



The Initiative for Sustainable Healthcare  
Financing in Europe

# THE FUTURE OF HEALTH TECHNOLOGY ASSESSMENT IN EUROPE

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## THE FUTURE OF HEALTH TECHNOLOGY ASSESSMENT IN EUROPE

Health Technology Assessment (HTA) is a rapidly evolving process that informs decisions about the benefits, risks, and costs of mainly new technologies, interventions and practices. Over the past 20 years, many European countries have started to use it, though usually to serve fairly narrow objectives. But HTA is developing rapidly, and considerable experience on good and less good practice is now available.

This report discusses these experiences and considers the future of HTA in Europe. It also looks at ways of improving international collaboration. The emphasis is on those HTA activities related to decisions on allocating resources, and on the relationship between the HTA and subsequent decision-making. The report considers four broad themes:

- The structure of HTA activities;
- Methods of HTA;
- Processes for the conduct of HTA; and
- Use of HTA in decision-making.

The growing use of HTA provides a greater opportunity to compare and contrast the various approaches and define best practice. Agreement on best practice is important because HTA is increasingly a fundamental part of the way organisations decide on which health technologies they will reimburse. The report proposes 15 principles and identifies seven important issues for the future. It also considers the key challenges to standardizing HTA in Europe.

**This booklet summarizes the main conclusions of the full report ‘The Future of Health Technology Assessment in Europe’, which can be downloaded at [www.sustainhealthcare.org](http://www.sustainhealthcare.org)**



## POLICY RECOMMENDATIONS – 15 KEY PRINCIPLES OF HTA BEST PRACTICE

It is becoming easier to define best practice now that HTA is being used in more countries. Agreement on best practice is indeed becoming increasingly important, now that HTA is more often formally linked with reimbursement and coverage decisions for health technologies.

In this context this report proposes 15 principles for best practice in HTA. While a number of commentaries on these HTA principles have been published and responded to, there seems to be broad agreement in the policy community that existing HTA programmes should aspire to these principles and that jurisdictions seeking to establish HTA programmes should seek to apply them.

### Principle 1: HTAs should have explicit and relevant goals and scope

A detailed scoping document should be developed before starting the HTA process, with broad stakeholder involvement. The document should focus on defining the questions to be addressed, plus the link between the HTA and any subsequent decisions about the technology to be assessed. This should help optimise the benefits.

### Principle 2: HTAs should be unbiased, rigorous and transparent

Given the inherently complicated and controversial nature of HTA-based decisions and their importance to multiple decision-makers and stakeholders, the HTA process is best conducted independently of the body ultimately responsible for adopting, paying and implementing the HTA decisions. Furthermore, the HTA process and the detailed basis on which recommendations and decisions are made must be transparent.

### Principle 3: HTAs should include all relevant technologies

Since potential inefficiencies exist in all forms of health care, all health technologies should be potential candidates for HTA. Otherwise, decision-making concerning the use of resources is likely to be distorted. Public health interventions and e-health should be included in the scope of HTAs and also subject to assessment.

### Principle 4: HTAs should have a clear system for setting priorities

A clear process for prioritising and selecting topics needs to be established, because unless all technologies are assessed, there will be distortions in decision making about the investment and use of resources.

### Principle 5: HTAs should incorporate appropriate methods for assessing costs and benefits

Development and consistent implementation of rigorous, analytical methods is required to engender stakeholder and public trust in the process and its findings. This requires clarity of HTA process and methods, as well as access to experts with appropriate clinical and multi-disciplinary methodological training.

### Principle 6: HTAs should consider a wide range of evidence and outcomes

HTAs require data from experimental, quasi-experimental, observational and qualitative studies, integration of both endpoint and validated surrogate data, and assessment of the incremental impact of and trade-offs among multiple clinical, economic and social outcomes in clinically relevant populations.

### Principle 7: HTAs should consider a full societal perspective

HTAs should adopt a broad societal perspective to optimise efficiency and societal benefit and to avoid and identify potentially distorted clinical decisions and health policies resulting from the narrow perspectives of various stakeholders.

#### Principle 8: HTAs should explicitly characterise uncertainty surrounding estimates

All data are imperfect point estimates of underlying distributions that incorporate a variety of errors. All analytical methods are subject to biases and limitations. Thus, extensive sensitivity analyses are required to determine the robustness of HTA findings and conclusions. The limitations of the analysis should always be acknowledged.

