What is ...?

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# What are the HTA processes in the UK?

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- **Health technology assessment (HTA)** has a long history in the UK. In recent years, HTA has become synonymous with the activities of the **National Institute for Health and Care Excellence (NICE)** in England, although important entities also exist in Scotland (**Scottish Medicines Consortium [SMC]**) and Wales (**All Wales Medicines Strategy Group [AWMSG]**).
- The NICE technology appraisal (TA) programme develops guidance on the use of new and existing medicines, treatments and procedures within the NHS.
- NICE commissions so-called technology assessment groups to prepare assessment reports for consideration by the **Technology Appraisal Committee (TAC)**, which is the primary decision-making body in the production of guidance on new health technologies. The TAC includes academics, healthcare professionals, NHS managers and commissioners, and lay members of the public; the appraisal of the specific technology includes representatives of the companies and of the patients affected.
- Guidelines on the methods of TA, which have been issued by NICE, embody the concept of the **reference case**.
- There are two approaches to TAs: **multiple technology appraisals (MTAs)** for the evaluation of all the relevant technologies for the same indication and **single technology appraisals (STAs)** for the evaluation of single technologies for a sole indication.
- MTAs started as the standard approach, taking 54 weeks from process initiation. In an MTA, the independent evidence assessment group reviews the evidence base and develops its own independent effectiveness and cost-effectiveness assessment, as well as critically appraising submissions from companies.
- STAs are currently the most common approach, taking 37 weeks from initiation. In an STA, the company submits evidence on the technology's effectiveness and cost-effectiveness; the independent evidence review group critically appraises the submission.
- Advantages of NICE's approach to TAs include its methodological rigour, the encouragement of extensive stakeholder involvement and transparency of the appraisal process.
- Issues of concern are a lack of independence of NICE from the government, timeliness of the assessments, the use of a cost-effectiveness threshold, the use of the quality-adjusted life-year as a measure of health benefit and the uneven implementation of NICE guidance across the NHS.
- The HTA procedures in Scotland and Wales are more timely, but the SMC and AWMSG face many of the other challenges also faced by NICE.

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# What are the HTA processes in the UK?

## Background to the use of health technology assessment

Health technology assessment (HTA) has been defined as 'a **multidisciplinary field of policy analysis** studying the medical, economic, social and ethical implications of the development, diffusion and use of health technologies.'[1]

HTA has a fairly long history in the UK. The first prominent studies took place in the late 1980s (eg, evaluation of breast cancer screening with mammography), funded by the UK Department of Health (DH). Although HTA became increasingly influential from the early 90s onwards with the creation of the NHS Research and Development programme, it was still not having sufficient impact in clinical practice. In addition, the absence or lack of attention to evidence on the clinical and cost-effectiveness of health technologies was leading to so-called 'postcode rationing', whereby expensive new technologies, such as interferon beta therapy for multiple sclerosis, were available in some locations but not others. In 1999, the DH, therefore, established the National Institute for Clinical Excellence (NICE) to produce guidance on whether treatments and procedures should be used by the NHS, based on evidence on their clinical and cost-effectiveness. In 2005, NICE merged with the Health Development Agency and began developing public health guidance. More recently, in April 2013, NICE (now called the National Institute of Health and Care Excellence) became a non-departmental public body (NDPB) and was tasked with developing guidance and quality standards in social care. As an NDPB, NICE is accountable to the DH but is operationally independent of the government.[2] Over time, NICE's role has expanded beyond HTA to produce evidence-based guidance on technologies and interventions (including drugs, devices, diagnostic tests, public health interventions and social care), to develop quality standards and performance metrics and to provide information services for health, public health and social services.[2]

## The NICE technology appraisal programme

The **NICE technology appraisal (TA) programme** develops guidance on the use of new and existing medicines, treatments and procedures within the NHS, based on clinical and cost-effectiveness evidence. NICE guidance applies in England and sometimes also in Wales. In Scotland, assessments of the clinical and cost-effectiveness of all new drugs are conducted by the Scottish Medicines Consortium (SMC).[3] In Wales, the All Wales Medicines Strategy Group (AWMSG) undertakes assessment of new drugs, particularly in areas where no NICE guidance is available.[4]

