Abstract
This report describes the results of the project across the seven MAST domains, 47 months after the Renewing Health’s project initiation in February 2010. In December 2013 the Project ended and thus the data collection in this report is analysed from this point.

Key Word List
Telemedicine, MAST, telemonitoring, eHealth, infrastructure, health care services, provision of health care, assessment of services, chronic disease management, personal health services, patient perspective, deployment of services, clinical outcome, COPD, CHF, Diabetes.

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Executive Summary

The Renewing Health approach to revolutionise the management of chronic diseases is to transfer parts of the care process from an acute care environment to a home care one in order to improve quality of life and use healthcare resources more efficiently, while maintaining or increasing quality care. This approach can be seen as a contribution to the vision of a healthcare paradigm shift.

To validate this approach, the nine regions of Renewing Health have designed and implemented different types of telemedicine services depending from the health conditions, the need to be answered by the new service and of course the environment in which the service is being implemented. The services are aimed at managing one or more of three chronic diseases: Diabetes Mellitus type 2, COPD and Congestive Heart Failure.

During the course of the Project, the nine regions in Europe have validated the services in 21 different pilots, and thus a total of about 7000 patients have participated in this study making it one of the largest studies in Europe. The evaluation has been conducted by the use of MAST, evaluating the service through seven domains.

- Domain 1: Description of the health problem and characteristics of the application.
- Domain 2 and 3: Clinical outcomes and safety.
- Domain 4: Patient perspectives.
- Domain 5: Economic aspects.
- Domain 6: Organisational aspects.
- Domain 7: Socio-cultural, ethical and legal aspects.

The 21 pilots were divided into 10 clusters, according to disease and type of intervention. Twenty of the pilots were carried out as pragmatic randomised controlled trials, with the final one an observational trial.

The results of the project are summarised in section 7, but overall all the trials showed that the interventions used were at least as good as usual care from the clinical point of view, and were generally well received by participants, though the services were not regarded as a replacement for usual care. Assessment of the economic impact showed mixed results. The domain which may require further investigation is the organisational domain. Because of the nature of the trials, no site was able to fully explore in practice the impact that the services could have on the care delivery model.

During the course of 2014 and 2015, scientific articles, abstracts and posters will present the scientific results of Renewing Health. This will be communicated on the Renewing Health web site.

A special thank you to the patients and health professionals that have participated in this study. Without their willingness to contribute, this study would never have happened.

This report is written by a team of experts, that have come together to conclude on the results of the Renewing Health project. Without their dedicated support in this project past working hours, this report would not have been possible. Thank you! All experts are mentioned in the author list.
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1. **Introduction**

1.1 **Purpose of this document**

This document is the public final report of the Renewing Health project. Results of the project are reported following the domains of MAST.

1.2 **Structure of the document**

Section 2 contains a description of the Renewing Health Consortium and contact details.

Section 3 contains information about the project objectives and gives an overview of the purpose of Renewing Health.

Section 4 contains information about the organisation of the project including a description of the healthcare systems and the assessment methodology MAST.

Section 5 contains information about the design of the studies including a description of the 11 clusters, the use of randomised controlled trials and the MAST methodology and its 7 domains.

Section 6 contains information about the patients and the telemedicine interventions including a description of the patient groups in the project and also a description of the current treatment and the telemedicine interventions in the clusters.

Section 7 contains the results from the 7 MAST domains.

Section 8 contains information about transferability

Section 9 contains the conclusion of the project including the 7 MAST domains, the methodological challenges and the deployment of Renewing Health services.

Section 10 contains information about the dissemination activities conducted in Renewing Health.

Section 11 contains the recommendations from the project including lessons learned and a section on implementing guidelines and recommendations.
### 1.3 Glossary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>CIED</td>
<td>Cardiac Implantable Electronic Device</td>
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<tr>
<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<tr>
<td>CVD</td>
<td>Cardio Vascular Disease</td>
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<tr>
<td>EHR</td>
<td>Electronic Healthcare Record</td>
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<tr>
<td>EHRS2</td>
<td>European Heart Rhythm Society</td>
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<tr>
<td>HRS</td>
<td>Heart Rhythm Society</td>
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<tr>
<td>ICD</td>
<td>Implantable Cardiac Defibrillator</td>
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<tr>
<td>MAST</td>
<td>Model for Assessment of Telemedicine</td>
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<tr>
<td>PHR</td>
<td>Patient Health Record</td>
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<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
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<tr>
<td>SUTAQ</td>
<td>Service User Technology Acceptability Questionnaire</td>
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<tr>
<td>WSD</td>
<td>Whole System Demonstrator (UK project)</td>
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</table>
The Renewing Health Consortium covers the entire value chain underpinning the Renewing Health business model, which comprises five different types of players:

- Regional Health Authorities. They have the responsibility for the delivery of healthcare to their resident population, and represent the natural owners of the services that Renewing Health intends to deploy.

- Regional Healthcare Providers. They are the organisations which run the healthcare delivery network, and which are going to play the key role in deploying the Renewing Health services and in adapting their structure to this novel way of providing care to chronic patients. In most public health systems, the Regional Health Authorities are also Regional Healthcare Providers in the sense that they own the delivery network.

- Competence Centres in Telemedicine. They provide to the Regional Health Authorities all the know-how that they have accumulated over the years in implementing networks for health and telemedicine at the regional, national and transnational level.

- Patients and professionals. They are extremely important stakeholders in any telemedicine project, because the success or failure of the project heavily depends on its acceptance by patients and healthcare professionals. These players were represented at two different levels: in the User Advisory Board, through their European associations, and at operational level in each of the participating regions through their local outlets (as subcontractors).

- Industrial companies. They had to supply the technological gear which was vital for the initial implementation and, even more, for the further deployment of sustainable telemedicine services in the context of which their marketing and sales activity is absolutely indispensable. As with patients and healthcare professionals, these players were represented at two different levels: in the Industry Advisory Board through their European and international associations, and at operational level in each of the participating regions through their local outlets selected and contracted according to public procurement rules.
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3. Project objectives

The objective of Renewing Health was to implement telemedicine services in nine European regions for the validation and subsequent evaluation of these services using a patient-centred approach and a common assessment methodology (MAST). The services should be targeting the telemedicine and treatment of chronic patients suffering from diabetes, Chronic Obstructive Pulmonary Disease (COPD) or Cardio Vascular Diseases (CVD).

The services provided in Renewing Health are designed to give patients a central role in the management of their diseases, fine-tuning the choice and dosage of medications, promoting compliance to treatment, and helping healthcare professionals to detect early signs of worsening. It is also the intention with the services to provide healthcare professionals with new tools and possibilities for collaboration and communication. During the project period, the services have been scaled up and integrated with mainstream healthcare systems. The services have been grouped into a limited number of clusters, bringing together services showing similar features, trialled and assessed with the use of MAST, and using a common set of primary indicators for pilots belonging to the same cluster.

The methodology used for the assessment was MAST. This ensured that the outcomes with regard to safety, clinical impact, patient perception, economic aspects and organisational aspects were assessed in accordance with scientific guidelines. In this project, this was done by data collection in pragmatic randomised controlled trials.

Each European region has operated as a multi-centre clinical trial, measuring the efficiency and cost effectiveness of the implemented solutions, giving scientific validity to the results of the trials, and so promoting the adoption of remote patient monitoring and treatment on a large scale.

Renewing Health is a good illustration of how working together across Europe can be beneficial for European citizens in their daily life, their comfort and their health. Based on the randomised controlled trials, Renewing Health has been able to identify which of the tested telemedicine applications are able to have a positive impact with regard to safety, clinical impact, patient perception, economic aspects and organisational aspects.

With about 7000 patients, it is considered that a sufficient critical mass has been included, with statistical evidence to demonstrate what the effects on healthcare services and coaching at a distances are.

With all the scientific papers stemming from the Renewing Health project due to be released in 2014 and onward, it is expected that decision makers and health professionals will find the necessary evidence and guidance they are looking for to revolutionise their healthcare system by introducing new ways of delivering health and social care.

About 7000 patients are included in Renewing Health making it the largest Randomised Controlled Trial study into telemedicine in Europe in 2014.
4. The organisation of the project

4.1 Pilot sites vs. European Regions

The Renewing Health Consortium comprises nine regional authorities or regional healthcare providers, eight of which have direct responsibility for the healthcare budget of their resident population.

Healthcare in Europe is provided through a wide range of different systems run at the national level. The systems are primarily publicly funded through taxation (universal healthcare). Private funding for healthcare may represent personal contributions towards meeting the non-taxpayer (re)funded portion of healthcare, or may reflect totally private (non-subsidised) healthcare either paid out of pocket or met by some form of personal or employer funded insurance.

The European regions present in Renewing Health cover all the described healthcare systems that are present in a European setting, as both the Beveridge and the Bismarician model are present in the project (Lameire et al 1999).

- Beveridge model: Named after William Beveridge, who designed Britain’s National Health Service, in this system healthcare is provided and financed by the government through taxation.
- Bismarck Model: Named after the Prussian Chancellor Otto von Bismarck, who invented the welfare state as part of the unification of Germany in the 19th century, healthcare is funded by a premium-financed social insurance system, with a mixture of public and private providers.

The regions also cover the very different geographic situations in Europe, for some of the most highly populated urban cities around Barcelona and in Veneto to the mostly rural areas in North Norway and Sweden.

The differences in the sites make it possible for other regions to identify solutions that fit their individual situation and needs.

4.2 Assessment methodology

As described in Kidholm et al. (2012), a number of methodologies and frameworks for assessment of telemedicine applications can be found in the literature. The EUnetHTA core model is a general framework intended to facilitate international collaboration and sharing of results in HTAs, see Lampe et al. (2009). The model includes nine domains and describes several topics and issues within each domain. Ohinmaa et al. (2001) describes an approach for assessment of telemedicine, which includes a business case and subsequent evaluation of technical aspects, effectiveness, user assessment, economic evaluation and sensitivity analysis. Similarly, Scott et al. (2007) describes the development of an assessment framework for telemedicine including 34 approved outcome indicators divided into four categories: quality, access, acceptability and costs.

Based on these reviews and an assessment of stakeholders’ need for information in decision making, a Model for Assessment of Telemedicine applications (called
MAST) was developed in the EC project MethoTelemed (see www.telemed.no/methotelemed).

MAST can be used if the objective of an assessment of telemedicine applications is to describe effectiveness and contribution to quality of care, and to produce a basis for decision making, see Kidholm et al. (2012).

MAST explicitly points out that before an assessment of outcomes is initiated, a number of preceding considerations should be evaluated, see Figure 1 below. These considerations mainly include an assessment of whether the technology and the organisation is mature and developed to a sufficient degree, e.g. whether pilot studies have been done beforehand to eliminate technical problems and optimise the use of healthcare professionals.

If the preceding considerations indicate that a technology is mature, a multidisciplinary assessment of outcomes can be done to summarise information about the medical, social, economic, and ethical issues related to the use of telemedicine in a systematic, unbiased, and robust manner.

In practice, MAST includes an assessment of the outcomes of telemedicine applications divided into seven domains, as described in the figure below.

Finally, a transferability assessment of the results needs to be carried out, in which the degree of transferability of the results is considered. This may include assessment of whether the results can be transferred to other countries (cross border), can be scaled-up from small to large scale, and generalised to other patient groups.

![Figure 1: The elements in MAST](Image)

To assist the pilot teams in their use of MAST, a detailed protocol was developed in which assessment of outcomes within each domain was described.
Similarly, a detailed “Guide for analysis and reporting of results within each domain”\(^1\) was produced to help the pilot teams in their analysis of the data collected. The guide describes in detail the types of analysis, tables and figures that need to be produced within each of the MAST domains. The guideline is based on international standards for reporting of the different types of studies, e.g. the CONSORT statement on pragmatic trials by Zwarenstein et al. (2008), a guideline in conduct and reporting of survey research in general by Kelly et al. (2003), and a guideline by Drummond et al. (2005) on reporting of health economic evaluations.

In February 2012, a one day seminar was arranged in Veneto in which all pilot teams were introduced to the guideline, and the content was presented by experts in the different domains.

Based on comments from the pilot teams and reviewers, the guideline was developed further by increasing the focus on description of co-morbidity, assessment of safety, factor analysis of patient acceptability questionnaire, qualitative studies of patient perception, how to estimate the subscales on patient acceptability, and information on “Intention To Treat” analysis and analysis of dropouts.

A scientific meeting was arranged in Copenhagen in September 2013 with the aim to ensure the scientific quality of the analysis of results from the project, as the project ended in December 2013. At the meeting, representatives from the different countries presented their data analysis within the MAST domains, and received comments from the members of the Internal Scientific Board.

To ensure the quality of the data, all pilots have been asked to produce a database including all data at patient level. A number of pilots have thus been using an Epidata database produced by the management team in the Region of South Denmark. Others have produced local databases. But all have been asked to follow some general rules on coding of data, including rules on coding of demographic data, SF-36, the patient acceptability questionnaire, and economic data.

In addition to these initiatives to ensure the quality of the data collection, monitoring of patient recruitment rates was carried out by contacting each of the pilots every second month. In the fall of 2011, this was done by video conferences with the possibility to discuss problems. In 2012 and 2013, this has been done by email contacts. Information was collected from each pilot regarding number of patients recruited, patients lost to follow-up, patients completing the data collection, and education of the staff in coding and handling of data.

In order to obtain the most value from the data from the pilots, a guideline was produced describing how the cluster managers should carry out the reporting of the results at cluster level (see also section 5.2)\(^1\). The guideline was based on the minimum dataset that is common to all pilots. The main content of the guideline is the description of how to use meta-analysis in order to estimate the overall effect on the primary outcome in all pilots at cluster level.

