



eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Policy
for the HTA Core Model[®]
and core HTA information

Version 1.1

Approved by the EUnetHTA Executive Committee on the 26th of June 2013.

Version history	
Version	Changes
1.0	Original version
1.1	Added “Terms of Use” in the Definitions. Several changes in sections A-C and E.

Contents

Introduction.....	4
Definitions.....	5
HTA Core Model	5
Core HTA information.....	5
Editorial Board.....	6
Commercial and non-commercial use.....	6
Terms of Use.....	7
Project protocol (within the Online Tool and Service).....	7
SECTION A: The HTA Core Model	8
Availability.....	8
Use for information production.....	8
Use as part of information systems	9
Use for other purposes	9
Registration	9
Availability of produced information	9
Versions	10
Disclosure of use.....	10
Development.....	10
SECTION B: Production of core HTA information	11
Assessment Topics.....	11
Access to production and submission of core HTA information.....	11
Composition of project groups.....	12
Language.....	12
Approval of project protocols	13
Conflict of interest statement.....	13
Methodological guidance.....	13
Transparency of information sources.....	13
Updating core HTA information.....	14

SECTION C: Publishing of core HTA information.....	16
Authorship and contributorship	16
Peer-review and approval.....	16
Intellectual property rights	16
Withdrawal of low-quality core HTA information	17
SECTION D: Storage and availability of core HTA information	18
Timeframe of information availability.....	18
SECTION E: Retrieval and utilization of core HTA information	19
Access to published collections	19
Access to project data prior to publication.....	19
Utilisation of core HTA information	20
Summary table of information production, publication and access policies	21
Appendix 1: Policy crafting process in brief	22
Appendix 2: Terms and Concepts.....	25

Introduction

This document defines the EUnetHTA policy to steer the utilisation and further development of the new HTA production and sharing framework, the *HTA Core Model*[®], hereafter also "*the Model*". The Model was designed within the EUnetHTA project 2006-2008 and further developed in the EUnetHTA Joint Action 2010-2012 (JA) and EUnetHTA Joint Action 2 2012-2015 (JA2). The Model is continuously utilised and developed within the EUnetHTA Network.

The policy is divided into five sections (A-E) that consider different aspects of the HTA Core Model and its utilization.

Section A is applicable to *any* use of the HTA Core Model. Sections B-E are applicable to *core HTA information* only, which in this context refers to any HTA information that has been produced and made available through the *Online Tool and Service* likewise developed within EUnetHTA WP4 in JA and WP8 in JA2. Currently the tool and service are known collectively as *HTA Core Model Online*.

Information produced and published outside the Online Tool and Service is subject to section A only.

Brief definitions of the HTA Core Model and core HTA information are included in sections A and B. More details on concepts and terms are available in Appendix 1. The policy crafting process is described in Appendix 2.

A separate document, *HTA Core Model - Terms of Use*, is available to indicate key principles of using the Model. The document contains two licenses, one for non-commercial and another for commercial use. The terms in both licenses are based on this policy document.

It should be emphasized that not all features of the Online Tool and Service referred to this document are yet functional. Some of the features are part of subsequent development work within WP8 of JA2.

Definitions

This chapter defines some key concepts relevant to this policy. Other definitions used primarily in the policy crafting process are available in Appendix 1.

HTA Core Model

The HTA Core Model is a methodological framework for 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. The policy applies to all three components.

Core HTA information

The *Online Tool and Service* was originally developed within the EUnetHTA Joint Action 2010-2012¹ to enable online utilisation of the HTA Core Model and the HTA information produced using the Model. Subsequent development takes place in Joint Action 2 in 2012-2015. *Core HTA information* refers to any information on health technologies that has been produced using the HTA Core Model and made available through the *Online Tool and Service*.

All core HTA information is 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*² that combines the cards into a coherent information package, and c) optional *appendices* that enable inclusion of additional information to e.g. the result cards without crowding the cards' content. Collections are divided into two categories, each of which may contain more than one collection type:

- *EUnetHTA Collection* contains a standardised set of information on health technologies that is published only through an editorial process controlled by EUnetHTA. Currently three types of EUnetHTA Collections exist: 1) *core HTAs* contain a thorough analysis of all nine domains of the HTA Core Model; 2) *rapid HTAs* contain a narrower analysis performed in a faster pace; 3) rapid relative effectiveness assessments (rapid REAs) contain a rapid analysis of a pharmaceutical product used for reimbursement decisions. Further EUnetHTA Collection types may be defined later³.
- *Other Collection* is not subject to any editorial process by EUnetHTA and its contents are the sole responsibility of its producers. Other Collection contains a freely selected set of

¹ The Online Tool and Service is available as the "HTA Core Model Online" at www.corehta.info.

² E.g. summary, introduction and conclusions.

³ The possibility of including an analysis within a single domain as a EUnetHTA Collection type will be explored within Joint Action 2.

information, including one or more result cards. The Online Tool and Service may also propose specific types to users (e.g. single result card or full domain with all questions of a domain or rapid HTA). Although the contents of Other Collections can be more freely defined by their users, the Online Tool and Service may require of them some content elements (e.g. summary) or other aspects (e.g. language).

