

# HEALTH TECHNOLOGY ASSESSMENT AND HEALTH POLICY-MAKING IN EUROPE

Current status, challenges and potential

Marcial Velasco Garrido  
Finn Børlum Kristensen  
Camilla Palmhøj Nielsen  
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## **Health Technology Assessment and Health Policy-Making in Europe**



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# Introduction

*Marcial Velasco Garrido, Finn Børlum Kristensen, Camilla Palmhøj Nielsen,  
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Thanks to research and innovation, new technologies with the potential to improve the health of populations through more effective care are continuously being introduced. Indeed, health care stands to benefit from the constant developments and technological innovations in the life and health sciences in general, and in medical science in particular. However, not every technological development results in net health gains. The history of medicine and health counts many examples of technologies which did not produce the expected benefits or even proved to be harmful. However, technologies of proven effectiveness – i.e. those associated with relevant health improvements – create a continuous challenge for health systems since their application may require additional (and not only financial) resources or existing (finite) resources to be redistributed within the health system. Health technologies pose similar challenges to health-care systems throughout the world. Thus, it is necessary to ensure that health technologies are evaluated properly and applied to health care efficaciously. In order to optimize care using the available resources, the most effective technologies should be promoted while taking consideration of organizational, societal and ethical issues.

Health technology assessment (HTA) aims to inform health policy and decision-making processes concerning health technologies precisely on these issues. HTA has a strong foundation in research on the health effects and broader implications of the use of technology in health care. Its potential for contributing to safer and more effective health care is widely acknowledged in Europe and interest in this field has been growing steadily. Since the establishment of the first national HTA agency in Sweden in the 1980s, the number of institutions involved in the assessment of health technologies has multiplied in Europe. Most European Member States have established a formal HTA programme or are considering the feasibility of establishing HTA intelligence to inform health policy-making.

Since its inception, the HTA community has acknowledged the need for international collaboration and networking. Interest in collaboration among



European HTA actors has been the impetus for a series of projects supported by the European Union. The EUR-ASSESS Project (1994-1997) contributed to the establishment of a common and consistent understanding of HTA and also identified the need for information sharing among European countries (Banta et al. 1997). The European Collaboration for Health Technology Assessment/ European Collaboration for Health Interventions (ECHTA/ECAHI) Project (2000-2002) built upon EUR-ASSESS's groundwork. It concluded that there was a need to create a sustainable network for HTA within the European Union involving those working actively on assessments in health care in Europe, focusing on those in the public sector but welcoming those working in other settings (Jonsson et al. 2002). The European Network for HTA (EUnetHTA) Project builds on these previous projects and connects public HTA agencies and academic institutions as well as ministries of health and international organizations.

This book has been produced as a collaboration between the EUnetHTA Project and the European Observatory on Health Systems and Policies with the aim of reviewing the relationship between HTA and policy-making from different perspectives, with a special focus on Europe. The purpose of this cooperation is to transmit the value of HTA to a wide public in decision-making and health-care management in order to increase their awareness of HTA activities and evidence-based decision-making.

In Chapter 1 the authors describe how transnational HTA collaboration has moved up the European health policy agenda to become a political priority and how EUnetHTA is facing the challenge of establishing a permanent collaboration that is useful for policy-making.

Chapter 2 provides an outline of the generalities of policy processes and includes a discussion of the potential role of HTA from a political science perspective.

In Chapter 3, HTA is defined as a process with an emphasis on its role in providing evidence-based information to policy processes. The chapter provides a common understanding of the field and an overview of the methodological developments since the 1990s, emphasizing the contributions of the EUnetHTA Project. Starting from a broad understanding of the concept of health technologies and HTA, Chapter 4 contains an overview of the types of decisions in which HTA can provide inputs to policy-making in the health system.

Chapter 5 gives an overview on the institutions performing HTA in Europe. The aim is not to present a collection of country by country studies but to depict the variety of institutional arrangements and the tendencies shared in the European context. In Chapter 6 the authors address the question of

whether HTA has an impact on decision-making and provide a framework to analyse the effects of HTA in the health system and a summary of the empirical evidence.

Decision-makers' perspective of HTA is introduced in Chapter 7 in which the barriers and facilitators for transferring research knowledge into policy-making are identified. Above and beyond the information provided by their contents, good illustrations of the power of systematic reviews (a methodological tool commonly used in HTA) to organize knowledge in a particular field and uncover areas that require further research are presented in Chapters 6 and 7.

Finally, the authors of Chapter 8 draw on previous chapters and on the discussions held at a workshop in Berlin in March 2007 which gathered HTA actors and potential users (i.e. policy-makers) from several European countries to present a discussion of the future challenges for HTA.

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## Chapter 1

# **Transnational collaboration on health technology assessment – a political priority in Europe**

*Finn Børlum Kristensen for the EUnetHTA partners*

### **Introduction**

Health-care provision is increasingly subject to policy decisions and is managed more than ever before. Health care is also becoming more international and collaboration is increasing as the health professions, research and industry all work across borders. Differing health-care systems across the countries of Europe result from national and regional history and policy developments and priorities. Despite these differences, common interests and policies (e.g. in professional training, health information and health systems) that impact on national health-care practice are being explored and developed at the European Union (EU) and wider European level (e.g. by WHO).

As described later in this chapter, health technology assessment (HTA) is a significant example of a field of common interest. All interventions and procedures in health care are basically technologies – including surgery and pharmaceuticals. HTA is a systematic, broad-ranging evaluation of the implications of using technologies within a particular health-care system (see Chapter 3). It aims to provide structured, evidence-based input to policy-making in order to inform the formulation of safe and effective health policies that are patient-focused and seek to achieve best value. Despite its policy

goals, HTA must always be rooted firmly in research and the scientific method (Kristensen, 2006).

In order to be most relevant, HTA in Europe must be undertaken within the policy context of a particular country (rather than at European level) taking account of national priorities and systems, including regionalization. The principle of subsidiarity is paramount, and must be observed, but collaboration among European countries can support and improve national HTA processes (EUnetHTA, 2008).

This chapter briefly introduces HTA and the EUnetHTA Project; illustrates some important challenges in the relationship between HTA and current international and European policy developments; and describes how a permanent collaboration on HTA in Europe is intended to meet these challenges.

## **Policy background for increased collaboration in HTA in Europe**

European health initiatives and HTA

Where EUnetHTA has been active, decision-makers and policy-makers have shown significantly more interest in the widespread use of HTA to inform policy over the last few years. The prospect of increased transnational collaboration has emerged following more widespread experience with the use of HTA in health-care planning and management in several countries. This process has been promoted by international HTA organizations and by the European Commission (see Chapter 3).

HTA's potential as a tool for decision-making in policy decisions on health interventions and technologies has attracted interest in many parts of the world and in international governmental organizations such as WHO, the Organisation for Economic Co-operation and Development (OECD) and the World Bank. At the global level, in its 120th session (22–29 January 2007), the WHO Executive Board forwarded a suggestion to the World Health Assembly to urge Member States to collect, verify, update and exchange information on health technologies as an aid to their prioritization of needs and allocation of resources (WHO, 2007).

The European Commission and EU Member States express support for the development of a sustainable collaboration and organizations for HTA at Member State level. Within the EU, HTA is now recognized as an essential element for improving the quality of health care in the different health systems. This is in line with the common values and principles that underpin all health-care systems in Europe (Official Journal of the European Union, 2006).

The overarching values of universality, access to good quality care, equity and solidarity have been widely accepted in the work of the different institutions and constitute a set of values that are shared across Europe. Universality means that no one is barred access to health care; solidarity is closely linked to the financial arrangement of national health systems and the need to ensure accessibility for all; equity relates to equal access according to need, regardless of ethnicity, gender, age, social status or ability to pay. EU health systems also aim to reduce the gap in health inequalities – a concern of EU Member States. This is closely linked to work on promoting healthy lifestyles in order to prevent illness and disease.

At the Informal Health Council in Aachen, Germany (19–20 April 2007) the Trio Presidency of the EU (German, Portuguese and Slovenian Presidencies, January 2007–June 2008) provided a document called *Health care across Europe: striving for added value*. This referred to values and policies by noting:

In line with the value of access to good quality care and the principle of patient safety, we can improve the health-care quality standards across the different health systems in the EU through the following: evidence-based medicine, health technology assessments, cost-benefit-analyses (Notes of the Trio Presidency, 2007).

The efforts for establishing a permanent network are also in line with the Programme of Community action in the field of health and consumer protection (2008-13) which states:

In order to ensure a high level of coordination between action and initiatives taken by the Community and Member States in the implementation of the Programme, it is necessary to promote cooperation between Member States and to enhance the effectiveness of existing and future networks in the field of public health. The participation of national, regional and local authorities at the appropriate level in accordance with the national systems should be taken into account in regards to the implementation of the Programme (European Commission, 2007).

### **Policy documents to improve stakeholder knowledge on the potential of HTA**

Recently, several publications have addressed the potential of HTA as an independent, analytical approach for informing health-care policy. *Financing sustainable healthcare in Europe: new approaches for new outcomes* (known as the Cox Report) is an international study that was endorsed and presented to the

**Box 1.1** *Cox Report: key statements on HTA*

- HTA can play a valuable role in health-care decision-making but the process must be transparent, timely, relevant, in-depth and usable.
- Assessments need to use robust methods and be supplemented by other important criteria.
- By maximizing the potential of HTA, decision-makers will be better able to implement decisions that capture the benefits of new technologies, overcome uncertainties and recognize the value of innovation, all within the constraints of overall health system resources.

*Source:* Sorenson, Kanavos & Drummond, 2007

European Commission in February 2007 (Sorenson, Kanavos & Drummond, 2007). Its key statements on HTA are presented in Box 1.1.<sup>1</sup>

The WHO Regional Office for Europe published a policy brief on HTA in June 2008 (Sorenson C et al. 2008). The key messages are presented in Box 1.2.

### **Articulate political commitment to implement HTA in health-care policy in Europe**

At the WHO European Ministerial Conference on Health Systems in June 2008, health ministers of 53 countries adopted The Tallinn Charter: Health Systems for Health and Wealth (WHO, 2008). This identifies HTA as an important means of creating resources for health-care systems (see Box 1.3).

In July 2008 the European Commission adopted a draft Directive to facilitate the application of European patients' rights in relation to cross-border health care (European Commission, 2008a). HTA (see Box 1.4) is indicated to be one of the Directive's major provisions and identified as a: "clear area of European added-value. This initiative will help to reduce overlap and duplication of efforts in this field and hence promote the effective and efficient use of resources." The explanatory memorandum which opens the Directive proposal explains the intentions for a European HTA network (see Box 1.5).

The draft Directive was accompanied by a Communication on improving cooperation between Member States. *A Community framework on the application of patients' rights in cross-border healthcare* also underscores that HTA is a field in which collaboration between Member States can yield relevant added value.

<sup>1</sup> Based on an initiative launched at a conference in 2005 at the European Investment Bank in Luxembourg and the endorsement of Luxembourg's Ministry of Health and the Finnish Innovation Fund (Sitra). Four reports were written and delivered as one policy document in 2007 – the Cox Report (<http://www.sustainhealthcare.org/cox.php>). The initiative has received continuing support from the project's founding partner and sponsor since 2005 – Pfizer Inc.

**Box 1.2** *Key messages in the WHO Health Evidence Network (HEN) policy brief**Policy issues*

- HTA is an important tool for informing effective regulation of the diffusion and use of health technologies.
- Key policy issues surrounding the use of HTA fall into three areas: (i) bodies, decision-makers and other stakeholders involved; (ii) methods and processes employed; and (iii) how HTA findings are implemented.
- The impact of HTA can be enhanced if key stakeholders (e.g. patients, providers, industry) are adequately involved; decision-makers give advance commitments to use assessment reports (and assessments meet their needs); 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 process can help to 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 compromised.
- 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 as mechanisms for managing the uncertainty surrounding new and emerging technologies while facilitating the timeliness and relevancy of HTA.
- International collaboration amongst HTA bodies can facilitate the development of methods and more efficient assessment processes; and facilitate knowledge transfer and capacity-building of 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 are appropriately aligned with decisions 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 linkages 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.



**Box 1.3** *Tallinn Charter: paragraph on innovations and HTA*

Fostering health policy and systems research and making ethical and effective use of innovations in medical technology and pharmaceuticals are relevant for all countries; health technology assessment should be used to support more informed decision-making.

Source: WHO, 2008

**Box 1.4** *Article 17 of the Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (presented by the Commission)*

Cooperation on management of new health technologies

1. Member States shall facilitate development and functioning of a network connecting the national authorities or bodies responsible for health technology assessment.
2. The objective of the health technology assessment network shall be:
  - (a) to support cooperation between national authorities or bodies;
  - (b) to support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information between national authorities or bodies.
3. Member States shall designate the authorities or bodies participating in the network as referred to in paragraph 1 and communicate to the Commission names and contact details of those authorities or bodies.
4. The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt the necessary measures for the establishment and the management of this network and specify the nature and type of the information to be exchanged.

It explicitly refers to the EUnetHTA Project as a basis for a clear framework that can be established under the Directive to take forward these activities on the basis of the results of this pilot (see Box 1.6) (European Commission, 2008b).

The proposed Directive will now undergo a legislative process with the Council of Ministers and the Parliament. It will be implemented through *comitology*, defined on the Europa web site as:

... forums for discussion consist of representatives from Member States and are chaired by the Commission. They enable the Commission to establish dialogue with national administrations before adopting implementing measures. The Commission ensures that measures reflect as far as possible the situation in each of the countries concerned.

**Box 1.5** *Explanatory memorandum of the Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare*

... this Directive provides for establishment of the Community network on health technology assessment (Article 17), which should support cooperation between responsible national authorities, support provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies, enable an effective exchange of this information within the network and provide support to policy decisions by Member States.

Currently there are wide variations and frequent duplication in such assessments between and within Member States in terms of the methodologies used and the consequent uptake of innovations, which act as a barrier to the free movement of the technologies concerned and (through the consequent variations in health care) undermine confidence in standards of safety and quality across the Union.

