EUnetHTA JA2
WP8 DELIVERABLE

HTA Core Model
User Guide

Version 1.1

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HTA Core Model User Guide

Version 1.1

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to support shared production and sharing of HTA information

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Contents

Version history

Version and Date	Main changes
1.1 26 Jan 2016	Content regarding terms of use / licence updated on page 5. Minor technical editing and update of some links. Appendices 1, 2 and 5 updated.
1.0 4 Dec 2015	First (original) version

Introduction

This User Guide provides you with all key information needed to utilize the HTA Core Model ® (later also 'the Model') in HTA projects.

The Model consists of the following three components, each with a specific purpose:

1. A standardized set of *HTA questions (the HTA ontology)* allows you to define your research questions based on a standard structure
2. *Methodological guidance* that supports you in answering your research questions
3. A *common reporting structure* for presenting your findings in a standardized format

Depending on your needs and preferences you can choose to use either one, two or all three of these components in your HTA project.

You will next be guided in using the Model through 5 steps:
Step 1 assists you in making some basic considerations regarding your project and how to use the Model in it.
Step 2 guides you in designing a project protocol, which in this context refers to selecting and formulating research questions and (possibly) making adjustments to your scope.
Step 3 steers you in using the HTA Core Model while answering your research questions.
Step 4 covers the options for making the final output of your project. This may be in the form of different EUnetHTA joint products, or for example a national or regional HTA report.
Step 5 considers publication of your work within the HTA Core Model Online or elsewhere.

A brief description of key terms and concepts is available in Appendix 1. Training materials are available through the EUnetHTA Intranet[1] for EUnetHTA member agencies.

Although this guide has been written primarily for researchers producing HTA information, most of its content may be applicable in any other health-related research projects as well.

If you plan to use the Model as part of an information system, please contact eunethta@thl.fi for guidance. This guide is not fitted for such purposes.

The HTA Core Model has been developed within EUnetHTA, the *European Network for Health Technology Assessment* (www.eunethta.eu).

The HTA Core Model Online

available at www.htacoremodel.info contains a) an online tool for producing and publishing HTA information according to the HTA Core Model and b) a database of produced information.

Information production features require a user name and password. If you are employed by a EUnetHTA member agency, you are entitled to a *EUnetHTA Id*, which can be used for logging in to any EUnetHTA tool [2]. Other users of the site may register a tool-specific user name.

Using the site is free of charge. The information production features are currently limited to non-commercial users. Publishing one's work within the site is limited to projects owned by EUnetHTA member agencies. Any other non-commercial users may use the tool for producing information, but should publish their results elsewhere.

Utilizing the HTA Core Model Online is not obligatory for using the HTA Core Model. The Model can be used in any other setting, following the instructions of this User Guide and the attached or linked documentation, in particular the *Terms of Use*.

Some advice in this Guide, separated with orange background (like this text), is specific for using the Model through the HTA Core Model Online.

[1] Go to www.eunethta.eu and use the search function for finding various training materials. New training materials will be announced also at www.htacoremodel.info.

[2] See https://eunethta.fedimbo.belgium.be/e-mail-notifications-newsletter for instructions on how to obtain a EUnetHTA Id.

Step 1: Plan your project

As in any research project, you first need to decide and make explicit what you want to study. Some very basic characteristics of your project such as selecting a name or topic for it are beyond the remit of the HTA Core Model, but – if you plan to use the Model – you should pay attention to the following general aspects very early on.

Where can I find the Model?

The Model is available free of charge at www.htacoremodel.info as web pages and downloadable documents. All documentation can be browsed by selecting Browse – Model from the left side menu.

Licence

The HTA Core Model ® is a registered trade mark and subject to a *Licence*[3] that you must follow when using the Model.

All in all, the terms of the licence should not be too difficult to follow. You may, for example, use the Model free-of-charge and for most purposes you can imagine. There are, however, some specific requirements. Before continuing with your HTA project, please read the licence. Pay particular attention to items discussed in Step 5 of this User Guide. If you cannot adhere to the licence, you are not allowed to use the Model.

Notice also that all use of the HTA Core Model requires registration. It can be done at www.htacoremodel.info .

Should I use the HTA Core Model Online?

The *HTA Core Model Online* provides you with an easy access to the Model, combined with features that allow you to conduct an HTA project from start to finish. Everything you need to use the Model in your project is available in the same place.

Where do you intend to publish your work?
The answer to this question defines whether you should use the HTA Core Model Online or not.

- If you plan to publish the work **within the HTA Core Model Online**, you should start using the tool from the beginning of your project.
- If you plan to publish **elsewhere using the non-commercial license**, you are still encouraged to utilize the tool from the beginning. At the end of your project you can download the results and use your own tools to make the final layout before publication.
- If you prefer **working with your own tools only**, or if you **use the commercial license**, you are welcome to use the offline (PDF or MS Word versions) of the Model and associated documentation (including this User Guide).

Whether or not you plan to use the HTA Core Model Online, please read this User Guide first carefully to get an overview of the whole process of utilizing the Model for information production purposes.

Model applications

The HTA Core Model is divided into several *applications*, each focusing on the assessment of a specific type of health technology (e.g. therapeutic interventions or diagnostics). All current applications can be further arranged into two groups. One group is designed for a comprehensive – or "full" – assessment of health technologies, whereas another group is directed to rapid relative-effectiveness assessment (REA). Consequently, two separate applications may exist for the assessment of a specific technology type (e.g. pharmaceuticals), one for full assessment and another for rapid REA.

Even though all applications draw on the same pool of questions, they may differ a) in the set of questions included depending on the application used for projects and b) in the included methodological guidance. The reporting structure is different for full assessments and rapid assessments.

[3] www.htacoremodel.info/PoliciesAndTerms.aspx

The *HTA Core Model Online* presents for each project only the relevant questions, methodological guidance and reporting structure, depending on which model application is selected in the beginning of the project.

Most contents are similar for the applications within both groups (full assessment vs. rapid REA) and all applications are distributed also as two downloadable documents (one for each group).

Once you know which technology you want to study and in which context, you should choose which model application is most suitable for your project, considering the purpose and inherent limitations of the applications. See Appendix 2 for a list of model applications and their key characteristics.

Notice that in the HTA Core Model documentation the applications are sometimes referred to as "models" (written with lowercase 'm'), e.g. the "screening model" or "diagnostic model". These should be regarded as synonyms for the model applications.

Ethics

The HTA Core Model recommends some ethical issues to be considered when conducting HTA. These are included here as Appendix 3. The aim is to safeguard against unethical use of technologies and to provide information about beneficial use of technologies. Please consider these when defining your project and the more detailed research plan (in Step 2).

Scope

Scoping is a process in which you define several key characteristics for your project, e.g. which technology or technologies you are going to assess and in which context[4]. You also decide what you compare the technology or technologies against, and choose the main outcomes you use in the comparison.

