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# MethoTelemed

## Final Study Report

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# MethoTelemed

**Methodology to assess telemedicine applications**
**SMART 2008/0064 – O.J.2008/S 107-142555**

## Preface

Final Study Report is the fifth internal deliverable of MethoTelemed, a one year study commissioned by the European Commission (EC). The study is led by MedCom and the Norwegian Centre for Integrated Care and Telemedicine in partnership with the University of Stirling and the Norwegian Knowledge Centre for Health Services.

The Final Study Report summarises the full work of the MethoTelemed study. The author team is: Kristian Kidholm, Janne Rasmussen, Anne G. Ekeland, Alison Bowes, Signe Flottorp, Claus Duedal Pedersen, Lise Kvistgaard Jensen, and Signe Dyrehauge.

The MethoTelemed team would like to thank the following for their valuable and essential contribution to the work created:

- The stakeholders and experts that participated in the workshops and provided continuous feedback to our work. Without their contribution it would not have been possible to achieve the objectives of the study.

- The European Commission for all the work they have put in to MethoTelemed. They have been a highly constructive and active collaboration partner.

- The colleagues in our own organisations that have supported the work in different ways.

**Summary**

This Final Study Report summarises the full work of the MethoTelemed study. The main part of the report presents a new model for assessment of telemedicine - MAST - to be used as a basis for decision making in EU and the European countries in decisions on use of telemedicine applications.

The model is a part of the results from the MethoTelemed project. The overall aim of MethoTelemed is to provide a structured framework for assessing the effectiveness and contribution to quality of care of telemedicine applications. The development of the model is based on results from two workshops with stakeholders and users of telemedicine in June and November 2009 and a systematic literature review. The model uses the EUnetHTA HTA Core Model for interventions as the point of departure.

MAST should be used if the purpose of an assessment is to describe effectiveness and contribution to quality of care of telemedicine applications and to produce a basis for decision making. If this is the aim, this manual defines the relevant assessment as a multidisciplinary process that summarises and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine in a systematic, unbiased, robust manner.

MAST includes three elements:

- Preceding considerations of a number of issues that should be considered before an assessment of a telemedicine application is initiated.
- A multidisciplinary assessment of the outcomes of telemedicine within seven domains
- An assessment of the transferability of results found in the scientific literature and results from new studies.

**Preceding consideration:**

- Purpose of the telemedicine application?
- Relevant alternatives?
- International, national, regional or local level of assessment?
- Maturity of the application?

**Multidisciplinary assessment**

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

**Transferability assessment:**

- Cross-border
- Scalability
- Generalizability

This report describes what to include in the preceding considerations and a number of aspects, methods and topics that can be relevant in each of the seven domains included in the multidisciplinary assessment. For each of the seven domains a number of measures of outcomes used in studies of telemedicine applications are also described in the appendix. These are also included in the MAST Toolkit, a tool that makes it possible for those who are planning an assessment of a telemedicine application to use the MAST as a checklist. The MAST toolkit can be downloaded at www.telemed.no/methotelemed

MAST is a part of the MethoTelemed Guidance which describes a number of different methodologies for assessment of telemedicine applications. MethoTelemed Guidance can be found at www.telemed.no/methotelemed.

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# 1. Introduction

This Final Study Report summarises the full work of the MethoTelemed study. The main part of the report presents a new model for assessment of telemedicine - MAST - to be used as a basis for decision making in EU and the European countries in decisions on use of telemedicine applications.

In the section below the purpose of the project and the model is described and the background of the project is presented. Hereafter the methodology used in the project is briefly described in section 2. Subsequently the results from the different parts of the project are described in section 3.1. and 3.2. including results from workshops with stakeholders and results from the literature review. These results have been used as inputs in the development of the main product of the MethoTelemed project: MAST. Section 3.3 describes the aim and the content of the model and how MAST and the MAST Toolkit can be used in practice. In section 3.3.6 the content of the seven domains in MAST is described in more details and section 3.3.7. describes how the transferability of the results of an assessment can be made. Section 3.3.8 describes methods which can be used for data collection and section 3.3.9 describes a practical example of how MAST can be used to assess a telemedicine application: The COPD Suitcase.

The achieved results and description of MAST is discussed in section 4 including an analysis of the strengths and weaknesses of the model and the relation between MAST and other kinds of models and frameworks for assessment of telemedicine. Comments from reviews of the model from two European HTA institutions are also presented in the discussion.

In the conclusion in section 11, the results in the MethoTelemed project are summarized and the possible future development of the model is considered.

## 1.1. Purpose

The overall aim of MethoTelemed is to provide a structured framework for assessing the effectiveness and contribution to quality of care of telemedicine applications. At the same time the framework or model should be based on the users' (e.g. the medical profession, payers, health authorities) need for information in order to make decisions on whether or not to use new telemedicine applications. The Model should also be based on a review of the scientific literature on methodologies for assessment of telemedicine.

## 1.2. The background

In preparing for the tender for the MethoTelemed project a review of existing literature on the effectiveness of telemedicine applications shows that assessment studies of telemedicine to date are not of high quality, are using questionable methodologies and techniques, or have a narrow focus thus disregarding other important outcomes.

Based on this and other reviews the European Commission (EC) has indentified a clear need for actions in regard to the assessment of telemedicine since the lack of high quality studies are considered a hindrance for wider implementation of the various applications for providing treatment and care at a distance in the Member States' health systems.

This background section shortly presents the recent EU initiatives in the area of telemedicine applications and the scientific background for the project.

**Telemedicine in a European context**
eHealth and telemedicine have for years had the attention of the EC and a number of initiatives, funding programmes, studies, reports, workshops, conferences and other actions have been launched and organised in order to communicate with and support Member States, politicians, stakeholders from the health sector and industry, patients, health professionals etc. in this issue.

Several reports and studies on eHealth have demonstrated the advantages, efficiency gains and cost-savings that are achievable by implementing technology and digitalising the systems and work processes in the health system. The EC has for years guided Member States and produced strategies for this area. Although eHealth to a large extent is the responsibility of the national, regional or local health systems, then the challenges as well as the possibilities are not isolated to one country or region alone but symptomatic to most health systems in Europe and these can learn from each other and achieve progress through an overall frame and collaboration (http://ec.europa.eu/information_society/activities/health/whatis_ehealth/index_en.htm).

In 2004 the eHealth Action Plan was adopted by the EC in order to facilitate a more harmonious and complementary European approach to eHealth (Commission Communication:eHealth – making healthcare better for European Citizens: An action plan for a European eHealth area COM/2004 356 final). eHealth was also an integral component of the EU's i2010 policy framework established in 2005 for promoting the positive contribution that information and communication technologies (ICT) can make to the economy, society and personal quality of life (Commission Communication: i2010 – A European Information Society for growth and employment. COM/2005/0229 final). More eHealth plans followed in the following years – the Lead Market Initiative (Commission Communication: A lead market initiative for Europe. COM/2007/856) identified eHealth as an area for focus and initiated policy tool – and further established eHealth as a key area and as having high priority with the EC. The EU2020 strategy (Commission Communication: EUROPE 2020: A strategy for smart, sustainable and inclusive growth. COM(2010) 2020) and the recently adopted Digital Agenda for Europe (Commission Communication: A Digital Agenda for Europe. COM(2010)245 final) have build on what has been achieved in the past and are restating the commitment of the EU to bring forward eHealth in Europe.

eHealth is a broad definition of the use of ICT in health and it often deals with the overall frame as interoperability, electronic communication between institutions and sectors using standards, IT systems and utilisation hereof (Electronic patient records (EPR), Radiology information systems (RIS), Picture and Archiving systems (PACS) Health information systems (HIS) etc). Telemedicine is a sub-area to eHealth and specifically concerns the delivery of healthcare services through the use of ICT in a situation where the actors are not at the same location. The actors can either be two health care professionals (for example in teleradiology) or a health care professional and a patient (for example in telemonitoring of patients with diabetes).

The EC is a strong supporter of telemedicine and sees it as one of the important mechanisms available to the Member States when addressing the challenges they all are facing as their populations become older and suffer from more chronic diseases, the supply of human resources to the sector is decreasing – both the general care as well as specialist resources, and the healthcare systems tend to centralise in bigger geographical units thus leaving citizens in rural areas with longer distances to the nearest hospital (Commission Communication: Telemedicine for the benefit of patients, healthcare systems and societies, COM 2008/689 final). This conclusion is generally supported in the health and research sector (COCIR Position Paper - For a better deployment and use of telehealth (2010), Hjelm NM (2005)).

Nevertheless over the years in which telemedicine has been budding, the EC has observed that despite the benefits and the maturity of the technology, we are still not witnessing a wide use and implementation of telemedicine services anywhere in Europe. Only small scale services that are not integrated into the local healthcare systems dominate the scene and the large scale implementation that will truly make a difference and fully explore the benefits of telemedicine are still missing.

Under the title Telemedicine and innovative ICT tools for Chronic diseases management, the EC launched in 2007 several actions with the intent to gather the necessary knowledge on the matter and to understand the perspectives of the different stakeholders in the area. The 'TeleHealth 2007' conference and the 'Telemedicine and innovative ICT tools for Chronic diseases management High Level Consultation Workshop with Industry' are the main inputs to the Consultation (Commission. TeleHealth 2007: Telemedicine and innovative technologies for chronic disease management (2008), Commission. High Level Consultation Workshop with Industry on Innovative ICT tools and Telemedicine services (2008)). Both events addressed specifically the question of why telemedicine has not been more widely deployed - despite the many projects focusing on developing and testing telemedicine applications in the different Member States and globally and discussed what the main barriers are and how to overcome them.

As a result of the work on Telemedicine and innovative ICT tools for Chronic diseases management, the European Commission issued on November 2, 2008, a Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on 'Telemedicine for the benefit of patients, healthcare systems and society' (COM/2008/689 final). The purpose of the Communication was to raise awareness of the potential of telemedicine and to define a set of actions to be taken by the Commission, the Member States and broader stakeholder community in order to ensure a progressing understanding and use of telemedicine in healthcare delivery.

Consequently, actions needs to be taken and a list of concrete actions are at the core of the Communication. Three overall goals categorise them:

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

The actions are as much the responsibility of the Member States as they are of the European Commission since the countries are themselves responsible for the organisation and provision of healthcare services. Therefore the actions are based on an ongoing collaboration between the Member States and the European Commission as part of Commission policy initiatives. All three goals are considered essential for achieving the benefits of telemedicine and they are interlinked, i.e. legal clarify is fundamental for confidence and acceptance. However, in relation to this report only the goal to build confidence in and acceptance of telemedicine services and the actions linked to it will be discussed, as it is directly tied to the MethoTelemed study.

*Building confidence in and acceptance of telemedicine services*
The Communication concludes that the existing evidence of the effectiveness and cost-effectiveness is based on too small datasets, poor quality in research and none of the scientific evidence is derived from large scale settings. Hence, we are at present not able to make clear statements on the effectiveness and cost-effectiveness of applications, which is a considerable obstacle to the further implementation of telemedicine. Therefore, the Communication encourages to further develop commonly accepted methodologies that are used in e.g. the pharmaceutical industry for assessing

effectiveness. It also states that not until large scale (e.g. high number of patients and length of trial) projects have been assessed, will it be possible to see and informatively evaluate all the found outcomes.

Two proposed actions are intended to contribute to building confidence and raising awareness (Commission Communication: Telemedicine for the benefit of patients, healthcare systems and societies. COM/2008/689 final, p.7):

- *The Commission will support the development, by 2011, of guidelines for consistent assessment of the impact of telemedicine services, including effectiveness and cost-effectiveness. This will be based on the work of experts in the field, Commission-supported studies, large scale pilot schemes and relevant research projects.*

- *In 2010, the Commission via its Competitiveness and Innovation Programme, will support a large scale telemonitoring pilot project. This will include a network of procurers and payers of healthcare services.*

Ultimately, the goal of these actions is to ensure "confidence and acceptance of telemedicine solutions by health professionals, patients and health authorities" (Commission Communication: Telemedicine for the benefit of patients, healthcare systems and societies. COM/2008/689 final, p.7). As a direct result of the first action a tender on 'Methodology to assess telemedicine applications' (Commission: Methodology to assess telemedicine applications. SMART 2008/0064 – O.J.2008/S 107-14255) was published. It is on the basis of this that MethoTelemed was formed and ran from February 2009 till January 2010. The second action was initiated in the Competitiveness and Innovation Programme (CIP) ICT PSP Work Programme 2009 (Commission: Competitiveness and Innovation Framework Programme (CIP), ICT Policy Support Programme, ICT PSP Work Programme 2009).

**Scientific background**

In preparing for the tender for the MethoTelemed project a review of literature on assessment of telemedicine applications, also concluded that irrefutable evidence regarding the positive impact of telemedicine on clinical outcomes still eludes us (MethoTelemed (2008)):

- A review of more than 150 articles concluded that *potential* effectiveness could only be attributed to teleradiology, telepsychiatry, transmission of echocardiographic images and consultations between primary and secondary health providers (Roine et al (2001).
- Another systematic review that assessed more than 1300 papers making claims about telemedicine outcomes found only 46 publications that actually studied at least some clinical outcomes (Hailey et al (2002)).
- Another review analyzed the suitability of telemedicine as an alternative to face-to-face care and concluded that establishing systems for patient care using telecommunications technologies is feasible; however, the studies provide inconclusive results regarding clinical benefits and outcomes (Currell et al's (2002)).
- A study which explored cost effectiveness of interventions concluded that there is no good evidence that telemedicine is or is not a cost effective means for delivering healthcare (Whitten et al (2002)).

The quality of studies is a returning concern in reviews and there is debate about appropriate methodologies and techniques for research. For example one review find that economic analysis of

telemedicine has not yet met accepted standards (Whitten et al (2002)); another suggest that many existing studies have not been well-designed (Hersch et al (2001, 2006)); a third stated that considering perceived difficulties of building a robust evidence base for recent innovations suggest that simulation modelling needs further development (Barlow et al (2005)). Last but not least one review calls for the development of an ‘evaluation template’ in the field (Barlow et al (2006)).

## 2. Methodology

This section describes the methods used in the workshops and the literature review that constitutes the basis for the development of the model for assessment of telemedicine applications.

### 2.1. Workshops with users and stakeholders

Workshop is a participatory and interactive method intended to inform, raise awareness and stimulate visioning and discussion through a proactive involvement of the participants. A workshop can be described as a pedagogical tool for establishing a creative process in which a creating interaction between the participants is taking place. The 'process of thought' is an essential part of workshops and can be brought about through different process techniques or using 'manipulatives' such as concrete objects or cases for stimulation. This will help the participants to process the information received, apply the knowledge they have to it and discuss it openly with others. Workshops are well suited for situations where there are not a high number of participants and the impact of it will be considerable if the participants consist of targeted stakeholders.

The main roles in workshops are the facilitator (the person(s) in charge of applying the techniques chosen and facilitating the process according to these) and the participants (the people invited to the workshop because of their knowledge, function etc. and who it is believed can contribute to the event).

In MethoTelemed, high priority was given to actions that helped us engage in discussions with stakeholders. In order to do so, we hosted together with the European Commission two workshops where we would create an environment in which they could apply their process of thought for the benefit of our study and work and we would be able to create results in collaboration with them (see all the participants in appendix 2).

In both workshops, we used a technique named "Brown Paper" and used two case presentations as manipulatives. The Brown Paper is a technique which is widely used and its force is its ability to help any group to collect its ideas and topically organise its thoughts. It is a kind of device for reducing topics and grouping ideas. The Brown Paper also allows workshop participants to contribute and explain their individual ideas.

A typical Brown Paper session could be:

- Each participant is given some post-its or pieces of paper (different colours might be used depending on the number of group elements to be achieved).
- Working individually participants fill in the post-its then stick them on the Brown Paper, which is a large piece of brown paper covering the surface of one of the walls of the meeting room.
- When the flow of contributions slows or when the time is up, the facilitator encourages the participants to group the post-its, either against criteria set by the participants, or against the criteria set by the resources themselves.
- The facilitator helps the group to analyse the results which have just been produced and might then re-group the post-its if needed.
- The facilitator and participants agree on the results that can be used for further analysis or as the subject of a new Brown Paper.

## 2.2. Systematic literature review

In the design of the systematic literature review the topics in the PRISMA checklist has been used give structure to the project.

The *rationale* of the review was, as described in section 1 that assessment studies of telemedicine to date are not of high quality, are using questionable methodologies and techniques, or have a narrow focus thus disregarding other important outcomes.

On the basis hereof the *objective* of the systematic literature review was to conduct a thorough review of reviews on impacts and costs of telemedicine services, consider qualitative and quantitative results, and explicit and implicit methodologies with the purpose of synthesizing proposals for further research methodologies. The review should include a specific focus on the use of health technology assessment (HTA).

