

Short version of

MethoTelemed

Methodology to assess telemedicine applications
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Methodology to assess telemedicine applications

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MethoTelemed Overview

This tender is led by MedCom, Denmark, in partnership with the Norwegian Centre for Integrated Care and Telemedicine (NST). The project team (hereafter, 'the MethoTelemed Team') also includes the Department of Applied Social Science, University of Stirling; the Norwegian Knowledge Centre for the Health Services; a panel of international expert advisers, in business, economics, health policy analysis, Health Technology Assessment, and medicine; and stakeholders in telemedicine including patient groups who will participate in structured consultation together with the WHO Observatory represented through the LSE Enterprise.

From the outset, we highlight the range of stakeholders and interests relevant to the work. We endeavour to recognise the diversity of these throughout. Decision and policy makers want to bring quality approved and economically effective telemedicine applications to health services; commercial interests view health services as markets for their products; technology developers focus on the needs of users in order to innovate; medical and care professionals seek the best telemedicine tools to provide quality services; patients seek the best quality care and partnership in its delivery. Our challenge is to bridge gaps between different scholarly perspectives to identify and recommend approved methodologies to assess quality and efficiency in a broader societal perspective. The main outcomes of this project are proposed methodologies to guide academic endeavours as well as policy decisions.

Components of the work are

- a systematic and academically rigorous review of research on telemedicine;
- an analysis of how the methodologies identified produce and validate results;
- careful attention to stakeholder perspectives through consultation workshops; and
- the production of guidance (hereafter 'the MethoTelemed Guidance') for methodologies that meet criteria of quality and can contribute to the development of the still limited evidence base on the impacts, benefits and costs of telemedicine.

The project started February 1, 2009 and runs to February 1, 2010.

1. Aims

The project aims to provide a benchmark document (the 'MethoTelemed Guidance') which will

- Provide systematic documentation of the manner and extent of telemedicine applications in healthcare systems and
- Provide a structured framework for assessing the effectiveness and contribution to quality of care of telemedicine applications.

2. EU background

The background for the bid is the SMART 2008/0064 TENDER SPECIFICATIONS: Methodology to assess telemedicine applications. The following EU activities and publications are taken into consideration.

1. European Commission Consultation towards the preparation of an initiative on *Telemedicine and innovative ICT tools for Chronic Diseases management*.¹
2. High Level Consultation Workshop with Industry: *Telemedicine and innovative ICT tools for Chronic diseases management*, Brussels, European Parliament, December 2007. The report encourages the members of the Union, and the wide range of stakeholders concerned, to explore what difficulties may have to be overcome to facilitate wider telemedicine deployment throughout Europe. Evaluation methodologies are among the difficulties.²
3. *Report of the Personal Health Systems 2007* conference in the European Parliament. Patient empowerment through ICT is critical. Further exploration of this is encouraged with a bigger role for education to improve performance and disseminate the potential of PHS technologies. These will require evaluation.³
4. The Report from the *Personal Health Systems consultation workshop*, Tampere, 30-31 January 2008 noted that healthcare is moving towards a holistic, citizen-centred model, where patients become active consumers, involved in care and decision-making processes and new technologies expand the possibilities for applications in healthcare. This shift points to challenges for quality assessment with quality involving more personal criteria.⁴
5. The report: *eHealth is Worth it; The economic benefits of implemented eHealth solutions at ten European sites* includes material concerning the validation of evidence.⁵
6. *e-Health -making healthcare better for European citizens: An action plan for a European e-Health Area*. The wider initiative i2010 envisages that e-Health can help to deliver better care for less money within citizen-centred health delivery systems. The development of assessment methodologies is considered part of this plan.⁶
7. The Communication from the Commission (2007) 856 on *A lead market initiative for Europe* of December 2007, and its associated action plan on eHealth WHITE PAPER COM (2007) *Together for Health: A Strategic Approach for the EU 2008-2013*. Ehealth is one of the lead markets in Europe, and this White Paper sets out a Strategy until 2013. The policies outlined will be important input for the analyses and recommendations to be prepared for the MethoTelemed Guidance.^{7 8}

¹ http://ec.europa.eu/information_society/events/telehealth_2007/index_en.htm

² http://ec.europa.eu/information_society/events/telehealth_2007/index_en.htm

³ http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=3469

⁴ http://ec.europa.eu/information_society/newsroom/cf/itemlongdetail.cfm?item_id=3857

⁵ <http://www.ehealth-impact.org/download/documents/ehealthimpactsept2006.pdf>

⁶ http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf

⁷ <http://ec.europa.eu/enterprise/leadmarket/leadmarket.htm>

⁸ http://ec.europa.eu/health/ph_overview/Documents/strategy_wp_en.pdf

3. Scientific background – telemedicine assessments

The SMART 2008/0064 call for tender specifically requests an assessment of the relevance of Health Technology Assessment (HTA) as a framework for telemedicine assessments, and a consideration of both quantitative and qualitative methods. We present an initial overview of telemedicine reviews and consider methodological issues and challenges.

