HTA-Methodology for Innovative Healthcare Technologies (Inno-HTA)

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for the Inno-HTA-Consortium*

Introduction

High expectations are related to innovations in healthcare with respect to improving treatment outcomes, saving healthcare expenditures and generating employment. Decisions about clinical development, market introduction, application in patients etc. have to be supported by scientific evidence. However, **regarding innovative healthcare technologies (IHTs), the potentials of HTA are not fully exploited yet.** In HTA to date the innovation component is nearly totally missing. Thus, advances in medical technologies in their early states are not sufficiently utilized.

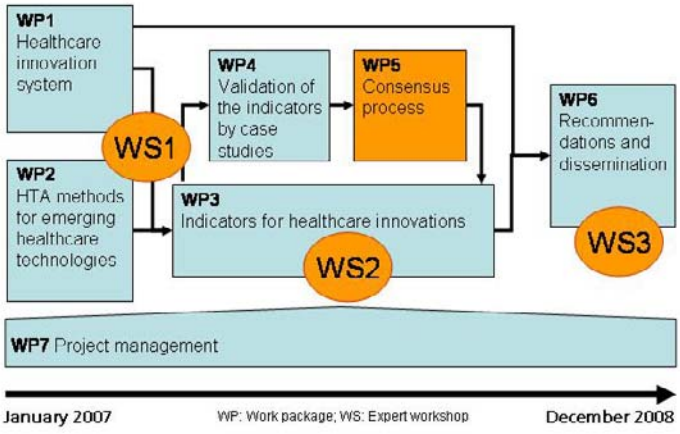
The EU-funded project ***Inno-HTA*** aims at helping close the gap between the development of new technologies and their application. **A generic methodology for the evaluation of IHTs is developed** that expands the focus of HTA to include aspects of the technology as such, its scientific foundation, potentials, implementation and effects on society as well as implications of adoption or non-adoption.

Methodological Approach

The approach for the assessment of emerging technologies for the healthcare sector is developed in five steps:

1. Adoption of the innovation system approach[1,2] to the healthcare system
2. Overview of approaches to the evaluation of healthcare innovations within "established" HTA (including "horizon-scanning" HTA reports and "early HTAs")
3. Elaboration of a first set of indicators and validation of the indicators in technology-specific case studies
4. Development of a broad consensus on assessment criteria and indicators for emerging healthcare technologies
5. Refinement of the assessment criteria and respective indicators and dissemination to the HTA and healthcare innovation community

Figure 1: Methodological approach



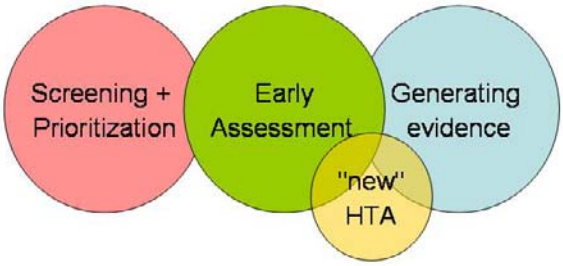
Besides having HTA-agencies and a strong link to the EUNetHTA project **within the consortium**, the approach includes external expertise by **workshops and surveys** to a considerable extent.

First results

One of the central outcomes of modern innovation research is that **innovations do not follow a linear path** from basic to applied research and further to industrial development and market introduction of new products and processes. Instead, innovation activities are characterized by complicated feedback mechanisms and interactive relations, involving different players which have a significant influence on the success of innovations. Innovation processes occur over time and are influenced by multiple factors. **In the evaluation of IHTs, these factors have to be assessed comprehensively.**

An overview of methods used to assess emerging technologies in "established" HTA has been compiled. The approaches to IHTs comprise three conceptual steps, that may be, but not necessarily need to be worked in a sequence.

Figure 2: Overview of HTA methods for emerging technologies



HTA element		Aims
Screening/Scanning	→	Identification of IHTs
Filtering/Prioritising	→	Sorting out technologies with high probability of relevant impact
Early Assessment	→	Estimation of probable impact (by modelling…)
Generating evidence	→	Monitoring of ethical, legal, and social implications (by clinical trials…)
"New" HTA	→	Integrating the social shaping perspective incl. constructive[3], participatory and interactive HTA

Conclusions

An **international workshop** with 16 external experts from regulatory and HTA agencies, pharmaceutical and medical technology industry, and academia incl. the EuroScan and MATCH projects, was held on 3rd May, 2007, in Vienna, Austria). The analytical framework of the innovation system approach (actors, roles, resources, key interactions) and the results regarding HTA methods for IHTs were discussed. The experts encouraged Inno-HTA to develop its approach to be more "constructive" and **include aspects of the social shaping of technologies**.

The next steps will involve the development of a preliminary set of indicators and their validation in case studies, as well as **a structured consensus process to which the broad HTA community will be invited**.

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[3] Douma, K.F.L.; Karsenberg, K.; Hummel, M.J.M.; Bueno-de-Mesquita, J.M.; van Harten, W.H. (2007): Methodology of constructive technology assessment in health care. In: International Journal of Technology Assessment in Health Care, 23 (2), pp. 162-168.

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