with those patients. This re-evaluation should be possible by the end of 2011.

Scientific summary

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OBJECTIVE AND SCOPE

Implantable Cardioverter Defibrillators (ICDs) are battery-powered, programmable electronic medical devices used for the prevention and treatment of life-threatening cardiac arrhythmias. Such arrhythmias are a common cause of sudden cardiac death. The therapy of defibrillation consists in delivering a well-timed therapeutic dose of electrical energy to the affected heart.

ICDs can be used for the primary prevention in persons at a high risk of sudden cardiac death, or for the secondary prevention in patients who already survived a previous cardiac arrest.

The advent of a new technology, known as remote cardiac monitoring, now allows Cardiovascular Implanted Electronic Devices (CIEDs) to be interrogated on a regular basis through telephone lines, mobile phone or internet technology.

Regular follow-up of these devices and the patients is always recommended and serves multiple purposes. These include: checking device integrity, interrogation of the device for recorded arrhythmias, clinical investigation of the patient, possible reprogramming of the device and/or a change in the patient's medication based on these findings, referring the patient for diagnosis and therapy to other medical speciality disciplines, providing healthy life-style and revalidation recommendations, determining fitness for work and driving, etc. It also important to note that these follow-up tasks are typically performed through the teamwork of several distinct healthcare personnel, being the electrophysiologist, the treating cardiologist, technician nurses, revalidation nurses, etc. as well as the manufacturer representatives, also called the Industry Employed Allied Professionals (IEAPs).[1]

This raises the central question: what does remote cardiac monitoring technology intend to replace, add to or do away with? The main implanting centres in Belgium have sufficiently trained electrophysiologists and technical nurses capable of performing a complete device follow-up and reprogramming. In other centres, physicians and nurses rely heavily on the assistance of an IEAP. Apart from expected marketing benefits, one of the other drivers for industry to develop and promote remote cardiac monitoring has been the prospect of long-term cost-savings in this area of clinical support.

The aims of this report are twofold. The first aim is to describe the technology of remote monitoring systems specifically for ICDs and to provide a systematic review of the available evidence on the clinical effectiveness and cost-effectiveness through a rapid HTA. The second aim is to focus on the organisational, reimbursement and legal aspects of emerging technologies of remote monitoring in a broader sense; i.e. irrespectively of being related to ICDs. The combination of these two aims has lead to a lengthy report that is mainly intended to be used as a reference document.

In this report we will mostly use the generic term of remote monitoring but this term actually covers three different practical concepts:

- remote monitoring (strictu sensu): transmission of device data on a regular (daily, weekly) basis with an automatic triage system allowing the physician to be informed on a regular basis of any pre-defined events;
- remote follow-up: transmission of device data at a pre-specified moment in order to replace an in-clinic follow-up or to prepare one;
- remote disease management: transmission of device data to remotely measure clinical parameters in order to warn about, prevent, anticipate or minimise a medical condition and/or to modulate the administration of therapy.

Depending upon the system used, transmission can occur automatically when episodes of arrhythmia are detected (device-initiated transmission), on a regular basis (daily or weekly monitor-initiated remote monitoring), or at pre-scheduled moments (physician-initiated remote follow-up) and in some cases even patient-initiated.

The matters discussed are rather complex. Moreover, the terminology is not always used consistently by different manufactures and clinical users. Therefore we included a list with acronyms and abbreviations in the following pages. A glossary with the terms as used throughout this report can be found in the appendix.

An HTA report specific to implantable defibrillators in the primary prevention of sudden cardiac death, was produced previously as KCE report 58C.[2]

ACRONYMS AND ABBREVIATIONS

2G	second Generation mobile telephone system (i.e. GSM)
2.5G	second Generation mobile telephone system with GPRS
3G	third Generation mobile telephone system (i.e. UMTS)
3.5G	third Generation mobile telephone system with HSPA
ACC	American College of Cardiology
AED	Automated External Defibrillator
AF	Atrial Fibrillation
AFL	Atrial Flutter
AHA	American Heart Association
AM	Ante Meridium; in the morning
AMI	Acute Myocardial Infarction
AT	Atrial Tachycardia
ATP	Anti-Tachycardia Pacing
BAN	Body Area Network
BeHRA	Belgian Heart Rhythm Association
bmp	beats per minute
BS	Brugada Syndrome
CABG	Coronary Artery Bypass Grafting
CC	Civil Code
CDC	Centres for Disease Control and Prevention
CEA	Cost-Effectiveness Analysis
CHD	Coronary Heart Disease
CHF	Congestive Heart Failure
CI	Confidence Interval
CIED	Cardiovascular Implanted Electronic Device
CPR	CardioPulmonary Resuscitation
CRD	Centres for Review and Dissemination
CRM	Cardiac Rhythm Management
CRT	Cardiac Resynchronisation Therapy
CRT-D	Cardiac Resynchronisation Therapy with Defibrillator
CRT-P	Cardiac Resynchronisation Therapy with Pacemaker
CS	Coronary Sinus
CUA	Cost-Utility Analysis
CVA	Cerebro Vascular Accident
CVD	Cardiovascular Disease
DPA	Data Protection Act (Belgium)
DPD	Data Processing Directive (EU)
DRG	Diagnosis Related Group

DSL	Digital Subscriber Line
ECA	Europe, Canada and Africa
ECG	Electrocardiogram
EEPROM	Electrically Erasable Programmable Read-Only Memory
EF	Ejection Fraction
EHR	Electronic Health Record
EHRA	European Heart Rhythm Association
EIRP	Equivalent Isotropically Radiated Power
EN	European Norm (standard)
EQ-5D	EuroQoL 5 dimensions
ERC	European Radio Communications Committee
ERI	Elective Replacement Indicator
ESC	European Society of Cardiology
etc.	etcetera; and so on
ETSI	European Telecommunications Standards Institute
EU	European Union
E-W	England and Wales
FCC	Federal Communications Commision
FDA	Food and Drug Administration
FFS	Fee For Service
FM	Frequency Modulation
FSK	Frequency Shift Keying
FU	Follow-up
GHz	Gigahertz or 109 hertz (unit of frequency)
GP	General Practitioner
GPRS	General Packet Radio Service (extension on the GSM system for data communication
GSM	Global System for Mobile Communications (or Groupe Special Mobil)
HF	Heart Failure
HIS	Health Information System
HL7	Health Level 7®
HRQOL	Health Related Quality of Life
HRS	Heart Rhythm Society
HSDPA	High Speed Downlink Packet Access
HSPA	High Speed Packet Access
HSUPA	High Speed Uplink Packet Access
HTA	Health Technology Assessment
HTTPS	HyperText Transfer Protocol Secure; should not be confused with S-HTTP
HV	High-Voltage
ICD	Implantable Cardioverter Defibrillator
ICER	Incremental Cost-Effectiveness Ratio

ICM	Implantable Cardiac Monitor
ICT	Information and Communication Technology
ICU	Intensive Care Unit
i.e.	id est; this is
IEAP	Industry Employed Allied Professional
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IEGM	Intracardiac ElectroGraM
INAHTA	International Network of Agencies for Health Technology Assessment
IP	Internet Protocol
IR	Incidence Rate
ISDN	Integrated Services Digital Network
ISHCOF	International Study of Health Care Organization and Financing
ISM	Industrial, Scientific and Medical radio bands
ISMS	Information Security Management Systems
ISO	International Organization for Standardization (from the Greek word ἴσος, not an acronym nor initialism)
ITT	Intention-To-Treat (population)
ITU	International Telecommunication Union
kbps	kilobit (1000 bits) per second; a unit of data transmission speed
kHz	kilohertz or 103 hertz (unit of frequency)
LBT	Listen Before Talk (communication protocol)
l.c.	locus citatum (legal texts)
LCD	Liquid Crystal Display
LE	Life Expectancy
LV	Left Ventricle; occasionally also Low-Voltage
LVEF	Left Ventricular Ejection Fraction
LY	Life Year
LYG	Life Year Gained
m	metre (unit of length)
µW	microwatt or 10-6 watt (unit of power)
mW	milliwatt or 10-3 watt (unit of power)
mA	milliampèreor 10-3 ampère (unit of electrical current)
Mbps	megabit or 106 bits per second; a unit of data transmission speed
MedRadio	Medical Device Radiocommunications Service
MeSH	Medical Subject Heading
MHz	Megahertz or 106 hertz (unit of frequency)
MI	Myocardial Infarction
MICS	Medical Implant Communication System
MS	Member State (EU)

MVD	Multi Vessel Disease (more than 1 coronary vessel affected)
nA	nanoampèreor 10-9 ampère (unit of electrical current)
nW	nanowatt or 10-9 watt (unit of power)
NCA	National Competent Authority (EU)
NYHA	New York Heart Association (classification of heart failure symptoms)
NZ	New Zealand
o.c.	opus citatum (legal texts)
OECD	Organisation for Economic Co-operation and Development
OOK	On-Off Keying
OSI model	Open Systems Interconnection model
PAN	Personal area network
PCM	Pulse Code Modulation
PDF	Portable Document Format
PET	Privacy Enhancing Technologies
PM	Pacemaker
POTS	Plain Old Telephone System
PP	Per-Protocol (population)
PPP	Purchasing Power Parities
PRA	Patients' Rights Act (Belgium)
PSK	Phase Shift Keying
PY	Person Years
QALY	Quality Adjusted Life Year
QOL	Quality of Life
RA	Right Atrium
RCT	Randomized Controlled Trial
RD	Royal Decree
RF	Radio Frequency
RFID	Radio Frequency IDentification
RV	Right Ventricle
s	second (unit of time)
SCA	Sudden Cardiac Arrest
SCD	Sudden Cardiac Death
SCSSH	Sector Committee of Social Security and of Health (Belgium)
SF-36	Medical Outcome Study Short Form 36-Item Health Survey
S-HTTP	Secure HTTP; should not be confused with HTTPS
SLA	Service Level Agreement
SMS	Short Message Service
SSL	Secure Sockets Layer
SVT	Supra-Ventricular Tachycardia
TETRA	Terrestrial Trunked Radio

TTM	TransTelephonic Monitoring
TTP	Trusted Third Party
ULP	Ultra Low Power
UMTS	Universal Mobile Telecommunications System (3th generation mobile network)
US	United States
USA	United States of America
VF	Ventricular Fibrillation
VOIP	Voice Over Internet Protocol
VPB	Ventricular Premature Beat
VT	Ventricular Tachycardia
WBAN	Wireless Body Area Network
WHAN	Wireless Home Area Network
WHO	World Health Organisation
WLAN	Wireless Local Area Network
XML	eXtensible Markup Language

1 BACKGROUND

1.1 THE DISEASE

Individuals suspected or known of having a relatively high risk for sudden cardiac death (SCD) should be properly risk stratified through clinical investigation.[3, 4] In function of this risk stratification patients can become eligible for implanting an Implantable Cardioverter Defibrillator (ICD). These therapeutic actions are labelled as secondary prevention for those patients who previously survived a life-threatening cardiac arrhythmia. Conversely, the therapy is labelled as primary prevention when administered to patients that are at high risk of experiencing a first life threatening arrhythmia.

Cardiac arrest is the consequence of either pulseless arrhythmia (cardiac arrest) or pump failure (heart failure or cardiogenic shock). In 2007, KCE published a Health Technology Assessment on the use of ICDs in primary prevention. In that report, a comprehensive description of the related underlying diseases can be found.[2] Here, only the clinical conditions leading to the implantation of defibrillators will be briefly described.

1.1.1 Sudden Cardiac Death

Sudden cardiac death (SCD) is defined as a natural death due to cardiac causes, heralded by an abrupt loss of consciousness within one hour of the onset of acute symptoms. Pre-existing heart disease may have been known to be present, but the time and mode of death are unexpected. Sudden cardiac death is among the most common causes of death in developed countries. It is estimated that yearly about 0.1 to 0.2% of the population dies suddenly. This means that in Belgium presumably 15 000 people die suddenly each year as a consequence of SCD. Approximately 50% of all coronary heart disease (CHD) deaths are sudden deaths and in approximately half of them SCD is the first and only manifestation of the disease.

Sudden cardiac arrest (SCA) is mostly caused by ventricular tachyarrhythmia, and although most cardiac diseases can lead to this phenomenon, the reason is most commonly coronary heart disease (CHD) resulting in an acute myocardial infarction (AMI). Especially, in the first few hours subsequent to an AMI the risk of experiencing life-threatening arrhythmia is at its highest. The intervention to restore normal heart rhythm is administering a well-timed electrical shock to the heart muscle, called defibrillation within a few minutes after onset. Waiting any longer, results in cerebral death in the majority of cases. External defibrillation (i.e. by placing electrodes on the chest of the patient) can be performed by physicians, nurses, paramedics, ambulance personnel and even bystanders using an automated external defibrillator (AED) available in hospitals, ambulances and in some public places and transport vehicles. Since sudden cardiac arrest most commonly occurs outside the hospital, patients stand only a chance of survival if they are lucky enough to receive effective cardiopulmonary resuscitation (CPR) by bystanders no later than three minutes after the moment of syncope and at least until successful defibrillation is performed and normal respiration has re-established.

Medication is only to a limited extent effective in the prevention of sudden cardiac arrest.[2, 4] Since resuscitation and external defibrillation is often unavailable in a timely fashion, implanting an implantable cardioverter defibrillator (ICD) may offer the only survival insurance available to individuals at high risk. Although the efficacy of ICDs in secondary prevention is generally accepted, primary prevention potentially concerns a much larger patient population and may therefore not happen to be cost-effective in all risk strata. Clearly delimiting these risk strata whilst maintaining sufficient sensitivity and specificity remains a problem even today. This is demonstrated by the fact that too many patients in primary prevention never present the need to receive an appropriate, life-saving shock. This was the case for almost 79% of the patients in the ICD group in the SCD-HeFT trial.over the five year follow-up time.[5]

1.1.2 Heart failure

Heart failure (HF) is a complex syndrome that can result from any structural or functional cardiac disorder that impairs the pumping function of the heart.

Coronary artery disease, arterial hypertension, cardiomyopathy and valvular defects are among the most common conditions that can affect this pumping ability subsequently giving rise to chronic heart failure (CHF)

The syndrome of HF is characterised by symptoms such as breathlessness, swollen legs and fatigue. There is no single diagnostic test for HF, and diagnosis largely relies on clinical judgment based on a combination of history and physical examination completed with appropriate investigations, such as a chest radiography and echography.

Because of widely varying definitions, the epidemiology of HF is difficult to interpret. European estimates of the prevalence of HF in the general population range from 0.4 to 2%. The prevalence of HF increases rapidly with age, with a mean age of the HF population being 75 years, of which nearly 50% female. HF has a poor prognosis, as bad as most cancers. Half of patients carrying a diagnosis of HF will die within 4 years, and in patients with severe HF more than 50% will die within a year. HF is the most frequent cause of hospitalisation among people older than 65 years of age.

The functional status of patients with HF is traditionally encoded by means of the New York Heart Association (NYHA) classification. Subjective symptoms are used to rank patients according to their functional capacity into four classes. Individuals in NYHA class II and III are more prone to SCD, while patients in the more severe class IV are more likely to die from heart failure.[2]

1.2 TERMINOLOGY USED IN THIS REPORT

In the context of ICD and remote cardiac monitoring some terms are not always used with the same meaning by different authors and companies. For the purpose of consistency in this report we will use a series of working definitions that are listed in the glossaries in appendix (8.1 to 8.3). It should be emphasised, however, that these definitions are from the authors of this report and therefore not necessarily officially endorsed by the cardiologic community.

1.3 THE DEVICES

1.3.1 Implantable Cardioverter Defibrillators (ICD)

Implantable Cardioverter Defibrillators (ICDs) are implantable, battery-powered, programmable electronic medical devices capable of monitoring the heart rhythm and delivering anti-tachycardia pacing (ATP), cardioversion and/or electric shock to restore normal rhythm when a life-threatening arrhythmia is detected. An ICD system consists of two main parts: the defibrillator and the leads with electrodes and shocking coils.

The defibrillator is a pulse generator, slightly larger in size than a pacemaker and weighs about 80 grams. It can have one or more leads. Early devices required open chest surgery to place epicardial shocking patches but current ICDs are placed under the skin in the pectoral region with transvenous endocardial leads into the heart inserted via one or more veins whilst under local or general anaesthesia.

The latest devices offer graded responses (so called "tiered therapy") to a sensed ventricular arrhythmia. Anti-tachycardia pacing, low-energy synchronised cardioversion and high-energy defibrillation shocks can be delivered successively via a transvenous endocardial lead system, terminating the arrhythmia. Furthermore, ICDs always incorporate a pacemaker that, apart from the usual indications, can be used for anti-tachycardia pacing (ATP) and back-up pacing following a shock.

Device longevity has been gradually extended with advances in battery technology. ICDs now last from 5 to 8 years before replacement is required, although statements from industry appear to be overly optimistic compared to observed device longevity in registries,[6] and manufacturer-issued product performance reports.[7] The price of an ICD has been decreasing over time and is largely country-dependent.[2]

1.3.2 Cardiac Resynchronisation Therapy including Defibrillator (CRT-D)

Patients with HF are traditionally treated by means of drugs, unless a surgical correctable underlying problem is present. In rare instances, cardiac transplantation is an option. Recently, a new mode of therapy for advanced HF has been introduced that is referred to as "cardiac resynchronisation therapy" (CRT). The therapy consists in implanting a specially designed biventricular pacemaker, called a CRT-P, which stimulates both the right and left ventricle and hence enables an optimally synchronised contraction of both ventricles, resulting in a better cardiac output.

A subgroup of cardiac patients with a depressed left ventricular function, indicated by a low ejection fraction (EF), and clinical HF have a combined problem of intractable symptoms of HF and increased risk of SCA, making them candidate for CRT and an ICD alike. This group includes a number of ICD patients who are surviving longer but who's underlying heart disease progressed into heart failure. For patients with this combined pathology, devices capable of offering both defibrillation and biventricular pacing, known as biventricular ICDs or CRT-Ds are available for clinical use. Whether or not to add ICD capability to a CRT device should be based on the indications for ICD therapy.[2, 4] These CRT-D devices will be part of the assessment in this report, although the term ICD will be employed throughout this document to indicate both types of devices that have defibrillator capabilities.

1.3.3 Current use of these devices

In Belgium, the reimbursement of ICDs including CRT-Ds is regulated by means of the so-called revalidation convention between INAMI-RIZIV and the certified implanting centres.[8] This convention intends to cap the yearly incidence of new ICD patients (i.e. primo implantations). The latest revision of this convention[8] dated July 1, 2009, caps the yearly incidence of total (i.e. primo + replacement) ICD implantations to 1300 units. This number includes the biventricular CRT-D devices.

1.4 IN-CLINIC FOLLOW-UP OF PATIENTS AND DEVICES

1.4.1 Purpose of the follow-up visit

One of the goals of introducing remote monitoring technology is to reduce the number of in-clinic follow-ups. This may be considered desirable because the number of patients with implantable devices and especially implantable cardioverter defibrillators (ICDs), has been growing steadily [9, 10] and follow-up resources mainly in terms of personnel are limited. However, before setting off investigating how remote monitoring may, albeit partially, replace a number of in-clinic follow-ups, it is deemed important to fully understand what a normal in-clinic follow-up really encompasses.

1.4.2 Time interval of scheduled follow-ups

In-clinic follow-ups serve two main purposes. First of all, relevant findings may be made that generally can be categorised as device-related, arrhythmia-related or as other clinical findings. Subject to these findings the physician may decide upon one or more actions that may include device reprogramming, medication change, scheduling for a lead system revision or device replacement, hospitalisation, referral to another medical discipline, etc.[1, 9, 11]

Guidelines developed by the professional cardiologic organisations recommend specific regular time intervals for follow-up visits, in function of the age and use of the ICD.[1] According to the ACC/AHA/ECS guidelines ICD patients should be followed-up every 3 to 6 months.[4]

Guidelines recommended scheduling a first ambulatory follow-up within two to four weeks after implantation of the ICD.[1] At this moment, the physician will inspect the incision for signs of infection or poor incision healing. This may also be the moment when the ICD is comprehensively programmed to the needs of this specific patient. Medication is discussed and adapted. The patient is reassured about living with an ICD and may be proposed to join the local self-help group. General life style guidance is given. Permission to drive a car or work in certain electromagnetic interfering environments is assessed with the patient.

When the battery approaches end-of-life, more frequent follow-ups are due. The patient is scheduled for device replacement as soon as the elective replacement indicator (ERI) warning is raised [1, 12] or slightly prior in anticipation of this event. When the ERI is raised, the patient may, when this feature is not programmed off, feel a brief vibratory alarm or hear several beeps daily. Patients are instructed to contact their implanting physician as soon as this happens. Anyhow, upon interrogation of the device with the programmer an ERI warning will be visible.

1.4.3 Unscheduled follow-ups

A number of specific events (i.e. machine alerts, a delivered appropriate or inappropriate shock, worsening of the underlying disease etc.) may trigger unscheduled in-clinic follow-up visits. In a study by Heidbüchel et al.,[11] only 9.6% of a total of 1739 follow-up visits were conducted prior to the planned follow-up date due to patient symptoms. Another 2.4% were due to planned surgery or device safety warnings. The remaining 88% of visits were performed according to the clinical schedule and in 78.2% of those, no relevant finding was made.

1.4.4 The follow-up procedure

ICD manufacturers supplement their devices with an external programmer for device testing, (re-)programming and interrogation. Most follow-up clinics normally receive at least one external programmer per ICD brand for use by the cardiologist, a nurse technician or an invited industry employed allied professional (IEAP) or manufacturer representative. The programmer communicates with the ICD either via an magnetically inductive programming wand, or more recently, via wireless low power radio frequency (RF) transmission.

During a follow-up the device is interrogated for arrhythmic episodes, delivered therapeutic device responses and tested for overall system integrity. When automatic pacing capture is not available, this includes manual pacing threshold testing. If the patient is continuously paced, another test temporarily interrupts pacing in order to evaluate any intrinsic rhythm. Both tests have a high risk of resulting in asystole and need to be manually interrupted as soon as this occurs. For this reason, a simultaneous surface ECG is recorded. The physician also clinically examines the patient for symptoms of heart failure, valve defects etc. The patient is probed for medication compliance and undesired side-effects. Where necessary, medication therapy is altered and prescriptions are written. Occasionally, one or a combination of the above observations may call for device reprogramming. At the end of the procedure, the retrieved episodes and the programming parameters are archived on an external disk.

1.4.5 Workload of the in-clinic follow-up

All in all, follow-ups require frequent patient displacements to the outpatient clinic, and a significant workload for the team of healthcare workers; being the electrophysiologist, the treating cardiologist, technician nurses and revalidation nurses. At least in a number of centres, manufacturer representatives, also called industry employed allied professionals (IEAPs) [1] are frequently asked to assist with in-clinic follow-ups. This time-intensive and costly service is not separately charged for, but has been accounted for in the selling price of the device.

1.5 REMOTE MONITORING

Major ICD manufacturers offer systems that allow communicating data from the device remotely to the implanting physician and referring colleague physicians. In reality, the effective data transmission occurs in several steps. First, data from the device is communicated to a bedside or wearable mobile monitor in the patient's immediate vicinity. To this end, either an inductive programming wand or wireless RF technology is employed. From this monitor, the data is then send to a data server via either a normal telephone land line or a mobile phone network. (More technical detail will be provided in the next chapter.) The treating physician may access this data through a secured web application running on this server. Depending upon the system used, remote data transmission can occur automatically when episodes of arrhythmia are detected (device initiated transmission), on a regular basis (daily or weekly monitor-initiated remote monitoring), or at scheduled moments (physician-initiated remote follow-up) and in some cases even patient-initiated.

Although the different systems all claim remote monitoring capability, the systems are quite different in some essential technical features and are therefore employable to varying degrees for each of the above-mentioned purposes (see next chapter). Interestingly, none of the manufacturers is claiming capabilities for offering emergency services response, although at least one manufacturer could clearly do so. It might be assumed this responsibility is being avoided out of fear of liability litigations.

The areas of application for remote monitoring technology are generally categorised as follows:

- Physician alerts for arrhythmia episodes,
- Alerts for system integrity; both for the device and lead system,
- Follow-up replacement, either as an alternative for a face to face follow-up or to prepare for the regular follow-up visit,
- Disease management, including clinical event and trend alerts.

This categorisation will be followed for the remainder of this text. Absent on this list is reprogramming capability. Nonetheless, a few manufacturers envision adding this capability at an unspecified moment in the future.

1.6 CLAIMED POTENTIAL BENEFITS OF REMOTE MONITORING

The earlier mentioned remote monitoring applications claim to bring a number of potential benefits to different groups of stakeholders. Without the intention of expressing any judgement for now about their validity, the following claims were noted:

For the patient:

- Reduction of in-clinic visits,
- Improved patient safety,
- Speedier physician interventions when required,
- Immediate follow-up and reassurance after an event,
- Better health and potentially less or shorter hospital admissions,
- A perception of security,
- Increased satisfaction about the quality of care.

For the health care provider:

- Reduction of the number in-clinic visits,
- Reduction of the number of clinically irrelevant follow-up procedures,
- Increased patient satisfaction,
- Potential cost savings,
- Improved workflow in the follow-up clinic,

- Remote disease management leading to better patient health and potentially less or shorter hospital admissions.

For the health care payer:

- Reduction of in-clinic visits,
- Potential cost savings,
- Remote disease management leading to better patient health and potentially less or shorter hospital admissions.

Although never specifically mentioned in peer reviewed literature, remote monitoring also potentially brings a number of benefits to the manufacturers and potentially also to service providers such as call centres:

- Product differentiation from competitors,
- Less need for costly clinical support personnel; In a substantial number of hospitals, ICD follow-ups are actually performed by a representative of the ICD manufacturer (IEAPs),
- Potential remuneration for servicing and physician assistance costs,
- A new revenue source to compensate for ICD price erosion,
- Potentially a market for call centre businesses.

Finally, the authors of this report have the impression that remote monitoring technology also beholds the potential to serve the medical scientific community by greatly simplifying the execution of device-related clinical studies.

1.7 POTENTIAL ISSUES WITH REMOTE MONITORING

In spite of the many claimed potential advantages to remote monitoring, a number of potential inherent problems as well as external adoption hurdles may also be identified:

For the patient:

- Some patients may be technically over-challenged, especially with the installation of fixed line connected bedside monitors, the visual indicators on bedside monitors and/or older CIEDs requiring the use of an inductive interrogation wand,
- In some remote locations, the quality of the fixed telephone line or the poor coverage for mobile telephone networks may render remote monitoring inapplicable,
- Patient privacy and security,
- A false sense of security, also for the family,
- Conversely, an initial decrease in the quality of life [13] and more anxiety, that both may be triggered by the day-by-day confrontation with his or her condition,
- A feeling of mobility restriction,
- A dependency of the monitor device,
- A fear of being constantly observed,
- A feeling of exclusion from care for patients without remote monitoring.

For the health care provider:

- An increase in the number of event-triggered follow-ups with the risk of becoming burdened,
- Need to organise timely inspection of alerts,
- Increased liability exposure and related legal aspects,
- Required change in follow-up clinic workflow,
- Requirement for relying more upon specially-trained technician and/or ICU nurses,

- Overconfidence in technology with the risk of neglecting the patient's anamnesis, physical examination and drug therapy and compliance,
- Conversely, a risk of over-interpretation of remote monitoring data or over-diagnosis; An example may be the yet unproven thoracic volumetric impedance measurements in the diagnosis of acute congestive heart failure,
- Potential lack of compliance with existing follow-up guidelines,
- Disincentive due to the absence of reimbursement for the remote follow-up act versus reimbursement for the in-clinic follow-up act,
- A different web application platform for each manufacturer,
- Therefore, a risk of becoming more dependent on one specific manufacturer,
- A risk for more scrutiny between physicians,
- A risk for difference in patient-perceived quality of care between patients with, and without remote monitoring.

For the health care payer:

- Legal aspects,
- Reimbursement for remote monitoring; both for the physician act as for the data management services.

For the manufacturers:

- Telephone costs from the monitor to the data centre,
- Data centre, web site hosting, backup and bandwidth costs,
- Development and maintenance costs of the web application,
- Region, country, language and hospital specific adaptations of the software,
- Development and manufacturing cost of the monitor hardware,
- Training of personnel and roll-out costs,
- Occasional installation assistance with technology-challenged patients,
- Increased exposure to legal liability.

1.8 AIM OF THIS REPORT

This report aims to describe the technology of remote monitoring of ICDs and to address the issues of real-world clinical effectiveness and cost-effectiveness based on a literature review. Furthermore, the conditions, legal hurdles and organisational aspects of remote monitoring in general will be explored.

2 DESCRIPTION OF THE TECHNOLOGY

2.1 METHODOLOGY

Remote cardiac monitoring relies heavily on the use of information and communication technology. In this chapter, the stack of technological building blocks enabling remote cardiac monitoring will be described. Furthermore, significant differences between the systems that are on offer, are described in detail from a user perspective. Conversations with physicians and staff of implanting centres, information provided by the involved ICD manufacturers in early 2010, as well as peer-reviewed overview literature[9, 10], and a recent NHS report,[14] formed the basis for the content of this chapter.

The authors would like to particularly express their gratitude to Dr. Dirk Stockman of AZ Middelheim in Antwerpen and Mrs. Veerle Demeyer of UZ Gent who invested a great amount of their personal time sharing with us their user experiences with the different systems.

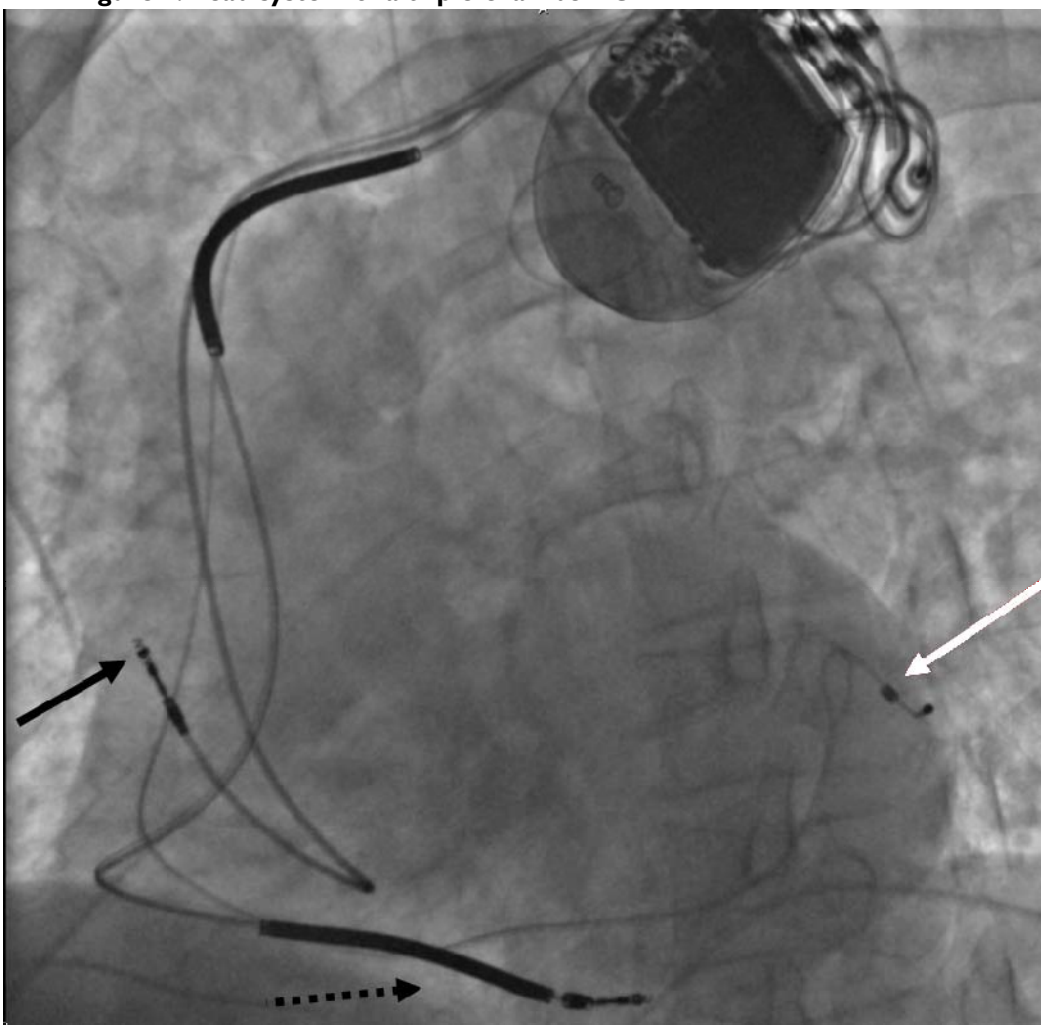
In order to contact the involved ICD manufacturers in a due manner, it was decided to first contact Unamec (www.unamec.be), the Belgian professional association of producers, importers and distributors of medical devices. Subsequently, individual meetings were held with those ICD manufacturers offering remote monitoring technology.

It should be emphasised, however, that this technology is evolving rapidly and that this assessment was made in the summer of 2010.

2.2 IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

As mentioned before, throughout this report the term ICD will be used to indicate all possible types of implantable devices offering cardioverter defibrillator (high-voltage, HV) capabilities. This encompasses single-chamber, dual-chamber as well as triple-chamber ICDs, the latter also being referred to as biventricular ICD or CRT-D devices, i.e. cardiac resynchronisation therapy (CRT) combined with defibrillator (D) therapy. The main differentiator between all these defibrillator types are the sites in the heart where pacing (low-voltage) therapy can be delivered. Single-chamber ICDs are capable of delivering pacing therapy exclusively to the right ventricle (RV), whereas dual-chamber ICDs can pace both in the right atrium (RA) and right ventricle (RV). Finally, triple-chamber ICDs, offer pacing therapy in the right atrium (RA), the right ventricle (RV) and the left ventricle (LV). (See Figure 1.) LV-pacing is achieved by either placing a lead intravenously in a tributary of the coronary sinus (CS) vein or by surgically placing an epicardial lead on the outer wall of the left ventricle (LV).

Figure 1: Lead system of a triple-chamber ICD



Three leads of a triple-chamber ICD (CRT-D) system can be discerned on this radiography: a right atrial pacing lead (solid black arrow), a right ventricular pacing & shock lead (dashed black arrow), and a coronary sinus pacing lead (white arrow). The coronary sinus pacing lead wraps around the outside of the left ventricle, enabling pacing of the left ventricle. Note that the right ventricular pacing & shock lead in this case has 2 thickened aspects corresponding to the shock coils. By courtesy of Gregory Marcus, MD, MAS, FACC.

2.3 DEVICE INTERROGATION

All implanted ICDs can be interrogated and reprogrammed by placing a manufacturer-specific inductive programming wand on the skin of the patient over the site where the device is implanted. This inductive programming wand connects to a proprietary designed computer called the programmer that allows the visualisation, printing and storage of the interrogated data and programming parameters.

Only recently, radiofrequency-enabled ICDs have appeared. These incorporate a small RF antenna in their connector block, also known as header. Biotronik, the first company to implement this, used this technology initially for remote monitoring only. However, other manufacturers followed quickly upon this idea by employing wireless radiofrequency (RF) transmission to interrogate and program the ICD. This circumvented the problem of keeping a programming wand sterile during the implantation procedure. Soon after, these other manufacturers also added remote monitoring capabilities. These distinct routes towards remote monitoring are reflected in some minute but occasionally significant differences between the systems on offer. This is discussed further on in this chapter.

2.4 TRANS TELEPHONIC MONITORING: AN EARLY PRECURSOR

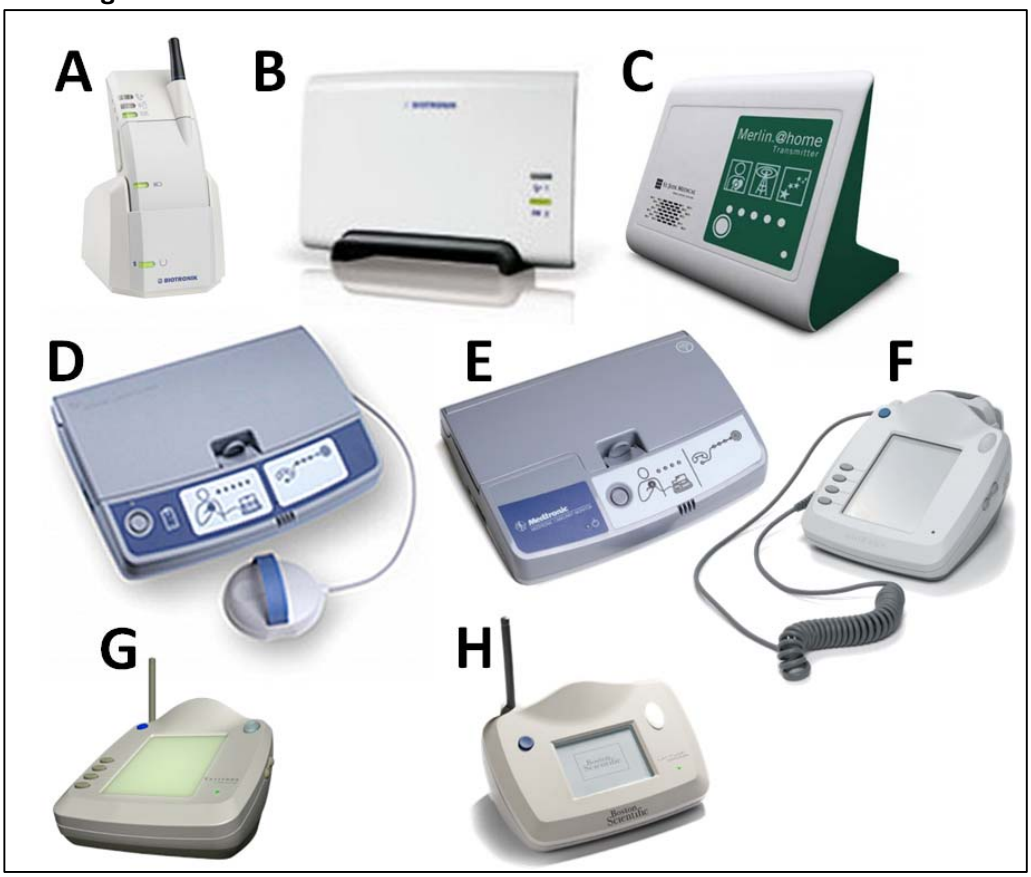
The earliest emanation of remote monitoring was without doubt the concept of Trans Telephonic Monitoring (TTM), introduced in the US in the early 1970s.[15, 16] The system consisted basically in extending the cable of the inductive programming wand over an analogue telephone line. At first, this allowed the pacemaker battery of remote patients to be checked remotely. In subsequent decades this concept gradually evolved offering more advanced device and lead system checking, including real-time basic IEGM and even reprogramming and pacing threshold testing. To our knowledge, TTM was not or only scarcely adopted in Europe. However, in the USA and Canada it is (still) widely employed. The major drawbacks of TTM are the need for patient compliance and the absence of device-initiated transmission triggered by events. Remote monitoring overcomes these deficiencies by offering both scheduled monitoring and device-initiated communication. However TTM allows for device reprogramming, which is currently not offered by remote monitoring.

2.5 OVERVIEW OF AVAILABLE REMOTE MONITORING SYSTEMS

2.5.1 Commonalities

All currently available remote monitoring systems have a number of things in common. When within range, the implanted device communicates on predefined intervals and/or in case of an event (this is manufacturer-specific, see below) with the patient's bedside or wearable monitor. The currently available monitors are depicted in Figure 2. Once this remote monitor has successfully interrogated the implanted device, the data is transmitted either over a mobile network or through an analogue or ISDN telephone line to a central database server at a secured data centre. The treating physician(s) has access to the data of the devices under his guidance through a secured web application. This application may also aid with the organisation of the workflow at the follow-up clinic, for example by prioritising alerts through a triage system. The physician(s) can also be alerted about specific urgent events by e-mail, SMS, fax or phone messages. The kind of events triggering alerts can be customised to a certain extent. The implementation of the systems differs from one supplier to another and will be described in more detail below.

Figure 2: Current monitor models



A: Biotronik – CardioMessenger™ II Mobility; **B**: Biotronik – CarioMessenger™ II-S Simplicity; **C**: St. Jude Medical – Merlin@home™; **D**: Medtronic – battery-powered CareLink® Monitor with inductive programming wand; **E**: Medtronic – mains-powered CareLink® Monitor with Conexus™ logo; **F**: Boston Scientific – wanded Latitude® Communicator with push buttons; **G**: Boston Scientific – wireless Latitude® Communicator with push buttons; **H**: Boston Scientific – wireless Latitude® Communicator with touch screen. (The monitors are not depicted to scale.)

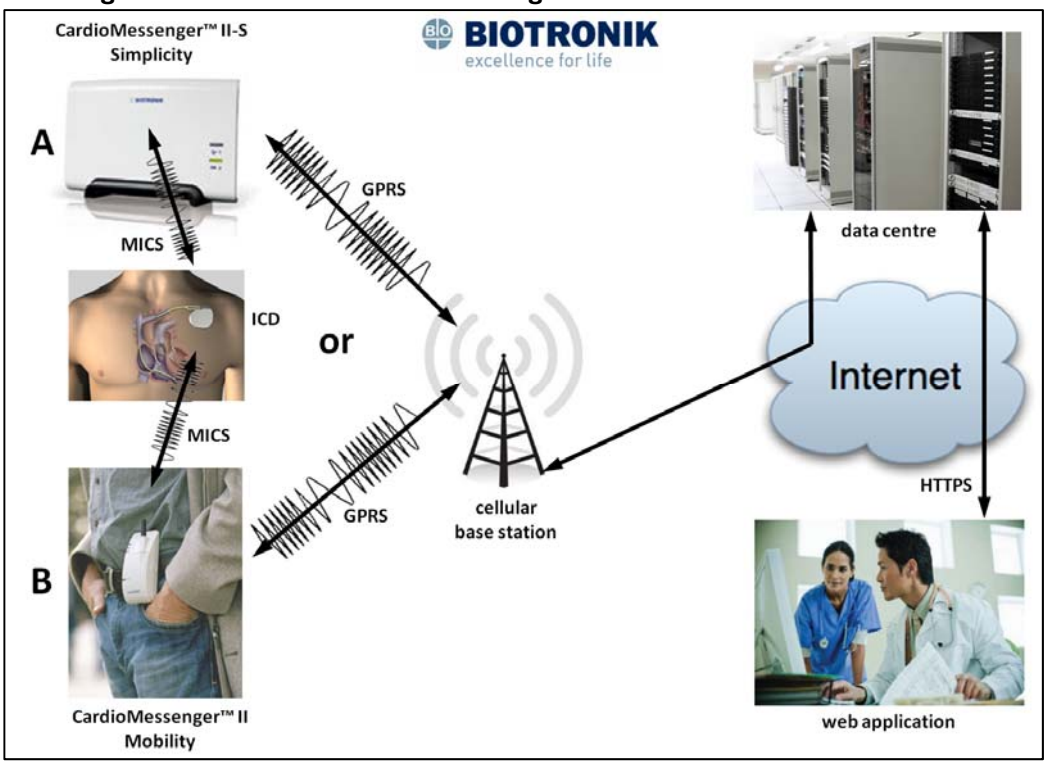
2.5.2 No remote programming

So far, none of the systems offer remote reprogramming of the device although during our meetings with the ICD manufacturers, two manufacturers indicated us that their current technology platform could allow for this. It appears to us that device manufacturers are hesitant to introduce this feature for both safety and liability reasons. At least for now, the patient will still have to attend the outpatient clinic if remote monitoring indicated a need for reprogramming.

2.5.3 Biotronik Home Monitoring®

Biotronik, a German company based in Berlin, pioneered remote monitoring of its ICD devices. This first system, called Home Monitoring®, received FDA approval in 2001.[9], sparking competing ICD manufacturers to start development of their proprietary systems for remote cardiac monitoring.

Figure 3: Biotronik Home Monitoring®



Communication diagram of the Biotronik Home Monitoring® system for **A**: the second generation bedside monitor and **B**: the second generation wearable mobile monitor

Biotronik currently features two styles of remote monitors; the bedside CardioMessenger™ II Simplicity and the only wearable mobile monitor, the CardioMessenger™ II Mobility. Both models are actually also replicated in blue-coloured first-generation models for compatibility with first-generation implantable devices. These first-generation models were originally designed for communication via Short Messaging Service (SMS) only and differ only from second-generation models in the quality of transmitted IEGMs. First-generation Biotronik monitors, although still available, will therefore not be further mentioned for the remainder of this text.

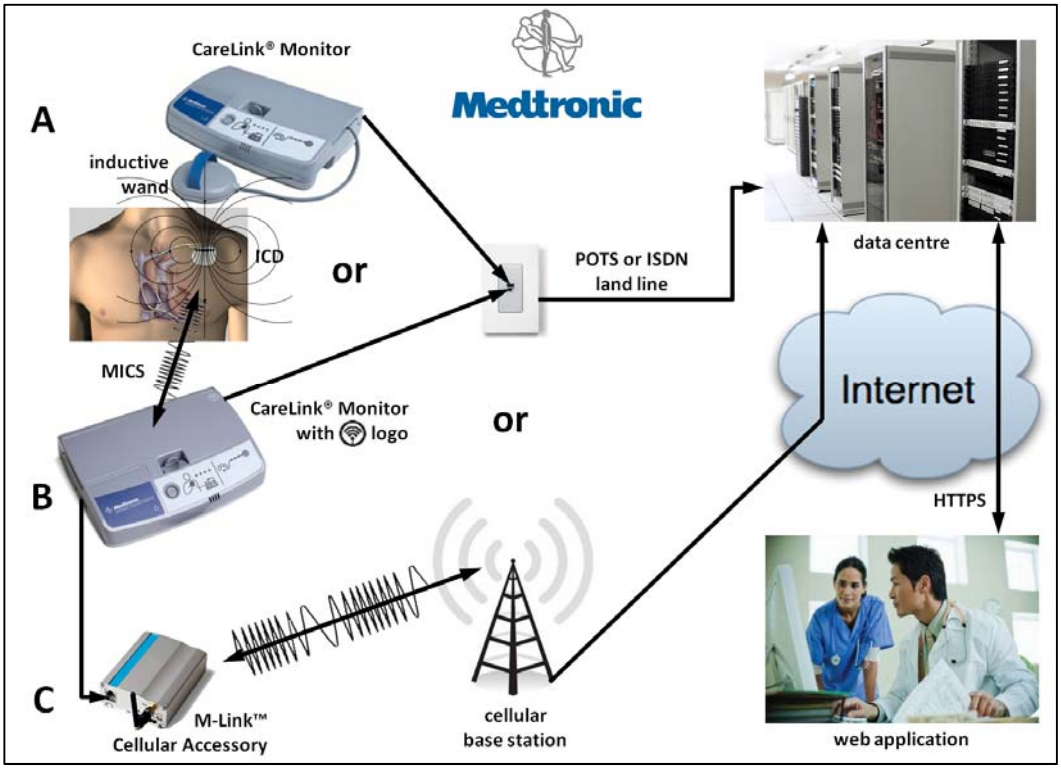
The patient-wearable transmitter is a fairly bulky, keyless special-purpose mobile phone that communicates wirelessly with the ICD over a range of 2m. Being a four-band device it is capable of sending the retrieved data to a data centre in Germany through whatever international standard of second generation mobile phone networks.(GSM, CDMA, etc.) as well as with GPRS. The CardioMessenger has a rechargeable battery that allows it to be carried around by patients. Hence, the patient's device can be remotely monitored even if the patient is absent from home or abroad. For a few years this was the only system offering transmission through mobile phone networks, but in recent months Medtronic and St Jude also announced a GSM adapter as an ad-on to their home transmitter. Moreover, only very limited patient interaction is required from this system; Patient need to plug in or charge the CardioMessenger, switch it on and remain regularly a few minutes in its vicinity to be compliant.

Transmission typically occurs every night via the assigned CardioMessenger for routine transmissions or immediately via whatever CardioMessenger in case of alerts or episodes. Alert triggers can be set per patient and with predefined degrees of urgency (yellow or red alerts) allowing for a better triage of alerts at the physicians office. Alert triggers can be fully configured on a secured webpage by the treating physician, without any need for the patient to attend the clinic.

2.5.4 Medtronic CareLink Network™

The advent of radiofrequency-enabled ICDs effectively opened the route for convenient, unobtrusive remote monitoring of the ICD at the patient's premises. With remote monitoring, device interrogation occurs through a portable or fixed bedside monitor; either at the patient's initiative or automatically without any patient interaction when the ICD has RF capabilities.[9] Wireless RF transmissions offer the advantage of being less dependent on patient compliance and could, at least in theory, allow for more frequent transmissions.

Figure 4: Medtronic CareLink Network™



Communication diagram of the Medtronic Carelink® system for **A**: a wanded Carelink® monitor, **B**: a bedside Carelink® monitor with the Conexus™ logo and **C**: the latter connected via the optional M-Link™ Cellular Accessory instead of via a landline

The Medtronic CareLink® system is compatible with all Medtronic ICDs (through a telemetry wand or wireless) and was introduced in Europe during a test phase in 2005.[9] The current ICDs communicate wirelessly with the CareLink® Monitor within a range of 3m. This special-purpose modem-transmitter is usually placed near the patient's bed. Data are sent via a normal fixed phoneline to a data centre in the UK (for Europe, Africa and the Middle East). This data centre works as a post-office, transmitting the data to the treating physician through a secured web application or through other means in case of alerts. No data interpretation occurs at the data server level, and the full data set is only reformatted for presentation through the web application.

This system works with pre-scheduled follow-up transmissions that can be programmed remotely, and the ICD can be programmed to sound an audible alarm in case there is a prolonged time period without a home monitor connection.

In addition, pre-specified events can trigger alerts that the ICD will attempt to communicate to the transmitter immediately. If the transmitter is not within reach at the moment of the alert, repeated attempts will be made to make the transmission at regular intervals during several days and with audible alerts from the ICD. Those alerts can be set per patient and with predefined degrees of urgency (yellow or red alerts) allowing for a better triage of alerts. For the setting of certain alert triggers the ICD needs to be reprogrammed. Alert triggering might be also be patient initiated when problems are suspected based on symptoms.

Some of the recent generation ICDs have added abilities to automatically perform several test, including the Optivol® algorithm that monitors trans-thoracic impedance for detecting lung fluid accumulation, which, although not proven, might be useful in monitoring patients with HF.

The CareLink® web application is conceived in such a way that it also offers workflow management for the follow-up clinic through agendas, scheduling etc. Initially, Medtronic apparently hoped that the distinctive features of this service would firmly solidify its market share in implanting centres. However, many implanting physicians prefer to implant approximately equal shares of one or more device brands in order to mitigate the device recall risk. Therefore, one or more specifically trained technician nurses usually have to handle the hassle of working with two or more proprietary workflow systems since the CareLink® web application only works with Medtronic devices.

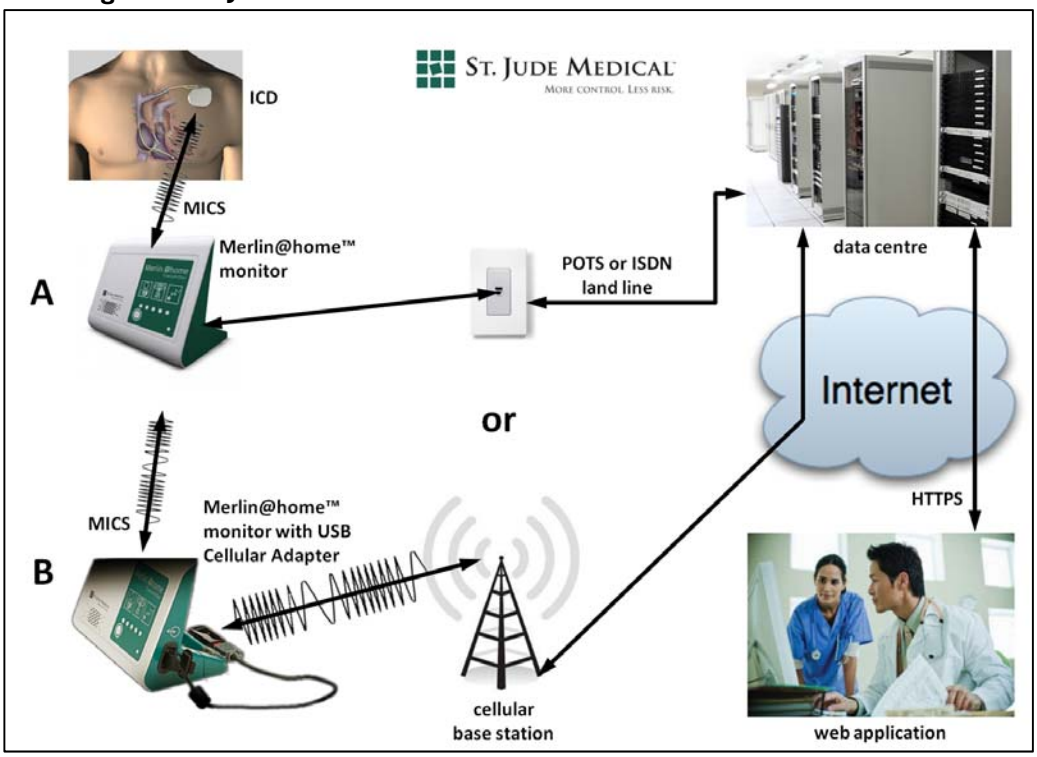
In December 2001 Medtronic acquired Paceart, a company specialised in database systems for pacemakers, implantable defibrillators and arrhythmia management systems. Apart from the ability of directly linking to Medtronic's CareLink® server, The Paceart® system also reads data files of an extensive range of competitor devices (communication from Medtronic representatives), and according to the same source a few implanting centres in Europe employ this system. However, this Paceart system does not offer an open standard for accessing data servers.

Finally, hospitals that would like to implement the CareLink® system have to comply with a check list that Medtronic, out of precautionary measures, self imposes upon its business. This checklist includes items such as workflow management, responsibilities etc.

2.5.5 St Jude Medical Merlin.net™ Patient Care Network

This system has been introduced in Europe since 2010. The wireless transmitter (Merlin@home) communicates wirelessly with the ICD and sends data to the physician using normal telephone lines, DECT telephones or optionally a mobile telephone adapter. A potentially useful feature is the fact that the physician can indicate alerts or reminders of scheduled in-clinic visits on the screen of the patient's transmitter. Moreover, automated phone calls can be made to patients indicating the results of the remote follow-up.

Figure 5: St Jude Medical Merlin.net™ Patient Care Network



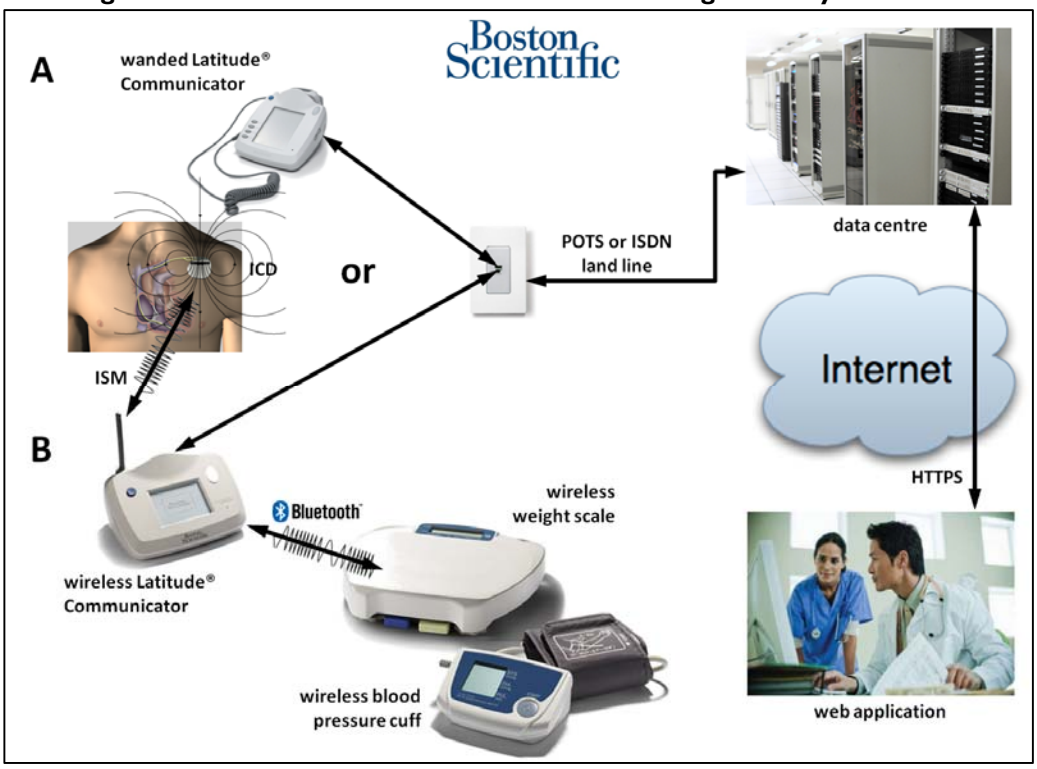
Communication diagram of the St. Jude Medical Merlin.net™ Patient Care Network (PCN) for **A**: the bedside Merlin@home™ monitor connected via a landline and **B**: the same connected via the optional USB Cellular Adapter

2.5.6 Boston Scientific Latitude® Patient Management System

This system has been introduced in Europe since mid 2009. The transmitter makes use of normal phone lines for data transmission. A unique feature of this system is the possibility to connect (wireless) weight scales and blood pressure measurement devices for the remote monitoring of heart failure. The patient also has the ability to self-report specific HF symptoms through the system.

This system also allows for pre-scheduled remote follow-up transmissions. The scheduling of these can be customised for each of the involved physicians, such as the GP or general cardiologist in addition to the electrophysiologist.

Figure 6: Boston Scientific Latitude® Patient Management System



Communication diagram of the Boston Scientific Latitude® Patient Management System for **A**: the wanded Latitude® Communicator with push buttons, **B**: the wireless Latitude® Communicator with push buttons in combination with a wireless weight scale and a wireless blood pressure cuff

2.6 FUNCTIONS PERFORMED BY REMOTE MONITORING

The technology of remote monitoring may serve up to four functions when combined with ICDs. Without any doubt, the most evident and dramatic functions are those of delivering system integrity alerts and alerts for arrhythmic episodes. However, remote monitoring technology also bears the promise of replacing a number of the mandatory in-clinic follow-ups by remote follow-ups, as well as helping the physician a hand with managing a number of cardiovascular diseases remotely. This section will briefly introduce each of the four functions. However, whether there exists scientific proof that the latter two functions hold their promise, will be discussed in Chapter 3 on clinical effectiveness and safety.

2.6.1 System integrity alerts

Although ICDs are capable of sounding audible alerts to warn the patient, regular patient initiated or scheduled remote monitoring could provide added value, especially in deciding whether or not an in-patient visit is required. One of the earliest applications of remote monitoring of ICDs was to check device and lead system integrity.[9, 10] Device and lead system data is regularly automatically acquired by the device and sent using the bedside monitor to the data centre where it is left for periodic evaluation by the physician. This system of periodic system integrity reporting offers the potential of greatly reducing the number of trivial, uneventful in-clinic visits.

Most modern devices automatically execute periodic system tests that coincide with those that are normally performed during a manual outpatient clinic follow-up. This includes tests for battery status, lead impedances, sensing, pacing capture thresholds with the caveat that many older devices still sold and in use today, come without automatic pacing capture capabilities on all or some of the pacing channels. Lastly, ICD operational mode (monitor & therapy, monitor only, electrocautery safe or off) is also reported on.

A 2004 study queried the US FDA Manufacturer and User Facility Device Experience Database for ICD-related adverse events resulting in death.[17] Ironically, of the 212 retrieved mortal events involving ICDs, 11 resulted from ICDs that were found to be off or deactivated. These devices appeared to have been deactivated accidentally or by exposure to strong external magnetic fields, or they were not reactivated and therefore unintentionally left in "electrocautery-safe" mode after elective surgery.

This may also happen towards the end of the proper ICD implantation procedure when the device is temporarily switched to "monitor only" in order to protect the surgeon from receiving any inappropriate shock during wound closure. At this instance, an absentminded industry-employed allied professional (IEAP), technician nurse or physician may forget to reprogram the device back to the "monitor+therapy" mode before leaving the operation theatre. Something similar may occur when the ICD patient undergoes surgery for other reasons and the ICD is left in "electrocautery-safe mode". ICDs can also be switched to "monitor only" modus by placing a permanent magnet over them. This is actually a safety feature allowing ambulance personnel to deactivate the ICD in case of recurrent inappropriate shocking. However, this deactivation may also occur inadvertently when the ICD patient is close to strong magnetic fields of industrial presses and electromotors.

A number of remote monitoring systems offer the ability to send system integrity alerts almost as soon as they occur, i.e. as soon as the patient enters in the immediate vicinity of the bedside or portable monitor. Thresholds for these alerts are, depending on the manufacturer, either pre-set at in-office follow-up or, more interestingly, configurable from the web application. Differently coloured alerts allow for a triage of the alerts arriving at the physician's office. When combined with ad hoc system integrity alerts, the remote monitoring system may reduce in many instances the time to respond to system faults.

2.6.2 Arrhythmic episode alerts

The remote reporting and alerting of arrhythmia alerts happens in a similar fashion as described for system integrity reports and alerts. The only difference is that intracardiac electrograms (IEGMs) recorded over the duration of the arrhythmic episodes are now also transmitted to the data centre and made available to the physician for interpretation.

In this context, it is noticeable that none of the manufacturers offers the service of centralised IEGM interpretation in Europe. Nonetheless, a number of tertiary healthcare service providers in both Europe (e.g. Vitaphone GmbH[18]) and America are offering Holter recording interpretations and/or around-the-clock physician-supervised services of ECG interpretation via remote monitoring.

Especially recently implanted patients are asked to visit the clinic as soon as possible after their first experienced shocks for a device interrogation and possible reprogramming. On the basis of the stored IEGM episode(s), the treating physician may conclude that the ICD delivered or, in additional incidences, was about to deliver an inappropriate therapy. Remote monitoring offers here the possibility of triaging shocked patients for a clinic visit in function of the appropriateness of the delivered shocks. Moreover, remote monitoring may pre-emptively warn about inappropriate episode detections that resulted in aborted shocks. Common causes for inappropriate ICD therapy are oversensing, T-wave sensing, far-field sensing, the sensing of myopotentials, and the wrongful classification and detection of a supraventricular tachycardia (SVT). If this is the case, the device will be reprogrammed with the intent to avoid future inappropriate shocks. the patient is asked for his or her convenience to visit the clinic as soon as possible

It has been demonstrated that the remote reporting of arrhythmic episodes through alerting may reduce the number of trivial scheduled in-clinic follow-ups, whilst simultaneously increasing the number of actionable unscheduled in-clinic follow-ups. [11]

As with device integrity alerts and depending on the manufacturer, arrhythmic episode alert triggers can be either pre-set at in-clinic follow-up or, more interestingly, configurable from the web application. Differently coloured alerts allow for a triage of the alerts arriving at the physician's office. In many instances, ad hoc arrhythmic episode alerts may significantly reduce the time to respond to actionable events requiring reprogramming of the device.

2.6.3 Replacement of in-clinic follow-ups by remote follow-ups

Routine follow-up visits for ICD patients are scheduled every 3 to 6 months. More frequent visits are also due shortly after implantation and towards the end of battery life. The frequency of this follow-up is obviously very dependent on the patient condition, the underlying pathology. and whether the ICD is for primary or secondary prevention of SCD.

