What is ...?

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What is health technology assessment

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- **Health technologies** include: 'interventions used to promote health, to prevent, diagnose or treat acute or chronic disease, or for rehabilitation. They include pharmaceuticals, devices, procedures and organisational systems used in healthcare'.

- **Health technology assessment** (**HTA**) has been defined as 'the systematic evaluation of the properties of a health technology, addressing its direct and intended effects, as well as its indirect and unintended consequences, to inform decision-making'.

- **Key stakeholders** in healthcare policy and decision-making include: patients, healthcare professionals, industry, third-party payers and government.

- HTA has groundings in different methodological streams – policy analysis, evidence-based medicine, health economic evaluation and social science. It gives context-specific input into the policy-making process.

- The HTA process and related research findings are just one input into the decision-making process. Other factors include: expertise and experience, lobbyists, policy context and values, and available resources.

- **There has been a growth in HTA to support the decision-making process** in many countries, in line with a reduction in available resources. Although there are many similarities in the process in terms of methodologies used for assessment and attributes evaluated (clinical, cost-effectiveness, safety and quality of life), there is also considerable variability, predominantly in terms of remit and funding.

- The process of defining best practice in HTA has been ongoing for several years at a national level. Work has been carried out to streamline HTA processes transnationally towards a practical collaboration to bring about more effective use of national HTA. To date, this work has taken the form of improving reporting standards (**the International Network of Agencies for Health Technology Assessment**); development of **the HTA Core Model®** and toolkit to aid transferability between settings (**the European network for Health Technology Assessment**); and suggestions for **benchmarking the outputs** from HTA agencies.

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Defining health technology assessment

Health technologies include: 'interventions used to promote health, to prevent, diagnose or treat acute or chronic disease, or for rehabilitation. They include pharmaceuticals, devices, procedures, and organisational systems used in healthcare'.[1] Health technology assessment (HTA) has been defined as 'the systematic evaluation of the properties of a health technology, addressing its direct and intended effects, as well as its indirect and unintended consequences, to inform decision-making'.[1] By its nature, **HTA is a multidisciplinary activity** that systematically evaluates the short- and long-term consequences of the application of a healthcare technology, and its impact on health, on the availability and distribution of resources, and on other aspects of health-system performance such as equity and responsiveness.[2,3]

Importance to decision-makers

HTA is usually conducted in response to, or in anticipation of, a need for information to support a decision.[4] The HTA process shares its principles with evidence-based medicine and clinical practice guidelines – that is, the collection and analysis of research evidence in a systematic and reproducible way, made accessible and usable for decision-making purposes.[2,5] The HTA process is considered to be the 'bridge between evidence and policy-making' as it provides a range of stakeholders with **evidence-based information that will guide decisions about technology and the efficient allocation of resources**.[6] Key stakeholders in healthcare policy and decision-making include: patients, healthcare professionals, industry, third-party payers and government.

HTA process

In contrast to the licensing processes for drugs and medical devices, which assess quality, safety and efficacy, **HTA focuses on the relative ('comparative') effectiveness of medicines** in order to assess usefulness to a given healthcare system; it is the so-called 'fourth hurdle'.[7] Some agencies also take the financial cost of technologies and their economic value into account in accordance with national legislation.

HTA involves the assessment of one or more properties, impacts or other attributes of health technologies, including: technical properties; safety, efficacy and/or effectiveness; economic attributes or impacts; and social, legal, ethical and/or political impacts.[4,8] For the majority of decisions, the information needs are determined by the requirements laid down in the regulatory frameworks governing the decision-making process (Figure 1).

