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Good practice guidelines concerning regional telemedicine services for chronic cardiovascular disease (CVD)

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Executive Summary

The good practice guidelines described in this report are based on contributions from five RTF partners in Estonia, Poland, Scotland, Italy and France. Each region describes a telemedicine service provided for patients with chronic cardiovascular disease (CVD). Services are described in operational terms and reflect good practice as well as ongoing concerns given that telemedicine is a relatively new innovation.

A brief description of CVD set within the context of the European Union is presented. Consideration is given to a needs analysis at the individual (patient), clinical, organizational, legal and economic levels. Chronic cardiovascular disease is a major financial and social challenge for European healthcare systems and requires effective disease prevention and management that needs to be well established.

The role of telemedicine within CVD is explored using exemplars from the five different regions noted above. Although it is known that telemedicine can be effective, the evidence base is limited and inconsistent. Therefore there is a need for evaluation to be applied systematically and within agreed definitions and parameters to facilitate the sharing and learning from others’ experience. Reference is made to other ongoing telemedicine projects.

Strategies to encourage, support and enhance the delivery of telemedicine are detailed along with suggestions for the efficient operationalization of strategy at regional and health authority levels. It is agreed that there is no ‘one-size fits all’ approach to telemedicine. However financial support must allow for sustainable development of telemedicine services. As such projects should be integral to routine healthcare in order to understand their impact on usual care.

Lessons learned based on the partner contributions include:

- a requirement for additional security of electronic patient records given recent breeches in global internet systems and the rejection of complacency regarding medical data security;
- robust systems of evaluation with the resulting reports communicated widely across the user community (patients, healthcare professionals, policy makers);
- that any future research should be funded only if the questions are precise, clear and focused on deliverables;
- that the testing of telemedicine needs to occur in the actual clinical environment to ensure that advancing technical, clinical and funding issues are resolved satisfactorily;
- that any future funding proposals include a detailed business plan with the cost benefits itemized in terms of actual money rather than theoretical propositions.

The future of Telemedicine is bright but there are serious considerations regarding security of information, financial benefits and embedding innovation into current healthcare delivery. It is now necessary for policy makers and legislators to ensure that the conditions are set for that promise to be fully realized.
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1. Introduction

1.1 Purpose

The Regional Telemedicine Forum (RTF) is a project whose goal is to exchange experiences of telemedicine. The project is led by the Region of Southern Denmark and involves regions from eight different countries in Europe: Catalonia, Spain; Veneto, Italy; Malopolska, Poland; Auvergne, France; Norrbotten, Sweden; North Norway; Estonia; Scotland, UK [http://regional-telemedicine.eu/]. The purpose of this document is to describe 5 good practice guidelines for telemedicine services for Chronic Cardiovascular Disease. These guidelines are based on the regions taking part in the CVD Regional Telemedicine Forum: Estonia, Veneto Region, Italy, Auvergne, France, Scotland, UK.

These guidelines are intended to provide background information, guidance and practical observations in order to share experiences and inform the decision making required to operationalise a telemedicine service. This document should be placed in the context of the growing literature in the field as evidenced by the European Society of Cardiology and the American Heart Association heart failure guideline committees and multidisciplinary CVD management.

1.2 Structure of document

This report is divided into 3 chapters and 5 Annexes. Chapter 1 provides the Introduction and outlines the structure of the document. Chapter 2 presents the context of CVD and a brief description of the disease also an analysis of CVD based on selected literature. The role of telemedicine in CVD and parameters of evaluation are also stated. Chapter 3 contains 5 Annexes that summarize the good practice identified in 5 of the participating partner regions involved in the RTF, detailing their most relevant CVD pilot service.

1.3 Acronyms

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<td>CIEDs</td>
<td>Cardiac Implantable Electronic Device</td>
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<td>CEAP</td>
<td>Clinically Employed Allied Professionals</td>
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<td>DALY</td>
<td>Disability Adjusted Life Year</td>
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<td>EPR</td>
<td>Electronic Patient Record</td>
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<td>GSM</td>
<td>Global System for Mobile Communications</td>
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<td>ICT</td>
<td>Information and Communication Technologies</td>
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<td>Acronym</td>
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<td>LHA</td>
<td>Local Health Authority</td>
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<td>MAST</td>
<td>Model for Assessment of Telemedicine</td>
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<td>NHS</td>
<td>National Health Service</td>
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<td>RTF</td>
<td>Regional Telemedicine Forum</td>
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<tr>
<td>UMTS</td>
<td>Universal Mobile Telecommunications System</td>
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2. Context of Chronic Patient with cardiovascular disease (CVD)

2.1 Description of disease

2.1.1 CVD inclusion/exclusion criteria for searches

Inclusions:
Cardiovascular disease
Stroke
Heart failure
Hypertension
Coronary heart disease
Ischaemic heart disease
Coronary artery disease

Exclusions:
Children/paediatrics
Diabetes
Peripheral arterial disease
Rheumatic heart disease
Congenital heart disease
Deep vein thrombosis and pulmonary embolism

Databases searched:
Cochrane
Medline
Embase
CINAHL
Web of Science

Limits:
Abstracts available; written in English; relates to humans; 2006 to date

Keywords:
Cardiovascular disease, stroke, heart failure, hypertension, coronary heart disease, ischaemic heart disease, coronary artery disease, needs, management, patients, clinicians, public health care organizations, telemedicine, telehealth

2.1.2 Description of disease

Cardiovascular diseases, as a group, are the leading cause of disability and death worldwide and are major causes of disability, hospital admissions and death in
Europe. Chronic cardiovascular disease is an umbrella term used to cover ischaemic heart disease and cerebrovascular disease. Co-morbidity, the presence of more than one disorder, is common in CVD. Subtypes of CVD include:

- coronary heart disease (angina and myocardial infarction)
- hypertension
- heart failure
- stroke.

Cardiovascular disease is a major cause of long term disability and the main contributor to disease burden, or morbidity, in Europe.

Modifiable risk factors for cardiovascular disease include poor diet, insufficient physical activity and smoking; non-modifiable factors include age and heredity. Promoting healthy lifestyles and screening early to identify established disease, can prevent progression to chronic conditions.

2.2 Needs analysis of patients, clinicians, public healthcare organizations, payers (insurance, institutions)

2.2.1 Patient level

Chronic cardiovascular disease is associated with a lower quality of life, particularly for patients with stroke or those with multiple co-morbidities.

The prime health needs of patients with chronic cardiovascular disease include:

- monitoring and medication
- regular interaction with healthcare providers
- adherence to treatment regimes

• specialist assessment and management of incontinence (stroke)
• management of breathlessness and fluid retention (via drug therapy or exercise training)
• support and education of patient and family/carers to self manage their condition
• assistance with activities of daily living
• consideration of implantable cardiac devices or heart transplant (later stages heart failure)
• consideration of end of life care needs when appropriate.

For patients with multi-morbidities, balancing the management of various conditions can be challenging. Poverty, social deprivation and lack of access to healthcare are further barriers to effective disease management⁶.

Services delivered in the home may be more effective than those delivered in a formal healthcare setting and telemedicine can be utilised to address the healthcare needs of patients with chronic cardiovascular disease⁷.

2.2.2 Clinical level

In 2008, 17.3 million (30%) of deaths globally were due to cardiovascular diseases⁴. In Europe each year, cardiovascular diseases cause over 4.3 million (48%) deaths and in the EU over 2 million (42%) deaths⁹.

In terms of chronic disability, cardiovascular diseases are responsible for 151,377 million DALYs¹⁰ worldwide. The Disability Adjusted Life Year (DALY) is a widely used WHO measure of disease burden where one DALY represents one lost healthy year of life. Within the EU, cardiovascular disease accounts for over 12 million lost DALYs (19% of total)¹¹.

There is an east/west mortality gradient in cardiovascular disease across Europe as shown in Figures 1 and 2¹². Mortality rates for stroke and heart disease are falling in western, high income countries while rising rapidly in Eastern Europe¹³. However, since populations are living longer, it has been argued that the

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⁷ Inglis SC, Clark RA, McAlister FA, Ball J, Lewinter C, Cullington D, et al. Structured telephone support or telemonitoring programmes for patients with chronic heart failure. Cochrane Database of Systematic Reviews 2010, Issue 8
¹⁰ Mendis et al 2011 ibid,
¹¹ Allender et al 2008 ibid
¹² Allender et al 2008 ibid
¹³ Allender et al 2008 ibid
prevalence and hence the burden of cardiovascular disease is actually increasing\textsuperscript{14}.

The main clinical challenges involved in managing chronic cardiovascular disease are\textsuperscript{15}:
- delivering primary and secondary prevention
- ensuring adherence to medication regimes
- providing education and support to enable self-management strategies
- reducing frequency of hospital admissions\textsuperscript{16}
- supporting informal carers on whom much of the care burden falls.

\textsuperscript{15} Thompson DR, Stewart S. Chronic cardiovascular disease management: how can it be improved? European Journal of Cardiovascular Prevention & Rehabilitation 2008 Feb 1;15(1):1-2
\textsuperscript{16} Hobbs FDR. Clinical burden and health service challenges of chronic heart failure. European Journal of Heart Failure Supplements 2009 Apr 1;8(suppl 1):11-14.
Figure 1: Standardised Death Rate, ischaemic heart disease, all ages per 100,000

Figure 2: Standardised death rate, cerebrovascular diseases, all ages per 100,000
Prevention of chronic cardiovascular disease is a vital part of disease management and of public health policy. Prevention strategies should target individuals, organizations and nations\(^\text{17}\).

At the level of the individual, prevention - whether primary or secondary - may take the form of screening, counselling, advice or drug therapy. Giving dietary advice leads to short term improvements in diet (fruit and vegetable intake) and cardiovascular risk factors (blood pressure, cholesterol levels, sodium excretion) but it is unclear whether these effects continue in the longer term.

Prescription medications are commonly part of cardiovascular disease management along with lifestyle modification. Barriers to adherence with medication regimes include\(^\text{18}\): coping with side effects, practical issues like cognitive or sensory problems, a need for information and difficulty in accessing services or organization of services. Patient education is needed to overcome these barriers and promote self-management of medication. Self management programmes improve health status and health behaviours and reduce hospitalisations in chronic cardiovascular disease and have been effective even for stroke patients with severe impairments. Adequate social support, particularly from spouses, may enhance self management.

The location of care provision is relevant; for example providing rehabilitation services to stroke patients in their own home increases their independence with activities of daily living and their ability to maintain that independence. Involvement of a community stroke liaison worker reduces mortality and disability in patients with mild to moderate disability after stroke and increases patients and carer satisfaction with service provision\(^\text{19}\).

Providing information in a way that actively involves patients and carers and includes planned follow up for clarification and reinforcement improves patient satisfaction and mood scores. The internet can be used to provide information to people with chronic cardiovascular disease. However, this may help them to make decisions but is not enough to make them engage in self management. They will also need social and emotional support, which is more difficult to deliver electronically\(^\text{20}\).

The use of telemedicine can help to address the needs of patients with chronic cardiovascular disease. For example, telephone support and telemonitoring are successful strategies in chronic heart failure management, particularly where access to health care services is limited. They appear to reduce mortality, improve quality of life and reduce costs\(^\text{21}\). Telemedicine in chronic cardiovascular disease is

\(^{17}\) Halpin HA, Morales-Suarez-Varela MM, Martin-Moreno JM. Chronic disease prevention and the new public health. Public Health Reviews 2010. 32 (1); 120-154


\(^{21}\) Inglis et al 2010 ibid
acceptable to most patients, including the elderly. Patients tend to cope well with the technology and are satisfied with care.

The scope of telemedicine in cardiovascular disease varies in complexity. At one end of the spectrum are simple measures like telephone contact. Mid-range is the electronic transmission of self-monitored physiological measurements like weight or blood pressure; at a more complex level, data from an implanted device transmit data wirelessly via broadband to staff at a remote site. Its use reduces geographical inequities in health care provision and enables patients to access a level of diagnostic and management expertise which may not be available locally. Telemedicine in chronic cardiovascular disease empowers self-management by providing a system for patients to report their self-monitored parameters easily and quickly to health care professionals.

Telemedicine is likely to be cost-effective and provide value for money but further robust international economic analyses are required. Telemedicine has been found to reduce emergency admissions for heart failure but not the rate of all-cause admissions in heart failure patients. Successful use of telecardiology requires the availability of trained, skilled personnel to operate systems and assess incoming data. The evidence base is still limited - many of the trials to date have been small - and further research is required to establish the best ways of using telecardiology; for example, there is potential to collect large volumes of data and clear international guidelines are needed on which parameters should be measured and how often.

