Glossary of HTA Adaptation Terms

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The aim of the Glossary of HTA Adaptation Terms is to identify and highlight key words and concepts that are easily misunderstood between countries. It provides a series of descriptions for such terms and contains examples of where the usage of these terms may differ between countries.

Please note: This glossary is intended to be a resource for identifying issues related to different uses and meaning of various HTA terms with a view to aiding the adaptation of HTA reports between settings.

Terms

A

C

D

E

G

H

M

Mini HTA

P

Planning
Policy
Policy Makers
Policy Questions
Pre-assessment
Primary Research
Protocol
Purchasing

R

Rapid Review
Relevance
Reliability

S

Secondary Research
Setting
Speedy Shifting

T

Toolkit
Transferability

Term	Description
Adaptation **Adoption** See comments on these descriptions	EUnetHTA Issue The purpose of adaptation is to enable an HTA agency in one country (or region or setting) to make use of an HTA report produced elsewhere, thus saving time and money. This sounds simple but in reality, the adaptation process is complex. Different types of HTA reports Not all 'HTA reports' are the same. Some just contain information about technologies, some also contain recommendations about how they should be used (in the English context, these are respectively 'assessment' and 'appraisal'). Of those that contain information, some are reports of new studies and some are a synthesis of research i.e. systematic reviews. Some are produced very quickly, in a few days; some take a year or more to produce. Adaptation is a part of a spectrum Making use of all or part of an HTA report from elsewhere could be done in a wide range of ways (see items 1 to 4 below). There is a spectrum, with progressively more of the original report being used and so more possibility of saving time and money through reduced duplication. Items 1 to 3 require further work beyond the use of information from the report to

Back to Top	develop your own report. *Summarising*: translate the summary and use this for background information *Updating searches*: using the original search strategy to identify any more recent evidence or adding to the search strategy and extending it. *Adapting*: the systematic extraction of relevant HTA information from an existing report (from a whole report or from part of a report) *Adopting*: making use of the report without making any changes at all (except perhaps translation into your own language) Adaptation is a process The 'product' of the adaptation process is information that has been extracted from the report that is (a) relevant to your needs, (b) quality assessed (c) critically appraised and d) is ready to be incorporated into a new framework for an HTA report in your own setting or country. The process of adaptation therefore involves, to varying degrees, the following steps: a) checking the relevance of the question(s) addressed in the original report to the question you are facing, b) identifying the information in the report which is relevant and most likely to be transferable to your setting, c) assessing the reliability of the information under various domains (benefits, harms, cost-effectiveness, organisational aspects, social and legal issues, etc), d) identifying and setting out the problems which may occur when the extracted, relevant, quality assessed information is transferred into a local HTA report; and deciding how to deal with them.
Affordability See comments on these descriptions Back to Top	DACEHTA, Denmark Here I am afraid that we cannot give any insights from a Danish setting, since it is not a term which is often used (except perhaps in economic contexts). Also we are not sure about the specific relation to adaptation. This answer might not seem very productive, but we need to consider whether it is relevant in relation to adaptation. We endorse the general descriptions, even though it could have many different meanings (affordability of an HTA-project, a technology etc.).
Back to Top	DSI, Denmark There is no standard definition of affordability, as it relates to the extent a patient or a service provider can pay for it. This will for example depend on the funding mechanism/income level and the cost of service. What is affordable health care in one country is not necessarily affordable in another country.
	FinOHTA, STAKES, Finland The main aim of determining affordability in the health care sector is to evaluate whether the expenses of the intervention can be met. In addition to an intervention's effectiveness, decision-making requires consideration of the intervention's feasibility, sustainability and

	affordability. Affordability also tells us something about the value of alternative health-care services. While considering affordability, it is important to take into account all possible costs and consequences of an intervention.
Back to Top	Iceland, Editor of Clinical Guidelines, Directorate of Health Affordability describes the means a nation / health care system has at its disposal and could allocate to a particular purchase (service). This has nothing to do with the actual decision whether to purchase or not, as this would depend on, amongst other things, the relative and absolute values of the goods. In a system, like in Iceland, where the social security service is the main purchaser (apart from hospitals) and has a fixed budget for a defined population, affordability could be affected by changes in other services (reduced or increased demand in one sector could affect another – drug expenditure vs physician services).
Back to Top	PHGEN Affordability is the capability to allocate financial funds to an individual or societal need. Thus, we see a need to differ between a society's capability to afford a health technology and the individual capability to afford a health technology which is not financed by the health care system / health insurance. The affordability is closely related to the idea of choice. Affordability has different degrees, depending on the allocation and trade-offs.
	Servicio de Evaluacion y Planificacion, Canary Islands **Description of the concept** The concept of affordability is related to the capacity of being affordable. Something is affordable when one can manage it in terms of time, money or resources. There is another context in which this term is used, which is related to the capacity to provide something. In HTA it should be a criteria to take in account when one has to make decisions about inclusión or exclusion of some intervention, treatment or diagnosis procedure, by the means of being able to cope within the budget and resources of each country. **Problems in interpretation** One of the problems in interpretation could be to assume that something which is not affordable, it is because it is expensive. This would not be correct, as what is affordable for one person; could be not affordable for another person, even though it would have the same price. It is not question of price, but of its cost in the context of the budget and resources of each health care system. Another problem is that one could only use it in the context of financial aspects, and sometimes it refers to other aspects as affordable in meanings of resources or time. Examples of how this term is used in different countries**.-** Reading the scientific literature, we can find the use of this term in different context, but basically it seems to have the same meaning in all countries. The references used to present examples of the use of the term of affordability come from different countries as Germany, Sweden, India, USA, United Kingdom and Italy.

Back to Top	• Financial context: Frequently the word affordability is used in monetary terms: • Availability of time: Affordability can be referred to with reference to time limits. • Affordability can be considered as a criteria to select interventions. Affordability can be seen as a criterion related to access to services.
Applicability (see also Generalisability & Transferability and Relevance & Reliability) See comments on these descriptions *Back to Top*	INAHTA Glossary The degree to which the results of an observation, study or review hold true in other settings.
Back to Top	AETSA, Spain Applicability should be taken into account before adaptation is undertaken. One important task should be giving recommendations to do a first judgment about applicability of a HTA report considering epidemiological, biological, organizational and socio-economic issues. Applicability is not the same that generalisability. Generalisability is a characteristic of a report whereas applicability is a judgment made taking in account the particular characteristics of a country. (I can judge a report as generalisable in more or less extend but my country may have very particular circumstances that prevent the application).
	DSI, Denmark **Issue** Applicability is closely related to generalisability, which is a prerequisite for adapting a HTA report to a local setting. As health care systems and patients are not the same in different countries, the approach or studies do not always apply to the local context Therefore, the applicability of the report must be reviewed. **Process** When testing for, or when considering, the applicability of a HTA report the researcher must decide whether the treatment effect will be similar in the population they are facing. Issues that must be considered are for example: Epidemiological issues - Does the population face the same incidence and prevalence of the conditions, or is it likely that differences significantly will alter the potential benefits and risks of the treatment or screening program? Organizational issues - Do differences in the structure of the health care

system make the technology more or less relevant (e.g. pre-hospital care in Greenland vs. pre-hospital care in Denmark)?

Socioeconomic issues - Are differences in patient or provider compliance to be expected?

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Biological Issues - Are there genetic or demographic differences in the illness under study that may lead to a different treatment response?

FinOHTA, STAKES, Finland

Applicability, in research terminology, is used when studies conducted in one setting are assessed to determine whether their results/conclusions can be used or implemented in other settings. Examples: e.g. "We appraise foreign results against local conditions and evaluate their *applicability* in Finland"

Another example of the use of term applicability comes from the implementation stage of a research project. Researchers should ensure that their results are communicated in such a way that they are applicable in daily practice.

When considering the applicability of a study report, issues on population, intervention, settings, used outcomes, and found benefits or harms should be evaluated against ones own situation or setting at hand. Specific questions on applicability are in Table 1.

Table 1. Questions on clinical applicability[1, 2]

Population	1) Are the patients described sufficient enough to decide whether they are comparable to those that you see in your practice?
Intervention	2) Are the interventions described well enough so that you could provide the same for your patients?
Settings	3) Are the treatment settings described well enough so that you could provide the same for your patients?
Outcome measures	4) Were all clinically relevant outcomes measured and reported?
Benefits worth harms	5) Are the likely treatment benefits worth the potential harms?

1. van Tulder M, Furlan A, Bombardier C, Bouter LM, the Editorial Board of the Cochrane Collaboration Back Review Group. Updated method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group. Spine. 2003;28(12):1290-1299.
2. Guyatt G, Drummond R. Users' guides to the medical literature. Essentials of evidence-based clinical practice. Chicago: American Medical Association; 2002.

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HTA agency, Poland

What we understand by ‘applicability’ is the application/use of the results from clinical trials (done on restricted, specially selected populations) to other groups/individual people for the use in one’s own medical practice (in other words, “usefulness of these results in own clinical practice”). A randomised trial only provides direct evidence of causality within that specific trial. As individual characteristics will affect the outcome for this person, it takes an additional logical step to apply this result to a specific individual.

Although closely related to concepts of generalisability and external validity, ‘applicability’ is broader in its scope, including issues related to the

[Back to Top](#)	overall impact of treatment on individual patients. Wanting to make informed decisions on health care, when considering applicability it is important to take relevant individual factors/issues into consideration like [1] : Biological Issues - differences between patients, pathophysiologic differences in the illness (whether the biology of the treatment effect will be similar in patients they are facing). Social and Economic Issues - important differences in patient as well as provider compliance (their own ability to deliver the intervention in a safe and effective manner). Epidemiologic Issues - co-morbid conditions, important differences in untreated patients' risk of adverse outcomes (their patients' risk of the target event that treatment is designed to prevent and of the side effects that may accompany treatment). 1. Antonio L. Dans, Leonila F. Dans, GH Guyatt, S. Richardson, for the Evidence-Based Medicine Working Group; How to Decide on the Applicability of Clinical Trials Results to Your Patient; Based on the Users Guides to Evidence-based Medicine and reproduced with permission from JAMA. (1998; 279(7):545-9). Copyright 1998, American Medical Association.
[Back to Top](#)	IHPRS, Slovenia ***Applicability*** of different standards or evaluations might be a problem in certain countries. Different countries have to find a criteria or a factor to apply assessments from other countries as it can not be done 1:1, especially not HTA reports related to economic or epidemiologic aspects. Applicability depends on the nature of certain HTA study. Some studies (RCT) can be transferred directly from country to country, other like economic evaluations or epidemiologic studies are not cross country applicable. In Slovenia, according to experience from other countries, the MoH suggests measures for assessment of new methods of treatment, such as: medical effectiveness (necessity of medical treatment and efficiency of the program), economic efficiency of the program, as well as social and population view.
	NOKC, Norway The Norwegian Knowledge Centre does not currently have a structured approach to assessing the applicability of external HTA reports or reviews, although issues tied to applicability and transferability are dealt with frequently. In practice, our approach when evaluating these documents resembles processes described by other institutions, including the New Zealand Guideline Group (NZGG) [1]. These issues are also described in a recent publication co-authored by two of the Norwegian Knowledge Centre's staff members as background for advice from the WHO Advisory Committee on Health Research [2]. As an important first step we begin by appraising the quality of the document by checklists developed for assessing the quality of systematic reviews. If the document is evaluated as being of high enough quality, we then go on to evaluate its relevance or potential transferability to the Norwegian setting. This is particularly done for the following areas; • the health setting or professional groups involved in intervention delivery, • the patients or consumers the intervention targets, including their specific health condition, baseline risk, expected compliance, etc, • the intervention, its current availability, cost, etc,