Collaborating on providing common criteria with a view to establish such an evidence base at Community level will help to spread best practice, avoid duplication of resources and develop common core information packages and techniques that can then be used by Member States, to help them make best use of new technologies, therapies and techniques and ... will also help realise the potential of the internal market in this area by maximising the speed and scale of diffusion of innovations in medical science and health technologies.

## **EUnetHTA Project and EUnetHTA Collaboration**

### EUnetHTA Project

In 2004, EU Member States in the High Level Group on health services and medical care requested the establishment of a sustainable network for HTA in Europe. This was endorsed by the Council of Health Ministers and the European Commission. Following a call for proposals, the EUnetHTA Project was established in 2006 and co-funded for three years by the European Commission. It established an effective European network to connect public HTA agencies, research institutions and health ministries; enable effective exchange of information; and support policy decisions on the use of health technologies in Member States at national or regional levels. A total of 63 HTA institutions and organizations joined the EUnetHTA Project, organized as an open network with extensive communication facilities.

The EUnetHTA Project was built on previous European collaborative projects supported by the EU (Banta et al. 1997; Banta and Oortwijn, 2000; Jonsson et al. 2002) and on the OECD Project on Health Technologies (OECD, 2005).

**Box 1.6** *Excerpt from: A Community framework on the application of patients' rights in cross-border healthcare which accompanied the Directive proposal*

– *European cooperation on health care*: the directive establishes a framework for European cooperation in areas such as: European reference networks, health technology assessment, data collection and quality and safety, in order to enable the potential contribution of such cooperation to be put effectively in practice and on a sustained basis.

*2.3 Future practical European cooperation on health care*

There are situations where European cooperation can add value to the actions of the Member States because of the scale or nature of the health care concerned. The framework established by the Directive will help to realise the potential of this European added-value. It makes provision for developing future practical cooperation at European level in three areas in particular.

*2.3.2 Health Technology Assessment*

Constant innovations in medical science and health technologies bring benefits in better health care. However, they also create a continuing challenge for health systems to ensure that they are properly evaluated and used in the most cost-effective manner possible. Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology, in order to ensure this. This is a clear area of European added-value, where cooperation at Community level can help to reduce overlap and duplication of efforts and hence promote the effective and efficient use of resources.

The Commission is supporting a pilot European network on health technology assessment called "EUnetHTA". The overall aim of EUnetHTA is to establish an effective and sustainable European network for health technology assessment that informs policy decisions. EUnetHTA connects public HTA agencies, research institutions and health ministries to enable effective exchange of information and support to policy decisions by the Member States. The EUnetHTA Project is being co-financed by the European Commission and contributions from network members. As with European reference networks, a clear framework for taking forward these activities can be established under the Directive on the basis of the results of this pilot.

The EUnetHTA partners developed practical tools to share methodological frameworks and scientific evidence for HTA (see e.g. Chapter 3). These tools facilitate information sharing across national or regional systems when health technologies are assessed for new or continued use in health-care systems. This cross-border collaboration on HTA can be used to reduce duplication of effort and save time and resources within individual countries.

The EUnetHTA Project worked as a network on specific tasks focused on creating practical tools to produce HTAs and for local adaptation of existing HTAs. It also generated information and models to monitor new technologies and inform decision-makers on emerging technologies. This practically driven collaborative work raised interest among the institutions, professionals and researchers involved in producing HTAs and among stakeholders at the policy level because of its innovative tools and high level of communication and collaboration.

International HTA organizations have shown interest in EUnetHTA. Its partners have already developed new methods and produced information that can be shared among those involved in producing HTA information and reports. Thus the project has been at the forefront of methodological developments.

### **From project to permanent collaboration**

The European Commission co-funded the EUnetHTA Project from 2006 to 2008. Building on their positive interaction the EUnetHTA partners decided to create a sustainable, permanent European HTA collaboration in order to ensure continuation of communication, collaboration networks and activities (EUnetHTA, 2008). This will involve HTA agencies and others involved in the production of HTA information, with support from European governments, the European Commission and international health organizations.

One key challenge for the EUnetHTA Project was to convince governments and the EU that investing in EUnetHTA is cost effective and provides important benefits through better health-care decisions. As described in this chapter, the European Commission is now taking concrete steps to ensure the sustainability of EUnetHTA.

By focusing on collaboration on HTA in Europe, the EUnetHTA Collaboration sets out to:

- help reduce unnecessary duplication of HTA activities
- develop and promote good practice in HTA methods and processes
- share what can be shared
- facilitate local adaptation of HTA information.

The EUnetHTA Collaboration intends not only to coordinate work more effectively but also, when feasible, to divide the work on specific technology assessments in a methodologically sound and transparent way. The volume of

high quality HTA input to policy and decision-making must be multiplied from this tight network.

The collaboration aims to fulfil the following main functions:

- act as a contact point to provide a gateway to the HTA community in Europe;
- be the European HTA information and communication system;
- develop and improve common processes for performing and reporting HTA;
- provide information on emerging/new technologies and facilitate generation of new evidence;
- facilitate the establishment and continuous development of HTA institutions;
- pilot processes for the production of HTA core information.

The organization will establish standing committees to oversee its functions and working groups to take forward specific projects or tasks. A plenary assembly of member organizations will take a strategic overview of the work of the EUnetHTA Collaboration. An elected subgroup will serve as a management board for a fixed term and a forum will be established. This will have broad and balanced stakeholder representation from European umbrella interest organizations among the identified stakeholders.

The functions will be serviced and facilitated by a EUnetHTA Collaboration secretariat. It is paramount that an adequately resourced secretariat is in place to coordinate and manage the basic communication and tools of the EUnetHTA Project that can be utilized in the long-term EUnetHTA Collaboration.

It should be emphasized that the EUnetHTA Collaboration will not be a “European Agency” (EUnetHTA, 2008).

### **Focus on HTA collaboration in Europe**

The EUnetHTA Collaboration aims to support HTA in Europe. At the outset, work will focus on HTA agencies and institutional producers of HTA in the 27 EU Member States and the countries in the European Economic Area (EEA) and European Free Trade Association (EFTA). The EUnetHTA Collaboration will also continue the collaboration established between HTA agencies and producers in other European countries by the EUnetHTA Project and develop links with new organizations and countries. The EUnetHTA Collaboration will explore ways of coordinating and collaborating with WHO in Europe. However, EUnetHTA’s focus on collaborating with institutions in European countries should not be seen as lack of interest in HTA activities elsewhere or at global level. The focus on Europe allows EUnetHTA to engage in spheres of

interest that can be influenced and that influence the implementation of HTA in health policy. This provides a unique added value compared with other HTA networks.

## **Relations with global HTA community and international organizations**

Within the international HTA community, a number of global organizations are natural collaborators for the EUnetHTA Collaboration. For example, the International Network of Agencies for HTA (INAHTA), HTA International (HTAi), International Information Network on New and Changing Health Technologies (EuroScan), Guidelines International Network (G-I-N) and the Cochrane Collaboration. It is an explicit goal to avoid duplication of activities between the organizations and to seek synergies through coordination. The EUnetHTA Collaboration's focus on European added value and on decision-making in Europe sets it apart from other organizations in the international HTA community. However, the activities of the organizations are linked in different ways and coordination and division of work is necessary to obtain the best possible synergies of interaction. This will be accomplished through ongoing dialogue with the relevant organizations.

The EUnetHTA Collaboration is particularly interested in working with international organizations related to health, including:

- European Commission
- Council of Europe
- WHO Regional Office for Europe.

In addition, consideration will be given to links with international organizations such as the OECD.

The longstanding interest and support from the Directorate-General for Health and Consumer Protection (DG SANCO) will be stimulated to enable the EU to support the EUnetHTA Collaboration, which will facilitate HTA to inform health policy in Member States and other countries across Europe.

## **Stakeholders in HTA**

Patients, health management, the health professions, industry, third-party payers and government are some key stakeholders in health-care policy and decision-making. Each has legitimate interests in the search for, and handling of, information on the best use of health technologies that inform policy processes.

EUnetHTA plans to establish an advisory council to ensure transparency and early involvement of HTA-relevant stakeholder groups in the development process, depending on the needs of the stakeholders and the project.

The EUnetHTA Collaboration acknowledges the interests of stakeholders in general issues related to HTA processes, specific HTAs at the national level and in the general work of the EUnetHTA Collaboration. The by-laws/statutes of the EUnetHTA Collaboration will ensure that its obligations relate to its partners, funders and the work they undertake, and are independent of stakeholder interest. However, the views of stakeholders will be sought in a systematic way to inform EUnetHTA's work and its development.

Within the HTA process, the EUnetHTA Collaboration focuses on methodological development, information collection and analysis of specific health technologies with the aim of presenting information that may be used at national or regional level for context specific HTA. The EUnetHTA Collaboration has an interest in communicating with stakeholders about general HTA processes and issues. As such it will engage with stakeholders that are partnership- or interest-based umbrella organizations working at the European level. It will have no role in stakeholder involvement at national or regional level.

The points of contact for engagement with stakeholders include:

- national and regional policy-makers;
- policy-makers at hospital level, in statutory health insurance or health maintenance organizations;
- patients' organizations;
- health-care professionals and their organizations;
- industry;
- health-related media.

Clear and transparent stakeholder involvement processes will be developed (e.g. rules of engagement and disclosure of competing interests) to ensure that balanced stakeholder views are obtained to advise on the work of the EUnetHTA Collaboration.

## **Conclusions**

Articulate political commitment to, and European collaboration on, HTA has made it possible to obtain extensive political support from national and regional governments and the European Commission for the EUnetHTA Collaboration.

A group of founding partner organizations will develop this on the basis of the proposal endorsed by the EUnetHTA Project Steering Committee in 2008 (EUnetHTA).

Further reporting on the EUnetHTA Project's results in the Autumn 2009 *Journal of Technology Assessment in Health Care*.

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## Chapter 2

# **Policy processes and health technology assessment**

*Camilla Palmhøj Nielsen, Antonio Sarriá Santamera, Hindrik Vondeling*

### **Introduction**

Decision-makers throughout Europe have a common goal of raising health standards in order to improve the health status of the European population. Health service delivery is carried out under conditions of growing political and economic complexity – rapid technological change puts pressure on health-care systems to add new preventive, diagnostic, treatment and rehabilitative interventions to their existing arsenal of technologies. This pressure is ongoing and it is difficult for providers of health services to live up to the expectations of all users. Limited resources require decisions on the introduction of new technologies and the use of those already available.

Health technology assessment (HTA) provides evidence-based input to the policy-making processes concerning the use of technology in health services and thereby seeks to promote evidence informed policy-making. It has the potential to function as a mediating mechanism between policy and research domains by providing a problem oriented systematic overview of research. However, this is dependent upon HTA producers having a thorough and detailed knowledge about policy-making and its conditions, and its users being aware (and having positive experiences) of the use of HTA. This need to share knowledge and experiences between producers and users sets the standard for future success in ensuring evidence informed policy-making. Therefore, the utilization of HTA in policy-making depends very much on mutual understanding and responsiveness to user needs.

In this chapter we aim to describe the role of HTA in policy processes from the perspective of political science. We begin with a brief introduction to HTA, presenting its role and function in both policy processes and democratic processes in general. This is followed by a discussion of the barriers to utilizing HTA in policy-making with a focus on the disconnect between research and policy.<sup>2</sup> We argue that this presents challenges that require improved connections between research and policy in order for HTA to provide successful input to policy-making. As a starting point, a number of research utilization models are presented and discussed in terms of their potential contribution to solve this problem. Finally, we present some recent global developments to illustrate how societal changes can potentially act as facilitating factors to increase the demand and use of HTA in health-care policy-making.

## **HTA**

It is necessary to know what HTA is in order to get an impression of how it can function as an input to policy-making. Described and discussed in detail in Chapter 3, in short – HTA is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased robust manner. It aims to inform the formulation of safe, effective, health policies that are patient-focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method ([www.eunetha.net](http://www.eunetha.net)).

HTA primarily aims to support policy-makers in making evidence-informed decisions on the application of health technologies. It can be regarded as a flexible, ongoing process, guiding technology from its future status to the phase of obsolescence (Banta & Luce, 1993).

Health technology (see Chapter 3 for more detail) is defined as the application of scientific knowledge in health care and prevention. It covers a broad range comprising diagnostic and treatment methods; medical equipment; pharmaceuticals; rehabilitation and prevention methods; and the organizational and supportive systems within which health care is provided.

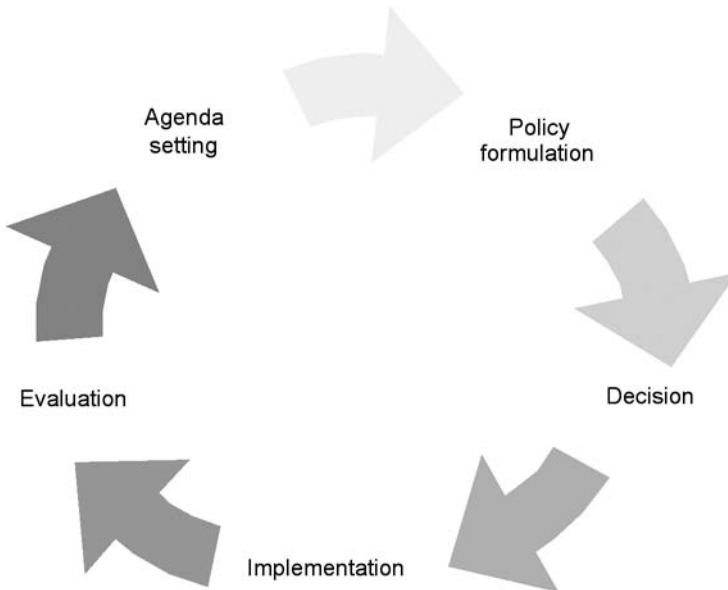
## **The role and function of HTA**

### Policy processes

Policy processes are typically understood as connected stages during which

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<sup>2</sup> The empirical evidence on the barriers and facilitators from the perspective of HTA users is summarized and discussed in Chapter 7.