2.2.3 Organizational level

Healthcare organizations face challenges in managing chronic cardiovascular disease. There is scope for telemedicine to be utilised to address at least some of these challenges, which include:

- Integrating secondary and primary care
- Moving the focus away from disease management to management of individual cases
- Delivering health education, training and public awareness
- Promoting and facilitating self-management and monitoring
- Improving access to services.

Additionally, where primary and secondary care sectors are integrated, there is better ability to care well for individuals with complex needs. It has been

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recognised\(^{23}\) that the disease management programmes (DMPs) used by some health care organizations limit the ability to support patients with complex needs such as those with chronic cardiovascular disease and there is a shift towards integrated models of care. Sharing care between secondary and primary sectors has been successful in England, Germany and the Netherlands. In England, the high degree of computerisation in general practices has facilitated a system to ensure quality of chronic disease care and health outcomes.

Healthcare organizations may deliver primary disease prevention at the level of communities through health promotion, education, training and public awareness campaigns. To support patients in the self-management of their medication and to deliver secondary disease prevention, health professionals require a comprehensive approach that ranges from patient education to service organization\(^{24}\).

### 2.2.4 Legal level

Addressing chronic cardiovascular disease at a legal level hinges on the formulation of public policy and legislation directed at prevention. Governments can act on issues such as tobacco sales, fiscal measures and advertising as well as configuring health care systems to support the prevention and management of chronic cardiovascular disease. For example, the Scottish government recently introduced legislation to control the pricing of alcohol; in recent years, across the UK bans on smoking in public places have been introduced. There is a legal requirement for data protection safeguards to be built into telemedicine services.

Additionally, there have been calls for clear European legislation to direct telemedicine services in managing chronic disease. A recent European Commission Directive for cross-border healthcare sets forth which legislative system applies in cross border telemedicine, requires informed choices for patients and regulates quality and safety standards. However legal clarification is still required on issues such as informed consent for telemedicine, systems for audit, reimbursement and systems for resolving legal disputes external to the EU\(^{25}\). These obstacles must be addressed before telemedicine can be implemented widely and systematically.

### 2.2.5 Economic level

Despite the east/west disparity in cardiovascular disease mortality across Europe, expenditure on health as a percentage of GDP is considerably lower in Eastern Europe (Figure 3). Chronic cardiovascular disease is costly to manage because it


is so common; large numbers of patients requiring frequent and lengthy hospital stays places an expensive burden on healthcare budgets. In 2006, the cost of cardiovascular disease to the EU was nearly €192 billion; almost €110 billion were for health care costs and €82 billion resulted from lost productivity and informal care costs. These figures reflect an average cost of €223 for each EU resident, for direct care alone\textsuperscript{26}.

\textbf{Figure 3: Total health expenditure as % of gross domestic product (GDP), WHO estimates}

In summary, chronic cardiovascular disease is a major financial and social challenge for European healthcare systems. Effective disease prevention and management is required. Telemedicine has a place in meeting many of the needs of patients living with chronic cardiovascular disease. Further research is called for to strengthen the evidence base underpinning the use of telemedicine; this is a developing field requiring international co-operation and support.

\textsuperscript{26} Allender et 2008 ibid
2.3 Role of telemedicine within CVD

CVD causes poor quality of life, high mortality and makes a significant impact on the economy of the EU through loss productivity, direct and indirect health care costs including the burden of care placed on informal caregivers. Given financial constraints and an increasingly elderly population, telemedicine offers the real possibility of home-based care and/or a more local service to CVD patient groups who find it difficult to travel to clinic appointments or for whom contact with centres of excellence and specialists would be difficult to access. Telemedicine can therefore provide expert healthcare to disadvantaged groups (e.g. financial, disability, location) as well as the opportunity of more patients being monitored effectively by the multidisciplinary team.

At the patient level, telemedicine can reduce hospital outpatient appointments, can facilitate regular patient monitoring, and can ensure that patients who live in remote and rural communities have the same opportunities and exposure to clinical expertise as others living closer to centres of excellence. In addition telemedicine can provide a system within which patients and carers are able to request additional information, or receive further training through a remote demonstration of an action or rehabilitation technique. Home-monitoring, providing it is conducted in a safe and responsive mode, should encourage and support patients and carers to better self-manage chronic CVD. A Cochrane review on using information technology to monitor chronic heart failure (CHF) patients, found lower mortality, reduced hospitalisation and improved quality of life including for elderly patients who learned to use technology easily and were satisfied to receive healthcare in this way\(^\text{27}\).

At this stage clinical evidence for the effectiveness of telemedicine in CVD is reliant on studies from elsewhere that indicate that ICT improves evidence-based prescribing, patient knowledge and self-care\(^\text{28}\).

The organizational benefits of telemedicine in CVD promise to reduce the burden of patients on hospitals through fewer repeat admissions and emergency callouts and by home-base, regular monitoring. Multidisciplinary working may be enhanced as a variety of healthcare professionals can be trained to act as the primary contact with patients choosing to speak to a particular healthcare professional group.

At the economic level, if hospital visits are reduced and transport payments lowered as a consequence, direct hospital costs should fall. Equally if there is
- a reduced need to maintain and/or offer clinic space and/or
- if hospital stays are shortened and/or
- there are reduced episodes of hospitalisation that can be attributed directly to telemedicine,

\(^{27}\) Inglis SC, Clark RA, McAlister FA, Ball J, Lewinter C, Cullington D, Stewart S, Cleland JGF. Structured telephone support or telemonitoring programmes for patients with chronic heart failure. *Cochrane Database of Systematic Reviews* 2010, Issue 8.

\(^{28}\) Ibid
then service re-design may allow for a more efficient and effective resource allocation model.

However there is a need to ensure that telemedicine facilities and services are properly funded and maintained over time. Pilot projects provide information and incentives to test new ways of working but they must be built into a strategic vision if they are to be sustained and embedded in mainstream services; for example Scotland’s Better Heart Disease and Stroke Care Action Plan’s ‘Recommended actions for thrombolysis’ ensured that health authorities engaged with policy and actioned changes in the delivery of thrombolysis to eligible stroke patients.

2.4 Parameters of evaluation

Based on the systematic reviews of Inglis et al (2010) and Ekeland et al (2010) we know that that telemedicine can be effective. However evidence for effectiveness remains limited and inconsistent with researchers failing to address systematically all the key questions related for example to the ethical, clinical, organizational and technical challenges that surround telemedicine. Therefore the defined parameters for any evaluation are critical if there is to be shared learning based on others’ experience.

At one level evaluation can be regarded as “a set of procedures to judge a pilot’s merit by providing a systematic assessment of its aims, objectives, activities, outputs, outcomes, and costs”. Evaluation therefore becomes a practical tool to help decision makers determine whether to continue a service or not.

Using Ekeland’s et al’s review as a guide, the EC commissioned a project to develop a standardized assessment for the effectiveness and contribution to quality care of telemedicine applications. MAST – a Model for Assessment of Telemedicine – is currently being tested in an EU-funded project ‘Renewing Health’ (http://www.renewinghealth.eu/) conducted in 26 sites across 9 EU countries. The Veneto Region project outlined in Annex C is one of the participating ‘Renewing Health’ sites.

The elements of MAST

<table>
<thead>
<tr>
<th>STEP 1: Preceding consideration</th>
<th>Purpose of the telemedicine application?</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Relevant alternatives?</td>
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<tr>
<td></td>
<td>International, national, regional or local level of assessment?</td>
</tr>
<tr>
<td></td>
<td>Maturity of the application?</td>
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</tbody>
</table>

| STEP 2: Multidisciplinary | 1. Health problem and characteristics of the application |

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### assessment

2. Safety  
3. Clinical effectiveness  
4. Patient perspectives  
5. Economic aspects  
6. Organizational aspects  
7. Socio-cultural, ethical and legal aspects

#### STEP 3: Transferability assessment

- Cross-border  
- Scalability  
- Generalizability

The MAST manual[^32] provides detailed information on the elements above along with examples drawn from a range of telemedicine studies.

[^32]: http://www.renewinghealth.eu/project-overview/overview/assessment-method/manual
Elsewhere ‘Would it work here?’ is the question that practitioners and policy makers want answered when considering service innovation\textsuperscript{33}. The checklist below can facilitate decision makers’ reflections on where funding should be allocated but can also aid innovators to structure their arguments in order to secure adequate and continued resourcing.

<table>
<thead>
<tr>
<th></th>
<th>System A</th>
<th>System B</th>
<th>Desirability and/or feasibility of changing practice, procedures and context of system B to match those of system A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The innovation</strong></td>
<td>What are the salient features of the innovation as it is currently used in system A?</td>
<td>What are the salient features of the innovation as it is intended to be used in system B?</td>
<td>Where there is a mismatch, could and should the system B adopt the same innovation as is used by system A?</td>
</tr>
<tr>
<td><strong>The resources</strong></td>
<td>What resources were used in producing the outcomes (staff time, money, equipment, space, etc) in system A?</td>
<td>What resources are available to system B?</td>
<td>Has system B got the resources to emulate the practice of system A? If not, would it be feasible or desirable for system B to enhance or redeploy resources?</td>
</tr>
<tr>
<td><strong>The people</strong></td>
<td>What are the salient characteristics of the key actors in system A in terms of expertise, experience, commitment and so on?</td>
<td>What are the salient characteristics of the key actors in system B?</td>
<td>Insofar as there is a mismatch, would it be desirable or feasible to recruit different staff, invest in training, go through teambuilding activities etc?</td>
</tr>
<tr>
<td><strong>Institutional factors</strong></td>
<td>How far were the outcomes dependent on (for example) organizational / departmental structure, organizational culture, etc</td>
<td>How far does the organizational structure and/or culture of system B determine practice?</td>
<td>Insofar as there are differences, would it be feasible or desirable to change the institutional structures and/or cultures in system B?</td>
</tr>
<tr>
<td><strong>Environmental factors</strong></td>
<td>How far were the outcomes dependent on particular environmental factors (e.g. political, legislative, etc)?</td>
<td>How far is the external environment of system B comparable?</td>
<td>Insofar as there is a difference, would it be feasible or desirable to change the external environment of system B?</td>
</tr>
<tr>
<td><strong>Measures</strong></td>
<td>What baseline, process, outcome and other measures were used to evaluate success?</td>
<td>Does system B (or could it) use the same measures:</td>
<td>Would it be desirable or feasible for system B to change the way it measures and records practice?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>What exactly was done in system A that led to the outcomes reported?</td>
<td>What were the key outcomes, for whom, at what cost, and what are they attributable to (see previous rows)? What was the cost per successful outcome?</td>
</tr>
<tr>
<td>Does system B do exactly the same (or could it)?</td>
<td>What key outcomes are measured in system B? Are they achieved for the same actors as in system 1? What outcomes does system B achieves that system A does not? To what are these outcomes attributable? What is the cost per successful outcome in system B?</td>
</tr>
<tr>
<td>Insofar as there are differences, would it be desirable or feasible for system B to change what it does?</td>
<td>Insofar as the outcomes are different, to what are the differences attributable? Are there outcomes that system B is not achieving that it would be desirable for it to? Could system B achieve the same outcomes at a lower cost? Would system B have to forgo some current outcomes in order to achieve the same outcomes as system A?</td>
</tr>
</tbody>
</table>
In answering the question ‘Will it work here?’ pilot projects aim to produce local knowledge and insights to allow transferability of that knowledge to other contexts and environments with their own internal and external conditions. Evaluation is therefore often local and it is through reports such as this, where the context and methods are detailed, that others can then read and analyze in order to determine whether the information from that situation can be reasonably transferred to their own particular context.
3. Good Practice Guidelines

3.1 Methodology used

The good practice guidelines described in this report are based on the contributions from the RTF partners as outlined in Annexes A-E and a workshop held in Edinburgh, Scotland in February 2011. They are described in operational terms and reflect good practice as well as a few ongoing concerns given that telemedicine services are a relatively new innovation.

Two of the five exemplars reported are part of larger EU projects. ‘Renewing Health’ involves Italy, Denmark, Sweden, Norway, Spain, Finland, Greece, Austria and Germany while ‘Dreaming’ is being piloted in Estonia, Denmark, Germany, Italy, Spain and Sweden. ‘Telestroke’, ‘Delivering Medical Tele-consultation’ and ‘Regional Telemedicine’ are regional programmes located in Scotland, Poland and France respectively.