[4] For example the following two scopes 'device X for the diagnostics of disease Y' and 'device X for the screening of disease Z' share the same technology, but differ in the setting (diagnostics vs screening) and disease.

A template for scoping your project is included as Appendix 4. The template derives from the method of defining and registering a project scope within The HTA Core Model Online, designed for being explicit and structured. It is not mandatory to use the template in projects outside the tool (if you e.g. prefer some other way of scoping your work), but it is included here to remind you of several key characteristics of HTA projects that bring clarity for the effort. Leaving the characteristics undefined may complicate the practical work within the project and reduce the scientific validity of the findings.

Metadata

If you use the *HTA Core Model Online*, you must define a set of keywords for your project. The keywords are used by the system for various information search and retrieval purposes. MeSH terms, free keywords, as well as ICD-10 and ATC codes can be used to describe projects and publications.

Step 2: Design project protocol

The HTA Core Model allows you to organize your work – and subsequently the final output – according to a standard hierarchy of generic questions. The protocol design step described here serves primarily this function, i.e. it focuses on *research questions*, as well as on further scoping of the work in an optional process called *domain framing*.

Many details about the format and contents of research protocols are beyond the remit of the HTA Core Model and are dependent on your and your organization's needs and standards. Consequently, please notice that this step does not cover all aspects needed to make an actual *research protocol*. Instead, what is presented here should be viewed only as part of the process leading into your final research protocol.

Selecting questions to be included

After selecting (in Step 1) an appropriate model application for your project, you have a list of potential questions to be answered in your project.

Each model application contains a somewhat different set of questions, tailored for the type of technology.

Detailed lists of questions for each application are currently available only online[5]. The complete question lists for different domains, along with some relevant data on the questions, are included as Appendix 5.

The questions are included in the Model in a generic format, referred to as *issues*, intended to be applicable in very different settings and projects. The issues are organised into *domains*, each of which providing a wider perspective for the assessment. The following domains are included in the HTA Core Model (abbreviations in parentheses):

- Health problem and current use of technology (CUR)
- Description and technical characteristics of technology (TEC)
- Safety (SAF)
- Clinical effectiveness (EFF)
- Costs and economic evaluation (ECO)
- Ethical analysis (ETH)
- Organisational aspects (ORG)
- Patient and Social aspects (SOC)
- Legal aspects (LEG)

Brief descriptions of the domains are included as Appendix 6. Within the domains, the questions are further organized under *topics*, each of which defining a more specific aspect of analysis (e.g. 'Safety (Domain) / Patient Safety' (Topic) or 'Safety / Occupational Safety').

The domain and topic put the issue in a specific context and the combination of a domain, topic and issue defines one *assessment element* (Figure 1). Each of these 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 disease for which the technology is applied.

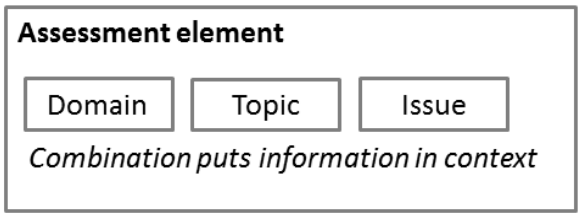

Figure 1. Assessment element

You must next choose which questions (defined by the assessment elements) you want to include in your project. You may choose to utilize all domains or only some of them. Likewise, you can utilize either full domains or parts of them, i.e. to select all questions of one domain or only a set within a domain. The choice regarding the questions – and ultimately the contents of your research – is yours and dependent on your needs and resources. Notice that some specific rules apply for selecting questions within EUnetHTA projects (see respective chapter below).

If you are not sure what a question in the Model is intended to mean or cover, you can look for more details in the *clarification* of the question. The clarification is easily available for users of the HTA Core Model Online. Others should consult the *assessment element tables*[6].

Notice that questions in one application should cover the key questions relevant for that area (e.g. assessment of diagnostic technology). Although not recommended, you can – in principle – also mix questions from different applications, if for some reason the mix is more suitable for your project. In such cases you should let readers of your end product know which applications were used.

Combining questions from different applications is currently not available in the HTA Core Model Online.

Notice also that some questions are related to each other – they may sound similar or answers to them may be dependent on each other. See Step 4 for more information on *sequential relations* and *content relations.*

Due to the large number of generic questions in each model application, model developers have

[5] See www.htacoremodel.info/BrowseModel.aspx.

[6] Available at www.htacoremodel.info/BrowseModel.aspx.

aimed at dividing the questions into two groups, prioritizing the ones assumed to be more significant for utilizing the projects' findings in other settings than the original production country or region. The prioritized group is identified as *core elements* and the other group as *non-core elements*. It should be emphasized that the division of elements into two groups should be viewed as indicative only. Very significant questions for your project may be available among the elements, which the developers have deprioritized, and consequently you are encouraged to browse and consider the whole list of questions.

Formulating research questions

After selecting the questions to be included in your project, you need to translate them into answerable research questions, specific for your project. One generic question in the HTA Core Model may be translated into either one or a few research questions – the choice is up to you[7].

Also *how* you formulate the research questions depends primarily on your project's needs and the style you want to use. You may prefer using shorter "to-the-point" format or longer, more explicit questions.

Independent of what style you use, you should always aim at covering the original idea of the generic question. Before accepting your final list of research questions, it is a good idea to read one more time the clarifications of the original questions (the "issues") in the Model to make sure that your final set of research questions truly matches the Model.

[7] If you need to use questions from more than one application or translate a generic question into several (4 or more) research questions, it would be useful if you could provide feedback to the Model developers so that your experience can be taken into account when making the subsequent versions of the Model. You can contact developers through eunethta@thl.fi.

Example
The EFF domain contains the following issue: *"What is the effect of the technology on work ability?"*
In a project studying laser surgery for myopia, the project may use e.g. the following research question: *"What is the effect of laser surgery on work ability?"* This short format is easy to read, but assumes that readers remember the scope of the project. Another project might translate the question differently e.g. into *"What is the effect of laser surgery on the work ability of 40 – 50 year old males with myopia?"* This question is much longer, but also more explicit. The Model does not require any specific format to be used.

Order of questions

The HTA Core Model suggests a specific order for questions within each domain – organized under topics.

You can change this order based on your needs and preferences by changing the order of any level of hierarchy. You may for example change the order of topics within a domain, or the order of questions within a single topic. You may even change the order of domains if it better suits your work.

To maintain a logical structure for your end product it is recommended that you present information included in each domain as a coherent entity (e.g. chapter of a report). Likewise it is recommended that you present all questions that belong to the same topic within a single entity (e.g. a subchapter). If you are convinced that presenting information in a different manner is beneficial for the users of your end product, you may also present it differently, but in that case you will not be utilizing the *common reporting structure* (see Step 4).