Provided the patient is in a stable clinical condition, in many but not all of those in-clinic visits there is no real need for the patient to be physically present; i.e. no physical examination, nor hospitalisation or ICD reprogramming is required. It is therefore argued that part of these visits could be replaced by remote monitoring at regular intervals.[11]

2.6.4 Remote disease management

More recently, remote monitoring is also being employed to manage underlying diseases and comorbidities remotely. Without the need for any special sensors, remotely monitored dual-chamber ICDs can easily alert the onset of asymptomatic paroxysmal or persistent atrial fibrillation (AF).[14] The incidence of AF increases with age. About 20% of the population aged 80 years or more is confronted with AF. Early termination of AF through drug therapy or cardioversion is important in the prevention of possibly irrevocably incapacitating and certainly costly cerebral vascular accidents (CVAs).[14] These CVAs are caused by the detachment of blood cloths from the left atrium. There are also indications that a delay in the termination of paroxysmal or persistent AF may cause remodelling of the atrial tissues, resulting in a disease progression towards permanent AF. This concept is called: "AF begets AF."[19]

Congestive heart failure (CHF) is another very common degenerative comorbidity of a number of heart diseases.. A number of device manufacturers are offering to remotely predict and prevent congestive heart failure decompensation. This is achieved either by dedicated transthoracic impedance measurements to indicate lung fluid accumulation or by coupling the remote monitor to a compatible wireless weight scale and blood pressure cuff. Early detection of lung fluid accumulation potentially could help controlling patient drug compliance as well as potentially lead to less frequent and shorter hospital admissions.

2.7 COMPARISON OF REMOTE MONITORING SYSTEMS

In this section, the currently available remote monitoring systems are compared mainly from a user perspective, firstly on a systems level and subsequently on a monitor level. The comparison is based on information retrieved from literature,[9, 14] company communications and end-user interviews.

2.7.1 Adoption of the systems

No official data on the use of cardiac remote monitoring systems in Belgium is currently available. Therefore, any estimate of its usage (see Table 8 in appendix) is based on personal communications and claims by the manufacturers.

2.7.2 Data centre locations and data handling roles

Of major legal importance are the legally defined roles of data controller and data processor. The manufacturer usually seeks to attribute these by contractual means to itself, the implanting centre and possibly also to other companies that partner with the operation as outsourced data centre. This leads us to the fact that it is considered best practices to, amongst many other things, replicate data servers at geographically distinct locations. Doing so, may limit down-time and data loss in case of a disaster at one of the data centre locations. The certified implementation of international standards of the ISO/IEC 27000 family of Information Security Management Systems (ISMS) standards is a good measure for the disaster-preparedness of a data processing organisation. More details can be found in Table 9 in the appendix to this chapter. Finally, some patients may be sensitive to the fact that their data is stored in the USA, and can hence be ordered under the Patriot Act to be disclosed to certain US goverment agencies.

2.7.3 Communication between the data centre and the physician

All manufacturers have developed a proprietary web application as the standard means for data retrieval and configuration of their remote monitoring system by the treating physician(s). In addition to that, physicians and technician nurses can be notified by either e-mail, SMS, fax or telephone call about urgent alerts. Not all options are offered by each manufacturer.

The involved healthcare workers lament to great extent the fact that every system features its own web application, differing significantly among one another. Most centres implant devices of more than one manufacturer, implying that more than one web application needs to be checked almost daily to keep up with the steady stream of incoming alerts and notifications. Furthermore, many hospitals actively pursue centralising all clinical patient data in electronic health record (EHR) systems that are either commercial or developed in-house. For these reasons, it is highly desirable that remote monitoring data servers would communicate directly with the EHR system in place. Moreover, the available EHR system could be further developed to present a common interface to the different remote monitoring systems. This could be achieved by employing one of the widespread data exchange formats that exist for this purpose, like for example XML or Health Level 7® (HL7). Unfortunately, as can be appreciated from Table 10 in appendix, most manufacturers seemed so far only little concerned about these customer wishes and rather prefer to further develop their proprietary web applications as a main differentiator from competing systems. Unfortunately, the only common ‘interface’ at this moment is the PDF text format.

2.7.4 Web application security

All manufacturers covered the basics of web application security by employing the HTTPS internet application layer protocol and by requiring a username with password at log in. However, not every manufacturer offers user accounts for site administration or for referring physicians or non-physician healthcare personnel (see table). Moreover, the granularity by which different users are granted different permissions such as no access/read only/full access, can be considered insufficient for the majority of the systems. Finally, it occurred only to one manufacturer that patients may wish to change treating physicians and/or follow-up centres. Consequently, only this manufacturer offers the possibility to hand over a patient to a different centre via the web application. More details can be found inTable 11.

2.7.5 Workflow

Remote monitoring web applications may play a role in helping to organise the workflow in and around a follow-up clinic. They can achieve this in various ways. An obvious one is the triage of incoming alerts according to severeness. All manufactures have implemented this and a few even allow configuring the alarm severeness to different extents (see Table 12). However, in view of the possible pending liability issues (see chapter 5), it is of concern to notice that only half of the manufacturers have implemented a very basic form of alert acknowledgement, i.e. a simple indication whether the alert has been viewed. None of them allow to effectively know who acted upon an alarm and by taking what action. Neither does any of the systems show an overview of alarm acknowledgements. The authors of this report feel that manufacturers should prioritise adding this kind of accountability to their systems in order to protect their customers and reduce misunderstandings. On the other hand, only a couple of manufacturers recognise the fact despite remote follow-ups, in-clinic follow-ups will continue to exist and consequently offer in-clinic follow-up scheduling from within their web application. However, it remains very questionable whether this functionality will end up being used by a centre that uses more than one remote monitoring system. Finally, the number of days that a centre remained without receiving any transmission from one specific patient, is also a very useful data point for identifying communication problems.

2.7.6 Monitors

In total, there are eight most recently available monitors presented in Table 13. Interestingly, only one monitor, the Biotronik CardioMessenger II Mobility is a truly patient-wearable mobile monitor. Incidentally, this monitor is the direct descendent of the very first available monitor that happened to be also patient-wearable. This unit also features a rechargeable battery, similarly to an ordinary mobile phone. All, but the first-generation CareLink® Monitor can be mains-powered. The latter is powered by alkaline batteries. Most units tend to limit the amount of user buttons and visual indicator lights, with the noteworthy exception of the Latitude Communicators® that feature either four additional push buttons or a touch screen enabling the patient to answer a number of questions every day. Originally, the here presented monitors varied greatly in their travel-readiness with the Biotronik and Boston Scientific models, each in its own way, being the more prepared. Boston Scientific achieved this by incorporating an automatic international dial-up directory, whereas Biotronik offers incorporated mobile telephone network connectivity. (There is, however, a serious issue with employing wireless Boston Scientific monitors outside their original ITU region, see Section 2.7.8 for more details.) Only very recently, the other market players tried to catch up on this by offering accessories for cellular network connectivity. However, one of these proposed patches turned out to be rather clumsy, comprising two fairly large boxes and requiring two mains power outlets, two power adapters and cabling in between.

Figure 7: CareLink® Monitor with the M-Link™ Cellular Accessory



The travel setup as proposed by Medtronic, comprising a CareLink® Monitor with Conexus™ logo connected via a cable to the M-Link™ Cellular Accessory and two external power adapters. Not shown: the power extension block you may need if your hotel room has no two adjacent wall outlets.

Finally, a unique feature of the Merlin@home™ monitor is its ability to forward automated physician calls for providing patients with feedback about for example a recently completed remote follow-up.

2.7.7 Compatible devices

Second-generation Biotronik monitors –the white ones– are compatible with second-generation -T models of Biotronik CIEDs only. Likewise, first-generation Biotronik monitors –the blue ones– are only compatible with first-generation -T models of Biotronik CIEDs. On the other hand, all Medtronic CareLink® Monitors, including those with a Conexus™ logo are equipped with an inductive programming wand and are therefore compatible with all Medtronic CIED models, including implantable loop recorders (ILRs) and discontinued CIED models. However, automated wireless interrogation will only work between the CareLink® Monitor with Conexus™ logo and newer Medtronic CIED models with RF capabilities. This also holds true for Merlin@home™ monitors which are compatible with RF-enabled St. Jude Medical CIEDs only. As for Boston Scientific, its wanded Latitude® Communicator is capable of interrogating all Boston Scientific and legacy Guidant branded CIED models. However, automated wireless transmission is only possible between RF-enabled Boston Scientific and Guidant ICDs, including CRT-Ds and both models of wireless Latitude® Communicators: Note that Boston Scientific does not have any RF-enabled pacemaker, CRT-P nor ILR on offer. However, the Boston Scientific Latitude® Communicators are the only monitors in the market that can receive data from a wireless weight scale and blood pressure cuff via Bluetooth™. On the other hand, only Medtronic and St. Jude Medical have currently ICDs and CRT-Ds featuring transthoracic lung fluid impedance measurement capability for heart failure patients while Biotronik has an investigational device. Whereas, ST deviation trending for ischemia monitoring is only available on certain St. Jude Medical CIEDs.

Recently, St. Jude Medical also launched a completely new type of CIED; an implantable wireless left-atrial pressure monitoring device, marketed under the name of HeartPOD™. So far, this device is only compatible with its own specific patient advisor module that is, however, not connected to the Merlin.net™.patient Care network. Details about compatible devices can be found in Table 14.

2.7.8 Communication between the device and the monitor

This section deals specifically with the physical communication layer between the available CIEDs and monitors. Please, refer to Section 2.7.9 for information about the session layer and alerting in particularly.

Focussing on the wireless radio frequency (RF) communication, it is interesting to see in Table 15 that all manufacturers, except Boston Scientific, employ the Medical Implant Communication System (MICS) as the main radio band for the communications between CIED and monitor. The MICS RF band consists of 10 radio channels allocated in the spectrum between 402 and 405MHz. Although initially not, this MICS RF band is now currently available worldwide for this purpose. However, the MICS RF band is shared with or adjacent to a number of other services, such as weather balloons[20], TErrestrial Trunked RAdio (TETRA) for emergency services and military in Europe and land-mobile communications in Australia. For this reason, on some occasions, MICS-based remote monitoring devices may be expected to suffer interference from at least some of these other services.

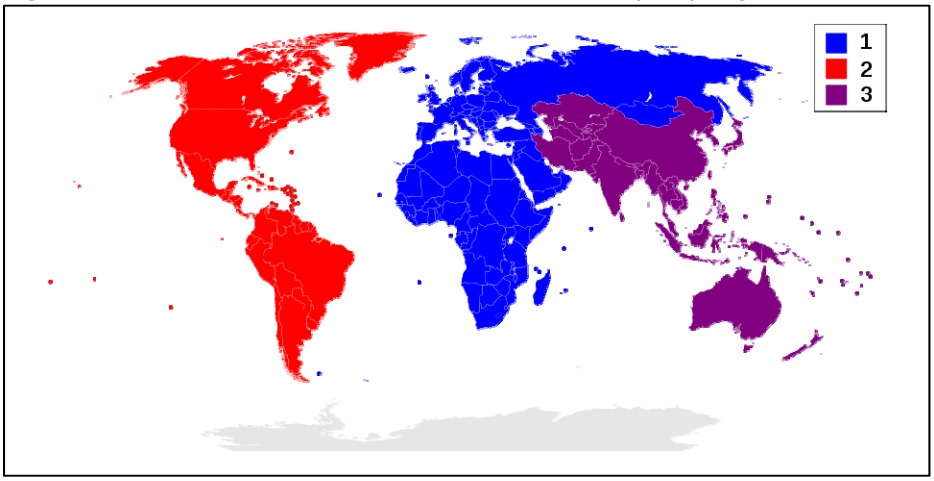
Furthermore, all MICS-based monitors except Biotronik models employ a carrier frequency at 2.45GHz on-off-keyed (OOK) in a sequential code to wake up the MICS-based integrated circuit inside the CIED, prior to exchanging data on the MICS band. Incidentally, this wake-up frequency of 2.45GHz happens to be shared on a worldwide level by a plethora of other services; Industrial Scientific Medical (ISM, see also below), amateur radio, WiFi, RFID, Bluetooth and ZigBee. The waking of the MICS-based chip inside the CIED may be hampered due to interference when the patient is using or is located in the immediate vicinity of a device based on one of these services. ISM and amateur radio may cause this effect at even larger distances due to their significant higher power levels and antenna gains. However, the chances of accidentally waking up a MICS-based chip inside a CIED and hence wasting the CIED's valuable battery energy are rather limited thanks to the OOK code sequence protection of the wake-up signal.

According to the original MICS protocol that was developed under Medtronic sponsorship, MICS-based chips ought to listen before they talk (LBT) and then choose a vacant MICS channel. The MICS implementations of Medtronic and St. Jude Medical follow this protocol. The Biotronik implementation does not and in this respect, Biotronik had to initially obtain a waiver from the US Federal Communications Commission (FCC). Later on, the FCC adapted regulations to amongst other relaxations, formerly allow this and renamed the band allocation to Medical Device Radiocommunications Service (MedRadio). For now, Biotronik's decision not to implement LBT may have little impact on overall MICS performance. However, the FCC actively promotes MedRadio as the de facto radio band for both implanted and body-worn medical devices. As more useful applications are found for this technology, it has become conceivable to find patients wearing more than one MedRadio device, for example: A diabetes patient may wear simultaneously a glucose monitoring device and an ICD. Moreover, MICS technology is been considered for use in the waiting room of follow-up clinics: While patients wait for their doctor, a technician nurse may already interrogate their CIEDs wirelessly with a programmer using the very same MICS band. Evidently, leaving out listen-before-talk may prove to be cumbersome in the above-sketched situations.

As said before, Boston Scientific is the only ICD manufacturer using frequency bands different from the MICS band. Being a company with its CRM engineering located predominantly in the USA, it originally set out to employ the carrier frequencies of 914 and 916.5MHz within the 902-928MHz Industrial, Scientific and Medical (ISM) band allocation. Now, two remarks need to be raised about this: Firstly, the pool of available ISM bands are actually intended for employing RF electromagnetic fields *other than communications*.

Use for communications is allowed, but any interference generated by possibly more powerful other ISM equipment must be accepted. Secondly, 914 and 916.5MHz ISM happen to be available only in the Americas, Greenland and a number of eastern Pacific islands, i.e. International Telecommunication Union (ITU) region 2 (see Figure 8). For this reason, Boston Scientific employs in ITU region 1 the frequency of 869.85MHz, allocated by ETSI EN 300 220 subclass 31 for non-specific short-range devices. In ITU region 3, Boston Scientific does not market any of its RF model ICDs.

Figure 8: International Telecommunication Union (ITU) regions



The International Telecommunication Union (ITU) divides the world into three ITU regions for the purpose of managing international radio spectrum allocations. **Region 1** comprises Europe, Africa, the Middle East west of the Persian Gulf including Iraq, the former Soviet Union and Mongolia. **Region 2** covers the Americas, Greenland and some of the eastern Pacific Islands. **Region 3** contains most of non-former-Soviet-Union Asia, east of and including Iran, and most of Oceania.

This situation gives rise to the following question: What happens when an ICD patient starts travelling intercontinentally with his wireless Latitude® Communicator? Firstly, wireless Latitude® Communicator can be made aware of its location, because it needs this information for looking up the correct dial-up phone number. However, in a formal written communication, a senior Boston Scientific European Tech Services person confirmed that ICDs come in two RF models and can currently not switch frequencies between ITU regions 1 and 2. This implies that a patient wearing an ITU region 1 Boston Scientific ICD would actually commit an offence attempting to interrogate it with his wireless Latitude® Communicator outside of ITU region 1. The same holds true for a patient wearing an ITU region 2 ICD, visiting ITU region 1 or 3. Note however, that communication via inductive magnetic coupling with a wanded Latitude® Communicator or programmer remains possible.

2.7.9 Alerting

This section deals with the session layer, or more specifically, how alerts are raised within the different remote monitoring systems. Please note, that for the benefit of understanding and in order to keep the information herein contained as generic and widely applicable as possible, the authors decided to introduce a set of novel terminology. The full meaning of every new term will be concisely explained either here or in the glossary of remote monitoring terminology.

Three types of alerts can be discerned, being: System integrity alerts, arrhythmia event alerts and trend alerts. Furthermore, the algorithms responsible for discerning alerts can reside either in the CIED firmware, in the application that runs on the data server, or on both. Table 17 shows the situation for each of the systems. This is of particular importance in remote monitoring for two reasons: Firstly, systems that discern alerts only at the CIED level, as is the case with Medtronic, will need to call-in the patient for in-clinic reprogramming each time the physician changes his mind about which events he would like to be alerted.

Secondly, CIEDs that are not capable of discerning certain alerts independently from the programmer or the data server miss a necessary condition for what we call "urge" alerts. With alert urging we mean the more expedient transmission of alerts (system integrity and arrhythmia episode alerts in particular) through device-initiated communication. Alert urging CIEDs will attempt to transmit the raised alert(s) as soon as they are within reach of a/their monitor. Biotronik and wireless Medtronic ICDs are capable of doing so and in the process, Biotronik ICDs will not be picky about whether the monitor is actually assigned to them or to any other CIED of the same brand.

A number of systems offer the patient the possibility to initiate a IEGM recording and communicate to the data centre. This is useful when the patient occasionally suffers from poorly defined symptoms (e.g. dizziness, pre-syncope), allowing the following physician to associate or exclude a cardiac origin.

Finally, some systems allow for a programmable one-off device-initiated communication, this to assure the follow-up centre that the remote monitoring system is set up properly and functioning.

2.7.10 Communication between the monitor and the data centre

Table 18 provides the physical layer details about how each monitor communicates with its data centre. Noticeable is the fact that direct internet protocol (IP) over a digital subscriber line (DSL), ISDN and VOIP are not or poorly supported, the latter because of technical issues, similar to those encountered when attempting to send a fax over VOIP. This lack of support might be an issue with younger and/or technically savvy patients that have eliminated their need for a classic and often more expensive analogue telephone line. Whereas in some European countries, ISDN is broadly used in households. Less technical savvy patients, by contrast, are often also left at their own devices due to the absence of a technician delivering installation service at home.

2.7.11 Remote follow-ups

As mentioned before, virtually all companies present remote monitoring as a means to eliminate (albeit partially) in-clinic follow-ups. However, as can be inferred from Table 19, it comes to a surprise that not all manufacturers have actually implemented the concept of "a remote follow-up" procedure in their web application. This is also reflected by the fact that not all systems allow for IEGM scheduling by date. Another obstacle towards the complete abolition of in-clinic follow-ups is the observation that automatic pacing threshold technology is not always available on all CIED pacing channels.

However, it is good to see that all systems have the possibility of producing follow-up reports in portable document format (PDF). This may offer the first step towards integrating (remote and in-clinic) follow-up reports with the electronic health record (EHR) system of a hospital, although direct data exchange between data servers would be better of course. Equally important, PDFs may help formalising a remote follow-up procedure with the objective of receiving reimbursement for this act.

Some systems also provide a means for delivering feedback to the patient. This can be in the form of a request to phone the follow-up centre, or more assuringly for the patient; an automated phone call to the patient with a message about the outcome of the remote follow-up.

2.8 ACTORS INVOLVED IN REMOTE MONITORING

Phone operators

Repair Services

Home nurses

Treating physician

Technician nurses

Cardiology departments

Referring physicians

Data centre

2.9 FINANCING OF SYSTEM AND SERVICES

In Belgium no reimbursement is currently available, and the service is offered for free by the manufactures as part of their marketing strategy. Neither do hospitals nor physicians receive any fee for the service of monitoring remote monitoring data nor for performing follow-ups remotely.

2.10 CONCLUSION

At first glance, the different available systems appear to be quite similar in basic setup. However, a more detailed comparison reveals that each of the different systems, through the subtle interplay of differences in hardware and software, will serve to different extents each of the four functions of remote monitoring, being system integrity alerting, arrhythmia episode alerting, in-clinic follow-up replacement and remote disease management. Implanting physicians should disregard the many "me too" statements launched by the manufacturers' marketing departments, and rather take time to figure out what system(s) offer the best trade-off to serve a set objective for a specific patient subpopulation.

Notwithstanding the current advancements of remote monitoring technology, travelling patients should still take care to obtain the location details of the nearest hospital at their travel destination that has experience with interrogating their specific brand of ICD. This information can easily be obtained from the manufacturer's web site and/or customer service department.

Key points

- **All ICDs can be interrogated and reprogrammed during an in-clinic visit using an inductive programming wand. Most current ICDs also have the potential to be remotely monitored.**
- **Remote monitoring technology is currently very much evolving.**
- **Remote monitoring can be used to check system integrity, to alert on arrhythmic episodes, to potentially replace in-clinic follow-ups and potentially for remote disease management.**
- **Remote programming of ICDs is currently not available.**
- **The implementation of remote monitoring of ICDs, such as the frequency of interrogation, the alerting procedures and the workflow organisation are different between manufacturers.**
- **All systems deliver system integrity alerting. However, some systems seem to be better geared to fast arrhythmic alerting, whereas other systems appear to be more intended for remote follow-up or supplemental remote disease management.**
- **Every system features its own web application, differing significantly among one another. Not only do health care workers need to learn each application, all applications used at the centre need to be routinely checked for alarms.**
- **The integration of remote monitoring with electronic health record (EHR) systems that are open-source, commercial or developed in-hospital is for most systems very poor. At the moment, the only commonly available output data format is a simple Portable Document Format (PDF). Open or commercial standards for clinical data exchange with EHR systems are not commonly implemented.**
- **Because of this diversity of implementations, the value of the systems, the real cost of the systems and the impact on the workload of provider and clinicians may turn out to be very different.**

3 CLINICAL EFFECTIVENESS AND SAFETY

3.1 EVALUATION STRATEGY

Being a rapid HTA, existing HTAs, systematic reviews and horizon scanning reports were searched first. The search was limited to the years 2006-2010 in order to ensure describing only current state of the art remote monitoring. The search was performed through the CRD databases[a] (DARE, NHS EED, HTA) and the Cochrane library. Additionally websites of member organisations of the INAHTA network[b] were searched.

After identifying the most relevant published HTAs and systematic reviews an incremental search was performed in order to identify additional clinical trials and studies of particular interest that were published after the last comprehensive HTA or systematic review. These particular areas of interest included aspects of safety, quality of life and patient acceptance. Since the last identified HTA report included articles retrieved up to June 2008,[14] the incremental search for the present report was limited to articles published since 2008. Furthermore, only published peer-reviewed articles were included in this incremental search, hence excluding meeting proceedings and news media. Two researchers selected independently the potentially relevant articles based on the title and abstract (CDL and SS), resulting in 22 additional articles which texts were subsequently retrieved in full. Reading these full texts revealed many of those articles to be irrelevant to the topic of remote monitoring of ICDs.

In an attempt to identify any additional potentially missed studies as well as ongoing and planned studies, the EUnetHTA Joint Action database was searched for related ongoing projects.[c] Moreover, a request was sent to identify studies through the INAHTA 'List Serv' network.[d] Furthermore, the US registration site of clinical trials[e] was searched for ongoing clinical studies

These searches were conducted during spring 2010 and a final search was conducted on June 4th 2010 (August 25th 2010 for the clinical trials database). More details can be found in the appendix to this chapter.

a http://www.crd.york.ac.uk/crdweb/
b www.inahta.org
c http://www.eunethta.eu
d Special thanks go to Oksana Petersen for her assistance in this INAHTA List Serv inquiry
e http://www.clinicaltrial.gov

3.2 LITERATURE SEARCH

The result of the primary search on HTAs, systematic reviews and horizon scanning reports is presented in Table 1.

Table 1: Recent HTAs, systematic reviews and horizon scanning reports

Year	Reference	Scope
2009	NHS Centre for Evidence-based Purchasing. Implantable cardiac devices with remote monitoring facilities.[14]	ICD and PM
2008	Medical Services Advisory Committee (MSAC). Remote monitoring systems for patients with implanted cardiac devices[21]	ICD and PM
2008	Medical Services Advisory Committee (MSAC). Remote monitoring systems for patients implanted with cardiac devices (cardioverter defibrillators and pacemakers[22]	ICD and PM Update of 2006 report
2008	Agency for Healthcare Research and Quality (AHRQ). A proposed framework to evaluate home tests for use in the Management of Chronic Diseases.[23]	General on home tests in chronic diseases
2007	Agency for Healthcare Research and Quality (AHRQ). Remote cardiac monitoring. [24]	ICD and PM
2006	Medical Services Advisory Committee (MSAC). Remote monitoring systems for patients implanted with cardiac devices (cardioverter defibrillators and pacemakers[25]	ICD and PM
2006	National Horizon Scanning Centre (NHSC). Remote monitoring of implantable cardiac devices.[26]	ICD and PM

3.3 DATA SOURCES USED

The evidence in this chapter is primarily based on the most recent comprehensive evidence review from the NHS Purchasing and Supply Agency that was published in April 2009.[14] This review also contains evidence tables for the retrieved studies. It considered evidence retrieved up to June 2008. The evidence tables were used in this report in the description of results

Evidence from recently published trials not included in this NHS evidence review and additional hand-searched relevant evidence is described where appropriate (see appendix for details on inclusion and exclusion criteria). All of these studies (mainly observational case series and an occasional RCT) were industry sponsored.The research objectives were as diverse as the impact on early diagnosis of rhythm disorders, detection of device integrity problems, improved disease management, resource use, diagnostic reliability, impact on health related quality of life and the safety of replacing in-clinic visits with remote follow-up. All these studies had very different designs and outcome measures making comparison difficult. Moreover, many of the 22 retained articles dating after 2008 focussed more on the clinical aspects of specific ICD use rather than the remote monitoring aspects of the technology.

3.4 THE SAFETY OF REMOTE CARDIAC MONITORING

First and foremost, the safety of remote cardiac monitoring needs to be established in comparison to that of regular scheduled in-clinic visits.

Guidelines recommend regular in-clinic follow-up every 3 months to 6 months for patients with ICDs,[4] and more frequent follow-up when there are signs of battery depletion. The central question is whether these in-clinic follow-ups can safely be replaced by remote monitoring.

When remote monitoring is used only as a tool, in addition to normal in-clinic follow-up visits there are few safety concerns. However, if remote monitoring is employed with the aim of substituting some in-clinic follow-up visits, safety aspects can no longer be ignored.[14]

Brugada et al. studied this question by approaching it from the diagnostic test point of view. The diagnostic predictability of clinician-analysed remote monitoring data of 239 patients was tested (Biotronik system) prior to the gold-standard of routine in-clinic follow-up.[14, 27] Patients were followed for one year with scheduled follow-up every 3 months. Before the in-clinic follow-up the remote monitoring data were used to predict whether the follow-up was needed and whether actions such as reprogramming would be necessary. In 908 pairs of data they found 608 true negatives, 141 true positives, 30 false positives and 129 false negatives. This corresponds to a very high false negative rate of 48%. There were various reasons for this high rate of false negatives but it was suggested that some of those false negatives could have been avoided with a better management scheme of the scheduled follow-ups, such as always performing an in-clinic follow-up after 3 months, and not skipping follow-ups in patients who had episodes.

Heidbüchel et al. evaluated the potential effect of remote monitoring on scheduled and unscheduled ICD follow-ups in a retrospective analysis of the data of 1739 prospectively coded in-clinic follow-ups of a random set of 169 patients without remote monitoring.[11] Most ICDs in this population were implanted for secondary prevention. Of the in-clinic visits, 88% were performed according to schedule and in 78% of those, no relevant findings were made. In only 8 patients (0.52% of the 1530 scheduled visits) remote monitoring would not have detected pacing threshold increases in absence of automatic pacing capture or any other way to remotely determine pacing tresholds.

The recently completed TRUST randomised clinical trial sponsored by Biotronik primarily focuses on the safety of replacing in-clinic visits by remote monitoring, as well as the impact on the number of scheduled on unscheduled in-clinic visits.[28] The final results of this study were published just before finalising this report.[29] This study enrolled and randomised 1339 patients after ICD implantation with a 2:1 intervention to control randomisation ratio. The conventional follow-up patients were evaluated with in-clinic visits only at months 3, 6, 9, 12 and 15 after implantation, or upon request. In the intervention group automatic daily remote monitoring was used with scheduled in-clinic visits only at 3 and 15 months, or, upon request. This study included relatively paucisymptomatic patients (about 70% NYHA Class I or II), and most patient characteristics were similar between both groups. In the intervention group, 85.8% of all 6-, 9-, and 12-month follow-ups were performed remotely only, indicating that remote monitoring provided sufficient assessment. In the intervention group in-clinic follow-up was reduced by 45% without affecting morbidity. For all arrhythmic events the median time to evaluation was 2 days in the intervention group compared with 36 days in the conventional group ($P<0.001$). The authors conclude that remote monitoring is safe and allows more rapid detection of actionable events compared with conventional monitoring in patients with implantable electronic cardiac devices.

No specific reports on interactions of other electronic devices such as MP3 players with remote monitoring were found, although a few studies found some indications of interference with wireless transmissions of PMs and ICDs but no serious interferences with the functioning of the CIED.[30-34]

3.5 REMOTE DETECTION OF DEVICE AND LEAD FAILURES

System-related events can be classified as either device- or lead-related.[35] Reports of device failure, either failure of the pacing system, mechanical or electrical lead failures, or increased risk of battery depletion or degraded capacitor charge times are somewhat rather anecdotic and are described in only two studies reported in the NHS evidence review.[14, 36, 37]

The study by Joseph et al. on the St Jude monitoring system reported on 32 mechanical or electrical lead or ICD generator problems during 570 monthly transmissions in 124 patients during a 6 month follow-up.[37] In 20 selected patients that were at increased risk of battery depletion, remote monitoring was used by clinicians to prevent device malfunctioning. The interim report by Wallbrück et al with the Biotronik system included 93 patients followed for 3 months, leading to over 5000 reports. In this study only one case device malfunction was detected.[36]

A more recent prospective observational study evaluating the Biotronik remote monitoring system for ICDs, CRT-Ds and CRT-Ps, included 69 patients with an average follow-up of 18 months.[38] From a total of 206 event reports, most reports were related to clinical situations requiring the device to deliver therapy. However, the home monitoring system also detected some device malfunctions including four times abnormal pacing impedance, two incidences of battery depletion, five occurrences of RV lead fracture, one connector defect, one sensing defect and one RV lead dislodgement. The study estimated that home monitoring could lead to an earlier detection of adverse events of 1.9 month in the first year and 4.9 months in following years.

In the study from Sacher et al, one patient in the control group (no remote monitoring) died because of a lead failure triggering an inappropriate defibrillation shock,resulting in an unrecoverable VF.[39] Post mortem ICD analysis demonstrated that early signs of this lead failure were present and that remote monitoring would probably have detected this problem before death.

In an observational study from Spencker et al. fifty-four patients who had to undergo re-surgery due to malfunctions of the ICD leads were included.[40] Eleven of them were on remote monitoring interrogating the device daily with the Biotronik remote monitoring system,. The 43 other patients had ICDs from three different companies. It should be noted, however, that there was quite an imbalance in the study population; in the 11 patients on remote monitoring the indication was primary prevention for 72% of these patients, while in the control group this indication accounted only for 44%. The rate of inappropriate shocks and symptomatic pacemaker inhibition due to oversensing in the group of 11 patients with remote monitoring was compared to the group of 43 patients without remote surveillance. Remote monitoring sent alert messages in 91% of all incidents and all lead failures became obvious because of oversensing of high frequency artefacts. Eighty percent of the patients were asymptomatic at the first onset of oversensing. Only one patient suffered an inappropriate shock as first manifestation of lead failure. Compared with the patients without remote monitoring, inappropriate shocks occurred in 27.3% in the remote monitoring group vs. 46.5% (not significant) in the control group. However, this trend gained statistical significance when the compound endpoint of symptomatic lead failure consisting of inappropriate shocks and symptomatic pacemaker inhibition due to oversensing was considered: 27.3% event in the remote monitoring group vs. 53.4% in the group without remote monitoring ($p = 0.04$). In 91% of all lead-related ICD complications, the diagnosis could be established correctly by an alert of the remote monitoring system. Mostly, the first incident sent was oversensing of artefacts, falsely detected as ventricular fibrillation. The authors conclude that the automatic remote monitoring surveillance system enables physicians to detect severe lead problems early and to react quickly; thus, potentially avoiding inappropriate shocks due to lead failure and T-wave oversensing.

Varma et al. studied another aspect of device functioning; the prevalence of aborted shock therapy.[41] Aborted or cancelled shock therapy may be an precursor of subsequent inappropriate real shock delivery but may also shorten battery longevity of ICDs. But, since it is silent, it often goes by without attention, and may become undetectable during scheduled in-clinic follow-up since data may become overwritten due to a saturated device memory. In a retrospective analysis of 4960 patients with (Biotronik) remote monitoring follow-up for on average 445 days, cancelled shock therapy occurred in 28% of patients, mostly as a single episode. However, 2.9% of the patients with ICDs had more than 10 cancelled shocks, which can have an important and unexpected impact on battery longevity. In about one third of patients a cancelled shock was followed by a real shock but in more than halve of those cases the real shock occurred more than 10 days after the cancelled shock, indicating that appropriate intervention (medication or reprogramming) might have avoided the real shock delivery.

From the recently completed TRUST randomised controlled trial it was reported that, ICD lead and generator malfunctions were infrequent and mainly asymtopatic.[42] Only a minority of these events required surgical intervention. Daily remote monitoring allowed for longitudinal parameter trending and early detection, facilitating medical management. A recent report from the ECOST randomised controlled trial comes to similar conclusions.[43]

3.6 CLINICAL EFFECTIVENESS OF REMOTE DISEASE MANAGEMENT

The NHS evidence review of 2009 [14] considers six studies discussing the clinical benefits of remote monitoring.[36, 37, 44-47] Four reported on the detection of ventricular arrhythmias,[37, 44-46] and five of these considered atrial fibrillation (AF),[36, 37, 44, 45, 47] Whereas two discussed the benefits of early detection of device failure.[36, 37]

Subsequent studies, mainly relatively small observational studies and one small RCT, generally confirmed the findings of the before-mentioned HTA report of 2009 and are repeated in this report when relevant.

3.6.1 Remote management of ventricular episodes

In the NHS evidence review,[14] the following questions were asked concerning ventricular arrhythmias:

- How often and by how much time can adverse ventricular events recorded by the cardiac implanted electronic device (CIED) be discovered earlier with remote cardiac monitoring than by device interrogation during scheduled follow-ups and/or patient symptom triggered unscheduled follow-ups?
- How often and by how much time can inappropriate ICD detection of supra-ventricular tachycardia be prevented earlier through remote cardiac monitoring than with device interrogation at scheduled follow-up and/or patient symptom triggered unscheduled follow-up?
- Is the incidence of detected ventricular arrhythmias via remote monitoring comparable to that found with standard follow-up?

Answers:

None of the four articles considering ventricular arrhythmias compared incidence rates detected by in-clinic follow-up to follow-up rates detected by remote monitoring, but all reported specific incidents detected through remote monitoring.[37, 44-46] In the study by Nielsen et al.[46] 38% of the ICD patients experienced ventricular arrhythmias, while in the study by Joseph et al.[37] 54 VTs were treated by the ICD device in 124 patients. Schoenfeld et al.[45] reported a few patients in whom VT was detected by remote monitoring. Lazarus et al.[44] reported on the time interval between last follow-up and occurrence of events; for ICDs the average interval was 33 days and for CRT-D devices it was 28 days. The authors concluded that, on average, the events would have been detected 64 days earlier through continuous remote monitoring than through three-monthly in-clinic follow-up.[14]

In a later observational follow-up study performed by Santini et al. 67 patients performed 264 transmissions during 3 months using the Medtronic CareLink Network.[48] Ventricular tachyarrhythmias were reported in nine patients during 16 data reviews.

In the previously mentioned Italian study,[49] nine percent of the reported events were ventricular arrhythmias.

3.6.2 Management of atrial fibrillation (AF)

In the NHS evidence review, [14] the following questions were asked concerning AF:

- How often and by how much time can paroxysmal or persistent AF recorded by the cardiac implanted electronic device (CIED) be discovered earlier with remote cardiac monitoring than by device interrogation during scheduled follow-ups and/or patient symptom triggered unscheduled follow-ups? How do incident rates of paroxysmal and persistent AF compare for these different methods of follow-up, i.e. in-clinic vs. remote monitoring?

Answers:

Episodes of AF are stored in ICD devices. Furthermore, the burden of AF is recorded as a trend over time. However, none of the studies actually compared incidence rates of AF detected by in-clinic visits with rates detected by remote monitoring. However, a number of individual cases were described where patients developed AF shortly after implantation or shortly after the previous in-clinic follow-up that were detected by remote monitoring.[36, 44] These studies suggest that for a very limited number of individual cases the time between detection of AF and adequate therapy can be shortened through remote monitoring.

Varma et al. measured the frequency and burden of AF.[47] Of 107 patients enrolled, 29 had a history of AF. On average, most of these patients had less than 30 days with AF per year. However, when AF did occur, the proportion of the day with sustained AF was high, with a mean of time of around 16 hours. Overall, the authors concluded that remote monitoring could help the cardiologists in making better informed treatment decisions.

A subsequent Italian study followed 117 patients with the Biotronik home monitoring system during an average of 227 days with daily remote monitoring transmissions, 133 events were detected through this system.[49] The most common (47%) of these cardiac events was AF.

3.6.3 Remote management of heart failure

Specific results on the effectiveness of disease management (mainly HF), apart from the early detection of atrial fibrillation or ventricular arrhythmias, were not specifically discussed in the NHS evidence review,[14] probably because the different remote monitoring systems available are indeed difficult to compare. Some systems provide specific additional options: lung fluid monitoring, electronic weighing scales etc, electronic blood pressure measurement etc. However, it remains unclear how intensively those additional features are used in practice.

The study by Santini et al. (Medtronic CareLink system) concluded that remote follow-up is an efficient method to manage heart failure episodes in CRT-D patients, when heart congestion alerts are based on intra-thoracic impedance measurements relayed by remote monitoring.[48] 70% of the patients could be managed successfully entirely remotely, avoiding any emergency visits to the hospital.

3.6.4 Overall health outcomes

A recent small RCT from Duke Medical Centre enrolled 151 patients in early 2007. Patients who qualified for the inclusion criteria were randomised (1:1) to either quarterly in-clinic follow-up or to scheduled remote follow-up (Medtronic system).[13] The primary endpoint in this study was a composite measure for cardiovascular hospitalisation, Emergenc room (ER) visit for a cardiac cause and unscheduled visits to the electrophysiology clinic for a device-related issue at 1 year post-implantation. Moreover, health related QOL (EQ-5D and Visual Analogue Score), cost, and patient satisfaction were measured. Despite the small number of participants in this RCT, balanced baseline characteristics for most parameters in both study arms were obtained through the randomisation. However, no significant difference was observed in the primary endpoint.

The ongoing CONNECT trial is currently examining whether or not remote monitoring reduces the time to clinical decision making for arrhythmias and whether it improves health outcomes and health-related quality of life. This study is expected to provide important information on remote monitoring but results have not been published in peer-reviewed literature yet.[13, 50]

The recently completedTRUST clinical randomised trial found an important difference in the time to detecting of arrhythmic events: median time to evalution was less than 2 days in the remote monitoring group, compared with 36 days in the conventional group ($p<0.001$).[29] However, the clinical relevance of this finding is unclear.

3.7 CHANGES IN RESOURCE USE DUE TO REMOTE MONITORING

The NHS evidence review of 2009,[14] also examined resource use changes caused by home monitoring. The key results will be briefly described here. A more comprehensive discussion of these results will be in the next chapter. Ricci et al. measured the time it takes for clinicians to review patient information delivered by remote monitoring (Biotronik system with daily alerts).[49] In this study and during a mean follow-up of 227 days, 117 patients (both ICD and PM) were followed-up remotely. A total of 25 545 daily messages were sent and 1665 alerts were transmitted after alert triage. Average connection time in the clinic was 71 minutes per week, with only 12 minutes of this time spent by a clinician and the rest by a cardiac nurse. The nurse transmitted 133 critical cases in 56 patients. Although it is unclear how the alerts were configured, the authors concluded that this technology allows for optimization of medical treatment and device programming with a low consumption of health-care resources.

Nielsen et al. conducted a similar study exclusively with ICDs, again employing the Biotronik remote monitoring system with daily transmissions.[46] A total of 260 patients were monitored for an average of 10 months. After alert triage, about 41% of patients ended up with remote monitoring alerts. In this study 38.1% of patients caused only clinical alerts, 0.8% of patients had only device integrity alerts and 2.3% had both device integrity and clinical alerts. An average of 0.86 alerts per 100 patients was received daily. More than 60% of alerts occurred within the first month after the initial follow-up and it took the physician on average 5 minutes to evaluate the triaged alerts and to decide on the consequences for the patient. These authors also conclude that remote monitoring is feasible for the hospital organisation and leads to an early detection of clinical conditions and device integrity problems.

In a case-control study on remote ICD monitoring with Brugada Syndrome (BS) patients, 35 patients from one French hospital with the Biotronik remote monitoring system were compared to 35 age and gender matched patients from another French hospital without remote monitoring.[39] The patients with remote monitoring were seen once after implantation and at least once per year unless there were specific alerts or requests from patients. The patients without remote monitoring received in-clinic follow-up as recommended by the guidelines. During a mean follow-up of 33 months, the number of cardiology consultations was significantly lower in the remote monitoring group (3 vs. 7, $p<0.001$).

In ten of the remote monitoring patients alerts occurred, in five cases requiring immediate reprogramming of the device, potentially preventing inappropriate ICD therapy.

In the previously mentioned study by Santini et al. a three month follow-up of 67 patients resulted in 13 alerts. In two cases only, an in-clinic visit was considered necessary, while in 11 (85%) no action was needed and an in-clinic visit could be avoided.[48]

Theuns et al. analysed 57 148 transmissions by remote monitoring of ICDs using the Biotronik system.[35] The study population consisted of 146 recipients of ICD capable of remote monitoring. Data were transmitted daily or in case of pre-specified events (e.g., arrhythmia, out-of-range lead and/or shock impedance). During a mean follow-up of 22 months, a total of 57 148 daily remote transmissions were recorded. Of these transmissions, 1009 (1.8%) were triggered by a pre-specified event, including induced VF episodes during defibrillation threshold testing. The median number of events/patient/month was 0.14. Event rates were similar in patients with primary and secondary prevention indications for ICD (0.15 vs. 0.11). After exclusion of the induced VF episodes, 5.6% of transmitted events were classified as system-related and 94.4% as clinical. The median number of clinical events/patient/month was 0.023. The clinical event-free rates were 62% and 45%, at 1 and 4 years, respectively. The authors conclude that remote monitoring of ICD patients is feasible and that despite the large number of data transmissions, remote monitoring imposed a minimal additional burden on the clinical workload. The rate of triggered data transmissions by critical events was low.

A short qualitative Italian study funded by Medtronic evaluated during 3 months the workload for hospitals and physicians and the patient acceptance of remote monitoring in 67 relatively stable patients.[51, 52] The majority of patients received a CRT-D for reasons of primary prevention (84%), and were mainly in NYHA class II (70%) while none of them were in NYHA class 4. To be included they had to have a CRT-D device for at least 6 months. The device was interrogated by the patient using a magnetic wand at week 2, and months 1 and 2 with a total of 267 transmitted device interrogations. At month 3 a control in-clinic visit was scheduled. The overall duration of the device interrogations by the patient was on average 7 minutes and the time needed for the review in the participating electrophysiologists centres was less than 5 minutes per transmission, compared to 15 minutes for a conventional follow-up.[52] In total 23 clinical events occurred during the three month study period, but only two cases required a clinical visit, thus reducing inappropriate hospital visits. The clinicians judged the data available for remote review completed and adequate to provide a high standard of care.

A Finish study performed by Raatikainen et al. followed 41 patients for a period 9 months.[53] During 119 scheduled (remote follow-up) and 18 unscheduled data transmission with the (Medtronic) remote monitoring system no device-related adverse events were found. Both patients and physicians reported the system as easy to use. Compared with the in-clinic visits remote monitoring required less time from both patients (6.9 vs. 182 minutes) and physicians (8.4 vs. 28.8 minute) to complete regular follow-up.

An Italian study from Ricci et al. on PMs and ICDs with the Biotronik remote monitoring system followed 117 patients who had daily transmissions.[49] During an average follow up of 227 days more than 25 000 transmissions were received. Fifty-nine and 12 minutes/week were spent for the home monitoring data analysis, by respectively the nurse/technician and the physician during 267 web-connections. Mean connection time per patient was 115 seconds. In 133 instances (56 patients) the nurse forwarded the information to the physician for further clinical evaluation.

3.8 QUALITY OF LIFE

Joseph et al. monitored quality of life in patients with remote monitoring of ICDs.[14, 37] The study was performed in 124 patients in 2004 and might therefore not be representative for current (St. Jude Medical) systems. Main outcome measures were SF-36 measurements and patient satisfaction surveys obtained at baseline, and at 3 and 6 months. The SF-36 results were similar at baseline and at 3 and 6 months, while over 90% of patients indicated high satisfaction with the remote monitoring.

A recent RCT from Duke Medical Center compared quality of life (QoL) in 151 patients randomly assigned to in-clinic visits or to remote monitoring using the Medtronic system. Patients were either seen three-monthly in-clinic or had three-monthly remote follow-up. All patients were seen at inclusion for baseline measurements and training. At 12 months.[13] QoL was measured using both the EQ-5D instrument and the Visual Analogue Scale (VAS). Baseline patient characteristics were similar and mainly included patients for primary prevention. The median EQ-5D score at baseline was 100% in both groups This is rather surprising for this ICD population with an average age of 63 years. During follow-up, the EQ-5D scores decreased but were not significantly different between both groups. QOL measured with VAS was slightly better in the remote monitoring population at baseline (84 vs. 80 % NS). However, at 6 months quality of life measured by VAS was in favour of the control arm (83 vs. 75%, p=0.002). At twelve months, this difference disappeared. The authors stress that larger multi-centre studies are needed to confirm or invalidate these results.

3.9 PATIENT ACCEPTANCE

Patient acceptance is mainly determined by the effort a patient has to deliver in order to comply with the requirements of the telemonitoring system. Since recent ICDs offer RF telemetry, the patient is only required to plug in the bedside monitor and to sleep regularly sleep in its immediate vicinity. Previously, the patient had to hold an inductive telemetry wand on his skin exactly over the site of the implant in order to transmit data.

The NHS evidence review,[14] considers two studies. In both studies the patient needed to use the inductive telemetry wand, requiring active involvement.[37, 45]

In the study by Schoenfeld et al.[45] the ease of use of the bedside monitor (Medtronic system) was measured by the number of successful transmissions and what help was needed by the patient to make the transmission. In 110 transmissions, 91% of patients needed no help from the service provider. In general, the patients rated the device as easy to set up and use. Only three of the 53 participants had difficulties in positioning the wand or using the monitor.

In the study by Joseph et al.[37] the bedside monitor performance (St Jude system) was measured by ease of learning the system, using the system to transmit, time saved, convenience of routine follow-up and confidence. Of 124 patients, over 90% rated all these parameters as 'very much satisfied' or 'completely satisfied'.

In those two studies, patient interaction was required for the transmission but this appeared to be a small problem. Moreover, most current systems require no patient interaction and automatically download data from the implanted ICD through RF.

In the previously mentioned qualitative Italian study by Marzegalli et al. the patients had to intervene themselves in order to interrogate a Medtronic CRT-D device with the use of an inductive telemetry wand.[51, 52] Despite this required patient interaction for the transmission, acceptance in those 67 patients followed for three months and during three scheduled transmissions (267 transmissions in total) appeared satisfactory. The feasibility and acceptability of remote monitoring was also reported for other European countries.[38, 46, 53, 54]

The previously mentioned RCT from early 2010 confirmed the relatively good acceptability and satisfaction of behalf of the patient satisfaction with regards to the remote monitoring system.[13]

A recent study by Ricci et al. administered a custom made questionnaire to 119 patients who had been followed with remote monitoring for 1 year.[55] At the scheduled in-clinic follow-up at one year this study found a high level of acceptance and satisfaction in patient with remote monitoring, but there was no control group in this study.

3.10 ONGOING STUDIES

Evidence about the performance of remote monitoring is limited at this very moment. However, this is likely to change dramatically in the near future due to many ongoing studies. Through the website of www.clinicaltrials.gov several ongoing studies were identified.

A search on August 25th, 2010 with the search terms monitoring AND ("cardiac resynchronization therapy" OR ICD OR CRT-D OR defibrillator) identified 55 current studies (see list in appendix to this chapter).

Although not all of these studies specifically deal with remote monitoring as such, many do. The sheer number of ongoing studies makes it clear that the evidence on potential benefits and harms of remote monitoring of ICDs is very likely to change in the near future. Therefore, an updated evaluation will be needed when sufficient evidence has been produced.

3.11 CONCLUSIONS

Although the routine use of remote monitoring of ICDs is spreading widely in clinical practice, both in the US and in Europe, its comparative effectiveness and potential benefits versus regular in-clinic visits has not been demonstrated yet. The few RCTs that have results available at this moment are mainly dealing with so called healthier ICD patients. Those are predominantly patients with a prophylactic ICD for primary prevention. Few or no of the studied patients belonged to the higher NYHA classes. It is obviously easier to demonstrate the safety of replacing in-clinic follow-ups by remote follow-ups with this category of patients.

There is limited evidence coming from mainly observational studies and relatively small case series that, when used in addition to regular in-clinic visits, specific clinical events such as AF, ventricular arrhythmias and inappropriate supraventricular detections can be identified earlier than without remote monitoring, especially in the absence of clinical symptoms. It is unclear, however, whether this earlier detection also leads to better disease management and better health outcomes.

Most evidence is available for the monitoring of device and lead integrity. However, in practice this appears to be a minor problem, evidenced by the small proportion of device integrity alerts. Battery depletion and problems with the leads can be detected adequately via remote monitoring, and more quickly than through scheduled in-clinic follow-up.

It has to be emphasised that the frequency of remote follow-up and transmissions of results to the treating physician differs largely between manufacturers; A once a day transmission cannot be compared, and should not be considered equal to a once every three months remote follow-up, both financially and from an organisational point of view.

Despite the potential for earlier detection of clinical conditions and the potential to detect device integrity, little evidence is available on really important health outcomes, such as mortality, better disease management or health-related quality of life. The promise of enhanced disease management, especially for heart failure patients is yet unproven by solid evidence. The main reason is that most studies were performed on relatively healthy patients.

Apart from the theoretical potential to improve health outcomes for patients, a reduction of healthcare resource use might be gained as well. Many studies have focussed on this aspect trying to demonstrate that it is safe to replace some of the in-clinic visits with remote follow-up. However, little evidence is available that shows that these potential benefits are indeed realised in practice.

Moreover, cultural, country and reimbursement differences might make this transition from in-clinic to remote follow-up unlikely.

Especially when patient involvement is minimal -nowadays often limited to plugging in the bedside monitor into an electric outlet-, acceptance by patients does not seem to be a major problem. For older devices, where patient interaction using an inductive telemetry wand is mandatory, minor problems do occur.

Concerning safety aspects and assuming the patient is properly informed that remote monitoring is only an additional monitoring system and not a continuous alert and rescue system no major problems seem to appear.

An important problem with comparing these heterogeneous studies is the large differences in study population subgroups: primary prevention or secondary prevention, disequilibrium among HYHA classes across comparisons groups etc. Those differences hamper comparisons across studies.

The absence of sufficient evidence about the efficacy and effectiveness is mainly due to a lack of large RCTs. Henceforth, most current conclusions are based on relatively small observational studies or case series.

Key points

- **Current evidence about the clinical efficacy, effectiveness, safety and patient acceptance of remote ICD monitoring is mainly based on small observational case series and expert opinion.**
- **Most clinical studies, both observational studies and occasional RCTs, were performed on relatively healthy patients with mild NYHA classification (mainly NYHA class II). Therefore, results from these studies cannot be directly extrapolated to severe HF patients who are more likely to need direct and personal clinical attention.**
- **In all studies that considered both clinical events and device integrity, the majority of alerts were for clinical events and only a small proportion (around 5%) was for device integrity alerts.**
- **There is limited evidence that specific patient events (mainly arrhythmias) are detected earlier when remote monitoring is added to regular follow-up.**
- **Most evidence is available for the detection of device malfunctioning. This can indeed be detected earlier when remote monitoring is added to regular follow-up. However, as mentioned before, device malfunction alerts form a minor portion of all alerts received through remote monitoring.**
- **There is limited evidence for an ICD population with no or only mild symptoms indicating the safe partial replacement of in-clinic follow-up by remote monitoring or remote follow-up.**
- **Given adequate alert triage, the workload for both technical nurses as for clinicians in electrophysiology centres appears to be limited even with daily transmissions of data.**
- **Little evidence was found on relevant health outcomes (mortality, general health, health related quality of life, adverse events).**
- **Evidence on quality of life is currently perplexing. The only RCT that reported on quality of life reported lower health-related quality of life for the remote monitoring group. However, evidence from this small trial is not solid and should be reassessed by larger and better studies.**
- **Several major trials are ongoing implying that these conclusions may need to be revised in the near future.**

4 ECONOMIC LITERATURE REVIEW

4.1 INTRODUCTION

In this chapter we review the literature on economic evaluations comparing the use of remote monitoring systems with regular clinical practice, i.e. in-clinic follow-up or unscheduled follow-up following alerts, device delivered therapy or symptomatic episodes.

4.2 METHODS

4.2.1 Literature search strategy

The research questions for the current review are:

- What is the evidence, based on full economic evaluations, on the efficiency of remote monitoring systems compared to regular clinical practice?
- What are the key parameters driving the efficiency of remote monitoring system?
- What are the costs related to these key parameters?

To answer those questions the following electronic databases were searched: MEDLINE, Econlit, Psychinfo, Embase, the NHS Economic Evaluation Database (NHS EED), the Health Technology Assessment (HTA) database, the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials and the Database of Abstracts of Reviews of Effects (DARE). In addition, the reference lists of the selected articles were searched for relevant articles.

The research for this economic literature overview was performed in July 2009 and updated in June 2010. The keywords used and the search results are detailed in the appendix to this chapter.

4.2.2 Selection criteria

Retrieved references were assessed against selection criteria defined in Table 2.

Table 2: Selection criteria

	Inclusion criteria	**Exclusion criteria**
Population	Patients who have a pacemaker (PM), an implantable cardioverter defibrillator (ICD) or a cardiac resynchronization therapy (CRT); with remote monitoring capability	Other patients
Intervention	Remote monitoring of PM, ICD, or CRT	Other interventions: e.g. transtelephonic monitoring, etc.
Outcome	Incremental cost-effectiveness ratio (ICER). Key cost parameters: e.g. cost of equipment, technology, organization, and follow-up.	No cost data
Design	Full economic evaluations, cost and cost-outcome comparisons, cost and cost-outcome descriptions, review of economic evaluation.	Other design

As shown in the table, every type of economic study design was eligible for inclusion:

- Full economic evaluations which compare both costs and outcomes of at least two interventions and allow to calculate an incremental cost-effectiveness ratio (cost-effectiveness analyses, cost-utility analyses, cost-benefit analyses, cost-minimisation analyses);

- Cost-outcome comparisons which compare both costs and outcomes of at least two interventions but which do not allow to calculate an incremental cost-effectiveness ratio (e.g. different time frame, no relevant primary outcome, etc.);
- Cost comparisons which only compare the costs of at least two interventions;
- Cost-outcome descriptions which examine costs and outcomes of one intervention;
- Cost descriptions which only examine the costs of one intervention.

Reviews of economic evaluations were also investigated to determine whether additional information can be retrieved from these reviews. No language restriction was used. A first selection was based on titles and abstracts. One researcher (SG) assessed abstracts for relevance. Full papers were obtained and assessed for all potentially relevant studies.

4.2.3 Data extraction and quality assessment strategies

An economist (SG) extracted data using a structured data extraction form and assessed the quality of full economic evaluations using a standard quality assessment checklist for economic evaluations based on the checklist by Drummond et al.[56] (see appendix) and a narrative discussion of the results.

4.2.4 Conversion in Euro 2007

Costs were transformed into 2007 prices for each country using Consumer Price Indices available on the OECD website (http://www.oecd.org). Then we applied the Purchasing Power Parities (PPP) index to obtain comparable costs in Euro across the different countries. These PPP index were obtained from the website of Eurostat (http://epp.eurostat.ec.europa.eu). The PPPs used correspond to 2007 Euro for the 27 member states of the European Union. If no costing year was mentioned, an interval of two years before the publication year was chosen. The original cost figures (i.e. before conversion) are presented in the appendix.

4.3 RESULTS

4.3.1 Quantity of research available

After excluding 53 duplicates, 130 unique citations were identified from the databases. Of these 130 references, 106 did not meet the inclusion criteria based on title and abstract evaluation. Among the 24 citations retained for full-text assessment, 16 studies had an inappropriate design,[1, 10, 15, 16, 49, 50, 52, 57-65] and 5 did not meet the inclusion criteria concerning the intervention.[66-70] Ultimately only three studies were thus retained, one cost comparison[71] and two cost-outcome comparisons.[53, 72]

Further exploration of the references of selected studies (both economic and clinical studies) allowed the identification of 6 potentially relevant additional citations.[14, 21, 51, 73-75] Of these 6 references, one was a duplicate of a selected study[75] and one reference concerned only a conference abstract that could not be retrieved.[73] Thus, this manual retrieval resulted in four additional relevant studies, two cost-outcome comparisons[51, 74],one review of economic evaluations,[21] and one study which performed both an economic evaluation and a systematic review of economic evaluations. The flow chart of this selection process is shown in the appendix. These studies were not retrieved by the analyzed databases because they came from an online journal not indexed in these databases or because no keywords related to cost data were present.

Because of a long time period between the initial search strategy and the publication of the report, an update of this literature search was performed in June 2010. One additional study was identified during this update [13].

4.3.2 Primary economic evaluations

4.3.2.1 Studies description

Studies' characteristics are summarised in Table 3. Four studies were cost-outcome comparisons,[51, 53, 72, 74] one study was a cost comparison,[71] one study was a cost-minimisation [13], one study was a review of economic evaluations,[21], and one study performed both a review of economic evaluations and a full economic evaluation.[14]

Three studies (two cost-outcome comparisons and one cost-minimisation analysis) were performed[13, 72, 74] alongside a randomised clinical trial but the randomisation method was only explained in two studies.[13, 72]

One study was performed using a Markov model. [14] Event rates were derived from clinical studies but details on the design of these studies were not given and methods used to identify them were not described (studies selected for this model did not come from the clinical literature search performed in the beginning of their HTA). Moreover, population of these selected studies seemed to not always fit with the population of the model. For example, patients were assumed to enter the model with a history of AF and an implantable cardiac device and the risk of stroke was derived from a cohort study of patient with AF without specification on the presence of an implantable cardiac device. Concerning the cost estimates, the cost of the remote monitoring device, transmission and service was derived from a personal communication and was an ones-only cost of £1000. Other unit costs were obtained from the literature. Once again, details on the studies design and methods used to identify them were not fully described. It should also be noted that because almost no data on effectiveness of remote monitoring was available, the model was mainly based on assumptions and different scenarios were used, assuming a reduction of the rate of stroke due to AF with a remote monitoring ranging from 1% to 20%.

Concerning the perspective adopted in the selected studies, the study of the NHS adopted the health care provider perspective (NHS) and the study of Al-Khatib adopted the societal perspective. Other studies did not mention the perspective adopted but the analysis showed that they all adopted the societal perspective. However, even if they considered transportation costs (except the study of the NHS), only three studies took into account, at least partially, productivity losses.[13, 53, 74]

Concerning the study period, no study assessed the impact of remote monitoring for a lifelong period (maximum study period = 10 years). Moreover, costs and outcomes were only discounted in one study (3.5% for both costs and outcomes according to NHS guidelines).[14]

Four studies compared remote monitoring to conventional follow-up for patients with ICDs. Devices assessed were the "home monitoring" system (Biotronik) in one study,[71] and "CareLink" (Medtronic) in three studies.[13, 51, 53] With CareLink, data transmission was not performed daily and patients had to send the data at pre-scheduled moments (see Table 3).

The study of the NHS compared the use of remote monitoring for patient with an implantable cardiac device but did not differentiate the different devices and techniques, a major drawback since the systems proposed by the four providers are very different in their concepts and applications. This was allegedly done because, according to the others, no data were available to allow for this differentiation.[14]

Another study compared the remote monitoring of patients with ICD to conventional follow-up of these patients combined with remote monitoring. The device studied was the "home monitoring" system (Biotronik).[74]

The last study concerned patients with a dual-chamber pacemaker. This study analysed the impact of an early discharge of patients with a first implant (discharge within 24h) or a pulse generator replacement (hospital discharge within 4-6h) and a remote follow-up of these patients compared to a conventional follow-up of these patients (and no early discharge).[72] However, since our report basically deals with ICDs, it is less relevant in this context.

Table 3: Description of primary economic evaluations

	Study design	Population	Intervention	Comparator	Perspective	Time horizon	Discount rate
Fauchier France 2005	Cost comparison	Patients with ICD	Remote monitoring (Home Monitoring)	Conventional follow-up	Societal**	5 years	None
Elsner Germany 2006	Cost-outcome comparison	Patients with ICD	Remote monitoring (Home Monitoring)	Conventional follow-up + remote monitoring	Societal	1 year	NA
Marzegalli Italy 2008	Cost-outcome comparison	Patients with CRT-D	Remote monitoring (CareLink : Data transmission at 2 weeks, 1 months, and 2 months)	Conventional follow-up	Societal**	outcomes: 3 months costs: 6 years	None
Raatikainen Finland 2008	Cost-outcome comparison	Patients with ICD	Remote monitoring (CareLink: 2 remote data transmission)	Conventional follow-up	Societal	9 months	NA
Halimi France 2008	Cost-outcome comparison	Patients with dual-chamber PM	Early hospital discharge* + remote monitoring (Home Monitoring)	Conventional follow-up	Societal**	1 month	NA
	Study design	Population	Intervention	Comparator	Perspective	Time horizon	Discount rate
NHS UK 2006	Cost-utility analysis and cost-minimisation analysis	Patients with an implantable cardiac device and a prior episode of AF	Remote monitoring	Conventional follow-up	NHS	10 years	3.5% for both costs and outcomes
Al-Khatib USA 2010	Cost-minimisation	Patients with ICD	Remote monitoring (CareLink: 3 remote data transmission per year)	Conventional follow-up	Societal	1 year	NA

*Within 24 hours after first implant and within 4-6h after pulse generator replacement.**Without taken into account productivity losses.

4.3.2.2 *Cost data and results*

ICD or CRT-D follow-up with remote monitoring compared to conventional in-clinic follow-up

Cost data specific to the remote monitoring can be divided into a cost for data management (bedside monitor, data transmission, data server) and a cost for the remote follow-up (data analysis by the physician or the nurse, etc.). Only the study of Fauchier et al (2005)[71] included the cost for data management in the calculations (€1127 for 5 years) and only the studies of Raatikainen et al (2008)[53] and Al-Khatib et al[13]took into account a cost of remote follow-up (see Table 4). Moreover, uncertainty was not handled by a sensitivity analysis and confidence intervals for cost data were not given. Only Fauchier et al assessed the impact of transportation costs on results.[71]

The analysis showed that the in-clinic visit fees ranged from €47/visit to €205/visit across the studies. Transportation and total costs also varied strongly due to study design and assumptions. Results are summarised in Table 4.

In the assumption of two in-clinic visits prevented by remote monitoring and by taking into account the cost of the device, Fauchier et al showed that direct medical costs were higher with remote monitoring of ICD patients compared to a conventional in-clinic follow-up of these patients (around +€49/year; own calculation). The study also showed that by taking into account transportation costs, remote monitoring becomes a cost-saving strategy (around €178/year; own calculation). The mean distance between the patient home and the medical centre in this study was 69 km and the sensitivity analysis on this parameter showed that if only patients living at a distance of no more than 50 km from the medical institution, the mean cost-saving would be -€166 for a 6 year period, with a break-event point reached at 52 months. However, elements included in the cost of the home monitoring system (€1127) were not described. Moreover, transportation costs used in this study were high due to the assumption that all patients were transported in medical vehicles.[71] These results are therefore not easily transferable to a Belgian setting.