3.2 Strategies to facilitate telemedicine

Telemedicine holds out great promise to its advocates and supporters. The exemplars in Annexes A-E demonstrate variation in scope of practice, implementation and funding arrangements that can be seen as representative of the current situation in the European Union. Where telemedicine is embraced by a Government, progress can be made strategically as there is a clear direction of travel with accompanying financial and infrastructure support.

CVD incorporates a wide range of conditions and syndromes that affect the population of Europe. Therefore exemplars that include the testing of a user friendly alarm and monitoring system for chronically-ill patients in the context of a nationwide medical records system (Estonia), a regional, specialist service such as stroke (Scotland), cardiac implanted devices (Italy), remote medical consultation for cardiac patients (Poland) or cardiac telemonitoring (France) provide insights into the development and functionality of telemedicine.

There is no ‘one-size fits all’ approach. Equally there are key issues that require attention no matter the telemedicine application including technical aspects, legal frameworks and sustainable funding. Implementation may take many shapes so that the approach adopted best fits that country’s health service, its geography and its population’s access and familiarity with the internet. The use of common evaluation parameters currently being piloted in the EC-funded ‘Renewing Health’ project should ultimately inform governments and key policy and decision makers as to potentially successful ways forward.

3.2.1 Clinical aspects

At the clinical level a range of points are identified to facilitate the implementation of telemedicine services for patients with chronic CVD. It should be noted that this

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34 http://ec.europa.eu/information_society/apps/projects/factsheet/index.cfm?project_ref=250487
35 http://www.dreaming-project.org/general_information.html
36 http://www.sctt.scot.nhs.uk/stroke.html
37 http://regional-telemedicine.eu/partners/poland
38 http://regional-telemedicine.eu/partners/france
is unlikely to represent a comprehensive list as several of the projects in Annexes A-E are still at an early stage and therefore have yet to accumulate significant experience. Each issue that follows is outlined and then followed by a good practice point.

- **Patient recruitment when testing new telemedicine services**
  In the projects included in this report, patients seemed to be generally receptive and were willing to engage in the remote service. Age in itself was not an issue although some older patients later withdrew from pilots. This is in line with research elsewhere that found elderly CHF participants could manage technological monitoring but usually withdrew because of hearing or health literacy issues while others chose not to engage in and learn the technology as their lives were already fully occupied\(^39\).

Therefore where possible, if conducting research into telemedicine, it may be useful to over-recruit patients as some inevitably will drop out; or may find the technology too much of a burden once they have to physically engage with it; or there may be difficulties in literacy or hearing; or unexpected patient deaths.

- **Maintaining patient contact**
  In several reports reference is made to patients and health professionals being able to contact each other regularly, perhaps on a weekly basis as well as for emergencies and untoward events.

Given that telemedicine services are used primarily for patients in remote and/or rural communities at present but will be extended to densely populated areas in the future, staff at the central hub need to be available and accessible. Furthermore there needs to be capacity for a rapid response mode if an emergency arises. Patients and carers require the assurance of knowing that if they require help, that help will be forthcoming.

- **Use of standards of care**
  Telemedicine may be introduced in order to achieve a standard of care; for example a door to needle time of 90 minutes.

Where telemedicine is introduced in relation to a specific standard, clinically competent staff must be available and accessible in order for that standard to be delivered.

- **Rapid referral pathways/algorithms**
  A pathway for rapid referral needs to be identified so if emergencies occur, that central hub staff are primed and know how to manage that situation efficiently, effectively and ensuring that the patient is not placed at risk.

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\(^39\) Clark et al Adherence, adaptation and acceptance of elderly chronic heart failure patients to receiving healthcare via telephone-monitoring European Journal of Heart Fail (2007) 9 (11): 1104-1111
Therefore it may be useful to weigh up a ‘what if...’ scenario so that rapid referral and risk management strategies are considered, designed and tested before the implementation of such a strategy is ever required.

- **Balancing physician commitments**
  Telemedicine projects should be built and integrated into real-time and as part of everyday, regular care delivery system rather than developed as isolated projects or pilots with dedicated staff additional to the usual staff complement. One-off projects, are unlikely to be able to inform decision makers of the complexities of introducing a real-time telemedicine service other than at a superficial level.

  Physicians, nurses and other health professionals who are involved and fully committed to the development of telemedicine initiatives and services, usually have other clinical duties. Therefore a clear decision making pathway of when to contact a doctor and having a backup team, can reduce concerns over how to manage competing demands on physician-time.

  Auditing the service as it develops provides healthcare professionals with specific information regarding the current state of delivery, potential problem areas and the benefits accrued thus far. On-going audit also alerts project managers of actual difficulties which may require immediate intervention.

- **Evaluation parameters**
  Research requires cross-comparability between measured outcomes. While there is no formal agreement as of yet on evaluation parameters, MAST is being piloted and it would seem a reasonable way forward for telemedicine projects to use this approach in the absence of anything else more useful.

### 3.2.2 Organizational aspects

Although each area within the ‘Good Practice Guidelines’ section is treated individually, nevertheless considerable co-dependency exists between these aspects. Organization is a consequence of funding decisions made by policy makers who are reliant or indeed have an expectation that the technical ‘know-how’ as to how to design, develop and implement a new telemedicine service exists and that the innovation is addressing a real need. Furthermore leadership is required if a major change in service delivery is to be effected.

- **Leadership**
  One of the most important aspects of organization is that of leadership. Strong clinical leadership can facilitate a project, whether a trial, pilot or implementation of a full telemedicine service. Good leadership brings key stakeholders together to ensure the smooth running of a project as well as identifying potential trouble-spots or ‘at risk’ elements. Good leadership can alert decision makers to changes in circumstances or situations that need alteration if a project is to stay ‘viable’.
Having said that, leadership in a complex environment such as healthcare, using a relatively new technology that has yet to achieve universal acceptance, is challenging. It requires an individual to have access to a range of resources and the authority to bring vested interests together to work out solutions to the inevitable problems that arise.

- **Project management**
  The introduction of telemedicine services can be regarded as a process with change at its core. Change involves structure, process, outcomes and a very human component.

  The establishment of a new service is an important venture for any health authority. Without doubt such innovation carries risk. Therefore a risk management assessment, carried out prior to a project's onset, may help those involved in the implementation to reflect on the relationship between components and the ensuing elements of risk.

  The use of a project management approach with a steering or project management group can be an extremely useful tool to help oversee the process. It can provide authority and support for the project manager to implement change. Responsibility for key decisions and ways forward can be considered with stakeholders providing the potential for good decision making as well as commitment and ‘buy-in’ from critical individuals. Successful implementation therefore becomes the corporate responsibility of the project management group.

  A management group can scrutinised the various stages of the project so that patient risk is minimized and a successful outcome more assured. As each step is completed, lessons learned and regular updates keep vested interests informed and should help maintain confidence in the project to its eventual completion.

- **The commitment or ‘buy-in’ of staff to the project**
  Whether one is introducing a totally new service or re-organising existing services through service re-design, all staff need to invest and commit to that project. It may be that a project that is tested in the real-world of regular hospital routine, receives more recognition and acceptance contributing potentially to a successful outcome. Therefore it is worth spending the time and effort to listen to concerns and expectations so that maximum benefit can be accrued from any trial and before implementation of the service.

  Commitment may extend beyond usual boundaries; for example if backup in emergencies requires transport then the briefing and involvement of those personnel becomes critical to the safe, efficient implementation of the service.

  It may also be pertinent to recognise that chronic CVD patients often have a range of co-morbidities. As such other areas of medicine may have to be involved. If this is likely to be the case, then a wider distribution of information related to the project could be advantageous, again to ensure safe and efficient telemedicine care delivery.

- **Monitoring standards of care**
Evaluation and modification of clinical performance requires data. Therefore organizationally audit systems ought to be built into the telemedicine service protocol. Reports should be issued regularly and disseminated widely across all vested interests, including patients and other healthcare workers so that all involved remained committed and interested in seeing the project through to a successful completion.

Project leads need to make it their business to analyse and seek alternative strategies if a new service is failing to meet its objectives or standards of care.

- Continuing service user input and education
  Organizationally new patients will enter a system as it develops and as the service perhaps expands over time. Consequently continuing support for users so that they remain compliant and satisfied with the alternative service provided is helpful. If users are ‘happy’ with the service provided they are more likely to stay engaged until a project is completed or they no longer need that particular intervention.

  In addition the availability of ongoing training for patients regarding the equipment they must operate, can enhance technical confidence so that the use of equipment remains effective and efficacious.

3.2.3 Technical aspects

The following issues are presented based on the comments and observations of the RTF partners, Annexes A-E.

- Equipment functionality and reliability
  A telemedicine service can only be as good as its equipment. If the equipment fails to run as planned, if there are technical mistakes, if interfaces do not allow interaction, if the speed of the connections is such that interventions or diagnosis is delayed, then the service cannot meet the required standards for patient care. Therefore specification of the technical requirements of the telemedicine service, its testing and its operationalization are critical to a project’s success and business plan.

- Developing technical specifications
  Intelligent data management systems are required that can store large amounts of data and hold information securely but remain intuitive so that healthcare professionals can extract required information, need to be designed. Involving healthcare professionals at an early stage of planning allows the service to be developed to meet clinical demands.

  A dedicated technician/engineer should form part of the specification given the necessity for technical functionality; (e.g. one would not consider offering a CVD telemedicine service without clinically competent physicians attached to that service).

  A specification that requires all involved companies to work to a single data collecting and/or monitoring system facilitates information sharing and patient wellbeing. For example there may be occasions when several different medical device companies collaborate in an EC-funded telemedicine project. While collaboration is beneficial in terms of a project’s scope, scale and funding, it does require management, particularly if companies operate different data collection methods or follow-up services.
Where electronic patient records (EPRs) exist or are being introduced, a specification that allows a seamless flow of information from the telemedicine project to the patient’s EPR should be considered at the protocol stage. As noted in the Annexes, technical inter-operability between home monitoring equipment, the central hub and patients’ electronic health records remains an issue.

- Organisation of installation
  The ease and speed of equipment installation prior to the start of a telemedicine service is observed and judged by patients and relatives. It is therefore important to visit the patient’s home to review how equipment and devices should be connected and what power sources are required such as cables, additional sockets, etc. This is best done by a dedicated technician (preferably one attached to the telemedicine project) along with a healthcare professional e.g. nurse involved in the service. It is suggested that a telemedicine project engineer/technician installs equipment in the home that has been previously lab-tested and sensor-connected. After connection, the installed equipment should be tested in situ before going ‘live’ to guarantee that the monitoring systems and platforms perform as anticipated.

  Patient and relative confidence is enhanced through such activity and withdrawal from a project may be less likely if installation runs efficiently and is completed on time.

- User involvement
  Telemedicine projects require patients and relatives/carers to have or develop sufficient technical facility to operate dedicated equipment. This includes regular monitoring as well as situations where users may be under considerable stress such as emergencies or unexpected events. Therefore home monitoring equipment that is ‘user-friendly’ with a minimum number of technical ‘things’ that have to be done or installed is beneficial.

  In pilots or trials, it may be necessary to ensure that internet familiarity is part of the patient recruitment criteria if projects are to run to time and to budgeted funding.

  However in real-time projects, it is likely that at least some of the potential patients of a telemedicine service will not have the Internet. This requires consideration by policy and decision makers as to whether to fund the development of access to the Internet as part of the overall specification for a telemedicine service.

  Patients may be concerned that a telemedicine service does not provide the same degree of medical record protection and security as a face-to-face consultation. Therefore the use of robust encryption for data and an explanation thereof to patients is recommended so that confidence in the system is established.
• Healthcare professionals’ technical ‘know-how’

In the same way as users may require education and ongoing training, so may the healthcare professionals who are using telemedicine to monitor and evaluate patients’ medical status.

Interfaces that allow the sharing and reviewing of clinical information between various healthcare professionals e.g. viewing CT scans remotely, facilitate clinical decision making and instil confidence in healthcare professionals who are yet to be convinced of the ‘worthiness’ of telemedicine as a care delivery system.

3.2.4 Economic aspects

Funding is a critical aspect of developing and operationalizing a telemedicine service for it is not a cheap option. Without adequate funding telemedicine cannot be implemented. It has ongoing infrastructure and personnel costs as do other healthcare services. Intelligent auditing of telemedicine services however should provide the information to evaluate the cost effectiveness and safety of the system.