The questions to be addressed in the review are, based upon systematic reviews:

1. How are telemedicine services defined and described in terms of (a) participants, (b) interventions, (c) comparisons, (d) outcome measures
2. What are the reported effects of telemedicine?
3. Which methodologies were used to produce knowledge about telemedicine in studies included?
4. What are the strengths and weaknesses of these methodologies, including HTA methodologies?
5. What are the knowledge gaps and what methodologies can be recommended for future research?

A review *protocol* was also produced (available at http://www.telemed.no/methotelemed immediately after the publication of the results).

With regard to *eligibility criteria* articles describing reviews from 2005 and onward was included. In the project systematic review was defined as an overview with an explicit question and a method section with a clear description of the search strategy and the methods used to produce the systematic review. The review should also report and analyse empirical data.

Participants in the articles included: patients and consumers, health professionals and family caregivers, regardless of diagnoses or conditions.

Articles regarding the following interventions were included: All e-health interventions, information and communication technologies for communication in health care, Internet-based interventions for diagnosis and treatments, and social care if important part of health care and in collaboration with health care for patients with chronic conditions were considered relevant.

There was no language restriction on the project.

The following *information sources* data sources was included:

- ACM Digital Library
- Social Services Abstract (CSA Illumina, Cambridge)
- Cochrane Library
- ComAbstracts
- Cumulative Index of Nursing and Allied Health Literature (CINAHL)
- EconLit
- Embase
- ERIC (CSA Illumina, Cambridge)
- International Bibliography of the Social Sciences
- Medline
- PsycInfo
- PychLit
- Pubmed
- Science Direct
- Sociological Abstracts (CSA Illumina, Cambridge)
- TIE
- Web of Knowledge (Science Citation Index, Social Sciences Citation Index)

A *search strategy* was produced (available at http://www.telemed.no/methotelemed immediately after the publication of the results).

*Study selection* was made by two reviewers independently screened the lists of titles/abstracts identified in the literature searches, and identified potentially relevant studies. The basis for the selection was the criteria for inclusion and exclusion. The two reviewers independently screened the lists of titles/abstracts identified through searches for systematic reviews. The potentially relevant systematic reviews were retrieved in full texts.

The *data collection process* was made by use of a data extraction form and the data collection was done online. Each potentially relevant systematic review was assessed in full text by one member of the expert team. A revised check list from EPOC (Cochrane Effective Practice and Organisation of Care Group) was used to assess the quality of the systematic reviews. The quality domains assessed according to this checklist were methods used to identify, include and critically appraise the studies in the review, methods used to analyse the findings and an overall assessment of the quality of the review. One member of the review team checked for agreement regarding the inclusion and exclusion criteria.

The data extraction from and the full list of data items are available at http://www.telemed.no/methotelemed immediately after the publication of the results.

With regard to *data items* collection of data was made for type of participants, interventions and outcomes included in the reviews. Other data items were: Geographical coverage of review, time frame of included studies, range of data collection methods used in studies included in the reviews, disciplines/areas covered and methodological traditions included in the review. The reviewers were also asked to indicate emerging issues identified by the authors of the reviews.

The members of the expert team assessed the *risk of bias in the individual studies* by assessment of quality of the systematic reviews, including questions regarding the degree to which the systematic reviewers had assessed risk of bias in individual studies.

The review team analysed the data collected by the members of the expert team. Due to the expected heterogeneity of studies, both regarding participants, interventions, outcomes and study designs there was not used quantitative *summary measures* of the results. In stead a qualitative and narrative summary of the results of the systematic reviews was made.

> In order to produce a *synthesis of the results* identification was made of the theoretical positions behind various methodologies in order to analyze the use of methodologies in the reviews. A qualitative synthesis was carried out using analytical concepts described in a later section of the report.

To reduce the *risk of bias across studies* exclusion was made of systematic reviews with major limitations. Assessment was also made of the quality of studies in the field of telemedicine, based on the assessments of the included reviews, and based on the review authors' assessments of risk of bias in the primary studies.

No *additional analysis* was planned, but qualitative analyses was performed both regarding the effects of the telemedicine interventions examined in the included reviews, and of the methodologies used in the identified reviews and primary studies.

# 3. Results

## 3.1. Results from workshops

*Workshop 1*
In June 2009 a workshop with 20 stakeholders and users of telemedicine was arranged with the purpose of gaining knowledge of the needs for documentation and evidence to simplify the decisions on whether or not to use telemedicine applications. In the workshop the EUnetHTA HTA Core Model (see Lampe et al. (2009), Kristensen et al. (2009A) and Kristensen et al. (2009B)) was used as a starting point and a number of adjustments were requested. Firstly, it was pointed out that an assessment should start with a strategic consideration of the level (local, regional, national) at which the assessment should be carried out. Among the questions to be answered is: Are legislation, organization and reimbursement in place for a local assessment to be made, or should the assessment be made at the regional or national level?

Secondly it was requested that the model should have special focus on a number of specific aspects of telemedicine. These were for example:

- The economic sustainability (return on investment) for the institution using telemedicine
- The patients' perception of the telemedicine application and the effects
- Safety aspects
- Effects on workflow and co-operation between primary and secondary care
- Ethical and legal aspects of telemedicine

Finally the transferability of results from an assessment of telemedicine, e.g. when going from small scale to large scale, was discussed and pointed out as a subject to be considered in new assessments.

The workshop process and the results from workshop 1 are described in detail and available as a report (http://img7.custompublish.com/getfile.php/1023659.357.bbbrftaxqx/MethoTelemed-Users_needs-Report_on_the_results_of_Workshop_One.pdf?return=telemed.custompublish.com).

*Workshop 2*
The second workshop was held in November 2009 with 20 stakeholders and users of telemedicine. The purpose was to present to first draft of the model including the content of the domains and to discuss and validate the model.

The participants gave a large number of comments to the model. The mains comments are summarised below:

- The purpose of the model should be clearer, e.g. the term model should be defined and potential users should be described.
- The description of the purpose of the telemedicine application should be part of the preceding consideration and separated from the first domain.
- The proposed 7 domains were generally considered relevant, although all domains need to be developed further, especially safety, economics and organization.
- Inclusion of examples of outcome measures for each domain would strengthen the description of the model.
- Potential outcomes for the relatives of the patients using telemedicine, e.g. effects on the relative's time spent helping and assisting the patients should be included.

- The possibility of using the EUnetHTA HTA Core Model as it is should be considered.
- The development of new telemedicine applications is a dynamic process and involves an element of time. Before studies of the clinical, economic and patient related outcomes of telemedicine can be initiated, other studies of safety and technical feasibility must be done.
- Assessment of transferability should focus on the assessment of the transferability of results from other studies to the specific situation or setting in which use of a telemedicine application is planned.

As mentioned one of the main outcomes of the workshop was a confirmation from the stakeholders of the relevance of dividing the different aspects or outcomes of telemedicine applications in 7 domains. There is no strong scientific argument for the use of the 7 domains and the main reason for the division is that it is practical and that the aspects or outcomes within each domain are similar and can be assessed by use of similar methods. This issue is examined further in the discussion in section 4 of the relations between MAST and other models for assessment of telemedicine.

The workshop process and the results from workshop 2 are described in detail in a report (http://www.telemed.no/getfile.php/1281280.357.spxarssvax/MethoTelemed%20Validation%20Report_v%5B1%5D.final.pdf ).

### 3.2. Results from the literature review

In March 2009, a search for reviews of reviews of telemedicine assessments from 2005 to the present resulted in 1486 hits. In addition, a follow up search for review papers was accomplished in July 2009, which resulted in 107 new hits. In total 1593 abstracts were identified. Two individual reviewers reviewed the abstracts. In the end 80 systematic reviews were included for full text analysis.

Based on these reviews the evidence for telemedicine application for different patient groups has been described by Anne Granstrøm Ekeland and Alison Bowes. The results are presented in detail at http://www.telemed.no/methotelemed.

With regard to the gaps in the evidence for telemedicine and the need for further research the preliminary results were:

- The majority of studies reviewed were quantitative outcome/effect studies.
- More studies with standardized interventions, larger numbers of coherent participants and more standardized assessment tools (better RCTs and health technology assessments (HTA)) and outcome measures were generally reported throughout.
- Very few reviews reported from qualitative studies.
- The need for qualitative and formative research.
- Need for studies including the ongoing change in interventions
- Need for exploring attitudes/motivations from service providers
- Need for studies including individual preferences that affect use and quality
- Need for studies to include more diverse patient populations
- The need to explore differences between groups in service utilization
- Cultural diversities in adoption patterns
- Ethical issues in homecare

These were presented at the second workshop (http://img7.custompublish.com/getfile.php/1034627.357.perpaebews/Preparations+from+the+Research+Team.pdf?return=www.telemed.no).

The systematic review has resulted in two articles on the methodologies for assessing telemedicine applications and the effectiveness of telemedicine, Ekeland et al (paper under review).

However, the literature found in the review has been included in the development of the model described in section 3.3. both as a basis for the overall description of the model and as examples of measurement of the different outcomes of telemedicine applications, see section 3.3.6.1-7.

### 3.3. Model for assessment of telemedicine - MAST

#### 3.3.1. Definition of the assessment

As the described in section 1.2. about the scientific background of the project and in section 3.2. about the results from the literature review, different kinds of quantitative and qualitative methods have been used in assessment of many different sorts of outcomes of telemedicine applications. These differences in outcomes and methods for data collection reflect mainly that assessments are made and used for various purposes.

Similarly, the definition of a new structured framework for assessment of telemedicine applications should also use the purpose of the assessment as the point of departure.

Therefore, based on two workshops with stakeholders the MethoTelemed project has found that - if the purpose of an assessment of telemedicine applications is (1) to describe effectiveness and contribution to quality of care and (2) to produce a basis for decision making, the relevant assessment of telemedicine should be defined as:

> A multidisciplinary process that summarizes and evaluates information about the medical, social, economic and ethical issues related to the use of telemedicine in a systematic, unbiased, robust manner.

The main concepts in the definition are the terms “multidisciplinary” and “systematic, unbiased, robust”. The first term means that the assessments should try to include all important outcomes of telemedicine for the patients, clinicians, health care institutions and for society in general. The following terms imply that assessments should be based on scientific studies and methods and on scientific criteria for quality of evidence.

The above definition is based on the definition of HTA in the EUnetHTA project, see Lampe et al. (2009), Kristensen et al. (2009A) and Kristensen et al. (2009B). The main reasons are:

- That HTA also has the purpose of informing policy making for technology in health care, by assessment of the direct and intended consequences of technologies as well as their indirect and unintended consequences, as described by e.g. Goodman (2004). Thus, HTA also aims to produce a basis for decision making.
- HTA is a familiar concept to stakeholders in the EU, national health authorities, industry, academics and health professionals.
- The EUnetHTA Collaboration, the EU Member States and the European Commission are currently working on the implementation of the EUnetHTA HTA Core Model in the EUnetHTA Joint Action (see www.eunethta.eu). Currently core models exist for diagnostics and medical and surgical interventions. However, a core model for telemedicine could be a future product from the EUnetHTA Collaboration. By using the core model terminology and structure, the MAST can be an important starting point for a future EUnetHTA HTA Core Model for telemedicine and thereby prepare the way for one common model for assessment of telemedicine in the EU countries.

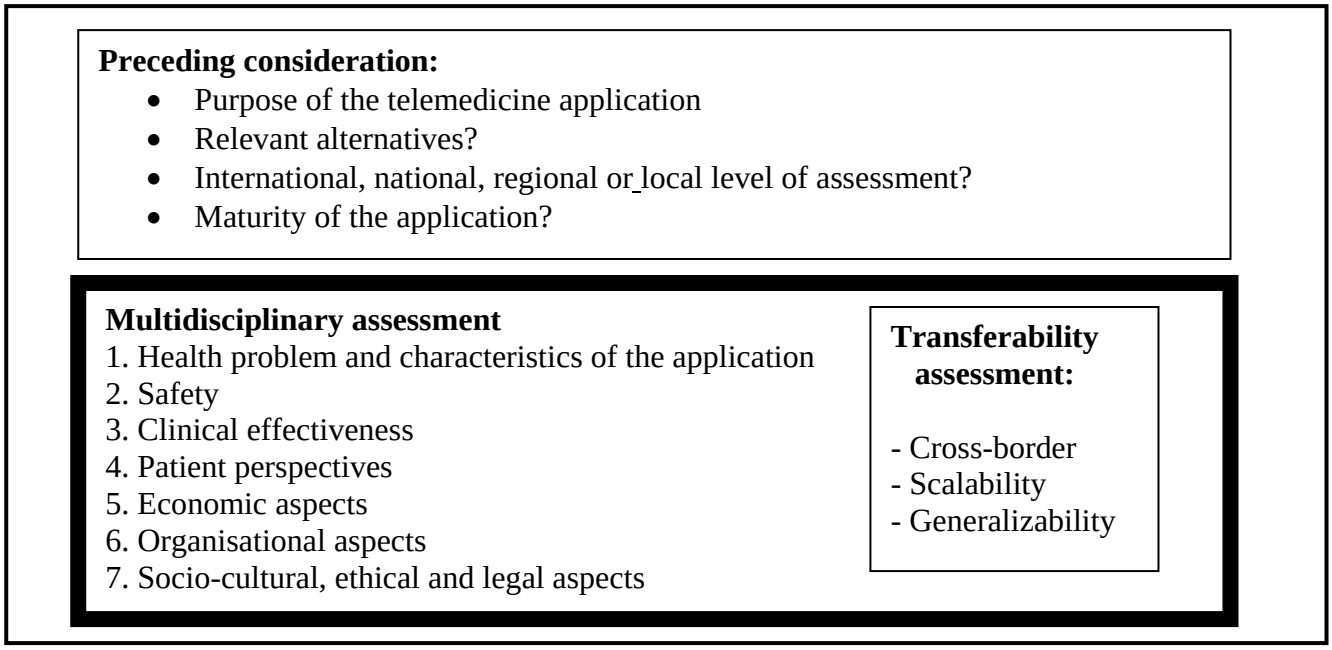
I section 4 the relation between MAST and the EUnetHTA HTA Core Model and other methodologies for assessment of telemedicine applications is discussed.

#### 3.3.2. The elements in MAST

The figure below presents the different elements in the model for assessment of telemedicine, subsequently called MAST.

When using the model the assessment should start with a number of preceding considerations. The main focus should be on the determination of (1) the purpose of the telemedicine application, (2) the relevant alternatives that should be compared in the assessment, (3) the level in the health care system (local, regional, national) at which the assessment should be produced and (4) whether the telemedicine application is a mature technology.

**Figure 1: Elements in MAST**




After the preceding assessment the multidisciplinary assessment is carried out in order to describe and assess the different outcomes and aspects of the specific telemedicine application. As shown in figure 1, the different outcomes can be divided into 7 groups or domains. This division of the outcomes is based on the EUnetHTA HTA Core Model, see Lampe et al. (2009) and results from the two workshops with stakeholders. The domains are described further in section 3.3.6.

In relation to the description of the outcomes an assessment should also be made of the transferability of the results found. If the assessment of a telemedicine application is based partly on results from a systematic literature review, this mainly includes an evaluation of whether the results can be transferred to the local context. Issues like cross border transfer of results, scalability of results e.g. from small scale to large scale and generalizability of results can be included in the assessment of the results found in the literature, see section 3.3.7.

### 3.3.3. The aim of MAST

As described above the aim of this model for assessment of telemedicine is to provide a structure for assessment of effectiveness and contribution to quality of care of telemedicine applications which can be used as a basis for decision making. In other words the aim is that clinical, administrative and political decision makers in hospitals, communities, regions, government department etc. will use the model as a structure for the description of the outcomes of telemedicine

and as an important basis for decisions on whether or not to implement telemedicine services in the health care systems.

Similarly, the producers of telemedicine, the biotech industry, can use MAST as a structure for description of the outcomes of their products for patients, hospitals etc.

It is the overall aim that MAST will improve the possibilities for decision makers to choose the most appropriate technologies to be used in the most cost-effective way by providing a multidisciplinary assessment based on scientific methods and results.

In this context the term assessment model here is understood as a structure of aspects or outcomes of telemedicine applications that should be included in a certain order (with the preceding considerations before the multidisciplinary assessment) in the assessment of the applications.

It should be noted that even though MAST can be used generally and by many kinds of decision makers as the basis for decisions on whether or not to introduce a new telemedicine application, MAST is limited by focusing only on the prerequisites for and consequences of use of telemedicine application. Therefore use of MAST does not result in information on why telemedicine works. This information needs to be produced in other kinds of scientific studies. Similarly the model does not include description of the processes when implementing the application. As an example information about how nurses can be trained in the use of a telemedicine application will not be included, even though the time and cost needed for trained is a relevant part of an assessment based on MAST. This kind of information about the process of implementation must be produced by using other kinds of assessments as described in the MethoTelemed Guidance.

