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The HTA Core Model®—10 Years of Developing an International Framework to Share Multidimensional Value Assessment

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ABSTRACT

Background and Objectives: The HTA Core Model® as a science-based framework for assessing dimensions of value was developed as a part of the European network for Health Technology Assessment project in the period 2006 to 2008 to facilitate production and sharing of health technology assessment (HTA) information, such as evidence on efficacy and effectiveness and patient aspects, to inform decisions. **Methods:** It covers clinical value as well as organizational, economic, and patient aspects of technologies and has been field-tested in two consecutive joint actions in the period 2010 to 2016. A large number of HTA institutions were involved in the work. **Results:** The model has undergone revisions and improvement after iterations of piloting and can be used in a local, national, or international context to produce structured HTA information that can be taken forward by users into their own frameworks to fit their specific needs when informing decisions on technology. The model has a broad scope and offers a common ground to various stakeholders through offering a standard structure and a transparent set of proposed HTA questions. It consists of three main components: 1) the HTA ontology, 2) methodological guidance, and 3) a common reporting structure. It covers domains such as effectiveness, safety, and economics, and also includes domains covering organizational, patient, social, and legal aspects. There is a full model and a focused rapid relative effectiveness assessment model, and a third joint action is to continue till 2020. **Conclusion:** The HTA Core Model is now available for everyone around the world as a framework for assessing value.

Keywords: decision making, health care, health technology assessment, methodology.

Introduction

This article aimed to present the ideas behind the HTA Core Model® (hereafter referred to as "the model") and its development, piloting, and implementation as a framework for production and sharing of health technology assessment (HTA) information. We find that a scientific discussion on value frameworks should be informed about our network's experience. It is important to underline that the model, although developed in Europe, is generic and is thus for global use. This model comes from the European network for HTA (EUnetHTA), which involves more than 70 institutions in 32 European countries since 2006 and is supported by the European Union [1].

Value frameworks, explicit and nonexplicit, vary across health care decision contexts such as pricing and reimbursement of pharmaceuticals and the formulation of clinical pathways and practice guidelines. They involve varying compositions of decision makers and stakeholders. Nevertheless, a substantial amount of scientific evidence on health technologies (e.g., evidence of efficacy and effectiveness) is relevant and applicable across organizational and national contexts. There is therefore a great potential in sharing and reusing information (the "building bricks") if this can be done in a reliable way and through a shared repository.

Building on previous international work, the intention in developing the model was to enable transparent structures, procedures, and standards for handling evidence and information across various forms of HTAs, economic evaluations, and other forms of assessments of the value of interventions—and across institutions and countries [2].

In 2004, ministries of health in 25 European countries and the European Commission were developing policies regarding patient mobility across borders within the European Union. Researchers

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from 17 of these countries provided scientific considerations in this policy development on how a science-based policy-oriented cooperation could produce so-called common core information ("global evidence") on a technology to be combined with context-specific information for adaptation into national HTAs [3]. This led to the development of the model in the EUnetHTA project in the period 2006 to 2008 [2,4]. Subsequent development and testing of concept, applications, joint productions, and usability took place in two consecutive projects (Joint Actions 1 and 2 [JA1 and JA2]) from 2010 to 2016.

The Model

The model is built to enable broad-scoped, multidisciplinary HTA, be it comprehensive (broad scope) or rapid (limited scope), done early or late in the life cycle of a technology (Fig. 1). The aim of the model is to 1) improve the applicability of evidence and information for HTA across (e.g., national or regional) HTA projects; 2) enable actual collaboration between HTA agencies by providing a common framework for the production and reporting of HTA information; and 3) reduce unnecessary duplication of work.