[Back to Top](#)	• the control intervention, and the degree in which the comparison is a relevant one in Norway, • the outcomes, and the degree in which they reflect the values and goals of Norwegian health care users and policy makers. The issue that most often hinders the applicability of an HTA-report from another agency, is uncertainties regarding the methods for how the review was undertaken. Thus developing a core model for HTA will facilitate the use of HTA-reports from other agencies. When assessing applicability of another HTA-report or systematic review we consider whether there are special circumstances that may modulate the efficacy obtained in the research setting. For instance percutaneous coronary interventions (PCI) has proven to be better than thrombolysis in acute myocardial infarction (MI). PCI need to be given within a period of less than 3 hours, but if PCI is decentralised to hospitals with few annual procedures, patient outcomes are worse than in more experienced hospitals. Thus there are certainly other factors, that are unlikely to have been dealt with in the trial setting that may modulate the expected effectiveness of the technology when applied in another setting. These factors may relate to health care system, geography, population, need for education or special competence etc. Another issue that might relate to the applicability of HTA-reports is the timeliness. If an issue is emerging with great importance, exchange of information may be extremely helpful. This may be not be a complete HTA report, but preliminary information. We have for example shared a preliminary version of our HPV-vaccination report so that other agencies may assess whether this report may be relevant to their question.
[Back to Top](#)	PHGEN The idea behind the term “applicability“ is related to the general idea of adaptation because the application of foreign HTA reports is only possible if an adaptation is possible and worth the effort. **Application as a Task** We would like to point out the key focus of the term by referring to computer sciences and the term “application software”. According to a definition “Application software is a defined subclass of software that employs the capabilities of a computer directly to a task that the user wishes to perform”. This should be contrasted with system software which is involved in integrating a computer's various capabilities, but typically does not directly apply them in the performance of tasks that benefit the user. The term application refers to both the application software and its implementation. To come back to HTA, the importance of applicability is the underlining of the wishes of the user. Thus, applicability has a different notion as the focal point is opposite to the adaptation. Adaptation calls for a general standardisation beyond the users` wishes. Applicability is reached if HTA reports are “open” to the wishes of users. **Application as a Need** The overall need for applicability is obvious and the conceptual contrast to the term of adaptation will melt away if the general standardisation acknowledges the individual need of a user. Thus, we feel the term applicability must be defined in the context. For HTA reports we should draw a distinction between the application of a HTA report as a science base as a support for an appraisal (with the new user drawing a

	conclusion) and as the appraisal itself (in the sense of an adoption).
Commissioning **Planning** **Purchasing** See comments on these descriptions *Back to Top*	DSI, Denmark Commissioning, planning and purchasing are different stages in the process of getting from a strategy or an idea to providing a service In the commissioning process, an agent will be granted authority to undertake certain functions, for example determining priorities within the defined objective. The second step in the process is the planning process. In a HTA perspective, this could involve an assessment of status quo in the given country or region and a review of strategies and services that deliver the most health gains for the patient and the best value for money for the given context. Purchasing involves choosing how to deliver the strategy and services and selecting the most appropriate service providers.
	HTA agency, Poland **Commissioning** Commissioning is sending or officially charging an individual or group to undertake certain functions or to complete certain tasks. Usually one commissions tasks that can't be completed within one's own sources to people more competent for the task. Commissioning may refer to: - report (Agency for HTA commissions academic entity to produce HTA, Minister of Health commissions producing HTA on given subject to AHTAPol); - new research (to fill gaps in knowledge). **Planning** Planning is one of the functions/activities usually carried out by top-level management /project leaders. It focuses on the preparation of plans and arrangements in order to design and control development/progress of: - the organizational structure, - the work division/tasks (for example: planning the work on a HTA report in a team of employees of Agency of Health Technology Assessment), - the project, - the budget etc. It is process of defining goals for future organizational performance, and deciding on tasks and resources necessary to attain these goals. It answers the questions: - what goals are to be achieved within given time frame, - why this goals need to be achieved, - how could/should they be achieved, - what actions are needed to be undertaken in order to achieve them, and - how to verify whether these goals have been achieved or not (and if not what other/alternative actions should be undertaken to achieve these goals). Development of the strategic plan greatly helps to clarify the organization's/project plans. When generating the plan it is essential to clearly define the purpose of the organization / project and to establish realistic goals and objectives consistent with that mission in a defined time frame within the organization's capacity for implementation. **Purchasing**

Back to Top	Purchasing is the act of buying goods (licensed medical devices, medical services) by entering into contractual agreements with suppliers by National Health Fund or health care practitioners/providers. The act of buying goods (devices) is carried out strictly in compliance with purchasing policy. According to this policy purchasing must be based on gathering information on needs from staff and patients, assessing the urgency of these needs, weighing the options and on these bases try to make informed decisions. Once placed purchasing requests for items (addressed supply requirements) are acknowledged by management and a vendor/supplier is chosen by tender. Usually the vendor who presents the most cost-effective contract pricing for the items/service/medical devices is chosen for fulfilling the purchase order.
Back to Top	Iceland, Editor of Clinical Guidelines, Directorate of Health **Commissoning** This has many meanings depending on the situation / reference. Relating to HTA it adaptation is the deligation of some task/assignment to an individual or group. This usually involves transferring some authority and responsibility to those being asked/ordered (commissioned) to performe some task. **Planning** Describes the *a priori* formulation of a scheme or strategy to attain some specific accomplishment. **Purchasing** The act of buying /obtaining goods (services) by a health funding authority with money or by other means. In Iceland this is usually the Social Security system or hospitals.
Back to Top	IHPRS, Slovenia ***Purchasing*** of health services is the process by which the most needed and effective health interventions are chosen and provided in an efficient and equitable manner, and the providers are paid appropriately from the pooled financial resources for delivering defined sets of services and interventions. Purchasing has three interwoven elements; allocating financial resources", establishing "provider payment options" and "contracting" with providers.
	Institute of Molecular Medicine, Portugal. **Commissioning** We usually use it as someone (or Institution) who is been put in charge of a specific project, or designated to lead the project e.g. "Infarmed has been commissioned to perform a thorough inspection on Pharmacies". "The Ministry of Health is commissioning The Health Observatory for finding why there is a huge waste on drugs". **Planning** The word planning is somewhat more vague in Portuguese than commissioning. Planning is mostly used when a plan is still in its first

[Back to Top](#)	steps, and nothing has been really delineated yet. Nevertheless it can also mean a real plan, and "Planning" in fact, by definition is the act of producing a plan. I think that the best word to define Portuguese "planning" is the English expression "thinking of". "Planning" is best described as "delineating a plan" or "building a plan" or "building a project". **Purchasing** We usually mean by purchasing the act of acquiring something, be it real estate, other objects or services. Considering this last aspect, in Portuguese you can say "we purchased John for this specific task" (highly used in football). It means an exchange that involves money.
[Back to Top](#)	TU Berlin, Germany The term *commissioning* can be applied to both: commissioning an HTA report or commissioning services. In the first sense it is related to the process of HTA. In Europe there are HTA agencies that have a so called general mandate which allows them to identify priorities and conduct assessments own their own initiative. However many HTA agencies in Europe perform assessments in the context of a formalised decision-making process in which an institution may (or should, or must) *commissions* the agency with the assessment of a relevant topic to inform a specific deliberative process. The *commissioning* institution assigns the HTA agency with the task of assessing an specific topic. The second sense – *commissioning services* – is more closely related to the term *purchasing.* These terms can be best understood in a model of health system in which there is an institutional separation between the health services and the institution ultimately responsible for the health of a population (i.e. community). In such a model, the providers of primary health care, hospitals, rehabilitation services etc. represent in a way the means by which the institution accountable for health care (i.e. the local health authority, the regional government, etc. depending on the organisation and on the degree of decentralisation of the system) tries to achieve its ultimate goal: the production of population health. For example a regional health authority is responsible for the health of the population living within its administrative borders and has to reach agreements for service delivery with providers in order address the health needs of its population as well as guaranteeing equal access. *Commissioning* can thus be understood as the action of assigning tasks to providers. In addition, the term *purchasing* implies a money flow between the *commissioning* institution and the provider of health services, i.e. an amount of money is allocated to the provider in relation to the task assigned. Purchasing usually implies a greater degree of separation between both actors. *Planning* refers more to the action of elucidating the health needs of a given population and allocating resources in order to meet them. In a model of separation between provider and purchaser/commissioner *planning* can be considered to be the necessary step previous to *commissioning* and/or *purchasing.* The three terms are closely interrelated and it may be difficult to draw a clear conceptual border between them when there is no clear separation of roles (provider, purchaser, etc.) in the health system. Thus in some situations they may be used interchangeably.
Core model for HTA	FinOHTA, STAKES, Finland The Core Model for health technology assessment defines and