Only a few technologies are selected for appraisal. The selection process starts with the referral of technologies for NICE to appraise by the UK Secretary of State for Health. A technology is not considered if it meets one of the elimination criteria: (i) it is not licensed or there are no plans to license it; (ii) the topic is similar or identical to NICE guidance that has been published or is in progress; (iii) it is similar or identical to a technology that is currently in the selection process, previously considered and eliminated in the selection process, or previously considered and not prioritised within three years; (iv) widely accepted and implemented published guidance from the UK DH or other government agencies is in existence; and (v) it is out of NICE's remit (population screening, vaccination, HIV technology or therapy). In addition, a technology is not considered unless all these four conditions apply: (i) it is likely to be of significant benefit to patients, in terms of administration, efficacy or improved side effect profile; (ii) it is likely to be available at a significantly different price to that of the current standard treatment; (iii) there is appropriate evidence, either available or anticipated to be available in the near future, to support the appraisal; and (iv) the relevant clinical questions can be addressed by applying the TA methodology. Technologies undergo prioritisation for appraisal according to the prioritisation criteria. These consider the expected benefits of the technology (health benefits and others, such as reduction of health

inequalities), its impact on NHS resources, variation in its use across the country and whether NICE guidance is likely to add value to the NHS.[5]

NICE TA guidance is prepared by the **Technology Appraisal Committee (TAC)**. The TAC is an independent entity with membership drawn from the NHS, patient organisations, academia and industry, and it is the primary decision-making body in the production of guidance on new health technologies.[6] While the TAC represents the views of its varied membership, its advice is intended to be separate from any vested interests. The TAC considers the evidence submitted by the company (ie, manufacturer(s) or sponsor(s) of the technology(ies) under appraisal or of the comparator technologies), evidence submitted by the independent Evidence Review Group (ERG; for single technology appraisals [STAs]) or Assessment Group (AG; for multiple technology appraisals [MTAs]), and the views of consultees and commentators. The ERG/AG are independent academic research centres commissioned by NICE to review the evidence on the technology. The NHS in England and Wales is required to provide funding and resources to implement NICE TA guidance within three months from the date of publication. The consultees can submit evidence during the appraisal, comment on the appraisal and appeal against the TAC's decision. They include national groups representing patients or carers, bodies representing healthcare professionals, and companies of the technologies under appraisal. The commentators can comment on, but are not asked to prepare, a submission and include relevant comparator technology companies, Healthcare Improvement Scotland, the relevant National Collaborating Centre, related research groups and other groups, where appropriate.[5]

The *'Guide to the methods of technology appraisal'* (methods guide) provides an overview of the principles and methods of HTA and appraisal used by NICE.[7] This, together with the companion document *'Guide to the processes of technology appraisal'*[5] and *'Guide to the technology appraisal and highly specialised technologies appeal process'*[8] form the template for the company submissions and independent review. The methods guide embodies the concept of the **'reference case',** whereby preferred methods are outlined but companies can also submit alternative analyses, if they think these are superior. The objective is to achieve some degree of standardisation of submissions without stifling methodological development.

The 2013 NICE reference case is shown in Table 1.[7] Briefly, NICE prefers a cost–utility analysis, comparing the technology with the relevant comparators in use by the NHS with full incremental analysis from the perspective of the NHS and personal social services (PSS) for costs. Health benefits are expressed as quality-adjusted life-years (QALYs), preferably measuring health-related quality of life with the EuroQol five dimensions (EQ-5D) tool directly from patients (or carers, if applicable).

NICE's standard approach to technology appraisals, called **multiple technology appraisal (MTA),** takes 54 weeks from initiation of the process to issuing of guidance. Key features of the process are **scoping of the topic,** which includes a scoping workshop involving the company and other key consultees, **companies' submissions** and an **independent technology assessment report (TAR)** by one of the AGs mentioned above. The TAR normally includes a systematic review of the clinical literature and an economic model, and can be quite extensive, especially since more than one technology is being assessed. The report and any other relevant evidence are considered by the TAC and an **appraisal consultation document** is issued. Consultees are then given an opportunity to comment before the **final appraisal determination** is issued, following a second discussion by the TAC. Consultees then have the opportunity to appeal, in which case an appeal hearing takes place. If no appeal is launched, the guidance is issued to the NHS within six weeks.[5]