The term "*core HTA*" is reserved for EUnetHTA Collections only. *Rapid HTAs* can be either EUnetHTA Collections, in which case they are referred to as "EUnetHTA rapid HTA", or Other Collections, in which case they are referred to simply as "Other rapid HTAs".

Editorial Board

Currently no Editorial Board exists for core HTA information within EUnetHTA. The nomination, composition and detailed functions of such a Board are not included in the current version of this policy document. Such definitions will be considered within the first 15 months of Joint Action 2, i.e. before end of 2013.

The Coordination Working Group (CWG) of Joint Action WP4 has tasks similar to those of an editorial board, and a similar CWG continues the work within Joint Action 2, particularly to coordinate the efforts of the HTA Core Model infrastructure (WP8) and production of core HTAs (WP4) and rapid HTAs (WP5). The future Editorial Board is anticipated as an international board of experts from EUnetHTA Partners that oversees the development and management of the HTA Core Model as well as production and publication of core HTA information. This is done in collaboration with the Executive Committee of EUnetHTA. Details regarding responsibilities and tasks of these two bodies will be agreed on by the end of 2013.

EUnetHTA will appoint the Editorial Board for a specific period and through a process defined later, including its relations to the EUnetHTA Executive Committee. For the intermediate period the coordination between the aforementioned work packages will cover the functions of the Editorial Board.

Commercial and non-commercial use

Commercial use in this context is defined as any use that is intended for or directed toward commercial advantage or private monetary compensation⁴. This includes but is not limited to the following settings:

- Use of the HTA Core Model or core HTA information for producing HTA information when the resulting HTA information is made available to its users only against a fee that is an essential source of income for the information producer. Use by companies that produce

⁴ Modified from definitions of "noncommercial" by the Creative Commons, http://wiki.creativecommons.org/Defining_Noncommercial

and sell HTA information typically fall into this category. Use of the Model by public organizations charging a fee to cover costs e.g. for printing does not belong to this category.

- Use of the HTA Core Model or core HTA information as part of an information system that is sold to customer(s) or that is otherwise available only against a fee. Such systems include but are not limited to decision support systems, electronic health records, knowledge bases and systems used for producing HTA information.

Non-commercial use in this context is defined as any use that is not connected to commercial advantage or private monetary compensation. Use by public HTA bodies and government agencies fall in most cases to this category.

If the use in a specific setting cannot clearly be attributed into either of the aforementioned definitions of commercial or non-commercial, the intended use should be described in advance to the Editorial Board / CWG that decides into which category the use is assigned.

Terms of Use

The HTA Core Model is subject to Terms of Use. These were first developed in EUnetHTA Project 2006-2008. The terms addressed non-commercial use only and all commercial use was prohibited. The Executive Committee of EUnetHTA decided in 2012 that commercial utilisation of the Model would be allowed through a commercial license that should be crafted within Joint Action 2. These decisions rendered the 2008 Terms of Use partially obsolete and a new version of Terms of Use was developed based on this policy document.

The Terms of Use and included licenses apply to the HTA Core Model only, not the core HTA information included in the database of HTA Core Model Online. The core HTA information should be seen as any publication that is protected by international and national intellectual property rights. At the moment no separate license has been crafted for core HTA information.

Project protocol (within the Online Tool and Service)

In the Online Tool and Service a project protocol defines the intended use of the HTA Core Model within a specific project to produce a collection of core HTA information. It defines the domains of interest, the relevant research questions, and the roles and responsibilities of project participants (e.g. primary investigators, investigators, reviewers). A project protocol must be defined in the beginning of each project aiming at producing core HTA information.

SECTION A: The HTA Core Model

Availability

The HTA Core Model is available through designated distribution web sites, listed at www.htacoremodel.info and www.eunethta.eu.

Only sites controlled by EUnetHTA or one of its member organisations can distribute the HTA Core Model. EUnetHTA decides on the distribution location (one or more) and may grant distribution rights to other trusted parties.

All contents of the HTA Core Model are available to anyone as PDF documents.

The Model may be distributed also in other formats (e.g. HTML/XML), which will also be available to anyone, but only through separate request and registration.

Use for information production

The HTA Core Model can be used for producing non-commercial scientific information on health technologies (e.g. HTAs, literature reviews or other scientific studies).

The information produced can analyse one or more of the nine domains of HTA contained in the Model, or any other aspects of health technology.

Use for any commercial information production purposes requires a specific commercial license that allows anyone to use the HTA Core Model for free until the end of September 2015. Conditions and contents of the license will be reconsidered during 2015 for the period after Joint Action 2 (i.e. after September 2015).

The following clarification of two special circumstances may be of relevance for the operations of some EUnetHTA Partners and Associates:

- Use is permitted in situations, in which a EUnetHTA Partner or Associate uses in its HTA process dossiers submitted by technology manufacturers. In those settings the dossier may be prepared using the HTA Core Model, including its information structure and methodological guidance. Use in such settings, however, requires the aforementioned license.
- Use is permitted in situations, in which a EUnetHTA Partner or Associate subcontracts information production to another commercial or non-commercial organization. If the activity can be regarded as commercial for the subcontractor's side, the subcontractor must acquire a license.

