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HEALTH SYSTEMS AND POLICY ANALYSIS

POLICY BRIEF

How can the impact of health technology assessments be enhanced?

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This policy brief, written for the WHO European Ministerial Conference on Health Systems, 25–27 June 2008, Tallinn, Estonia, is one of the first in what will be a new series to meet the needs of policy-makers and health system managers.

The aim is to develop key messages to support evidence-informed policy-making, and the editors will continue to strengthen the series by working with authors to improve the consideration given to policy options and implementation.

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Contents

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Key messages

Policy issues

- Health technology assessment (HTA) is an important tool for informing effective regulation of the diffusion and use of health technologies.
- The key policy issues surrounding the use of HTA fall into three areas: (a) the bodies, decision-makers and other stakeholders involved, (b) the methods and processes employed; and (c) how the findings of HTAs are implemented.
- The impact of HTA can be enhanced if: key stakeholders (e.g. patients, providers and industry) are adequately involved; decision-makers give a prior commitment to use assessment reports (and assessments meet their needs); the necessary resources are available for implementing decisions; there is transparency in the assessment and decision-making processes; and collaboration, knowledge and skills are transferred across jurisdictions.

Policy measures

- Increased stakeholder involvement throughout the HTA process can help capture and improve the real-world value and applicability of HTAs. Nevertheless, stakeholder involvement needs to be transparent and well-managed in order to ensure that the objectivity of assessments is not influenced.
- HTAs must be timely in relation to the decisions they seek to inform. Simpler studies, early-warning systems and conditional approvals are increasingly being used to manage the uncertainty surrounding new and emerging technologies while facilitating the timeliness and relevancy of HTA.
- International collaboration among HTA bodies can facilitate the development of methods and more efficient assessment processes, and facilitate knowledge transfer and capacity-building in less established HTA systems and programmes.
- To facilitate the use and implementation of HTA reports in decision-making, incentives within a given health care system must be appropriately aligned with the decisions that are based on (or informed by) HTA.

Implementation considerations

- Problems with applying technical information and national recommendations to local decision-making can be reduced if there are formal links between the producers and users of HTA.
- Learning through collaboration and exchange of experience can help to overcome those institutional and capacity barriers that often hinder implementation.

Executive summary

Growth in the diffusion of new health technologies has led to remarkable improvements in health and quality of life. These benefits, however, also bring challenges in ensuring value for money and concerns over the willingness of third party payers and patients to pay for expensive treatments, devices and drugs. As policy-makers seek to obtain maximum benefit from limited resources, and do so in legitimate and transparent ways that reflect the values underpinning health systems, health technology assessment (HTA) is a tool increasingly used to support this aim and encourage the efficient use of health technologies *(1,2)*.

Within the last 30 years, many European countries (European Union (EU) countries in particular) have established HTA programmes to inform a variety of decisions, from determining pricing and reimbursement to setting health service standards. Others, particularly smaller EU countries, are beginning to develop more informal programmes. The aim is to provide policy-makers and other key decision-makers with evidence-based information on the relative costs and benefits of available treatments, based on a systematic assessment process. This enables one to make decisions centred on value, by maximizing health for a given health budget for example, and gives patients and providers the information they require in making the best treatment choices. However, the way HTA is conducted and employed varies considerably, generating a number of issues surrounding its use in decision-making.

This brief examines selected issues in the application and uptake of HTA in Europe. First, the impact of HTA can be affected by the bodies and stakeholders involved in the assessment and appraisal process. National HTA bodies throughout Europe differ in their remit and responsibilities, but typically involve independent review bodies or entities under governmental mandate. This often affects their role in decision-making. The breadth of participation of key stakeholders, such as patients and providers, also plays an important role. While it can enhance the relevance, transparency and uptake of HTA, it may be resource and time intensive. The extent to which stakeholders are involved varies across countries, with few systems offering formal mechanisms for participation.

Second, along with its distinct scientific and policy objectives, HTA should be grounded in robust and transparent methods and processes, and be based on clear and standardized guidelines that outline evidence and methodological requirements. This is not always the case, and concerns remain over processes for identifying and prioritizing topics for assessment, for providing the required evidence for review and data transferability, and for conducting assessments of high quality with rigorous methods. It is also important that HTA methods and

processes recognize the unique needs and circumstances of individual countries. This is especially true of smaller, low-capacity countries, which frequently lack the resources needed to develop and implement more formal and comprehensive assessments.

Third, the impact of HTA depends on effective and timely application in decision-making and subsequent implementation. The overall transparency of the HTA process and the extent to which the information generated meets decision-makers' needs (for example, some require that broader social and ethical issues be considered while others do not) also influence the use of HTA. Successful implementation thus remains one of the least developed areas of HTA. With assessments and decisions typically made at national level, there are additional challenges in ensuring implementation at local level. For instance, national decisions or guidance may not be relevant to local circumstances and needs or coincide with available budgets and resources. This often results in uneven or delayed implementation.

To address these issues, the governance of HTA could be improved in three key areas. First, it could be enhanced by involving a broad range of stakeholders throughout the HTA process, including setting priorities in the choice of topics for HTA, reviewing and interpreting evidence, and commenting on decisions. As decisions affect a variety of stakeholders, their perspectives should be captured to the extent possible. This will help provide decision-makers with the most relevant information, especially regarding ethical, social and organizational considerations. Several national European HTA bodies have mechanisms to address this.

Second, the methods and processes employed in HTA could be enhanced by improving their timeliness while maintaining high-quality assessments. Some countries, such as France and the United Kingdom, use simpler approaches and early warning programmes to provide more timely information on products deemed of policy, clinical or cost importance. Also, as is the case in the Netherlands and the United Kingdom, for example, decision-makers are increasingly using conditional approvals to manage the uncertainty surrounding new and emerging technologies. This allows for a technology to be fully reviewed and validated after additional, real-world data have been collected. Other approaches include formal and informal mechanisms for international collaboration across HTA bodies or programmes. This not only enhances transparency but also facilitates the transfer of knowledge and skills between countries, especially from more established HTA systems to lower-resource countries.

Finally, the impact of HTA on decision-making can be advanced with better implementation at local level. Measures include: targeted local communication

of relevant decisions through either newsletters or expert ambassadors or networks; regulatory mandates for implementation; and formal or informal re-evaluation (upon availability of additional data).

While these strategies offer European governments opportunities for more informed decision-making, challenges remain. Some are specific to the HTA process itself, while others pertain to broader social and system-level considerations. The impact of HTA depends in large part on the quality and transparency of the assessment and decision-making process, in addition to the broader institutional, organizational, political and cultural dynamics of national health care systems. As many countries increasingly gear their health systems towards policies that emphasize measurement, accountability, transparency and evidence-based practices, the challenges of HTA should be addressed in order to achieve concurrent health system goals and support those services that offer greatest value for money and impact on health outcomes.