Changing the order of domains is (for the time being) not available in the HTA Core Model Online because of technical limitations, but you can change the order of topics and questions within a domain when working with the tool.

If you use the system, but do not publish your end product through it, you may change the order of the domains prior to publication using you own tools (see yellow box in Step 4).

Domain framing

When defined according to the aforementioned recommendation, the project scope provides a robust base for the project. Particularly when the analysis is extensive or the number of researchers is large, it is important that everyone involved has their focus set on the same target.

Example
A research project is assessing the screening of disease A, which is a form of cancer. If the person(s) working on the ethics domain know(s) in advance – or finds out through test searches – that they will most likely end up with a very limited or non-existent body of evidence regarding 'screening of disease A', they may set either of the following frames for the ethics domain to allow more feasible analysis: 'screening of cancer' or 'screening in general'. The project scope is included in the new frame of the ETH domain.

In some projects it may be useful to consider a somewhat different breadth of analysis for one or more of the domains. Defining a separate *frame* for each domain is an optional, pragmatic method for utilizing the HTA Core Model. It should not, however, be viewed as part of the Model itself.

If answering the research questions of a specific domain precisely according to the project scope is likely to be unfeasible, you may choose to widen the angle of view to enable a more feasible analysis. The wider view may apply to the technology, its utilization or the target condition or population. In your final documentation you should be transparent about the frame used in different domains' analyses and discuss the possible impact of the modified scope on the findings. If you make modifications to the project scope through domain framing, you should always ensure that the original scope is included within the new frame of analysis.

Final research protocol

Once you have a) selected relevant questions, b) translated them into your own research questions, and c) potentially defined domain-specific frames, you should use these data to make an actual research protocol that is in accordance with your organization's policies and practices, as well as with your own needs. Several details regarding the content and format of a research protocol are beyond the remit of the HTA Core Model and hence not discussed here.

EUnetHTA projects

Some standard project types have been defined for work within EUnetHTA. A *core HTA* is an extensive analysis of a health technology (also referred to as "full HTA"). When working on such a project, researchers must go through all core elements in all 9 domains of the HTA Core Model and consider whether each of these is relevant in the context of the technology their project is assessing. Relevant questions are included in the project and translated into research questions.

A *rapid HTA* is a faster, more limited analysis of a health technology. In rapid HTAs only 4 domains are included in full, addressing 1) the technical characteristics of technology, 2) the health problem and current use of technology, 3) safety and 4) clinical effectiveness. Researchers in such projects must go through all questions marked "mandatory" and consider whether these are relevant in the context of the technology they are assessing. As with core HTAs, the relevant questions are included in the project and translated into research questions. Aspects from the other five domains can be included in rapid HTAs by using a so-called checklist (see documentation on the rapid REA model for further details).

When considering relevance, one should be practical, i.e. not to try to find "artificial" relevance, but not to reject questions too easily either.

If you are producing a core HTA, you should involve the researchers of the *Ethical analysis* domain actively in the discussion about selecting and formulating 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 a core HTA, but also guides the work in other domains.

Further instructions elsewhere

All projects utilizing the HTA Core Model may get more detailed advice on running their projects from the document *Methodological Standards and Procedures (MSP)* available within the HTA Core

Model Handbook.[8]. It provides guidance primarily on producing a core HTA, but the same advice is likely to be useful in other HTA projects as well.

If you are working on a EUnetHTA project as a project manager/leader, make sure to familiarize yourself with the document *Policy for the HTA Core Model and core HTA Information*[9]. Sections B and C of that document contain relevant guidance for both core HTAs and rapid HTAs.

When using the HTA Core Model Online, you can select and translate the questions within the web interface.

The system allocates each question an identifier that indicates the domain and order of questions within the domain (for example EFF1, EFF2). You can change the order of topics within a domain and questions within the topics.

You can view the project protocol and use it to discuss within your research group the questions, scope, domain framing and how to prepare to answer the questions.

If you are the project owner, remember always to inform the whole project group of any changes made to the protocol so that the work remains coordinated.

Step 3: Answer the questions

Once you have a research protocol that includes the questions selected and defined in Step 2 and all possible other features you want in it, you are ready to start answering the questions through appropriate research.

The HTA Core Model provides methodological guidance on how to answer the questions within each domain. Such guidance exists both for whole domains and individual questions.

Domain-specific guidance is included in each domain as a lengthy text chapter. It provides an overview of research methodologies within a given domain, possibly along with some recommendations or tips regarding which methodologies to use in specific settings. The guidance may also contain links to further, more detailed instructions in other documents, including the EUnetHTA Guidelines[10].

Question-specific guidance provides instructions on how to answer a specific question. Each generic question (assessment element) in the Model may be associated with guidance on that particular question. Notice that also the *clarification* of each question may contain information that assists in formulating the answer to the question.

Due to the extensive amount of guidance available in the Model, it is not included as appendices in this User Guide. Instead, you can find it in the project protocol when using the HTA Core Model Online.

When working without the tool, you can find the guidance at www.htacoremodel.info/BrowseModel.aspx. The page contains all relevant documentation of the various model applications. Identify the application you are using and open or download the respective documents. Domain-specific guidance is available either in the individual applications (link format "View [html]") or in the PDF document "All contents of version x.y". Notice that the latter is an extensive technical document including all contents of the HTA Core Model. Question-specific guidance is available in "Assessment elements [pdf]" of each application (see field *Methodology*). Do not forget to view the *clarification* of questions too (included in the same table).

Relations between questions

The generic questions are included in the Model not only as simple lists. Instead, the *HTA Ontology* (one of the three main components of the Model) identifies several *relations* between the questions to assist practical research work. Two types of relations have been recorded:

- *Sequential relations* indicate associations between two questions relevant for the working sequence. If having the answer to question A makes it easier to answer question B, a sequential relation exists

[8] See www.htacoremodel.info/ViewHandbook.aspx .

[9] See www.htacoremodel.info/BrowseModel.aspx.

[10] See www.eunethta.eu/eunethta-guidelines.

between A and B. This relation is recorded in the Model in data associated with question B. Users of the HTA Core Model Online can find it in the project protocol and others should consult the *assessment element tables*[11], column "Sequential relations". Using this data when preparing to answer question B, you can always see which question(s) should be answered before that one.

- *Content relations* indicate associations between questions that deal with partially similar themes. Two questions identified with a content relation could for example look at similar characteristics of a technology, but will do so from a different perspective (e.g. from the perspective of clinical research vs. ethics/philosophy), therefore the approach to answering the research question is different and the questions are specified in the Model as separate assessment elements.

Before embarking on finding answers to your research questions, please study carefully both the sequential and content relations identified for the questions you have included in your project. If you find sequential relations, plan your research so that you can utilize the identified sequences. If you find content relations, consider if the questions (or parts of them) can be answered through a joint process, e.g. shared literature search.