**Fig. 2.1** Simple ideal model of a policy process

policies are formulated, decided and implemented in particular social, political and historical contexts. These contexts matter – they have distinct influences on what is put on the agenda; how policies are formulated, resources allocated and policies implemented; and on the outcomes of the policies (Mackintosh, 1992). The policy process has been described in different ways by different policy researchers and therefore the models generally include different terminology and/or stages. A very simple ideal model of a policy process is illustrated in Fig. 2.1.

This model implies that policy-making is a technical, linear and rational process. This is rarely the case. Policy analysts are preoccupied with explaining and conceptualizing policy processes and have proposed several different models that represent both (partly) rational and less rational models. A few of the models which have impacted on the theoretical discussions and empirical studies of policy processes are outlined below.

- *Muddling through model* (Lindblom, 1959). A reaction to the rational understanding of policy processes. It emphasizes incrementalism as a predominant characteristic of policy processes. Lindblom claims that policy develops through evolution rather than revolution therefore the wise policy-maker makes incremental changes to reduce uncertainty and avoid mistakes.

- *Garbage can model* (Cohen et al. 1972; March & Olsen, 1976). Reflects the understanding that uncertainty in organizations triggers behaviour which (at least from a distance) appears irrational. In contrast to earlier models it separates problems, solutions and decision-makers. Policy processes comprise different streams: problems, solutions, choice opportunities and participants. These enter a “garbage can” which functions as a reservoir for policy-making when problems arise that demand the formulation of policies. Specific policy decisions do not follow an orderly process from problem to solution but rather are outcomes of several relatively independent streams of events.
- *Easton’s model of a political system* (Easton, 1953). Represents a system approach to policy-making. A dynamic and open model which assumes that decisions are made in response to pressure/input from voters. This input leads through decision-making to the formulation of policies. The model treats the decision-making process as a “black box” and does not describe how this part of the process takes place. Policies change continually in response to voters’ input.
- *Advocacy coalition framework* (Sabatier & Jenkins-Smith, 1993 & 1999). Also takes a system approach, focusing on the analysis of long-term changes in a policy field explained by coalitions formed between policy-makers, influential actors and pressure groups. The model settles with the stage heuristics (an integral part of most policy process models) by focusing on long-term developments rather than specific policy processes.

All the models have contributed to the understanding of how policy processes function in reality under everyday conditions and have been formulated as different reactions to linear, rational understanding of the processes. Empirical studies of policy processes are typically concerned with questions regarding why, how, who and by whom. They also focus on the context parameters of specific policy processes in order to understand the actual course of action. When policy is conceptualized as a process affected by context there is an immediate implication that the processes are likely to vary between them (e.g. across political systems, countries, regions, lower administrative levels and organizations). Nevertheless, some of the more general theories are relevant across different settings and can therefore structure broader discussions across contexts.

The role and function of HTA are often discussed in general terms using a simple linear model of the policy process as a starting point (see Fig. 2.1). Typical questions are: How can HTA contribute as an input to decision-making? How do HTA producers ensure that policy-makers are aware of HTA reports

that can support policy-making? HTA's role is to create links between the policy and the research domains. It is an activity that can be understood only by analysing its context as this determines the best timing and the best possible way in which influence can be exerted on policy processes. At a project level – i.e. for a particular assessment – the link between HTA and policy-making is ensured when an HTA takes a specific policy question as a starting point. This is transformed into a number of HTA questions which can be answered through systematic reviews and analysis of research results. The answers and results are synthesized in an HTA report which is used as a basis for evidence informed decision-making within the policy process (Busse et al. 2002; Kristensen & Sigmund, 2007).

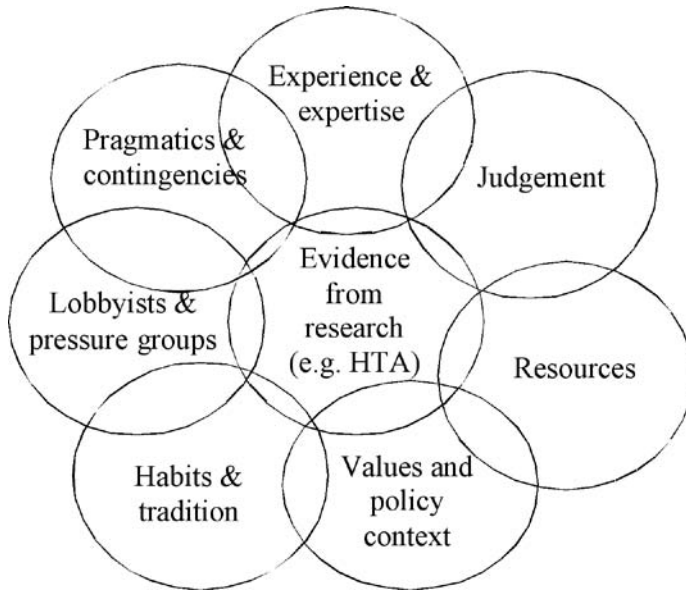
The actual utilization of HTA in policy processes takes very different shapes and depends on a number of factors such as the remit and responsibility of the HTA agency; timing of a specific project; or the way that HTA enters into the process. However, it is characteristic that HTA aims to bring more rationality as it can help to solve policy problems that lack the information or understanding to either generate a solution or select among alternative solutions (Weiss, 1977). The goal is to provide policy-makers with information on policy alternatives such as the allocation of research and development funds; formulation of regulations; or the development of legislation (Banta & Luce, 1993). Generally, this implies that HTA is most suited for (and most successful in relation to) approximated rational policy processes. Policy-makers are involved in formulating the policy problems and demand HTA as the basis for decision-making, with the HTA process timed in accordance with their needs.

It is recognized that HTA provides only one input for decision-making. It is usually not the only source, nor is it always the most important input (see also Box 4.3 in Chapter 4). For this reason an HTA (or its recommendations) should not be confused with the actual decision taken. Fig. 2.2 illustrates this point.

Nevertheless, HTA can provide important evidence-based input and thereby inform policy-makers even though public opinion cannot perceive the process (and perhaps also the decisions) as rational. Though research findings are not directly employed in a specific policy they can still influence the process of agenda-setting, the terms used and the way in which policy problems are framed and understood.

If policy processes are not always rational this also suggests that policy-makers may use HTA results in a manner other than that originally intended. Weiss (1977) and Vedung (2000) suggest that HTA can be used as ammunition in political debates. From time to time constellations of interests around a

**Fig. 2.2** Factors that influence policy-making



Source: adapted from Davies, 2005

policy issue predetermine the position that policy-makers take and ensure that they are not receptive to new evidence. A stand adopted for reasons of ideology, interest or political pressure is not likely to be changed by HTA. However, the results of a particular HTA report can still be used by those that find its results most congenial and supportive. This can also be considered utilization of HTA in policy processes, even if it does not qualify as “intended use by intended users” (Patton, 1990).

In addition, HTA may be used to avoid taking responsibility for a decision, to postpone action or take credit for successful interventions. But even in instances where reports are not used rationally (but rather for strategic or tactical purposes) HTA can still have a valid and instrumental function. The analysis can form the basis of efficient implementation if it is decided that the technology should be introduced.

### Democratic processes

Although not always utilized as intended in policy processes, HTA can still play an important role in democratic processes. Democracies in Europe are typically organized as representative democracies in which politicians are elected to act on behalf of voters. Voters elect the politicians that best represent their preferences and opinions. When dissatisfied, they have the opportunity to vote

differently in the next election. However, politics is very complex and difficult to assess so voters need as much insight and transparency as possible to allow them to evaluate the performance of their elected politicians. HTA provides transparency and thereby offers a foundation for ensuring accountability for government decisions and performance (Chelimsky, 2006). In particular, citizens can gain more insight into arguments for and against the decisions made and can use this information to evaluate the legitimacy of the policy-makers (De Peuter, 2007).

### **Barriers – disconnect between research and policy**

The idea of linking policy and research through HTA seems obvious but some basic barriers have to be addressed. A main issue is that researchers and policy-makers comprise two very different communities with different values, ideologies, languages, backgrounds, institutional settings and reward systems etc. As discussed in Chapter 7, these two communities have very different interests which influence the traditionally expected output from research and the demands for input to policy. The characteristics of the two communities are summarized in Table 2.1.

**Table 2.1** *Policy and research communities: different notions of knowledge*

	<b>Policy</b>	<b>Research</b>
Understanding of knowledge	Colloquial	Scientific
Time frame for production of knowledge	On time, timely	Systematic, as long as it takes
Relevance of knowledge	Policy relevant	Research relevant, theoretically driven
Criteria for validity of knowledge	Anything that seems reasonable	Proven empirically
Format of knowledge	Short and to the point, clear messages	Thorough; discuss caveats, strengths and weaknesses

*Source:* adapted from Davies, 2005

Policy-makers need context-specific input to fit the particular purpose. This input should be timely; reliable (therefore useful in policy negotiations); concise (so policy-makers waste no time) and address specific policy problems (thereby ensuring relevance). By contrast, researchers often provide more context-free knowledge using systematic and cogent approaches which do not



always allow timely inputs to policy-making. The general demand that output should be research relevant means that often it does not capture current policy problems on the political agenda. Validity and thoroughness are good qualities from the research perspective but they may collide with the need of policy-makers. Basically, researchers are occupied with science while policy-makers are action-oriented and concerned with obvious and immediate issues.

These generalized descriptions emphasize the differences between the two communities but do not reflect that these barriers have already been lowered by collaboration between policy-makers and researchers. There are many good examples of research driven by interest in providing policy relevant knowledge for health-care problems that require political action (e.g. research on the social determinants of health). However, despite the limitations and simplicity of the model, the differences between the two communities can largely explain why research is underutilized in the relationship between the researcher/research system and the policy-maker/policy-making system. Given that the values and ideologies of the two communities constitute patterns of behaviour, a great deal of effort is required to break down the barriers. More and better contact between the groups may improve understanding but will not necessarily increase the use of research in policy-making. More structured attempts will be necessary to overcome these barriers.

The different research utilization models are categorized below in order to enable more detailed discussion of this subject.

- *Technological* – science push model. Supply of research findings is the major determinant of knowledge utilization and uptake.
- *Economic* – demand pull model. Use of knowledge is increased when researchers focus their projects on the needs of users rather than the advancement of scholarly knowledge alone.
- *Institutional* – dissemination model. Two factors influence the level of knowledge utilization: (i) disseminated research products adapted to meet policy-makers' needs, and (ii) dissemination effort.
- *Social interaction* – the more sustained and intense the interaction between researcher and users at all stages of knowledge production, dissemination and utilization, the more likely it is that the research will be utilized.

The first model corresponds with the described disconnected relationship between researchers and policy-makers. The three other models present alternatives where the links and interaction between the two become increasingly intense. The social interaction model is compatible with the notion that a particular new kind of knowledge production (Mode 2) has come into being (Gibbons

et al. 2002). In this context, traditional academic research is called Mode 1 knowledge production. Mode 2 knowledge production has, for example, the following characteristics.

- Produced in a context of application – knowledge production is organized around a particular application or policy problem. It is intended to be useful for someone, and this imperative is present from the beginning of the knowledge production. Mode 2 must include the interests of the users.
- Socially accountable – sensitivity to the impact of the research is built in from the outset. Social accountability permeates the whole knowledge production and is reflected not only in the interpretation and diffusion of results but also in the definition of the problem and the setting of research priorities.
- Incorporates a range of interest within the specific context of application – in addition to traditional scientific quality control (peer review), the ability to incorporate stakeholder interests and produce socially acceptable inputs to policy-making are part of the quality criteria.

HTA may be considered to be Mode 2 knowledge production, and linked with the social interaction research utilization model, as it is often recommended to maintain ongoing dialogue with stakeholders for specific projects and for the performance of HTA organizations (Kristensen & Sigmund, 2007; Kristensen, 2006; OECD, 2005; Sorensen et al. 2008). Thus, HTA offers a bridge between the research and policy communities. Barriers and challenges remain (and HTA producers can clearly become better at overcoming these) but HTA is now considered to be an important tool for informing the effective regulation of the diffusion and use of health technologies (Sorensen et al. 2008).

### **Factors that facilitate the role of HTA in policy-making**

In order to improve HTA's input to policy-making it is necessary to understand potential facilitating factors. In the wider political and societal context, these may positively influence the uptake of HTA in decision-making at different levels of the health-care system and are discussed in more detail below.

Evidence-informed policy has been promoted by general trends towards a *knowledge society* (Bhatti et al. 2006; De Peuter, 2007). Governance and policy-making have generally become more knowledge intensive and there has been a growth of related institutions (e.g. HTA organizations, Cochrane Collaboration, Campbell Collaboration). Growing complexity and the rapidly increasing pace of change have made knowledge production and management within government increasingly important points of interest. At the same time

views of quality standards of information and of what constitutes knowledge/evidence are heavily debated (Wothern et al. 2003). HTA is part of this debate and also one of the driving forces in promoting evidence-informed policy-making.

*Fiscal distress* is a potential driver for the use of HTA within the public sector as it often promotes a focus on value-for-money and effective use of resources during attempts to decrease budget deficits (De Peuter, 2007). Economies under pressure require politicians to pay extra attention to how they spend money; HTA can provide valuable information to assist politicians to prioritize and allocate budgets to the most cost-effective activities.

*Intergovernmental policy-making* also facilitates the utilization of HTA. This takes place between national and subnational (regional/ local) government levels and between national government and European levels. National and subnational government levels are handling more and more policy issues in concerted action within network models (Rhodes, 1999). This shift has an impact on the information flow within governments as successful coordination and control depends on the way that the supply and demand of policy information is matched within and between public sector organizations. Intergovernmental collaboration is also visible between the European institutions and Member States, regional actors and interest groups. Even as these relationships change, some policy issues are difficult to solve at Member State level (e.g. globalization and innovations) and therefore there are external pressures for cross-border and supranational collaboration on a number of policy problems (De Peuter, 2007). This also applies to HTA – the EUnetHTA Project clearly addresses the needs for Member State and European intergovernmental collaboration.

