

MethoTelemed

Validation report Workshop Two

December 2009

Submitted by
MedCom & Norwegian Centre for Telemedicine

In association with
University of Stirling & Norwegian Centre for the Health Services

MethoTelemed

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

Preface

Validation report is the fourth internal deliverable of the project MethoTeleMed, a one year study commissioned by the European Commission (EC).

At Workshop Two, international academic excellence, policy makers and European networks were brought together to present, discuss and validate the MethoTelemed Guidance as well as a specific evaluation Framework for Assessment of Telemedicine (FAST) that has been developed in MethoTelemed. The workshop was held after nine months work.

The report shows how the findings of the workshop will contribute significantly to the finalising process of developing FAST and the Guidance.

The project 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 project team (hereafter ‘the MethoTelemed team’) also includes a panel of international expert advisers in business, economics, health policy analysis, Health Technology Assessment (HTA) and medicine; and stakeholders in telemedicine including patient groups, who are taking part in structured consultation of which this Workshop.

The report builds upon the outcome from Workshop Two held in Brussels on November 5, 2009.

The MethoTelemed team would like to express their gratitude to the participants for having set aside time to participate in the workshop.

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Chapter 1: Workshop aims and structure

In this chapter the main considerations about the workshop are described.

1.1 The MethoTelemed team's aims and expectations

The key focus was to bring forward the participants' explicit knowledge about the field and to validate the work in the MethoTelemed project so far.

Our aims and expectations for the workshop were:

- to present the results from the systematic literature review and a framework for general guidelines for evaluations models based on the evidence, and
- to present, discuss and validate a specific assessment framework for the decision process for telemedicine services.

1.2. Structure of the day and methods used

To achieve the aims and expectations mentioned above, it was important to get the participants involved in discussion. In order to do this, they were divided into two groups, each working with an experienced facilitator. To structure the group discussions in the afternoon, the facilitators used 7 posters – one representing each domain in the FAST framework. Outcomes from the group work were presented in plenum before lunch and in the afternoon before ending the workshop.



After finishing the second part of the literature review, the research team presented the results from the review. These findings, together with an introduction of the MethoTelemed Guidance, as well as a demonstration of the Online MethoTelemed Guidance were used to provide background for the participants before the group work in the morning. In the groups the discussion focused on the strengths, weaknesses, gaps and methodologies of the MethoTelemed Guidance. The comments and feedback from the groups will be used in the further work.



After lunch the Framework for Assessment of Telemedicine (FAST) – a framework that has been developed in MethoTelemed was presented. The presentation was used to provide background for the participants before the group work. It was also mentioned that the two cases: ‘the Danish Case of COPD’ and ‘Telemedicine in the handling of patients with chronic foot and leg ulcers’ could be used in the discussion as practical examples. The participants who attended the first workshop are familiar with the cases, the rest of the participants had a description of the cases in the report of workshop one, included in the material circulated beforehand. The group work focused on discussing the domains, topics and methods in the FAST framework. Again the comments and feedback from the groups will be used in the further work.

1.2 Material for the workshop

The material presented by the team was intended to give the participants a common basis and understanding of a number of terms and concepts before the workshop. It was important that the participants who did not attend the first workshop felt that they were not missing any knowledge about the project.

It included:

- an introduction paper (see appendix 1a)
- the agenda and participation list (see appendix 1b)
- a preparation paper from the research team (see appendix 1c)
- a paper presenting a description of FAST (see appendix 1d)
- the short version of the MethoTelemed project ([see MethoTelemed homepage](#))
- the Users needs report - results of Workshop One ([see MethoTelemed homepage](#))

1.3 Participants

The invited participants were selected so that they represented the key stakeholder groups - patients, health professionals, health insurance, IT industry, international organisations, and legal and health authorities. The list of those invited was based on the list of proposed workshop participants listed in table 7.4.1, page 24 in the tender and on the list of the participants attending workshop one. The final selection of participants invited was agreed with the EU Commission.

PARTICIPANTS

Group 1

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, Professor of Economics, University of Stirling. UK
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Group 2

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Jane Clemensen, Consultant MedCom Denmark
Janne Rasmussen, Consultant MedCom Denmark
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Chapter 2: Comments from the participants

This chapter contains a description of the comments from the participants at the workshop regarding 1) the guidance and 2) the FAST.

2.1 Comments from the participants to the Guidance

2.1.1 Session 1

The structure of the validation of the MethoTelemed Guidance is organised according to categories and themes and the two groups comments is provided jointly. The validation is organised in the following categories: Structure, Readers/users and content, Update/continuation, and Dissemination.

1. Structure of the Guidance

The structure of the Guidance should be improved on a number of points:

- Segmentation of the Guidance website visitors – guiding different readers to the right place
- Front of the Guidance should make clear how a visitor/user begin their search and how it works.
- Knowledge focused on back-end rather than front-end of the Guidance
 - E.g. front could be organised differently
 - Should help/guide the reader more
 - Two groups of readers with different needs:
 - Planning an evaluation study
 - Wanting to see what others have done but nothing evaluating themselves
- Approach of questions is good but include subject also – e.g. economics
- More structure is needed in order to work. E.g. data privacy is an issue for all stakeholders, but is e.g. nationally dependent.

2. Readers/users and content of the Guidance

- Target audience – Who is the Guidance meant for? Must be clearer if the readers/users are scientific/research communities; decision and policy makers; industry; EU; local projects or only EU projects and/or all of them. Structure and content must then reflect this.
 - Consider the overlapping access of the visitors/users of the Guidance
 - Consider the entry to the Guidance – Who am I and what are my interests? (Wikipedia)
 - Consider a structured knowledge base/different pathways depending on who the visitor/user is
 - Consider language as these groups use and understand different terminology etc.
 - Consider providing a common glossary
- Implementation - For evaluation to be valid must focus on implementation.
 - Evaluation should help implementation so have focus on implementation
 - Contain information on how to go from pilot to implementation
 - Business case aspects should be incorporated (for certain stakeholders this is the main argument for implementation)
 - A block on how to implement telemedicine
- Incorporate use cases/examples for demonstrate how the Guidance can be used (i.e. the different group of readers)

- Who else is doing what – describe research being done and provide contact information to relevant people
- Links must reflect the reality, e.g. HTA can be linked to from most questions.
- It should be highlighted that there is a literature base behind the Guidance and its content and references to it provided. Also what the quality criteria are for the included literature/research. Discussion of the grey literature – should it be included or excluded in the Guidance?