In this process you may also notice that one of the questions (D), which you *have included* in your project identifies a sequential relation to a question (C), which you *have not included* in your project. In such situation you are by no means obliged to include question C in your protocol, but you should carefully consider its inclusion, as – after all – you may need to find an answer to that question anyhow before you can properly answer question D. On the other hand you may also need only a small part of question C's contents for answering question D and hence it might be more feasible to leave it out. Again, the choice is yours.

Further useful advice on how to organize the work within your project is available in the *Methodological Standards and Procedures,* available through the HTA Core Model Handbook.

Shared questions

Most generic questions within the HTA Core Model have been placed in one domain only. There are, however, some questions that cannot easily be attributed to a single domain. Such situations are dealt in the Model with a flexible inclusion of the same question in two domains, under the same or different topics[12]. Such questions are in the Model referred to as *shared questions* (or shared elements) and they have the same identification code (Element Id, see Appendix 5).

If your project contains shared questions, make sure that the persons working on the two domains containing the question are aware of the inclusion in both domains. If you have two separate working groups working on the domains, the groups should collaborate in finding and answer to the question. This is to prevent redundant work and to ensure that both domains' views are incorporated in the answer.

When publishing your results outside the HTA Core Model Online, you may choose how to include in your end product answers to shared questions. Some may prefer to include the shared question and answer under both domains (e.g. chapters of report) while others may prefer including it only under one domain. In the latter case it is probably user-friendly to indicate under both domains that the answer to the shared element has been placed under one domain only. Readers of the end product may have a different perception of the "best" positioning of the answer.

In the HTA Core Model Online shared questions are visible in the project protocol under both relevant domains and the question identifier contains both domains and order within them (if the question is e.g. the second in CUR domain and fifth in ORG domain, the identified would be CUR2/ORG5).

[11] Available at www.htacoremodel.info/BrowseModel.aspx.

[12] Theoretically the same question could belong to more than two domains, but for the time being the developers have not found such questions.

Citations and reference lists

The HTA Core Model does not require any specific citation or reference list style to be used in the final output of projects. Your choice of using one depends on where you intend to publish your work and the requirements of that medium.

The HTA Core Model Online assists you in displaying citations in correct parts of the end product. This requires that you follow specific citing instructions available in the system. In short, you should compile domain-specific citation lists, use the Uniform Style (also known e.g. as "Vancouver System") and indicate in-text citations with curvy brackets. A citation would look like this: *The recent study by Smith et al. {12} is clearly stated to be retrospective.* Each domain of the final work should have its own reference list. An additional reference list is used for all material outside domains (e.g. introduction to the whole work). See Appendix 7 for further details.

Result cards

The *common reporting structure* of the HTA Core Model organizes information into question-answer pairs that provide the final output with high level of structure and make it easy for readers to find specific information. These pairs can be stored and displayed as *result cards*, each containing the answer to one research question in your project. If you have divided a generic question of the Model into more than one research questions, all these questions and answers are included in a single result card.

The result cards should allow readers of your end product to easily find and comprehend the answers you have provided to your research questions. Consequently, the answers in the cards should be relatively concise, and definitely fit within 1 or 2 pages per card. More extensive materials, such as long texts and large evidence tables, can be included as appendices.

Organising information in this manner was designed with electronic information repositories (such as the HTA Core Model Online) in mind, but it can be used also in paper-based end products. Whether or not to use result cards in your end product depends on whether you want to use the common reporting structure, and if you do, what type of assessment you are conducting (core HTA vs. rapid REA) and where you intend to publish your work.

Selecting publication method

At this point (the latest) you need to decide where you intend to publish the results of your work. Depending on your choice you may or may not choose to utilise the third component of the HTA Core Model, the *common reporting structure*. You have here the following three options:

1. Publish the project **within the HTA Core Model Online**.
   → The common reporting structure is always used. Option available to projects owned by EUnetHTA member agencies only.

2. Publish the project **anywhere else** (e.g. report series, standalone publication or journal article) **using the common reporting structure**.
   → Make sure that the publisher accepts the structure to be used.

3. Publish the project **anywhere else** (e.g. report series, standalone publication or journal article) using the guidance from the publication series.
   → **Common reporting structure not used or used only partially.**

If you decide to go for options 1 or 2, move on to Step 4.

If you go for option 3, you should now proceed to answering the questions defined in Step 2 and writing your end product following the instructions of your selected publication platform (e.g. report series or scientific journal). In this case you can skip Step 4 and go directly to Step 5. Please do not omit Step 5 though.

Step 4: Make your end product

The *common reporting structure* of the HTA Core Model organizes the information within HTAs according to a standardized structure, with the aim of making the often vast amount of information contained in an HTA easier to browse, search, utilize and – also – update.

The structure is based on presenting the key contents as question-answer pairs organized by the domains and topics. These pairs are accompanied by specific text chapters (e.g. introduction, summary) that bind the question-answer pairs into a coherent information package.

The common information structure allows different kinds of end results. Two definitions for the common reporting structure are currently available:

- Basic structure utilized in *EUnetHTA Core HTAs* (i.e. extensive assessments of health technologies). Presents question-answer pairs as *Result Cards*. Can be used for any other projects as well.
- Rapid assessment structure for *EUnetHTA rapid assessments*. Does not necessarily utilize Result Cards but instead aims at a more report-like format.

The basic definition is available as Appendix 8. For rapid assessment definition, please consult the documentation on rapid REA. The basic structure is useful when high level of organization is desired for the end product, e.g. when the results are further utilized in other documents or subsequent processes. Anything between 1 and 9 domains can be included. The rapid assessment structure is useful particularly when the end product should be in the form of a more traditional (paper) report and needs for reutilization of information are not as high. The structure utilizes only the following domains in full: CUR, TEC, SAF, and EFF. Possible questions from the other 5 domains are included under a separate heading.

Select which definition you prefer to use and follow further instructions in the Appendix 8.

If you plan to publish your work anywhere else than the HTA Core Model Online, you can still utilize the common reporting structure within your publication. Using the structure does not prevent you from incorporating other types of content in your publication. You may e.g. use your own front and back covers, and additional pages either before or after contents organized according to the reporting structure. Notice that even in such situations you may find certain features of the HTA Core Model Online useful when making your end product, e.g. a scientific report (see below).

If you plan to publish your work within the HTA Core Model Online, you should (preferably) use the tool from the beginning of your project, following principles outlined in earlier steps of this User Guide. Using the tool from the beginning of your project prevents you from redundant work and allows easy access to the Model and relevant further guidance in the tool.

All projects within the HTA Core Model Online can be converted into *collections* of HTA information that utilize the common reporting structure. These can be downloaded and edited further using any editing tools and published either within the system or anywhere else.

Although publishing within the system is limited to projects of EUnetHTA member agencies, any project using the non-commercial license can utilize the information production features of the HTA Core Model Online.

