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# What is health technology assessment?

- **Health technology assessment (HTA)** is a multidisciplinary activity that systematically examines the safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organisational implications, social consequences, legal and ethical considerations of the application of a health technology – usually a drug, medical device or clinical/surgical procedure.
- In the UK, HTA broadly focuses on two questions:
  - **Clinical effectiveness** – how do the health outcomes of the technology compare with available treatment alternatives?
  - **Cost-effectiveness** – are these improvements in health outcomes commensurate with the additional costs of the technology?
- HTA acts as '**a bridge**' between evidence and policy-making. It seeks to provide health policy-makers with accessible, useable and evidence-based information to guide their decisions about the appropriate use of technology and the efficient allocation of resources.
- Over the last decade, three key national policy-making 'HTA customers' have emerged: the **National Institute for Health and Clinical Excellence**, the **Scottish Medicines Consortium** and the **All Wales Medicines Strategy Group**.

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## What is health technology assessment?

### Defining health technology assessment

**Health technology assessment (HTA)** has grown out of the tension between new and often costly health technologies and limited healthcare budgets. HTA has been called 'the bridge between evidence and policy-making', because it seeks to provide a range of stakeholders (typically those involved in funding, planning, purchasing and investing in healthcare) with accessible, useable and evidence-based information that will guide decisions about technology and the efficient allocation of resources.<sup>1</sup> Health technologies include drugs, medical devices and clinical/surgical procedures.

HTA is a 'multidisciplinary activity that systematically examines the technical performance, safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organisational implications, social consequences, legal and ethical considerations of the application of a health technology'.<sup>2</sup> HTA has to take into consideration all aspects that might be influenced by the technology as well as those influencing the technology.

### The importance of HTA to healthcare decision-makers

In contrast to the licensing processes for drugs and medical devices, which assess quality, safety and efficacy, HTA focuses on '**the value**' (clinical and economic) of the technology relative to current (or best) clinical practice – the so-called 'fourth hurdle'.<sup>3</sup>

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- **Clinical effectiveness** – how do the health outcomes of the technology compare with available treatment alternatives?
- **Cost-effectiveness** – are these improvements in health outcomes

commensurate with the additional costs of the technology?\*

HTA can help policy-makers decide which technologies are effective and which are not, and define the most appropriate indications for their use. HTA can reduce or eliminate interventions that are unsafe and ineffective, or whose cost is too high compared with the benefits. That said, to date, most international HTA activity has been directed at quantifying the use of new and expensive pharmaceuticals.<sup>5</sup>

### HTA processes in the 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 ([www.nchta.org](http://www.nchta.org)), based at the University of Southampton, the UK has had a highly active HTA research programme of international reputation. Over the last decade, three key policy-making 'users' of HTA have emerged in England, Scotland and Wales.

### National Institute for Health and Clinical Excellence

The **National Institute for Health and Clinical Excellence (NICE;** [www.nice.org.uk](http://www.nice.org.uk)) was established as an NHS special health authority in 1999, and is responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.

NICE was established to produce national guidance on specific health technologies, including both drugs and medical devices (through its technology appraisal process), and clinical practice (through its clinical guidelines development process). It has subsequently assumed the responsibilities of the Health Development Agency and is now structured across three different centres: the Centre for Public Health Excellence, the Centre for Health Technology Evaluation, and the Centre for

\* This is often assessed using the cost-effectiveness metric of the cost per quality-adjusted life-year. See *What is cost-utility analysis?*<sup>4</sup> for further details.

Clinical Practice. Created in April 2005, the Centre for Public Health Excellence develops guidance on the promotion of good health and disease prevention.