Most reviews of telemedicine conclude that irrefutable evidence regarding the positive impact of telemedicine on clinical outcomes still eludes us. Amongst others, Roine et al (2001) concluded that *potential* effectiveness could only be attributed to teleradiology, telepsychiatry, transmission of echocardiographic images and consultations between primary and secondary health providers. Hailey et al (2002) found only 46 publications of 1300 identified that actually studied at least some clinical outcomes. Currell et al (2002) concluded that establishing systems for patient care using telecommunications technologies is feasible but that studies provide inconclusive results regarding clinical benefits and outcomes. Hirsch et al (2006) concluded that telemedicine use is not often supported by high-quality evidence. Reviews on cost outcomes have fared similarly with Whitten et al (2002) for example concluding that there is no good evidence that telemedicine is or is not a cost effective means for delivering healthcare.

Gammon et al (2007) confirm that norms for the conduct of research and assessments in telemedicine have yet to emerge. As late as 2008, two systematic reviews conclude that telemedicine may very well be effective, but that the quality of studies reviewed is not good enough to allow for conclusions across studies (Deshpande, Khoja et al. 2008; 2008). This repeats concerns for the quality of studies expressed earlier (Demiris and Tao, 2005; Hailey, Roine, and Ohinmaa, 2002; Hersh et al., 2006; Roine, Ohinmaa, and Hailey, 2001; Whitten et al., 2002).

Typically, reviews express concern about the quality of primary data. However, there is debate about appropriate and relevant methodologies and techniques for research. For example Whitten et al (2002) find that economic analysis of telemedicine has not yet met accepted standards; Jennet et al (2003) find a relative lack of exploration of the socio-economic impact of telemedicine; Johnson et al (2006) identify a lack of evidence on factors promoting uptake of telemedicine; Murphy et al (1998) argue that the use of qualitative methods remained relatively undeveloped at that time; Hersh et al (2001, 2006) suggest that many existing studies have not been well-designed; Barlow et al (2005), considering perceived difficulties of building a robust evidence base for recent innovations suggest that simulation modelling needs further development. Barlow et al (2006) call for the development of an 'evaluation template' in the field.

Ammenwerth et al (2004:484) note that many studies lack robust theoretical grounding, and do not use existing evaluation methods well. They perceive shortcomings in the design of many evaluations. We would suggest that some of the shortcomings of telemedicine evaluation are based in challenges both in the ways quantitative and qualitative research standards are fulfilled, but also in issues concerning which research traditions are suitable for relevant assessments. Qualitative

and quantitative traditions are generally considered as diverging. We will elaborate this issue in the next section.

4. Methodological challenges

The concept of methodology is differently perceived in different research and stakeholder communities. To some stakeholders methods, models and methodologies are equivalent concepts. In research however, methodology is more precisely defined. One important challenge for MethoTelemed is to obtain a common understanding of the concept.

The in depth work of the HTA institutions to refine their research methodologies includes considerations of the relations between **ontological assumptions** (consideration of the object of study), **theories or models** (hypotheses and statements about causality etc) **epistemology** (the relation between the object of study and the researcher), **methodology** (research strategies and validation) as well as **methods** (data collection techniques) (See for instance *Health Technology Assessment 1998*, vol 2). The MethoTelemed literature review, the assessment of HTA-methodologies and the proposed Guidance will respond to these extensive efforts.

An example of a key methodological challenge lies in the differences of approach between positivist and constructivist research traditions, as identified by Ammenwerth (2004). Positivist traditions try to obtain objective and generalised knowledge by applying controlled studies. This methodology assumes fixed entities: a defined research object in a relatively stable world, a defined and controllable intervention and an objective researcher. Quantitative methods, especially RCT's represent the gold standard, and validation is obtained through causal explanations and evidence.

