



eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

The HTA Core Model®

Guiding principles on use

Purpose of the document

To outline fundamental principles for the utilisation of the *HTA Core Model*® (the Model)¹ in various settings contributing to Health Technology Assessments (HTAs)², and to the production and use of a reliable, timely, transparent and transferable knowledge in healthcare supporting patients' access to effective health technologies³.

Definition and purpose of the Model

- The HTA Core Model is a *methodological framework* for production and sharing of HTA information. The HTA Core Model® is a registered trademark.
- The Model consists of the following three components, each with a specific purpose:
 1. A standardised set of *HTA questions (the ontology)* allows users to define their specific research questions within a hierarchical structure (see below)
 2. *Methodological guidance* to assist in answering the research questions that
 - Recommends use of already existing, generally recognised guidance and guidelines (e.g. EUnetHTA methodological guidelines, Cochrane Handbook⁴, EQUATOR network⁵), along with other methodological recommendations

¹ The HTA Core Model® and the Online Tool and Service (also known as the HTA Core Model Online) are two related but separate products of EUnetHTA. This document refers only to the HTA Core Model®. The HTA Core Model Online contains features that assist in using the Model in certain settings, but should not be viewed as part of the Model.

² **Health technology assessment (HTA)** is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health 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.

³ Health technology is the application of scientific knowledge in health care and prevention. Examples of Health Technology: Diagnostic and treatment methods, Medical equipment, Pharmaceuticals, Rehabilitation and prevention methods, Organisational and supportive systems within which health care is provided

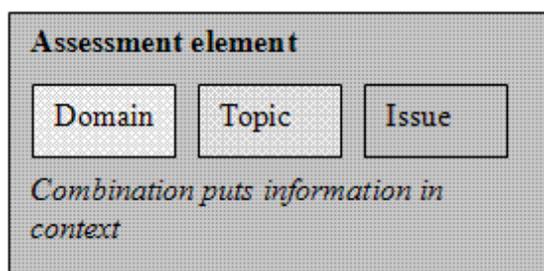
⁴ Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

⁵ The EQUATOR (Enhancing the QUALity and Transparency Of health Research) Network is an international initiative that seeks to improve the reliability and value of published health research literature by promoting transparent and accurate reporting and wider use of robust reporting guidelines. <http://www.equator-network.org/>

- Requires transparency on the methods used when applying the HTA Core Model.

3. A *common reporting structure* for presenting findings in a standardised “question-answer pair” format

- HTA information produced by using the Model following the ontology and the common reporting structure can be designated as core HTA information, with high potential for being shareable and transferable knowledge. In order to facilitate re-use of information, registered users (see below) of the HTA Core Model should facilitate the traceability of the core HTA Information they produce.
- The assessment elements are units of the structure of the Model, which consists of *domain*, *topic* and *issue* (*translated further into one or more specific research questions in concrete projects*) that are used to assess a health technology. In this way, within a hierarchy, all research questions relate to a specific domain and subordinate topic.



- Flexibility in the choice and combination of these structural elements is an important characteristic of the Model and its utilisation. It means that to produce and to present core HTA information, users can choose from an overall set of assessment elements those relevant for their project and use them in their own order and combination. This flexibility in choice and order allows collecting assessment elements (i.e. question-answer pairs) and building them into a structure of reporting, tailored to the needs of the user and a specific health technology assessment
- The Model does not mandate either a certain order or hierarchy (apart from the Domain, Topic, Issue hierarchy presented above) of its structural units or any specific process of producing the information. Any further structuring of core HTA information is done at the discretion of the Model users.

Open access and collaboration values

- The design of the Model is and will remain publicly accessible
- EUnetHTA’s objective is and has always been to deliver a model that can be shared and its use customised to the needs and objectives of the users, provided that the defining characteristics of the model described in this document are respected
- The “open” approach to developing and welcoming wide use of the EUnetHTA outputs – among which the HTA Core Model is one - designates a set of values and refers to something that can be further developed by EUnetHTA and others because its design is publicly accessible. The HTA Core Model is intended for general use, and all stakeholders in HTA and health research and policy are welcome not only to use it as a final and complete tool, but also to build upon it and develop their own products, tools and systems by using the defined

and standardised framework of the Model. Those who utilise the HTA Core Model in derivative products (e.g. information systems) should clearly disclose to users whether they have used the Model as it is made available by EUnetHTA or whether some parts have been modified/revised.

- The standardised “question-answer” format and open access to the Model explicitly support users to produce, share, access and re-use HTA information in a reliable, timely, transparent and transferable manner

Intended use

- The HTA Core Model is free of charge provided that its use is registered by using the registration form and providing information about the user (including but not limited to contact details) and intended use of the Model. The registration is performed at www.htacoremodel.info.
- The Model offers a common ground to various stakeholders at any and all stages of the development of health technologies and their application by facilitating a common HTA language worldwide and through offering a standard structure and a transparent set of proposed HTA questions for consideration by health technology assessors and stakeholders
 - The Model can be used at any and all stages and for any purpose in a technology’s life cycle and in the systems within which health technologies are applied, e.g. (but not limited to):
 - In agreeing on the scope of an HTA, selecting relevant assessments elements in the early phases of an assessment
 - In agreeing on the content of submission files/dossiers, according to relevant assessment elements
 - In providing structure to early scientific advice /early dialogues between HTA entities and health technology developers, in early and later stages of development and evidence generation
 - In identifying evidence gaps and in generating further evidence for technologies that are already introduced to healthcare
 - In providing a framework from which further recommendations and other steps in informing decision-making on health technology reimbursement or policy can be derived
- EUnetHTA welcomes any legitimate use of the HTA Core Model and any efforts to ensure compatibility between derivative works and the HTA Core Model and efforts to facilitate a consistent experience with using the Model and core HTA information
- Transparency of the methods used to answer the research questions derived from the ontology is mandatory when using the HTA Core Model.

Availability and versions

- The HTA Core Model is available on the EUnetHTA website (www.eunethta.eu) and www.htacoremodel.info in pdf and MS Word formats.

Intellectual property rights

- Use of the HTA Core Model, including information on its version, must be disclosed in the final product(s) as indicated in the HTA Core Model® Licence.