Use as part of information systems

The Model and its information structure can also be utilized in academic, governmental and other non-commercial information systems that are built for production and publishing of HTA information, provided that all other policies in section A are followed.

Use as part of information systems for any commercial purposes requires use of commercial license that allows anyone to use the HTA Core Model for free until the end of September 2015. Conditions and contents of the license will be reconsidered during 2015 for the period after Joint Action 2 (i.e. after September 2015).

Use for other purposes

Use for any other purpose than for information production or as a component of an information system is not permitted without written approval of the Editorial Board / CWG⁵.

Registration

Use of the HTA Core Model can be registered by filling out an online form at www.corehta.info.

Registration is recommended but not obligatory for producing information using the HTA Core Model for non-commercial purposes.

Use of the Model as part of any information system (both non-commercial and commercial) requires registration.

Any commercial use of the Model must be registered.

Availability of produced information

Any information produced using the Model must be made publicly available either on the Internet or in printed format. This applies only to non-commercial use of the Model. Requirements for commercial use of the Model are defined separately in the commercial license.

When using the HTA Core Model for non-commercial purposes, no fees must be collected from end-users of the produced information, i.e. from those who read/view the information and use it for their own purposes. This rule does not, however, prevent scientific researchers from using the Model in their work and publishing the results as articles in scientific journals (that may or may not be available for free).

Publicity of produced information is not required in cases where a non-commercial party uses the HTA Core Model to produce information that must be kept confidential because of legal requirements on confidentiality.

⁵ During 2013 subject to endorsement by the Executive Committee.

Versions

The HTA Core Model must always be used unaltered and in the most recent version available.

In cases where the Model is updated during an ongoing work, users of the Model may choose whether to finalize their work using the version they originally started with, or to adjust their work to the updated version.

Disclosure of use

Use of the HTA Core Model, including information on its version, should always be disclosed in the final product(s), such as reports, articles or other documents, or in any information systems, by including the following text in the final product(s): *"The HTA Core Model[®], developed within EUnetHTA (www.eunetha.eu), has been utilised when producing the contents and/or structure of this work. The following version of the Model was used: [include name and version here]."*

Development

The Editorial Board / CWG oversees the development of the HTA Core Model. The Board approves proposed changes and can nominate expert groups to perform various development tasks.

The HTA Core Model is updated by expert groups that periodically review its content and bring relevant parts up-to-date. Such expert groups can be set up e.g. within Work Packages of EUnetHTA JA2 or subsequent EUnetHTA activities, or other relevant projects. If update is done outside official EUnetHTA activities, it requires and approval by the Editorial Board / CWG.

Anyone can suggest changes to the HTA Core Model. A feedback mechanism is available in the Online Tool and Service. Depending on the nature of the suggestions, they are considered by different expert groups or the Editorial Board.

Further detailed policies on updating the HTA Core Model will be defined later when more experience on its use has been gained. The overall aim is to keep existing content up-to-date with periodic updates and to expand the content based on actual needs identified by EUnetHTA.

SECTION B: Production of core HTA information

Assessment Topics

An effort is made by EUnetHTA to identify and promote topics of common interest and utility, but choosing such a topic is not mandatory for research groups. Various EUnetHTA tools (e.g. POP database, EVIDENT, IMS) can be utilized in this process.

EUnetHTA Partners and Associates as well as Stakeholder Forum members and EU Member State governments can propose assessment topics.

Any research group that otherwise fulfils relevant requirements defined in Section B of this document and commits to the Terms of Use of the HTA Core Model may start a core HTA information project and choose its topic independently.

Research groups starting core HTA projects may decide themselves whether they aim at producing a EUnetHTA Collection (which includes an editorial process) or an Other (non-EUnetHTA) Collection (without editorial process).

EUnetHTA may (or may not) choose joint topics for collections of core HTA information to be produced within the EUnetHTA.

Access to production and submission of core HTA information

Only EUnetHTA partners and associates can use the Online Tool and Service to *produce* and submit core HTA information to be *published* there. This applies both to EUnetHTA Collections and Other Collections.

Any non-commercial party can use the Online Tool and Service to *produce* Other Collections of core HTA information. Collections produced by organisations that are not EUnetHTA Partners or Associates are not eligible for publication in the Online Tool and Service. Instead, information produced by such parties should be published elsewhere by the producer(s). All policies defined in section A also apply in these cases.

The possibility of granting other parties than EUnetHTA Partner and Associates the right to publish core HTA information within the Online Tool and Service will be reconsidered during EUnetHTA Joint Action 2 with the involvement of the EUnetHTA Stakeholder Forum.

Collections produced by EUnetHTA Partners or Associates through subcontracting may be submitted and published as any EUnetHTA Collection or Other Collection. The subcontracting party (i.e. the EUnetHTA Partner or Associate) must, however, always act as the primary publisher. If the subcontractor is the only publisher and not either a EUnetHTA Partner or Associate, the collection cannot be published within the Online Tool and Service.

