eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Policy

for the HTA Core Model ®

and core HTA information

Version 2.0

Approved by the EUnetHTA Executive Committee on the 22nd of January 2016.

Version history	
Version	**Changes**
2.0	Major revision based on developments within Joint Action 2 (2012 – 2015). Key changes: - Definition of core HTA information changed. - All use of the HTA Core Model now requires registration. - Themes overlapping with the new document, the 'HTA Core Model Guiding Principles on Use', removed and the new document included as appendix. - References to activities not implemented within Joint Action 2 removed (e.g. Editorial Board). - Definition of Collections revised.
1.1	Added "Terms of Use" in the Definitions. Several changes in sections A-C and E.
1.0	Original version

Contents

Introduction

This document defines the EUnetHTA policy to steer the utilisation and further development of a) the *HTA Core Model* ®, hereafter also *"the Model"*, as well as b) the core HTA information produced using the Model. Two further key documents exist with focus on *using* the Model:

- The *HTA Core Model Guiding Principles on Use (*hereafter also *"the Guiding Principles")* document outlines fundamental principles for the utilisation of the Model in various settings.
- The *HTA Core Model Licence (*hereafter also *"the Licence")* governs the use of the Model in any type of setting.

Both the Guiding Principles and the Licence are available as separate documents and can be found at www.htacoremodel.info. The Guiding Principles are included also in this policy document as appendix 1.

The Model was designed within the EUnetHTA project 2006-2008 and further developed in the EUnetHTA Joint Action 2010-2012 (JA), EUnetHTA Joint Action 2 2012-2015 (JA2) and may be further improved and updated in EUnetHTA Joint Action 3 (scheduled to start in 2016). 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 a specific type of HTA information (see definition below).

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

Definitions

This chapter defines some key concepts relevant to this policy. Other definitions are available in the HTA Core Model Handbook.

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 *HTA 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

Core HTA information refers to **any information produced following the HTA ontology and the common reporting structure**.

In the production of such information it is recommended to use the Model's methodological guidance, as described in the Guiding Principles, as well as to register the resulting work within the HTA Core Model Online at www.htacoremodel.info so that it can be searched and accessed through a common interface.

The HTA Core Model Online provides a knowledge base where EUnetHTA agencies can publish their core HTA information, but publication within the HTA Core Model Online system is not required.

Collections

All core HTA information is produced and published in the form of *collections*, each of which contains a) a set of question-answer pairs (in some collections called *result cards*) in which each research question is answered in a concise manner, b) *general content*[1] that combines the answers (or cards) into a coherent information package, and c) optional *appendices* that enable inclusion of additional information. 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 follows EUnetHTA processes, procedures, requirements and guidance as defined in relevant manuals and other documentation (e.g. Standard Operating Procedures). EUnetHTA

[1] E.g. summary, introduction and conclusions.

Collection can be produced a) by EUnetHTA partners as so-called joint, collaborative or other assessments, or b) by external parties (not related to EUnetHTA), provided that the following conditions are followed:

- At least two organisations are involved in the production. No geographical limitations to where these organisations are registered and/or located apply.
- Project Plan including protocol / project description for the assessment has been registered by the EUnetHTA
- HTA Core Model was used and was a base for a scoping exercise during the scoping phase of the assessment
- EUnetHTA processes and procedures for joint assessments were applied throughout the entire scoping and production phases
- Information collected and analysed is presented in a structured, transparent way, for example in the form provided in the relevant EUnetHTA assessment templates.

- *Other Collection* is any other collection of core HTA information produced with use of the HTA Core Model®, but without adherence to the EUnetHTA processes and procedures, requirements and guidance as included in the relevant EUnetHTA manuals (i.e. SOPs etc.)

The aforementioned division is intended to distinguish between core HTA information that either follows or does not follow EUnetHTA standards. Further specific types of collections may be defined by EUnetHTA based on the extent and purpose of the collection.

Core HTA

A *"Core HTA"* is a specific type of EUnetHTA Collection that considers all nine domains of the HTA Core Model and utilises Result Cards in its reporting.