As well as demonstrating an understanding of the aetiology and prevalence of disease and knowledge of best practice treatment pathways, an HTA also evaluates the **comparative effects (harms and benefits)** of an intervention on one or more health outcomes – for example, mortality.[4] In cases where observation of clinical outcomes requires a long follow-up period, surrogate endpoints are sometimes used.[1] These tend to be physiological or biochemical markers that can be relatively quickly and easily measured, and that are taken as being predictive of important clinical outcomes;[1] for example, prostate-specific antigen level is used as a surrogate for overall survival in metastatic prostate cancer. However, there needs to be good justification for their use. In addition, assessment in terms of impact on health-related quality of life and functional status is also increasingly used.[4,9]

Health technologies also have an **economic impact** via associated costs, prices, charges and payment levels.[4] Other factors include comparisons of resource requirements and outcomes (or benefits) of technologies for particular applications, such as cost-effectiveness, cost–utility and cost–benefit (see *What is cost-effectiveness?*[10] and *What is cost–utility analysis?*[11]). Other economic consequences include: national healthcare costs, resource allocation and shifts in the site of care, such as from inpatient to outpatient settings.[4]

Other issues for consideration include social, ethical, legal and/or political impacts – that is, the broader consequences of applying the technology to be assessed.

Planning and prioritisation

In recent years, most countries have experienced exponential growth in health technologies. In parallel, there has also been growth in the use of HTA to support the process of decision-making in healthcare at policy level by providing reliable information. All HTA agencies must therefore set priorities.[4]

Sources for identifying **research priorities** include: 1) widespread consultation of healthcare commissioners, providers and consumers; 2) research recommendations from systematic reviews; 3) reconsidering previous research priorities that had not been taken forward for funding; and, 4) horizon scanning (a process that aims to provide advance notice to national policy-makers of selected key new and emerging health technologies that might require evaluation, consideration of clinical and cost impact, or modification of clinical guidance prior to launch).[12]

Examples of criteria used in current priority setting across HTA agencies in Canada, the USA and the EU include: alternatives; budgetary impact; clinical impact; controversial nature of proposed technology; disease burden; economic impact; ethical, legal or psychosocial implications; evidence; expected level of interest; timeliness of review; and variation in rates of use.[13] Of these, the most common criteria applied when setting priorities were the clinical, economic and budgetary impacts of the technology, and disease burden criteria.[13]

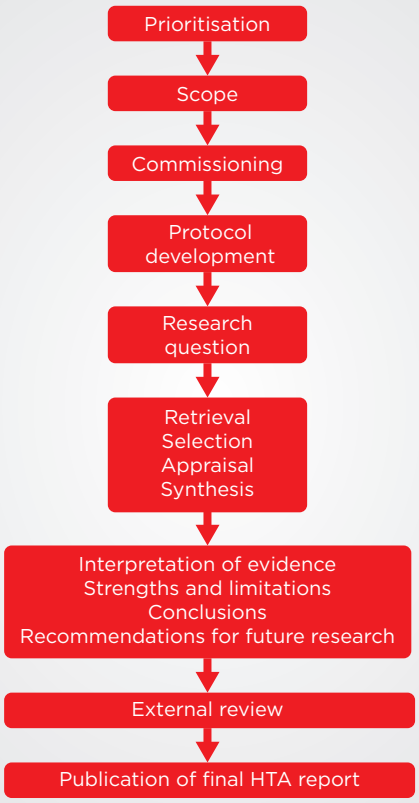
The timing of an assessment may be, to some extent, dependent on the availability of evidence.[4,13] For example, the results of a recently completed randomised controlled trial or meta-analysis may challenge standard practice, and prompt an HTA to consolidate these results with other available evidence for informing clinical or payment decisions.[4,5] Alternatively, an assessment may be delayed pending the results of an ongoing study that has the potential to shift the weight of the body of evidence on that topic.[4,5,13]

Assessment

To give an evidence-based solution to a decision problem, selected topics should be transformed into clearly defined policy questions of direct significance to the policy-maker; this process is often called **'scoping'**. Defining the scope of the review is a fundamental step in using research evidence to inform decision-making. To ensure that the right question is addressed, HTA agencies are spending more time at this scoping stage with stakeholders (industry, patient groups, clinical specialists and healthcare commissioners).

Based on the overarching question(s), **a protocol is developed** to plan the process of assessment and reporting. The protocol outlines the decision problem, search strategy (including data sources), identification and selection of studies, critical appraisal and data synthesis. The formulation of research questions using **PICOS criteria (population, intervention, comparators, outcomes and study design)** helps to guide the review.[5] A good review question should be clear and focused, relate

Figure 1. HTA process[2]



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to a specific patient problem, help to identify clinically relevant evidence, ensure that the research produces relevant results and guide many aspects of the review process.[5]

The next step in the process is to retrieve, select and evaluate the literature (assessment of eligibility against predefined inclusion criteria and quality appraisal to test evidence for validity, clinical relevance and applicability), and analyse and synthesise available evidence to respond to the information needed. This often includes the methodologies of systematic review, meta-analysis and decision-analytic modelling (see *What is a systematic review?*[14] and *What is meta-analysis?*[15]).