Finally, the *increasing complexity* of policy-making in general can act as a facilitating factor. As policy issues become more and more interdependent they involve a large variety of actors/stakeholders in collaborations to solve complex problems across administrative boundaries. Such horizontal interdependence between policy fields requires a broad view on the policy context as well as multidisciplinary inputs to policy-making (De Peuter, 2007).

These trends describe only a small number of possible factors that either promote or hinder the use of HTA. Other factors emerge in relation to HTA programmes (organizational set-up) and projects (project set-up). These are addressed in later chapters.

## Conclusions

HTA has a unique potential to contribute to policy-making, strategic planning, management and the implementation of technologies in health care. It can be used as a strategic tool to overcome the disconnect between policy and research but it cannot be guaranteed that fulfilling a number of preconditions ensures that HTA is used as intended. Nevertheless, it may still have the potential to be useful in strategic planning, management and the implementation of technologies.

Also, HTA has a general function in democratic processes since it creates transparency and can help to ensure accountability for government decisions and performance. This function is evidently linked to policy-making within the health-care field, but developments towards a more general knowledge society cause other sectors to use research as an input to decision-making and thereby promote transparency and accountability in government performance. Finally it is shown that global trends and societal developments potentially facilitate the demand for HTA. All in all HTA has a great potential to contribute to policy-making if it is performed wisely; in line with user needs and demands; and if the producers work to overcome the barriers between research and policy.

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## Chapter 3

# What is health technology assessment?

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### **Introduction**

In this chapter we provide a general introduction to the meaning of health technology assessment (HTA) and how it can contribute to informing health-care policy-making. We describe the methodological streams that contributed to forming HTA as a multidisciplinary field of policy analysis and briefly describe the process of moving from assessments through recommendations to policy-making.

The description of the process of performing HTA is based on the methodological developments which have taken place in both European and joint international HTA projects since the 1990s. This is followed by a description of the development of joint international HTA reports. We conclude by presenting the vision of the EUnetHTA Project in relation to improving European collaboration on the production of HTA.

### **Definition of HTA**

The International Network of Agencies for Health Technology Assessment (INAHTA) defines *health-care technology* as: "...prevention and rehabilitation, vaccines, pharmaceuticals and devices, medical and surgical procedures, and the systems within which health is protected and maintained." *Technology assessment* in health care is defined as: "...a multidisciplinary field of policy analysis. It studies the medical, social, ethical and economic implications of

development, diffusion, and use of health technology” (<http://www.inahta.org/HTA/>).

The EUnetHTA Project has added the following explanatory clarification that emphasizes the process and aims of an assessment:

*Health technology assessment (HTA)* is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method (Kristensen, 2006).

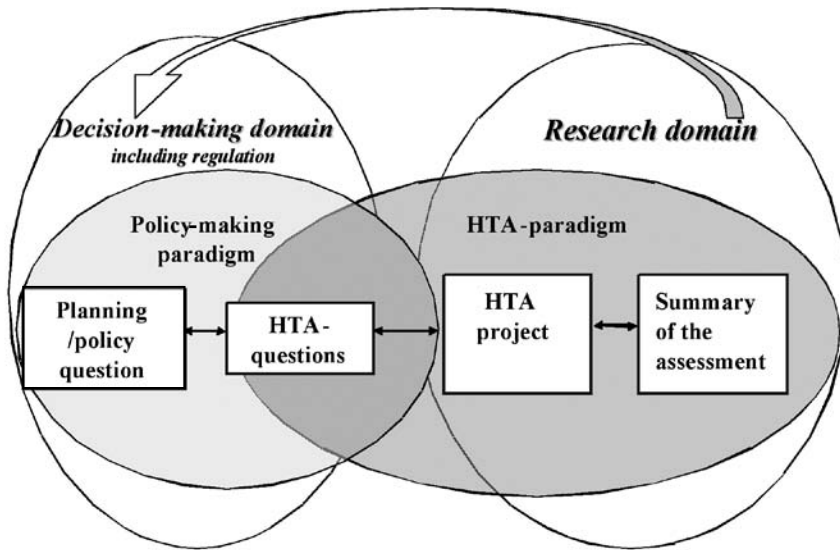
The practice of HTA within this definition varies considerably across national settings. It informs policy- and decision-making in specific political, economic and institutional contexts. In order to be useful HTA has to be designed with processes and outputs that fit the relevant context.

### **From assessment to recommendations and policy-making**

The role of HTA has been described as a bridge between research and decision-making (Battista & Hodge, 1995). Fig. 3.1 illustrates the close relation between HTA and policy-making and depicts the interdependence and separation between research-based assessment and decision-making. A successful process from a policy question to an HTA report that informs policy will span paradigms in a conscious and transparent way.

A majority of EU Member States have public sector HTA agencies that provide information for decision- and policy-making at regional or national levels. Their primary aim is to produce and disseminate HTA reports. In order to optimize the usefulness of HTA, the concrete format of the reporting has to fit into the policy setting for which it provides information. As a consequence some HTA reports may include specific recommendations for policy; others provide only synthesis and conclusions. The credibility of HTA information and clarity on roles in the policy processes depend on producers and users having clear knowledge of the formal status of HTA reports and the practice that reflects this, as reflected in the following example.

The HTA programme in England was established in 1993 as part of the National Institute for Health Research (the research arm of the English National Health Service) (Walley, 2007). The National Institute for Health and Clinical Excellence (NICE) was established in 1999 to appraise technologies at a national level, thereby avoiding local variations in approval and practice that

**Fig. 3.1** From policy questions to HTA reports that inform policy

Source: Kristensen, 2002.

are considered unacceptable in a *national* health service. The Secretary of State for Health decides on NICE's topics based on advice from expert review panels and filtered through a policy review board. The process is managed by NICE itself.

There is a clear distinction between assessment (a scientific process and the role of the HTA programme) and appraisal (the role of policy-makers like NICE). The HTA programme supports all NICE technology appraisals by commissioning independent assessments of the evidence, accompanied by economic evaluations and reviews of manufacturers' submissions. These inform the decisions of NICE's appraisal committees and are made publicly available once a preliminary decision has been made. The assessments do not provide recommendations to the committee.

It is necessary to recognize that practice varies considerably across national settings, and it is extremely important to have a clear understanding of the formal status of HTA reports in a specific context (see also Chapter 4).

### Development of HTA

The advance of scientific knowledge has been accompanied by opportunities and problems. In 1967, recognition of the growing importance of accurate, timely and independent information to enhance understanding led to the



first legislative proposal for an agency to evaluate the impact of technological developments in the United States of America. In 1972, the proposal was enacted into law with the creation of the congressional Office of Technology Assessment (OTA). Although this closed in 1995 (OTA, 1996), remarkably the director's statement in the first annual report still reflects the ethos of international HTA:

Technology assessment is a process designed to ask the right questions, and to seek answers based – as much as is possible – on hard, factual information which can be obtained through disciplined analysis. Where important data are unavailable, the need for additional research can be spotlighted. Technology assessment is an aid to, not a substitute for, the judgments which must be reached by elected officials in policy-making positions (OTA, 1975).

The rapid increase in new diagnostic and therapeutic interventions in health (such as scanners and pharmaceuticals) quickly led to OTA initiatives to address health technologies (Banta, 2003).

After its introduction in the 1970s, technology assessment developed into two main streams.

1. International development of technology assessment which over time has maintained focus on informing parliamentary committees. Uses consensus conferences and other means to combine scientific input with citizens' views. European Parliamentary Technology Assessment (EPTA) partners advise parliaments on the possible social, economic and environmental impact of new sciences and technologies. Common aim is to provide impartial and high-quality accounts and reports of developments in issues such as bioethics and biotechnology; public health; environment; and energy (<http://www.eptanetwork.org/EPTA>).
2. International development of HTA with the establishment of more than 50 agencies serving national or regional governments; a scientific society; an international journal; an international association of agencies; and several EU funded projects (see Chapter 1).

### **Methodological streams**

Four main streams of applied research methodology have contributed to the development of HTA: (i) *policy analysis*; (ii) *evidence-based medicine*; (iii) *health economic evaluation*; and (iv) *social and humanistic sciences*. Policy analysis sets a general framework for HTA as an input to policy-making. Evidence-based medicine (i.e. clinical epidemiology) and health economic evaluation

set the methodological frames for the analyses carried out as part of an HTA. In addition, HTA includes the application of methodologies from social sciences and humanistic research. This is especially true when meeting the requirements of a full HTA in accordance with INAHTA's general definition.

### Policy analysis

Traditionally, policy analysis includes analysis of policy content, outputs and processes (Hill, 2005). HTA has particularly been inspired by the part of the policy process that focuses on how policy decisions are made and how policies are shaped in action with the involvement of stakeholders. This is particularly important since HTA needs to enter into the policy processes in order to be able to fulfil its aim of functioning as an input to decision-making.

Chapter 2 describes policy processes in more detail and presents a simple ideal model of a policy process (Fig. 2.1) that includes the following stages:

- agenda setting
- policy formulation
- decision
- implementation
- evaluation.

HTA can potentially enter the policy process at different stages (e.g. agenda setting, policy formulation or evaluation) but always with the aim of informing the decision.

Systematic policy analysis typically includes the following inputs: goals to be achieved; alternatives available to achieve them; and relations between goals and alternatives. Typical outputs are tentative conclusions on the best alternative, combination or allocation as well as “what-if” analysis to show how these may be affected by changing inputs (Nagel, 1994). In this framework HTA provides a policy analysis which aims to include both the input (e.g. the goals, alternatives and relations surrounding the specific policy) and the output elements. Effective HTAs require close communication and dialogue between policy-makers (having most involvement in setting inputs) and HTA producers (those producing the outputs).

HTA differs from traditional policy analysis in one important respect. Policy analysis is predominantly retrospective – contrasting the outcomes of existing policies with their original goals and using this analysis to propose further policy development. In contrast, HTA is primarily prospective – aiming to inform policy processes *before* the formulation of policies or a formal decision.

However, analysis of the context of existing policies and their implementation may also be a relevant element of an HTA report.

Within policy analysis, a growing literature on “information for policy-making” is currently contributing to the development of HTA. This is mostly concerned with analysing the potential barriers to, and consequences of, using evidence in policy-making (Hill, 2005; Davies et al. 2000). This literature has the potential to influence HTA to clarify its relation to policy processes.

#### Evidence-based medicine

The roots of evidence-based medicine (EBM) stem from the introduction of the scientific method in clinical medicine during the nineteenth century (e.g. the contributions of Bernard, Koch, Pasteur and Fibiger in France, Germany and Denmark) and the development of clinical epidemiology and systematic reviews of research literature. However, the concept of EBM was first introduced in a number of seminal journal articles from a group led from McMaster University in Canada (Evidence-Based Medicine Working Group, 1992).

During the 1980s, work on systematic reviews in perinatal medicine led to the publication of *Effective care in pregnancy and childbirth* by a large international group led from Oxford (Chalmers et al. 1989). This helped to build a solid foundation for determining the degree and application of evidence for diagnosis and intervention in one field of health care and encouraged a number of initiatives. For example, BMJ Clinical Evidence covers an increasing range of health-care interventions. The establishment of the Cochrane Collaboration in 1993 has made a key contribution and EBM is now well-established as a vision (and increasingly as a practice) in European health care (Cochrane, 1989).

#### Health economic evaluation

Health economics aims at a societal perspective and emerged as a separate field in the 1970s (Maynard, 2005). Cost-benefit analyses had been applied to other public sectors, such as transport, but increasing pressure on health-care budgets led to the development of academic and practical health economics (Williams, 1974). Reflecting the diverse needs for economic analysis from institutional to societal level the scope and tools of health economics now range from simple cost analyses to cost-effectiveness analyses – in which the effects are measured in clinically relevant parameters e.g. cost per saved life or cost per avoided stroke. Cost-benefit analyses – in which effects are also valued in monetary units – are undergoing new developments (Poulsen et al. 2007). The methods of health economic analyses are not standardized across Europe. However, best practice is increasingly identifiable while methodology is still being developed and debated

in areas such as the incremental cost-effectiveness ratio with modelling based on quality-adjusted life years (QALYs) (Poulsen et al. 2007).

Health economic analysis in HTA assesses the socioeconomic consequences of the influence of health technologies on patients' return to the labour market; the need for disability compensation and other macroeconomic factors. However, HTA does not assess all macroeconomic aspects of health technologies. It is beyond its scope to assess the influence of the degree of application of certain technologies (such as devices or pharmaceuticals) on the gross domestic product, or to provide supporting evidence to increase the competitiveness of certain industries. These issues can be addressed by stakeholders.

The Lisbon Strategy for Growth and Jobs was the basis for the establishment of the Pharmaceutical Forum by the Directorate-General for Health and Consumer Protection (DG SANCO) and the Directorate-General for Enterprise and Industry. This aims to balance a high level of public health with support for a competitive pharmaceutical industry to ensure that Europe continues to benefit from new medicines. In 2007, the European Medical Technology Industry Association (Eucomed) and three universities<sup>3</sup> founded the European Health Technology Institute for Socio-Economic Research (2007). This is intended to address the lack of evidence on the macroeconomic value of medical technology, including influence on gross domestic products.

### Social and humanistic sciences

The social and ethical aspects of health technologies include issues that are not addressed by the assessment of clinical effectiveness and health economic analysis. These include legal matters; the organization of health care; wider societal consequences of health technologies; patient perceptions; and ethics.

As with assessments of effectiveness and cost effectiveness, the assessment of social and ethical issues follows a systematic approach. However, the standards and best practice for this are (by far) most developed for addressing the issues of clinical efficacy and effectiveness in HTA. The review methods of anthropology, sociology and other social sciences are increasingly mobilized for systematic assessments of qualitative research into (say) patients', citizens' or organizational aspects (Paterson et al. 2001; Hansen, 2007). This is reflected in the EUnetHTA HTA Core Model, a tool that provides a framework for comprehensive analysis of the elements required in a robust HTA.

<sup>3</sup> Technische Universität Berlin, Università Bocconi and London School of Economics.