\(^1\) [http://www.renewinghealth.eu/assessment-method](http://www.renewinghealth.eu/assessment-method)
5. Design of the studies

5.1 Scientific background

The existing evidence for the use of telemedicine services for patients with diabetes, COPD and CVD is described in detail in the protocol. For all diagnoses, evidence on clinical benefits in terms of health related quality of life is almost missing, and little evaluation of patient perception of the services and acceptance by healthcare professionals has been carried out. Thorough economic analysis is also not available, while organisational aspects of the interventions, e.g. changes in healthcare workflow, are generally not addressed by previous studies.

In summary, there is a need for a more robust and comprehensive assessment of the benefits of home telemedicine programmes in the chronic diseases which are targeted by the Renewing Health project.

5.2 Combination of trials into clusters

As described earlier, the aim of Renewing Health is to assess telemedicine services belonging to nine different European countries. These service solutions were selected and had to be operational before the beginning of the project at local level. They covered the remote monitoring and the treatment of chronic patients suffering from diabetes, COPD or cardiovascular diseases. This criterion was setup to ensure that the technologies that were included in the trials would be sufficiently mature that the use of the MAST model would be relevant.

In the project, these services were then scaled up, integrated with mainstream health systems, and grouped into a limited number of clusters bringing together services showing similar features for similar patient groups.

Clusters were introduced to Renewing Health during the negotiation phase with the EU Commission in order to group trial sites with similar clinical approaches, and to allow for a better focus and more representative sample sizes during trial conduct and evaluation. Clusters were originally arranged according to the three main areas of clinical interest (diabetes mellitus, cardiovascular diseases, COPD) covered by the project.

They were then further divided into short-term follow up and life-monitoring interventions. Also considered was whether the interventions consisted of pure monitoring of physiological parameters, or a combination of monitoring and health coaching. The organisation of clusters was revised during the first clinical meeting with the Commission when two partners requested to be associated with a different cluster (Carinthia moved from cluster 2 to cluster 1 due to the health coaching aspect of its intervention, and Thessaly moved from cluster 5 to cluster 4 due to its short-term approach). The two cardiovascular clusters were split into four different clusters which better reflected the diversity of the respective clinical targets and interventions. Since then, the cluster structure has been followed and continued without modifications during the whole process of protocol development.
Clusters have been coordinated in their activities by their cluster leaders and through a series of meetings and teleconferences. The final cluster organisation is represented in the following table.

Table 1: Counties included in each cluster

<table>
<thead>
<tr>
<th>Type of service</th>
<th>Pathology</th>
<th>Veneto</th>
<th>Syddannmark</th>
<th>Northbotten</th>
<th>Northern</th>
<th>Norway</th>
<th>Catalonia</th>
<th>South Karelia</th>
<th>Thessaly</th>
<th>Carinthia</th>
<th>Berlin</th>
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</thead>
<tbody>
<tr>
<td>Cluster 1: Medium-term health coaching and life-long monitoring</td>
<td>DIABETES</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>Cluster 3: Ulcer monitoring</td>
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<td>Cluster 4: Short term follow-up after hospital discharge</td>
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<td>Cluster 5: Life-long monitoring</td>
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<td>Cluster 7: Remote monitoring of Congestive Heart Failure</td>
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<td>Cluster 8: Remote monitoring of implantable cardiac devices (ICD &amp; PM)</td>
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<td>Cluster 10: Life-long monitoring of frail patients with chronic diseases</td>
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<td>Cluster 11: CHF with high blood pressure</td>
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To enforce homogeneity and comparability of results at the single cluster level, all clusters agreed on identical objectives, eligibility criteria and primary outcomes.

In order to facilitate the use of the most relevant aspects of MAST, and to ensure the required common assessment methodology, a common minimum dataset has been developed which was adopted by all clusters as a basic common scheme with regard to the collection and evaluation of:

- Demographic and clinical baseline data.
- Health related quality of life.
- Economic evaluation.
- Organisational changes.
- Patient perception.

In most clusters, these elements have been adopted in a similar way, with minor local modifications, such as the addition of locally relevant topics in questionnaires,
or the use of additional instruments in the economic evaluation. The common evaluation methodology is presented in detail in the protocol and described briefly below.

5.3 Randomised controlled trial design

According to the project’s Technical Annex, Renewing Health had the objective to produce comprehensive results with a high level of scientific evidence, wherever possible by following a randomised controlled trial design. It is generally recognised that RCTs represent the ‘gold standard’ for obtaining high level evidence, even if recently alternative quasi-experimental study designs have been proposed (Chumbler et al. 2008). There is, however, little experience with alternative methods; adopting these would have put at risk the credibility of the project, and later acknowledgement of trial results by the medical community and health decision makers.

The Consortium therefore agreed to adhere to the required standards, choosing for most clusters an RCT approach for trial conduct. Only clusters eight and ten preferred an observational approach, in part for organisational reasons given the large numbers of involved subjects, and in part because an observational approach was considered to be equally valid for the assessment of outcomes (see cluster protocols for details).

RCT reporting today generally follows CONSORT guidelines. These have been developed by a collaboration between scientists and medical journal editors, and published in their latest and revised edition in 2010 (Schulz et al. 2010). CONSORT provides a series of methodological items that should be reported when publishing results, and that therefore need to be considered during the development of the trial protocols.

In recent years, more attention has been paid to the concept of “pragmatic” trials, originally coined in 1967 (Schwartz et al. 1967) to study complex interventions in a real life situation, as opposed to the classical highly selective “explanatory” RCT which has its main application in the development of new drug treatments. CONSORT has also considered the growing use of pragmatic trials, publishing a dedicated extension with guidelines for reporting pragmatic RCTs (Zwarenstein et al. 2008).

Pragmatic RCTs are characterised by broad inclusion criteria with little selection beyond the point of clinical interest (e.g. diabetes or COPD) with the evaluation of complex interventions (e.g. telemonitoring and health coaching) introduced into normal practice. Outcomes of pragmatic trials are often patient-reported (e.g. by standardised questionnaires) and based on indirect measures such as health related quality of life and cost analysis which are considered to be more relevant to participants and stakeholders than the often more technical measures (e.g. change in blood pressure, time to remission) of an explanatory trial. There is a continuum between explanatory and pragmatic trials; the trials in Renewing Health can be considered to be close to the pragmatic end of this scale, a circumstance that is reflected throughout all protocols. The CONSORT recommendations and checklist for pragmatic trials have been followed during the layout of the cluster protocols.
5.4 Assessment methodology

MAST is used as the overall assessment model or framework to structure the collection and analysis of data, see Kidholm et al. (2012). MAST includes assessment of the outcomes of telemedicine applications divided into seven domains:

1) Health problem and characteristics of the application.
2) Safety.
3) Clinical effectiveness.
4) Patient perspectives.
5) Economic aspects.
6) Organisational aspects.
7) Socio-cultural, ethical and legal aspects.

The data collection within each cluster is described in detail in the protocol, but a summary is presented below.

5.4.1 Domain 2 and 3: Clinical outcomes and safety

The primary outcome, that was the point of departure to estimate the sample size in each trial, was:

- Cluster 1: Health related quality of life, measured by SF-36 v2 and HbA1c.
- Cluster 2: Health related quality of life, measured by SF-36 v2.
- Cluster 3: Number of acute contacts to hospital.
- Cluster 4: Number of hospital readmissions.
- Cluster 5: Health related quality of life, measured by SF-36 v2.
- Cluster 6: Health related quality of life, measured by SF-36 v2.
- Cluster 7: Combined end point of all cause mortality and number of hospitalisations for heart failure.
- Cluster 8 (Observational study): Number of rehospitalisations.
- Cluster 10: Health related quality of life, measured by SF SF-36 v2.
- Cluster 11: Health related quality of life, measured by SF SF-36 v2.

5.4.2 Domain 4: Patient perspectives

Patient perception of the use of the telemedicine services was assessed by a questionnaire developed within the UK National Health Service Whole System Demonstrator (WSD) project. A collaboration agreement has been signed between all pilots and the WSD team. The questionnaire includes 22 questions. Questions can be answered on a six point Likert scale going from "strongly agree" to "strongly disagree".

Questionnaires were translated to local languages and validated by an expert reviewed back-translation process. For details of the translation process into all languages, see deliverable D3.5 Questionnaire for data collection.

In addition to this, Norway and Norrbotten have conducted qualitative interviews of patients about their experiences with the intervention. Patients in both regions have been interviewed with a semi-structured interview guide. Scientific papers will present the results in detail.
5.4.3 Domain 5: Economic aspects

In accordance with Drummond et al. (2005), each pilot has been collecting data regarding:

- Investments in the telemedicine application:
  - Running costs of delivering the telemedicine service and the comparator.
  - Time used by the staff (number of minutes, estimated).
  - Time used by the patient (number of minutes, estimated).
  - Use of utensils and devices.

- Each patient's use of healthcare service:
  - Number of hospital admissions (including readmissions).
  - Number of bed days (days of hospitalisation).
  - Number of GP visits.
  - Number of visits to emergency department.

- Reimbursement of the telemedicine service.

These data were collected at patient level for each patient. The data was used to estimate the mean costs per patient in the intervention and control group, and the total business case for the relevant institutions implementing the telemedicine services.

5.4.4 Domain 6: Organisational aspects

Information about the following indicators was collected to evaluate the organisational changes related to the implementation of the telemedicine services:

- Effects on work processes:
  - Workflow: Effects on number of patients treated and procedures performed.
  - Staff: Changes in distribution of work (task shifting).
  - Resources: Changes in working hours for each profession.
  - Training: Time spent on training to learn to use the application.
  - Internal communication: Changes in the way the staff communicate within the organisational unit.
  - External communication: Changes in the communication with staff in external units.

- Effects on structural outcomes:
  - Description and number of units collaborating in the production of the service.
  - Changes in organisation of generalist and specialist tasks.
  - Changes in geographical spread.
  - Changes in time spent on travel.

- Effects on cultural outcomes:
  - Staff attitudes towards the application.
  - Staff experiences with the use of the application.

5.4.5 Domain 7: Socio-cultural, ethical and legal aspects

Finally each trial and cluster was asked to describe the potential socio-cultural, ethical and legal aspects of the implementation of the telemedicine services.
The socio-cultural aspects include the social-cultural arenas where the patient lives and acts during the use of the application.

The ethical analysis appraises the ethical questions raised by the application itself and the consequences of implementing it or not.

Legal aspects focus on the legal obligations which must be met, and any specific legal barriers that may exist to the implementation of the application.
6. The patients and the telemedicine interventions

In this section, the patient groups included in the trials and clusters and the telemedicine interventions are described. Thus, this section presents the contents of domain 1 in the MAST model.

6.1 The patients

The studies included patients with chronic disease suffering from diabetes, COPD or cardiovascular diseases.

In Europe, about 55 million people aged 20–79 had diabetes in 2010; this number is expected to rise to 66 million by 2030 unless effective preventive strategies are implemented. Lack of physical activity and unhealthy diets are well known factors for patients suffering from diabetes. The following complications are very common: neuropathy, retinopathy and foot ulcers.

COPD is caused primarily by tobacco smoking, which triggers an abnormal inflammatory response in the lung. Other factors, such as exposure to indoor and outdoor air pollution, infections or an Alpha-1 antitrypsin deficiency are also important. Ageing is also a risk factor for COPD, with lung function starting to decline from its peak in young adulthood to lower levels in later life. The rate at which it gets worse varies among individuals. An exacerbation of COPD is a sudden worsening of COPD symptoms that typically lasts for several days. Infections cause 75% or more of the exacerbation. Often exacerbations need hospital treatment, and are related to a higher mortality.

Cardiovascular diseases (CVDs) are the largest cause of deaths worldwide. It is reported that more than 17 million people died from CVDs in 2008. Of these deaths, more than 3 million occurred before the age of 60, and could largely have been prevented. Out of the 17.3 million cardiovascular deaths in 2008, heart attacks were responsible for 7.3 million, and strokes were responsible for 6.2 million deaths. Tobacco smoking, physical inactivity, unhealthy diets and the harmful use of alcohol are the main behavioural risk factors for CVDs. Long-term exposure to behavioural risk factors results in raised blood pressure (hypertension), raised blood sugar (diabetes), raised and abnormal blood lipids (dyslipidemia) and obesity. Major cardiovascular risk factors such as hypertension and diabetes link CVD to renal disease.

The patients in Renewing Health were divided into these three chronic conditions; they were then further divided into use of short-term follow up and life-monitoring interventions. Also considered was whether the interventions consisted of pure monitoring of physiological parameters, or a combination of monitoring and health coaching.

The patients in the 10 clusters are described below:

6.1.1 Patients with diabetes

- Cluster 1: The patients were diagnosed with type 2 diabetes. They were living in their own home, and participating in a lifestyle-intervention using modern self-management tools. Patients were invited to participate by the inclusion
criteria (age >18; diagnosed type 2 diabetes >3 months prior to study inclusion; HbA1c >7% or ≥6.5; capability of understanding and filling in questionnaires; able to use the system provided; cognitive able to participate) and the ability to walk independently. Patients did not have severe prevalent comorbidity, and their life expectancy was more than 12 months. None of the patients were pregnant.

- Cluster 2: The patients were diagnosed with type 2 diabetes requiring life-long monitoring. Patients were invited to participate by the inclusion criteria of HbA1c >7.0; capability to complete questionnaires in native language; able to use the system provided; cognitively able to participate. The patients did not have severe prevalent comorbidity, and their life expectancy was more than 12 months. None of the patients were pregnant.