### 3.3.4. How to use MAST and the MAST Toolkit?

As described in the section above, MAST can be used in three ways:

1. As a model for design of new studies of telemedicine
2. As a checklist for inclusion of domains and outcomes in new studies of telemedicine
3. As a model for an assessment based on literature reviews and other existing information on the specific telemedicine application

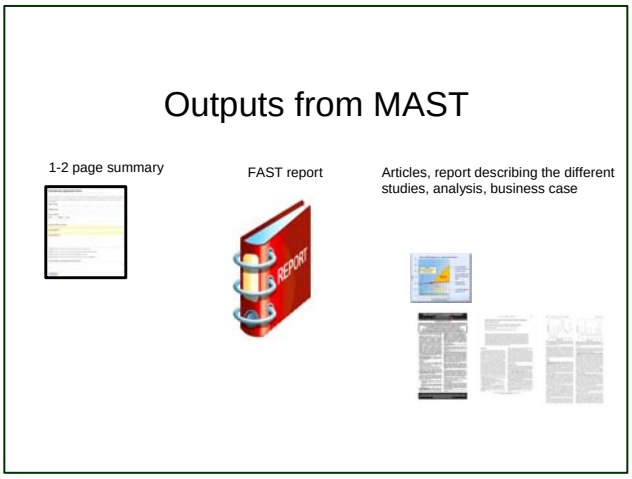
MAST can be used as the basis for design of new studies of the outcomes of telemedicine applications. In the description of the domains suggestions for topics, methods for data collection and examples of specific outcome measures can be found.

It is important to notice that only domains and outcomes that are expected to be relevant and an important part of the outcomes of the specific telemedicine application should be included in an assessment.

The description of outcome measures used in empirical studies of the effects of telemedicine applications in the appendix can also be used as a checklist in the design of new studies. Therefore a MAST Toolkit has been developed. The toolkit provides decision makers and users of telemedicine with checklists for each of the 7 domains describing outcome measures that have been included in other primary studies of the effects of telemedicine applications. The toolkit can be used e.g. as the basis for decisions on which measures of outcome that should be included in new empirical studies. The MAST Toolkit can be downloaded at www.telemed.no/methotelemed

In the latter use, MAST resembles a checklist for the assessments of telemedicine based on existing studies. In this way hospitals and other institutions can use MAST to gain an overview of their knowledge and the level of evidence with regard to the different outcomes of a specific telemedicine application by going through the different domains and topics and try to answer the most relevant questions based on the highest possible level of evidence

It is also possible to combine the different approaches e.g. by using existing studies to describe the safety of the application and by starting new studies of the organizational outcomes locally.
If the model is used as the basis for new studies on the effects of telemedicine, the main output will be a number of studies presented in e.g. articles in scientific journals. The results from the studies can also be put together in a larger report describing the purpose, methods and results from the different studies and combining the evidence. Finally, the results can be summarized in a 1-2 pages small report or policy brief to be used as a basis for decision makers in e.g hospital board meetings.




### 3.3.5. Preceding considerations

Before a health care institution e.g. a hospital begins assessing the different outcomes of a telemedicine application it is important that a number of preceding considerations are made in order to determine whether it is relevant for this institution to do the assessment at this point in time. This point was one of the main results from the workshops with stakeholders (http://img7.custompublish.com/getfile.php/1023659.357.bbbrftaxqx/MethoTelemed-Users_needs-Report_on_the_results_of_Workshop_One.pdf?return=telemed.custompublish.com). First it is important to determine the aim of the telemedicine application and relevant alternatives to which the application must be compared in the assessment.

The description of the aim of the telemedicine application should include description of the patients, their health problem and the aim of using the technology. Thus, it should be described how this telemedicine application is expected to be an improvement compared to other technologies used for the same health problem. This is important, since these aims determine the primary outcomes that should be included in the assessment.

It is also important to describe the alternatives to which the telemedicine application should be compared. In general the comparator will be status quo, i.e. the treatment used so far. However,

making comparisons with an improved or upgraded system or other technologies should also be considered.

Secondly, as a minimum the following conditions need to be considered:

- Does the telemedicine service fit into the existing legislation?
- Is the telemedicine service reimbursed?
- How mature is the telemedicine application?
- What is the relevant number of patients expected to use the application?

**Legislation**
Before the introduction of a new telemedicine service by e.g. a hospital, the hospital must assess whether the implementation of the application is in accordance with national and regional legislation (it is assumed that national and regional legislation is in-line with the relevant EU level legislation). These issues would include **legislation regulating medical care provision** (is care at a distance allowed, does it require a pre-existing relationship between healthcare provider and patient); **accreditation systems for care providers** (are there special rules about accrediting telecare providers); **liability for care provision** (do current rules of liability include providers outside the physical control of the primary care providers), and other relevant issues.

The MAST model provides an outline for assessing if these issues are potential barriers to the implementation of the proposed telemedicine service, and indicates that these issues must be addressed before a full analysis of the appropriateness of a given telemedicine solution can be made

**Reimbursement**
Reimbursement refers to the amount of money that national or regional health authorities' and insurance bodies pay to e.g. hospitals or general practitioners for their services. For many hospitals reimbursement is determined nationally as a number of DRG-rates (Diagnose Related Groups) which are paid fully or partially to the hospital for each medical or surgical procedure performed. In some cases telemedicine does not change the DRG-rate of a service, but in other cases e.g. when a patient stays at home and has contact to a nurse or phycisian by use of a telemedicine application, the DRG-rate of the service is reduced. In some cases there is no DRG-rate for telemedicine services.

This has a significant impact on the result of the economic analysis of telemedicine applications and should therefore be considered before an assessment is initiated. If reimbursement is a problem, it should be considered to let the national health authorities produce the assessment. Another possibility is to involve national institutions e.g. The National Board of Health in the production of the assessment with the purpose of using the assessment report as the basis for changing reimbursement.

**Maturity and timing**
The development of telemedicine applications takes time. This is not different from the development of new pharmaceutical products which often takes 10-15 years to develop before the product is ready for the market. Therefore evaluation of telemedicine application must consider the maturity or phase of development of the application, as described as one of the main findings in a review by The Lewine Group (2000).

Taylor (2005) has pointed out that evaluation of telemedicine should first try to establish that it is safe. After this has been demonstrated, evaluation can be made of the feasibility or practicality e.g. describing how telemedicine can be implemented in practise in qualitative studies. Finally, after establishing the safety and feasibility, an evaluation can be made of the effectiveness of telemedicine in order to determine whether the application is worthwhile. Thus, only in this phase of the development of the application studies of the outcomes can be carried out in summative studies.

Before an assessment of the outcomes of telemedicine is initiated it is therefore important to determine whether the telemedicine application is ready or mature. If the application is still being developed and still needs to be improved, an assessment of the outcomes by the use of MAST should not be started. Instead other kinds of assessments should be carried out, e.g. in formative studies (http://img7.custompublish.com/getfile.php/1034627.357.perpaebews/Preparations+from+the+Research+Team.pdf?return=www.telemed.no). If an assessment of the outcomes of a telemedicine application is started too soon, the assessment will not be able to show the full potential of the technology.

Similarly, Drummond et al. (2008) have described the frequent modification of new devices as a general problem in design of the economic evaluation of medical devices. They argue that if the development of a new device is not in a substantial “steady-state” period, an evaluation based on a RCT can be problematic. This underlines the point, that the maturity of the telemedicine should be considered before MAST is used as the basis for an evaluation.

**Number of patients**

Implementation of telemedicine often involves large investments in equipment and in integration with other information systems. Often it is also necessary to educate clinical staff in the use of telemedicine and to change the organization and planning of work. Because of this the fixed costs of implementing telemedicine are often substantial. It is therefore very important that assessment of telemedicine applications includes a large number of patients, because this makes it possible to approximate the estimated costs to the cost in real life use of the technology. In practice this means that the sample size in the clinical studies cannot only be based on the number of patients needed to estimate the effects on a certain clinical outcome. It also means that if e.g. a hospital does not have enough patients per year with the relevant characteristics, cooperation must be made with other hospitals in order to be able to test the application on the required number of patients.

### 3.3.6. The domains in MAST

In this section the content of the 7 domains in the multidisciplinary assessment is described in detail. For each domain the content is defined and the different topics are listed. Topics are here defined as issues within the domain that it is desirable to assess. The description of the similar domains in the EUnetHTA HTA Core Model for interventions (2008) is used as the point of departure for the description of the domains in MAST (see also Lampe et al. (2009)).

The description of the 7 domains also includes the results from the systematic literature review. Results from studies that specifically discuss outcomes or provide instructive comments within each domain are briefly described below.

In the appendix each domain is described further with regard to topics included, issues related to transferability, methods for data collection and examples of outcomes measures used in assessments of telemedicine for diabetes, heart failure and COPD. Thus, the outcome measures are examples of how the different (theoretical) topics can be measured empirically either in quantitative or qualitative terms.

The examples of outcome measures are mainly from a large review on "Home Telehealth for Chronic Disease Management" by Tran et al. (2008). This review is based on a systematic review of articles published from 1998 to 2008 (with no language restrictions) on home telehealth for patients with diabetes, heart failure and COPD. By search in a large number of relevant databases 6.236 articles were identified and from these 79 reports were included.

#### 3.3.6.1. Health problem and characteristics of the application

This domain includes description of the health problem of the patients expected to use the telemedicine application and description of the application being assessed. These two issues are included in one common domain because the description of the patients and the telemedicine application serve as an overall description of the background for the assessment

The following descriptions of the topics are based on the corresponding description of the domains in the EUnetHTA HTA Core Model for interventions (2008) p. 38-39 and 53.

The topics within this domain include the epidemiology of the target health problem, the burden – both on individuals and on society – caused by the health problem, the regulatory status of the telemedicine application and the requirements for its use.

The description of the current status of the telemedicine application provides a baseline description which is a useful starting point for other parts of the assessment. It also provides information relevant for the construction of economic and/or organisational models in order to assess the impact of, for example, the introduction of a technology, the promotion of its utilisation, etc. It is thus an important part of the assessment. Dealing with the issues included in this domain at the early stages of an assessment is also needed in order to refine the research questions (e.g. choosing relevant outcome measures) and to formulate the methodological approach to be taken in other domains of the assessment.

To some extent elements of this domain will overlap with elements of the economic domain (e.g. costs of target health problem), organisational domain (e.g. conditions for implementation, patterns of use). Thus, the elements described in this section of the core model are not to be understood as

obligatory chapters of an assessment. They represent information pieces which are needed when conducting an assessment.

The second part of this domain is a description of the technical solution that will be used in providing the service. The aim of this part of the assessment is to provide the decisions makers with a description of the application, the features that are available, needs for training resources, division of responsibility between organisation for the technical solution and support systems etc. It must also deal with the questions about the maturity of the telemedicine application and the market situation, e.g. how robust are the providers in the market.

The other part of the technical assessments deals with the technical characteristics of the telemedicine application. This includes issues like the need for infrastructure and must include all organisations involved and the need for a common infrastructure, interoperability that is the integration needs with regards to other clinical of administrative systems like electronic healthcare records, patient administrative systems, clinical databases, other applications etc. The assessment must also include a description of the need for user support, help disk functions and back-up systems and procedures.

It should be noticed that telemedicine applications are complex interventions involving many stakeholders and participants. The detailed description of the application and the technical characteristics in this domain is therefore an important part of the full description of the application being assessed that will enable other institutions considering use the application to replicate and make a synthesis of the evidence.

**Results from the MethoTelemed literature review**

The review, Ekeland et al. (paper under review), shows that even the descriptions of the telemedicine applications are not standard in the literature and that there is a need for standardisation of what to include in the description of the health problem and the telemedicine application.

**Topics**
This domain includes the following topics:

- Health problem
- Description of the application
- Technical characteristics

### 3.3.6.2. Safety

Safety is here defined as the identification and assessment of harms. As an example the use of telemedicine application can potentially result in wrong diagnostic and management decisions that could harm the patient.

With regard to telemedicine applications issues of safety are here divided into clinical safety and technical safety on the basis of the results from the workshop with stakeholders, see section 3.1.

Clinical safety includes mainly the assessment of harms for the patients using telemedicine, based on a description of the types of harms, their incidence and severity.

On the other hand technical safety includes issues related to the technical reliability of the telemedicine application. This involves assessment of potentials with backup, interference and security of data.

It should be noted that patient safety and clinical safety are highly related. As an example problems with the technical reliability of the telemedicine application may results in wrong decisions made by the clinical staff and this could harm the patient. However, in the presentation of collected data on safety it can be practical to divide the data in to information about either patient safety and information about more technical issues.

Issues related to liability and responsibilities of patients and members of the clinical staff etc. are described in the section below on the domain including legal aspects (see section 3.3.6.7)

As described by Taylor (2005) the purpose of studies of safety of telemedicine applications is generally focused on the clinical safety and can be divided in two:

- Studies with the purpose of showing that using telemedicine does not result in disadvantage of interpretation of the information of interest compared to conventional methods, or
- Studies with the purpose of showing that the overall process of management by telemedicine does not disadvantage the patient compared to care delivered by conventional means.

Further recommendations for description of safety can be found in EUnetHTA (2008) and in The Cochrane Handbook for systematic reviews of interventions.

**Results from the MethoTelemed literature review**

In the review, Ekeland et al. (paper under review), a number of articles considering safety of telemedicine applications and the need for inclusion of unintentional consequences and side effects were found:

- Clarke and Thiagarajan (2008) focus on technical evaluations, and find no available standards-based evaluation framework. Their discussion considers technical issues such as the quality and reliability of transmission. They identify a number of papers that suggest good practice, but call for development of a framework that can become a standard.
- Crosbie et al (2007) look at side effects of technology – virtual reality use in stroke rehabilitation can induce feelings of sickness or dizziness. This suggests that questions should be asked about side effects or unintended effects.
- Garcia-Lizana and Sarria-Santamera (2007) find that “None of the papers included in the review identified any adverse or negative effects on health or quality of life indicators”. Based on this they call for attention to the need to look at negative as well as positive effects.
- Murray et al (2009:4) state that they found “no list of possible harms of IHCAs (Interactive Health Communication Applications) for people with chronic disease”. However, they find a set of possible areas of concern which are equity, false or misleading information, privacy, malpractice, lack of consistent quality criteria and regulation and recommend that these should be explored.

- Price et al (2009) focus on safety in a review of studies of stroke thrombolysis services. They note that the criteria for safety are specific to the condition and treatment. In their study they include response times, protocol violations and proportion of SICH (spontaneous intra-cerebral haemorrhage).
- Scott et al. (2007) mention that the use of telemedicine applications may reduce the risk of patients having delayed treatment by making treatment more accessible to patients, and that this improvement in the safety of the patients should be included in assessments of safety effects.

**Topics:**

The following topics can be included in the assessment of safety:

- Clinical safety (patients and staff)
- Technical safety (technical reliability)

### 3.3.6.3. Clinical effectiveness

When defining clinical effectiveness it is important to make distinction between effectiveness and efficacy. Efficacy of telemedicine refers to the health benefits of a telemedicine application for the patients under ideal circumstances (i.e. carefully controlled conditions). Effectiveness refers to the performance of a technology in regular clinical practice.

In practise efficacy is usually studied in controlled randomised trials (RCT) where all relevant conditions or aspects are held constant or controlled for and where patients are selected based on strict criteria. To determine the effectiveness one can either try to study the effects under more pragmatic circumstances (in pragmatic RCT) or make judgements about the size of the expected effects under more ordinary circumstances based on RCTs.

In studies of effectiveness of telemedicine it is often the case that the first studies by the inventors or early adopters show a higher degree of effectives than can be found in the following studies. This can reflect a difference between efficacy and effectiveness, and it underlines the fact that generally more than one study of a telemedicine application is needed before effectiveness can be said to be established.

Which particular outcome measure is used in an evaluation depends on which topics and issues that is considered relevant to assess. It is sensible to use validated outcome measures where these are appropriate, as they can facilitate comparisons between the findings of different studies, but suitable validated instruments are not always available.

With regard to health status of the patients Kairy et al. (2009) mention SF-36 as a good general scale for measuring health status. Similarly Scott et al. (2007) mention SF-36 and SF-12 as the most commonly used measures.

Before the health benefits of a telemedicine application can be estimated a number of PICO questions must be answered:

- Patients: How is the patient group described?
- Intervention: What is the intervention to be assessed?
- Comparator: What alternative is the intervention going to be compared to?
- Outcomes: What measurable outcomes for assessing effectiveness and safety are relevant?

The answers to these questions are also relevant for the assessment of the safety and economic aspects of telemedicine.

When reporting results from assessments of the clinical effects of telemedicine - whether based on a systematic literature review or new clinical studies - general guidelines for reporting clinical results should be followed. These guidelines are described in detail in the MethoTelemed Guidance (http://www.telemed.no/methotelemed.4565273-125741.html). Central guidelines are:

- Cochrane Handbook for Systematic Reviews, see Higgins (2009)
- The CRD guidance for systematic reviews, see http://www.york.ac.uk/inst/crd/systematic_reviews_book.htm
- CONSORT statement for RCTs, see http://www.consort-statement.org/
- QUOROM statement for reporting of systematic reviews, see http://www.prisma-statement.org/
- Checklist for HTA reports by INAHTA, see Hailey (2003)
- GRADE Working Group recommendations for grading quality of evidence and strength of recommendations, see Atkins (2004)
- EQUATOR: Reporting guidelines for Health research, see Altman (2008)

**Results from the MethoTelemed literature review**

The results from the literature review in the MethoTelemed Project, Ekeland et al. (paper under review) show that the description of clinical effectiveness of telemedicine applications is very specific and that there are hundreds of instruments and outcome measures relating to the specific conditions of the patients in the studies. Based on this it is a general recommendation to seek expert advice from clinicians regarding appropriate clinical outcome measures to include in the design of new studies.