## **Process of HTA – best practice**

The process of defining best practice in HTA has been ongoing for several years at a national level and within academia. In 1997 a methodology subgroup of the EUR-ASSESS Project proposed a framework for conducting and reporting HTA (Liberati et al. 1997). Based on this work, and on existing guidelines from HTA agencies and other institutions, a subgroup in the European Collaboration for HTA (ECHTA) Project provided an updated methodological framework in 2002. This proposes a common understanding on HTA reports made by European agencies (Busse et al. 2002).

The ECHTA subgroup concluded that all European HTA producers appear to use a similar process (Fig. 3.2).

It was emphasized that each step of the process might be handled very differently by individual agencies and institutions but analysis of these differences was not included in the ECHTA Project. Instead, attention was directed at providing a general understanding of, and agreement on, the overall steps in the HTA process and the accompanying demands for reporting HTA in order to make the findings generally accessible to other agencies or institutions.

As indicated, HTA is not necessarily the same between organizations or across Europe – a recent study covering 11 countries reports significant differences in the practical application (Draborg et al. 2005). That being said, common characteristics have been identified in reports from previous European HTA projects and are further developed and implemented in the EUnetHTA Project. These characteristics are summed up briefly below.

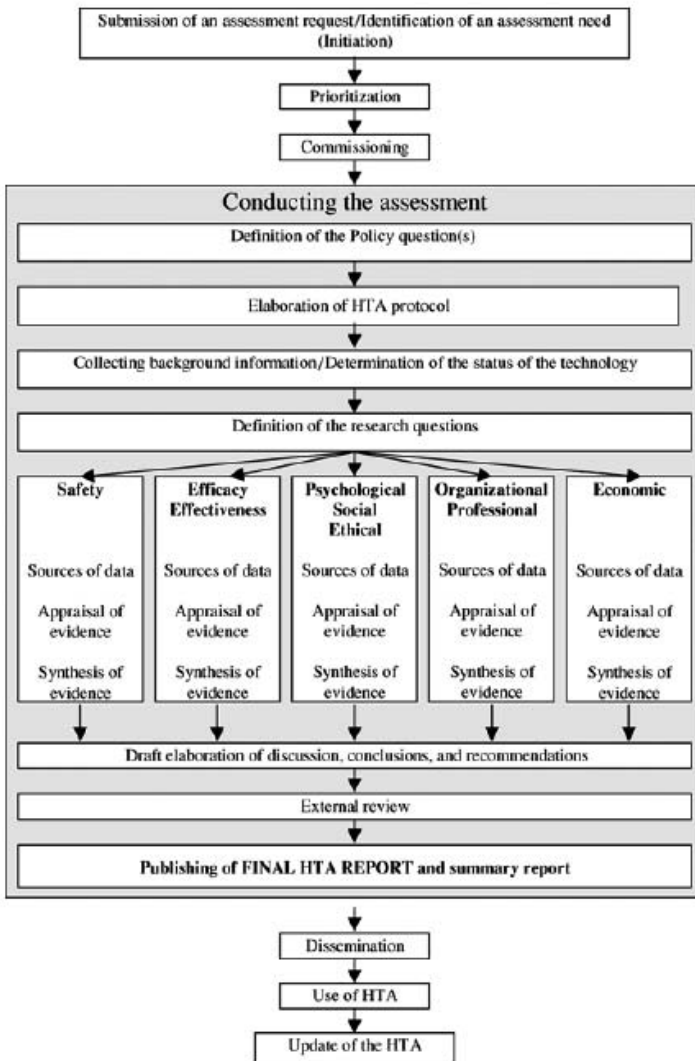
The ECHTA Subgroup on best practice description of the HTA process is summarized in Appendix 3.1. This guidance constitutes well-recognized and internationally agreed characteristics of the HTA process. These were partly the result of a summing up of HTA practice but ECHTA also strove to obtain a common understanding of the process in order to improve collaboration and explore ways of networking.

## **Coordinated or joint international HTA**

Nordic HTA agencies collaborated on two joint HTA projects on hearing impairment and sleep apnoea (Sorri et al. 2001; DACEHTA, FINOHTA, NOKC, SBU, 2007). These combined surveys of current practice and systematic literature review but performed only limited HTA synthesis.

A few syntheses of national HTA reports into a common report have been produced under the auspices of INAHTA. Several HTA reports on positron

**Fig. 3.2** HTA process



Source: This figure first appeared in Busse et al. 2002. Now reproduced courtesy of Cambridge University Press.

emission tomography (PET) published by agencies across the world led to controversy over variations in conclusions based on more or less the same evidence base (Adams et al. 1999; Hastings & Adams, 2006; Adams et al. 2006). Leading representatives of nuclear medicine saw these variations as an indication of a lack of scientific rigour (Højgaard, 2003). The INAHTA Board responded to this criticism.

We believe that HTA is a complex task based on science and INAHTA agencies continue to improve their methodology, individually and

collectively. INAHTA has developed a common HTA checklist for assessing the quality of HTA reports which is available at the INAHTA website. However, although HTAs are principally based on systematic reviews, it is important to stress the difference between scientific validity of a systematic review and the recommendations of an HTA report targeted at a specific health system. The review should be reproducible, but the recommendations may not be (Kristensen et al. 2004).

More positively, this controversy stimulated the international HTA community to consider ways to elevate international collaboration to a new level.

### **Transnational HTA**

Current thinking on the challenge of international HTA is to globalize the evidence and localize the decision. Typically, the use of evidence is most successful when local differences are factored into the decision-making process – whether at clinical, system or policy level (Eisenberg, 2002). While it is possible to develop evidence at a global level, it is important to incorporate local context in order to ensure that HTA is relevant for decision-makers. Also, it should be ensured that transnational cooperation on HTA production does not interfere with national competences for health-care organization. The way forward is to increase international collaboration on development of the evidence while incorporating local context in national/regional HTA reporting in a structured, transparent way. However, decisions should be localized since the provision of health care is a national/regional responsibility.

The EUnetHTA Project took up the challenge of improving conditions for collaborative international HTA in order to decrease duplication of effort and increase the volume of HTA (Kristensen, 2006). It was developed as a very practical project to provide tools for transnational collaboration in HTA.

### **EUnetHTA Project – contributions to international HTA**

Despite international efforts to define the concept of HTA (<http://www.inahta.org/HTA/>) and methodological guidance of European projects (Busse et al. 2002), there are still significant differences in the practical application. In some countries HTA practice consists of clinical effectiveness and cost effectiveness only, others apply a broader perspective and also study issues such as ethics or the social impact of technology. National differences in implementation and organization challenge the international use of HTA as certain considerations (e.g. ethics) are simply not included in some countries' assessments.

The information structure of HTA reports is another challenge when utilizing foreign assessments. Contemporary reports follow the traditional format of scientific papers, containing sections such as abstract, background, methods, results, conclusions and references. Relevant standards for presenting information have been developed by groups within HTA (INAHTA, 2001). Typically, these list requirements for *what* should be included in a report and perhaps *how* or *in which order* the information should be presented. This is an improvement on earlier reporting standards which relied largely on authors' personal judgements on what should be reported. Despite the current guidance, there is still great variation in the internal structures of various sections of HTA reports. A mixture of text, graphics and tables lacks the more refined structure that would enable efficient identification and extraction of relevant data without having to read reports in their entirety.

The EUnetHTA Project aimed to take forward the contributions of previous EU projects and other international networks into practical collaboration and several of the working groups contributed to the development of practical methodologies and tools for HTA. The three central developments in relation to the production of HTA in EUnetHTA are:

- Work stream to develop a generic methodological HTA framework (core information) based on current best practices in order to allow for collaborative production of those parts of an HTA which can be shared and used across different contexts.
- Work stream to produce an adaptation tool kit to enable existing reports and core information to be adapted to fit other contexts – e.g. different countries or regions.
- Work stream to provide tools to enable countries to monitor the development of (emerging, new or established) health technologies and to share these data and results.

### **Developing common core of information that can be shared**

There is still the challenge of avoiding duplication of work and obtaining a more effective use of national HTA. There is a need to find more standardized approaches in order to provide tools that help HTA actors to reuse the work of others. For this reason the EUnetHTA Project aimed at developing a core model and tools that help to adapt existing reports/core HTAs by defining and standardizing the elements of an HTA.



The model tackles two problems of HTA reports: varying content and unrefined structure. Firstly, it facilitates a shared understanding, i.e. what kinds of information should be found in an HTA report and, perhaps, in an ideal comprehensive assessment. This can contribute to reducing the differences in content across local (national, regional, etc.) reports but should not be understood as an attempt at complete standardization. The aim is to provide the HTA community with a model that enables researchers to take account of important aspects of assessment. Secondly, the model should enable better international use of HTAs as the shared structure makes it easier to find and extract information, electronically or manually.

The core model follows the definitions of HTA that emphasize the multidisciplinary nature of assessments. The current first version of the model employs the following domains originally identified in the EUR-ASSESS Project: current use of the technology (implementation level); description and technical characteristics of the technology; safety; effectiveness; costs – economic evaluation; and ethical, organizational, societal and legal aspects.

The basic unit of the model is an *element*, i.e. a piece of information that describes the technology or the consequences and implications of its use. In clinical research an element may describe a clinical outcome (e.g. reduction of symptoms) whereas in social science it may describe the technology's impact on a patient's life (e.g. ability to work). The nature of elements may vary across scientific domains since the consequences and implications are understood and studied differently in each. The common denominator is that all elements provide information that may be useful when deciding on the use or non-use of any given technology.

HTA has many possible elements and therefore the core model is limited to those that (a) deal with context-independent information, and (b) are particularly significant for HTA (even if they contain context-dependent information). Context independence implies that a specific piece of information is transferable to another context (e.g. another geographical area, health-care system or policy setting) when applying the same technology.

The core model builds on earlier work in the EUR-ASSESS (Liberati et al. 1997), HTA-Europe and ECHTA/ECAHI (Busse et al. 2002) projects, and on other theoretical guidance (Banta & Luce, 1993; Kristensen et al. 2001; INAHTA, 2001). These previous efforts to agree a common structure for HTA reports have mainly been based on the classical structure of a scientific paper rather than proposing a structure to facilitate extraction and usability (Busse et al. 2002). This is addressed in the core model proposed here which aims to

construct a clear structure and presentation of information by structuring HTA according to the basic concepts listed below.

- *Domain*: a wide framework within which the technology is considered. An angle to view the use and consequences of any technology. A standard set of domains is currently agreed within the EUnetHTA Project, corresponding with those identified by the EUR-ASSESS Project.
- *Topic*: more specific area of consideration. One domain is divided into several topics and similar topics may be addressed within more than one domain. For example: clinical effectiveness/life expectancy; current use of technology/regulatory status; societal aspects/ability to work; societal aspects/family life.
- *Issue*: even more specific area of consideration. One topic typically consists of several issues, though it may contain only one. An issue is expressed as a question. Such questions may be similar to research questions within scientific studies, for example: clinical effectiveness/life expectancy – What is the direct effect of the technology on the mortality of patients? Clinical effectiveness/life expectancy – Does the technology affect the expected length of patients' lives in some other (indirect) manner? Current use of technology/regulatory status – Has the technology been approved by relevant authorities in the EU?

The combination of a domain, a topic and an issue defines a single *assessment element*. The model structure is based on such domain-topic-issue combinations. Similar issues may exist within different domains, perhaps even within different topics within one single domain. The combination of domain-topic-issue reveals the context of an issue.

Topic-specific judgements are necessary when applying the core model to a single HTA. In many cases the issues defined in the model are too general to be used as research questions without modifications. Each issue presents a problem on a general level that must be translated into one or more research questions to be answered in an assessment. The model guides researchers in selecting which aspects of the technology or its use to study and provides a common structure for presenting the findings. Within each domain, guidelines and research tradition help in formulating the questions. In clinical research it is often useful to apply the PICO structure (patient/population, intervention, comparison, outcomes) at this phase.

### **Problems with HTA transfer**

A number of difficulties hinder the transferability of HTA reports. These arise

**Table 3.1** *How issues defined in the model may be translated into research questions*

MODEL	CORE HTA
Issue	Research question (in different settings)
Does the technology reduce the severity of symptoms of disease?	Do drug eluting stents reduce chest pain in patients with angina pectoris?
Can informed consent be given?	Are stroke patients able to provide informed consent for anticoagulation?
Does the technology challenge cultural values?	Is screening for fetal malformations accepted by all subgroups in the population?

because of inherent differences between the settings in the countries in which research is carried out and those in the countries that might wish to apply the findings. The types of differences include those relating to the demographic make-up and the epidemiology of the disease in the target populations. Also, transferability is affected to some degree by differences in other factors concerning unit costs, the relative efficiencies of health systems, health-care practices, social values and preferences.

The variation in methodology used (for example, to estimate costs) and the way in which HTA research is reported can also be major barriers to transferability. Spath et al. (OECD, 2005) found that the lack of detail in reporting health-care resources and prices used and a lack of specificity in defining the study setting were the most common obstacles to transferability.

**Strategies to address problems with HTA transferability – EUnetHTA adaptation tool kit and glossary**

In 2005 the OECD suggested a number of ways to improve HTA transferability. These included a suggestion that reporting frameworks should be developed in order to assist decision-makers in assessing the relevance of economic evaluations to their local setting and to extrapolate results more easily (OECD, 2005).

Another approach (and objective of the EUnetHTA Project) seeks to ensure better use of existing HTA reports by developing a tool kit to adapt the “core” of an assessment into advice appropriate to other contexts (social, political, economic and health systems) within which it may be implemented through policy. Commonly, HTA agencies in different countries require HTA reports on the same health technology. If one report could be adapted to different contexts this would reduce costs and time and increase the capacity to develop further new HTAs.

The benefits of adaptation would seem intuitive but the process is less so. Depending on the purpose, the use of all or part of an HTA from elsewhere can be undertaken in a range of ways. The minority of reports simply require translation and adoption to enable their use within another context. More often, they require a degree of adaptation of both information and data – that is, the need for systematic evaluation and extraction of relevant information and data from (all or part of) an existing report.