Marzegalli et al assumed in their study that, beside the 2 scheduled in-clinic visits prevented by remote monitoring, one additional unscheduled visit per year could be avoided, given an average incremental cost-saving of €196.28 per year and €1177.71 for 6 years. However, neither the cost for data management and the cost of remote follow-up were taken into account in this study.[51]

Raatikainen et al. showed that with a reduction of 2 scheduled in-clinic visits (due to the study protocol), remote monitoring allowed cost-savings of €462 for 9 months compared to a conventional follow-up. With the inclusion of the gain due to unscheduled in-clinic visits avoided, cost-savings were estimated to range between €462 and €661. However, this study took into account the cost of remote follow-up but not the cost for data management. Moreover, it concerned patients living in an area characterized by long travelling distance to the clinic, implying high transportation costs, and the cost of in-clinic visits were high compared to the other studies (€205/visit vs. €88 and €47). Results of this study are therefore not transferable to a Belgian setting.[53]

Finally, Al-Khatib et al. showed that with a reduction of 3 scheduled in-clinic visits (due to the study protocol), the incremental medical cost of remote monitoring compared to in-clinic visits was €90.69 per patient per year. This was due to a higher cost of the remote follow-up (€85.3) compared to the cost of in-clinic follow-up (€55.07). If patients required ICD programming during their clinic visits (for a total cost of €74.62/visits), the incremental cost of remote monitoring decreased to +€32.04 per patient per year. By taking into account both transportation costs and productivity losses, results improved and the total incremental cost of remote monitoring compared to a conventional follow-up amounted to -€57.06 if patients required ICD programming during their clinic visits and +€1.59 if patients did not required ICD programming. However, items included in the remote follow-up cost were not clear and the transfer of these results to our country setting is difficult (Medicare tariffs).

Table 4: Cost items and incremental costs of ICD follow-up with remote monitoring compared to conventional follow-up

	Fauchier 2005 (Home monitoring)	Marzegalli 2008 (CareLink)	Raatikainen 2008 (CareLink: 2 remote visits)	Al-Khatib 2010(CareLink: 3 remote visits)
Cost of in-clinic visit	€88.29/visit.	€47.23 /visit.	€204.71/visit.	€55.07- €74.62/visit
Cost for data management	€1127.12 for 5 years. Cost for data transmission and data server included?	Not included.	Not included.	Not included?
Cost of remote follow-up	Not included.	Not included.	€48.53/analysis (2 per patient per 9 months).	€85.30/device interrogation
Mean transportation cost/visit	€113.65/visit.	€18.20+/-33.30 /visit.	€65.61+/-91.66/visit (range: 1.06-703.96).	€5.27/visit
Accommodation cost	/	/	€17.81/night (mean of 0.2 nights per patient per 9 months).	/
Indirect cost	Not included.	Not included.	€38.82/day (=Sickness allowance) (mean of 0.5 days per patient per 9 months).	€24.43/visit of 2 hours
Incremental number of scheduled in-clinic visits	-2 per year (assumption).	-2 per year (assumption).	-2 per 9 months (protocol).	-3 per year (protocol)
Incremental number of unscheduled in-clinic visits	Not assessed.	-1 per year (assumption).	-18/41 (0.4) per 9 months.	Not included (because no significant difference).
Mean incremental direct medical cost	+€48.84 per year*. +€244.21 for 5 years*.	-€141.68 per year*. -€850.09 for 6 years.	-€312.36/patient for 9 months* (Without unscheduled visits).	Between +€32.04/patient/year and +€90.69/patient/year
Mean incremental direct non medical cost	-€227.30 per year*. -€1136.51 for 5 year*.	-€54.60 per year*. -€327.61 for 6 years*.	-€131.66/patients for 9 months* (Without unscheduled visits).	-€15.81/patient/year
Mean incremental indirect cost	/	/	-€17.99/patients for 9 months* (Without unscheduled visits).	About -€73.29/patient/year*
Mean incremental cost	Around -€178.46 per year*. -€890.42 for 5 years. Break event point after 33.5 months.	-$196.28 per year. -$1177.71 for 6 years.	Without unscheduled visits: -€462.01 for 9 months. With unscheduled visits: -€462.01 to -€660.90 for 9 months.	Between about -€57.06 and +€1.59/patient/year*

* Own calculation based on study data

Follow-up of patients with implantable cardiac devices with remote monitoring compared to conventional in-clinic follow-up

Two kinds of full economic evaluations were performed by the NHS, with different assumptions: 1) effectiveness of the two strategies was assumed to be identical (cost-minimisation study) and 2) effectiveness in term of incidence of stroke differed (cost-utility analysis).

With the first assumption of no additional benefit to the patient (base case scenario), the cost of remote monitoring was not offset by the use of remote monitoring. Only a reduction of at least one in-clinic visit per patient per year with remote monitoring would allow cost-savings after six years. However, there is no evidence to safely support such a scenario according to the report.

However, assuming a reduction in stroke incidence, the study showed that if remote monitoring would lead to a 5% relative risk reduction or more (baseline assumed annual incidence 4.5%) compared to routine monitoring, the incremental cost-effectiveness ratio (ICER) would fall below £30 000/QALY[f] for a 10 year period. With a larger reduction in stroke incidence rates, the ICER obviously became more advantageous. Unsurprisingly, the sensitivity analysis showed that the ICER was sensitive to the cost of the remote monitoring system and the cost of stroke.

However, as specified in the method section, authors did not differentiate between the different devices and techniques, methods to value cost and effectiveness data were not clear, the model is mainly based on assumptions and scenario analyses, and results are not easily transferable to our country setting. Moreover, sensitivity analysis was not performed on all uncertain parameters.

ICD follow-up with remote monitoring compared to conventional follow-up combined with remote monitoring

In the study of Elsner et al, patients in the remote monitoring group were required to visit the clinic one time per year while patients in the conventional follow-up and remote monitoring group were required to visit the clinic 4 times per year (= -75% of scheduled visits). This study also showed that the number of unscheduled visits induced by remote monitoring and induced by the patient himself was higher in the remote monitoring group (+3.9% and +7.9% respectively), given a total reduction of visits of 63.2%. Cost-savings were €729.72 per patient per year in total. However, no more cost details were given, uncertainty was not handled by a sensitivity analysis and confidence intervals were not given. Moreover, cost items included in the calculations were not clear. The cost of remote follow-up seems to be included but it is not clear whether the cost for data transmission was also taken into account. Then, because remote monitoring was used in both strategies, the cost of the device was not included. It should have been more interesting to compare remote monitoring of ICD patients to a conventional follow-up without remote monitoring.[74]

Early discharge of patient with pacemakers and remote monitoring (Home Monitoring) vs. conventional follow-up

Halimi et al assessed the impact on both costs and outcomes of an early discharge of patients with dual chamber PM due to the use of a remote monitoring system compared to a conventional follow-up. Hospitals tariffs were used for calculations. Costs related to the remote monitoring system were not included. No difference between the costs incurred in the remote monitoring study group (€6684.34+/-€1447.57) compared to the costs of the conventional follow-up group (€6955.47+/-€1556.40; p=0.08) was highlighted by the study. However, cost items included in the calculation were not clear, no more cost detail was given, uncertainty was not handled by a sensitivity analysis and confidence intervals were not given.[72]

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[f] Willingness to pay threshold for a QALY in UK.

4.3.2.3 Outcome data and results

No study assessed the impact of remote monitoring on a final outcome such as the number of life years gained or quality-adjusted life years (QALY) gained. The impact on adverse events was only assessed in the study of Halimi et al and showed that with an early discharge of patient with PM and a remote follow-up, the number of adverse events was not higher than for patients in conventional follow-up (absolute RR: 1.1; 95%CI: -6.9-9.1). Interesting findings for cost analysis such as time losses and the number of unscheduled transmissions or in-clinic visits are described in Table 5 and Table 6. These outcomes, when specified, varied strongly among studies. Other results such as patient and physician satisfaction can be found in the appendix.

No study assessed the impact of remote monitoring on hospitalisation rate for cardiac events.

Major outcomes of primary economic evaluations for the CareLink system

Table 5: Major outcomes of primary economic evaluations for the CareLink system

	Marzegalli 2008	Raatikainen 2008
Mean time per routine in-clinic visit	/	Physician time: 25.8+/-17.0 min (range: 5-90 min) Additional hospital staff time: 45.3+/-30.6 min
Mean time per routine in-clinic visit for the patient (including travel time)	116+/-90 min	391+/-282 min (range: 41-1346)
Mean time to review data per patient	5+/-2 min	Physician time: 8.4+/-4.5 min (range: 2-30 min). Additional hospital staff time: 9.3+/-15.9.
Number of unscheduled transmission	1.37 per patient-year	Around 0.4 for 9 months*
Percentage of unscheduled transmission leading to an in-clinic visit	17%*	0%
Incremental number of unscheduled in-clinic visit with remote monitoring compared to a conventional follow-up	CareLink: 0.24 per patient-year; Conventional follow-up: 1.37 per patient-year; Incremental = -1 per patient-year	CareLink: 0 per patient for 9 months Conventional follow-up: 0.4 per patient for 9 months* Incremental: around -0.4 per patient for 9 months*

*own calculation

Table 6: Major outcomes of primary economic evaluations for the Home Monitoring system

	Elsner 2008	Halimi 2008
Number of warning messages	/	1+/-1.5 messages/patient/month
Percentage of warning messages leading to an in-clinic visit	/	7%
Incremental number of unscheduled in-clinic visit with remote monitoring compared to a conventional follow-up	+ 0.473 visits per patient-year (+0.157 induced by the remote monitoring system and +0.316 induced by the patient)	Around + 0.07 visits per patient-month*

*own calculation

4.3.3 Review of economic evaluations

The Australian MSAC performed a literature review of economic evaluations on remote monitoring systems.[21] Beside, the study of Fauchier et al and the study of Elsner et al, they identified one additional study (Chan and Chun 2002).[73] The authors from MSAC could not retrieve this conference abstract to evaluate the quality of the study but summarised the anecdotal reports by the applicant. The Australian authors concluded that the identified studies had major limitations and were not transferable to their country setting. They added that appropriate clinical evidences on patients outcomes and resources cost-savings of remote monitoring systems were insufficient to conduct an economic analysis.

The NHS Centre for Evidence-based Purchasing in the UK conducted in 2009 a review of implantable cardiac devices with remote monitoring facilities.[14] This review identified five studies analysing resources consumptions or the impact of remote monitoring on the quality of life.[37, 46, 49, 71, 76] Among these studies, only the study of Fauchier et al was included in our review. Other studies were not retained because they did not include cost data [37, 46, 49] or because they did not assess one of the remote monitoring system described in our inclusion criteria. [76]

4.4 DISCUSSION

Because of a lack of effectiveness data, the research question about the efficiency of remote monitoring systems could not be fully investigated through this literature review. Nevertheless, even if the quality of identified studies was limited, this research allowed us to identify key parameters driving the efficiency of remote monitoring systems.

To conduct an economic evaluation of remote monitoring systems, the following cost parameters should be taken into account:

- The cost of scheduled and unscheduled in-clinic visit
- The cost of the remote monitoring system (device)
- The cost of data transmission for the remote monitoring system
- The cost to process the data (physician and/or nurse cost)
- Transportation costs
- Productivity losses

However, estimation of these parameters for the Belgian setting was not possible from the analysed studies. Only the cost of regular in-clinic follow-up in Belgium is currently available (calculated in the previously mentioned KCE report from 2007 for secondary prevention patients). This cost was dependent on the time after implantation and decreased from €345 in the first year to around €280 in the following years.[2]

Moreover, most of these studies did not assess the following relevant parameters:

- Hospitalisation costs
- Infrastructure and overhead costs
- Other investment costs such as a computer or a printer

Clinical data on the hospitalisation rates for cardiac events, the number of alarms (true positive, false positive), the number of unscheduled visits, the physician and/or nurse time to analyse the data, and on a final outcome such as the number of Quality Adjusted Life Years gained are needed to conduct appropriate economic evaluations.

Potentially, remote monitoring would seem to be attractive for patients by increasing the frequency of monitoring and reducing the need for in-clinic follow-up. However evidence on real benefits is currently lacking. Several clinical and cost studies are ongoing (also see chapter 3). Therefore, also the economic evaluation of the remote monitoring of ICDs will need to be re-evaluated in the near future.

Key points

- **The quality of the studies identified by the economic literature research was limited.**
- **The cost-effectiveness of remote monitoring systems could not be investigated due to the lack of effectiveness data, the absence of cost data for the Belgian setting and a perceived general reluctance of care-givers to replace in-clinic follow-up by remote monitoring.**
- **Therefore, there is currently insufficient evidence to conclude on the cost-effectiveness and on the potential financial impact for the Belgian health care payer.**

5 LEGAL ASPECTS

5.1 INTRODUCTION

A wide range of legal issues such as privacy and security, professional secrecy, professional and product liability, patients' rights,… undoubtedly play an important role in the implementation and the successful functioning of remote monitoring. There is, however, no custom made regulatory framework regarding the issue of telemonitoring. Telemonitoring is considered to be one of the multiple eHealth applications. Since there is a mass of heterogeneous applications covering a range of particular needs, it is difficult to create an overarching regulatory framework applicable to each specific individual case. Hence the focus of this chapter will be the applicability and the impact of different regulations affecting the particular issue of cardiac remote monitoring. It should be stressed that although the report primarily focuses on remote cardiac monitoring, the legal and the organizational framework described in another chapter can be extrapolated to other telemonitoring applications. Therefore, we started from the principle to inventarise the most significant legislation that can be considered when practising telemonitoring (and the difficulties in it's application) rather than departing from the current state of affairs based on the contracts between the different intervening parties involved in remote cardiac monitoring.

This chapter aims to summarize the legal framework at the EU level and in Belgium. A more detailed description with complete references can be found in the appendix to this chapter. Although today remote cardiac monitoring across borders (where monitored patients are located in another home country than the treating physician) is practised to a limited extent, the rise of hospital chains providing healthcare all over Europe (e.g. Capio[g]) and the scarcity of healthcare professionals will probably increase the use of cross border telemonitoring. In that scope legislation considering the cross border use of telemonitoring will also be taken into account.

5.2 METHODOLOGY

The study uses traditional legal research methods. Standard European legal databases, the records of the European Court of Justice, as well as wider European regulations databases are consulted. Regarding the Belgian legal framework, the legal databases Juridat and Jura and the national websites of the courts served as data source.

5.3 DEFINITIONS

As mentioned in the introduction, *telemonitoring* is only one of many eHealth applications. To enhance clarity, it is important to situate the issue of telemonitoring in a larger scope and define the notions that will be used in the report. The definitions of the European Commission will be used throughout the report. It should be noted that whereas the notion "remote monitoring" is mainly used in a clinical context (i.e. scientific,reports on clinical studies) the concept "telemonitoring" is mainly used in legislative texts. Both terms, however, broadly cover the same content.

eHealth is an overarching term for a wide range of services and tools. Although it has become a global topic, there is no universal definition. The European Commission defines eHealth very generally in terms of a series of characteristics specified at varying levels: information and communication technologies, tools and services for health. eHealth covers the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals. Examples include health information networks, electronic health records, telemedicine services, wearable and portable systems which communicate, health portals, and many other ICT-based tools assisting disease prevention, diagnosis, treatment, health monitoring and lifestyle management.[h]

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g http://www.capio.com/

h http://ec.europa.eu/information_society/activities/health/whatis_ehealth/index_en.htm

There is no uniform definition on telemedicine either. In the communication of the European Commission on telemedicine for example, the concept of telemedicine is defined as follows:[i] *"Telemedicine is the provision of healthcare services, through the use of ICT in situations where the health professional and the patient, or two professionals, are not in the same location"*. The Commission refers to telemonitoring as an example, defining it as a telemedicine service aimed at monitoring the health status of patients at a distance. [77, 78] Data can be collected either automatically through personal health monitoring devices or through active patient collaboration (e.g. by entering weight or daily blood sugar level measurements into a web-based tool).

5.4 EUROPEAN LEGAL FRAMEWORK RELATED TO TELEMONITORING

Although healthcare is a competence that remains largely under the competence of the member states, European legislation from other policy domains that are not directly targeted at regulating healthcare have an important impact on the issue of healthcare. Particularly relevant for the issue of telemonitoring is the European legal framework for privacy protection of personal data, medical devices, regulating the market access, product liability, patient safety etc.

In this section a description of the key elements of the legal provisions at EU level that are particularly applicable to the issue of telemonitoring is elaborated. The applicable EU legislation is implemented in Belgian legislation and a more extensive analysis of the Belgian legislation specifically relevant to the topic of telemonitoring, in particular data protection legislation will be described later in this chapter.

5.4.1 Directive 95/46 EC: common European standards

There are a number of elements that increase the danger of breaching the privacy and the confidentiality in applying telemonitoring. Non-medical staff, in particular technical and, administrative support staff is often involved in the delivery of care. This increases the risk of divulging health data in an unauthorised way. Furthermore the transmission of data over a network may lead to interception. The European Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (hereinafter referred to as Data Protection Directive, DPD)[79, 80], aims at protecting the rights and freedoms of persons with respect to the processing of personal data and sets a number of requirements regarding the confidentiality and security that have to be met in order to safeguard individuals' rights[j].

The Data Protection Directive (DPD) has been transposed into national legislation of the member states. Divergent implementation however hampers uniformity in data protection modalities for the application of cross border eHealth services.[82] For the telemonitoring application this might be an issue since data processing mostly is performed in another member state than the patient's home country and the data protection legislation of the respective state may apply. Since it is impossible to highlight all divergences in national data protection legislation within the scope of this study, we solely focus on the general principles relevant for the telemonitoring application described in the DPD and then apply and discuss more extensively the issue of telemonitoring in the perspective of the Belgian data protection legislation (see below).

[i] http://ec.europa.eu/information_society/activities/health/docs/policy/telemedicine/commn_telemedicine_en.pdf

[j] For an comparison of national data protection laws we refer to D. KORFF, Study on the implementation of the data protection Directive. Comparative summary of national laws.[81]

Principal actors and fundamental principles

The data protection rules in the DPD are targeted to various actors. The most important ones are the data subject, the data controller and the processor. The DPD requires a specific quality level and requires fundamental data protection principles fpr the data processing. These data protection rules are mainly translated into duties addressed to the data controller. According to the Directive, personal data used in telemonitoring applications must be processed fairly and lawfully (art. 6.1. a. DPD). Furthermore, data must be collected for specified, explicit and legitimate purposes (art. 6.1. b. DPD) and not further processed in a way incompatible with the initial purposes. The data must be adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed (art. 6.1. c. DPD). The controller should therefore balance the necessity of the personal data against the purpose. Personal data must be accurate and, where necessary, kept up to date (art. 6.1. d. DPD). Moreover data must be kept in a form that permits identification of data subjects for no longer than is necessary (art. 6.1. e. DPD).

Rights of the data subject

The DPD grants a set of rights to data subjects, such as patients. Patients have the right to information (art. 10 DPD) on the processing of data, to access the personal data (art. 12 DPD), to request correction (art. 12 DPD), erasure or blocking and under some conditions the right to object to the processing of personal data.

Automated decisions

According to the DPD (Art. 15 DPD), member States must assure that individuals are not subject to a decision which produces legal effects concerning him or significantly affects him and which is based solely on automated processing of data intended to evaluate certain personal aspects relating to him, such as his performance at work, creditworthiness, reliability, conduct, etc.

This disposition can be interesting with regard to the issue of telemonitoring since the patient's health status will highly depend on the output of the automated processing of the data that were transmitted by the bedside monitor. Although it is up to the physician to define the parameters that will be monitored and data revealed by the telemonitoring need to be interpreted by a health care professional, the processing of the data is highly automated. Therefore it could be argued that in the light of this disposition the remote monitoring can not entirely replace the in-clinic follow-up visits in clinic (see also chapter organisation).

Confidentiality and security of processing (art. 16 and 17 DPD)

In order to ensure confidentiality, the person who has access to personal data must not process them except based on the instructions from the controller, unless there is a legal exception. The controller has the duty to implement appropriate technical and organizational measures[k] to guarantee that the identification data is kept secured. Particular protection should be granted as regards unauthorized disclosure or access, accidental or unlawful destruction or accidental loss, alteration and unauthorized disclosure or access. Examples of technical measures are back-ups, restricted access to the database to authorized persons, use of software protecting the system against viruses.[84]

A level of security appropriate to the risks represented by the processing and the nature of the data should be provided. If the controller entrusts part of processing to a processor, he or she should ensure that this processor also provides sufficient guarantees on technical security measures and organizational measures. Additionally, transfers to a data processor should be secured by a data processing agreement between the controller and the processor meeting minimum requirements (specified in art. 17 DPD).

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[k] Recommendation (97)5 of the Committee of Ministers on the protection of health data has listed some examples of measures.[83]

Specific provisions for health data

The processing of personal medical data is prohibited in principle, but an exclusive list of exemptions is given (art. 8.2 and 8.3 DPD).

In the case of telemonitoring three exceptions in particular can be considered:

- The data subject has given explicit consent to the processing of those data
- Processing is necessary to protect the vital interests of the data subject or to another person if the data subject is physically or legally incapable of giving his consent.
- Processing for the purposes of preventive medicine, medical diagnosis and the provision of care or treatment of the management of health-care services if the data are processed by a health professional under national law or rules to the obligation of professional secrecy or by another person also subject to an equivalent obligation of confidentiality.

Transfer of data between member states

Health data in the telemonitoring application will be regularly transferred to other member states since the server to which data from the bedside monitor are sent is often located in another country than the patient's home country. It should be noted, however, that the mere transfer of data for technical reasons has not so many important implications with regard to the impact of the data protection legislation. If the controller is not established on EU territory and, for purposes of processing personal data makes use of equipment, automated or otherwise, situated on the territory of the said Member State, the legislation of this member state is applicable *unless such equipment is used only for purposes of transit through the territory of the Community* (art. 4 DPD).

With regard to the transfer of data between member states, the protection of data will in principle be performed correctly, since the receiving member state will have to provide a similar level of protection of personal data according to the European DPD If data are transferred to third countries, the DPD stipulates that the member state shall provide that the transfer of personal data that are undergoing processing or are intended for processing after transfer may take place only if, with prejudice to compliance with national provisions adopted pursuant to the other provisions of the Directive, the third country in question ensures an adequate level of protection. Since personal data is often transferred between the EU and the US, the US Department of Commerce issued the "Safe Harbour Principles" in order to clarify the notion of adequacy.[85] These principles have been recognized by the European Commission.[86] Hence, if health data of patients in the EU member states in the telemonitoring application are transferred to a server located in the US, the safe harbour principles apply, once they are transferred to the US. For those countries where there is no adequate level of protection, a transfer may take place on the condition that e.g. the data subject unambiguously consented to the proposed transfer (art. 26 a. DPD). A member state may also authorize such a transfer if the controller adduced adequate safeguards with respect to the protection of the privacy and fundamental rights and freedoms of individuals though appropriate contractual clauses (art. 26, 2. DPD).

Applicable member state's data protection law

The applicable member state's data protection law is usually the law of the member state where the data controller is established. This solution is not very patient-friendly in cross-border situations. If their rights are infringed in another member state than their home country, they will often be forced to exercise their rights in the data processors' Member State and thus overcome all possible barriers related to e.g. language, legal assistance, etc…(SMART 2007-0059 Study on the Legal Framework for the Interoperable eHealth in Europe, p. 58[82]). Moreover, patients will be confronted with slight differences in national data protection acts. Whereas in application of the Belgian data protection act for instance, patients have a right to direct access to their data, Portuguese data protection legislation for instance solely allows indirect access through a physician. Furthermore other matters (such as credit, consumer protection, environmental matters, advertising or criminal matters) may be subject to the law of the country where goods or services are offered or bought, or where the consumer is officially registered.

5.4.2 Privacy in the electronic communications sector

Directive 2002/58/EC, concerning the processing of personal data and the protection of privacy in the electronic communications sector (Hereinafter called, the E-privacy Directive[87]), amended by directive 2009/136/EC[88] lays down specific requirements on providers of electronic communications services over public communications networks to ensure confidentiality of communications and security of their networks.[87]. The E-privacy Directive was implemented in the Belgian legal order by way of the Law regarding Electronic Communications.[89] The E-privacy Directive aims to "translate" the principles set by the DPD into specific rules for the telecommunications sector, but they do not abridge each other in any way. Service providers who fall under the scope of the E-privacy Directive will thus have to comply with both directives. The E-privacy Directive applies to "the processing of personal data in connection with the provision of publicly available communications services in public communications networks in the Community" (art. 3).

An information society service provider will fall under the E-privacy Directive when:

- it provides a electronic communications service (as defined by art. 2, (c) of the Framework Directive – see appendix);
- which consists wholly or mainly in the conveyance of signals on electronic (public) communications networks;
- with regards to which the service provider does not exercise or provide editorial control;
- and this service is made publicly available (i.e. open for use by third parties; without restricting it to closed group or a specific end-user);
- and this service is provided over a public communications network (i.e. an electronic communications network used wholly or mainly for the provision of publicly available electronic communications services).

The data transmissions in the telemonitoring application are always targeted at specific end-users or a closed user group (such as for instance the health professionals having secured access to the website where patient data are available). Moreover, solely the mere transmission of data falls within the field of application of the E-Privacy Directive. As soon as the service includes other services such as the first assessment of the data by a nurse, the E-Privacy Directive is not applicable any more.[90] Consequently it is unlikely that the E-Privacy Directive will be applicable to the telemonitoring application.

5.4.3 Product safety

The Directive on general product safety is intended to ensure a high level of product safety throughout the EU for consumer products that are not covered by specific sector legislation.[91, 92] The Directive provides a generic definition of a safe product. If there are no specific national rules, the safety of a product is assessed in accordance with European standards, Community technical specifications, codes of good practice and the state of the art and the expectations of consumers.

In addition to the basic requirement to place only safe products on the market, producers must inform consumers of the risks associated with the products they supply. They must take appropriate measures to prevent such risks and be able to trace dangerous products. The Directive provides for an alert system (the RAPEX system) between Member States and the Commission that ensures that the relevant authorities are rapidly informed of dangerous products. In the case of serious product risks, the Directive provides for temporary decisions to be taken on Community-wide measures. As consumer products in eHealth become more common, this will probably serve a useful purpose in the eHealth sector.[93] Until now no telemonitoring devices were subject of the alert system.

5.4.4 Defective products

The directive concerning liability for defective products establishes the principle of objective liability or liability without fault of the producer in cases of damage caused by a defective product.[94] If more than one person is liable for the same damage, it is joint liability. A more detailed description is elaborated of the implemented directive in the Belgian legislation is given in section 1.5.7.7.

5.4.5 Medical devices

The medical devices directives harmonize the legislation on the free circulation of medical devices in the EU.[95]

The Directive concerning medical devices defines a medical device as "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specially for diagnostics and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for, among other things, the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap and the control of conception." (art. 1 a.) Consequently, the implanted apparatus, the bedside monitor as well as the software used to program the monitoring are considered as medical devices and have to comply with the medical devices directive. Depending on a risk classification, different safety conditions and procedures apply. Cardiac devices are categorized in class III which is the highest risk category.[96] In this class, a CE mark for marketing (in the European Economic Area) can only be affixed by the manufacturer after approval of the "Design Dossier" by a Notified Body (an organisation assessing the conformity with the essential requirements and to ensure consistent technical application of these requirements), designated by a Competent Authority (National regulatory authority). The CE mark denotes a formal statement by the manufacturer of compliance with the directives' essential requirements regarding safety and specified administrative requirements. In order to demonstrate compliance with the essential requirements, a clinical evaluation can be performed in different ways (Directive 2007/47 appendix 10, 1.1.[95]). For class III medical devices a clinical investigation is obligatory unless it is duly justified to rely on existing clinical data (Directive 2007/47 appendix 10, 1.1a.[95]). In contrast with CE marking, FDA's Pre-Market Authorization (PMA) requires the demonstration of a medical device's clinical effectiveness as a precondition for marketing. The technical CE label does by no means provide evidence for the clinical effectiveness nor the clinical safety and potential long term adverse events in the patient populations concerned. For class III implants, clinical trials should be performed in order to demonstrate that it can be regarded as a necessary first step to guarantee technical safety and good manufacturing of a device, but its value in health technology assessment for health insurance is limited.[97, 98]

Therefore post-market vigilance procedures are of an utmost importance. The European legislation regarding medical devices was transposed into Belgian legislation.[99]

5.4.6 E-Commerce

The Directive 2001/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market, also known as the E-Commerce Directive [100] draws up the rules for the provision of information society services that are defined as any service normally provided for remuneration, at a distance, by electronic means, for the processing and storage of data and at the individual request of a recipient of a service (both within and between member states)(art. 2, 1). The European Directive was implemented in Belgian legislation by the Law of 11 March 2003 concerning certain legal aspects of information society services.[101]

5.4.6.1 Applicability of the E-commerce Directive to telemonitoring

Tthe E-Commerce Directive does not apply to information transfer between the patient and the service provider via a telephone line or mobile phone. The use of the physicians (and other medical personnel having access) of the online database located at a server containing the health data transferred from the bedside monitor however falls within the field of application (P. Van Eecke, p 374)[102].

5.4.6.2 Transparency

The service provider (being the natural or legal person providing an information society service) running the website in the telemonitoring application has to inform the users of his identity, address and other details allowing the physician to contact rapidly and communicate in a direct and effective way and the relevant VAT (Value Added Tax) number.

5.4.6.3 Liability

The E-Commerce Directive also includes rules limiting the liability of information society providers, when they act as intermediaries, in case of illegal acts initiated by others. Exemption of liability is foreseen for acts of transmission of information in communication networks, caching and hosting.

The exemptions from liability established in this Directive cover only cases where the activity of the information society service provider is limited to the technical process of operating and giving access to a communication network over which information made available by third parties is transmitted or temporarily stored, for the sole purpose of making the transmission more efficient; this activity is of a mere technical, automatic and passive nature, which implies that the information society service provider has neither knowledge of nor control over the information which is transmitted or stored. A service provider can benefit from the exemptions for when he is in no way involved with the information transmitted; this requires among other things that he does not modify the information that he transmits; this requirement does not cover manipulations of a technical nature which take place in the course of the transmission as they do not alter the integrity of the information contained in the transmission (Consideration 42 E-Commerce Directive). If the information society service provider is also in the data processing, he acts as a processing. Liability issues of the processor then have to be enclosed in the contract between the processor and the data controller (art. 17.3 DPD). It is conceivable that in the telemonitoring application an appeal is made to intermediaries, e.g. for the storing of health data or provision of internet access. If for instance a webserver hosts a website or database of a third party containing medical information, the webserver cannot be held liable for wrong information (P. Van Eecke, o.c. p 378[102]).

5.4.7 Distant contracting

In case a contract is concluded by electronic means (or other means allowing the conclusion of a contract without the simultaneous presence of the supplier and the consumer) under an organised distance sales or service provision scheme between a professional (for instance a physician) and a consumer (for instance a patient), the Directive 1997/7/EC applies.[103] The Directive imposes to the supplier the duty to provide, prior to the conclusion of the contract, to the consumer written information regarding his identity, the main characteristics of the product or the service, the price, the arrangements for payment, delivery or performance and the existence of the right of withdrawal. The consumer benefits from a right to withdrawal during 7 days without any penalty or for any particular reason.

5.4.8 Electronic signatures

Electronic communication and commerce necessitate electronic signatures. The Electronic signatures directive aims to create a harmonized and appropriate legal framework for the use of electronic signatures within the Community and to establish a set of criteria which form the basis for legal recognition of electronic signatures.[104]

The Directive defines an "electronic signature" as "data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication." Additionally, the Directive defines 'advanced electronic signature' as an electronic signature:

- which uniquely links the signature to the signatory;
- is capable of identifying the signatory;
- is created using means that the signatory can maintain under his sole control;
- whereby any changes after signature are detectable.

The principal legal effect of the electronic signatures directive is that Member States should ensure that advanced electronic signatures satisfy the legal requirements of a signature in relation to data in electronic form in the same manner as a hand written signature satisfies those requirements in relation to paper-based data. The electronic signatures Directive has been implemented in Belgium.[105]

- **Although EU legislation does not address any particular issues related to eHealth systems and services specifically, several Directives have a direct impact on telemonitoring applications.**
- **Processing of personal (health) data is mainly governed by the European Directive on Personal Data Protection. Usually the law of the member state where the data controller is established applies. The divergent implementation of the Directive on Personal Data Protection in the different member states may lead to legal uncertainty for patients within the EU.**
- **In the domain of liability, liability regulations for multiple possible intermediaries in the telemonitoring application are available in a fragmented way (objective liability for the producer of a defective product, liability of the data controller, liability of information system providers, etc…). There is, however, no harmonised liability regime for professional liability for damage caused by healthcare services. The EU could play a role in stimulating member states to enhance the protection of patients via (no fault) liability schemes.**
- **Dispositions with regard to transparency and identification of suppliers or service providers and other consumers' protection rules for e-services are foreseen in several Directives.**

5.5 BELGIAN LEGAL CONTEXT

The scope of this report taken into account, we will not discuss all the rights and obligations imbedded in the different legislation, but rather limit ourselves to discussing the dispositions that are relevant for telemonitoring applications.

5.5.1 The Data Protection Act (DPA)

The Belgian Data Protection Act (DPA) [106] together with its executing Royal Decree (RD DPA)[107] set the conditions the processing of health data has to comply with. The Belgian Data Protection Act (DPA) is mainly based on the European Data Protection Directive (DPD).

5.5.1.1 Field of application

The Belgian DPA applies to "the processing of personal data wholly or partly by automatic means, and to the processing otherwise than by automatic means of personal data which form part of a filing system or are intended to form part of a filing system" (art. 3, § 1 DPA).

The broad notion of data processing applies to different steps in the trajectory of remote monitoring. For instance, the data transfer from the bedside monitor to the server as well as the consultation of the data by the treating physician (or other persons having access to the data) is perceived as data processing to which the dispositions of the privacy legislation apply.

Since data obtained via telemonitoring devices are linked to the patient, they can be considered as personal data related to the health status. It has to be noted that the same set of data can also be linked to the treating physician. In the latter case, it concerns personal data as such that are not linked to the health status (hereinafter called health data). This distinction is important since sensitive data such as health data have a special status and are subject to a more rigid regime. Since within the scope of this study, health data linked to patient deserve particular interest, we limit ourselves to highlight the regime applied to health data.

5.5.1.2 The basic data protection principles

The basic data protection principles requiring that data are processed fairly and lawfully, legitimately, proportionately, accurately and up-to-date and for a limited duration, incorporated in the DPD are implemented in the DPA (cfr. supra).

5.5.1.3 Identification of the principal actors in the DPA

In order to identify who has to comply with the obligations and who benefits the rights stipulated in the DPA, the notions data subject, processor and data controller have to be interpreted. In the telemonitoring application, different actors are eligible for one or more roles.

Data subject (art.1 § 1)

Depending on whom the data can be linked to, the patient, the treating physician or other persons involved in the data processing can be considered as the data subject and thus benefits from the rights included in the DPA.

Data controller (art. 1 § 4)

The controller is the entity that determines the purposes and means of the processing of the personal data. If different entities decide respectively on the purpose and the means, the entity setting the purpose should rather be seen as the data controller.[108]. Whereas the European DPD explicitly recognizes the possibility to have multiple controllers for the same data set, the Belgian DPA does not explicitly mentions the concept of 'co-controller'. It is conceivable that in the telemonitoring application, different actors can be considered as controllers (or processors) linked to the different processing operations, depending on the specific situation. Once an entity becomes sufficiently involved in the determination of the purpose and means of the processing, it will be considered as a (joint) controller (C. KUNER, o.c. 62-63[80, 109]). Service providers offer an already established telemonitoring service, each with their own focus, to a range of interested parties. The currently available monitoring systems all offer a predefined set of parameters that can be selected (per patient) by the physician. One could argue that the service provider has set the purposes and the modalities of processing and thus is to be considered as data controller. On the other hand, the physician or the hospital decides what data are to be transmitted for what purpose. Moreover the hospital or the physician will also have to transfer general data to the service provider in order to initiate the monitoring service. It is thus conceivable that for these processing operations, the physician or the hospital is considered to be a data controller. Although the initiative to use telemonitoring applications for a certain purpose may come from one individual physician, the decision on the system and the final selection of the parameters will often come from one or more physicians, it is more reasonable for the hospital or the hospital manager to take up the role as data controller. Indeed, different reasons plead for the centralization of the role of controller within the hospital: telemonitoring applications in a hospital will mostly be available for different cardiologists, not only for the initiator, and the hospital manager has the general and the final responsibility for the functioning, the organisation and the finances of the hospital (Art. 16 Hospital law[110]).

The industry partner can be seen as a processor, when working on behalf of the hospital. If for instance a hospital hires a provider of electronic communications services to develop and operate a telemonitoring system that is completely predefined by the hospital without there being any real input by the service provider in this regard, the hospital would be acting as a controller and the provider as a processor.

Given the diversity of possible situations and the responsibilities and the possible liability linked to the different functions, it is of a primordial interest to set the roles clear from the beginning. The best strategy is to define the roles in a contract between the parties involved.

Data processor (art. 1 § 5)

The data processor is the entity which, on behalf of the controller, processes the personal data, except for the persons that are processing the data under direct authority of the data controller. The latter category of persons mainly refers to the employees working for the data controller. For the telemonitoring application, different actors can be identified as possible processors. The treating physician will decide on the use of parameters that are to be included for monitoring and will be responsible for the clinical interpretation of the data. As far as they are not considered to be data controller, they can fulfil the role of a processor. Physicians working as employees at the hospital, however, are not seen as processors since they work under direct authority of the hospital, being (possibly) the data controller at stake. Other personnel working as employees at the hospital and involved in the telemonitoring process (administrative staff, nurses, technical staff etc.) are not considered to be processors.

Intermediary entities providing telemonitoring services such as for instance the company supplying and maintaining the devices, the company involved with the data transmission and archiving, the call center, etc… processing personal data on behalf of the data controller are processors.

Third parties (art. 1 § 6)

A third party is any person or body other than the data subject, the controller, the processor and the persons who, under the direct authority of the controller or the processor are authorized to process data. It is conceivable that in the telemonitoring application personal data are transmitted to third parties, e.g. family members of the patient. It can be questioned if subcontractors of the processors for instance are considered to be a third party. One can argue that if the subcontractor works under the same contractual conditions regarding the privacy, safety and confidentiality clauses as the processor himself or the personnel of the processor, the subcontractor can be considered to work under direct supervision of the processor and hence is not a third party[1].[112]

5.5.1.4 Specific requirements and safeguards for the processing of health data

Informed consent as a legitimization of the processing of sensitive data

In principle, the processing of sensitive data, such as health data, is prohibited. An exception to this principle however is the patient's consent (Art. 7, § 2, a, DPA). In contrast with the European DPD, the Belgian DPA requires written patient consent instead of explicit consent (which can be oral as well as written).

Is processing of health data allowed without the patient's consent?

The DPA contains other legitimization bases for the processing of sensitive data such as health data. The processing of health data is allowed when the processing is necessary to protect the vital interest of the data subject or of another person if the data subject was not physically or legally capable of consenting (art. 7, § 2, f DPA) or for the management of health care services and if the data are processed under the supervision of a health care professional. Although one could argue that these options apply to telemonitoring (argumentation see appendix) there are different caveats. Firstly, the legitimization bases are exceptions to the prohibition of processing of health data that have to be interpreted very narrowly. Moreover other legislation possibly applicable to the telemonitoring application requires the (written) patient's consent in case health data from the patient file or the electronic registration are exchanged between health care professionals (art. 19 Flemish Decree of 16 June 2006 concerning the healthcare information systems[113]; see also on this topic: HAUSMAN, J-M, «Le droit d'accès au système d'information Santé organisé par le décret du 16 juin 2006 de la Communauté flamande"[114], HAUSMAN, J-M, «Le décret relative au système d'information Santé: l'arrêt n° 15/2008 de la Cour constitutionelle du 14 février 2008 – Considérations autour des règles de repartition de competences en matière de santé et de protection de la vie privée", [115], Art. 29 data protection working party - Working document on the processing of personal data relating to health in electronic records[116]). Furthermore, as patients will need to consent to the telemonitoring as a medical intervention (cfr. infra), it seems obvious that they simultaneously consent to the data processing as an "all-in package".

[1] Reference measure 3 of the Privacy Commission[111] considers it as primordial that if a subcontractor is hired to process the entire set of personal data or a part of it, the organization must ensure that the subcontract agreement includes the same security obligations as those in effect for the organization itself.

Processing of health data under the responsibility of a healthcare professional

According to art. 7 § 4 DPA, processing of health data is solely allowed under the responsibility of a healthcare professional, unless

- the data subject has consented in writing
- processing is necessary to prevent an sudden danger
- for the suppression of a criminal offence

The notion healthcare professional is not defined in the DPA. One could argue that, similar to the definition in the Patients' Rights Act (PRA), 'Health care professionals' must be understood as the people enumerated in the Royal Decree number 78 (Royal Decree 78 of 10 November 1967 concerning the practice of health care professions, hereafter named RD nr. 78[117]) and the non-conventional practitioners as mentioned in the Law of 29 April 1999 related to the exercise of non-conventional medical practices[m] (cfr. infra).[118] The Commission for the Protection of Privacy (hereinafter called the Privacy Commission) section Sector Committee of Social Security and of Health however stated that personal data in general should be processed under the supervision of a physician whenever possible.[119]

Health data must be obtained from the data subject

Health data can be collected from other sources if this is necessary for the purposes of processing or if the data subject is not capable of providing the data him/herself (art. 7 § 5 DPA). In case of telemonitoring data are directly obtained from the patient.

5.5.1.5 Right and responsibilities of the principal actors

Each of the above described persons or entities bear specific responsibilities or benefit particular rights. It is obvious that obligations for one party create rights for another party.

Duties of the data controller

Overall responsibility for violation of DPA

The data controller has an elaborated responsibility since he/she must ensure that all obligations and all stipulations stated in the DPA are respected (art. 4 §2; art. 9 §1-2, art. 10 §1 art. 15bis DPA). He can be held liable (cfr. infra) if the data subject suffers any damage by infringement of stipulations imposed by the DPA unless he proves that he has not caused the damage (art. 15bis DPA).

Notification to the Belgian Commission for the Protection of Privacy

In order to ensure transparency on the processing, the data controller needs to introduce a notification of the processing to the Privacy Commission prior to the start of processing and when the data processing has ended or when the respective information is no longer accurate (art. 17 DPA). Details on the content of the notification can be found in appendix.

It has to be noted that the notification to the Privacy Commission does not imply an authorization. The notification serves on the one hand as an information tool to the Privacy Commission of the processing of the health data. On the other hand, the notification is registered in a public register on the website of the Privacy Commission, guaranteeing maximal transparency of the data processing[n].

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m The particular disposition of the law related to the exercise of non-conventional medical practices did not yet enter into force

n https://www.privacycommission.be/elg/searchPR.htm?eraseResults=true&siteLanguage=nl

Information regarding data processing issues

As mentioned above, the data have to be processed fairly which implies that transparency has to be guaranteed. Therefore, the data controller has to inform the patient on the name and the address of the controller or his representative, the purpose(s) of the processing and the recipient(s) of the data (art. 9 §1 DPA). The law also stipulates that the patient should be informed on the right to object to the processing for direct marketing purposes. Next to this right to object, there is a more general right to object in case of ponderous justifying reasons (art. 12 §1 DPA). Since in the telemonitoring application, data are mainly processed in the patient's interest these provisions make little sense here. Other additional information such as the recipients or the categories of recipients, the presence or the absence to answer and possible consequences; the existence of a right to access and correction of his personal data can be mentioned unless this information is redundant to guarantee fair processing towards the patient. There are exceptions to the obligation to provide information. However they seem not to be applicable to the telemonitoring application. Art. 25 RD DPA provides some additional information obligation for the processing of health data. In particular the data processor needs to designate the categories of individuals who may access the data, and specify their capacity regarding the data processing. Moreover the data controller of the processor has to keep a list of the authorized users at the Privacy Commission's disposal. He has to specify the legal basis legitimizing the processing of the health data when informing the patient pursuant to art. 9 DPA or in the notification to the Privacy Commission (art. 17 § 1 DPA).

If the processing of health data is solely legitimated on the basis of patient consent, the controller additionally has to inform the patients of the reasons for processing the data, as well as provide him with a list of categories of persons who have access to the data (art. 26 RD DPA).

Data subjects' specific rights in the DPA

Right to access

For medical personal data, a specific right of access stipulated in the DPA applies (art 10 § 1 DPA). The patient has access to the following information:

confirmation as to whether or not data relating to him are being processed and information at least as to the purposes of the processing, the categories of data concerned and the recipients or categories of recipients to whom the data are disclosed;

communication of the data undergoing processing in an intelligible form and of any available information as to their source;

knowledge of the logics on which any automatic processing of personal data is based in case of automated decisions implying important consequence for the person concerned;

knowledge of the possibility to lodge and appeal and eventual consultation of the public register.

The right to access specified in the DPA can be exercised by the data subject himself (direct access)(Art. 10, § 2, DPA). On the request of the data subject or the data controller, access can take place with the help of a health care professional (indirect access). When the health data are part of a patient file, the patient will anyhow have a direct access to the patient file.

Right to correct, erase data or object to processing

Data subjects have the right to have inaccurate personal data corrected, the right to erase certain data or to prohibit the use of the data and the right to object to the processing (art. 12 DPA).

Relation between the data controller and the processor

The data controller has several obligations towards the data processor. If the processing is entrusted to a processor, the data controller or his representative in Belgium has to (Art. 16 § 1 DPA):

- choose a processor that can offer sufficient guarantees regarding the technical and organizational safety for the intended processing;
- supervise the compliance with these measures, in particular by including them in a contract;
- specifying the liability of the processor in relation to the data controller in the contract;
- agree with the processor that the processor solely acts on behalf of the data controller and that the processor is bound to the same obligations as the data controller regarding the access and processing limitations for people working under his authority;
- the elements 3° and 4° have to be confirmed in writing or on an electronic carrier.

5.5.1.6 Security of the data processing

According to the Privacy Commission security of information can be summarized in 7 characteristics.

- Confidentiality: Solely authorized users have access to the information.
- Integrity: Unauthorized (intended or unintended) modifications must be prevented.
- Availability: the information is accessible and usable whenever an authorised person asks for it.
- Accountability: Authors and users of the information must be traceable.
- Incontestability: It can be proven that the processing or a fact did take place.
- Authentication: the truthfulness of someone's identity.
- Reliability: the expected result will be accomplished.

These characteristics are mainly covered by the legal requirements set in the DPA. Furthermore the Privacy Commission has elaborated legally non-binding but authoritative reference measures.[111] Other authoritative bodies such as the National Council of the Order of Physicians[120] and the former Telematics Commission (that has been discontinued and whose tasks are currently transferred to the eHealth platform[121] have issued recommendations with regard to security regarding data processing.

General security obligations

The data controller and the processor have the **general** obligation to take adapted technical and organizational security measures regarding the data processing to protect personal data against accidental or unlawful destruction, accidental loss, the modification of or the unauthorized access and any other non authorized processing of personal data (art. 16 § 4 DPA). Technical measures comprise physical and logical measures; organizational measures comprise the set of policies aiming at the enhancement of security. The organizational as well as the technical measures must on the one hand ensure an appropriate level of security, taking into account the state of the art of the technique and the cost for the implementation of the measures and on the other hand the nature of the data to be protected and the potential risks. The general security obligation qualifies as an obligation of means, which implies that the data controller and the processor are not bound to a particular result but have to act according to the best of their ability (D. DE BOT, o.c., 254[109]). Additionally the DPA adds some **specific** organizational security measures to be taken by the data controller (art. 16 §2). A typical specific organizational security measure for the controller is to inform his employees of the restrictions and obligations surrounding data processing

(Art. 16, § 2, 3° DPA). In practice this means that every controller should draft some form of a "privacy policy", which informs employees of the basic principles underlying the DPA and the specific restrictions that are applicable to them (e.g. professional secrecy). Hospitals have the explicit legal duty to draft a privacy policy (Art. 9° quater, a) of Appendix N1, III of the Royal Decree of 23 October 1964 "tot bepaling van normen die door ziekenhuizen en hun diensten moeten worden nageleefd")[122].

Specific security measures for transmission of health data via the internet or e-mail

In the telemonitoring application, health data of the patient can be accessed by the physician or other qualified medical personnel via a secured website on the internet. Urgent alerts can also be sent to the physician through other means of communications such as e-mail or SMS. It was reported by the providers of the monitoring service that the information sent by e-mail or SMS contains a patient identificator and the reason of the alert. For the particular details on the alerts the physician is referred to the website.

The National Council of the Order of Physicians issued several recommendations regarding the transmission of health data transmitted over a network or through e-mail.[120, 123, 124]

Health data transmitted over a network or through e-mail should be protected by asymmetric encryption and certified digital signatures. With regard to the encryption keys, specific requirements were defined by the National Council of the Order of Physicians.[123] Moreover the encoding and decoding of the content has to occur within the computers of the bedside monitor and the respective recipient.

However, it should be noted that these recommendations are not legally binding and that they should be updated according to the state of the art at a particular moment.

5.5.1.7 Applicable law and jurisdiction

Art. 3bis DPA states that the Belgian DPA is applicable if data processing is effected in the frame of the real and effective activities of a fixed establishment of the controller on Belgian territory or on a place where Belgian law is applicable on the account of international public law. This is a straightforward implementation of art. 4 of the European DPD (cfr. supra).

- **Several duties, rights and responsibilities are linked to the different roles (data controller, data processor, data subject) defined in the Data Protection Act. Therefore a contract between the respective parties involved, clarifying and defining the roles and responsibilities of the different parties is necessary.**
- **The data controller must ensure that all obligations included in the DPA are respected. He/she is exempted from liability if he/she proves that he/she did not cause the damage.**
- **Prior to the data processing, the data controller needs to file a notification to the Privacy Commission.**
- **The law specifies several information elements that have to be communicated to the patient such as the name and the address of the controller or his representative, the purpose(s) of the processing and the recipient(s) of the data,…These can also be included in the informed consent form.**
- **Other data subjects' rights defined in the DPA are the right to access and the right to correct data, erase data or object to processing.**
- **Persons accessing the health data need to be bound by a duty of professional secrecy or an equivalent contractual obligation.**

- **Patients need to sign an informed consent form in which they explicitly consent to the processing of their personal health data. In order to enhance clarity and transparency, the identification of the different parties involved in the telemonitoring trajectory as well as their roles and responsibilities could be noted in the informed consent form.**
- **The data controller and the processor have the general obligation to take adapted technical and organizational security measures regarding the data processing to protect personal data against accidental or unlawful destruction, accidental loss, the modification of or the unauthorized access and any other non authorized processing of personal data. Additionally the DPA adds some specific organizational security measures to be taken by the data controller.**

5.5.2 eHealth platform

The telemonitoring application is closely linked to the introduction of shared electronic health records. Today, some systems enable the direct integration of the telemonitoring data in the electronic patient record. The use and the exchange of information in electronic health records enables the interaction between different health care professionals involved in the telemonitoring trajectory. A legal framework for a platform for sharing electronic health records has been created in 2008.[125] The eHealth platform is government initiated and managed by representatives of stakeholders in the healthcare sector and allows the secured electronic exchange of information about patients, the provided care and the result of it. Several basic services are now fully operational: coordination of electronic processes, web portal (https://www.ehealth.fgov.be), integrated user and access management, logging management, system for end-to-end encryption, personal electronic mailbox for each healthcare supplier with limited features, electronic time stamping and coding and anonymisation. Furthermore the platform coordinates the development of functional and technical interoperability standards. The platform does not perform studies itself and provides no intrinsic policy support in the area of healthcare There is no central storage of personal health data and the use of the eHealth platform is optional. The safe operation of the eHealth platform is controlled by an independent Sectoral Committee of the Privacy Commission.

5.5.3 Health information system (HIS)

In 2006, the Flemish legislation enacted legislation creating a Health information system.[113] The systems contains two platforms: an operational information system and an epidemiological system. Both platforms enable the exchange of health data among health care providers and other institutions but the operational system aims at ensuring high quality care for a particular patient involved whereas the epidemiological system aims to organise the public health system. The scope of HIS decree is rather limited since it is mainly mandatory for health care providers and organisations whose activities are financed by the Flemish government. There is some overlap between the HIS and the eHealth platform with regards to the health data exchange platform. The use of the eHealth platform however is optional.

5.5.4 Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross border healthcare

Although some member states, as Belgium, have created a legal framework for sharing electronic health records through national eHealth platforms, cross border situations are not integrated since these frameworks solely focus on the relationships between patients, health care providers and institutions on the national level. The recent proposal for a Directive on the application of patient's rights in cross border healthcare engages the Commission to elaborate guidelines on the data to be included in patient files and the modalities of sharing patient information between health care professionals in cross border care (art. 14). [126]

- **Decentralised electronic patient health records can be shared in a secured way between health care providers and institutions via a Flemish (HIS) or a national platform (eHealth platform).**
- **The proposal for a Directive on the application of patients' rights in cross border healthcare engages the Commission to elaborate guidelines enhancing the sharing of data in cross border healthcare.**

5.5.5 Patients' rights act (PRA)

Patients' rights are defined by national legislation and differ form country to country. The implementation and the enforceability varies significantly according to the member states.[127] Although the existing rules on patient rights rarely explicitly refer to eHealth, they indirectly have an impact on eHealth applications such as telemonitoring. In the near future however, new European legislation for the application of patients' rights in the context of cross-border care within the European Union aims to provide patients with more treatment perspectives within a framework of guaranteed protection of patients' rights. [126]

The Belgian Patients' rights act enumerates several rights. The most important rights for the telemonitoring are the right to qualitative care (art. 5), the right to free choice of a healthcare professional (art. 4), the right to information (Art. 7), the right to free and informed consent (Art. 8), direct access to the patient file and the right to have a copy of it (Art. 9). Solely this set of rights will be described in the report°.

5.5.5.1 Right to information regarding the health status

The right to information is covered by the DPA as well as by PRA. The main difference with the right to information granted by the DPA is that the information in the PRA concerns the health status (e.g. the diagnosis) and the probable evolution. As far as the results contains information regarding the health status, the results of the telemonitoring should be communicated to the person. The right to be informed about the health status has to be distinguished from the right to informed consent. Whereas the right to informed consent is linked to a decision regarding a medical intervention (e.g. telemonitoring), the right to information about the health status is not. Since the right to information on the health status is but indirectly linked to the telemonitoring application the details on the modalities will not be elaborated in this report.

5.5.5.2 Right to informed consent

Whereas patient consent in the DPA is linked to the data processing, patient consent in the PRA applies to every medical intervention,. According to the content of the information that is linked to the consent a non-exhaustive list is enumerated by the law: The patient has to be informed about the nature, the purpose, the urgency, the frequency, the follow-up care of the intervention, the relevant contra indications, the risks and the side effects of the intervention, alternatives and the financial information. It is questionable, however, to what extent physicians are obliged to inform patients on emerging technologies, such as telemonitoring, for which no sound evidence on the effectiveness exists (cfr. Infra).

Once telemonitoring is applied, it is of an utmost importance to inform the patients on the limitations and the modalities. Burri mentions the examples of the fact that telemonitoring does not replace an emergency service or absence of dealing with alert events outside office hours.[9] Moreover, while some systems perform a daily transmission, some other systems are based on scheduled follow-ups only (typically 3 months) unless there are specific device alerts. Possible technical and functional limitations such as the lack in mobile network coverage should be mentioned. Moreover the required patient input has to be stressed. It is of an utmost importance that the treating physician informs the patient on the use of the monitoring system. A clear manual can be provided in addition of the oral information.

° For an overview of literature on the patients rights see [128-132]

In principle consent has to given explicitly which implies that consent can be given orally as well as in writing[p]. For the telemonitoring application an integrated approach using a written consent containing information elements regarding data processing as well as the information linked to the telemonitoring as medical intervention is preferable. As mentioned above it is conceivable that several entities act as data controller. The use of different informed consent forms covering each separately the information duty of the respective data controller is not optimal in terms of organization and centralization of the information. Hence it is advisable to draft one consent form specifying all the different players and their roles in the data processing trajectory. Once telemonitoring is integrated in care networks, it may become extremely difficult to define who is responsible for what and to disentangle the different roles.

It has to be stressed that the signature of the patient can only be regarded as valid if the patient has gone through or reasonably could have gone through the information. Extremely technical or unclear forms do not meet this condition.[133] Moreover information has to be given in advance and timely. Before starting telemonitoring the patient should thus be requested to sign a written consent form. Physicians who did not obtain informed consent may be held liable (in case of damage) if the patient proves that he/she would not have chosen the respective intervention if he/she had been fully informed.[134, 135] For the telemonitoring application however this seems rather hypothetical since the risk for bodily harm in the application of telemonitoring is rather low. Moreover the patient is able to stop the telemonitoring application whenever he/she does not feel comfortable with it.

5.5.5.3 Right to a patient file, direct access and a copy

The PRA stipulates the right to an accurate and carefully stored patient file from the health care professional and the right to add documents to the file.

The patient has a right to direct access to the file and to a copy of the entire file or a part of it. Access has to be permitted at the latest within 15 days following the request. After the patient's death, the spouse, the legally cohabiting partner, the partner and the relatives till the second degree of affiliation, have an indirect right to access via a physician chosen by the requesting party as far as the request was sufficiently motivated and specified and the patient didn't explicitly opposed to it during life.

The patient has the right to obtain a copy of his patient file. The standards on how to store and archive the patient file safely, are also determined in the DPA.[128] The right to access stipulated in the PRA is a particular case of the right to take note of the personal data being processed elaborated in the DPA.[133] This implies that the PRA is applicable if health data is processed by a health care professional and is part of the patient file. The DPA also applies to health data that is no part of the patient file as far as they adhere to a processing system(cfr. supra).[128] The PRA does not exactly define the content of the patient file but other legislation does (see appendix). The results of the telemonitoring can be considered as data as part of the patient's medical file.

5.5.5.4 Right to qualitative care

The right to qualitative care implies that the applicable standards according to the actual scientific state of affairs have to be applied. The preparatory documents of the PRA refer to guidelines elaborated by professional organisations, but specify that other sources can also be taken into account.[136] It was also explicitly stated in these documents that not every possible individual need has to be fulfilled. It could thus be argued that the right to qualitative care does not imply that the patient can require that telemonitoring should be applied -for a particular individual case- as far as this is not (yet) evidence based.

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[p] Patients as well as physicians however have the right to ask for a written consent form that will be added to the medical file. If the patient refuses to give a written consent, while the physician thinks that a written consent is necessary, the refusal can be noted in the patient's medical file

5.5.5.5 Patient collaboration

Physicians have to respect the PRA as far as patients collaborate (art. 4). This "duty" to collaborate is particularly interesting in the scope of follow-up. If the patient needs an in-clinic follow-up every three months, it is not up to the physician to check if the patient indeed showed up.[137]

5.5.5.6 Right to free choice of the healthcare professional

In principle the patient has the right to freely choose a healthcare professional. This right, however, is not absolute and can be limited for reasons of public health. In the scope of telemonitoring, it is clear that the patient will not be able to choose who will preview the transferred data (whether this will be the nurse or a physician) or to freely choose a healthcare professional the during on-call duty.

- **In the scope of the right to informed consent, it is unclear whether the physician should inform the patient on the telemonitoring application as an alternative way of follow-up since there is no sound evidence on the clinical effectiveness.**
- **If telemonitoring is applied, the patient has to be clearly informed on the limitations and the modalities of the system. Moreover, the patient should be informed on the fact that the service is not reimbursed.**
- **In principle, oral patient consent suffices. For the telemonitoring application, however, an integrated approach using a written consent containing information elements regarding data processing as well as the information linked to the telemonitoring as medical intervention is preferable.**
- **The patient has a right to direct access to the patient file and a copy of it. The health data (or the derived results) revealed by the telemonitoring application are part of the patient file. After the patient's death, particular relatives have the right to access the patient file via a physician of their choice, as far as the request was sufficiently motivated and the patient did not oppose during life.**
- **Physician need to respect patients' rights, as far a patients collaborate in the patient-physician relationship.**
- **Patients can freely choose a healthcare professional. In case of telemonitoring, however, it is not possible to require a particular health care professional for the preview of the transmitted data or to choose a particular person during guard duty.**
- **The right to qualitative care does not imply that patients can require the application of telemonitoring since no sound evidence on the clinical effectiveness was demonstrated.**

5.5.6 Professional secrecy

Multiple actors intervene in the process of telemonitoring. On the one hand, there is the medical staff such as the electrophysiologist, the treating cardiologist, the referring physician, the GP, nurses and paramedics. On the other hand, there is the technical support, the administrative support, the staff of the service provider etc. In the following section we study the applicability of the different confidentiality dispositions to the different parties at stake. Next to the medical professional secrecy as stipulated in the Criminal Code, other dispositions deal with the confidentiality duty of the health care professional (see appendix).

Duty of professional (medical) secrecy

Many data produced in the scope of telemonitoring reveal information about the health care condition and thus are subject to the professional secrecy.

As a rule, professionally obtained secret information cannot be disclosed by health care providers. Legislation and case law however have specified instances in which information covered by the professional secrecy duty may be lawfully disclosed (see appendix).

Can health data be disclosed to the medical staff involved in the telemonitoring application?

The treating physician and his medical staff involved and related to the telemonitoring application fall within the scope of the professional secrecy. Health data within the telemonitoring application can be shared between the treating physician, his/her (para)medical team and the referring physician if the addressee is also bound by the duty of professional secrecy; if the sharing of the confidential information must be necessary to ensure continuity and quality of care and if the patient has to give his explicit or tacit consent or the disclosure should at least be in his/her best interest. According to the Constitutional Court written consent is required for each data transfer from the electronic patient file, except for the data exchange within the treating team providing healthcare for which the initial consent of the patient to the treating physician suffices.[138]

Can health data be disclosed to non-medical personnel involved in the telemonitoring application?

Non-medical personnel such as ICT support staff are involved in the telemonitoring application. In practice, the extent to which data have to be disclosed to ICT personnel is (or can be) limited. The data processing is based on coded data. The patient is identified by means of the serial number of the implant, which can be done by the treating physician. The coded data are technically processed by the supporting services. The medical interpretation is performed by the physician and/or his medical staff. Hence, access to the health data produced by the monitoring application can be and should be restricted to the treating physician and the (para) medical team. Disclosure of personal health data to supporting personnel is only needed for the start-up of the telemonitoring application. In principle, however, the sole knowledge that the respective patient can be linked to treatment for a particular disease can be considered as a violation of confidentiality. As mentioned above, the data controller needs to make sure that access to the data and possibilities of processing for the persons who are acting under his authority are limited to what is necessary for the exercises of their duties or for the requirement of the service (art. 16 §2 DPA). According to Herveg the necessity of the intervention of ICT staff and other experts in the treatment of personal data of the patient necessitates to consider them as "collaborators" sensu lato of the health care professionals and thus justifies the sharing of certain secrets in accordance with the theory of shared professional secrecy.[139] Anyhow, the data processor is obliged to assure that the persons processing the health data respect the confidential character of the data by contractual clauses, or legal or statutory provisions (Art. 25, 3° RD DPA). Technical staff, administrative support and other persons involved in the remote monitoring process should thus be subjected to strict rules stipulated in contracts with regard to privacy and confidentiality of the respective health data.

- **As a general rule, health care professionals involved in the telemonitoring application can not disclose health data they have been entrusted by virtue of their profession. Exceptions exist in legislation and in jurisprudence.**
- **Health data within the telemonitoring application can be shared between the treating physician, his/her (para)medical team and the referring physician if the addressee is also bound by the duty of professional secrecy; if the sharing of the confidential information must be necessary to ensure continuity and quality of care and if the patient has to give his explicit or tacit consent or the disclosure should at least be in his/her best interest (shared professional secrecy).**
- **The necessity of the intervention of ICT staff and other experts in the treatment of personal data of the patient necessitates to consider them as "collaborators" of the health care professionals and thus justifies the sharing of certain secrets in accordance with the theory of shared professional secrecy.**

5.5.7 Liability issues

Compared to the classical treatments, not only health care professionals are involved in the telemonitoring chain and thus risk to be held liable when a patient is confronted with damages. Non-medical staff such as technical members and administrative staff is also involved in the delivery of telemonitoring care. Moreover device suppliers, organizations that provide some kind of communications service, storage service or processing service or a combination can also be held liable for the defective products if damage has been caused to the affected party. Several liability dispositions applying to telemonitoring are integrated in EU legislation that is not directly targeted at regulating healthcare (cfr. supra; Product liability, E-commerce Directive,…). For professional medical liability however, national legislation comes into play. In cross-border situations, the rules identified in the Rome I[140] and Rome II[141] regulations identify which national law is applicable.