Publication of any collection in the Online Tool and Service is voluntary. The Online Tool and Service can be used for the production phase only.

Composition of project groups

Requirements regarding project groups depend on the collection type as defined below.

EUNETHTA COLLECTIONS

Core HTAs

When producing a core HTA, at least one expert BOTH on the topic (e.g. medical specialist, nurse, physiotherapist, engineer, clinical chemist, or microbiologist) AND on the domain's typical methodology (e.g. an ethicist in ethical analysis domain) should participate actively as investigators in each domain.

When producing a core HTA, one organization may do the research work. Another organization from another country must provide internal reviewers. This is the minimum configuration for a core HTA project group, but a broader participation is recommended to ensure wider usefulness of the assessment. Similar requirements regarding organisational participation do not apply to Other Collection types.

Rapid HTAs

When producing a EUnetHTA rapid HTA, at least two researchers with adequate competence regarding HTA and the technology being assessed should participate actively as investigators in each domain.

Rapid relative-effectiveness assessment (REA) of pharmaceuticals

When producing a EUnetHTA rapid REA of pharmaceuticals, at least two researchers should participate actively as investigators in each domain.

OTHER COLLECTIONS

When producing any Other Collection of core HTA information, at least two researchers should participate actively as investigators in each domain. This policy does not limit HTA organisations from using the Online Tool and Service to produce their local HTA reports that are not included in the core HTA information pool. Policies regarding composition of project groups producing local HTA reports are decided on locally.

Language

Core HTA information is published in English language. This applies to the project protocol as well as all contents of EUnetHTA Collections and Other Collections, including their result cards and appendices produced within the same project.

The only exception to the language requirement is granted to appendices not produced within the core HTA information project they are attached to (e.g. previously existing local language reports or local data). If non-English language attachments are used, the parts referred to in the core HTA information must be conveyed in English in the appropriate part(s) of the collection or its result cards.

Language restrictions do not apply to local reports that are based on core HTA information. Local information producers choose independently the language they use.

Approval of project protocols

Protocols of projects aiming at producing a EUnetHTA Collection of core HTA information must be approved by the Editorial Board / CWG. The contents of the approval process will be considered in 2013 by the CWG.

Approval of project protocols of Other Collections is not required.

Conflict of interest statement

All members of research groups producing core HTA information must provide a conflict of interest statement that will be included in the collection and published together with the collection.

Methodological guidance

The HTA Core Model contains methodological guidance on how to answer research questions within core HTA information projects. The guidance is made available to information producers within the Online Tool and Service. Information producers should follow the guidance taking into account the nature of each part of the guidance (e.g. a recommendation vs. definite requirement), which typically is indicated within the guidance.

Production and utilization of core HTA information takes place in the international context. Core HTA information can be produced either a) by making a reasonable effort to produce information that is likely to be useful in contexts beyond producers' own setting, or b) as any information for national/regional settings. In the latter case (b), a warning of potentially high context-dependence must be included.

Transparency of information sources

The HTA Core Model advocates transparency of information. All core HTA information projects should strive to use publicly available information only (including information in subscription-based scientific journals).

All core HTA information collections, except certain rapid HTAs (see below), must be based on publicly available information. When producing any collection, producers may – if needed – with extreme caution use completely or partially confidential background information (e.g. to increase

the investigators' understanding of the topic). Even in those cases the actual results and conclusions must be based on publicly available information only.

Producers of core HTA information should be particularly careful when requesting confidential information from any other party, and particularly when committing to any type of non-disclosure agreements⁶. This is to prevent situations where such agreements may prevent full or partial publication of core HTA information producers' results, or where the information producers may be forced to publish results that are not in accordance with all available evidence that would affect relevant conclusions.

The only exceptions to the principle of transparency are rapid HTAs produced by EUnetHTA Partners and Associates that base their analysis on manufacturers' submission files. When producing such collections, use of information not publicly available is decided on by the HTA producer and it should follow the organization's standard procedures. If any information not publicly available has been used when producing a collection, the use must be clearly disclosed in the collection, including the collection's summary and relevant sections of methodology and conclusions.

Updating core HTA information

No time requirements are set for updating core HTA information collections or individual result cards within them, but a follow-up mechanism is designed to identify those collections that would most likely benefit from updating. Specific calls within EUnetHTA are made for updating them.

Producers of core HTA information do not need to commit to updating their work.

The full or partial contents of a core HTA information collection is updated by creating a new collection and result card(s) that refer to the old version(s). The new collection and its result card(s) contain the updated information.

The original producers of any core HTA information within EUnetHTA Collections retain an exclusive, but time-limited right, a protection period, to update their collection(s) or individual result cards within their collection(s). During the protection period no-one else may update the collection or result cards within the Online Tool and Service. The protection period is not applicable to Other Collections.