- Cluster 3: The patients were diagnosed with diabetes and had a diabetic foot ulcer for which they were treated at the hospital. The ulcer was examined by telemonitoring. In general, approximately 15% of patients with diabetes get at least one foot ulcer due to diabetes. About 70% of these will recur during the course of the disease.

6.1.2 Patients with COPD

- Cluster 4: Patients were eligible for the study if they had an exacerbation of COPD verified by spirometry, were above the age of 40 years, and had the capability to use the devices with the willingness to participate, provided that they had not been included in a previous COPD monitoring study.

- Cluster 5: Patients were diagnosed with COPD in accordance with GOLD Class III-IV. They were above the age of 18 years, and had a life expectancy of more than 12 months. They were also considered able to use the equipment provided (alone or assisted).

6.1.3 Patients with CVD

- Cluster 6: The patients were diagnosed with ischemic heart disease and aged above 18 years. Also blood pressures should be within general recommendations. Patients were also considered capable to fill in questionnaires in their own language, to use the devices provided, and cognitively able to participate.

- Cluster 7: The patients were diagnosed with Congestive Heart Failure and aged 65 years or older. Patients were discharged from hospital after acute heart failure in the previous three months and EF <40% or EF >40% plus BNP >400 (or plus NT-proBNP >1500) during hospitalisation. Patients were also considered to have life expectancy of more than 12 months.

- Cluster 8: Patients had implantable devices (PM and ICD) and were aged above 18 years. Patients were expected to have a life expectancy of more than 12 months.

- Cluster 10: The patients were elderly, above 65 years, with limited daily living activities (Nottingham Extended Activities of Daily Living Scale less or equal to 18) and with two or more chronic diseases with at least one of the following: Congestive Heart Failure, diabetes type 1 or 2, or COPD. Besides these specific clinical problems, the patients enrolled in the cluster suffered from a reduced functional ability in daily routines which is quite frequent in elderly people having home assisted care.
• Cluster 11: Comprised of patients diagnosed with ischemic heart disease combined with high blood pressure. Patients were older than 18 years; they were also considered capable to fill in questionnaires in their own language, to use the devices provided, and cognitively able to participate.

6.2 The telemedicine interventions and the treatment of patients in the control groups

6.2.1 Interventions for patients with diabetes

6.2.1.1 Cluster 1: Diabetes - Medium-term health coaching and life-long monitoring

**Intervention:** One primary aim in Cluster 1 was to improve patients' self-management. Participants were living in their homes, treated by their GPs and diabetes nurses in primary healthcare (Norrbotten, Norway, S-Carelia). With the use of the different technical devices provided in the cluster, patients had the opportunity to take control of their own health and health development, and to self-monitor their health in real time. In addition, the aim was to integrate the telemedicine applications into the local healthcare systems. Patients have been offered an individually tailored service to stimulate participation and self-determination based on their own precondition. In all these trials, patients received health coaching / health counselling to support and empower them to self-management and to reach recommended lifestyle changes. The trials differed somewhat according to the devices and the techniques, such as, for example, in the interaction between the patient and the provider, in the feedback from the provider to the patient, and in the health counselling programmes. The countries' applications are shown in more detail below.
Cluster 1: Mobile self-help tool for T2 diabetes
Northern Norway (NO) ©

Cluster 1, 6: Diabetes & CVD
South Karelia - (FI) ©
Current management: Medical check-ups are offered by diabetic outpatient services in hospitals at intervals between 6-12 months; they are used only by a fraction of patients however. Check-ups include a medical visit with measurement of blood pressure and weight, collection of smoking and alcohol consumption, screening for new manifestations of complications such as myocardial infarction, stroke, vision loss, ulcers and neuropathy. In addition, laboratory tests of glucose, HbA1c, kidney function and blood lipids are performed. The current guidelines offer recommendations for the diagnosis, screening, prevention and treatment of diabetes and its complications.

6.2.1.2 Cluster 2: Diabetes - Life-long monitoring

Intervention: The trial was based on a set of measuring devices (a scale to measure weight, a sphygmomanometer to measure blood pressure and pulse, a device to measure blood sugar) connected to a client software application implemented on mobile telephones via Bluetooth, and on a web-based database where the collected data is stored. Measurements were performed with a variable frequency indicated by the GP, and more frequent telephone contact was established. A different device applied to the wrist of the patient was a wireless and all-in-one monitoring system which measures blood sugar level. The data were automatically transmitted to the gateway and then to the eHealth centre. The alarms with different values can be found in the Home Care portal giving healthcare personnel the possibility to react and take action at any time.
Current management: Type 2 diabetes is treated first with weight reduction, a diabetic diet, and exercise. When these measures fail to control the elevated blood sugars, oral medications are used. If oral medications are still insufficient, treatment with insulin is considered. There are different forms of insulin (rapid-acting, short-acting, intermediate-acting, long-acting and pre-mixed) and application (with different kinds of pens and injectors, or with an implanted insulin pump).

6.2.1.3 Cluster 3: Diabetes - Ulcer monitoring

Intervention: The visiting nurse attended to the ulcer treatment following practice guidelines, took pictures of the ulcer, and uploaded the picture to the database “Pleje.net”. The pictures could be uploaded when desired. The specialist estimated the state of the ulcer, and decided whether there was a need for further diagnosis. A follow up at the outpatient clinic was arranged if necessary, or physical evaluation. Through the transfer of images, the assigned medical specialist could assess the images, and thereby the ulcers, without consulting the patient face-to-face, e.g. at the hospital.
Cluster 3: Diabetes
Southern Denmark (DK) ©

Current management: The patients in the control group visit the out-patient clinic for all consultations. A nurse removes the bandage, cleans the ulcer, removes skin if necessary, and provides a new bandage. A specialist attends to the ulcer, and estimates whether more diagnosis is necessary. The specialist prescribes ulcer treatment with products relevant for the treatment, and the attending nurse is notified about the planned treatment.

6.2.2 Interventions for patients with COPD

6.2.2.1 Cluster 4: COPD - Short term follow-up after hospital discharge

Intervention:

In two regions, the intervention included home-based telemonitoring using videoconsultation and wireless pulse oximetry. In one of the trials, the patients were stratified according to their clinical complexity and the intervention intensity was customised accordingly. One Renewing Health trial had a specially designed transportable patient briefcase which made live video-consultations possible, together with real-time data transmission which was performed on a daily basis for a week (in some cases +2 days).

In the third region, patients in the trial group received software installed on mobile phones which allowed monitoring of measurements which were transmitted to the electronic health record (EHR) used for managing the information about the patients. Health personnel had access to the Health Telematics Database, connected with telemetry software to EHR. The data were transmitted daily to the telehealth centre, and reviewed by the specialists there; support was provided if necessary. A follow up call by the project nurse was scheduled one week after discharge.
Cluster 4: COPD
Southern Denmark (DK) ©

Cluster 4: COPD
Catalonia (ES) ©
Current management: Transitional care immediately after hospital discharge where the COPD patient shows increased frailty, in order to reduce the rate of early re-admissions and avoid diagnosis during a severe disease exacerbation. Treatment is often given for crisis or severe episodes without considering co-morbidities, lacking early preventive strategies, and better knowledge of disease.

6.2.2.2 Cluster 5: COPD - Life-long monitoring

Intervention: The patients were given a sphygmomanometer to measure blood pressure and pulse, a spyrrometer to measure Peak Expiratory Flow and other breathing data, a pulse-oxymeter to measure blood oxygen saturation and pulse; these were connected via Bluetooth to a mobile device, a smart phone that collected and sent the data to a centralised web-based database. Statistics were stored in an electronic Patient Health Record. The smart phone included a reminder function combined with an alarm in order to guarantee that appropriate measurements were taken, and telephone contact was more frequent. A different device applied to the wrist of the patient was a wireless and all-in-one monitoring system, which measured heart rate and SpO₂. The data were automatically transmitted to the gateway, using radio-frequency with a proprietary protocol. Alarms with different values could be found in the Home Care portal for the healthcare personnel to react and take action at any time, and also monitored the patients’ condition at any time. Patients in the intervention groups undergo daily monitoring of their health status and screening for eventual clinical deterioration by using the COPD assessment test. Data transmissions occurs through an automated call centre service, or alternatively via a web based service; data can also be collected through the PDA's of the home nursing organisation.
Cluster 5: COPD
Veneto Region (IT) ©

Clusters 1, 5: Diabetes, COPD - Carinthia (AT) ©
Clusters 5: COPD
Berlin (DE) ©

**Current management:** Smoking cessation and evaluation thereof combined with drug therapy for COPD to reduce symptoms, and the frequency and severity of exacerbations, in order to improve health status and exercise tolerance. The long-term administration of oxygen (>15 hours per day) to patients with chronic respiratory failure and NIV is increasingly used for patients with stable, very severe COPD. GP is responsible for chronic disease telemonitoring and arranging outpatient visits every three months, and if necessary contacts the pulmonologist immediately in case of exacerbations.

**6.2.3 Interventions for patients with CVD**

**6.2.3.1 Cluster 6: CVD - Medium-term health coaching and life-long monitoring**

**Intervention:** A number of measuring devices (blood pressure meter, weight scale, 2-channel ECG, and pedometer), together with mobile phone or iPad or own PC supplied with a web PHR application that allowed storage and management of personal health data, which provided options to view the data by both patients and care personnel. The patients were supported in the measuring by care personnel; reminders / alarms could also be created. The data was transmitted via secure services, as well as video messages, physical exercise registration, treatment instructions and medication support.
**Current management:** For patients diagnosed with uncomplicated angina pectoris, hypertonia, hyperlipidemia and/or benign arrhythmia, it is of great importance to engage the patients in smoke cessation and attention to blood cholesterol levels, keep systolic blood pressure below 149 mmHg and diastolic pressure below 85 mmHg, often regulated with a combination of drugs. Alarming levels are prevented with laboratory tests and preventive measures against the progression of the disease.

### 6.2.3.2 Cluster 7: CVD - Remote monitoring of Congestive Heart Failure

**Interventions:** Wrist Clinic is a wireless and “all-in-one” monitoring system; it measures heart rate, blood pressure, pulse-oxymeter and 1-lead ECG. This device is applied to the wrist, like a wristwatch. The Wrist Clinic signalled correct working of devices both acoustically and visually. When measurements were taken, data were automatically transmitted to the gateway; transmission was wireless, using radio frequency with a proprietary protocol. Web Portal assured integrated management of all services.
Current management: Patients in the control group receive usual care delivered by primary care physicians and cardiologists. Patients are approached as outpatient visits or emergency departments of the hospital whenever they become symptomatic. Usual care consists of regular visits to the specialist or primary care clinics every time a medication change is required, or a medical examination is needed.
6.2.3.3 Cluster 8: CVD - Remote monitoring of implantable cardiac devices

**Intervention:** By telemonitoring, the implanted devices (ICDs) were programmed to relay data periodically (according to the device typology and the patient), and daily in case of alarm events, to a home gateway. The gateway automatically transmitted data to a web server, where data were processed in order to recognise potential alarm values, according to the threshold set by the clinician for the patient. The in-clinic professional in charge of data management (a nurse or a health technician) periodically checked and examined the patient's data, accessing them through web-portal. In case of an alarm situation, the nurse or technician received an alert notification via email, fax or text, and could then alert the physician about the critical situation. The physician evaluated the data, and decided if the patient needed a specialist visit, in-clinic device follow-up, a therapy modification, or other actions. When needed or appropriate, the nurse or technician could inform the patient about the decision taken by the physician.

![Diagram of Cluster 8: CVD](image)

**Current management:** The last guidelines on the frequency of CIED follow-up, including the possibility of remote follow-up, submitted by HRS and EHRS2, are:
- 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 either in person or remote.

6.2.3.4 Cluster 10: CVD - Life-long monitoring of frail patients with chronic diseases

**Intervention:** The use of telemonitoring by the Wrist Clinic allowed monitoring of chronic patients directly in their homes. The parameters measured depended on the pathology that the patients suffered. The patients were also provided with a digital scale, and a Onetouch®Vita™ glucometer, which sent the data collected to the Medic Gateway. All measurements were transmitted to the gateway wirelessly. The solution carried out provide two services: tele-care (the devices provided could trigger an alarm) and tele-health (to measure the clinical parameters) which
monitored the patients not only for purely clinical aspects linked to the pathology in question, but also offered the possibility for timely and appropriate care from healthcare institutions, social care and caregivers. The permanent monitoring of relevant vital parameters and the necessary check of conditions avoided slowdown or worsening of their disease e.g. the insurgence of complications.

**Cluster 10: Multi-pathology**
Veneto Region (IT) ©

**Current management:** This is generally based on the recommendations of national and international guidelines in order to monitor and support older people with comorbidities and reduced autonomy. The patients need periodic medical controls to monitor some parameters and register data on their health status, and the evolution of the most common chronic diseases for their age group which are diabetes, COPD and CVD. Therefore it is done by health personnel, and limitations can occur due to lack of personnel.

**6.2.3.5 Cluster 11: CVD - CHF with high blood pressure**

**Intervention:** A personal health coach or team had the role of motivating and empowering patients to achieve recommended lifestyle changes. An IT application for PC/iPad was used by patient and care personnel. A programme for sampling and fitness activities was arranged for the patient. The patient was instructed to measure blood pressure at home, and to report the values in the application along with completed exercise activities. Both patients and care personnel could review all measurements in a graphical display.
Cluster 11: Hypertension
Norrbotten (SE) ©

Current management: Consists of medication and regular visits to the GP, typically once a year. In case of a very severe condition, additional clinic or home visits by nurses could be organised for the purpose of collecting blood samples and blood pressure measurements. Treatment for atrial fibrillation was monitored at intervals between two and eight weeks. Groups for change of lifestyle and smoking cessation were offered.
7. Results at domain level

In the following, the results within the six MAST domains are described. The results are described at domain level, and conclude in the final section of this chapter.