5.5.7.1 Professional liability of the physician

Cardiac remote monitoring, being an emerging technology, raises particular liability questions. Does a physician risk liability for not applying telemonitoring? What if the physician misses an alert and the patient dies? Today, the answers to these questions are often unclear. This can lead to a defensive behaviour of physicians, being on the one hand the refusal to apply telemonitoring for fear of liability for damage caused by the application modalities or on the other hand, the systematic application of telemonitoring, although not evidence-based, for fear of liability claims for having omitted telemonitoring. Today there is no relevant (published) jurisprudence regarding the issue of liability in telemonitoring cases. Based on the general principles in liability, some key principles regarding the possible liability of the physician will be highlighted.

Choice of telemonitoring as therapy support

A first important question will be whether telemonitoring is the most suitable treatment support for the patient. What is the appropriate standard of care for the follow-up and management of patients suffering from particular cardiac conditions? The answer to this question is particularly relevant for the liability assessment since in the case of fault-based liability (see appendix on contractual liability and tort liability), the parameters for determining fault consist a violation of the general duty of care or in a violation of a law (for instance: if the physician doesn't inform the patient, he violates the PRA and consequently commits a fault). The duty of care is the level of care that can be expected from a reasonably prudent physician of the same specialty and in the same circumstances. The burden of proof remains with the patient that suffered the damage. When defining the standard of care, several elements can be taken into account: protocols and guidelines,[142] the state of the art of medical treatment, the opinions of colleagues, the actual state of the science, legislation (patients' rights legislation, DPA,..), case law,…

As indicated in the previous chapters there is no sound evidence on the clinical effectiveness (nor on safety or the cost-effectiveness) of telemonitoring supporting that this technique would be the current standard of care.

It is generally accepted that a surgeon is responsible for the aftercare linked to the operation (T. Vansweevelt, De civielrechtelijke aansprakelijkheid van de geneesheer en het ziekenhuis, p. 356[143]). Particularly relevant for telemonitoring is the duty to information linked to the aftercare. As far as adding telemonitoring to regular follow-up can be considered to be the standard of care, it is arguable that if a patient is eligible for telemonitoring, the physician should inform the patient on the existence of telemonitoring as part of the aftercare. The fact that the telemonitoring application is currently not reimbursed, is not an argument to withhold the information.

Continuity of care: what if the physician misses an alert?

Another problem related to the telemonitoring application is the assurance of the continuity of care to the eligible patients. Most telemonitoring systems contain an alert application. The problem is, however, that the delay within which the physician needs to respond to the alert is not defined. Although the telemonitoring service (in general) is presented by all companies as not being an emergency system, timely notification of (clinical or device -related) problems by the telemonitoring application can prevent harm or can even be life-saving for some patients (e.g. early detection of lead fracture). In principle physicians are obliged to ensure the continuity of care for any treatment, including the post-operative follow-up (art. 8 Royal Decree nr. 78 [117], Nys, o.c. 192[144], T. Vansweevelt, o.c., p. 356 [143]). In that scope they need to take all necessary measures to guarantee the appropriate quality of care to their patients during their absence. The question raises to what extent a 24-hour assistance should be organised to respond to these alerts? What if the physician misses an alert?

It is important to distinguish the telemonitoring for regular follow-up or for disease management and the alert system. It is primordial to inform the patient orally and in the written consent form that the telemonitoring service for continuous follow-up or disease management is not an emergency system and that it is up to the patient to contact the emergency services in case of urgency, that the transferred information will only be viewed within a specific delay, during specified hours (for instance office hours and not during the weekend). If alert systems are used however, the physician needs to make sure that short term attention is assured within the reasonable organizational limits and that back-up is assured in case of longer periods of absence. The validity of clauses in contracts stipulated by firms considering that the telemonitoring system in general (the alert function included) is not an emergency system while it is de facto an emergency tool and functions and is conceived as an emergency tool, is questionable.

In case of a liability claim, judges will compare the situation to the care that can be expected from a reasonably prudent physician of the same specialty in the same circumstances. If the patient (or the relative) can prove that with the telemonitoring application or with a timely response to the alerting data he/she had a chance of recovery or survival (e.g. because of the earlier detection of a problem), the physician (or the hospital) can possibly be held liable.[145-147] In the liability assessment the judge will take into account the dispositions that were legally contracted between the patient and the physician, such as the dispositions on availability of the physician and the system characteristics and limitations.

Clinical evaluation at a distance

Clinical evaluation at a distance by the physician is in principle legally allowed. Yet, physicians need to be careful for the possible incomplete image presented by the data. For the telemonitoring application for instance, the physician can decide to interrogate the device in case of a symptomatic event, in order to evaluate specific parameters and to decide whether a patient needs to be referred to the hospital or not. If the physician fails to give accurate instructions to the patient or put the wrong diagnosis he/she may be liable (see jurisprudence cited in footnotes nr. 45-49 S. Callens en J. ter Heerdt, Juridische beschouwingen bij telegeneeskunde, p. 311[148]).

5.5.7.2 *Fault of the patient or any other third party*

As mentioned above, clear instructions need to be given to the patient pursuant to the duty to information in the light of aftercare. In case of telemonitoring these instructions can deal with technical as well as clinical matters. For instance, the patient will have to plug in the bedside monitor. If the patient omitted to follow the instructions, the physician can defend himself by stating that the damage was (partly) caused by the patient. Indeed, the general duty of care also applies to the patient (T. Vansweevelt, o.c. p. 410[143]). Moreover, the PRA stipulates that physicians need to respect the patients' rights as far as patients collaborate in the physician-patient relationship. It has to be noted however that the current telemonitoring systems report if there was no transmission within a predefined term (mostly 2 weeks).

5.5.7.3 *Role of industry employed technical specialists*

Persons who are employed or contracted manufacturer representatives, field clinical engineers, and industry employed technical specialists (IEAPs or industry employed allied professionals [1]) often assist physicians during pacemaker/ICD implantation, programming, analysis of malfunctions and follow-up. This brings us to the important question to what extent these persons can legally play a role in the telemonitoring application. Which acts can be legally performed by these persons? Who is liable if something goes wrong?

Technical nursing acts such as the preparation, the assistance and the instrumentating during medical and surgical interventions can solely be carried out by nurses (professional title of nurse or a registered nurse with a diploma homologated by the competent medical commission (art. 21 quater e.v. KB nr. 78 van 10 november 1967 betreffende de uitoefening van de gezondheidszorgberoepen[117] and Koninklijk besluit van 18 juni 1990 houdende vaststelling van de lijst van de technische verpleegkundige verstrekkingen en de lijst van de handelingen die door een arts aan beoefenaars van de verpleegkunde kunnen worden toevertrouwd, alsmede de wijze van uitvoering van die verstrekkingen en handelingen en de kwalificatievereisten waaraan de beoefenaars van de verpleegkunde moeten voldoen[149]). If IEAPs non-qualified nurses perform (technical) nursing activities, illegal medicine is practiced, which can be sanctioned with fines and imprisonment. Technical information and advice regarding the appropriate use of the medical devices however falls within the legally allowed acts of the IEAPs.

According to the law on pharmaceuticals, it is prohibited for companies to grant financial benefits or in natura to hospitals or prescribers, delivering, administering medical devices (art. 10 § 7 Geneesmiddelenwet van 25 maart 1964[150]). If a firm systematically puts IEAPs at the disposal of physicians for free for assistance during surgery or during follow-up, this can be considered as illegal. IEAPs may, however, provides technical information regarding for instance new medical devices[q].

5.5.7.4 *Liability of the physician or the hospital for damage caused by medical or paramedical staff working at the hospital*

Medical or paramedical staff at the hospital often works under the authority of other persons (for instance the surgeon) of the hospital. If for instance a nurse viewing the telemonitoring data fails in transferring alerting data, the affected patient can claim the person exercising the authority over the nurse, e.g. the physician or the hospital. Employees can in principle solely be held liable in case of fraud, major fault or repetitive minor faults (for a detailed description see T. Vansweevelt, De civielrechtelijke aansprakelijkheid van de geneesheer en het ziekenhuis [143])

[q] For the position of UNAMEC on the role of IEAPs see http://www.unamec.be/data/doc/Standpunt%20UNAMEC%20aanwezigheid%20OK.pdf

5.5.7.5 *Central liability of the hospital (Art. 30 Hospital Law[110])*

Each hospital has to comply with the patients' rights (formulated in the PRA) concerning the medical, nursing and other professional aspects in the relation towards the patient. This implies that the hospital needs to assure that nurses working as employees meet the requirements of the PRA (H. Nys, l.c. 1123[128]). Moreover each hospital has to make sure that the self employed health care professionals or external personnel working in the hospital respect the patients' rights. The hospital is liable for the breaches of the patients' rights committed by the health care professionals working at the hospital, except if the hospital explicitly and informed the patient in advance that it will not be liable, given the legal relationship between the health care professional and the hospital. The hospital needs to inform the patient on the categories of healthcare professionals working at the hospital and the legal relation between the hospital and former mentioned personnel. If the hospital exempts from liability, this has to be notified in writing to the patient at the latest at the hospital admission.[151] Even if the patient is not hospitalised, as in the telemonitoring application, it is likely that the hospital can be held liable in case patients' rights are violated by the personnel performing the monitoring at the hospital. For a detailed description of the Central Hospital liability we refer to doctrine.[152] Although the idea to centralise liability for the wrongful acts of personnel working at the hospital is a step in the good direction to alleviate the burden of proof for the patient, the telemonitoring application goes beyond the hospital environment. Different questions arise: What if the hospital works with independent physicians working at a distance? Is the hospital responsible for the organisation of a guard system in case alert systems are applied?[153]. Moreover it is questionable if the hospital can be held liable for violation of patients' rights by IEAPs (non –qualified nurses or physicians). The hospital law does not specify whether the notion "health care professionals" in the disposition on the central liability is limited to medical personnel (as defined in artikel 2, § 1, van het koninklijk besluit nr. 78 van 10 november 1967 betreffende de uitoefening van de geneeskunde, de verpleegkunde, de paramedische beroepen en de geneeskundige commissies[117]).

5.5.7.6 *No-fault system*

It is clear that in telemonitoring cases there's quite a spectrum of "mishaps" where the fault is difficult to prove or to quantify. A Law of 31 March 2010 on the compensation of damage resulting from healthcare (re-)introduced the concept of no fault liability in the healthcare sector.[154] The idea is that victims of damage (above a certain degree of gravity) that was caused by an act of healthcare do no longer need to prove the existence of fault by the health care professional. However, the proof of a causal link between the act/element that caused the damage (or the absence of an act) and the damage still has to be proven. A compensation fund will evaluate whether the damage was caused by a medical mishap or by fault. In case of fault, the Fund will - in principle - not compensate. It is up to the healthcare professional or his/her insurer to make a compensation proposal to the injured patient or to go to court to continue the discussion regarding the liability. Hence, the current no-fault system does not solve the above mentioned problems regarding the assessment of the physician's fault. Probably many disputes will arise within the Fund whether there was a faulty act or not.

In contrast with an earlier version of the Belgian no-fault legislation (art. 3 § 1 Wet van 15 mei 2007 betreffende de vergoeding van schade als gevolg van gezondheidszorg[155]), the current version does not mention that solely damage caused in Belgium is covered. It is indeed questionable whether the limitation of compensation to damage caused in Belgium conforms to the EU Treaty as it does not regulate the damage caused in Belgium by a physician at a distance in Belgium in the same way as the damage caused in Belgium by a physician in another country.[156]

5.5.7.7 Liability related to defective products

In the telemonitoring application different technical apparatus and software is used. When damage is caused to a patient because of a telemonitoring equipment failure (such as for instance defective devices or telecommunication network deficiencies) liability of the physician, the hospital, the software developer, the device supplier, etc is conceivable. Different legislations regulate the (possible) liability for damage caused by faulty products (see appendix). The easiest way for the patient to obtain compensation for the damages caused by a defective product is a claim based on the Law regarding Product Liability. Decision-supporting software for remote monitoring, the implanted device and the bedside monitor are considered to be products. According to this law a producer is liable for damages caused by his product as far as the affected party proves the existence of the product and the flaw in the product, regardless whether there is a contractual relationship or not.[157] Since no fault of the producer needs to be proven, the burden of proof for the affected person is relatively low.

- **As far as adding telemonitoring to regular follow-up can be considered to be the standard of care, it is arguable that if a patient is eligible for telemonitoring, the physician should inform the patient on telemonitoring as part of the aftercare. Today however, there is no sufficient evidence on the clinical effectiveness of telemonitoring to consider it as the standard of care for the follow-up management of chronic patients suffering from heart diseases. Yet, in order to prevent defensive (and inappropriate) behaviour by physicians fearing liability, guidelines should be elaborated for physicians how to deal with this emerging technology.**
- **The current Belgian no-fault system does not solve the problems regarding the evaluation of the physicians liability.**
- **If telemonitoring is applied for continuous follow-up or for disease management, patients need to be informed orally as well as in writing on the modalities (frequency of viewing the data, during specific hours etc.) and the limitations of the system.**
- **Contractual clauses stipulating that the telemonitoring application for continuous follow-up or for disease management is not an emergency system can be considered to be valid.**
- **Contractual clauses stating that alerts systems can not be considered to be emergency systems even if they do function as emergency systems should be analysed with caution. In case alert systems are applied, short term attention needs to be assured and back-up must be assured in case of periods of absence. Guidelines regarding the maximum response time for alerts and protocols regarding the assurance of continuity (who should organise the guards, status of the physician during on call time,…) are necessary to enhance (medical and) legal certainty for patients and physicians.**
- **Providing technical expertise and advice regarding the medical devices falls within the legally allowed acts of Industry Employed Allied Professionals (IEAPs). However, IEAPs performing (technical) nursing activities can be sanctioned with fines and imprisonment.**
- **If a firm systematically puts IEAPs at the disposal of physicians for free for assistance during surgery or during follow-up, this could be considered as illegal according to the Belgian law on Pharmaceuticals.**
- **As telemonitoring implies the involvement of many players, particularly outside the hospital, the centralisation of liability at the hospital (for the acts of the personnel working there infringing the PRA) does not offer a proper solution.**
- **A producer is liable for damages caused by defective product (for instance the decision- supporting software, the implanted device, the bedside monitor,...). The affected person does not have to prove the producer's fault.**

5.5.8 Reimbursement of telemonitoring

Legislation requires the physical presence of the physician for the reimbursement of medical interventions (art. 1, § 4 bis Koninklijk besluit van 14 september 1984 tot vaststelling van de nomenclatuur van de geneeskundige verstrekkingen inzake verplichte verzekering voor geneeskundige verzorging en uitkeringen).[158] The reasoning behind this requirement is the guarantee for qualitative care. One could argue that the fact that the patient and the physician are not present at the same place hampers the interaction. According to Callens, this argument is only reasonable in a moment in time where ICT was not at the same level as today.[156]. Ideally, the quality of care offered by each telemedicine application should be assessed according to scientific evidence as is the case for "classical" medicine. It can be questioned, however, to what extent the effectiveness of the telemonitoring application, which is partly a disease management tool and serves for the pre-organisation of in-clinic follow-up, can be measured with hard endpoint such as for instance decreased mortality.

It is questionable if the criterion of physical presence of the physician for reimbursement of medical interventions forms an obstacle to the free movement of services. Several arguments take the edge off this statement.[156] First, the criterion of physical presence can not be tested against Community law since the former is a rule of social security which falls mainly within competence of the member states because of a lack of harmonisation at Community level. According to the Court of Justice however, the existence of social security rules in a member state do not exclude the EU treaty disposition on the free movement of services (art. 56 and 57[159].[160, 161] As the physical presence rule counts for telemedicine practices as well as for classical therapy and applies to Belgian as well foreign physicians, the rule is as such not discriminatory. Moreover this obstacle to the trade in services can be justified in the light of a public health reason (art. 62[159]) or an imperative reason in the common interest, such as for instance the financial balance of the social security system. The real impact of the reimbursement of (some) telemedicine acts however is not studied until today. According to Callens, the reimbursement of certain types of telemedical interventions will have to be accepted under Community law if the safety of the patient is guaranteed and if the telemedical treatment is cost neutral.[156]

5.6 CONCLUSION

There is no harmonised legal framework for the telemonitoring application. Yet, various general European rules (can) apply to telemonitoring. Despite the extensive regulations at EU level and at the national level that play a role in the field of telemonitoring, the existing legislative framework often seems difficult in its application since telemonitoring covers a variety of specific situations in which solely a case-specific answer offers an appropriate solution. Hence, specific juridical guidance for the interpretation and application of the relevant legislation should be developed.

In particular the regulations regarding the liability and the reimbursement of telemonitoring draw the attention.

Regarding the liability issue, several EU level liability dispositions in various legislation that is not directly targeted at regulating healthcare apply to telemonitoring. A distinction as to the type of liability should be made. No-fault liability is for instance included in the Directive on product liability. In the E-commerce Directive, intermediaries (for instance internet providers) are exempted from liability for mere conduit, caching or hosting. For medical and services liability however member states come into play since until recently personal injury law has been seen as a matter of exclusive national competence, strictly linked to national needs and the financial sources available for delivering compensation to victims. Many member states have regulated liability issues in their hospital legislation or have drafted specific no-fault legislation for medical harm resulting from a medical act (cfr. France, Belgium, Nordic countries). The different approach of the member states regarding liability issues related to medical harm may result in the unequal protection for citizens.

Yet, if a widespread implementation of eHealth applications is a near-future target, initiatives at the European level are needed to encourage member states to provide similar rules for compensation, by preference no-fault compensation. On the other hand, the diversity of the systems, and the different treatment of evidence and civil procedure across Europe, hamper the harmonisation of issues such as the medical assessment of physical and/or mental injury, and the applicable criteria for the assessment of damages.[162]

The current (Belgian) malpractice rules do not offer a sound solution for promising emerging technologies for which no sound evidence on the effectiveness has been established such as the telemonitoring application. One the one hand, the fear for liability leads to a defensive reaction by physicians that can go in two directions: either they apply systematically remote monitoring for fear of liability for omitting life saving technology (in individual cases), although there is no sound evidence on the overall effectiveness; either they do no apply it at all for fear of liability for faults in the application. The current no-fault system does not come forward to these problems.

Today telemonitoring (nor the equipment and the supporting services) is not reimbursed in Belgium. It is questionable if the physical presence requirement forms an obstacle to the free movement of services. If reimbursement of telemonitoring would be considered however, limitations in reimbursement in the interest of public health (e.g. overconsumption) are likely to be imposed. Before telemonitoring can be considered for reimbursement, legal and organisational barriers will have to be removed. Providing clear answers to the (legal) challenges resulting from emerging technologies, such as telemonitoring, goes hand in hand with the definition of an organisational framework. In that scope guidelines and procedures on how telemonitoring should be organised are primordial.

6 ORGANISATIONAL ASPECTS

Today the remote monitoring landscape is very fragmented. Different barriers hinder the widespread implementation. Although gaps and bottlenecks can be situated at the level of clinical evidence, cost-effectiveness, technology and legislation (cfr. supra), the innovation focus of telemonitoring is all the more situated on the institutional (reimbursement) and on the organisational level. In this chapter we zoom in to these issues. Scientific and grey literature and contacts with ICD manufacturers formed the basis for the content of this chapter.

6.1 REIMBURSEMENT OF REMOTE MONITORING IN BELGIUM AND A SELECTION OF OTHER COUNTRIES

A major barrier for the implementation of telemonitoring is the lack of an incentive framework that rewards both the monitoring equipment and the services linked to remote monitoring as well as the telemonitoring itself. In order to reimburse telemonitoring services, however, healthcare providers will have to convince payers that telemonitoring has an added value through sound evidence. As indicated in chapter 3, there is no sufficient evidence regarding effectiveness of remote monitoring to justify the reimbursement of the telemonitoring application.

The following section describes the current reimbursement status in Belgium and in a selection of other countries and the barriers hampering the reimbursement of telemonitoring application. Additionally, some possible funding mechanisms for a future reimbursement are listed.

6.1.1 Current situation in Belgium and options for the future

6.1.1.1 ICDs and pacemakers

Since 1987 ICDs have been reimbursed by the Belgian sickness insurance based on a model convention[r] concluded between the implant centre and the NIHDI. Since 2005 prices of pacemakers and ICDs are capped. (art. 17 Wet van 27 april 2005 diverse bepalingen betreffende gezondheid[18], not entered into force yet). Price reductions are regularly applied. The actual price of an ICD is about €16 000.

6.1.1.2 Telemonitoring equipment and service

Today telemonitoring equipment can not be reimbursed by the compulsory health insurance. Medical devices additional to ICDs or pacemakers can solely be reimbursed as far as they serve for one or more reimbursed interventions or interventions that are charged to the hospital budget (art. 17 Wet van 27 april 2005 diverse bepalingen betreffende gezondheid[18], not entered into force yet).

Services supporting the telemonitoring application, such as the technical support, the education of the health care professionals involved in the remote monitoring, data transmission and storing services, etc… can legally not be included in the price of the ICD or the pacemaker.

Companies offering the telemonitoring services in pilot projects abroad (cfr. infra) sometimes charge a one-off fee for the device and monthly subscription fees paid by the patient privately, or reimbursed by an insurance company. Sometimes a contract is negotiated directly with a healthcare provider for a number of patients. Mostly however, companies provide the telemonitoring equipment and the service for free, as part of their marketing strategy. It is questionable, however, if this situation is legal. According to the law on pharmaceuticals, it is prohibited for companies to grant financial benefits or in natura to hospitals or prescribers, delivering, administering medical devices (art. 10 § 7 Geneesmiddelenwet van 25 maart 1964[150]). The systematic provision of the telemonitoring equipment and the supporting services for free by the companies could thus be considered as illegal.

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r http://www.riziv.be/care/nl/revalidatie/convention/defibrillator/pdf/agreement20090701.pdf

When considering reimbursement of the telemonitoring equipment and the service, different options are conceivable. One possibility is to opt for a leasing contract where the fee includes the use of the equipment and the supporting services or to charge a one off fee for the equipment and a fee per patient per year (or per month or per day) which includes all services (e.g. pilots in Italy).

Another option is to grant a price premium (% or a lump sum) on the price of the device (e.g. France for Biotronik devices). There are different drawbacks to this system. First, the granted amount for the monitor and the accompanying services is linked to the lifespan of the device (4 years on average) or the life expectance of the patient, which may vary. Moreover, in Belgium, prices of ICDs are regularly reduced and not indexed. If a price premium is granted as a percentage of the price of the device, the reimbursement of the monitor and the services will be linked to the price variations of the ICD.

6.1.1.3 Reimbursement of the telemonitoring

There's no fee for the physician for remote follow-up or the telemonitoring nor for the preparatory work by skilled nurses of other clinical allied professionals involved in the remote follow-up or telemonitoring. Today physicians are reimbursed up to 113,36 euro per in-clinic follow-up visit (ICDs). In principle, maximum 3 follow-up sessions are eligible for reimbursement.

Table 7 summarises the reimbursement of the telemonitoring in a selection of countries. Some countries reimburse the remote follow-ups in the same way as in-clinic follow-ups (UK, Germany, Portugal, Finland and Sweden). This option presumes that telemonitoring can replace (or be additional to) the in-clinic follow-up visit. Earlier in the report it was argued that the routine in-clinic follow-up visit, where the presence of the patient is not really needed could eventually be replaced by remote follow-up. The problem is however that the number of additional in-clinic unscheduled follow-up may increase because of for instance the remote reporting of arrhythmic episodes. One could argue, however, that because of the presumed time gained by replacing the routine follow-up with telemonitoring, a fee for service system where the telemonitoring is reimbursed up to the same level as the in-clinic follow-up could be maintained. In this idea, the extra money for the remote follow-up would compensate the extra work "at the desk" or resulting from unscheduled extra follow-ups. Moreover the time gained with the remote follow-up, can be spend to other medical activities generating extra income.

It is obvious that the reimbursement for remote follow-up (at scheduled moments) should be distinguished from the reimbursement of telemonitoring. In the latter case data are reviewed on a more regular basis which increases the workload for the physician (or another clinical allied professional). An option is to pay a flat fee per patient per year for the telemonitoring.

6.1.2 Reimbursement of remote monitoring in other countries

Table 7: Reimbursement of telemonitoring in a selection of European countries (information up to date till 2009)

Country	Reimbursement/funding system	Reimbursement for in-house device follow-up	Reimbursement for telemonitoring	Reimbursement of equipment and supporting services
Austria	DRG system with floating values	No. but in preparation	No	No
Belgium	Reimbursement of hospital activities plus devices with fixed reimbursement levels	Yes, per FU	No	No
Denmark	NordDRG, DRG not used for individual funding	Yes, per FU IPG, ICD: €90, Biv. Pace/ICD: €205	Not yet, but on its way for 2010	No
Finland	Hospital budget	Yes, €200/FU for hospitals. Patient receives funding of his costs	€200	No
France	DRG system with fixed price list for implants	Yes:€55/IPG and €61/ICD	No	No, but price premiums on ICD and IPG for Biotronik
Germany	DRG system	Yes, around €40 for FU in outpatient care (i.e. 100% of LV FU and 50% of HV FU)	Yes, around €40 for FU in outpatient care (i.e. 100% of LV FU and 50% of HV FU)	No
Italy	DRG system in private and some public hospitals; global budget in other public hospitals	Yes, €23	No	No
The Netherlands	DRG system, with pacemakers already in "B segment", i.e. free pricing between hospitals and sickness funds	Yes	No	No
Portugal	Mix between DRG system and hospital budget		Yes, €66 (IPG), €81 (ICD, CRT)	No
Sweden	Mix between DRG system and hospital budget	€173	€173	No
Switzerland	Global budget; DRG to be introduced by 2011		No	No
UK	DRG system	€124	€124	No

Source: St. Jude Medical

This table does not take into consideration the pilot programs and other local initiatives (cfr. infra).

6.1.2.1 Managed uptake of telemonitoring

Decision on the strategy: "wait and see" or conditional reimbursement

The Belgian Healthcare Knowledge Centre (KCE) elaborated a model for the managed uptake of new medical devices which can be extended to emerging technologies, such as remote cardiac monitoring.[163] In order to decide upon the strategy, a rapid assessment on safety and efficacy has to be performed. If the rapid assessment concludes that the emerging technology is less efficacious (than the existing one) or that there are still substantial safety concerns, this technology can not be regarded as an emerging technology (yet) and a wait and see policy should in principle be the strategy to be followed. In the other case the assessment will provide arguments for a promising emerging health technology (possibly as efficacious and at least as safe) and if budgetary possibilities exist, conditional reimbursement can be allowed. Until today there is little evidence on the clinical effectiveness of remote cardiac monitoring. In principle the "wait and see" strategy should thus be considered as the best option. However, safeguards for safety and budgetary impact will have to be taken. A "wait and see" strategy risks leading to an uncontrolled dissemination of a possibly inferior (or even harmful) technology being paid by the patient, by private insurance or even by the obligatory health insurance through the assimilation of other health insurance billing codes. It is thus up to the NIHDI to carefully balance the risks against the benefits.

Conditional reimbursement and scientific evaluation by field assessment (HTA)

The managed uptake strategy implies a scientific evaluation by field assessment in combination with conditional reimbursement. In a preparatory phase the research design and formalities of the implementation are discussed. Next, there's an evaluation phase over a period extending in general from 1 to 5 years including data registry, intermediary analysis and possibly auditing. Finally a full HTA concludes on the clinical effectiveness and cost-effectiveness of the new technology.

Research design

The controlled diffusion of an emerging technology is accompanied by a research design to objectively prove the hypothesized added value of the technology. In order to specify the research design behind the conditional reimbursement an advisory expert group with, next to clinical experts, methodological experts in clinical research, HTA and data registry is pivotal.

In order to strengthen the evidence base of the emerging technology, either a controlled clinical trial, ideally with random allocation to the emerging technology (remote follow-up) and an established treatment (in-clinic follow-up), or an observational trial with longitudinal data registry and possible audit are the two main research designs. In some cases an RCT will not be possible, based on practical issues such as feasibility or problems with patient recruitment.

For the conditional reimbursement, the use of the new technology needs to be restricted to a specific population and for specific indications. Moreover, the research setting has to be specified. In that scope it is necessary to establish criteria determining which research settings can be eligible for the technology at stake. In case of remote cardiac monitoring, the criteria for the centres that are allowed to perform the remote follow-up or the telemonitoring, qualification and training of the staffing, standard procedures/protocols, …are elements that need to be defined. Furthermore the contract typology (for instance service contract between the patient and the centre; lease contract between the firm and hospital) and payment modalities for all parties involved in the telemonitoring application need to be specified. This could be integrated in a Convention between the NIHDI and the respective centre (e.g. the ICD Convention as far as the implanting centre also performs the follow-up).

Clinical experiments can only be performed if they are guided by scientific interest. In order to guarantee the independency and transparency of the research team eventual conflicts of interest must be declared. Moreover the clinical trial should have the approval of an ethical committee and should be registered.

Data registry and audit

Depending on different criteria such as the amount of patients involved, the nature of the technology at stake, and the potential budgetary impact on health insurance, the evaluation period should be specified and in general will cover one to five years. During this period, data gathered in the collaborating hospitals should be registered and possibly audited. In order to allow a timely intervention in case of lapses in the research (e.g. extreme mortality rates in one centre), data should be exploitable for intermediary analysis and the research team should present a brief yearly progress report. At the end of the evaluation period there should be an evaluation of the clinical effectiveness and cost-effectiveness by a full HTA. In that scope the results of the HTA can offer an independent guiding tool for decisions regarding reimbursement on governmental level.

6.1.2.2 Reimbursement proposal UNAMEC[s]

UNAMEC proposes to lease the telemonitoring technology on a daily basis and to include the reimbursement modalities in a convention with the NIHDI. UNAMEC suggests the reimbursement of €1,5/patient/day for:

- The rental of the bedsite monitor (included the costs for developing the system, the software and the upgrade, the maintenance, …)
- The costs of data transmission
- Assistance by the hospital or by a technician

An amount of €1,2/patient/day is addressed to the equipment and the service and €0.3/patient/day for the assistance. Neither the cost of telemonitoring nor the remote follow-up by the health care provider is included in these amounts.

Another option is the reimbursement of the cost for the telemonitoring system, service included on an annual basis at €400.

The proposed amounts are based on the average investments made by the firms offering telemonitoring services and the real costs linked to data transmission.

- **Today, nor the telemonitoring equipment and the supporting services, neither the remote follow-up nor remote monitoring is reimbursed by the Belgian obligatory health insurance. Companies mostly provide the service for free as part of their marketing policy. The systematic provision of this service for free may be illegal.**
- **Some countries reimburse the remote follow-up in the same way as in-clinic follow-up. The monitoring equipment and the supporting services is currently not reimbursed in most of the European countries.**
- **Conditional reimbursement of remote cardiac monitoring can be considered once there is sufficient proof of efficacy and safety or as a strategy to avoid uncontrolled dissemination of a possibly inferior or harmful technology being paid by the patient, by private insurance or provided for free by the company. The research design and modalities of the implementation should be defined and the technology should be evaluated in a 1 to 5 year time span. This could be integrated in a Convention between the NIHDI and the centre performing the follow-up and/or the telemonitoring.**

[s] UNAMEC is the professional association of firms producing, importing and/or supplying medical devices

- **According to the workload for the physician (or another clinical allied professional) the reimbursement for remote follow-up (at scheduled moments) should be distinguished from the reimbursement of telemonitoring (continuous or more regular transmission). An option is to pay a flat fee per patient per time unit (day, month, year,..) for the remote monitoring. If remote follow-up replaces (or is added to) in-clinic follow-up, the same amounts can be granted for both. If reimbursement of remote monitoring/follow-up is considered, incentives for the referring physicians in order to stimulate an adequate referral policy could be considered.**
- **For the financing of the equipment and the supporting services provided by the supplying companies, leasing could be an option.**

6.2 OPPORTUNITIES AND BARRIERS RELATED TO TELEMONITORING FROM THE PERSPECTIVES OF THE DIFFERENT PLAYERS

6.2.1 From the perspective of the suppliers:

6.2.1.1 Barriers

- Today there is no reimbursement for the telemonitoring equipment and the supporting services. Investment decisions in telemonitoring are mainly driven by growth perspectives in the medium or long term. Although the telemonitoring application is considered by the suppliers as a high potential market, the current market is limited to pilots and fragmentary use by local hospitals (cfr. infra).[164] The set-up of a telemonitoring service requires a considerable investment and return on investment only can be realised if it is done on a sufficiently large scale. Consequently specialised companies primarily focussing at remote cardiac monitoring are scarce, since business sustainability requires diversification of (profitable) services.

6.2.1.2 Opportunities

- Telemonitoring changes the relationship between the patient and the industry. Whereas in a classical model there is no (or hardly) contact between the patient and the industry, there will be more interaction and even direct contact in the telemonitoring application. The industry will assist in the implanting procedure of the programmable device, give information about the functioning and will interpret device failure data and eventually reprogram the device (cfr. supra on what acts can be done by IEAPs).
- At the same time the relationship between the industry and the physician is intensified. Industry employed allied professionals IEAPs often have expertise about specific features of pacemakers or ICDs that is unique to the manufacturer's product. They render technical assistance during pacemaker/ICD implantations, programming, analysis of malfunctions, and follow-up. This expertise may be extremely valuable to physicians and the clinical professionals.

6.2.2 From the perspective of the patient:

6.2.2.1 Barriers

- There is currently no reimbursement of the monitoring equipment and the service. While some companies provide the equipment and the services for free as part of their marketing strategy, some companies charge a fee for the device and monthly subscription fees (cfr. pilot projects). These amount are paid out-of-pocket by the patient if there was no arrangement with an insurer.[164].

6.2.2.2 Opportunities

- (Potential) clinical benefits such as reduced mortality, early detection of exacerbations
- (Potential) improvement of patients' quality of life:
  - reduced anxiety between follow-up visits;
  - reduced patient journeys and unnecessary hospital admissions;
  - diminution in workdays lost, reduction in waiting and travel time for the patient[53];
  - patient satisfaction: several studies show that patients are satisfied as regards to the usability of the remote monitoring application. [45, 52] In a Italian multicenter study evaluating the ease of use and the acceptance of telemonitoring (with the Medtronic Carelink system), a general preference for remote versus in-clinic follow-up was reported [51];
- Individualised patient-centered care (patient empowerment) ensures that decisions respect patients' wants, needs and preferences. It solicits patients' input on the education and support they need to make decisions and participate in their own care. The drawback however is that the more patients are involved in the care process, the higher their responsibility for their own health situation. In that scope the acts of patients can be taken into account when considering liability (shared liability) when something goes wrong (e.g. the patient failed to switch on the bedside monitor) (cfr. supra).

6.2.3 From the perspective of the physician

6.2.3.1 Barriers

- Lack of reimbursement for the telemonitoring or the remote follow-up (cfr. supra);
- The fear for liability in case something goes wrong (e.g. missing of an alert) can lead to a defensive attitude, where the physician rather chooses not to make use of telemonitoring (as far as this is not set as the standard of care).
- As mentioned in chapter 2 the involved healthcare workers lament to great extent the fact that every system features its own web application, differing significantly among one another. Most centres implant devices of more than one manufacturer, implying that more than one web application needs to be checked almost daily to keep up with the steady stream of incoming alerts and notifications.
- Furthermore, many hospitals actively pursue centralising all clinical patient data in electronic health record (EHR) systems that are either commercial or developed in-house. For these reasons, it is highly desirable that remote monitoring data servers would communicate directly with the EHR system in place.

6.2.3.2 Opportunities

- Telemonitoring can facilitate the physician's work since there is (can be) a better differentiation of the tasks. Some of the telemonitoring tasks can be outsourced to skilled nurses or other medical professionals or to (commercial) intermediary parties (cfr. infra);
- The reviewing of transmitted data on the computer, allows to reduce the time spent on in – clinic follow-up visits when there was no event.[52, 53] More time is available for complex device follow-up. Given the importance of clear expectations on the patient side regarding what to expect in terms of follow-up, it should be common practice to send a follow-up notice with the findings and when the patient's next in-clinic visit or remote follow-up is scheduled.[165]
- Unanticipated events like alerts can be remotely reviewed and a clinical decision can rapidly be taken. Unscheduled unnecessary in-clinic visits or emergency room visits can thus be avoided.
- There is an important interdependent relationship between the referring physician, the implanting center, the implanting physician and the follow-up clinic. Through the telemonitoring application multiple users are allowed to monitor multiple patients at the same time. In that scope access to the patient's data can be shared with outside clinicians such as referring physicians and heart failure specialists. In all available systems, the level of access granted to each user can be controlled with a programmable settings of full access, read only, and no access. Responsibilities for reviewing transmissions and for taking action need to be defined and training in using the system and reviewing the transmissions needs to be provided for all users.

6.2.4 From the perspective of the payer:

6.2.4.1 Barriers

- Regardless of the question whether telemonitoring should be reimbursed or not, the structure of the current incentives in healthcare delivery and financing which is based on a classical model of in-patient care should be reconsidered. The models of DRG based fixed prospective budget payment (for hospital accommodation services, nursing activities and emergency services), fee for service (dominant scheme in Belgium for specialists and the majority of GPs although the amount of fixed payments is increasing (e.g. for the use of medical imaging, clinical biology) and capitation (reimbursement of a few primary health care centres) run against telemonitoring. For instance, keeping patients out of the hospital as is aimed at by telemonitoring reduces the fee for output the hospital may receive.

6.2.4.2 Opportunities

- Telemonitoring can play a positive role in cost containment. Marzegalli et al.[51] indicated that considerable cost savings could be achieved, assuming that 2 of the scheduled in-clinic follow-up visits could be replaced by remote follow-up and that remote monitoring could displace nearly one unscheduled outpatient visit per year. Indeed, unanticipated events like device shocks or alerts that once required an unscheduled office or emergency room visit can now be remotely reviewed and quickly decided on. Similar findings were demonstrated by a French study by Fauchier et al.[71]
- With the arrival of remote monitoring, the need to develop new financing mechanisms becomes evident. These should not only cover care delivered at one specific moment and place, but also patient care and monitoring that occurs remotely and over longer time periods.

6.3 ORGANISING THE WORKFLOW

6.3.1 Event triggered transmission (alerts for system integrity and alerts for arrhythmia episodes): on-call system

The integrity of the implanted device is essential to offer appropriate device therapy. Most of the system related complications are lead-related and usually occur within three months after implantation.[16] Since the lead impedance is part of the pre-defined alerts in the remote monitoring in most of the systems or can be requested as alert by the physician, these complications can be detected earlier with remote monitoring than with routine in-clinic visits. Notification for alerts can occur through different channels: email, fax, sms or website. Most of the systems have a daily interval reporting of alerts with a monitor-initiated transmission of the data at a programmable time or usually standard at night. The Biotronik and Medtronic (for the newest) devices provide a device-initiated communication in case of an event. Although device supplying companies state that their system can not be conceived as an emergency system, short term attention is needed and late reaction can have lethal consequences for the patient. It's of an utmost importance that transmitted data are timely accessed and responded to if events are observed. As mentioned in the legal chapter clauses in the informed consent form stipulating that the telemonitoring service is not considered to be an emergency system and that information will only be treated during the office hours are in principle valid since they do not touch upon the essence of the contract, as far as being the continuous follow-up or disease management. If alert systems are used, it is questionable if such clauses are valid, since the core of the alert system is the sudden reaction to an event. It could thus be argued that the physician needs to make sure that short term attention is assured within the reasonable organizational limits. Therefore the elaboration of guidelines and protocols on the reaction time for alerts is pivotal. Furthermore back-up should be assured in case of longer periods of absence. In order to do so, the physician could be supported by a service provider that is available 24/7. Another option is the organisation of an on-call system between fellows at the same hospital or between several hospitals. Despite the concerns of physicians to be deluged with alerts, the actual event rate is only 0.86 alerts (clinical alerts as well as device integrity alerts) on average per 100 patients daily [46], which makes the on-call system between fellows of the same specialty a valuable option.

6.3.2 Telemonitoring and remote follow-up: centralisation or dedicated time in hospital by physician or other clinical allied professional

The frequency of the data check (daily, weekly, …) is on the on hand up to the physician who can adapt his/her decision to the individual situation and depends on the other hand on the system (e.g. For the Boston Scientific Latitude® Communicator web application data is updated only weekly). It is obvious that the workload differs according to the frequency. Off-schedule transmissions initiated by the patient are also possible (for instance if they have symptoms or if they received a shock), but should only be done upon request of the physician in order to avoid unknown transmissions on the website.[49] Whereas daily or weekly remote monitoring does not necessarily reduce the daily work load, it redesigns the flow of work into a more efficient operation of the clinic.[165] The organisation of the workflow of telemonitoring can vary from one practice setting to another. Ricci et al.[49] propose an organizational model whereby a specialized nurse daily connects to the home monitoring website and submits critical cases or unclear interpretations to the physician. The data of the 117 patients were checked at least every 15 days and whenever an event report was received. Only 6% of events were then relayed to the physician for further evaluation. This workflow resulted in a mean of 59 min/week for the nurse and 12 min/week for the physician to analyse home monitoring data. The study did not reveal the extent of the programmed parameters.

In a pilot study in Nîmes (France) the competence requirements for the nurse, involved with this task[166] were set:

- Training offered by the different firms needs to be completed
- The nurse needs to have notions of electrophysiology
- The nurse needs to participate to continued training in order to keep up to date

Another possibility to lower the workload for the physician and to optimise the expertise is to outsource the data triage to a specialised external party. Fully integrated telemonitoring services, however, are not widespread. Mostly the service provision of the providers stops at the point where medical care to the patient is needed.[164] Anyway, it is questionable if end-to-end provision by suppliers would be accepted by the medical profession.

The remote follow-up at a pre-specified moment replacing face to face in-clinic follow-up and the pre-organising of the regular face to face follow-up visit demand dedicated time in hospital by the physician of other clinical allied professional.

- **In case alert systems are used, physicians need to make sure that timely reaction is assured and that back-up during absence is guaranteed. The elaboration of guidelines and protocols defining the adequate reaction time to alerts is primordial. Since the alert rate is rather limited, an on-call system between fellows of the same specialty can be considered.**
- **The workload for the physician or other clinical personnel involved in telemonitoring depends on the frequency of data reviewing. Dedicated time in hospital for the respective personnel or centralisation of data triage within a specialised (external) centre are possible options to manage the workload.**
- **The fact that every system features its own web application, differing significantly among one another, is an important barrier for the implementation of remote monitoring, since most centres implant devices of more than one manufacturer.**
- **Many hospitals actively pursue centralising all clinical patient data in electronic health record (EHR) systems that are either commercial or developed in-house. For these reasons, it is highly desirable that remote monitoring data servers would communicate directly with the EHR system in place.**
- **The remote follow-up at a pre-defined moment replacing face to face follow-up and the pre-organising of the regular in-clinic follow-up visit demand dedicated time in hospital by the physician or other clinical allied professional.**

6.4 REMOTE MONITORING INITIATIVES IN BELGIUM AND IN OTHER COUNTRIES

All around the world pilot projects and initiatives regarding remote cardiac monitoring have been set up. By means of illustration we focus on a selection of these in the next section.

6.4.1 Germany: agreements with insurances

6.4.1.1 Vitaphone

The key activity of Vitaphone is the monitoring of patients with chronic heart conditions in collaboration with Biotronik. Reimbursement is partly granted by the "betriebskrankenkassen", i.e. government regulated public health insurances for telecare of patients with cardiac arrythmias, heart failure and hypertension. However, most of the subscribers to the service pay for the device and the service privately. To date, 25.000 patients are served in Germany, Austria and Switzerland.

The core of the system is the around-the-clock service availability and the Telemedical Service Center in Chemnitz/Sachsen, which is staffed by physicians and other qualified medical professionals. The team cares for the patient, manages the electronic patient file, documents findings, evaluates ECGs and other health data and forwards these to the treating physicians at the hospital or medical practice. In emergency situations the Telemedical Service Center will take over the entire emergency management. The Telemedical Service Center is ISO certified.

6.4.1.2 TAUNUS BKK Disease Management Programme

The TAUNUS BKK (health insurer)[t] Disease Management Programme – home tele-health reimbursed telehealth solutions for disease management programmes for chronic heart conditions and diabetes which have been tested in several regions (e.g. as of 2007, 2000 patients with chronic heart problems and 200 with diabetes were monitored through a BKK Taunus telemedicine system at home, in the German state of Hessen) under an insurance based system. The applications are now offered to all members of the Taunus BKK on a nationwide scale.

6.4.2 Italy: agreements with public healthcare

6.4.2.1 Lombardy

In Lombardy, as a result of 5 years of experimentation there is a reimbursement protocol (similar to a DRG) for telemonitoring for CHF: As of 2009 full therapeutic protocols were completed with 3000 patients. The Lombardy Region reimburses €720 per patient per 6 months service for the remote monitoring provided in accredited hospitals. This comes down to 4 euro per day per patient split 50/50 between hospitals for the work of a skilled nurses and the intervention of the cardiologist and suppliers (devices, call centers, data transmission and preliminary analysis). Nurses in a call center do the preliminary data triage. In case of a presumed problem, the nurse contacts the patient. If no problems were reported by the patient, there is no further action. If there are, the nurse contacts the cardiologist.

6.4.2.2 Piedmonte

A tender for the provision of remote cardiac monitoring for chronic heart failure to patients in remote mountainous areas of the regions was adjudicated in 2009. A part of the work is done by nurses and a highly specialised call centre operator. The cost varies between €232 (€7.7 per patient per day) per patient per month and €273 (€9 per patient per day). The service will be initially provided to about 400 patients for a 2 year period, and it is expected to be subsequently scaled up.

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[t] http://www.taunus-bkk.de; http://www.ict-ageing.eu/?page_id=1330

6.4.3 USA

6.4.3.1 Mix of provision by public agencies (e.g. Veterans Administration) and private healthcare providers/agencies (e.g. MEDICARE)

In the USA, Medicare and Medicaid have expanded reimbursement for remote device monitoring for all states since 2006. Reimbursement rates vary from state to state, and in some instances are the same as an in-office visit without device programming.

6.4.3.2 The Veterans Health Administration's CCHT Programme (VHA CCHT) [u]

From 2003 till 2007, VHA introduced the national home telehealth program "Care Coordination/Home Telehealth" (CCHT), which basically upgraded an existing disease management approach for non-institutional care (NIC) services with a telemonitoring component. The number of patients treated increased from 2000 to 750 and the diseases addressed included, among others, diabetes, CHF, and COPD.[167]

6.4.4 Northern Ireland

The European Centre for Connected Health (ECCH)v has since 2008 been running a procurement exercise for the Remote Telemonitoring Northern Ireland (RTNI) for 5000 people (heart disease, COPD, diabetes). This is part of the wider chronic disease management agenda, closely aligned with Health and Social Care strategy. Central government funding is made available, supported by the Economic Ministry's Innovation Fund.

6.4.5 Belgium

- Early detection of worsening HF condition using OptiVol Fluid Status Monitoring (i.e. OLVZiekenhuis – Aalst),
- Early detection of undocumented AT/AF (i.e. Maria-Middelares – Gent),
- ICD Shock delivered (i.e. CHR de la Citadelle),
- Pre-organizing Regular In-Clinic Follow-up (i.e. CHR de la Citadelle | C.U. de Mont-Godinne),
- Follow-up of near EOL pacemakers (i.e. C.U. de Mont-Godinne),
- Monitoring ICM Reveal (i.e. OLVZiekenhuis – Aalst),
- Parent Clinic / Satellite Clinic – CareLink workflow efficiency (i.e. CHR de la Citadelle – CCKM).

6.5 CONCLUSION

Although the implementation of small scale, local pilots can be achieved reasonably easily, different barriers hinder the widespread application of remote cardiac monitoring. Overall, the major barrier holding remote cardiac monitoring back is the current lack of reimbursement. The justification of reimbursement of remote cardiac monitoring as an alternative care model heavily relies on the existence of evidence on predefined outcomes. Conditional reimbursement of remote cardiac monitoring can be considered once there is sufficient proof of efficacy and safety or as a strategy to avoid uncontrolled dissemination of a possibly inferior or harmful technology being paid by the patient, by private insurance or provided for free by the company. The research design and modalities of the implementation need to be defined and the technology should be evaluated in a 1 to 5 year time span. Yet, even if remote monitoring appears to be efficacious, effective and safe, the organisation needs to be integrated in the operational processes and protocols used by the existing service in delivering care. This not only requires local efforts, but also a long term vision of how out-of-hospital health care services should be organised and incentivised.

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[u] http://www.carecoordination.va.gov/telehealth/ccht/index.asp

[v] http://www.eu-cch.org/pin-remote-monitoring-procurement-information.pdf

7 SUMMARY AND CONCLUSIONS

The objectives of this report were twofold:

- to describe the technology of remote monitoring systems specifically for Implantable Cardioverter Defibrillators (ICDs) whilst providing a systematic review of the available evidence on the clinical effectiveness and cost-effectiveness through a rapid HTA;
- to focus on the organisational, reimbursement and legal aspects of remote monitoring. This is done in a broader sense, i.e. irrespective of being related to ICDs.

The combination of these two aims has led to an extensive report that is also intended to be used as a reference document.

7.1 THE DISEASE

Individuals suspected or known to have a relatively high risk for sudden cardiac death need to be risk-stratified through clinical investigation. As a result of this risk assessment, patients can become eligible for implanting an ICD. These therapeutic actions are labelled as secondary prevention for those patients who previously survived a life-threatening cardiac arrhythmia. Conversely, the therapy is labelled as primary prevention when administered to patients that are at high risk of experiencing a first life-threatening arrhythmia.

By consequence, a mixture of different types of patients receive ICDs, ranging from individuals with an increased primary risk for cardiac arrest with relatively mild symptoms as well as patients with an advanced degree of symptomatic heart failure. The latter group needs much more medical attention, apart from controlling the well-functioning of their ICD. However, both groups are dependent on the correct functioning of their ICD-system for surviving an episode of cardiac arrest.

7.2 THE DEVICES

ICDs are implantable, battery-powered, programmable electronic medical devices capable of monitoring the heart rhythm and delivering anti-tachycardia pacing (ATP), cardioversion and/or electric shock to restore normal rhythm when a life-threatening arrhythmia is detected. An ICD system consists of two main parts: the defibrillator and the leads with electrodes and shocking coils.

The defibrillator is a pulse generator, slightly larger in size than a pacemaker and weighs about 80 grams. Current ICDs are placed subcutaneously under local or general anaesthesia in the pectoral region with transvenous endocardial leads connecting to the heart through one or more veins.

The latest devices offer graded responses (so called "tiered therapy") to a sensed ventricular arrhythmia. Anti-tachycardia pacing, low-energy synchronised cardioversion and high-energy defibrillation shocks can be delivered successively via the transvenous endocardial lead system, terminating the arrhythmia. Furthermore, ICDs always incorporate a pacemaker that, apart from the usual indications, can be used for ATP and back-up pacing following a shock.

Device longevity has been gradually extended with advances in battery technology. ICDs now last from 5 to 8 years before replacement is required, although statements from industry appear to be overly optimistic compared to observed device longevity in registries and in some manufacturer-issued product performance reports. The price of an ICD has been decreasing over time and is largely country-dependent.

This report covers both regular ICD devices as well as CRT devices with defibrillator capability (CRT-Ds).

7.3 IN-CLINIC FOLLOW-UP OF PATIENTS AND DEVICES

ICDs are complex pieces of electronics that interact directly with the patient. Therefore, regular follow-up of both patients and devices is recommended. This follow-up covers both the functioning of the device and the condition of the patients. Depending upon type of device and patient conditions, several follow-up schedules have been recommended in the relevant guidelines. On top of this, unscheduled follow-ups may be necessary because of device alerts or patient condition.

In-clinic follow-up requires frequent patient displacements to the outpatient clinic and a significant workload for the team of healthcare workers.

7.4 PRINCIPLES OF REMOTE MONITORING

One of the expressed goals of introducing remote monitoring technology for ICDs is to reduce the number of in-clinic follow-ups needed. This might offer advantages because the number of ICD patients has been growing steadily and follow-up resources are limited, mainly in terms of personnel. Additionally, remote monitoring can be used to monitor system integrity, to alert on tachyarrhythmia episodes and potentially for remote disease management.

In this report we have often used the generic term of remote monitoring but it should be remembered that in practice this term covers very differenent concepts::

- remote monitoring (strictu sensu): transmission of device data on a regular (daily, weekly) basis with an automatic triage system allowing the physician to be informed on a regular basis of any pre-defined events;
- remote follow-up: transmission of device data at a pre-specified moment in order to replace an in-clinic follow-up or to prepare one;
- remote disease management: transmission of device data to remotely measure clinical parameters in order to warn about, prevent, anticipate or minimise a medical condition and/or to modulate the administration of therapy.

Depending upon the system used, transmission can occur automatically when episodes of arrhythmia are detected (device-initiated transmission), on a regular basis (daily or weekly monitor-initiated remote monitoring), or at pre-scheduled moments (physician-initiated remote follow-up) and in some cases even patient-initiated.

7.5 TECHNOLOGY OF REMOTE MONITORING

All ICDs and CRT-Ds can be interrogated and reprogrammed during an in-clinic visit using an magnetic inductive programming wand and most current devices also have the potential to be remotely monitored.

The earliest emanation of remote monitoring of implantable cardiac devices was the concept of Trans Telephonic Monitoring (TTM) introduced in the US in the early 1970s. The system consisted basically in extending the cable of the inductive programming wand over an analogue telephone line. At first, this allowed the pacemaker battery status to be checked remotely. In subsequent decades this concept gradually evolved offering more advanced device and lead system checking, including real-time basic IEGM and even reprogramming and pacing threshold testing. TTM was not or only scarcely adopted in Europe. However, in the USA and Canada it is still widely used. The major drawbacks of TTM are the need for patient compliance and the absence of device-initiated transmission triggered by events. Remote monitoring overcomes these deficiencies by offering both scheduled monitoring and device-initiated communication. However TTM allows for device reprogramming, which is currently not offered by remote monitoring.

In recent years, major ICD manufacturers started to offer remote monitoring systems that allow communicating data from the device remotely to the implanting physician and referring colleague physicians. In reality, the effective data transmission occurs in several steps. First, data from the device is communicated to a bedside or wearable mobile monitor in the patient's immediate vicinity. To this end, either an inductive programming wand or wireless radiofrequency technology is used. Depending upon the system used, remote data transmission can occur automatically when episodes of arrhythmia are detected (device-initiated transmission), on a regular basis (daily or weekly monitor-initiated remote monitoring), or at pre-scheduled moments (physician-initiated remote follow-up) and in some cases even patient-initiated.

Once this remote monitor has successfully interrogated the implanted device, the data is transmitted either over a mobile network or through an analogue or ISDN telephone land line to a central database server at a secured data centre. The treating physician(s) has access to the data of the devices under his guidance through a secured web application. This application may also aid with the organisation of the workflow at the follow-up clinic, for example by prioritising alerts through a triage system. The physician(s) can also be alerted about specific urgent events by e-mail, SMS, fax or phone messages. The triage system and the kind of events triggering alerts can be customised to a certain extent by the physician.

Remote monitoring technology is currently very much evolving and the practical implementation of remote monitoring of ICDs, such as the frequency of interrogation, the alerting procedures and the workflow organisation are very different between manufacturers. Therefore, systems cannot be compared to each other on a one to one basis. Some systems seem to be geared more to checking system integrity and arrhythmic alerting, whereas other systems appear to be more intended for remote disease management. Because of this diversity of implementations, the value of the systems, the real cost of the systems and the impact on the workload of provider and clinicians may turn out to be very different.

7.6 CLINICAL EFFECTIVENESS AND SAFETY

Being a rapid HTA, existing HTAs, systematic reviews and horizon scanning reports were searched first. The search was limited to the years 2006-2010 in order to ensure describing only current state of the art remote monitoring. Specific additional articles were retrieved and the EUnetHTA and INAHTA networks were queried for additional information.

Current evidence about the clinical efficacy, effectiveness, safety and patient acceptance of remote ICD monitoring is mainly based on small observational case series and expert opinion. Most clinical studies, both observational studies and occasional RCTs, were performed on relatively healthy patients with mild NYHA classification (mainly NYHA class II). Therefore, results from these studies cannot be directly extrapolated to severe heart failure patients who are more likely to need direct and personal clinical attention.

7.6.1 Events detected

In all studies that considered both clinical events and device integrity, the majority of alerts were for clinical events and only a small proportion (around 5%) was for device integrity alerts. Most evidence in literature, though, is available for the detection of this infrequently occurring device malfunctioning. This can indeed be detected earlier when remote monitoring is added to regular follow-up. There is also limited evidence that specific patient events (mainly arrhythmias and inappropriate arrhythmia detections) are diagnosed earlier when remote monitoring is added to regular follow-up. Given adequate alert triage, the workload for both technical nurses and clinicians in electrophysiology centres appears to be limited, even with daily transmissions of data.

7.6.2 Safety of replacing some in-clinic follow-up by remote follow-up or remote monitoring

There is limited evidence indicating the safe replacement of some of the in-clinic follow-up visits by scheduled remote follow-up or regular remote monitoring for ICD patients with no, or only mild symptoms. There is however no evidence to enable extending these findings to more symptomatic congestive heart failure patients.

7.6.3 Patient outcomes

Very little evidence was found on important health outcomes (mortality, general health, health related quality of life, adverse events). Evidence on quality of life is currently perplexing: the only RCT that reported on quality of life reported lower health-related quality of life for the remote monitoring group.. However, evidence on quality of life from this small trial is not solid and should be reassessed by larger and better studies.

Several major trials are ongoing implying that at least some of these conclusions may need to be revised in the future.

7.7 COST-EFFECTIVENESS

Due to the lack of clinical evidence, the economic literature is very inconclusive and the quality of the studies is low. The cost-effectiveness of remote monitoring for Belgium could not be investigated due to the lack of effectiveness data, the absence of cost data for the Belgian setting and a perceived general reluctance of care-givers to replace in-clinic follow-up by remote monitoring. By consequence, there is currently insufficient evidence to conclude on the cost-effectiveness and on the potential financial impact for the Belgian health care payer.

7.8 LEGAL ASPECTS

A wide range of legal issues such as the duty of professional secrecy and security aspects, professional and product liability, patients' rights, etc… are conditioning the implementation and successful functioning of a remote monitoring system, be it for ICDs or any other medical device alike.

There currently exists no regulatory framework specifically dealing with the issue of remote monitoring specifically. Both the EU and the local Belgian legal framework applicable to remote monitoring in general were investigated.

7.8.1 Relevant EU legislation

Although EU legislation does not address specifically eHealth systems and services, several Directives have a direct impact on telemonitoring applications.

- Processing of personal (health) data is mainly governed by the European Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
- In the domain of liability, regulations are available in a fragmented way: objective liability of the producer of a defective product, liability of the data controller, liability of information system provider, etc… There is, however, no harmonised liability regime for professional liability for damage caused by healthcare services.
- Dispositions with regard to transparency and identification of suppliers, service providers and other consumers' (patients) protection rules for e-services are provided in several Directives.

7.8.2 Duties, rights and responabilities of data controller, data processor and data subject

A number of duties, rights and responsibilities linked to the different roles (data controller, data processor, data subject) of intermediaries in the remote monitoring application are defined in EU data protection legislation and implemented in Belgian legislation (issued on 8 December 1992, hereinafter called as the Data Protection Law, DPL). The data controller must ensure that all obligations included in the DPL are respected. Prior to any data processing, the data controller needs to file a notification to the Belgian Privacy Commission, and must communicate several information elements to the patient, including the purpose(s) of the processing and the recipient(s) of the data. A contract between the parties involved, clarifying and defining their respective roles and responsibilities, is thus of an utmost importance.

Persons accessing the personal health data need to be bound by a duty of professional secrecy or an equivalent contractual obligation. Both the data controller and the data processor have the obligation to take appropriate technical and organisational data protection measures against accidental or unlawful destruction, accidental loss, modification or unauthorised access or any other non authorised processing.

As for all health data, health data collected within the telemonitoring application can be shared between the treating physician, his/her (para)medical team and the referring physician if the addressee is also bound by the duty of professional secrecy, if the sharing of the confidential information is necessary to ensure continuity and quality of care and if the patient has given his explicit or tacit consent, or if the disclosure is at least in his/her best interest. The necessity of the intervention of ICT staff and other experts in the treatment of personal data of the patient requires considering them as "collaborators" of the health care professionals bound by the same confidentiality rules.

7.8.3 Patient rights and duties

The Belgian Patient's Rights Law (issued on 22 August 2002) defines several patients rights that have a direct impact on the telemonitoring application.

7.8.3.1 Informed consent

Patients should receive all adapted and relevant information they need on the telemonitoring as a medical intervention and on the processing of their personal health data. The information given to the patient should include amongst others the identity of the different parties involved in the telemonitoring trajectory as well as their roles and responsibilities and the limitations and modalities of the telemonitoring system. Moreover, the patient should be informed on the fact that the service is currently not reimbursed and that it is not an emergency service.

It is unclear whether the physician would be legally obliged to inform the patient about the possibility of remote monitoring as an alternative or additional method of follow-up since there is no sound evidence on the clinical effectiveness.

For the telemonitoring application an integrated approach using a written consent containing information elements regarding data processing as well as the information linked to the telemonitoring as medical intervention is preferable.

7.8.3.2 Right to data access

The patient has a right of direct access to his or her own file including the data (or the derived results) revealed by the telemonitoring. He or she can request a copy of it, but has also the right to request correction or destruction of the data and the right to object to processing.

7.8.3.3 Right to freely choose a healthcare professional

Although patients can in principle freely choose a healthcare professional, in case of telemonitoring, however, this will not always be possible for the preview of the transmitted data or during on-guard duty.

7.8.3.4 Patient collaboration

The physicians need to respect the patient's rights as far as the patient collaborates in the patient-physician relationship.

7.8.4 Liability issues

7.8.4.1 Telemonitoring, not considered as the standard of care (yet)

As of today, there is no sufficient evidence on the clinical effectiveness of telemonitoring to consider it as the standard of care for the follow-up management of chronic patients suffering from heart diseases. Yet, in order to prevent defensive behaviour by physicians fearing liability, guidelines should be elaborated for physicians on how to deal with this emerging technology. The Belgian no-fault system does not solve the problems regarding the evaluation of the physicians' liability.

7.8.4.2 Contractual clauses and emergency systems

Contractual clauses stating that telemonitoring and alerts systems cannot be considered to be emergency systems even if they do function as emergency systems should be analysed with caution. Guidelines and corresponding service level agreements regarding the maximum response time for alerts and protocols regarding the assurance of continuity (who should organise the guards, status of the physician during on-guard time,…) are necessary to enhance medical and legal certainty for patients and physicians.

7.8.4.3 Industry Employed Allied Professionals

Industry Employed Allied Professionals (IEAPs) are professionals that are employed by industry with the aim to give technical council to the health professionals. IEAPs are legally authorised to provide technical expertise and advice regarding medical devices, but if they perform (technical) nursing activities, they could be sanctioned with fines and imprisonment. If a company systematically puts IEAPs at the disposal of physicians for free for assistance during surgery or during follow-up this could be considered as illegal according to the Belgian law on Pharmaceuticals.

7.8.4.4 Centralisation of liability

As telemonitoring implies the involvement of many players, particularly outside the hospital, the centralisation of liability at the hospital does not offer a proper solution.

7.8.4.5 Product liability

A producer is liable for damages caused by a defective product (for instance the decision-supporting software, the implanted device, the bedside monitor,...) as far as the affected party proves the existence of the product and the causal relation between the flaw in the product and the incurred damage. The affected person does not have to prove the producer's fault.