The protection period affects only projects that have the same scope as the original collection or its result cards.⁷

The right is reserved for the original primary investigators of collections and for the organisations they represented when producing the information. Investigators, reviewers and other experts participating in the project are not entitled to such rights. In the case of subcontracted collections, the right is reserved only for the original subcontracting organization (i.e. the EUnetHTA Partner or Associate).

⁶ Also known as confidentiality agreements, confidential disclosure agreements, proprietary information agreements or secrecy agreements.

⁷ Consequently the existence of a collection or a result card that considers technology A in disease B does not prevent another group from producing a collection on technology A in disease C or technology D in disease B.

The purpose of this limitation in topic selection is to avoid intellectual property right conflicts that might arise due to assessment projects that have a too similar scope.

The protection period starts from the publication of a collection. The period is limited to 6 months for individual result cards, 1 year for rapid reviews and 2 years for core HTAs. The original producers, i.e. primary investigators or their organisations, must inform the Editorial Board within the period about their interest and intention to update their collection, and they must start their new project and submit for publication the respective collections within a reasonable timeframe, promoting rapid exchange of HTA information.

After the protection period anyone with appropriate rights can update existing EUnetHTA Collections of core HTA information, provided that other relevant policies are followed and that origins of each piece of information can be traced back to its original source, references and author.

Original authors may also waive their right to the protection period at any point, if they do not intend to update their collection. In those cases, the collection can be updated before the protection period is over by anyone with appropriate other rights. In such cases, all those entitled to the protection period must allow the early updating of the collection.

The protection period is not intended to hinder development of new collaborations. On the contrary, original producers of a collection and any new parties interested in updating the collection are urged to actively seek forms of collaboration that strengthen the competence of the research group that will perform the updating.

Users of core HTA information have the possibility to attach comments to collections and cards, without creating a new collection or result card⁸. The comments are meant to assist further users of the same core HTA information. The aforementioned time limitations and updating rights do not apply to these comments.

The Editorial Board reserves the right to withdraw any comments attached to core HTA information from publicity, if they violate these policies or otherwise are not in accordance with good scientific practice and ethical conduct.

⁸ The add comment feature will be added to HTA Core Model Online during Joint Action 2.

SECTION C: Publishing of core HTA information

Authorship and contributorship

Authorship and contributorship of any core HTA information follow the requirements of ICMJE, http://www.icmje.org/ethical_1author.html.

Peer-review and approval

Any EUnetHTA Collection of core HTA information is subject to external peer-review and approval by the Editorial Board / CWG. The content and extent of this process will be considered by the CWG during 2013.

Other Collections can be published without peer-review or approval by the Editorial Board, provided that their primary publisher is a EUnetHTA Partner or Associate.

Other Collections must contain a description of the quality assurance process (e.g. editorial process) that the collection has undergone.

A special statement is attached to any Other (non-EUnetHTA) Collections declaring that the collection as a whole or any of its contents is not endorsed by EUnetHTA and that its quality is the sole responsibility of its producer(s). Users are also urged to consider the quality assurance process disclosed by the producers of such collections. The Editorial Board / CWG decides on the actual statement periodically.

Intellectual property rights

Intellectual property rights of authors are fully respected in any core HTA information.

Authors of any core HTA information must, however, give a permission to freely reuse any information they have produced (in its original format) in any Other Collection of core HTA information included in the Online Tool & Service. This permission includes the right to reuse result cards (or parts of their content) as part of Other Collections.

When reusing any existing information, core HTA information producers must indicate the original sources in an appropriate manner, following principles of good scientific practice and the citing methods defined in the Online Tool and Service.

When reusing and updating existing core HTA information, producers must take into account the special rights of original information producers. They should also take advantage of the possibility to only comment existing information. (See "Updating core HTA information" in Section B).

Intellectual property rights of third parties are fully respected in any core HTA information. Authors of core HTA information are responsible for acquiring and preserving necessary permissions in writing.

Core HTA information producers should also be aware that they cannot grant exclusive publication rights to a third party after they have published the same information in the Online Tool and Service.

Withdrawal of low-quality core HTA information

Core HTA information is expected to be of high scientific quality, and - wherever feasible⁹ – based on scientific evidence. Although some collections (the “Other Collections”) are not subject to an editorial process, EUnetHTA and the core HTA information hosting organisation both reserve the right to withdraw from publicity any core HTA information collection (or parts of a collection) that contains information of low quality.

In this context low quality information is regarded as any misleading or fraudulent information, or information that does not follow good scientific conduct. Such information can be withdrawn from publicity.

Any withdrawal described above is first temporary and can be done at any time without warning. The producer of the information is notified of the withdrawal and the issue is brought to the Editorial Board that decides whether the information should be made again available, whether changes are requested from original producer(s) or whether the withdrawal is permanent. If the information is not re-released after these considerations, it can be deleted from the core HTA information database and EUnetHTA does not commit to storing or archiving it.

⁹ This requirement does not prevent including information that is in accordance with the scientific practice within the different domains. For example it may not be feasible to demand that all reflections in the ethical analysis domain are based on “evidence”.