Policy brief

Introduction: the policy context

Considerable growth in health technologies in recent years in the realms of medicines, diagnostic tools, telemedicine and surgical equipment has brought remarkable improvements in health gains, quality of life and the organization and delivery of treatment. In the United States, it is estimated that some 70% of the improvement in surviving heart attacks is a result of technological advances *(3)*. Alongside the benefits comes the challenge of investing in those services that offer the best value for money. Health-related services have consumed increasingly greater proportions of GDP since the 1970s, with expenditure on health technologies and pharmaceuticals being the principal causes *(4–8)*.[1] In the context of lower economic growth, ageing populations and the expansion of health technologies, governments face continuous pressure to ensure sustainable health care financing while also stimulating and supporting innovation (the technological imperative) (*9,10*). Decision-makers must find a balance between providing high-quality, innovative care on the one hand and managing health care budgets and safeguarding the basic principles of equity, access and choice on the other.

Also, there is widespread variation in the utilization and diffusion of technology among (and within) countries. This may be due to different health care needs, economic conditions and health system features, but it can also indicate suboptimal use of technology and potential inequities in patient access. This can bring unnecessary economic costs and/or reduced health outcomes. Alongside increased scrutiny of health care priority-setting, there remains a need for more accountable, transparent and legitimate decision-making processes.

Governments have employed various strategies to address these issues, principally through regulation, financing schemes or information-sharing, such as global budgeting, provider capitation payment schemes, and concentration of specialized services that require expensive technology investment *(1)*. Health technology assessment (HTA) has increasingly emerged as a tool for informing more effective regulation of the utilization and diffusion of health technologies. While there are various definitions, often relating to evidence-based medicine and comparative effectiveness research, HTA can be seen as "a multi-disciplinary process of policy analysis that examines the medical, economic,

[1] Measuring the impact of new health technology on health care spending is difficult, as innovation in the health care sector occurs continuously and the impacts of various changes are often interrelated.

social, and ethical implications of the incremental value, diffusion, and use of a medical technology in health care" *(11)*. HTA thus seeks to consider the broader impacts of health technologies and to evaluate their benefits and costs in both medical and economic terms. It helps to identify a particular intervention's optimal utilization, its appropriate placement in the spectrum of care, and the patients who will benefit. Historically applied to expensive medical devices and pharmaceuticals, HTA is increasingly employed to evaluate a range of other interventions, including medical and surgical procedures, organizational and support systems for care provision and, to a lesser extent, public health programmes.

Over the last 30 years, many European countries – and particularly those in the European Union (EU) – have established HTA systems or are currently developing or considering them. Many, including France, Sweden and the United Kingdom, are also investing considerable resources to support the production and improvement of HTA and other evaluative activities *(12–14)*. Nonetheless, health services research and HTA represent less than 0.05% of total national health care spending *(15)*. Countries with social insurance health systems or national health services demonstrate the highest annual budgets for such activities *(16)*.

While there is general consensus that HTA is needed and provides value, the ways in which assessments are produced and employed vary considerably, raising issues around its most effective use in policy-making. These issues fall within three areas concerning who is involved in HTA, what HTA entails and how HTA is applied and implemented (Table 1).

This policy brief outlines the key issues surrounding each of these areas and identifies policy approaches to tackle the challenges and opportunities outlined, providing supporting examples from different countries. The policy areas and associated issues were identified from a comprehensive review of the existing literature, including grey literature. While it was not possible to address the entire scope of HTA evidence, the policy issues included here represent the principal, outstanding challenges and opportunities relevant to HTA faced by the majority of countries across established and developing HTA systems.

Factors affecting the impact of HTA

Who is involved in HTA?

The remit and governance of HTA bodies and associated decision-makers and stakeholders differ across countries according to their general mission and overall policy objectives *(17)*. As one component of the broader health care decision-making process, the role of HTA programmes typically reflects a health

Table 1. Core areas influencing the impact of HTA

Core areas Description	Key issues
WHO is involved?	
Governance and organization of HTA bodies, decision-makers, and involvement of other stakeholders in HTA processes	Remit, role(s) and responsibilities of different HTA systems in assessments, appraisals and broader decision-making. Independence of HTA bodies in relation to government, payers and special interest groups. Transparency and accountability of involvement, centred on the extent to which a broad range of stakeholders (e.g. health care professionals, patients and industry) are included and represented.
WHAT is involved?	
Methods, processes and procedures employed in HTA	Topic prioritization and selection through consideration of key criteria (e.g. public health gains, financial impact and assessment feasibility) and an open, systematic and unbiased selection process. Evidence requirements and transferability among countries in the use of clinical data, application of models and adaptation of existing HTAs to reflect different country contexts. Review of evidence, giving due consideration to safety, efficacy, cost–effectiveness, ethical considerations and organizational impacts. Specific methodological issues in conducting assessments, including measuring health benefit, capturing relevant costs and accounting for uncertainty in available evidence. Timing of assessments, entailing the length of time required to complete assessments and provide relevant decision-makers with required information.
HOW is HTA applied and implemented?	
Application and support of HTA in decision-making, and implementation of decisions in national and local policy contexts	Use of HTA in decision-making, which is often influenced by specific product characteristics (e.g. broad use and significant budget impact), the overall transparency of the HTA process, adequate resources, processes for reassessment, policy requirements, and local support/uptake of recommendations. Implementation of decisions, including adequate communication to key stakeholders, reinforcement of compliance or accountability, aligned political and financial drivers/incentives, and recognition of local variation in resource capacity, health needs, etc.

system's history, ethos and values as well as key policy objectives. Consequently, assessments often coincide with decisions on the reimbursement, pricing and utilization of drugs or other current policy measures *(2)*.

HTA programmes typically involve several functions, from coordinating assessments and producing and disseminating reports (for example SBU, the Swedish Council on Health Technology Assessment), advising decision-makers on the reimbursement and pricing of health technologies (for example IQWiG, Germany's Institute for Quality and Efficiency in Health Care) to actually taking decisions themselves (for example LFN, Sweden's Pharmaceutical Benefit Board). Some HTA bodies are independent and largely self-governing, and may or may not be secured through different funding mechanisms, such as the Danish Centre for Health Technology Assessment (DACEHTA) or the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom. HTA bodies often collaborate on various aspects of assessments or coordinate independent reviews by external bodies such as university research centres *(2,17)*. The use of independent reviews may lend greater transparency to the HTA process and help to prevent or resolve potential disputes *(18–19)* but can also generate challenges relating to the ownership and accountability of the assessment.