Constructivist traditions in contrast assume flux: a research object under development, interventions which are also subject to change, a relatively subjective researcher, and validity is addressed by asking for what the study is valid (Aguinaldo 2004:127). Typically, qualitative methods are used, such as ethnography, observations and interviews. Validation criteria are elaborated to include validity as culture, ideology, gender issues, language, relevance, standards and as reflexive accounting. (Altheide and Johnson 1994)

Bridging the gaps between these two and other traditions should be important for assessments of telemedicine, as health care and technologies are both stable and in flux. In addition, technological, medical and social innovations and interventions affect each other, and their implications can be individual, ethical, political and societal. One goal for the MethoTelemed Guidance is to open the borders between traditions and identify how evaluators may draw on the benefits that different ones have to offer.

The reviews considered in section 3, which do not explicitly specify methods, hypotheses, theories etc, might nevertheless implicitly be conducted within a methodological tradition, such as a positivist or a constructivist framework. In medical research, for instance, there is not a widespread tradition of referring explicitly to theory. In MethoTelemed review, we will also consider studies with implicit methodologies and theories.

We underline that we do not aim to produce value statements about the superiority of either positivist or constructivist (or other) methodologies to assess telemedicine, but, based upon the review, to incorporate qualities of both into the MethoTelemed Guidance.

5. Complimentary assessment traditions

Telemedicine exists at crossroads of *medicine, technology and social/organisational* research communities. These differ in ways that reflect the differences in the nature of their study matter, norms for the conduct of research, and what they and their stakeholders would consider important outcomes (Clarke, 2000). Figure 1 illustrates the complex relationships between subject matter and methodological approaches in telemedicine evaluation. The MethoTelemed Guidance will need to synthesize and adapt best practice traditions from the broader context of research communities.

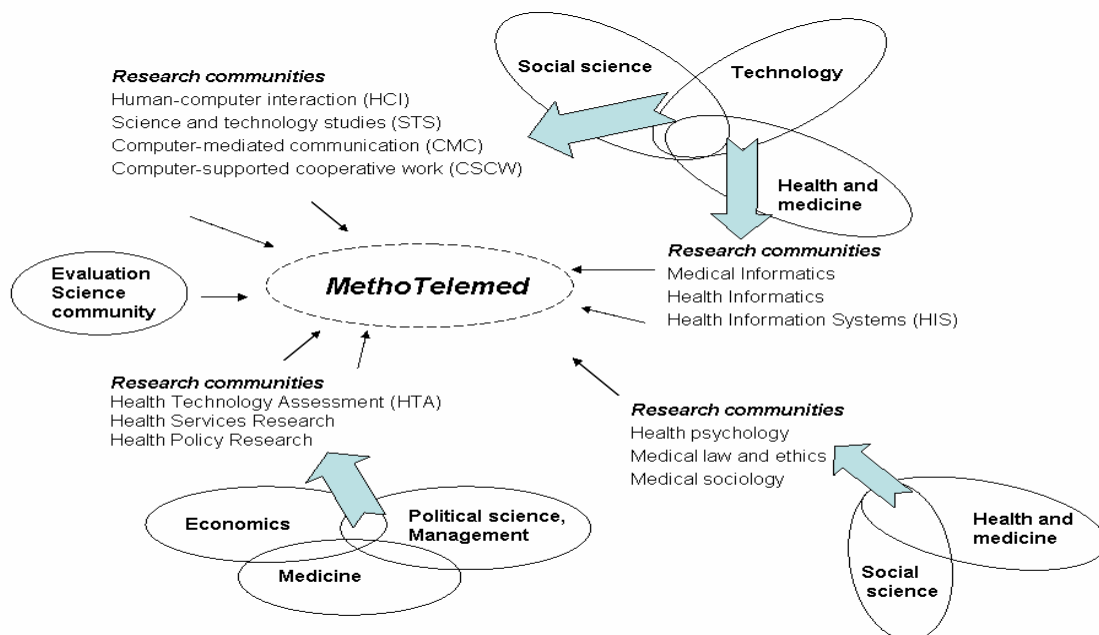


Figure 1. Complimentary assessment traditions (Adapted from Gammon, D. (submitted)).

Increased collaboration between differing communities appears to be accompanied by an increasing awareness of their respective methodological shortcomings. This is reflected in calls for mixed methods within Health Technology Assessment (HTA), within Health Service Research (Cathain, Murphy, and Nicholl, 2007), within Health Information System (HIS) communities (Ammenwerth et al., 2004), as well as within clinical research communities (Malterud, 2001). Communities clustered in the upper left of Figure 1 (Gammon 2007) largely share overriding perspectives and are often referred to as *sociotechnical* (Bjerknes and Bratteteig, 1995), also within the context of health care (Coriera, 2004). Constructivist and participatory design often characterise their approaches to evaluation (Muller, 2004).