SECTION D: Storage and availability of core HTA information

Timeframe of information availability

The overall aim of EUnetHTA is to store all core HTA information in the Online Tool & Service in a fully reusable format for a minimum period of 10 years after its publication. After this period the information will be archived in electronic format in a separate archive maintained by EUnetHTA.

Taking good care of existing core HTA information is of central importance to EUnetHTA. In the possible event of substantial organizational or technical difficulties, the Editorial Board may change this timeframe in the future, also retrospectively. Hence the overall aim described here should not be seen as a legal commitment by EUnetHTA or the organization(s) maintaining the Online Tool and Service to keep the material available for 10 years.

The Editorial Board will design a separate archiving policy and process in due time before the first 10-year period has passed.

SECTION E: Retrieval and utilization of core HTA information

Access to published collections

Anyone can access published core HTA information, including EUnetHTA Collections and Other Collections.

Browsing and utilisation of core HTA information is free of charge.

The aim of the free access is to promote easy and rapid flow of HTA information and hence the primary publication method is to make all contents of a collection public.

The producers of EUnetHTA Collections may, however, in exceptional cases limit access to some parts of their collection so that only EUnetHTA Partners and Associates can access the material. Such situations may arise e.g. when material of semi-public nature has been used as part of the background documentation or when a health economic model used in the analysis is distributed to a limited audience. The Editorial Board must approve all such limitations.

EUnetHTA may choose to make browsing and utilisation of core HTA information fee-based in the future, but such a potential change will apply prospectively only to projects that have started after the possible change.

Access to project data prior to publication

The protocol of a core HTA information project is public whenever the project group decides to make it public. If, however, the protocol is still undergoing changes, it is visible only to EUnetHTA Partners and Associates. Possible incomplete protocol status is indicated.

Completed project protocols are automatically made public by the Online Tool and Service. This applies to all core HTA information projects, i.e. to those aiming at producing an EUnetHTA Collection, as well as any other core HTA information collection. Protocols of projects aiming at producing any other HTA information, not published in the Online Tool and Service, are currently not made public, but their publicity can be reconsidered later (affecting only new projects that are started after the change).

A project group working on a EUnetHTA Collection may make full or partial results accessible to EUnetHTA Partners and Associates before a formal approval (defined in other policies) has been completed. Results in this phase will be labelled "preliminary results, work in progress, not for citation". Others than EUnetHTA Partners and Associates may not access EUnetHTA collections that have not been formally approved.

Since there is no editorial control for Other Collections, any results of such collections can be made public whenever the producers so decide. Producers must clearly indicate the level of completeness of their collection (i.e., whether it is still a work in progress or final version).

Utilisation of core HTA information

All principles in the paragraph "Utilisation" of section A regarding information produced using the HTA Core Model apply as such also to utilisation of core HTA information.

In order to assist further users of the same information, users of core HTA information must provide an English language summary of the final conclusions of their local report. The summary will be included in the Online Tool & Service and linked to the information it was based on.

Summary table of information production, publication and access policies

The following table summarises the policies steering production, publication and access to information produced using the HTA Core Model and/or the Online Tool and Service (OTS). The values in table cells reflect the individual policies described above. Important restrictions to the values have been indicated.

Function	EUnetHTA Partners and Associates	Other non-commercial organisations	Commercial organisations
Production and publication of any HTA information using the HTA Core Model outside the OTS	Yes	Yes	Yes Commercial license required if resulting information is produced or used for commercial purpose
Production of any HTA information or core HTA information using the OTS	Yes	Only Other Collections to be published outside the OTS	No
Publication of core HTA information through the OTS	Yes	No	No
Access to EUnetHTA Collections within the OTS	Free	Free	Free
Access to Other Collections within the OTS	Free	Free	Free

Appendix 1: Policy crafting process in brief

The policies affect the following three entities¹⁰:

1. The *HTA Core Model* is a methodological framework for producing and sharing HTA information.
2. The *Core HTA Structure* is a conceptual HTA information production and sharing system where information produced according to the HTA Core Model is organized into standardized *collections*, providing a knowledge base for local reports, which in turn can feed back to the system.
3. The *Online Tool and Service* enables production of information using the HTA Core Model, as well as sharing and utilizing the resulting structured HTA information. It is the primary service in which the HTA Core Model and the Core HTA Structure are *made available as an active knowledge base* that fosters production, sharing and utilization of HTA information in real-life settings across borders.

The policy crafting process was agreed on in 2010 in two WP4 workshops. A survey to EUnetHTA member organizations was prepared by an international working group containing representatives from 11 HTA organisations from 9 countries. The survey listed 35 individual policies and provided various options, as well as identified some positive and negative implications or consequences for different options. The actual survey was sent to all EUnetHTA organisations in July 2011 and responses were gathered until early October 2011. The survey consisted of two documents, one of which contained instructions and the other all the policy options, some pros and cons of each option (identified by the working group) and information on terms and concepts and the overall policy crafting process.

Two email messages containing corrections to survey errors and further definition to “commercial use” were sent to survey recipients in August 2012.