HTA core model See comments on these descriptions *Back to Top*	standardizes elements of assessment. It supports the production of HTAs that are independent of specific context and identifies issues relevant for adaptation in national settings. The elements within the HTA Core model have been evaluated for two key characteristics: importance and transferability. In this context importance indicates how essential the element is from the viewpoint of decision making. Transferability indicates how easy it is to transfer the results from one setting to another. The importance and transferability of each element of assessment - and hence the inclusion in the HTA Core model - have been agreed on within the EUnetHTA project.
Back to Top	Institute of Molecular Medicine, Portugal. Common core HTA is best translated to “Apreciação de Tecnologia Nuclear da Saúde” or “Apreciação de Tecnologia Central da Saúde”. The first suggests more the main core of the system, whilst the second can be a little broader.
Back to Top	NOKC, Norway The HTA core model describes how HTAs are produced. Therefore, it can be described as either the method for producing an HTA or the content of an HTA. The core model can also be viewed as the product resulting from an HTA.
Back to Top	Servicio de Evaluacion y Planificacion, Canary Islands Essential common parts in the reports of HTA, independently of the topic about which it is treated.
Back to Top	TU Berlin, Germany Core model can be understood as the minimum components of an HTA report, and thus may vary from country to country. Core model can be also understood as the agreement on the minimum components of an HTA-report from an international perspective, thus representing a kind of European Standard. For Core-model definitions please refer to the EUnetHTA definition.
Conflict of Interest **Competing Interests** See comments on these descriptions *Back to Top*	INAHTA Glossary A situation in which the private interests of someone involved in the assessment or evaluation process (e.g. interviewer, rater, scorer, evaluator) have an impact (either positive or negative) on the quality of the evaluation activities, the accuracy of the data, or the results of the evaluation.
Back to Top	DSI, Denmark A conflict of interest is a situation in which a corporation or individual is in a position to exploit a professional or official capacity for their corporate or personal benefit. Competing interests can make it difficult to act impartially. Even if there is no evidence of improper actions, a conflict of interest can undermine confidence in the ability of that person to use his/her position with proper ethics. Common forms of conflicts of interest or competing interests in HTA are when outside employment or privately held business interests are in some way related to the subject of the HTA, or

	are interested in its outcome.
Back to Top	IHPRS, Slovenia A conflict of interest is a situation in which someone in a position of trust has competing professional or personal interests. Such competing interests can make it difficult to fulfill this person's duties impartially. Even if there is no evidence of improper actions, a conflict of interests can create an appearance of impropriety that can undermine confidence in the ability of that person to act properly in his/her position. A conflict of interest might exist when a person working for one organisation does research for an e.g. pharmaceutical company and presents the results at the congress. The payment of the person's trip by the pharmaceutical company in question might cause conflict of interests. In order to avoid it, no direct link between the researcher and the pharmaceutical company in financial terms should exist. Conflict of interests can occur when, for example, researchers or experts in a randomised controlled trial in a special field (e.g. neurology) do the research, write the final report and present the trial and its outcomes. In spite of this, they then also sit on the board where the adoption of the application for the specific treatment is being decided. Conflict of interests can increase into competing interests, when there is a priority list of treatments or medication. The experts in question might vote against one other proposed treatment or medication so that "theirs" does not loose a spot in the priority list. Pharmaceutical companies and the doctor who travels with the company have to sign a statement with the content that the medical doctor will not favour the specific pharmaceutical company and its products. A competing interest exists when the interpretation of data or presentation of information may be influenced by a personal or financial relationship with other people or organizations. Often researchers are asked to disclose any financial and non-financial competing interests that may cause them embarrassment were they to become public. Declaring their competing interests does not prevent an evaluation from being published.
	Institute of Molecular Medicine, Portugal. **Conflict of Interest** There has been a little arguing about what "Conflito de interesses" in Portuguese really means. We used to refer this to when a person or a group had a particular (economic or professional) interest in a task or product, and was being part of a party designated to assess the utility of this product. But its range can be wider, especially when we are speaking of health professionals, who should have different scopes for the same path: for instance physicians should use the patient perspective in some aspects of health, but should also take into account the Ministry of Health perspective or the Medical Society perspective in others, not to think of his own personal perspective. Therefore we now tend to consider "conflict of interest" as the personal perspective against the party or group perspective, as the most important "Conflict" of all the interests in stake. **Competing Interests** Competing interests add a temporal vector to the possible conflicting interests. However, competing interests may not be conflicting. Sometimes they compete for the same window of opportunity. Therefore, the success of one project (one interest) may jeopardize the success of the other. Sometimes the interests can be conflicting, e.g. "The interests of the

Back to Top	population go against the interests of the Army, competing for the ownership of the land on the east side of the river".
Back to Top	FinOHTA, STAKES, Finland The development and research activities should always be based on the principle of transparency. Internationally, financial and other conflicts of interest are being declared with increasing openness. Especially in research projects it is important to declare any financial or other interests that might influence the approaches taken by the researchers in the project or while drafting the final report. The persons' own assessment in this matter should be trusted and the information given should be dealt confidentially. Declaring financial and other conflicts of interest do not mean that the person would not be in a position to participate in the research, or that his or her conclusions would be incorrect or biased. A significant financial or other interest may, however, constitute a reason for the person concerned to decide to withdraw from participation. Unclear cases should be negotiated. If the expert has financial or other interests that he or she does not want to declare, it is preferable to withdraw from participation.
Back to Top	NCCHTA, UK The BMJ Editors and the International Committee of Medical Journal Editors define competing interests as including: financial relationships with industry (for example through employment, consultancies, stock, ownership, honoraria, and expert testimony), either directly or through immediate family; personal relationships; academic competition; and intellectual passion. Source: BMJ Editors (http://bmj.bmjjournals.com/advice/editorial_policies.shtml#competing) and the International Committee of Medical Journal Editors (http://www.icmje.org/index.html#conflict).
	NOKC, Norway In health technology assessment "conflict of interest" relates to two issues: - conflict of interest in published studies (authors, sponsors) and - conflict of interest of the people involved in the HTA. The issue of conflict of interest in published studies may interfere with the objectivity of the study. All studies should declare conflict of interest from all authors, and how the study was sponsored. How does the issue of conflict in publications apply to HTA? Conflict of interest relates to the fact that sponsoring from industry has been associated with restricted or selective publication of data. Thus, such studies may introduce bias if industry sponsored studies tend to more often report positive results (which they actually do), and withhold data from studies showing no or harmful effects. Thus should studies may introduce the bias of overestimating the effectiveness of the technology. Conflict of interest may also apply to those involved an HTA whether researchers or clinical experts. This conflict of interest should be declared in the final HTA report, and is referred to in the INAHTA checklist. When considering conflict of interest the issue relates not only to financial interests but also other issues such as allocation of money for research

Back to Top	etc. In Norway conflict of interest is declared by all involved in the HTA-process. The issue of competing interests could be viewed in relation to the issue of conflict of interest and the fact that different interests may compete with each other, and thus relate to the comments above. On the other hand competing interests may also apply to the process of HTA. Do we have competing interests in HTA? And if yes, how does competing interests apply to the HTA-process? Do we have competing interests when prioritising technologies for assessment (for instance do we prioritise questions from our payers – and are these questions the important questions for society? Do we have competing interest when selecting studies for assessment (for instance use of confidential data versus open access data)? Do we have other competing interests?
Context Specific Setting See comments on these descriptions *Back to Top*	EUnetHTA Context and setting both refer to the *place* and *time* from which the evidence for the HTA report has come and/or in which the HTA report will be used. Time and place are both important dimensions of context/setting, as are level (national, regional, local), the kind of decision being made. 'Setting' in particular is commonly used in HTA to refer narrowly to an organizational dimension of health care, such as primary, secondary or tertiary care, or community care. We commonly say that legal issues around a technology's use are context-specific, but sometimes estimates of clinical efficacy and safety can also be context-specific. This is specially likely, for instance, with surgical procedures. If HTA evidence or an HTA report are 'context-specific', this may mean that something about them cannot or should not be applied to other settings without careful adpatation. Context-specific, therefore, implies 'not generalisable' and 'not transferable'.
Back to Top	INAHTA Glossary Context: The conditions and circumstances that are relevant to the application of an intervention, for example the setting [in hospital, at home, in the air], the time [working day, holiday, night-time], type of practice [primary, secondary, tertiary care; private practice, insurance practice, charity], whether routine or emergency.
Back to Top	NOKC, Norway Context applies to the local setting in which the output of the HTA-process should apply, and may be viewed as the brokering of science into decision-making processes. In this process issues to consider are the facilitators or restrictions for applying the HTA-conclusions into the local setting. These issues are financial restrictions/facilitators, organisational issues such as hospital structure, education, speciality services, legal issues such as patients access to treatment. Clinical efficacy may be influenced by the context (trial setting). This may be especially important when assessing surgical procedures, but other contextual factors such as organisational issues, socio-demographic issues may influence the overall measured effect.

Back to Top	TU Berlin, Germany **Setting** In general "Setting" seems to be understood as the place where something occurs. The "setting" for example is the where a technology is implemented. There seems to be some confusion for this term since sometimes it seems to be a geographical concept (national setting, regional setting, local setting), sometimes seems to be a concept referred to the type of health system (NHS-setting, SHI-setting) and sometimes a concept related to the type of care or institution (ambulatory setting, hospital setting, academic setting). When a sentence like "In our setting…" is found, it is not clear which of the above it refers when further information is not provided. Thus the term shouldn't be used alone, since it might be difficult to interpret. A more accurate description of what is meant in each case (i.e. geography, health system, institutions, etc.) should be clearly preferred. **Context Specific** The term context seems to refer to quite the same issues as the term "Setting" (see "Setting") and in general it is being used interchangeably. The term "Context" however seems to be used with the intention to refer more explicitly to further aspects which characterize the "where" a technology is applied, such as cultural issued, preferences, interests, etc. "Setting" seems in contrary to be used when referring only to the characteristics of the place discussed previously (see "Setting"). "Context" seems to cover more than "Setting" and be used when referring to the whole environment. "Context Specific" seems to be used to describe such aspects or issues related to the implementation of technology which varies depending on the "where" it is the technology applied. The term it is frequently used to highlight that a piece of evidence might not be transferable to the own situation since the findings could have been different had the evidence be produced elsewhere. In this form "Context Specific" seems to be used as an equivalent to saying "Not Generalisable" or "Not Transferable".
Critical Appraisal *Back to Top*	INAHTA Glossary The process of assessing and interpreting evidence by systematically considering its validity, results and relevance.
	DACEHTA, Denmark The process of assessing and interpreting evidence by systematically considering its validity, results and relevance is a central part of doing HTA. **This definition is clear and should be preserved**. The specific process of critical appraisal is probably done in different ways in different organisations/projects, but the main request must be that **the process is reliable and is documented in a transparent way**.
	DSI, Denmark Critical appraisal is the process of systematically examining research evidence to assess its validity, results and relevance before using it to inform a decision. Critical appraisal is one step in the process of evidence-based decision making. Critical appraisal skills are necessary to determine what the evidence is for the local contest. Relevance of health care

Back to Top	research might be different countries, as different countries have organised there health care systems differently Most health care research is not perfect or perfectly relevant for a specific decision context and critical appraisal is not an exact science, but systematically applied it can guide decisions of whether a reported piece of research is good enough to be used in decision making. If research has flaws, it is up to readers to use their critical appraisal skills to decide whether and how this affects the usefulness of the research paper.
Back to Top	IHPRS, Slovenia ***Critical Appraisal*** is the process of systematically examining research evidence to assess its validity, results and relevance before using it to inform a decision. In Slovenia, both assessment and critical appraisal have the same meaning and they are used for closing the gap between research and practice. Critical appraisal means that the bias needs to be avoided and the most appropriate design for studying the effectiveness of an intervention or treatment has to be implemented. Systematic reviews are particularly useful because they usually contain an explicit statement of the objectives, materials and methods, and should be conducted according to explicit and reproducible methodology. Randomised controlled trials and systematic reviews are not automatically of good quality and should be appraised critically.
Back to Top	NCCHTA, UK The process of deciding whether a piece of research can help you in answering your clinical question. There are three questions you need to ask about any kind of research: - Is it valid? - Is it important? - Is it applicable to the patient? Source: Centre for Evidence Based Medicine, Oxford
Efficacy **Effectiveness**	**Please note**: The term "**efficacy**" has a specific definition when used by drug licensing companies.
See comments on these descriptions *Back to Top*	INAHTA Glossary **Effectiveness:** The benefit (e.g. to health outcomes) of using a technology for a particular problem under general or routine conditions, for example, by a physician in a community hospital or by a patient at home. **Clinical Effectiveness:** The extent to which a specific intervention, procedure, regimen, or service does what it is intended to do under ordinary circumstances, rather than controlled conditions. Or more specifically, the evaluation of benefit to risk of an intervention, in a standard clinical setting, using outcomes measuring issues of importance to patients (e.g. ability to do daily activities, longer life, etc.). **Efficacy:** The benefit of using a technology for a particular problem under ideal conditions, for example, in a laboratory setting, within the protocol of a carefully managed randomized controlled trial, or at a "center of excellence."
	HTA agency, Poland **Effectiveness and Efficacy** As for Effectiveness and Efficacy, we do not think, that there can be problem with mistaking this two terms.