Understanding these different functions and their rationale is important for those with new or developing HTA systems. In many countries, the HTA process is overseen by the Ministry of Health but the governance and organization of any HTA entity depends on whether it is established primarily to serve the decision-making requirements of the government or a broader range of needs. Here, the wide scope of HTA overlaps somewhat with the more focused assessment processes employed in pharmaceutical marketing approval, pricing and reimbursement. Increasingly, however, as HTA-based methods begin to be used in decision-making, these activities fall under the rubric of HTA.

HTA bodies also play different post-assessment roles. Those with a regulatory function are normally responsible for making decisions and setting priorities on the reimbursement and listing of health technologies, typically pharmaceuticals. In other countries, reimbursement and pricing decisions may fall to national authorities or a self-governing body. Part of this difference is reflected in the role that an HTA entity assumes in undertaking assessments (i.e. evidence generation and interpretation) as opposed to appraisals (i.e. production of guidance for decision-makers). The majority of HTA organizations limit their role to assessments only. NICE, however, is involved in both phases: during the assessment, issues of efficacy, safety, effectiveness and cost are addressed while broader impacts on the National Health Service (NHS), patients and society may be attended to in the appraisal.

The HTA process can have a significant effect on treatment availability and

access, as well as on clinical practice. Consequently, a range of stakeholders – providers, insurance and industry representatives and patients – may also wish to provide input. The better integration of stakeholders is increasingly supported in order to improve the policy and practical relevance of the process, enhance transparency and facilitate the accountability of decisions. Nevertheless, the extent to which these actors are included in the HTA process and subsequent decision-making differs significantly among systems. It is also debated whether such input is given sufficient consideration when reviewing both the relevant evidence and the resulting recommendations.

In all the above-mentioned elements, it is important that HTA systems are as independent as possible, particularly as the findings from HTA reports are often controversial. Without sufficient independence, decisions might not be supported owing to perceptions that the process was driven by a particular agenda, most often associated with payers or industry *(19)*. For example, when NICE guidance is considered by the media, the Institute is often referred to as the Government's health watchdog or NHS rationing body.

What is involved in HTA?

Assessments often involve similar principles and requirements, although countries employ different methods to inform recommendations and decisions on health technologies. Differences exist in key areas, including topic selection, evidence requirements and economic evaluative methods, all of which can affect the relevance and successful uptake of HTA *(20–22)*.

Identifying and prioritizing topics

Given limited resources, most governments struggle to keep pace with the introduction of new health technologies. This is especially true in smaller countries, where resources for the evaluation of health technologies may be limited. Prioritizing topics for assessment has therefore become an important part of the HTA process. Reflecting the divergent policy needs of governments and remits of assessment bodies, some review bodies have their agenda set by government bodies or manufacturer submissions (in accordance with market approval and product licensing processes) while others encourage a range of stakeholders to submit topics for assessment. In Norway, the public (including patients and health professionals) can suggest a topic for guidance by completing and submitting a form to the Norwegian Knowledge Centre for the Health Services (NOKC). Box 1 presents key selection criteria used in the prioritization process.

For countries with greater capacity constraints, it is important to consider the total available budget, available human capital (trained HTA evaluators), accessibility of data, and the capacity of the health care system to use the

Box 1. Key criteria for prioritizing topics for assessment

Health impact: impact on health outcomes (mortality, morbidity, quality of life)

Disease burden: population(s) affected; common health problem, with significant health/economic/social consequences

Cost impact: short- and long-term impact on health system, patients and broader public sector resources

Ethical and social implications: equity, fairness and access

Clinical and policy relevance: importance to clinical practice (to reduce variation); addresses government policy priority area(s)

Assessment feasibility: availability of relevant evidence, time and resources required to complete assessment

Degree of innovation: extent to which a technology addresses an area with few or no treatment alternatives

results *(23)*. These factors often influence the number and range of assessments that can be conducted. Moreover, determining which technologies or interventions to assess is often influenced by the availability of data or published reports of economic analyses, known clinical relevance (e.g. significant public health gains) and the prospective budget impact.

Topic selection, as the initial step in the HTA process, establishes the credibility and technical integrity of the subsequent assessment and is important in ensuring the accuracy of decisions. While this should be as open, systematic and unbiased as possible, with all relevant stakeholders afforded the opportunity to participate, studies have highlighted failings in these areas *(24,25)*. A lack of transparency (real or perceived) can exacerbate tensions among stakeholders and may result in challenges to the review process and appeals against recommendations or decisions. Without a transparent process, including clearly defined priority-setting methods and decision criteria, certain technologies may be inappropriately assessed or left unassessed. This can distort policies and clinical practices towards those interventions that have not undergone evaluation and for which regulatory barriers are lower.

Evidence needs

The type and quality of evidence required and reviewed varies across countries. Some assessment bodies require only effectiveness data, while others also call for cost–effectiveness evidence. This might be supplemented with a request for evidence on the organizational, social and ethical implications of a given product (although it may still not be considered) *(21,22)*. Other differences relate to the role of manufacturing data, reliance on randomized controlled trials and the use of economic modelling *(21)*. While there is a strong preference for evidence from randomized controlled trials, they are greatly limited in that they do not usually compare all possible treatments or collect a comprehensive range of health economic evidence. Many manufacturers develop models to address these issues, but HTA bodies may not consider them owing to concerns about technical rigor or conflicts of interest, or because they have their own models.

Another increasingly important issue is the transferability of evidence: clinical and epidemiological evidence is usually considered transferable, while resource utilization, costs and cost–effectiveness are more context-specific. The transferability of economic data is especially pertinent for small- and middle-income countries, where the capacity for undertaking health economic analysis is limited *(23,26)*. The use of general models populated with local data, despite their limitations, may address some of these issues. Another option is to base priority-setting of assessments on products or interventions already evaluated by other systems.

Methodological issues

There is no standard approach to conducting assessments. Although most HTA systems use similar methodologies, there are variations owing to resource constraints and other factors. Key methodological issues include:

- assessment approaches
- measuring health benefit
- choice of comparator
- accounting for differences among patient populations
- capturing relevant costs
- recognizing uncertainty in available evidence *(21)*.

Several of these, particularly measuring health benefit, choice of comparator and comparability of treatment patterns and populations, affect the transferability of cost–effectiveness estimates *(27)*. Included in these considerations are the quality and transparency of the methods employed,

which affect whether decision-makers and other stakeholders accept the evidence produced by HTA. Most countries have published guidelines for stakeholders and reviewers on evidence and methodological requirements, although such documents vary in level of detail and transparency *(28)*.

How is HTA applied and implemented?

