

Costs and economic evaluation

domain identifies, measures, values and compares the costs and outcomes of technologies being considered to inform value-for-money judgments about the intervention. The main aim is to provide information in order to improve decision-making in the health care sector regarding priority-setting between different health technologies.

Topics	Issues
Resource utilisation	What types of resources are used when delivering the assessed technology and its comparators?
Outcomes	What are the incremental effects of the technology relative to its comparator(s)?

Ethical analysis

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

Topics	Issues
Justice and Equity	How are technologies presenting with similar (ethical) problems treated in health care system?
Rights	Does the implementation or use of the technology affect the realisation of basic human rights?

Organisational aspects

domain focuses on the delivery models of the technology analysing processes, resources, management and cultural issues within variety of stakeholders in the intra- and inter-organisational level and in health care system level. The assessment of the organisational issues is highly context-dependent because of the inherent complexities of the health care system and multiplicity of objectives.

Topics	Issues
Processes	What kind of work flow and patient flow processes are needed?
Structure	What kinds of investments are needed (material or premises)?

Social aspects

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

Topics	Issues
Major life areas	What kind of support and resources are needed or might be released as the technology is put to use?
Individual	How do patients and important others react and act upon the technology?

Legal analysis

domain scrutinizes relevant legal sources that are codified in national, international and/or supranational legislation or has been agreed on in international conventions or are implicitly or explicitly agreed upon by the manufacturer (or seller) and buyer of the technology. It includes questions on basic rights of patients (autonomy, informed consent, privacy and confidentiality) and legal requirements (authorisation, guarantee, and regulation of market).

Topics	Issues
Authorisation & safety	Has the technology proper national/EU level authorisation?
Ownership & liability	Does the technology infringe some intellectual property right?

Work Package 4

Common Core HTA

Main deliverables

- Two HTA Core Models
- Two pilot Core HTAs
- Handbook on Core HTA production and use



Building a framework for HTA

WP4 develops a **Core HTA Structure**, which is a framework for effective collaboration and sharing of information between HTA agencies and end-users.

Building on earlier European HTA projects we have further operationalized HTA by asking and answering the following questions:

- What should be studied in HTA?
- What is the state-of-the-art methodology when studying various aspects?
- How should HTA information be organized?

Core Models

The Core HTA structure is based on generic models. Two of these **HTA Core Models** are developed within the project - one for medical and surgical interventions and the other for diagnostic technologies. The models aim at capturing the "core of HTA".

Core HTAs

Utilization of the Core Models leads to production of **structured HTA information**, ie. standardized pieces of information on a technology. The information can be further compiled into **Core HTAs**, standard-format reports that can be used as the foundation or building blocks of national HTA reports.

Feedback from pilot projects

In this project two Core HTAs are conducted: one on drug eluting stents and the other

on multi-slice CT angiography. The pilot Core HTAs will put the models into practical tests that provide feedback to further development of the models.

Domains

Work within WP4 is organized in 10 expert groups. One of them delineates the general design of the HTA Core Models and Core HTAs. The other groups focus on the following viewpoints or **domains** of HTA:

- describing the technology
- its current use
- safety
- effectiveness / accuracy
- costs and economic evaluation
- ethics
- organisational
- social and
- legal aspects.

Assessment elements as cards

Each group identifies pertinent **topics** and more detailed **issues** for assessment within their domain. The issues are included in the generic structure of the model as **assessment elements**. The elements are rated for their importance and transferability, and various standards, such as preferred research methods, can be linked to them. Each element - together with all the information that describes it - is presented in the model as a "card". An online system will be developed for the elements and cards.

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Advanced drafts of the Core Models and Core HTAs are available in the EUnetHTA Conference in Paris. Final versions will be published in December 2008.

How to use the Core Model?