Back to Top	As “Efficacy” refers strictly to the trial setting it is difficult to even assume to what extent, the effects obtained in such “ideal” setting can be generalized outside to clinical practice, where the conditions as well as characteristics of treated population differs. Although high quality, randomized clinical trials provide the most reliable evidence on the benefit of the new treatment over the standard, the Polish guidelines for conducting HTA reports suggest, that the effectiveness of the medical technology should be taken into consideration, as it reflects the effects of an intervention as measured in a situation similar or very similar to common clinical practice.
Back to Top	Iceland, Editor of Clinical Guidelines, Directorate of Health **Efficacy:** Describes how well or badly some input (intervention/ health technology like drugs, screening program etc) works under ideal circumstances whether artificial (research setting) or natural (created by for example geography, captive population). **Effectiveness:** Describes how well or badly some input (specific interventions / health technology like drugs, screening program or other services etc) works under usual circumstances (real world or usual practice).
Back to Top	NOKC, Norway Efficacy refers to the trial setting, and thus any HTA need to consider whether the results obtained in clinical trials can be generalized outside to clinical practice. In some instances “real world” studies are conducted to evaluate real world effectiveness, such studies are however often registry based and thus not of a design comparable to study designs most often included to analyse efficacy. We and probably other HTA-agencies are often faced with the question – what is sufficient documentation of effectiveness? This question would be important to discuss within EUnetHTA, and one might consider some approaches that include consideration of the amount and quality of clinical trials, use of surrogate measures, time for follow up etc. Another potential problem arises when efficacy is derived from confidential information. How do we handle the fact that agencies within Europe have different approaches to the use of confidential information and how would this influence the sharing and using of reports from other agencies?
Back to Top	PHGEN Efficacy is the extent to which a specific intervention, programme or service produces a beneficial result under ideal conditions. The definition of ideal conditions is based on the results of a randomized controlled trial. Effectiveness is the extent to which a specific intervention, programme or service, when developed in the field, does what it is intended to do for a defined population.
	Servicio de Evaluacion y Planificacion, Canary Islands In a medical context it indicates that the therapeutic effect for a given intervention (e.g. intake of a medicine, an operation, or a public health measure) is acceptable. Efficacy in this context refers to a consensus that

[Back to Top](#)	it is at least as good as other available interventions to which it will have ideally been compared to in a clinical trial. For example, an efficacious vaccine has the ability to prevent or cure a specific illness in an acceptable proportion of exposed individuals. In strict epidemiology language, efficacy refers to the impact of an intervention in a clinical trial, differing from effectiveness which refers to the impact in real world situations. Effectiveness: Doing things "right" Efficacy: Doing the "right" things
[Back to Top](#)	TU Berlin, Germany The terms “effectiveness” and “efficacy” seem to be used as synonyms and to be quite interchangeable, despite formal conceptual differences between both. To my knowledge this might be due to translation difficulties (in German for example “Efficacy” is usually translated as “Wirksamkeit” and “Effectiveness” as “Wirksamkeit unter Alltagsbedingungen”, which is then too often shortened leaving “Wirksamkeit” alone again). The confusion might be also due to lack of clarity on interpreting whether the conditions of a trial were so far a way from conditions in every day practice. Thus in front of a piece of evidence it might be difficult to separate both terms clearly, this leading to interchangeable use of both. Some separate both concepts depending on how the evidence was gathered; speaking of “Efficacy” when they refer to the effect measured in a randomized controlled trial and of “Effectiveness” when the effect has been measured based for example on routinely collected data (epidemiological, administrative, etc.). Another way to separate both concepts might be along the phases of drug developing i.e. depending of the results come from a Phase II, III or IV trial, this however could only be applied to drugs since the phase differentiation does not apply to other kinds of interventions. Other differentiations can be made on the basis of whether the data analysed refer only to the persons who got the intervention (analysis per protocol) or in contrast the persons who did not get the intervention (intention-to-treat analysis). The former would give an estimate of “Efficacy” the latter would be closer to the concept of “Effectiveness”. In order to facilitate adaptation following simplified definitions of both concepts could be taken as a starting point: - “Efficacy” effects of an intervention as measured in a situation unlikely to be widely found. - “Effectiveness” effects of an intervention as measured in a situation similar or very similar to common practice. Following this understanding, a report should speak about “Efficacy” when referring to evidence of effects gathered in studies whose conditions are very artificial and not likely to be found in common practice (independently of whether they were RCTs or other kinds of studies). “Effectiveness” should be used when referring to evidence of effects gathered in studies in which the conditions are similar or very similar to common practice (independently of whether they were RCTs or other kinds of studies). One can also speak about “Efficacy” when the assessment has modeled the effect taking evidence from studies on “Efficacy” as starting point and adding evidence from other sources on other terms of the equation (e.g. compliance, diagnostic accuracy, etc.).
Equity	INAHTA Glossary

See comments on these descriptions *Back to Top*	Fairness in the allocation of resources or treatments among different individuals or groups.
Back to Top	FinOHTA, STAKES, Finland Within an HTA project equity can be defined as fairness when allocating resources and interventions among individuals or groups. Equity issues are important both in relation to needs and access to services. Equity as an ethical imperative has to be taken into account when organizing health care systems, setting goals, and allocating health care resources. It is important that decision makers understand that they hold equity assumptions, which are likely to have implications to their decisions. They have to think which individuals or population groups may benefit from a health intervention or perhaps be penalised by that intervention. Population characteristics such as age, gender, ethnicity, geographical area, socioeconomic conditions, or health status may be relevant for equity purposes. Due to limited health care resources it is not possible to afford everything. Equity includes also the right to get effective and safe treatment. Choosing outcome measures may have equity implications. For example the use of QALY as an outcome measure implies that each unit of measurement is considered equal regardless of who gains. By using QALYs, it is assumed that a small gain to many people is equally desirable as a large gain to a few as long as the QALY totals are the same. One example of the use of equity is reported by Teperi et al. (2006)(http://www.stakes.fi/verkkojulkaisut/raportit/M233-VERKKO.pdf) where they concluded that allocating services has not happened according to equity principles. In relation to needs, well paid people get more surgical treatments, physical examinations and psychotherapy.
	NOKC, Norway The Norwegian Knowledge Centre has paid little attention to the issue of equity in our work in general and in the use of external HTA reports and reviews in particular. Our responsibility for an international conference on the issue of equity in 2006 [3] has, however, raised our awareness of this issue. The conference also led to a publication that serves as background for advice from the WHO Advisory Committee on Health Research [4]. Here, the authors give recommendations of how issues of equity should be addressed in the development of systematic reviews and guidelines. The authors make use of Braveman and Gruskin's definition of equity as "the absence of disparities in health that are systematically associated with social advantage or disadvantage" [5]. In addition, they refer to Whitehead's definition of inequity: "differences in health which are not only unnecessary and avoidable but, in addition, are considered unfair and unjust" [6]. The authors point to a number of dimensions that can influence a person's access to healthcare and health, including economic status, occupation, gender, ethnicity, class, caste, religion, status grouping, age, disability, place of residence, geographical location, and manifest sexual orientation" [4]. All of these dimensions are of relevance in Norway, although some

Back to Top	aspects may be more important than others. *NOKC do include ethical considerations in selected HTA-reports, and equity is dealt with as part of the ethical assessment.*
Back to Top	PHGEN The idea of equity in health services must be seen in close relation to the principles of justice, fairness and non-discrimination. Equity can refer to both the level of health care provide and the access to health care. Equity therefore can be outcome or "opportunity" oriented. Equity also requires health literacy as health care users must be empowered to use health care system. From an individual point of view, equity describes what the individual reasonably can expect from a solitary health care system.
Back to Top	Servicio de Evaluacion y Planificacion, Canary Islands **Issue** Equity, together with efficiency are two of the main driving principles in health care planning and provision of care in publicly financed health care systems. The concept of equity is a complex concept, but most would agree with the definition of "equal access to equal treatment for people with similar level of need". One of the main objectives of the policy makers is to reach the adequate balance between equity and efficiency. **Relevance and dimensions of equity in HTA** Equity has a relevant role in different stages of HTA 1.- Allocating resources according economic evaluation results from (eg.) cost-effectiveness analysis. It is important to note, however, the lack of consensus about the adequacy of cost-effectiveness analysis to promote equity in health care resources distribution. 2. - Fair distribution of health technologies, ensuring "equal access" once the incorporation of a specific technology has been decided. **Example** A good example of a health technology that increases equity in access to care is telemedicine; given its capabilities to provide a wide range of health care services to underserved people in remote places. Telemedicine is also a good example of a technology that adequately combines equity and efficiency.
Back to Top	TU Berlin, Germany For this term I cannot figure many conflicts or misunderstanding in its use. To my knowledge it is predominantly used according to existing definitions. Sometimes it might be confused with "equality" or with "justice". To my knowledge most of HTA-reports to date did not deal with "Equity" at least formally or in a systematic way.
Evidence Synthesis **Secondary Research** Back to Top	*Please note: "Evidence synthesis" and "Secondary Research" are treated here as meaning the same.* INAHTA Glossary Research that does not generate primary data but that involves the qualitative or quantitative synthesis of information from multiple primary studies. Examples are literature reviews, meta-analyses, decision analyses and consensus statements.