Most HTA agencies have a standard report template. In general, the resultant HTA report incorporates: methodology of the assessment; evidence used (quality, validity and generalisability); assumptions made; discrepancies and uncertainties identified; and expected changes (in technology or evidence). In addition, limitations should be considered in relation to their possible influence on the results in order to be able to formulate conclusions.

In drawing conclusions from the HTA, the principal aim is to provide a response to the research question(s) based on the available evidence. In addition, recommendations for further research are made; for example, highlighting areas where more data are required. It is not generally accepted that HTAs should include policy recommendations, although this varies dependent on the mandate of the HTA agency.

The summarised evidence from the HTA is considered, together with other inputs (for example, experience and expertise, judgement, resources, lobbyists and pressure groups, habits/traditions, pragmatics and contingencies, values and policy context), enabling policy-makers to make policy recommendations for use (guidance/guidelines), and allowing several countries to make decisions from the HTA that are aligned with reimbursement.

International use of HTA

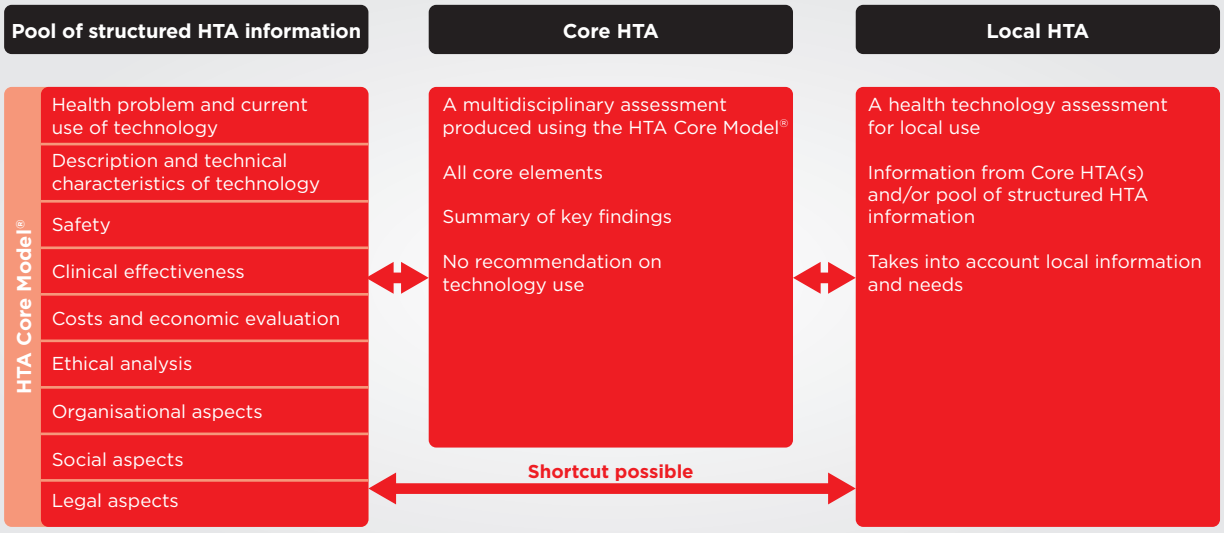
HTA is an important part of evidence-based, healthcare decision-making worldwide. In addition to safety and efficacy information, economic and outcomes research data are also taking on an increasing role. Although there are some similarities between the various HTA bodies – for example, in the methodologies used (systematic review, meta-analysis and economic modelling), and attributes evaluated (effectiveness, cost-effectiveness, safety and quality of life)[16] – there is also considerable variability. For example, some HTA agencies have national mandates and some have regional mandates; and some agencies are funded by national or regional governments and others by non-governmental organisations.[3] Regardless of these similarities and differences, **all HTA research has a common aim** – predominantly to support decision-making based on the best available evidence.[3]

