

Paper for the MethoTelemed Work Shop, June 17th 2009 in Brussels

Presentation of HTA – an approach for assessment of telemedicine

Introduction

The purpose of this paper is to give a short introduction to Health Technology Assessment, HTA, an approach used for assessment of health care technologies like telemedicine applications. At the same time the paper will provide a starting point for the workshop in the discussion of users' needs for a new methodology of assessment of the effectiveness of telemedicine applications.

HTA

HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health care technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method (www.eunethta.net/HTA).

In HTA health care technology is defined broadly as prevention and rehabilitation, vaccines, pharmaceuticals and devices, medical and surgical procedures, and the systems within which health is protected and maintained.

It is important to notice that in principle all kinds of issues or effects of a technology (e.g. a telemedicine application) can be included in a HTA. What is included in practise is determined by the technology and what users and decision makers find relevant.

In the European project EUnetHTA, established to create an effective and sustainable network for HTA across Europe, the potential issues or effect of health technologies are divided in 9 domains:

1. Health problem and current use of the technology
2. Description and technical characteristics of technology
3. Safety
4. Effectiveness (mortality, morbidity, function, QoL, patient satisfaction)
5. Costs, economic evaluation
6. Ethical aspects
7. Organisational aspects
8. Social aspects
9. Legal aspects

Methods for data collection

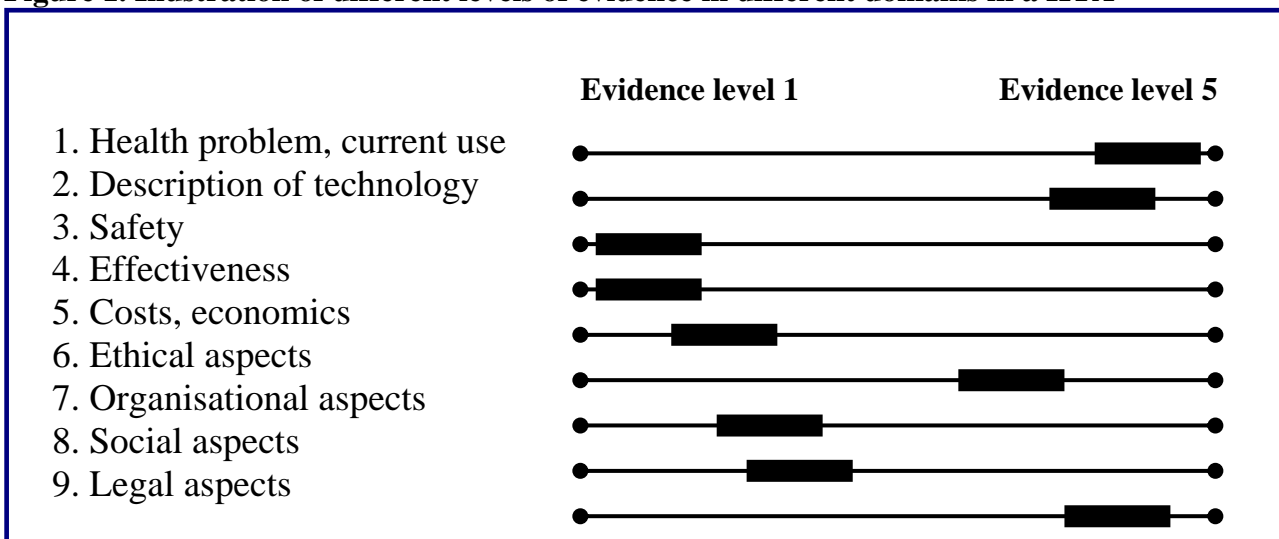
According to the definition HTA is a multidisciplinary process. Similar HTA can include methods for data collection from all scientific disciplines, in practise mainly *health sciences* (e.g. medicine, surgery, pharmacology, public health, epidemiology, nursing) and *social sciences* (e.g. economics, sociology, organisational science).