The evidence derived from HTA is generally used to inform reimbursement and pricing decisions and to support the development of clinical practice guidelines and health service standards (Box 2). Nevertheless, while access to high-quality evidence is necessary, it is not sufficient to ensure that HTA is applied in decision-making. Even where assessments are conducted or commissioned by national authorities, the resulting evidence is not always considered or implemented. Some countries often do not consider health economic information when determining reimbursement, even though cost–effectiveness analysis is recommended in manufacturers' submissions, such as in Denmark and France. Evidence resulting from HTA is usually considered more important for new indications and premium-priced products; it therefore appears to have most effect on decisions about treatments with a broad use and significant potential budget impact, and when cost–effectiveness varies by indication or

Box 2. Key evidence used to support decision-making

- Health benefit (mortality, morbidity)
- Cost–effectiveness (cost per quality-adjusted life year (QALY))
- Necessity (e.g. disease burden, severity)
- Availability of treatment alternatives
- Public health impact (population level)
- Equity
- Innovative characteristics (e.g. pharmacological properties, ease of use)
- Budget impact
- Ethical/legal considerations
- Feasibility of decision/guidance implementation
- Projected uptake/utilization

patient subgroup *(17)*. In such cases, it is often used to restrict access, particularly of expensive treatments or where there is uncertainty about use.

Where such evidence is taken into account, there is often a lack of transparency regarding what criteria or evidence is actually applied in the decision-making process, and how. Some HTA bodies rarely, if ever, outline the relative weight and importance of the evidence and criteria used for recommendations *(17)*. This is especially true of non-quantifiable considerations such as equity and quality of life. Better understanding of these factors, in addition to any decision rules or thresholds, is required for a transparent and coherent decision-making process.

A recent systematic review of the impact of HTA on health policy found that only 50–70% of HTA reports have an impact on the decision-making process, even if the reports were found to contribute valuable information *(28)*. Effective use thus depends on several factors, including:

- comparability between the evidence and recommendations generated by the assessment and the information needs of decision-makers;
- timing and duration of assessments;
- overall transparency of the process;
- possibility for reassessing the evidence and integrating new data;
- limited knowledge and understanding of the assessment process among policy-makers; and
- broader system issues, such as decentralized decision-making and management, inadequate public resources, and ideologies concerning rationing *(2,15,29–31)*.

There is also considerable variation in the manner and extent to which HTA is integrated into policy and practice after a decision is reached, partly influenced by the aims and objectives of individual HTA systems and available resources. For example, an analysis of public comments on NICE suggests that there is a significant concern regarding the patchy and slow implementation of recommendations, with many stakeholders deeming this a key issue in terms of the Institute's effectiveness, efficiency and public credibility *(18)*. Moreover, while a transparent and well-communicated decision-making process needs to be in place before recommendations can be successfully implemented, other factors that can hinder or facilitate implementation include:

- insufficient or misaligned political drivers (differences in objectives between HTA and decision-makers or lack of commitment to HTA);
- a lack of a holistic approach to implementation, whereby not all relevant

stakeholders are adequately informed of decisions or there is ineffective and poor dissemination of decisions or guidance;

- minimal reinforcement of compliance or accountability (limited formal mechanisms to enforce implementation);
- poor financial planning (inadequately estimating the costs and resource requirements of implementation and related technology diffusion); and
- rapidly changing political situations *(2,29–35)*.

Local variations in resource capacity, patient populations, health needs and available budgets can also hinder implementation of national decisions or guidance. Moreover, local decision-makers may delay making treatment available to patients until a formal assessment is complete and guidance is produced. This is exacerbated if the decision and general HTA process are not accepted by stakeholders. For instance, a recent survey of HTA initiatives in the EU concluded that clinicians fail to change their practice in line with HTA results *(36)*. In this vein, local providers and other stakeholders may consider HTA processes as political, informal or ad hoc, or they may not possess the necessary resources, skills and knowledge to appropriately interpret and implement HTA reports or guidance.

In summary, successful implementation can be facilitated if there are: appropriate policy instruments and regulatory levers available; a prior commitment by decision-makers to use assessment reports in decision-making processes; available resources to implement decisions; stakeholder involvement; and transparency in both the assessment and the decision-making process. It nevertheless remains a challenge and one of the least developed areas of the overall HTA process.

Measures to support increased HTA uptake

Countries are placing greater emphasis on ensuring that HTA assessments are robust, transparent and practical and that the results are considered in key decision-making processes. This section highlights three approaches to enhancing the impact of HTA in relation to the issues already mentioned:

- formal and informal mechanisms for improving stakeholder involvement in the HTA process;
- initiatives to ensure better assessment methods and procedures; and
- actions to advance local applicability and implementation of national decisions or guidance.

Table 2 illustrates how various countries are addressing the challenges and opportunities posed by HTA.

Improving stakeholder involvement

European HTA agencies usually have some level of stakeholder involvement, but the degree of participation varies. Manufacturers, clinical experts and policy-makers are often involved; patients and consumer groups tend to be least represented. Patient perspectives are generally taken into account indirectly through safety, effectiveness and quality of life measures, but such indicators may not adequately capture important patient values such as equity, acceptability of side-effects and implications for daily life. There is often a discrepancy between the content of HTA evidence and the criteria required by decision-makers. A recent study revealed that while only 42% of the HTAs reviewed contained information on equity considerations, approximately 80% of decision-makers thought that this was important, particularly in their funding and investment decisions *(28)*. Inclusion of such considerations in the assessment process can lead to better informed estimates of the effectiveness and cost–effectiveness of a technology and provide useful insights into real-world value. Greater efforts should, therefore, be directed towards capturing patient views on these issues.

Both Sweden and the United Kingdom have sought to improve stakeholder representation and participation, most notably among patients and the general public. NICE encourages stakeholder comments in its technology appraisal and clinical guideline programmes, and has a Citizens Council that helps capture public views on key issues surrounding the development of guidance, especially in terms of social values and judgements. Feedback from the Council helps to create a framework of scientific and social value judgements, which is used to guide the work of assessment groups and improve methodologies used to develop NICE guidance. In Sweden, the respective HTA agencies involve a broad array of stakeholders in their assessment and review groups, from health economists to representatives of health care organizations and patient groups. Stakeholders are also able to comment on SBU Alert reports once publicly available via the Internet.

Given their role in producing and analysing much of the clinical data employed in assessments, the greater and earlier involvement of industry representatives has also been promulgated. Typically, once they submit the required evidence, manufacturers are not involved until the assessment is complete. This can hinder the possibility of addressing any outstanding questions regarding the available evidence. Improved participation could result in greater efficiencies and ensure that the required evidence is integrated into continuing clinical studies. Nevertheless, the involvement of manufacturers raises concerns that greater collaboration between HTA entities and industry may influence the objectivity of the assessment process and subsequent recommendations *(21)*.

