HEALTH TECHNOLOGY ASSESSMENT AND EVALUATION OF THE DEVELOPMENT AND IMPLEMENTATION OF NEW TECHNOLOGIES IN HEALTH CARE

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INTRODUCTION

This document describes the use of Health Technology Assessment (HTA) as input for decision making concerning the use of new technologies in health care and clinical practice. It gives a brief introduction to the concept of HTA, its products and use of HTA in the setting of OUH. The description is elaborated with examples of HTA's on various types of technologies, based on reflections on the scope of evaluations in regard to the maturity of emerging and known technologies in health care.

HEALTH TECHNOLOGY ASSESSMENT (HTA)

HTA provides a framework for multidisciplinary[1], comprehensive assessments of new medical technologies in a systematic, unbiased and robust manner. The Danish National Board of Health defines HTA as a '*versatile, systematic assessment of prerequisites for and consequences of using a medical technology*'. Medical technologies are defined as '*procedures and methods aimed at preventing, diagnosing, treating, nursing or rehabilitation including apparatus and pharmaceuticals'* (Kristensen and Sigmund 2007). Thus, any kind of new treatment or device, medical or surgical procedure can be regarded a medical technology and is assessed as such.

The framework includes four main elements:

Technology:	This element includes a description of the new technology and describes the clinical effect of the treatment in quantitative terms (Relative risk reduction, odds ratio, QALY). The description can be based on results from a systematic literature review and collection of primary data in relation to a clinical study. The aim is to describe the technologies using study results with the highest possible level of scientific evidence.
Patients' perspectives:	The patients' perspectives are included in an HTA in terms of patient satisfaction, their ability to return to work and ethical issues.
Organisational perspective:	This element includes a description of which parts of the organisation will be affected by introducing the new technology – and how. E.g. it includes information on the need for further education of staff, new facilities or changes in workflow and cooperation.

[1] According to EUnetHTA, HTA is usually defined as a multidisciplinary field of research (EUnetHTA 2008)

Economic aspect:	The economic aspect is assessed according to the perspective of the decision. Thus, for a countrywide implementation of technology, societal perspective is generally used, and a cost-effectiveness analysis can be developed. If the decision on implementation is made only by a hospital a business case can be produced comparing expenditures and revenues for the hospital.

HTA PRODUCTS AND THEIR USE AT OUH

At Odense University Hospital (OUH) HTA is often produced in the form of a mini-HTA prior to decisions on investment in new health technologies.

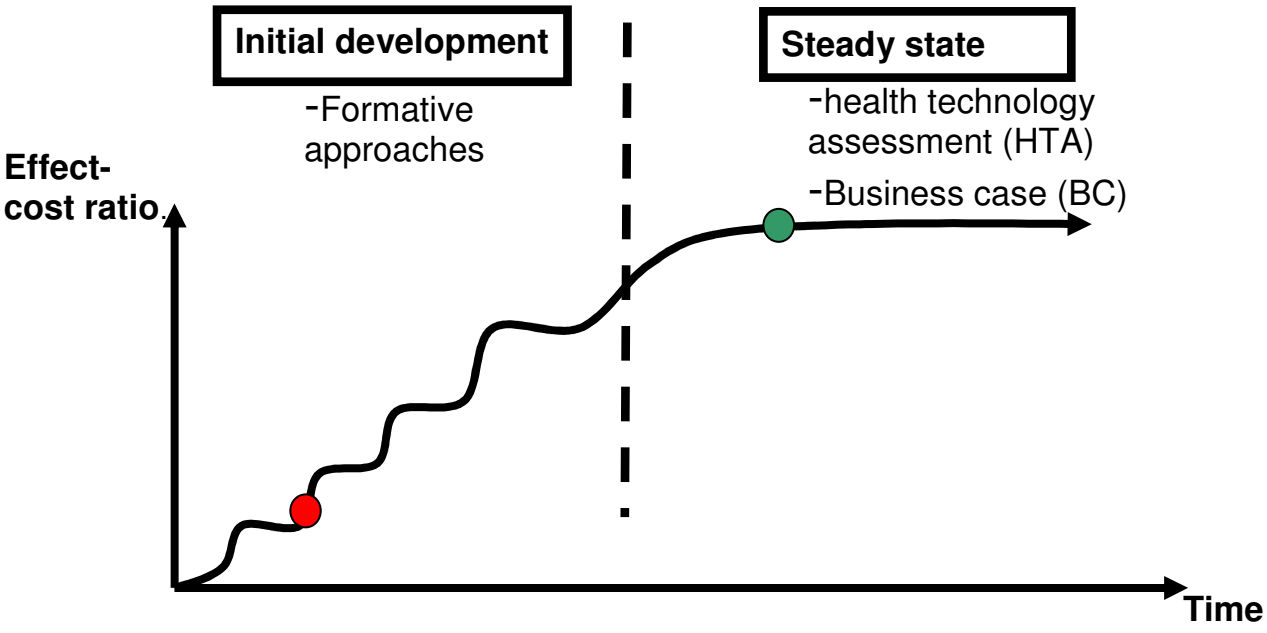
Mini-HTA includes a 4-5 pages description of the consequences of implementing a new technology – assessed in all four aspects, technology, patient perspectives, organisational perspective and economy. A mini-HTA can be used within the single clinical departments or at hospital basis.