A single response was expected from each agency, representing the view of the agency, not individual respondent. The organisations were to rate each policy option with the following scale:

- Preferred = Your agency finds this a very good policy. You can assign this value to more than one options of one policy.
- OK = Your agency finds this policy acceptable, but another option would be clearly better.
- Bad = Your agency would not want to see this policy implemented.
- Cannot say = Your agency is not sure if this policy is good or bad.

In addition, respondents were able to provide free text comments to each policy.

¹⁰ These are described in more detail in the HTA Core Model Handbook (available at www.corehta.info).

Altogether 24 organisations from 17 countries responded to the survey. A weighted rating score for each policy option was calculated using the following weights: Preferred = 10 points, OK = 5 points, Bad = -10 points, Cannot say = 0 points¹¹.

Additionally, two exclusion criteria were applied to identify options that are either

- a) opposed to by more than 20 % of organisations or
- b) perceived as too difficult to rate by more than 20 % of organisations.

The exclusion criteria were used to ensure a clear and widely accepted policy set. The accuracy of these criteria and the chosen threshold level of 20 %, however, is relative at best. Hence some exceptions were made, particularly when none of the available options was free from too many opposing views or ambiguity.

Through this process, a *preferred option* and a *runner-up option* were identified for each policy. These were first identified among those options that did not meet any of the exclusion criteria, by selecting the option with highest score (preferred option) and second highest score (runner-up). In cases where only one option would be available after applying the exclusion criteria, no runner-up was selected in most cases. Some exceptions to this were made in cases where an excluded option actually scored higher than the preferred option, or when the exclusion criteria were met with a very low margin. In these cases a runner-up was also identified. In cases where all available options met one or both exclusion criteria, the best available options (based on highest score and least opposition) were identified as preferred option and runner-up.

Two policies were excluded from this formal process. A policy A3-3 on updating the HTA Core Model and its applications still required some further conceptual and technical clarification before a policy could be crafted. Another policy on intellectual property rights of third parties was regarded as self-evident when aiming at information production and sharing that follows the principles of good research conduct and legal regulation.

Based on the detailed data regarding the policies, the Lead Partner of WP4 drafted the first proposal of policy options to be selected. WP4 members' opinions on this policy set were sought through a further small survey among WP4 members in May 2012.

In total 28 (76 %) of the 37 WP member organisations responded to the survey, including 19 (86 %) of the 22 Associated Partners and 9 (53 %) of the 17 Collaborative Partners. A clear majority (93 %) of the respondents agreed that the proposed policy options were fine or mostly fine from the viewpoint of their agency's policies and practices. Likewise, a clear majority (86 %) agreed that the proposed policy set would adequately cover the foreseen utilization of the HTA Core Model and core HTA information.

¹¹ Consequently, a policy option that was preferred by 10 agencies, regarded as acceptable by another 10 agencies and regarded as bad by 2 agencies would score a total of $[(10*10) + (10*5) + (2*-10)] = 130$ points.

Based on the results of this second survey, WP4 Lead Partner brought the policy set for a discussion within the EUnetHTA Executive Committee in an e-meeting on the 13th of June 2012. The version was not yet a final policy document, but instead contained questions and proposed policy options in table format. In that discussion some concerns regarding the applicability and clarity of the set in all EUnetHTA member organizations' use settings were identified. These included situations where an HTA agency does not produce the information itself but instead subcontracts the production or uses information produced by industry, or when a rapid relative-effectiveness assessment is produced. Also the need to discuss further possible fees associated with associated with the use of HTA Core Model and core HTA information was identified. It was agreed that Lead Partner would consider the feedback and prepare an amended version to be discussed again.

During summer 2012 the Lead Partner compiled a new version where several shortcomings of the June version are addressed. Also some new content was added to address various other notions along the crafting process. In this version the earlier questions and answers used in the surveys were converted into sentences containing the basic content of the policy without the questions and answers.

The new version was sent to another review by WP4 organisations and the Executive Committee after the Summer. The Executive Committee discussed the policies in October and November and a final version was sent to WP4 agencies' approval on the 3rd of December.

Twenty-one agencies responded to the request. Nineteen (90 %) approved the policy. Two agencies responded "cannot say". One of them was hesitant about including the Other Collections in the same database as EUnetHTA Collections. The other respondent indicated that since they are not an HTA agency, the document is not applicable to them. Similarly, the clear majority (90 %) indicated that the policy fits their agency's principles, practices and expectations very well (3 agencies) or mostly well (16 agencies). Two answered "cannot say".

After receiving this data, the same version was brought for approval by the EUnetHTA Executive Committee in its e-meeting on the 12th of December 2012. The Committee approved the version. Due to difficulties in timeline, the Policy had not been subjected to feedback from the WP4 Stakeholder Advisory Group or public consultation. It was agreed in the meeting that the policy document will be subjected to a review by the Stakeholder Advisory Group and the general public during the first half of year 2013 and an updated version would be prepared by May 2013.