The results are based on the scientific evaluation of the telemedicine services in the Renewing Health project. However, since a large number of scientific papers are coming out of this project, the results will be at a general level. As the confidentiality period of 12 – 24 months expires, the reports from the pilot sites as well as the cluster reports will be made public. In addition, scientific articles will be published during the next couple of years coming from the project.

Follow progress on the web site of Renewing Health: [www.renewinghealth.eu](http://www.renewinghealth.eu).

Note that domain 1 is presented in section 6 above with a description of the patients and interventions.

7.1 Domain 2 & 3: Safety and clinical effectiveness

7.1.1 The aim

The Renewing Health project expands a variety of pre-existing telemedicine and health coaching services directed at three main chronic diseases, DM, COPD and CVD, in order to produce high level evidence and decision support for healthcare authorities and the medical community, regarding the future deployment of these services in those fields where they can lead to improved care.

The main objective of the project was to compare the innovative new services with usual care, and to demonstrate any potential clinical benefits. The primary outcomes of the RCTs were:

- Quality of life assessed by the SF-36v2 questionnaire; and
- Hospitalisations and other healthcare contacts.

A large number of secondary outcomes was also assessed in the 21 pilots, including mortality, specialist and GP visits, laboratory exams, anxiety and depression, physical activity, disease specific questionnaires, and others.

7.1.2 Results

The evidence produced by the Renewing Health project trials demonstrates that all the tested services are at least as safe as usual care.

Diabetes (cluster 1, 2 and 3)

A trend for improvement of the HbA1c, the primary outcome, has been demonstrated. But it was not statistically significant. The only exception was Central Greece, where the reduction was clinically and statistically significant. The results on QoL, assessed with the SF36v2 questionnaire, were neutral or positive. So, no significant differences have been found in some cases, but improvement of the quality of life in terms of the physical or the mental component of the SF-36v2 scale.
was found in a few. Finally, in some of the pilots, a lower, but statistically insignificant number of outpatients visits to specialists or GPs have been reported for the intervention group.

**COPD (cluster 4, 5)**

Telemedicine does not seem to improve quality of life or to reduce hospital readmissions, the two primary outcomes of the two clusters. However, the results are to some extent difficult to interpret, mainly because two of the pilots did not reach the target sample size, and the analysis of the results has not completed yet, e.g. Spain presented only 3-month follow-up for 63% of the study population. The number of outpatient visits is not significantly different in the three pilots, but is significantly less in the intervention group for two pilots, and for one pilot is less in the control group. There was also an interesting but difficult to explain lower number of deaths in the intervention group of the Spanish pilot (1 vs 7, or 0.7% vs 5%, p=0.07).

**CVD (cluster 6, 7, 8, 10 and 11)**

These clusters include very different subpopulations and services under evaluation. Medium-term health coaching and life-long monitoring in ischemic heart disease with or without hypertension (cluster 6 & 11) does not seem to improve quality of life, despite a trend in all subscales to increase in the intervention group. In cluster 7, the sample size was estimated at cluster level; consequently, the lower than planned number of recruited patients in the Greek pilot weakens the statistical power of this study to demonstrate significant improvement. Despite limitations, remote monitoring of CHF demonstrated a significant reduction in hospitalisations for CHF, outpatient visits for CHF, and cardiologist visits, and a trend for reduction in the combined end-point of all-cause mortality and number of hospitalisations for HF.

The study also showed that this service is much more effective in the first 3-6 months, where a reduction was demonstrated for the primary outcome.

The only observational study of the project demonstrated that remote monitoring of implantable cardiac devices reduced the number of in-clinic CIED follow-ups without compromising patients’ clinical status with no significant differences about accesses to emergency department and hospitalisations. Moreover, cardiac visits were significantly reduced in the intervention group, and no clinical adverse event or malfunction of devices were observed.

### 7.1.3 Methodological quality

#### 7.1.3.1 Study design

The Renewing Health project consists of 21 pilots, including 20 randomised controlled parallel-group unblinded trials and one observational study, divided in 10 clusters reflecting the different diseases and services provided. The consolidated standards for reporting parallel group randomised trials are followed (CONSORT statements), which ensure the quality and validity of the results.

The only observational study is cluster 8 – remote monitoring of implantable cardiac devices - because the main objective of this study was not to demonstrate clinical
effectiveness, but to assess organisational changes and economic outcomes by recruiting a large number of patients.

7.1.3.2 Sample size and recruitment

At the time of reporting approximately 7000 patients have been recruited, which represent 98% of the planned sample size (Figure 2), and one of the highest ratios among all the European projects. This is particularly interesting if we consider that we have noticed an unexpectedly high refusal-to-participate ratio, about 43% for the total project, ranging from 1% to 85% among the different pilots.

The most important problem about the planned sample size was at the Greek pilot of cluster 7, where because of the financial crisis and some restrictions from the so-called “troika” in employing new personnel, there were no personnel to monitor the patients for a long time. As a consequence of the low recruitment ratio (<50%), the cluster 7 RCT is underpowered to demonstrate clinical effectiveness.

More than 4600 patients have been analysed till now, with a lower than initially assumed lost-to-follow-up ratio, less than 10% for the whole project (in sample size calculations, a 20% ratio was assumed). This percentage was higher in the control group, supporting the quality of the provided services and the validity of the study.

![Figure 2: Recruitment of patients per disease during the project execution](image)

7.1.3.3 Randomisation

After the patients had signed an informed consent form, randomisation was performed following standard procedures. Randomisation was performed separately for each pilot by specialised departments or research organisations, usually using appropriate software. In only a few pilots, significant differences were found between the intervention and control groups in the baseline clinical and sociodemographic characteristics.
The baseline characteristics of the recruited patients indicate that the Renewing Health population seems representative of the profiles usually observed in patients with DM, COPD and CVD in the healthcare system, especially at hospital level. A clear predominance of elderly patients with significant co-morbid conditions and poly-pharmacy was observed.

7.1.4 Discussion and practical implication of the results

The starting point of Renewing Health is the weak and contradictory evidence base for the value of telemedicine in managing chronic diseases (Wootton, 2012). Although, the analysis of the results has not been completed yet, the Renewing Health project demonstrated that the services tested are safe and at least as effective as usual care. Concerning the primary outcomes of the project, in most cases there was a trend for improvement in quality of life, but this trend was not statistically significant.

In the quality of life results as measured by SF-36, only in a few cases was there a significant improvement in either the PCS or the MCS values. The higher PCS value could indicate lesser physical limitations and disabilities, and the higher MCS value reduced or no psychological distress, fewer limitations in social activities, and both of them an overall improvement in general health for those receiving the intervention. However, according to Osoba (Osoba, 1999), on a scale of 0 to 100, such as SF-36, a difference between two groups must be over 10 points in order to be perceived as meaningful, which is not the case for Renewing Health, and also for other research projects in telemedicine (Cartwright M & team, 2013).

Disease-specific hospitalisations have been significantly reduced in the CHF cluster, but in no other cluster. Moreover, this was particularly significant at the first 3-6 months after recruitment, when the composite end-point of all-cause mortality and CHF hospitalisations were also significantly reduced. This is in accordance with the literature showing that in the first months after a hospitalisation for CHF, there is an increased risk for rehospitalisation (Desai & Stevenson, 2012), and so telemedicine services might be more beneficial then, although the available evidence was controversial (Pandor A, 2013, and Clarke M, 2011).

The results for diabetes were in accordance with the literature (Cassimatis M, 2012, and Siriwardena LS, 2012) demonstrating in most cases a constant trend for reduction of the HbA1c, but also a significant reduction in one pilot. In addition, in some cases a lower number of outpatient visits has been reported. The low level of HbA1c for inclusion in the study may be one of the factors that made it difficult to demonstrate effectiveness.

Finally, although the COPD pilots have recruited more patients than in earlier studies (Cruz J, 2014), clinical effectiveness was not demonstrated. Some of the main barriers were: technical issues, the usefulness of telespirometry, the experience with teleconsultations, the duration of the intervention, and the lower than planned study population in some cases.

As the scientific papers are published, the knowledge will be further expanded, and the specific characteristics of the patients and the services which will provide benefits will become clearer.
7.2 Domain 4: Patient perspectives

The fourth domain of MAST was explored both quantitatively and qualitatively.

7.2.1 Quantitative studies

One of the major aims of Renewing Health was to understand the patient perspective regarding telemedicine. Taking into account patient views was thought to be indispensable, since patient satisfaction is nowadays an objective of health care systems and an additional outcome of great interest to policy makers.

In order to fully explore patient beliefs, these were approached both by quantitative and qualitative research methods. The emphasis was mainly placed on quantitative measurement of the levels of acceptability of the new technology among its users. This would allow comparisons across pilot sites in different countries, and perhaps even across chronic conditions. A common measurement instrument was chosen, namely the Service User Technology Acceptability Questionnaire (SUTAQ), developed in the UK. This was translated and culturally adapted in each pilot setting. SUTAQ has been found to be reliable in its country of origin. It quantifies beliefs (that can be weak, moderate or strong, positive or negative) regarding:

- Enhanced Care: Did patients believe telemedicine enhanced the care they receive?
- Increased Accessibility: Did they think that it increased accessibility to health care services?
- Privacy and Discomfort: Did they believe that it created problems related to their privacy and/or made them feel uncomfortable?
- Care Personnel Concerns: Did they have concerns about the personnel involved in the process of telemedicine?
- Kit as Substitution: Did they see it as a substitute to their usual care?
- Satisfaction: Were they overall satisfied with it?

In addition, the potential effect of demographic characteristics (gender, age etc.) on these views was also quantified in order to assess whether certain groups of patients can benefit from telemedicine more than other. The samples used throughout the various pilot studies exceeded 3600 patients.

7.2.1.1 Results

Results are greatly in favour of telemedicine in almost all pilot sites. In fact, although some views slightly change over time, the main conclusions remain robust. Unsurprisingly, some discrepancies do exist that seem plausible given the differences in pilot settings and actual interventions. Nevertheless, encouraging findings are found for all chronic conditions monitored with the new technologies.

COPD

Table 2: Average median SUTAQ subscale scores across COPD studies,3 and 12 months after the start of the telemedicine intervention

<table>
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<tr>
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<th>Average of study medians</th>
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<tr>
<td>Enhanced Care</td>
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<td>Increased Accessibility</td>
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<td>Kit as Substitution</td>
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<td>Satisfaction</td>
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Table 2 above summarises study findings at 3 and 12 months for the COPD trials. Specifically, in all but one pilot site, COPD patients expressed a moderate to strong belief that they were overall satisfied with the telemedicine experience, since they felt knowledgeable about and trusted it. In the remaining pilot, they were indifferent, neither satisfied nor dissatisfied with telemedicine. This discrepancy was not unexpected, since in the latter pilot the service setting was different and did not influence the experience of the patients.

Patients with this chronic condition also thought that their care was enhanced and accessibility increased by telemedicine. In particular, they mildly to strongly believed (strength of beliefs differed across pilots) that telemedicine allowed them to be less concerned about their healthcare; made them more actively involved in their health; allowed their carers to better monitor them and their condition; made it easier to get in touch with health professionals; saved time from physician visits; improved health; and increased access to healthcare. They would thus be willing to recommend telemedicine to other people.

Regarding the potential negative aspects of telemedicine, it seems that COPD participants mildly to strongly believed (again, depending on the pilot) that the new technology did not create privacy or discomfort issues, nor did it raise concerns about the personnel monitoring them. In more detail, it has not interfered with their everyday routine, and has not invaded their privacy; it has not made them feel uncomfortable or worried about the confidentiality of the private information exchanged through it; it has not obstructed continuity of care; and it has not made them worried that the person who monitored their health status had inadequate information about their personal healthcare history or inadequate level of expertise.

In most pilot sites, COPD patients expressed a mild to moderate belief that telemedicine would not substitute usual care. That is, they were satisfied with it, but were unwilling to give up their standard healthcare services. In two countries, participants were indifferent on whether it can act as a substitute or not, and in one pilot they had a mild belief that it could in fact substitute their standard care.

### Diabetes

Our findings from the samples of diabetes patients are very similar and reinforce those of the COPD participants. The only minor difference is that evidence is mixed regarding the role of telemedicine as a potential substitute. Participants in various countries have different views ranging from slightly in favour of this role to moderately against it. The common denominator still is that in essence no strong belief exists in favour of substituting current care schemes with telemedicine.
CVD

Patients with heart conditions were also highly satisfied with telemedicine. However, they seemed to have somehow less strong beliefs – yet still positive - that the intervention enhanced their care and accessibility to health care services. Moreover, patients with multiple conditions and those with a pacemaker had similar views, in that they did not feel there were negative concerns involved with the intervention, but had somehow stronger beliefs in favour of telemedicine enhancing care and increasing accessibility. They were thus very satisfied, but still disagreed that the telemedicine kit could serve the role of a substitute. The same was the case for hypertensive cases, with the only difference being that they in fact were mildly in favour of substituting standard care with it.

Effect of socio-demographic and other patient characteristics

One pilot found that the health-related quality of life of participants influenced their beliefs regarding telemedicine. COPD patients with better mental health tended to report higher acceptability and satisfaction with telemedicine than those with worse. In contrast, patients with better physical health seemed to have lower levels of satisfaction with telemedicine than those with worse. This might be explained, for instance, by the fact that patients who are more able to move around and visit physicians on a face-to-face basis might in fact be more willing to do so, and place a lower value on the distant monitoring process with the kit.