7.9 ORGANISATIONAL AND FINANCIAL ASPECTS OF REMOTE MONITORING OF ICD AND OTHER MEDICAL DEVICES

To date, no specific regulatory framework exists for remote monitoring in Belgium. Neither the telemonitoring equipment and supporting data processing services nor the remote follow-up or monitoring by local physicians are reimbursed by the compulsory health insurance. Companies mostly provide the service for free as part of their marketing policy for selling ICDs, but the systematic provision of this service for free might be illegal.

Some countries reimburse remote follow-up in the same way as in-clinic follow-up, but the monitoring equipment and supporting services are currently not reimbursed in most European countries.

Whenever reimbursement would be considered, remote follow-up (at scheduled moments) should be distinguished from remote monitoring (continuous or more regular transmission with a triage system), as the workload for physicians and allied personnel could be quite different.

In the case that alert systems with triage are used, timely reaction is mandatory. Since the number of alerts per day is rather limited, rotating on-guard systems between colleagues of the same specialty can be considered. The workload for the physician or other clinical personnel involved in telemonitoring depends on the frequency of data reviewing. Either dedicated time for the involved personnel or the centralisation of data triage within a specialised centre (external or outsourced) are possible options to manage the workload.

The currently available systems and web applications differ significantly between manufacturers, which constitutes an important barrier for the implementation of remote monitoring, since most centres implant devices of more than one manufacturer. Furthermore, direct communication of the monitoring data to the centre's electronic health record system would be highly desirable.

7.10 DISCUSSION AND CONCLUSIONS

Remote monitoring of ICDs and other devices seems promising and attractive in theory, and the field is currently in constant evolution, with different approaches and solutions depending on the suppliers. There is currently very little evidence on direct patient benefits although the partial replacement of the in-clinic follow-up by remote monitoring seems reasonably safe in ICD patients with no, or only mild symptoms.

Whether this is also feasible and safe in the Belgian context is not yet clearly established, and will undoubtedly depend on the organisational and financial framework that will be provided, and the availability of sufficiently detailed guidelines that orient clinicians to deal with this emerging technology.

A variety of new applications of remote monitoring will undoubtedly emerge in the near future. According to expert opinion these will relate to different medical domains including obviously cardiac monitoring, but also diabetes care, elderly care, remote monitoring of pregnancies at risk etc… The legal and organisational hurdles that are identified in this report need to be addressed. Hence, specific juridical guidance for the interpretation and application of the relevant legislation should be developed. Doing so, would prepare the healthcare system to deal in an effective manner with this emerging technology.

As long as benefits for the patient or the healthcare system are not clearly demonstrated, regular reimbursement for remote monitoring should remain out of scope. Even conditional reimbursement of remote monitoring irrespective of the medical application, should only be considered once there are sufficient indications of efficacy and safety, and needs imperatively to be accompanied by a system of additional pre-defined evidence gathering. This could be integrated in a convention between the NIHDI (RIZIV/INAMI) and the centre performing the regular follow-up and/or the remote monitoring or remote follow-up. More in general, dissemination of an unproven, and, hence, even potentially inferior or harmful technology paid by the patient, private insurance or provided for free by the company, without due data collection and timely evaluation, seems hard to justify from an ethical point of view.

With the arrival of remote monitoring, the need to develop new financing mechanisms becomes evident. These should not only cover care delivered at one specific moment and place, but also patient care and monitoring that occur remotely and over longer time periods.

8 APPENDICES

8.1 GLOSSARY OF CLINICAL TERMINOLOGY

Arrhytmia	Any deviation from the normal heart rhythm, either in presence, rate, regularity, impulse origin and/or sequence of activation.
Atrial Fibrillation (AF)	An arrhythmia in which minute areas of the atrial myocardium are in various uncoordinated stages of depolarisation and repolarisation. Instead of intermittently contracting, the atria quiver continuously in a chaotic pattern, causing a totally irregular, often rapid ventricular rate.
Atrial Flutter (AFL)	An arrhythmia in which the atrial contractions are rapid (250 to 350bpm), but regular. The ventricles are unable to respond to each atrial impulse, so that at least a partial atrioventricular block develops with a rate of approximately 150bpm.
Atrial Tachycardia (AT)	A rapid cardiac rate, usually between 160 and 190bpm, originating from an atrial locus. It may result from impulse reentry or enhanced automaticiy.
Beats per minute (bpm)	A unit for heart rate, either atrial or ventricular.
Burden of atrial fibrillation	The percentage of time spent with (paroxysmal) atrial fibrillation between two consecutive follow-ups
Follow-up	A reoccurring examination of an implanted device and its patient, which comprises: checking and testing of the system integrity, interrogation of the device for recorded arrhythmias and inappropriately detections, clinical investigation of the patient, possible reprogramming of the device and/or a change in the patient's medication based on these findings, referring of the patient for diagnosis and therapy to other medical speciality disciplines, providing health, life-style and revalidation recommendations, counselling, determining fitness for work and driving, etc..
Paroxysmal	Recurring suddenly and disappearing spontaneously, e.g. paroxysmal AF.
Persistant	Recurring suddenly but not disappearing spontaneously without therapy; e.g. persistant AF.

Permanent	Recurring as soon as terminated by therapy; e.g. permanent AF.
Primary prevention	The delivery of a therapy in prevention of a first occurrence of a specific condition (cardiac arrest in the case of ICDs).
Prophylactic	By means of primary prevention. (See primary prevention)
Secondary prevention	The delivery of a therapy in prevention of a reoccurrence of a specific condition (cardiac arrest that was successfully resuscitated in the case of ICDs).
Sensing	The measurement of electrical signals between two electrodes.
Sudden Cardiac Arrest (SCA)	The unexpected cessation of normal circulation of the blood due to failure of the heart to contract effectively.
Sudden Cardiac Death (SCD)	A natural death due to cardiac causes, heralded by an abrupt loss of consciousness within one hour of the onset of acute symptoms, very often caused by ventricular fibrillation.
Supra-Ventricular Tachycardia (SVT)	Any tachycardia of which the origin is located above the bundle branches, i. e. either in the sinus node, atria, or atrioventricular junction. It may also include those arising from large reentrant circuits encompassing both atrial and ventricular pathways.
Surface Electrocardiogram (ECG)	A graphic tracing of the variations in electrical potential caused by the excitation of the heart muscle and detected at the body surface.
Tachycardia	Excessive rapidity in the action of the heart, often further specified by the locus of origin.
Ventricular Fibrillation (VF)	A very rapid and irregular heart rhythm caused by abnormal impulses originating from different locations of the ventricle. The heart beats too fast to effectively pump a sufficient amount of oxygenated blood to the organs. With VF, the heart rate may be in excess of 300bpm. In absence of immediate medical treatment, a VF is mortal. Defibrillation is the only available treatment for VF.
Ventricular Tachycardia (VT)	An abnormally rapid, though regular, ventricular heart rhythm with a rate between 160 and 240bpm and aberrant ventricular complexes (wide QRS complexes), originating in the ventricle and most commonly associated with atrioventricular dissociation. Evidence implicates a reentrant pathway as the common cause.

8.2 GLOSSARY OF DEVICE TERMINOLOGY

Anti-Tachycardia Pacing (ATP)	An ICD-therapy consisting in delivering a series of critically timed pacing pulses in an attempt to terminate a reentrant monomorphic ventricular tachycardia.
Automated External Defibrillator (AED)	A portable electronic device, designed for layman use and capable of automatically diagnosing ventricular tachycardia (VT) as well as ventricular fibrillation (VF), and delivering treatment through defibrillation.
Automatic pacing capture	A pacing technology that allows to measure beat-to-beat the effectiveness of a delivered pacing impulse and automatically adapt the pacing amplitude (or pulse width) to slightly above the pacing treshold. As such, it allows to automatically measure the pacing treshold.
Biventricular ICD	An implantable cardioverter defibrillator capable of sensing and pacing in the right atrium as well as both the right and left ventricle (and therefore also called triple-chamber ICD). This defibrillator type is indicated for the prevention of sudden cardiac arrest due to ventricular fibrillation in a selected group of heart failure patients.
Biventricular pacemaker	A pacemaker capable of sensing and pacing in the right atrium as well as both the right and left ventricle. This pacemaker type is indicated in a selected group of heart failure patients for whom prevention of sudden cardiac arrest is not desired.
Cardiac Resynchronisation Therapy (CRT)	A pacemaker therapy aiming at restoring the synchronous contraction of both ventricles lost due to heart failure through stimulation of both ventricles.
Cardiac Resynchronisation Therapy with Defibrillator (CRT-D)	Term used to indicate the therapy delivered by a biventricular ICD or to indicate the device itself.
Cardiac Resynchronisation Therapy with Pacemaker (CRT-P)	The therapy delivered by a biventricular pacemaker.
Cardiovascular Implantable Electronic Device (CIED)	A grouping term used to jointly denominate pacemakers, ICDs, CRT-Ds, implantable loop recorders and pressure monitors.
Cardioversion	A therapy consisting in applying a low- to medium-energy electric shock in order to terminate a tachyarrhytmia, either ventricular or atrial.
Defibrillation	A therapy consisting in applying a high-energy shock in order to terminate a life-threatening ventricular tachyarrhytmia, very often ventricular fibrillation.

Detection of tachyarrhtyhmia	An ICD detects a tachyarrhythmia by sensing a minimum number of fast beats within a row of consecutively sensed heart beats. Fast beats are defined by the detecion window.
Detection window	One or more ranges of time intervals between two consecutive heart beats that define the latter beat as fast. Usually, the detection window needs to remain satisfied for a minimum proportion of consecutive beats, a certain amount of time and a number of optional descrimination enhancements in order to start a corresponding series of progressively programmed therapy deliveries with intermediate redetections.
Discrimination enhancements	A set of additional algorithms and parameters with the purpose to enhance the correct distinction between supraventricular tachycardia (i.e. atrial and sinus tachcardia) on one hand and (polymorphic) ventricular tachycardia on the other hand.
Dual-chamber ICD	An implantable cardioverter defibrillator capable of sensing and pacing in both the right ventricle and atrium. This defibrillator type is often indicated for the prevention of sudden cardiac arrest due to ventricular fibrillation when enhanced discrimination from supraventricular tachyarrhythmias is deemed necessary.
End Of Life (EOL)	The CIED no longer guarantees the availabilty of all therapies. For an ICD, this may be due to battery depletion and/or capacitor degradation.
Elective Replacement Indicator (ERI)	An indication that the CIED needs replacement, 3 to 1 months in advance of the end of life (EOL) of the device.
Electrogram (EGM)	The recording of the amplitude of electrical potentials measured between two intracardial electrodes or one intracardial elactrode and the CIED can, plotted as a function of time.
Episode	A recording of all events from the time a tachyarrhythmia is intially detected to the termination of the tachyarrhythmia.
Firmware	The fixed, usually rather small, programs and/or data structures that internally control various electronic devices. The firmware of many electronic devices can often be upgraded, through a procedure called EEPROM flashing. This procedure is not without risk and is therefore often obfuscated from the end-user. A failure in the flashing procedure usually "bricks" the device, rendering it unfunctional. Should this happen, only a specially trained electronics expert may salvage the device by opening the device and desoldering the EEPROM for external programming.

Operational mode status	An ICD can be programmed into one of the following operational modes: monitor & therapy, monitor only, electrocautery safe and off. Operational mode programming is normally performed using the programmer of the ICD brand. However, in absence of, applying the field of a large permanent magnet immediately over the ICD for a brand-specific amount of time will achieve the same by actuating a reed switch in the ICD. Changing the operational mode of an ICD should not be confounded with the mode switching in pacing therapy.
Implantable Cardioverter/Defibrillator (ICD)	A cardiovascular implantable device capable of detecting and terminating ventricular tachycardia (VT) and ventricular fibrillation (VF) through high-energy electric shocks, low-energy cardioversion and antitachycardia pacing (ATP). All ICDs are also capable of delivering single- and some models optionally, dual or triple chamber bradycardia (pacing) therapy when necessary. ICDs offering additional tachycardia therapies for atrial tachyarrhythmia do also exist.
Implantable Loop Recorder (ILR)	A small leadless CIED which is implanted subcutaneously and usually inferior to the left collar bone in vicinity of the heart. With a battery autonomy of up to two years, the device offers the ability to record the electrical activity of the heart in stored episodes of rhythm disturbances satisfying a number of preset parameters. However, patients also have the option to trigger episode recording by placing an activator over the device and pushing a button. It is employed to determine whether rare spontaeous syncopes are of arrhythmic origin in patients that are asymptomatic at the time of clinical evaluation.
Inappropriate detection/therapy	An ICD may incorrectly detect a supraventricular tachyarrhythmia, T-wave repolarisations, non-cardiac myopotentials, an intermittent lead defect or electromagnetic interference as a tachyarrhytmia of ventricular origin. If the detection persist through the duration of the detection window, the ICD will charge its output capacitor and after detecion reconfirmation deliver a painful, unnecessary and therefore energy-waisting defibrillation shock. Reprogramming the available detection enhancements of the ICD may remediate this problem.
Insertable Cardiac Monitor (ICM)	See: Implantable Loop Recorder (ILM)
Intracardial Electrogram (IEGM)	An electrogram where the recorded electrical potential is measured between two electrodes inside the heart. (See also Electrogram.)

Inductive programming wand	An encapsulated electrically conductive and tuned coil that, connected to a programmer, is used to interrogate and program a CIED. The physical communication consists in a low-frequency modulated alternating magnetic field of the wand's coil coupling inductively with a tuned coil in the CIED when placed in its immediate proximity, i.e. on the patient's skin immediately above the CIED.
Industry-Employed Allied Professional (IEAP)	A representative of the CIED's manufacturer, who's role it is to provide technical expertise on the implant on order and under direct or incident physician supervision at close proximity.
Operational mode	An ICD can be programmed into one of the following operational modes: monitor & therapy, monitor only, electrocautery safe and off. Operational mode programming is normally performed using the programmer of the ICD brand. However, in absence of, applying the field of a large permanent magnet immediately over the ICD for a brand-specific amount of time will achieve the same by actuating a reed switch in the ICD. Changing the operational mode of an ICD should not be confounded with the mode switching in pacing therapy.
Pacemaker (PM) or artificial pacemaker	A cardiovascular implantable device capable of detecting heart beats and, in absence of the latter, stimulating one or more heart chambers by delivering electrical impulses through one or more electrodes in contact with the heart muscle. The primary purpose of a pacemaker is to maintain an adequate heart rate, either because the heart's native pacemaker is not fast enough, or there is a block in the heart's electrical conduction system.
Pacing treshold testing	For a given pacing pulse width, determination of the minimum pacing voltage, or conversely, for a given pacing pulse amplitude, determination of the minimum pacing pulse width that still results in an effective contraction of the paced heart chamber.
Rhythm discrimination	See: Discrimination enhancements.
Sensing	The measurement of electrical signals between two electrodes.
Sensitivity of an ICD	The minimum voltage amplitude of IEGM signals still resulting in the correct detection of all tachyarrhythmias. The term may also refer to the programmed sensitivy setting of the ICD. In that sense, testing of the ICD during the implantation procedure is usually performed with least sensitivity, i.e. the greatest sensitivity voltage setting.

Single-chamber ICD	An implantable cardioverter defibrillator capable of sensing and pacing only the right ventricle. This defibrillator type is often employed as a first device choice for the primary prevention of sudden cardiac arrest due to ventricular fibrillation when discrimination from supraventricular tachyarrhythmias is not deemed expected to occur.
Specificity of an ICD	The proportion of all detected tachyarrhythmia that the ICD correctly identifies as being of ventricular origin. This is normally tested in a laboratory setup against a database of tacharrhythmia.
Therapy	Therapy administered by the device: either various modes of low-energy bradycardia, resynchronisation or anti-tachycardia pacing over one or more of the pacing leads, or a high energy electric shock over one or more shocking electrodes and the device can.
Triple-chamber ICD	See biventricular ICD.
Ventricular Electrogram (VEGM)	An electrogram where the recorded electrical potential is measured between the tip and ring of a ventricular lead, or between a tip or ring of a ventricular lead and the CIED can. (See also Electrogram, CIED.)

8.3 GLOSSARY OF REMOTE MONITORING TERMINOLOGY

Alert triage	Severeness prioritisation of alerts in the web application by means of visual indicators.
Alert urging	The more expedient transmission of alerts (system integrity and arrhythmia episode alerts in particular) through device-initiated communication. Alert urging CIEDs will attempt to transmit the raised alert(s) as soon as they are within reach of a/their monitor.
Bedside monitor	A monitor (see below) intended for stationary use. It cannot be worn on the patient, however, it may or may not be taken on travel.
Bluetooth	An open wireless technology standard for exchanging data over short distances between fixed and mobile devices, creating personal area networks (PANs) with high levels of security. Bluetooth uses a radio technology called frequency-hopping spread spectrum, which chops up the data being sent and transmits chunks of it on up to 79 bands of 1MHz width in the range 2402-2480MHz. This is in the globally unlicensed Industrial, Scientific and Medical (ISM) 2.4GHz short-range radio frequency band. In classic Bluetooth, which is also referred to as basic rate (BR) mode, the modulation is Gaussian frequency-shift keying (GFSK). It can achieve a gross data rate of 1Mbps. In extended data rate (EDR) π/4 differential quadrature PSK (DQPSK) and 8 differential PSK (DPSK) are used, giving 2, and 3Mbps respectively. Bluetooth is a packet-based protocol with a master-slave structure. One master may communicate with up to 7 slaves in a piconet.
Clinical alert	An episode or trend alert.
Data centre	The protected physcial location of server systems for the data storage and the generation of web application pages. It is considered a good practice to have the data centre mirrored at a geographically distinct location for the purpose of disaster recovery. Data centres can be managed by the CIED manufacturer, a subcontractor or a completely independent company.

Device follow-up	The interrogation and testing of the implanted device for system integrity subsequent to the implantation or previous follow-ups. The system integrity data for ICDs consists of operational mode, battery status and voltage, and the date and charge time of the last capacitor re-formation. System integrity testing consist in measuring the intrinsic amplitudes on all sensing channels, and very rarely, under sedation, the measurement of the high-voltage shocking impedance.
Device-initiated communication	An instance where the device takes the initiative to start a communication session with the monitor. This is indepent of which apparatus initiated the communcation channel at the lower transport layer.
Equivalent Isotropically Radiated Power (EIRP)	The amount of power that a theoretical isotropic antenna (one that evenly distributes power in all directions) would need to emit in order to produce the same maximum power density as observed in the direction of the actual maximum antenna gain. EIRP takes into account the losses in transmission lines, connectors and includes the gain (or loss) of the antenna in its surrouding medium.
Episode alert	An alert raised at the occurrence of a tachyarrythmia episode. See also "episode" in hte glossary of device terminology
Event	The occurrence of either a system integrity or arrhythmia alert.
Federal Communcations Commission (FCC)	The United States of America telecommunications regulator.
Frequency Shift Keying (FSK)	A digital modulation scheme that conveys data by changing, or modulating, the frequency of the carrier signal.
General Packet Radio Service (GPRS)	A packet oriented mobile data service available to users of the 2G cellular communication systems global system for mobile communications (GSM), as well as in the 3G systems. In 2G systems, GPRS provides data rates of 56-114 kbit/s. GPRS data transfer is typically charged per megabyte of traffic transferred, while data communication via traditional circuit switching is billed per minute of connection time, independently of whether data is actually transferred or not. 2G cellular systems combined with GPRS are often described as 2.5G, that is, a technology between the second (2G) and third (3G) generations of mobile telephony.

High-Speed Downlink Packet Access (HSDPA)	An enhanced 3.5G mobile telephony communications protocol in the High-Speed Packet Access (HSPA) family that allows networks based on Universal Mobile Telecommunications System (UMTS) to have higher data transfer speeds and capacity. Current HSDPA deployments support down-link speeds of 1.8, 3.6, 7.2 and 14.0Mbit/s.
High Speed Packet Access (HSPA)	A collection of two mobile telephony protocols, High Speed Downlink Packet Access (HSDPA) and High Speed Uplink Packet Access (HSUPA), that extends and improves the performance of existing UMTS protocols. A further standard, Evolved HSPA (also known as HSPA+), was released late in 2008 with subsequent adoption worldwide into 2010.
High-Speed Uplink Packet Access (HSUPA)	A 3.5G mobile telephony protocol in the HSPA family with up-link speeds up to 5.76 Mbit/s.
Hypertext Transfer Protocol Secure (HTTPS)	A combination of the Hypertext Transfer Protocol with the SSL/TLS protocol to provide encryption and secure identification of a website server. HTTPS connections are often used for sensitive transactions on the World-Wide Web. HTTPS should not be confused with Secure HTTP (S-HTTP).
Inductive programming wand	An encapsulated electrically conductive and tuned coil that, connected to a programmer, is used to interrogate and program a CIED. The physical communication consists in a low-frequency modulated alternating magnetic field of the wand's coil coupling inductively with a tuned coil in the CIED when placed in its immediate proximity, i.e. on the patient's skin immediately above the CIED.
Industrial, Scientific and Medical (ISM) radio bands	A pool of radio bands originally reserved internationally for the use of RF electromagnetic fields for industrial, scientific and medical purposes other than communications. In general, communications equipment must accept any interference generated by possibly more powerful ISM equipment. For the purpose of remote monitoring, only the company Boston Scientific utilises the 914MHz carrier frequency in the 902-928MHz ISM band, which is available only in ITU region 2.
Integrated Services Digital Network (ISDN)	A set of communications standards for simultaneous digital transmission of voice, video, data, and other network services over the traditional circuits of the public switched telephone network

International Telecommunication Union (ITU) region	The International Telecommunication Union (ITU) divides the world into three ITU regions for the purpose of managing international radio spectrum allocations. Region 1 comprises Europe, Africa, the Middle East west of the Persian Gulf including Iraq, the former Soviet Union and Mongolia. Region 2 covers the Americas, Greenland and some of the eastern Pacific Islands. Region 3 contains most of non-former-Soviet-Union Asia, east of and including Iran, and most of Oceania.
Medical Device Radiocommunications Service (MedRadio)	An ultra-low power, unlicensed, mobile radio service for transmitting data in support of diagnostic or therapeutic functions associated with implanted and body-worn medical devices. MedRadio permits individuals and medical practitioners to utilise ultra-low power medical implant devices, such as cardiac pacemakers and glucose monitoring devices. In the USA, the FCC allocated the band segment from 401 to 405MHz for this service.
Medical Implant Communications Service (MICS)	A radio frequency technology for communication with implanted medical devices which uses 10 radio channels allocated in the spectrum between 402 and 405MHz. In Europe, MICS is described in ETSI EN 301 839-1, whereas in the USA, MICS foms a subband of the MedRadio service as defined by the FCC. Australia has also allocated this band for MICS.
Mobile monitor	See: wearable monitor. Take note that "mobile" does not refer to the communication channel used to contact the data centre.
Monitor	Electronic external device at the patient's premises capable of automatically and at regular intervals interrogating a CIED and transmitting the data through a telephone network to the data centre of the CIED manufacturer.
Monitor-initiated communication	Periodic, usually daily, interrogation of the attributed CIED for transmission to the data centre and eventually generating trend report. For systems without alert urging, this is the only communication mode by which alerts are generated.
Open Systems Interconnection model (OSI model)	A way of sub-dividing a communications system into smaller parts called layers. A layer is a collection of conceptually similar functions that provide services to instances of the layer above it and receives services from instances of the layer below it. The OSI model defines seven layers being: physical layer, data link layer, network layer, transport layer, session layer, presentation layer and application layer.

Patient-initiated communication	An instance where a patient at the touch of a button takes the initiative to start a communication session between the device and the monitor.
Phase Shift Keying (PSK)	A digital modulation scheme that conveys data by changing, or modulating, the phase of the carrier signal.
Physician notification	The means by which the physicians and/or their nursing-technician staff responsible for the follow-up of a CIED are notified about system integrety, episode and trend alerts
Physician-initiated communication	An instance where the physician uses the web application to order a communication session between the device and the monitor. This order may be programmed to take place in the future.
Plain Old Telephone System (POTS)	Analogue landline telephone system
Programmer	A dedicated portable computer used to interrogate and program CIEDs of the same brand.
Radio Frequency (RF)	Denominating the use (usually for communication purposes) of electromagnetically propagating waves with a frequency of 3kHz to 300GHz.
Radio Frequency IDentification (RFID)	The use of a tag comprising an integrated circuit and antenna, which is applied to or incorporated into a product, animal, or person for the purpose of identification and tracking using radio waves. Some tags can be read from several meters away and beyond the line of sight of the reader.
Remote disease mangement	The application of remote monitoring technology to remotely measure clinical parameters in order to warn about, prevent, anticipate or minimise a medical condition and/or to modulate the administration of a medical therapy.
Remote follow-up	Transmission of CIED data at a pre-specified moment in order to avoid either a in-clinic follow-up, or to prepare for one
Remote monitoring	Daily, weekly or two-weekly interrogation of a CIED at the patient's location for transmission to a data centre. This includes the transmission of system integrity and episode alerts.
Secure Sockets Layer (SSL) Certificate	A cryptographic protocol component that is issued by a trusted authority to provide secure communications over networks such as the Internet.

Server	One or more computer systems at the data centre that handle the data storage and the generation of web application pages.
Small Messaging System (SMS)	Basic 168-character texting service of the GSM mobile telephone network.
System integrity alert	All alerts concerning the CIED and lead system. This includes alerts for ICD mode status, ERI, EOL, capacitor charge time, lead impedances, undersensing and, when available pacing treshold increases.
TErrestrial Trunked RAdio (TETRA)	A specialist professional mobile radio and two-way transceiver (colloquially known as a walkie talkie) specification. TETRA was specifically designed for use by government agencies, emergency services (police forces, fire departments, ambulance), rail transportation staff, transport services and the military. TETRA is an ETSI standard endorsed by the European Radio Communications Committee (ERC) and mandated for use in Europe. Depending on each country one or more TETRA bands are allocated in the frequency ranges of 380-470MHz and 870-921MHz.
Trans-Telephonic Monitoring (TTM)	The technology of extending the inductive programming wand and surface electrocardiogram leads over an analogue telephone line in order to conduce a remote follow-up procedure.
Trend alert	An alert raised when a clinical value progresses outside a predetermined range.
Triage	(See alert triage.)
Universal Mobile Telecommunications System (UMTS)	One of the third-generation (3G) mobile telecommunications technologies. The name UMTS, introduced by ETSI, is usually used in Europe. Outside of Europe, the system is also known by other names such as FOMA or W-CDMA. In marketing, it is often just referred to as 3G. UMTS requires new base stations and new frequency allocations. However, it is closely related to GSM/EDGE as it borrows and builds upon concepts from GSM. Further, most UMTS handsets also support GSM, allowing seamless dual-mode operation.
Wearable monitor	The monitor can be worn on the patient.
Web application	A system software application that is accessed over a network such as the Internet or an intranet. Web applications are popular due to the ubiquity of web browsers, and the convenience of using a web browser as a client, sometimes called a thin client. The ability to update and maintain web applications without distributing and installing software on potentially thousands of client computers is a key reason for their popularity, as is the inherent support for cross-platform compatibility.

WiFi	A trademark of the Wi-Fi Alliance that manufacturers use to brand certified products that are wireless local area network (WLAN) devices for computer communication in the 2.4, 3.6 and 5GHz frequency bands based on the IEEE 802.11 standards.
Workflow	The scheduling, documenting, reviewing, response to, archiving and retrieval of follow-up procedures, both in-clinic and remote.
ZigBee	A specification for a suite of wireless communication protocols using small, low-power digital radios based on the IEEE 802.15.4-2003 standard for wireless home area networks (WHANs), such as wireless light switches with lamps, electrical meters with in-home-displays and other consumer electronics equipment. It is intended to be simpler and less expensive than other WPANs, such as Bluetooth. ZigBee is targeted at applications that require a low data rate, long battery life, and secure networking. This standard specifies operation in the unlicensed 2.4GHz (worldwide), 915MHz (Americas) and 868MHz (Europe) ISM bands.

8.4 APPENDIX FOR THE CHAPTER ON DESCRIPTION OF TECHNOLOGY

Table 8: Adoption of the systems

	System			
	Biotronik	**Medtronic**	**St. Jude Medical**	**Boston Scientific**
System	Home Monitoring®	CareLink®	Merlin.net™ Patient Care Network (PCN)	Latitude® Patient Management System
first introduction				
USA	2001	2002	2004	2004
EU	2003	2005	2008	2009
Belgium	not disclosed	2007	2009	2009
devices on-line (worldwide)	not disclosed	> 530 000	not disclosed	> 132 800
USA	not disclosed	> 490 000	not disclosed	> 130 000
EU	not disclosed	> 34 000	not disclosed	> 2800
Belgium	not disclosed	> 600	not disclosed	> 25
clinics (worldwide)	> 3000	> 4150	not disclosed	> 2700
USA	not disclosed	> 3100	not disclosed	> 2400
EU	not disclosed	> 735	not disclosed	300
Belgium	not disclosed	23	not disclosed	5
countries	> 50	30	not disclosed	16
data transmissions (worldwide)	> 10 000 000	> 3 000 000	not disclosed	> 15 600 000
FDA approval for follow-up replacement & early detection	2009	no	no	no

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Table 9: Data centre locations and data handling roles

	System			
	Biotronik	**Medtronic**	**St. Jude Medical**	**Boston Scientific**
System	Home Monitoring®	CareLink®	Merlin.net™ Patient Care Network (PCN)	Latitude® Patient Management System
Data centres				
location				
for EU patient data	Berlin (DE)	UK	Sweden (SE) & Sylmar, California (USA)	Amsterdam (NL) & Greater London (UK)
patient informed consent				
allows data processing in the USA	no	no	yes	yes
roles				
data controllers	Biotronik Germany & implanting centre	physician, follow-up clinic or implanting centre	physician & follow-up clinic	Guidant Europe nv/sa & implanting centre
data processors	Biotronik Germany, implanting centre & outsourced data centre	Medtronic	Pacesetter, Inc. acting under the name of St. Jude Medical CRMD	Guidant Europe nv/sa, implanting centre & outsourced data centres
international standards compliance				
information security management system	ISO-IEC 27001:2005	ISO-IEC 27001:2005 & 27002:2005	ISO-IEC 27001:2005	ISO-IEC 27001:2005 & 27002:2005
information technology security evaluation				ISO-IEC 15408:1999

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Table 10: Communication between the data centre and the physician

	System			
	Biotronik	**Medtronic**	**St. Jude Medical**	**Boston Scientific**
System	Home Monitoring®	CareLink®	Merlin.net™ Patient Care Network (PCN)	Latitude®
Data centre - physician communication				
web-application	yes	yes	yes	yes
e-mail	alert notification	alert notification	alert notification	no
SMS	alert notification	alert notification	alert notification	no
fax	alert notification	no	alert notification	yellow alert notification only
telephone	no	no	no	red alert notification only by call-centre
data exchange formats				
proprietary to ICD-manufacturer	none	Medtronic PaceArt®, in the USA only	none	yes, Medtronic PaceArt®
XML	planned for Oct. 2010	no	yes	no
CEN ISO/IEEE 11073	planned for Oct. 2010	no	yes	no
Health Level 7® (HL7)	experimentally in some centres	no	yes	yes, HL7 version 2.x
custom-made interface to proprietary electronic health record	experimentally in some centres	no	yes, EHRDirect™	no

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Table 11: Web application security

	System			
	Biotronik	**Medtronic**	**St. Jude Medical**	**Boston Scientific**
System	Home Monitoring®	CareLink®	Merlin.net™ Patient Care Network (PCN)	Latitude®
Security				
web application				
HTTPS	yes	yes	yes	yes
trusted authority for issuing SSL web server certificate	Thawte Consulting cc	Equifax	Equifax	VeriSign Trust Network
location of SSL web server certificate issuer	Cape Town (ZA)	USA	USA	not disclosed in SSL certificate (headquarters: Dulles, Virginia, USA)
password protection	yes	yes	yes	yes
browser-independent web design	yes	yes	no, designed for Internet Explorer version 7	yes
user accounts				
administrator account per implanting centre	yes	no, managed by Medtronic	yes	yes
multiple user accounts per implanting centre	yes	yes	yes	yes
user accounts for referring physicians with limited permissions	yes	yes	no, only on demand	yes
user accounts for assistants, deligates and allied professionals	no	no	yes	yes
permissions				
user permissions per patient (CIED serial number)	no	no	yes	no, only in the USA
user permissions per group of patients	yes	no	no	yes
user permissions per site (implanting vs. peripheral centre)	yes	yes	yes	yes
user permissions can be set from within the web application	yes	no	no	yes
CIED handover to other centre via web application	no	no	yes	yes

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Table 12: Workflow

	System			
	Biotronik	**Medtronic**	**St. Jude Medical**	**Boston Scientific**
System	Home Monitoring®	CareLink®	Merlin.net™ Patient Care Network (PCN)	Latitude®
Workflow				
alert severeness triage	yes	yes	yes	yes
urgent (red)	yes, programmable per patient (CIED serial number)	yes	yes, programmable per CIED-type (PM, CRT-P, ICD, CRT-D)	yes, nonconfigurable red alert list
intermediate (yellow)	yes, programmable per patient (CIED serial number)	yes	no	yes, programmable per patient (CIED serial number), physician and clinic
standard (white)	yes	yes	yes, programmable per CIED-type (PM, CRT-P, ICD, CRT-D)	not applicable
event acknowledgement	yes: "Done"	yes: "Viewed"	no, only: "Last accessed by"	yes
acknowledgment with user name	no	no	not applicable	yes
acknowledgment with mentioning of action undertaken	no	no	not applicable	no
overview of acknowledgements	no	no	not applicable	yes
in-clinic follow-up				
scheduling	no	yes	yes	no
scheduling per user/centre	no	no	no	no
remote follow-up				
scheduling	no	yes	yes	yes
scheduling per user/centre	no	no	no	yes
indication of number of days since last transmission	yes	no	yes	yes
remote monitoring can be switched on/off via web application	yes	no	no	yes
transmissions can be archived	no	no	yes	no

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Table 13: Comparison of monitors

	System							
	Biotronik		Medtronic		St. Jude Medical	Boston Scientific		
Monitor	CardioMessenger™ II Mobility	CardioMessenger™ II-S Simplicity	CareLink® Monitor	CareLink® Monitor with Conexus™ logo	Merlin@home™	wanded Latitude® Communicator with push buttons	wireless Latitude® Communicator with push buttons	wireless Latitude® Communicator with touch screen
generation	2nd	2nd	1st	2nd, with Conexus™ logo	2nd	1st	1st	1st
physical configuration								
mains-powered	yes	yes	no	yes	yes	yes	yes	yes
rechargeable battery	yes	no	no	no	no	no	no	no
alkaline battery-powered	no	no	yes	no	no	no	no	no
bedside	yes	yes	yes	yes	yes	yes	yes	yes
travel-ready	yes, if compatible mobile network is present (> 100 countries)	yes, if compatible mobile network is present (> 100 countries)	yes, with the M-Link™ Cellular Accessory since May 2010	yes, with the M-Link™ Cellular Accessory since May 2010	yes, with the Wireless USB Adaptor since May 2010	only within the USA	only within the USA	yes, but only within its ITU region with automatic international dial-up directory
wearable	yes	no	no	no	no	no	no	no
connectors	1: power	1: power	1: telephone	2: power & telephone	3: power, telephone & USB	2: power & telephone	2: power & telephone	2: power & telephone
user interface								
buttons	1: power	none	1: interrogation	1: interrogation	1: start (for setup and patient-initiated transmissions)	8: interrogation, action, 4 menu selection, 2 volume	8: interrogation, action, 4 menu selection, 2 volume	2: interrogation & action + touchscreen
visual independent indication signals	5: power, battery, status, transmission, callback request	2: status & callback request	3: battery, interrogation & transmission	3: power, interrogation & transmission	5: power, progress, interrogation, transmission & stars (= status & callback)	2: power & tri-coloured translucent action button + LCD screen	2: power & tri-coloured translucent action button + LCD screen	2: power & tri-coloured translucent action button + touchscreen
screen	no	no	no	no	no	ordinary LCD screen	ordinary LCD screen	touchscreen
speaker	no	no	yes	yes	yes	yes	yes	yes
special monitor features								
automated physican phone calls	no	no	no	no	yes	no	no	no
patient symptom questionary	no	no	no	no	no	yes	yes	yes

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Table 14: Comparison of compatible devices

	System							
	Biotronik		Medtronic		St. Jude Medical	Boston Scientific		
Monitor	CardioMessenger™ I Mobility & Simplicity	CardioMessenger™ II Mobility & Simplicity	CareLink® Monitor	CareLink® Monitor with Conexus™ logo	Merlin@home™	wanded Latitude® Communicator with push buttons	wireless Latitude® Communicator with push buttons	wireless Latitude® Communicator with touch screen
Compatible devices								
CIEDs								
ICDs	1st generation -T models only	2nd generation -T models only	all models, including discontinued	all models, including discontinued	RF models only	all models, including discontinued	RF models only	RF models only
biventricular ICDs (CRT-Ds)	1st generation -T models only	2nd generation -T models only	all models, including discontinued	all models, including discontinued	RF models only	all models, including discontinued	RF models only	RF models only
pacemakers	1st generation -T models only	2nd generation -T models only	all models, including discontinued	all models (none wireless), including discontinued	RF models only	all models, including discontinued	none	none
biventricluar pacemakers (CRT-Ps)	1st generation -T models only	2nd generation -T models only	one model	one model	none	all models, including discontinued	none	none
implantable loop recorders (ILRs)	none	none	all models, including discontinued	all models (none wireless), including discontinued	none	none	none	none
left-atrial pressure monitors	none	none	none	none	planned	none	none	none
special CIED features for remote disease management								
transthoracic lung fluid impedance measurement	no	planned for Oct. 2010	yes, OptiVol® on all premium ICDs & CRT-Ds	yes, OptiVol® on all premium ICDs & CRT-Ds	yes, CorVue™ Congestion Monitoring	no	no	no
ST deviation trending for ischemia monitoring	no	no	no	no	yes	no	no	no
other compatible devices								
wireless weight scale	no	no	no	no	no	yes	yes	yes
wireless blood pressure cuff	no	no	no	no	no	yes	yes	yes

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Table 15: Communication between devices and monitor

	System						
	Biotronik		Medtronic		St. Jude Medical	Boston Scientific	
Monitor	CardioMessenger™ II Mobility	CardioMessenger™ II-S Simplicity	CareLink® Monitor	CareLink® Monitor with Conexus™ logo	Merlin@home™	wanded Latitude® Communicator with push buttons	wireless Latitude® Communicators
Device - monitor communication							
inductive wand communication	no	no	yes	no	no	yes	no
frequency	not applicable	not applicable	175kHz	not applicable	not applicable	75.7 +/- 11.25 kHz	not applicable
modulation	not applicable	not applicable	PCM or FM	not applicable	not applicable	OOK/QPSK	not applicable
data rate	not applicable	not applicable	< 50kbps	not applicable	not applicable	> 64kbps	not applicable
wireless radio frequency communication	yes	yes	no	yes	yes	no	yes
main radio frequency band	MICS - ETSI EN 301 839: 402-405MHz	MICS - ETSI EN 301 839: 402-405MHz	not applicable	MICS - ETSI EN 301 839: 402-405MHz	MICS - ETSI EN 301 839: 402-405MHz	not applicable	ITU region 1: ETSI 869.85MHz ITU region 2: ISM 914 & 916.5MHz ITU region 3: not available
wake-up sniffer frequency	not applicable	not applicable	not applicable	2.45GHz	2.45GHz	not applicable	not applicable
physical communication protocol	not compliant with Listen Before Talk (LBT) MICS protocol	not compliant with Listen Before Talk (LBT) MICS protocol	not applicable	Listen Before Talk (LBT), selects 1 of the 10 MICS channels	Listen Before Talk (LBT), selects 1 of the 10 MICS channels	not applicable	Listen Before Talk (LBT), try later if busy (only 1 channel)

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Table 16: Comparison of radio frequencies

	Radio bands		
	Medical Implant Communications Service (MICS) band	**Industrial, Scientific and Medical (ISM) bands**	**ETSI EN 300 220 subclass 31**
	ETSI EN 301 839 subclass 47		
System	CareLink®, Home Monitoring® and Merlin.net™ PCN	Latitude® Patient Management System	
Radio frequency			
main radio frequency band			
in ITU region 1	ETSI EN 301 839: 402-405MHz	not allowed	ETSI EN 300 220: 869.85MHz
in ITU region 2	FCC 74 FR 22696 MICS: 402-405MHz	FCC 47 CFR part 15.231 ISM: 914 & 916.5MHz	not allowed
in ITU region 3	ACMA LIPD: 402-405MHz	not allowed	not allowed
potentially susceptible to interference from			
in all ITU regions	weather balloons	not allowed	not allowed
in ITU region 1	weather balloons, TErrestrial Trunked RAdio (TETRA)	not allowed	non-specific short-range devices
in ITU region 2	weather balloons	ISM, private land-mobile, amateur radio, certain wireless LANs and cordless phones, ULP hearing aids & camera pill	not allowed
in ITU region 3	weather ballons, land-mobile (Australia)	not allowed	not allowed
wake-up sniffer frequency	2.45GHz (not applicable to Biotronik)	not applicable	not applicable
potentially susceptible to interference from			
in ITU region 1	ISM, amateur radio, WiFi, RFID, Bluetooth™, ZigBee®	not applicable	not applicable
in ITU region 2	ISM, amateur radio, WiFi, RFID, Bluetooth™, ZigBee®	not applicable	not applicable
in ITU region 3	ISM, amateur radio, WiFi, RFID, Bluetooth™, ZigBee®	not applicable	not applicable
wireless weight scale & blood pressure cuff frequency	not applicable	not applicable	Bluetooth™ ISM: 2402-2480MHz
potentially susceptible to interference from			
in ITU region 1	not applicable	not applicable	ISM, amateur radio, WiFi, RFID, Bluetooth™, ZigBee®
in ITU region 2	not applicable	not applicable	ISM, amateur radio, WiFi, RFID, Bluetooth™, ZigBee®
in ITU region 3	not applicable	not applicable	ISM, amateur radio, WiFi, RFID, Bluetooth™, ZigBee®
maximum allowed transmitter power on main band	25µW	not applicable	5mW
maximum allowed field strength on main band	not applicable	FCC 47 CFR part 15.231: 5mV/m @ 3m	not applicable
Equivalent Isotropically Radiated Power (EIRP) by device	100nW	not disclosed	not disclosed
battery current drain	TX/RX: <5.5mA, sleep: <250nA	not disclosed	not disclosed
range	2m guaranteed, up to 5m	2m guaranteed, up to 5m	2m guaranteed, up to 5m
link type	half duplex	half duplex	half duplex
modulation			
for data	2FSK or 4FSK	FSK	FSK
for wake-up	OOK (not applicable to Biotronik)	not applicable	not applicable
signal bandwidth	300kHz	<50kHz	<50kHz
data transmission speed	200-400-800kbps	85.3kbps	85.3kbps

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Table 17: Comparison of alerting procedures

	System					
	Biotronik	Medtronic		St. Jude Medical	Boston Scientific	
Monitor	CardioMessenger™ II Mobility & Simplicity	CareLink® Monitor	CareLink® Monitor with Conexus™ logo	Merlin@home™	wanded Latitude® Communicator with push buttons	wireless Latitude® Communicators
Alerting						
system integrity alerts						
are discerned by the CIED	yes	yes	yes	yes	yes	yes
are discerned by the data server	yes	no	no	yes	yes	yes
arrythmia episode alerts						
are discerned by the CIED	yes	yes	yes	yes	yes	yes
are discerned by the data server	no	no	no	no	yes	yes
trend alerts						
are discerned by the CIED	no	yes	yes	yes, on newer devices	no	no
are discerned by the data centre server	yes	no	no	yes	yes	yes
device and monitor serial numbers are linked	only for monitor-initiated communication, not for device-initiated communication	yes	yes	yes	yes	yes
device-initiated communication	only for alerts	no	for alerts & monitoring	no	no	yes
interval	not applicable	not applicable	daily	not applicable	not applicable	daily communication for red alerts, but yellow alerts and other data is updated only weekly
time	not applicable	not applicable	scheduled between 03:00 and 05:00 AM	not applicable	not applicable	whenever within range, recovers interrupted transmissions
alert urging	yes	no	yes, for CIEDs with Conexus™ wireless technology	no	no	no
retry interval	every 15 minutes	not applicable	every 3 hours	not applicable	not applicable	not applicable
retry duration	during 30 days	not applicable	during 3 days	not applicable	not applicable	not applicable
monitor-initiated communication	yes	yes	no	yes	no	no
interval	daily	not applicable	daily	daily	not applicable	not applicable
time	programmable time, usually at night	not applicable	03:00 AM	self-adaptable	not applicable	not applicable
patient-initiated communication with IEGM	no	always	yes, via hand-held Conexus™ activator	yes, when allowed in web application	always, via blue interrogation button	yes, via blue interrogation button
patient-initiated alerting can be switched on per patient	not applicable	not applicable	no	yes	not applicable	yes
patient-initiated alerting can be switched on per user/centre	not applicable	not applicable	no	no	yes	yes
required interval	not applicable	daily	ad hoc	ad hoc	weekly	ad hoc
interrogation duration	not applicable	typically < 3 minutes, up to 12 minutes in case of many stored episodes	typically < 3 minutes, up to 12 minutes in case of many stored episodes	not disclosed	typically 10-15s, but takes longer in case of many stored episodes	typically 10-15s, but takes longer in case of many stored episodes
programmable one-off device-initiated communication	yes	no	no	no	no	no

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Table 18: Comparison of communication between monitor and data centre

	System				
	Biotronik	**Medtronic**		**St. Jude Medical**	**Boston Scientific**
Monitor	CardioMessenger™ II Mobility & Simplicity	CareLink® Monitor	CareLink® Monitor with Conexus™ logo	Merlin@home™	all Latitude® Communicators
Monitor - data centre communication					
analogue telephone landline	no	yes	yes	yes	yes
ISDN	no	no	no	yes	no
VOIP	no	no	no	no	yes, if VOIP has analogue interface
direct internet protocol over DSL	no	no	no	no	no
mobile telephone network	yes	yes, with the M-Link™ Cellular Accessory since May 2010	yes, with the M-Link™ Cellular Accessory since May 2010	yes, with the USB Cellular Adapter since May 2010	no
2G: GSM, CDMA	yes, as from 1st generation	no	no	yes	no
2.5G: GPRS	yes, as from 2nd generation	yes	yes	yes	no
3G: UTMS	no	no	no	yes	no
3.5G: HSPA (HSDPA & HSUPA)	no	no	no	yes	no
transmission duration	typically 3 to 5 minutes, exceptionally longer with overloaded SMS-network	typically 3 to 6 minutes, up to 23 minutes in case of poor telephone line or many stored episodes	typically 3 to 6 minutes, up to 23 minutes in case of poor telephone line or many stored episodes	not disclosed	typically < 5 minutes, longer in case of poor telephone line or many stored episodes
technician delivering optional installation service at home	not required	no	no	yes	no

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Table 19: Comparison of remote follow-up procedures

	System			
	Biotronik	**Medtronic**	**St. Jude Medical**	**Boston Scientific**
Monitor	CardioMessenger™ II Mobility & Simplicity	all CareLink® Monitors	Merlin@home™	all Latitude® Communicators
Remote follow-up				
concept defined in web application	no	yes	yes	yes
scheduling				
scheduling on a specific date	no	yes	yes	yes
alternative method of scheduling	periodicity of IEGM transmissions in months	not applicable	switch to temporary schedule	yes, at predefined time intervals
scheduling per user/centre	yes	no	no	yes
automatic pacing capture & treshold measurements on newest RF-capable ICD models				
RA-lead	CRT-Ps only	yes	yes	yes
RV-lead	yes	yes	yes	yes
LV-lead	yes	yes	yes	yes
real-time IEGM at remote follow-up	yes, 30s as monthly periodic follow-up	yes, 10s	yes, 10s	yes, 30s
follow-up report in PDF	yes	yes	yes	yes
patient feedback				
physician-initated request	yes, visual request to phone up implanting centre	no	yes	yes
automated phone calls by follow-up clinic to patient	no	no	yes	no

Legal disclaimer: Above data represents the perception of the KCE about the remote monitoring systems as available on September 1, 2010 and as obtained through earlier industry and physician interviews. Although the KCE attempted to be as accurate as possible, it waives any responsibility for the correctness or completeness of this data. In any case, please, refer to the respective user guide for a complete up-to-date description of each system.

8.5 APPENDIX FOR THE CHAPTER ON EFFECTIVENESS

8.5.1 Relevant MeSH terms for searches[w]

8.5.1.1 Telemedicine

Delivery of health services via remote telecommunications. This includes interactive consultative and diagnostic services.

Year introduced: 1993

Previous Indexing: Telecommunications (1976-1992)

Includes: Remote Consultation, Telepathology, Teleradiology

8.5.1.2 Telemetry

Transmission of the readings of instruments to a remote location by means of wires, radio waves, or other means. (McGraw-Hill Dictionary of Scientific and Technical Terms, 4th ed)

Year introduced: not mentioned

Previous Indexing: none

Includes: no other MeSH terms

8.5.1.3 Defibrillators, Implantable

Implantable devices which continuously monitor the electrical activity of the heart and automatically detect and terminate ventricular tachycardia (TACHYCARDIA, VENTRICULAR) and VENTRICULAR FIBRILLATION. They consist of an impulse generator, batteries, and electrodes.

Year introduced: 1993

Previous Indexing: none

Includes: no other MeSH terms

8.5.1.4 Pacemaker, Artificial

A device designed to stimulate, by electric impulses, contraction of the heart muscles. It may be temporary (external) or permanent (internal or internal-external).

Year introduced: not mentioned

Previous Indexing: none

Includes: no other MeSH terms

8.5.2 Search for HTAs, systematic reviews and horizon scanning reports

For this primary search we searched the CRD databases and the Cochrane library for reports since 2006. Apart from ICDs we also included Pacemakers as a search criterion to avoid missing those reports that concerned both pacemakers and ICDs and that might be misclassified for this reason.

[w] Source : National Center for Biotechnology Information (NCBI), http://www.ncbi.nlm.nih.gov

8.5.2.1 CRD (search last repeated June 4th,2010)

#1	MeSH Telemedicine EXPLODE 1 2 3	392
#2	MeSH Telemetry EXPLODE 1	34
#3	MeSH Defibrillators, Implantable EXPLODE 1 2 3	175
#4	MeSH Pacemaker, Artificial EXPLODE 1	81
#5	#1 or #2	412
#6	#3 or #4	235
#7	#5 AND #6	7
#8	#5 AND #6 RESTRICT YR 2006 2010	3
#10	ICD* OR defibrillator* OR cardioverter* OR pacemaker*	433
#11	remote	105
#12	#5 or #11	483
#13	#6 or #10	476
#14	#12 AND #13	13
#15	#12 AND #13 RESTRICT YR 2006 2010	5

Summary: this search yielded 3 relevant references while using the MeSH terms only.[25, 26, 53] Adding specific free text keywords did yield two more results, but these proved to be irrelevant.[168, 169] Therefore, and to avoid too much noise we limited further searches to the MeSH terms only.

8.5.2.2 Cochrane Library (search last repeated June 4th,2010)

#1	MeSH descriptor Telemedicine explode all trees	852
#2	MeSH descriptor Telemetry explode all trees	152
#3	MeSH descriptor Defibrillators, Implantable explode all trees	687
#4	MeSH descriptor Pacemaker, Artificial explode all trees	530
#5	((#1 OR #2) AND (#3 OR #4)), from 2006 to 2010	13

Summary: this search yielded 13 references, 9 clinical trials and trial design descriptions, and 3 technology assessments, but two of these technology assessment were the same as in the CRD search, .[25, 26] and the third was a project record.[170]

8.5.2.3 Overall result of these searches for HTAs, systematic reviews and horizon scanning reports

The overall yield of the search of bibliographic databases was disappointing. However, the other methods of searching through websites, and through international organisations as described in the chapter on clinic effectiveness and safety finally yielded 7 studies published since 2006 as shown in Table 1.

8.5.3 Incremental search in PubMed (last repeated June 4th, 2010)

The aim of this incremental search was to identify additional clinical trials, and other relevant studies that were published after the most recent, valid HTA. Since the most recent HTA was from 2009 and included evidence retrieved up to June 2008,[14] this incremental search was limited to studies published between 2008 and 2010.

This search was based on the same MeSH terms as the searches described above.

#5	Search telemedicine [Mesh]	10940
#6	Search telemetry [mesh]	6287
#7	Search Defibrillators, Implantable [Mesh]	7862
#8	Search Pacemaker, Artificial [Mesh]	20247
#9	Search #5 or #6	16846
#10	Search #7 or #8	26967
#11	Search #9 and #10	330
#12	Search #11 Limits: Publication Date from 2008 to 2010	68

Assessment of those 68 studies:

Overview	
Total	68
Potentially relevant for chapter 3	**21**
Not Relevant for chapter 3	47

Reasons for not being relevant for chapter 3	
Narrative review/Commentary	26
Case report / Case series	8
PM only	3
Specific Subpopulataion	1
Trial design	3
Not remote monitoring	2
Other topic	4

Reasons for being relevant for chapter 3	
Prospective Study	12
Retrospective Study	2
Safety Aspects	5
Unclear	2

Summary: As a result, twenty-one articles were retained and an additional recently published study that was not yet indexed in Pubmed.[13] Of those 22 articles, only one was previously included in the NHS review.[46]

8.5.4 Current clinical trials (last repeated August 25th 2010)

A search in www.ClinicalTrials.gov with the search terms monitoring AND ("cardiac resynchronization therapy" OR ICD OR CRT-D OR defibrillator) identified 55 current studies. Although not all listed studies specifically deal with remote monitoring of cardiac devices the majority do and the list was reproduced in full as a reference to the studies in progress.

1	Recruiting	Influence of Home Monitoring on the Clinical Status of Heart Failure Patients With an Impaired Left Ventricular Function	
		Conditions:	Ventricular Fibrillation; Ventricular Tachycardia; Congestive Heart Failure
		Interventions:	Device: ICD or CRT-D with Home Monitoring feature deactivated; Device: ICD or CRT-D with Home Monitoring feature activated
		Sponsor:	Biotronik SE & Co. KG
		Number Enrolled:	620
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
		Start Date:	July 2007
		Completion Date:	July 2010
		Acronym:	IN-TIME
		Outcome Measures:	Composite Score of death, hospitalization for heart failure, NYHA class and global assessment (Packer Score); Rehospitalizations due to worsening heart failure; Correlation of Home Monitoring values with the clinical status; Incidence and reasons for Home Monitoring based interventions; Home Monitoring workflow analysis
2	Recruiting	Follow-up of Patients With Implantable Cardioverter Defibrillators by Home Monitoring (ANVITE)	
		Conditions:	Cardiac Pacing; Electric Countershock; Ventricular Tachyarrhythmia
		Interventions:	Device: Implantable cardioverter defibrillator with Home Monitoring function; Device: Standard implantable cardioverter defibrillator
		Sponsor:	Biotronik SE & Co. KG
		Number Enrolled:	300
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Supportive Care
		Start Date:	March 2009
		Completion Date:	September 2012
		Acronym:	ANVITE
		Outcome Measures:	Significant adverse events, especially death, hospitalization, inadequate device therapies; All-cause mortality; Number of device follow-ups; Quality of life
3	Active, not recruiting	Benefits of Implantable Cardioverter Defibrillator Follow-up Using Remote Monitoring	
		Conditions:	Implantable Cardioverter-Defibrillators; Ventricular Fibrillation; Tachycardia, Ventricular
		Intervention:	Other: ACTIVATION of HOME MONITORING

		Sponsor:	Biotronik SE & Co. KG
		Number Enrolled:	440
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Health Services Research
		Start Date:	January 2007
		Completion Date:	August 2010
		Acronym:	ECOST
		Outcome Measures:	Number of patients with more than one Significant Serious Adverse Event (SSAE) since home-monitoring activation. SSAE is a composite comprising all-cause mortality, cardiac or device related Serious Adverse Events; Total costs minimization analyse; Delay of Home Monitoring to manage adverse events; Sensitivity of Home Monitoring to detect ICD dysfunction; Number of capacitor charge and incidence on ICD-battery longevity; Difference of cardiac and device related Adverse Event
4	Recruiting	Psychosomatic Effects of Implantable Cardioverter Defibrillator With Home Monitoring Function (QUANTUM)	
		Conditions:	Arrhythmia; Quality of Life
		Interventions:	Device: BIOTRONIK Lexos-T implantable cardioverter-defibrillator with home monitoring; Device: Lumos-T implantable cardioverter-defibrillator with home monitoring
		Sponsor:	Biotronik SE & Co. KG
		Number Enrolled:	150
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
		Start Date:	August 2006
		Completion Date:	December 2010
		Acronym:	
		Outcome Measures:	Hospital Anxiety and Depression Scale (HADS) anxiety score; HADS depression score; Quality of life (SF-12); Prevalence of Type D personality among ICD patients; Frequency of contacts between patient and physician; Patient's perception of ICD therapy; Patient mobility
5	Recruiting	Home-Monitoring in Implantable Cardioverter Defibrillator (ICD) Patients	
		Condition:	Ventricular Arrythmias
		Intervention:	Device: Home-monitoring provided by LUMAX ICD device and CardioMessenger II
		Sponsors:	Charite University, Berlin, Germany; Biotronik SE & Co. KG
		Number Enrolled:	416
		Funded By:	OTHER / INDUSTRY
		Study Type:	Interventional

	Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
	Start Date:	October 2008
	Completion Date:	November 2011
	Acronym:	Monitor-ICD
	Outcome Measures:	Comparison of disease specific costs from a societal perspective.; Number of shocks; Hospital admissions; Cardiac events; Quality of life; Disease specific Costs from third party payers perspective; Overall costs from societal and third party payers perspective
6 Recruiting	European Health Economic Trial on Home Monitoring in ICD Therapy (EuroEco)	
	Conditions:	Ventricular Fibrillation; Tachycardia, Ventricular; Ventricular Flutter
	Interventions:	Device: Home Monitoring provided by Biotronik ICD devices; Device: No Home Monitoring
	Sponsor:	Biotronik SE & Co. KG
	Number Enrolled:	312
	Funded By:	INDUSTRY
	Study Type:	Interventional
	Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
	Start Date:	July 2008
	Completion Date:	September 2012
	Acronym:	EuroEco
	Outcome Measures:	Euro spent to follow up ICD patients; Average number of in-hospital follow-up visits per patient; Time to first in-hospital follow-up visit beyond the first post-implantation visit; Effective financial impact on hospitals / physicians; Proportion of in-hospital consultations with relevant findings (i.e. necessitating changes in medical therapy, device programming or re-hospitalisations/ interventions); Proportion of patients with HM-triggered interventions that, without remote monitoring, would have first been discovered at a subsequent scheduled follow-up; Incidence of inappropriate ICD shocks; Changes in quality-of-life (SF-36) from baseline to the 12- and to 24-month follow-up visits
7 Recruiting	Clinical effecT of Heart Failure Management Via Home Monitoring With a Focus on Atrial Fibrillation (effecT)	
	Conditions:	Heart Failure; Atrial Fibrillation
	Interventions:	Device: Home Monitoring (Cardiac resynchronization therapy and atrial fibrillation therapy with Home Monitoring feature); Device: Home Monitoring (Cardiac resynchronization therapy and atrial fibrillation therapy, without Home Monitoring)
	Sponsor:	Biotronik SE & Co. KG
	Number Enrolled:	300
	Funded By:	INDUSTRY
	Study Type:	Interventional
	Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment

		Start Date:	May 2008
		Completion Date:	August 2010
		Acronym:	effecT
		Outcome Measures:	Clinical composite outcome based on the days lost during 1 year due to: cardiovascular mortality, cardiovascular hospitalization, inappropriate ICD therapy; Heart Failure Clinical Composite Score (Packer Score); Reverse remodelling (LA diameter, LVESV, mitral regurgitation); Progression of AF and AT/AF burden
8	Active, not recruiting	A Randomized Trial of Remote Monitoring of Implantable Cardioverter Defibrillators Versus Quarterly Device Interrogations in Clinic	
		Conditions:	Tachycardia, Ventricular; Ventricular Fibrillation
		Intervention:	Device: carelink monitoring system
		Sponsors:	Duke University; Medtronic
		Number Enrolled:	151
		Funded By:	OTHER / INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
		Start Date:	December 2006
		Completion Date:	February 2009
		Acronym:	Medusa SAK
		Outcome Measures:	Re-hospitalization and ED visits for cardiac causes, unscheduled clinic visits for device-related issues, medications, patient logs, patients' level of satisfaction with their device care at baseline, 6 months, and 12 months.; Health-related quality of life at baseline, 6 months, and 12 months. Health utilization costs incurred during the study period.
9	Completed	Home Monitoring in Cardiac Resynchronisation Therapy	
		Condition:	Heart Failure, Congestive
		Interventions:	Device: Cardiac resynchronisation therapy; Device: Implantable cardioverter-defibrillator
		Sponsor:	Biotronik SE & Co. KG
		Number Enrolled:	513
		Funded By:	INDUSTRY
		Study Type:	Observational
		Study Design:	Time Perspective: Prospective
		Start Date:	March 2005
		Completion Date:	November 2008
		Acronym:	HomeCARE
		Outcome Measures:	Sensitivity and specificity of (single or combined) HFM-parameters (onset of arrhythmias, duration of physical activity, mean heart rate at rest and over 24h, %CRT, lead impedance); Predictive power of HFM-parameters regarding cardiovascular-based death or rehospitalisation (overnight stay); Effectiveness of HM (within sub-study); Correlation of HM-values with the clinical status; Evaluation of the predictive power of HM parameters not implemented in

			the HFM and of parameters not transmitted by HM (diagnostic memory of device); Sensitivity of HM-parameter regarding change of drug therapy; Incidence and reasons for HM-based interventions
10	Recruiting	Clinical Evaluation Of Remote Monitoring With Direct Alerts To Reduce Time From Event To Clinical Decision	
		Condition:	The Patient Meets ACC/AHA/ESC Guidelines for Implantable Cardioverter Defibrillator (ICD) or Cardiac Resynchronization Therapy (CRT-D) Device
		Interventions:	Device: Implantation of an ICD/CRT-D device; Device: Merlin.NET PCN
		Sponsor:	St. Jude Medical
		Number Enrolled:	200
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Single Blind (Subject); Primary Purpose: Diagnostic
		Start Date:	March 2010
		Completion Date:	January 2012
		Acronym:	REACT
		Outcome Measures:	time between the detection of an event and the point in time when the physician or delegate takes a clinical decision; The sufficiency of the device data retrieved through the Remote Monitoring feature to make a clinical decision; The physician or delegate time required for remote follow up as compared to in-clinic follow up; The changes over one year in the Hospital Anxiety and Depression Scale (HADS) for the two different randomization arms
11	Recruiting	Monitoring of Fluid Status in Heart Failure Patients by Intrathoracic Impedance Measurement (HomeCARE II)	
		Conditions:	Heart Failure; Arrhythmias, Cardiac
		Intervention:	Device: Intrathoracic impedance measurement
		Sponsor:	Biotronik SE & Co. KG
		Number Enrolled:	300
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Control: Uncontrolled; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Supportive Care
		Start Date:	July 2008
		Completion Date:	August 2011
		Acronym:	HomeCARE II
		Outcome Measures:	Long-term impedance trends in patients with clinically relevant heart failure events, to support the development of impedance based detection algorithms. A posterior assessment of sensitivity and false alarm rate of the detection algorithms.; Further improvement of the Heart Failure Monitor based on collected data