Furthermore, some parts of some reports are more context dependent than others. For instance, most evidence on safety and effectiveness for many health technologies can be readily transferred to different contexts (being context independent). However, specific attributes or acceptable trade-off levels may vary between contexts (e.g. evidence appraisal is context dependent). Legal and ethical information is heavily context dependent and it is unlikely that such information could be readily adopted or easily adapted without significant appraisal concerning the local context.

EUnetHTA's work on transferability aimed to develop an adaptation tool kit and glossary to support HTA agencies through this process. The tool kit comprises a series of checklists and resources which address the relevance, reliability and transferability of data and information from existing reports. In other words, it helps users to determine whether an existing report addresses similar concerns, is of sufficient quality and is applicable to their setting. It supports the adaptation of HTA reports that are a synthesis of evidence and can be used to adapt a whole report or parts of it. The tool kit has two sections:

1. *Speedy sifting* – screening tool which enables rapid sifting of existing HTA reports to assess their possibility for adaptation.
2. *Main tool kit* – more comprehensive tool with questions on reliability and transferability in five key HTA areas (technology use and development; safety; efficacy and effectiveness; economic evaluation; organizational aspects).

An accompanying glossary has also been developed. This provides descriptions of adaptation terms from HTA agencies within different countries and settings with the objective of highlighting differences in their meanings.

A number of methods were used to develop the tool kit and glossary: literature searches; a survey of experience of adaptation; a two-round Delphi survey; and discussions at meetings. It also drew on the expertise and experience of EUnetHTA partner organizations and a literature review. Furthermore, the tool kit has been used to adapt a number of HTA reports through two rounds of quality assurance testing undertaken within the EUnetHTA partnership.

Both tools are publicly accessible and available on the EUnetHTA web site (<http://www.eunetha.net/>).

Links between common core information and the adaptation tool kit

The link between the production of common core information and the adaptation tool kit is very important. The tool kit is a necessary instrument for adapting core HTA information into context-specific HTA reports which in turn are relevant to local, regional and national policy-making. It is crucial that the two are coherent and mutually support the production of policy-relevant HTA. Both instruments use a common generic HTA methodological framework and taxonomy to avoid duplication of work and enable HTA producers to be able to use the work of others.

### **Providing information on emerging/new technologies and facilitating the generation of new evidence**

Policy- and decision-makers face real challenges with increasing pressure to adopt new technologies as early as possible and to ensure fast access to innovations. Currently, a new technology is generally considered ready to be introduced into the health-care system despite uncertainties about the true benefits and risks of its use. Decisions have to be taken increasingly early in the life cycle of an innovation, in a climate of uncertainty, with the risk that the decision may prove medically and/or financially inappropriate. Solutions to reduce the risk of inappropriate decisions (without unduly delaying patient access to innovative technologies) usually involve early intervention; high-quality and timely assessments; and monitoring procedures.

Monitoring the diffusion of emerging/new technologies is a recent and expanding activity that is being developed in several countries. Monitoring systems are being set up to gather new or additional evidence on the value of technologies expected to have a high impact on health care. In general, such technologies are introduced conditionally, i.e. their early introduction or coverage is conditional on their use within a defined framework and the collection of additional data to reduce uncertainty. The aim is to gather a critical mass of data quickly and prospectively to form the basis of a more robust decision after the provisional period of coverage.

A number of countries are developing monitoring activities (such as conditional coverage mechanisms) but information on these is generally scarce and not easily accessible. Moreover, it takes time and resources to generate new evidence, for instance by performing clinical studies or setting up registries. There is thus a strong need to: (i) share useful and timely information about planned, ongoing

or completed systematic data collection, and (ii) encourage the setting up and funding of pragmatic trials to generate new evidence. Collaborative efforts would be most valuable in this context.

The EUnetHTA Project has prepared tools consisting of structured and standardized questionnaires and a dedicated database for storing and obtaining information. These aim to support collaboration on monitoring activities and to facilitate information sharing with quick and easy access to information about evaluations and decisions relating to early and conditional introduction of emerging/new technologies into the health-care system and about ongoing or planned data collection in different countries.

The next scheduled step is the development of tools to facilitate collaborative actions for generating evidence or knowledge in order to reduce uncertainty. For instance, this could mean agreeing a common set of criteria for data collection, e.g. common core study protocols. Data would be collected either simultaneously or collaboratively in a number of countries. Collaborative actions should help to achieve timely adoption of high-value technologies on a more robust evidence base.

## Conclusions

HTA is developed with contributions from different methodological streams – policy analysis; evidence-based medicine; health economic evaluation; and social and humanistic sciences. These streams have helped to shape HTA (which is by definition eclectic) and enable it to function as a bridge between decision-making and research domains.

Best practice for performing HTA has developed over the years through contributions from HTA producers all over the world. In particular, the EUR-ASSESS and ECHTA projects have contributed to describing frameworks for conducting and reporting HTA. The EUnetHTA Project aimed to build on these and the work of other international networks to build practical collaboration based on the development of practical tools. This includes the development of a model for common core information, an adaptation tool kit and a system for monitoring the diffusion of new health technologies.

Further reporting on the EUnetHTA Project's results are planned in the Autumn 2009 issue of *International Journal of Technology Assessment in Health Care*.

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## Appendix 3.1 HTA process

HTA is policy driven and focused on delivering support for policy-making, therefore a decisive condition for a successful HTA process is the selection of topics that are relevant for the targeted policy-makers. Consequently, well-functioning systems for identification and prioritization of topics are of utmost



importance and the selected topics should be transformed into clearly defined policy question(s) of direct significance to policy-makers (Busse et al. 2002).

Based on the overarching question(s), an elaborate HTA protocol is developed to plan the process of assessment and reporting. In this process the policy question(s) will be transformed into a number of specific research questions and the protocol will describe:

- aspects of the problem to be addressed (e.g. safety; efficacy/effectiveness; societal, organizational or economic aspects);
- how each aspect will be addressed (e.g. literature searches, data sources);
- methods that will be used in the assessment;
- what kind of synthesis will be performed (Busse et al. 2002).

This protocol functions as a guideline on how to undertake the planned HTA. In order to prepare a protocol it is necessary to gather background information that supports the transformation of a policy question into more specific research questions. According to the best practice described in the ECHTA Project, the research questions drive how the rest of the assessment will be conducted – the aspects that will and will not be evaluated. Also, the formulation of the research questions is essential as they dictate which methods will be used. Often it is fruitful to ensure feedback from policy-makers to ensure that the research questions are a useful translation of the policy question. To ensure that research questions are formulated in a useful way, they should:

- be clearly worded
- be answerable
- be limited in number
- address meaningful outcomes
- address other relevant treatment alternatives (Busse et al. 2002).

The next stages in the HTA process are to search systematically for literature/information; select and evaluate the literature/information (i.e. appraise the evidence); and synthesize the data obtained in order to answer the research questions. The literature selection process, methods of grading and of synthesizing the evidence are described in more detail in the report of the ECHTA Project. Important features of these stages are:

- a systematic and substantiated approach
- transparency
- clear inclusion/exclusion criteria (Busse et al. 2002).

These characteristics are self-evidently part of the assessment of each aspect included in the HTA. The analysis of safety; efficacy/effectiveness; and societal, organizational and economic aspects need to reflect a systematic and transparent approach. Specific guidance on how to perform the analysis of each aspect is discussed briefly in the ECHTA report. However, it is emphasized that specific expertise should be included in the project if primary research is conducted within an HTA in order to ensure high quality. It is underlined that its multidisciplinary nature requires broad competences and expertise from those performing an HTA. Also, it is emphasized that the following methodological aspects should be discussed – preferably in a separate section:

- methodology of the assessment
- evidence used (quality, validity, generalizability)
- assumptions made
- discrepancies and uncertainties identified
- expected changes (in technology or evidence) (Busse et al. 2002).

Possible methodological limitations should be considered in relation to their possible influence on the results in order to be able to formulate conclusions/recommendations.

The conclusions' principal aim should be to answer the research questions based on the available evidence. It should include all the assessed aspects in order to reflect the broad nature of HTA. It is important that a conclusion highlights areas that require more research as this is a major finding which enables future focusing of research strategies. It is not generally accepted that HTAs should include recommendations – some include them but others do not. Often, this difference in practice is due to differences in the mandates of HTA organizations or those commissioning HTA projects. When recommendations are given it is necessary to ensure that the advice is in line with the findings of the assessment.

Finally, the ECHTA report on best practice in undertaking and reporting HTA gives guidance on how to: (i) ensure quality by providing a peer review process for each HTA report; (ii) ensure the validity of the HTA findings by updating assessments when necessary; and (iii) report HTA findings in a format that is directed at the maximum number of target groups by dividing each report into an abstract, a scientific summary and a technical report (Busse et al. 2002).



## Chapter 4

# Health systems, health policy and health technology assessment

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### **Introduction**

Health technology assessment (HTA) is defined by its aim – to provide input to decision-making in policy and practice (EUR-ASSESS, 1997). The intention is to facilitate the consideration of research knowledge in the deliberations of those involved in the process of taking decisions and formulating policies. Thus, HTA is understood as a process which begins with the identification of decision-makers' needs for information – i.e. the original policy question, the problem faced by the decision-makers – and its translation into questions compatible with scientific research. This concludes with the compilation of an assessment report containing a sound and systematic analysis of the relevant research and information as well as a synthesis accessible to the intended target audience – the decision-makers (EUR-ASSESS, 1997, Busse et al. 2002) (see also Chapter 3).

The purpose of this chapter is to provide a conceptual overview of the different levels at which decisions are taken in a health system, the decision-makers involved and the different types of decisions made in the context of health care, with a particular focus on coverage. We begin by providing a general definition of the health system and its organizational levels in order to place HTA in context – highlighting the role of technology. We also define the terms policy-maker, decision-maker and the assessment-appraisal tandem since the latter helps to elucidate HTA's role in policy-making.

A simple typology of the decisions concerning technology in the health system is followed by a more detailed description of the characteristics of the decision-

making on health technologies that are made available and covered (at least to some extent) in the health-care system. Coverage has long been an important issue in health-care policy and since the 1990s HTA has been advocated as necessary for improving coverage decisions (Cranovsky et al. 1997). Decision-making on coverage is highly formalized in some European countries, at least for some types of technologies, and HTA is increasingly being used in these processes.

### **Health system, health-care system and technologies**

The *health system* consists of all the people and actions whose primary purpose is to improve health (WHO, 2000). This definition covers a plurality of professions and institutions as well as a broad range of activities to promote, restore and protect health. A health system includes health care of ailing individuals, ranging from informal care provided by relatives to the highly specialized and technologically advanced medical care delivered in tertiary hospitals. It also includes actions targeting whole populations – from educational campaigns to public health laws (e.g. smoking bans). The latter are a fundamental tool for the practice of public health (Mensah et al. 2004). In addition, this broad perspective of the health system includes any other kind of intervention that is explicitly or predominantly intended to protect the health of populations (e.g. environmental protection, workplace safety, food and water safety policies) (WHO, 2000).

WHO acknowledges that this definition of the health system does not imply any degree of integration or of coordinating oversight. Thus, every country of the world can be considered to have a health system (WHO, 2000) although each has developed according to different approaches and at different paces. Contemporary health systems show different degrees of complexity, integration and coordination, reflecting the diverse political and social conditions as well as the economic resources available in each country. Notwithstanding this diversity, a modern health system should ideally pursue the following fundamental goals proposed by WHO (WHO, 2000), to:

- improve the health of the population they serve
- respond to the wishes and expectations of individuals about how to be treated
- provide financial protection to individuals against the costs of ill-health.

In most countries, the majority of financial and workforce resources available to address health-system goals are committed to the organization and delivery of preventive, curative, rehabilitative and palliative health services. These make up the *health-care system* which has been defined as the arrangements, individuals

and institutions through which personal health services are provided, organized and controlled (Myers, 1986). The Organisation for Economic Co-operation and Development (OECD) System of Health Accounts follows a functional definition of health care, covering the activities of individuals or institutions that apply medical, paramedical and nursing knowledge and technology to promote health, prevent and cure disease, care for people with disabilities and provide and administer public health (e.g. school health services, prevention of communicable diseases or occupational health care) (OECD, 2000).

The health-care system also includes the activities of other professions, such as physiotherapists and pharmacists. Moreover, the planning, management, regulation and collection of funds as well as the handling of claims for the delivery system are covered by the OECD's functional approach. Activities such as the education and training of the professionals who deliver services, research and development in health, environmental health, or food and water control are considered health-related activities representing relevant areas of health policy. However, these are considered to be part of the broader health system rather than core health-care functions (OECD, 2000).

The design of health-care systems also shows great diversity between countries due to the considerably different contexts of their genesis and development. There are differences in the ways that financial resources for each system are obtained and distributed; organizational structure of service provision; specific services provided and in the professions involved. However, the application of health technologies to achieve its goals is common to all health-care systems. Thus, in any health-care system, decisions on health technologies are an important part of the everyday business of service design and delivery.

Technology has been defined as the organization of knowledge for practical purposes, i.e. tools in the general sense – from machines to linguistic and intellectual tools (Mesthene, 1977). Based on this general definition, health technologies have been defined as the “drugs, devices, and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided” (Banta et al. 1978). The term covers a wide range of interventions used in health care and health promotion. Since the health-care system includes more than medical care (i.e. other professions and settings) and is only part of the wider health system, this definition of health technology can be expanded to include any tools applied with the aim of improving the performance of the broader health system in the achievement of its ultimate goal and practical purpose – health gain (Velasco-Garrido & Busse, 2005). According to the definitions of the health system and health-care system given above, three different areas of health technologies are identified (see Box 4.1).

Health systems can address major health problems through the combination of health technologies from these three areas, as illustrated in Box 4.2 for one chronic disease. Specific technologies may present different degrees of complexity in any of the areas of health technologies.