After setting up a project protocol, you can download a Microsoft Word template that contains all questions defined in Step 2 and – depending on your choice – follows either the basic structure or the rapid assessment structure as defined in Step 4. You can use this template to write answers to all your research questions and to include all other content.

Like any text document, the aforementioned file can be circulated and worked on by the whole project group. Once the contents are final or close to final, you can upload the file to the HTA Core Model Online. The system puts each part of the content automatically into its correct place and creates a collection of information. After the upload, you can further edit the content using the online interface.

Alternatively, you may choose not to use the MS Word Template at all, and instead create all your content online. The tool contains a web interface for writing text and including tables, images and attachments to your product.

You may download and upload content using the MS Word template as many times as you want and freely use the online editing features. Just be careful in managing the versions and coordinating your work so that everyone involved is working on the correct document using correct editing method.

Be careful when uploading the document, as new content will replace old content in the system. Empty fields in the MS Word template will erase any existing content in the system. **Read carefully the instructions in the tool regarding this process.**

If you plan to not publish the work within the HTA Core Model Online, you may omit the uploading of materials completely. Instead, you can simply use the downloaded MS Word template to make your product and finalize it using your own tools.

Step 5: Publish your work

Irrespective of where and how you publish your work, you should take some aspects into consideration prior to publishing it.

The *Terms of Use* (see Step 1) require certain things from you if you have used the HTA Core Model. The requirements differ in the commercial and non-commercial license. Some key requirements relevant for publishing your end product are listed here:

Using the non-commercial license

- You must make your work publicly available
- You must not collect fees from those who produce information or from the end users of the produced information
- Registering your product is not obligatory, but it is recommended

Using the commercial license

- All use of the Model must be registered
- The terms 'EUnetHTA', 'THL' or 'HTA Core Model' must not be used for any kind of marketing purposes
- Some limitations apply regarding advertisements and claims related to using the Model in the final product

Common for both licenses

- You must disclose your use of the Model in a specific manner
- You are encouraged to provide feedback to model developers

Notice that for using the Model, you must use either of the two licenses. Before publishing your end product, please read the license you are using one more time carefully to be able to follow the requirements relevant for the license you are using. The aforementioned bullet points list only some key requirements in abbreviated format to provide examples in this User Guide. The full requirements are available in the Terms of Use document.

Finally, if you have used any third-party materials in your work, ensure that you have all necessary permissions from the respective parties.

Once you are certain to fulfil the requirements, you are free to publish your work anywhere and in any format that best meets your needs.

Currently users of the online tool can publish only drafts by themselves and the administrators are needed for final publication. When you are ready with your final product, you can make it public by contacting eunethta@thl.fi and requesting publication. See the HTA Core Model Online User Guide[13] for more information. Your product will be published typically within a few days or a week after your request has been sent.

[13] Available at www.htacoremodel.info/ViewHandbook.aspx.

APPENDICES

Appendix 1: Terms and concepts

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. Separate applications may exist for different types of assessments (e.g. full vs. rapid assessment).

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/projects, and hence their relevance is considered separately for each assessment. Elements are defined through a combination of domain, topic and issue.

Collection: Core HTA information published in a standardized format. Each collection contains a) a set of question-answer pairs (e.g. as 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 questions and answers (or result cards) into a coherent information package, and c) optional appendices that enable inclusion of additional information to the results without crowding the result cards' content. Appendices may also be relevant to one or more domains (these are respectively called domain-level and collection-level appendices).

Core HTA information: Any information on a technology that has been produced following the ontology and the common reporting structure of the HTA Core Model. This information has high potential for being shareable and transferable knowledge.

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. Some elements may be defined as irrelevant, but such exclusions 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.

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. See also Topic and Issue.

Element card: Each assessment element is connected in the Model 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).

HTA Core Model: A methodological framework for joint 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.

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. See also Domain and Topic.

Result card: After a question deriving from an assessment element has been answered through appropriate research, the answer can be recorded in a result card. The information should be in a concise form, fitting into 1 or 2 pages. 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 created through answering the issues defined in the assessment elements of 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. See also Domain and Issue.

The content of this appendix is an excerpt from the HTA Core Model Handbook, available at www.htacoremodel.info/ViewHandbook.aspx.

Appendix 2: HTA Core Model Applications

Application	Purpose of use	Purpose
Diagnostic technologies	Full assessment	Assessment of any technology or procedure used to confirm, exclude or classify disease, or to monitor progress of the disease or the response to therapy. Does not include all generic questions or other content relevant for prognostic tests.
Medical and surgical interventions	Full assessment	Assessment of all therapeutic acts or methods of interfering with the aetiology, symptoms, or progress of a health condition.
Pharmaceuticals	Full assessment	Assessment of pharmaceutical products.
Screening technologies	Full assessment	Assessment of full population screening programmes. Not suitable for a) assessing the accuracy of a single test to determine exposure/risk factor or disease, or b) the effectiveness of opportunistic screening practices.
Rapid relative effectiveness assessments (REA)	Rapid REA	Rapid relative-effectiveness assessment of pharmaceutical products, diagnostic technologies, medical and surgical interventions, and screening. Notice: while the model application does not separate between different types of technology, separate sets of assessment elements have been marked as “mandatory” in a separate procedure manual.

Appendix 3: Ethics of HTA

Ethical aspects of health technologies should be considered in HTAs and thus they are included in the HTA Core Model. Ethics, however, also has a broader application within the field of HTA. The assessments themselves should be designed in such a way that key ethical principles are considered and respected.

In order to safeguard against unethical use of technologies and to provide information about how they can instead be used in a beneficial way, every HTA process should be performed with consideration paid to the following ethical issues:

- The driving forces (and valued interests) behind the plan to perform the assessment at this particular stage should be identified, including the stakeholders and the whole HTA organisation.
- The morally relevant reasons for performing/not performing an HTA on the topic should be identified.
- The interests of the technology producers should be identified.
- Possible related technologies that are morally contentious should be identified.
- The interests of the content expert group should be discussed openly in order for the work to be conducted in an objective and independent way.
- The choice of endpoints in the assessment has to be carefully considered.
- The morally relevant issues related to the selection of meta-analyses and studies the HTA means to include must be identified.
- The scope of the HTA and the choice of research methods (e.g. inclusion of other assessment aspects than effectiveness in the literature searches).

These issues are discussed in further detail in the Appendix Intro-Eth.

The content of this page is an excerpt from the HTA Core Model 3.0, chapter *Introduction*. See Model documentation at www.htacoremodel.info/BrowseModel.aspx (all contents of version 3.0) for the appendix.

Appendix 4: Scoping template

Sufficiently detailed and well communicated scope is particularly essential in large collaborative HTA projects. It should guide all participants 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 (see instructions on 'Domain framing' in the User Guide.