The flip side of adequate funding is sustainability of funding. One-off initiatives that are not embedded in the strategic planning of health services or local health authorities are in themselves risky. Telemedicine initiators who set out innovation in the context of their LHA’s planning forecasts and deliver a well-evaluated, ‘on-time’ and within budget project, are more likely to receive a favourable welcome but of course there are no guarantees of continued financial support.

In a Cochrane review of structured telephone support and telemonitoring for chronic heart failure patients, the cost per intervention was dependent on the technology employed and the frequency and intensity of the intervention40 with most studies indicating savings from 14%-86% as a result of fewer hospitalisations or through a lesser cost of care per admission.

Across the EU, healthcare is the responsibility of the individual state. Consequently each country has its own healthcare system with its own mechanisms for funding their healthcare services. Different NHSs have different models of care and different funding arrangements within which public and private financing operate alongside each other. As noted earlier when telemedicine is a government-sponsored initiative, funding may be accessed directly. If telemedicine services are developed as the result of an EC research funding call or in response to some other EU initiative, there is often an expectation that part-funding will come from elsewhere. This can prove problematic for telemedicine innovators in seeking reimbursement from a number local health authorities across a region. For some the “biggest obstacle to the large scale deployment of a home monitoring service for CVD patients remains the issue of reimbursement”.

3.2.5 Legal aspects

Healthcare via telemedicine is like any other care delivered by a health service. It requires

• quality standards of care including the use of appropriately certified equipment
• evidence-based medicine
• healthcare professionals to act within their scope of professional practice and statutory/regulatory framework
• due regard for patient safety and wellbeing
• clinical and research governance
• ethical behaviour.

40 Inglis et al. Structured telephone support or telemonitoring programmes for patients with chronic heart failure. Cochrane Database of Systematic Reviews 2010, Issue 8.
In these matters, telemedicine for patients with chronic CVD in the EU, is no different from any other care provided in a hospital or in the community. It is generally agreed that referring clinicians and sites retain responsibility for a patient’s care even though they are being managed through a telemedicine service. When research is being conducted alongside a telemedicine service, ethics approval is required for that project. As such patients agree and provide informed consent and failing this, should not be included in a study.

Legal frameworks exist within the EU which deal with a number of aspects related to telemedicine. As an example manufacturers of devices are responsible for ensuring that their products meet the essential requirements ensured by ‘CE marking’ certification (‘Conformité Européenne’). Likewise in relation to the security of patients’ medical data in the UK, the Data Protection Act (1998) lays out the requirements for the secure storage of patient information, protection of patient identity and access to that information. Having said that some variation occurs across the EU; for instance not all EU members have Compulsory ID cards but where they are required, ID cards may be used for authentication in order to access data. There are also variations in the EU regarding patients’ rights to access their own medical data.

Nevertheless concerns are expressed regarding the security of transfer of information from home monitoring equipment via the Internet and/or mobile telephone networks. Some believe that there is a lack of legal clarity in this area and hold a view that the law is not keeping up with advancing technology. Also while healthcare professionals have specific clinical responsibilities within a telemedicine service, others’ roles are not so defined by regulation. Legal challenges may arise in the future which will be tested in European courts.

3.2.6 Policy aspects

Policy is set at the highest level by Government which has the responsibility and duty to ensure that the appropriate legal and regulatory frameworks are in place for decision makers. Within this context regional governments and LHAs interpret and develop Government policy according to the context in which they operate taking due cognisance of local factors. Key decisions related to telemedicine include the following:

- **Sustainable funding**
  Given that health service demand is unrelenting in the face of an ageing population, advances in medical technology etc, telemedicine services inevitably compete for funding in an increasingly difficult economic climate. If telemedicine is to find its place in the delivery of mainstream health services, policy makers are critical to the establishment of sustainable funding for well-evaluated projects. Policy must be clear on the requirement to embed CVD telemedicine services in routine care delivery as appropriate. Without such direction, telemedicine is likely to develop as ad hoc, one-off, isolated projects that fail to enter mainstream health provision.

  A tender process operated initially by regional governments based on the ‘lessons learned’ from the RTF project in telemedicine might offer a reasonable way forward to attract cost-effective, patient outcome driven services. Future funding would be dependent on achievement in delivering outcomes.

- **A central hub**
  Organizationally different projects may require different approaches. As noted previously a ‘one-size fits all’ does not represent the most effective strategy. Policy makers need to take due cognisance of the region within which they operate and the type of service and patient that is expected to use that system.
For some regions the management of a particular telemedicine service may be by
developing a national centre or central hub/spoke may be the most cost effective and
organizationally efficient stratagem as it allows health authorities a mechanism within which
"to facilitate design, development and implement and evaluate telehealth models of care" as
advocated in the Scottish exemplar (Annex E).

Whatever the preferred model, the decision taken must be communicated by Government
policy makers to regional decision makers and cascaded out to LHAs so that they can
develop services in line with Government policy.

- Infrastructure planning: broadband
  As noted before not all of a targeted telemedicine population is likely to be connected to the
  Internet. If policy makers support telemedicine, then by extension, support should be
  forthcoming for the expansion of broadband access if all potential patients are to have equity
  of access. This can be done through incentives, brokering deals with internet providers etc.

### 3.3 Conclusions: lessons learned

The relationship between electronic patient records, security of patient data, access to that data and technical know-how deserves further consideration. Assurances that all data are held securely and that confidentiality of patient information is guaranteed, are not convincing. Recent breeches in global internet systems by determined hackers leads one to suspect that there is a degree of complacency regarding electronic medical records and consequently telemedicine data.

We know from systematic reviews that telemonitoring and structured telephone support can aid
the routine management of CHF patients. There is no reason to suspect that this is not the case
for the group of patients who are the subject of this report. Nevertheless robust systems of
evaluation must be instituted and these reports communicated more widely. If funding is to be
given for regional projects, then the resulting reports should be fulsome so that shared learning
occurs. Failure to do so could result in the inability to obtain future funding or receive only limited
funding.

Other questions may arise in respect of telemedicine including ‘Are different telemedicine
strategies required for different age groups and/or ethnic minorities?’

It is reported\(^{41}\) that the “division between research study and clinical service is
likely to make home monitoring less efficient and less effective.”, that healthcare
professionals require experience and training in home monitoring in order to
deliver effective services and that the ideal situation is to integrate home
monitoring into routine service. Throughout this report we have argued that the
testing of telemedicine needs to occur in the clinical environment as it exists to
ensure that advancing technical, clinical and funding issues are resolved
satisfactorily.

\(^{41}\) Inglis et al. Structured telephone support or telemonitoring programmes for patients with chronic heart failure. *Cochrane Database of Systematic Reviews* 2010, Issue 8.
While economic benefits are hypothesized in the various reports contained in Annexes A-E, there are no hard data available as the projects are ongoing. Nevertheless greater consideration is required concerning the cost benefits of telemedicine. Funding proposals could be required to include a detailed business model with the cost benefits articulated within the proposal in terms of actual money rather than theoretical propositions.

Telemedicine holds out the promise of great things. It is now necessary for policy makers to ensure that the conditions are set for that promise to be fully realized.
4. ANNEX A - Good Practices of Telemedicine Services

4.1 The identified good practice in Estonia

4.1.1 Title of the practice

DREAMING project – Elderly friendly alarm handling and monitoring. DREAMING is an international ICT-PCP project to deliver monitoring and alarm handling services, e-Inclusion services (an e-service that provides person with options to be more involved in society) and non-technology based services. The project aims to deliver home monitoring for chronically ill patients suffering from either cardiovascular disease, diabetes and/or chronic obstructive pulmonary disease.

4.1.2 Objectives of the practice

The DREAMING services facilitate the management of chronic conditions in a home setting reducing the need to use the resources of acute hospitals. The project’s objective is to demonstrate that the DREAMING service platform produces clinical benefits to its users and economic benefits to health authorities. The main aim is to keep elderly people in their home environment as long as their physical and mental conditions allow this.

The outcome of the project is evaluated by collecting primary and secondary clinical outcome results, quality of life questionnaires, economic impact and user satisfaction. The primary clinical outcome is evaluated using a health status questionnaire, that is the SF-36 v2 (health related quality of life) while the Hospital Anxiety and Depresssion Scale (HADS) questionnaire was used to measure secondary outcomes (e.g. depression). Quality of life is evaluated using SF-36 and HADS questionnaires.

The DREAMING solution is being piloted in Denmark, Estonia, Germany, Italy, Spain and Sweden. The pilots are aimed at verifying the impact of the service on economic and clinical indicators, its financial sustainability and the satisfaction of users. This will help to refine the DREAMING business case with a view to large-scale deployment.

4.1.3 Location and Background

East Tallinn Central Hospital (ETCH) is the municipal hospital in Tallinn, Estonia. It has approximately 500 beds and 450,000 outpatient visits (2010). ETCH provides a large spectrum of healthcare services. There is active care for inpatients and outpatients as well as rehabilitation and long-term care. Great attention has been paid to the development of a hospital information system to integrate different care units and develop e-services for patients.
4.1.4 Detailed description of the practice

4.1.4.1 Bodies involved which allow to follow the implementation

The DREAMING service in Estonia is provided by the East Tallinn Central Hospital (ETCH). The team consists of a physician, three nurses and technical staff including specialists from a medical engineering and software group and a project manager. The hospital administration of ETCH is also attached to the Dreaming project in order to keep track of the budget and to ensure the effective functioning of the project.

The involvement of general practitioners of particular patients included in the service is to a level that ensures up to date information their patients’ condition and the project’s progress.

The municipality of Tallinn, call centres and public are informed about the general aspects of the project by dissemination events, e.g. meetings with officials, leaflets delivered to GP practises, and newspaper articles.

4.1.4.2 Timescale

The project will last 36 months, 30 of which will be devoted to trials. The trials started in 2009 and end in 2012. It is expected that over such a relatively long period of time, significant differences between the Study Group (SG) and Control Group (CG) will be observed. DREAMING is based on state-of-the-art technologies which are available off the shelf.

4.1.4.3 Process and detailed content of the practice

4.1.4.3.1 Workflow of the service

The project setup and service workflow include the following steps:

- Selection of SG and CG patients from the ETCH patient pool according to clinical criteria.
- A Contact Centre formed of nurses; every patient has his/her dedicated nurse.
- Contact all patients in the SG in order to agree on a visit to their homes. According to the agreement with the patients, determine an equipment installation schedule.
- Negotiate with the Estonian ISP (Internet Service Provider) in order to provide an internet connection for the patients. Before the installation, visit patients with the company technician in order to make sure that it is possible to provide an internet service.
- Install equipment and conduct the necessary testing at the patient’s home.
- Sign a deed of receipt about the equipment that was installed.
- Visit patients at their home; train them in how to use the equipment, explaining the nature of the DREAMING project. Provide them with a user manual containing information (including pictures and short descriptions) on how to use the DREAMING equipment. Ask patients to sign the informed consent forms and SF-36 and HADS questionnaires during a domiciliary visit.
• Monitor patient data on a daily basis. Conduct telephone consultations with the patients at least once a week.

• Send the SF-36 and HADS questionnaires to the CG patients.

• Solve technical problems with the equipment. If necessary consult with the central platform provider.

• Deliver the monitoring system which is composed of a set of self-operated medical devices, the number and the type of which is determined according to the specific health condition of each individual and the main health threats to which he/she is exposed.

• The medical devices provided to each patient are selected according to the specific health conditions of that individual from the following list:
  - Weight scale (with body fat, water content)
  - Pulse and blood pressure
  - Glucometer (for people suffering from diabetes or at risk of developing diabetes)
  - 1-Lead ECG monitor
  - 1-12 Lead ECG monitors (for people with serious heart conditions)
  - Pulse/oxymeter monitors (for people with respiratory or heart disease).

Measurement of the vital parameters of each individual are taken according to a schedule which is personalised to the specific needs of that individual. The single devices give an audible or visual confirmation that the measurement has been taken.

Measurements are automatically sent to the central unit that acknowledges receipt of the data by a vocal message which, optionally, also includes the values of the readings. For people with hearing impairments, the measurements can be read on the embedded display of each of the medical devices.

Whenever a network connection is available (this represents the overwhelming majority of cases) the data collected are immediately sent to the Contact Centre for further processing by the Decision Support System. In the infrequent case that the connection to the network is temporarily suspended, the data are stored locally and automatically sent as soon as the connection has been re-established.

4.1.4.3.2 Standard used

The monitoring equipment is connected to the central platform using legacy software; that is software produced by a company using its own non-standardised data communication protocols. In the future there is a plan to use IHE (Integrating Healthcare Enterprise: an international standard profile) profiles for patient data sharing.

