HTA Core Model Handbook

This Handbook is currently written primarily for people who use the HTA Core Model to conduct assessments, i.e. to produce HTA information. It contains also brief instructions on how to view existing core HTA information available within the HTA Core Model Online. Future versions of the Handbook will include more specific advice on searching and using the available information.

The Handbook is divided into four sections.

Section 1 contains a general introduction to the HTA Core Model. It is necessary background reading for understanding how the system is designed and how it functions. Details are, however, kept to a minimum.

Section 2 is a practical guide for using the HTA Core Model to produce a health technology assessment. The production process is divided into five phases.

Section 3 provides an introduction to the methodological guidance included in the HTA Core Model.

Section 4 provides instructions on viewing existing information in the HTA Core Model Online.

Any feedback on the Handbook is welcome, please send it to eunethta@thl.fi.

Section 1. Introduction

Health technology assessments normally contain a vast amount of information on the technology that is the object of the assessment. The HTA Core Model divides this information into standardized pieces, each of which describes one or more aspects of the technology that is likely to be useful when considering whether or not to use the technology. These pieces of information are referred to as assessment elements. The elements that are most likely useful to share in the international context are defined as core elements. Each assessment element contains a generic, i.e. a non-technology-specific question referred to as an issue. The issues define in a generic manner the aspects of technology that one should consider.

Basic concepts

The following basic concepts define the HTA Core Model and its derivatives and applications.

HTA Core Model: A methodological framework for shared production and sharing of HTA information. The Model consists of three components: 1) an ontology containing a set of generic questions that define the contents of an HTA, 2) methodological guidance that assists in answering the questions and 3) a common reporting structure that enables standardised reporting of HTAs. Information is created and presented as assessment elements. Some elements are prioritized over others to support European collaboration through defining them as "core elements".
**Assessment element:** The basic unit of the model. Defines a piece of information that describes the technology or the consequences or implications of its use, or any other aspect relevant for the assessment, such as the patients and the disease for which it is applied. Each assessment element contains an "issue", which is a question that should be answered in an HTA. Not all issues, however, are relevant to all technologies/settings, and hence their relevance is considered separately for each assessment. Elements are defined through a combination of domain, topic and issue.

**Domain:** A wide perspective within which technology is considered. It provides an angle of viewing the use, consequences and implications of technology. A standard set of domains is used in the HTA Core Model.

**Topic:** A more specific area of consideration within the domains. One domain is divided into several topics. Similar topics may be addressed within more than one domain.

**Issue:** An even more specific area of consideration within any of the topics. One topic typically consists of several issues, but it may also contain only one issue. An issue is always expressed as a question that can be answered through answering one or more research questions.

**Application of the HTA Core Model:** Different kinds of technologies (e.g. surgical interventions or pharmaceuticals) may require different questions to be asked in an assessment and the answers to the questions may require different research methods. An application of the HTA Core Model is built for assessing a specific kind of health technology. Different applications all draw from the same pool of assessment elements, but not all elements are used in all applications. Currently applications exist for the following five types of technologies:

- medical and surgical interventions
- diagnostic technologies
- screening technologies
- pharmaceuticals
- rapid relative effectiveness assessment of pharmaceuticals

**Element card:** Each assessment element is connected to an element card, which provides tangible information on the element and its relations to other elements. A card may provide advice on how to answer the question defined by the element. Two characteristics within a card (importance and transferability) define whether an element is a "core element" or "non-core element". While assessment elements are generic (i.e. one element can belong to several applications of the HTA Core Model), element cards are application-specific (i.e. the cards describing an element within different applications may be different).

**Result card:** After a question deriving from an assessment element has been answered through appropriate research, the answer is recorded in a result card. The information should be in a concise form and more extensive materials (e.g. long texts or large tables) can be added as appendices, which can be relevant to one or more result cards.

**Structured HTA information:** Information on any aspect of health technology that has been created through answering the issues defined in the assessment elements of the HTA Core Model.