The **International Network of Agencies for Health Technology Assessment (INAHTA)** is a non-profit organisation that was established in 1993 and has now grown to 57 member agencies from 32 countries, including in North and Latin America, Europe, Africa, Asia, Australia and New Zealand.[17] All members are non-profit-making organisations that produce HTAs and are linked to regional or national government.[17] The organisation has done much to set out the reporting standards for HTA; for example, development of a common HTA checklist, including what should be included in an HTA report and the order in which to present it.[18] However, although HTA is principally based on the fundamentals of the systematic review process, the recommendations are typically targeted to a specific health system and, as such, may not be reproducible.[3,5]

In Europe, to enhance co-operation between countries, the European Commission has set up a permanent, voluntary HTA network.[19] The network aims to facilitate efficient use of HTA resources in Europe, create a sustainable system of HTA knowledge-sharing and promote good practice in HTA methods and processes.[3]

The **European network for Health Technology Assessment (EUnetHTA)** was established to create an effective and sustainable network for HTA across Europe. Its aim is to develop timely, transparent and

Figure 2. Core HTA structure[8]



Detailed diagrammatic (2013) available in EUnetHTA Final Technical Report 2010-2012

transferable information to contribute to HTAs in European countries. A generic **'HTA Core Model®** (hereafter referred to as 'the model') is being developed to guide future assessments (Figure 2).[8] It follows the definitions of HTA and emphasises the multidisciplinary nature of the process. **The model has nine core domains** (Box 1). The basic idea of the core model is to structure the contents of an HTA into pieces of information.[8] These 'elements', comprising a 'topic' and an 'issue', are formulated as questions (for example, the impact of a technology on mortality or on the ability to work).[8] The common theme is that all elements provide information that is useful for deciding whether or not to implement a technology. This enables a consistent structure of HTA, allowing users to find relevant information easily, and transfer into research question(s) to be answered in an assessment.[5,8]

In addition, EUnetHTA is working to overcome issues of transferability due to inherent differences between settings; for example, demographics and epidemiology of the disease in the target populations, as well as differences in costs and relative efficiencies of the healthcare system. The toolkit comprises a series of checklists and resources that address the relevance, reliability and transferability from existing reports. A glossary has also been developed.

Box 1. EUnetHTA HTA Core Model®: Domains of HTA[8]

1. Health problem and current use of technology
2. Description and technical characteristics of technology
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Social aspects
9. Legal aspects

HTA: health technology assessment.

Although the EUnetHTA model emphasises the harmonisation of approaches in HTA, it does not attempt to benchmark. Given the greater emphasis on the use of HTA, Drummond *et al* (2012) set out to develop standards of good practice against which the HTA organisations could be benchmarked.[20] They proposed a set of **15 key principles** (Box 2) for the conduct of HTA for resource-allocation decisions.[20] The principles cover elements of good practice in setting out the structure and remit of organisations, the methods and processes

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Box 2. Key principles of HTA[20]

1. The goal and scope should be explicit and relevant to its use
2. HTA should be an unbiased and transparent exercise
3. HTA should include all relevant technologies
4. A clear system for setting priorities for HTA should exist
5. HTA should incorporate appropriate methods for assessing costs and benefits
6. HTAs should consider a wide range of evidence and outcomes
7. A full societal perspective should be considered when undertaking HTAs
8. HTAs should explicitly characterise uncertainty surrounding estimates
9. HTAs should consider and address issues of generalisability and transferability
10. Those conducting HTAs should actively engage all key stakeholder groups (eg professional bodies, patient organisations, manufacturers)
11. Those undertaking HTAs should actively seek all available data
12. The implementation of HTA findings needs to be monitored
13. HTAs should be timely
14. HTA findings need to be communicated appropriately to different decision-makers
15. The link between HTA findings and decision-making processes needs to be transparent and clearly defined

Adapted from: Drummond *et al*. *Int J Technol Assess Health Care* 2012; **28:** 159–164.

for conducting HTA, and its use in decision-making.[20] The proposed principles are subject to further development – for example, wording of the audit questions associated with each of the principles; and the assessment of alternative methods for weighting the various principles and generating a summary score.[20]

Conclusions

Governments face a continual challenge to provide care within budget constraints while protecting the basic principles of equity, access and choice. Strategic allocation of resources – that is, the investment in technologies that deliver the best health outcomes – is key. The purpose of HTA, therefore, is to facilitate the decision-making process by providing policy-makers, funders and healthcare professionals with the information required to understand the comparative clinical and cost benefits of health technologies, and to inform policy, funding and clinical decisions.