In different clinical specialities, validated measures of clinical outcomes exist, and these are regularly used in evaluations of telemedicine. The literature review shows that e.g. standard mental health instruments, or measures of lung function, or mobility or whatever is relevant for the intervention, are used in standard ways.

The clinical outcome measures used in primary studies are described in e.g.:

- Reger and Gahm (2009) in a review of outcome measures used in studies of internet and computer-based CBT for anxiety. They classify the measures used in the studies reviewed and find 9 for depression; 32 for anxiety; 5 for general distress; 6 for dysfunctional thinking; and 3 for functioning/QOL.
- Spek et al (2007) list a range of standard measures of anxiety and depression that have been used in studies of internet based CBT.
- Jaana et al (2009) find consistent reporting of positive effects on patient behaviour when using home telemonitoring for respiratory conditions. The measures used included equipment used and clinical measures transmitted.
- Neubeck et al's (2009) discussion of telehealth interventions for heart disease finds that five out of the eleven trials included examined psychosocial state using a range of standardised mental health scales
- Many reviews highlight changes in hospital referrals and lengths of stay as key outcomes, with reductions in these seen as positive. Examples include Kairy et al (2009), Clark et al (2007)

- Jackson et al (2006) find studies that measure outcomes such as foot examinations, primary care use and HbAIc tests in relation to IT use in diabetes care. These are specific health care uses for the condition involved in the review.
- Postel et al (2008) suggest 'compliance' as a key outcome variable in e-therapy for mental health problems recommending that it is defined in advance if it relates to how much time is spent, how many sessions completed. They also see treatment credibility for patients as important in a context in which blinding is not possible. They raise the issue of co-interventions, which needs to be specified and considered if present.
- Van den Berg et al (2007) explore interventions which aim to promote physical activity. They note that several studies did not report outcomes in terms of actual physical activity, but used *indirect measures* such as heart rate or weight. They see these as limiting the evidence produced in the studies.
- Sanders and Aronsky's (2006) review of informatics applications for asthma care identified behavioural outcomes such as dust mite prevention and increased knowledge about self-management.
- Garcia-Lizana and Sarria-Santamera (2007) found in a review of randomised studies of telemedicine applications for chronic disease management that the applications generally did not show improvement in clinical outcomes. They also concluded that at present the evidence about the clinical benefits of telemedicine for managing of chronic disease is limited.
- Scott et al. (2007) mention that studies of the effectiveness of telemedicine applications often include effects on the patients utilization of health care services. Examples of outcome measures are number of readmissions or lengths of stay. If telemedicine increases the patients' access to a treatment, changes in the number of patients using the right treatment can also be included.

**Topics**
The following topics can be included in the assessment of the clinical effectiveness:

- Effects on mortality
- Effects on morbidity
- Effects on health related quality of life (HRQL)
    - Generic measures of quality of life
    - Disease specific measures of quality of life
- Behavioural outcomes (e.g. exercise)
- Utilization of health services (e.g. number of readmissions)

Notice that the division of the clinical effects is based on the description of the clinical effectiveness domain in the EUnetHTA HTA Core Model, see EUnetHTA (2008) p. 68 where clinical topics are divided in: Mortality, morbidity, HRQL and patient satisfaction. Examples of measures of effects on morbidity are changes in the severity of the progression and the symptoms of the disease e.g. changes in HbA1c, lung function, saturation.

Based on the literature review, the topics "behavioural outcomes" and "utilization of health services" have been added, because they frequently appear in the literature. As examples Tran et al.

(2008) mention e.g. readmissions and bed days as primary indicators in their review of clinical studies of telemedicine.

Similarly Hersh et al. (2001) mention hospitalisation and lengths of stay as examples of clinical outcomes in the review of studies of the clinical outcomes of telemedicine. Of course, utilization of health care services also reflect the economic outcomes of telemedicine (see section 3.3.6.5), but at the same time e.g. the number of readmissions can be used as an indicator for the health of the patients. Therefore the patients' use of health care is both a clinical and an economic outcome in MAST.

#### 3.3.6.4. Patient perspectives

Patient perspectives are issues related to the perception and satisfaction of the patient or the relatives of the telemedicine application.

The patients' perception and satisfaction of telemedicine applications are important aspects of telemedicine because telemedicine often affects the way health care is delivered to the patients and the way patients interact and communicate with the clinical staff. Telemedicine can be expected to affect the patients' perception of the overall treatment process.

Generally patient satisfaction can be defined as the fulfilment of the expectations or perceived needs of the patients. However, in practise it is difficult to define which kinds of perceptions, expectations or preferences that should be included in this domain. Correspondingly Mair and Whitten (2000) concluded, based on a systematic review of studies of patient satisfaction with telemedicine that empirical studies generally do not define what patient satisfaction means.

Many different aspects of patient satisfaction can be found in the literature, e.g. in Williams et al. (2001):

- Feelings/experiences and Comfort
- Professional-Patient Interaction
- Timeliness and Convenience
- Overall Satisfaction
- Preference between face-to-face and telemedicine
- Privacy and Confidentiality
- Professional Competence/ Personal Manner
- Technological
- Informativeness
- Potential for Future Use/ Usefulness

It is therefore important that new studies of patient perception define which aspect of the patients' perception and preferences they aim to study.

The patients' acceptability is sometimes used synonymously with the patients' satisfaction of telemedicine applications in empirical studies. Here the two terms are also used as synonyms.

The patient perception domain also includes the perception of the relatives since the use of telemedicine application can have effects on how and to what extent the relatives are helping and caring for family members with diseases e.g. for patients with dementia.

In practice measurement of outcomes within the domains of clinical effectiveness and patient perspectives are closely related and some outcomes e.g. the health related quality of life can be said to include both clinical effectiveness and aspects of patients' perception and views.

Telemedicine is often used as a tool to improve patients' ability to handle their disease. Therefore effect of telemedicine application on patients' self-efficacy, i.e. the patients' belief in their ability to handle the disease and the consequences of the disease, can be included in studies of telemedicine. Similarly, patient empowerment can be included. Patient empowerment can be defined as an individual being an active participant in his/her disease management e.g. being able to participate in decisions regarding the treatment.

If patients' acceptance and confidence in a telemedicine application is considered a relevant outcome, measurement of the outcome should be included in the empirical studies. This can be done by inclusion of questions on acceptance etc. in questionnaires to the patients who participate in e.g. a RCT. However, it should also be considered to ask patients, who are unwilling to participate in a study of telemedicine, why they are not willing to participate.

**Results from the MethoTelemed literature review**

The results from the literature review in the MethoTelemed Project, Ekeland et al. (paper under review), shows that various ways to measure patient views exist. These include use of standard consumer surveys and creation of questionnaires or interview schedules suitable for the outcomes desired to be measured. Based on a review of 92 articles Scott et al. (2007) conclude that very few studies use specific or validated instruments in the assessment of patients' satisfaction.

In the literature review a number of different perspectives and outcome measures are described regarding the patients' perception of telemedicine applications:

- Akesson et al (2006) review a small number of studies on consumers' experiences of ICT. They provide detailed descriptions of studies which have used qualitative methods including interviews and diary keeping, to collect consumers' views.
- Gagnon et al's (2009) review of interventions for promoting information and communication technologies adoption in healthcare professionals identifies use of self reporting techniques (though these are professionals, they are people using the intervention)
- Griffiths and Christensen's (2006) review of randomized controlled trials of internet intervention for mental disorders and related conditions reports self recording by patients of their own symptoms as a frequently used measure, as well as the use of survey research to identify their views.
- Hailey et al (2007) illustrate variation among studies in how effectively they assess patient satisfaction with teleoncology services. The give a typology of approaches, listing references to satisfaction within the text; simple questionnaire approach without comparative element; questionnaire with implied comparison; comparative study with simple outcome measures; comparative study using developed satisfaction outcome measures with statistical summary; randomized study. Their overall conclusion is that "Mixed methods results may be more informative than single method studies, given the nature of the goal at hand supporting patients and their families living with cancer in varied circumstances and locations".

- Hyler et al (2005) who explore whether telepsychiatry can replace in-person psychiatric assessments report one case of the use of a standard consumer survey (the Group Health Association of America Consumer Satisfaction Survey), whilst also listing a number of 'satisfaction surveys' drawn up by the researchers concerned.
- Mo et al (2008) find tentative evidence of gender differences in computer mediated communication: they suggest that in such cases, gender difference should be explored to identify whether they are a factor affecting use and efficacy.
- Polisena et al (2009) found that a range of instruments had been used to study patient satisfaction in studies of diabetes management at home. Frequently, these included questionnaires drawn up for the purposes of a particular study, as well as standard instruments such as DQOL (Diabetes Quality of Life).
- Scott et al. (2007) mention that telemedicine can improve the patients' satisfaction with the health care services by improving access to care. Increased access may also improve the overall level of satisfaction with life in rural communities. Therefore improved access should be considered as a factor that can be included in studies of patient perception.
- Van Nooten et al (2006) highlight one trial on spiritual care via ICT which used the Posttraumatic Growth Inventory Scale to measure spiritual outcomes (see http://tmt.sagepub.com/cgi/pdf_extract/11/4/207 for further information).

**Topics**
The following topics can be included in the assessment of patient perspectives on telemedicine applications:

- Satisfaction and acceptance
- Understanding of information
- Confidence (in the treatment)
- Ability to use the application
- Access
- Empowerment, self-efficacy

### 3.3.6.5. Economic aspects

The economic aspects of new telemedicine applications are important because the cost of health care is rising and the need for prioritizing the limited resources is growing. This is relevant at the societal level, but also within the specific health care institutions who must decide whether or not to implement new technologies.

The economic aspects of a telemedicine application can be described in:

1. A societal economic evaluation comparing a telemedicine application with other relevant alternatives in terms of both their costs and consequences.
2. An analysis of the expenditures and revenues for the health care institutions using the telemedicine application.

Whereas the first analysis can be made as a health economic evaluation, e.g. a cost-effectiveness analysis, the second can be made as a business case in which the return on investment (RoI) for the institution is estimated. RoI is the ratio of money gained by increasing the revenue by an investment in telemedicine relative to the amount of money invested and spent.

*Economic evaluation*
Health economic evaluation can be divided into different types described in the table below. The table also describes when different types of evaluations are appropriate and their valuation of costs and outcomes. Based on this the institutions using MAST must decide which type of economic evaluation is most relevant. As mentioned by Scott et al. (2007) cost-effectiveness analysis is used most frequently.

**Table 1. Types of economic evaluations (from EUnetHTA (2009), p. 84)**

| Type of economic evaluation | Appropriate if ... | Valuation of costs | Valuation of outcomes | The question to be answered |
|---|---|---|---|---|
| Cost-minimisation analysis (CMA) | the compared technologies are equally effective; data on costs suffice. | Monetary units | None | Which intervention is the least costly? |
| Cost-effectiveness analysis (CEA) | the effectiveness of the compared technologies is different (e.g. the difference in costs have to be weighted against the difference in effectiveness); activities with the same aim and measure of effectiveness are compared. | Monetary units | Natural units (e.g. life years gained, disability-days saved, points of blood pressure reduction, etc.) | What is the intervention‘s incremental cost per additional unit of outcome as compared to its best alternative? |
| Cost-utility analysis (CUA) | Health related quality of life is an important health outcome; *and/or* activities across specialities or departments in the health care sector are compared. | Monetary units | Quality Adjusted Life Years (QALY), Healthy Years Equivalent (HYE) | What is the intervention‘s incremental cost per additional unit of outcome as compared to its best alternative? |
| Cost-benefit analysis (CBA) | non-health effects are also of importance (e.g. the treatment process itself, utility of information); *or* only one technology is assessed (net benefit); *or* there is a wish that individual life's are valued in monetary units; *or* activities across different sectors in society have to be compared. | Monetary units | Monetary units | What is the economic trade-off between different activities that matter for society? |

In a societal economic evaluation costs are defined as the value of the resources used e.g. when a new telemedicine application is implemented at a hospital. Costing involves both (a) measurement of quantities of resource use and (b) assignment of unit costs or prices. With regard to prices the theoretical proper price for a resource is its opportunity costs, that is, the benefits forgone because the resource is not available for its best alternative use. In practise existing market prices are used unless there is a particular reason to do otherwise (e.g. prices are subsidized or determined politically with no relation to the costs of production).

In the societal economic evaluation all kinds of resources used should be included. Thus resources used by the hospital, the municipality, the patient and the relatives should be included. If telemedicine e.g. result in a reduction of the time spent by the patients and the relatives for transportation, the value of this reduction should be included in the estimated costs. These costs, called indirect costs, can be estimated by use of the human capital approach as a percentage of the average wage rate.

In practise the perspective and the types of costs included in an economic evaluation often vary. It is therefore very important that the perspective of the analysis is explicit (as mentioned by e.g. Sisk and Sanders (1999)) and that the aim, methods and results are as transparent as possible in the reporting of the studies.

In assessment of the costs of telemedicine applications handling of capital costs or investments in for example hardware, software and technical infrastructure is important. These investments results in a cost because the money cannot be used for other purposes (opportunity cost) and because of the depreciation of the equipment etc. over time. This can be handled by calculation of the "equivalent annual cost" (see Drummond et al. (2005) for the annuitization procedure). Similarly, the calculation of the costs of investments should also take into account the fact that equipment can be used by more than one programme or intervention. Therefore, the costs of e.g. an infrastructure for transmission of data should be divided between several programmes. Methods for handling of these shared costs can also be found in Drummond et al. (2005).

Related to this is the distinction between the fixed and the variable costs. Fixed costs are defined by Drummond et al. (2005) as costs that do not vary with the quantity of output produced in the short run, e.g. during one year. On the other hand, variable costs vary with the number of outputs produced. The division of the use of resources into the fixed and the variable costs is often important since this is necessary to be able to estimate how the average costs per patient vary with the number of patients, as described in the section above about assessment of transferability.

The effect of using telemedicine on the use of time for the clinical staff is also an important aspect in estimation of costs. If the description of the organisational aspects of a telemedicine application (in the organisational domain) reveals that a treatment can be produced with less use of labour or result in task shifting (e.g. from physician to nurse) the related change in the costs should be reflected in the estimated cost per patient.

In relation to this it is important to notice that the effects of a telemedicine application on the use of labour will depend on the degree of interoperability, or the degree to which the applications work together with other electronic systems in the health care system and the organizations. When designing the collection of data on the cost of telemedicine applications it is therefore important to consider the degree of interoperability and the influence on the use of ressources.

As described above the preceding considerations made before the assessment of a telemedicine application is carried out should include a judgement of the relevant number of patients to include in a study of the costs of using the application. The reason is that cost per patient often varies with the number of patients using the application, because of large investments or fixed costs. This special aspect of telemedicine should also be handled by sensitivity analysis, in which the average cost per patient is estimated under different assumptions of the annual number of patients.

As mentioned by Scott et al. (2007) the use of telemedicine applications may improve patients' access to health services e.g. by reducing geographical and economical barriers. This may result in an increased use of health care and the related change in the cost per patient and the annual total cost should be included in the cost-analysis. If increased access results in reduction in time off work for the patients or reduced costs of transportation, this should also be included. Examples of studies including these outcomes are Young and Ireson (2003) and Brown-Connolly (2002). Similar the potential increase in e.g. the revenue at a hospital producing telemedicine services should be included in the business case as described below.

*Business case*
In the business case the expenditures and the change in the revenue by an investment in telemedicine are estimated. Expenditures are estimated e.g. as the annual expenditures for the hospital using the application during a five year period. In most cases the expenditures can be estimated based on the estimation of the resources included in the cost calculation in the economic evaluation. However, it should be noted that not all resource use is related to an expenditure e.g. for the hospital.

In the estimation of the change in revenue the reimbursement of the telemedicine service is crucial. For many hospitals reimbursement is determined nationally as a number of DRG-rates (Diagnose Related Groups) which is paid fully or partially to the hospital for each medical or surgical procedure performed. In some cases telemedicine does not change the DRG-rate of a service, but in other cases e.g. when a patient stays at home and has contact with a nurse or a physician by use of a telemedicine application, the DRG-rate of the service is reduced. This has large impact on the result of the business case and can change a positive economic impact for the institution to a negative impact.