12	Recruiting	Bispectral Index Monitoring During Testing in the Electrophysiology Lab	
		Condition:	Tachycardia, Ventricular
		Interventions:	Device: Bispectral index monitoring using Aspect Monitor; Other: Ramsey Sedation Scale
		Sponsor:	Baystate Medical Center
		Number Enrolled:	60
		Funded By:	OTHER
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Supportive Care
		Start Date:	October 2007
		Completion Date:	October 2010
		Acronym:	
		Outcome Measures:	A change in OAAS scores of one point at the 30 minute data collection time period.; comfort
13	Completed Has Results	TRIAGE-CRT Telemonitoring in Patients With CHF and Indication of CRT-D	
		Conditions:	Congestive Heart Failure; Cardiac Resynchronization Therapy
		Intervention:	Device: Kronos LV-T, Lumax HF-T
		Sponsor:	Biotronik, Inc.
		Number Enrolled:	66
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Non-Randomized; Control: Uncontrolled; Endpoint Classification: Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
		Start Date:	November 2006
		Completion Date:	January 2008
		Acronym:	
		Outcome Measure:	Patient Compliance of Weight and Blood Pressure External Monitoring and Home Monitoring Transmissions. Percentage of Days Transmitted.
14	Recruiting	The IMPACT of BIOTRONIK Home Monitoring Guided Anticoagulation on Stroke Risk in Patients With Implanted ICD and CRT-D Devices	
		Conditions:	Atrial Fibrillation; Atrial Flutter; Stroke; Systemic Embolism; Major Bleeding
		Interventions:	Drug: warfarin, according to a predefined anticoagulation plan; Drug: warfarin, physician-directed based on conventional criteria
		Sponsor:	Biotronik, Inc.
		Number Enrolled:	2718
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: P

		arallel Assignment; Masking: Single Blind (Investigator); Primary Purpose: Prevention
	Start Date:	February 2008
	Completion Date:	February 2014
	Acronym:	IMPACT
	Outcome Measures:	The study hypothesis states that early detection of AF/AFL based on BIOTRONIK HM technology combined with a predefined anticoagulation plan will reduce the rate of the composite endpoint of stroke, systemic embolism and major bleeding.; Rates of all-cause mortality, stroke (ischemic and hemorrhagic, disabling and non-disabling, cardioembolic and non-cardioembolic), and major bleeding, as well as the AF burden, quality of life, and mean heart rate reduction.
15 Enrolling by invitation	Cardiac Resynchronization Therapy (CRT) Based Heart Failure Monitoring Study	
	Condition:	Heart Failure
	Intervention:	Device: Cardiac resynchronization therapy and HeartPOD® system
	Sponsor:	St. Jude Medical
	Number Enrolled:	12
	Funded By:	INDUSTRY
	Study Type:	Interventional
	Study Design:	Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
	Start Date:	January 2008
	Completion Date:	May 2012
	Acronym:	zLAP
	Outcome Measure:	Determine which heart failure monitoring feature acquired by the CRT device correlates most closely with simultaneously measured left ventricular filling pressure, as measured by left atrial pressure.
16 Completed Has Results	TRUST: Lumos-T Safely RedUceS RouTine Office Device Follow-up	
	Condition:	Patient Indicated for an ICD
	Interventions:	Other: Home Monitoring; Other: In-Office Conventional Follow-up
	Sponsor:	Biotronik, Inc.
	Number Enrolled:	1450
	Funded By:	INDUSTRY
	Study Type:	Interventional
	Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
	Start Date:	November 2005
	Completion Date:	June 2009
	Acronym:	TRUST
	Outcome Measures:	Home Monitoring Effectiveness; Percent of Participants Experiencing Death, Incidence of Stroke, or Event Requiring Surgical Intervention.; Early Detection of Cardiac Events; Patient Initiated Follow-up

17	Recruiting	Observational Study of Patient Comprehension, Perception, Fears and Appreciation Following Home-Monitoring Implementation	
		Conditions:	Defibrillators; Tachycardia
		Intervention:	Other: Remote monitoring by Home Monitoring system
		Sponsors:	Biotronik France; Biotronik SE & Co. KG
		Number Enrolled:	480
		Funded By:	INDUSTRY
		Study Type:	Observational
		Study Design:	Observational Model: Cohort; Time Perspective: Prospective
		Start Date:	February 2009
		Completion Date:	June 2010
		Acronym:	Educ@t
		Outcome Measure:	At 1 month: evaluation of centers training, knowledges and constraints of Home Monitoring implementation. At 6 months follow-up: observe and describe the behavior, the perception, the fears and the appreciation degree linked to this new technology
18	Recruiting	Clinical Status Monitoring in Implantable Cardiac Defibrillator (ICD) Patients by Physiological Diagnosis (PhD) Function	
		Condition:	Heart Failure
		Intervention:	Device: ICD
		Sponsor:	Sorin Group
		Number Enrolled:	558
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Non-Randomized; Control: Active Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Diagnostic
		Start Date:	September 2009
		Completion Date:	September 2011
		Acronym:	TUTOR
		Outcome Measure:	The objective is to demonstrate that agreement correlation is superior to 67%
19	Completed	CRT-D Based Impedance Monitoring Study	
		Condition:	Heart Failure
		Intervention:	Device: Transthoracic Impedance
		Sponsor:	St. Jude Medical
		Number Enrolled:	75
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Non-Randomized; Control: Uncontrolled; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Gr

			oup Assignment; Masking: Open Label; Primary Purpose: Diagnostic
		Start Date:	July 2007
		Completion Date:	August 2008
		Acronym:	
		Outcome Measure:	To assess the use of the impedance feature in conjunction with other functions of the CRT-D device
20	Completed	Remote Follow-up of Patients Receiving Implantable Cardioverter Defibrillator for Prophylactic Therapy	
		Conditions:	Ventricular Fibrillation; Ventricular Tachycardia
		Intervention:	Device: Implantable Cardioverter Defibrillator
		Sponsor:	Biotronik SE & Co. KG
		Number Enrolled:	155
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: P arallel Assignment; Masking: Open Label; Primary Purpose: Health Services Research
		Start Date:	January 2004
		Completion Date:	July 2008
		Acronym:	REFORM
		Outcome Measures:	Number of follow-up visits; Total costs; Mortality from any cause; Quality of life (SF-36); Hospitalization
21	Recruiting	OptiLink HF Study: Optimization of Heart Failure Management Using Medtronic OptiVol Fluid Status Monitoring and Medtronic CareLink Network	
		Condition:	Heart Failure
		Intervention:	Device: Access Arm
		Sponsors:	Medtronic Bakken Research Center; Medtronic; ikfe-CRO GmbH
		Number Enrolled:	1000
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Uncontrolled; Endpoint Classification: Efficacy Study; Intervention Model: Parallel A ssignment; Masking: Open Label; Primary Purpose: Prevention
		Start Date:	September 2008
		Completion Date:	October 2013
		Acronym:	OptiLink-HF
		Outcome Measures:	All-cause of death or unplanned admission to hospital for cardiovascular reason from day of patient informed consent sign off; Number of HF-related hospitalization during follow-up, HF-related hospitalization, Sum of follow-up days minus days alive and out of the hospital, All cause mortality, Cardiovascular Mortality,
22	Completed	Automatic External Defibrillation Monitoring in Cardiac Arrest	
		Conditions:	Death, Sudden, Cardiac; Ventricular Fibrillation; Tachycardia, Ventricular
		Intervention:	Device: Defibrillation of pulseless ventricular tachycardia/ventricular fibrillation by automatic external cardioverter

		defibrillator.
	Sponsors:	Atlanta Research and Education Foundation; Emory University
	Number Enrolled:	3000
	Funded By:	OTHER
	Study Type:	Interventional
	Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
	Start Date:	October 2006
	Completion Date:	September 2009
	Acronym:	
	Outcome Measures:	Time to defibrillation; Comparisons of successful defibrillation; Survival to discharge; Cerebral performance at discharge and follow up
23 Recruiting	The Use of Dual Chamber ICD With Special Programmed Features to Lower the Risk of Inappropriate Shock	
	Conditions:	Ventricular Tachycardia; Ventricular Fibrillation; Atrial Fibrillation; Supraventricular Tachycardia
	Intervention:	Device: ICD
	Sponsors:	Mayo Clinic; Medtronic
	Number Enrolled:	100
	Funded By:	OTHER / INDUSTRY
	Study Type:	Interventional
	Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
	Start Date:	November 2008
	Completion Date:	December 2011
	Acronym:	RAPTURE
	Outcome Measures:	Rate of inappropriate shock per unity time follow up.; Improved quality of life, reduced health care expenditure, reduced burden of atrial fibrillation, incremental cost-effectiveness of dual versus single chamber ICDs in dollars per quality adjusted life year gained.
24 Completed	Clinical Usefulness and Efficacy of Intrathoracic Impedance Monitoring Using the OptiVol Patient Alert(TM)	
	Condition:	Heart Failure
	Intervention:	
	Sponsors:	Catharina Ziekenhuis Eindhoven; Medtronic
	Number Enrolled:	29
	Funded By:	OTHER / INDUSTRY
	Study Type:	Observational
	Study Design:	Observational Model: Case-Only; Time Perspective: Prospective
	Start Date:	July 2007
	Completion Date:	January 2009

		Acronym:	
		Outcome Measures:	clinical efficacy and value of ambulatory intrathoracic impedance measurement of the Optivol alert as an indicator of decompensated heart failure reflected by sensitivity and positive predictive value; influence of left ventricular filling pattern and brain natriuretic level on the positive predictive value of the Optivol alert
25	Recruiting	Data Collection Study of Wedge Pressure Data in Patients With CRT-D Devices	
		Condition:	Heart Failure
		Intervention:	Device: CRT-D (Intra-thoracic Impedance Monitoring)
		Sponsor:	St. Jude Medical
		Number Enrolled:	30
		Funded By:	INDUSTRY
		Study Type:	Observational
		Study Design:	Observational Model: Cohort; Time Perspective: Prospective
		Start Date:	December 2008
		Completion Date:	June 2010
		Acronym:	zWedge
		Outcome Measure:	
26	Recruiting	Health Economic Evaluation of Remote Follow up for Implantable Cardioverter Defibrillator (ICD) Patients	
		Condition:	Implantable Cardioverter-Defibrillators
		Intervention:	
		Sponsor:	St. Jude Medical
		Number Enrolled:	200
		Funded By:	INDUSTRY
		Study Type:	Observational
		Study Design:	Observational Model: Cohort; Time Perspective: Prospective
		Start Date:	December 2009
		Completion Date:	December 2011
		Acronym:	TARIFF
		Outcome Measures:	To determine cost minimization analysis from hospital's point of view and to determine cost utility analysis from patient's and third payer's point of view using Merlin@home and Merlin.net versus standard follow up in the Italian real life setting.; To evaluate the differential procedural costs for SSN (Italian Health Economic System) coming from the two follow up techniques.; To evaluate patients' quality of life through EQ-5D questionnaire performing standard and remote care follow up.
27	Active, not	COSMO Post Approval Registry: Corox OTW Steroid LV Lead Monitoring	

	recruiting	Condition:	Congestive Heart Failure
		Intervention:	Device: Corox OTW Steroid Left Ventricular Lead
		Sponsor:	Biotronik, Inc.
		Number Enrolled:	1000
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Non-Randomized; Control: Uncontrolled; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
		Start Date:	October 2006
		Completion Date:	June 2010
		Acronym:	
		Outcome Measures:	Long-term effectiveness of the COROX OTW Steroid in providing biventricular pacing; Safety of the COROX OTW Steroid LV pacing lead
28	Terminated	Diagnostic Outcome Trial in Heart Failure (DOT-HF Trial)	
		Condition:	Heart Failure
		Intervention:	Device: Programming (CRT-D, ICD OptiVol® and Cardiac Compass®)
		Sponsor:	Medtronic Bakken Research Center
		Number Enrolled:	336
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
		Start Date:	March 2007
		Completion Date:	January 2012
		Acronym:	DOT-HF
		Outcome Measure:	Primary objective is to investigate if a reduction in combined endpoint of HF hospitalizations and all-cause mortality, in HF subjects managed with standard clinical assessment and using OptiVol® Fluid Status Monitoring with Cardiac Compass Report
29	Not yet recruiting	Clinical Evaluation Of The SonR Atrial Lead In Paradym RF Device	
		Condition:	Heart Failure
		Intervention:	Device: CRT-SonR 9770
		Sponsor:	Sorin Group
		Number Enrolled:	99
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Non-

			Randomized; Control: Uncontrolled; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Diagnostic
		Start Date:	September 2010
		Completion Date:	February 2012
		Acronym:	
		Outcome Measures:	Evaluation of the SonR lead safety; Incidence of adverse events; ICD electrical performances; Evaluation of the SonR a trial lead performance; Evaluation of the AV/VV delays optimization; Evaluation of the left ventricular lead performances; Evaluation of the Remote Monitoring Solution; Evaluation of the right ventricular autothreshold performances
30	Not yet recruiting	Sheba Medical Center Home Monitoring Clinic Registry	
		Condition:	Clinical Workload Assessment Based Upon a Home Monitoring System
		Intervention:	
		Sponsor:	Sheba Medical Center
		Number Enrolled:	100
		Funded By:	OTHER_GOV
		Study Type:	Observational
		Study Design:	Observational Model: Case-Only; Time Perspective: Prospective
		Start Date:	June 2010
		Completion Date:	January 2012
		Acronym:	
		Outcome Measure:	
31	Recruiting	Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy	
		Condition:	Advanced Heart Failure
		Intervention:	Device: HeartPOD™ System or Promote® LAP System
		Sponsor:	St. Jude Medical
		Number Enrolled:	730
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy ☐tudy; Intervention Mode☐: Parallel Assignment; Masking:☐Open Label; Primary Purpose: Diagnostic
		Start Date:	April 2010
		Completion Date:	August 2013
		Acronym:	LAPTOP-HF
		Outcome Measures:	Freedom from study-related major adverse cardiovascular and neurological events (MACNE); Heart Failure Hospitalization
32	Active, not	Biventricular Tachycardias Outcome Trial	

	recruiting	Condition:	Biventricular Tachycardias
		Intervention:	Device: Ovatio CRT 6750
		Sponsor:	Sorin Group
		Number Enrolled:	474
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Single Blind (Subject); Primary Purpose: Treatment
		Start Date:	May 2006
		Completion Date:	September 2011
		Acronym:	BITAC
		Outcome Measures:	Incidence of slow ventricular tachycardias (Slow VTs) in CRT-ICD pts;; ATP therapy efficacy on slow VTs conversion.; Efficacy of ATP therapies on Slow VTs according to therapy setting (delivery in LV only, in RV only, or in LV+RV); Tvar risk stratification; "unscheduled visits" or "hospital re-admissions" due to slow VTs;; Incidence of adverse events (AEs) in the studied population
33	Terminated	BOAT: Beta Blocker Uptitration With OptiVol After Cardiac Resynchronization Therapy (CRT)	
		Condition:	Congestive Heart Failure
		Interventions:	Drug: Beta blocker (carvedilol or metoprolol succinate); Procedure: CRT (cardiac resynchronization therapy)
		Sponsors:	St. Luke's-Roosevelt Hospital Center; Medtronic
		Number Enrolled:	60
		Funded By:	OTHER / INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Dose Comparison; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
		Start Date:	January 2007
		Completion Date:	June 2013
		Acronym:	
		Outcome Measures:	LVESVI change in patients with CRT/ increased dose of beta-blockers vs CRT and no change in beta-blocker dose.; Correlation of Optivol fluid measurement increases (decreased impedance) with symptomatic worsening of heart failure during beta blocker uptitration; Optivol measurements (decreased impedance, increase volume index) correlated with the need for adjusting diuretic therapy when uptitrating beta blocker dose; Functional improvements; Exercise - 6 minute walk; QOL - NYHA, Minnesota LWHFQ, Symptom Assessment Questionnaire; Ejection fraction; LVEDVI; Remodeling; HF Hospitalizations/ Mortality; Evaluation of LVESVI in patients who actually achieve target dose; Comparison of LVESVI changes based on initial beta-blocker dose; Plasma Brain natriuretic peptide (BNP) change; 12 month comparison after Group 2 has been uptitrated.
34	Recruiting	Effects of Atrial Rate-adaptive Pacing on Exercise Capacity in Patients With Chronic Heart Failure Complicated by Chronotropic Incompetence	
		Conditions:	Heart Failure; Exercise Tolerance
		Interventions:	Other: Rate-adaptive pacemaker programming; Other: VVI at 40 bpm

		Sponsor:	Federico II University
		Number Enrolled:	20
		Funded By:	OTHER
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Placebo Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
		Start Date:	November 2009
		Completion Date:	August 2011
		Acronym:	
		Outcome Measures:	Peak Oxygen consumption on cardiopulmonary exercise testing; Peak Heart Rate on Cardiopulmonary exercise testing; Quality of life as assessed by Minnesota Living with Heart Failure and SF-36 Questionnaires; Heart Rate Variability on Holter Monitoring; Acute Change in Peak Oxygen Consumption after reprogrammation; NT-proBNP levels
35	Active, not recruiting	Evaluation of the " Tele-follow-up " for the Follow-up of Implantable Defibrillators	
		Conditions:	Defibrillators, Implantable; Telemedicine
		Interventions:	Other: Tele- follow-up; Other: Conventional follow-up
		Sponsors:	Rennes University Hospital; Ministry of Health, France
		Number Enrolled:	1501
		Funded By:	OTHER / OTHER_GOV
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label
		Start Date:	January 2008
		Completion Date:	January 2011
		Acronym:	EVATEL
		Outcome Measures:	Rate of major cardiovascular events: all cause death, hospitalisation for a cardiovascular event, unsuccessful ICD therapies, and inappropriate ICD therapies.; Time to onset of the first major cardiovascular event (censored criterion); Death rate; Hospitalisation rate for a cardiovascular event; Rate of unsuccessful or inappropriate ICD therapies; Mean costs of each follow-up strategy; Number of non programmed additional consultations at the implantation centre; Number and cause of device re-programming; Number of drop-outs in the tele-follow-up group; Adherence of the patients to the tele-follow-up strategy; Feasibility of the tele-follow-up in implantation centres; Cost-benefit analysis
36	Recruiting	Evolution of Management Strategies of Heart Failure Patients With Implantable Defibrillators	
		Conditions:	Heart Failure; Sudden Cardiac Death; Implantable Defibrillator
		Intervention:	Device: The Medtronic CareLink system (Minneapolis, MN, USA).
		Sponsors:	Regione Lombardia; CEFRIEL, Milan Italy; Politecnico di Milano; Medtronic Italia
		Number Enrolled:	200

		Funded By:	OTHER / UNKNOWN / INDUSTRY
		Study Type:	Observational
		Study Design:	Observational Model: Cohort; Time Perspective: Prospective
		Start Date:	May 2008
		Completion Date:	September 2010
		Acronym:	EVOLVO
		Outcome Measures:	The rate of cardiac or device related clinic visits; Rate of visits related or not to episodes of worsening of heart failure. Rate and related costs of total health care utilizations (all planned and unplanned hospital admissions involving and not an overnight stay) for cardiac or device related events
37	Recruiting	Feasibility Study of an Integrated Diagnostic System to Manage Heart Failure	
		Condition:	Heart Failure
		Interventions:	Other: Integrated diagnositic system; Other: Routine in office visits
		Sponsor:	Medtronic Cardiac Rhythm Disease Management
		Number Enrolled:	240
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Diagnostic
		Start Date:	March 2010
		Completion Date:	
		Acronym:	INDICATE HF
		Outcome Measures:	Change in subject self-care utilizing the Self-Care of Heart Failure Index; Proportion of time clinician and subject complied to protocol requirements for the new heart failure diagnostic system (patient tools and HF clinician website); Number of clinical actions and types of health care utilizations in which actions are initiated; Subject outcomes including emergency room (ER) visits, hospitalization and death; Functional class using measurements including 6-minute hall walk and New York Heart Association class; Quality of life and depression scores utilizing measures including the Minnesota Living with Heart Failure Questionnaire and Patient Health Questionnaire
38	Recruiting	Deutsches Herzinsuffizienz Register - DHI	
		Condition:	Heart Failure
		Intervention:	
		Sponsors:	Stiftung Institut fuer Herzinfarktforschung; Medtronic; Novartis Pharmaceuticals; Sanofi-Aventis
		Number Enrolled:	2000
		Funded By:	OTHER / INDUSTRY
		Study Type:	Observational
		Study Design:	Observational Model: Cohort; Time Perspective: Prospective
		Start Date:	February 2009

		Completion Date:	February 2012
		Acronym:	DHI
		Outcome Measures:	Characteristics of consecutive patients with chronic cardiac insufficiency and an EF ≤ 40% in hospital daily routine within Germany; Specification of the medical therapy according to the guidelines; Monitoring of innovations of new therapy possibilities once these are introduced on the market; Specifications of implantable devices including ICD and CRT as well as the procedure of implantation and the success of the surgical intervention; Further interventions during clinical stay, after the index-event; Hospital mortality and non-fatal complications; Mortality and non-fatal complications within the first year; Symptomatic and frequency of rehospitalisation; Medicinal and non-medicinal therapy after 12 months
39	Recruiting	MOnitoring REsynchronization deviCes and cARdiac patiEnts	
		Condition:	Heart Failure
		Intervention:	Device: Medtronic CareLink® Network
		Sponsor:	Medtronic Bakken Research Center
		Number Enrolled:	1721
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: O pen Label; Primary Purpose: Prevention
		Start Date:	June 2009
		Completion Date:	June 2014
		Acronym:	MORE-CARE
		Outcome Measures:	Phase 1: mean time between event onset time and clinical decision for each subject.; Phase 2: death from any cause, cardiovascular and device-related hospitalizations (at least 48 hours stay).; Costs of healthcare resources (including hospitalizations, exams, in-office visits and ED admissions) on a per subject basis.
40	Not yet recruiting	Anti-Arrhythmic Medication v. MRI-Merge Ablation in the Treatment of Ventricular Tachycardia	
		Condition:	Ventricular Tachycardia
		Interventions:	Procedure: MRI guided VT ablation; Drug: Increased dose of amiodarone
		Sponsor:	Johns Hopkins University
		Number Enrolled:	70
		Funded By:	OTHER
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
		Start Date:	August 2008
		Completion Date:	August 2012
		Acronym:	

		Outcome Measures:	Freedom from ventricular tachycardia documented by implantable defibrillator cardioverter 6 months post ablation.; inducible arrhythmia at the end of the procedure,; Procedure time; Comparison of endocardial voltage mapping to scar on delayed enhancement MRI images; Complications of the procedure
41	Recruiting	Comparison Between Remote Patient Management and Standard Care in CRT-D and ICD-patients to Assess the Impact on Hospital Length of Stay Because of Heart Failure	
		Conditions:	Heart Failure; Ventricular Tachycardia; Cardiac Desynchronization
		Interventions:	Behavioral: Device triggered remote telephone contact because of Care Alert; Behavioral: Control Arm
		Sponsors:	Medtronic Bakken Research Center; Medtronic
		Number Enrolled:	180
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
		Start Date:	November 2007
		Completion Date:	February 2012
		Acronym:	ConnectOptiVol
		Outcome Measures:	Hospital length of stay due to worsened heart failure; Time from device detected onset of arrhythmias, cardiovascular disease progression and system issues to clinical decision making
42	Not yet recruiting	CareLink® Evaluation	
		Condition:	Heart Failure
		Intervention:	Other: Medtronic CareLink® Network
		Sponsor:	Medtronic Bakken Research Center
		Number Enrolled:	520
		Funded By:	INDUSTRY
		Study Type:	Observational
		Study Design:	Observational Model: Cohort; Time Perspective: Prospective
		Start Date:	January 2010
		Completion Date:	
		Acronym:	
		Outcome Measures:	Comparison of remote device check and in-clinic device assessment; Patient ease of use of, and satisfaction with, the Medtronic CareLink® Monitor (including percentage of patients who prefer follow up with Medtronic CareLink® compared to traditional in-clinic device follow-up); Clinician ease of use of, and satisfaction with, the Medtronic CareLink® Monitor and Website (including clinician general preference, if any, for Medtronic CareLink® compared to traditional in-clinic device follow-up); Clinic-specific clinical value of Medtronic CareLink® Network (change of workflow, increase of flexibility); Time and cost savings for patients; Time and costs savings for physicians; Efficiency through increased flexibility and per procedure time; Handling of unscheduled activities (for example, symptoms and events)

43	Recruiting	RAMYD Study - Evaluation of Arrhythmic Risk in Myotonic Dystrophy	
		Conditions:	Myotonic Dystrophy; Sudden Cardiac Death
		Interventions:	Procedure: Electrophysiological study; Device: pacemaker (PM) implant, internal cardiac defibrillator (ICD) implant, loop-recorder implant
		Sponsors:	Catholic University of the Sacred Heart; Telethon Italia
		Number Enrolled:	537
		Funded By:	OTHER / UNKNOWN
		Study Type:	Interventional
		Study Design:	Allocation: Non-Randomized; Control: Uncontrolled; Endpoint Classification: Safety Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
		Start Date:	January 2003
		Completion Date:	
		Acronym:	
		Outcome Measures:	Evaluate incidence of: major cardiac events (sudden death; resuscitated cardiac arrest; ventricular fibrillation; sustained ventricular tachycardia; sinoatrial and atrioventricular [AV] blocks); Evaluate with diagnostic non-invasive (standard electrocardiogram [ECG]; 24-hour monitoring ECG; signal-averaged ECG; echocardiography) and invasive procedures (electrophysiology study [EPS] and implantable loop recorders) the risk to develop cardiac arrhythmias in DM patients
44	Completed	Monitoring of Intubation and Ventilation During Resuscitation	
		Condition:	Cardiac Arrest
		Intervention:	Device: endotracheal intubation
		Sponsors:	University of Oslo; Laerdal Medical; Ullevaal University Hospital; Health Region East, Norway; Norwegian Air Ambulance Foundation; University of Stavanger
		Number Enrolled:	15
		Funded By:	OTHER / INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Non-Randomized; Control: Uncontrolled; Endpoint Classification: Efficacy Study; Intervention Model: Crossover Assignment; Masking: Open Label; Primary Purpose: Diagnostic
		Start Date:	September 2004
		Completion Date:	April 2007
		Acronym:	
		Outcome Measures:	sensitivity/specificity for lung ventilation detection; correlation ventilation volume - impedance change
45	Recruiting	Actions Elicited by In-hospital Follow-up of Cardiac Devices	
		Conditions:	Pacemaker, Artificial; Defibrillators, Implantable
		Intervention:	Procedure: In-hospital follow-up of cardiac device

		Sponsor:	Cliniche Humanitas Gavazzeni
		Number Enrolled:	3000
		Funded By:	OTHER
		Study Type:	Observational
		Study Design:	Observational Model: Cohort; Time Perspective: Prospective
		Start Date:	February 2010
		Completion Date:	June 2010
		Acronym:	ATHENS
		Outcome Measures:	Intervention rate (INT_RATE); PM_INT_RATE; ICD_INT_RATE
46	Recruiting	Pacing for Heart Failure With Preserved Ejection Fraction	
		Condition:	Heart Failure
		Intervention:	Device: Cardiac Resynchronization Therapy-Defibrillator (CRT-D)
		Sponsor:	Medtronic Cardiac Rhythm Disease Management
		Number Enrolled:	60
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Crossover Assignment; Masking: S ingle Blind (Subject); Primary Purpose: Treatment
		Start Date:	June 2010
		Completion Date:	August 2013
		Acronym:	HFpEF
		Outcome Measures:	Number of adverse events while the Fusion Pacing download is active vs. inactive.; Percentage of time the Fusion Pacing is active throughout a four-month follow-up period.; Change in Minnesota Living with Heart Failure Questionnaire score.; Change in peak VO2 during Cardio-pulmonary Exercise Testing (CPX).; Change in echocardiography measures: E/E', Ejection Fraction, LV EDV.; Change in NT-proBNP.
47	Recruiting	Cardiac Resynchronization Therapy (CRT) Efficacy Study	
		Condition:	Heart Failure
		Intervention:	Device: CRT
		Sponsors:	Medtronic Bakken Research Center; Medtronic
		Number Enrolled:	25
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Non-Randomized; Control: Uncontrolled; Intervention Model: Single Group Assignment; Masking: Open Label
		Start Date:	December 2008
		Completion Date:	December 2010
		Acronym:	

		Outcome Measure:	classified
48	Completed	Study to Characterize Atrial Fibrillation in CHF Patients Indicated for CRT	
		Condition:	Congestive Heart Failure, Atrial Fibrillation
		Intervention:	Device: Vitatron biventricular pacemaker
		Sponsor:	Medtronic BRC
		Number Enrolled:	172
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Non-Randomized; Control: Uncontrolled; Endpoint Classification: Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Diagnostic
		Start Date:	October 2003
		Completion Date:	December 2005
		Acronym:	
		Outcome Measures:	AF burden at 6 months; NYHA class,; Ejection Fraction,; all cause and sudden death,; QRS duration,; Left Ventricular End Diastolic Dimension,; QT interval and; T wave amplitude
49	Recruiting	T-wave Alternans and Intrathoracic Impedance Measurements	
		Conditions:	Congestive Heart Failure; Arrhythmias
		Intervention:	Other: Congestive heart failure
		Sponsors:	Columbia University; Medtronic
		Number Enrolled:	20
		Funded By:	OTHER / INDUSTRY
		Study Type:	Observational
		Study Design:	Observational Model: Cohort; Time Perspective: Prospective
		Start Date:	August 2008
		Completion Date:	July 2011
		Acronym:	
		Outcome Measure:	
50	Completed	Activity of AVE1625 in Mild to Moderate Alzheimer's Patients.	
		Condition:	Alzheimer Disease
		Intervention:	Drug: AVE1625
		Sponsor:	Sanofi-Aventis
		Number Enrolled:	162
		Funded By:	INDUSTRY
		Study Type:	Interventional

	Study Design:	Allocation: Randomized; Control: Placebo Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
	Start Date:	September 2006
	Completion Date:	July 2007
	Acronym:	
	Outcome Measures:	Safety and tolerability throughout the study:adverse events collected by spontaneous report; physical examination and neurological assessment; vital sign monitoring, clinical laboratories, and ECGs.; Efficacy variables:measures of change in cognition, global functioning and behavior at week 12.; Pharmacokinetic parameters will be assessed throughout the 12-week treatment period.
51	Completed	Long Term Safety and Tolerability of SR58611 in Patients With Major Depressive Disorder
	Condition:	Major Depressive Disorders
	Intervention:	Drug: amibegron (SR58611A)
	Sponsor:	Sanofi-Aventis
	Number Enrolled:	527
	Funded By:	INDUSTRY
	Study Type:	Interventional
	Study Design:	Allocation: Non-Randomized; Control: Active Control; Endpoint Classification: Safety Study; Intervention Model: Single Group A ssignment; Masking: Open Label; Primary Purpose: Treatment
	Start Date:	September 2005
	Completion Date:	July 2007
	Acronym:	
	Outcome Measures:	Clinical monitoring of adverse events (AEs), laboratory parameters, vital signs, physical examinations, and physician withdrawal checklists; 17-item Hamilton Depression rating Scale, Clinical Global Impression, Sheehan Disability Scale, Qol Enjoyment and satisfaction Questionnaire - Short Form,Medical Outcomes Study Short Form, Endicott Work Productivity Scale.
52	Completed	Placebo Controlled Double-blind Dose Ranging Study of the Efficacy and Safety of SSR149744C 50, 100, 200 or 300 mg OD With Amiodarone as Calibrator for the Maintenance of Sinus Rhythm in Patients With Recent Atrial Fibrillation/Flutter
	Conditions:	Atrial Fibrillation; Atrial Flutter
	Intervention:	Drug: CELIVARONE (SSR149744C)
	Sponsor:	Sanofi-Aventis
	Number Enrolled:	673
	Funded By:	INDUSTRY
	Study Type:	Interventional
	Study Design:	Allocation: Randomized; Control: Placebo Control; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
	Start Date:	December 2004

		Completion Date:	May 2006
		Acronym:	MAIA
		Outcome Measures:	The primary endpoint is the time from randomization to first documented AF/AFL recurrence indicated by 12-lead ECG or trans-telephonic ECG monitoring tracings showing AF/AFL.; The secondary endpoints will be the following:time from randomization to first symptomatic AF/AFL recurrence - mean ventricular rate during AF/AFL at first recorded AF/AFL recurrence.
53	Active, not recruiting	Evaluation of Weekly Subcutaneous Biotinylated Idraparinux Versus Oral Adjusted-dose Warfarin to Prevent Stroke and Systemic Thromboembolic Events in Patients With Atrial Fibrillation	
		Condition:	Atrial Fibrillation
		Interventions:	Drug: SSR126517E "biotinylated idraparinux"; Drug: warfarin
		Sponsor:	Sanofi-Aventis
		Number Enrolled:	9600
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Active Control; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Prevention
		Start Date:	December 2007
		Completion Date:	September 2010
		Acronym:	BOREALIS-AF
		Outcome Measures:	composite of all strokes or non central nervous system (CNS) systemic embolic events (SE); separate components of the primary study outcome; composite (stroke or non CNS SE or major bleeding or death)
54	Completed	Efficacy and Safety of SR58611 Compared to Placebo and Paroxetine	
		Condition:	Major Depressive Disorders
		Interventions:	Drug: amibegron (SR58611A); Drug: placebo; Drug: paroxetine
		Sponsor:	Sanofi-Aventis
		Number Enrolled:	317
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Control: Placebo Control; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
		Start Date:	November 2003
		Completion Date:	October 2004
		Acronym:	
		Outcome Measures:	change from baseline of the total score of the HAM-D 17 items.; HAM-D subscores; HAM-D responders and remitters; HAM-A total score and subscores; MADRS total score; clinical global impression

			(CGI) severity and improvement scores; patient global impression (PGI) improvement score; social and occupational functioning assessment scale (SOFAS) score; clinical monitoring of adverse events (AEs); laboratory parameters; electrocardiogram (ECG) parameters, change in vital signs and body weight
55	Recruiting	6-month Comparison of Morning Lantus Versus Neutral Protamine Hagedorn Insulin in Young Children With Type 1 Diabetes	
		Condition:	Type 1 Diabetes Mellitus
		Interventions:	Drug: INSULIN GLARGINE (HOE901); Drug: Neutral Protamine Hagedorn (NPH) insulin
		Sponsor:	Sanofi-Aventis
		Number Enrolled:	120
		Funded By:	INDUSTRY
		Study Type:	Interventional
		Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
		Start Date:	October 2009
		Completion Date:	March 2011
		Acronym:	PRESCHOOL
		Outcome Measures:	Event rate of "all hypoglycemia" during treatment with study drugs, which consists of: CGM glucose <70 mg/dL (3.9mM) , Self-Monitored Blood Glucose values <70 mg/dL (3.9mM), symptomatic hypoglycemia episodes; Rates of symptomatic, severe, nocturnal, nocturnal symptomatic, and severe nocturnal symptomatic hypoglycemia; HbA1c change from baseline to end-of-treatment; HbA1c at end of treatment; Percentage of patients reaching HbA1c target of less than 7.5% at the end-of-treatment visit; Average daily blood glucose (BG) based on CGM (both the end-of-treatment value and the change from baseline to end of treatment)

8.6 APPENDIX FOR THE CHAPTER ON ECONOMIC LITERATURE

8.6.1 Main search terms

Pacemakers, Implantable cardioverter defibrillators, or cardiac resynchronization therapy; remote monitoring, telemonitoring, telemedicine, Home Monitoring (Biotronik), CareLink (Medtronic), Latitude (Boston Scientific), or Merlin.net (St Jude); and cost or economic

8.6.2 Search strategy (initial search)

Date	July 23, 2009
Database (name + access ; eg Medline OVID)	Ovid MEDLINE®
Date covered (segment)	1950 to Present
Search Strategy (attention, for PubMed, check « Details »)	1 exp Cardiac Pacing, Artificial/ or exp Pacemaker, Artificial/ (33678) 2 exp Defibrillators, Implantable/ (7479) 3 Heart, Artificial/ (4704) 4 exp Heart-Assist Devices/ (5779) 5 exp Assisted Circulation/ (10593) 6 implantable defibrillator$.mp. (1118) 7 implantable cardioverter-defibrillator$.mp. (4325) 8 implantable cardioverter defibrillator$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (4325) 9 pacemaker$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (32134) 10 heart assist device$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (5820) 11 heart assist pump$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (3) 12 artificial ventricle$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (89) 13 ventricle assist device$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (33) 14 artificial heart ventricle$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (25) 15 artificial heart.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (2233) 16 mechanical heart.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (968) 17 assisted circulation.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (3271) 18 circulation assistance.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (9) 19 circulation support.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (32) 20 ventricular assistance.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (324) 21 biventricular pacing.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (809) 22 (ICD or ICDs).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (12165) 23 (cardiac resynchronization or cardiac resynchronisation or ventricular resynchronization or ventricular resynchronisation).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (1972) 24 CRT.mp. (3872) 25 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14

	or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 (77999) 26 exp Telemedicine/ or exp Remote Consultation/ (10452) 27 exp Telemetry/ (5963) 28 exp Monitoring, Ambulatory/ (15980) 29 exp Electrocardiography, Ambulatory/ (7577) 30 telemedicine.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (8151) 31 (tele monitoring or telemonitoring or teleconsultation or tele consultation or tele cardiography or telecardiography or tele cardiology or telecardiology or tele radiometry or teleradiometry or telesensing or tele sensing or telehomecare or tele homecare).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (774) 32 (ambulatory monitoring or remote monitoring or home monitoring or long distance monitoring).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (2703) 33 (remote consultation$ or long distance consultation$ or ambulatory sensing or remote sensing or outpatient monitoring).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (3866) 34 (telemetry or biotelemetry or telemetries or radiotelemetry or radioelectrocardiography).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (8032) 35 (carelink or cardiomessenger or (biotronik and home monitoring) or (boston scientific and latitiude) or (St Jude and merlin)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (25) 36 or/26-35 (36464) 37 25 and 36 (1762) 38 exp "Costs and Cost Analysis"/ (144607) 39 exp "Cost of Illness"/ (11909) 40 exp Health Care Costs/ (33426) 41 exp Economics, Hospital/ or exp Economics, Nursing/ or exp Economics/ or exp Economics, Medical/ (410049) 42 exp "Value of Life"/ (5057) 43 exp Quality-Adjusted Life Years/ (3957) 44 exp Models, Economic/ (6636) 45 exp Markov Chains/ (5705) 46 exp Monte Carlo Method/ (12668) 47 exp Decision Trees/ (6943) 48 econom$.tw. (107967) 49 cost$.tw. (231230) 50 (pharmacoeconomic$ or (pharmaco adj economic$)).tw. (2223) 51 (price$ or pricing$).tw. (16761) 52 budget$.tw. (13061) 53 expenditure$.tw. (25442) 54 (cea or cua or cba).tw. (21027) 55 or/38-54 (685580) 56 37 and 55 (77) 57 from 56 keep 1-77 (77)

Date	July 23, 2009
Database (name + access ; eg Medline OVID)	Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations
Date covered (segment)	<July 22, 2009>
Search Strategy (attention, for PubMed, check « Details »)	1 implantable defibrillator$.mp. (25) 2 implantable cardioverter-defibrillator$.mp. (218) 3 implantable cardioverter defibrillator$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (218) 4 pacemaker$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (475) 5 heart assist device$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (1) 6 heart assist pump$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (0) 7 artificial ventricle$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (1) 8 ventricle assist device$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (0) 9 artificial heart ventricle$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (0) 10 artificial heart.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (25) 11 mechanical heart.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (33) 12 assisted circulation.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (3) 13 circulation assistance.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (0) 14 circulation support.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (2) 15 ventricular assistance.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (7) 16 biventricular pacing.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (34) 17 (ICD or ICDs).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (571) 18 (cardiac resynchronization or cardiac resynchronisation or ventricular resynchronization or ventricular resynchronisation).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (140) 19 CRT.mp. (240) 20 telemedicine.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (184) 21 (tele monitoring or telemonitoring or teleconsultation or tele consultation or tele cardiography or telecardiography or tele cardiology or telecardiology or tele radiometry or teleradiometry or telesensing or tele sensing or telehomecare or tele homecare).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (65) 22 (ambulatory monitoring or remote monitoring or home monitoring or long distance monitoring).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (101) 23 (remote consultation$ or long distance consultation$ or ambulatory sensing or remote sensing or outpatient monitoring).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (471) 24 (telemetry or biotelemetry or telemetries or radiotelemetry or radioelectrocardiography).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (131) 25 (carelink or cardiomessenger or (biotronik and home monitoring) or

	(boston scientific and latitiude) or (St Jude and merlin)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (4) 26 econom$.tw. (4903) 27 cost$.tw. (10804) 28 (pharmacoeconomic$ or (pharmaco adj economic$)).tw. (101) 29 (price$ or pricing$).tw. (712) 30 budget$.tw. (613) 31 expenditure$.tw. (819) 32 (cea or cua or cba).tw. (350) 33 or/1-19 (1460) 34 or/20-25 (917) 35 or/26-32 (16257) 36 33 and 34 (15) 37 36 and 35 (0)

Date	July 23, 2009
Database (name + access ; eg Medline OVID)	Econlit - Ovid
Date covered (segment)	<1969 to July 2009>
Search Strategy (attention, for PubMed, check « Details »)	1 implantable defibrillator$.mp. (1) 2 implantable cardioverter-defibrillator$.mp. (1) 3 implantable cardioverter defibrillator$.mp. [mp=heading words, abstract, title, country as subject] (1) 4 pacemaker$.mp. [mp=heading words, abstract, title, country as subject] (7) 5 heart assist device$.mp. [mp=heading words, abstract, title, country as subject] (0) 6 heart assist pump$.mp. [mp=heading words, abstract, title, country as subject] (0) 7 artificial ventricle$.mp. [mp=heading words, abstract, title, country as subject] (0) 8 ventricle assist device$.mp. [mp=heading words, abstract, title, country as subject] (0) 9 artificial heart ventricle$.mp. [mp=heading words, abstract, title, country as subject] (0) 10 artificial heart.mp. [mp=heading words, abstract, title, country as subject] (1) 11 mechanical heart.mp. [mp=heading words, abstract, title, country as subject] (0) 12 assisted circulation.mp. [mp=heading words, abstract, title, country as subject] (0) 13 circulation assistance.mp. [mp=heading words, abstract, title, country as subject] (0) 14 circulation support.mp. [mp=heading words, abstract, title, country as subject] (0) 15 ventricular assistance.mp. [mp=heading words, abstract, title, country as subject] (0) 16 biventricular pacing.mp. [mp=heading words, abstract, title, country as subject] (0) 17 (ICD or ICDs).mp. [mp=heading words, abstract, title, country as subject] (22) 18 (cardiac resynchronization or cardiac resynchronisation or ventricular resynchronization or ventricular resynchronisation).mp. [mp=heading words, abstract, title, country as subject] (0) 19 CRT.mp. (16) 20 telemedicine.mp. [mp=heading words, abstract, title, country as subject] (15) 21 (tele monitoring or telemonitoring or teleconsultation or tele

	consultation or tele cardiography or telecardiography or tele cardiology or telecardiology or tele radiometry or teleradiometry or telesensing or tele sensing or telehomecare or tele homecare).mp. [mp=heading words, abstract, title, country as subject] (0) 22 (ambulatory monitoring or remote monitoring or home monitoring or long distance monitoring).mp. [mp=heading words, abstract, title, country as subject] (1) 23 (remote consultation$ or long distance consultation$ or ambulatory sensing or remote sensing or outpatient monitoring).mp. [mp=heading words, abstract, title, country as subject] (116) 24 (telemetry or biotelemetry or telemetries or radiotelemetry or radioelectrocardiography).mp. [mp=heading words, abstract, title, country as subject] (1) 25 (carelink or cardiomessenger or (biotronik and home monitoring) or (boston scientific and latitiude) or (St Jude and merlin)).mp. [mp=heading words, abstract, title, country as subject] (0) 26 econom$.tw. (239502) 27 cost$.tw. (74158) 28 (pharmacoeconomic$ or (pharmaco adj economic$)).tw. (229) 29 (price$ or pricing$).tw. (86241) 30 budget$.tw. (12853) 31 expenditure$.tw. (15504) 32 (cea or cua or cba).tw. (203) 33 or/1-19 (47) 34 or/20-25 (133) 35 or/26-32 (353339) 36 33 and 34 (0) 37 36 and 35 (0)

Date	July 23, 2009
Database (name + access ; eg Medline OVID)	PsycINFO - Ovid
Date covered (segment)	<1806 to July Week 3 2009>
Search Strategy (attention, for PubMed, check « Details »)	1 implantable defibrillator$.mp. (6) 2 implantable cardioverter-defibrillator$.mp. (84) 3 implantable cardioverter defibrillator$.mp. [mp=title, abstract, heading word, table of contents, key concepts] (84) 4 pacemaker$.mp. [mp=title, abstract, heading word, table of contents, key concepts] (1010) 5 heart assist device$.mp. [mp=title, abstract, heading word, table of contents, key concepts] (0) 6 heart assist pump$.mp. [mp=title, abstract, heading word, table of contents, key concepts] (0) 7 artificial ventricle$.mp. [mp=title, abstract, heading word, table of contents, key concepts] (0) 8 ventricle assist device$.mp. [mp=title, abstract, heading word, table of contents, key concepts] (1) 9 artificial heart ventricle$.mp. [mp=title, abstract, heading word, table of contents, key concepts] (0) 10 artificial heart.mp. [mp=title, abstract, heading word, table of contents, key concepts] (13) 11 mechanical heart.mp. [mp=title, abstract, heading word, table of contents, key concepts] (3) 12 assisted circulation.mp. [mp=title, abstract, heading word, table of contents, key concepts] (0) 13 circulation assistance.mp. [mp=title, abstract, heading word, table of contents, key concepts] (0) 14 circulation support.mp. [mp=title, abstract, heading word, table of

	contents, key concepts] (0) 15 ventricular assistance.mp. [mp=title, abstract, heading word, table of contents, key concepts] (0) 16 biventricular pacing.mp. [mp=title, abstract, heading word, table of contents, key concepts] (0) 17 (ICD or ICDs).mp. [mp=title, abstract, heading word, table of contents, key concepts] (3649) 18 (cardiac resynchronization or cardiac resynchronisation or ventricular resynchronization or ventricular resynchronisation).mp. [mp=title, abstract, heading word, table of contents, key concepts] (0) 19 CRT.mp. (874) 20 telemedicine.mp. [mp=title, abstract, heading word, table of contents, key concepts] (1145) 21 (tele monitoring or telemonitoring or teleconsultation or tele consultation or tele cardiography or telecardiography or tele cardiology or telecardiology or tele radiometry or teleradiometry or telesensing or tele sensing or telehomecare or tele homecare).mp. [mp=title, abstract, heading word, table of contents, key concepts] (73) 22 (ambulatory monitoring or remote monitoring or home monitoring or long distance monitoring).mp. [mp=title, abstract, heading word, table of contents, key concepts] (297) 23 (remote consultation$ or long distance consultation$ or ambulatory sensing or remote sensing or outpatient monitoring).mp. [mp=title, abstract, heading word, table of contents, key concepts] (63) 24 (telemetry or biotelemetry or telemetries or radiotelemetry or radioelectrocardiography).mp. [mp=title, abstract, heading word, table of contents, key concepts] (585) 25 (carelink or cardiomessenger or (biotronik and home monitoring) or (boston scientific and latitiude) or (St Jude and merlin)).mp. [mp=title, abstract, heading word, table of contents, key concepts] (1) 26 econom$.tw. (55937) 27 cost$.tw. (42582) 28 (pharmacoeconomic$ or (pharmaco adj economic$)).tw. (217) 29 (price$ or pricing$).tw. (7037) 30 budget$.tw. (3596) 31 expenditure$.tw. (4438) 32 (cea or cua or cba).tw. (786) 33 or/1-19 (5573) 34 or/20-25 (2083) 35 or/26-32 (104498) 36 33 and 34 (9) 37 36 and 35 (1) 38 from 37 keep 1 (1)
Note	

Date	July 23, 2009
Database (name + access ; eg Medline OVID)	Embase
Date covered (segment)	1974 to present
Search Strategy (attention, for PubMed, check « Details »)	#1. 'artificial heart pacemaker'/exp 23,328 #2. 'pacemaker electrode'/exp 989 #3. 'artificial heart'/exp 2,036 #4. 'defibrillator'/exp 12,489 #5. 'assisted circulation'/exp 5,865 #6. 'heart pacing'/exp 18,814 #7. 'cardiac resynchronization therapy'/exp 2,774 #8. pacemaker*:ab,ti 26,910 #9. 'heart ventricle prosthesis':ab,ti OR 'mechanical 3,625

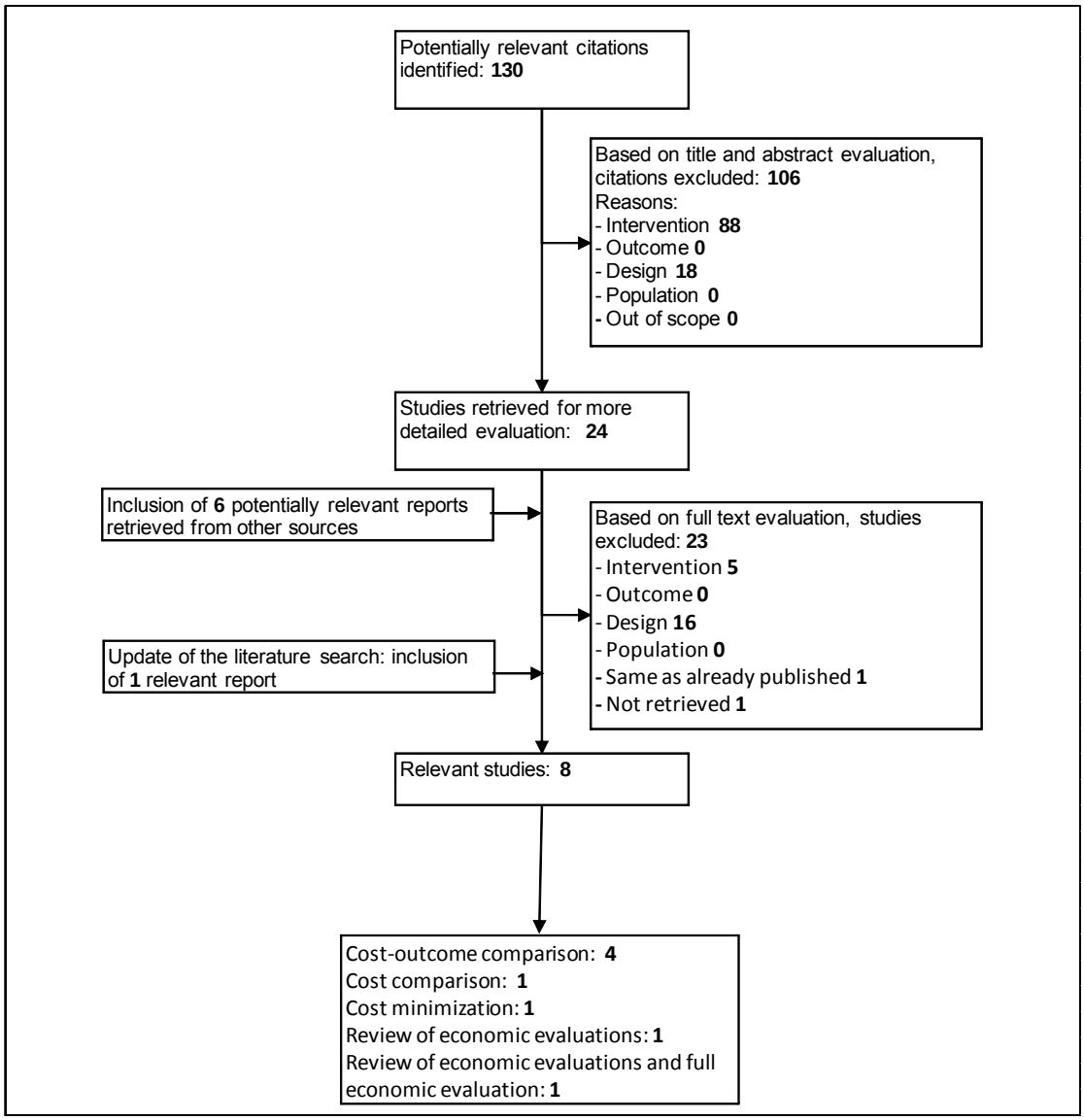
	heart':ab,ti OR 'artificial heart':ab,ti	
	#10. 'implantable defibrillator':ab,ti OR 'implantable defibrillators':ab,ti	1,233
	#11. 'heart ventricle assist':ab,ti OR 'heart-assist devices':ab,ti OR 'heart-assist device':ab,ti OR 'heart assist devices':ab,ti OR 'heart assist device':ab,ti OR 'heart assist pump':ab,ti OR 'heart assist pumps':ab,ti OR 'artificial ventricle':ab,ti OR 'artificial ventricles':ab,ti OR 'artificial heart ventricle':ab,ti OR 'artificial heart ventricles':ab,ti OR 'ventricle assist devices':ab,ti OR 'ventricle assist device':ab,ti	272
	#12. 'circulation assistance':ab,ti OR 'circulation support':ab,ti OR 'assisted circulation':ab,ti OR 'circulatory support':ab,ti OR 'heart auxillary':ab,ti OR 'heart ventricle assistance':ab,ti OR 'heart ventricular assistance':ab,ti OR ('ventricular assistance'/exp OR 'ventricular assistance')	7,146
	#13. 'biventricular pacing':ab,ti OR 'cardiac resynchronisation':ab,ti OR 'cardiac resynchronization':ab,ti OR 'ventricular resynchronisation':ab,ti OR 'ventricular resynchronization':ab,ti	2,990
	#14. icd:ab,ti OR icds:ab,ti OR crt:ab,ti	19,593
	#15. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14	84,952
	#16. 'telemedicine'/exp	4,220
	#17. 'teleconsultation'/exp	1,139
	#18. 'telemetry'/exp	8,230
	#19. 'ambulatory monitoring'/exp	6,535
	#20. 'home monitoring'/exp	1,964
	#21. 'telemonitoring'/exp OR 'telecardiology'/exp	234
	#22. 'remote sensing'/exp	1,273
	#23. 'tele monitoring':ab,ti OR telemonitoring:ab,ti OR teleconsultation:ab,ti OR 'tele consultation':ab,ti OR 'tele cardiography':ab,ti OR telecardiography:ab,ti OR 'tele cardiology':ab,ti OR telecardiology:ab,ti OR 'tele radiometry':ab,ti OR teleradiometry:ab,ti OR telesensing:ab,ti OR 'tele sensing':ab,ti OR telehomecare:ab,ti OR 'tele homecare':ab,ti	911
	#24. 'ambulatory monitoring':ab,ti OR 'remote monitoring':ab,ti OR 'home monitoring':ab,ti OR 'long distance monitoring':ab,ti OR 'remote consultation':ab,ti OR 'remote consultations':ab,ti OR 'long distance consultation':ab,ti OR 'long distance consultations':ab,ti OR 'ambulatory sensing':ab,ti OR 'remote sensing':ab,ti OR 'outpatient monitoring':ab,ti OR telemetry:ab,ti OR biotelemetry:ab,ti OR telemetries:ab,ti OR radiotelemetry:ab,ti OR radioelectrocardiography:ab,ti	9,421
	#25. carelink:ab,ti OR cardiomessenger:ab,ti	20
	#26. biotronik:ab,ti AND 'home monitoring':ab,ti	6
	#27. 'boston scientific':ab,ti AND latitude:ab,ti	0
	#28. 'st jude':ab,ti AND merlin:ab,ti	0
	#29. #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28	26,240
	#30. #15 AND #29	1,019
	#31. ('health economics'/exp OR 'health economics') OR 'health economic':ab,ti OR 'health economics':ab,t	445,592

	i #32. ('health care cost'/exp OR 'health care cost') OR ('economic evaluation'/exp OR 'economic evaluation') OR ('pharmacoeconomics'/exp OR 'pharmacoeconomics') 332,430 #33. (expenditure:ab,ti NOT energy:ab,ti) OR (expenditures:ab,ti NOT energy:ab,ti) 15,578 #34. econom*:ab,ti 133,927 #35. cost:ab,ti OR costs:ab,ti OR costly:ab,ti OR costing:ab,ti OR price:ab,ti OR prices:ab,ti OR pricing:ab,ti OR pharmacoeconomic:ab,ti OR pharmacoeconomics:ab,ti 276,520 #36. budget*:ab,ti 16,310 #37. 'value *2 money' 760 #38. #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 696,495 #39. #30 AND #38 87
Note	

Date	July 24, 2009
Database (name + access ; eg Medline OVID)	Cochrane Library: Cochrane Database of systematic reviews, DARE, Cochrane Central Register of Controlled Trials, HTA, NHS EED, Cochrane groups and Methods studies.
Date covered (segment)	1800 to present
Search Strategy (attention, for PubMed, check « Details »)	#1 MeSH descriptor Pacemaker, Artificial explode all trees 487 #2 MeSH descriptor Cardiac Pacing, Artificial explode all trees 803 #3 MeSH descriptor Defibrillators, Implantable explode all trees 624 #4 MeSH descriptor Heart, Artificial explode all trees 139 #5 MeSH descriptor Heart-Assist Devices explode all trees 134 #6 MeSH descriptor Assisted Circulation explode all trees 262 #7 (implantable defibrillator):ti,ab,kw or (implantable defibrillators):ti,ab,kw or (implantable cardioverter defibrillator):ti,ab,kw or (implantable cardioverter defibrillators):ti,ab,kw 735 #8 (pacemaker):ti,ab,kw or (pacemakers):ti,ab,kw 919 #9 (heart assist device):ti,ab,kw or (heart assist devices):ti,ab,kw or (heart assist pump):ti,ab,kw or (heart assist pumps):ti,ab,kw 171 #10 (artificial ventricle):ti,ab,kw or (artificial ventricles):ti,ab,kw or (ventricle assist device):ti,ab,kw or (ventricle assist devices):ti,ab,kw or (artificial heart):ti,ab,kw 1080 #11 (artificial heart ventricle):ti,ab,kw or (artificial heart ventricles):ti,ab,kw or (heart pump):ti,ab,kw or (heart pumps):ti,ab,kw or (mechanical heart):ti,ab,kw 1103 #12 (heart auxillary):ti,ab,kw 0 #13 (assisted circulation):ti,ab,kw or (circulation assistance):ti,ab,kw or (circulation support):ti,ab,kw or (circulatory support):ti,ab,kw or (ventricular assistance):ti,ab,kw 485 #14 (biventricular pacing):ti,ab,kw or (cardiac resynchronization):ti,ab,kw or (cardiac resynchronisation):ti,ab,kw or (ventricular resynchronization):ti,ab,kw or (ventricular resynchronisation):ti,ab,kw 228 #15 (ICD):ti,ab,kw or (ICDs):ti,ab,kw or (CRT):ti,ab,kw 1183 #16 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15) 4584 #17 MeSH descriptor Telemedicine explode all trees 761 #18 MeSH descriptor Remote Consultation explode all trees 279 #19 MeSH descriptor Telemetry explode all trees 136 #20 MeSH descriptor Monitoring, Ambulatory explode all trees 1910 #21 MeSH descriptor Electrocardiography, Ambulatory explode all trees 913 #22 (telemedicine):ti,ab,kw or (tele medicine):ti,ab,kw or (telemonitoring):ti,ab,kw or (tele monitoring):ti,ab,kw 679 #23 (teleconsultation):ti,ab,kw or (tele consultation):ti,ab,kw or

	(telecardiography):ti,ab,kw or (tele cardiography):ti,ab,kw 26 #24 (telecardiology):ti,ab,kw or (tele cardiology):ti,ab,kw or (teleradiometry):ti,ab,kw or (tele radiometry):ti,ab,kw 13 #25 (telesensing):ti,ab,kw or (tele sensing):ti,ab,kw or (telehomecare):ti,ab,kw or (tele homecare):ti,ab,kw 12 #26 (ambulatory monitoring):ti,ab,kw or (remote monitoring):ti,ab,kw or (home monitoring):ti,ab,kw or (long distance monitoring):ti,ab,kw 3196 #27 (remote consultation):ti,ab,kw or (remote consultations):ti,ab,kw or (long distance consultation):ti,ab,kw or (long distance consultations):ti,ab,kw 306 #28 (ambulatory sensing):ti,ab,kw or (remote sensing):ti,ab,kw or (outpatient monitoring):ti,ab,kw 743 #29 (telemetry):ti,ab,kw or (biotelemetry):ti,ab,kw or (telemetries):ti,ab,kw or (radiotelemetry):ti,ab,kw or (radioelectrocardiography):ti,ab,kw 240 #30 (carelink):ti,ab,kw or (cardiomessenger):ti,ab,kw 2 #31 (biotronik):ti,ab,kw and (home monitoring):ti,ab,kw 0 #32 (St Jude):ti,ab,kw and (Merlin):ti,ab,kw 0 #33 (boston scientific):ti,ab,kw and (latitude):ti,ab,kw 0 #34 (#17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33) 5409 #35 (#16 AND #34) 163 #36 MeSH descriptor Costs and Cost Analysis explode all trees 28312 #37 MeSH descriptor Cost of Illness explode all trees 3309 #38 MeSH descriptor Health Care Costs explode all trees 11256 #39 MeSH descriptor Economics explode all trees 30166 #40 MeSH descriptor Economics, Hospital explode all trees 3084 #41 MeSH descriptor Economics, Nursing explode all trees 26 #42 MeSH descriptor Economics, Medical explode all trees 283 #43 MeSH descriptor Value of Life explode all trees 297 #44 MeSH descriptor Quality-Adjusted Life Years explode all trees 2292 #45 MeSH descriptor Models, Economic explode all trees 2067 #46 MeSH descriptor Markov Chains explode all trees 1025 #47 MeSH descriptor Monte Carlo Method explode all trees 357 #48 MeSH descriptor Decision Trees explode all trees 745 #49 (economic):ti,ab,kw or (economics):ti,ab,kw or (economical):ti,ab,kw or (economy):ti,ab,kw 32671 #50 (cost):ti,ab,kw or (costs):ti,ab,kw or (costing):ti,ab,kw or (costly):ti,ab,kw 40140 #51 (price):ti,ab,kw or (prices):ti,ab,kw or (pricing):ti,ab,kw 610 #52 (pharmacoeconomic):ti,ab,kw or (pharmacoeconomics):ti,ab,kw 1129 #53 (budget):ti,ab,kw or (budgets):ti,ab,kw or (budgeting):ti,ab,kw 352 #54 (expenditure):ti,ab,kw or (expenditures):ti,ab,kw 2804 #55 (cea):ti,ab,kw or (cua):ti,ab,kw or (cba):ti,ab,kw 401 #56 (#36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55) 48064 #57 (#35 AND #56) 18
Note	Cochrane Database of Systematic Reviews [0] | Database of Abstracts of Reviews of Effects [0] | Cochrane Central Register of Controlled Trials [14] | Methods Studies [0] | Health Technology Assessment Database [0] | NHS Economic Evaluation [4] | Cochrane Groups [0].