Back to Top	NCCHTA, UK Using scientific methods to summarise knowledge in an area. HTA evidence synthesis usually includes a systematic review (based on a clearly formulated question, using systematic and explicit methods to identify, select and critically appraise relevant research, and to collect and analyse data from the studies included in the review). It may also include meta-analysis (statistical methods to combine research) and economic evaluations based e.g. on decision modeling.
Generalisability **Transferability** (see also Applicability and Relevance & Reliability) See comments on these descriptions Back to Top	**Please note**: There is no consensus agreement as to the exact definition of the word "**transferability**" with reference to HTA. Please be aware that your personal views as to the exact meaning of this term is likely to differ from that of the author(s) of a HTA report in which you read it.
	EUnetHTA – WP5 Toolkit Generalisability refers to whether the results of an HTA report can be extrapolated to other settings. This is sometimes referred to as 'external validity'. For the WP5 toolkit, transferability is about the ability to apply information and/or data from one report into a report for the user's target setting. Transferability is dependent on context specificity. Generalisable information/data can be readily adopted. However, the more context specific, the less likely that data/information in one report can be adopted into another i.e. transferred without making any changes or additions. Each domain of the WP5 toolkit includes transferability questions and links to relevant resources. The purpose being to help the user decide whether they can adopt, need to adapt or disregard specific information/data when applying these to their target setting.
Back to Top	INAHTA Glossary Generalizability is the degree to which the results of a study or systematic review can be extrapolated to other circumstances, in particular to routine health care situations.
	DACEHTA, Denmark Generalisability and transferability both refer to the degree to which results of an HTA can be extrapolated to other circumstances or settings. The two terms are often seen as having the same meaning, and are very closely related. It could however be desirable to ascribe different meaning to the terms. One possible way of separating the two terms is as follows: Generalisability basically refers to the external validity of an HTA. In general this refers to both interventions, outcomes, units and settings. Generalisability as a concept grows out of research methodology Transferability refers to the organisational context dependent questions. Is it possible to envision transfer to another setting based on the information in the HTA? Transferability grows out of policy analysis / political science. Transferability can be seen as a subcategory of generalisability. It is however extremely important to focus on the transferability (setting) question when it comes to adaptation (especially concerning

Back to Top	organisational questions) since the selection of relevant HTAs (or other parts of the HTAs than the core) for adaptation relies heavily on an assessment of the context dependent parts of the HTA. Furthermore it is important to stress that question of generalisability both include statistical and analytical generalisation; external validity and construct validity. Another interpretation of transferability (often used in organisational theory) could be that it is not as closely related to generalisability, but rather related to the description of the process of transferring one idea, in this case the HTA report, from one field to another.
Back to Top	FinOHTA, STAKES, Finland In our view transferability should not be understood as something related to "organisational context" only. Two countries may have similar organisational structure, but transferability may still be an issue (if e.g. the genetic profile of the populations is different).
	HTA agency, Poland **Generalisability** 'Generalisability' is the extension of specific research findings and conclusions from a study conducted on a (relatively limited) sample population to the population at large (for example to the whole population of the country). In many ways, generalisability amounts to nothing more than making predictions based on a recurring experience. Having collected sufficient data to support a hypothesis, a premise regarding the behavior of that data can be formulated, making it generalisable to similar circumstances [1]. There is small but significant difference between 'applicability' and 'generalisability' - The more generalisable a finding (ex. multinational RCT) the better regarded it is, however the more generalisable a result the less applicable it is to specific populations (ex. specific race). **Transferability** Transferability is the ability to apply something that has already been implemented in another context with regard to consequences resulting from certain differences. Example: Transferring chosen (applicable) data, results/conclusions on medical technology in question from existing HTA report. Ability to transfer experience, results, conclusions from one research to other (different but comparable) population. This term may refer to possibility to 'transfer': data (economic, clinical results/published evidence), methods, principals, policies. Transferability of economic data in health technology assessment defines key variable economic data, defines guidelines for acceptance data from outside a country taking into consideration existing national guidelines. Transferability of costs (and cost-effectiveness) estimates between populations/countries remains problematic. When transferability of data is doubtful/limited due to their specificity - calculations and even conclusions may need to be reworked for different setting. Transferability can be considered in regard to developing organization (like AHTAPol), where it enables to set its own principles, objectives (although

Back to Top	based on the best practice/experience of other Agencies) own priorities, to have control over institutional building, and to evaluate progress in development from its own perspective rather than from that of an external agency. Transferability can be understood as process performed by readers of research (doers of HTA report among them). This process is based on comparing the specifics of the research situation to the specifics of an environment or situation, which are familiar to the reader. If there are enough similarities between the two situations, it is possible to infer that the results of the research would be the same or similar in the other situation [1]. Whereas 'generalisability' is based on the extension of the use/application of conclusions, the 'transferability' is done based on parallel transfer/application of these conclusions to other but comparable settings. 1. Overview: Generalisability and Transferability, Colorado State University web site - http://writing.colostate.edu/guides/research/gentrans/index.cfm
Back to Top	IPHRS, Slovenia **Generalisability** - is the degree to which the results of a study or systematic review can be extrapolated to other circumstances, in particular to routine health care situations. Measurements can be used for different purposes. The same measurements will be used for introduction of new programmes or new technologies, such as equipment, medical-technical devices and pharmaceuticals, for extension of the current programmes and treatments (as well as reduction of waiting periods) and organisational and other changes in the health care system. In controlled clinical trials some research or introduction of new pharmaceuticals or technologies might look efficient; however it may not be when applied to real life, with no control and different knowledge of staff having to deal with other factors. And if the study is transferable with no major problems, the degree of generalisability is high. **Transferability** - The ability to use knowledge appropriately and fruitfully in a new or different context from that in which it was initially learned. For example, the new technological solution can be applied to other hospitals in the country or even into other countries.
Guideline **Guidance** **Advice** **Protocol** (see also Health Technology Appraisal) See comments on these descriptions *Back to Top*	**Please note**: • In the UK, the term "**guidance**" in the context of HTA refers to the reports produced by NICE. • In France, the term "**advice**" in the context of HTA refers to whether health insurers are required to reimburse the cost of a health technology. INAHTA Glossary Clinical Practice Guideline: A systematically developed statement to assist practitioner and patient decisions about appropriate health care for one or more specific clinical circumstances. The development of clinical practice guidelines can be considered to be a particular type of HTA; or, it can be considered to be one of the types of policymaking that is informed or supported by HTA.
	FinOHTA, STAKES, Finland

What is a Guideline?

The purpose of a guideline is to assist practitioners and patients in making decisions about healthcare interventions in a specific situation (IOM 1990?)

Different types of guidelines

Guidelines are produced through different processes and their quality varies. Evidence based guidelines are based on a systematic analysis of existing literature and appraisal of the evidence. Guidelines can also be based on a consensus of clinical experts, stakeholders etc.

The level of evidence for each existing guideline depends on the quality and amount of existing studies and on uniformity of this evidence.

Guidelines need to be updated at regular intervals. New research may either strengthen or weaken the evidence.

What is guidance?

Guidance is information or counseling as to how or where a particular disease or situation can be handled. Guidance can been given orally, in written documents or through media (TV, web, videos). In clinical practice the purpose of guidance is to help people make their own decisions based on their values. Within health care the purpose of guidance is to instruct the health care providers for optimal use of resources.

Guidance is a spectrum

Guidance includes information on a range of topics. Guidance can e.g. give information to pregnant women on the content, meaning and consequences of participating in screening for fetal abnormalities. Guidance provides information on how to calculate your personal risk for a disease (e.g. heart diseases- blood pressure, age, cholesterol level etc.). Guidance can also include recommendations on reducing your risk (e.g. how to stop smoking, reduce drinking etc.).
The legal status of guidance varies from country to country and may also be dependent on the context of the issue in question. It may provide legally binding boundaries for those patient groups that are to receive a specified treatment (e.g. reimbursement of a drug for only specified types of patients with the same disease). It may also give various options as to how a specified issue should be handled within a health care system (e.g. alcohol abuse).

Guidance is a process

Guidance does not give straightforward answers to the patient but helps the person to understand the process or intervention. The person should be given as much guidance as she/he needs in order to make her/his own decision.
Guidance is changed with increasing knowledge, changes in existing resources etc.

What is advice?

Advice is a statement or opinion as to how one should proceed. The purpose of advice is to influence.

Advice can be based research evidence, professional experience, personal opinion/experiences or even societal norms.

	As advice tries to influence it includes clear recommendations as to what to do, where to go, what to decide etc. The advisor has already made the value laden weighing of different options. **What is Protocol?** Protocol is a set of directions or rules regarding a sequence of activities in a specified situation or setting. The directions are formulated in advance and are recorded in some way. The purpose of a protocol is to give a general structure for the activities and by doing so to help collaboration between persons, organisations and societies. **Different types of protocol** Since a protocol has been devised for a special operational environment, it varies from one context to another. A protocol can direct a clinical procedure. Other examples are research protocols (including those for HTA) and specified rules regarding data transmission. Updating of protocol
Back to Top	A protocol should be amended when it becomes necessary e.g. to improve functioning of an organisation.
	HTA agency, Poland **Protocol** In terms of HTA, protocol is a detailed plan that by providing a list of steps or procedures, guides the development of full HTA report. A protocol usually contains: introduction, objectives of the report, methodology to be followed (ex. inclusion criteria for clinical trials, methodology of data extraction and their analysis), role of each person involved in the process, detailed search strategy, time frame for all stages of the developing full HTA process. The objective of a protocol is to inform all stakeholders and other HTA agencies about the undertaken HTA report and avoid the unnecessary doubling of the work. Protocol also enables reviewer to verify whether the whole process has been carried out properly, and if yes it enables others to update search on topic in question, by using search strategy determined in protocol. In accordance with the Order of the Director of the AHTAPol of the 27th of March 2007 on preparing recommendations regarding financing medical technologies from public sources, protocol shall constitute a fixed step in procedures of developing full HTA report, implemented by the AHTAPol. As we have no good example of protocol developed by AHTAPol yet, but we consider that the best example of a protocol would be any protocol regarding systematic reviews provided by Cochrane Collaboration. **Guidelines** There is no doubt, that the purpose of a guideline is to assist practitioners and patients in making decisions about healthcare interventions in managing a specific health condition. Guidelines are produced through different processes and their quality varies. Evidence based guidelines are (usually published) documents based on a systematic review of existing literature and appraisal of the evidence, which are updated regularly. The level of evidence for each existing guideline depends on the quality and amount of existing studies and on uniformity of this evidence. Guidelines need to be updated at regular intervals as the results of new research may either strengthen or weaken the evidence on effectiveness or safety of the medical technology in question.