If e.g. one or more hospitals in a country start using a telemedicine application based on scientific studies of effectiveness, this can lead to a process with the national or regional health authorities about new DRG-rates for telemedicine. Generally DRG-rates are expected to reflect the average cost of using the treatment. Therefore studies of the costs and effects of telemedicine using MAST can be used as a basis for a change in the reimbursement and thereby change the result of a business case of the technology. Potential problems with reimbursement of a telemedicine service should therefore be described in the assessment of the economic aspects.

**Results from the MethoTelemed literature review**

A large number of reviews considering the economic aspects of telemedicine were identified in the literature review, Ekeland et al. (paper under review):

- Economic analysis frequently includes consideration of hospital resources saved, such as reduced admissions or length of stay, see Kairy et al (2009); Clark et al (2007)
- Deshpande et al (2008) and Farmer et al (2005) find that studies of telemedicine report no consistency in economic analyses
- Kairy et al (2009:444) note that costs may change over time as the technology becomes increasingly used for similar or other activities or as therapists gain experience with the technology for example. It may therefore be appropriate to conduct sensitivity analyses by adjusting some of these parameters.
- Kalthenthaler et al (2006) make use of submissions by sponsors of the software packages examined. Their results are presented as QALY ratios and cost effectiveness acceptability curves according to various purchasing scenarios.
- Rojas and Gagnon (2008) find that there is no agreed upon set of cost indicators or effectiveness indicators for assessing telehomecare cost-effectiveness. They give tables of the most widely used indicators in the studies they reviewed.
- Seto et al (2008) highlight that few studies consider ‘indirect costs’ of heart failure interventions. Some look at the costs to the individual patient of time spent visiting clinics as compared with remote monitoring. None considered indirect costs to society, such as decreased work productivity.

- Verhoeven et al (2003:18) report five studies of teleconsultation in diabetes care that show *increased* consultation time with physicians, with decreases elsewhere. These studies illustrate the need to be alert to where costs occur, and that both increases and decreases may occur.

**Topics**

The following topics can be included in the assessment of the economic consequences of telemedicine applications in the economic evaluation or business case:

- **Economic evaluation (societal perspective)**
    - Amount of resources used when delivering the assessed telemedicine application and its comparators in the health care sector and other sectors. The different types of resources are:
        - Investments in equipment etc.
        - Training of staff
        - Maintenance
        - Use of staff (for each of the relevant type of staff)
        - Medication
        - Utensils
        - Patients' use of time
        - Relatives' use of time
        - Transportation
    - Unit costs or prices for each resource used
    - Related changes in use of health care resources
        - Primary care
        - Emergency unit
        - Outpatient visits
        - Hospitalization
        - Bed days
        - Tertiary care
    - Clinical effectiveness of the telemedicine application and comparators (to be used in the cost-effectiveness analysis – see domain on clinical effects)

- **Business case (institutional level)**
    - Expenditures per year (including expenditures related to the resource use described in the cost estimation above)
    - Revenue per year:
        - Activity (number of patients or services)
        - Reimbursement (e.g. DRG-rate) per service or patient

### 3.3.6.6. Organisational aspects

An organisation is a consciously coordinated social unity with clear boundaries and continuous activities which target certain goals. The organisational domain considers what kind of resources have to be mobilized and organized when implementing a new application, and what kind of changes or consequences the use can further produce in the organisation.

Health care organisations are complex and dynamic, and therefore multiple approaches are often required for analysis of organisational aspects, as pointed out by Plsek and Greenhalgh (2001). In the analysis of telemedicine devices, the organisational aspects often play a major role, since telemedicine may necessitate – or enable - major organisational changes. However, it will often be impossible to isolate the effects of a single organisational change on the outcomes of a new treatment, as described in EUnetHTA (2008).

In relation to the complex nature of organisational aspect, it is important to notice that the effects of a telemedicine application on the use of human resources will depend on the degree of interoperability, i.e. the degree to which the applications work together with other electronic systems in the health care system and the organizations. When describing telemedicine applications it is therefore important to consider the degree of interoperability and the influence on the use of resources.

The organisational domain is crucial when it comes to evaluating telemedicine services because the implementation of telemedicine often changes the working routines or the distribution of tasks between health professions for health care providers. Telemedicine enables medical staff to treat or monitor patients at a distance or to cooperate over long distances, which may necessitate changes in existing organisational structures. Working with telemedicine may require new skills in actually operating the technology involved as well as in new work processes.

As an example a study by Aas (2001) found that implementation of telemedicine might have consequences such as organisational restructuring, changed mechanisms for internal coordination, different flow of patients through the health care system, improved coordination of care, new job descriptions, relocation of the place of work, employment of personnel living far away from the workplace, less travel by staff and patients and limited opposition to the adoption of the technology.

An important question to be asked is whether the telemedicine application will fit smoothly into the existing organisational framework. If not, major change may be necessary. As described by Aas (2000) organisations can handle this challenge in two fundamentally different ways: either the organisation is adapted to fit the technology or the technology is adapted to fit the organisation.

The organisational domain is quite complex. Even though this models aims at suggesting outcomes which can be isolated and measured through a reasonable effort, descriptions on the various process and the organisational relations often include description or relations and diagrams rather than statistical measures.

The EUnetHTA HTA Core Model suggests that the natural starting point for an organisational analysis of change in processes will be to map the current work flow and patient flow. Although the core model was developed for medical and surgical interventions, this is relevant for analysing the changes in processes caused by application of telemedicine devices as well. The MethoTelemed review has shown that it is useful to identify stages in the workflow process and explore the time needed to complete them. The cost for the stages can then be estimated (see domain 5).

The different aspects or outcomes included in the organisational domain can be divided into three topis: Process, Structure and Culture. The same division is used in the Danish HTA Handbook (2007). In the EUnetHTA HTA Core Model a fourth topic, Management, is added.

Systematic literature reviews rarely yield many hits when searching for articles on organisational aspects. Studies are often of a qualitative nature, including very few respondents, e.g. Aas (2001). Therefore it is often necessary to perform primary studies. The relevant methods for data collection may include both qualitative and quantitative methods:

- Qualitative methods:
    - interviews
    - observations
- Quantitative methods
    - surveys
    - registration of data.

**Results from the MethoTelemed literature review**

A number of the articles from the literature review, Ekeland et al. (paper under review), included measurement of organisational aspects of telemedicine applications:

- Clark et al (2007:6) point out: "Although we have shown substantial and statistically significant benefits with remote monitoring for patients with chronic heart failure, monitoring is not a treatment but rather a different way of systematically organising effective care"'. Therefore the impact of telemedicine may not be clinical in itself, but may be organisational.
- Mathur, Kvedar and Watson (2007) use a 'functional framework' which allows the interaction of different elements in the process of delivering ICT in Type 2 diabetes care, to be systematically evaluated. The patient is at the centre and the other elements considered are remote monitoring, dynamic feedback, motivation and support, coordination of care and structured education.
- Shojania et al (2009) focus on the efficacy of on-screen, point of care computer reminders. Some outcomes are clinical, but they also include 'process outcomes' which refer to numbers of patients receiving different elements of a care process, or whose care followed a guideline and also any continuous measures of processes of care.
- Wu and Langhorne's (2006) review of telemedicine in acute stroke management includes discussion of acceptability of the interventions to medical staff, focusing on particular aspects such as consultation times and subjective measures such as levels of confidence and quality.

**Topics**
The following topics can be included in the assessment of the organisational aspects of telemedicine applications:

- Process
    - Workflow
    - Staff, training and resources
    - Interaction and communication

- Structure
    - Spread of technology, centralization or decentralization

    - Economy (see domain on economic aspects)

- Culture
    - Attitude and culture

- Management

### 3.3.6.7. Socio-cultural, ethical and legal aspects

**Socio-cultural aspects**

The social-cultural part of the domain focuses on more general socio-cultural implications of telemedicine applications. The focus of the domain is on the diverse social-cultural arenas where the patient lives and acts during use of the application.

The life of a patient takes place in various arenas (hospitals, general practitioner, everyday life, homes, schools, workplace, etc.). The telemedicine application or service moulds and is moulded by them all. Irrespective of the site, where a certain application is used, the implications of its use for a patient may extend far beyond the health care setting, e.g. the hospital or the general practitioner's consultation. The patients may have considerations, worries and experiences both before, during and after the application has been put to use.

**Topics:**

- Changes in the patient's role in major life areas (e.g. social life, working life)
- Patients' relatives and others' understanding of the telemedicine application
- Societal, political context and changes. Will the application influence the general model for the delivery of healthcare services if deployed?
- Changes in responsibility. Are the patients and/or relatives capable of handling the responsibility?
- Gender issues. Has the service any consequences on the position of gender?

**Ethical aspects**
The following descriptions are based on the corresponding description of the domain in the EUnetHTA HTA Core Model for interventions (2008) p. 92:

Following the lines of the EUnetHTA model, MAST considers the prevalent morals, values and behavioural models of society relevant for assessment of telemedicine applications in ethical analysis. These values, moral principles and social rules (norms) form the basis of social life as well as national laws and consequently it is important to understand them. These factors play a key role in shaping the context in which telemedicine applications are used. The moral rules of the society reflect the values of the society and the values may be weighted differently in various societies. Evident cultural (e.g. religious) and economic (e.g. gross national product) differences also have a major impact on the moral value of the consequences that the implementation of a telemedicine application can have.

Within a MAST evaluation, the ethical analysis appraises the ethical questions raised by the application itself and by the consequences of implementing / not implementing it. Although ethical analysis may be practically approached in this domain of the MAST process, moral issues are relevant to all domains and the methods of ethical analysis should take this into account.

The ethical analysis is an appropriate place to go beyond the limits of the PICO approach (patients, intervention, comparison, outcomes, see section on "Effectiveness"). Strictly applying the PICO

model to ethics implies that the comparison application is ethically problem-free and that, if there are no ethically relevant differences between the applications, applying the telemedicine application is equally ethically problem-free. As it is unlikely that a thorough ethical analysis has been conducted on the comparison application, it is important to consider also this issue in order not to overlook essential moral issues only because they also affect the comparison application.

The results from the literature review in the MethoTelemed Project shows that only Marziali et al 2005 explicitly consider ethical issues in relation to practice standards and research ethics in technology-based home health care intervention programs for older adults. Key pointers to assessment are:

- Marziali et al: 'Issues related to professional practice standards and research ethics were not well reported. When reported, adherence to practice standards included pre-intervention training, use of intervention protocols, supervision, and mechanisms for risk management. Research ethics most commonly reported were informed consent, REB/IRB approval, and protection of privacy.' They express concern that ethical issues are not being properly considered when telemedicine interventions are planned and implemented.

Their work suggests topics to be considered – they do not recommend particular approaches, but we should probably suggest interviews with key stakeholders regarding whether these have been considered, referral to ethics committees, or seeking to establish consensus (e.g. through Delphi exercises).

The review indicated that consideration of ethical issues of telemedicine applications is a neglected area. Interviews with key stakeholders are recommended regarding whether these have been considered, referral to ethics committees, or seeking to establish consensus (e.g. through Delphi exercises).

**Results from the MethoTelemed literature review**

The literature review, Ekeland et al. (paper under review), indicate that socio-cultural, ethical and legal aspects of specific telemedicine applications are a neglected area with only a few empirical studies.

Only Marziali et al (2005) explicitly consider ethical issues, in relation to practice standards and research ethics in technology-based home health care intervention programs for older adults. Marziali et al argue that issues related to professional practice standards and research ethics were not well reported in the studies reviewed. When the studies reported these aspects adherence to practice standards included pre-intervention training, use of intervention protocols, supervision, and mechanisms for risk management was described. The authors express concern that ethical issues are not being properly considered when telemedicine interventions are planned and implemented.

Koch (2006) makes an important point about telehealth and societal change, relating its development to changing views about relationships between patients and professionals and who is responsible for healthcare. She writes (p. 573): "Organisational and societal changes, such as increasing demands for shared care and patient empowerment and an ageing population are the main driving forces for this change".

**Topics**

- Overall questions: Does the application challenge religious, cultural or moral beliefs?
- Potential ethical problems, e.g. giving the responsibility to the patients
- Autonomy: Is the patient's autonomy challenged or increased?
- Equity among different groups in society

**Legal aspects**

This domain of MAST focuses on the legal obligations which must be met and will identify any specific legal barriers that may exist to the implementation of the application.

The legal assessment will have to be conducted in two steps.

First, there will have to be an assessment of the readiness of the existing legal framework to accommodate telemedicine approaches. Thus, if in a given region or country telemedicine services may only be provided where a pre-existing relationship exists between the care provider and the patient, then only limited use of many telemedicine applications can be made. There may also be requirements that state that only certain types of telemedicine intervention may be offered – e.g. psychiatric only. It may also reveal that while the telemedicine services may be legally delivered, that they may not be reimbursed in the traditional way because they do not involve the traditional players. If this first step reveals such a major barrier to telemedicine further steps in addressing that high level framework of regulation will be necessary before it is possible to further assess the legal aspects related to a particular telemedicine tool. Note however that much of this high level legal framework should have been revealed as part of the preceding considerations (see section 3.3.5).

Once the legal framework within which telemedicine services can be provided has been established, the second step is assessing which particular regulatory requirements will affect a given telemedicine application. In an assessment based on MAST, the legal analysis appraises the legal and regulatory questions raised by the application itself and by the consequences of implementing or not implementing it. The legal aspects in this second level assessment will focus on two main levels: the internal organisation of the care organisation and the patient.

In the second level the core issues to be considered are:

- Clinician accreditation
  - Are the clinicians accredited to deliver services at a distance and is their accreditation accepted at the point of delivery (i.e. where the patient resides) as well as at the legal registration location of the clinician.
- Information Governance
  - Are all the necessary aspects of transfer and access to patient identifiable information duly considered
- Professional Liability
  - Closely associated to the issues on accreditation
  - Need to ensure that the flow and share in liability is clear across different actors in the telemedicine system.

Looking first at issues within the organisation it will be important to assess if the healthcare professionals to be involved in the telemedicine application have the relevant professional accreditation needed to offer services at a distance. It may in some regions be necessary for courses to be completed and certifications obtained to ensure that a nurse may, for example, take readings from devices remotely. All necessary accreditations will have to be met to ensure that the care institutions can meet existing legal liabilities and any new liabilities that arise from the use of the telemedicine application. It will also be necessary to assess if additional insurance coverage will be required to provide a telemedicine service.

A significant part of the legal assessment will necessarily have to focus on issues of information governance. Given that any telemedicine application will involve the processing of large amounts of patient identifiable data which come in to the healthcare domain from outside its usual security settings it will be very important to assess the information governance model operated by the hospital or other healthcare institution and ensure that it is suitable enabled to accept data from outside its firewalls. It will also be important to ensure that any liability issues related to the processing of data coming from outside the firewalls are properly clarified and that all lines of responsibility are clearly established before implementation of the service takes place – thus important time, infrastructure and training resource issues must be addressed to ensure that any new requirements in meeting the information governance standards can be appropriately met.

Finally, in terms of a legal assessment of internal issues it the MAST appraisal should also assess any legal impact of NOT implementing the system. If the other aspects of the appraisal show that implementation would add significantly to patient safety or clinical outcome then it is possible that in not implementing the solution the healthcare institution would not be meeting its legal duties to provide safe, high quality care to the patient. In case where the technology is already widely adopted in other institutions it could amount to a tort on the part of hospital not to offer the service.

In terms of external legal issues it will be important to assess if the application raises any patient rights which will need to be accommodated into the internal information governance system. In particular it is important to note that where a telemedicine application uses patient data (as almost all will) the patient will have the right to know what data is collected, how it is stored and who may have access to it. In many countries the patient will also have the right to access the data himself and to require changes to be made to the data. The MAST assessment will have to examine in how far such rights will arise with the telemedicine application and if they would cause any organisational issues for the institutions concerned.

**Topics :**

- Clinical accreditation
- Information governance
- Professional liability
- Patient control – consent, access

### 3.3.7. Assessment of transferability

If an assessment of a telemedicine application includes collection and analysis of data from new studies, the assessment must also include considerations of whether the results can be generalised from one setting to another. This consideration should be made within each of the seven domains.

As an example the assessment of the clinical outcomes should include some kind of analysis of whether the circumstances during the trial were so special and controlled that the same results cannot be expected in real life (effectiveness).

Another example is that estimation of the cost of using telemedicine should be followed by an assessment of how the cost per patient can be expected to vary if the number of patients is increased by 100% or 1000%. If possible a cost function describing the relation between cost per patient and the number of patients should be estimated, thereby making it possible for readers to estimate the expected cost per patient in their local setting. Alternatively the costs can be divided in fixed and variable costs as described in section 3.3.6.5.