In the assessment of safety, clinical effectiveness and the economic aspects (domain 3, 4 and 5), the level of evidence in the clinical studies of the technology is often assessed. Levels of evidence is a ranking system and describes the strengths of the results from clinical studies in relation to the internal validity. The highest level (1a) is systematic reviews based on randomised controlled trials (RCT) followed by individual RCTs (1b). After this comes systematic reviews of cohort studies (2a) and

individual cohort studies (2b). The lowest level (5) is expert opinion without explicit critical appraisal (see e.g. www.cebm.net).

In a HTA of a telemedicine application a number of different designs and methods for data collection are often used at the same time. For example clinical effectiveness (domain 3) can be estimated in a RCT, whereas the organisational aspect (domain 7) can be described in a case study, in which managers and members of the staff has been interviewed about the consequences of implementing telemedicine in the department. In the same HTA the social and legal aspects (domains 8 and 9) can be based on interview with experts (see a hypothetical example in the illustration). Thus, qualitative studies can also be included in HTA e.g. giving information about the perspectives, meanings, values, and interests the different stakeholders.

Figure 1. Illustration of different levels of evidence in different domains in a HTA



HTA based on systematic reviews

HTA is often based on a systematic literature reviews in which all relevant scientific studies of e.g. a telemedicine application are identified in large data bases of journal articles in the life sciences (e.g. Medline and Cochrane Library). In a systematic review the quality of each article is assessed by use of check lists and the unbiased and robust estimates from each study is combined in a statistical analysis of the general effect of the telemedicine application.

Challenges for HTA in practice

Even though HTA in principle can include all possible effects of a health technology by use of a variety of data collection methods, in practice HTA sometimes has a more narrow focus. In some cases a HTA primarily describes the clinical effectiveness and the costs and is based only on results from RCTs. This has been a general challenge for the production of HTA and is not specific for telemedicine (see e.g. Draborg et al. 2005, IJTHAC). This is also one of the main reasons for the EUnetHTA project, which emphasizes the multidisciplinary basis of HTA by introduction of the 9 domains. Similarly, many HTA institutions are now strengthening the patient and consumer involvement in HTA.

The use of HTA as the basis for decision making in health care

The production and use of HTA in the health care systems in Europe have been growing for many years. Almost all European countries have national institutions for HTA and several international HTA organisations exist (e.g. INAHTA, HTAi, EUnetHTA). Within the last 5 years HTA has also been used increasingly by regional authorities and hospitals as the main basis for decisions about

implementation of new health technologies. Concepts like mini-HTA, rapid-HTA, GANT and similar models are now being used locally e.g. in hospitals in at least 8 European countries.

Therefore a new methodology for the assessment of the effectiveness of telemedicine applications based on the concept of HTA will have the advantage of being familiar to many decision makers in Europe.

Appendix: Central terms in HTA and other assessments

In the assessment of telemedicine applications a number of central terms are often used to describe the approach or methods used in the assessment and for collection of data. Below a number of these terms are defined:

1. Framework: The general frame or approach for the assessment

Examples:

- HTA – Health Technology Assessment
- Economic evaluation
- Multiple stakeholder perspectives
- Evaluation science

2. Study design: The way an epidemiological study is designed

Examples:

- Observational study, e.g. cohort study, case-control study, cross sectional studies
- Experimental studies, e.g. randomised controlled trial, pretest-posttest, studies with intervention group and control group (without randomisation)

3. Effects or domains: Types of effects or consequences for patients, relatives, clinical staff, others or society in general of health technologies

Examples:

- Clinical effects, e.g. effects on mortality
- Safety, e.g. adverse effects
- Effects from a user perspective, e.g. satisfaction
- Societal effects
- Organisational effects
- Economics effects, e.g. costs, expenditures
- Policy effects
- Legal effects
- Environmental effects

4. Methods: Methods for collection of data in the study

Examples:

- Questionnaire
- Personal interview
- Focus group interview
- CRF- Case Report Form (e.g. used by clinical staff to report clinical data)
- Data from registers