Currently, the typical procedure for appraising a new technology is the **single technology appraisal (STA)** for the review of single technologies for a sole indication. This

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**Table 1.** The NICE reference case[7]

| Element of health assessment | Reference case |
|---|---|
| Defining the decision problem | The scope developed by the institute |
| Comparator | Alternative therapies routinely used in the NHS as listed in the scope developed by NICE |
| Perspective on costs | NHS and PSS |
| Perspective on outcomes | All direct health effects on individuals (patients or carers) |
| Type of economic evaluation | Cost–utility analysis with full incremental analysis |
| Time horizon | Long enough to reflect all important differences in costs and outcomes between the technologies being compared |
| Synthesis of evidence on outcomes | Based on systematic review |
| Measure of health benefits | QALYs |
| Source of data for measurement of health-related quality of life | Health states reported directly by patients or carers |
| Method of preference elicitation for health state valuation | Choice-based method, preferably the EQ-5D for adults |
| Source of preference data | Representative sample of the UK population |
| Evidence on resource use and costs | NHS and PSS resource use valued using the prices relevant to the NHS and PSS |
| Discount rate | • An annual rate of 3.5% on both costs and health effects<br>• A discount rate of 1.5% for costs and benefits may be considered if it is highly likely that long-term health benefits are likely to be achieved. Long-term health benefits occur when a treatment restores people who would otherwise die or have a very severely impaired life to full or near full health over a long period (≥30 years) |
| Equity position | • An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit: 'a QALY is a QALY is a QALY'<br>• Additional QALY weighting is possible for 'life-extending treatment at the end of life' |

EQ-5D = EuroQol five dimension; NICE: National Institute for Health and Care Excellence; PSS: Personal Social Services; QALY: quality-adjusted life-year
Reproduced with permission from National Institute for Health and Care Excellence (NICE). *Guide to the methods of technology appraisal 2013.* Manchester: NICE, 2013[7]

was introduced in 2005 in response to criticisms surrounding the length of time taken by the MTA process. The STA process is similar to that of the full MTA process previously described. However, in an STA the company submits the principal evidence and the ERG produces a review of the evidence submitted. The timelines for the STA process also differ from the MTA process.[4] Specifically, STAs require less time to produce the guidance; approximately 37 weeks from initiation of the appraisal to publication. The timeline for STAs is, however, not substantially compressed and with any delays in the appraisal or appeals, it could approach the duration required for an MTA. To date, the STA process has been applied only to drugs – mainly cancer drugs – although it is increasingly being employed in other disease areas.[6] The processes for MTAs and STAs are outlined in Table 2.[5]

The new STA process developed by NICE is similar to the appraisal process that has been in operation in Scotland for several years, where, if a company wishes guidance on the use of its drug to be issued, it submits a dossier to the SMC. The dossier is then evaluated by the consortium's assessors before guidance is issued. There has been some interest in comparing and contrasting the costs and outcomes (in terms of decisions) of the English and Scottish approaches. It is clear that the SMC's approach is quicker and less costly. The outcomes of the assessments are quite similar, although it appears that NICE sometimes makes more detailed recommendations relating to specific patient subgroups.

## Decision-making

The TAC formulates its decision based on the evidence submitted by the company, ERG/AG, consultees and commentators on effectiveness and cost-effectiveness. The technology can be recommended, when it