Regarding education, it seems that illiterate COPD patients and those that only graduated from an elementary school believed to a greater degree that telemedicine enhanced their care and increased access to healthcare services, than secondary school graduates. In another pilot of COPD patients, weak evidence suggested that women were more concerned with the personnel involved in telemedicine. Moreover, participants who were more familiar with the use of mobile phones believed more strongly that the intervention enhanced their care. A more concrete finding was that people living alone were less concerned about the telemedicine personnel. A clinical trial has also found higher education to have a significant effect on care personnel concerns. The resulting conjecture was that a higher level of education implies a higher degree of awareness about chronic illness management and implications: that could explain why COPD patients could be more concerned about care personnel involved in the telemedicine service.

For patients with diabetes, there was evidence in a pilot study that men might have benefited more than women. Furthermore, those that had a greater familiarity with a personal computer, believed less strongly that the intervention increased accessibility. Finally, male patients with pacemakers were more satisfied and more convinced that telemedicine enhanced care and increased accessibility to services. In addition, the level of education was also found to affect their views on whether the intervention increased accessibility. Patients with higher education were more aware that the telemedicine service was only available during working hours and hence were more concerned about chronic illness management through the kit. And older patients could have a lower degree of awareness about chronic illness management and its implications, which might explain why they felt less concerned about care personnel involved in the telemedicine service.

7.2.1.2 Methodological interpretation

The reliability and validity of the SUTAQ questionnaire used to derive the above findings differed across studies. This measurement instrument was developed in the
UK, and was the most promising tool at the time identified by Renewing Health experts. The common denominator nevertheless is that in all pilot studies there were some problems observed, thus necessitating methodological refinements in future telemedicine projects. It was also not suitable for services where it was the healthcare professionals and not the patients that where the primary users of the equipment, as in the case of cluster 3.

7.2.1.3 The practical implication of the results in domain 4

Summing up, in almost all pilot sites, telemedicine left patients highly satisfied, believing that it enhanced their care, increased accessibility, without causing concerns about privacy, discomfort or personnel involvement. In general, however, it was not seen as a substitute to usual care. It should be noted nevertheless that in certain pilot settings the views regarding potential substitution of standard care were more positive than in other, still only mildly so. Several demographic and other characteristics of patients should be taken into account by policy makers in order to identify patients who can benefit the most from the intervention.

The main conclusion remains that telemedicine is associated with high users’ satisfaction and acceptability, a very significant result in an era of undisputable consumer sovereignty and patient-centered health care systems.

7.2.2 Qualitative studies

In the Renewing Health project, three regions, Norrbotten (cluster 1, 6 and 11), Norway (cluster 1), Region of Southern Denmark (cluster 3 and 4), have performed qualitative studies. In this summary, the findings from Norrbotten and Region of Southern Denmark are reported below.

In South Denmark, the aim of the fieldwork was to observe and video record each patient as both an "inexperienced" and "experienced" tele-patient at least twice.

In Norrbotten, the aim was to evaluate whether the introduction of large-scale personalised and technology supported telemedicine and health coaching interventions produce benefits in terms of health related quality of life, health status, and empowerment of patients with a cardiovascular disease.

In South Denmark, the patients took an active part in their own observation and measurements, and thereby got a better insight into their own illness and treatment. In the intervention, the patient role changed, allowing patients to be more active, self-managing patients. The tele-devices were used by patients, aside from the consultations, to measure spirometry, these measurements were not intended. Patients seemed to have got an extra experience of their own body, the hermeneutic relation. Patients’ experiences indicate that it is possible to create a close relationship and proximity between the two (patient and carer) in technology-mediated care.

In Norrbotten, the patients considered the technology to be user friendly, and had no thoughts about disturbed privacy or integrity. The intervention gave them control over their own health, and they got a different insight of the importance of how exercise affects their health. The intervention improved patient’s self-management. Although being strengthened in self-management, it was also important to get feedback from healthcare staff on reported values. The overall view was that to pursue healthcare in this way will be a common and natural part in the future.
In total, the results indicate that patient acceptability of the telemedicine services is high. Participants in the studies expressed that their ability to self-manage is enhanced, since they have the control over and understand the relation between their physical activities and the medical measurement values. These insights lead to improved self-management and better control of their health. Since it seems that the technical applications / devices are not a problem to handle, the focus is on the encounter were participants considered that a caring relationship is possible.

In conclusion, the qualitative results indicate that the use of telemedicine applications is not a problem for the patients, and that their empowerment is improved. Patients in general are ready and interested in having control of their own health. The results from the Danish study (COPD – cluster 4) also indicate that the use of telemedicine solutions changes the relationships between the patient and the healthcare professionals in favour of the patients; they feel more in control and less stigmatised. For people with more severe diseases, or people not used to computers and mobile phones, or people who are frail, further studies are needed into how to approach them.

### 7.3 Domain 5: Economic aspects

Regarding the economic aspects of the telemedicine interventions, the aim was to carry out:

- A societal economic evaluation comparing a telemedicine application with relevant alternatives in terms of both their costs and consequences.
- A budget impact analysis of the expenditures and revenues for the healthcare institutions using the telemedicine application (the business case).

Whereas the first analysis has a broad perspective including costs for all sectors, the second business case is focused on the payments to and from healthcare institutions.

#### 7.3.1 Results

As a consequence of the general lack of effects on the clinical outcomes, the societal evaluation was carried out as a cost-minimisation analysis. The results show that only one of the 20 RCT studies was able to demonstrate a statistically significant change in the costs per patient; this was in the CHF study in Finland, in which the mean cost per telemedicine patient was higher than the cost per usual care patient.

If one looks at the relative differences between the costs per patient in the two groups in each pilot, one finds that it varies from a cost reduction of 41% to a cost increase of 163% when using telemedicine. In half of the studies, the difference was less than +/- 10%. On average, the studies found that the cost per patient using telemedicine is 20% higher than the cost per patient in the control group.

The main reason for the lack of reductions in the costs per patient using telemedicine is the costs of the telemedicine interventions, including both the costs of staff and equipment. These costs are on average €650 per patient; in five pilots, the costs are more than €1000. Thus, while in several pilots a reduction in the cost of readmission or similar was found, the added costs of the telemedicine service exceeds these savings, resulting in a total increase in the costs per patient.
The results from the business cases show that the telemedicine services in most countries are reimbursed, but that the reimbursement is lower than the expenditures of the institutions who implement the telemedicine services. Thus, telemedicine is a net-expenditure for the hospitals etc. who implement the new services.

7.3.2 Methodological interpretation

Many economic evaluations of telemedicine in the literature do not follow guidelines for analysis and reporting of health economic studies, see Mistry (2012). Therefore a specific guideline was produced for the pilot teams in accordance with Drummond et al. (2005).

Generally, the pilots in Renewing Health have collected the information needed and include both the costs of investment in equipment, use of staff, and overall use of healthcare. Tables describing the cost elements, the prices, the mean use of resources and the mean cost per patient for each cost element have also been produced for all pilots. So, even though a few pilots do not include the full costs of the telemedicine devices, or miss information about a proportion of the sample, the quality level in Renewing Health is generally higher than in the published health economic studies of telemedicine as described by Mistry (2012).

It should be noted that cost estimates are often not normally distributed, but highly skewed, because some patients do not use healthcare at all, while others have extremely high costs of care. This makes the variance in the estimated costs per patient vary large, and explains why even a 50% increase or decrease in the costs per patient is not statistically significant in a normal t-test.

7.3.3 The practical implication of the results

The pilots in Renewing Health did not find a reduction in the costs per patient as expected at the beginning of the project. This may have many reasons:

A. The randomised design.
B. The maturity of the interventions.
C. The short time frame.
D. The high costs of the telemedicine service.
E. Insufficient organisational change.
F. Exclusion of relevant patient groups.

The strength of the randomised design (A) is the internal validity of the results. During an RCT, the content of the interventions need to be constant. However, this means that if e.g. healthcare staff find better ways to deliver telemedicine during the trial, these changes or improvements cannot be made. As an example, in a Danish trial it was decided to have all patients in the hospital for three days before they were included in the trial. But during the trial it was realised that telemedicine patients in some cases could be discharged after one day. This potential benefit could not, however, be included in the study at that point in time. It was also part of the RCT protocol that the patients were discharged from the telemedicine services after seven days, even though the telemedicine nurse predicted that if the patient had the service for 1 – 3 days more, the patient may have been able to avoid a readmission.
Even though the plan was only to include mature telemedicine interventions in the project, the duration of the implementation and completion of the services and the data collection could indicate that some of the interventions were not fully mature (B). A similar indication was found in the assessment of the organisational aspects of the project. Lack of maturity of the interventions can lead to organisational problems and lack of minimisation in the use of resources. Thus, if the telemedicine interventions were assessed again, and the knowledge about the organisation problems was used to adjust the services, the results may have been different.

The follow up time (C) in the studies was 6 to 12 months. However, some of the clinical and economic benefits may require more time to be measured, e.g. for patients with diabetes. Therefore a longer time frame may have resulted in different economic result.

The costs of the telemedicine interventions (D) in the pilots are high. On average, €650 per patient and in some pilots more than €1000. These are the costs for each of the patients in the whole sample, and therefore the total costs are substantial. Over time, the price of telemedicine equipment is expected to fall in the same way as the price of computers etc. has been falling; therefore the results of the health economic evaluation will change over time. Similar, some of the costs are fixed and do not vary with the number of patients. Thus, inclusion of more patients may have reduced the costs per patient. However, we also need to look at the use of staff in the production of telemedicine services, e.g. can we reduce the costs of running a call centre or the costs of monitoring data. Since telemedicine is a new technology in the healthcare sector, it may be possible to use methods like LEAN to reduce the costs of staff in the telemedicine services over time.

In the interpretation of the results from the economic evaluation, comparison with the Whole System Demonstrator (WSD) programme is useful, since WSD used similar data collection and estimation of costs in their trial (Henderson et al. 2013). In the WSD, the cost per patient in the telehealth group was 15% higher compared to the control group. The main reason was that the average annual cost per participant for the telehealth equipment and support was £1847 (per patient for whom cost data were available at 12 months follow up). These costs more than outweigh the savings in the hospital costs. Thus, the results from Renewing Health and WSD are quite similar with regard to the economic aspects.

Due to the need for a control group with usual care in the pilots, the usual care services were maintained during the project. Therefore, there is a risk that the organisational changes were insufficient (E) compared to a situation in which telemedicine was used for all relevant patients. This may have reduced the possibilities to demonstrate a reduction in the costs per patient. However, the only way to test this is to carry out observation studies in which the service is implemented into daily operation, and this type of study has other problems with internal validity.

Due to the need for patients to be able to answer to questions etc, some of the trials excluded patients groups (F) that may have potential benefits from telemedicine. E.g. in cluster 3, patients with abuse problems and dementia were excluded even though those patients would probably benefit by not having to go to the hospital.
7.4 Domain 6: Organisational aspects

In domain 6, Organisation, the aim of the study was twofold: to look at the organisational changes made during the implementation of the telemedicine interventions, and to explore the way these changes were experienced by the healthcare professionals involved.

7.4.1 Results

Generally, the health professionals who participated in the Renewing Health project consider telemedicine projects interesting, but there is great diversity in perceived results. Typically, less time is saved than expected. An example of this is a case where most, but not all critical measurements were included in the telemedicine solution. This meant that the patients still needed to attend the outpatient clinic at regular intervals.

A certain amount of task shifting was seen, but often this aspect did not reach its full potential due to the pilot nature of the project.

In some cases, staff saw patients becoming more involved in the handling of their own disease as they assume responsibility for monitoring their own conditions. In other cases, the perception of staff was that patients reportedly felt less responsible, because most of the communication concerning their conditions takes place between health professionals without them being directly involved.

The level of maturity of the telemedicine application is crucial. If the product is not fully developed, health professionals find that too much focus (and time) is spent on fixing technological problems, thus diverting focus away from the patients and their health issues. In some cases, this would even make the patients question the professional skills of the staff involved. Also, the MAST tool is designed for mature solutions, and may not yield the correct results if applied to immature telemedicine solutions.

The correct match between patient groups and telemedical solution must be found. In some projects, many patient were already well-managed and in control of their condition, which meant that the extra benefits to be found using telemedicine were quite small. At the other end of the scale, some patients were too ill, or their health issues so complex, that they did not achieve the full benefit of the telemedicine application. In both cases, results below the level expected must at least partially be ascribed to a less than perfect match.

Many health professionals reported that the project had led to improved communication between professions and sectors. Examples of this are clearer communication lines between municipal nurses and hospital based specialists. In some cases, participating health centres set up websites and gave interviews on regional radio or television to inform the region about the project. Some of those who saw no improvement said that this was due to the fact that communication was already very good.

7.4.2 Methodological interpretation

The methods used to reveal the results of this domain were mostly qualitative. Single interviews and focus group interviews were used in many projects. A few used an online questionnaire. In some cases, results from domain 5, economics,
were used in order to add some quantitative results as well. Qualitative interviews do not lead to statistically significant results, but should be seen as a way of revealing experiences and attitudes towards telemedicine, which could be further investigated on a larger scale.

There is great diversity in the results. Some aspects of the project may cause the telemedical interventions to be tested in a less than ideal situation. In some pilots, the expected organisational changes such as task shifting between professions or a decline in outpatient consultations failed to materialise because of the pilot nature of the project. Since the project was scheduled to run for a limited amount of time, some healthcare professionals or managers were unwilling to implement the same level of thorough changes which they would for a full scale launch of the telemedicine solution.