**Core HTA information:** Any information on a technology that has been produced through using the HTA Core Model and published through the HTA Core Model Online at [www.corehta.info](http://www.corehta.info).
This information is very likely to be useful in the European context (i.e. also in another country) due to its importance and/or transferability.

**Collection:** All core HTA information is currently produced and published in the form of collections, each of which contains a) a set of *result cards* in which each research question is answered in a concise manner, b) *general content* (e.g. summary, introduction and discussion) that combines the cards into a coherent information package, and c) optional *appendices* that enable inclusion of additional information to the result cards without crowding the cards' content. Appendices may also be relevant to one or more domains (these are respectively called domain-level and collection-level appendices).

**Core HTA:** An actual assessment that a) has been conducted using the HTA Core Model and b) has considered all core elements of all 9 domains. (Note: through this consideration some elements may be defined as irrelevant, but that should be documented). A core HTA contains a summary chapter that draws together key findings of various domains, but does not make recommendations regarding the use of technology. Through the wide scope, focus on core elements and the summary, a core HTA gives an overview of a technology that is likely to be useful in the European context. A core HTA can be used as a basis for producing local HTA reports that take into account local circumstances (e.g. epidemiology, organisation, resources, values). A core HTA is published as a collection within the HTA Core Model Online.

**Domains of HTA**

The HTA Core Model employs a multidisciplinary view of HTA. Any technology that is being assessed is considered through domains, each of which provides a wide framework for the analysis. Brief definitions of the domains follow. More detailed information on domains is available in the actual Model applications.

**Description and technical characteristics of technology**

Domain gives an overview of what the technology is, when it was developed and for what purposes, who will be using the technology, in what manner, and at which level of health care. The material requirements, premises, equipment and staff, are described, as well as the training and information needs the new technology brings along.

**Health problem and current use of technology**

Domain describes the health problem and target population to be intervened with the technology under assessment; the epidemiology and the burden of disease on individuals and the society. It describes the availability, patterns of use, life cycle, and regulatory status, as well as the alternatives to the technology. It is essential background information for core HTA investigators in other domains as well as for those who read and utilise a core HTA.

**Safety**

Safety domain describes the direct and indirect harms of a technology for patients, staff and environment, and how to reduce the risk of harms. There is usually a spectrum of known and unknown harms, which can be intended or unintended, of different seriousness, and dose or time dependent.
Clinical effectiveness

Domain describes the spectrum and amount of beneficial health effects and quality of life that is expected through the use of the technology. In diagnostic technologies the test accuracy and beneficial changes in management are considered as outcomes of indirect effectiveness as well. Proven effectiveness and safety of a technology is fundamental, considering further assessment and the potential use of the technology.

Costs and economic evaluation

Domain identifies, measures, values and compares the costs and outcomes of technologies being considered to inform value-for-money judgments about the intervention and priority-setting between different health technologies. The issues deal with resource utilization, unit costs, indirect costs, outcomes/consequences, and incremental cost-effectiveness of the technology.

Ethical analysis

Domain considers prevalent social and moral norms and values relevant for the technology in question. Ethical questions are addressed both with regard to the technology itself and with regard to the consequences of implementing or not implementing a health technology. In addition, the moral and ethical issues inherent in the entire HTA process are identified and evaluated.

Organisational aspects

Domain focuses on the delivery models of the technology, analysing processes, resources, management and cultural issues within variety of stakeholders, in the intra- and inter-organisational and health care system level. Understanding organisational aspects may reveal essential challenges and barriers in implementing health technologies.

Social aspects

Domain focuses on the patients' and his or her significant others' considerations, worries and experiences before, during and after the implementation of the technology. It describes how the technology moulds diverse social arenas and is moulded by these arenas where the patients use it (hospitals, general practitioner, everyday life, homes, schools, and workplace), and what specific meanings people give to the technology.