The different HTA products that are available are ranging from mini-HTA to full HTA reports. The kind of HTA used depends on stage of development of the technology and the time frame for assessment.

SCOPE OF EVALUATION BASED ON MATURITY OF TECHNOLOGY

Evaluation needs to be adapted to the particular technology in question. One of the key parameters in choosing the right level of evaluation is how mature the technology in question is. Figure 1 illustrates the relationship between maturity and level of evaluation:

Figure 1: Maturity and evaluation



The Department of Research and HTA evaluates health technologies in the following manner:

1) Initial development of a technology is evaluated using different formative approaches, e.g. describing the development process, organizational changes and documenting the feasibility of

the technology. At this stage it is not possible to evaluate effectiveness and economic consequences due to major fluctuations in cost and effect of the technology and lack of data.

2) At steady state the technology is to some extent developed and a well described product exist. These technologies are evaluated using the framework of HTA and BC (compared to HTA a BC approach has a more narrow focus on economic consequences, key performance indicators and implementation / project management).
3) In between those two extremes (initial development and steady state) we adapt the evaluation depending on available data and resources for the evaluation. It is possible to produce quick evaluation such as mini-MTV over a HTA based on a literature review to a HTA with a randomised controlled trial (RCT).

Evaluation in the Department of Research and HTA is always a multidisciplinary process for example involving decision makers, clinical personal and personal with evaluation experiences. Therefore evaluation is always made in collaboration with clinical experts

CASES

The cases below represent examples of HTAs and evaluations conducted on technologies of various levels of maturity, from immature technologies in the process of development to mature products and technologies that are widely used and documented in the scientific literature.

1. HTA as a framework for a formative evaluation of a technology in initial development (ePatch)

EPatch is a developmental project financed by a fund under the Danish Ministry of Finance supporting new, innovative technologies in the public sector. The project is based on an electronic plaster prototype platform developed by DELTA, a private microelectronic company. The idea is to develop a wireless tele-monitoring device for detection of cardiac arrhythmias in patients in their own homes. The technology will replace current diagnostic procedures of standard wired ECG during 2-5 days of hospital admission, thereby reducing the demand for nursing resources and hospital services without compromising patient safety or - satisfaction.

As illustrated on Figure 1 the technology in question is in initial development phase meaning that there is no steady state technology and no data. Data are collected alongside the development of the plaster prototype, which is under constant change. The fluctuations in cost and effectiveness means that, in HTA-terms, it is not possible or meaningful to evaluate and measure on outcomes related to clinical effectiveness, costs or patient related outcomes such as quality of life etc. As a fundamental part of an HTA a systematic review of the scientific literature is conducted, to gather information on the clinical effect of comparative technologies (ambulatory electrocardiography devices, external event recorders etc.) as well as patient perspectives, organizational aspects and cost-effectiveness. This information can uncover knowledge gaps in the use of comparative technologies as well as important barriers and promoters for implementation of the new technology.