4.1.4.4 Legal framework

The conduct of the DREAMING services was approved by the Ethics Committee of the Estonian National Institute for Health Development.
4.1.4.5 Financial framework

Public healthcare services in Estonia are reimbursed through compulsory health insurance.

According to the future model of nursing care, financing home monitoring in Estonia could be partially funded by the Health Insurance Fund, by the person himself and/or by the local municipality. First changes in the implementation of this model took effect from January 1, 2010, when patients’ own contributions were established. Some local municipalities already support institutions providing long term nursing care. One alternative is to add Dreaming-like services to the list of long term nursing care services and to receive financial support similar to the model of long term nursing care. There is a potential to expand the nature of home care nursing service (the service is part of the long term nursing care) and to pursue differentiated prices.

Another possibility is to pursue through professional associations, that Dreaming-like services should be added as a new service to the price list of the Health Insurance Fund.

The third possibility comprises closer co-operation between the healthcare and social fields, and the elaboration of integrated services and joint funding in both areas.

Our hospital has experience of providing ‘out-of-pocket’-based healthcare services and one method of financing could be that patients or their relatives pay 100% themselves for the services. Given the emotional benefit achieved from this service (patient lives at home and is monitored), this kind of funding is acceptable for certain groups of people.

4.1.4.6 Policy level

The aim is to provide a health monitoring service, using hospital personnel and facilities. The purpose for the hospital in using telemonitoring services is to reduce the period of hospitalization among chronically ill patients and to reduce their return to the hospital. Telemonitoring services help to extend the period during which the elderly (for example) can live independently in their own homes. Also the elderly may feel more socially included and this helps to contribute to both social and more effective use of healthcare resources.
The strength of our hospital is that nursing care is integrated with active care and there is a home care nursing service at hospital. At the moment we are able to offer less nursing care service compared to the demand for this service. Our role will be to promote the Dreaming services as a new innovative e-service in the field of elderly care and monitoring in Estonia. This means that patients will be securely monitored (thus improving the health service quality); but also kind of service helps to strengthen the relationship between hospital and patient.

So far our experiences have shown that thanks to the telemonitoring service, the communication between patients and hospital has increased and patients are more oriented in using hospital-provided services. In the future and with good co-operation between hospital and family doctors, there is also the possibility of providing medical telemonitoring services to patients through family doctors practices.

4.1.5 Evaluation

4.1.5.1 Target achievement

The aim was to recruit 30 users, randomized to either a SG or a CG.

Clinical impact is divided into primary and secondary outcome. Primary outcome includes health status questionnaire SF-36 v2 (health related quality of life). Secondary outcome includes the number of episodes of depression as measured by the HADS, number of hospitalisations and permanent transfers to elderly homes, time to permanent transfer to elderly homes, total and average length of stay in hospital, number of consultations with GPs and consultations with specialists, number of home visits by nurses and by social operators, the number of ambulance transports and accesses to the emergency rooms, and the number of falls and femur fractures.

Quality of life is evaluated using SF-36 and HADS questionnaires.

Quality of life is evaluated using SF-36 and HADS questionnaires and economic impact by calculating tangible and non-tangible benefits. User satisfaction will also be assessed.

4.1.5.2 Qualitative feedback

The feedback from the study group has been positive. We have noticed a tendency that patients prefer to call the nurse, who monitors their data, rather than the family physician.

Users feel increased security regarding their independent living when they know that their health condition is monitored remotely and they receive a quick response in case of deterioration in their chronic disease or health status.

4.1.5.3 Success factors

In ETCH the roll-out of DREAMING is concentrating on clinical health monitoring and e-Inclusion. Clinical monitoring is conducted by the home care nurses consulted by the physicians of ETCH. The most critical factor influencing the roll-out is the integration of DREAMING equipment and arrangement of a seamless workflow. The service should be easy to understand for the patient. This means that the hospital has to offer a complete package of monitoring services including patient specific profiles, user manuals, delivery of the equipment to the patient home, monitoring services, and behaviour algorithms for different clinical situations.
Another critical factor is the user friendliness of the home monitoring equipment. It is important to have minimum number of technical ‘things’ in the home environment. The simplicity also applies for the user interfaces of monitoring devices.

4.1.5.4 Issues and barriers encountered, and strategies take to overcome barriers

4.1.5.4.1 Clinical level

Patient recruitment was successful in the initial phase but some patients dropped out owing to delays in installing technical equipment.

The Estonian trial originally required 30 participants in each group. Nine patients dropped out before they had equipment installed, thus leaving 21 patients in the study group. Dropouts were caused by death (one patient), transfer to nursing home, or being unwilling to continue due to their serious health condition.

The nurses check clinical data daily. If required, the nurse asks the patient to repeat the measurements and, if necessary, the nurses consult with the physician. The patients are in contact by phone with the nurses at least once a week. If necessary, treatment is adjusted by telephone; alternatively the patient can be asked to see their physician by appointment, and if needed the patient can be hospitalised. In the case of emergencies, the patients or relatives call the emergency centre.

4.1.5.4.2 Organizational level

Patients are trained in their own homes by the healthcare team session during one session. Ongoing training and support is needed in order to ensure user satisfaction and an acceptable level of equipment exploitation.

In the case of an alarm, the nurses are the first ones to respond and will if necessary, address the problem to the physician.

Before installation, it is important to do a visit together with the company technician to the patient’s home as technicians know how devices should be connected and what is needed (cables, power strips, additional sockets, etc.). If it is possible, our engineer installs the previously lab-tested and sensor-connected equipment to the site. After connection, we test the installed equipment and perform measurements in order to see if the set is working.

4.1.5.4.3 Technical level

The ADSLs (Asymmetric Digital Subscriber Lines) have been negotiated with the Estonian ISP provider and are paid for centrally by our organization.

The equipment installation process took longer than planned because there were problems with connecting some equipment (e.g. pulse oxymeter and glucometer) to the central unit; also, some defective equipment had to be replaced. After installation, problems occurred that as some equipment failed to send data to the central unit. We tried to solve these problems from a distance but sometimes it was necessary to go to the patient’s home in order to solve the technical problem.

The installation of the equipment was also delayed due to the fact that only one patient had an internet connection. Setting up the internet connections took a lot of time and effort in order to find a mutual time that suited the patient, the internet provider and our technical people. The Internet has now been established for all 19 patients in the pilot. The process might have been easier if there had been an inclusion criterion from the start; e.g. that all participants in the project must
4.1.8

Other possible interesting information

Overview of the Estonian nationwide Electronic Health Record System
Citizens in Estonia have had online access to their medical data through the Estonian Electronic Health Record System (EHR) since the beginning of 2009. The EHR serves simultaneously healthcare professionals and citizens. There is a Patient Portal application which allows citizens to view his or her medical data and related information and is a service implemented through the EHR. The Estonian EHR is a single nationwide global EHR system as it comprises the whole country, registers virtually all residents’ medical history from birth to death, and is based on the comprehensive State-developed basic IT infrastructure. The Estonian nationwide EHR was launched at the end of December 2008. Since the 1st of January 2009 all healthcare providers have the obligation to send an agreed number of standardized medical documents to the EHR. The content of the information stored centrally is indicated by the legislation.

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have an internet connection. On the other hand, this criterion would have further reduced the potential number of patients to include in the project.

4.1.5.4.4 Economic/Financial level

The reimbursement of home monitoring services is not solved in Estonia and remains the main obstacle to the large scale deployment of telemedicine. The Estonian Health Insurance Fund does not cover home monitoring expenses. As stated above there are three potential scenarios to proceed with reimbursement: 1) To include home monitoring services in the Insurance Fund service list. This is a time-consuming procedure and has a high probability of not being approved; 2) Include the service in municipality social services; 3) Out-of-pocket payment.

4.1.5.4.5 Legal level

The legal environment regarding e-government and e-health services is well covered in Estonia. Legal issues are not an obstacle for telemedicine and telemonitoring service deployment.

4.1.6 Lessons learnt from the practice

Users are satisfied with the home monitoring services and are willing to continue after the end of the project. The service was also well accepted by healthcare professionals. For successful implementation there has to be careful planning of every aspect of the service. Technical interoperability between home monitoring equipment, the central unit and electronic health records remains an issue as there is no seamless information flow between the patient, central unit and hospital electronic patient record system. The biggest obstacle to the large scale deployment of a home monitoring service for CVD patients remains the issue of reimbursement.

4.1.7 Contact information

- Peeter Ross e-mail: peeter.ross@itk.ee
- Responsible for the telemedicine service (to have more information) Marko Parve, Head of the Department of Medical Engineering; e-mail: Marko.Parve@itk.ee
Electronic documents are formatted as standard HL7 CDA documents that are stored in a central database (i.e. archived electronically). The content of medical and health-related information in the central database consists of the following services:

- **Medical files**
  - Time critical data (allergy, chronic diseases)
  - GP and hospital visits
  - Summary of ambulatory and stationary cases
  - Link to medical images
  - Prescribed and dispensed medication
- **Expressions of will/preferences**
  - Closing medical records (opt out)
  - Names of trusts
  - Donation of organs
- **Overview of logs**

Currently there is no service for the booking of specialists or GPs appointment or comparing waiting lists of different healthcare providers.

The person compiling the medical document has to be identifiable: documents containing medical information or a physician’s decision must have the physician’s digital signature, or it must be date-stamped by the healthcare service provider's information system. In spite of more than a ten-year history of digital collection of medical data by doctors, the medical data collected prior to 1st of January 2009 were not transferred to the EHR due to their poor quality and insufficient standardisation.

The EHR is a database that is a part of the State information system. The healthcare related data is processed in this database in order to conclude and execute the healthcare services provision contract; to ensure patients’ rights; to protect public health and quality of healthcare services; to maintain the registers of health conditions; and to manage healthcare.

To secure access to the EHR, the Estonian countrywide data exchange platform X-Road is used. X-Road is based on a principle of using one integral set of user interfaces for organising communication with databases. The system ensures sufficient security for the treatment of inquiries made to databases and responses received. It is suitable for managing a dialogue between the consumer (citizen, civil servant and entrepreneur) and numerous databases as well as for realising co-operation between application programs and databases. The technical solution of the X-Road does not lie in the transition of all databases to some larger data management system but in the creation of unified user interfaces for different databases. Citizens and institutions can join and use the X-Road free of charge.

Identification of the person is based on the compulsory ID-card issued by the State. ID-card is used both for identification of the user and for digital signing of documents, e.g. discharge letters, radiology reports, etc.

Certain legal regulations are adopted to secure access to the EHR. As mentioned above all healthcare providers must send agreed data to EHR. All access rights and data usage is regulated by the law. Compulsory ID-card is used for authentication and digital signature for both, doctors and citizens. Access is enabled only to licensed medical professionals.
Citizens can access their own data through the Patient’s Portal, where they can also declare their intentions and preferences. The patient has a right to set access restrictions to documents, cases of illness, and to all his/her information in the EHR. The access ban can be set to one specific document or applied to the complete data in the EHR. The EHR will record information about when, how, and why the data was used (logging information), enabling citizens to monitor who has viewed their health data.

The EHR is built according to the best practices of Service Orientation. Service implementatins are based on standards that Estonian E-Health Foundation publishes openly on its website.

Interaction with end users is established via alternative channels. Also, there are portals that are served by the Estonian E-Health Foundation (e.g., Patient’s Portal). Patient’s Portal allows patient representatives (adult patient, parent of an underage, legal representative, trustee) to browse patient’s health record, download documents, submit consents, update demographics data, get overview of prescribed and dispensed medication, and review patient health record usage logs via Web.

By April 2011 the EHR system contained the medical data of 583,114 citizens which represents 44% of the total population. There have been 670,666 queries by 27,623 different citizens since the launch of the patient portal at the beginning of 2009.

The most used service based on the EHR is electronic prescription. By the end of 2010 approximately 75% of prescriptions were issued in electronic form. ePrescription allows citizens to buy medications in any pharmacy in Estonia based on electronic identification. Physicians make electronic prescriptions which are automatically uploaded to the Prescription Centre. Pharmacists in any location in Estonia can download the prescription, see the dispensing status, make a note about the dispensing of the medications, and see also other prescribed medications.
5. **ANNEX B - Good Practices of Telemedicine Services**

5.1 **The identified good practice in Auvergne area, France**

5.1.1 **Title of the practice**

Regional Telemedicine in Auvergne Area, France

5.1.2 **Objectives of the practice**

Improve the concerted care of patients with chronic diseases, optimise healthcare and reduce morbidity and mortality.