Legal aspects

Domain scrutinizes aspects of basic rights of patients, such as autonomy, informed consent, privacy and confidentiality, and legal requirements, such as authorisation, guarantee, and regulation of market. The European Union is producing ever more health technology related legislation. Harmonisation of national legislation is likely to occur in the health care sector, as the patients and professionals are allowed free movement within Europe. Proper knowledge of relevant legal questions has often relevant legal consequences in decision making.

Section 2: Production of HTA information

Introduction
This section is written for those who conduct HTAs using the HTA Core Model and hence produce information on technologies that may be useful beyond the original location or setting in which the HTA was conducted. Although the text describes the production process as it is implemented in the HTA Core Model Online, projects using the HTA Core Model without the web interface are likely to benefit from a similar process.

The process is divided into five phases, each of which is explained in more detail below. The project and its participants are defined in phase 1 and the assessment protocol designed in phase 2. Phase 3 contains tools for the research phase, where answers to the questions are sought. After finding answers, the process continues in submitting the results of the research in the online database of structured HTA information (phase 4) and publishing the results (phase 5). An editorial process precedes the final publication.

Some general policies are defined at the end of this section.

**Utilisation**

The HTA Core Model is a registered trademark and subject to Terms of Use available at [www.corehta.info](http://www.corehta.info) (see footer of page). The document contains two licenses, one for non-commercial and the other for commercial use.

The Model is available and can be used either as PDF documents or through the web interface of the HTA Core Model Online at [www.corehta.info](http://www.corehta.info). The PDF version is available at the same web site, by selecting Browse-Model from the left side menu. One can choose to use all three components of the Model (i.e. ontology, methodological guidance and/or reporting structure) or just one or two of them.

Currently there are two main options for utilising the Model through the HTA Core Model Online. The primary option leads to production of standardized EUnetHTA Collections, such as a core HTA, which is a collection of all core elements complemented by more general sections of text. Also rapid assessments are such collections, but these have not been implemented in the online system yet. For the time being, see instructions from EUnetHTA Joint Action 2, WP5 regarding rapid assessments (at [www.eunethta.eu](http://www.eunethta.eu)). The secondary option is to utilize a free selection of assessment elements. While the free selection may be more appealing in the sense that it allows the user to focus only on topics of local interest, one should notice that very important aspects of technology may be omitted in the process. The choice also reduces the overall usefulness of the resulting pool of core HTA information.

Any con-commercial party can utilise the HTA Core Model Online to produce HTA information. EUnetHTA member agencies can publish the resulting collections through the same service. Other organisations and researchers must publish the information elsewhere (e.g. at their own web sites).

The HTA Core Model can also be fully utilised using the PDF versions of the Model. The resulting information can be published in the form of a collection utilising the reporting structure or in some other format of the producer's choice. The Terms of Use should be followed when publishing the information (see footer of page).

**Production phases**

**Phase 1: Project definition**
The assessment you want to conduct is first defined as a project on the general level. This includes definition of the technology, its assessment and scope.

The following information should be provided:

- Name of project
- Model version: which application (or "model") of HTA Core Model will be used? Select one that matches your technology. An additional demo application is available for testing purposes.
- Project type: select whether you will a) produce a core HTA, ie. a full package of core HTA information (as defined by the EUnetHTA Collaboration), including a summary of findings (recommended selection), or b) apply a free selection of assessment elements. Additional temporary types may be available for piloting and testing purposes.
- Scope: description of the technology, its intended use and the comparator (see details below)

**Project scoping**

Sufficiently detailed and well communicated scope is particularly essential in large collaborative HTA projects. It should guide all the domain teams throughout the assessment and ensure that the analysis within different domains has the same target. Further adjustments and extensions to the project scope may be done at domain level at a later phase (see "domain framing" below).

The scope is structured in the following way:

- Technology and its intended use
- Target condition (disease or health condition)
- Target population
- Comparison
- Main outcomes for each domain

**Technology and its intended use**

The authors should describe the technology detailedly enough to distinguish it from other relevant technologies. There is possibly a need to restrict the scope e.g. to certain types of the technology or to the newer device generations. The intended use of the technology in this particular assessment, whether treatment (first line/second line) or prevention, diagnosing or screening, or monitoring or determining prognosis, should be provided.