In the evaluation of ePatch much attention is given to the organizational aspects of implementing ePatch, based on hypothetical estimates of effect. Work flow and work processes are described through interview with clinical staff and the descriptions are validated through field observation. The work flow analysis conceptualizes the possible organizational effects which can be used for simple economic estimates of operating costs when the technology is developed and implemented.

The documentation gathered from such evaluations is not to be considered as sufficient input for decision making in clinical practice but can be used as a basis for the initiation of further feasibility studies or randomized, controlled trials.

Time used for production of the evaluation: 2 years.

2. HTA as a clinical Ph.D.-study of percutaneous vertebroplasty

In the beginning of year 2000 the Department of Orthopaedic Surgery started introducing a new surgical procedure, Percutaneous Vertebroplasty (PVP) for patients with painful vertebral fractures. The treatment involves injection of technically bone cement in the vertebral body under fluoroscopic control.

The evidence for the clinical outcomes of the treatment was weak and therefore the department initiated a 3-year Ph.D. study of the clinical, patient related, organisational and economic consequences of using PVP for patients with painful vertebral fractures. The project was designed as a randomised

controlled trial (RCT) including two samples of 25 patients that was followed for a period of 12 months.

The assessment of the clinical outcomes including quality of life was carried out by a clinical PhD. student (medical doctor) at the Department of orthopaedic surgery. The assessment of the organisational and economic aspects was done by the Department of Research and HTA.

Time used for production of the evaluation: 3 years.

3. HTA of patient falls

The report was initiated because patient falls constitute a frequent adverse event in hospitals (10% in Denmark), and because the consequences of patient falls range from minor bruises to death. The different technologies related to prevention of patient falls are mature. Also, plenty of research has been carried out within the area, so the HTA was based on a systematic literature search and review of the literature.
The project was organised with a steering committee and external review of the report for quality insurance. The systematic literature search was carried out in 13 clinical databases (pubmed, Cochrane, Embase, Cinahl, Psycinfo, web of science, up to date, svemed+, den danske forskningsdatabase, projektdatabasen for MTV og evaluering, SBU, Den nationale mini-MTV-database and bibliotek.dk) and resulted in approximately 3.000 references. The inclusion of literature was based on quality of the articles and level of evidence. The recommendations of the report were:

- Do not use any risk assessment tool that is developed in another setting
- Multiple interventions can result in a risk reduction of approximately 20%, although it is not possible to identify which types of interventions to include
- Patient education can reduce the risk of falling by 47% (based on one RCT)
- Medication review can reduce the risk of falling by 72 % (based on one RCT)
- There is a lack of evidence on the patients' perspectives and organisational aspects of falls prevention in hospitals – particularly related to multiple interventions
- Falls prevention is expensive, so measures should be taken in order to assure that resources are spent wisely

Time used for production of the evaluation: 1 year.

4. HTA as a mini-HTA project of intra cranial stents

Patients with apoplexy and stenosis in the cranial arteries have for some time been treated medically. Many patients respond well to the treatment, but not all. The patients that are not responding to the medical treatment are expected to have a 22% risk of a new infarct within 2 years based on the scientific literature.

However, in 2007 new evidence indicated that treatment with intracranial stents could reduce the risk to 6-7%. This was based on results from two cohort studies with 78 and 45 patients. Based on these positive new results the clinical department decided to produce a mini-HTA of the expected consequences of introducing intracranial stents at Odense University Hospital.

A group of experts from the Neurological Department, the Department of Radiotherapy and the Department for Research and HTA therefore produced a mini-HTA based on a systematic review of the scientific literature. The mini-HTA concluded that the use of intracranial stents will:

- Reduce the risk of a new infarct within 2 years from 22% to about 10%.
- Result in diagnostic examination of 100 patients and surgical procedure for 10 patients
- Include quality control by registration of data in a clinical multicenter database
- Result in substantial social and occupational effects for the patients
- Result in annual costs of € 50.000 for utensils and € 70.000 for staff.
- Have an economic DRG-value for the hospital of € 220.000.

Time used for production of the evaluation: 2 months.

References:

EUnetHTA 2008. Core model. http://www.eunethta.net/upload/WP4/Final%20Deliverables/HTA%20Core%20Model%20for%20Medical%20and%20Surgical%20Interventions%201%200r.pdf [23.07.2010]

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