Similarly, if an assessment is completely or partly based on a systematic literature review, the potential problems with validity and reliability of the studies included should be described.
If the studies found are made in other countries it should also be considered to what extent cross border transfer of results is possible or whether differences in e.g. legislation, reimbursement or organisation of the health care sector makes transferring the results impossible. Drummond et al. (2005) describe corresponding problems with transferring results from economic evaluations from one setting to another. A number of reasons why cost-effectiveness may vary between countries or locations are described:

- Differences in basic demography and epidemiology of disease
- Differences in availability of health care resources and variations in clinical practice
- Differences in incentives to health care professionals and institutions, e.g. in reimbursement systems
- Differences in relative prices and costs e.g. in prices of different type health care professionals
- Differences in population values

Drummond et al. generally suggest the use of statistical models including clinical and cost data as an approach to adapt results from one setting to another. If possible resource data should be collected for each country based on routinely available statistics or free-standing cost studies. However, in practice it will generally be difficult to transfer results from country to country and the potential problems and uncertainties must be described in each case.

The problem with transferability and generalizability of results from local studies of telemedicine has been stressed by example Ohinmaa et al. (2001), and transferability of data and results is also an important element of the EUnetHTA HTA Core Model (see EUnetHTA (2008)).

The issue of transferability of results from health economic evaluations in general are discussed in the literature, see e.g. Bourlenger et al. (2005). Checklists for assessment of transferability of results from empirical studies have also been produced. An article by Knies et al. (2009) describes checklist by Bourlange et al. (2005), Welte et al. (2004), Urdahl et al. (2006), Nixon et al. (2000) and provides an empirical example of the use of these checklists.

### 3.3.8. Methods for data collection

When choosing between different designs of studies and methods for data collection within each of the seven domains, the general principle is that the designs and methods must be able to produce valid and reliable estimates of the outcomes of the telemedicine application. For example, if new studies of clinical effectiveness are planned, a well designed randomised controlled trial (RCT) or a cluster RCT should be used, if possible, to produce information on the clinical outcomes at a high level of evidence (see the evidence levels at Centre for Evidence Based Medicine, http://www.cebm.net/index.aspx?o=1025). This recommendation was also found in the literature review, Ekeland et al. (paper under review).

In a RCT patients and practitioners should ideally be blinded, thus neither the patient nor the e.g. clinical staff nor the persons assessing the outcomes should know who belongs to the control group and the experimental group. The reason is that both patients and the staff may have preferences for the telemedicine application and this can result in bias. This is usually not possible for complex interventions like telemedicine applications, see Medical Research Council (2000) and this can make it difficult to produce assessment without the risk of bias. A potential solution is the "preference trail" where patients are asked about their preferences before entering the trail. Patients with no preferences are then randomised as usual, but patients with preferences refusing randomisation receive their preferred treatment. After the study statistical analysis is made of data from the randomised trial and of data from the observational study of the two groups of patients with preferences.

With regard to the other domains data collection should also be designed in order to produce high level evidence. Thus studies of the organisational aspects should use methods like interview or focus group interview with e.g. the clinical staff to collect valid and reliable data on the organisational consequences of using the telemedicine application.

The relevant methods for data collection within each of the 7 domains can be found in the appendix.

**Outcome measures**

The specific outcome measures and instruments for data collection used in an assessment will depend on the diagnoses of the patient group, the purpose of the telemedicine application and the organisations using the application.

This is generally recommended in the scientific literature e.g. by Wootton et al. (2006) who argue that the choice of outcome measure depends on the aim with which the telemedicine application is set up. Similarly Scott et al. (2007) emphasize that appropriate measurement of the outcomes of telemedicine require careful consideration and that outcomes included must be linked clearly to the intervention. Craigh et al. (2008) argue in the same way that assessment of complex interventions like telemedicine must be based on a good understanding of how the intervention works. An assessment should therefore start by a review of the existing literature and results from pilots. The information collected can also be used in the development of a theoretical understanding of the causal relations. Finally the information and understandings can then be used to indentify the relevant outcomes that must be included.

As expected the systematic literature review in the MethoTelemed project,, has found large variation in the outcome measures used in studies of telemedicine applications. As an example Barak et al (2008) in a review of Internet-based psychotherapeutic interventions state that "The interventions analyzed were evaluated by a total of 746 measures of effects. Some studies…were

evaluated by a single outcome measure …..whereas others were assessed by several measures, up to as many as 21". On average, the studies used eight measures to determine the effectiveness of treatment.

Generally, the choice of instruments and outcome measures should reflect the recommendations in the scientific literature. These recommendations can be found in http://www.telemed.no/methotelemed

The use of validated instruments for data collection, e.g. when measuring health related quality of life, makes it possible for the results to be used in future meta-analysis of the telemedical applications, as described in the MethoTelemed review.

Finally it should be noted that if potential confounding factors exist in empirical studies, these should also be included and measured. As an example if there is a risk of systematic differences between an intervention group and a control group with regard to e.g. the age, sex or educational background of the patients, measurement of these factors must be included in the data collection.

### 3.3.9. Example: Using MAST to assess the COPD Patient Briefcase

At Odense University Hospital, Denmark, an assessment of the COPD Briefcase is being planned at the moment (February 2010). This study can be used as an example of the use of the model. The COPD Briefcase is a mobile communication interface which COPD patients are given when discharged from hospital. The COPD Briefcase makes it possible for the patients to communicate with the doctor via video conferences from their homes and to enter their own measurements of their health.

A preceding assessment has shown that all legal issues regarding the use of the suitcase have been resolved. Reimbursement is still being discussed with the Region of Southern Denmark and the problem can be resolved at the regional level. Based on experiences from another Danish hospital the internal and external organization has also been adapted to the use of the COPD suitcase. Finally it has been determined that the usual treatment of the patients can be used as the comparator in the study.

The multidisciplinary assessment will consist of one large RCT at the hospital with about 270 patients. In this study the clinical and economic outcomes will be estimated.

To study the patients' perception of the application and the organizational aspects two other interview studies with a sample of patients and a sample of the clinical staff will also be carried out. The assessment of safety will be based on an analysis of results from all studies of the COPD Briefcase made so far.

Finally the legal aspects will be described based on a description of the legal aspects in the laws regulating patient treatment in Denmark. Interviews with a number of relatives and focus group interviews with stakeholders will also be carried out.

The main outcome measures in the RCT are based on a literature review and presented in the table below. Notice that data on the patients use of health care are include both as a measure of the clinical outcome of the COPD Briefcase and as an element in the calculation of the mean cost per patient of using the telemedicine application.

**Table 2. Outcome measures in assessment of the COPD Briefcase**

| Clinical effectiveness | Economic outcomes | Patient perspectives | Organisational aspects |
|---|---|---|---|
| Mortality<br>FEV1<br>SAT<br>MRC<br>BMI<br>SF-36<br>Exercise<br>Depression (HADS)<br><br>Number of readmissions<br>Time to first readmission | Total cost per patient of using the COPD suitcase<br><br>Estimation of costs include:<br>Number of consultations<br>Number of telephone calls<br>Number of readmissions<br>Number of bed days<br>Number of outpatient visits<br>Number of home nurse visits<br>Use of emergency<br><br>Effect on reimbursement of using the COPD suitcase | Interview and questionnaire based on validated instruments for patient perception and acceptance | Interview with nurses from the hospital using the COPD Briefcase<br><br>Interview with home nurses from the municipality |

## 4. Discussion

Based on two workshops with stakeholders and users of telemedicine and a systematic literature review this report presents a new model for assessment of telemedicine applications.

The model called MAST can be used if the purpose of the assessment is to describe effectiveness and contribution to quality of care of telemedicine applications and to produce a basis for decision making. If this is the aim, this report defines the relevant assessment as a multidisciplinary process that summarises and evaluates information about the medical, social, economical and ethical issues related to the use of telemedicine in a systematic, unbiased, robust manner.

An assessment based on MAST should include three elements:

- Preceding considerations of a number of issues that should be considered before an assessment of a telemedicine application is initiated (see section 3.3.5).
- A multidisciplinary assessment of the outcomes of telemedicine within seven domains of outcomes and aspects (see section 3.3.6)
- An assessment of the transferability of results found in the scientific literature and results from new empirical studies (see section 3.3.7).

With regard to the measurement of outcomes in new empirical studies the use of MAST implies that:

- Design of studies and methods for data collection within each of the seven domains should be able to produce valid and reliable estimates of the outcomes of the telemedicine application. For example, a study of clinical effectiveness is planned a well designed RCT or cluster RCT should be used, if possible, to produce information on the clinical outcomes at a high level of evidence.
- The specific outcome measures used in an assessment must reflect the aim of the telemedicine application and results from pilots and other relevant studies in the scientific literature.

- Validated and reliable outcome measures should be used if possible

### 4.1. Strengths and weaknesses

The main strengths of the model are:

- It is based on the requests and comments from a large group of stakeholders and users of telemedicine.
- It is multidisciplinary and comprehensive
- It is based on scientific studies and criteria for quality
- Transferability of the estimated outcomes is described
- It is based on HTA and EUnetHTA and therefore familiar to stakeholders in the EU, national health authorities, industry, academics and health professionals.

The main weaknesses of the model can be described as:

- It can be time consuming if new empirical studies must be initiated
- It does not result in information on why telemedicine works. This information needs to be produced in other kinds of scientific studies.
- The model focuses on the outcomes of telemedicine (including organizational outcomes) and not the working processes when introducing the applications. Information about the process of implementation of telemedicine must be produced by using other kinds of assessments, as described in the MethoTelemed Guidance.
- MAST is only relevant in assessment of matured telemedicine applications. If the application is still being developed and still needs to be improved, other kinds of assessments should be carried out, e.g. in formative studies.
- The quality of the reports and publications based on MAST can vary because the model does not state a number of criteria to be fulfilled. However, the scientific criteria for quality of research within the different scientific disciplines can also be used as criteria for the quality of reports using the model. Further description can be found in the MethoTelemed Guidance at http://www.telemed.no/methotelemed.

### 4.2. Relation to other models

This section includes a brief discussion of relations to similar models or frameworks for assessment of telemedicine and other interventions.

**EUnetHTA**
As described in section 3.3 MAST is based on the EUnetHTA HTA Core Model and adjusted to the special characteristics of telemedicine applications as a result of the discussions with stakeholders and users of telemedicine at two workshops in 2009. The HTA Core Model includes 9 domains, see see Lampe et al. (2009), Kristensen et al. (2009A), Kristensen et al. (2009B) and EUnetHTA (2008).

The main differences are that “Current use of the technology” and “Description and technical characteristics of technology” are two separate domains. Ethical, social and legal aspects are also divided in three separate domains. Finally the patients perception of the technology (e.g. patient satisfaction) is part of the “Effectiveness” domain, thus it is not a domain of it’s own in the HTA Core Model.

The reasons for combining these five domains from the HTA Core Model into two domains in MAST are firstly a wish to produce a simpler and clearer model. Secondly it can be argued that both the current use of the technology and the description of the technology constitute the basis or background of the assessment of the effects of the technology. In the same way the ethical, social and legal aspects of telemedicine can be said to make up the broader social or societal aspects of telemedicine. Another common property of these aspects of telemedicine is that the description of these issues in relation to a specific telemedicine application often will be based on more qualitative judgments and not quantitative, empirical studies.

**Wootton et al. (2006)**
To a large degree MAST is based on results from workshops with stakeholders, but arguments for a model similar to MAST can also be found in the literature. Wootton et al. (2006) argue that when telemedicine introduces new kinds of services, the outcomes should be measured when possible. They also argue that the outcomes of telemedicine can be divided in measurements of user satisfaction, measurements of medical outcomes and financial measurements. These are all part of MAST.

**Ohinmaa et al. (2001)**
Ohinmaa et al. (2001) describe an approach for assessment of telemedicine applications based on a literature review. Their approach includes many of the same topics as described in the seven domains of MAST. They also point out that results from local studies may not be generalisable to other settings and that this should be considered when using results from other assessments.

**Donabedian's model for quality of care**
Another approach for assessment of quality of care is the Donabedian model, see eg. Donabedian (1978). In this model quality can be classified under three categories: Structure, process, outcomes. Structure denotes the attributes of the settings in which care occurs (e.g. equipment, human resources, organization). Process denotes what is actually done in giving and receiving care (e.g. activities made by doctors, nurses and patients). Finally outcomes are the effects of care on the health status of patients and the population including changes in knowledge and patient satisfaction. This model is often used as a basis for studies of quality of health care and is helpful as a framework for collection and analysis of data. MAST, on the other hand, has a more narrow focus on the outcomes of technologies. The reason is that stakeholders in health care in general are more interested in information about e.g. clinical, organizational and economic outcomes of using telemedicine when making decisions about use or not use of a specific application and less interested in the content of the processes leading to the outcomes. This was one of the main results from the workshops with stakeholders in the MethoTelemed project.

**The National Telehealth Outcome Indicator Project**
Scott et al. (2007) have reported the results from a study with objectives very similar to MethoTelemed. Their project called the National Telehealth Outcome Indicator Project was designed to provide a national Canadian guidance on specific outcome indicators for use when evaluating telehealth applications. The project was based on a systematic literature review, a workshop with national experts and a consensus process. The project ended with a list of 34 outcome indicators and measures considered to be most suitable for evaluations of telemedicine applications. These are divided into four themes: Quality, access, acceptability and costs. Even though the division of the different types of outcomes into themes by Scott et al. (2007) is different, to a high degree the outcomes are included in MAST.

One main difference is that legal, ethical and socio-cultural issues of telemedicine are generally not included and that organisational aspects are mainly included as part of the economic aspects. Another difference between the guidance by Scott et al.(2007) and MAST is that “access”, constitute a theme or domain in itself. The focus on access and accessibility of patients can also be found in other models and frameworks for assessment of telemedicine. Access can be defined as the relative ease or difficulty of obtaining health services (see Bashshur (1995)). From the clients perspective this can be expressed as the degree to which they face geographical, economical, cultural or social barriers to care.

If a telemedicine application is expected to result in improved access for patients, this can be included in several of the domains in MAST:

- Effects on the health of the patient caused by e.g. an increase in the proportion of patients getting the right treatment should be included in the clinical domain.
- Effects on the number of users should be included in the clinical and economic domain.
- Increased satisfaction of patients should be included in the patient perspectives domain.
- A reduction in the resources used for transportation should be included in the economic domain

**MRC: Complex interventions**
A framework for evaluation of complex interventions has been described by the Medical Research Council MRC in the United Kingdom; see Craig et al. (2008). Complex interventions are interventions that contain several interacting components e.g. where several groups or organisations are involved in the delivery and where the behaviour of the involved parts is expected to have effect on the outcomes. It is argued that the characteristics of complex interventions make it necessary to adjust the design of assessments of outcomes. Among the main recommendations are to:

- Base the assessment on a good understanding of how the intervention works and causes changes. This can be done by a review of the existing literature and by development of a theoretical understanding of the causal chain. The information can then be used to indentify the relevant outcomes which must be included.
- Not just include a single primary outcome, but a range of outcome measures to be able to pick up the consequences of the interventions.
- Use a larger sample size to take account of the extra variability caused by the many interaction components.
- Always consider randomisation in the experimental design because this is the most robust method for preventing selection bias. It is also recommended to use cluster randomisation as a solution to the potential problem of contamination of the control group.
- Report the intervention fully by including a clear description of the intervention to enable replication and synthesis of the evidence.

The recommendations by the Medical Research Council seem highly relevant for assessment for the outcomes of telemedicine application and in general telemedicine must also be considered a good example of a complex intervention. As described in the section above regarding methods for data collection, there is a high degree of agreement between MAST and the recommendations by the council. As described in section 3.3.6.1. and 3.3.6.6. MAST also recommends a full description of telemedicine application including the features, technical characteristics and the organisational aspects as a part of the assessment.

### 4.3. Comments from HTA-institutions

In order to have an external assessment of MAST and its usability in future assessments of telemedicine we have asked two European HTA-institutions to give an overall assessment of MAST as it is described in this report.

From Finn Børlum Kristensen, National Board of Health, Coordinating Secretariat, EUnetHTA we have received the following:

> "The field of information and communication technologies needs applications like MAST to inform those decision makers who are responsible for best allocation of health care resources. The MAST Manual is an important contribution to the development of robust, structured, research based tools for evaluating the consequences of using telemedicine in health care practice.
>
> It is well researched, builds on a theoretical base, and is oriented towards practical applications to inform decision making.
> Applications of telemedicine are "technologies" just like other health interventions are "technologies" in the practice of Health Technology Assessment (HTA). In that sense it seems well chosen to explore the general HTA Core Model of the EUnetHTA Project for practical usefulness in telemedicine.
>
> The similarities of the MAST and parallel developments in the general field of assessment of heath technologies that take place in the EUnetHTA Joint Action should be kept in focus. The hierarchical and modular structure of the HTA Core Model with its question-answer dyads should allow a fruitful development of assessments of IT applications in heath care by EUnetHTA and the Renewing Health Project. Further testing is important for this development.
>
> Not only is this important for the European Commission and the EU member states that sponsor the activities. It is equally important for the sustainability of European collaboration in HTA and sound evaluation of information and communication technologies in Europe."