8.6.3 Retrieved studies from initial search



8.6.4 Data extraction forms

Authors (Year)	Fauchier L, Sadoul N, Kouakam C, Briand F, Chauvin M, Babuty D, Clementy J (2005).
Funding	Not specified.
Country	France.
Design	Cost comparison - Retrospective observational study (6 university hospitals).
Perspective	Not specified (seems to be the societal perspective (without taken into account opportunity costs)).
Time window	5 years (Device life expectancy).
Interventions	ICD follow-up with remote monitoring compared to conventional follow-up. Device: Home monitoring (Biotronik).
Population	Patients with implantable cardioverter defibrillator (ICD). N = 502 patients (87% male; 61 +/- 13 years).
Assumptions	1) Remote monitoring obviates 2 visits per year. 2) Patients were transported in a medical vehicle without physician attendance for a cost of $10.75 until a distance of 5 km and $0.75 for additional km. 3) Medical services: $45.73/visits (physician's fees and electrocardiogram) + $48/visit (ICD surveillance). 4) Life expectancy of the device: 5 years. 5) Cost of the HM system: $1200.
Data source for costs	Hospitals tariffs and assumptions. Distances were assessed using a free software available on internet: www.mappy.fr.
Cost items included	Cost of medical services (physician fees, electrocardiogram, and ICD surveillance) and transportation for each visit (mean distance between home and the medical institution = 69+/-57km). Cost of the HM system.
Data source for outcomes	/
Discounting	No discounting.
Costs	Mean transportation cost per visit = $121. Mean cost for medical services per visit = $94. Mean total cost per visit = $215. Cost of the HM system = $1200. Mean cost of conventional follow-up over 5 years: $4297 +/- $1767. Mean cost-saving over 5 years, excluding the cost of the HM system: $2148 (= +/- 2*5*215). Mean cost-saving over 5 years, including the cost of the HM system: $948. Break event point reached after 33.5 months.
Outcomes	/
Cost-effectiveness	/
Sensitivity analysis	If only patients living from a distance of at least 50 km away from the medical institution, the mean cost-saving would be $2722, with a break-event point reached at 26 months. If only patients living from a distance of no more than 50 km away from the medical institution, the mean cost-saving would be $177, with a break-event point reached at 52 months.
Conclusions	Transportation costs had a major impact on results.
Remarks	1) Savings due to an early detection of medical events or the reduction of the number of inappropriate shocks were not assessed. 2) Cost of the staff time to analyse the information send by the HM system was not taken into account. Training of the patient was also not included. Moreover, the study did not specified what is included in the stated cost of $1200 for the HM system. 3) The number of visits prevented by remote monitoring was based on an assumption. Moreover, the costs of required visits or device reprogramming due to clinical events or technical issues identified by HM

	were not taken into account. 4) The study is only applicable for patients with ICD and not for patients with pacemakers (with less follow-up visits required). 5) The study results are not transferable to our study setting (e.g. transportation costs are expected to be reduced: shorter distance and patients are not transported in medical vehicle). 6) Uncertainty was only partially analysed (only a sensitivity analysis on the distance between home and the institute was performed).

Authors (Year)	Elsner CH, Sommer P, Piorkowski C, Taborski M, Neuser H, Bytesnik J, Geller JC, Kottkamp H, Wiesmeth H, Hindricks G (2006).
Funding	Not specified.
Country	Germany
Design	Cost-outcome comparison - Randomised clinical trial (randomisation method not explained)
Perspective	Not specified (seems to be the societal perspective (without taken into account opportunity costs)).
Time window	117 days → interpolated for one year with 100 patients
Interventions	ICD follow-up with remote monitoring alone (annual follow-up visits) compared to conventional follow-up + remote monitoring (quarterly follow-up visits). Device: Home monitoring (Biotronik).
Population	Patients with implantable cardioverter defibrillator (ICD). N = 115 patients (86% male; 62 +/- 8 years) → interpolated for one year with 100 patients.
Assumptions	1) In the "remote monitoring" group: 1 visit/year is required. In the conventional group + remote monitoring: one visit every 3 months is required. 2) Observations of the 115 patients do not fluctuate over time (interpolation of results for 1 year). 3) Transportation cost: €65 for one way in ambulance (3.9%) and €20 for one way by car or common transport (self transport).
Data source for costs	International benchmark database for clinical process time,[171], German database for clinical process costs [172], pricelists for furniture and equipment[173], pricelists for ambulance transportation[174], Mileage allowance[175].
Cost items included	Revenues per average case in the Centers (fees), Physician and nursing cost (real cost), Overhead costs, transportation cost
Data source for outcomes	This randomized clinical trial.
Discounting	/
Costs	1) Transportation costs: conventional follow-up + remote monitoring: €174/patient/year; remote monitoring group: €64/patient/year; Incremental transportation cost: -€110/patient/year (-63.2%). 2) Total incremental cost: -€712.31/patient/year (-60.9%).
Outcomes	1) Reduction of visits: 63.2% (-75% of required visits; +3.9% of remote monitoring induced visits; +7.9% of patients induced visits). 2) Physician time: conventional follow-up + remote monitoring: 120min/patient/year; remote monitoring group: 71.4 min/patient/year; Incremental physician time: -48.6 min/patient/year (-40.5%).
Cost-effectiveness	/
Sensitivity analysis	/
Conclusions	The study showed a potential cost-saving (-60.9%) and a reduction of patient visits (-63.2%).
Remarks	1) Remote monitoring was compared to conventional follow-up with remote monitoring but not with conventional follow-up

	without remote monitoring. 2) Sources and method for cost calculation are not clear. Both fees and real cost are calculated and some cost items could be taken into account two times (total cost per case according to G-DRG (fees) + real cost for the physician and the nurse + overhead costs). Moreover, it is not clear whether transportation time is included in the calculation (Patient time and cost for transportation = €20). Patients' training was also not included. 3) Transportation costs are not adapted to our country setting. 4) Uncertainty was not analysed (no confidence interval or sensitivity analysis)

Authors (Year)	Marzegalli M, Lunati M, Landolina M, Perego GB, Ricci RP, Guenzati G, Schirru M, Belvito C, Brambilla R, Masella C, Di Stasi F, Valsecchi S, Santini M (2008).
Funding	Not specified. NB. Di Stasi F and Valsecchi S are employees of Medtronic. According to authors, no other conflict of interest exists.
Country	Italy.
Design	Cost-outcome comparison - Before and after study.
Perspective	Not specified (seems to be the societal perspective (without taken into account opportunity costs)).
Time window	3 months (for costs: 6 years).
Interventions	CRT-D with remote monitoring compared to conventional follow-up. Device: CareLink (Medtronic). Number of scheduled transmission during the 3 months: after 2 weeks, 1 month, and 2 months.
Population	Patients with biventricular defibrillator for cardiac resynchronization therapy (CRT-D) indications for more than 6 months. N = 67 patients (87% male; 64 +/- 9 years; 84% were implanted for primary prevention of sudden cardiac death).
Assumptions	Remote monitoring obviates 2 scheduled visits/year and 1 unscheduled visit/year.
Data source for costs	This before and after study + Italian national tariffs and assumptions.
Cost items included	Cost of medical services and transportation for each visit (Italian national tariffs for clinical assessment, electrocardiogram, and device surveillance). Cost of the remote monitoring system.
Data source for outcomes	This before and after study.
Discounting	/
Costs	1) Mean distance between home and the medical institution = 10km (1-400km). 2) Mean transportation cost per visit: €18.41 +/- 33.68. 3) Mean cost for medical services per visit = €47.77. 4) Mean total cost per visit: 47.77 + 18.41 = €66.18. 5) Mean cost-saving over 6 years, excluding the cost of the remote monitoring system: $1 191.24 (= (2+1)*€66.18*6).
Outcomes	1) Total mean time per routine in-clinic visit: 116 +/- 90 min (transportation, waiting and visit time). 2) Number of unscheduled remote transmissions: 23 (1.37 per patient-year) 3) Number of unscheduled in-hospital visit: 4 (17%; 0.24 per patient-year) 4) Mean interrogation procedure duration: 7+/-5 min (39% of patients needed assistance). 5) Number of session of review of remove transmissions: 32 (for 67 patients) 6) Median number of remove transmissions reviewed per sessions: 7 (1-15) 7) Mean session duration: 32+/-23 min. 8) Mean time for the review per patient with a transmission: 5+/-2

	min. 9) Overall ease of use after 3 months for the patients: very easy: 67%; easy: 33%; difficult: 0%, very difficult: 0%. 10) 78% of patients preferred the remote monitoring system compared to in-clinic visits.
Cost-effectiveness	/
Sensitivity analysis	/
Conclusions	The ease of use, satisfaction, and acceptance of the CareLink Network is elevated both for patients and clinicians.
Remarks	1) The cost of the device and of the patients' training was not included. 2) Savings due to an early detection of medical events or the reduction of the number of inappropriate shocks were not assessed. 3) Cost of the staff time to analyse the information send by the remote monitoring system was not taken into account. 4) The number of visits prevented by remote monitoring was based on an assumption. Moreover, the costs of required visits or device reprogramming due to clinical events or technical issues identified by HM were not taken into account. 5) The study is only applicable for patients with ICD or CRT and not for patients with pacemakers (with less follow-up visits required). 6) Patients were not controlled continuously (i.e. each day), as it is the aim of these devices. 7) The study results are not transferable to our study setting. 8) Uncertainty was not analysed.

Authors (Year)	Halimi F, Clémenty J, Attuel P, Dessenne X, Amara W, investigators of the OEDIPE trial (2008).
Funding	Biotronik.
Country	France.
Design	Cost-outcome comparison-Randomised controlled trial (RCT) (no blinding).
Perspective	Not specified (seems to be the societal perspective (without taken into account opportunity costs)).
Time window	1 month (recruitment between April 2005 and December 2006).
Interventions	A follow-up using remote monitoring and with early discharge from the hospital (within 24 h after first implant or within 4-6h after pulse generator replacement) compared to conventional follow-up. Device: Home monitoring (Biotronik).
Population	Patients with a dual-chamber pacemaker. N = 379 patients (Active group: n = 184; control group: n = 195) (61% male; 75+/-9.8 years).
Assumptions	For the active group: early discharge (=study protocol).
Data source for costs	This RCT (private tariffs and public reimbursement tariffs). Sources to assess and value distances were not communicated (seems to be reimbursed transportation cost in ambulance).
Cost items included	Not clear: private tariffs and public reimbursement tariffs. Costs related to the remote monitoring system were not included.
Data source for outcomes	This RCT.
Discounting	No discounting.
Costs	Mean total cost per patient: for the active group: €7125+/-1543; for the control group: €7414+/-1659 (p-value= 0.08).
Outcomes	1) Adverse events: absolute RR: 1.1 (95%CI: -6.9 to 9.1; p=0.78) 2) Major adverse events: absolute RR: 4.1% (95%CI: -2.2 to 10.4; p=0.98) 3) Technical adverse event = 9.2% (17/184) in the active group and

	5.6% (11/195) in the control group. Medical adverse event = 12.5% (23/184) in the active group and 13.8% (27/195) in the control group. 4) Total number of transmission: 8144 for 346 patients. Total number of warning messages: 167 for 108 of the 172 patients whose telecardiology was successfully implemented in the active group (In total: 1+/-1.5 messages/patient/month in the beginning and 0.5 message/patient/month past the fifth day after the implantation procedure). Moreover, 12 of these warning messages (7%) prompted patient visits and the detection of 4 major events and 8 non major events (9/12= technical). 5) The negative predictive value of the absence of warning by remote monitoring was 94% (95%CI: 91%-98%). 6) The mean duration of hospitalisation was 34% shorter in the active group (95% CI: 19%-49%). Post-operative period: gain of 1.4+/-3.3 days (95%CI: 0.89-1.85; p<0.001) (1.4+/-2.5 versus 2.8+/-2.2). 7) SF-36: Mean psychological score: 66+/-20 (active group) vs. 68+/-18 (control group); mean physical score: 60+/-20 vs. 62+/-19; overall score: 64+/-19 vs. 67+/-19.
Cost-effectiveness	/
Sensitivity analysis	/
Conclusions	Early discharge with remote monitoring after PM was safe and remote monitoring facilitated the monitoring of patients in the month following the procedure.
Remarks	1) Costs of the remote monitoring system were not included. Cost of the staff time to analyse the information send by the remote monitoring system also seems not to be taken into account. 2) Cost items were not clear. Method to measure and value transportation costs was not explained. 3) The study period was too short (1 month). 4) Uncertainty was not analysed. For costs, 95% confidence intervals were not given.

Authors (Year)	Raatikainen MJP, Uusimaa P, van Ginneken MME, Janssen JPG, Linnaluoto M (2008).
Funding	Medtronic.
Country	Finland.
Design	Cost-outcome comparison-Prospective non-randomised single-centre trial.
Perspective	Not specified (seems to be the societal perspective).
Time window	9 months (recruitment between May 2005 and October 2006).
Interventions	ICD follow-up with remote monitoring (2 in-clinic visits + 2 scheduled data transmission + patient or physician induced transmission) compared to conventional follow-up (4 in-clinic visits). Device: CareLink (Medtronic).
Population	Patients with an ICD. N = 41 patients (83% male; 62+/-10 years (41-76)). "Patients with no access to a standard analogue telephone line or who had a hearing or other physical or mental problems hindering the use of the system were excluded from the study."
Assumptions	Remote monitoring obviates 2 scheduled visits/year (=study protocol).
Data source for costs	Tariffs of the Oulu university hospital.
Cost items included	Direct medical costs: Reimbursement tariffs and patients' fees for in-clinic visits and remote data analysis. Direct non-medical costs: Allowance for transportation cost and accommodation if necessary. Indirect cost: productivity losses valued by a sickness allowance of €44/day). Costs related to the remote monitoring system were not

	included (device and data transmission).
Data source for outcomes	This non randomized clinical trial.
Discounting	No discounting.
Costs	1) In-clinic visits: €210/visit + €22/visit for the patient = €232/visit. 2) Remote data analysis: €55/analysis. 3) Travelling cost: €77.68/visit. 4) Accommodation cost: €20.18/night. 5) Sickness allowance: €44/day. 6) Mean incremental direct medical cost: -€354/patient. 7) Mean incremental direct non medical cost: -€149.21/patient. 8) Mean incremental indirect cost: -€20.39/patient. 9) Mean incremental cost (total): -€523.60/patient. 10) Mean incremental cost including the gains for avoided unscheduled visits: between -€524 to -€749/patient.
Outcomes	1) The rate of unanticipated serious adverse device defect was < 7.5% 2) Transmission without troubleshooting: 90% (95%CI: 85%-95%) (All during the first test). 3) 80% of the remote monitoring sessions were performed by the patients without assistance. 4) The use of the device was judged by the patients as better than expected in 40% of cases and as expected in 54% of cases. The physicians judged transmissions as easy or very easy in 97% of cases and website navigation in 100% of cases. 5) Physician time: Mean physician time for in-clinic visit: 25.8+/-17.0 min (range: 5-90min); Mean physician time to review data transmitted: 8.4+/-4.5 min (range: 2-30 min) (p<0.001). 6) Additional hospital staff time: Mean time for in-clinic visit for the additional hospital staff: 45.3+/-30.6 min; Mean time to review data transmitted for the additional hospital staff: 9.3+/-15.9 min (p<0.001). 7) Patient time: Mean patient time for in-clinic visit: 391+/-282 min (range: 41-1346min) (including travel time); Mean patient time for remote data transmission: 6.9+/-3.7 min (range: 2.3-17.5 min) (p<0.001); Travel time: 182+/-148 min (range: 10-670 min); Travel distance: 130+/-95 km (range: 3-350km). 8) Number of unscheduled patient- or physician- initiated data transmission: 18 (all solved remotely).
Cost-effectiveness	/
Sensitivity analysis	/
Conclusions	Remote monitoring offer a safe, feasible, time-saving, and cost-saving solution to ICD follow-up
Remarks	1) The costs of the remote monitoring system (device and transmission) were not included. 2) Uncertainty was not analysed and 95% confidence intervals were not given. 3) Transportation costs and indirect costs are not transferable to our country setting. Area = characterized by long travelling distances to the clinic. 4) Authors concluded that remote monitoring was a cost-effective solution to ICD follow-up but no cost-effectiveness analysis was performed (=> replaced by cost-saving).

Authors (Year)	NHS. Colechin ES, Reay CA, Bousfield DR, Saxby R, Trueman P, Hutton J, Sims AJ (2009)
Funding	NHS Purchasing and Supply agency

Country	UK.
Design	Cost minimisation and full economic evaluation (cua) - Markov model
Perspective	NHS (health care provider).
Time window	10 years.
Interventions	Implantable cardiac device follow-up with remote monitoring compared to conventional follow-up. Device: all devices (no distinction).
Population	Patients with an in-dwelling implantable cardiac device and a history of atrial fibrillation.
Assumptions	1) In the first analysis (cost-minimisation), rates of clinical events were assumed to be identical in the two groups. 2) Remote monitoring lead to a reduction in hospital consultation rate (-0.453/year) but other aspect of resource use were assumed to remain constant. 3) The remote monitoring device costed £1000 (one-off cost) with no ongoing costs associated with device maintenance
Data source for costs	Number of in-hospital visits: Ricci et al 2008 (observational study) / Remote monitoring device cost: Personnal communication (£1000)/ other cost units: NHS reference costs 2006-2007 (department of Health) (= average hospital costs including overheads), Curtis 2007, Taylor 2008.
Cost items included	Medical costs: Device cost, physician and nurse visits, non-consultation led follow-up face to face, exercise tolerance test, angiography, percutaneous coronary intervention, coronary artery bypass grafting, cost of stroke and post-stroke follow-up (seems to be the real cost).
Data source for outcomes	Risk of stroke: Gage et al 2001; Probability of death if stroke, non stroke mortality and post-stroke mortality: Dennis et al 1993; utility values: Heidenreich 2004.
Discounting	Both costs and outcomes : 3.5%
Costs	/
Outcomes	/
Cost-effectiveness	In the base-case scenario (no impact on clinical events and reduction of consultations (-0.453/year): Remote monitoring is not a cost-saving strategy.
Sensitivity analysis	1) If remote monitoring couldn reduce the number of out-patients consultations to one per patient per year, remote monitoring would become cost saving in less than 6 years. 2) If remote monitoring could reduce the incidence of stroke by 1%, the ICER would be £155 499/QALY 3) If remote monitoring could reduce the incidence of stroke by 2%, the ICER would be £75 810/QALY 4) If remote monitoring could reduce the incidence of stroke by 5%, the ICER would be £27 949/QALY 5) If remote monitoring could reduce the incidence of stroke by 10%, the ICER would be £12 050/QALY 6) If remote monitoring could reduce the incidence of stroke by 20%, the ICER would be £4069/QALY 7) If remote monitoring could reduce the incidence of stroke by 5% and the incidence of death following stroke by 5%, the ICER would be £21 608/QALY 8) A longer time period or the adoption of the societal perspective would improve the ICER 9) Results are sensitive to the cost of stroke, the cost of post-stroke follow-up and the cost of the remote monitoring device. "Reducing the cost of the device to £500 per patient, resulted in the cost-effectivenss of remote monitoring falling below $30 000 with just a 2% reduction in stroke incidence compared with standard practice".
Conclusions	Remote monitoring should reduce the incidence of stroke by 5-10% to

	represent a cost-effective use of NHS resources. More evidence are needed.
Remarks	1) The study does not make the distinction between patients with ICD or patients with pacemakers (with less follow-up visits required). 2) Effectiveness and cost data came for the literature but no details on their study design and on method used to identify them were provided. Population of these studies seems not to be always adapted to the population of the model. 2) The transfer of the study results to our country setting is difficult (NHS costs). 3) Uncertainty was only partially analysed. 4) More information on the cost of the device and on the impact of remote monitoring on the incidence of stroke and death events are needed.

Authors (Year)	Al-Khatib SM, Piccini JP, Knight D, Stewart M, Clapp-Channing N, Sanders GD (2010).
Funding	Medtronic, Biotronik, Merck, Boston Scientific, Duke University Strategic Alliance
Country	USA
Design	Cost-minimisation analysis – prospective randomised single-centre clinical trial.
Perspective	Societal perspective.
Time window	One year (recruitment between December 2006 and November 2007).
Interventions	ICD follow-up with remote monitoring (use of the remote system every 3 months and one clinical visit at 12 months + more if needed) compared to conventional follow-up (quarterly follow-up visits in clinic + more if needed). Device: CareLink (Medtronic).
Population	Patients aged 18 years or older, with an ICD (with or without CRT), followed at Duke, having a landline telephone and being able to provide informed consent. N = 151. Remote monitoring group : 76 patients (69 completed the trial), 72% male; 63 years (25th percentil: 54; 75th percentil: 70); Conventional follow-up group: 75 patients (70 completed the trial), 73% male; 63 years (25th percentil: 54; 75th percentil: 72)
Assumptions	Remote monitoring obviates 3 scheduled visits/year (=study protocol).
Data source for costs	Medicare Tariffs (2009 US$).
Cost items included	Direct medical in-patient and out-patient costs: cost of the ICD implantation procedure and device ($31990) and follow-up cost (scheduled and unscheduled visits, hospitalisations, device interrogations: $66.36 and $89.92 in the conventional group and $102.79 in the remote monitoring group). Direct non-medical costs: Transportation cost (67 minutes and 55 miles on average = $6.35/visit). Indirect cost: productivity losses: $29.44 per 2-hour visit (based on an average annual income of $30613)
Data source for outcomes	This randomized clinical trial.
Discounting	3% as specified in the study. However, because of the one year period, neither costs and outcomes were discounted;
Costs	1) Implantation of the ICD: $31 990 in both groups 2) In-clinic visits: $66.36-$89.92/visit= $265.44-$359.68 four 4 visits 3) Remote monitoring group: (Remote data analysis: $102.79/analysis = $308.37 for 3 analyses) + (1 clinic visit: $66.36-$89.92) = $374.73-$398.29. 4) Travelling cost: $6.35/visit.

	5) Opportunity cost: $29.44 per 2-hours visit 6) Mean incremental direct medical cost: $109.29; $38.61/patient. 7) Mean incremental direct medical and non medical cost: $90.24; $19.56/patient. 8) Mean incremental direct and indirect cost (total): about +$1.92; -$68.76/patient (own calculation).
Outcomes	Remote monitoring group vs in-clinic follow-up group: 1) Probability to receive an angiotensin receptor blocker at 6 months: 11% vs 24%; p = 0.04 – at 12 months: 9% vs 23%; p = 0.02 2) Probability to receive a potassium-sparing diuretic at 6 months: 19% vs 34%; p = 0.05 – at 12 months: no significant differences 3) Other medications: no significant differences 4) Rate of hospitalisations and emergency room visits for a cardiac cause or of unscheduled visits for device-related issues: 32% vs 34% (p= 0.77) 5) Rate of hospitalisations: 23% vs 24% (p=0.88) 6) Rate of emergency room visits for a cardiac cause: 7% vs 5% (p= 0.74) 7) Rate of unscheduled visits for device-related issues: 7% vs 7% (p= 0.98) 8) Rate of atrial fibrillation and flutter detected by the ICD: 45% vs 26% (p= 0.01) 9) Rate of death: 5% vs 4% (p=0.99) 10) Other data on ICD detection and therapy: no significant differences 11) Quality of life and patient satisfaction measures at baseline: no significant differences (p>0.05) 12) Quality of life and patient satisfaction measures at 6 months: no significant differences (p>0.05) except for the EuroQoL VAS: 75 (50-85) vs 83 (70-90) (p= 0.002); general satisfaction: 75 (75-88) vs 88 (75-100) (p= 0.03); and communication: 75 (75-88) vs 88 (75-100) (p = 0.0008). 13) Quality of life and patient satisfaction measures at 12 months: no significant differences (p>0.05)
Cost-effectiveness	/
Sensitivity analysis	/
Conclusions	No significant reduction in cardiac-related resource utilization with remote monitoring of ICDs
Remarks	1) Items included in the cost of the remote follow-up were not clear. The cost of the remote monitoring system (device) seems not to be included. 2) Uncertainty was not analysed and 95% confidence intervals were not given. 3) The number of visits prevented by remote monitoring was based on the study design (assumption). 4) Costs are not easily transferable to our country setting (Medicare fees).

8.6.5 Quality assessment checklist

Study design	Fauchier	Elsner	Marzegalli	Halimi	Raatikainen	Al-Khatib	NHSC
The research question is stated	Yes	Partially	Partially	Yes	Yes	Yes	Yes
The economic importance of the research question is stated	Yes	Yes	Yes	No	Yes	No	Yes
The viewpoints of the analysis are clearly stated and justified	No	No	No	No	No	Yes	Yes (NHS guidelines)
The rationale for choosing the alternative programmes or interventions compared is stated	Yes	No	Yes	No	Yes	Yes	Yes
The alternatives being compared are clearly described	Partially	Partially	Partially	Partially	Partially	Partially	Partially
The form of economic evaluation used is stated	NA	NA	NA	NA	NA	Yes	Yes
The choice of form of economic evaluation is justified in relation to the questions addressed	NA	NA	NA	NA	NA	Yes	Yes
Data collection							
The sources of effectiveness estimates used are stated	NA	Yes	Yes	Yes	Yes	Yes	Yes
Details of the design and results of effectiveness study are given (if based on a single study)	NA	Partially	Yes	Yes	Yes	Yes	Partially
Details of the method of synthesis or meta-analysis of estimates are given (if based on an overview of a number of effectiveness studies)	NA	NA	NA	NA	NA	NA	NA
The primary outcome measure(s) for the economic evaluation are clearly stated	NA	No	No	No	No	NA	Yes
Methods to value health states and other benefits are stated	NA	Yes	Yes	Yes	Yes	Yes	Partially
Details of the subjects from whom evaluations were obtained are given	Yes	Yes	Yes	Yes	Yes	Yes	No
Productivity changes (if included) are reported separately	Not included	No	Not included	Not included	Yes	Yes	Not included
The relevance of productivity changes to the study question is discussed	No	No	No	No	Yes	Yes	No
Quantities of resources are reported separately from their unit costs	Yes	Partially	Yes	No	Yes	Yes	Partially
Methods for the estimation of quantities and unit costs are described	Yes	Partially	Partially	Not clear	Yes	Yes	Partially
Currency and price data are recorded	Partially	Partially	Partially	Partially	Partially	Yes	Partially
Details of currency or price adjustments for inflation or currency conversion are given	No	No	No	No	No	Yes	Partially
Details of any model used are given	NA	NA	NA	NA	NA	NA	Yes
The choice of model used and the key parameters on which it is based are justified	NA	NA	NA	NA	NA	NA	Yes

Analysis and interpretation of results	Fauchier	Elsner	Marzegalli	Halimi	Raatikainen	Al-Khatib	NHSC
Time horizon of costs and benefits is stated	Yes	Yes	Yes	Yes	Yes	Yes	Yes
The discount rate(s) is stated	NA	NA	NA	NA	NA	NA	Yes
The choice of rate(s) is justified	NA	NA	NA	NA	NA	NA	NHS guidelines
An explanation is given if costs or benefits are not discounted	No	NA	No	NA	NA	NA	NA
Details of statistical tests and confidence intervals are given for stochastic data	No	No	No	No	No	Not for cost data	No
The approach to sensitivity analysis is given	Partially	Not performed	Not performed	Not performed	Not performed	Not performed	Yes
The choice of variables for sensitivity analysis is justified	No	NA	NA	NA	NA	NA	No
The ranges over which the variables are varied are stated	Yes	NA	NA	NA	NA	NA	Yes
Relevant alternatives are compared	Yes	No	Yes	Yes	Yes	Yes	Yes
Incremental analysis is reported	Yes	Yes	Yes	No	Yes	Partially	Partially
Major outcomes are presented in a disaggregated as well as aggregated form	Yes	No	Yes	No	Yes	Yes	No
The answer to the study question is given	Yes	Partially	Yes	Yes	Partially	Yes	Yes
Conclusion follow from the data reported	Yes	Yes	Yes	Yes	Partially	No	Yes
Conclusions are accompanied by the appropriate caveats	No	No	No	No	No	No	Partially

8.7 APPENDIX TO THE CHAPTER ON LEGAL ASPECTS

8.7.1 Introduction

This annex adds more extensive argumentation to some of the legal issues that were focused on in the core report.

8.7.2 Definitions

Telemonitoring is but one of the many eHealth applications. To enhance clarity, it is primordial to situate the issue of telemonitoring in a larger scope and define the notions that will be used in the report. The definitions of the European Commission will be used throughout the report.

eHealth is an overarching term for a wide range of services and tools. Although it has become a global topic, there is no universal definition. The European Commission defines eHealth very generally in terms of a series of characteristics specified at varying levels: information and communication technologies, tools and services for health. eHealth covers the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals. Examples include health information networks, electronic health records, telemedicine services, wearable and portable systems which communicate, health portals, and many other ICT-based tools assisting disease prevention, diagnosis, treatment, health monitoring and lifestyle management.[x]

There is no uniform definition on telemedicine either. In the Communication of the European Commission on telemedicine for example, the concept of telemedicine is defined as follows:[y] "Telemedicine is the provision of healthcare services, through the use of ICT in situations where the health professional and the patient, or two professionals, are not in the same location". The Commission refers to telemonitoring as an example, defining it as a telemedicine service aimed at monitoring the health status of patients at a distance. [77, 78] Data can be collected either automatically through personal health monitoring devices or through active patient collaboration (e.g. by entering weight or daily blood sugar level measurements into a web-based tool).

8.7.3 EU policy regarding ehealth

Since the end of the '90s, the European Commission launched several initiatives, research programmes and set up working groups related to eHealth. One of the core strategic policy documents of the last decade is the European eHealth action plan setting out targets for the years up to 2010. [176]. Despite all the initiatives and the attention given to different eHealth issues, the European Commission recognized in 2008 that the use of telemedicine services was still limited. In its communication on telemedicine for the benefit of patients, healthcare systems and society, it tries to identify the barriers hampering the wide use of telemedicine.[177] In order to overcome these barriers ten action points were formulated.[178]

Error! Reference source not found. gives an overview of the identified barriers, the action points and the current status at the time of writing of this report.

Regarding the legal framework, two studies have contributed to the actions of the eHealth Communication and Action Plan. The "Legally eHealth" report has clustered the issues of privacy, confidentiality and security; product & service liability and consumer protection and trade and competition aspects of (e)Health.[93] Building further on the "Legally eHealth" report, the study on 'the Legal Framework for Interoperable eHealth in Europe' identified and analysed the legal and regulatory framework for electronic health services in the EU Member States and for cross border services when provided through eHealth applications. Whereas the scope of these two studies was the entire field of eHealth application, this report only focuses on the issue of telemonitoring.

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x http://ec.europa.eu/information_society/activities/health/whatis_ehealth/index_en.htm

y http://ec.europa.eu/information_society/activities/health/docs/policy/telemedicine/commn_telemedicine_en.pdf

Table 20: Summative table EC eHealth action plan: Barriers, action points and state of affairs

Barrier	Action point	Status
Lack of legal clarity, particularly with regard to licensing, accreditation and registration of telemedicine services and professionals, liability, reimbursement, jurisdiction	By the end of 2011 the member states should have assessed and adapted their regulations with regard to licensing, accreditation and registration of telemedicine services and professionals, liability, reimbursement, jurisdiction in order to enable wider access to telemedicine services In 2009, the Commission will establish a European platform to support Member States in sharing information on current national legislative frameworks relevant to telemedicine and proposals for new national regulations In 2009, the Commission, in cooperation with Member States, will publish an analysis of the Community legal framework applicable to telemedicine services.	High Level Cooperation on eHealth - eHealth Governance Initiative between the Member States is being built-up European Commission will release a staff working document on the legal issues beginning of 2010 Study on the Legal Framework for Interoperable eHealth in Europe (September 2009)[z]
Limited confidence in and acceptance of telemedicine services among users due to: lack of (timely) involvement in telemedicine developments weak validity of methodology for the assessment of the effectiveness of telemedicine application lack of training for professionals concerns regarding the protection of personal health data no financial incentive and impossibility of charging telemedicine services for the health professionals limited awareness by patients of the benefits of telemedicine	The Commission will continue to contribute to European collaboration between health professionals and patients in key areas with the potential for greater application of telemedicine, in order to make specific recommendations on how to improve confidence in and acceptance of telemedicine, also taking into account ethical and privacy related aspects. The Commission will support the development, by 2011, of guidelines for consistent assessment of the impact of telemedicine services, including effectiveness and cost-effectiveness. This will be based on the work of experts in the field, Commission-supported studies, large-scale pilot schemes and relevant research projects. Member States are urged to assess their needs and priorities in telemedicine by the end of 2009. These priorities should form part of the national health strategies to be presented and discussed at the 2010 eHealth	Member States in cooperation with the European Commission discuss the high level cooperation platform on eHealth. This platform will associate stakeholders including associations, patients and industry. Study Methodology to assess Telemedicine Applications (02-2009/02-2010) Study Economic Impact of Interoperable Electronic Health Records and ePrescription in Europe (01-2008/02-2009) The High level cooperation on eHealth mechanism brought forward by the Member States Health State Secretaries will be discussed during the Health State Secretary meeting on 23 October 2009. It should operationally start in 2010, it will be an instrument to carry on this first action. eHealth in Action - Good Practice in European Countries eHealth priorities and strategies in European countries eHealth2010 conference (15-18 March 2010) i2010 subgroup on eHealth (next meeting 24/11/2009, Brussels) Telemedicine on ePractice: knowledge sharing (filter > eHealth >

[z] http://ec.europa.eu/information_society/activities/health/docs/studies/legal-fw-interop/ehealth-legal-fmwk-final-report.pdf

Barrier	Action point	Status
services.	Ministerial Conference. The Commission will support the collection of good practice on deployment of telemedicine services in the different Member States.	Telemedicine services) eHealth in Action - Good Practice in European Countries (February 2009)
Technical issues such as interoperability and standardisation in telemonitoring are crucial to allow widespread use of technologies, to enable to benefit from the single market and to contribute to its completion (Health information network Europe (HINE), 2006, European eHealth forecast (report)).	(8) By the end of 2010, the Commission invites industry and international standardisation bodies to issue a proposal on the interoperability of telemonitoring systems, including both existing and new standards (mandate M403). (9) By the end of 2011, the Commission, in cooperation with Member States, will issue a policy strategy paper on how to ensure interoperability, quality and security of telemonitoring systems based on existing or emerging standards at European level. (10) In 2010, the Commission, via its Competitiveness and Innovation Programme, will support a large-scale telemonitoring pilot project. This will include a network of procurers and payers of healthcare services.	

8.7.4 European Legal framework related to telemonitoring

In this section a description of the key elements of the legal provisions at EU level that are particularly applicable to the issue of telemonitoring is elaborated. Since the relevant EU legislation is implemented in Belgian legislation a more extensive analysis of the Belgian legislation applied to the topic of telemonitoring, in particular data protection legislation will be described later in this chapter.

8.7.4.1 European Community Competence in the field of telemonitoring

With the coming into force of the Treaty on the Functioning of the European Union (hereafter "Treaty of Lisbon") on 1 December 2009, article 152 EC Treaty dealing with Public Health is replaced by article 168 of the Treaty of Lisbon.[159] The former article 152 defines the role of the EU in public health as complementing national policies, setting out procedures by which the EU institutions may act in the health field, and delineating the types of measures that may be enacted. At the same time it explicitly bars the use of harmonization measures. Article 168 reaffirms the principle of subsidiarity in public health which implies that the EU does not take action (except in the areas which fall within its exclusive competence) unless it is more effective than action taken at national, regional or local level. The EU must fully respect Member States' responsibilities for the definition of health policies and organising, delivering health services and medical care and, as added by art. 168 for the 'management of health services and medical care and the allocation of the resources assigned to them'. Regarding cross border care art. 168.2 contains an explicit reference to the role of the EU in encouraging cooperation between Member State." The reinforcement of the subsidiarity principle and of the possibility for the Union to take action encouraging cooperation and coordination exclude any prospect of harmonization of public health laws and regulations of Member States[aa].

Although healthcare is a competence that remains largely under the competence of the member states, European legislation from other policy domains that are not directly targeted at regulating healthcare has an important impact on the issue of healthcare. Particularly relevant for the issue of telemonitoring is the European legal framework for privacy protection of personal data, medical devices, regulating the market access, product liability, patient safety etc.

8.7.4.2 The protection of individuals regarding the processing of personal data and on the free movement of such data

There are a number of elements that increase the danger of breaching the privacy and the confidentiality in applying telemonitoring. Non-medical staff such as technical staff, administrative support staff etc. is often included in the delivery of care. This increases the risk of divulging health data in an unauthorised way. Furthermore the transmission of data over a network may lead to interception. The European Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (hereinafter referred to as Data Protection Directive)[79, 80], sets a number of requirements regarding the confidentiality and security that have to be met in order to safeguard individuals' rights.

[aa] The European Parliament and the Council may also adopt incentive measures to "protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonization of the laws and regulations of the Member States". The legal force and the scope of these incentive measures however are not defined in the Treaty.

The Data Protection Directive (DPD) has been transposed into national legislation of the member states. Divergent implementation however hampers uniformity in data protection modalities for the application of cross border eHealth services.[82] For the telemonitoring application this might be an issue since data processing mostly is performed in another member state than the patient's home country and the data protection legislation of the respective state may apply. Since it is impossible to highlight all divergences in national data protection legislation within the scope of this study, we solely focus on the general principles relevant for the telemonitoring application described in the DPD and then apply and discuss more extensively the issue of telemonitoring in the perspective of the Belgian data protection legislation (cfr. infra). For an extensive overview of national data protection laws we refer to D. KORFF, Study on the implementation of the data protection Directive. Comparative summary of national laws.[81]

Field of application

The directive applies to the (wholly or partly) automatic processing of personal data and to the processing of personal data by other means, which form part of a filing system. Data processing is considered to be the collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, blocking, erasure or destruction of personal data (art. 2 b) DPD[79]). Hence, this broad concept applies to different steps in the trajectory of remote cardiac monitoring. Personal data are any information relating to an identified or identifiable person. An identified or identifiable natural person is a person who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, psychological, mental, economic, cultural or social identity (art. 2 a) DPD[79]). Telemonitoring necessarily involves the processing of medical information that is linked to a patient. The processing of such personal health data is thus subject to Data Protection Directive.

Principal actors and fundamental principles

The data protection rules in the Data Protection Directive are targeted to various actors. The most important ones are the data subject, the data controller and the processor.

The Data Protection Directive requires a certain quality level and has set fundamental data protection principles the data processing needs to meet. These data protection rules are mainly translated into duties addressed to the data controller. According to the Directive, personal data used in telemonitoring applications must be processed fairly and lawfully (art. 6.1.a. DPD). Furthermore, data must be collected for specified, explicit and legitimate purposes (art. 6.1. b. DPD) and not further processed in a way incompatible with the initial purposes. The data must be adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed (art. 6.1. c. DPD) The controller should therefore balance the necessity of the personal data against the purpose. Personal data must be accurate and, where necessary, kept up to date (art. 6.1. d. DPD) Moreover data must be kept in a form that permits identification of data subjects for no longer than is necessary (art. 6.1. e. DPD)

Rights of the data subject

The Data protection Directive grants a set of rights to data subjects, such as patients. Patients have the right to information (art. 10 DPD[79] on the processing of data, to access the personal data (art. 12 DPD[79], to request correction (art. 12 DPD[79]), erasure or blocking and under some conditions the right to object to the processing of personal data.

Automated decisions

Art. 15 DPD states that member States shall grant the right to every person not to be subject to a decision which produces legal effects concerning him or significantly affects him and which is based solely on automated processing of data intended to evaluate certain personal aspects relating to him, such as his performance at work, creditworthiness, reliability, conduct, etc.

This disposition can be interesting with regard to the issue of telemonitoring since the patient's health status will highly depend on the output of the automated processing of the data that were transmitted by the bedside monitor. Therefore it could be argued that in the light of this disposition the remote monitoring can not entirely replace the clinical follow-up visits in clinic (but can eventually replace the routine follow-up).

Confidentiality and security of processing (art. 16 and 17[79])

In order to ensure confidentiality, the person who has access to personal data must not process them except based on the instructions from the controller, unless there is a legal exception. The controller must implement appropriate technical and organizational measures[bb] to guarantee that the personal data is kept secured. Particular protection should be granted as regards unauthorized disclosure or access, accidental or unlawful destruction or accidental loss, alteration and unauthorized disclosure or access. Examples of technical measures are back-ups, restricted access to the database to authorized persons, use of software protecting the system against viruses.[84]

A level of security appropriate to the risks represented by the processing and the nature of the data should be provided. If the controller entrusts part of processing to a processor, he or she should ensure that this processor also provides sufficient guarantees on technical security measures and organizational measures. Furthermore transfers to a data processor must be secured by a data processing agreement between the controller and the processor, which must meet a number of minimum requirements specified in art. 17 of the Directive.

Specific provisions for health data

The processing of medical personal data is in principle prohibited, but an exclusive list of exemptions is determined (art. 8.2 and 8.3 DPD[79]).

In the case of telemonitoring 3 exceptions in particular can be considered:

- The data subject has given his explicit consent to the processing of those data
- Processing is necessary to protect the vital interests of the data subject or to another person if the data subject is physically or legally incapable of giving his consent.
- Processing for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment of the management of health-care services if the data are processed by a health professional under national law or rules to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.

bb Recommendation (97)5 of the Committee of Ministers on the protection of health data has listed some examples of measures.[83]

Transfer of data between member states

Health data in the telemonitoring application will be regularly transferred to other member states since the server to which data from the bedside monitor are sent is often located in another country than the patient's home country. It should be noted, however, that the mere transfer of data for technical reasons however has not so many important implications with regard to the impact of the data protection legislation. If the controller is not established on Community territory and, for purposes of processing personal data makes use of equipment, automated or otherwise, situated on the territory of the said Member State, the legislation of this member state is applicable *unless such equipment is used only for purposes of transit through the territory of the Community* (art. 4 of the DPD).

With regard to the transfer of data between member states, the protection of data will in principle be performed correctly, since the receiving member state will have to provide a similar level of protection of personal data according to the European Data Protection Directive (art. 25 DPD). If data are transferred to third countries, the Data Protection Directive stipulates that the member state shall provide that the transfer of personal data that are undergoing processing or are intended for processing after transfer may take place only if, with prejudice to compliance with national provisions adopted pursuant to the other provisions of the Directive, the third country in question ensures an adequate level of protection. Since personal data is often transferred between the EU and the US, the US Department of Commerce issued the "Safe Harbour Principles" in order to clarify the notion of adequacy.[85] These principles have been recognized by the European Commission.[86] Hence, if health data of patients in the EU member states in the telemonitoring application are transferred to a server located in the US, the safe harbour principles apply, once they are transferred to the US. For those countries where there is no adequate level of protection, a transfer may take place on the condition that e.g. the data subject unambiguously consented to the proposed transfer (art. 26 a) DPD). A member state may also authorize such a transfer if the controller adduced adequate safeguards with respect to the protection of the privacy and fundamental rights and freedoms of individuals though appropriate contractual clauses (art. 26, 2) DPD).

Applicable member state's data protection law

Art. 4 a) of the Data Protection Directive states as a general principle[cc] that each Member State shall apply the national provisions it adopts pursuant to the Directive to the processing of personal data where the processing is carried out in the context of the activities of an establishment[dd] of the controller on the territory of the Member State. When the same controller is established on the territory of several Member States, he must take the necessary measures to ensure that each of these establishments complies with the obligations laid down by the national law applicable.

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cc Art. 4 b) and c) provide solutions in case the controller is not established in a Member state
(b) the controller is not established on the Member State's territory, but in a place where its national law applies by virtue of international public law;
(c) the controller is not established on Community territory and, for purposes of processing personal data makes use of equipment, automated or otherwise, situated on the territory of the said Member State, unless such equipment is used only for purposes of transit through the territory of the Community. In the circumstances referred to in paragraph 1(c), the controller must designate a representative established in the territory of that Member State, without prejudice to legal actions which could be initiated against the controller himself.

dd On the notion establishment see preamble 19 Directive 95/46/EC:"Whereas establishment on the territory of a Member State implies the effective and real exercise of activity through stable arrangements; whereas the legal form of such an establishment, whether simply branch or a subsidiary with a legal personality, is not the determining factor in this respect; whereas, when a single controller is established on the territory of several Member States, particularly by means of subsidiaries, he must ensure, in order to avoid any circumvention of national rules, that each of the establishments fulfils the obligations imposed by the national law applicable to its activities"

This solution is not very patient-friendly in cross-border situations. If their rights are infringed in another member state than their home country, they will often be forced to exercise their rights in the data processors' Member State and thus overcome all possible barriers related to e.g. language, legal assistance, etc…(SMART 2007-0059 Study on the Legal Framework for the Interoperable eHealth in Europe, p. 58[82]). Moreover, patients will be confronted with slight differences in national data protection acts. Whereas in application of the Belgian data protection act for instance, patients have direct access to their data, Portuguese data protection legislation for instance solely allow indirect access via a physician. Furthermore other matters (such as credit, or consumer protection, or environmental matters, or advertising, or criminal matters) may be subject to the law of the country where goods or services are offered or bought, or where the consumer is domiciled.

8.7.4.3 Privacy in the electronic communications sector

Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector (Hereinafter called, the E- privacy Directive)[87], amended by directive 2009/136/EC[88] lays down specific requirements on providers of electronic communications services over public communications networks to ensure confidentiality of communications and security of their networks.[87]. The E-privacy Directive was implemented in the Belgian legal order by way of the Law regarding Electronic Communications.[89] The E-privacy Directive aims to "translate" the principles set by the DPD into specific rules for the telecommunications sector, but they do not abridge each other in any way. Service providers who fall under the scope of the E-privacy Directive will thus have to comply with both directives. The E-privacy Directive applies to "the processing of personal data in connection with the provision of publicly available communications services in public communications networks in the Community" (art. 3). The E-privacy Directive does not provide a definition for this category of services as such. However, according to the E-privacy Directive (art. 2), the definitions in Directive 95/46/EC ("Data Protection Directive") and in Directive 2002/21/EC[179] ("Framework Directive") apply to the terms used in the E-privacy Directive. An "electronic communications service" is defined in the Framework Directive (art. 2, c) as "a service, normally provided for remuneration, which consists wholly or partly in the conveyance of signals on electronic communications networks, including telecommunications services and transmission services in networks used for broadcasting, but excludes services providing, or exercising editorial control over, content transmitted using electronic communications networks and services; it does not include information society services (…) which do no consist wholly or mainly in the conveyance of signals on electronic communications networks". The notion "publicly available" is not defined by either of the Directives referenced by art. 2 of the E-privacy Directive. Inspiration can be sought in other relevant Community law. In recital (4) of the former Universal Services Directive[180] there is some guidance as to whether or not a telecommunications service is publicly availableee:

"Whereas the regulatory framework for interconnection covers those situations where the interconnected networks are used for the commercial provision of publicly available telecommunications services; whereas the regulatory framework for interconnection does not cover cases where a telecommunications network is used for the provision of telecommunications services available only to a specific end-user or to a closed user group."

The data transmissions in the telemonitoring application are always targeted at specific end-users or a closed user group (such as the health professionals having secured access to the website where patient data are available). Moreover, solely the mere transmission of data falls within the field of application of the E-Privacy Directive. As soon as the service includes other services such as the first assessment of the data by a nurse, the E-Privacy Directive is not applicable any more. Consequently it is unlikely that the E-Privacy Directive will be applicable to the telemonitoring application.

[ee] For a more detailed argumentation on this issue, see documents of the IM3 project of IBBT; www.ibbt.be/en/project/im3

8.7.4.4 Product safety

The Directive on general product safety is intended to ensure a high level of product safety throughout the EU for consumer products that are not covered by specific sector legislation.[91, 92] The Directive provides a generic definition of a safe product. If there are no specific national rules, the safety of a product is assessed in accordance with European standards, Community technical specifications, codes of good practice and the state of the art and the expectations of consumers.

In addition to the basic requirement to place only safe products on the market, producers must inform consumers of the risks associated with the products they supply. They must take appropriate measures to prevent such risks and be able to trace dangerous products. The Directive provides for an alert system (the RAPEX system) between Member States and the Commission that ensures that the relevant authorities are rapidly informed of dangerous products. In the case of serious product risks, the Directive provides for temporary decisions to be taken on Community-wide measures. As consumer products in eHealth become more common, this will probably serve a useful purpose in the eHealth sector.[93] Until now no telemonitoring devices were subject of the alert system.

8.7.4.5 Defective products

Directive concerning liability for defective products establishes the principle of objective liability or liability without fault of the producer in cases of damage caused by a defective product.[94] If more than one person is liable for the same damage, it is joint liability. A more detailed description is elaborated of the implemented directive in the Belgian legislation is given in section 1.5.7.8.

8.7.4.6 Medical devices

The medical devices directives harmonize the legislation on the free circul ation of medical devices in the EU.[95]

The Directive concerning medical devices defines a medical device as "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specially for diagnostics and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for, among other things, the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap and the control of conception." (art. 1 a.) Consequently, the implanted apparatus, the bedside monitor as well as the software used to program the monitoring are considered as medical devices and have to comply with the medical devices directive. Depending on a risk classification, different safety conditions and procedures apply. Cardiac devices are categorized in class III which is the highest risk category.[96] In this class, a CE mark for marketing (in the European Economic Area) can only be affixed by the manufacturer after approval of the "Design Dossier" by a Notified Body (an organisation assessing the conformity with the essential requirements and to ensure consistent technical application of these requirements), designated by a Competent Authority (National regulatory authority). The CE mark denotes a formal statement by the manufacturer of compliance with the directives' essential requirements regarding safety and specified administrative requirements. In order to demonstrate compliance with the essential requirements, a clinical evaluation can be performed in different ways (Directive 2007/47 annex 10, 1.1.[95]). For class III medical devices a clinical investigation is obligatory unless it is duly justified to rely on existing clinical data (Directive 2007/47 annex 10, 1.1a.[95]). In contrast with CE marking, FDA's Pre-Market Authorization (PMA) requires the demonstration of a medical device's clinical effectiveness as a precondition for marketing. The technical CE label does by no means provide evidence for the clinical effectiveness nor the clinical safety and potential long term adverse events in the patient populations concerned. For class III implants clinical trials should be performed in order to demonstrate that It can be regarded as a necessary first step to guarantee technical safety and good manufacturing of a device, but its value in health technology assessment for health insurance is limited.[97, 98]

Therefore post-market vigilance procedures are of an utmost importance. The European legislation regarding medical devices was transposed into Belgian legislation.[99]

8.7.4.7 *E-Commerce*

On this issue see also (P. Van Eecke, " Electronic Health Care Services and the E-Commerce Directive", in J. Dumortier, F. Robben and M. Taeymans (eds.), A decade of research@the crossroads of law and ICT[102] and S. CALLENS, Telemedicine and the E-Commerce Directive,[181].

The Directive 2001/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market, also known as the E-Commerce Directive [100] draws up the rules for the provision of information society services that are defined as any service normally provided for remuneration, at a distance, by electronic means, for the processing and storage of data and at the individual request of a recipient of a service (both within and between member states)(art. 2, 1). The European Directive was implemented in Belgian legislation by the Law of 11 March 2003 concerning certain legal aspects of information society services.[101]

Applicability of the E-commerce Directive to telemonitoring

It can be questioned if the current telemonitoring applications can fall within the scope of the E-commerce Directive since the service and the device are currently not remunerated. The European Court of Justice however has stated that the notion remuneration does not necessarily refer to the specific way in which the service is financed, but rather refers to the existence of an economic activity or an activity for which an economic consideration is given in return.[182, 183] The fact that a service is reimbursed by social security for instance should not influence the qualification (C. Van Doosselaere, J. Herveg, D. Silber and P. Wilson, Legally eHealth, putting eHealth in its European Legal Context, European Communities 2008, p. 26[93]). Since the telemonitoring service is a marketing instrument for ICD's and the service is offered by the providers with an economic consideration (in the long term), one can argue that the condition of remuneration is met.

At a distance implies that the service is provided without the parties being simultaneously present. The notion "by electronic means" excludes the communication by means of a telephone, mobile phone or fax (S. Callens en K. Cierkens, Juridische aspecten van e-health in Europa, T. Gez. 2007-2008, 347).[184] Since the data transfer between the service provider and the patient in the telemonitoring application mostly happens via a telephone line or mobile phone, the E-Commerce Directive does not apply to this information transfer. The use of the physicians (and other medical personnel having access) of the online database located at a server containing the health data transferred from the bedside monitor however falls within the field of application (P. Van Eecke, " Electronic Health Care Services and the E-Commerce Directive", in J. Dumortier, F. Robben and M. Taeymans (eds.), A decade of research@the crossroads of law and ICT, Ghent, Larcier, 2001, p 374)[102].

Transparency

The service provider (being the natural or legal person providing an information society service) running the website in the telemonitoring application has to inform the users of his identity, address and other details allowing the physician to contact rapidly and communicate in a direct and effective way and the VAT number.

Liability

The E-Commerce Directive also includes rules limiting the liability of information society providers, when they act as intermediaries, in case of illegal acts initiated by others. Exemption of liability is foreseen for acts of transmission of information in communication networks, caching and hosting.

The exemptions from liability established in this Directive cover only cases where the activity of the information society service provider is limited to the technical process of operating and giving access to a communication network over which information made available by third parties is transmitted or temporarily stored, for the sole purpose of making the transmission more efficient; this activity is of a mere technical, automatic and passive nature, which implies that the information society service provider has neither knowledge of nor control over the information which is transmitted or stored. A service provider can benefit from the exemptions for when he is in no way involved with the information transmitted; this requires among other things that he does not modify the information that he transmits; this requirement does not cover manipulations of a technical nature which take place in the course of the transmission as they do not alter the integrity of the information contained in the transmission (Consideration 42 E- Commerce Directive). It is conceivable that in the telemonitoring application an appeal is made to intermediaries, e.g. for the storing of health data or provision of internet access. If for instance a webserver hosts a website or database of a third party containing medical information, the webserver can not be held liable for wrong information (.(P. Van Eecke, o.c. p 378[102]).

8.7.4.8 Directive on distant contracting

In case a contract is concluded by electronic means (or other means allowing the conclusion of a contract without the simultaneous presence of the supplier and the consumer) under an organised distance sales or service provision scheme between a professional (for instance a tele-cardiologist) and a consumer (for instance a patient), the Directive 1997/7/EC applies.[103] The Directive imposes to the supplier the duty to provide, prior to the conclusion of the contract, to the consumer written information regarding his identity, the main characteristics of the product or the service, the price, the arrangements for payment, delivery or performance and the existence of the right of withdrawal. The consumer benefits from a right to withdrawal during 7 days without any penalty or for any particular reason.

8.7.4.9 Electronic signatures

Electronic communication and commerce necessitate electronic signatures. The Electronic signatures directive aims to create a harmonized and appropriate legal framework for the use of electronic signatures within the Community and to establish a set of criteria which form the basis for legal recognition of electronic signatures.[104] The Directive defines an "electronic signature" as "data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication." Additionally, the Directive defines 'advanced electronic signature' as an electronic signature:

- which uniquely links the signature to the signatory;
- is capable of identifying the signatory;
- is created using means that the signatory can maintain under his sole control;
- whereby any changes after signature are detectable.

The principal legal effect of the electronic signatures directive is that Member States should ensure that advanced electronic signatures satisfy the legal requirements of a signature in relation to data in electronic form in the same manner as a hand written signature satisfies those requirements in relation to paper-based data. The electronic signatures Directive has been implemented in Belgium.[105]

8.7.5 Belgian legal context

8.7.5.1 The Data Protection Act (DPA)

The Belgian Data Protection Act [106] together with its executing Royal Decree (RD DPA)[107] set the conditions the processing of health data has to comply with. The Belgian Data Protection Act is mainly based on the European Data Protection Directive (DPD). Derogations will be highlighted.

Field of application

The Belgian Data Protection Act applies to "the processing of personal data wholly or partly by automatic means, and to the processing otherwise than by automatic means of personal data which form part of a filing system or are intended to form part of a filing system" (art. 3, § 1 DPA).

The broad notion of data processing applies to different steps in the trajectory of remote monitoring. For instance, the data transfer from the bedside monitor to the server as well as the consultation of the data by the treating physician (or other persons having access to the data) is perceived as data processing to which the dispositions of the privacy legislation apply.

Since data obtained via telemonitoring devices are linked to the patient, they can be considered as personal data related to the health status. It has to be noted that the same set of data can also be linked to the treating physician. In the latter case, it concerns personal data as such that are not linked to the health status (hereinafter called health data). This distinction is important since sensitive data such as health data have a special status and are subject to a more rigid regime. Since within the scope of this study, health data linked to patient deserve particular interest, we limit ourselves to highlight the regime applied to health data.

The basic data protection principles

The basic data protection principles requiring that data are processed fairly and lawfully, legitimately, proportionately, accurately and up-to-date and for a limited duration, incorporated in the DPD are implemented in art. 4 of the DPA (cfr. supra).

Fair and lawful (art. 4, 1° DPA).

Fairly processing implies that transparency towards the data subject is guaranteed. This principle is further translated into the right to information of the data subject (cfr. infra). The lawful character of the data processing refers to the fact that data processing has to comply with other laws and regulations. In the scope of the telemonitoring application, it would be for instance unlawful to process data in violation of professional secrecy (cfr. infra). Since the data controller can be held liable if the data subject suffers any damage by infringement of stipulations imposed by the DPA (unless he proves that he has not caused the damage), he/she can be hold liable if damage was the result of unlawful processing.

Legitimate (art. 4, 2° DPA).

Data may only be processed for specified, explicit and legitimate purposes. This provision implies that the reasons for processing have to be explained.

Furthermore data may not be further processed in a way incompatible[ff] with the original purposes, taking into account all circumstances, in particular the reasonable expectations of the data subject and the applicable laws and regulations. It would be unlawful if medical information gathered in the telemonitoring application was later on transmitted by a service provider to a university researcher to perform scientific research (unless the data subject was informed about it at the time of the primary information collection and consented in writing).

[ff] On the concept of "compatible purposes" see Verslag aan de Koning bij het Koninklijk Besluit van 13 februari 2001, B.S. 13 maart 2001

Proportional (art. 4, 3° DPA).

Personal data need to be processed in an adequate, relevant and non-excessive way, taken into account the purposes they were collected for. This implies that for each purpose, a sufficient connection must be established between the purpose and the data collected. The proportionality principle is embodied in the concept "data minimization"; as it requires that the least possible amount of data is processed taking into account the purpose for which it is being processed.

Accurate and up-to-date (art. 4, 4° DPA).

The embodiment of this principle can be found in the reference measures drafted by the Privacy Commission (cfr. infra) stating that the data controller has to make sure that the data is updated and that incorrect, incomplete and irrelevant data as well as data that were obtained or further processed in violation with the articles 4 to 8 DPA is corrected or erased.

Limited duration (art. 4, 5° DPA)

Finally, the DPA requires that personal data not be kept "in a form which permits identification" longer than is necessary for the purposes for which it was collected or for which it is further being processed.

Identification of the principal actors in the DPA

In order to identify who has to comply with the obligations and who benefits the rights stipulated in the DPA, the notions data subject, processor and data controller have to be interpreted. In the telemonitoring application, different actors are eligible for one or more roles.

Data subject (art.1 § 1)

Depending on whom the data can be linked to, the patient, the treating physician or other persons involved in the data processing can be considered as the data subject and thus benefits from the rights included in the DPA.

Data controller (art. 1 § 4)

The controller is the entity that determines the purposes and means of the processing of the personal data. If different entities decide respectively on the purpose and the means, the entity setting the purpose should rather be seen as the data controller.[108]. Whereas the European DPD explicitly recognizes the possibility to have multiple controllers for the same data set, the Belgian DPA does not explicitly mention the concept of 'co-controller'. It is conceivable that in the telemonitoring application different actors can be considered as controllers linked to the different processing operations. Once an entity becomes sufficiently involved in the determination of the purpose and means of the processing, it will be considered as a (joint) controller (C. KUNER, o.c. 62-63[80, 109]. Service providers offer an already established telemonitoring service, each with their own focus, to a range of interested parties. The currently available monitoring systems all offer a predefined set of parameters that can be selected (per patient) by the physician. One could argue that the service provider has set the purposes and the modalities of processing and thus is to be considered as data controller. On the other hand the physician or the hospital decides what data are to be transmitted for what purpose. Moreover the hospital or the physician will also have to transfer general data to the service provider in order to initiate the monitoring service. It is thus conceivable that for these processing operations, the physician or the hospital is considered to be a data controller. Although the initiative to use telemonitoring applications for a certain purpose may come from one individual physician, the decision on the system and the final selection of the parameters will often come from one or more physicians, it is more reasonable for the hospital or the hospital manager to take up the role as data controller.

Indeed, different reasons plead for the centralization of the role of controller within the hospital: telemonitoring applications in a hospital will mostly be available for different cardiologists, not only for the initiator, and the hospital manager has the general and the final responsibility for the functioning, the organisation and the finances of the hospital (Art. 16 Hospital law[110]).

The industry partner can be seen as a processor, when working on behalf of the hospital. If for instance a hospital hires a provider of electronic communications services to develop and operate a telemonitoring system that is completely predefined by the hospital without there being any real input by the service provider in this regard, the hospital would be acting as a controller and the provider as a processor.

Given the responsibilities and the possible liability linked to the different functions, it is of a primordial interest to set the roles clear from the beginning. The best strategy is to define the roles in a contract between the parties involved.

Data processor (art. 1 § 5)

The data processor is the entity which, on behalf of the controller, processes the personal data, except for the persons that are processing the data under direct authority of the data controller. The latter category of persons mainly refers to the employees working for the data controller. For the telemonitoring application, different actors can be identified as possible processors. The treating physician will decide on the use of parameters that are to be included for monitoring and will be responsible for the clinical interpretation of the data. As far as they are not considered to be data controller, they can fulfil the role of a processor. Physicians working as employees at the hospital, however, are not seen as processors since they work under direct authority of the hospital, being (possibly) the data controller at stake. Other personnel working as employees at the hospital and involved in the telemonitoring process (administrative staff, nurses, technical staff etc.) are not considered to be processors.

Entities providing telemonitoring services (hereinafter called service providers) such as for instance the company supplying and maintaining the devices, the company involved with the data transmission and archiving, the call center, etc… processing personal data on behalf of the data controller are processors.

Third parties (art. 1 § 6)

A third party is any person or body other than the data subject, the controller, the processor and the persons who, under the direct authority of the controller or the processor are authorized to process data. It is conceivable that in the telemonitoring application personal data are transmitted to third parties, e.g. family members of the patient. It can be questioned if subcontractors of the processors for instance are considered to be a third party. One can argue that if the subcontractor works under the same contractual conditions regarding the privacy, safety and confidentiality clauses as the processor himself or the personnel of the processor, the subcontractor can be considered to work under direct supervision of the processor and hence is not a third party[gg].[112]

gg Reference measure 3 of the Privacy Commission[111] considers it as primordial that if a subcontractor is hired to process the entire set of personal data or a part of it, the organization must ensure that the subcontract agreement includes the same security obligations as those in effect for the organization itself.

Specific requirements and safeguards for the processing of health data

Informed consent as a legitimization of the processing of sensitive data

In principle, the processing of sensitive data, such as health data is prohibited. An exception to this principle however is the patient's consent (Art. 7, § 2, a, DPA). In contrast with the European DPD, the Belgian DPA requires written patient consent instead of explicit consent (which can be oral as well as written). This requirement is possibly not compliant with the Directive.[185, 186] In a judgement of 6 November 2003[185], the European Court of Justice stated with regard to the issue that measures taken by the Member States to ensure the protection of personal data must be consistent both with the provisions of Directive 95/46 and with its objective of maintaining a balance between freedom of movement of personal data and the protection of private life. Nothing prevents a member state from extending the scope of the national legislation implementing the provisions of Directive 95/46 to areas not included in the scope thereof provided that no other provision of Community law precludes it.

Is processing of health data allowed without the patient's consent?

The DPA contains other legitimization bases for the processing of sensitive data such as health data. Two options can be considered for the telemonitoring application. The processing of health data is allowed when the processing is necessary to protect the vital interest of the data subject or of another person if the data subject was not physically or legally capable of consenting (art. 7, § 2, f DPA). The notion "vital interest" must be understood as "essential for life". Since telemonitoring is not used as an emergency service tool but as a support tool, the data processing cannot be considered as necessary for the patient's vital interest.
Another possible legitimization basis is Art. 7, § 2 j) DPA allowing the processing of health data if this is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment to the data subject or a relative or for the management of health care services and if the data are processed under the supervision of a health care professional. According to the Data protection working party this derogation only covers processing of personal data for the specific purpose of providing health-related services of a preventive, diagnostic, therapeutic or after-care nature and for the purpose of the management of these healthcare services, e.g. invoicing, accounting or statistics.[116] Furthermore the processing of personal data must be "required" for the specific purposes mentioned. The data protection working party also stresses that the mere "usefulness" of having such personal data contained in an electronic health record would not be sufficient. The third condition is that the processing of sensitive personal data is performed by medical or other staff subject to professional (medical) secrecy or an equivalent obligation to confidentiality. As telemonitoring contributes to a large extent to diagnosis and prevention, one can consider this legitimization as applicable as far as the conditions of necessity for the purpose and the supervision of a health care professional are met. It has to be noted that whereas the European DPD requires that the processing is performed by a health care professional or other staff subject to professional (medical) secrecy or an equivalent obligation to confidentiality, the DPA seems at first sight to be less stringent stating that the processing is done under the supervision of a health care professional. However, the DPA requires that the data processor is obliged to assure that the persons processing the health data respect the confidential character of the data by contractual clauses, legal or statutory provisions (Art. 25, 3° RD DPA). Moreover, even if data are processed by technical staff these persons are likely to be bound by professional secrecy as they can be considered as necessary collaborators in the process (cfr. infra).