Licence

Using the HTA Core Model is subject to a licence (available at www.htacoremodel.info).

SECTION A: The HTA Core Model

Availability

The HTA Core Model is available through designated distribution web sites, listed at www.htacoremodel.info. Only sites controlled by EUnetHTA or one of its member organisations can distribute the HTA Core Model. EUnetHTA may grant distribution rights to other trusted parties.

All contents of the HTA Core Model are available to anyone under the terms of the Licence. in appropriate formats.

- Formats intended primarily for reading or browsing the Model's content are distributed by EUnetHTA without specific user registration, but with a reminder to register any use of the Model.
- Formats more likely to be used in practical work are distributed only after registration of the user.

Use for information production

The HTA Core Model can be used by non-commercial and commercial parties for producing information on health technologies (e.g. HTAs, literature reviews or other scientific studies) in any phase of technology development and use.

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

All use of the Model is subject to the HTA Core Model Licence.

Use as part of information systems

The Model and its information structure can be utilized also in information systems. Such systems may be used for example in production and publishing of HTA information or in supporting internal and external processes within various non-commercial or commercial organisations.
All use is subject to the HTA Core Model Licence.

Development

The HTA Core Model is developed and updated within EUnetHTA. The EUnetHTA Executive Committee oversees the development. The Committee 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 or other relevant projects or expert groups. If an update or extension of the Model is done outside official EUnetHTA activities, it requires an approval by the Executive Committee before inclusion in the HTA Core Model.

Anyone can suggest changes to the HTA Core Model. A feedback mechanism is available in the HTA Core Model Online (www.htacoremodel.info). Depending on the nature of the suggestions, they are considered by different expert groups or the Executive Committee.

SECTION B: Production of Core HTA Information

Assessment Topics

The choice of topics for assessment is beyond the remit of the HTA Core Model. Consequently, no specific policies are defined in this document.

Starting core HTA information projects

Any research group that commits to the HTA Core Model Licence may start a core HTA information project and choose its topic independently.

Anyone starting a core HTA information project may decide what kind of output they aim at, e.g. EUnetHTA Collection or an Other (non-EUnetHTA) Collection and whether they aim at publishing the work within the HTA Core Model Online or somewhere else.

Selecting assessment elements

Researchers are free to select the assessment elements to be included in their project and how these are translated into research questions.

Specific requirements regarding EUnetHTA Collections may apply and are further discussed in relevant procedure manuals and/or tools. Considering the relevance of some assessment elements in a project may be mandatory for such projects.

Production and submission of core HTA information within the HTA Core Model Online

Only EUnetHTA Partners and Associates can use the HTA Core Model Online 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 available at www.htacoremodel.info to *produce* 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 can be published elsewhere by the producer(s), e.g., in their own report series. Such information should be made publicly available either on the Internet or in printed format, unless local legal requirements on confidentiality prevent this.

The possibility of granting other parties than EUnetHTA Partners and Associates the right to publish core HTA information within the Online Tool and Service will be reconsidered during EUnetHTA Joint Action 3.

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 HTA Core Model Online is voluntary. Researchers may limit their use of the system to the scoping or information production phases only.

Transparency of project groups

In order to increase trustworthiness and transparency, all core HTA information should clearly disclose its authors, as well as their qualifications and affiliations.

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 possible 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.

The language requirements will be revisited within Joint Action 3.

Methodological guidance

The HTA Core Model contains methodological guidance on how to answer research questions within core HTA information projects. Information producers should pay attention to 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 by the authors.

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 agreements[2]. This is to prevent situations where such agreements may prevent full or partial publication of core HTA information as a result of the specific producers' work 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

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

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

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 EUnetHTA Collection or its result cards. The protection period is not applicable to Other Collections.

[2] Also known as confidentiality agreements, confidential disclosure agreements, proprietary information agreements or secrecy agreements.

The protection period affects only projects that have the same scope as the original collection or its result cards. [3]

The right is reserved for the original primary investigators (first authors) 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).

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 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 REAs and 2 years for core HTAs. The original producers, i.e. primary investigators or their organisations, must inform EUnetHTA 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.