Table 2. Select strategies to enhance the impact of HTA

Country	Strategy(ies)	Description	Objective
Sweden, United Kingdom (England and Wales)	Stakeholder involvement in policies or programmes	Information is gathered through formal or informal mechanisms on issues such as equity, social benefits and patient preferences.	Greater synergy between the content of HTA evidence and the criteria required by decision-makers Better capture of qualitative considerations of technology use
Finland, France, Spain, Sweden	Rapid reviews; horizon scanning	Mechanisms identify new and emerging technologies that might require urgent evaluation. They typically involve products of policy, clinical or cost importance.	Improved timeliness and relevance of assessments
United Kingdom (England and Wales)	Single technology assessments (STAs)	A new fast-track process places more emphasis on (less detailed) manufacturer's data and less on extensive external review or consultation. It reduces timelines from 56 to 39 weeks.	Reduced assessment time
Various	International collaboration/ networks	Formal and informal mechanisms facilitate knowledge and skill exchange, methodological and procedural development, and building HTA capacity and infrastructure.	Better cooperation between assessment bodies Facilitated HTA transferability Improved communication and implementation of HTA Enhanced efficiency and effectiveness of HTA

Country	Strategy(ies)	Description	Objective
Sweden	Local ambassadors	Team of local experts, operating throughout Sweden, promulgates use of decisions/guidance by decision-makers and providers.	Improved local implementation
United Kingdom (England and Wales)	Regulatory mandate	Local primary care trusts must implement NICE guidance within 3 months of dissemination.	Facilitated timely implementation of guidance and decreased variation
Finland, France, United Kingdom (England and Wales)	Reassessment	Health technologies are reassessed after a specified period of time or upon availability of new data.	Enhanced effective and efficient decision-making and technology utilization over time Ensured value for money

Beyond more consistent stakeholder involvement in general, there are particular points in the assessment process where greater stakeholder input could positively influence the impact of HTA. First, stakeholders could help identify assessment topics and guidance priorities in order to strengthen transparency of the priority-setting process, reduce the potential for bias and generally enhance credibility and accountability. Box 3 illustrates a potential strategy for involving stakeholders in topic selection. Second, stakeholders could play a greater role in the submission, review and interpretation of evidence. Once the evidence is assembled and reviewed by the relevant body, stakeholders might provide a broader, more qualitative perspective on the relative value of a product, such as views on side-effects, potential usability and impact on daily living. Indeed, as health technologies potentially affect the health and lives of many people, the articulation and consideration of the values of a wide range of stakeholders have been argued to be an ethical and social imperative in decision-making *(34,37)*. The appeals process, where one exists, offers a third opportunity. In several countries, stakeholders can appeal the findings or recommendations of HTA bodies. A formal appeals process can impose consistency, improve the transparency of the assessment and decision-making processes, and reduce the chances of legal challenge.

Box 3. Use of specialty mapping

Specialty mapping entails describing and mapping existing HTA guidance, clinical guidelines and evaluative research on the cost–effectiveness of health technologies in order to identify gaps in the evidence base.

Stakeholder workshops involving national authorities, clinical experts and patients use Delphi techniques to prioritize the identified topics *(38)*.

These mechanisms for stakeholder involvement enhance public and professional ownership in decisions or guidance, increasing the likelihood that HTA will effectively guide decision-making and clinical practice. Moreover, a broader representation of stakeholders may help foster perceptions that a given HTA body is independent, neutral and aligned with decision-makers and users of the technology – all key factors in promoting the impact of HTA *(28)*. Nevertheless, greater stakeholder involvement needs to be carefully managed, as the influence of various groups on the guidance process and resulting decision-making is unclear *(39)*. The technical nature of HTA may hinder meaningful participation of some stakeholders, especially if there is no explanation of the various study results and any limitations in the corresponding

evidence. Transparency of stakeholder involvement, where their relative input and impact on the assessment and resulting decision(s) are clearly specified and reported by HTA bodies, is thus crucial. Systems should also ensure increased training of key staff on how to present technical evidence to groups that include lay representatives.

Enhancing assessment methods and processes

Given the various points in the HTA process, there is a variety of measures that assessment bodies and governments could take to enhance assessments. This section focuses on fast track mechanisms, conditional approvals, improved transparency and international collaboration.

The time required for and the timing of assessments are critical for HTA bodies, as well as for other stakeholders. The different approaches and aims of HTA systems mean that assessment times vary. Simple assessments can be completed in as little as a month, while complex studies can take over a year *(33)*. The duration of the assessment process is due, in part, to the complexity and depth of the task in hand, especially when there is extensive consultation with stakeholders. This must be tempered, however, by the need to ensure that decisions are made in a timely manner. This is so as to grant access to innovative treatments and the best health care services, and so that recommendations or guidance remain relevant (i.e. that the evidence used in the review is not quickly superseded).

There has been a general move towards mechanisms for issuing guidance on the use of new technologies immediately after or prior to market entry *(40–44)*. These include fast-track assessments, early-warning and horizon-scanning systems, examples of which are the SBU in Sweden, the Haute Autorité de Santé in France, the Finnish Office for Health Technology Assessment (FinOHTA) and the Basque Office for Health Technology (OSTEBA) in Spain. FinOHTA, for example, produces rapid reviews when information on a given health technology is needed quickly. These are typically based on international assessment reports, and the findings are reviewed, appraised and applied in the Finnish context. Since 2005, NICE has used STAs as a fast-track tool for the review of single technologies for a sole indication *(45)*. Only manufacturer's evidence is considered in the review, and formal consultation with stakeholders and experts is limited. The aim is to reduce assessment timelines, typically by about 15 weeks, for products close to market launch and for new, life-saving treatments. To date, NICE has initiated more than 25 STAs, primarily for cancer drugs.

Fast-track assessments reduce the opportunity for stakeholders to provide input. The absence of this critical step may undermine the consultative nature

of HTA and lead to delays if any discrepancies need to be addressed later in the process. Moreover, transparency may be hindered and decision-makers may not feel comfortable making decisions using early data without proper consultation. Also, some products may be best assessed together with other relevant alternatives rather than in isolation.

Nonetheless, rapid assessments offer promise and potentially an important model for conducting HTAs, especially when there is limited evidence or an urgent health need. They may better reflect the realities of available evidence at the time of assessment and the subsequent need for real-world data to confirm the actual value of new technologies. Nevertheless, they should be monitored and evaluated for effectiveness and impact on access to new technologies. It may also be necessary for HTA bodies using rapid reviews to be realistic about what evidence can be provided in the early stages and to accommodate a greater degree of uncertainty.