**Target condition**

The authors should provide a name and a brief description for the disease or health condition (of certain grade or severity) that is targeted by the use of the technology and provide ICD-10 code and MeSH-terms for it.

**Target population**

The target population is typically a subgroup of all the individuals who have the disease or who are in (low/high) risk of having the disease. There may be limits for e.g. age and sex.

**Comparison**
The technology can be compared to e.g. another specific technology, management pathway without the technology, usual care, not doing anything, or a placebo intervention. This should be described detailedly enough to distinguish it from other relevant comparators.

**Main outcomes for each domain**

Authors should provide an overview of the main outcomes for this project, considering each domain. The aim is to ensure overall clarity of the project scope; more detailed definition of all relevant outcomes or areas of interest will be provided in the subsequent phases of the project.

**Project participants and roles**

The user starting the project will become the project leader. A project may in addition have an unlimited number of users participating in various roles listed below. The roles of each participant are defined separately for each domain. Participants must have an account within the HTA Core Model Online. Staff members of EUenetHTA member agencies can have a EUenetHTA ID. Contact EUenetHTA Secretariat to obtain IDs for those who need one (http://www.eunethta.eu/Public/Contact/, email eunethta@sst.dk). Others can register a local user name within the HTA Core Model Online.

**Phase 2: Protocol design**

This phase can be divided into the following four steps that lead into formulation of the final project protocol. Notice that the resulting protocol is not intended to replace a more detailed research protocol. Instead, the protocol contains the questions you should answer in your project and guidance on finding answers.

1. The relevance of each assessment element in the context of your project or the technology your project is about to assess is considered. Relevant issues are selected and translated into practical research questions (to be answered in your project). If you are producing a core HTA, you must consider all core elements of all nine domains.

2. A specific framing for each domain may be defined, as these may differ across domains.

3. Each domain is locked once the research questions and framing are complete.

4. The protocol is reviewed and locked.

**Selecting relevant issues and translating them into research questions**

This is a fundamental part of your project, as here you will define the questions you intend to answer and hence the contents of your HTA.

If you are producing a core HTA, you should start this phase by involving the researchers of the Ethical analysis domain actively in the discussion. The idea is to provide guidance and arguments for considering the relevance of each assessment element and for formulating the actual research questions. What are the identified and possible ethical implications when using this technology?
What should be researched? This discussion forms a substantial part of the ethical analysis in core HTA, but also guides the work in other domains.

In this phase your research team(s) should go through all the domains you are interested in and consider each assessment element in those domains one by one. You should define each assessment element as relevant or irrelevant.

The issues defined as relevant will be studied in the assessment. Elements can also be tagged as "consider later" to allow flexibility in the working process.

The relevance is based on considering whether the issue presented within the element is relevant in the context of the particular technology that is being assessed. One should be practical: not to try to find "artificial" relevance, but not to reject issues too easily as irrelevant either.

When producing a core HTA, defining the relevance of core elements in all domains is an obligatory process. A brief justification should always be provided for those core elements that are regarded as irrelevant. The final core HTA will include this information, as it may be useful for its users.

This step as a whole results in a list of research questions. The issues of assessment elements are generic in nature, as they are intended to be useful in various settings and for various technologies. The relevant issues must here be translated into one or more research questions. Often an issue can well be replaced with a single research question, but sometimes you may want to split it into two or more questions. One should formulate research questions according to the research tradition of each domain. Notice that not all issues require thorough scientific research to be conducted, e.g. a systematic literature review. Some issues may be answered e.g. through finding the information in a suitable register (e.g. whether a technology is approved for use). You may save and re-edit the relevance of assessment elements and research questions within a domain as many times as you want.