3. Update/continuation of the Guidance

- How is going to be kept up to date?
 - Community driven update: is it to be community developed and sustained (like Wikipedia?) Anthology approach.
 - Maintained by an organisation: then who will pay for it? The European Commission? Research institutions or societies? Or who?
- Long term consequences: will it end up pushing the costs for implementing telemedicine further and slow us down?

4. Dissemination of the Guidance

- Branding to ensure knowledge of its existence. Otherwise the Guidance will not have the intended effect and reach a wider audience.

In conclusions the Guidance was overall considered of good quality by the experts but will require further work in order to be useful. A more precise presentation of who the Guidance is intended for (audience) and how it can help (structure/content) must be made. The critical issue is that of maintenance and update of the Guidance. If it is to be relevant and useful in the future it is essential that the literary research base is updated, maintained and sustained. It will also be necessary to disseminate the Guidance properly to the intended user groups.

2.2 Comments from the participants to the FAST

The charts below are the MethoTelemed teams attempt to structure the general comments from the Commission received after the workshop.

No.1	General comments from the Commission
1.1	The general framework is validated after the second workshop
1.2	You should consider separating the first domain, Health problem and technologies, as well as Legal aspects in other items. Consider the experts' suggestions.
1.3	We need to develop every domain. Every domain should be supported by evidence from the literature. Every domain should be well structured, not a list of different variables.
1.4	The method should propose not only indicators to be assessed but also how to assess them (i.e. quality of life to be assessed, how, according to which methodology?). Not only a list or type of studies will be admitted. A serious and justified discussion should be introduced when the evidence is lacking or weak.
1.5	The weakest domains are: safety, economic aspect and organisational aspect. A

	model for each one should be presented. Specific indicator should be described
1.6	<p>In order to standardize and analyse a minimal effectiveness, a specific methodology for cardiovascular diseases, COPD and diabetes should be presented, like examples of the general context proposed. As these proposes were not validated by the experts, these proposes should be based on literature.</p> <p>Example: For Cardiovascular diseases:</p> <ul style="list-style-type: none"> - Mortality - Quality of life: questionnaire: Minnesota Living - Behaviour change: Adherence to treatment: number of patient who compliance treatment - Patient Satisfaction: a questionnaire - Professional Satisfaction: a questionnaire - Safety: propose a measurement of adverse effect - Use of resources: readmission: number of day in the hospital...

The charts below are the MethoTelemed teams attempt to structure the notes from the group work in the afternoon at the workshop regarding the FAST. We hope that the participants can recognise their statements; otherwise the MethoTelemed team would very much like to know.

No.2	General comments to the FAST
2.1	Health problem step 0
2.2	<p>Discussion of whether or not to go back to the original 9 EUnetHTA.</p> <ul style="list-style-type: none"> - Domain 1 in two by moving Health problem to pre-assessment, - Domain 7 in two - Domain 4 stays. - Move ethical and legal to pre-assessment also? - Topics in domain 7 are often neglected and by giving them each a domain they are brought in to focus - 9 domains are already recognised in the HTA communities
2.3	The FAST should be simpler.
2.4	More focus on the users, including the industry
2.5	What do you mean with framework? Is it different from method?
2.6	Maybe the system can be made better from the application
2.7	Common base should be there in some cases
2.8	Health problem is outside the domains (at strategic level instead)
2.9	What is the timeline for measuring benefits? At what point is it appropriate to make the investment with new technology waiting around the corner?
2.10	Time aspect in developing telemedicine.
2.11	Use Donabedians Framework: structure, process, outcome
2.12	The framework refers to projects rather as people and their diagnoses. There is an issue if you will start to make this to a higher level. First you need to ask, what are the system issues?

No.3	Comments to the preceding assessment (On what level should the assessment be made: National, regional or local? Relevant alternatives?)
3.1	Is it a method or framework?
3.2	Clinical effectiveness is cross-border, but everything else is not. General assumption that telehealth works, depends on many other factors.

3.3	'Other aspects' must be defined
3.4	What are the components of an intervention that make it successful? Much more than the technology itself.

No.4	Comments to domain 1 <i>Health problem and characteristics of the application</i>
4.1	Provision – what is the problem we are trying to solve? Lifecycle management What problem are we trying to solve (not just disease as in health problem)
4.2	Clinical evidence is not enough
4.3	Domain 1 should be split – technology removed from health problem Suggestion to split domain 1 into two domains. Clinical and health problem. Agreement that this is possible. Suggestion to add life value to the domain. Split in two parts; health problem and characteristics of the application
4.4	There should not be a domain no. 8. The technology should be connected with domain no. 1 and not alone.
4.5	Include description of the patients incl. bi-diagnosis
4.6	Domain 1 should be put together with “preceding assessment”
4.7	It lacks a description of how the technology affects the quality of the treatment. The purpose of using the technology. The intention.
4.8	It needs an introduction called “what is the decision you are trying to make” and not a domain. A description of the problem
4.9	Include expected gains

No. 5	Comments to domain 2 <i>Safety</i>
5.1	Dependence on technology – what if the system breaks down? Maybe the system can be made better from the application
5.2	Balancing risk against benefit, not against an ideal world. Are you increasing safety for the patients?
5.3	Technical safety. SLA away from safety.
5.4	The domain needs to be changed. There are a lot of issues we have not included.
5.5	Addition of a privacy element and suggestion of moving several elements like data security, infrastructure to domain no. 4
5.6	Suggestion of changing the security of the patient to protect the data. There are two issues. If you want to have a safe system, you need to secure the data
5.7	There is missing the aspect that patients' needs to choose for themselves

No. 6	Comments to domain 3 <i>Clinical effectiveness</i>
6.1	Standard way of producing clinical evidence
6.2	Broader clinic effects. Effect on life situations?
6.3	Mental health – a part of effects on morbidity
6.4	We have to look for clinical processes. There are two elements in this. Telemedicine changes clinical processes, sometimes it is only a part of the process. You need to find a way to asses the clinical process

6.5	You need to collect the economic elements
6.6	Clinical processes are just as important as clinical outcomes. Whether or not you give the right drug to the right person. To improve the quality.