#### Principle 9: HTAs should consider and address issues of generalisability and transferability

Examination of the generalisability and transferability of HTA findings across clinical populations and policy relevant perspectives is required, given the inherent variability of disease, intervention responses and outcomes across patients, populations, providers, health care delivery sites and health care systems.

#### Principle 10: HTAs should actively engage all key stakeholder groups

HTA programmes should actively engage all key stakeholders in all stages of the HTA process, as this is likely to result in technology assessments of higher quality that are more widely accepted and stand a greater chance of being implemented. Moreover, such an open process will enhance transparency and trust in the process as stakeholders develop a greater understanding of the criteria and standards used. Contact with HTA agencies should also be encouraged at early stages prior to assessment or review.

#### Principle 11: Those undertaking HTAs should actively seek all available data

Those conducting HTAs should actively seek all available data, whether confidential or not. In situations where confidential data are used, confidentiality should be defined as narrowly as possible and efforts should be made to make it publicly available as soon as possible, in the interests of maintaining transparency and engendering understanding of, and trust in, decisions.

#### Principle 12: The implementation of HTA findings needs to be monitored

Implementation of HTA findings need to be monitored, both to ensure that the original investment in conducting HTAs is valuable and to ensure that findings are implemented fairly and even-handedly.

#### Principle 13: HTA should be timely but separate from other regulatory review

HTAs should be conducted when they can inform key decisions in the diffusion and use of health technologies, and assessments should be kept up to date. Accomplishing this requires timely conduct of studies by manufacturers and other advocates and, in selected circumstances, limited reimbursement conditional upon enrollment in a study to inform safety, effectiveness and cost-effectiveness. In addition, HTAs should be separate from regulatory reviews for the grant of a marketing authorisation.

#### Principle 14: HTA findings need to be communicated appropriately to different decision makers

Given the multiple audiences for HTA findings, effective communication strategies need to be developed to meet the disparate needs of different users.

#### Principle 15: The link between HTA findings and decision making processes needs to be transparent and clearly defined

A clear distinction needs to be made between the HTA itself and the resulting decisions. The link between the assessment and the decision will be different in various settings, but in all cases it should be transparent.

## POLICY RECOMMENDATIONS – IMPORTANT ISSUES FOR THE OPERATION OF HTA

In the course of this research, a number of broader issues emerged relating to the way HTAs operate. The report proposes seven important issues for stakeholders involved in the implementation of HTA to keep in mind.

### Important issue 1: Technology foresight

It would be hugely beneficial for HTA agencies to have ‘early warning’ and ‘horizon scanning’ systems in place to identify new and emerging technologies that might require urgent evaluation, consideration of clinical and cost impact, or modification of clinical guidance activities. While there is limited evidence regarding their impact on decision-making, there is some concern that premature assessment may be biased against new technologies.

### Important issue 2: Affordability in the context of HTA

Overall, the HTA process per se should be independent of the affordability question; the latter falls into the realm of political decision-making; at the same time, budget impact analysis should not influence the decision but inform the implementation of the decision. It is important that the link between HTA findings and decision-making processes needs to be transparent and clearly defined.

### Important issue 3: HTA in the context of ‘value-based pricing’

Although HTA can help define ‘value’ of new medical technologies, its use in ‘value-based pricing’ may be subject to constraints, particularly related to data quality and availability. In addition, and for HTA to be used constructively in this context, both static and dynamic considerations should be taken into account and a balance found in order to ensure optimal returns to society from both a short-term and long-term perspective.

### Important issue 4: HTA and disinvestment

The need for disinvestment must be explicitly recognised and integrated into the scoping, researching and deliberation phases of guidance development by focusing on questions of effectiveness, ineffectiveness and harm, as well as questions of benefit, but, in practice, offering judgement on what technologies to disinvest from.

### Important issue 5: Appropriate resourcing and expertise

HTA agencies should be appropriately resourced (i.e. funded and staffed). Appropriate resourcing will enable HTAs to be performed in a timely fashion and may also broaden the remit to encompass public health and preventive technologies and disinvestment, in addition to investment decisions. Without appropriate expertise and funding HTAs can be subject to imprecision, inconsistency, and methodological flaws.

### Important issue 6: Operating in a partnership environment

Manufacturers and HTA agencies should operate in an environment of partnership. This should cover the treatment of uncertainty, but also the assessment of new data when these become available, and should be governed by a spirit of cooperation among the stakeholders. In an ideal system, obtaining conditional reimbursement could be a valid way forward and allows flexibility for all parties without compromising access.