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Case study: UK

HTA has long been a policy priority in the UK. Since 1993, and the establishment of the National Coordinating Centre for Health Technology Assessment (NCCHTA) based at the University of Southampton, the UK has had a highly active HTA research programme of international reputation.[21–24] Although HTA is synonymous with the activities of the National Institute for Health and Care Excellence (NICE) in England, important entities also exist in Scotland (Scottish Medicines Consortium [SMC]) and Wales (All Wales Medicines Strategy Group [AWMSG]). Although the underlying principles for HTA are the same, there are some important differences in the remit and processes of NICE, the AWMSG and the SMC.

Summary of remit and processes of NICE, AWMSG and SMC

	NICE[a]		**AWMSG**	**SMC**
HTA agency	NCCHTA		–	
Established	1999		2002	2002
Remit	England and Wales[b]		Wales	Scotland[c]
Decision-making criteria	Clinical and cost-effectiveness		Clinical and cost-effectiveness	Clinical and cost-effectiveness
Referrals	Department of Health priorities		All newly licensed formulations/medications	All newly licensed medicines/ formulations/indications not on the NICE programme
	MTA	**STA**		
Evaluable technologies	Drugs, medical devices, diagnostic tests	Drugs	Drugs	Drugs
Assessment	Independent academic group (HTA report)	Independent academic group (critique of industry submission)	In-house team and NMG	In-house team and NDC
Appraisal	NICE Appraisal Committee	NICE Appraisal Committee	AWMSG	SMC
Timing of assessment	Any timing	Close to launch	Close to launch	Close to launch
Timing of appraisal	18 months	9 months	6 months[d]	18 weeks
Stakeholder involvement	Industry, patient interest group and royal college submissions	Industry, patient interest group and royal college submissions	Industry, patient interest group and medical expert submissions	Industry and patient interest group submissions
Status of guidance	Mandatory within 3 months of issue	Mandatory within 3 months of issue	Mandatory within 3 months of issue	Advisory[e] to 14 health boards
Open appraisal committee meetings?	Yes	Yes	Yes	No
Appeal process?	Yes	Yes	Yes	Yes
Recommendations	Recommended; optimised; only in research; not recommended	Recommended; optimised; only in research; not recommended	Recommended: (a) for use; (b) as an option for use; (c) for restricted use; (d) as an option for restricted use; not recommended for use; and cannot be endorsed for use	Accepted: (a) for use; (b) for restricted use; not recommended for use; withdrawn; superseded
Number of appraisals in 2013	4	28	110[f]	143

AWMSG: All Wales Medicines Strategy Group; HTA: health technology assessment; MTA: multiple technology appraisal; NCCHTA: National Coordinating Centre for Health Technology Assessment; NDC: New Drugs Committee; NICE: National Institute for Health and Care Excellence; NMG: New Medicines Group; SMC: Scottish Medicines Consortium; STA: single technology appraisal

(a) Technology appraisal programme; (b) NICE does not give advice to NHS Scotland on medicines and NICE STAs of new medicines do not apply in Scotland. NICE MTAs are reviewed by NHS Quality Improvement Scotland and, if appropriate, deemed to apply within the Scottish context. NICE MTA recommendations replace published SMC advice; (c) The Department of Health has indicated that the SMC is one source of advice that primary care trusts and others within NHS England may consult, especially if new medicines have not been subject to NICE technology appraisal; (d) AWMSG: 21 weeks from receipt of Form B AWMSG recommendation (FAR) sent to Welsh Government for ratification (subject to request for independent review); (e) Mandatory for 'unique' medicines; (f) Of 110 appraisals, 20 were excluded

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