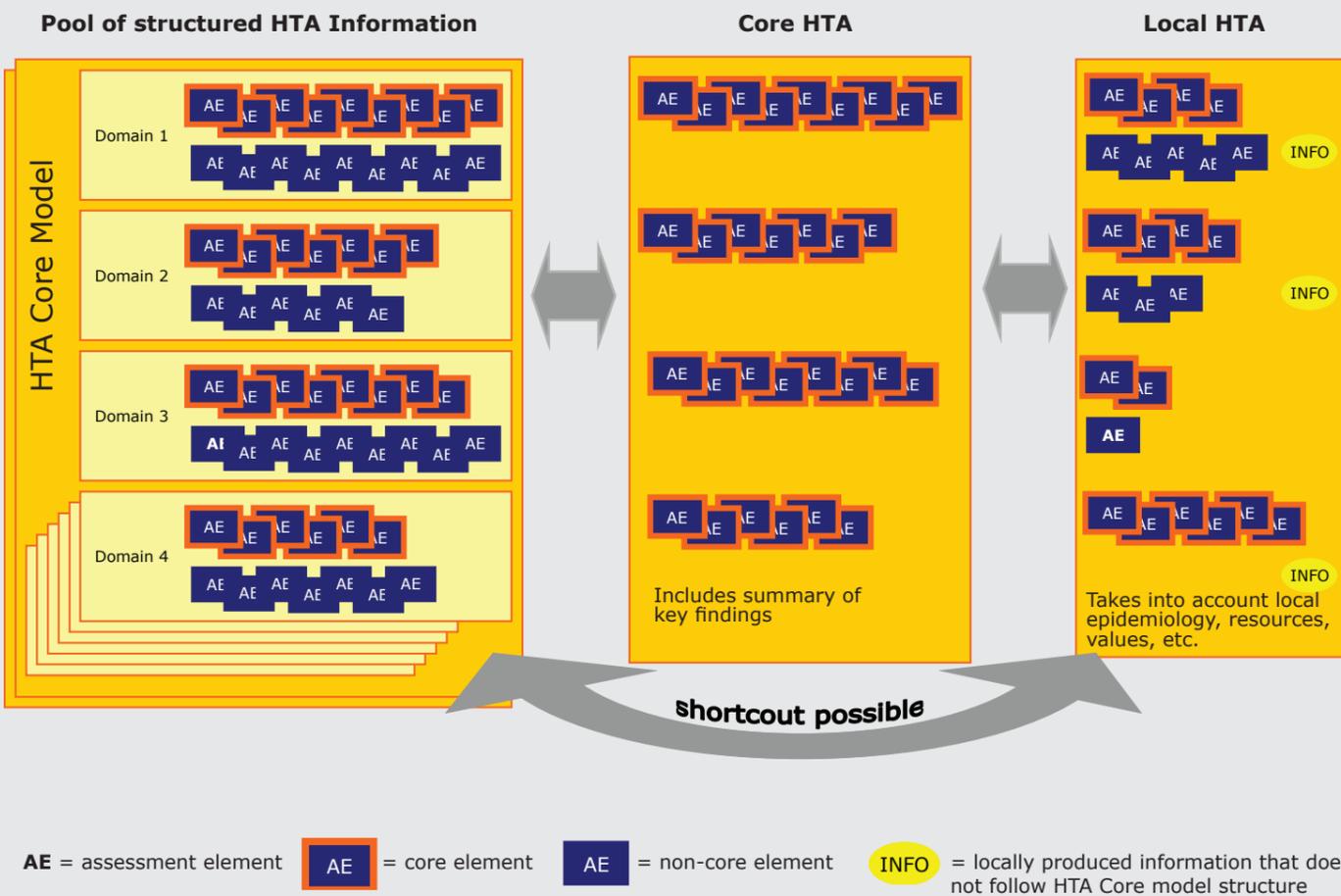
When designing and conducting an HTA, the assessment elements are first rated for their relevance. Relevant elements are then translated into practical research questions, which are answered through appropriate research. The HTA Core Model is an attempt to define and standardise elements of a health technology assessment. It facilitates a shared understanding of HTA and results in **consistent report structure** that is formed through question-answer pairs.

Reading a Core HTA

The consistent structure helps readers find the information they are looking for. For example, if one is interested in the direct effects of a technology on mortality of patients, the information can be found at a standard location. The approach also enables computerized dissemination and utilisation of information.

Core HTA Structure

HTA Core Models and their applications



Examples of topics and issues within the domains

Health problem and current use of technology

domain considers the health problems of the populations the technology is used for; the epidemiology, the burden of disease on individuals and the society caused by the health problem. It provides information of the availability and patterns of use of the technology, and describes the alternatives and regulatory status of the technology.

Topics	Issues
Target condition	For which disease/health problem/potential health problem will the diagnostic intervention be used?
Current management of the condition	What are the other evidence-based alternative diagnostic procedures, if any?

Description and technical characteristics

domain details and separates the technology in question from related technologies, and gives an overall understanding on functioning and use of the technology under assessment. Investments and the information needs regarding the technology are also considered.

Topics	Issues
Features of the technology	Who are the users of this technology? Who will be applying the technology?
Training and information needed for utilizing the technology	What information do patients and their families and general public need on the technology?

Clinical effectiveness and accuracy

domain considers the efficacy or effectiveness of the technology in terms of health outcomes and patients' quality of life. The gold standard for intervention effectiveness research is randomised controlled trial (RCT). In diagnostic technologies inferences of effectiveness are often made based on linked evidence from accuracy, change-in-management and treatment effectiveness studies, because test-treatment RCTs are rare.

Topics	Issues
Function / HRQL	What is the effect of the intervention on health related quality of life?
Change-in management	Does the use of the technology lead to a change in the physicians' management decisions?

domain also considers the potential of the diagnostic technology to correctly distinguish those with the target condition from those without (diseased from non-diseased), or to reduce the uncertainty about the presence or absence of the target condition. Sufficient accuracy is a basic requirement for a diagnostic technology that can improve management or patient outcomes. In certain situations, accuracy information alone may be sufficient to determine comparative effectiveness, e.g. when the new test is cheaper and/or safer than the existing test.

Topics	Issues
Accuracy measures	What is the reference standard and how likely does it classify the target condition correctly?
Reliability and transferability	What is known about the intra- and inter-observer variation in test of reported accuracy interpretation?

Safety

domain considers the direct and indirect harms due to the technology itself (e.g. invasiveness) or to the use of the technology (e.g. proper patient selection or learning curve), or to particular patient susceptibility (e.g. pregnancy). In addition to patient safety, the harms of the technology posed to the families and close ones of the patient, health care professionals, public and the environment, are considered.

Topics	Issues
Use or user dependent safety risks	What are the special features in using (applying/interpreting/maintaining) the technology that may worsen patient safety?
Occupational safety	What kind of employee protection is needed?