### Important issue 7: The use of mini-HTAs

Mini-HTAs are a management and decision support tool based on the reasoning involved in HTAs and can be used regionally or locally. Mini-HTAs should be seen as flexible and dynamic tools. As they are prepared locally or regionally, they can be developed further and adapted to local or regional objectives and to the current requirements of the decision-makers. It is important to define locally or regionally when a mini-HTA should be undertaken and it is also important to consider when a proposal for new health technology requires undertaking a more comprehensive HTA.

## POLICY RECOMMENDATIONS – TOWARDS INTERNATIONAL STANDARDS FOR HTA?

Economic evaluation is an important part of HTA, and it is essential to develop international standards if there are to be any meaningful comparisons. The report outlines a number of areas where there have been differences of opinion, and where standardisation efforts need to be focused.

### Defining the decision problem

A major issue is whether analyses are intended to inform decisions across all disease areas, or within a particular disease area only. A decision-maker may only have jurisdiction over therapies for cancer, for example, but this is not the way most health ministries or health insurers are structured. Few international methods guidelines currently advocate a true societal perspective, although some do allow consideration of productivity changes, or costs falling on the patient and family. An international guideline for economic evaluation should probably adopt a broad societal perspective and then allow individual decision-makers to consider a narrower range of costs.

### The role of evidence-based medicines in assessing economic benefit

While most experts agree the best evidence on relative treatment effect comes from systematic overviews of the randomised clinical trials, it is hard to imagine an approach based only on such data. Most national guidelines for economic evaluation allow some economic modelling, but few foresee a broad role since many decision-makers still have concerns about the assumptions involved. Initiatives to improve the quality of models are therefore essential. One obvious recommendation for international standards in economic evaluation is that alternative therapies should also be subject to a cost-consequences analysis. This would ensure that all the relevant dimensions of clinical outcome are included, and would add transparency to QALY calculation.

### Assessment of value for money:

Once the costs and benefits have been estimated, the decision-maker needs to estimate value for money. The notion of a threshold value of the incremental cost-effectiveness ratio has been extensively debated. This is often described as a decision-making process, where the decision-maker is 'searching for the threshold'. Certainly, it is envisaged that many factors, such as equity of access to health care and the severity of a disease, are important components of any decision.

### An international standard for economic evaluation?

An international reference case for economic evaluation has been proposed, but more debate is required before it can be adopted. It is worth exploring what can and can not be standardised. For example, the principle that future costs should be discounted to present values should probably be an international standard, but the actual discount rate could vary between countries.

### International collaboration

The development of international standards in methods would be a fruitful form of international collaboration as it would make it easier to compare assessments and make it easier for those making submissions in several countries.

The main argument for common assessments is that they would avoid duplication of effort. Of course, progress will depend on the extent to which there is agreement on common methods and requirements. Perhaps clinical systematic reviews have greater potential for common assessments than economic evaluations. Even if there were agreement on common methods for economic evaluation, various data inputs could vary between jurisdictions. Better understanding of how these variations affect cost-effectiveness is needed, as well as methods to increase the international transferability of economic evaluations.

The final step in international collaboration would be common decision-making, as currently happens for drug licensing within the EU. Quite apart from the principle of subsidiarity in EU health care decision-making, it is unlikely that there will be much early progress in this area. Different countries have different levels of resource to devote to health care, and different decision-makers, faced with the same assessment, may still come to different decisions about the same technology.

## THE INITIATIVE FOR SUSTAINABLE HEALTHCARE IN EUROPE

The Initiative for Sustainable Healthcare Financing in Europe was established in 2005 in the context of Luxembourg's EU Presidency and its priority of sustainability. Its aim has been to sponsor new forward-looking and practical research into the sustainability challenges facing healthcare in Europe.

With the endorsement of Luxembourg's Ministry of Health and Finland's Innovation Fund SITRA, four reports were written and delivered as one policy document - the first Cox Report - at a Conference in Helsinki in February 2007.

The two papers unveiled at the 'Securing Europe's Healthcare Future' conference in Prague – **Managing Chronic Disease in Europe** by Dr. Reinhard Busse and **The Future of Health Technology Assessment in Europe** by Dr. Panos Kanavos – represent a more in-depth follow up to that research. These two pieces of original research feed directly into the current high-profile debates on the future of European healthcare - both at Member State and EU level - as European societies face the increasing challenge of ageing populations and the quest to ensure value in healthcare.

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