[Back to Top](#)	In terms of HTA, the AHTAPol has developed the Guidelines conducting Health Technology Assessment that has recently been implemented into practice with the Order of the Director of AHTAPol of 27th of March 2007. The basic objective of this guidelines is to assure a high quality standard of conducting health technology assessment in Poland, namely a high reliability credibility of assessments carried out in accordance with the guidelines. The second, equally important objective is to assure the highest possible repeatability of results and to limit differences occurring in assessments of the same technology by different authors, as well as to increase verifiability of results of assessments made for the use of the Agency. The guidelines for conducting health technology assessments are aimed at: • enabling the Consultative Council to formulate their recommendations according to transparent and open principles, based on reliable and credible assessments of medical technologies, • enabling decision-makers, on the basis of presented recommendations, to establish to what extent they can rely on those recommendations, i.e. to what extent the recommendations are justified and credible. **Guidance** In Poland there are few clinical practice guidelines, the most common document that serves as assistance for practitioners in making decision on adequate management of specific conditions is “guidance”. The guidance is usually developed by a consensus of clinical experts, usually based on the reference guidelines developed in other countries, which quality of evidence for making recommendations has been approved and acknowledged. Guidance refers to best practice used at local setting (sometimes region, sometimes hospital). For instance the practice used in treating one condition may slightly differ from one hospital to another, although both are accepted and in accordance with guidelines. Example: One hospital may treat a mild relapse of multiple sclerosis with regard to its severity and use 0,5g of methylprednisolone administered i.v. for 5 consecutive days for mild relapse and 1,0 g of methylprednisolone administered i.v. for 3 consecutive days for medium and severe relapses, whereas other hospital may administer 1,0 g methylprednisolone i.v. for 3 consecutive day with no regard to “severity” of a relapse. **Advice** In our hierarchy of sources of recommendation for medical technology, advice places at the very bottom, as often it’s a recommendation made by an individual, who is guided by his subjective opinion and beliefs based on own experience and not necessarily based on EBM reasoning.
	Institute of Molecular Medicine, Portugal. Guidance is best translated to “Orientação” or “Guias”. The first one is the nearer to English version. Nevertheless, it is very similar lexically to the next word Guidelines which in Portuguese has been translated to “Normas de orientação” for some time now.

Back to Top	Guidelines has been translated to “Normas de orientação” and the term is well consolidated in our country. Protocol has long been translated into “Protocolo” in our country. Advice is best translated to “Aconselhamento” which literally means counselling in Portuguese, and is much nearer the English version than “Conselhos”.
Back to Top	NCCHTA, UK Guidance in the UK context is the generic term for advice given to health services. It may have the force of law or it may be more optional; it may be produced by NICE or by other national bodies, or it may be produced locally. NICE guidance aims to ensure that the promotion of good health and patient care in local health communities is in line with the best available evidence of effectiveness and cost effectiveness. NICE produces guidance in 3 main areas: Guidelines Health technologies (there are two kinds of guidance here, technology appraisals and interventional procedures guidance) Public health (there are two kinds of guidance here, intervention guidance and programme guidance) NICE guidelines are recommendations on the appropriate treatment and care of people with specific diseases and conditions within the NHS. “They are based on the best available evidence. While clinical guidelines help health professionals in their work, they do not replace their knowledge and skills. Good clinical guidelines aim to improve the quality of healthcare. They can change the process of healthcare and improve people's chances of getting as well as possible.” (Source: NICE website)
	PHGEN The interconnection of the given terms: Guidance is the concept involved when a HTA reports guides the new user through a certain field. We feel that this term is rather far from the core of HTA as HTA reports should either empower the user to make his own decision or to offer the user an option that the user can either adopt or modify. Guidance might refer to HTA reports as a science base but due to the other terms mentioned we assume that this is not meant here. Guidelines are used as a very broad concept in Germany which makes it difficult to apply it directly to HTA. Guidelines are widely used as a checklist which puts a duty for justification on anybody who wants to withdraw from the guidelines. Guidelines in the sense we use it are part of a normative, regulatory concept and we do not see how HTA is connected to this normative concept. Guidelines may follow due to the results of an HTA report but a HTA report is not a guideline itself as the guideline must be approved by a relevant, democratically legitimised body. The term Protocol is used very seldom in Germany with reference to HTA. In the computer sciences protocols are used to prove who has been working on which issue at what time. We don’t see any connection between a protocol and the adaptation except the possibility to inform a foreign user who has changed reviewed or modified the HTA report at what time. Usually only the group of scientists, the institution and the dates when the literature review and the submission were performed are highlighted. We would not call this a protocol.

[Back to Top](#)	Advice is one layer of the HTA report as we understand the concept of HTA in Germany. Many HTA reports do not include a straight advice but rather deduce certain advice from the science base as described in the report. Advice in its core sense would refer to appraisal as a final step of a HTA report. We would not use the term advice directly with regard to the science base of a report, neither the medical nor the health-economic evidence presented. How to link the terms for the purpose of HTA? From the German perspective we would not use these terms at all. As already mentioned the Protocol is far from being HTA relevant. Guidelines are a normative concept and therefore do not fit into HTA reports. Guidance is somewhat too neutral and refers to an idea of HTA which is not shared in Germany. Advice seems to be limited to the appraisal and this is the part of the HTA report which should have the least impact on other health care scientists and decision makers as advice only works in a situation where the foreign state can adopt the HTA report. Due to the different health care systems and the different spread-sheet-models used we assume that adoption is rather unrealistic in most cases. Thus, we would not use these terms for the adaptation process as they might be misleading.
[Back to Top](#)	TU Berlin, Germany These terms may be used as synonyms in many situations, specially by non-native English-speakers. In some languages, the translation for *guideline, guidance* and *protocol* may refer to the concept of Clinical Practice Guidelines and thus be completely interchangeable. However, the terms may have slightly different meanings specially concerning the degree of legal-binding. In some countries a *guideline* has to be followed, otherwise some kind of sanctions may be the consequence (i.e. not reimbursement of a procedure). Guidance can be interpreted as "orientation", i.e. as something which can or should be followed, but without any sanctioning enforcement (i.e. it is not legally binding). Protocol can be understood as a road map on how to act in front of a specific clinical situation (e.g. fever of unknown origin, weight loss). Protocols are often illustrated with a flow chart, in which the different steps as well as the decision-nodes are shown. In some countries/ contexts protocols my refer to local (e.g. hospital or primary health care centre) action plans which should be followed when a clinical problem presents. Advice can be translated as recommendation or orientation. Thus it can be considered to have no legal-binding character. In contrast to guidance – which may refer more to providers or clinical decision-making – advice refers more to decision-making at the macro- or meso-level.
Health Technology [Back to Top](#)	INAHTA Glossary Any intervention that may be used to promote health, prevent, diagnose or treat disease, or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures and organisational systems used in health care.
Health Technology Assessment **Health Technology Appraisal**	INAHTA Glossary Health technology assessment (HTA): the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a

(see also Guidance) See comments on these descriptions *Back to Top*	variety of methods.
Back to Top	Austrian Health Institute We agree with the definition from the European Parliment (1998): Health Technology assessment is the comprehensive evaluation and assessment of existing and emerging medical technologies including pharmaceuticals, procedures, services, devices and equipment in regard to their medical, economic, social and ethical effects. http://www.europarl.europa.eu/workingpapers/saco/pdf/101_en.pdf
Back to Top	DACEHTA, Denmark HTA is a multidisciplinary process that summarises information about the medical, social, economic, and ethical issues related to the use of 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 scientific methods. **The content of HTA** HTA is currently being done in a lot of different ways, partly due to political demands and traditions in different countries. In some places HTAs consist of systematic reviews and economic evaluations while other organisations do more broad-spectred assessments. However, the concept of HTA has traditionally been defined by multidisciplinarity and inclusion of a wide number of issues, which can contribute to assessment of prerequisites / conditions for and consequences of the use of technologies in health care. **HTA vs. Health Technology Appraisal** HTA is a general term which is used in all organisations that are working with HTA, whereas Health Technology appraisal seems to be used mainly in the UK. The two terms relates to the fact that HTA when it successfully meets its aim of informing policy is taken into a political process with (possible) recommendations and policy advice. In some countries, UK being the best example, the actual assessment and the policy advice is (organisationally) separated into assessment (the scientific evaluation) and appraisal (the policy advice or perhaps even the actual policy based on the assessment). In other countries the term HTA also include the process of recommending and giving policy advice, even though the active involvement in this part of the policy process is limited in most HTA-organisations.
	Institute of Molecular Medicine, Portugal. Health Technology Assessment can be translated to “Descrição de Tecnologias da Saúde”or “Avaliação de Tecnologias da Saúde”. The first stresses more the descriptive part of the assessment, without critical evaluation. The second takes into account some type of basic evaluation, which sometimes do not include judgment. The second one is the most near the English version.

Back to Top	Health Technology Assessment is more like “There is a health technology which…” Health Technology Appraisal is best translated to “Apreciação de Tecnologias da Saúde” or “Análise crítica de Tecnologias da Saúde”. Both imply some kind of judgement. The first is more polite, whereas the second is more rude and face-to-face. The first one is perhaps the nearer to the English version. Health Technology Appraisal is more like “There should be” or “There should also be provided” or “There is but shouldn’t”.
Back to Top	NCCHTA, UK The aim of HTA is to ensure that high quality information about the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, provide care in, make policy for and manage the NHS. In the UK context, the distinction between assessment and appraisal is (put simply) the difference between information and guidance. Health technology assessment is the analytical process of gathering and summarising information and then presenting it. Health technology appraisal, by contrast, is the political process of producing guidance [cross link here to guidance], taking into account the assessment information but also other factors (e.g. values, political factors, the availability of resources). The term 'appraisal' is also used to refer to a particular kind of guidance: specifically, NICE guidance on technologies.
Back to Top	Servicio de Evaluacion y Planificacion, Canary Islands Health technology assessment is concerned with the evaluation of medical, organizational, economic and societal consequences of implementing health technologies or interventions within health systems. To do so, a high degree of multidisciplinary cooperation and scientific (methodological) competence is required. Health technology appraisal is a more recent concept and still not well enough known and implemented in countries other than the UK. HT appraisal is a process that follows after some specific health technology assessment has been made. Its main concern is about guiding the use of the technology. Although the aim of HT appraisal is attractive, the process (methods) to develop the appraisal as well as its expected outcomes are still in a very early stage of development. More over, to perform the appraisal, a different group profile is needed, with the presence of clinicians and patients. Both terms are clearly additive.
Policy Policy Makers Policy Questions Clinical Question See comments on these descriptions	EUnetHTA Clinical question. In the field of evidence based healthcare, the patient-intervention-comparison-outcome (PICO) formula is widely used to construct a clinical question. P - patient, population of patients, problem I - intervention (e.g. a therapy, test) C - comparator or control (e.g. another therapy, placebo) O - outcome This formula helps users to combine all elements of the clinical scenario in