No.7	Comments to domain 4 <i>Patient perspectives</i>
7.1	Broader view than just patient, should stakeholder perspectives be included?
7.2	Advocacy as an issue - for people who cannot speak for themselves
7.3	Relatives have an important role and should be mentioned in one of the domains. Should it be domain 4? Relatives to be included in domain 4.
7.4	Acceptance from patient's perspective? <ul style="list-style-type: none"> • Will it solve my health problem? • Will it improve quality of life? • What about respect?
7.5	We need the patients to be active in order to succeed.
7.6	Include "what is the technology doing to the patient"
7.7	Equity is missing
7.8	In this solution we cannot discuss patient aspect alone; you also need to include the clinical professionals' perspectives. The patients' interaction with the clinical professionals. In telemedicine this is very important. The patient has a perception but also listens to the professionals
7.9	How you work with patients from the patients' perspective. It gives you different aspects. E.g. patient should be allowed to make their own choices?
7.10	Is the system flexible enough to reflect the changes on how the patients take control?. The control starts to shift

No. 8	Comments to domain 5 <i>Economic aspects</i>
8.1	Who will benefit from the telehealth solution?
8.2	Who gains from the benefits? Benefit from whom? Who gains from the benefits? Incentive structures, time aspects
8.3	Incentive structures: what if the gains are achieved elsewhere?
8.4	Time aspects
8.5	Lack of link between practical business cases and the other kinds of analysis
8.6	Decide which method should be used. How do you estimate cost benefit? Decide on one method, e.g. cost-benefit, but how is benefit measured in telemedicine? Cost-benefit means you translate everything in to numbers
8.7	Do we need societal cost as part of economic analysis?
8.8	Electronic records? Who looks at the economics? No one. Perceived usefulness
8.9	You can have a cost-benefit analysis that looks great, but if the incentives are not in place for all stakeholders (acute care, primary care, social care e.g.) it is pointless = incentive structures needed
8.10	Include incentives

No.9	Comments to domain 6
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Organisational aspects	
9.1	Leadership
9.2	Ownership (often across department or organisations)
9.3	You are not just dealing with your own organisation
9.4	Organisational changes: intended or unintended
9.5	You won't always end up with satisfied employees
9.6	Staff education may not include technology
9.7	More details in e.g. organisations (what management issues should be looked for)
9.8	Basic organisational stuff (physical things) and then the human part (staff)
9.9	Leadership is missing in domain 6 and is critical for success. Exceeds management (=local) is broader, meaning it goes across institutions etc.
9.10	Discuss the usability. There is organisational learning. Acceptance, usability. Interaction between the patients and the staff. Spread of knowledge. Culture means a lot of things. Also private and public hospitals
9.11	Intermediate outcomes should be included

No.10	
Comments to domain 7	
Socio-cultural, ethical and legal aspects	
10.1	Binding constraints (Cannot do anything if it is not safe or legal). Should be considered in the preceding assessment/considerations
10.2	Problem of merging aspects in domain 7. Problem in domain 7 as the topics contain very different things
10.3	Where are the gender and ethnicity aspects?
10.4	Gender in domain 7 missing (important when technology enters the home) + ethnicity
10.5	Adding media to domain 7?
10.6	Ethical and legal work together in domain 7
10.7	Legal is mandatory, but perhaps ethical can be optional, apart from ethical approval e.g.
10.8	What is meant by equity? Maybe it should be under ethical
10.9	Who has the responsibility if something goes wrong? If somebody dies at home e.g. the COPD suitcase
10.10	You always have to consider if the patient got worse because the doctor used the telemedicine or not. The responsibility should be on a person (=doctor) not on the system.

No.11	
Comments to transferability	
11.1	Think about transferability from the beginning
11.2	Important question: what do you want to transfer? Is it the technology, the organisational setup, the whole package?
11.3	Perhaps some of parts of a telehealth solution can be used universally, and the rest must be developed locally
11.4	Transfer, import or export? When developing telehealth solutions in a hospital setting, transferability in terms of export does not have priority
11.5	Most health professionals will find important – can we import solutions which others

	have invented? Statement: terms of trade
11.6	Should researchers assess transferability themselves?
11.7	Those who fund research may not be willing to fund studies in transferability
11.8	In EUneHTA they have approached it in the way that part can be transferred, i.e. a good set of questions re ethical issues or a micro model where local data is added to it
11.9	The term transferability is dangerous. Transferability is more about importing knowledge and evidence rather than exporting it. Include statement on which conditions the assessment is done in terms of recognising what can be imported
11.10	Import for each domain
11.11	FAST implies the researchers should assess the transferability, but perhaps the transferability is better assessed by the potential new user rather than the first ones who do <ul style="list-style-type: none"> • Researchers will have to guess how it is transferred • Conflicts with funding of research

Chapter 3: The process towards the final version of the Guidance and the FAST framework

The process towards the final version of the framework includes a number of activities.

1. Comments from the experts to the workshop report
All experts has had the opportunity to correct mistakes, add comments and make new suggestions.
2. Presentation of the MethoTelemed framework to the I2010 group
The outcome of the review, the suggestion for guidance and the FAST has been presented to the I2010 group at their meeting on November 24th 2009. Comments and feedback from that meeting will be included in the final version of the framework.
3. Finalising the web-page with the Guidance for methods for evaluation of telemedicine services
Based on the feedback from the workshop the web page will give access to the results from the literature review and the Guidance with regards to methods etc. The web page will be ready for use by the end of January 2010. This will also include a suggestion for future use and update of the knowledge in the database.
4. Development of the FAST
Comments and suggestions from the workshop will be included in the Guidance as well as in the FAST. In future work, the comments will be summarized in 5-6 themes. Subsequent a track record on actions taken by the MethoTelemed team according to the themes is made. The next version of the FAST will be available for comments from the experts by December 17th and feedback should be sent back to the MethoTelemed team no later then the January 8, 2010. The final version of the FAST framework will then be ready by the end of January 2010.

Appendix

Appendix 1

1.a Introduction to the MethoTelemed workshop

The MethoTelemed team is very pleased that you have set aside time to participate in the second expert workshop of the project. The first workshop was held in June this year. In this letter you will find some information about the process for the second workshop and the expected outcomes.

Our aims and expectations for the workshop are:

- to present the results from the systematic literature review and a framework for general guides for evaluations models based on the evidence, and
- to present, discuss and validate a specific evaluation framework for the decision process for telemedicine services.

To achieve this we have planned a workshop in several steps. First you will be presented with a status of the literature review and an introduction of the MethoTelemed Guidance. You will also get a demonstration of the Online MethoTelemed Guidance.

We will then divide you into two groups and ask you to focus on the strengths, weaknesses, gaps and methodologies of the MethoTelemed Guidance. After the plenary session and lunch there will be a presentation of Framework for Assessment of Telemedicine (FAST) – a framework that has been developed in MethoTelemed. After this you will be divided into groups that will then discuss the the domains, topics and methods in the FAST.

We kindly ask you to bring all your knowledge and experiences to the table, using your usual professional roles. Your role in the workshop will be to give feedback and qualify the framework for assessing telemedicine, as well as to discuss and validate the domains and methods that are suggested.