Very few participants report that time is saved using the telemedicine solutions. Part of the explanation lies in the scientific nature of the trials, which requires extensive registration of data, far more so than in the case of a full scale implementation.

7.4.3 The practical implication of the results

Based on the results, the practical implication is that telemedicine holds a large potential, but a number of caveats can be learned from this project.

For a telemedicine application to reach its goal in a project, a number of preceding considerations must be made:

- The pilot nature of the project: How does it affect participants’ willingness to take the steps needed to reach the full potential in terms of task shifting, actual changes in patient pathways etc.?
- The scientific nature of the project: How do you calculate and allow for the extra time spent on documenting everything according to the scientific protocol which would not be necessary in a full scale implementation?
- The match between patient and telemedicine application: How do you make the best match, thus allowing the telemedicine application to function to its full potential? Apparently the ideal patient is someone whose condition is not already perfectly managed and whose health issues are not very complex.
- More research is needed where these aspects are taken into consideration from the start.

7.5 Domain 7: Socio-cultural, ethical and legal aspects

The seventh domain includes three different aspects of the telemedicine applications: the socio-cultural aspects, the ethical analysis, and the legal aspects. In the following sections, these three aspects are covered with regards to the overall results of the analysis of the 21 pilots in Renewing Health.

7.5.1 Socio-cultural aspects

Regarding the socio-cultural aspects, this has been approached from the patients' and health professionals' perspectives, including any changes of responsibility with the introduction of new services. When new services are implemented, it is important also to address the societal and political context and changes.
When patients were involved in the care of their chronic condition, all sites experienced an empowerment of the patient. In the project, the experience of the empowered patient was one that was able to take an active role in the decisions made about his or her own healthcare, and in the care of the chronic condition. Empowerment required the patient to take responsibility for aspects of care such as communication with his/her healthcare professionals and other providers, etc. This also meant that for some sites, the patient could stay in the labour force, and did not have to take time out to go to hospital.

With regards to the technology, patients as well as care providers had a good understanding of the technology. However, in some instances, this was only due to the fact that the patient was either supported by a relative or a health professional. What is interesting is that some health professionals saw the technology as something for the future, which strongly contradicted the patients’ experiences, as they found the telemedical solutions mature enough.

As reported in the section regarding organisation, since a majority of the pilots have been run on a temporary project basis, the new services have not influenced society or the political level as such. In some cases, the reimbursement system was the major obstacle for further roll-out. However, in the case of Denmark, the diabetic foot ulcer treatment evaluated was found feasible for national deployment, changing the way society handles diabetic foot ulcers.

The introduction of telemedicine services means a change in responsibility. Because the treatment is carried out at a distance, this is bound to happen. As discussed under the section about legal issues, healthcare professionals are given a new role, and in some cases an extra work load, which again is reflected in the fact that the service is often an add-on service and not an integrated service. With the new services, the patient is given the responsibility to take care of his/her own health, and health professionals the responsibility to assess the chronic condition from a distance. Treating health professionals are placed in a more up-front position.

7.5.2 Ethical and legal aspects

The aim of describing ethical and legal aspects in the project is to ensure the new ways of delivering healthcare comply with applicable laws and ethical aspects - and to ensure that all projects have addressed this.

The legal framework varies from country to country, and the experience of using telemedicine services also varies. Therefore, to what extent ethical and legal aspects are considered a barrier differs regarding the use of telemedicine services. In no cases were the trials hindered due to legal issues. However, the lack of legal clarity in many countries (and internationally) makes ethical and legal assessment complex, because many sets of rules need to be considered – and the rules are not designed for telemedicine services.

In the project, the primary focus has been on e.g. informed consent (both to participate in the trial, and to process the personal data), confidentiality, protection of data, liability and product safety.

None of the participating countries have legal instruments specifically dealing with telemedicine, which makes legal assessment regarding telemedicine services more complex and complicated than “face-to-face”-services. In the nine pilot regions, the
approach regarding the legal aspects was handled either by a legal expert in their team, or by approaching and receiving legal advice from experts outside the project, or from national / local supervisory authorities. Some regions conclude that general national or international (EU) guidelines or laws may be useful in order to make it easier to implement telemedicine services. They also conclude that the lack of legal clarity for example makes it complicated to assess professional liability. Other countries describe the legal framework as very advanced, due to experience from many evaluated projects.

The telemedicine equipment varies in the different projects, and there are differences in role, number and education of healthcare professionals, which also makes it difficult to generalise the results from one project to another. Also, the legal framework diverges from country/region to country/region, which means that often it will not be possible to transfer results from one country/region to another.
8. Transferability

8.1 Status

Five out of the ten clusters included more than one pilot site implying the opportunity for meta-analyses. Three clusters that have provided meta-analyses showed that:

- Cluster 1: A slight overall decrease in blood glucose.
- Cluster 4: No statistically significant difference in admission of patients.
- Cluster 6: No statistically significant difference in quality of life.

The difference among clusters in terms of the number of pilot sites enrolled has an impact on the possibilities of analysing transferability. Clusters with more than one pilot site have the advantage of being able to carry out meta-analyses. Clusters with one pilot site only were unable to support any described experiences with statistical analyses.

At an overall level, most clusters have provided information on transferability issues for three of the MAST domains, i.e. clinical, economic and organisational aspects. Some clusters have provided additional information on patients’ perspectives, socio-cultural, ethical and legal aspects as well. So this summary of cluster status on transferability is similarly subdivided.

8.1.1 Clinical aspects

Generally, clusters have not discussed the transferability of clinical results. Cluster 10 and 11 did discuss the possible consequences of widening criteria for inclusion, but it is unclear how or if that would have affected the overall results.

The meta-analysis conducted in cluster 1 showed a low level of heterogeneity, indicating that results across countries could be combined. This result was obtained in spite of the fact that cluster 1 was the largest cluster including four different regions of Europe. So, in terms of blood glucose control, other European telemedicine interventions similar to those provided in cluster 1 could expect a similar result.

8.1.2 Economic aspects

Transferability of economic aspects is a difficult task. It requires a thorough knowledge of the organisation of healthcare and reimbursement systems across pilot sites. Such information has been lacking in the pilot reports, so the cluster reports all mention that implementation of similar services in other countries have unclear economic consequences.

8.1.3 Organisational aspects

In general, cluster reports touch upon organisational aspects. Also, a few learning points have been established:
• Changing organisation of work is time consuming.
• Different stakeholders can experience different advantages / disadvantages from the same technology, and thus have diverging attitudes toward implementation.
• Availability of technology or skills to master the technology might differ across countries.

8.1.4 Additional domains

Patients’ perspectives

Among the clusters that have reported on patients’ perspectives (cluster 1, 5 & 6), they all find that patients are satisfied with the services and do not feel that their privacy is being invaded or have concerns regarding privacy.

Also, patients regard the telemedicine services as a supplement rather than a substitution for their usual treatments.

These results should be transferable to other European settings.

8.2 Methodological considerations

The main problem within transferability assessments throughout the pilot and cluster reports is the general lack of interest within the field, leading to limited dedicated local resources.

There is no strong tradition within the field of transferability or generalisability on methodology or reporting. So in most reports, the section has been used more as a section for ‘final conclusions’ rather than assessing what others need to keep in mind if they wish to reproduce the results.

8.3 Future research

In addition to the meta-analyses carried out, there would be a large added European value by further emphasis on meta-analyses.

First, it would have been interesting to have overall meta-analyses on the aspects that were measured across all pilot sites, i.e. quality of life and SUTAQ. Second, further exploration of the analyses carried out with individual patient data could have provided valuable information on subgroup differences in the effectiveness of the interventions.

Cluster 1 serves as a great example of the value of meta-analyses. Relatively small sample sizes distributed across four pilot sites were unable to show a difference on an individual site basis. Whereas the combined result showed a statistically significant reduction in HbA1c. The reduction was found overall in spite of the relatively low level at entry. So in this case, individual patient data would enable further knowledge on a possible relationship between effect size based on blood glucose at entry. As an example, it would be possible to see if higher levels at entry enables larger reductions – or if that is not the case.
9. Transferring services to other regions

There is much learning that can be taken from the Renewing Health project, when it comes to transferring the Renewing Health services from one European region to another. One has to learn from the service re-design and deployment experience of other organisations, but all these lessons learned and good practices cannot be transferred “as is” and need to be interpreted and adapted. Tools and methods are therefore indispensable to help.

In the following, the most important factors for making a telemedicine service a success are listed as expressed by the partners of Renewing Health. In addition, the Momentum project has also listed some lessons which can be useful for the scale up of services.

Organizational adaptation

How a healthcare system is organised can have a great impact on the telemedicine services, their set-up and subsequent implementation. If healthcare delivery systems are different for each region, the telemedicine services are not easily transferred to other parts of a country. This may slow down national implementation. The importance of national implementation has to be seen in the perspective of cost-effectiveness, where a larger number of users can lower the cost of the procured technology.

Telemedicine services need to fit seamlessly into the existing practice and organization of services. However, this is not always the case, and it is therefore important to have a specific focus on the organizational and financial aspects when implementing a telemedicine service.

The structure of the healthcare sector is also important, as this can create new challenges which have to be dealt with. This can pose a problem in countries where health and social care providers are paid by different payers (eg. Regions and municipalities), and tasks are shifted from one category of professionals to another. If the health professionals at the hospital are employed by one entity and the home nurses by another, this requires organisational adaptation as the tasks shift from one entity to the other. The hospital may have lower costs as the consultations are moved out of the hospital setting, but the social care providers may have an increase in cost as they take over tasks from hospital staff. However, for telemedicine to be cost-saving, it is important that the use of the services reduces bed days, readmissions or outpatient visits. This can also apply to nursing homes, where the caregivers may help with transmission of data and check the parameters for the patients, increasing their burden for the care of the patient compared to regular services.

In the implementation phase of the telemedicine service, it is often clear that there will be structural challenges, and thus an increase in the demand for other resources. For instance, in some cases the training of staff takes extra resources, and this must be accounted for. The organisation should be capable of handling these changes. It is also important that there is an acceptance of the telemedicine service at all levels within the organisation in order to create the best possible

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2 http://telemedicine-momentum.eu/
environment for the introduction of the services. This means both at the highest decision level of the organisation, and at the level of the staff actually carrying out the services.

Integration and interoperability

One of the most important factors for making telemedicine a success is the integration of these services. Integration exists on different levels, and it depends on the type of services. Integration could include device integration, but also data integration with existing systems. For the Renewing Health project, many of the partners have commented on system integration as an important factor, since systems that provide fully integrated and interoperable solutions have proven to be a path towards patient centric and professional orientated care.

In order to provide fast and easy access to necessary patient data for the healthcare professionals, it is necessary to have the telemedicine service integrated directly into the existing mainstream healthcare information systems. This could lead to the elimination of the risk of double documentation. If health professionals have several systems to add data into, human mistakes are also likely to occur.

The remote patient monitoring system should also be directly integrated with the information systems of other healthcare providers. By doing so, it is possible to avoid having fragmented information about patients, where the information is spread out over several systems. Specific for cluster 8, one of the problems with the use of Remote Monitoring (RM) was the need to connect to five different providers to review data and the lack of RM data integration with the Electronic Medical Record. By having one system with all relevant data, it would be less time-consuming for healthcare professionals to retrieve data needed. If it is not possible to have one system, it is important to have a single sign-on system that allows healthcare professionals to use the same authentication method on multiple systems. The use of such integrated system is more efficient as it saves time and efforts of the professionals and thus, can be a facilitator for faster adoption of the service.

When implementing telemedicine services, several systems must often communicate together; therefore the organization of the healthcare sector is also important when dealing with integration. There has to be either a single system or a standard for sending integrated messages, if communication has to happen between different sectors. If there is no standard system, it can be hard for all stakeholders to have access, and supply data for a patient, limiting the cross sectorial care. One solution could be to set up a decentralized and simple access for all stakeholders, and thus give better access to the cross-sectorial care. In the Renewing Health project, some countries have struggled with the lack of an interoperability standard, and the unclear regulatory framework around telemedicine services. These must be tackled at a national and European scale in order to provide for the smoother transition to telemedicine services and their implementation.

With a focus on integration and interoperability of systems and devices, it is important that the technology is tested prior to implementation to prove its maturity and feasibility, and to test how the organization should be changed to accommodate the new telemedicine services.
Technology

Technical robustness, data safety, usability and user-friendliness are also important factors for the success of telemedicine services. Safety of the services is of great importance, as personal clinical data are highly sensitive. When the services consist of remote monitoring, and the data has to be transferred from patients’ homes to hospitals or care centres, this has to be done in a secure manner.

It is essential that the services are user-friendly. If users are not comfortable with the services, and do not know how to use them, it is less likely that these will become part of the daily routine. This especially applies to elderly people, who may not be as familiar with technology as the younger population.

The technology must be running smoothly from the beginning, otherwise it is more likely to be discarded as a viable solution. Furthermore, the devices should be up-to-date and of high quality, as low quality devices may create frustrations, and patients will not use them regularly.

When the devices had to be updated, it proved difficult to do so remotely, and some patients have been required to visit healthcare centres in person in order to update or change their devices. It is not always possible for the patients to visit the healthcare centre, which can complicate an update or exchange.

See also the deliverable regarding the technical recommendations at the Project web site

Technical support

The technical support of telemedicine services is important, as not only must logistics be handled, but also set-up, installations and alarms. In some pilots, a dedicated eHealth Centre was set up to manage the false alarms, resulting in clinicians only handling the true alarms, limiting their interventions to alarms requiring medical competence.