Back to Top	an orderly fashion. PICO works well for HTA effectiveness questions. PICO is also used to help formulate search strategies, when clinicians are looking for relevant evidence to help them answer a clinical question. An HTA research question is the question which the HTA report seeks to answer in a scientific way. Typically, it will include a number of different PICO questions and other research questions. A policy question is a question posed by policy makers, those who in the context of HTA have to make decisions about the health care that groups of people will be offered. It may be very poorly differentiated (such as, "what are we going to do about drugs for Alzheimer's disease?") or more precise ("for which patients should donepozil be prescribable on the NHS?"). In summary, a policy question is about what to do; an HTA question is about what we know; and a clinical question is about the evidence relating to a particular patient or group of patients.
Back to Top	DSI, Denmark A policy is an overall plan embracing general goals or ideas. It will almost always include an objective and some method of action selected among alternatives to guide decisions. A policy question is the object for the overall policy or related one of the alternatives. For example a heath policy could be treatment of patients' diabetes and a policy question related to that policy could be how often the patients with diabetes type II should be screened for retinopathy. Policy makers are individuals who make decisions at the policy level that have a political impact. It is often individuals who have reached their office via the electoral process (or are appointed by those who did). In an HTA perspective, it could just as well be leading doctors or hospital department who are so respected among there peers, that other professionals generally follow their policies or guidelines.
Back to Top	NCCHTA, UK A policy is a course or principle of action adopted or proposed by an organisation or individual. A policymaker is a person responsible for or involved in formulating policies. (Source: Oxford English Dictionary)
	Servicio de Evaluacion y Planificacion, Canary Islands Policy A **policy** is a predefined plan of action to guide decisions and actions. The term may apply to governments, private sector organisations, groups, or individuals. The policy process includes the identification of different alternatives, programs or priorities, and choosing among them on the basis of the evidence about the impact they will have. Policies can be understood as political, management, financial, and administrative mechanisms arranged to reach explicit goals. The goals of policy may vary widely according to the organisation and the context in which they are made. Policies are typically instituted in order to avoid some negative effect that has been noticed in the organisation, or to seek some positive benefit. The **policy cycle** is a tool used for the analysing of the development of

[Back to Top](#)	a policy item. It includes the following stages: 1. Agenda setting 2. Policy formation 3. Decision-making 4. Policy implementation 5. Policy evaluation (continue or terminate) **Policy Typology** Policies may be classified in many different ways. The following is a sample of several different types of policies broken down by their effect on members of the organization: 1.- Distributive policies extend goods and services to members of an organization, as well as distributing the costs of the goods/services amongst the members of the organization. Examples include government policies that impact spending for welfare, public education, highways, and public safety, or a professional organization's policy on membership training. 2.- Regulatory policies, or mandates, limit the discretion of individuals and agencies, or otherwise compel certain types of behavior. These policies are generally thought to be best applied in situations where good behavior can be easily defined and bad behavior can be easily regulated and punished through fines or sanctions. An example of a fairly successful public regulatory policy is that of a speed limit. **Policy-maker** A person with power to influence or determine policies and practices at an international, national, regional, or local level. Policy makers have the responsibility and commitment for making the appropriate use of the best available evidence for policy making and decision taking. The policy maker is someone who sets the plan pursued by a government or organization. A person whose actions and opinions strongly influence the course of events. Frequently the term “policy-maker” may be interchangeable by “decision-maker” in many situations and contexts. In some other instances policy making might be closer to the health planner or policy developer activities. **Policy question** Is a relevant question (gap) concerning policies and /or strategic issues or directions in an specific context (governments, organizations, etc.) that have to be addressed by a policy maker (decision maker) to affect the ‘real’ world, by guiding the decisions that are made. These policy questions may be formally written or not. Most organizations identify their gaps (policy questions) and define policies to solve them.
[Back to Top](#)	[NOKC, Norway](#) The success of HTA is its impact on decision-making processes. Thus the concept of HTA was developed to suit the demand for policy making by apply the context specific analysis for brokering science into policy. Whether the HTA process meets the demand from policy makers is an important question, and there is a tension between the need for rigorous and high quality assessments on the one hand, and relevant and timely outputs to feed into decision-making processes on the other hand. International collaboration might enable more HTA-reports to be in time with policy making processes.

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Policy

In a restrictive way “policy” may be understood as norms issued by governmental institutions and seems to be equivalent to “laws” (independently of these need to be approved in a parliament or are directly issued by a Ministry –i.e. decree). It can be also used to refer to the rules which govern the functioning of the health system in general, including both the ones issued from governmental institutions and the ones issued by non-governmental institutions (i.e. self-governing institutions, sickness funds, professional associations, etc.). Common to both understanding of the term policy is that it refers to the regulatory framework of the health system.
Another meaning of the term “policy” which is frequently found is that it refers to any rules at any level of the health system, independently of whether they are legally binding or not. In this context, the area of application of a policy might be as small as a ward of a hospital or a single surgery. In these cases the term “policy” is understood as set of statements aiming at providing guidance on how to act in some situations. So for example one may find “The policy of this hospital for avoiding deep vein thrombosis after major surgery is to…” or “From this point of view Clinical Practice Guidelines are also considered a kind of “policy”.

Compared to the former, the latter understanding of “policy” is much broader and implies much more types of policy and much more types of individuals involved (see “Policy Makers”).

Policy Makers

The general understanding is that this term refers to the persons involved in the process of formulating policies. Which persons are actually meant under the term will depend on the understanding of the term “policy” (see “Policy”). Since the latter shows some variation, so too will the term “policy maker” vary. Related to HTA policy makers can be understood as the ones who are supposed to make use or take into account evidence from assessments (i.e. the persons for which HTA-reports are written). The term may be understood restrictively meaning persons operating only in a macro level (i.e. institutions with influence at the national level) or persons operating in governmental institutions. To some extent it might be confused with politicians (i.e. persons elected) or persons occupying political positions (Ministers, etc.).
Frequently the terms “policy maker” and “decision maker” are used as synonyms. In fact “policy makers” are also “decision makers”, since the process of policy formulation implies taking decisions (i.e. making choices among available options). However not all “decision makers” should be considered to be “policy makers” too. As said before decision makers are the ones who make choices among available options to solve a problem, thus a patient or a clinician are considered decision makers. Since their decisions affect only the individual situations and are not intended to guide the actions of a group or to establish a general rule, they cannot be considered “policy makers”.

The following persons can be considered to be policy-makers in different countries:
Politicians (MPs, Ministers, etc.), civil servants at national, regional or local authorities, managers (hospital managers, PHC managers, sickness funds managers, private health insurance managers), (clinical) staff involved in formulating CPGs (incl. local use CPGs), persons operating in provider associations (e.g. medical associations, hospital associations) or in purchaser associations, persons operating in self-governing institutions

Back to Top	(e.g. joint committees of provider and purchasers). **Policy Question** The term “policy question” seems to be mostly understood as the problem motivating the initiation of an HTA project. Some refer to the term as the questions that policy makers have concerning a technology assuming that policy-makers have formulated concise questions –which can be found in, for example, the commissioning document. The term can also be understood more generally as the problem policy makers face and for which information from HTA is required/ can be provided. Similarly it may mean the policy process in which the assessment is/ should be embedded. In those cases actually no questions have been worded by policy makers. In some HTA-reports “Policy Question” refers to a section in which -beside the problem / policy process which has motivated the assessment- the circumstances surrounding the assessment are also described. These include the sources of funding of the report, who commissioned the assessment and to whom is it addressed.
Primary Research *Back to Top*	INAHTA Glossary 1. "Original research" in which data are first collected. The term primary research is sometimes used to distinguish it from "secondary research" (reanalysis of previously collected data), meta-analysis, and other ways of combining studies (such as economic analysis and decision analysis). However, because systematic reviews can provide answers not possible from individual studies they can also be considered to be primary research. 2. An investigation that collects original (primary) data from patients, e.g. randomized controlled trials, observational studies, series of cases, etc.
Back to Top	NCCHTA, UK Original research conducted to collect new data to answer a question. HTA primary research aims to test the real life impact of an intervention by comparing it with another intervention. This is most often, but not always, in the form of a randomised controlled trial.
Rapid Review **Mini HTA** **Pre-assessment** See comments on these descriptions	DACEHTA, Denmark **Rapid review** (or rapid HTA or rapid assessment) is a designation of HTAs that are done within a shorter timeframe than “regular” HTAs. However, it is not easy to give a clear definition since rapid has been used as a concept for HTAs done within the time frame of a few days and up to a year. **Mini HTA** Is a management and decision support tool for the hospital service based on the reasoning involved in HTA. A mini-HTA is a form or a check list with a number of questions concerning the pre-requisites and consequences of introducing new technology. The purpose is to provide part of the basis for decision-making related to a proposal to introduce a specific new technology or in connection with changes in the indication for the use of an existing technology. Both the preparation and use of mini-HTA may take place at a local or regional level and be adapted to local/regional objectives, decision criteria, and time schedules. **Brief HTA**: Equivalent to ”rapid HTA”.

Back to Top	**Pre-assessment** Is the preparation of a potential HTA project. The pre-assessment may include a preliminary literature search, a preliminary review of the literature, and possibly a pre-assessment report, if the assessment indicates that it is not possible (or desirable) to do a HTA.
Back to Top	FinOHTA, STAKES, Finland Rapid review is an HTA report produced through an accelerated process. The form and contents of the review may vary according to the needs of stakeholders and availability of resources. A rapid review addresses only select aspects of a full HTA, and the methods used to gather and analyse the data may be limited. Rapid reviews may be limited in one or more ways *Question framing*: the scope of the assessment may be narrowed to a narrow aspect *Identifying relevant literature*: the search may be based only on databases on systematic reviews or HTA reports *Quality assessment*: may be omitted or rely on previous quality assessments made by other parties. *Evidence summary*: the assessment may be based on only a few or the best available systematic review/HTA report *Interpreting the findings*: As all available information has not been systematically assessed, the findings should be regarded as preliminary or interpreted with caution. Different kinds of technology assessments that are not comprehensive exist. Mini HTAs, brief HTAs or pre-assessments are examples of such.
	HTA agency, Poland **Pre-assessment** In AHTAPol pre-assessment constitutes the initial stage in the procedure of developing HTA report (that has been recently implemented by the Order of the Director of the AHTAPol of the 27th of March 2007). Pre-assessment of health technology is a summary of information, that is relevant for making a recommendation regarding terms of funding specific technology from public sources, for example: • The description of a technology and alternative technologies, taking into consideration also availability and accessibility of those technologies for specific disease, health condition or indication the description of disease, health state or indication, in which the technology referred for analysis is to be applied to, mainly taking into consideration the significance for the health of the society, basic health priorities, prevalence, incidence or morbidity and significance of the consequences of the disease (e.g. partial or total incapacity for work, inability to exist unaided, reduced quality of live or even death). • Scientific evidence (on clinical effectiveness and safety, the levels of cost-effectiveness or cost-utility for analyzed technologies, the budget impact) obtained from secondary sources - systematic reviews, HTA reports, meta-analyses or clinical practice guidelines, either submitted by the applicant together with the

request for the analysis of specific health technology (in accordance with the Order of the Director of the AHTAPol of the 27th of March 2007) or found through search of available database for the purposes of the pre-assessment report. The material is verified and appraised by the AHTAPol with regard to their consistency with guidelines and reliability of the material and evidence.