We hope that you after the workshop will participate in the further discussion and the finalisation of the work of MethoTelemed and your expertise and time spent will be greatly appreciated.

We hope that you will enjoy participating in the process and allow the MethoTelemed team the full benefit of your knowledge and experience.

On behalf of the MethoTelemed Team – Sincerely,

Christina E. Wanscher
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1.b Agenda and participants

MethoTelemed Work shop November 5th in Brussels, 2009

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MEETING LOCATION

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AGENDA

10.00 – 10.20	Welcome and introduction to the workshop, including participants' introductions and summary of workshop I <i>By Claus Duedal Pedersen & Francisca-Rosario Garcia-Lizana</i>
10.20 – 10.40	Status of the literature review and introduction of the MethoTelemed Guidance <i>By Anne Granstroem Ekeland & Alison Bowles</i>
10.40 – 10.50	Demonstration of the online MethoTelemed Guidance <i>Anne Granstroem Ekeland</i>
10.50 – 11.00	Coffee break and dividing into 2 groups
11.00 – 12.00	Group work focusing on MethoTelemed Guidance - Strengths - Weaknesses - Gaps - Methodologies
12.00 – 12.45	Plenary session – group feedback and panel discussion
12.30 – 13.30	Lunch
13.30 – 14.15	Presentation of Framework for Assessment of Telemedicine (FAST) – a framework developed in MethoTelemed <i>By Kristian Kidholm</i>
14.15 – 16.00	Group work focusing on FAST. Discussion of: - Domains - Topics - Methods
16.00-16.45	Plenary session – group feedback and panel discussion reflecting on strengths and weaknesses of the toolkit from participants points of view. Feedback and suggestions on possible improvements.
16.45 – 17.00	Conclusions and next steps <i>By Claus Duedal Pedersen</i>

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Moirra Mackenzie, Scottish Government, UK
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Hasse Petersen, Consultant, Region Syddanmark
Jane Clemensen, Consultant MedCom Denmark
Janne Rasmussen, Consultant MedCom Denmark
Signe Christensen, Consultant MedCom Denmark

1.c Preparations from the Research Team

Dear participants in MethoTelemed Workshop 2.

The research team of the MethoTelemed project would like to provide the following background and questions for the workshop.

The research team and the review

The research team consists of Professor Alison Bowes, University of Stirling, Scotland, Research Director Signe Flottorp, Norwegian Knowledge Centre for the Health Services, Dr. Oecon Kristian Kidholm, Odense University Hospital and Research team leader, Dr. Polit Anne G. Ekeland, Norwegian Centre for Integrated Care and Telemedicine. We have performed a systematic review of review articles of telemedicine assessments and we are in the process of reviewing primary studies. The review articles have been reviewed, based upon a protocol and an electronic proforma, in collaboration with a group of ten external experts. The work to analyse the data from the review is ongoing. One of the results from the review and workshop 1 and 2 will be methodological guidance to assess telemedicine applications, which is the theme for this workshop.

Based upon the review, the results from workshop 1 and discussions in the project team, we have prepared this document as a basis for discussion of the MethoTelemed Guidance.

1. Extracts from the review (the results from WS 1 are presented in a separate document)
2. Proposed approach, structure and content of the MethoTelemed Guidance to assess telemedicine applications

1. Extracts from the review

In March 2009 a search for reviews of reviews of telemedicine assessments from 2005 – present resulted in 1486 hits. Two individual reviewers reviewed the abstracts, and included 138 reviews for full text analysis. These 138 reviews included in the first selection round, identified 5977 primary studies of telemedicine, of which 3339 were included in the reviews following the authors' quality assessment. The time span of the primary studies covered is from 1960 to 2007.

In addition, a follow up search for review papers was accomplished in August 2009, which resulted in 107 new hits. The abstracts were reviewed by 2 individual experts, and we identified 36 new review papers which have been reviewed by our team of experts.

A total of 76 reviews of reviews have now been included after the team's quality review process.

Thematic areas addressed in reviews	Number of Reviews
Home telehealth (diabetes, high-risk pregnancy monitoring, heart failure and cardiac diseases, the general area of mental health and smoking cessation)	12
Treatment for anxiety and depression/mental health	11
Heart failure/telecardiology	9
Diabetes/diabetes care	6
Acute-stroke management	6

Chronic disease management and control	6
Asthma and COPD	3
Smoking cessation	3

In addition, we included one review on each of the following subjects

- Telemedicine and medical encounters
- The evidence base of telemedicine
- Interventions for college drinking
- Primary care
- Research methodologies in telemedicine
- Asynchronous Telehealth
- Telepsychiatry replacing in-person psychiatric assessments
- Weight loss programs
- Support for carers of people with dementia
- Physical activity interventions
- Technical evaluation
- Definitions of telehealth
- Definitions of telemedicine - dynamics
- Value of electronic patient records
- Determinants of successful telemedicine applications
- Consumer experiences with ICT in Healthcare
- Gender differences in use of online tools
- Spiritual Care and internet
- Promoters of adoption among health care professionals
- Clinical outcome, process and cost combined

Selected outcome and emerging issues based upon the latest reviews from the largest thematic areas

The purpose of the review is to assess results produced, methodologies used, and strengths and weaknesses of the various approaches to evaluation. Based upon input from workshop 1 and conclusions from review authors, gaps have been identified that will be addressed in a scientifically rigorous and practical useful guidance for methodologies to assess telemedicine applications, the MethoTelemed Guidance. See section 2.

The results will be presented in more detail at workshop 2. Below we will present some examples that the literature review has revealed. These examples are selected from the latest included reviews in thematic areas in the table above. We present main conclusions and gaps identified by review authors and our reviewers in accordance with the headlines in the table.

Example 1: Home telehealth

Most of the studies reviewed demonstrate the feasibility of the technological solution. Technical, ethical, legal, clinical, economical and organisational implications and challenges need to be studied in-depth for the field to grow further. The review considers quantitative studies.

In spite of the growing number of initiatives, the field is in its relatively early stages and is currently lacking an extensive body of evidence. This review is considered consistent, but has a very limited scope and the methods used in the studies reviewed are not stated. This review aims to describe different solutions and different evaluations done. It describes existing projects, their targeted audiences and technologies used. It provides a snapshot of current state of this new health care concept. It provides conclusions beyond this objective, but there is a lack of evidence.

Review: Demiris G, Hensel BK. Technologies for an aging society: a systematic review of "smart home" applications. *Yearb Med Inform* 2008;33-40.