Since January 2002, it has been a mandatory requirement for NHS organisations in England and Wales to provide funding for medicines and treatment recommended by NICE in its technology appraisal guidance. Furthermore, NHS organisations must review clinical management following publication of NICE clinical guidelines.<sup>6,7</sup>

### **All Wales Medicines Strategy Group**

The **All Wales Medicines Strategy Group (AWMSG; [www.wales.nhs.uk/awmsg](http://www.wales.nhs.uk/awmsg))** was established in 2002 to advise the Welsh Assembly of future developments in healthcare to assist in its strategic planning; to develop timely, independent and authoritative advice on new drugs and on the cost implications of making these drugs routinely available on the NHS in Wales; to advise the Assembly on the development of a prescribing strategy for Wales; and to advise the Assembly on the implementation of a range of strategic Prescribing Task and Finish Group recommendations.

The AWMSG makes a recommendation soon after the launch of a product and within 18 months of notification by a company. However, the AWMSG will not normally consider appraising a product if NICE intends to publish its final appraisal of the same product within an 18-month period.

Initially, the AWMSG appraisal process focused on high-cost medicines (that is, those costing more than £2,000 per patient per annum), but it has begun to broaden its consideration to other categories of medicines and plans to review all new indications are currently under discussion. Since its establishment, AWMSG appraisal meetings have been held in public.

### **Scottish Medicines Consortium**

The **Scottish Medicines Consortium (SMC; [www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk))** was established in January 2002 and is now under the umbrella of NHS Quality Improvement Scotland. The role of the SMC is to assess the status of all newly licensed medicines, all new

formulations of existing medicines and any major new indications for established products in terms of their cost-effectiveness for use in the NHS in Scotland.

Like the AWMSG, the SMC assesses new products or indications at the time of launch and aims to issue advice to NHS Scotland on all newly licensed medicines within 12 weeks of products being made available. If a product is approved by the SMC, it is automatically added to the area drugs and therapeutics committee (ADTC) formularies, which allows it to be prescribed on the NHS in Scotland. If a product is not recommended by the SMC, it will not be included on the ADTC formularies and access will be limited.

The provision of healthcare in Scotland is devolved to regional health boards. Although funded centrally from the UK Department of Health, NHS Scotland manages the allocation of funding to the nine health boards of Scotland. The health boards are then responsible for the provision of healthcare to their areas. Each health board has an ADTC, as mentioned above. It is this committee that advises on the use of medicines for its respective geographical area.

### **NICE, AWMSG and SMC - similarities and differences**

Although all are policy 'users' of HTA, there are some important differences in the remit and processes of NICE, the AWMSG and the SMC (Table 1). These include the scope of the agency and the use of single or multiple technology assessments.

#### **Topic selection**

- In contrast to the AWMSG and SMC, NICE does not evaluate all new medicines as they reach the market, but according to specific selection criteria set out below.
- Is the technology likely to result in a significant health benefit, taken across the NHS as a whole, if given to all patients for whom it is indicated?
- Is the technology likely to result in a significant impact on other health-related government policies (for example, reduction in health inequalities)?
- Is the technology likely to have a significant impact on NHS resources

**Table 1. Summary of remit and processes of NICE, the AWSMG and the SMC**

	NICE*		AWSMG	SMC
<b>Decision-making criteria</b>	Clinical and cost-effectiveness		Clinical and cost-effectiveness	Clinical and cost-effectiveness
<b>Topic selection</b>	Department of Health priorities <sup>†</sup>		All newly licensed and new formulations	All newly licensed and new formulations
	<b>MTA</b>	<b>STA</b>		
<b>Evaluable technologies</b>	Drugs, medical devices, diagnostic tests	Drugs	Drugs	Drugs
<b>Independent academic HTA report?</b>	Yes	No	No	No
<b>Timing of assessment</b>	Any timing	Close to launch	Close to launch	Close to launch
<b>Timescale of appraisal</b>	18 months	Nine months	Six months	18 weeks
<b>Recipients of guidance</b>	NHS England, Scotland and Wales	NHS England	NHS Wales	NHS Scotland
<b>Stakeholder involvement</b>	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
<b>Status of guidance</b>	Mandatory within three months of issue	Mandatory within three months of issue	Mandatory within three months of issue	Advisory <sup>‡</sup> to nine health boards
<b>Open appraisal committee meetings?</b>	Yes <sup>§</sup>	Yes <sup>§</sup>	Yes	No
<b>Appeal process?</b>	Yes	Yes	Yes	Yes
<b>Number of appraisals in 2008**</b>	11	11	24 <sup>††</sup>	105