The model reflects the generic broad scope and multidisciplinary nature of HTA and consists of three main components:

1. The HTA *ontology* that encompasses 136 standardized questions called *assessment elements* within a framework with nine *domains* (such as effectiveness, safety, organizational, economic, patient, and social aspects) that comprise all aspects potentially relevant for HTA and thus value assessment (Fig. 1). The assessment elements are potentially relevant for the assessment of a health technology. Each element contains a question that researchers should consider to include and answer in a specific assessment project. Here are a few examples [2,5]:
   Topic: Features of the technology; Issue B0002: What is the claimed benefit of the technology in relation to the comparators?
   Topic: Health delivery process; Issue G0002: What kind of involvement has to be mobilized for patients/participants and important for others and/or caregivers?
   Topic: Resource utilization; Issue G0007: What are the likely budget impacts of implementing the technologies being compared?
2. *Methodological guidance* that foremost recommends the use of already existing, generally recognized methods guidance (e.g., EUnetHTA guidelines or Cochrane Handbook), along with other methodological recommendations.
3. A common *reporting structure* that provides a standard format for recording and displaying the results of a specific HTA in *collections*, in which the resulting information is displayed within so-called *result cards* containing the answers to the specific research questions defined by using the ontology [3,6]. The modular and hierarchical structure enables researchers to "scan" the ontology and focus on producing information relevant for decision making on the technology at hand. Transparent reporting enables review of the information at a highly detailed level.

Methods

During the initial years from 2006 to 2008, a general design team led the development together with a lead organization, the Finnish Office for HTA [2]. More detailed work was done in nine multidisciplinary "domain teams." Sixty researchers from 12 countries participated in the model development and piloting, and 34 reviewers commented on the work. Details are available in the EUnetHTA project technical report [7].

Since 2006, multidisciplinary teams of researchers and managers in EUnetHTA partner institutions; stakeholders including payers, patients, providers, and industry organized in a stakeholder forum; and the European Commission were involved in the development, field testing, and implementation of the model [5, 8]. Table 1 lists the partner organizations that participated in EUnetHTA JA2. The development and application of the model in joint piloting and production in EUnetHTA were rigorously defined in agreed research protocols, leading to publication of joint assessments intended for adaptation into national contexts. The EUnetHTA Web site has been live since 2006 and includes archived outputs [1].

Figure 2 describes the temporal relation between the publishing of the model versions, the HTA Core Model Handbook [6], joint assessments [9], and 14 methodological guidelines to help the assessors of evidence to process, analyze, and interpret the data [10]. The EUnetHTA output also includes a planned and ongoing projects database with standardized information reported by the partners [11], evidence submission templates for requesting evidence from companies [12], work on evidence generation (early scientific advice and additional evidence generation) [13,14], and a list of the national uptake of EUnetHTA joint assessments [15].

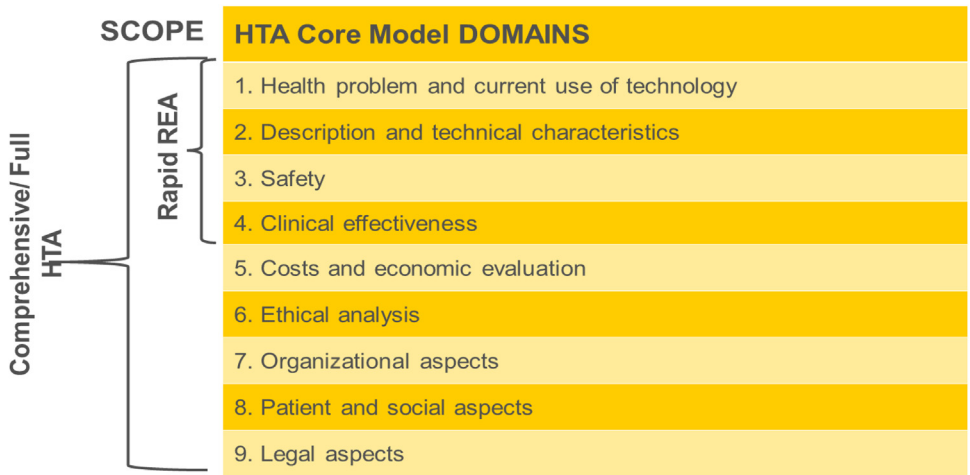

Fig. 1 – The domains of the HTA Core Model. HTA, health technology assessment; REA, relative effectiveness assessment.