Example 2: Treatment for anxiety and depression/mental health

The effects of ICT delivered treatment were found to be equal to therapist-delivered treatment across anxiety disorders. However, conclusions were limited by small sample sizes, the rare use of placebo controls, and other methodological problems. In addition, the number of available studies limited the opportunity to conduct analyses by diagnostic group; there was preliminary support for the use of ICT for panic disorder and phobia. Only quantitative studies were considered.

The results of this meta-analysis provide preliminary support for the use of Internet and computer-based CBT for the treatment of anxiety.

For participants with panic disorder, ICT may be superior to no treatment (i.e. waiting list control) and to placebo assignment; the benefits of ICT also were equivalent to TAU (treatment as usual) in the few studies available. For participants with a phobia, post treatment symptoms were reduced following ICT compared to both waiting list and placebo assignments. For participants with putative PTSD, there was preliminary support for ICT compared to no treatment.

Additional research is considered to be needed on a variety of topics related to ICT. Significant numbers of individuals may prefer ICT to walking into a counseling center, sitting in a waiting room, and talking with a therapist. The assumption that a traditional therapist is generally preferred over ICT may be inaccurate for significant subgroups of the population, but this possibility requires additional study.

ICT also may be useful as a research tool to explore the essential components of CBT (cognitive behaviour therapy). ICT allows researchers to add, modify, or delete specific treatment interventions while truly leaving all other treatment components unchanged for a comparison group. For example, Schneider, Mataix-Cols, Marks, and Bachofen (2005) recently examined the differences between Internet-guided treatment of panic and phobia with or without exposure instructions. Thus, ICT may provide a tool to help refine CBT theory and practice.

Review: Reger MA, Gahm GA. A meta-analysis of the effects of Internet- and computer-based cognitive-behavioral treatments for anxiety. [References]. *J Clin Psychol* 2009;65(1):53-75.

Example 3: Heart failure/telecardiology

This study reviewed studies conducted in HF telemonitoring, to describe the nature of the modality, the methods and the results. Telemonitoring appeared to be an acceptable method for monitoring HF patients. Controlled, randomized studies directly comparing different modalities and evaluating their success and feasibility when used as routine clinical care are now required.

To compare the different modalities in this field is necessary. But the variety of different telemonitoring modalities and the small sample size of many of the studies hindered a metaanalysis which is a limitation to this review. Despite a large number of studies, this research is still in its infancy and larger, RCTs are needed. This review only considered quantitative studies.

Review: Maric B, Kaan A, Ignaszewski A, Lear SA. A systematic review of telemonitoring technologies in heart failure . European Journal of Heart Failure 2009;11(5):506-17.

Example 4: Diabetes/diabetes care

Study results indicated that home telehealth helps to reduce the number of patients hospitalised, hospitalizations and bed days of care. Home telehealth was similar or favourable to UC across studies for quality-of-life and patient satisfaction outcomes.

In general, home telehealth had a positive impact on the use of numerous health services and glycaemic control. More studies of higher methodological quality are required to give more precise insights into the potential clinical effectiveness of home telehealth interventions. Quantitative studies were included.

Reviewer's conclusion:

There was great variability in the quality of studies in this review because of methodological limitations in the study designs or small sample sizes. More studies of higher methodological quality (e.g. multicentered RCTs) are required to give more precise insights into the potential clinical effectiveness of home telehealth interventions. Studies should also include more diverse patient populations with diabetes to increase the external validity of their outcomes and examine the impact of various clinical approaches used with the health technology to determine its optimal use. Furthermore, a common approach to the evaluation of home telehealth initiatives should be developed to help increase the quality of studies and the amount of evidence available.

Review: Polisen J, Tran K, Cimon K, Hutton B, McGilland S, Palmer K (2009), Home telehealth for diabetes management: a systematic review and meta-analysis, Diabetes, Obesity and Metabolism 2009.

Example 5: Acute-stroke management

Stroke is a neurological condition that affects many people, resulting in socioeconomic costs. The use of thrombolysis that is delivered within a narrow window of time after the presentation of symptoms has been shown to significantly reduce the burden of illness.

The systematic review included 22 original studies from the 863 citations identified. The included studies had diverse designs, interventions, and outcomes, precluding a meta-analysis. Eight studies were judged to be of high quality using standardized quality assessment tools. Most study reports included outcomes related to process of care issues and reported improved access to thrombolysis, acceptable "door-to-needle times" (time elapsed from the patient's arrival in hospital and the start of thrombolysis), and a decreased need to transfer patients across institutions. Three and six month post-event functional outcomes using telestroke services were comparable with those of face-to-face stroke care. Mortality rates were also similar. Patients and health care providers reported high levels of satisfaction, although few studies assessed this outcome in detail. Several telerehabilitation studies were identified during the search on telehealth services for post-acute stroke management. Although it is difficult to draw conclusions from this small sample of studies, the trend suggests that in post-stroke patients, telehealth led to improvements in caregivers- mental health and high levels of patient satisfaction. There was minimal evidence regarding the impact on resource utilization. Quantitative and qualitative satisfaction studies were considered.

Review: Deshpande A, Khoja S, McKibbin A, Rizo C, Jadad AR. Telehealth for acute stroke management (Telestroke): systematic review of analytic studies and environmental scan of relevant initiatives. 2008. <http://cadth.ca/index.php/en/hta/reports-publications/search/publication/783>.

Example 6: Chronic disease management and control

Home telehealth was found to be cost saving from the healthcare system and insurance provider perspectives in all but two studies, but the quality of the studies was generally low. An evaluative

framework was developed which provides a basis to improve the quality of future studies to facilitate improved healthcare decision making and an application of the framework is illustrated using data from an existing programme evaluation of a home telehealth program.

Current evidence suggests that home telehealth has the potential to reduce costs, but its impact from a societal perspective remains uncertain until higher quality studies become available. They suggest that a better economic evaluation framework is needed, in the light of the poor quality of existing work.

Review: Polisena J, Coyle D, Coyle K and McGill S (2009) 'Home telehealth for chronic disease management: a systematic review and an analysis of economic evaluations' *International Journal of Technology Assessment in Healthcare* 25,3:339-349

Example 7: Asthma and COPD

Twenty-three studies were found that presented effects of telemonitoring for various pulmonary conditions in this review. Good levels of data validity and reliability were reported, when assessed. However, little quantitative evidence exists about its effects on patient medical condition and utilization of health services. Positive effects on patient behavior were consistently reported. Only 2 studies performed a detailed cost analysis of this approach.

Home telemonitoring of respiratory conditions results in early identification of deteriorations in patient condition and symptom control. Positive patient attitude and receptiveness of this approach are promising. However, evidence on the magnitude of clinical and structural effects remains preliminary, with variations in study approaches and an absence of robust study designs and formal evaluations.