Taking this broad perspective of HTA, any technology that aims to improve the health of the population should be subject to an assessment that follows HTA principles. In a health system that demands evidence-based health care it can be claimed that policies related to the organization of health-care delivery must be evidence-based too (Ham et al. 1995). That is, interventions in health-care services, health-care reform (i.e. interventions targeting the system itself) and policies beyond the health-care system should be assessed in terms of their capacity to improve health and to explore other possible social and ethical consequences. There is a need for multidisciplinary assessments, particularly in health-sector reform, although these are methodologically challenging (Niessen et al. 2000). The specific research design for estimating the consequences of applying a specific technology will vary according to its type (see Box 4.1) (Banta, 2003a; Briss et al. 2000).

**Box 4.1** *Areas of health technologies*

1. Whole range of *interventions* which can be provided *within* the health-care system as it delivers health services.
2. *Interventions applied* to the health-care system in order to organize service delivery, access, payment of providers, etc.
3. *Tools* for promoting and protecting health outside the health-care system – i.e. in the broader health system.

**Organizational levels of the health system**

There is general agreement that the health and health-care systems are divided into three levels: i) macro, ii) meso and iii) micro. However, there may be differences in the interpretation of the level at which institutions and decision-makers belong, depending on whether the focus is geographical or organizational. From a geographical perspective, macro level can refer to both international and national (i.e. decision-making within central government) institutions; meso level is the underlying administrative level (i.e. regional or provincial health authorities); and micro level is local institutions.

From an organizational perspective the macro level may refer to the actors and institutions within which the general organizational and regulatory frameworks of the broad health system (particularly the health-care system) are established, whether or not these coincide with national borders. Macro level is concerned

**Box 4.2** *Technologies in the health system: the example of cardiovascular disease*

Cardiovascular disease (CVD) is one of the leading causes of amenable mortality and morbidity worldwide. In 2005, cardiovascular disease accounted for 30% of mortality worldwide – a total of 17.5 million deaths including 7.6 million from heart attacks (WHO, 2008). Thus, in this example, reduced mortality from CVD and improved survival after myocardial infarction are practical purposes of the health system in order to achieve the goal of overall health gain.

The risk factors for developing CVD include age, smoking, hypercholesterolaemia, obesity and diabetes mellitus. Patients with CVD are at increased risk of serious vascular events and mortality. The risk can be reduced by lifestyle changes; treatment with aspirin, lipid-lowering drugs and ACE inhibitors; and direct treatment of vessel lesions (SIGN, 2007). In general, European health systems could improve the quality of care for chronic conditions like CVD (WHO, 2004).

Drawing on this knowledge, and according to the definition of technology given above, several tools or technologies can be applied to address the practical purpose of reducing CVD mortality. These range from health-care services to interventions outside the health-care system, as shown below.

<b>Specific technology (tool)</b>	<b>Area</b>	<b>Type</b>
Aspirin, lipid-lowering drugs, ACE inhibitors	Intervention provided in health-care services	Drug
Stent/stenting Coronary artery bypass grafting (CABG)	Intervention provided in health-care services	Device/ procedure
Rehabilitation programme Educational interventions	Intervention provided in health-care services	Multifaceted intervention
Disease management programme for CVD	Intervention applied to the health-care system (organization of service provision)	Multifaceted intervention
Pay for performance (e.g. targeting higher prescription of aspirin for CVD)	Intervention applied to the health-care system (payment of providers)	Policy
Smoking ban	Intervention outside health-care system	Policy

with the organization of the whole delivery system as well as public health interventions. Meso level refers to medium-sized units of service provision such as primary health-care units or hospitals. There are also commonalities between these two levels as decision-making in each affects collectives, e.g. inhabitants of a nation or a region, members of a health insurance scheme, or persons covered by statutory health insurance. Macro- and meso levels together constitute the policy level (see also Chapter 8).



Micro level refers to the interactions between individual patients and health-care professionals. In contrast, decision-making at this level refers to the decisions taken as a result of the interaction between individual health-care providers and individual patients. This is the level of clinical decision-making where decisions on the use (or not) of technology must be made by health care professionals and patients, weighing the expected benefits and potential harm for the individual in a particular clinical situation. Evidence-based medicine is about the appropriate use of evidence in these clinical interactions (Sackett et al. 1996) and thus refers to the micro level. In contrast, HTA aims primarily at providing evidence syntheses for the macro- and meso levels of decision-making. Nevertheless, HTA may also directly influence decision-making at the micro level, since HTA results are public and available to clinicians and patients involved in clinical decision-making. Decisions at the micro level refer exclusively to the area of interventions provided in the health-care system whereas decisions at the macro- and meso levels also concern other technology areas (see Box 4.1).

### **Policy-makers and decision-makers**

Policy remains an ambiguous term. One of a plethora of definitions applies according to the setting in which it is used (McDonald et al., 2005). For the purposes of this chapter, policy is defined as: “a purposive course of action followed by an actor or a set of actors in dealing with a problem or matter of concern” (Anderson, 1984); “a course or principle of action adopted or proposed by an organization or an individual” (Oxford University Press, 2001); and “a general statement of intention, past or present actions in particular areas or a set of standing rules to guide actions” (Blank & Burau, 2007).

This collective definition allows several interpretations. A restrictive view sees policy as the norms issued by governmental institutions. These can be equivalent to laws (independent of these that need parliamentary approval or are issued directly by a ministry – i.e. ministerial decree), since they are the tools by which governments implement policy. Policy can also be used to refer to the rules which govern the functioning of the health system in general, including those issued by both governmental and non-governmental institutions (i.e. self-governing institutions, sickness funds, professional associations, etc.). Reference to the legal and organizational framework of the health system is common to both of these definitions. In accordance with the aforementioned distinction between the broader health system and the health-care system, it is possible to differentiate between health policy and health-care policy. Health-care policy is

a narrower term that refers to the courses of action that deal with the financing, provision and governance of health services (Blank & Burau, 2007).

From the definitions provided above it may be deduced that policy can include any rules to guide actions at any level of the health system, whether or not they are legally binding. In this context it might be applied to an area as small as a hospital ward or a single surgery, where policy refers to the set of statements that aim to provide guidance on how to act in some situations – i.e. “the policy of the surgical department of our hospital for avoiding deep vein thrombosis after major surgery is to...”. From this point of view clinical practice guidelines (CPGs) – from local to national – can also be considered a kind of policy. This type of policy affects collectives too, namely the patients who are the object of the guideline.

Policy-makers are the individuals involved in the process of formulation. They vary according to the particular interpretation of the term and whether a broad health policy or narrower health-care policy is under consideration. According to the meanings of policy described above, and in relation to the levels of the health system, the term policy-maker may be understood restrictively to mean people operating in institutions with influence at the national level or those operating in governmental institutions. Such policy-makers can be politicians (those elected to government) or individuals occupying political positions (appointed by those elected) (EUnetHTA, 2007). Policy-makers can also be a group of individuals at the local level (e.g. in a hospital department) whose recommendations will be followed by other professionals.

At times, policy-maker and decision-maker are used interchangeably. Policy-makers are indeed decision-makers, since the process of policy formulation implies taking decisions. However, not all decision-makers can be considered to be policy-makers. For example, a patient or clinician addressing a clinical case are decision-makers making choices from available options to solve a problem. While this has specific information needs decisions taken affect only the individual clinical situation; the output of the decision is not intended to guide the actions of a group or to establish a general rule, i.e. it is primarily restricted to the micro level.

Policy-makers are decision-makers acting at the macro- or meso level. They make decisions covering each of the three areas (see Box 4.1) of health technology, affecting collectives. Policy-makers targeted by HTA may include those listed below.

- Politicians: elected persons and those appointed by them (members of national, regional or local parliaments or assemblies; ministers; state secretaries; heads of departments).

- Civil servants: technical experts in national, regional or local authorities.
- Managers: in hospitals, primary health-care, sickness funds, private health insurance.
- Members of corporations: persons operating in provider associations (e.g. medical or hospital associations); purchaser associations; self-governing institutions (e.g. joint committees of provider and purchasers, as in SHI systems).
- Clinical and non-clinical staff involved in formulating both local and national CPGs.
- Multidisciplinary decision-making committees on which several of the above are represented.

Health-care decision-makers and health policy-makers do not understand evidence in the same way as researchers. The former appear to have a *colloquial* view in which evidence is everything that establishes a fact and is defined by its relevance (Lomas et al. 2005). This is a broad view that includes expert opinion, personal experiences and judgements on political acceptability as well as survey data or evidence from scientifically sound research (Culyer & Lomas, 2006). This perspective considers evidence to be any kind of information that supports a conclusion or a view. By contrast, researchers adopt a more restrictive understanding in which evidence refers only to information generated through the scientific method (Lomas et al. 2005).

Certain types of information which are accepted as evidence under the colloquial view of relevance are unacceptable from the scientific perspective. For example, expert opinion emerging from non-systematic personal observations or lacking explicit critical appraisal ranks lowest in the hierarchies of scientific validity of evidence e.g. in the Oxford Centre for Evidence-Based Medicine Levels of Evidence (Phillips et al. 2001) or the US Preventive Service Task Force Hierarchy of Evidence (Harris et al. 2001). The scientific perspective requires information accepted as evidence to be generated by following the scientific method, characterized by systematic gathering of data starting from a formalized hypothesis, and by its explicitness and replicability (Lomas et al. 2005) (see also Box 4.3 below). Policy-makers' colloquial perspective on evidence implies that evidence from research is only one of the factors taken into account in decision-making processes (see also Fig. 2.2 in Chapter 2). In many cases, research evidence is not even the prevailing factor (Culyer & Lomas, 2006).

## Concepts of assessment and appraisal

The existing informal distinction between the assessment and the appraisal of health technologies was consolidated and formalized with the creation of the National Institute for Health and Clinical Excellence (NICE) for England and Wales in 1999 (Stevens & Milne, 2004). In this context, assessment refers to the scientific/technical analytical process of gathering and summarizing information on the relevant aspects of a health technology; appraisal refers to the political process of making a decision about health technologies, taking account of assessment information as well as values and other factors (Stevens & Milne, 2004).

The term appraisal is potentially confusing since it denotes a specific approach to interpreting research,<sup>4</sup> above and beyond the definition provided above. In addition, the assessment-appraisal tandem originally described the specific situation in decision-making on technologies in the National Health Service (NHS) of England and Wales. Accordingly the assessment-appraisal model is frequently interpreted as implying the existence of an explicit, formal decision-making process.

In spite of both limitations, we consider the distinction between assessment and appraisal of technologies to be conceptually attractive since it reflects two facts relevant for the general understanding of HTA's role in decision-making. First, it acknowledges that HTA and health policy-making are two separate elements although ideally in close collaboration. HTA is an input to policy-making but it does not mandate decisions nor is it, in and of itself, policy-making. This understanding (i.e. the distinction between policy analysis and policy-making) is shared by the majority of the European HTA community (EUnetHTA, 2008). Second, it highlights the fact that (as explained above) in most cases policy-makers draw on different sources to satisfy their information needs when taking decisions. Again, this does not seem to be exclusive to the English NHS (Lomas et al. 2005).

Decisions about health technologies require information on context-free factors of the technology in question and on context-dependent issues (see Box 4.3). An assessment (i.e. HTA report) can provide such information as it is a summary<sup>5</sup> of the relevant research on context-free and context-sensitive evidence. However, as evidence from research on contextual factors is frequently limited, or entirely lacking, relevant colloquial evidence is the information most often included in decision-making processes (Culyer & Lomas, 2006). In the appraisal process

<sup>4</sup> Critical appraisal is commonly used to describe the process of assessing and interpreting a single piece of evidence by systematically considering its validity, results and relevance (i.e. by asking – Is it valid? Is it important? Is it applicable?). Critical appraisal of research is central to the performance of an HTA (EUnetHTA 2007).

<sup>5</sup> The concept of HTA includes both primary and secondary research. Summary of research does not mean that HTA is limited to synthesizing existing research. Depending on the resources available, an HTA project may also include primary data collection and analysis.

**Box 4.3** *Types of evidence in health-care system decisions*

*Colloquial evidence*: not necessarily generated through scientific research. Includes information about available resources; expert and professional opinion; political judgement; values and traditions; views from stakeholders; and particular contingencies of a situation.

*Scientific evidence*: generated by following the scientific method. Can be differentiated in two categories.

- *Context-free scientific evidence*: elucidates whether a technology can work and whether it is safe; patients for whom it is intended, etc. Aims to reveal universal truths. Examples related to technology include a meta-analysis of several clinical trials or a multicentre clinical trial.
- *Context-sensitive scientific evidence*: elucidates whether a technology which works in general will also work in a specific context; whether it would be of value in this context; and what resources would be necessary to implement it. For example – patients' and providers' preferences and views on acceptability, economic constraints, available resources, etc.

*Source*: Lomas et al. 2005

the information produced in the assessment is combined with other kinds of evidence in order to reach a policy decision.

Some European countries have explicit decision-making processes in which an assessment-appraisal model is clearly visible, as is the case for coverage decisions. However, other less formalized or explicit decision-making processes are used in health-care policy. Although *prima facie* the appraisal-assessment model seems not to apply in these cases, the conceptual distinction holds and is useful for the understanding of HTA's role in decision-making.

### **Types of decisions concerning technologies**

The organization and delivery of health care is a complex matter which requires different types of decisions to be taken at the different levels of the health-care system outlined above. Policy-level decisions concern the general framework of the health-care system; services offered to the public; how to provide them; and requirements for quality and delivery, etc. The different types of decisions outlined here are summarized in Table 4.1. Health technologies in the sense of health-care interventions require decisions about whether they are to be made available (market approval, coverage) and how they will be made available and supplied (organization and management).

Market approval or licensing is required for medical goods (e.g. drugs, devices) but not for other kinds of health technologies such as medical or surgical procedures or complex multidisciplinary interventions. Market approval is typically centralized at the macro level, which can be represented by supranational authorities such as the European Medicines Agency (EMA) or others at national level. The market approval decision-making process is highly formalized. Few actors are involved (mainly the manufacturers and the licensing institution), the flow of information between them is clearly stipulated and the licensing criteria are explicit concerning quality, efficacy and safety. There are specific institutions, licensing processes and criteria for the market approval of pharmaceuticals (EMA and national drug licensing agencies) and devices, but these differ considerably between different categories of medical goods.