[3] 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.

SECTION C: Publishing of Core HTA Information

Authorship and contributorship

Authorship and contributorship of any core HTA information follow the requirements of ICMJE[4].

Peer-review and approval

EUnetHTA Collections are subject to standards defined in relevant other documents describing EUnetHTA standards and procedures.

Other Collections can be published with or without peer-review. Other Collections must contain a description of the quality assurance process (e.g. editorial process) that the collection has undergone.

A special statement shall be attached to any Other (non-EUnetHTA) Collections declaring that the collection as a whole or any of its contents is not made according to EUnetHTA procedures and standards. The Other (non-EUnetHTA) Collection's quality assurance process 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.

Intellectual property rights

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

Authors of any core HTA information published **within the HTA Core Model Online** 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 HTA Core Model Online. This permission includes the right to reuse parts of the collections of result cards (or parts of their content) as part of newer Collections.

It is recommended that authors of any core HTA information published **outside the HTA Core Model Online** give similar permission to freely reuse the information they have produced by including in their work an explicit disclosure of such permission and its (potential) limitations. Such authors should in this process consider the intellectual property rights and other requirements of the publication forum/media they are using (e.g. report series or scientific journal) and ensure that their permission does not violate the rights of any third party..

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 citing methods.

[4] http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

When reusing and updating existing core HTA information, producers must take into account the special rights of original information producers (see chapter '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 be aware that they cannot grant exclusive publication rights to a third party after they have published the same information in the HTA Core Model Online. Similarly, if anyone wants to publish material at one of the EUnetHTA websites (e.g. within the HTA Core Model Online) after it has (or parts of it have) already been published elsewhere, the authors must ensure that they have the necessary permission to republish the material within the EUnetHTA sites.

Withdrawal of low-quality core HTA information

Core HTA information is expected to be of high scientific quality, and - wherever feasible[5] – based on scientific evidence. EUnetHTA and the hosting organisation of the HTA Core Model Online both reserve the right to withdraw from publicity any such core HTA information that is published within the HTA Core Model Online (or other EUnetHTA web sites) and 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 as well as links or references to it can be withdrawn from publicity within the HTA Core Model Online and other EUnetHTA sites.

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 EUnetHTA Executive Committee 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 respective sites and EUnetHTA does not commit to storing or archiving it.

[5] 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 aim of EUnetHTA with regard to core HTA information published in the HTA Core Model Online is to store it 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 published within EUnetHTA services is of central importance to EUnetHTA. In the possible event of substantial organizational or technical difficulties, the EUnetHTA Executive Committee 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 HTA Core Model Online to keep the material available for 10 years.

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

It is recommended that core HTA information published outside of the HTA Core Model Online would similarly be available for at least 10 years after its publication in a fully reusable format.

SECTION E: Retrieval and Utilisation 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.

Utilisation of core HTA information

In order to assist further users of core HTA information published within the HTA Core Model Online, its users must provide an English language summary of their local report. The summary will be included in the HTA Core Model Online 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 the production, publication and access to information produced using the HTA Core Model and/or the HTA Core Model Online, indicating whether various functions are available for different types of organisations (as users).

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 HTA Core Model Online	Yes	Yes	Yes
Production of any HTA information or core HTA information using the HTA Core Model Online	Yes	Yes	No
Publication of core HTA information through the HTA Core Model Online	Yes	No	No
Access to EUnetHTA Collections within the HTA Core Model Online	Free	Free	Free
Access to Other Collections within the HTA Core Model Online	Free	Free	Free

Appendix 1: Guiding Principles on Use

Purpose of the Guiding Principles

To outline fundamental principles for the utilisation of the *HTA Core Model*® (the Model)[6] in various settings contributing to Health Technology Assessments (HTAs)[7], and to the production and use of a reliable, timely, transparent and transferable knowledge in healthcare supporting patients' access to effective health technologies[8].