The need for standardised studies and larger samples is communicated. However, this is questioned by the ongoing change in interventions, and the review also identifies the need to explore attitudes of service providers.

Review: Jaana M, Pare G, Sicotte C. Home telemonitoring for respiratory conditions: A systematic review *Am J Manag Care* 2009;15(5):313-20.

Example 8: Smoking cessation

The meta-analysis of RCTs in this review indicates that there is sufficient clinical evidence to support the use of Web- and computer-based smoking cessation programs for adult smokers. They find a difference between age groups in that the programmes are effective for adults, but not for adolescents.

Review: Myung SK, McDonnell DD, Kazinets G, Seo HG, Moskowitz JM. Effects of Web- and computer-based smoking cessation programs: meta-analysis of randomized controlled trials 64. *Arch Intern Med* 2009;169(10):929-37

Gaps identified, research needed

The majority of studies reviewed were quantitative outcome/effect studies. More studies with standardised interventions, larger numbers of coherent participants and more standardised assessment tools (better RCT's and HTA's) and outcome measures were generally reported throughout.

Very few reviews reported from qualitative studies. Some research topics were identified that pointed to the need for qualitative and formative research. These included:

The ongoing change in interventions, which points to the need for exploring attitudes/motivations from service providers

Individual preferences that affect use and quality

The need for studies to include more diverse patient populations

The need to explore differences between groups in service utilization, to tailor interventions

Cultural diversities in adoption patterns
Ethical issues in homecare

2. Proposed approach, structure and contents of the MethoTelemed Guidance to assess telemedicine applications

We would like to summarise the review and the discussions in workshop 1 by presenting three overviews. These overviews represent a broad sketch of a structure and content of the MethoTelemed Guidance.

1. Research questions that have been addressed
2. The methodological approaches that have been used to address the different questions
3. Different scientific institutions and networks that are currently producing results and evidence in the field of assessments and evaluations of telemedicine. We propose to include links to their websites and to tested methodologies for addressing different research questions.

We are currently working to establish a web-page based upon these overviews. This web page will be presented at the workshop. The development of the web page can be found in this link:

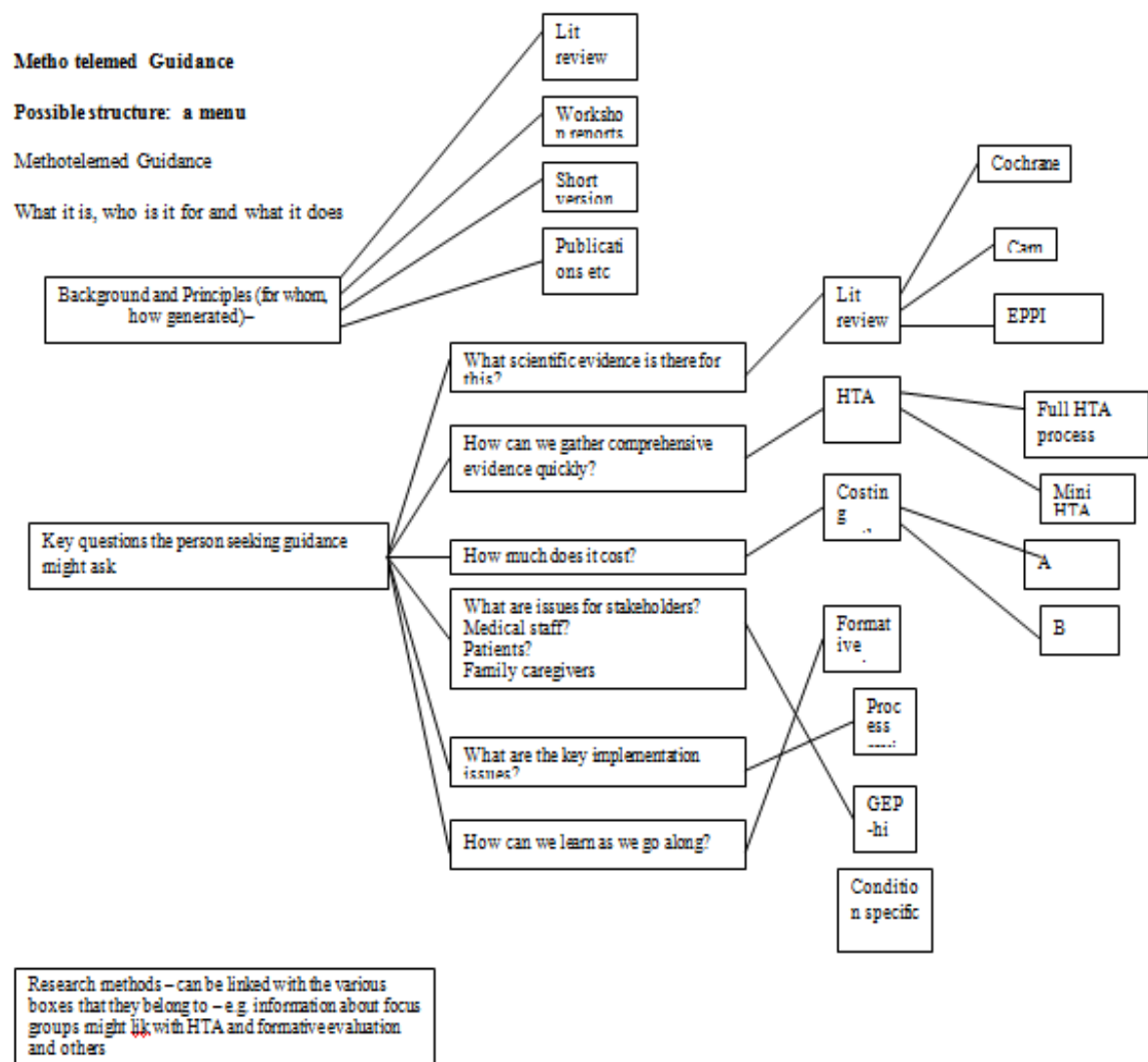
<http://telemed.custompublish.com/index.php?id=4645193&cat=145839>

The page below illustrates different research questions that have been addressed (1). These will be linked to a page with different methodologies (2) and from there to different scientific institutions (3) and their approved approaches to assessment and evaluations of telemedicine

Questions to participants:

1. Is this a relevant way of developing Guidelines to Assess Telemedicine Applications?
2. Are there other relevant questions to be included?

Below is the proposed opening side. It is a menu including research questions that have been raised. This will represent the opening page of the web site. The question boxes will be linked to 2 and 3 (next pages) and to other established web sites (1)



A link directly to the database from the literature review will be provided from the 'Background and Principles' box (upper left corner) A link directly to the FAST framework will also be visible on this front page.