Early decisions followed by post-launch revalidation are another mechanism. Conditional approvals, or coverage with evidence development (CED), for example, allow a technology to be made available under specific conditions, usually for a defined period, after which the benefits of the technology are reviewed. They facilitate access by patients to promising new technologies "while also generating additional evidence to reduce any uncertainty about the value of the technology" *(46)*. They provide an incentive to industry to be innovative and lessen the possible opportunity costs of making inappropriate coverage decisions, such as where reimbursement may be restricted for technologies that, subsequent to the initial coverage decision, prove to be clinically and cost-effective. Many systems, including those of the Haute Autorité de Santé in France and the Dutch Health Care Insurance Board, are considering the use of conditional approvals, and these have been utilized mainly with promising but unproven technologies for indications that possess limited treatment alternatives (i.e. high unmet need). In the Netherlands, for every positive decision to reimburse a new innovative drug, a post-reimbursement assessment is required to evaluate whether claims on therapeutic usage, effectiveness and cost–effectiveness can be validated with real-world data.

Such processes can help alleviate some of the uncertainty inherent in HTA and thus facilitate decision-making. Moreover, stakeholders may be less likely to appeal negative decisions if it is possible to re-evaluate a decision with additional data. To be effective, however, further collection of data is essential and decision-makers must be able to re-evaluate their decisions. This introduces important practical issues, such as the logistics and funding of further trials or post-reimbursement studies and the feasibility of removing a product from the reimbursement list if further data proves mediocre.

Transparency of HTA methods and processes is crucial for stakeholder (and public) acceptance of HTA processes and subsequent decisions, and can also facilitate the effective use of HTA in decision-making by ensuring a systematic, open and unbiased process. Nevertheless, as discussed above, HTA methods and processes generally lack transparency. This applies to a wide range of areas, from topic selection to evidence and methods requirements, and also extends to decision-making.

There are a number of strategies for improving transparency. The use of standardized methodological guidelines for HTA can help facilitate notions of transparency, especially if the guidelines are clear and comprehensive. A number of HTA bodies are currently collaborating through organized networks to devise a core HTA framework or guidance based on current best practice (see below). While some HTA entities may make the evidence and documents used in the assessment process publicly available, disclosure of evidence and other supporting documentation is generally limited. This may be due to the confidential nature of commercial data often used in assessments, the lack of a formal process for dissemination, or limited resources to manage information exchange. Key documents should be made publicly available whenever possible, and stakeholders should have the opportunity to review such material and provide comments and feedback.

Many countries address these issues through an external expert advisory committee or group comprising academics, health care professionals, and patient and industry representatives. For example, while the LFN in Sweden is an independent public authority established to evaluate applications and prepare decisions, the actual decisions on reimbursement are taken by its governing board, involving a broad representation of stakeholders.

International collaboration across HTA bodies can help facilitate methods development and more efficient assessment processes, thereby improving the impact of HTA. Partnerships and networks have recently been employed to more effectively use national resources dedicated to HTA, improve related activities, and enhance its overall applicability and relevance. An example is the European Network for Health Technology Assessment (EUnetHTA), which was developed in response to an EU request for a formal, sustainable European network *(47)*. EUnetHTA builds on previous European projects and aims to improve coordination, reduce duplication of effort, develop practical tools for HTA and improve the transfer of HTA into policy *(48)*.

Improved cooperation between assessment bodies through such networks or partnerships can facilitate the development of advanced methodologies, improve dissemination efforts, enhance the transparency of HTA processes and, potentially, improve the efficiency and accountability of the process itself.

International coordination can also support HTA capacity-building and infrastructure in countries with limited experience or without formal systems. Many international HTA networks are working to develop tools and approaches for transferring or adapting existing HTA evidence to other countries, as well as to establish models to provide and share core information on health technologies. This is particularly advantageous for smaller countries, which may lack the requisite resources to evaluate health technologies or institutionalize an HTA programme. Moreover, regional champions or teams could be developed to synthesize evidence on given health technologies, thus assisting countries that cannot conduct original or comprehensive evaluations owing to resource and/or data limitations.

Advancing local applicability and implementation of national decisions and/or guidance

Local decision-makers often face difficulties in determining whether the results of HTA and economic evaluations, which are usually carried out at national level, are relevant to their own circumstances and coincide with available budgets and resources. This often results in uneven implementation of guidance, especially positive guidance because of its funding implications. Bureaucratic hurdles may also exist, particularly when a treatment is new to the market, rendering it difficult for providers to prescribe the product for patients. These issues can all be heightened if a new intervention is not selected for review or if an appraisal takes several years to complete, and can result in inefficiencies, increased costs and inequitable access by patients.

Uncertainty over the extent to which evidence can be transferred between settings also hinders uptake. This is partly due to the frequent lack of transparency in the reporting of assessments, often making it difficult for decision-makers to assess the relevance of economic evaluations in their local setting or to extrapolate the results. Even when the knowledge base is robust, the extent to which specific evidence can be taken into account in decisions may depend on local circumstances. Also, local decision-makers may not fully understand the technical nature of HTA or national guidance, especially if no expertise is available to assist in understanding the evidence and placing national decisions in context to account for local conditions.

Incentives within a given health care system need to be appropriately aligned with HTA recommendations. This may include adequate funding and education to effectively and equitably implement decisions, institutionalizing local political drivers (e.g. prior commitment by decision-makers to implement recommendations or guidance) or employing a mixed portfolio of information dissemination strategies to apprise national and local stakeholders of recent decisions and policy changes *(21)*. For instance, although all its guidance is

available online, NICE also sends copies to key stakeholders and end-users, including local government organizations, health professionals working in the area, NHS staff responsible for clinical governance, and consultants in relevant specialties. FinOHTA uses newsletters and similar communications media to apprise stakeholders of recent reports. Sweden supports a network of local experts to initiate and promote local (frequently regional) efforts to help ensure that reports are understood and used by decision-makers and that findings are applied in clinical practice. Assisting decision-makers with appropriate financial planning and helping them understand the potential opportunity costs of funding one technology over another is also important.

Regulatory levers also affect implementation. In the United Kingdom, for instance, it is mandatory that NICE's guidance from technology appraisals be implemented within three months of dissemination. To aid local application, each set of NICE guidance is assigned to a team that ensures that dissemination activities are targeted to various audiences, engages with local NHS and government representatives, and raises awareness of NICE decisions and guidance among the wider community.

Problems in applying technical information and national recommendations to local decision-making can be further mitigated through formal links between the users and producers of HTA. A formal infrastructure between technical experts and ministries (or other decision-making bodies) can foster knowledge and expertise within the relevant arms of government, and provide an avenue for local policy representatives to lend their perspectives. Both Italy and Spain have taken steps to strengthen links and collaboration between regional and national bodies. This can assist in developing policies that adequately account for variations in local circumstances, thus facilitating acceptance by stakeholders. Greater cooperation between national and local actors might also afford more opportunity to effectively monitor the implementation of decisions and related guidance.

