The term “health technology” is commonly understood to mean a drug or medical device. However, the officially recognised definition encompasses any method used by those working in health services to promote health, prevent or treat disease, or improve rehabilitation and long-term care of patients.

A health technology assessment (HTA) can be defined as the structured evaluation of properties or effects of a health technology, or both. This broad definition encompasses both primary research (e.g., randomised controlled trials) and the analysis and assessment of the results of primary research (e.g., meta-analysis and economic modelling). HTAs are designed to answer questions, such as:

- Does the treatment work?
- Who does it work best for?
- At what cost do we get the results?
- How does the treatment compare with alternatives?

**Background to HTAs**

One of the prime drivers for the recent rise in HTA activities has been the evidence-based medicine revolution. This grew from awareness that many technologies used in health care were not backed by evidence or, conversely, effective technologies were not being used enough.

In addition, increased sophistication of technologies, rising expectations and aging populations have all contributed to rising health care costs. The reality is that there will always be more demand for health technologies than current resources can supply and difficult choices might have to be made between competing technologies and, in some circumstances, between patient groups. In recent years, HTA has shifted from evaluating whether or not technologies are effective to maximising effectiveness by deriving the maximum units of health outcome for a given resource. These are the principles underpinning cost-effectiveness analysis.

Every country has some system of HTA and, while the methods of evaluating clinical and cost-effectiveness are broadly similar, the way in which topics are chosen, the processes and the interplay with policy making differs. In this context it is helpful to distinguish between “assessment” (the application and outputs of HTA methodology) and “appraisal” (the consideration of the assessment information in conjunction with context-specific values and factors in order to inform health policy).

Medicines are assessed in order to derive maximum units of health outcome

**England and Wales**

NHS reforms in the early 1990s led to the development of a NHS research and development strategy and wider discussions on the role of HTA to deal with the uncertainties surrounding the effectiveness of NHS health care. The reforms also meant that what are now known as primary care trusts and NHS trusts were responsible for their own budgets and were, therefore, free to make decisions at a local level. HTA conducted at a local level coupled with local price negotiations with suppliers led to what was termed “postcode prescribing” — whether or not you could have a particular technology on the NHS depended on where you lived.

The variation in accessibility to health care was highly controversial and a number of policy changes were implemented to encourage a nationally consistent approach to health care. This led in 1999 to the establishment of the National Institute for Clinical Excellence (NICE). Designated a NHS special health authority, the remit of NICE was to provide authoritative recommendations for the NHS in England and Wales on the clinical- and cost-effectiveness of health care interventions and on the treatment of clinical conditions.

NICE originally had two core programmes: technology appraisals (called “guidance”) and clinical guidelines. Technology appraisals issue guidance on the clinical- and cost-effectiveness of specific health care interventions. Guidelines have a broader remit and look at wider aspects of the management of a condition.

The interventional procedures programme was added to the NICE repertoire in February 2002, replacing the safety and efficacy register of new interventional procedures (SERNIP), which reviewed novel
In April 2000, the Health
The Northern Ireland
The achievement of significant health
The impact on NHS or societal resources
5
Any de-
Wales.

Panel: NICE topic selection
In order to select a topic for assessment, two main criteria are applied. First, the guidance on the
Second, guidance on the topic must add value. There should be a sufficient evidence base for
surgical techniques. With the merger of the
The Health Development Agency and NICE (renamed the National Institute for Health and Clinical Excellence) in April this year the
providing for the NHS in Northern Ireland. Currently, NICE guidance does not apply in Northern Ireland and there is no local requirement to implement it.

Northern Ireland

Assessment of pharmaceuticals

Scotland In April 2000, the Health Technology Board for Scotland (HTBS) was formed. The role of the HTBS was to
improvement in patient care given the available
Surgical techniques. With the merger of the

The All Wales Medicines Strategy Group (AWMSG) was established by the Welsh Assembly Government in 2002 as a

The AWMSG remit is to advise the minister for health and social services on strategic developments in prescribing, which includes managing the entry of all new pharmaceuticals into Welsh health care. NICE guidance is also applicable in Wales.

Scotland In April 2000, the Health Technology Board for Scotland (HTBS) was formed. The role of the HTBS was to comment, from a Scottish perspective, on NICE guidance and to undertake further health technology assessments as required. In October 2001, the clinical effectiveness bodies in Scotland, including HTBS, were reorganised to achieve better integration and coordination. This led to the formation of NHS Quality Improvement Scotland (NHS QIS), which was established as a special health board by the Scottish Executive in 2003. The NHS QIS produces a number of publications designed to respond to the needs of NHS Scotland, with the aim of improving the quality of health care. The NHS QIS also serves as an umbrella organisation for the Scottish Medicines Consortium (SMC), the Scottish Intercollegiate Guidelines Network and the Scottish Health Council. The SMC considers all newly licensed medicines, new formulations of existing medicines and any major new indications for established products. The AWMSG only looks at new high-cost pharmaceuticals (over £2,000 per patient per year, including associated administration costs) and those high-cost pharmaceuticals with a major new indication. AWMSG decisions to appraise are made on a case-by-case basis.

Although the topics appraised differ, SMC, AWMSG and NICE technology appraisals will only issue recommendations on pharmaceuticals within their licensed indications. This means that guidance can only be issued for drugs with a marketing authorisation (licence) by the regulatory authorities — the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Evaluation Agency. This ensures that the pharmaceutical company has satisfactorily demonstrated that the medicine does what it claims, is safe in that context, and is manufactured to a high standard. Any device that NICE examines must also have obtained a CE marking from the MHRA, which ensures that the device has demonstrated safety, efficacy and performance under normal conditions of use. NICE guidelines can, however, examine pharmaceuticals outside their licensed indications.