Definition and purpose of the Model

- The HTA Core Model is a *methodological framework* for production and sharing of HTA information. The HTA Core Model® is a registered trademark.
- The Model consists of the following three components, each with a specific purpose:

    1. A standardised set of *HTA questions (the ontology)* allows users to define their specific research questions within a hierarchical structure (see below)

    2. *Methodological guidance* to assist in answering the research questions that

        - Recommends use of already existing, generally recognised guidance and guidelines (e.g. EUnetHTA methodological guidelines, Cochrane Handbook[9], EQUATOR network[10]), along with other methodological recommendations
        - Requires transparency on the methods used when applying the HTA Core Model.

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

- HTA information produced by using the Model following the ontology and the common reporting structure can be designated as *core HTA information*, with high potential for being shareable and transferable knowledge. In order to facilitate re-use of information, registered users (see below) of the HTA Core Model should facilitate the traceability of the core HTA information they produce.

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

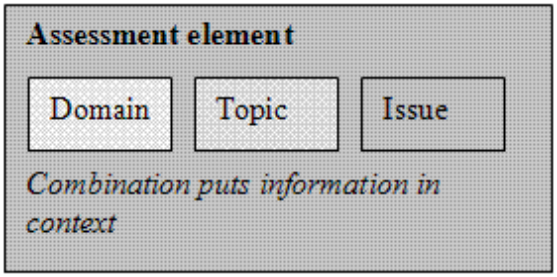
[7] **Health technology assessment (HTA)** is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.

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

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

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

- The assessment elements are units of the structure of the Model, which consists of *domain*, *topic* and *issue (translated further into one or more specific research questions in concrete projects)* that are used to assess a health technology. In this way, within a hierarchy, all research questions relate to a specific domain and subordinate topic.



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

Open access and collaboration values

- The design of the Model is and will remain publicly accessible
- EUnetHTA's objective is and has always been to deliver a model that can be shared and its use customised to the needs and objectives of the users, provided that the defining characteristics of the model described in this document are respected
- The "open" approach to developing and welcoming wide use of the EUnetHTA outputs – among which the HTA Core Model is one - designates a set of values and refers to something that can be further developed by EUnetHTA and others because its design is publicly accessible. The HTA Core Model is intended for general use, and all stakeholders in HTA and health research and policy are welcome not only to use it as a final and complete tool, but also to build upon it and develop their own products, tools and systems by using the defined and standardised framework of the Model. Those who utilise the HTA Core Model in derivative products (e.g. information systems) should clearly disclose to users whether they have used the Model as it is made available by EUnetHTA or whether some parts have been modified/revised.
- The standardised "question-answer" format and open access to the Model explicitly support users to produce, share, access and re-use HTA information in a reliable, timely, transparent and transferable manner

Intended use

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

Availability and versions

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

Intellectual property rights

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

Appendix 2: Policy crafting process in brief

The policy crafting process was agreed on within EUnetHTA Joint Action in 2010 in two WP4 workshops. Two surveys to EUnetHTA member organizations were used to gather feedback on 35 individual policy items and to prepare the first policy proposal. A clear majority (86 %) of WP4 member agencies agreed that the proposed policy set would adequately cover the foreseen utilization of the HTA Core Model and core HTA information. After further editing into a more coherent policy document and another review by WP4 member agencies, a clear majority of respondents (90 %) again approved the policy. The EUnetHTA Executive Committee subsequently approved the policy version 1.0 in its e-meeting on the 12th of December 2012.

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

The policy was revisited during fall 2015 as joint effort of WP8 and EUnetHTA Secretariat, with the intention to 1) align the policy with practical experience from JA2 and any relevant changes in the European HTA environment and 2) promote global use of the HTA Core Model. Members of WP 8 and the Executive Committee were consulted in the process and subsequently the LP of WP8 and the Secretariat produced a joint proposal of version 1.2. The *HTA Core Model Guiding Principles on Use*, outlining fundamental principles for the utilisation of the Model in various settings, was produced as part of the policy review process as a joint effort between the EUnetHTA Secretariat and WP8 LP, and approved by the Executive Committee in December 2015. The Executive Committee approved version 2.0 of this policy document on the 22nd of January 2016.