Different methodological traditions (2)

Assessment and evaluation paradigms

Paradigm	Task	Focus	Methods
Positivist (Objective knowledge, expert driven)	Goal attainment, produce evidence and control effects	Clinical, behavioural, econ. and org. effects/outcome	Quantitative; Explaining outcome/effects of interventions
Hermeneutic (Interpretivist, give voice to, relativist ..)	Understand and interpret contributions and efforts and their results	Meaning and perspectives. Background, process/action	Qualitative: Understanding different perspectives
Constructivist (Pragmatic, improving new services as they develop)	Develop practices and innovations solving problems.	Stakeholders interaction and contributions to results. Meaningful constructions	Formative: Dialogue/confrontation, transparency, legitimacy,

Once a question is ticked on the opening page, the user will be linked to this page where the correct row will be highlighted. From the METHODS column in this table, the user will have two alternatives. One: Institutions, points to the next page where the Assessment and Evaluation institutions/networks identified through this work are listed. Their approved methods and published tools will be available (3). Two: Methods, which links to practical tools and methods already well tested and under constant improvement.

HTA, GEP-HI, STS and "Evaluation Science"

- HTA: Health Technology Assessment

- http://mrw.interscience.wiley.com/cochrane/cochrane_clhta_articles_fs.html
- <http://www.eunetha.net/>
- http://www.nlm.nih.gov/nichsr/hta101/ta101_c1.html

- GEP-HI: Medical Informatics Evaluation

- <http://www.ncbi.nlm.nih.gov/pubmed/18930696>
- http://iiq.umat.ac/efmi/mie09/MIE2009_GEPHI.pdf

- STS: Science and Technology Studies

- <http://www.easst.net/>
- <http://sss.sagepub.com/>
- http://www.stswiki.org/index.php?title=STS_concepts

- Evaluation Science

- <http://www.cgu.edu/pages/665.asp>
- <http://www.kingspssq.org.uk/>



These networks and institutions are constantly in processes to develop their methodologies and tools. These links are to be elaborated for the Guidance.

This way we will provide links between practical evaluation and assessment questions, different methodological traditions, approved methodologies within the different traditions and the best tools available for the variety of evaluation and assessment questions that needs to be addressed.

Our proposal for the MethoTelemed Guidance is the following: (to be discussed in the workshop)

1. To build alliances between different scholarly perspectives and their approved methodologies
2. To strengthen the resources present and elaborate the already developed and well tested methodologies and tools
3. To utilize and recognize the need for diversity in research questions, paradigms and methodologies

1.d Framework for ASsessment of Telemedicine - FAST - Preliminary results from MethoTelemed

Introduction

This paper presents the first draft of a new framework for assessment of telemedicine to be used as a basis for decision making in EU and the European countries in future decisions on use of telemedicine applications.

As described in the tender, the overall aim of the MethoTelemed project is to provide a structured framework for assessing the effectiveness and contribution to quality of care of telemedicine applications. The framework 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 framework should also be based on a review of the scientific literature on the effects of telemedicine.

Results from workshop 1

In June 2009 a workshop with 20 stakeholders and users of telemedicine was arranged with the purpose of gaining knowledge about the needs for documentation and evidence to simplify the decisions on whether or not to use telemedicine applications. In the workshop the EUnetHTA Core Model 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 are: 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 framework 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 framework for assessment of telemedicine - FAST

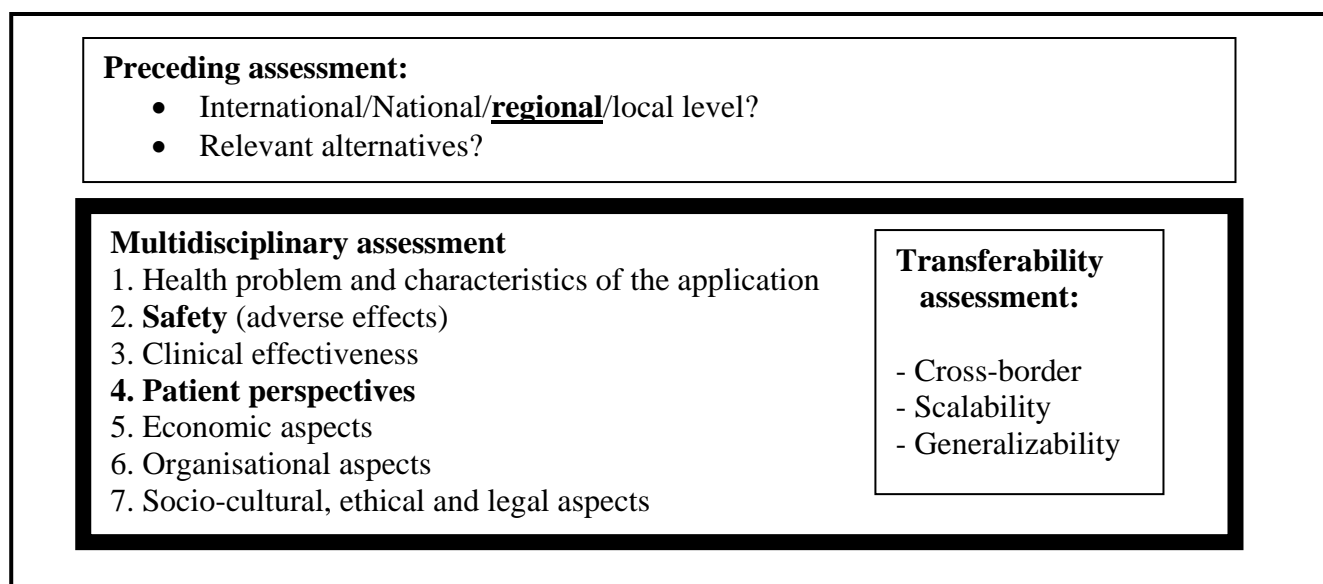
As the literature review will show, a large number of methodologies for assessment of telemedicine applications exist and can be used for various purposes. However, the MethoTelemed project has found that, if the purpose of an assessment of telemedicine applications is to describe effectiveness and contribution to quality of care and to produce a basis for decision making, an assessment based on the following definition is recommended:

The assessment of telemedicine should be 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, the institution and for society in general. The following terms implies that assessments should be based on scientific studies and scientific criteria for quality of evidence.