**Relations between issues and possible overlaps**

In this phase the coordinator of the project and investigators in the domain teams should consider the relations between the issues and possible overlap across various domains. Although the research questions may look very similar at first glance, they still might have different angle to the assessment and therefore require different information sources and approach (e.g. legal requirements versus ethical considerations related to patients’ rights to receive balanced information). Still, there may be common sources of information and assessment methodologies that the domain teams would benefit sharing. Sometimes it may be necessary for certain domain to wait for the information from another domain before starting their own work in finding answers. In order to avoid double work, the teams should map the relations, both content and time related, and discuss how to sequence or share some parts of the assessment. There are certain observations already identified in earlier projects:

- The Health problem and current use domain should start early together with the Description and technical characteristics as well as the Organisational aspects domains. They provide information essential to all other domains.
- Next start effectiveness and safety domains. They most probably share information and require each others’ information.
• Costs domain start their work when the results from effectiveness and organisational domain are available.
• Social domain requires information at least from safety and ethical domains.
• Legal domain requires information from the two first domains and organizational and ethical domain.
• Ethical domain requires information from all domains and its work should last throughout the project.

These observations are still somewhat incomplete and will be refined when more experience on core HTA projects is gathered.

The version 2.0 of the HTA Core Model contains information on the relations of elements. These are divided into content relations and sequential relations. Content relations indicate assessment element that deal with similar (but not the same) themes. Sequential relations indicate such relations between elements that are relevant for obtaining information from another assessment element, or for providing information for another element. These help producers to identify elements that should be studied and at least partially answered before the current element and also elements that require information from the current element.

**Domain framing**

All domains should consider the commonly defined project scope. The common scope is usually specific and thus quite narrow. Therefore, at least in some domains there may be a need to look at the technology from a broader frame. Otherwise the issue would be graded as irrelevant for assessment. For example, in a core HTA comparing drug eluting and bare metal stents in coronary artery disease, a researcher in Social domain assessing patient experiences might want to explore "stents in general" or "compared to bypass operation". On the other hand, it may be necessary, especially in rapid assessments, to strictly stay within the project scope, and exclude issues that are not relevant for the scope. Notice also that there are several questions where no comparison is required (e.g. what are the known risk factors of the condition?).

The basic rules are:

1. Omitting completely the predefined project scope (certain Technology, Indication and Comparison), i.e. excluding these from the analysis, is not allowed
2. Extending the frame around the often quite narrow definitions in the project scope is allowed. You may select a broader group e.g. for the technology (CT instead of multi-slice CT), or target population (all coronary artery disease patients instead of severe cases only).

**Viewing and locking protocol**

You can view the protocol at any time during the design process. The protocol may be missing some of the unfinished content or content that you have no rights to view, until the design process is fully completed and the protocol has been locked.

The complete project protocol contains the following:

• A list of research questions that the project should seek answers to
• Domain-specific methodological guidance
• Issue-specific guidance for information sources
• A list of assessment elements that were regarded as irrelevant in the context of the technology under assessment and brief notes on such choices.

Based on the project protocol the research group should define a more detailed research plan that includes all the typical parts of such a plan. Methodological guidance within the project protocol you just designed should be useful in this process, and may be used as the foundation of a research plan. As the HTA Core Model does not aim at standardizing HTA agencies' research protocols, the more detailed phase must be done elsewhere. In the future, however, the HTA Core Model Online may contain a more detailed research protocol template to be used in such a context, but on a voluntary basis.

Locking the protocol indicates that the project moves to the next phase, i.e. finding answers to the questions defined by the protocol. A locked protocol may not be altered unless it is unlocked first. Only the project leader may unlock the protocol.

**Phase 3: Research**

In this phase the questions defined by the project protocol are answered through research that is appropriate for each domain. The project coordinator has a major role in this phase, and the project requires a predefined project plan including timeline and relevant check points or each domain separately.