Reassessment after a technology has been used in practice is also an important mechanism in ensuring effective implementation. This can help address the so-called moving target problem, whereby assessments become outdated by changes in a technology *(21)*. Regular review and re-evaluation are also crucial in ensuring the availability of cost-effective and value-added products. This applies both to new technologies and to those already on the market. Reassessment may further reassure local decision-makers concerning the funding of new technologies whose cost–effectiveness is somewhat uncertain at the time of initial assessment. Finland, France and the United Kingdom have a structured process, conducting re-evaluation at fixed or variable intervals, while Austria and Switzerland initiate review if new characteristics of the product emerge or if new or better clinical and/or economic evidence becomes

available *(29)*. Finally, as discussed above, greater stakeholder involvement can improve the applicability and impact of HTA, including the transferability of national guidance to local decision-making.

Despite these strategies, however, successful local implementation remains a challenge and the uptake of decisions or guidance is considered slow, variable and without adequate incentives to encourage implementation. Securing funding to offer recommended technologies and interventions where resources are scarce is a further hurdle. Given a fixed budget, the mandatory uptake of guidance may require that local decision-making bodies forego other (possibly higher-priority) investments or make cutbacks elsewhere. There is therefore significant tension between local and centralized decision-making in terms of understanding local circumstances and opportunity costs combined with the need for national, standardized guidance. Nonetheless, guidance produced nationally is more likely to be policy-relevant and thus have greater impact. Further, it enables the interaction between scientific evidence and national (and local) values.

Some of these broader system issues could be addressed by ensuring that there are established structures and processes to manage implementation and improve financial planning. Other potential actions include more stringent sanctions on local bodies for non-compliance, joined-up commissioning and financial incentives, and integrating adherence to HTA recommendation or guidance as a part of broader health system performance measurement and related frameworks *(18)*.

Summary

HTA has become an important mechanism for supporting priority-setting and decision-making. In particular, the growth of HTA reflects the demand for well-founded information to support evidence-based decisions on the adoption and provision of health technologies. While there is general consensus that HTA provides value, this brief has highlighted a number of issues that can affect – positively and negatively – the effectiveness and impact of HTA. These include: the remit and role of HTA in the national policy context; governance of the HTA process and the actors involved; the methods and processes employed in assessments; the transparency of assessments and decision-making; and timely and successful dissemination and implementation of decisions or guidance. Many of these concerns are similar across countries, but the diversity in European health systems, policy objectives and more normative orientations must be taken into account when devising strategies and initiatives to improve the impact of HTA. Smaller countries with limited experience or capacity to institutionalize HTA programmes face additional challenges concerned with adequate resources, human capital and infrastructure.

The first measure for enhancing the impact of HTA focused on mechanisms to improve stakeholder involvement. While most countries involve a range of stakeholders at various points in the HTA process, further efforts are needed to involve patients and consumers in selecting topics, developing guidance and commenting on results. To ensure meaningful participation, overly technical material and discussions should be avoided. Early involvement of manufacturers is also important, given their role in conducting studies on which assessments are based. Stakeholder involvement is generally resource-intensive, but it may lead to improved relevance and trust in the evidence produced by the assessment. Accordingly, a higher level of engagement may lead to better assessments, reduce the number of appeals, and result in improved implementation of HTA recommendations and guidance *(19)*.

The second measure, enhanced assessment methods and processes, highlighted ways:

- to reduce the time required to complete and implement HTAs, such as fast-track assessments that can address decision-makers' needs for timely information and patients' access to innovative technologies;
- to better account for uncertainty in assessment and decision processes, such as conditional approvals to make new technologies available while gathering additional data to address areas of uncertainty;
- to improve the transparency of HTA, such as mechanisms for generating transparency, including the use of standardized methodological guidelines and public availability of relevant evidence; and
- to facilitate the development of efficient methods.

Conditional approvals provide for the later collection of real-world data and reduce the potential opportunity costs of making inappropriate or inaccurate decisions. Transparency is a prerequisite for a systematic, open and unbiased process that can generate confidence in the HTA process, thus resulting in greater acceptance and sustainability of its use in decision-making. International partnerships or networks can improve the effectiveness and efficiency of related processes, reduce duplication of effort between HTA bodies, facilitate the exchange of skills and knowledge, build capacity and infrastructure for HTA, and enhance the use, dissemination and transferability of evidence used in assessments and subsequent reports.

The third measure centred on ways to advance the local applicability and implementation of national decisions and guidance. Countries should aim for national guidance that aptly accounts for local conditions and is implemented at both levels. Appropriate incentives, resources and organizational capacity must be in place to allow effective and timely local implementation. This

includes adequate funding, education and training to implement decisions and dissemination strategies that inform national and local stakeholders. The involvement of stakeholders, through networks or the use of experts or ambassadors, can help disseminate information on decisions and facilitate greater acceptance. Regulatory levers and requirements for re-evaluation can facilitate timely implementation and efficient use of national and local resources over the long term. Finally, stronger formal associations should be forged between entities involved in producing HTAs (at national level) and end-users (at local level). Such collaboration offers opportunities to monitor the success of implementation and related impacts on health service delivery, costs and patient outcomes, as well as taking local requirements into account.

HTA offers extensive opportunities to support governments and other stakeholders, although issues remain concerning its use in, and impact on, health care policy and decision-making. Many of these have been highlighted. The role of HTA in decision-making has grown substantially, but the need and demand for policy-makers to employ and translate evidence-based decisions into direct effects on health care costs and outcomes will probably increase. Countries should therefore seek to capitalize on the strengths of established HTA systems while pioneering solutions to address outstanding challenges and strengthen the HTA enterprise across Europe.

References

1. Jonsson E, Banta HD, Management of health technologies: an international view. *British Medical Journal*, 1999, 319:1293.

2. Hutton J et al. Framework for describing and classifying decision-making systems using technology assessment to determine the reimbursement of health technologies (fourth hurdle systems). *International Journal of Technology Assessment in Health Care*, 2006, 21:10–18.

3. Cutler D, McClellan M. Is technological change in medicine worth it? *Health Affairs*, 2001, 20:11–29.

4. Goldman DP et al. Consequences of health trends and medical innovation for the future elderly. *Health Affairs*, 2005, 24(Suppl. 2):W5R5–17.

5. Jones CI. Why have health expenditures as a share of GDP risen so much? *SSRN*, 2002 (http://ssrn.com/abstract=355400, accessed 7 April 2008).

6. Fuchs V. Economics, values and health-care reform. *American Economics Review*, 1996, March:1–24.

7. Newhouse JP. Medical care costs: how much welfare loss? *Journal of Economic Perspectives*, 1992, 6:3–21.

8. *OECD health data 2007*. Paris, Organisation for Economic Co-operation and Development, 2007.

9. Hoffman B. Is there a technological imperative in health care? *International Journal of Technology Assessment in Health Care*, 2002, 18:675–689.