In addition to a particular focus on HTA, the MethoTelemed team will review and draw lessons from other approaches to assessments, in particular the following:

GEP-HI: An important initiative (similar to the SMART 2006/0064 tender) is that which originated by ESF (European Science Foundation) and subsequently followed up by the European Federation of Medical Informatics: ‘Working Group for Assessment of Health Information Systems’. The Working Conference HIS-EVAL led to the Innsbruck Declaration; see Ammenwerth et al. (2004). The Stare-HI guidelines are recently published.

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Evaluation science: The community calling itself *evaluation science* (Donaldson and Lipsey, 2006) has long traditions in studying the implications of complex interventions (often called ‘programs’), policies, and practices in complex social contexts (Shaw, Greene, & Mark, 2006). This field also explicitly addresses challenges of balancing the decision-making needs of stakeholders, negotiating conflicting interests, while maintaining legitimacy as science. While evaluation literature does not appear to be well known within medicine (Clarke, 2000) or technology fields, it appears highly relevant for telemedicine, for example in strengthening the role of theory and methodology in selecting appropriate methods.

Multiple stakeholder perspectives: The review conducted by Obstfelder et al (2007) on characteristics of successfully implemented telemedicine services concluded that the interplay between different stakeholders and factors produced particular outcomes. This review has a constructivist approach to assessments. Recent constructivist approaches integrate social, technological and natural aspects and technologies, users, policies, etc. which in sum produce empirical outcome. Qualitative research can thus contribute to the pursuit of evidence based healthcare independent of other methodologies.

Constructive technology assessment (Douma et al 2007). In addition to traditional HTA elements, this approach takes into account technology dynamics by emphasizing sociodynamic processes. With a CTA approach, comprehensive assessment can be combined with an intentional influence in a favorable direction to improve quality. This approach thus has similarities with Action Research. CTA is created on the basis of the ontological assumptions that services are emerging and adjustable as they develop, a constructivist methodology. The idea is to shift the focus of HTA away from assessing fully articulated technologies and introduce anticipation of technology impacts at an early stage in the development. Qualitative designs are considered complimentary to quantitative, as in Popay and Williams’ (1997) ‘enhancement model’.

6. Summary and implications for approach

The SMART-tender call is a timely initiative in light of:

- the state of the art of telemedicine assessments as outlined above, indicating that telemedicine applications are not yet routinely assessed for their impact, benefits and safety;
- the i2010 initiative, especially the ehealth Action Plan for Telemedicine in Europe;
- the lead market initiative for Europe, fostering the emergence of a lead market in eHealth

- the economic benefits of implemented eHealth solutions assessed by the Study of the Economic Impact of eHealth (www.ehealth-impact.org) envisioning a great potential for rapid, sustained growth;
- challenges for established HTA methodologies and propositions of alternative methodologies in the light of flux, personalised services and emerging issues on a personal and societal level influencing health and health care provision.

Future telemedicine assessments will profit greatly from an array of methodologies that encourage and support adherence to quality norms and standards.

7. Outcome of MethoTelemed

The main outcome of MethoTelemed will be the MethoTelemed Guidance for assessing the effectiveness of telemedicine services. This will form part of the final report and will provide a practical toolkit and framework for assessing the quality and effectiveness of telemedicine. The MethoTelemed Guidance will:

- Deliver an extensive review of relevant published literature (including ‘grey’ literature) on impacts, costs and benefits of telemedicine, principally but not exclusively English language literature, which has used a range of research methods;
- Assess the appropriateness or otherwise of existing HTA methods for evaluating telemedicine;
- Be developed to ensure that the interests of different stakeholders in varied outcomes are incorporated and can be explored in a complementary fashion – quality of care needs for example to be considered in relation to costs and to acceptability for patients and medical staff;
- Propose methodologies for systematic academic assessment in the short, medium and long term, (informed also by the work of Tromso Telemedicine Laboratory) of the usefulness, durability, and acceptability of telemedicine for relevant stakeholders and in relation to a range of outcomes;
- Be accessible to a range of stakeholders including telemedicine developers, academic evaluators, health care professionals, service providers, commissioners and policy makers. By providing guidelines for academic assessments, other stakeholders can draw on statements of appropriate usage of these to be informed about the quality of the outcome of telemedicine assessments, whilst addressing key challenges for healthcare systems including population ageing; increasing demand for complex treatments; the developing emphasis on patient empowerment and involvement in healthcare, especially through self care; and the need for effective deployment of limited resources.

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