The HTA Core Model Online contains some templates and further technical instructions for conducting the research and collecting the results, as well as handling references to other studies. It is highly recommended that you use the available MS Word templates, as they contain the basic structure needed in Phase 4 to enter results.

**Phase 4: Results**

In this phase the results of the assessment are organised into a coherent collection. If you are using the HTA Core Model Online, the collection is included in the electronic database. This happens both for those who are allowed to publish the final result within the system (EUnetHTA member agencies) and those who must publish it elsewhere (other organisations). Each protocol in the database is associated in this phase with a collection of HTA information. Each collection contains a set of "result cards", each of which contains one research question (or a few questions if you earlier split an assessment element into more than one question) and collection-level texts that put the result cards into context.

Currently the following format is used for all collection types (the type of your collection was defined in Phase 1):

- Collection Summary
- Collection Introduction
- Collection Methodology
- Collection Scope
- Domain-specific sections (one for each domain included in the collection)
  - Introduction of domain
  - Domain methodology, including assessment element table of the domain
  - Assessment elements within domain (each element contains the following sections)
    - Method (optional)
- Results (answer to the research question)
- Comment (optional)
  - Discussion of findings within a domain
  - References of a domain
  - Appendices of a domain
- Collection Appendices (apply to the whole collection or more than one domains)

Another kind of reporting structure is currently being designed for rapid assessments and will be available after further testing and agreement with EUnetHTA WP5.

The result cards should contain all relevant information in a rather concise format. No definite character limitation have been placed at the moment, but it is recommended to keep the answer to each question within 1-2 pages of text. In the future character limits will most likely be introduced. Any further information (e.g. very long texts, evidence tables, results of surveys conducted during the project) should be included as appendices.

**Phase 5: Review and publishing**

This phase includes a review and publication process, after which your collection is available for use by others. Publication within the HTA Core Model Online is currently restricted to EUnetHTA member agencies. Others must download their collection and publish it elsewhere.

If you publish the collection within the HTA Core Model Online, a specific process is being developed within Joint Action 2. If you publish elsewhere, consult the relevant (local) possibilities for making your work public. Notice that the non-commercial license requires that your work is made public either on the Internet or in paper format.

**Policies**

A set of policies has been crafted for using the HTA Core Model. Only a few most relevant for information producers are highlighted here. If you produce core HTA information to be included in the HTA Core Model Online, please consult the Policy for HTA Core Model and core HTA information for further important details. The document is available at www.corehta.info (see page footer).

**Authorship of collections**

General international standards are used when defining authorship of Core HTAs and the assessment elements within them, particularly the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication* available at http://www.icmje.org/.

**Consensus on the content**

The research team working on each domain should reach a consensus on the contents of their section of the final core HTA. Within the unpublished draft phase one can also include tentative content and mark it with a question mark or other means.

**Content from other sources**
Authors of any content of a core HTA or any other collection intended for publication within the HTA Core Model Online should ensure that appropriate permissions have been acquired for any images, graphs or tables that are originally made or published by someone else. Authors of core HTA information are responsible for acquiring and preserving necessary permissions in writing.

Section 3: Methodological guidance

Methodological guidance exists in the HTA Core Model in several places. Most guidance provides advice on how to answer the research questions within different domains. It is typically available in the "domain methodology" chapter of each domain. Further, more detailed guidance may exist for different assessment elements in their respective element cards. Some guidance for the ethics of HTA is included in the introductory chapter of the HTA Core Model and it should be considered within all projects utilising the Model.

Earlier this Handbook contained links to the actual guidance within the Model. The links have been removed from this version of the Handbook since in some cases it was difficult for users to identify the actual source of guidance. Please consult individual model applications for the actual guidance, available at www.corehta.info (select Browse-Model).

Section 4: Searching and viewing HTA information and collections

Currently the HTA Core Model Online contains only few pilot collections, i.e. the two core HTAs produced within Work Package 4 of EUnetHTA Joint Action and Joint Action 2. You can access these collections from the left side menu. Further instructions will be included in this Handbook later.