In the HTA Core Model Online, the scope contains the following elements:

- Technology and its intended use
- Target condition (disease or health condition)
- Target population (often a subgroup of those who have or may have the target condition)
- Comparison
- Main outcomes for each domain

Scoping element	**Description**
Technology and its intended use	The authors should describe the technology in a detailed enough manner 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 should be described, e.g. whether it is about treatment (first line/second line) or prevention, diagnosing or screening, or monitoring or determining prognosis of the target condition.
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 in a detailed enough manner 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 included in the project. 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.

The scoping template presented here is closely related to the PICO system (Patients, Intervention, Comparison, Outcomes) used in clinical research. It is, however, more explicit regarding some choices. This is to ensure that potentially very large research groups, containing experts from both clinical and non-clinical scientific

disciplines, would be able to focus their effort on the same scope as well as possible. For those more familiar with the PICO, the following table indicates the relations of these two systems:

PICO	**HTA Core Model Online**
Patients	Target condition AND Target population
Intervention	Technology and its intended use
Comparison	Comparison
Outcomes	Main outcomes for each domain AND outcomes defined later for individual assessment elements (if relevant)

Appendix 5: HTA Questions (Assessment elements)

The generic questions included in various domains are listed in the following tables, organised by topics. The *assessment element ID* is a unique identifier for each element, but no other meanings are attached to it, i.e. it does not indicate the domain or the order of elements within a domain. The order in which the elements are presented below represents the model developers' view on a logical order within domains. Researchers may, however, use the elements in any order that best meets the project's needs. Shared elements are displayed in all domains they belong to. Notice that not all elements are included in all model applications. Please consult the application-specific assessment element tables, available at www.htacoremodel.info/BrowseModel.aspx for more specific lists of elements within particular applications and for further information on the elements (e.g. their clarifications and question-specific methodological guidance). The aforementioned information is easily available for users of the HTA Core Model after selecting a model application for their project.

The assessment elements listed in this appendix are from the HTA Core Model 3.0 for the production of core HTAs (i.e. full assessments). For assessment elements within the rapid REA application, please see the relevant application and its separate procedure manual.

Health Problem and Current Use of the Technology (CUR)

Topic	Issue	Assessment element ID
Target Population	What is the target population in this assessment?	A0007
Target Population	How many people belong to the target population?	A0023
Target Condition	What is the disease or health condition in the scope of this assessment?	A0002
Target Condition	What are the known risk factors for the disease or health condition?	A0003
Target Condition	What is the natural course of the disease or health condition?	A0004
Target Condition	What are the symptoms and the burden of disease or health condition for the patient?	A0005
Target Condition	What are the consequences of the disease or health condition for the society?	A0006
Target Condition	What aspects of the consequences/burden of disease are targeted by the technology?	A0009
Current Management of the Condition	What are the other typical or common alternatives to the current technology?	A0018
Current Management of the Condition	How is the disease or health condition currently diagnosed according to published guidelines and in practice?	A0024
Current Management of the Condition	How is the disease or health condition currently managed according to published guidelines and in practice?	A0025

Topic	Issue	Assessment element ID
Utilisation	For which health conditions and populations, and for what purposes is the technology used?	A0001
Utilisation	How much are the technologies utilised?	A0011
Utilisation	What kind of variations in use are there across countries/regions/settings?	A0012
Utilisation	Who decides which people are eligible for the technology and on what basis?	G0009
Utilisation	Is the technology a new, innovative mode of care, an add-on to, or modification of a standard mode of care, or a replacement of a standard mode of care?	F0001
Regulatory Status	For which indications has the technology received marketing authorisation or CE marking?	A0020
Regulatory Status	What is the reimbursement status of the technology?	A0021

Description and technical characteristics of technology (TEC)

Topic	Issue	Assessment element ID
Features of the technology	What is this technology and the comparator(s)?	B0001
Features of the technology	What is the claimed benefit of the technology in relation to the comparator(s)?	B0002
Features of the technology	What is the phase of development and implementation of the technology and the comparator(s)?	B0003
Features of the technology	Who administers the technology and the comparator(s) and in what context and level of care are they provided?	B0004
Features of the technology	Are reference values or cut-off points clearly established?	B0018
Regulatory Status	For which indications has the technology received marketing authorisation or CE marking?	A0020
Regulatory Status	What is the reimbursement status of the technology?	A0021
Investments and tools required to use the technology	What material investments are needed to use the technology?	B0007
Investments and tools required to use the technology	What kind of special premises are needed to use the technology and the comparator(s)?	B0008
Investments and tools required to use the technology	What equipment and supplies are needed to use the technology and the comparator(s)?	B0009
Investments and tools required to use the technology	What kind of data/records and/or registry is needed to monitor the use of the technology and the comparator(s)?	B0010
Training and information needed to use the technology	What kinds of requirements in terms of qualification and quality assurance processes are needed for the use or maintenance of the technology?	B0012
Training and information needed to use the technology	What kinds of skills and training characteristics and information are needed for the personnel/caregivers using this technology?	B0013
Training and information needed to use the technology	What kind of training resources and information should be provided to the patient who uses the technology, or for his family?	B0014
Training and information needed to use the technology	What information about the technology should be provided to patients outside the target group and to the general public?	B0015
Other	Who manufactures the technology?	A0022

Safety (SAF)

Topic	Issue	Assessment element ID
Patient safety	How safe is the technology in relation to the comparator(s)?	C0008
Patient safety	Are the harms related to dosage or frequency of applying the technology?	C0002
Patient safety	How does the frequency or severity of harms change over time or in different settings?	C0004
Patient safety	What are the susceptible patient groups that are more likely to be harmed through the use of the technology?	C0005
Patient safety	What are the consequences of false positive, false negative and incidental findings generated by using the technology from the viewpoint of patient safety?	C0006
Patient safety	Are the technology and comparator(s) associated with user-dependent harms?	C0007
Occupational safety	What kind of occupational harms can occur when using the technology?	C0020
Environmental safety	What kind of risks for the public and the environment may occur when using the technology?	C0040
Safety risk management	How can one reduce safety risks for patients (including technology-, user-, and patient-dependent aspects)?	C0062
Safety risk management	How can one reduce safety risks for professionals (including technology-, user-, and patient-dependent aspects)?	C0063
Safety risk management	How can one reduce safety risks for the environment (including technology-, user-, and patient-dependent aspects)	C0064
Safety risk management	What kind of data/records and/or registry is needed to monitor the use of the technology and the comparator(s)?	B0010

Clinical Effectiveness (EFF)