Catalan Agency for Health Technology Assessment (CAHTA), Spain, produced a review including a number of specific suggestions to incorporate in the model and which the MethoTelemed team have used to further improve the model . The overall conclusion of the review was:

> "Overall, this is an excellent document, well written, balanced, user-friendly and presents very useful information.
>
> The present document introduces a new comprehensive Model for Assessment of Telemedicine (MAST) developed as a structured framework for assessment of the effectiveness of telemedicine applications and their contribution to quality of healthcare.
>
> The methodology used for its elaboration combines qualitative research techniques and systematic review of the literature.

> This manual and the MAST Toolkit offer an extensive list of outcomes to be considered when planning an assessment of telemedicine applications. Additionally, it provides useful methodological orientation for the design of new telemedicine evaluation studies. In our review we give few suggestions to be considered in the final version.
>
> The next step would be the elaboration of a checklist ("question/answer" style) and a scale (or scoring) to assist decision makers in deciding on the adequacy of selected outcomes in each particular context, and to discriminate between different levels of quality of the available evidence, in more practical way."

Based on these comments MAST appear to be a useable structure for future assessments of telemedicine applications that will be helpfull to those planning an assessment and at the same time provide a sound basis for decision on implementation of telemedicine in Europe. However future development and testing of MAST is also needed to make the model even more practical.

# 5. Conclusion

This report described the results from the MethoTelemed project with special focus on a new model for assessment of telemedicine – MAST.

MAST should be used if the purpose of an assessment is to describe effectiveness and contribution to quality of care of telemedicine applications and to produce a basis for decision making. If this is the aim, this report defines the relevant assessment as a multidisciplinary process that summarises and evaluates information about the medical, social, economical and ethical issues related to the use of telemedicine in a systematic, unbiased, robust manner.

The development of MAST is based on results from two workshops with stakeholders and users of telemedicine in June and November 2009 and a systematic literature review. The model is also to a high degree based on EUnetHTA HTA Core Model for interventions.

This report describes what to include in the preceding considerations and a number of aspects, methods and topics that can be relevant in each of the seven domains included in the multidisciplinary assessment. For each of the seven domains a number of measures of outcomes used in studies of telemedicine applications are also described in the appendix. These are also included in the MAST Toolkit, a tool that makes it possible for those who are planning an assessment of a telemedicine application to use the MAST as a checklist. The MAST toolkit can be downloaded at www.telemed.no/methotelemed

MAST is a part of the MethoTelemed Guidance which describes a number of different methodologies for assessment of telemedicine applications. The Guidance can be found at www.telemed.no/methotelemed.

## 5.1. Steps in the development of MAST

An empirical test of the model will be carried out in 2010-2012 in the Renewing Health project (CIP ICT PSP) initiated by the European Commission. In this project assessment will be made of telemedicine applications for patients with diabetes, heart failure, and COPD in 9 EU countries. Based on the project an evaluation will be made of the model and the need for future adjustments.

During 2010-2012 the EUnetHTA Joint Action will also develop an electronic tool for applying the HTA Core Model and test the model across borders in Europe (see www.eunethta.eu). The EUnetHTA Joint action between the European Commission and 23 EU member states, Norway and Croatia includes several activities of significance to telemedicine and IT in health care.

It is thus important that these parallel developments are aligned so that those who want to assess technologies in health care in general and those who are focused on assessing telemedicine applications can work with the same general approaches to the structuring and reporting of assessments.

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## Appendix 1: The domains

**Domain: Health problem and description of the application**

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| Definition | This domain includes description of the health problem of the patients expected to use the telemedicine application and description of the application being assessed. The content of this domain serve as a description of the background for the assessment. |
| Topics | Health problem<br>• Definition of target condition/disease<br>• Symptoms, consequences<br>• Number of patients (epidemiology)<br>• Burden of disease, resource use<br>• Current management of health condition<br>• Existing quality standards<br>• Relations to other conditions or treatments. (Does the service have implications for treatment of competing disease)<br>• Change in patient segments (will the service increase or decrease the group of patients who can benefit from or will get the service offered)<br><br>Description of the application<br>• Features of the application<br>• Tools required for using the application<br>• Training and information needed for utilizing the application (staff and patients)<br>• Maturity of the telemedicine application (life cycle)<br>• Division of responsibility for the technical solution between involved organisations.<br>• Regulatory status<br>• Technical platform<br>• Market situation<br><br>Technical characteristics<br>• Infrastructure requirements<br>• Interoperability: Integration needs (EPR, devices, with current applications, technical standards etc.)<br>• Technical support<br>• Technical environment<br>• Standard situation.<br>• User support<br>• Back-up systems and procedures |
| Transferability issues | Are demography and patient characteristics similar?<br>Is the application based on international standards for data communication? |
| Methods for data collection | Systematic literature review<br>Analysis of register data<br>Interview with manufacturers, clinical experts |

| | Mapping of technical infrastructure and facilities |
|---|---|
| Examples of Outcome measures used in studies of telemedicine for diabetes, heart failure and COPD, see Tran (2008) | Baseline characteristics<br>• Inclusion/exclusion criteria<br>• Comparison arms<br>• Number of patients (male/female)<br>• Mean age<br>• Educational level<br>• HbA1c (%) – for diabetes<br>• LVEF – for heart failure<br>• NyHA class – for heart failure<br>• FEV – for COPD<br>• O – for COPD<br>• BMI<br>• Number of admissions in previous year |

**Domain: Safety**

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| Definition | Safety is mainly the identification and assessment of harms. |
| Topics | **Clinical safety (patients and staff)**<br>• What are the direct or indirect harms when using the telemedicine application?<br>• What is the scope of the harms?<br>• What are the types of harms?<br>• Are there estimates of incidence of harms?<br>• What is the timing of onset of harms?<br>• What is the duration and severity of the harms?<br>• What can be done to minimise the harms?<br><br>**Technical safety (technical reliability)**<br>• Is there a backup system and how does it work?<br>• What do the Service Level Agreements cover?<br>• Does the technology experience interference and what are the consequences?<br>• How is the safety compared to alternative technologies?<br>• How is security of data and the database (data privacy) and quality of data managed?<br>- encryption/cryptography<br>- data storage and ownership<br>- data ownership |
| Transferability issues | External validity: Can results be transferred to other patient groups?<br>Is the assessment of technical safety transferable to another organisation or cross-border? |
| Methods for data collection | Systematic literature review<br>New studies: Observational design, e.g. case-control studies, cohort studies<br>Analysis of register data (clinical databases)<br>Interview with manufacturers, clinical experts |
| Examples of outcome measures | o Types of harms (e.g. mortality, morbidity or disability)<br>o Incidence and duration of harms (frequency)<br>o Timing of onset of harms<br>o Severity of the harms (mild, moderate, severe or life threatening)<br>o Minimisation guidelines |
| References | Relevant studies from the literature review:<br><br>Crosbie JH, Lennon S, Basford JR, McDonough SM. Virtual reality in stroke rehabilitation: still more virtual than real. Disabil Rehabil 2007;29(14):1139-46 |

**Domain: Clinical effectiveness**

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| Definition | When defining clinical effectiveness it is important to make distinction between effectiveness and efficacy. Efficacy of telemedicine refers to the health benefits of a telemedicine application for the patients under ideal circumstances (i.e. carefully controlled conditions). Effectiveness refers to the performance of a telemedicine application in regular clinical practice. |
| Topics | • Effects on mortality<br>• Effects on morbidity<br>• Effects on health related quality of life (HRQL)<br>• Behavioural outcomes (e.g. exercise)<br>• Utilization of health services |
| Transferability issues | Can results be transferred to other diagnostic groups or other patient groups?<br>External validity<br>Efficacy versus effectiveness |
| Methods for data collection | Systematic literature review<br>New clinical studies: RCT, Cluster RCT, Controlled studies<br>Statistical studies on health care registers, clinical databases |
| Examples of outcome measures used in studies of telemedicine for diabetes, heart failure and COPD, see Tran (2008) | Diabetes<br>• HbA1c<br>• SF-36<br>• Diabetes quality of life score DQOL<br>• SF-12<br>• VAS<br>• The five item Centre for Epidemiologic Studies Depression Scale (CESD),<br>• Number of hospitalizations<br>• Number of rehospitalisations<br>• Number of bed days for hospitalised patients<br>• Number of primary clinic visits<br>• Number of specialist visits<br>• Number of visits at emergency department<br><br>Heart failure<br>• All-cause deaths<br>• Heart failure related deaths<br>• Revised Heart Failure Self-Care Behaviour Scale,<br>• MLHFQ: The 21-item Minnesota Living with Heart Failure Questionnaire<br>• 6 minute walk test<br>• NYHA FC<br>• Health Failure Self-Efficacy;<br>• Hospital Anxiety and Depression Score<br>• SF-12<br>• SF-36 v. 2<br>• EQ 5D<br>• Health distress scores<br>• VAS<br>• PHQ-9 |

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| | • CES-D<br>• CSQ: Reliability and Validity of Communication Skills Questionnaire<br>• Number of hospitalizations<br>• Number of heart failure related rehospitalisations<br>• Number of bed days for hospitalised patients<br>• Number of primary clinic visits<br>• Number of specialist visits<br>• Number of heart failure related visits at emergency department<br><br>COPD<br>• All caused deaths<br>• The SGRQ<br>• The Chronic Respiratory Questionnaire (for QoL)<br>• The Clinical COPD Questionnaire for health related quality of life<br>• SF-36<br>• The Minnesota Living with Heart Failure Questionnaire<br>• Number of hospitalizations<br>• Number of rehospitalisations<br>• Number of bed days for hospitalised patients<br>• Number of primary clinic visits<br>• Number of specialist visits<br>• Number of visits at emergency department<br>• Number of office visits<br>• Number of home visits |
| References: | Examples of relevant studies from the literature review:<br><br>Kairy D, Lehoux P, Vincent C, Visintin M. A systematic review of clinical outcomes, clinical process, healthcare utilization and costs associated with telerehabilitation. Disabil Rehabil 2009;31(6):427-47 |

**Domain: Patient perspectives**

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| Definition | Patient perspectives are issues related to the perception of the patient or the relatives of the telemedicine application including the patients and relatives acceptance of the technology. |
| Topics | • Satisfaction and acceptance<br>• Understanding of information<br>• Confidence (in the treatment)<br>• Ability to use the application<br>• Access and accessibility<br>• Empowerment, self-efficacy |
| Transferability issues | External validity: Can results be transferred to other patient groups?<br>Cultural differences, differences between subgroups |
| Methods for data collection | Systematic literature review<br>New studies (independent or part of controlled trials):<br>o Surveys<br>o Questionnaires<br>o Focus group interview<br>o Telephone interview |
| Examples of outcome measures | Studies of home telecare using locally designed questionnaire for patient satisfaction, see Tran (2008):<br>• Diabetes: Biermann 2002, Chase 2003, Maljanian, 2005: DQIP Scale for patient satisfaction, Piette, 2001, Wong, 2005<br>• Heart failure: Laramee, 2003, Riegel, 2002, Schofield, 2005, Shah, 1998<br>• COPD: Vontetsianos 2005<br><br>Examples of questions about patient satisfaction from The Lewin Group, Inc., 2000:<br>• Overall, how satisfied are you with today's telemedicine session?<br>• How easy was it to talk with the provider on the other end of the telemedicine connection?<br>• Are you comfortable that the provider was able to understand what your health problem was?<br>• How much did the telemedicine provider seem to care about you as a person?<br>• Did you feel relaxed or tense during the telemedicine session?<br>• Did the telemedicine make it easier for you to get care today?<br>• Do you think telemedicine improves your medical care?<br>• Do you think your telemedicine session was as good as a regular in-person visit?<br>• How well did the telemedicine equipment work today?<br>• Would you use telemedicine again?<br>Examples of questions about patient perception of increased access described by |

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| | Scott el al. (2007):<br>o Do you feel this consultative service will affect the health care of the rural community?<br>o Do you feel this system may have an impact on rural physicians?<br>o Do you feel this system may have an impact on rural patients' families or support systems?<br>o Do you think this system may have an impact on the patient's health status?<br>o Do you agree that you have been receiving good service and that with telehealth things are out in the open?<br>o Do you feel that the doctor is not there but the clinic is still good?<br>o Do you like telehealth because it is quick and you do not have to wait so long?<br><br>Examples of studies of self-efficacy:<br><br>o Benatar (2003)<br>o Piette (2000)<br>o Wong, 2005<br><br>Examples from a number of studies described by Scott et al. (2007):<br>**Outcome: feelings, experiences and comfort**<br>• The presence of the TV camera made me feel self-conscious<br>• By the end of the consultation I was comfortable with speaking to my specialist through telehealth<br>• I was comfortable throughout the assessment<br>• I could reveal my thoughts and feelings over the phone<br>• I was comfortable with telephone talks<br>• I was comfortable speaking to the nurse<br>• I enjoyed talking to the doctor in this way<br>**Outcome: professional–patient interaction**<br>• What was being done was explained to me<br>• I could discuss everything fully with my midwife<br>• The community midwife encouraged me to ask all the questions I wanted to ask<br>• The physician's activities were made clear and understandable to me<br>• I could communicate well with the patient and parent<br>• It was easy for me to talk to the psychiatrist<br>• The consultant understood my problem<br>• Telehealth provided improved communication with the patient<br>**Outcome: timeliness and convenience**<br>• The appointment took longer than expected<br>• The length of wait to get an appointment with a specialist was short<br>• The telehealth facility is located conveniently at the hospital<br>• The time I spent in the consultation was shorter<br>• The results of my tests were returned much quicker<br>Outcome: overall satisfaction<br>• I was satisfied with the visit overall |

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| | • Overall the amount of information given to me by the community midwife was satisfactory<br>• The assessment went well<br>• The assessment was helpful<br>• I was satisfied overall with the care received from the nurse<br>• I was satisfied overall with the telehealth system<br>**Outcome: preference between face-to-face and telehealth**<br>• I would rather see a patient/specialist using the telehealth system now, than wait a few days to see him/her in person<br>• A teleconsultation is just as good as going to the outpatient clinic to see the dermatologist<br>• I would rather have a video examination with a psychiatrist than an in-person examination with a general practitioner who knows a little less about<br>• psychiatry<br>• If you live two or more hours away from the hospital: I would rather travel to the hospital to see the psychiatrist than go to a place close to home and see<br>• them by video<br>• Overall, I preferred the video visit over a face-to-face visit<br>• The care I received from this video visit was as good as an in-person visit<br>• I would prefer using telehealth instead of travelling<br>**Outcome: privacy/confidentiality**<br>• I felt that my privacy was respected during the telehealth consultation<br>• I do not believe this system will make it easier for my private information to leak out<br>**Outcome: professional competence/personal manner**<br>• My surgeon showed confidence in interacting with me by telehealth<br>• The doctor showed high technical skills through his/her thorough, careful and competent use of the telehealth equipment<br>• The personal manner of my doctor was courteous, respective, sensitive and friendly<br>**Outcome: technological performance**<br>• I could hear everything that was being said<br>• The quality of the transmission was satisfactory<br>• The telehealth equipment worked well<br>• The technical effort necessary for conducting the telehealth service seemed great<br>• It was easy for me to see and hear the psychiatrist<br>• I could hear the interviewer well<br>• The interview seemed very mechanical<br>**Outcome: informativeness**<br>• The way I obtained information from my community midwife is best described as (choice)<br>• I was satisfied with my nurse's medical knowledge<br>**Outcome: potential for future use/usefulness**<br>• The teleconsultation was valuable in this individual case<br>• I would recommend telehealth for future investigations with this patient |

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| | • I would like the following changed or improved (choice)<br>• I will use the telepsychiatry service in the future<br>• I was satisfied with the health improvement of my client<br>• I would recommend the programme to my colleagues |
| References | Examples of relevant studies from the literature review:<br>Griffiths KM, Christensen H (2006), Review of randomized controlled trials of Internet intervention for mental disorders and related conditions, Clinical Psychologist, vol. 10, no. 1, pp. 16-29<br><br>Hyler SE, Gangure DP, Batchelder ST. Can telepsychiatry replace in-person psychiatric assessments? A review and meta-analysis of comparison studies. CNS Spectr 2005;10(5):403-13<br><br>**Studies measuring patient satisfaction in relation to telemedicine applications:**<br>Biermann E, Dietrich W, Rihl J, Standl E. Are there time and cost savings by using telemanagement for patients on intensified insulin therapy? A randomised, controlled trial. Comput Methods Programs Biomed 2002;69(2):137-46.<br><br>Chase HP, Pearson JA, Wightman C, Roberts MD, Oderberg AD, Garg SK. Modem transmission of glucose values reduces the costs and need for clinic visits. Diabetes Care 2003;26(5):1475-9.<br><br>Laramee AS, Levinsky SK, Sargent J, Ross R, Callas P. Case management in a heterogeneous congestive heart failure population: a randomized controlled trial. Arch Intern Med 2003;163(7):809-17. Available: http://archinte.ama-assn.org/cgi/reprint/163/7/809 (accessed 2008 Apr 25).<br><br>Maljanian R, Grey N, Staff I, Conroy L. Intensive telephone follow-up to a hospital-based disease management model for patients with diabetes mellitus. Dis Manag 2005;8(1):15-25.<br><br>Piette JD, Weinberger M, Kraemer FB, McPhee SJ. Impact of automated calls with nurse follow-up on diabetes treatment outcomes in a Department of Veterans Affairs Health Care System: a randomized controlled trial. Diabetes Care 2001;24(2):202-8.<br><br>Riegel B, Carlson B, Kopp Z, LePetri B, Glaser D, Unger A. Effect of a standardized nurse case-management telephone intervention on resource use in patients with chronic heart failure. Arch Intern Med 2002;162(6):705-12. Available: http://archinte.amaassn.org/cgi/reprint/162/6/705 (accessed 2008 Apr 28)<br><br>Schofield RS, Kline SE, Schmalfuss CM, Carver HM, Aranda JM, Pauly DF, et al. Early outcomes of a care coordination-enhanced telehome care program for elderly veterans with chronic heart failure. Telemedicine and e-Health 2005;11(1):20-7. |