5.1.3 **Location and Background**

The benefit of developing telemedicine in the Auvergne region lies in its very rural geography, with remote, difficult-to-access areas and few doctors outside cities and towns.

5.1.4 **Detailed description of the practice**

5.1.4.1 **Parties involved in implementation**

For telecardiology, the parties involved are interventional cardiologists implanting pacemakers, industry acting as an interface for communication of patient data and patients’ attending cardiologists. The health authorities are also involved via higher reimbursement of implants.

5.1.4.2 **Timescale Process and detailed content of the practice**

Activity currently conducted routinely

5.1.4.3 **Process and detailed content of the practice**

5.1.4.3.1 **Workflow of the service**

The following are involved in the management of telecardiology: nurse at the technical platform who receives alerts via internet or fax and performs initial triage, the implanting cardiologist who handles these alerts and the attending cardiologist who will be required to see the patient again rapidly in the event of destabilisation of his/her heart problem.

5.1.4.3.2 **Standard used**
5.1.4.4 Legal framework

5.1.4.5 Financial framework

5.1.4.6 Policy level

5.1.5 Evaluation

5.1.5.1 Target achievement

All interventional cardiologists working in the field of rhythmology at the Teaching Hospital are involved in the development of telemedicine. This currently concerns 5 full-time doctors, 4 nurses from the medical and technical platform and representatives of the various companies supplying implants. Not all our patients receive pacemakers or defibrillators enabling this type of monitoring; the proportion is around 40% telemonitoring in cardiology.

5.1.5.2 Qualitative feedback

The benefit perceived by patients is a feeling of greater security at home, fewer consultations and days in hospital. For doctors, there are fewer "one-to-one" consultations, more time spend on the computer and fewer cases of acute decompensation.

5.1.5.3 Success factors

The implementation of telemonitoring in cardiology has been facilitated by the experience of other centres, feedback following experience with the technology used and its reliability. The difficulty was to free up additional nurse time and train personnel.

5.1.5.4 Issues and barriers encountered, and Strategies implemented to overcome barriers

5.1.5.4.1 Clinical level

No particular problem relative to the clinical organization of monitoring

5.1.5.4.2 Organizational level

No particular problem relative to the clinical organization of monitoring

5.1.5.4.3 Technical level

The implants are identical to those used routinely, therefore no technical difficulties when implanting them. There are some programming differences but the doctors implanting the devices have received training by industry.

5.1.5.4.4 Economic/Financial level

The cost difference for implants fitted with telecardiology technology is currently covered by the French national health insurance system. Management of telephone and web platforms is covered by the manufacturer. The only problem that remains is the creation of nursing positions for management of the alerts and consultations resulting from telecardiology.

5.1.5.4.5 Legal level
5.1.6 Lessons learnt from the practice

We thought it would be possible to reduce the number of physical consultations but, in reality, patient consultations cover many other aspects of cardiology requiring conventional monitoring. In addition, it is not necessarily easy to organise telecardiology in the cardiology department and it requires the investment of both cardiologists and other personnel.

5.1.7 Contact information

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Head of the Rhythmology Department: Dominique Lamaison, same address

5.1.8 Other possible interesting information

Development by industry of other tools for the communication of medical information from patients to cardiologists (e.g.: weighing scales and blood pressure monitors with bluetooth, communicating via the same system as for pacemakers and defibrillators)
6. ANNEX C - Good Practices of Telemedicine Services

6.1 The identified good practice in Veneto Region, Italy

6.1.1 Title of the practice

Renewing Health – REgioNs of Europe WorkING toGether for HEALTH
RENEWING HEALTH is a European project. It involves 9 of the most advanced regions (Veneto region is one of these) in the implementation of health-related ICT services, inside a local system where service solutions are already operational for the telemonitoring and the treatment of chronic patients; in particular patients with cardiac implantable electronic device (CIED), cluster 8. The Veneto Region is one of the first cardiology departments to start a telemedicine service for cardiac implantable device in Conegliano Hospital, in LHA No. 7 (Local Health Authority).

6.1.2 Objectives of the practice

The project RENEWING HEALTH (RH) aims to implement large-scale, real-life test beds for the validation and evaluation of innovative telemedicine services by means of a patient-centred approach and a common rigorous assessment methodology (MAST).

The main objectives are:
- Improving the monitoring of patients with implantable cardiac devices
- Reducing workload in cardiomonitoring centres for the control and management of patients
- Separating the control activities of the device from patient care.

The remote monitoring of patients with implantable cardiac device already exists in the Veneto region but these tend to be isolated local health authorities (LHA) initiatives or NHS hospital trusts active in the region. The new RH services will allow all these isolated initiatives to conform to a single technical and organizational model. The Conegliano cardiology department could be an important organizational model to achieve these objectives.

6.1.3 Location and Background

Veneto Region inhabitants number 4.8 million. There are 21 LHAs, 2 hospital trusts and one speciality research institute. There are 6 clinics involved in the project. The total number of patients with an implantable cardiac device followed by these centres is 15,400, of whom 1,400 have a remote monitoring system and 189 are followed in the Conegliano electrostimulation department.
6.1.4 Detailed description of the practice

6.1.4.1 Bodies involved which allow to follow the implementation

The Conegliano Telemedicine Service was designed directly by the Cardiology Department of the LHA. There are three physicians and two nurses involved in the service.

The RH project in Veneto is provided by Arsenàl.it. Arsenàl.it is a consortium composed of all the 21 LHAs and 2 NHS hospital trusts of the Veneto Region. It is engaged in the design, development and assessment of supra-organizational e-health applications.

Three consortium project engineers, a sociologist and an economist manage the entire project which includes a physician with competence in cardiac electrostimulation.

As noted before there are 4 LHAs and 2 hospital trusts involved in the project and all respective general managers have agreed to be involved. All LHAs and hospital trusts individualize a clinical referral to follow the project in the cardiologic department.

The five companies that produced the monitoring system are engaged in supporting the project with the knowledge of their products.

6.1.4.2 Timescale


The Renewing Health project started on the 1st of February, 2010 with for a duration of 32 months. The work for cluster 8 (cardiac implantable devices) started 6 months later. The observational study will begin in approximately September 2011 and will last for 12 months.

6.1.4.3 Process and detailed content of the practice

6.1.4.3.1 Workflow of the service

The implanted device is able to record and store a complete set of data about its own functionality and the patient’s health status. Data stored are sent to a gateway device that can transmit them to an online server. Data are transmitted when a clinical or technical parameter exceeds the threshold or there is a programmed follow-up. Finally the clinical personnel can access the site to review technical and clinical information. The organizational workflow is described below:

Step and responsibility:

- Patient Selection (Physician)
- Order / delivery of the device, (Nurse)
- Recruitment of the patient in the site (Nurse)
- Training of the patient and family and delivery of device (Nurse)
- Planning of follow-up, site checking, alarm management and event (Nurse)
6.1.4.4 Legal framework

Report (Physician)

Follow Up:

- 1 standard control at one month after implanted to verify system integrity, optimization of parameters, etc ...
- Schedule clinical controls
- Controls monitored remotely every month for ICD (implantable cardiac defibrillation) and CRT (cardiac resynchronization therapy) and every 3 months for PM (pacemakers).
- Send report by email or mail (annual / monthly)
- Re-calling the patient if reprogramming / replacing of implant is necessary
- Re-calling the patient for a cardiology clinical visit in case of clinical event such as an arrhythmia, heart failure indices altered etc.

6.1.4.3.2 Standard used

The transmission between the device and the gateway happens through ISM band (902-928Mhz), MICS band (402-405Mhz) or SRD band (863-870Mhz) dedicated to medical transmissions.

The device's data from the gateway are sent to a web-server of the company producing the system, through GSM (Global System for Mobile Communications), UMTS (Universal Mobile Telecommunications System), and telephone cable lines depending on the company.

In the hospital the physician can access the data through a web-server.

Data can also be downloaded and integrated with the electronic medical records using the HL7 standard.

In the future the aim is to create a unique, integrated platform that collects the data coming from the different companies servers.

6.1.4.4 Legal framework

Parties that have specific responsibilities include the patient, caregivers who include the referring physician and the physician and authorized CEAP (Clinically Employed Allied Professionals) that do the actual monitoring, the device manufacturer and the government.

Prior to delivery of the remote monitoring system, a ‘care agreement’ should be in place that sets expectations for patient follow-up.

Data registration and maintenance (secure and permanent) is the joint responsibility of the device manufacturer, distributor (where involved), implanting centre and physician.

The responsibility for follow-up data is delegated to the implanting/follow-up physician or institution.
The manufacturer is responsible for ensuring that devices meet all of the essential requirements ensured by ‘CE marking’ certification (‘Conformité Européenne’).

The government’s responsibility is to ensure that appropriate legislation and regulations are in place to permit the timely, efficient and effective collection and sharing of data in patients with CIEDs (Cardiac Implantable Electronic Device). Effective oversight mechanisms are required in order to ensure the above legislation and policies are followed and that personal health information is protected.

The conduct of the study was approved by the Ethics Committee of the local Institute.

European guidelines concerning the remote control of devices (minimum frequency):
- Within 72 hours of CIED implantation (in person)
- 2–12 weeks post implantation (in person)
- Every 3–12 months pacemaker/CRT-P (in person or remote)
- Every 3–6 months ICD/CRT-D (in person or remote)
- Annually until battery depletion (in person)
- Every 1–3 months at signs of battery depletion (in person or remotely).

6.1.4.5 Financial framework

The Conegliano Telemedicine Service has not received financial funds and therefore the resources utilized are pre-existing.

The RH project is financed by the EU and local regional authorities.

In Veneto the financing for the entire RH project is provided by an EU contribution of €1,655,905.00 and by the Veneto Region for €1,670,349.00.

6.1.4.6 Policy level

There are still major limitations for the development of remote monitoring such as ethical and legal aspects, reimbursement issues and the lack of specific national and European-updated guidelines which need to be revised.

Organizational, policy and ethical issues have to be overcome to enable real-world implementation. This challenge may be relevant for the spread of the home-monitoring service.

Widespread implementation of telemedicine will entail the management of huge amounts of data, with important privacy implications. It will be essential to define responsibilities for data management/access (by hospital personnel, providers, public/private institutions, etc.) and the formulation of regulations to protect the rights of both patients and healthcare professionals.

Thorough analysis on how a remote monitoring system can be introduced into everyday routine and which organizational changes must be addressed and whether these changes can lead to increased clinical effectiveness, cost savings and an improved social perspective is required.

At this time some of the Veneto centres use remote monitoring but there are still ethical, legal and organizational hurdles to be resolved before large scale remote monitoring can be routine.

In many of these centres there is still a lack of proven and tested workflow that permits the capitalization of the potential of new technology that could improve clinical benefits and reduce time spent, personnel and space resources.
It is necessary to understand what the correct organizational model is to sustain telemonitoring and what are the needs and the worries of clinicians.

RENEWING HEALTH will put us in a position to overcome these obstacles and to elaborate and test a feasible organizational model.

The Conegliano Cardiology Department has already tested a workflow model (see answer at 1.1.4.3.1 workflow of the service) that will act as the standard to apply in other departments.

### 6.1.5 Evaluation

#### 6.1.5.1 Target achievement

Many studies have demonstrated that remote monitoring permits the safe extension of face-to-face encounters, improves adherence to scheduled checks, reduces the total number of in-person evaluations and results in more rapid evaluation of events with more rapid initiation of indicated therapeutic interventions.

This study is just starting (prevision 20th September 2011). All the six LHAs have involved a physician referral. The conduct of this study has been approved by the Ethics Committee of our local Institute.

In a series of selected LHAs, 2,080 patients will be enrolled who meet the inclusion criteria. A total of 1,850 patients will be monitored with remotely and 230 patients will be followed in usual care without remote monitoring.

Clinical outcome measures:
- Number of re-hospitalisations
- Number of specialist visits
- Number of early detections of acute episodes and time of intervention
- Number of visits at emergency departments
- Quality of life as measured by the SF36 v2

Our clinical outcomes will be evaluated by Crf, interviews, focus groups, bibliography analysis and regional registers:
- Changes in cost per patient and LHA
- Effects on work processes
- Structural outcomes
- Cultural outcomes
- Patient perception.