Topic	Issue	Assessment element ID
Mortality	What is the expected beneficial effect of the technology on mortality?	D0001
Morbidity	How does the technology modify the effectiveness of subsequent interventions?	D0026
Morbidity	How does the technology affect symptoms and findings (severity, frequency) of the disease or health condition?	D0005
Morbidity	How does the technology modify the magnitude and frequency of morbidity?	D0032
Morbidity	How does the technology affect progression (or recurrence) of the disease or health condition?	D0006
Function	What is the effect of the technology on patients' body functions?	D0011
Function	What is the effect of the technology on work ability?	D0014
Function	What is the effect of the technology on return to previous living conditions?	D0015
Function	How does the use of the technology affect activities of daily living?	D0016
Health-related quality of life	What is the effect of the technology on generic health-related quality of life?	D0012
Health-related quality of life	What is the effect of the technology on disease-specific quality of life?	D0013
Quality of life	Does the knowledge of the test result affect the patient's non-health-related quality of life?	D0030
Patient satisfaction	Were patients satisfied with the technology?	D0017
Test-treatment chain	Is there an effective treatment for the condition the test is detecting?	D0024
Test accuracy	What is the accuracy of the test against reference standard?	D1001
Test accuracy	How does the test compare to other optional tests in terms of accuracy measures?	D1002
Test accuracy	What is the reference standard and how likely is it to classify the target condition correctly?	D1003

Topic	Issue	Assessment element ID
Test accuracy	What are the requirements for accuracy in the context where the technology will be used?	D1004
Test accuracy	What is the optimal threshold value in this context?	D1005
Test accuracy	Does the test reliably rule in or rule out the target condition?	D1006
Test accuracy	How does test accuracy vary in different settings?	D1007
Test accuracy	What is known about the intra- and inter-observer variation in test interpretation?	D1008
Test accuracy	Is there evidence that the replacing test is more specific or safer than the old one?	D1019
Patient safety	What are the consequences of false positive, false negative and incidental findings generated by using the technology from the viewpoint of patient safety?	C0006
Change-in-management	Does use of the test lead to improved detection of the condition?	D0020
Change-in-management	How does use of the test change physicians' management decisions?	D0021
Change-in-management	Does the test detect other potential health conditions that can impact the subsequent management decisions?	D0022
Change-in-management	How does the technology modify the need for hospitalisation?	D0010
Benefit-harm balance	What are the overall benefits and harms of the technology in health outcomes?	D0029

Costs and economic evaluation (ECO)

Topic	Issue	Assessment element ID
Resource utilisation	What types of resources are used when delivering the assessed technology and its comparators (resource-use identification)?	E0001
Resource utilisation	What amounts of resources are used when delivering the assessed technology and its comparators (resource-use measurement)?	E0002
Resource utilisation	What were the measured and/or estimated costs of the assessed technology and its comparator(s) (resource-use valuation)?	E0009
Resource utilisation	How does the technology modify the need for other technologies and use of resources?	D0023
Resource utilisation	What are the likely budget impacts of implementing the technologies being compared?	G0007
Measurement and estimation of outcomes	What is(are) the measured and/or estimated health-related outcome(s) of the assessed technology and its comparator(s) (outcome identification, measurement and valuation)?	E0005
Examination of costs and outcomes	What are the estimated differences in costs and outcomes between the technology and its comparator(s)?	E0006
Characterising uncertainty	What are the uncertainties surrounding the costs and economic evaluation(s) of the technology and its comparator(s)?	E0010
Characterising heterogeneity	To what extent can differences in costs, outcomes, or 'cost-effectiveness' be explained by variations between any subgroups using the technology and its comparator(s)?	E0011
Validity of the model(s)	What methodological assumptions were made in relation to the technology and its comparator(s)?	E0013
Validity of the model(s)	To what extent can the estimates of costs, outcomes, or economic evaluation(s) be considered as providing valid descriptions of the technology and its comparator(s)?	E0012

Ethical analysis (ETH)

Topic	Issue	Assessment element ID
Benefit-harm balance	What are the symptoms and the burden of disease or health condition for the patient?	A0005
Benefit-harm balance	What are the known and estimated benefits and harms for patients when implementing or not implementing the technology?	F0010
Benefit-harm balance	What are the benefits and harms of the technology for relatives, other patients, organisations, commercial entities, society, etc.?	F0011
Benefit-harm balance	Are there any other hidden or unintended consequences of the technology and its applications for patients, relatives, other patients, organisations, commercial entities, society etc.?	F0003
Benefit-harm balance	Are there any ethical obstacles for evidence generation to support the effect of the intervention?	F0104
Autonomy	Is the technology used for individuals that are especially vulnerable?	F0005
Autonomy	Does the implementation or use of the technology affect the patient´s capability and possibility to exercise autonomy?	F0004
Autonomy	Is there a need for any specific interventions or supportive actions concerning information in order to respect patient autonomy when the technology is used?	F0006
Autonomy	Does the implementation or withdrawal of the technology challenge or change professional values, ethics or traditional roles?	F0007
Respect for persons	Does the implementation or use of the technology affect human dignity?	F0008
Respect for persons	Does the implementation or use of the technology affect the patient's moral, religious or cultural integrity?	F0009
Respect for persons	Does the technology invade the sphere of privacy of the patient?	F0101
Justice and Equity	How does implementation or withdrawal of the technology affect the distribution of health care resources?	F0012
Justice and Equity	How are technologies with similar ethical issues treated in the health care system?	F0013
Justice and Equity	Are there factors that could prevent a group or person from gaining access to the technology?	H0012

Topic	Issue	Assessment element ID
Legislation	Does the implementation or use of the technology affect the realisation of basic human rights?	F0014
Legislation	Can the use of the technology pose ethical challenges that have not been considered in the existing legislations and regulations?	F0016
Ethical consequences of the HTA	What are the ethical consequences of the choice of endpoints, cut-off values and comparators/controls in the assessment?	F0017
Ethical consequences of the HTA	Are there any ethical problems related to the data or the assumptions in the economic evaluation?	F0102
Ethical consequences of the HTA	What are the ethical consequences of the technology assessment?	F0103

Organisational aspects (ORG)

Topic	Issue	Assessment element ID
Health delivery process	How does the technology affect the current work processes?	G0001
Health delivery process	What kind of patient/participant flow is associated with the new technology?	G0100
Health delivery process	What kind of involvement has to be mobilised for patients/participants and important others and/or caregivers?	G0002
Health delivery process	What kind of process ensures proper education and training of staff?	G0003
Health delivery process	What kinds of co-operation and communication of activities have to be mobilised?	G0004
Health delivery process	In What way is the quality assurance and monitoring system of the new technology organised?	G0012
Structure of health care system	How do de-centralisation or centralisation requirements influence the implementation of the technology?	G0005
Structure of health care system	What are the processes ensuring access to the new technology for patients/participants?	G0101
Process-related costs	What are the costs of processes related to acquisition and setting up the new technology?	G0006
Process-related costs	How does the technology modify the need for other technologies and use of resources?	D0023
Process-related costs	What are the likely budget impacts of implementing the technologies being compared?	G0007
Management	What management problems and opportunities are attached to the technology?	G0008
Management	Who decides which people are eligible for the technology and on what basis?	G0009
Culture	How is the technology accepted?	G0010
Culture	How are other interest groups taken into consideration during the planning/implementation of the technology?	G0011