\* Technology appraisal programme; <sup>†</sup> See 'Topic selection' section; <sup>‡</sup> Mandatory for 'unique' medicines; <sup>§</sup> Since September 2008; <sup>\*\*</sup> Number of published guidance documents; <sup>††</sup> There were 24 full appraisals in 2008; a full appraisal is required for all new cardiac and cancer drugs, as well as for any new drugs above a cost threshold of £2,000 per patient per year

HTA: health technology assessment; MTA: multiple technology assessment; STA: single technology assessment

(financial or other) if given to all patients for whom it is indicated?

- Is NICE likely to be able to add value by issuing national guidance? For instance, in the absence of such guidance, is there likely to be significant controversy over the interpretation or significance of the available evidence on clinical and cost-effectiveness?

### Single versus multiple technology assessments

The AWSMG and SMC appraise drugs (or new drug indications) one at time using a **single technology assessment (STA)** process that focuses on an appraisal of an

HTA dossier submitted by the drug manufacturer. In contrast, the NICE technology appraisal programme can examine a disease area or class of technologies using a **multiple technology assessment (MTA)**. The MTA process is based on input from a broad range of stakeholders, with emphasis on an academic assessment group which critically reviews the available evidence (including the manufacturer's dossier) and produces an independent HTA report. Although arguably a more detailed and independent HTA process, MTAs take 18 months on average and in some notable cases longer. Under pressure to provide more timely guidance to

the NHS at or around the time of launch, NICE has shifted to an STA process for new drugs (or new drug indications). As a result, the time it takes NICE, the AWMSG and the SMC to produce guidance for the NHS on new drugs has become more aligned. A summary of recent appraisals of new cancer medicines by the three agencies is shown in Table 2.<sup>8-18</sup>

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**Table 2. Selected recent UK technology assessments of cancer drugs<sup>8-18</sup>**

Drug	Indication	Company	Assessment agency	Recommendation	Effect on access	Cost per QALY*
Taxotere (docetaxel)	Head and neck cancer (firstline)	Sanofi-Aventis	NICE	Not appraised	None	–
			SMC	Recommended if induction chemotherapy is appropriate	Restricted	£5,413–28,930
			AWMSG	Recommended in patients receiving chemotherapy	Restricted	£1,832–5,332
Fludara (fludarabine)	Chronic lymphocytic leukaemia	Schering	NICE	Not recommended as firstline therapy	Denied	£26,105–86,770
			SMC	Recommended in patients with sufficient bone marrow reserves	Restricted	£2,600–26,100
			AWMSG	No guidance available	None	–
Gemzar (gemcitabine)	Breast cancer	Eli Lilly	NICE	Recommended when docetaxel monotherapy or docetaxel plus capecitabine are considered appropriate	Restricted	£45,800
			SMC	Recommended for patients who have relapsed following adjuvant/neoadjuvant chemotherapy	Restricted <sup>†</sup>	£35,600 £16,534–17,168
			AWMSG	No guidance available	None	–
Avastin (bevacizumab)	Colorectal cancer	Roche	NICE	Not recommended as firstline treatment	Denied	£39,136–106,770
			SMC	Not recommended as treatment of metastatic colorectal cancer in combination with fluoropyrimidine-based chemotherapy	Denied	£25,806
			AWMSG	No guidance available	None	–
Erbix (cetuximab)	Colorectal cancer	Merck	NICE	Not recommended	Denied	£33,263–370,044
			SMC	Not recommended	Denied	>£34,450
			AWMSG	Recommended in combination with irinotecan for the treatment of epidermal growth factor receptor-expressing colorectal cancer after failure of irinotecan (including cytotoxic therapy)	Restricted	£34,454–129,956

\* As quoted in agency guidance; <sup>†</sup> Initial manufacturer submission rejected

QALY: quality-adjusted life-year

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