By having technical support handling strictly technical issues, healthcare professionals are not burdened by this, and can focus on the care of patients. In addition, by having technical support, patients can also have someone to call when problems with their installation occur, and hence can feel more secure. Technical support can be outsourced to specialized subcontractors, rather than adding a new task to the health providers.

With regards to the logistics of the telemedicine services, then there must be a private service provider or a unit in the healthcare provider responsible for storing, distributing and setting up the equipment in addition to the above mentioned support of it once installed.

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Adaptation to patient’s need

All the clusters emphasise the need to adapt the service to the patient’s need. If the service is not adapted to the specific patient, there may not be a high incentive to use the services as part of the daily routine. Patients have different courses of treatments and different needs, which should be reflected in the way they use the service, and, at the same time, on how the healthcare professionals respond to these. Patients with clinical complexity need frequent and close follow-up, but these patients would also benefit more from the service.

The needs of the patients can also be more complex, as the service is typically only related to one health status and one pathology, while the situation of e.g. elderly is not so simple.

There is also a call for other features to be implemented into the service, such as a medication tool, a diary for patients which can provide useful information, and also the possibility to register any kind of physical activities and also self-measurement when appropriate. It is therefore also important that it is technically possible to expand the services as new needs can appear while using the services.

There is also a focus on the importance of matching the right patient groups with the appropriate applications; patients in real need for lifestyle improvement are the best candidates for monitoring on a distance (telemetry). There should also be a focus on the situation of the patients; for example, patients living in rural areas and not having an easy access to healthcare services are likely to benefit more from the services.

Introduction of services

Generally the clusters have had the same experiences when introducing the services to the patients. Most appoint a dedicated coach or a trusted clinician when introducing the telemedicine service. The dedicated coach is more efficient and economic for implementation of the service. Patient compliance was higher when the new service was offered and provided by a clinician whom the patient already knew and trusted.

It is not only important who introduces the services to the patient, but also when this is done. It is argued that the patient should be introduced to the services during the hospital stay, or through a trusted clinician. By introducing the service during the hospital stay, patients may be more comfortable using the service afterwards, if they receive the device before discharge and have a chance to test it during the stay. In some clusters the support of the social sector was instrumental in getting better outcomes from the telemedicine services.

The introduction and training of the patients can also be done in groups of 10-15 people, which is also mentioned as a successful approach. By doing so, they can rely on each other; it is also recommended that two super users are trained to provide basic support for the rest of the group.

When introducing the services to the patients, it is also recommended that there is some equipment available for introduction and short-term loan in order to optimize the service to the patients. If possible, it is also a benefit being able to use equipment that patients already have at home, if they have any, as they are
comfortable with this, and will only require instructions on how to transfer data to a system. In this instance, it has been a success to use a mobile phone as the group targeted in the service all had mobile phones and were familiar with this technology.

Training

Most clusters also identify training to be an important factor in the success of telemedicine services. There are several levels of training, and can include both patients and healthcare professionals, and also caregivers and relatives, depending on the type of service and the needs of the patients. There is a difference between the training to use devices (technically) and training to manage the information (empowerment and self-care).

Training and education of patients is important in order for them to interpret their vital signals and efficiently utilize them in the management of their disease. In the same way, sufficient education of the healthcare professionals will lead to a better utilization of the monitoring data.

When introducing the devices, it is also important to train the patient, caregivers and relatives sufficiently. The caregiver and relatives can also be important, as they can assist the patient with monitoring and help if needed. Early involvement of the caregiver can prove valuable, as they are able to assist the patient from the beginning. Some devices are more complex and harder to understand, and require extensive training; it is therefore important that sufficient training is provided.

As mentioned, training could be carried out in groups of 10-15 people, where patients can assist and help each other. Training can also be carried out through leaflets and online manuals, depending on the service they are provided with.

Communication and feedback

Communication and feedback to patients with telemedicine services is very important in order to provide information of their monitoring results and to follow-up. It is advised that there is a follow-up every 3-4 month with patients; however, for some patient groups, the frequency should be higher.

Daily videoconferencing for follow-up was accepted and clinically useful. It is also important to maintain the tele-consultations, as they resulted in 76% of the patients feeling safer or more secure after discharge, because they could see each other and focus on both verbal and nonverbal communication.

There is also a need to rethink how communication and feedback is given to the patients, and have it in line with a new generation of online-based care models.

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4 Results from the pilot site
10. Conclusion

10.1 What results did we find

In the following section the overall results within each of the MAST domains are summarised below:

10.1.1 Patients and interventions

Renewing Health includes studies of telemedicine interventions for patients suffering from chronic diseases: Diabetes, COPD and CVD.

The content of the telemedicine interventions vary between patient groups and with regard to duration and content. Some include videoconferencing between patients and healthcare professionals, others monitoring of disease specific health data by use of medical devices, and some include also elements of health coaching. The interventions are described in detail in section 6.2.

10.1.2 Safety and clinical outcomes

The Renewing Health project has demonstrated that the services tested are safe and at least as effective as usual care. Concerning the primary outcomes of the project, in most cases there was a trend for improvement in quality of life, but this trend was not statistically significant. Similarly, only one cluster has been able to demonstrate a statistically significant reduction in the number of disease-specific hospitalisations.

Even though the results can be considered a disappointment, it should be noted that the overall result is not so different from previous studies of telemedicine. In the WSD, a statistically significant reduction was found in the number of admissions of patients and in the mortality. But not in the quality of life of the patients. Similarly, a review by Wootton (2012) of 141 randomised studies found that only 46% were able to shows statistically significant effects on the primary outcomes.

10.1.3 Patient perspectives

Looking across all clusters, the results show that patients are greatly in favour of telemedicine: They are highly satisfied, believing that it enhanced their care, increased accessibility, without causing concerns about privacy, discomfort or personnel involvement. However, the results also show that the patients generally do not believe that the use of telemedicine will reduce their use of other healthcare services. Thus, patients do not see the telemedicine services in Renewing Health as a substitute, but rather as an add-on to usual care.

10.1.4 Economic aspects

The analysis of the costs per patient shows that in general the cost per patient using telemedicine interventions are not statistically significantly different from the cost per patient in the control group. However, in most studies, the costs are higher in the telemedicine group, on average about 20% higher. The main reason for this
is the costs of the telemedicine devices and services. In several pilots, a reduction in the cost of readmission or similar was found, but the added costs of these telemedicine services exceeds these savings, resulting in a total increase in the costs per patient.

It cannot be excluded that the use of RCTs reduces the possibilities to demonstrate a reduction in costs. Firstly, by not allowing changes in the intervention during the trial, even if experiences show that changes are needed. Secondly, because organisational improvements may not be carried out when both the intervention and usual care are being used at the same time within the participating institutions during the trial.

10.1.5 Organisational aspects

Since the telemedicine interventions and the local organisational settings vary from pilot to pilot, the assessments of the organisational aspects also vary a lot. Some pilots find that time is saved by use of telemedicine, but typically less than expected. Some find that task shifting takes place, but often without reaching its full potential. Some find that patients gets more involved, others that patients gets less involved in their treatment through use of telemedicine. Some have found technical problems with the services that could indicate a lack of maturity of the interventions, which also may have been the reason for the general lack of organisational benefits in the pilots.

10.1.6 Socio-cultural, ethical and legal aspects

In none of the trials were any socio-cultural, ethical or legal problems found that would hinder the implementation of the interventions. However, the lack of legal clarity in many countries (and internationally) makes ethical and legal assessment complex, because many sets of rules need to be considered – and the rules are not designed for telemedicine services. In the project, the primary focus has been on e.g. informed consent (both to participate in the trial, and to process personal data), confidentiality, protection of data, liability and product safety.

10.2 Methodological challenges

As described in section 7, a number of methodological challenges have been found in the project. The main challenges are described below.

10.2.1 Randomisation

Generally, the randomisation of patients has worked well, and in most pilots there are only minor differences between the patients in the intervention and the control group. However, in the pilots in Germany and Austria, there seem to be substantial problems, and the two groups are not comparable. This makes the interpretation of the results from these two countries problematic.

10.2.2 The use of RCT design

The advantage of the randomised control trial design is that it minimises the risk of different types of biases in the results, and thereby increases the internal validity of the estimates. However, the use of this design requires that the interventions
remain constant and are similar for all patients during the study. In practice, this means that the experience of the clinical staff and the patients cannot be used during the trial to improve the interventions. Therefore the use of RCTs could have resulted in a less than optimal implementation of the telemedicine services, and thereby have resulted in a reduction in the clinical and organisational benefits. These experiences are similar to the experiences from the WSD, described by Hendy et al. (2012).

In a similar way, the fact that not all patients were offered the telemedicine intervention, but instead the hospitals etc. had to keep offering both the new and the old service, could have lead to insufficient organisational adjustment and implementation of the service. Since the organisation of the telemedicine service is crucial for the total impact of the intervention, this may also have lead to a reduction in the organisational impact.

10.2.3 Lack of blinding

In the pilots in Renewing Health, the patients, the clinical staff and the persons doing the analysis of the data have not been blinded. This may have caused a positive bias in the results that should be taken into account. Notice that this is similar to other studies, since lack of blinding is a general problem in studies of telemedicine.

10.2.4 The combination of pilots into clusters

As described in section 6, the pilots in Renewing Health were selected to be already operational before beginning of the project at local level. The advantage of this is that the regional health authorities were already familiar with the telemedicine solutions before the project started. The disadvantage is that the local solutions differ, both technically and organisationally. Even though common protocols were produced with similar primary outcome measures and inclusion criteria, there are differences between the interventions within the clusters. This may have increased the variation in the primary and secondary outcomes, and thereby reduced the possibility to identify statistically significant outcomes at cluster level, compared to a situation with completely similar interventions and studies in all pilots.

Even though the first analysis of the data across clusters has been carried out, there are still many possibilities for using the whole dataset to carry out analysis across pilots and clusters; for example, to indentify more clearly the patients with the highest acceptability, the highest clinical benefits and the best economic outcome, etc.

10.2.5 The maturity of the telemedicine interventions

Even though the regions as described above were asked to include mature telemedicine services in the project, some of the problems described with the organisational domain may be explained by a lack of local experience with the use of the telemedicine services. As an example, some pilots found that clinical staff had to spend time fixing technological problems. Such problems should have been fixed before the trial started, and may have reduced the possibility to identify clinical and economic benefits.
10.2.6 The validity of the patient perception questionnaire

As described in deliverable D3.5 no disease independent, validated questionnaire for assessment of patients’ acceptability of or satisfaction with telemedicine interventions was identified by the project. Instead the Service User Technology Acceptability Questionnaire (SUTAQ) from the WSD project in the UK was translated and used in the pilots in Renewing Health. Data from WSD on the validity of the instrument was presented to the Renewing Health management team, but publication of the data is still missing. Therefore, we still need more information on the validity of SUTAQ. Hopefully the results will form the basis for a general use of the questionnaire in European projects on telemedicine in the future, and thereby increase the possibility to compare results across projects and countries.

10.2.7 The economic evaluation

On the one hand, the estimation of the costs per patient in the pilots generally followed the guideline based on Drummond et al. (2005), and included all relevant types of costs based on patient level data. Compared to the existing cost studies of telemedicine, this is a substantial improvement, as described by Mistry (2012). On the other hand, the economic analysis in the pilots in Germany and Austria are problematic because the randomisation of patients did not work. Similarly, some of the pilots in Veneto did not include the full costs of the telemedicine devices, and therefore underestimate the mean costs per patient using telemedicine. These problems should be considered in the interpretation of the results from the project.

10.2.8 The need for valid instruments for assessment of organisational aspects

As described in deliverable D3.5 (Final questionnaire for data collection), no validated instrument for assessing the organisational aspects of implementation of telemedicine services has been found. Therefore a list of organisational indicators was developed, and used as the basis for data collection in the project. To some extent, this has lead to comparable results within the clusters. However, there is still a need for development of a validated instrument for assessment and reporting of organisational results in studies of telemedicine services. Renewing Health has now produced a large number of pilots and clusters that are described with regard to their organisational aspects; hopefully, this can be part of the basis for development of such a validated instrument.

10.2.9 Experiences with the use of MAST

As described in D3.9 (MAST critical assessment report) an assessment of whether the MAST framework works according to its aims and purposes, and the relevance of MAST for different pilots, was carried out as a part of the Renewing Health project. The study was done by submission of a questionnaire to the 11 cluster or pilot leaders in the project.

Based on the answers, the overall impression is that MAST was a valuable framework with its recommendations for preceding considerations, assessment within seven domains, and considerations of transferability.

Challenges included problems in obtaining scientific and rigorous knowledge on relevant alternatives and maturity for the preceding considerations, and on issues
within the seven domains. These issues are to some extent beyond the scope of MAST. Technological usability, responsible innovation, health literacy, behaviour change, caregiver perspectives and motivational issues of professionals are proposed as areas to be added to the domains for improvement of the framework.

In addition, it would be preferable if the assessment of ethical and legal aspects could be made more operational. However, the challenge is that the legal framework varies from country/region to country/region. What is considered as ethical aspects and what is considered as legal aspects, can also vary. Therefore, in all projects it is necessary to describe the legislative references and how they were met.

An important legal aspect is whether there is a change in the legal framework when a project changes from trial to large-scale implementation. This should be taken into consideration at a very early stage in the project – and could be a requirement in the MAST evaluation.

The growing use of MAST in telemedicine studies

As part of the Renewing Health project, a number of guidelines on data collection, analysis and reporting of results have been produced, see http://www.renewinghealth.eu/assessment-method. At the same time, the regional teams in the project have been trained in and have used MAST in the studies of the local telemedicine solution. Thus, the teams have got experience in the model.