- Costs of analyzed technologies and their components
- Decisions regarding terms of funding/financing the technology referred for analysis from public sources, made in other countries (with special regard to countries of comparable national income level)

A pre-assessment report is prepared by the AHTAPol, and consulted with clinical experts before submitting it to Consultative Council for discussion. It enables the Consultative Council to provide the Minister of Health with an informed recommendation for the terms of financing the analysed technology from public sources (either consider starting or ceasing financing referred technology or just changing the level of its financing). If the Consultative Council decides that there is not enough information to make recommendation, a scope of the HTA report that is to be undertaken (especially indications and technologies compared, perspective for the analysis, type of analysis: CEA, CUA, BIA, clinical safety). It is then discussed together with the representatives of appropriate department of the Ministry of Health and National Health Fund and clinical experts.

Rapid review

Generally, the term rapid review can concern any type of analysis which is done under time limitation (through an accelerated process) when urgent needs or the official procedure require very quick response to a given problem. The aim of this analysis is to help authorities to take good decision based on reasonable arguments and consistent with social and economic needs. Similarly, a rapid review of health technology assessment (or rapid HTA report) is done within shorter timeframe than a "regular" HTA report. It means that the process of producing this report is accelerated. There is no specific scheme for a rapid HTA report. It depends on aim of the analysis, needs and previous analyses available. For example, when government is going to protect people against an epidemic of a fatal disease, and the problem is very urgent, an economic analysis does not matter. Sometimes, when the evidence on effectiveness and safety of the therapy is established and commonly acknowledged (e.g. other HTA agencies has done full review) authorities dealing with political urgency need only economic analysis or budget impact analysis to make decision on the financing (and terms of such financing) of a specific medical technology.

Mini-HTA

Poland does not have any experience in producing mini-HTA.
As mini-HTA has analogous purpose, which is to serve as support in decision-making on introduction of a new technology and resulting from this introduction need for resource allocation. We would expect mini-HTA to be tool, that is based on reasoning involved in health technology assessments. The main difference between full HTA and mini-HTA is the target group and the time frame for this type of analysis. A mini-HTA is rather done for the purposes of local-scale (not national-scale) decision-making process. The tool for doing mini-HTA should be adapted, so its form would allow to make this type of assessment within a short timeframe, and to easily adapt its outcome to local or regional budget and planning processes (e.g. resembling the form of EUnetHTA's "HTA adaptation toolkit").

[Back to Top](#)	Taking into consideration the centralized healthcare system in Poland, where all of decisions on financing medical technologies are done at national-scale, we would rather expect that mini-HTA should prove useful for healthcare professionals at Polish hospitals, e.g. when considering investing in new technology for one of its wards, to prove justification for its acquisition expenditures. Similar to a full HTA, a mini-HTAs would need a multidisciplinary team comprising personnel from different departments involved in providing the service (clinicians and nurses) under the leadership of the consultant in specific specialty and economists.
[Back to Top](#)	Institute of Molecular Medicine, Portugal. **Rapid Review** This usually means a draft, more than a summary or abstract of a main report. “Quick view” might reflect better if the objective is to express the main issues of the report. **Mini HTA** This seems to be a small “concentrated” *resumé* assessment. It does not imply a “not so important” HTA. **Pre-assessment** This really means a draft or a first approach to a subject. It may mean an already performed “pilot study”, but usually means a draft of something to be thoroughly performed later on.
	Servicio de Evaluacion y Planificacion, Canary Islands **Issue** Rapid reviews are a term used to group a variety of health technology assessment procedures that has to be performed in a reduced time-frame. If a usual systematic review takes one year or more for at least two full time people, these kinds of rapid reviews are delivered in 6 months or less. The purpose of the rapid reviews is to give support to relatively urgent health policy decision making. **Different types of Rapid reviews** The compromise of health technology assessors with informing all possible policy, managerial or even clinical decision making has forced methodological simplifications to answer to urgent needs of information. Not all rapid reviews are designed and performed in the same way. So depending on the degree of urgency and/or the human resources availability, these rapid reviews has evolved towards mini HTA, Brief HAT or Technology briefs, pre-assessment, etc. **The wide range of rapid reviews** As rapid reviews have been developed to support real life decision making, assessors have been trying to fit the needs of decision makers (assuming that no informed decision making could be worse than an informed decision supported by a rapid review). So the available time frame and, as previously said, the availability of technical staff effects the kind of assessment that is delivered. Health Technology Assessment Agencies located in governmental organizations have different

Back to Top	commitments with decision makers which could force them to submit rapid reviews with the presence of methodological limitations: restrictions of literature searches in just one database (usually Medline), and/or abstract based assessment, single person process, etc. In my opinion, although some kind of criteria has been set to define what a rapid review is, informing health policy decision making about HTA sometimes requires a flexible interpretation of these criteria with the aim of ensuring some support to decision makers. **Consensus development** Academic and governmental HTA organizations have to revise the limits and risks of the flexible answers provided through a wide variety of rapid reviews; as well as the risk of losing the opportunities of informing decisions in this way.
Relevance **Reliability** see also Applicability and Generalisability See comments on these descriptions Back to Top	EUnetHTA In the context of adapting HTA reports, a reliable report is one that a potential user can trust and rely on: they can trust that what it says is true. If so, they may be adopted or considered for adaptation for another setting. One way of assessing reliability in a standardized way is through the use of quality checklists, such as those that are included in the EUnetHTA Toolkit. Note however that reliability is a tricky word and should be used with caution. Although reliability is widely used in HTA as above, in other situations, it refers to repeatability, which leads to the common observation that a repeatable test is not necessarily a valid one. However, in the case of HTA, reliability can also be used to mean “how far something can be relied on or trusted”, which is very close to (internal) validity. The relevance of an HTA report is determined by how closely the policy and research question(s) in the report match the research questions that are of interest to the user. Relevance is therefore a relative or subjective matter: it is the relevance for the user and not a general ‘standard’ relevance. Relevance therefore depends on the setting, the knowledge of the adapting person and the policy question. A report might be very relevant even if it is not reliable – and vice versa.
Back to Top	INAHTA Glossary Reliability: The extent to which an observation that is repeated in the same, stable population yields the same result (i.e. test-retest reliability). Also, the ability of a single observation to distinguish consistently among individuals in a population.
Back to Top	DACEHTA, Denmark Relevance refers to the extent to which an HTA is applicable for decision-makers and addresses an essential policy question. The main issue is whether the topic of a report is usable and needed by HTA users Reliability refers to the degree to which results from an HTA report can be replicated.
	IPHRS, Slovenia **Relevance** Relevance is a term used to describe how pertinent, connected, or applicable some information is to a given matter. Some diseases might

[Back to Top](#)	need additional measurements. One has to see if the current measurements are sufficient or if there have to be some new measurements implemented for special diseases. There are various perspectives of relevance: objective, subjective and a mixed perspective. **Reliability** In general, reliability is the ability of a system to perform and maintain its functions in routine circumstances, as well as hostile or unexpected circumstances. In natural language it may also denote people who act efficiently at proper moments/circumstances. In statistics, reliability is the consistency of a set of measurements or measuring instrument. Reliability does not imply validity. That is, a reliable measure is measuring something consistently, but not necessarily what it is supposed to be measuring. For example, while there are many reliable tests, not all of them would validly predict job performance. In experimental sciences, reliability is the extent to which the measurements of a test remain consistent over repeated tests of the same subject under identical conditions. An experiment is reliable if it yields consistent results of the same measure. It is unreliable if repeated measurements give different results.
[Back to Top](#)	NCCHTA, UK **Relevance** In the context of the WP5 adaptation toolkit, relevance is about similarities between the HTA report for adaptation and the needs of the user i.e. is the policy and/or research question posed sufficiently similar to warrant adaptation of this report? And do parts of this report address areas that the user wishes to address in their report? i.e. technology use and development, safety, effectiveness, cost-effectiveness and/or organisational aspects. Questions relating to the relevance of the entire HTA report are posed in the 'speedy sifting' section of the toolkit. Relevance questions specifically relating to parts of the HTA report are posed within the relevant toolkit domains. **Reliability** In relation to the WP5 adaptation toolkit, reliability is an assessment of the extent to which the findings of the report can be relied on i.e. critical appraisal. This is usually in the form of a checklist of questions. The types of questions asked are; what methods have been followed? Are they good enough? Are the results generally plausible? And are graphs, figures and models correct and easy to follow? Reliability questions, specific to certain parts (or domains) within the HTA report, can be found within the relevant domains of the toolkit.
	PHGEN **The interconnection between the terms:** The terms of relevance and reliability both refer to the quality of a HTA report. Therefore the terms are very important in the context of adaptation as foreign users would assess the quality of a report before they choose to adapt them. Still, there is a substantial difference between the concepts behind the two terms as they point in a different direction. The relevance of a report is conceived as relative or subjective, that means the relevance is the relevance for the user and not a general overall relevance. The

Back to Top	relevance therefore depends on the setting, the knowledge of the adapting person and the policy question. In contrast to that, reliability is an issue that users can assess in a standardised way, as a report is reliable if the science basis and the spread-sheet-models are of high quality. Relevance and reliability must be seen in different matrixes, as a report might be very relevant even if it is scientifically outdated and vice versa. **How to link the terms in HTA?** According to our experience and the way HTA reports are used in Germany, it is very important that these terms are not mixed up. We have many reliable reports which are totally irrelevant and we have many unreliable reports which are still used and therefore they are relevant (sometimes as negative examples). The reliability depends on the scientific quality of the report whereas the relevance depends on the policy question and its relevance in a given setting. The relevance might be different from country to country, but we should strive for unified standards of reliability measures as the reliability is the key to adaptation. Reliability and not relevance is the key incentive to use a foreign HTA report.
Toolkit Speedy Shifting Domain *Back to Top*	EUnetHTA The EUnetHTA adaptation toolkit has been developed to aid HTA agencies in the adaptation of HTA reports that are a synthesis of evidence. It contains checklists of questions and resources to enable the assessment of a report's relevance, reliability and transferability. Currently, the toolkit is in the form of a word document. It will be developed into something more interactive, in the context of the planned web-based clearing house. It consists of 6 of modules: one generic and 5 specific to certain parts (or domains) of HTA reports. The generic module ("Speedy Sifting") enables the rapid assessment of the relevance of the report. The five specific domains relate to technology use and development, safety, effectiveness, economic evaluation and organisational aspects. The reliability and transferability of information and data within these 5 domains can be assessed using these parts of the toolkit. The toolkit output is adaptation material that can be incorporated into a new framework for an HTA report in a target setting.