**Table 2.** NICE procedures for technology appraisals[5]

| Week | MTAs | STAs |
|---|---|---|
| 0 | Organisations invited to participate as consultees and commentators; consultees invited to make submissions; professional and patient consultees invited to nominate clinical specialists and patient experts | Companies invited to submit their submission; consultees invited to make submissions |
| 2 | | Companies' submission of decision problem received; professional and patient consultees invited to nominate clinical specialists and patient experts |
| 8 | Stakeholder information meeting | Evidence submissions and consultee comments received; start of report preparation by the ERG. NICE receives information from consultees |
| 10 | | NICE invites selected clinical experts, NHS commissioning experts and patient experts to attend the Appraisal Committee meeting and asks them to submit a written statement |
| 11 | | Request for clarification sent to company |
| 14 | Submissions received by consultees | |
| 15 | Submissions from companies sent to assessment group | |
| 16 | NICE invites selected clinical experts, NHS commissioning experts and patient experts to attend the Appraisal Committee meeting and asks them to submit a written statement | |
| 18 | | ERG report received; NICE sends ERG report to company for fact check. Selected clinical experts, NHS commissioning experts and patient experts submit written statements |
| 19 | | Evaluation report compiled and sent to Appraisal Committee |
| 21 | | Positive opinion required at this point for STA to proceed; Appraisal Committee meeting to develop ACD or FAD (if recommendation is positive) |
| 24 | | ACD consultation begins; marketing authorisation or regulatory approval issued |
| 25 | | ACD posted on NICE website for three weeks' public comment. FAD sent to consultees and commentators (15 working days for consultees to appeal) |
| 27 | | ACD consultation ends |
| 28 | Assessment report received by NICE | |
| 29 | | Appraisal Committee meeting to develop FAD |
| 30 | Assessment report sent to consultees and commentators for comment | |
| 32 | Selected clinical experts, NHS commissioning experts and patient experts submit written statements | |
| 34 | Comments on assessment report from consultees and commentators received by NICE | FAD distributed to consultees and commentators for 15 working days during which consultee can appeal |
| 36 | Evaluation report compiled and sent to Appraisal Committee | |
| 37 | Appraisal Committee meeting to develop ACD | Close of appeal period (if no appeal, guidance published within six weeks) |
| 40 | ACD consultation begins | |
| 41 | ACD posted on NICE website for three weeks' public comment | |
| 42 | FAD sent to consultees and commentators (15 working days for consultees to appeal) | |
| 44 | ACD consultation ends | |
| 45 | Appraisal Committee meeting to develop FAD | |
| 47 | Anticipated publication if no appeal received | |
| 51 | FAD distributed to consultees and commentators for 15 working days during which consultees can appeal | |
| 52 | FAD posted on NICE website | |
| 54 | Close of appeal period (if no appeal, guidance published within six weeks) | |

ACD: appraisal consultation document; ERG = Evidence Review Group; FAD: final appraisal determination; MTA: multiple technology appraisal; NICE: National Institute for Health and Care Excellence; STA: single technology appraisal
Reproduced with permission from National Institute for Health and Care Excellence (NICE). *Guide to the processes of technology appraisal. Process and methods guide.* Manchester: NICE, 2014[5]

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is recommended for the licensed patient population; optimised, when it is recommended in a subgroup population; recommended for use only in research; or not recommended. Although the cost-effectiveness of the technology is not the sole criterion for recommendation, it is a necessary consideration. The **incremental cost-effectiveness ratio (ICER)** of the technology is compared against the **cost-effectiveness threshold** range of £20,000 to £30,000 per QALY gained. The cost-effectiveness threshold represents the opportunity cost of those interventions displaced by new, more costly technologies. Technologies are usually recommended if their ICER is below £20,000 per QALY gained. Above £20,000, the TAC considers the degree of certainty around the cost-effectiveness of the technology, the evidence base around the effect of the technology on health-related quality of life, the innovative nature of the technology, whether the technology meets the criteria for special consideration as a 'life-extending treatment at the end of life' (more details below) and aspects that relate to non-health objectives of the NHS (eg, reduction of health inequalities).[5]

Currently, technologies that meet the criteria as a 'life-extending treatment at the end of life' can have their health benefits increased by assuming that the extended survival period is experienced at the full quality of life anticipated for a healthy individual of the same age.[5] The criteria are:

- The technology is indicated as a treatment for patients with a short life expectancy, normally less than 24 months
- There is sufficient evidence to indicate that it offers an extension to life, normally of at least an additional three months, compared with current NHS treatment
- The technology is licensed or otherwise indicated, for small patient populations normally not exceeding a cumulative total of 7,000 for all licensed indications in England
- The estimates of the extension to life are robust and can be shown or reasonably inferred from either progression-free survival or overall survival and the assumptions used in the reference case economic modelling are plausible, objective and robust.