By March 2014, a large number of national and international telemedicine studies in Europe now use MAST as the framework. Among these are:

- United4Health (3 trials – 15,000 patients).
- SmartCare (10 trials - 9,000 patients).
- inCASA: (5 trials).
- Integrated Home Care.
- MasterMind.
- Patient@home (10 trials – 2,000 patients).
- CareWell.
- Beyond Silos.

A number of regional and local health authorities have also adopted or implemented MAST as a basis for decisions on investment of telemedicine, e.g.:

- Norbotten Region, Sweden.
- Veneto Region; Italy.
- Basque Region, Spain.
- Region of Catalonia, Spain.
- Region of South Denmark, Denmark.

Even though there is still a need for valid instruments for assessment of e.g. the patient perception and the organisational aspects, Renewing Health has provided experience on how to use MAST in practice that hopefully can lead to a more well structured and solid assessment of telemedicine services in the future.
10.3 Deployment of Renewing Health services

The deployment plans for the Renewing Health services are inevitably affected by both the different organisational models in place in the different regions / countries, the different reimbursement regimes, and the different findings from the individual pilots with regards to clinical outcomes and financial justification. The current position for each region / country is shown below.

10.3.1 Austria: Carinthia

In general, the diabetes trial yielded to savings in running costs but there was no statistical significance. Organisational issues and costs need to be addressed in order to bring the service into the field, and to keep it up and running.

Because results of the trial are not conclusive, monitoring of COPD patients will not be the primary focus of further deployment. Further studies have to be done first. Organisational units will have to discuss the disease management process used, and also the dedication of resources to it.

10.3.2 Denmark: Syddanmark

Diabetes: A national ulcer monitoring project has already started, which will incorporate the Renewing Health service. By June 2014, 40% of all 22 municipalities in Denmark are expected to have ulcer monitoring as part of their daily operations. This number is expected to increase to 80% by March 2015.

COPD: The telemedicine service is in daily operations at the Odense University Hospital at two locations (Odense and Svendborg). How to implement the briefcase into other hospitals in other regions of Denmark is currently being investigated. Furthermore, the briefcase has been tested to include other chronically ill patients such as heart, diabetes, and asthma patients, as well as to use it for rehabilitation.

10.3.3 Finland: South Karelia

Eksote will offer the Personal Health Record (PHR) solution to all citizens in the region. The PHR solution passed public procurement process, and will be launched for Eksote / Finland in spring 2014. In addition, the health coaching model which has been developed in the project will be deployed beyond the RH project.

The results of the Renewing Health trial have shown that diabetic patients could benefit more than CVD patients. As a result, deployment beyond the end of the project will be targeted at diabetic patients both within the United4Health project and also outside the project.

10.3.4 Germany: Berlin

Diabetes & COPD: The project is identified by health insurances, the state government and professional associations to be very successful. Therefore, across the board support is agreed after the completion of the evaluation. A three step approach to deployment has been agreed.
10.3.5 Italy: Veneto

In the Veneto Region, deployment beyond the end of the Renewing Health project will be managed following the strategy set out in the Regional Health and Social Care Plan 2012-2016. The plan identifies chronic diseases as an area for attention.

How to extend the telemonitoring services trialed in the Renewing Health project into other Local Health Authorities in the Veneto Region is currently being investigated, but the Renewing Health results are essential as the first step to do this.

10.3.6 Spain: Catalonia

COPD: A complete assessment process for the economic, organisational, clinical and health status will be submitted to the public health insurer who is responsible for service reimbursement. During this period, no service is being provided to the population.

A redesign of the reimbursement and service contracting model is undergoing review. While no direct reimbursement for telemedicine services is expected to be assigned due to economic constraints, specific actions should be directed towards chronic patient management, as it is one of the strategic lines on the current Health Plan.

10.3.7 Sweden: Norrbotten

A regional Steering Committee has requested the development of a comprehensive deployment plan for Renewing Health services. This has been developed by the project, with a positive response from the Steering Committee.

Large-scale deployment will probably require a revision to the reimbursement system in order to provide economical incentives for healthcare providers.

Plans are in place for implementation of new applications which will support national deployment during 2015.

10.3.8 North Norway

The Renewing Health services are fully in line with national and regional strategies in the area, but a number of issues need to be addressed before full deployment takes place:

After the project, the tool has been made available for iPhone as well.

- The personal tool information needs to be integrated into the healthcare internal systems. This is under discussion
- Interoperability between sensors and mobile devices is not yet at the plug and play stage.
- Integration and security solutions, cost issues and treatment reimbursement needs to be addressed.
11. Dissemination activities

If one sentence can summarise to a “decision-making” oriented public what Renewing Health has achieved, one can quote the European Commission when the new “eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century” was released:

“Renewing Health has allowed nine leading regions to pool their efforts to revolutionise the management of chronic diseases. Diabetics and heart patients, among others, can manage their own diseases from the comfort of their own homes and take an active role in improving their conditions while achieving better health outcomes.”

This statement has inspired the title of a small booklet that was produced on the occasion of the final conference of the project, and that is available in the NEWS section of the project web site www.renewinghealth.eu.

During the four years that the Renewing Health project has run, numerous dissemination activities have been carried out and documented in deliverables of the project. However, some of the activities must be mentioned here, as they will continue after the project ended in December 2013.

A YouTube channel has been created (www.youtube.com/user/renewinghealth) with testimonials from the project. Here videos are broadcast to show to a wider public the scope of the project, how MAST has been applied, the recruitment process and its difficulties, together with the presentations from the final conference held in October 2013, to name a few.

In the participating regions in the project, there has been the challenge of extracting scientific conclusions to be published both in the final pilot project reports and in scientific journals. In the project there have been 21 pilots, varying from one pilot in Norway and Spain to five pilots in Italy. Each pilot has produced a Final Pilot Report, which will be available to the public in January 2015. The delay between the availability of the results and their accessibility to the public is due to the fact that the pilots will be writing papers for scientific journals. As the results are made public in scientific articles, these will be announced to the public on the Renewing Health web site. A news sign-up is offered on the home page to get publication alerts.

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5 Source URL: https://ec.europa.eu/digital-agenda/en/innovative-healthcare-21st-century (last access 2014-02-12)
12. Recommendations

The Renewing Health project was initiated in February 2010; since then the world has changed. The situation is different for many of the partners; organisations have been changed, the political situation has changed, the economic situation has changed, as well as the technical developments that have been significant. So when describing the results of the Renewing Health project, the results are being delivered in a different context in comparison to when the project started. Today in 2014, four years later, we bring you the lessons learned about implementing and evaluating telemedicine in nine European regions.

What has not changed are the changes in the healthcare systems in Europe. The economic crisis has put even more pressure on the systems to find new and more efficient solutions to provide care for an increasing elderly population with an increasing number of patients with a chronic condition, and still fewer people in the workforce. The structural changes in the European healthcare systems will escalate over the coming years, surely with different speed and strength, but all in the same direction – there will be fewer beds in hospitals, the primary care sector will get new tasks, and citizens will be forced to take more responsibility for their own care and treatment. So telemedicine solutions will become a tool in the box to deal with the changes. Renewing Health has provided important knowledge about how to (and how not to) help the decision makers selecting the services that should be deployed in the future.

12.1 Lessons learned

Renewing Health was started on the assumption that telemedicine would be a good tool for improving the clinical quality and economic efficiency in the European health care systems.

In 2008, when the call was launched for the Renewing Health project, the main problem was the lack of workforce that was expected due to the growing economy in EU. Since the impact of the economic crisis, this perspective has changed fundamentally: in many countries, there is no longer a focus on reducing the use of labour, due to high unemployment rates; in addition, the cost for labour has dropped in many countries.

However, even though the present economic situation does not force regions to make dramatic changes in the way they deliver healthcare, the demographic challenges have not disappeared. Quite the contrary: with the expectation of both a more elderly population and a reduced tax revenue in the future, the pressure on the healthcare system will increase significantly to produce healthcare at the same or better quality at a lower cost.

Renewing Health was set up to provide the scientific evidence for the regions to set up new ways of delivering healthcare, and create a common evaluation framework making the transfer of results from one region to another across Europe more efficient. In short, the conclusion is that Renewing has not been able to deliver the evidence for the efficiency and cost-effectiveness of telemedicine. But the assessments have demonstrated the need for more focus on the organisational aspects of implementation of telemedicine, and the price paid for the telemedicine devices. At the same time, the project has created a common understanding of how
to carry out assessment of telemedicine and structure the results in accordance with MAST. It has also demonstrated a huge diversity in the different ways telemedicine can be deployed in the field (e.g. because of different organisational conditions, financing environment, eligibility criteria) leading to very different assessment results.

One could even consider that the time may have an impact on the assessment results: an assessment performed after five years of operations of a telemedicine service may give different assessment results than those obtained at its launch. The consortium believes therefore that the need for telemedicine assessment – hence the need for assessment expertise - will increase.

In the future, the consortium believes that this will give the Europeans regions an efficient tool for the production and transfer of knowledge on the effectiveness of telemedicine, and thereby reduce the time from the creation of evidence to large scale implementation across the EU, and creating a European market for services and technology.

From the project, we have found that it is difficult to improve effective healthcare systems, and not least to document that the new innovative services are better than those already established. In order to reap the benefits of the new services, there will have to be substantial positive findings, in order for it to be beneficial for the system.

As we have seen in the organisational analysis, there have generally not been changes of the current organisation when the new Renewing Health services have been implemented. The services have been an add-ons to the organisation, and special healthcare staff have been appointed for them, rather than integrating the services into the organisation. To some extent, this has been because of the set-up of the assessment of the services and the RCT study, as previously mentioned in section 10.2. This has contributed to the difficulties of finding economic benefits.

It is clear that there are areas where there is a need for more knowledge in order to assess all the benefits of implementing telemedicine. One is how to secure and create the right incentive structure to go to large-scale implementation in a region or country. Another is the urgent need to get a far better foundation in order to implement the organisational changes that are necessary to reap all the benefits. Re-organising an organisation and its service provision is paramount when implementing a new innovative service or solution.

In the project, there have been remarkably few technical problems, but it is worth noting that the only service that has used video conference for clinical use is the COPD service that was implemented in the Region of Southern Denmark and Catalonia. Even though we have seen it working in hospital settings and implemented on a large scale in many regions and countries in Europe, we must realise that bringing video conferencing into the patients’ home is a different matter. It required specific solutions, since it is not possible to get sufficiently stable and secure internet connections of high quality.

Another important lesson learned in Renewing Health is that further RCTs on telemedicine are not going to cast any further light on the efficiency and cost-effectiveness of telemedicine in the pathologies addressed in the project. Renewing Health has confirmed the results of the survey of 141 RCT’s in this area conducted by Richard Wootton, already mentioned above. On the other hand, it is amply demonstrated by now that telemedicine has no adverse effects on patients. The
strong recommendation from the Consortium is that it is time to move from pilots to deployment of telemedicine to evaluate it in a real-life context where economic and organisational impact can be reliably assessed.

Renewing Health has also shown the difficulty of obtaining comparable data in a multicentre telemedicine trial. This is due to two main factors:

- The differences in the organisation of the healthcare delivery network and in usual care for chronic patients, not just between one country and another in Europe, but also between one region and another within the same country. Harmonisation of the healthcare delivery networks is not on the political agenda of the European Union, which has no mandate in this area.
- The fact that we are not any more working in a new area were interventions for a disease can be defined in common and applied unchanged throughout the Project. Almost without any exception, by the time the Project started, the services had been already designed and, in several case, even implemented. This situation can only become worse in the future, because more and more telemedicine initiatives will arise here and there, and nobody will be willing to scrap what has already been implemented to converge towards common interventions which can produce comparable data.

12.2 Implementing guidelines and recommendations

The results we have seen in Renewing Health project primarily show no change in effects at the same or higher costs. But many of the telemedicine services we have been testing in Renewing Health are still to be considered new and rather immature compared to the traditional older services implemented at the sites.

Therefore, it should come as no surprise that some projects will fail to become productive, while others will mature and become cost effective services – this is normal with innovation projects. Further, our findings in Renewing Health can be explained very well with the concept of hype cycles - a model that represents the maturity and adoption of technologies over time.

Gartner (a consultancy firm) has developed the concept of hype cycles. According to this model, there are five key phases of a technology's life cycle⁷:

- First the technology is invented.
- Then we move to “peak of inflated expectations”, a phase where we gradually get our hopes up (too high).
- Then reality kicks in - we enter “trough of disillusionment”, interest wanes as experiments and implementations fail to deliver.
- If the technology survives this far, we start to climb up the “slope of enlightenment”, and gradually, how the benefits of technology start to crystallise.
- In the last phase, “plateau of productivity”, the technology is now mainstream, and a cost effective service.

Fasterholdt (2008) assesses the economic maturity of telemedicine services in Denmark and internationally by using Gartner’s hype model, and finds that almost

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all initiatives are immature (results are achieved through a case study approach and a review of international literature). That is, at the moment most telemedicine solutions, including those in Renewing Health, are in phase 2 and 3 (peak of inflated expectations and trough of disillusionment). In time, we will expect that some of the services in Renewing Health will move on to the "plateau of productivity", and become a cost effective service.
References


Chumbler et al. Recommendations for research design of telehealth studies, Telemed J E Health 2008, 986


Schwartz and Lelloch: Explanatory and pragmatic attitudes in therapeutic trials, J Chronic Disease 1967, 637


Zwarenstein et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement, BMJ 2008, 337