Coming back to the question whether health data can be processed without the patient's consent, one could argue that is in principle possible. However, there are different caveats linked to this statement. Firstly, the legitimization bases are exceptions to the prohibition of processing of health data that have to be interpreted very narrowly. Moreover other legislation possibly applicable to the telemonitoring application requires the (written) patient's consent in case health data from the patient file or the electronic registration are exchanged between health care professionals (art. 19 Flemish Decree of 16 June 2006 concerning the healthcare information systems[113]; see also on this topic: HAUSMAN, J-M, «Le droit d'accès au système d'information Santé organisé par le décret du 16 juin 2006 de la Communauté flamande"[114], HAUSMAN, J-M, «Le décret relative au système d'information Santé: l'arrêt n° 15/2008 de la Cour constitutionelle du 14 février 2008 – Considérations autour des règles de repartition de competences en matière de santé et de protection de la vie privée", [115], Art. 29 data protection working party - Working document on the processing of personal data relating to health in electronic records[116]). Furthermore, as patients will need to consent to the telemonitoring as a medical intervention (cfr. infra), it seems obvious that they simultaneously consent to the data processing as an "all-in package".

Processing of health data under the responsibility of a healthcare professional

According to art. 7 § 4 DPA processing of health data is solely allowed under the responsibility of a healthcare professional, unless

- the data subject has consented in writing
- processing is necessary to prevent an sudden danger
- for the suppression of a criminal offence

The notion healthcare professional is not defined in the DPA. One could argue that, similar to the definition in the Patients' Rights Act (PRA), 'Health care professionals' must be understood as the people enumerated in the Royal Decree number 78 (Royal Decree 78 of 10 November 1967 concerning the practice of health care professions, hereafter named RD nr. 78[117]) and the non-conventional practitioners as mentioned in the Law of 29 April 1999 related to the exercise of non-conventional medical practices [hh](cfr. infra).[118] The Commission for the Protection of Privacy (hereinafter called the Privacy Commission) section Sector Committee of Social Security and of Health however stated that personal data in general should be processed under the supervision of a physician whenever possible.[119]

Health data must be obtained from the data subject

Health data can be collected from other sources if this is necessary for the purposes of processing or if the data subject is not capable of providing the data him/herself (art. 7 § 5 DPA). In case of telemonitoring data are directly obtained from the patient.

Right and responsibilities of the principal actors

Each of the above described persons or entities bear specific responsibilities or benefit particular rights. It is obvious that obligations for one party create rights for another party.

Duties of the data controller

[hh] The particular disposition of the law related to the exercise of non-conventional medical practices did not yet enter into force

Overall responsibility for violation of DPA

The data controller has an elaborated responsibility since he/she must ensure that all obligations and all stipulations stated in the DPA are respected (art. 4 §2; art. 9 §1-2, art. 10 §1 art. 15bis DPA). He can be held liable (cfr. infra) if the data subject suffers any damage by infringement of stipulations imposed by the DPA unless he proves that he has not caused the damage (art. 15bis DPA).

Notification to the Belgian Commission for the Protection of Privacy

In order to ensure transparency on the processing, the data controller needs to introduce a notification of the processing to the Privacy Commission prior to the start of processing and when the data processing has ended or when the respective information is no longer accurate (art. 17 DPA) (https://www.privacycommission.be/elg/main.htm?siteLanguage=nl). The notification must include:

- the date of the notification and, if such is the case, the law, decree, ordinance or regulatory instrument establishing the automatic processing;
- surname, first names and full address or name and registered office of the controller and, if such is the case, his representative in Belgium;
- the name of the automatic processing;
- the purpose or the entirety of related purposes of the automatic processing;
- the categories of the personal data that are processed with a specific description of the health data
- for the processing of health data, the notification to the Privacy Commission or to the data subject must mention the legal basis which warrants the processing of the data (cf. supra; art. 25, 4° RD DPA).
- the categories of recipients to whom the data may be provided;
- the guarantees that must be present when communicating data to third parties;
- the manner in which the data subjects are informed of the processing, where the right of access may be exercised and the measures taken to facilitate the exercise of that right;
- the period of time, after the expiration of which the data may no longer be stored, used or disclosed, if such is the case;
- a general description permitting a preliminary assessment of the appropriateness of the security measures taken pursuant to Article 16 DPA (cfr. infra);
- The Privacy Commission is entitled to ask for additional information, if needed. It has to be noted that the notification to the Privacy Commission does not imply an authorization. The notification serves on the one hand as an information tool to the Privacy Commission of the processing of the health data. On the other hand, the notification is registered in a public register on the website of the Privacy Commission, guaranteeing maximal transparency of the data processing (https://www.privacycommission.be/elg/searchPR.htm?eraseResults=true&siteLanguage=nl). An authorization of the Sector Committee of Social Security and of Health (SCSSH) for the communication of the health data to and between healthcare professionals who are bound by a professional duty of professional secrecy and who are involved in the diagnostic, preventive and curative care for the patient is not required (art. 42 §2, 3° Law 13 december 2006 containing several provisions regarding health[187]). However, it should be questioned if the transfer or communication of health data to individuals or entities that are not healthcare professionals involved in the telemonitoring application is subject to an the authorization of the SCSSH. Apart from some exceptions that are not likely to be applicable for the telemonitoring application; the Law containing several provisions regarding health states that

the authorization is in principle required for the communication of health data to third parties (art. 42 §2, 3° Law containing several provisions regarding health). The respective legal disposition however did not yet enter into force but application should be taken into consideration for the near future.

Information regarding data processing issues

As mentioned above, the data have to be processed fairly which implies that transparency has to be guaranteed. Therefore, the data controller has to inform the patient on the name and the address of the controller or his representative, the purpose(s) of the processing and the recipient(s) of the data (art. 9 §1 DPA). The law also stipulates that the patient should be informed on the right to object to the processing for direct marketing purposes. Next to this right to object, there is a more general right to object in case of ponderous justifying reasons (art. 12 §1 DPA). Since in the telemonitoring application, data are mainly processed in the patient's interest these provisions make little sense here. Other additional information such as the recipients or the categories of recipients, the presence or the absence to answer and possible consequences; the existence of a right to access and correction of his personal data can be mentioned unless this information is redundant to guarantee fair processing towards the patient. There are exceptions to the obligation to provide information. However they seem not to be applicable to the telemonitoring application. Art. 25 RD DPA provides some additional information obligation for the processing of health data. In particular the data processor needs to designate the categories of individuals who may access the data, and specify their capacity regarding the data processing. Moreover the data controller of the processor has to keep a list of the authorized users at the Privacy Commission's disposal. He has to specify the legal basis legitimizing the processing of the health data when informing the patient pursuant to art. 9 DPA or in the notification to the Privacy Commission (art. 17 § 1 DPA).

If the processing of health data is solely legitimated on the basis of patient consent, the controller additionally has to inform the patients of the reasons for processing the data, as well as provide him with a list of categories of persons who have access to the data (art. 26 RD DPA).

Data subjects' specific rights in the DPA

Right to access

For medical personal data, a specific right of access stipulated in the DPA applies (art 10 § 1 DPA). The patient has access to the following information:

confirmation as to whether or not data relating to him are being processed and information at least as to the purposes of the processing, the categories of data concerned and the recipients or categories of recipients to whom the data are disclosed;

communication of the data undergoing processing in an intelligible form and of any available information as to their source;

knowledge of the logics on which any automatic processing of personal data is based in case of automated decisions implying important consequence for the person concerned;

knowledge of the possibility to lodge and appeal and eventual consultation of the public register.

The right to access specified in the DPA can be exercised by the data subject himself (direct access)(Art. 10, § 2, DPA). On the request of the data subject or the data controller, access can take place with the help of a health care professional (indirect access). In principle the data subject has to submit a signed and dated request to the data controller. The controller has to answer at the latest forty-five days after its receipt.

When the health data are part of a patient file, the PRA is also applicable (cfr. Infra). The PRA stipulates a direct right to access (Art. 9 § 2 PRA). If both legislations are eligible

for application, the disposition of the PRA has to be applied since the DPA explicitly refers to the application of the patients' rights act. Hence, even if the data controller requests the intervention of a health care professional, the patient will anyhow have a direct access to the patient file. Whereas according to the DPA the patient must be granted access within 45 days, the PRA foresees a delay of fifteen days.

Right to correct, erase data or object to processing

Article 12 of the DPA specifies the right to have inaccurate personal data corrected, the right to erase certain data or to prohibit the use of the data and the right to object to the processing.

Relation between the data controller and the processor

The data controller has several obligations towards the data processor. Art. 16 § 1 DPA states that if the processing is entrusted to a processor, the data controller of his representative in Belgium has to:

- choose a processor that can offer sufficient guarantees regarding the technical and organizational safety for the intended processing;
- supervise the compliance with these measures, in particular by including them in a contract;
- specifying the liability of the processor in relation to the data controller in the contract;
- agree with the processor that the processor solely acts on behalf of the data controller and that the processor is bound to the same obligations as the data controller regarding the access and processing limitations for people working under his authority;
- the elements 3° and 4° have to be confirmed in writing or on an electronic carrier.

Security of the data processing

According to the Privacy Commission security of information can be summarized in 7 characteristics.

- Confidentiality: Solely authorized users have access to the information.
- Integrity: Unauthorized (intended or unintended) modifications must be prevented.
- Availability: the information is accessible and usable whenever an authorised person asks for it.
- Accountability: Authors and users of the information must be traceable.
- Incontestability: It can be proven that the processing or a fact did take place.
- Authentication: the truthfulness of someone's identity.
- Reliability: the expected result will be accomplished.

These characteristics are mainly covered by the requirements set in the DPA. Furthermore the Privacy Commission has elaborated legally non-binding but authoritative reference measures.[111] Other authoritative bodies such as the National Council of the Order of Physicians[120] and the Telematics Commission (that has been discontinued and whose tasks are currently transferred to the eHealth platform (Koninklijk besluit van 13 januari 2010 tot vaststelling van de datum van opheffing van het Koninklijk besluit van 3 mei 1999 houdende oprichting van een Commissie 'Standaarden inzake telematica ten behoeve van de sector van gezondheidszorg' en tot vaststelling an de nadere regels van de overname van haar opdrachten door het eHealth platform)[121] have issued recommendations with regard to security regarding data processing.

General security obligations

The data controller and the processor have the **general** obligation to take adapted technical and organizational security measures regarding the data processing to protect personal data against accidental or unlawful destruction, accidental loss, the modification of or the unauthorized access and any other non authorized processing of personal data (art. 16 § 4 DPA). Technical measures comprise physical and logical measures; organizational measures comprise the set of policies aiming at the enhancement of security. The organizational as well as the technical measures must on the one hand ensure an appropriate level of security, taking into account the state of the art of the technique and the cost for the implementation of the measures and on the other hand the nature of the data to be protected and the potential risks. The general security obligation qualifies as an obligation of means, which implies that the data controller and the processor are not bound to a particular result but have to act according to the best of their ability (D. DE BOT, o.c., 254[109]).

Security Policy

According to the reference measuresii any organization processing personal data should draw up a written document – the security policy – giving a precise description of security strategies and protection features selected for data security. Different security models or guidelines can serve as a guide: the OECD guidelines for the security of information systems and networks[188], the ISO/IEC TR 13335 information technology guidelines for the management of IT security[189], the ISO/IEC 27002 Code of practice for security management[190] and the ICT standards elaborated by CEN, the European Committee for Standardization (http://www.cen.eu/cen/AboutUs/Pages/default.aspx), and CENELEC, the European Committee for electro technical standardisation (http://www.cenelec.eu/Cenelec/Homepage.htm) In the scope of the data controller's and the processor's general obligation to take adapted technical and organizational security measures regarding the data processing, the European Commission recommends the use of Privacy Enhancing Technologies (PETs).[191] PETs can help to design information and communication systems and services in a way that minimises the collection and use of personal data and facilitate compliance with data protection rules. The use of PETs should result in making breaches of certain data protection rules more difficult and/or helping to detect them. Some examples are that can be of interest in the telemonitoring application are:

- Automatic anonymisation after a certain lapse of time support the principle that the data processed should be kept in a form which permits identification of data subjects for no longer than necessary for the purposes for which the data were originally collected.
- Encryption tools prevent hacking when the information is transmitted over the Internet and support the data controller's obligation to take appropriate measures to protect personal data against unlawful processing.

Although the above mentioned guidelines are not legally binding, they can serve in liability cases to interpret the standard of care.

Security Counsellor[ij]

Within the organization a security counsellor must be appointed, who is to be in charge of the implementation of the security policy.

ii reference measure 1

ij reference measure 2

Organization and Human Aspects of Security[kk]

The organization must clearly define the responsibilities and the management processes regarding personal data security and properly integrate them in its general organizational structure and functioning.

To guarantee efficient data protection, the organization should ensure that information classification procedures (e.g. by means of subfolders) are elaborated, so that an inventory can be drawn up and all personal data being processed can be localized, irrespective of the type of data carrier (see also art. 29 Data protection working party, Working document on the processing of personal data relating to health in electronic health records, 15 february 2007, 4)[116].

Specific security obligations

Additionally the DPA adds some **specific** organizational security measures to be taken by the data controller (art. 16 §2). Since the reference measures drawn up by the Privacy Commission explain or build further on these obligations they will be discussed in the section underneath.

Data accuracy

- The data controller has to watch that the data is updated and that incorrect, incomplete and irrelevant data as well as data that were obtained or further processed in violation with the articles 4 to 8 DPA is corrected or erased (art. 16 §2, 1°) The provisions in art. 4 to 8 refer to the data quality, legitimacy of processing and the processing of sensitive data requirements the data controller has to comply with. By explicitly referring to these provisions in the section on the organizational measures, the data controller is obliged to take steps to incorporate it into his quality assurance management system (D. DE BOT, o.c., 255).[109]

Access and processing limitations

The data controller needs to ensure that the access to the data and the possibilities of processing for the persons who are acting under his authority are limited to what is necessary for the exercise of their duties or for the requirements of the service (art. 16 §2, 2°).

The persons referred to in this article are considered to be the employees of the data controller. In order to determine if an employee can access to the data or the processing, the criterium "need to know" (≠ "nice to know") has to be applied (D. DE BOT, o.c., 255).[109]

In practice the data controller should list the functions of the personnel having access to the particular data sets, the names of the personnel and the specific access modalities (cfr. supra).

Physical security of personal data.

The organization must ensure that carriers of personal data and computer systems processing the data, according to their classification, are positioned on clearly identified and adequately protected premises, and that the access to these premises is limited to the persons having the necessary authorization and to the hours in which these persons work.

When continuity of service is necessary, equipment must be installed in order to prevent, detect and deal with physical threats such as fires or flooding. The equipment is to be inspected on a regular basis. The organization must also provide the necessary safeguards (backups) in order to avoid the loss or accidental modification of personal data.

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kk reference measure 3

For the telemonitoring application physical barriers such as the locking of the room and enabling access by means of a badge where the terminals for accessing the patient data are located is an option.

Logical security of personal data

Logical security measures are designed to protect operating systems or software applications against threats such as for instance hacking or information privacy. One of the reference measures[ll] drawn up by the Privacy Commission is the logical Access Security. In order to ensure that personal data, according to their classification, are only accessible to persons and application programmes explicitly having the necessary authorization, the organization shall keep an up-to-date list of the various persons authorized to access and process these data, as well as of these persons' respective authorizations. The various authorizations should be reflected in technical dispositions and access controls for all computer-related elements (programmes, procedures, storage, telecommunication equipment,…) involved in the processing of personal data. Technical dispositions must cover initial phase activities (development of application programmes) as well as final phase activities (backup management). If required by the level of security, the interveners' identification shall be completed with an authentication procedure.

Logging on to a system occurs trough a process of identification (process of identifying a user or a provider in a certain context or sector), authentication (verification if what is claimed, is also correct) and authorization (permission to fulfil a specified action or use a particular service).[192] After the user is registered with the service provider, he/she will get a username (identification), authentication can be verified by a password. A defined set of actions can be granted to the respective user. For the telemonitoring application it is primordial to define who can set and modify the parameters that will be monitored, who are authorized to consult which alerts and who is able to mark that alerts have been acknowledged.

Transmission of data over a network and storage of data in Electronic Health Record systems must be protected by encryption.[116, 193]

Access Logging, Audit Trails and Analysis[mm]

The service provider should implement logging and audit trail mechanisms. These mechanisms enable the identity retrieval of any person having accessed or processed personal data. Storage of this control information may relate to physical access, logical access or both, as the case may be. Moreover logging and tracing mechanisms may also serve to locate the origin of inaccurate data. Finally, they can be used to establish liability (cfr. infra). In that scope telemonitoring will probably lead to an easier evidence position for the patient since it will be easy to trace who has accessed and treated the health data. According to the National Council of the Order of Physicians the logging and tracing mechanism should not be realized within the server but with a trusted third party (TTP) that can assure independency. [120] The granularity of records, the localization and the duration of storage thereof, the frequency and the type of processing depend on the context. Additional mechanisms for intrusion detection could be required. The security counsellor must be able to justify the policy adopted.

Because detection data are also personal data, any operation performed on these data must be accompanied by adequate security measures.

[ll] reference measure 6
[mm] reference measure 7

Education of the persons having access

- The data controller needs to inform all persons acting under his authority about the provisions of the DPA and its implementing decrees, as well as with regards to all relevant provisions in respect of the protection of the privacy with regard to the processing of personal data (art. 16 §2, 3°).

Although the law addresses the duty to educate the persons working under his authority solely to the data processor, one can argue that this duty also applies to the processor. Since the data controller needs to guarantee that the processor can offer sufficient guarantees regarding the technical and organizational safety for the intended processing (art. 16 § 1), the duty to educate the personnel indirectly also applies to the processor (D. DE BOT, o.c.[109] 257). The means by which education needs to take place are not specified in law. It seems obvious however that the data controller and the data processor draw up a privacy policy which can be communicated to the personnel in different ways (individual or group, online information, providing the document, etc.).

Conformity of programs

- The data controller needs to ensure that the programmes used for the automatic processing of personal data are conform with the statements in the notification to the Privacy Commission and that no unlawful use is made thereof (art. 16 §2, 4°).

Today there is no homologated software for telemonitoring. The Telematics Commission (https://portal.health.fgov.be/portal/page?_pageid=56,4280446&_dad=portal&_schema=PORTAL) has homologated software for medical applications per group of medical practitioners (e.g. software for the management of patient files for general practitioners (https://portal.health.fgov.be/portal/page?_pageid=56,4280434&_dad=portal&_schema=PORTAL). The homologation task of the Telematics Commission has been transferred to the eHealth platform.

Network Security[nn]

The organization must make sure that the confidentiality and integrity of personal data are guaranteed if the equipment is connected to networks while processing the data. If the organization's internal network is connected to a public external network, the organization must provide the necessary safeguards in order to protect the network(s) against any unwarranted access (intrusions, viruses and malware etc.) for the duration of the processing.

Supervision, Inspection and Maintenance[oo]

The organization must assure that the technical or organizational measures have been validated and that they are regularly checked. Security maintenance needs should be determined by monitoring processing supervision, resource evolution and logging analysis. Since information systems and the risks they are exposed to are subject to permanent change, the organization must assure regularly (at least once a year) that the initial goals and the measures taken afterwards remain up-to-date, so that improvements can be made if necessary. Every time the organization is reorganized or modifies its infrastructure, security controls must be updated.

[nn] reference measure 5

[oo] reference measure 8

Security Incident and Continuity Management[pp]

The organization must have a security incident management plan. In case of incidents representing a risk for the confidentiality and integrity of personal data, a rapid intervention is of primary importance to decrease the impact of such situation. For this purpose the organization must elaborate procedures giving a precise description of the steps to be taken when a security incident relating to personal data is detected, as well as of the persons in charge of dealing with the incident, in order to return to the normal situation as quickly as possible. Electronic medical health systems should have effective back-up systems to secure the content of the system (art. 29 Data protection working party, Working document on the processing of personal data relating to health in electronic health records, 15 february 2007, 20[116])

Moreover, the circumstances of the incident must be analyzed to elaborate preventive measures or make adaptations so as to avoid a repetition of this type of incident, or to return to the normal situation as quickly as possible.

Organizations having the duty to ensure the continuity of their services must:

- draw up a recovery and continuity plan when security incidents occur, in order to avoid an interruption of services exceeding an acceptable period of time;
- see to it in particular that the confidentiality and integrity of personal data are guaranteed during the implementation of the various plans.

Documentation[qq]

For proper management of protected personal data, the organization should collect all the necessary documentation relating to security. This documentation should be complete and formalized, proportional to security needs, up-to-date at any time, and accompanied by a directory at the disposal of properly authorized persons whenever necessary.

The documentation should at least contain the following elements:

- the identity of the security counsellor;
- the security policy;
- the implementation of security measures;
- an inventory of the personal data being processed, their localisation and the operations performed on them;
- a nominative list of the bodies or appointees having access to the data;
- the system and network configuration;
- technical documentation about the security controls that were introduced;
- a schedule of planned operations;
- the detection policy;
- security control test plans;
- incident reports;
- audit reports, if any.

pp reference measure 9
qq reference measure 10

Specific security measures for transmission of health data via the internet or e-mail

In the telemonitoring application, health data of the patient can be accessed by the physician or other qualified medical personnel via a secured website on the internet. Urgent alerts can also be sent to the physician through other means of communications such as e-mail or SMS. It was reported by the providers of the monitoring service that the information sent by e-mail or SMS contains a patient identificator and the reason of the alert. For the particular details on the alerts the physician is referred to the website.

The National Council of the Order of Physicians issued several recommendations regarding the transmission of health data transmitted over a network or through e-mail.[120, 123, 124]

Health data transmitted over a network or through e-mail should be protected by asymmetric encryption[rr] and certified digital signatures. With regard to the encryption keys, specific requirements were defined by the National Council of the Order of Physicians.[123] Moreover the encoding and decoding of the content has to occur within the computers of the bedside monitor and the respective recipient.

However, it should be noted that these recommendation are not legally binding and that they should be updated according to the state of the art at a particular moment.

Applicable law and jurisdiction

Art. 3bis DPA states that the Belgian DPA is applicable if data processing is effected in the frame of the real and effective activities of a fixed establishment of the controller on Belgian territory or on a place where Belgian law is applicable on the account of international public law. This is a straightforward implementation of art. 4 of the European DPD (cfr. supra).

8.7.5.2 eHealth platform

The telemonitoring application is closely linked to the introduction of shared electronic health records. Today, some systems enable the direct integration of the telemonitoring data in the electronic patient record. The use and the exchange of information in electronic health records enables the interaction between different health care professionals involved in the telemonitoring trajectory. A legal framework for a platform for sharing electronic health records has been created in 2008.[125] The eHealth platform is government initiated and managed by representatives of stakeholders in the healthcare sector and allows the secured electronic exchange of information about patients, the provided care and the result of it. Several basic services are now fully operational: coordination of electronic processes, web portal (https://www.ehealth.fgov.be), integrated user and access management, logging management, system for end-to-end encryption, personal electronic mailbox for each healthcare supplier with limited features, electronic time stamping and coding and anonymisation. Furthermore the platform coordinates the development of functional and technical interoperability standards. The platform does not perform studies itself and provides no intrinsic policy support in the area of healthcare There is no central storage of personal health data and the use of the eHealth platform is optional. The safe operation of the eHealth platform is controlled by an independent Sectoral Committee of the Privacy Commission.

[rr] Asymmetric Encryption is a form of conversion of data into a form, which cannot be easily understood by unauthorized people, where keys come in pairs. What one key encrypts, only the other can decrypt.

8.7.5.3 *Health information system (HIS)*

In 2006, the Flemish legislation enacted legislation creating a Health information system.[113] The systems contains two platforms: an operational information system and an epidemiological system. Both platforms enable the exchange of health data among health care providers and other institutions but the operational system aims at ensuring high quality care for a particular patient involved whereas the epidemiological system aims to organise the public health system. The scope of HIS decree is rather limited since it is mainly mandatory for health care providers and organisations whose activities are financed by the Flemish government. There is some overlap between the HIS and the [127]eHealth platform with regards to the health data exchange platform. The use of the eHealth platform however is optional.

8.7.5.4 *Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross border healthcare*

Although some member states, as Belgium, have created a legal framework for sharing electronic health records through national eHealth platforms, cross border situations are not integrated since these frameworks solely focus on the relationships between patients, health care providers and institutions on the national level. The recent proposal for a Directive on the application of patient's rights in cross border healthcare engages the Commission to elaborate guidelines on the data to be included in patient files and the modalities of sharing patient information between health care professionals in cross border care (art. 14). [126]

8.7.5.5 *Patients rights act (PRA)*

Patients' rights are defined by national legislation and differ form country to country. The implementation and the enforceability varies significantly according to the member states.[127] Although the existing rules on patient rights rarely explicitly refer to eHealth, they indirectly have an impact on eHealth applications such as telemonitoring. In the near future however, new European legislation for the application of patients' rights in the context of cross-border care within the European Union aims to provide patients with more treatment perspectives within a framework of guaranteed protection of patients' rights. [126]

The PRA is applicable to (contractual and extra-contractual) private law and public law determined legal relations concerning healthcare provided by a health care professional to a patient" (Art. 3, § 1 PRA) [131, 144]. 'Health care professionals' are the people enumerated in the Royal Decree number 78 (Royal Decree 78 of 10 November 1967 concerning the practice of health care professions, hereafter named RD nr. 78)[117] and the non-conventional practitioners as mentioned in the Law of 29 April 1999 related to the exercise of non-conventional medical practices[118]. For the purpose of this report, the treating and referring physician and the medical team of nurses and paramedics involved in the telemonitoring process are subject to the PRA. The notion 'patient' refers to the person who receives health care, on his request or not on his request (Art. 2, 1° PRA). Health care is described in the PRA as 'all services provided by a health care professional with the intention to stimulate, assess, maintain, recover and improve the health condition of the patient'(Art. 2, 2° PRA). As remote monitoring is used to assess and maintain the patient's health condition, it can be considered as health care. Moreover the concept of "services" is not defined in the PRA and has to be interpreted broadly. There is no specification on the used method. Even if a distinction can be made between the means (the telemonitoring system) and the results (obtained medical and technical data), they are linked.

The Belgian Patients' rights act enumerates several rights. The most important rights for the telemonitoring are the right to qualitative care (art. 5), the right to free choice of a healthcare professional (art. 4), the right to information (Art. 7), the right to free and informed consent (Art. 8), direct access to the patient file and the right to have a copy of it (Art. 9). Solely this set of rights will be described in the report[ss].

[ss] For an overview of literature on the patients rights see [128-132]

Right to information regarding the health status

The right to information in the Patients' rights act (art. 7 PRA). The main difference with the right to information granted by the DPA is that the information in the PRA concerns the health status (e.g. the diagnosis) and the probable evolution. The right to be informed about the health status has to be distinguished from the right to informed consent. Whereas the right to informed consent is linked to a decision regarding a medical intervention (e.g. telemonitoring), the right to information about the health status is not. Since the right to information on the health status is but indirectly linked to the telemonitoring application the details on the modalities will not be elaborated in this report.

Right to informed consent

Whereas patient consent in the DPA is linked to the data processing, patient consent in the PRA applies to every medical intervention (art. 8 PRA). According to the content of the information that is linked to the consent a non-exhaustive list is enumerated by the law: The patient has to be informed about the nature, the purpose, the urgency, the frequency, the follow-up care of the intervention, the relevant contra indications, the risks and the side effects of the intervention, alternatives and the financial information. In case of telemonitoring it's of an utmost importance to inform the patients on the limitations of the system. Burri mentions the examples of the fact that it does not replace an emergency service or absence of dealing with alert events outside office hours.[9] Moreover, while some systems perform a daily transmission, some other systems are based on scheduled follow-ups only (typically 3 months) unless there are specific device alerts. Possible technical and functional limitations such as the lack in mobile network coverage should be mentioned. Moreover the required patient input has to be stressed. It is of an utmost importance that the treating physician informs the patient on the use of the monitoring system. A clear manual can be provided in addition of the oral information.

In principle consent has to given explicitly which implies that consent can be given orally as well as in writting[tt]. For the telemonitoring application however it is recommended to use a written consent given the fact that the information elements regarding data processing as well as the information linked to the telemonitoring as medical intervention can be integrated in one document. As mentioned above it is conceivable that several entities act as data controller. The use of different informed consent forms covering each separately the information duty of the respective data controller is not optimal in terms of organization and centralization of the information. Hence it is advisable to draft one consent form specifying all the different players and their roles in the data processing trajectory.

It has to be stressed that the signature of the patient can only be regarded as valid if the patient has gone through or reasonably could have gone through the information. Extremely technical or unclear forms do not meet this condition.[133] Moreover information has to be given in advance and timely. Before starting telemonitoring the patient should thus be requested to sign a written consent form. Physicians who did not obtain informed consent may be held liable (in case of damage) if the patient proves that he/she would not have chosen for the respective intervention if he/she had been fully informed. [134, 135] For the telemonitoring application however this seems rather hypothetical since the risk for bodily harm in the application of telemonitoring is rather low. Moreover the patient is able to stop the telemonitoring application whenever he/she does not feel comfortable with it.

tt Patients as well as physicians however have the right to ask for a written consent form that will be added to the medical file. If the patient refuses to give a written consent, while the physician thinks that a written consent is necessary, the refusal can be noted in the patient's medical file

Right to a patient file, direct access and a copy

The PRA stipulates the right to an accurate and carefully stored patient file from the health care professional and the right to add documents to the file (Art. 9, § 1 PRA).

The patient has a right (Art. 9, § 2, § 3 PRA) to direct access to the file and to a copy of the entire file or a part of it (Art. 10, § 2 PRA). The right to access can not be considered as a surrogate for the default in the right to information (as expressed in Art. 7 and 8 PRA). Access has to be permitted at the latest within 15 days following the request. Personal notes from the health care professional and data related to third parties are excluded from access. At his/her (written) request, the patient can be assisted by a reliable person who may or not be a health care professional. The identity of the reliable person has to be added to the patient file. If this person is a health care professional, this person is also allowed to consult the personal notes of the practitioner. After the patient's death the spouse, the legally cohabiting partner, the partner and the relatives till the second degree of affiliation, have an indirect right to access via a physician chosen by the requesting party as far as the request was sufficiently motivated and specified and the patient didn't explicitly opposed to it during life. This health care professional has also access to the personal notes of the practitioner.

The patient has the right to obtain a copy of his patient file. The physician can refuse to give a copy if he has clear indications that the patient was forced to provide a copy of the patient file to a third party. In the scope of the protection of private life of the patient, the concerned physician can refuse the request of the mandatory or the representative to access or copy of the patient file (Art. 15 § 1). In that case the right to access or a copy is exercised by a health care professional that is designated by the mandatary (assisting the patient) or representative (executing the rights of the patient who is unable to exercise his/her rights) . The physician having refused access or a copy of the patient file has to add a written motivation to the patient file (Art.15 § 3).

The standards on how to store and archive the patient file safely, are also determined in the DPA.[128] The right to access stipulated in the PRA is a particular case of the right to take note of the personal data being processed elaborated in the DPA.[133] This implies that the PRA is applicable if health data is processed by a health care professional and is part of the patient file. The DPA also applies to health data that is no part of the patient file (cfr. supra).[128] The PRA does not exactly define the content of the patient file. Next to the PRA and the DPA however the notion of patient file is defined in other legislation.

According to the Hospital law each patients has to have a medical file (art. 15 §1 hospital law) and a nursing file (Art. 17 quater). These two files form the patient file.

The Royal Decree of 3 May 1999 determining the minimum content of the medical file defines it as the file kept by the health care professional regardless of its carrier comprising all data concerning the patient's identity, the personal and familial antecedents, the actual history of the disease, data of previous consultations and hospitalisations, the results of clinical, radiological, biological, functional en histo-pathological examinations, the advices of the consulted physicians, the provisional and final diagnosis, the treatment, in case of an operation the operative protocol and the anaesthesia protocol, the evolution of the disease, the report of an eventual autopsy and a copy of the discharge report.[194]

A Royal Decree of 28 December 2006 defines the minimum requirements for the nursing file.[195]

In the Flemish Decree concerning the Health Information System (hereafter named, HIS decree), aiming at the creation of an operational information system and an epidemiological information system, the individual health care record is defined as the collection of all patient data that are registered by a health care provider or by an organization active in the scope of healthcare provision in writing or in an other information carrier (art. 2, 8° Flemish Decree on HIS).[113]

The results of the telemonitoring can be considered as data as part of the patient's medical file.

According to the Royal Decree determining the minimum content of the medical file (art 1 § 3) and the Code of medical conduct (Art. 46), a medical file should be kept for at least 30 years at the hospital. It is possible to store the medical files outside the hospital if there are sufficient guarantees regarding security and accessibility. A medical file can be kept electronically (Art. 1, § 3 RD minimum conditions medical file).[194, 196] Health data under the HL 7 format[uu] can be automatically connected to the electronic patient file. According to several legal texts, the head physician is responsible for the medical file.[197]

Right to qualitative care

The right to qualitative care implies that the applicable standards according to the actual scientific state of affairs have to be applied. The preparatory documents of the PRA refer to guidelines elaborated by professional organisations, but specify that other sources can also be taken into account.[136] It was also explicitly stated in these documents that not every possible individual need has to be fulfilled. It could thus be argued that the right to qualitative care does not imply that the patient can require that telemonitoring should be applied -for a particular individual case- as far as this is not (yet) evidence based.

Patient collaboration

Physicians have to respect the PRA as far as patients collaborate (art. 4). This "duty to collaborate" is particularly interesting in the scope of follow-up. If the patient needs an in-clinic follow-up every three months, it is not up to the physician to check if the patient indeed showed up.[137]

Right to free choice of the healthcare professional

In principle the patient has the right to freely choose a healthcare professional. This right, however, is not absolute and can be limited for reasons of public health. In the scope of telemonitoring, it is clear that the patient will not be able to choose who will preview the transferred data (whether this will be the nurse or a physician) or to freely choose a healthcare professional the during on-call duty.

8.7.5.6 Professional secrecy

Different actors are involved in the process of remote monitoring. On the one hand there is the medical staff such as the electrophysiologist, the treating cardiologist, the referring physician, the GP, nurses and paramedics. On the other hand there is the technical support, the administrative support, the staff of the service provider etc. In the following section we study the applicability of the different confidentiality dispositions to the different parties at stake.

[uu] Standards for electronic interchange of clinical, financial, and administrative information among health care oriented computer systems.

Duty of professional (medical) secrecy[vv]

Art. 458 of the Criminal code states that "Physicians, surgeons, pharmacists, midwives and all other persons who by virtue of their status or profession have knowledge of secrets that are entrusted to them and that are disclose these secrets except if they are called to testify in law or in front of a parliamentary investigation commission or in case the law obliges them to make secrets public, are being punished with imprisonment of 8 days to 6 months and a fine of one hundred (approx. €2,5) to five hundred franks (approx. 12,5 €)".[204] Important to stress is that the above listed persons only fall within the application field of art. 458 Criminal Code as far they are necessary confidents. This is clearly the case for the treating physician and the medical personnel charged with the care for the patient. Some authors argue that other individuals, such as the physician's secretary or the hospital managing director, contributing to the provision of health services can also be considered to be bound by the duty of professional secrecy. (Blockx F. o.c. 5-6)[198]).

The scope can be defined as 'secrets confided to a person by virtue of his profession". If a health care professional would have learned the same information in a private setting, he/she would not be bound by a pledge of secrecy.[198] The notion 'confided to' cannot be interpreted too literally. Not only secrets explicitly entrusted by the patient fall within the scope, but anything the health care practitioners have observed and every document describing or revealing the health condition of a patient [198, 200, 205]). Secrets can be defined as facts that because of their nature are secret or that are explicitly or tacitly entrusted to a physician.

The professional secrecy is violated if the entrusted information was disclosed on purpose. The notion disclosure does not imply that the information has to be spread in public.

Many data produced in the scope of telemonitoring reveal information about the health care condition and thus are subject to the professional secrecy. The treating physician and his medical staff, involved and related to the telemonitoring application fall within the scope of the professional secrecy.

Exceptions

As a rule, professionally obtained secret information cannot be disclosed. Legislation and case law however have specified instances in which information covered by the professional secrecy duty may be lawfully disclosed.

Legal exceptions

Art. 458 of the criminal code contains two particular situations in which the medical secrecy **can** be lifted.

- if the healthcare provider is called to testify in law or
- in front of a parliamentary investigation commission

It's important to underline that the healthcare provider is not obliged to disclose confidential information.

[vv] The theoretical part of the duty of professional (medical) secrecy is largely based on (Blockx F. Het medisch beroepsgeheim. Overzicht van rechtspraak (1985-2002). T.Gez. 2004(1):2-19[198]; Stevens J. Het beroepsgeheim van de advocaat en dat van de geneesheer. T.Gez. 2002(1):2-11[199]; Parisse M, Verbruggen V. Secret professionnel et vie privée: les traitement de données à caractère personnel (relative à la santé) couverte par le secret professionnel. R.D.T.I. 2006:15-68[200]; Allemeersch B. Het toepassingsgebied van art. 458 Sw. Over het succes van het beroepsgeheim en het geheim van dat succes. R.W. 2003:1-19[201]; Vandemoortel J, Stockman R. Beroepsgeheim voor de gezondheids - en welzijnswerker. In: Het beroepsgeheim in de zorgverleningssector, een confrontatie tussen recht en praktijk. Antwerpen: Intersentia; 1998. p. 135[202]- ; Balthazar T. Het gedeeld beroepsgeheim is geen uitgesmeerd beroepsgeheim. T.Gez. 2004:139-46[203]).

A third legal exception includes the instance where the law **obliges** healthcare providers to make secrets public. Examples are the disclosure of information in the scope of the legal duty to provide care (art. 422bis Criminal code), the duty to report contagious diseases, defence of necessity, etc. (refs).

Shared professional secrecy

It is accepted in doctrine that confidential information can be shared with other health care professionals if the following conditions are met:[206,Balthazar, 2004 #177,Verhaegen, 2002 #178,Van der Straete, 2004-2005 #179]

- the addressee is also bound by the duty of professional secrecy;
- the sharing of the confidential information must be necessary to ensure continuity and quality of care;
- the patient has to give his explicit or tacit consent or the disclosure should at least be in his/her best interest

Health data within the telemonitoring application can thus be shared between the treating physician, his/her (para)medical team and the referring physician if the above mentioned conditions are met. According to the Constitutional Court written consent is required for each data transfer from the electronic patient file, except for the data exchange within the treating team providing healthcare for which the initial consent of the patient to the treating physician suffices.[138]

Can health data be disclosed to non-medical personnel involved in the telemonitoring application?

Non-medical personnel such as ICT support staff are involved in the telemonitoring application. In practice the extent to which data have to be disclosed to ICT personnel is (or can be) limited. The data processing is based on coded data. The patient is identified by means of the serial number of the implant, which can be done by the treating physician. The coded data are technically processed by the supporting services. The medical interpretation is performed by the physician and/or his medical staff. Hence, access to the health data produced by the monitoring application can be and should be restricted to the treating physician and the (para) medical team. Disclosure of personal health data to supporting personnel is only needed for the start-up of the telemonitoring application. In principle, however, the sole knowledge that the respective patient can be linked to treatment for a particular disease can be considered as a violation of confidentiality. As mentioned above, the data controller needs to make sure that access to the data and possibilities of processing for the persons who are acting under his authority are limited to what is necessary for the exercises of their duties or for the requirement of the service (art. 16 §2 DPA). According to Herveg the necessity of the intervention of ICT staff and other experts in the treatment of personal data of the patient necessitates to consider them as "collaborators" sensu lato of the health care professionals and thus justifies the sharing of certain secrets in accordance with the theory of shared professional secrecy.[139] It should be underlined that even if persons contributing to the provision of health services such as ICT or technical personnel would not be legally bound by the medical professional secrecy, they are not allowed to disclose patient data. Apart from the duty to professional secrecy different other dispositions prohibit the disclosure of confidential data. The duty to discretion for instance applies for professionals with a particular confidential relation with his/her clients, necessitating the confidential treatment of information obtained within that professional relationship.[201] Employees are submitted to the legal duty to discretion (art 17 3°, a), Law of July 3rd 1978 concerning labour contracts.[207]. Moreover disclosure of patient data can be a violation of the general standard of care (Art. 1382 Civil Code) applying to every citizen. Finally, the data processor is obliged to assure that the persons processing the health data respect the confidential character of the data by contractual clauses, or legal or statutory provisions (Art. 25, 3° RD DPA). Technical staff, administrative support and other persons involved in the remote monitoring process should thus be subjected to strict rules stipulated in contracts with regard to privacy and confidentiality of the respective health data.

Consent of the patient

There is controversy about if the patient's consent alone is sufficient to release the health care professional from his oath of secrecy. Some decades ago, the Court of Cassation stated that the consent of the patient did not discharge the physician of his duty of professional secrecy.[208] The code of medical conduct confirms the opinion that consent alone does not discharge the physician of this oath of secrecy (Art. 64 code of medical conduct[209]). There are different arguments to support this idea. For an overview of opinions we refer to the doctrine referred to in H. NYS, Geneeskunde recht en medisch handelen. p. 546, nr. 1274)[144] For instance; as violations to the professional (medical) secrecy are subject to criminal sanctions and the duty of professional (medical) secrecy serves the interest of society, it is considered to be of public order (Stevens J. l.c., 3)[199]. This implies that the rights and obligations related to the professional (medical) secrecy cannot be validly limited by a contract or can be disposed of in another way. Today the vision that confidential information can be disclosed if the patient consented is supported by some doctrine and jurisprudence (Nys H. o.c., 714[144]. Callens S, Peers J. Organisatie van de gezondheidszorg[210]; Stevens J. Het beroepsgeheim van de advocaat en dat van de geneesheer[199]; a contrario see Herveg J, Verhaegen MN, Poullet Y., l.c. 61[206]; Parisse M, Verbruggen V. Secret professionnel et vie priv,ée: les traitement de données à caractère personnel (relative à la santé) couverte par le secret professionnel. l.c., 36[200]; Jurisprudence cited in footnote nr. 52 by S. Callens, Goed geregeld? Het gebruik van medische gegevens voor onderzoek.[211]

Valid consent implies that it was given in advance, free and informed and that the consenting person is the sole person having an interest (NYS, o.c., nr. 1279). The fact that there is a kind of hierarchic relationship between a physician and a patient could imply that patients are put under pressure to give their consent to warrant the disclosure of information. Art. 27 DPA explicitly states that consent alone is insufficient to allow processing of sensitive data when there is a position of dependency towards the data controller. An important exception for the telemonitoring application is however that this prohibition does not apply if the processing is done to procure an advantage to the data subject. This is clearly the case for the telemonitoring application.

Secrecy duty in other legislation

Next to the medical professional secrecy as stipulated in the Criminal Code, other dispositions deal with the secrecy duty of the health care professional. Physicians have the deontological obligation to protect the confidentiality of the information entrusted to them (art. 55 e.v. Deontological Code). The interpretation of this deontological responsibility is further elaborated trough the advices of the National Council of physicians. According to the DPA the health care practitioner, his appointees and authorized representatives are bound by secrecy (Art. 7, § 4, section 3 DPA). Instead of referring to existing professional secrecy rules, the legislator has chosen to create an independent obligation to secrecy.[109] This obligation to secrecy, as stated in the DPA, however, does not abridge other obligations to secrecy stipulated in the Criminal Code or in deontological documents. It should be noted however that whereas the violation of the criminal code is punished by criminal sanctions, DPA and deontological offences are punished by respectively civil sanctions and deontological sanctions.

It's important to stress that the entity or the person ensuring the compliance with the confidentiality of data as stipulated in the DPA is not necessarily the person subject to the duty of professional secrecy. Whereas the health care professional (or other parties contributing to the provision of health services) are bound by professional secrecy, the data controller (which can be for instance the hospital or the service provider) has to make sure that all categories are bound by legal or at least contractual confidentiality (Art. 25, 3° RD DPA).

8.7.5.7 Liability status of telemonitoring

Compared to the classical treatments, not only health care professionals are involved in the telemonitoring chain and thus risk to be held liable when a patient is confronted with damages. Non-medical staff such as technical members and administrative staff is also involved in the delivery of telemonitoring care. Moreover organizations that provide some kind of communications service, storage service or processing service or a combination can also be held liable if damage has been caused to the affected party. In the previous sections, we clarified the different roles of the players in the telemonitoring application and their responsibilities possibly leading to liability if they are not fulfilled. Besides the DPA, art. 458 Criminal Code and the PRA however other laws and general principles of civil law may generate liability if damage is caused by the patient.

Contractual liability

Civil liability arises when an obligation originating from a contract or from tort was not fulfilled. Contractual liability can only be invoked if there was a (written or oral) contract between the patient and the person or the entity that caused the damage (for instance a physician, a hospital, a service provider,…).In the relationship between a physician and a patient the contractual relationship will mostly be oral. The proof of a contractual fault depends on the character of what was stipulated in the contract.[212-214] The fault of the physician implies a violation of a law (for instance: if the physician doesn't inform the patient, he violates the PRA and consequently commits a fault) or a violation of the general standard of care. This standard of care is the level of care that can be expected from a reasonably prudent physician of the same category and in the same circumstances. Since the contract between a patient and a physician will mostly contain an obligation to perform the best of the physician's ability (obligation of means), not to a specific result (obligation of results), a contractual medical fault will therefore mostly consist of a violation of the „general standard of care".

Tort liability

If there was no (valid) contract (e.g. patient was not able to consent, damage is caused by a third party such as for instance the nurse-employee of the hospital) between the affected party and the party having caused the damage, **tort liability** can apply. The basic rule of tort liability (or extra-contractual liability) state that (in absence of a contract) when a person injures another, either intentionally or by negligence, a court may award compensation to the injured party. In principle contractual liability do not differ that much. For details on the differences see (T. Vansweevelt, De civielrechtelijke aansprakelijkheid van de geneesheer en het ziekenhuis, nrs. 601- 629[143]). If a contractual fault can simultaneously be regarded as a crime, one can choose to invoke tort liability or can base the claim on both systems simultaneously. This situation will often apply in medical cases since medical faults often will concur with the crime of bodily harm.

No fault liability

It is clear that in remote monitoring cases there's quite a spectrum of "mishaps" where the fault is difficult to prove or to quantify. A Law of 31 March 2010 on the compensation of damage resulting from healthcare introduced the concept of no fault liability in the healthcare sector.[154] The idea is that victims of damage (above a certain degree of gravity) that was caused by an act of healthcare do no longer need to prove the existence of fault by the health care professional. However, the proof of a causal link between the act/element that caused the damage (or the absence of an act) and the damage still has to be proven. The Belgian system is inspired by the French one (www.oniam.fr). The new system is characterized by a coexistence of patient insurance and liability system where the patient has the choice to go to the court or to make an appeal to a Fund depending on whether the medical act was negligence or a medical mishap. Compensation of the Fund is possible in case of (art. 4):

- medical mishap (as far as the conditions regarding the gravity of the damage are fulfilled);
- no liability insurance or insufficient coverage by the liable insurance;

- fund judged that the health care professional is liabel and the health care professional or the insurer disputes this position (as far as the conditions regarding the gravity of the damage are fulfilled);
- the insurer covering the health care professional's liability makes an offer for compensation judged as obviously insufficient by the Fund.

The damage is considered to be grave in case of (art. 5):

- permanent invalidity ≥ 25%;
- temporary invalidity ≥ 6 succeeding months of 6 non succeeding months over a period of 12 months;
- the damage has major implications for the life situation, including the economical situation of the affected person;
- the patient deceased.

In contrast with an earlier version of the Belgian no-fault legislation (art. 3 § 1 Wet van 15 mei 2007 betreffende de vergoeding van schade als gevolg van gezondheidszorg[155]), the current version does not mention that solely damage caused in Belgium is covered. It is indeed questionable whether the limitation of compensation to damage caused in Belgium conforms to the EU Treaty as it does not regulate the damage caused in Belgium by a physician at a distance in Belgium in the same way as the damage caused in Belgium by a physician in another country.[156]

Professional liability of the physician

A first important question will be whether the telemonitoring is the most suitable treatment support for the patient. What if a physician omitted to plan remote monitoring although indicated? Once the physician decides to apply telemonitoring he/she has to consider the information produced by the telemonitoring application in an appropriate way. What is the appropriate standard of care for telemedicine? Mostly the physician will determine which parameters will be selected for monitoring for the patient at stake, choose the modalities of the alert system (definition of what is urgent (red alarm), notification: by email or SMS), define the programming modalities for reporting (every day, week, month, ..). Another problem related to the telemonitoring application is the continuity of care to the eligible patients. What if the physician misses an alert? Today there is no relevant (published) jurisprudence regarding the issue of liability in telemonitoring cases. Based on the general principles in liability, the possible liability of the physician will be assessed.

Choice of telemonitoring as therapy support

As mentioned above the medical professional standard is the care that can be expected from a reasonably, prudent physician of the same specialty in the same circumstances. When defining the standard of care, several elements can be taken into account: protocols and guidelines,[142] the state of the art of medical treatment, the opinions of colleagues, the actual state of the science, legislation (patients' rights legislation, DPA,..), case law, …

Moreover it is generally accepted that a surgeon is also responsible for the aftercare linked to the operation. The duty for aftercare can be divided in two subcategories: the duty to supervision and the duty to information. (T. Vansweevelt, o.c., p. 356[143])

Particularly relevant for telemonitoring is the duty to information linked to the aftercare. It is arguable that if a patient is eligible for telemonitoring the physician should inform the patient on the existence of telemonitoring as part of the aftercare (as far as adding telemonitoring to regular follow-up can be considered to be the standard of care). The fact that the telemonitoring application is not reimbursed, is not argument to withhold the information. The eligibility of a patient does not solely depend on the pathology but also on patient-specific elements. A patient with dementia for instance might not be eligible for the telemonitoring application since a minimum of patient input (e.g. switching on the bedside monitor) is required.

Although the telemonitoring service is presented by all companies as not being an emergency system, timely notification of (clinical or device -related) problems by the telemonitoring application can prevent harm or can even be life-saving for some patients (e.g. early detection of lead fracture). In this case "the loss of chance theory" may be applied. The "loss of chance" theory aims to hold a doctor liable for a reduction in a patient's statistical chance of survival or recovery. There is a loss of chance if the patient has a realistic chance of survival or recovery and the fault of the physician has undone this chance. If the patient (or the relative) can prove that with the telemonitoring application he/she had a chance of recovery or survival (e.g. because of the earlier detection of a problem), the physician (or the hospital) can possibly be held liable.[145, Bocken, 2008 #195 ,Callens, 2008-09 #196}

Continuity of care: what if the physician misses an alert?

According to art. 8 Royal Decree nr. 78 physicians are not allowed to interrupt an ongoing treatment without taking all necessary measures to assure continuity of care by appointing another health care professional of the same discipline. The deontological code affirms this principle (art. 113-114 Deontological code). The scope of art. 8 RD nr. 78 is rather limited since it only applies to ongoing treatments. (NYS, o.c. 192[144]). It is not clear if this disposition also focuses on the aftercare linked to a treatment.

As mentioned above, it is advisable to inform the patient in the written consent form that the telemonitoring service is not an emergency system and that the transferred information will only be viewed within a specific delay. Such 'contractual' dispositions can be qualified as a specification of the obligations of the physician and are considered being valid, unless they annul the essence of the contract or if they violate public order or public decency (T. Vansweevelt, o.c., p. 762[143]). Such clauses need to be distinguished from exemption clauses limiting or excluding liability. Whereas clauses specifying the obligations of the physician limit the content of the obligation, exemption clauses do not limit the obligation but limit or exclude the liability resulting from the physician's negligence. Clauses limiting liability are not enforceable when prohibited by specific laws. According to the law a physician cannot exempt from or restrict liability if a patient dies or in case of bodily harm of the patient caused by the physicians negligence (fault) (Annex N 1) a Wet van 2 augustus 2002 betreffende de misleidende en vergelijkende reclame, de onrechtmatige bedingen en de op afstand gesloten overeenkomsten inzake de vrije beroepen[215]). In case of liability claim the judge will compare the situation to the care that can be expected from a reasonably prudent physician of the same specialty in the same circumstances. The judge will take into account the dispositions that were legally contracted between the patient and the physician.

Clauses in the informed consent form stipulating that the telemonitoring service is not considered to be an emergency system and that information will only be treated during the office hours are in principle valid since they do not touch upon the essence of the contract, as far as being the follow-up or disease management. If alert systems are used, the physician however needs to make sure that short term attention is assured within the reasonable organizational limits and that back-up is assured in case of longer periods of absence. The validity of clauses in contracts stipulated by firms considering that the telemonitoring system in general (the alert function included) is not an emergency system while it is de facto an emergency tool and functions and is conceived as an emergency tool, is questionable.

Clinical evaluation at a distance

Clinical evaluation at a distance by the physician is in principle legally allowed. Yet, physicians need to need to be careful for the possible incomplete image presented by the data. For the telemonitoring application for instance, the physician can decide to interrogate the device in case of a symptomatic event, in order to evaluate specific parameters and to decide whether a patient needs to be referred to the hospital or not. If the physician fails to give accurate instructions to the patient or put the wrong diagnosis he/she may be liable (see jurisprudence cited in footnotes nr. 45 -49 S. Callens en J. ter Heerdt, Juridische beschouwingen bij telegeneeskunde, T. Gez. 1999-2000, 311[148]).

Fault of the patient or a third party

As mentioned above, clear instructions need to be given to the patient pursuant to the duty to information in the light of aftercare. In case of telemonitoring these instruction can deal with technical as well as medical matters. For instance the patient will have to plug in the bedside monitor. If the patient omitted to follow the instructions, the physician can defend himself by stating that the damage was (partly) caused by the patient. Indeed, the general standard of care also applies to the patient (T. Vansweevelt, o.c. p. 410[143]). It has to be noted however that the current telemonitoring systems report if there was no transmission within a predefined term (mostly 2 weeks).

Medical instructions such as for instance the fact that a patient has to contact the hospital in case of an emergency or specific symptoms (instead of relying on the telemonitoring system) or are more difficult to back-up in case the patient neglected to follow the instruction.

Role of industry employed technical specialists

- Persons who are employed or contracted manufacturer representatives, field clinical engineers, and industry employed technical specialists (IEAPs or industry employed allied professionals [1]) often assist physicians during pacemaker/ICD implantation, programming, analysis of malfunctions and follow-up. This brings us to the important question to what extent these persons can legally play a role in the telemonitoring application. Which acts can be legally performed by these persons? Who is liable if something goes wrong?

Technical nursing acts such as the preparation, the assistance and the instrumentating during medical and surgical interventions can solely be carried out by nurses (professional title of nurse or a registered nurse with a diploma homologated by the competent medical commission (art. 21 quater e.v. KB nr. 78 van 10 november 1967 betreffende de uitoefening van de gezondheidszorgberoepen[117] and Koninklijk besluit van 18 juni 1990 houdende vaststelling van de lijst van de technische verpleegkundige verstrekkingen en de lijst van de handelingen die door een arts aan beoefenaars van de verpleegkunde kunnen worden toevertrouwd, alsmede de wijze van uitvoering van die verstrekkingen en handelingen en de kwalificatievereisten waaraan de beoefenaars van de verpleegkunde moeten voldoen[149]). If IEAPs non-qualified nurses perform (technical) nursing activities, illegal medicine is practiced, which can be sanctioned with fines and imprisonment. Technical information and advice regarding the appropriate use of the medical devices however falls within the legally allowed acts of the IEAPs.

According to the law on pharmaceuticals, it is prohibited for companies to grant financial benefits or in natura to hospitals or prescribers, delivering, administering medical devices (art. 10 § 7 Geneesmiddelenwet van 25 maart 1964[150]). If a firm systematically puts IEAPs at the disposal of physicians for free for assistance during surgery, this can be considered as illegal. IEAPs may, however, provides technical information regarding for instance new medical devices[ww].

Liability of the physician or the hospital for damage caused by medical or paramedical staff working at the hospital

Medical or paramedical staff at the hospital often works under the authority of other persons (for instance the surgeon) of the hospital. If for instance a nurse viewing the telemonitoring data fails in transferring alerting data, the affected patient can claim the person exercising the authority over the nurse, e.g. the physician or the hospital. Employees can in principle solely be held liable in case of fraud, major fault or repetitive minor faults (for a detailed description see T. Vansweevelt, De civielrechtelijke aansprakelijkheid van de geneesheer en het ziekenhuis [143])

[ww] For the position of UNAMEC on the role of IEAPs see http://www.unamec.be/data/doc/Standpunt%20UNAMEC%20aanwezigheid%20OK.pdf

Central liability of the hospital (Art. 30 Hospital Law[110])

Each hospital has to comply with the patients' rights (formulated in the PRA) concerning the medical, nursing and other professional aspects in the relation towards the patient. This implies that the hospital needs to assure that nurses working as employees meet the requirements of the PRA (H. NYS, l.c. 1123[128]). Moreover each hospital has to make sure that the self employed health care professionals or external personnel working in the hospital respect the patients' rights. The hospital is liable for the breaches of the patients' rights committed by the health care professionals working at the hospital, except if the hospital explicitly and informed the patient in advance that it will not be liable, given the legal relationship between the health care professional and the hospital. The hospital needs to inform the patient on the categories of healthcare professionals working at the hospital and the legal relation between the hospital and former mentioned personnel. If the hospital exempts from liability, this has to be notified in writing to the patient at the latest at the hospital admission.[151] Even if the patient is not hospitalised, as in the telemonitoring application, it is likely that the hospital can be held liable in case patients' rights are violated by the personnel performing the monitoring at the hospital. For a detailed description of the Central Hospital liability we refer to doctrine.[152] Although the idea to centralise liability for the wrongful acts of personnel working at the hospital is a step in the good direction to alleviate the burden of proof for the patient, the telemonitoring application goes beyond the hospital environment. Different questions arise: What if the hospital works with independent physicians working at a distance? Is the hospital responsible for the organisation of a guard system in case alert systems are applied?[153] Moreover it is questionable if the hospital can be held liable for violation of patients' rights by IEAPs (non –qualified nurses or physicians). The hospital law does not specify whether the notion "health care professionals" in the disposition on the central liability is limited to medical personnel (as defined in artikel 2, § 1, van het koninklijk besluit nr. 78 van 10 november 1967 betreffende de uitoefening van de geneeskunde, de verpleegkunde, de paramedische beroepen en de geneeskundige commissies[117]).

Liability related to faulty products

In the telemonitoring application different technical apparatus and software is used. When damage is caused to a patient because of a telemonitoring equipment failure (such as for instance defective devices or telecommunication network deficiencies) liability of the physician, the hospital, the software developer, the device supplier, etc is conceivable. Different legislations regulate the (possible) liability for damage caused by faulty products. In the next section a brief description of the different possibilities is listed. For an extensive overview see T. Vansweevelt, o.c. p. 627[143] and H. Bocken, Buitencontractuele aansprakelijkheid voor gebrekkige producten, in X. Bijzondere overeenkomsten[216].

Contractual liability

The existence of a medical contract between the patient and the physician (and/or the hospital) also implies that the physician and the hospital have to use safe material. There's a tendency in Belgian jurisprudence to consider the use of safe material as an obligation of results. [217] When the affected party proves that the damage is caused by defective material, compensation can be obtained from the physician or the hospital. Exemption from liability can be obtained if the physician or the hospital can prove there were circumstances beyond one's control or a fault of a third party or the affected party (e.g. the patient omitted to follow the instructions). Usually the patient will claim compensation from the hospital or the doctor who will then serve a third party notice on the producer or the supplier.[148] Since there is usually no contractual relationship between the patient and the provider of technical equipment, liability claims toward these persons cannot be based on contractual liability rules.

Liability of the supplier for visible or invisible flaws

It is conceivable to base a claim for compensation against the supplier based on visible (duty to conform delivery art. 1604 CC) or invisible flaws (art. 1641 CC). Since the application of the product liability law or Art. 1384 CC will usually be easier for the patient to obtain compensation (because it concerns in both cases objective liability in which case no fault has to be proved), we limit ourselves rather to refer to doctrine for the details on the theory regarding the visible and invisible flaws (Vansweevelt, o.c. p. 641 e.v.[143]).

Art. 1384 al. 1 Civil Code

If there was **no contractual relationship** between the affected party and the party that caused the damage, the patient can claim compensation for the damage caused by the damage causing object. Art. 1384, al. 1 CC imposes an objective liability on the keeper of the damage causing object. This implies that the affected patient solely has to prove that the person to whom the claim is addressed is the guardian (person that uses the object at his own expense or benefits or keeps it and has to right to supervise and control it) of the object that caused the damage, for instance the hospital, the server, software provider, etc.. The guardian can be exempted from liability if he proves that the damage was caused by any other cause. The extracontractual liability claim can also be based on the general basic article 1382 CC (cfr. Supra).

Law Product liability

According to the law of 25 February 1991 the manufacturer of a product can be held liable for damages caused by his product as far as the affected party proves the existence of the product and the flaw in the product, regardless whether there is a contractual relationship or not.[157] No fault of the manufacturer needs to be proven. A product is considered as each physical movable property, even if it is part of another movable or immovable property, or if it has become immovable by destination (such as for instance a battery integrated in a device) (art. 2). The notion of manufacturer must be understood as the manufacturer of end products or parts of it, the manufacturer of base materials and anyone who makes clear to be a manufacturer by the use of his name, brand or any other mark on the product (art. 3). Furthermore the importer of a product within the EC is also considered to be a manufacturer. If neither the manufacturer nor the importer can be identified the supplier will be regarded as manufacturer or importer unless he/she can identify within a reasonable time the manufacturer or the importer (art. 4). A flaw must be understood as if the product cannot offer the safety one might expect, all circumstances taken into account (Art. 5). In principle liability of the manufacturer cannot be exempted or limited towards the affected person by means of an exemption clause. This exclusion however does not apply if the damage was caused as well by the defective product as by the fault of the affected person or a person under the responsibility of the affected person. When the damage is caused both by a flaw in the product and any other cause (e.g. electricity rupture) the manufacturer is not exempted.

Art. 8 of the law foresees some specific exceptions:

- The manufacturer did not bring the product to the market
- It is likely that the flaw did not exist at the time the manufacturer brought the product to the market
- There was no intention to bring the product to the market neither with any other economical intentions, neither as part of the execution of the manufacturer's profession
- The flaw is caused by imperative legal obligations
- For the manufacturer of a part of the product, when the flaw is caused by the design of the end product where the part is used for or is caused by wrong instructions of the manufacturer of the end product.

There is no consensus regarding the fact if this law applies to defective software since it is no physical movable property (see doctrine cited in footnote number 224 J. Dumortier, ICT recht, p.167[218]). In preparatory documents of the law, however, it was argued that software needs to be regarded as a product in the sense of this law.[219]

In order to avoid discussions during the execution of the contract and in particular to clarify the specific obligations of the service provider, Service Level Agreements (SLA) are regularly used, in particular in the ICT sector. A SLA is a negotiated agreement between two parties where one is the customer and the other is the service provider. This can be a legally binding formal or informal "contract".

The SLA records a common understanding about services, priorities, responsibilities, guarantees, and warranties. Each area of service scope should have the "level of service" defined. It is important to describe the minimum service level and the consequences of exceeding and not reaching this level. In that scope the classification of obligations as either an obligation to obtain a result or an obligation to deliver a certain effort. The SLA may specify the levels of availability, serviceability, performance, operation, or other attributes of the service, such as billing.

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