## Patient access schemes

Patient access schemes (PAS) were introduced in 2009 to improve access to treatments whose balance of costs and benefits did not meet the NICE cost-effectiveness thresholds.[9] These schemes are proposed by the companies and consist of pricing agreements designed to improve cost-effectiveness and facilitate patient access to specific drugs or other technologies. PAS can take a number of formats. Free stock agreements take place when the company provides some cycles of treatment free of charge and the NHS bears the cost of subsequent cycles (eg, certolizumab for severe rheumatoid arthritis). Dose capping agreements mean that the NHS bears the cost of the first cycles of treatments and the company the subsequent treatments (eg, ranibizumab for acute wet macular degeneration). Discount agreements involve the company offering the drug at a confidential discount to the NHS (eg, omalizumab for severe persistent allergic asthma).[10]

## Main issues arising from NICE HTA activities

NICE's approach to TAs has several desirable features. First, there is considerable methodological rigour, especially in the conduct of MTAs. Second, compared with other comparable organisations, NICE encourages extensive stakeholder involvement in the scoping of appraisals, commenting on draft reports and appealing against decisions. Third, NICE's activities are fairly transparent, which is one of the reasons so much has been written about the institute. Nevertheless, several issues remain unresolved or of concern to some parties.[11]

### Lack of independence

Although NICE is classed as an 'arm's-length' organisation, there are accusations that the institute is essentially following a government, or payer's, agenda. Indeed, to a large extent this is true, since NICE's remit is to ensure that the use of NHS resources is consistent with the principles of clinical and

cost-effectiveness. On occasions it is, therefore, bound to issue negative guidance if a given technology, or its use in certain indications, does not meet the criteria. Whether this constitutes more rationing of care than would have occurred in the absence of NICE is open to debate. Because the determination of the NHS budget is made by the DH largely independent of NICE, it is likely that NICE has led to different rationing, as opposed to more rationing.

Although NICE views the DH as its major stakeholder, there are very few examples of government actions that impinge on NICE's work. When NICE made the decision not to issue positive guidance on the use of interferon beta for multiple sclerosis, the DH, perhaps fearing a negative political backlash, brokered a PAS with the companies. This allowed certain categories of patients to obtain, or to continue with, therapy, while limiting the financial risk to the NHS. Another example is the QALY weighting of 'life-extending treatment at the end of life', which was introduced in 2009 in the wake of rejection by NICE of drugs for advanced renal cell carcinoma. More recently, the government created the Cancer Drugs Fund in 2010 to make available to patients cancer treatments that had been refused by NICE.

## Timeliness

The concern has been raised that a period of 54 weeks (minimum) to conduct assessments is much too long. As mentioned previously, STAs were introduced to deal with this issue. However, STAs only reduce the core assessment time from 54 to 37 weeks and there are worrying signs that, with a higher proportion of appraisals going to appeal, the average time to issue guidance may increase. These concerns are compounded by the fact that, once a technology is selected for appraisal by NICE, the NHS is less likely to introduce it, pending the decision by NICE. The extent of so-called 'NICE blight' has not been formally studied, but does exist. Of course, the technology companies feel (in the case of drugs) that all licensed products should be used until NICE issues guidance to the contrary. On the other hand, the NHS is cautious about introducing new technologies, which will be hard to remove or restrict if they are subsequently shown to be poor value for money.

## Quality-adjusted life-years and social values

From the outset, NICE has been quite clear that the measure of health benefit to use in TAs is the QALY (see Table 1).[5] The theoretical and methodological weaknesses of the QALY approach have been well discussed elsewhere and will not be reiterated here (see 'Further reading' section). An additional issue has arisen, however, in discussions about the decisions taken by NICE; namely, does the QALY capture all the elements of social value that are relevant to decisions about the allocation of healthcare resources?

NICE uses QALYs in a 'standard' fashion in its TAs; namely, a QALY is considered of equal value regardless of who receives it. Some argue, however, that society, if consulted, would not apply this principle; for example, some research studies indicate that members of the public may value a QALY given to someone in a very poor health state higher than if it was given to someone in good health (a more detailed explanation of QALYs can be found in *What is a QALY?)*.[12]

## The cost-effectiveness threshold

The use, or non-use, by NICE of a threshold has been a continuing topic for debate, since it would be clear evidence that NICE rations care. Three criticisms have been raised: (i) there should not be a threshold; (ii) the threshold has been set at the wrong level or is arbitrary; and (iii) different thresholds should apply, depending on the nature of the treatments or patient populations being studied.