In EUnetHTA Joint Action 2 the policy was developed further by WP8. Version 1.0 of the policy was sent for review to EUnetHTA Partners and Associates, the WP8 Stakeholder Advisory Group (SAG) and the general public. The review took place in spring 2013 and feedback was used to develop the policy. EUnetHTA agencies approved the version 1.0 of the policy with a clear majority of 92 %. Three members of the WP8 SAG and two further organisations also responded. The feedback from these five organisations brought forward several reservations that were addressed when developing version 1.1.

Version 1.1 was approved by the EUnetHTA Executive Committee in its e-meeting on the 26th of June 2013.

Appendix 2: Terms and Concepts

The following definitions were used (as a direct copy) in the document that was sent to the survey respondents and that also contained the various policy options. Notice that most up-to-date versions of some of the definitions are available in this document (pages 5-7).

HTA Core Model is a framework for structured production and presentation of HTA information as assessment elements. The HTA Core Model enables collaborative production and sharing of information. It consists of a) an ontology for HTA, b) methodological guidance and c) a common reporting structure. The ontology provides a basis for structured research protocols. The answers to questions defined by a protocol are answered using the available methodological guidance and reported using the common reporting structure.

Assessment elements are the basic unit of the HTA Core Model. Defines a piece of information that describes the technology or the consequences of implications of its use, or any other implication that is relevant for the assessment, such as the patients and the disease for which it is applied. All assessment elements within the HTA Core Model form a common pool of elements that can be utilized by different applications (see below).

HTA ontology constitutes a formal representation of knowledge within HTA, defined as assessment elements and their relations. It does not contain methodological guidance.

Application of the HTA Core Model is built for assessing a specific kind of health technology. 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 kind of methodological guidance. Different applications all draw from the same pool of assessment elements, but not all elements are used in all applications.

Methodological guidance exists on two levels within the HTA Core Model. Domain-specific guidance provides general advice about how to answer research questions within a specific domain (e.g. effectiveness or ethics). More specific guidance may be available for answering questions within individual assessment elements. Various Core Model applications (see above) may contain different kind of guidance. All guidance is included in the applications of the HTA Core Model, not in the ontology.

Online Tool & Service is the deliverable under construction within WP4. It constitutes of a Tool with which one can use the HTA Core Model to produce and publish HTA information and a Database of information (a.k.a. the "Service") that has been produced using the Tool and that is available for various purposes.

Information systems in this document refer to any information system (including but not limited to "tools" and databases), in any format (e.g. electronic or paper format) that considers utilizing the HTA Core Model or parts of it.

Core HTA information refers in this document to any information that is a) produced using the Online Tool and b) made available through the Service. Some of the information is included in collections that follow a standard, "official" EUnetHTA template. For example core HTAs have a specific and extensive structure (see below). Other, more limited collections may be made available as official templates, such as rapid reviews. On the other hand, some of the information in the Service has been produced in a more ad hoc manner as "free selection of assessment elements" (e.g. if someone wants to use only one or few assessment elements to answer a very limited question). There may or may not be a need to distinguish between the official templates and other information when it comes to policies. Notice also, that the appropriateness of this term will be considered further within the Joint Action. It is used here for the purposes of this questionnaire and respondents should look more at the definition of it when responding.

Official EUnetHTA templates -> See "Core HTA information".

Core HTA is an assessment that a) has been conducted using the HTA Core Model and b) has considered all core elements of all 9 domains. A Core HTA is an extensive collection of information that contains also some standard text chapters, such as a common introduction and a summary that draws together key findings of various domains, but does not make recommendations on technology use.

(Project) protocol is the overall plan of producing any core HTA information. It defines – among other things – persons participating in a project, research questions that will be answered and possibly methodology used in answering.

Terms of Use are defined in a public document available to users of the HTA Core Model and the Online Tool & Service. The document defines in concise format the terms according to which the deliverables can be used. Terms are based on the more extensive policy document crafted within WP4 (i.e. this work).

Unauthorized use of the HTA Core Model is regarded as any use that violates the Terms of Use.

Commercial use is use in any manner that is primarily intended for or directed toward commercial advantage or private monetary compensation. This includes any use in a setting where the HTA Core Model is used for producing information made available only against a fee, or where the Model is used in information systems available only against a fee (including but not limited to systems used for producing HTA information). Notice that "commercial use" and "non-commercial use" are to some extent controversial terms and hence this definition may need reconsidering.

EUnetHTA Partners are organizations with full membership in EUnetHTA (same as Joint Action Associated Partners). See http://www.eunetha.net/Public/About_EUnetHTA/Organisation2/

EUnetHTA Associates: Organizations with limited membership in EUnetHTA (e.g. Joint Action Collaborative Partners). See http://www.eunetha.net/Public/About_EUnetHTA/Organisation2/

EUnetHTA Token is used here to represent a "currency" that is not money, but some other form of value or contribution that could be defined and used within the Network. EUnetHTA Token does not exist at the moment and would require a more general approval within the Network. For example an organization might have access to the Online Tool & Service only if the organization itself feeds information into the system as well. The Token in this context may be regarded as something that can be counted ("credits") or something that cannot be counted. The POP database utilizes the latter approach in the sense that only agencies that provide information into the database can use it.