Patient and Social Aspects (SOC)

Topic	Issue	Assessment element ID
Patients' perspectives	What are the experiences of living with the condition?	H0200
Patients' perspectives	What outcomes from the current standard of care (usual care) would patients most like to see improved?	H0100
Patients' perspectives	How do patients perceive the technology under assessment?	H0006
Patients' perspectives	What is the burden on care-givers?	H0002
Social group aspects	Are there groups of patients who currently don't have good access to available therapies?	H0201
Social group aspects	Are there factors that could prevent a group from gaining access to the technology?	H0012
Communication aspects	How are treatment choices explained to patients?	H0202
Communication aspects	What specific issues may need to be communicated to patients to improve adherence?	H0203

Legal aspects (LEG)

Topic	Issue	Assessment element ID
Autonomy of the patient	What kind of legal requirements are there for providing appropriate information to the user or patient and how should this be addressed when implementing the technology?	I0002
Autonomy of the patient	Who is allowed to give consent for minors and incompetent persons?	I0034
Privacy of the patient	Is there a possibility that the use of the technology produces additional information that is not directly related to the current care of the patient and may violate their right to respect for privacy?	I0007
Privacy of the patient	What do laws/binding rules require with regard to informing relatives about the results?	I0008
Privacy of the patient	What do laws/binding rules require with regard to appropriate measures for securing patient data and how should this be addressed when implementing the technology?	I0009
Equality in health care	What do laws/binding rules require with regard to appropriate processes or resources which would guarantee equal access to the technology?	I0011
Equality in health care	What are the consequences of various EU-level and national regulations for the equal access to the technology?	I0012
Ethical aspects	Does the implementation or use of the technology affect the realisation of basic human rights?	F0014
Ethical aspects	Can the use of the technology pose ethical challenges that have not been considered in the existing legislations and regulations?	F0016
Authorisation and safety	What authorisations and register listings does the technology have?	I0015
Authorisation and safety	What do laws/binding rules require with regard to the safety of the technology and how should this be addressed when implementing the technology?	I0017
Ownership and liability	What should be known about the intellectual property rights and potential licensing fees?	I0019
Ownership and liability	What should be known about the legal or binding rules regarding the width, depth and length of the manufacturers guarantee?	I0021
Regulation of the	What kind of legal price control mechanisms are there that are	I0023

Topic	Issue	Assessment element ID
market	relevant to the technology?	
Regulation of the market	What kind of regulation exists for the acquisition and use of the technology?	I0024
Regulation of the market	What legal restrictions are there for marketing the technology to the patients?	I0025
Regulation of the market	What should be known about the legal issues in cases of new technologies where the current legislation is not directly applicable?	I0026
Regulation of the market	Are there relevant concerns about conflicts of interest regarding the preparation of binding rules and their implementation?	I0037

Appendix 6: 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.

Health problem and current use of technology (CUR)

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.

Description and technical characteristics of technology (TEC)

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.

Safety (SAF)

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 (EFF)

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 (ECO)

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 (ETH)

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 (ORG)

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.

Patient and social aspects (SOC)

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 molds diverse social arenas and is molded 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. The domain was renamed from '*Social aspects'* to '*Patient and social aspects'* in version the HTA Core Model version 3.0.

Legal aspects (LEG)

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.

The content of this appendix is an excerpt from the HTA Core Model Handbook, available at www.htacoremodel.info/ViewHandbook.aspx.

Appendix 7: Creating in-text citations and reference lists

Note: this appendix applies only when you use the HTA Core Model Online.

Please create In-text citations and reference lists using the Uniform style. For more information, see Uniform Requirements for Manuscripts Submitted to Biomedical Journals:
http://www.nlm.nih.gov/bsd/uniform_requirements.html

We ask you to make the following change to the Uniform style:

- Replace the parentheses ( ) in in-text citations with curly brackets {}

After these changes your in-text citations should look like this:

The recent study by Smith et al. {12} is clearly stated to be retrospective.

You can make the changes by hand in your word processing program (e.g. Word). If you are using a reference management software (e.g. EndNote, RefWorks), you can edit the Uniform output style to automatically make the changes.

The purpose of this style is to make it easy for HTA Core Model Online to technically distinguish in-text citations from normal text and mathematical notations when documents are imported. This is necessary for automatically removing unused sources from the references list when a user views only a small part of the document. The system shows all citations again in standard Uniform style when the document is viewed.

Appendix 8: Common reporting structure

For core HTAs, the information is organised as follows:

Collection Summary
Contains an overview of all findings in the collection. No recommendation on the use or non-use of the technology in health systems must be included in core HTA information collections. Includes a standard table summarising the consequences of using or not using the technology and the comparator(s) used in the assessment (see below).

Collection Methodology
Indicates the process and overall methods used in producing the collection.

Collection Introduction
Provides an overview of the collection, including the reasons why, and the context in which, the collection was produced.

Scope
A structured project scope which provides a well-defined starting point for analysis within different domains. Ensures the coherence of analysis within different domains.

Domain-specific sections
(Each domain contains the following sections)

> **Introduction of domain**
> Indicates the specific features of the technology that are noteworthy from the domain's viewpoint, as well as the reasons for including the domain in the collection.
>
> **Domain methodology**
> Indicates the scientific methodology used within the analysis of this domain.
>
> **Assessment elements of the domain**
> (Each element contains the following sections):
>
> > **Method (optional):** Used when the overall domain methodology differs from the one used in answering questions defined by the assessment element, or when the domain methodology does not provide a detailed enough description.
> >
> > **Result:** Answer(s) to the research question(s) defined by one assessment element, with a focus on evidence or facts whenever feasible. Answers should adhere to each domain's scientific principles and style.
> >
> > **Comment:** (optional) While the result field typically focuses on evidence or facts, this field can be used to add researchers' views on the result and its quality. Similar to the discussion chapter found in journal articles, but with a focus on the question(s) included in the relevant result card.
>
> **Discussion**
> Also similar to the discussion chapter found in journal articles, with a focus on one domain. Interpretation, significance of methodological issues encountered, and indications for further research can be included here.

References
All references used in the result cards and domain texts (introduction, methodology, discussion).

Appendices
All appendices of a domain.

Collection Appendices
All appendices used in the collection-level chapters (summary, methodology, introduction, scope) or within the content of more than one domain.

A summary table representing the consequences of using/not using the technology that is being assessed is available for use in the summary of the collection.

Consequence	Using the technology under assessment	Using the comparator	Level of evidence (if applicable)	Comment

The template for rapid assessments is available through the HTA Core Model Online and the EUnetHTA Joint Action 2 / WP5 documentation.