Unlike the regulatory authorities, the HTA organisations examine the clinical- and cost-effectiveness of technologies relative to current NHS practice at the prices that are being charged. It must be emphasised that none of the three UK HTA bodies has authority to mandate prices. This is done by the Pharmaceutical Price Regulation Scheme — a voluntary, non-statutory, agreement between the Department of Health and the pharmaceutical industry. The scheme allows companies freedom of pricing for all new chemical entities but regulates the profits that companies can make on sales.

The HTA process

Although all three HTA bodies follow broadly the same process and give stakeholders a chance to comment at various stages there are a number of key differences. One of the major differences is the evidence used to inform the appraisal. In the case of NICE, an independent assessment report is prepared by one of a number of academic institutions throughout the UK. The assessment report is commissioned through the National Co-ordinating Centre for Health Technology Assessment (NCCHTA). The NCCHTA manages, supports and develops the NHS HTA programme under contract from the Department of Health research and development division. The report is subsequently published by the NCCHTA as part of the HTA monograph series.

The assessment report contains a systematic review of the literature that is informed by literature searches and submissions by patients, health care professionals, NHS bodies and the manufacturer of the technology. An evaluation of cost-effectiveness is also undertaken using the published literature, the economic models submitted by consultees and, usually, a specially developed economic model. The assessment report is circulated to stakeholders before the meeting to allow their comments to be taken into account. In addition to consulting with a large number of formal stakeholders NICE also publishes consultation documents on its website to allow comments to be made.

The SMC and AWMSG assessment processes differ from the NICE process because they are primarily based on the clinical and cost-effectiveness evidence that is submitted by pharmaceutical companies. The SMC in-house team (which includes economists and pharmacists) examines the strengths and weaknesses of the scientific and economic case as presented by the manufacturer and produce a written critique. The team also conducts independent literature searches to ensure all the key research has been included in the submission. The written critique is then presented to the New Drugs Committee alongside a draft of a detailed advice document. This committee considers the draft assessment and issues a final detailed advice document.

AWMSG assessments are undertaken by the Welsh Medicines Partnership team (a pharmacist, a clinical pharmacologist and an economist) that critically appraises the evidence submitted by the pharmaceutical com-
pany in conjunction with any relevant information that has been separately sourced. The pharmaceutical company has an opportunity to comment on the Welsh Medicines Partnership assessment before its circulation and provide the AWMSG with a written formal response to this report.

Appraisal of the evidence
All three bodies have an independent advisory committee comprised of lay representatives, health professionals, experts on methodology and people with experience of the pharmaceutical industry. The SMC is a collaboration of the 15 Scottish health boards and the main committee includes representation from these health boards (either health professionals, managers or directors of finance).

The AWMSG and the SMC meet once for each technology submission and consider recommendations that have been made by the Welsh Medicines Partnership and the New Drugs Committee, respectively, alongside the manufacturers’ comments on the preliminary recommendations. The AWMSG and the SMC also consider advice from clinical experts and patient interest groups.

The NICE appraisal committee is not provided with recommendations to work from and meets twice per topic. At the first meeting the assessment report is considered in conjunction with submissions from stakeholders (consultees) plus their comments on the assessment report. Organisations consulted include manufacturers of the technology and its comparators, health care professionals, patient groups and NHS bodies. After discussions, a preliminary recommendation is made (the appraisal consultation document), which is sent out to consultees and posted on the NICE website to allow comments from the public. The committee then meets for a second time to consider the proposed guidance in light of comments that have been received. A revised and final recommendation (the final appraisal determination) is then produced.

Guidance
The recommendations issued by all three bodies generally fall into three broad categories. At the extremes the technology is either recommended or not for general use. The third option is to recommend the technology for restricted use (eg, restricted by who should initiate the prescription or which patients should receive it).

The status of the guidance issued also differs. In the case of NICE, funding must be made available within three months unless, in exceptional circumstances, this requirement is waived by the Secretary of State in England. Health professionals are expected to take the guidance fully into account when exercising clinical judgement. The guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient. AWMSG guidance (once approved by the minister for health and social services) also has the same status in Wales.

In Scotland, if an accepted medicine is classed by the SMC as “unique” it must be introduced uniformly across each health board, usually within three months of the publication of SMC advice. If the medicine accepted by SMC is not classed as unique, health boards can decide whether or not to offer it to patients within their catchment area. Their decisions are influenced by factors such as geographical, population, illness and service provision profiles and the availability of equivalent alternative treatments within their area. If NICE comes to a different conclusion from the SMC about a medicine both have assessed, the NICE decision will normally take precedence on the grounds that it is usually informed by more evidence.

Conclusion
Decisions about allocating health care resources are often controversial and HTA provides information to inform those judgments. The Table provides a summary of how the three HTA bodies work. Pharmacists can get involved with HTAs in several ways. Via the NICE website, they can:

- Suggest a topic for appraisal via the topic selection facility on the NICE and Department of Health websites
- Keep up to date with ongoing appraisals
- Comment on draft scopes, assessment reports and appraisal consultation documents

References

Further information
- Scottish Medicines Consortium www.scottishmedicines.org
- National Institute for Health and Clinical Excellence www.nice.org.uk