Of course, the first criticism is rather meaningless, in that whenever decisions are made on whether or not to reimburse a particular technology, some assessment of value for money is being made. Perhaps a more relevant question is whether the cost-effectiveness threshold (or thresholds) should be explicitly stated. To apply an explicit threshold, the decision-maker needs to know what the right level would be. NICE has never claimed to know the answer to

this question and, in answering the concerns of the Health Select Committee, the institute described its decision-making process as a deliberative one, which, in essence, is searching for a threshold.[13] A recent study has estimated the NHS cost-effectiveness threshold at £12,936 per QALY gained.[14] However, the latest NICE methods guide (issued 2013) and the 2014 Pharmaceutical Price Regulation Scheme has retained the cost-effectiveness threshold between £20,000 and £30,000 per QALY gained.[15]

The third concern is that the cost-effectiveness threshold, if one can be determined, may differ depending on the treatments being evaluated or the patient populations being studied. In part, this links back to the discussion above; if the QALY does not fully capture all the relevant elements of social value, it may not make sense to apply a single threshold. This issue has been raised in the context of drugs for rare diseases (so-called orphan drugs). Even if these treatments do not appear very cost-effective (that is, if they have a very high cost-effectiveness ratio), society may still prefer to make them available, because many of the diseases treated with orphan drugs are life-threatening and because it would be unfair for someone not to be offered treatment just because their disease is rare.[16] This is also the case of the 'life-extending treatments at the end of life', in which the gain in life expectancy is assumed to be experienced at the full quality of life for a healthy individual of the same age; for example, if the ICER for the 'end-of-life' treatment is £60,000 per QALY, with QALYs being valued in the conventional way, the TAC would need to agree that the QALYs experienced by the patients concerned are worth twice the norm to recommend use of the therapy.

## Implementation of NICE guidance

The uptake of NICE-recommended technologies has been shown to be uneven across the NHS despite the fact that guidance resulting from TAs is mandatory on the NHS and should be implemented within three months.[17,18] This is particularly worrying since NICE was set up to reduce geographical variations in the adoption of new technologies (so-called 'postcode rationing'). NICE has established an implementation group to facilitate the implementation of its guidance, but full implementation remains difficult to achieve (see *Implementing NICE guidance* for more details[19]). The NICE Implementation Collaborative (NIC), a partnership between the NHS, the life sciences industry, healthcare professional bodies, key health organisations and the public, was established in 2013 to understand, analyse and propose ways to overcome the barriers to the implementation of NICE guidance. It is hoped that NIC will help ensure quick uptake of NICE-recommended technologies.[20]

## Value-based assessment versus value-based pricing

NICE is currently consulting on several aspects of its methods guidance, including aspects relating to the valuation of the benefits from treating different conditions, as part of its commitment to produce 'value-based assessments' of health technologies to support the government's Pharmaceutical Price Regulation Scheme. Value-based pricing was initially proposed by the Office of Fair Trading as a replacement for the Pharmaceutical Pricing Regulation Scheme in 2007 in order to incentivise pharmaceutical companies to develop innovative drugs.[21] Its potential advantages included ensuring fair prices for the NHS and avoiding negative recommendations by NICE. However, as discussions progressed, value-based pricing looks to become value-based assessment. Pharmaceutical companies retain the right of setting prices at launch, which NICE then uses for its (value-based) assessment.[15] This assessment is still under discussion and at this point, it is too early to predict the outcome of the consultation exercise and subsequent guidance. It is likely to follow the standard NICE TA process but include a weighting system for burden of illness that reflects the different value of treatments for the most serious conditions and taking into account the wider social impact (defined as the loss in a person's capacity to engage

with society as a result of the illness).[22] The challenge is in implementing these changes, since some technologies will be favoured (eg, treatments that reduce care-giving requirements) while others will be disadvantaged (eg, treatments that extend survival in a highly-dependent stage).

## Conclusions

HTA has a long tradition in the UK. In recent years, the practice of HTA has become synonymous with the activities of NICE in England, although other important HTA entities exist in Scotland and Wales. Since its inception in 1999, NICE has been widely debated and often criticised. It can, however, claim several major achievements and it still represents one of the more sophisticated attempts to integrate HTA into the decision-making process. Nevertheless, many important issues remain unresolved and NICE, the SMC and the AWMSG definitely remain a 'work in progress'.

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**Further reading**

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# Notes

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