10. Rothman DJ. *Beginnings count: the technological imperative in American health care*. New York, Oxford University Press, 1997.

11. Busse R et al. Best practice in undertaking and reporting health technology assessments. *International Journal of Health Technology Assessment*, 2002, 18:361–422.

12. SBU evaluates health care technologies [web site]. Stockholm, Swedish Council on Technology Assessment in Health Care, 2007 (http://www.sbu.se/en, accessed 7 April 2008).

13. Hansard (House of Commons Daily Debates) [web site]. London, House of Commons, 2007 (http://www.publications.parliament.uk/pa/cm/cmhansrd.htm, accessed 7 April 2008).

14. HAS, Haute Autorité de Santé [web site]. Saint-Denis, Haute Autorité de Santé, 2007 (http://www.has-sante.fr/portail/display.jsp?id=c_5443&pcid=c_5443, accessed 7 April 2008).

15. *Survey of pharmacoeconomic assessment in eleven countries.* Paris, Organisation for Economic Co-operation and Development, 2003.

16. Martelli F et al. Health technology assessment agencies: an international overview of organizational aspects. *International Journal of Technology Assessment in Health Care*, 2007, 23:414–424.

17. Anell A. Priority setting for pharmaceuticals. *European Journal of Health Economics*, 2004, 5:28–35.

18. Drummond M. *Health technology assessment. Has the UK got it right? Merck Trust Lecture 2005/2006.* London, London School of Economics, 2006.

19. Goodman CS. Healthcare technology assessment: methods, framework, and role in policy making. *American Journal of Managed Care*, 1998, 4:200–214.

20. Sorenson C et al. *National Institute for Health and Clinical Excellence (NICE). How does it work and what are the implications for the U.S.?* Arlington, VA, National Pharmaceutical Council, 2007.

21. Sorenson C, Drummond M, Kanavos P. *Ensuring value for money in health care: the role of health technology assessment in the European Union*. Copenhagen, WHO Regional Office for Europe, 2008 (Observatory Studies Series No. 11) (http://www.euro.who.int/document/e91271.pdf, accessed 7 April 2008).

22. Draborg E et al. International comparison of the definition and the practical application of health technology assessment. *International Journal of Technology Assessment in Health Care*, 2005, 21:89–95.

23. Gulacsi L, Boncz I, Drummond M. Issues for countries considering introducing the "fourth hurdle": the case of Hungary. *International Journal of Technology Assessment in Health Care*, 2004, 20:337–341.

24. Garcia-Altes A, Ondategui-Parra S, Neumann P. Cross-national comparison of technology assessment processes. *International Journal of Health Technology Assessment in Health Care*, 2004, 20:300–310.

25. Hagenfeldt K et al. Systems for routine information sharing in HTA: Working Group 2 report. *International Journal of Technology Assessment in Health Care*, 2002, 18:273–320.

26. Rutten F, Gulacsi L. Using economic evaluation in health policy: options for health care systems in transition. *European Journal of Health Economics*, 2002, Suppl. 1:S8–S9.

27. Welte R et al. A decision chart for assessing and improving the transferability of economic evaluation results between countries. *Pharmacoeconomics*, 2004, 22:857–876.

28. Gerhardus A, Dintsios CM. The impact of HTA reports on health policy: a systematic review. *GMS Health Technology Assessment*, 2005, 1:Doc02 (http://www.egms.de/en/journals/hta/2005-1/hta000002.shtml, accessed 7 April 2008).

29. Zentner A, Valasco-Garrido M, Busse R. Methods for the comparative evaluation of pharmaceuticals. *GMS Health Technology Assessment*, 2005, 1: Doc09 (http://www.egms.de/en/journals/hta/2005-1/hta000009.shtml, accessed 7 April 2008).

30. Rutten F, Brouwer W, Niessen L. Practice guidelines based on clinical and economic evidence. *European Journal of Health Economics*, 2005, 6:91–93.

31. Neumann J. *Using cost–effectiveness analysis to improve health care: opportunities and barriers*. New York, NY, Oxford University Press, 2004.

32. *Managing the financial implications of NICE guidance*. London, Audit Commission, 2005.

33. *Health technologies and decision-making*. Paris, Organisation for Economic Co-operation and Development, 2005.

34. Sheldon TA et al. What's the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients' notes, and interviews. *British Medical Journal*, 2004, 329:999–1003.

35. Henshall C et al. Health technology assessment in policy and practice: Working Group 6 report. *International Journal of Technology Assessment in Health Care*, 2002, 18:447–455.

36. Banta D, Oortwijn W. Health technology assessment and health care in the European Union. *International Journal of Technology Assessment in Health Care*, 2000, 16:626–635.

37. ten Have H. Ethical perspectives in health technology assessment. *International Journal of Technology Assessment in Health Care*, 2004, 20:71–76.

38. Shepherd J et al. Setting the future policy agenda for health technology assessment: a specialty mapping approach. *International Journal of Technology Assessment in Health Care*, 2007, 23:405–413.

39. Bridges JFP, Jones C. Patient-based health technology assessment: a vision of the future. *International Journal of Technology Assessment in Health Care*, 2007, 23:30–35.

40. Murphy K et al. Effective early warning systems for new and emerging health technologies: Developing an evaluation framework and an assessment of current systems. *International Journal of Technology Assessment in Health Care*, 2007, 23:324–330.

41. Douw K, Vonderling H. Selection of new health technologies for assessment aimed at horizon scanning systems. *International Journal of Health Technology Assessment*, 2006, 22:177–183.

42. Ehlers L et al. Doing mini-health technology assessments in hospitals: a new concept of decision support in health care? *International Journal of Technology Assessment in Health Care*, 2006, 22:296–301.

43. Douw K et al. Use of the Internet in scanning the horizon for new and emerging health technologies: a survey of agencies involved in horizon scanning. *Journal of Medical Internet Research*, 2003, 5(1):e6.

44. Carlsson P, Hultin H, Tornwall J. The early experiences of a national system for the identification and assessment of emerging health care technologies in Sweden. *International Journal of Health Technology Assessment*, 1998, 14:687–694.

45. *Guide to the Single Technology Appraisal (STA) process*. London, National Institute for Health and Clinical Excellence, 2006.

46. Hutton J, Trueman P, Henshall C. Coverage with evidence development: an examination of conceptual and policy issues. *International Journal of Technology Assessment in Health Care*, 2007, 23:425–435.

47. European Network for Health Technology Assessment [web site]. Copenhagen, National Board of Health, 2007 (http://www.eunethta.net, accessed 7 April 2008).

48. Kristensen FB. EUnetHTA and health policy-making in Europe. *Eurohealth*, 2006, 12(1):36–38.

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