The figure below presents the different elements in FAST. When using the framework the assessment should start with a number of preceding considerations. The main focus should be on the determination of (1) the level in the health care system (local, regional, national) at which the assessment should be produced and, and (2) what are the relevant alternatives (e.g. kinds of technologies) that should be compared in the assessment. For example, if these initial considerations show that legal or reimbursement issues need to be handled at a national level,, the assessment should be carried out with a national perspective e.g. by a national institution.

Figure 1: Elements in FAST



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. These are described further below.

In relation to the description of the outcomes an assessment is also made of the transferability of the results found. This includes for example an assessment of whether the estimated cost per patient of using the telemedicine application can be expected to change if the number of patients is multiplied by ten. In general, issues related to the scalability and generalizability of the results are assessed.

Topics in the domains

The tables below include a draft of the topics within each domain. Notice that the list is not at all complete but reflects the content of the domains in the MethoTelemed core model and the results from the first workshop. The domains and topics also need to be defined.

Table 1. Topics with the 7 domains

Health problem, characteristics of the application	Safety	Clinical effectiveness	Patient perspectives
Health problem Description of the application Technical characteristics	Patient safety Technical safety Security of data	Mortality Morbidity Health related quality of life Behavioral outcomes Mental health	Satisfaction Acceptance Empowerment/ Self-efficacy Understanding of info Confidence Ability to use

Economic aspects	Organisation	Socio-cultural, ethical and legal aspects
Economic evaluation (Societal) - Cost minimization analysis - Cost effectiveness analysis - Cost utility analysis - Cost benefit analysis Business case (institution level) - Expenditures per year - Revenue per year (reimbursement) - Sustainability- RoI	Changes in use of staff Changes in work processes Cooperation Communication Management issues Culture	Ethical: - Autonomy, equity - Beliefs challenged Legal: - Autonomy, equity - Authorization Social: - Changes in roles - Understandings

Methods for data collection

When choosing between different designs of studies and the 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. This recommendation was also found in the literature review. Similar 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 specific outcomes 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. Generally, the choice of instruments and outcomes should reflect the recommendations in the scientific literature. These recommendations can be found in the reviews in the MethoTelemed project. For example, in studies of diabetes, heart failure, and chronic obstructive pulmonary disease (COPD) the instruments described in the review of telemedicine for the patient groups by Than et al.(2008) can be used.

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.

Assessment of transferability

If an assessment of a telemedicine application includes collection and analysis of data from new studies, the assessment must also include a consideration 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 outcome should include some form of analysis of, whether the circumstances during the trial was so special and controlled that the same results can 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%.

Similar 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, including possible limitations in internal and external validity.

How to use FAST?

As described in the section about methods above, FAST can be used in two ways:

1. As a framework for design of new studies of telemedicine
2. As a framework for an assessment based on literature reviews and other existing information on the specific telemedicine application

In the latter use, FAST resembles a checklist for the assessments of telemedicine. This way hospitals and other institutions can use FAST to gain an overview of their knowledge and the level of evidence with regards 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 two approaches e.g. by using existing studies to describe the safety of the application and by starting new studies of the organizational outcomes locally.

Outputs from FAST

If the framework 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 page small report or policy brief to be used as a basis for decision makers in e.g. meetings of the board of directors at a hospital.

Example: Using FAST to assess the COPD Patient Briefcase

At Odense University Hospital in Denmark an assessment of the COPD Briefcase is being planned at the moment and this study can be used as an example of the use of the framework. 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 home 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 200 patients. In this study the safety aspects, the clinical outcomes and the 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.

Finally the socio-cultural, ethical and legal aspects will be described based on a description of the legal aspects in the laws regulating patient treatment in Denmark. Interview with a number of relatives and focus group interview with stakeholders will be carried out.

The main outcomes in the RCT are based on a literature review and presented in the table below.

Table 2. Outcomes in assessment of the COPD Briefcase

Clinical effectiveness	Economic outcomes	Patient perspectives
Mortality	Total cost per patient of using the COPD suitcase	Validated instrument for patient satisfaction
FEV1	Use: number of days	Validated instrument for self-efficacy
SAT	Use: Number of consultations	Additional questions on the confidence in the treatment
MRC	Use: Number of telephone calls	
BMI	Number of hospitalizations	
SF-36	Number of bed days	
Exercise	Number of outpatient visits	
Depression (HADS)	Number of home nurse visits	
	Use of emergency	
	Effect on reimbursement of using the COPD suitcase	

Strengths and weaknesses

The main strengths of the framework are:

- 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 will thus make the framework familiar to stakeholders in the EU, national health authorities, industry, academics and health professionals.

Similar the main weaknesses of the framework can be described as:

- It is time consuming because collection of data from reviews or new studies takes time.
- It does not result in information about why telemedicine works. This information needs to be produced in other kinds of scientific studies.
- The framework focus on the outcomes of telemedicine (including organizational outcomes) and not the working processes when using the applications.
- The quality of the reports and publications based on the framework can vary because the framework does not state a number of criteria to be fulfilled. However, the scientific criteria for good research within the different scientific disciplines can also be used as criteria for the quality of reports using the framework.

Next steps in the development of FAST

The framework described is based on the EUnetHTA Core model and results from the first workshop with stakeholders. However, arguments for a framework similar to FAST can also be found in the literature. Wooton et al. (2006) argue that when telemedicine introduces new kinds of services, the outcomes should be measured when possible. They also argue that the choice of outcome measurements depends on the aim with which the telemedicine service is set up and that the outcomes can be divided in measurements of user satisfaction, measurements of medical outcomes and financial measurements. These are all part of FAST. 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 FAST. 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.

On the basis of the workshop in Brussels on November 5th 2009 the framework will be revised. In connection with the revision the content of the domains and topics will be defined further.

Finally an empirical test of the framework will be carried out in 2010-2012 in the Renewing Health project, in which assessment will be made of telemedicine applications for patients with diabetes, heart failure, and COPD in 7-9 countries.

References

EUnetHTA, 2008, HTA Core Model for Medical and Surgical Interventions. www.eunethta.net

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.

Ohinmaa A, Hailey D, Roine R. 2001. Elements for assessment of telemedicine applications. Int J Technol Assess Health Care. Spring;17(2):190-202.

Wootton et al., 2006, Introduction of telemedicine. Royyal Society of Medicine Press.

Appendix 2 Presentations

Introduction & MethoTeled Guidance

Follow the link:

http://img7.custompublish.com/getfile.php/1053950.357.vacxaufuat/Metho_teled 05_11_09master.pdf?return=www.teled.no

Framework for ASsessment of Telemedicine (FAST)

Follow the link:

http://img7.custompublish.com/getfile.php/1053949.357.cqxssbdwue/FAST_10_edition_november_2009_new.pdf?return=www.teled.no