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| | Shah NB, Der E, Ruggerio C, Heidenreich PA, Massie BM. Prevention of hospitalizations for heart failure with an interactive home monitoring program. Am Heart J 1998;135(3):373-8.<br><br>Vontetsianos T, Giovas P, Katsaras T, Rigopoulou A, Mpirmpa G, Giaboudakis P, et al. Telemedicineassisted home support for patients with advanced chronic obstructive pulmonary disease: preliminary results after nine-month follow-up. J Telemed Telecare 2005;11(Suppl 1):86-8.<br><br>Wong FK, Mok MP, Chan T, Tsang MW. Nurse follow-up of patients with diabetes: randomized controlled trial. J Adv Nurs 2005;50(4):391-402.<br><br>**Studies measuring self-efficacy in relation to telemedicine applications**<br><br>Benatar D, Bondmass M, Ghitelman J, Avitall B. Outcomes of chronic heart failure. Arch Intern Med 2003;163(3):347-52. Available: http://archinte.ama-assn.org/cgi/reprint/163/3/347 (accessed 2008 Feb 27).<br><br>Piette JD, Weinberger M, McPhee SJ. The effect of automated calls with telephone nurse follow-up on patient-centered outcomes of diabetes care: a randomized, controlled trial. Med Care 2000;38(2):218-30.<br><br>Wong KW, Wong FK, Chan MF. Effects of nurse-initiated telephone follow-up on self-efficacy among patients with chronic obstructive pulmonary disease. J Adv Nurs 2005;49(2):210-22 |

**Domain: Economic aspects**

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| Definition | The economic aspects of a telemedicine application can be described in:<br>• A societal economic evaluation comparing a telemedicine application with other relevant alternatives in terms of both their costs and consequences.<br>• An analysis of the expenditures and revenues for the health care institutions using the telemedicine application. |
| Topics | **Economic evaluation (societal perspective)**<br>o Amounts of resources used when delivering the assessed telemedicine application and its comparators in the health care sector and other sectors<br>▪ Types of resources:<br>- Investments in equiptment<br>- Training of staff<br>- Maintenance<br>- Use of staff (for each of the relevant type of staff)<br>- Medication<br>- Utensils<br>- Patients' use of time<br>- Relatives' use of time<br>- Transportation<br>o Unit costs or prices for each resource used<br>o Related changes in use of health care resources<br>- Primary care<br>- Emergency unit<br>- Outpatient visits<br>- Hospitalization<br>- Bed days<br>- Tertiary care<br>Clinical effectiveness of the telemedicine application and comparators (to be used in the cost-effectiveness analysis – see domain on clinical effects)<br><br>**Business case (institutional level)**<br>• Expenditures per year (including expenditures related to the resource use described in the cost estimation above)<br>• Revenue per year:<br>• Activity (number of patients or services)<br>• Reimbursement (e.g. DRG-rate) per service or patient<br><br>**Sensitivity analysis** (Risk analysis) |
| Transferability issues | External validity: Are the conditions during the trial realistic in practice?<br>Cost function: To what extent does the cost per patient vary with number of patients?<br>Economic consequences for different regions |
| Methods for data collection | Systematic literature review<br>New studies (independent or part of controlled trials):<br>- RCT, cluster RCT<br>- Controlled trials, cohort studies<br>- Stat. analysis of register data |
| Examples of | |

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| outcome measures | Examples from studies described by Scott et al. (2007)<br><br>**Travel**<br>- Airfare<br>- Travel costs<br>- Consultant transportation costs<br>- Costs of travelling by different modes of transportation considered<br>- Changes in transportation costs<br>- Costs of travelling to hospitals for face-to-face – car mileage allowance, distance travelled, time spent travelling<br>- Patient non-emergency transportation costs<br>**Equipment**<br>- Equipment lease costs<br>- Equipment costs<br>- Maintenance costs – maintenance charges for equipment, should be calculated at<br>- 10–15% per year of the capital cost of equipment; include travel times and cost of<br>- maintenance provider<br>- Initial purchase of hardware<br>- Installation and maintenance<br>- Hardware<br>- Software<br>- Costs of implementation of home telecare system<br>- System costs<br>- Operational expenses<br>- Costs of each workstation<br>- Home fetal monitoring equipment costs<br>**Communication**<br>- Telecommunication costs<br>- Line rental and call charges<br>- Long-distance telecommunication charges<br>- Telecommunications and utilization charges<br>- Monthly communication line charges<br>- Running costs, e.g. telephone line<br>- Line charges<br>- Phone calls<br>- Modem costs<br>- Costs of telecommunication using ISDN lines<br>- Installation costs for digital telephone lines<br>**Staffing**<br>- Personnel for start-up and maintenance of the system<br>- Employment costs of a consultant<br>- Staffing costs<br>- Consultant and support staff fees/wages<br>- Nursing costs, e.g. labour and benefits<br>- Personnel costs<br>- Hourly rate of consultant dermatologist and neurologist<br>- Hourly rate of GP<br>**Cost of time** |

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| | - Consultant's time<br>- Midwife's time<br>- Time devoted by doctor/nurse team<br>- Patient time<br>- Physician time<br>- Time for work stoppage for patients<br>- Time spent on project for personnel<br>- Average cost of consultant time for teledermatology and for conventional consultation<br>- Average cost of GP time at a teledermatology consultation<br>**Hospital/care costs**<br>- Number of referrals<br>- Treatment costs<br>- Standard ancillary care costs (e.g. laboratory services, ambulance)<br>- Standard hospital costs (e.g. inpatient costs)<br>- Daily costs per patient<br>- Antenatal clinic visits<br>- Antenatal inpatient days<br>- Total cost of domiciliary care<br>- Costs should incorporate any savings and expenditures in treating a patient in the course of the condition<br>- Changes in the productivity of health-care professionals<br>- Costs per patient visit<br>- Costs of face-to-face depend on length of clinic sessions, number of investigations and number of reviews<br>- Prescription costs considered<br>**Administrative**<br>- Overhead costs<br>- Facility charges<br>- Supplies<br>- Administration charges<br>- Other project-specific costs<br>- Administrative overhead<br>**Subsistence costs**<br>- Accommodation<br>- Meals<br>**Other cost considerations**<br>- Emerging and evolving reliability of technology<br>- Skill level of users<br>- Uncertainty regarding the most efficient and effective applications<br>**Project establishment costs**<br>- Preparation of submissions for funding approval<br>- Recruitment of staff<br>- Selection process to decide which projects are to proceed<br>- Preparation of tenders for equipment |
| References | Drummond et al. 2005. Methods for the Economic Evaluation of Health Care programmes. Oxford Medical Publications.<br>The MethoTelemed Guidance at http://www.telemed.no/methotelemed.4565273-125741.html |

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| | Tran K, Polisena J, Coyle D, Coyle K, Kluge E-H W, Cimon K, McGill S, Noorani H, Palmer K, Scott R. *Home telehealth for chronic disease management* [Technology report number 113]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008.<br><br>Examples of relevant studies from the literature review:<br><br>Kairy D, Lehoux P, Vincent C, Visintin M. A systematic review of clinical outcomes, clinical process, healthcare utilization and costs associated with telerehabilitation. Disabil Rehabil 2009;31(6):427-47.<br><br>Clark RA, Inglis SC, McAlister FA, Cleland JGF, Stewart S. Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis. BMJ 2007;334(7600):942<br><br>Deshpande A, Khoja S, Lorca J, McKibbon A, Rizo C, Jadad A R. AsynchronousTelehealth: Systematic Review of Analytic Studies and Environmental Scan of Relevant Initiatives [Technology report no 101]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008<br><br>Farmer, A., O. J. Gibson*, L. Tarassenko* and A. Neil† A systematic review of telemedicine interventions to support blood glucose self-monitoring in diabetes. © 2005 Diabetes UK. Diabetic Medicine 22, 1372-1378<br><br>Jaana M, Pare G, Sicotte C. Home telemonitoring for respiratory conditions: A systematic review Am J Manag Care 2009;15(5):313-20 |

**Domain: Organisational aspects**

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| Definition | An organisation is a consciously coordinated social unity with clear boundaries and continuous activities which target certain goals. The organisational domain considers what kind of resources have to be mobilized and organized when implementing a new technology, and what kind of changes or consequences the use can further produce in the organisation.<br><br>In a telemedicine context the organisational aspect must be considered on three levels: health system level (national or regional), inter-organisational level (between organisations) and intra-organisational level (within organisations). |
| Topics | Process<br>• Workflow<br>• Staff, training and resources<br>• Interaction and communication<br>Structure<br>• Spread of technology, centralization or decentralization<br>• Economy (see domain on economic aspects)<br>Culture<br>• Attitude and culture<br>Management |
| Transferability issues | External validity: Can results be transferred to other organisations?<br>Can results be transferred to other patient groups?<br>Mapping pathways into the community – transfer beyond the health system.<br>Barriers and facilitators |
| Methods for data collection | Systematic literature reviews<br>New studies (independent or part of controlled trials):<br>- Surveys<br>- Questionnaires<br>- Interviews<br>- Focus group interviews |
| Examples of outcome measures | Examples of quantitative or qualitative outcomes:<br><br>**Process outcomes**<br><br>**Workflow**<br>• Number of patients treated<br>• Number of procedures performed<br>• Referral times<br>• Bed days<br><br>**Staff, training and resources:**<br>• Changes in distribution of work (working hours spent) between the professions involved (Task shifting)<br>• Changes in staff requirements (reduction or increase of working hours) for each profession involved<br>• Time spent by members of staff on training in order to learn to apply telemedicine devices<br>• Changes in hours spent on various procedures in clinical |

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| | pathways, measured for each relevant profession<br><br>**Interaction and communication**<br>• Amount of electronic communication<br>• Changes in information and reporting system<br>• Changes in number of face-to-face patient consultations<br>• Changes in the way medical staff communicate<br>• Changes in the way the medical staff work together (generalists/specialists, doctors/nurses, etc.)<br><br>**Structure outcomes:**<br>• Changes in the number of units offering treatment<br>• Number of organisational units set up especially for telemedicine (if any)<br>• Changes in the organisation of generalist and specialist tasks<br>• Changes in geographical spread<br>• Time spent on travel, staff<br>• Time spent on travel, patients<br><br>**Culture outcomes:**<br>• Staff attitudes towards telemedicine applications<br>• Staff experience with the use of telemedicine applications<br><br>**Management outcomes:**<br>• Changes in managers' span of control (on all relevant levels)<br>• Changes in leadership style |
| References | Examples of relevant studies from the literature review:<br><br>Deshpande A, Khoja S, Lorca J, McKibbon A, Rizo C, Jadad A R. AsynchronousTelehealth: Systematic Review of Analytic Studies and Environmental Scan of Relevant Initiatives [Technology report no 101]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008<br><br>Kairy D, Lehoux P, Vincent C, Visintin M. A systematic review of clinical outcomes, clinical process, healthcare utilization and costs associated with telerehabilitation. Disabil Rehabil 2009;31(6):427-47 |

**Domain: Socio-cultural, ethical and legal aspects**

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| Definition | The domain includes topics that identify the ethical, legal and socio-cultural aspects of the telemedicine application. |
| Topics | Ethical issues:<br>• Overall questions: Does the application challenge religious, cultural or moral beliefs?<br>• Potential ethical problems, e.g. giving the responsibility to the patients<br>• Autonomy: Is the patient's autonomy challenged or increased?<br>• Equity<br>Legal issues:<br>• Clinical accreditation<br>• Information governance<br>• Professional liability<br>• Patient control – consent, access<br>Social issues<br>• Changes in the patients role in major life areas (e.g. social life, working life)<br>• Patients' relatives and others' understanding of the technology<br>• Societal, political context and changes. Will the service influences the general model for the delivery of healthcare service if deployed<br>• Changes in responsibility. Are the patients and/or relatives capable of handling there responsibility?<br>• Gender issues. Has the service any consequences on the position of gender? |
| Transferability issues | External validity: Cultural differences, legal differences, differences between subgroups<br>Necessary legal basis<br>Transferability across borders |
| Methods for data collection | Systematic literature review<br>New studies (independent or part of controlled trials):<br>• Surveys<br>• Questionnaire<br>• Focus group interview<br>• Laws<br>Interviews with key stakeholders<br>Referral to ethics committees<br>Seeking to establish consensus (e.g. through Delphi exercises). |
| Examples of outcome measures | A list of reports on ethical and legal considerations in relation o telemedicine can be found in Tran (2008) appendix 3B.<br><br>Other examples:<br>• Liability - who is responsible for the treatment?<br>• Is special authorisation and licensing of health professionals needed?<br>• Autonomy and privacy of the patient<br>• Equity (fairness) in health care<br>• Authorisation |

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| | • Ownership and liability<br>• Legal regulation of novel/experimental techniques |
| References | Examples of relevant studies from the literature review:<br><br>Marziali E, Serafini JMD, McCleary L. A systematic review of practice standards and research ethics in technology-based home health care intervention programs for older adults. J Aging Health 2005;17(6):679-96 |

## Appendix 2: List of experts and stakeholder participants in workshops

### PARTICIPANTS WORKSHOP 1 – USERS' NEEDS

Peeter Ross, Dr., East Tallinn Centra Hopspital, Estonia
Jan Norum, MD, Helse Nord, Norway
David Kelly, Dr., Managing Director Scotland and Ireland, Tunstall, UK
Mikko Nenomen, Prof, Dr. Department of Health Policy and Management, University of Kuopio Finland and Member, European Health Management Association,
Daniel Mart, Dr., Standing Committee of European Doctors (CPME), Luxembourg
Rod Mitchell, Mr., Secretary General International Alliance of Patients' Organizations (IAPO) UK
Kart Stroetmann, Dr., EMPIRICA Consultancy, Germany
Marc Lange, Mr., Director EHTEL - European Health Telematics Association, Belgium
Kjersti Halvorsen Engeseth, advisor, Norwegian Directorate of Health, Norway
Bjoern Bergh, Dr., Center for Information Technology and Medical Engineering, Germany
Joan Guanyabens, Dr., Director, TICSALUT Barcelona, Spain
Thomas Børner, commissioner, Ministry of finance, Denmark
Michèle Thonnet, Ms., Ministry of Health, France
Moira Mackenzie, Telecare Programme Manager, Joint Improvement Team, Scottish Government
Isabelle Andoulsi, Lawyer, University of Brussels, and Member of Brussels Bar, Belgium
Kim Cierkens, Lawyer, Callens Law Firm
Anne Strauss, Professor, MD, PHD
Petra Wilson, Dr, Director, Healthcare, Internet Business Solutions Group
Michael Hansen-Nord, MD, Odense University Hospital, Denmark
Rolf Jelnes, MD, Sønderborg Hospital, Denmark

### PARTICIPANTS WORKSHOP 2 - VALIDATION

David Kelly, Managing Director- Scotland and Ireland, Tunstall Healthcare (UK)
Marc Lange, Director EHTEL - European Health Telematics Association, Belgium
Björn Bergh, Prof. Dr. Med., University Hospital Heidelberg, Centre for Information technology and Medical
Engineering, Germany
Gordon Peterkin, Professor Scotland
Karl A. Stroetmann, Dr. PhD MBA FRSM Empirica Communication & Technology Research
Kristian Lampe, THL/Finohta, Finland
David Bell, UK
Elinaz Mahdayv, Orange Healthcare, France
Veronique Thouvenot, Dr. WHO
Isabelle Andoulsi, Lawyer, Exelia, Belgium
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Pirkko Nykanen, Department of Computer Sciences University of Tampere Finland
Rod Mitchell, International Alliance of Patients' Organisations, UK
Stephan Schug, MD, MPH, EHTEL, Germany
Moira Mackenzie, Scottish Government, UK

George Dafoulas, MD, Municipality of Trikala, Greece
Richard Wootton, Professor, Scottish centre for Telehealth, Journal of Telemedicine and Telecare, UK
Patrice Cristofini, Orange Healthcare
Deede Gammon, Dr., Norwegian Centre for Integrated care and Telemedicine
Gro Berntsen, Dr., Norwegian Centre for Integrated Care and Telemedicine