#### 6.1.5.2 Qualitative feedback

Pacemakers and implantable defibrillators continuously collect a myriad of diagnostic information. These data have the potential to assist in clinical decision making for the management of underlying cardiac disease. With remote monitoring system it is possible to access these data continuously and receive alerts in case of device malfunction or clinical events. With the remote monitoring system it is possible to reduce the in-clinic, follow-up of the devices.

Better monitoring of patient events

Possibility to prevent acute events
More attention to the performance or failure of the devices

Reduction of control time and in-person follow-up

Optimization of human resources

Reduction of costs to the LHA

Reduction of costs borne by the patient (reimbursement, travel expenses, absence from work)

A new organizational model that could improve physician satisfaction and the ability to follow the patient

6.1.5.3  Success factors

Following devices remotely will allow the Conegliano Centre to achieve a reduction in the length of follow-up from 20 minutes for an in-clinic visit versus 5 minutes for remote follow-up.

With the new organizational model the Conegliano Centre will be able to manage 189 patients with remote monitoring system successfully.

6.1.5.4  Issues and barriers encountered, and Strategies take to overcome barriers

6.1.5.4.1  Clinical level

The study will be observational in design and not a randomized trial. This could be a limit to the evaluation of clinical benefits.

However we are convinced that the main emphasis of our study should not be on clinical effectiveness as analyzed by a randomized controlled trial but should be on a thorough analysis on how remote monitoring system can be introduced into everyday routine and which organizational changes must be addressed and whether these changes can lead to increased clinical effectiveness, cost savings and an improved social perspective.

6.1.5.4.2  Organizational level

Each cardiology department has a different approach to follow-up patients with implanted devices. This approach compromises the standardization of patient care. With the RH project we will individualize the best standard workflow to apply in single units.

In addition each company producing implantable devices has a different system to follow up patients at home and a different web-site to check diagnostic information from the device. Clinical staff

have to access 5 different web-sites consuming a lot of time. In the future this could be improved through a single system collecting data from all device companies.
6.1.5.4.3 Technical level

The equipment is supplied by the company producing the devices. Devices are tested and have a CE marking certification.

The gateway that transmits the data can operate with different types of data transmission lines. Two companies producing the gateway can operate only through telephone cable lines while the others can also operate through GSM or UMTS line systems. Some patients could be left out of the service because of the lack of telephone cable lines. Very soon all the involved companies will provide equipment that does not require a telephone cable line.

Lack of personal computers dedicated to the service.

Problems concerning access to single company web-sites due to intranet LHA blocks.

6.1.5.4.4 Economic/Financial level

One of the major limitations for the development of remote monitoring is the lack of a reimbursement code. Many LHAs use the same code of a standard follow-up or do not take reimbursement and provide a free service.

With this project we would like to assign a reimbursement value to the remote monitoring service.

6.1.5.4.5 Administrative level

The major administrative barrier is the lack of reimbursement for the remote monitoring service.

6.1.6 Lessons learnt from the practice

The project has only just commenced.

6.1.7 Contact information

- Technical Coordinator of RH project for the Veneto Region:
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6.1.8 Other possible interesting information

http://www.renewinghealth.eu/
7. ANNEX D- Good Practices of Telemedicine Services

7.1 The identified good practice in Malopolska Region, Poland

7.1.1 Title of the practice

‘Delivering Medical Teleconsultation’, University Centre of Telemedicine in Krakow.

7.1.2 Objectives of the practice

Running highly specialized medical consultations by specialists from University Hospital using hospitals’ IT networks and telecommunication connections.

The outcome of the project is the possibility of sending of medical data and images from regional centres to the reference centre hub at the University Hospital in Krakow. The main objective of the project is to improve the results of treatment of patients with acute coronary syndrome by decreasing the death rate and disabilities caused by cardiovascular disease, vascular diseases, brain degeneration diseases and diseases of nervous system.

7.1.3 Location and Background

24 hour, 7 days a week, telemedical consultations are offered by the Centre for Invasive Cardiology at the University Hospital, Krakow, for cardiology district centres in the Malopolska, Podkarpacie and Świętokrzyskie Regions. The cardiology centres from these regions have declared their willingness to cooperate and participate in the creation of a macro regional network of cooperation with the Centre for Invasive Cardiology. The Hemodynamic Laboratory of University Hospital, Krakow is the Centre for Invasive Cardiology for invasive treatment of acute coronary syndromes. Coronary heart disease is the most common cause of death in Polish people in working age.

7.1.4 Detailed description of the practice

7.1.4.1 Bodies involved which allow to follow the implementation

The University Hospital in Krakow – project coordinator, reference centre.

The University Hospital in Krakow, with over 200 years of history, is one of the biggest health care centres in Poland and the biggest medical institution in the Malopolska Region. The main objective of the Hospital's activity is providing highly specialized health services and health promotion combined with educational and research tasks of the Collegium Medicum of the Jagiellonian University.

The district centres of invasive cardiology from the Małopolska, Podkarpacie and Świętokrzyskie Regions – cooperate with the Centre for Invasive Cardiology.
The project has received grants from the EEA and Norway Grants.

### 7.1.4.2 Timescale

At the end of 2009 the Hospital started telemedical consultations. Patients benefited from this kind of specialized consultation without paying additional money to the centre where they were treated until the end of the project on 30th March 2011.

### 7.1.4.3 Process and detailed content of the practice

#### 7.1.4.3.1 Workflow of the service

The hospitals’ IT networks and telecommunication connections were used for the telemedical consultations given by the University Hospitals’ specialists. While the project is now completed in terms of grants (the Norwegian Fund), teleconsultations are being continued through a network of 24 hospitals. Within consultations the physicians from the district centres were able to send angiographic pictures of coronaryography and PCI (Percutaneous coronary intervention) to the reference centre. Thus they were also able to discuss the optimal model of percutaneous treatment for each patient, discuss treatment results or the action to be undertaken in case of complications and determine the mode of transferring patients to the reference centre if there was a need for complicated cardiologic invasive procedures that are available only in the reference centre.

#### 7.1.4.3.2 Standard used

Internet connections are secured.

### 7.1.4.4 Legal framework

The „University Centre of Telemedicine in Krakow” project was approved by the Ministry of Health.

### 7.1.4.5 Financial framework

On 12.10.2009 the Financial Agreement Nr 56/PL0354/07/NMF/MFEOG/2009 for the University Centre of Telemedicine in Krakow” project from the Norwegian Financing Instrument was signed. The agreement had been signed between the Minister of Health, as an intermediary institution for the Priority “Health Care and the Child Care” indicating the International Relations Office of the Health Care Programmes for realization of the agreement as a Supporting Institution and the Collegium Medicum of the Jagiellonian University and SP ZOZ University Hospital in Krakow as a Beneficiary. Moreover between the mentioned Parties there has been signed an agreement Nr 7/2009 of November 2009, together with an Amendment Nr 1 of December 2009 regarding grant of the Minister of Health for co-financing the project PL0354 „University Centre of Telemedicine in Krakow”.

### 7.1.4.6 Policy level

No policy has been instituted by health care authorities.

### 7.1.5 Evaluation

#### 7.1.5.1 Target achievement

There were 21 hospitals participating in the project at the end of February 2011.
Until the end of February 2011, the physicians of the University Hospital in Krakow performed 7,291 telemedicine consultations in the area of cardiology, neurology, neurosurgery, and radiology within the Project.

The current organizational model of interventional myocardial infarction treatment in the Malopolska Region allows 700 primary PCI in STEMI (ST Elevation Myocardial Infarction) per 1 million inhabitants to be performed which is consistent with the current indications of the European Society of Cardiology for treatment of myocardial infarction STEMI.

7.1.5.2 Qualitative feedback

Based on the work of Dr Jacek Legutko the following was reported:

HEART TEAM CONSULTATIONS:
- all high-risk, selective cases scheduled for revascularization

INTERVENTIONAL CARDIOLOGIST CONSULTATIONS:
- 24/7 access to experienced interventional cardiologist from reference center

Immediate (within 10-15 minutes) consultation in relation to:
- all difficult angiograms and/or difficult patients with acute coronary syndromes
- PCI strategy in emergency situations
- treatment of CAG (coronary angiography)/PCI complications

Next day consultation of:
- all PCI procedures performed in regional cathlab
- next steps of revascularization in ACS (Acute Coronary Syndromes) patients with LM (left main) and/or MVD (multivessel disease)

7.1.5.3 Success factors

- facilitation of decision making process in patients with complex anatomy (left main, multivessel disease, Ostial LAD/CX, last remaining vessel, CTO (complex chronic total occlusion)
- selection of the optimal technique of PCI
- treatment of PCI complications
- shortening the time from CAG to PCI/CABG (coronary artery bypass grafting)
- facilitation of the training program for invasive cardiologists
- improvement of outcome in cad (coronary artery disease)

7.1.5.4 Issues and barriers encountered, and strategies taken to overcome barriers

7.1.5.4.1 Clinical level

For further shortening of time from diagnosis till intervention in myocardial infarction STEMI, ECG teleconsultations should be commonly used in the invasive cardiology centres.

The telemonitoring of patients with chronic heart failure should be considered in order to detect early-on the symptoms of cardiac decompensation and the early implementation of adequate ambulatory therapy to prevent unnecessary and expensive hospitalizations.
There is a need reperfusion therapy for patients with ischemic stroke to be used more widely based on telemedical consultations performed by the reference centre for district centres.

7.1.5.4.2 Organizational level

For the further shortening of time from diagnosis until intervention in myocardial infarction STEMI (i.e. door to needle time) it is necessary to increase the number of patients transported directly from home to the invasive cardiology centre in Krakow.

7.1.5.4.3 Technical level

Data security and data privacy need to be assured.

Broadband networks should be developed.

7.1.5.4.4 Economic/Financial level

Telemedicine services are not viewed as other more usual medical services which can be refunded by the State within the National Health Fund’s health insurance scheme.

In order to extend telemedicine it is necessary to solve some essential issues: first of all there is lack of the public financing for telemedicine services. Currently telemedicine is being developed under single projects run by physicians and IT experts. It is necessary to convince the decision makers that telemedicine makes sense and is cost-effective.

7.1.5.4.5 Legal level

The lack of legal clarity.

There is lack of law regulations regarding the technical possibilities of using telemedicine – the law does not keep up with the technology.

The issue of the provision of remote medical services is connected with the necessity to maintain medical data protection, relevant description of realized procedures and responsibility of the provider of the medical service. For example the standards of telemedical procedures used in practice should be described including the quality of technical transmission of images: high quality scenario (on-line transmission), medium and low quality scenario (on-line transmission), series of immobile images (on-line transmission), transmission on-line). Such technical development would allow the doctor to take decisions based on what is seen and therefore enhance clinical responsibility. Secondly it would aid the process of creating a correct telemedical application - the programmer would know the medical procedures being used with new solutions verified in practice. According to IT trends “e-Health Poland” for 2011-2015, the most urgent need is to identify and establish legal regulations to enable the development of telemedicine in Poland.

7.1.5.4.6 Administrative level

Policy-makers’ awareness of the importance of the development of telemedicine services should be raised. Support for telemedicine projects is needed.
7.1.6 Lessons learnt from the practice

Implementation of telemedical consultations in the Centre for Invasive Cardiology and cardio surgery centre largely improved the efficacy of treatment of the patients in district centres. It shortened the time coronary treatment to revascularization. It helped to improve the results of treatment. Application of interventional treatment for all patients with acute coronary syndromes require the following conditions to be met:

- In the case of STEMI patients the time from the first contact of the patient to the physician to the PCI treatment cannot exceed 90 minutes (door to needle time). It requires the functioning of an adequate number of invasive cardiology centres in the area working 24h/7h and the creation of a network of hospitals co-operating with the Centre for Invasive Cardiology. Their task would be a quick qualification of the case and transfer of the patient to the place of invasive treatment.

- The treatment has to be performed by the qualified medical staff. The lack of highly qualified medical staff and the lack regular consultations with the Centre for Invasive Cardiology has had a negative effect on the therapeutic decisions taken and on treatment results.

- The invasive cardiology centre should be supervised by the cardio surgery centre. Some patients with acute coronary syndromes and stable angina require an urgent or planned cardio surgery intervention. That is why there is a need for quick access to cardio surgery for all invasive cardiology centres in the region.

7.1.7 Contact information

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7.1.8 Other possible interesting information

Edinburgh Meeting February 2011: Poland –

Speaker: Jacek Legutko, Jagiellonian University, Institute of Cardiology, University Hospital Krakow.

Dr Legutko outlined the objectives of the European Society of Cardiology’s “Stent 4 Life” initiative - chiefly to ensure that at least 70% of eligible (STEMI) patients receive stents (PCI) and to empower PCI centres to offer 24/7 services for primary PCI. He then profiled the availability of 24/7 PCI centres in the Polish regions, which number 112 in total with an average of approximately 3 centres per million
patients, and illustrated the yearly rise in availability of such services since 2001 and the results of key studies relating PIC use to patient outcomes. Next he presented a map of cathlabs for the treatment of high risk patients across Poland, showing how 4 regions have telemedicine links to cardiac reference centres in the capital city of Krakow. High risk, elective cases scheduled for revascularisation are evaluated by a Heart Team supported by teleconferencing and tele-imaging. (Telemedicine helps to improve compliance with European guidelines, which require that patients undergoing myocardial revascularisation are managed by suitably experienced operators with appropriate back-up.) In addition to team discussions, telemedicine supports Interventional Cardiologist Consultations for difficult cases within 15 minutes of seeking them, as well as next day consultations following up PCI procedures performed in regional cathlabs. Dr Legutko then gave further details of a service he coordinates at the Central University of Telemedicine in Krakow, which provides remote services to 9 primary PCI centres in the central area of Poland.

In summary, telemedicine consultations are used to facilitate decision making in patients with complex anatomy, to select optimal PCI treatment for the patient; and in the treatment of PCI complications. This shortens the time between CAG and PCI/CABG and also facilitates the training programme for invasive cardiologists, leading to improved outcomes in patients with CAD.

(See also http://www.healthindicators.gov/Indicators/Timely-PCI-therapy-STEMI--
8. ANNEX E Good Practices of Telemedicine Services

8.1 The identified good practice in Scotland

8.1.1 Title of the practice

Scottish Telestroke Programme – Programme of projects aimed at increasing the equity of access to stroke thrombolysis across Scotland

8.1.2 Objectives of the practice

To provide a robust telestroke network(s) improving access to acute stroke thrombolysis decision support across Scotland, evaluate the service and identify the optimal way to provide a sustainable national telestroke network for the future.

8.1.3 Location and Background

Scotland covers an area of 78,782 square kilometers, with an estimated population of 5,220,000. Within this population there are on average 10,000 acute strokes per annum, approximately 8,000 of these are ischaemic strokes and of these approximately 10% (800) are eligible for thrombolysis (clot busting) treatment.

Before the decision to treat is made the patient needs to get to an acute hospital, have a CT scan of the brain and be assessed by a stroke specialist - all within four and a half hours from onset of symptoms. Prior to the provision of telestroke services and mainly because of Scotland’s remote and rural issues, many patients were ineligible on admission at local sites therefore not transferred or were in eligible following lengthy transfer to one of the few specialist centres.

Telestroke provides access to the specialist from a local acute hospital via videoconferencing (VC) and picture achieve communication systems (PACS). The projects within the Telestroke Programme are located in 12 of the 14 territorial Health Boards across Scotland and involve 22 acute hospitals. By the end of 2011 will there will be five Health Boards whose stroke specialists will have video conferencing home access to these 22 acute hospitals.

Across Scotland there are currently four networks in place, two provide 24/7 cover and two are required for out of hours cover only. For the purposes of this document the South of Scotland network will be described. This network is a hub and spoke model, providing out of hours cover for five Health Boards: Borders, Dumfries and Galloway, Fife, Forth Valley and Lothian. The network involves 9 hospitals. The hub support is provided by the on call stroke specialists in Lothian Health Board and covers an estimated population of 1,693,000.
8.1.4 Detailed description of the practice

8.1.4.1 Bodies involved which allow to follow the implementation

National Level -

- Scottish Centre for Telehealth and Telecare (SCTT), now part of NHS 24 – Provided telehealth expertise, general leadership and programme management
- Scottish Government Health Department - Stroke National Advisory Committee and managed clinical network sub-group (which includes representation from all Health Boards, Scottish Ambulance Service (SAS), patients, voluntary sector and national audit) – provided specialist clinical leadership and the initial steering group

Regional Level –

- South East Regional Planning Group (SEAT) – responsible for planning and commissioning regional services
- South Scotland Telestroke Network Project Board – chaired by NHS 24, includes representation from SCTT, SEAT, South Network Boards (planning and medical representation), voluntary sector, and patient/public.
- Regional Coordinator group – chaired by SCTT, regional clinical lead, regional IT lead, regional coordinator and local Health Board coordinators – monthly meeting ongoing through first year of service. Responsible for data collation, continued route for lessons learned to be disseminated and action taken where necessary.

Locally –

- Telesstroke project team – A core team includes: SCTT chair, local clinical lead, project coordinator, IT lead, local representatives from emergency department, radiology department, stroke team, SAS and patients through the managed clinical network involvement – these teams now only meet virtually as an when required, but were the driving force in each health Board.

8.1.4.2 Timescale

The South Network was first discussed in 2006. In 2008 a project team was set up to deliver a phased roll out, there are four phases:

- Planning (including testing and pilots within the network) complete July 2010
- Regional planning /agreement – complete November 2010
- Fully operational – March 2011
- Evaluation and identification of optimal sustainable model for future – March 2012
8.1.4.3 Process and detailed content of the practice

8.1.4.3.1 Workflow of the service

- Stroke patient admitted as emergency
- SAS pre alert the emergency department and patient is admitted to the VC site in the emergency department
- Stroke Thrombolysis integrated care pathway put in place - patient assessed, hub notified, head CT ordered (may or may not have VC consultation at this point)
- CT image viewed by stroke specialist via PACS, if eligible for treatment patient returns to VC site, if not patient continues on local stroke integrated care pathway or relevant care
- Patient has consultation with specialist via VC, if patient still eligible treatment commenced
- CT image viewed by stroke specialist via PACS, if eligible for treatment patient returns to VC site, if not patient continues on local stroke integrated care pathway or relevant care
- Hub consultation record sent electronically to spoke site for inclusion in patient record
- Patient transferred to high dependency area for completion of treatment (12-24 hours).
- Patient transferred for normal stroke care under local integrated stroke pathway

8.1.4.3.2 Standard used

**South Scotland**
**Telestroke Codec Sites**
8.1.4.4 Legal framework

As with the EU member requirements, the British Medical Association state that the use of e-Health and other telemedicine services adhere to the same quality and safety standards as those in use in non-electronic healthcare provision; and that they offer adequate protection to patients notably through the application of regulatory requirements for telemedicine practitioners, wherever their location, identical to those in use for non-electronic healthcare provision.

The Programme has worked with local clinical governance teams during the planning phase and is currently working, in collaboration with the national managed clinical network, in the development of a governance checklist, which will allow local teams to assess and compare the governance around their thrombolysis and telestroke services.

No patient consultations are recorded, the PACS images are kept in the national repository and a written record of the consultation is taken at both the hub and spoke site, both stored in the patient’s record.

8.1.4.5 Financial framework

Initial capital funding for acute sites was through SGHD. During the initial operational year, including out of hours consultant professional allocation time of 4 sessions per week and the ongoing evaluation the funding will be from NHS 24.

The outcome of the evaluation will decide the ongoing resource requirements, it will also allow the requisite information to decide whether this will be met by the individual Health Boards or regionally funded.

8.1.4.6 Policy level

- Better Health, Better Care (SGHD 2007) - Encourages consideration of use of telehealth in all new services or service improvement.
- Better Heart Disease and Stroke Care Action Plan (SGHD 2009) - States the actions required to improve CVD, due to the effectiveness of the acute Telestroke pilots, regional telestroke planning and development of larger networks was recommended.
- Scottish Centre for Telehealth Strategic Framework (NHS 24 2010-2012) – Sets out the SCTT priorities for the two year period and stroke is one of the four.

8.1.5 Evaluation

8.1.5.1 Target achievement

March 2011 – September 2011 – evaluation of service measured at both hub and spoke ends. It is designed to include the requisite data to allow the decision for an ongoing regional service to continue and if so, in what format.

- SAS pre notification
• Designation of referring clinician
• Number and time of calls & number of thrombolysed, by spoke site
• Number of tel only / tel & PACS / tel, PACS & VC / tel & VC, by spoke site
• Door to needle time, by spoke site
• Hub Consultant and time taken for each call/consultation
• Radiologist involvement
• Quality of VC both audio and visual
• Immediate patient outcome
• % of total number thrombolysed in each spoke site via the telestroke network*
• Increase in total number of patients thrombolysed by measuring number for previous six month period*

*data from the Scottish Stroke Care Audit (SSCA)

8.1.5.2 Qualitative feedback

• Patient perspective – Via Interview by researcher (Lothian)
• Consultant – Via questionnaire
• Spoke site staff (Lothian) – Via questionnaire
• Lessons learned update on monthly basis

8.1.5.3 Success factors

There have been various success stories to date, evidence of one is the quote taken from an email sent to the hub from a Fife thrombolysed patient’s relative:

"I just wanted to pass on sincerest thanks on behalf of my Mum, my brother and myself for the treatment you were able to provide my Dad on Saturday. The progress Dad has made in the space of a few days is incredible and we know that has a lot to do with the clot busting drug you were able to prescribe -Thank you so much"
Across the south of Scotland region and prior to the telestroke development, only one out of the eight hospitals involved in the network were able to provide out of hours thrombolysis treatment as a specialist centre. In the first 11 weeks of the service 28 patients were thrombolysed, who would otherwise not had access to treatment.

8.1.5.4 Issues and barriers encountered, and Strategies taken to overcome barriers

8.1.5.4.1 Clinical level

During planning there was some anxiety from the radiologists and specialist neuro radiologists working in the hub Health Board that this development would require their involvement at most calls. This has been audited and is not the case, < 10% to date.

Until the result of the evaluation the stroke specialists at the hub are working within existing staffing levels, this will be addressed once the six month evaluation is complete.

Organizational level

In the initial planning phase there were several changes in the leadership and resource allocation to telestroke from the SCT, there was also a change in leadership at regional planning level – both delayed the development of the larger South Telesstroke Network. The SCT move into NHS 24 facilitated regional discussions and provision of ongoing funding.

8.1.5.4.2 Technical level

To proceed with a regional network it was identified that a dedicated IT engineer would be required. This took several applications, over a nine month period to various bodies, to eventually agree the funding for this post.

Uploading the PACS image from another Health Board, to the hub via the national repository, can cause up to a 50 minute delay in some cases, a network for specialist’s direct access to all spoke PAC systems is now being set up.

8.1.5.4.3 Economic/Financial level

Although the wider economic health benefit of providing stroke thrombolysis for all eligible patients is expected to be considerable, without resource intensive evaluation of treated patients and potential cost of ongoing care/dependency, this is very hard to establish. This made the business case for the initial agreement on larger networks in Scotland challenging.

8.1.5.4.4 Legal level

The referring spoke site maintains the responsibility for the patient’s care. The stroke specialist at the hub site is providing a decision support service.

8.1.5.4.5 Administrative level

There have been difficulties in identifying a standard approach to sending and receiving the electronic record from the hub at the spoke site. It has not been possible to set up a generic email
address for this at all spoke sites; therefore it is dependent on the hub specialists including all the relevant addresses post treatment on each occasion.

8.1.6 Lessons learnt from the practice

Cognisance of individual Health Board requirements needs to be taken. The regional approach is not necessarily ‘one size fits all’ across the region. Each Board has their own stroke thrombolysis integrated care pathway and referral to hub protocol, not all hospitals have the same VC equipment in place, but they can all communicate with each other and with the specialists. Although this makes evaluation more complicated, it allows individual IT and clinical staff to have ownership of their service.

Having a national centre for telehealth provides Health Boards with an objective organization to facilitate design, development and implement and in some cases evaluate telehealth models of care.

8.1.7 Contact information

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<td>Professor Martin</td>
<td>National Clinical lead for Stroke/</td>
<td><a href="mailto:Martin.dennis@ed.ac.uk">Martin.dennis@ed.ac.uk</a></td>
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<tr>
<td>Dennis</td>
<td>Consultant Stroke Specialist Western General</td>
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<td></td>
<td>Hospital, Edinburgh</td>
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<td>07825 386323</td>
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<td>0131 5371719</td>
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8.1.8 Other possible interesting information

- SCTT Telesstroke web site –
  [www.sctt.scot.nhs.uk/stroke.html](http://www.sctt.scot.nhs.uk/stroke.html)

- Scottish Stroke Care Audit -

- STARS Stroke training web site
http://www.strokecorecompetencies.org/node.asp?id=home

- Chest Heart and Stroke, voluntary sector website
  http://www.chss.org.uk/stroke/