Agencies that license pharmaceuticals draw on a thorough analysis of scientific evidence. This ranges from pharmacokinetic studies to animal model experiments and human clinical trials to assess the efficacy, quality and safety of the technologies in question. Pharmaceutical regulation has thus been considered to be a good model for the application of technology assessment to inform policy-making (Banta, 2003b). However, the scope of market entry regulatory bodies differs from that of HTA. Market approval decisions are based on a comprehensive assessment of the context-free evidence from research whereas HTA aims to summarize both the context-free and the context-sensitive evidence. In addition to the assessment of efficacy and safety, HTA assesses whether the implementation of the considered technology can produce any clinical or economic benefits in the specific system by comparison with current management of the target condition (see Chapter 3). Regulatory assessments are mainly carried out on information submitted by manufacturers. These are legally obliged to submit all available evidence. Although evidence is reviewed following a systematic and comprehensive approach, it does not necessarily include comparisons with existing alternatives in order to determine added value, for example in patient- or society-relevant outcomes (Zentner et al. 2005).

The requirements for licensing medical devices are rather distant from the philosophy of HTA. CE marking shows that a device conforms to the relevant regulatory requirements. It requires the manufacturer to prove that the device is safe and achieves its intended purpose, based on clinical data (cf. to Council Directive 93/42/EEC). Further assessments of other potential consequences or implications of the use of the technology are not required.

Decisions concerning funding (also called reimbursement) and investment/planning are taken at the macro- and meso levels (OECD, 2005). Together both types of decisions comprise what we call coverage decisions in this chapter.

Coverage decisions complement market approval in at least two ways. First, they have a wider scope and refer to the whole range of interventions provided by the health-care system (including not only drugs and medical devices but also medical or surgical procedures or complex multidisciplinary interventions). Second, they refer to the actual availability of market-approved technologies and to their level of reimbursement in the publicly funded health-care system. Coverage decisions can thus be seen as a tool for rationalizing health care since they break the former automatism of market approval determining public funding (Jonsson & Banta, 1999). In the following section we provide more detail on coverage decisions since the establishment of explicit decision processes has increased HTA's visibility in the recent past.

Decision-making at the macro- and meso levels is also concerned with the management and organization of the health system and involves at least two aspects. First, organization of the availability and delivery of specific technologies for which coverage has been granted. There is a need to take decisions on the placement of the technology in the health-care system, i.e. the setting in which the intervention is to be delivered (primary care/specialized care/outpatient/inpatient); and the resources necessary to ensure access to, and achieve optimal results from, the technology. For example, a decision to implement mass screening for breast cancer requires the screening programme to be designed and organized in detail. For example: will there be an invitation system? If so, which? Where will the screening be performed? By what professionals (i.e. quality requirements)? These kinds of management and organizational decisions are closely related to coverage decisions, the former relate to *how* the technology will be provided; the latter refer to *whether* it will be provided. HTA focuses not only on the effects of the technology but also on such organizational issues and thus is already designed to supply valuable information to support such decisions.

Second, there is a need to decide which interventions could, or should, be applied to the health system in order to organize general service delivery (e.g. hospital bed supply), access to health-care services, financing of the system, payment of providers and health-care reform (in the broad sense proposed above this can also be understood as health technology) (Velasco-Garrido & Busse, 2005).

In European countries, the management and organization of decisions (i.e. decision-making on interventions applied to the health system to improve performance, access, responsiveness, etc.) are essentially taken by governments and the health authorities responsible for the general direction of health-care system policy and the development of health plans. At the macro level of national and regional executives the policy process is closely related to the

process of legislation, sharing its characteristics and following the legislative paths specific to each country (e.g. Bills proposed by the responsible ministry; amendments and approvals in Cabinet and approval in parliament, etc.). In general, decision-making of this type should be guided by objectives such as ensuring the equity and/or solidarity of the system, promoting quality and ensuring access to health care – the principles shared by European health-care systems (cf. European Union, 2006).

In many of the countries where HTA agencies have been established, the government can commission assessments in order to support these policy processes. The relevant executive decides whether or not this possibility is used. The publication lists of European HTA programmes shows that assessments on topics relevant to the organization of health care are commissioned from time to time – for example, on the relationship between procedure volume and quality of care (Norderhaug et al. 2007) or the organization of primary health care (Health Council of the Netherlands, 2004).

Investment decisions take place at multiple levels. Within the same system, the levels and the number of actors involved in such decisions vary according to the complexity of the technology (OECD, 2005). The acquisition of technologies can be considered to be an essential element of the implementation of health plans, thus decision-making on investment at the macro level overlaps extensively with managing and organizing the system and shares similar mechanisms to those outlined above. Some countries have established HTA units specifically to support investment decision-making in the hospital sector or even in single hospitals (see Chapter 5) but HTA's role in these kinds of decisions has not yet been systematically enforced by law.

Finally, policy-makers take decisions on the interventions for promoting and protecting health outside the health-care system. These could be labelled as public-health decisions in order to differentiate them from market approval, coverage and management and organizational decisions which refer to health care. Decisions relevant to public health are taken in the policy fields which together comprise the broader health system, e.g. environmental policy, road safety, etc. HTA of public health and health promotion interventions that take place outside the health-care system (such as road traffic policies) has generally played a very limited role (Banta et al. 2002).

## **Coverage decisions**

In European countries, coverage decisions generally appear to be developing into a highly formalized process with the use of HTA enforced by law in some cases. In this section we describe coverage decisions in more detail. We first



**Table 4.1** *Decisions related to health technologies*

<b>Technology area</b>	<b>Decision types</b>
<i>Health-care interventions</i> – interventions provided within the health-care system	Market approval Coverage Managing/organizing
<i>Health-care reform</i> – interventions applied to the health-care system	Managing/organizing
<i>Health interventions</i> – interventions outside the health-care system but in the broader health system	Public health decisions

provide a definition of coverage and then present a general model for formalized decision-making processes as well as the decision-making criteria used in such coverage decisions.

#### Definition of coverage

In general, coverage decisions refer to the inclusion or exclusion of a service or product in the portfolio of health care provided or reimbursed within the context of a health system, whether a tax-funded (national or regional) health service, public (statutory or mandatory) health insurance or private insurance scheme. Coverage means that the costs of the health-care intervention are fully or partly financed by the health-care system (Cranovsky et al. 1997). In publicly funded health-care systems, coverage decisions are those that relate to the definition of a benefit basket which sets the boundary between the activities, services and goods financed – at least to some extent – with public money and those to be financed fully by individuals through private expenditures (as out-of-pocket payments or through voluntary private health insurances).

The notion of the benefit basket originated in health systems organized on the model of social health insurance (SHI) – Bismarckian systems (Gibis et al. 2004). However, it is also applicable to NHS systems since neither system covers all possible health-care technologies or provides all possible services within publicly funded health care. For example, many complementary, alternative or unconventional therapies are excluded from the benefit catalogues of both NHS and SHI systems (Polikowski & Santos-Eggimann, 2002; Velasco-Garrido et al. 2006). Thus, both types of system require decisions about which technologies are to be provided and which excluded. In this context funding (or reimbursement) refers more to the explicit definition of individual entitlements typically found in SHI systems.

Investing (or planning) is another way to define the benefit basket. Purchasing and providing a technology (e.g. as a result of a health plan) means that de facto it is covered by the health-care system (conversely, a technology not provided/made available is de facto not covered by the health-care system). A benefit basket defined by a positive list of included (and a negative list of excluded) goods and services is more explicit and obvious to the public than one shaped through investment and planning decisions. Fig 4.1 shows the different types of decisions according to the intensity of their relationship to the process of shaping benefit baskets; from left to right the degree of explicitness of this relationship decreases.

**Fig. 4.1** Relationship between types of decisions and the definition of benefit basket



Most European countries provide only partial coverage for some elements of the benefit basket (Thomson et al. 2003). Therefore, the definition of a benefit basket requires decisions not only between two alternatives (i.e. covered or not covered) but also on the level of coverage (i.e. the level of co-payment), often defined according to a variety of factors. Such cases require decision-makers to define the conditions under which a technology is fully covered (i.e. for which population groups or clinical situations) or which of the existing co-payment arrangements would apply. The majority of European Union countries control the price of pharmaceuticals directly or indirectly (Gemmil & Kanavos, 2005). In such health systems decisions related to pricing are usually closely related to coverage decisions. For example, in France the level of co-payment and the price negotiations depend on the added value in terms of effectiveness (Sandier et al. 2004).

Another possible decision establishes provisional coverage over a limited period during which further evidence is generated. The decision is revisited and revised in accordance with the results obtained during the evaluation period. This policy option has been defined as coverage with evidence development (CED) and can be used for promising technologies of considerable uncertainty

(e.g. on cost effectiveness) (Hutton et al. 2007). There is evidence that this policy option is being used increasingly to balance uncertainty due to lack of data against demands for early access to technologies, especially for health problems with unmet need (OECD, 2005). However, such CED decisions need further research, especially on their consequences for the health-care system. For example, there is a need to assess whether it would be difficult to implement negative decisions (e.g. denying coverage) if the evidence period concludes with negative results given the customary practice established during the period of conditional coverage. There is also a need to assess the potential for (un)intentionally fostering demand of the technology in question during the CED period.

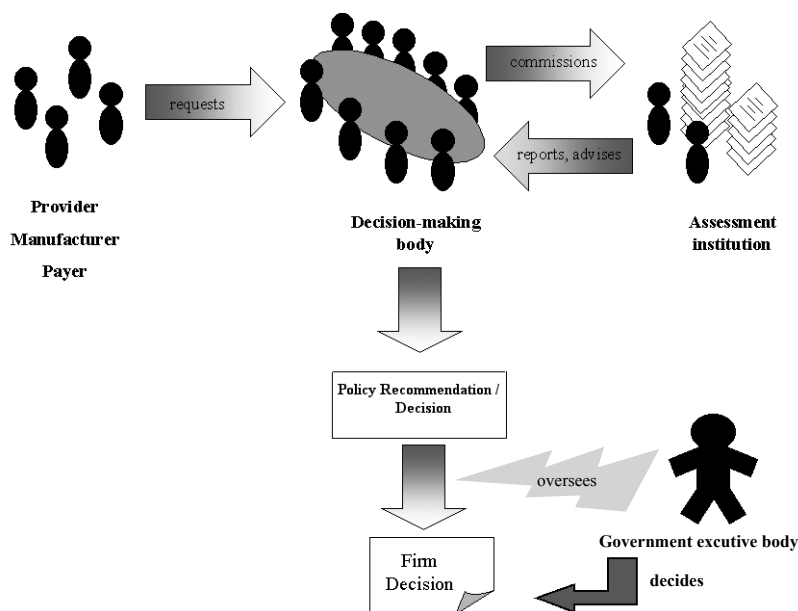
### Decision-making process

In the European Union, health-care policy (and its related coverage decisions) remains under the sovereignty of individual Member States at national or regional level. Obviously, there is no central institution such as EMEA to decide on coverage at the European level. The level of formalization of the coverage policy process varies both between and within countries depending on the type of technology. Typically, but not exclusively, SHI health systems have explicit decision-making processes to determine the benefits basket.

Despite their differences, there seems to be a general model for explicit coverage decision-making. Several European countries have established paths that define (to different extents) the steps to be taken between the initiation of the process and the final decision, as well as the responsibilities of the several actors involved. Within this general decision-making framework (see Fig. 4.2), the process is initiated with a request or an inquiry on coverage. The actors entitled to initiate the process may include payers, providers, manufacturers and patients, depending on the specific country.

In this model, the coverage decision is taken or prepared by a committee established for the purpose. Such committees bear the appraisal function that includes consideration of the assessments produced by their corresponding HTA units. However, the institutional boundary between both tasks is not always as straightforward as it is in England and Wales. For example, French appraisal committees are integrated under the same institutional roof as the units responsible for the assessments – i.e. the Haute Autorité de Santé (HAS). Table 4.2 provides some examples of the division of work between some assessment agencies and appraisal committees in European countries.

Across Europe, the bodies responsible for decisions about coverage range from governmental organizations through institutions at arms-length of the state to

**Fig. 4.2** *General model of coverage decisions*

self-governing bodies. Different institutional forms may coexist in the same system, reflecting the different health-care and political systems as well as their historical development. Decision-making in one country might be specific to a certain type of technology or to the setting in which a technology is to be implemented. Some countries have a plurality of decision-making bodies, each exclusively responsible for decisions in one health-care sector or concerning one type of technology. For example, in countries (including both SHI- and NHS systems) such as Belgium, Finland, Hungary, Italy, Norway, Portugal or Sweden pharmaceutical coverage decision-making is the responsibility of specific bodies that deal only with coverage and pricing decisions for drugs (Hutton et al. 2006). In England and Wales, decision-making is spread among several committees (Stevens & Milne, 2004) as shown in Table 4.2. In contrast, Germany has concentrated decision-making within a single Federal Joint Committee which makes decisions on all types of health technologies in the ambulatory and hospital sectors, including the levels of pharmaceutical reimbursement (see Box 4.4). France has separate committees for drugs, medical procedures and devices but these are all under the institutional roof of the HAS (see Box 4.5).

**Table 4.2** *Appraisal committees and corresponding assessment units (selected examples)*

Country	Technology	Assessment	Appraisal
Austria	Pharmaceuticals	Pharmaceutical Evaluation Commission (HEK)	Federation of Austrian Social Insurance Institutions
France**	Medical and surgical procedures Pharmaceuticals Devices	Department of Assessment of Health Products and Procedures	Committee for the Evaluation of Medical and Surgical Procedures Transparency Committee Committee for the Evaluation of Devices and Health Technologies
Germany	Pharmaceuticals, devices, procedures	Institute for Quality and Efficiency in Health Care (IQWiG)	Federal Joint Committee (G-BA)
England/ Wales	Screening programmes  Vaccinations  Services  Pharmaceuticals, devices, procedures, public health programmes	National Coordinating Centre for Health Technology Assessment (NCCHTA)*	National Screening Committee (NSC) Joint Committee on Vaccination and Immunisation (JCVI) National Specialist Commissioning Advisory Group (NSCAG) National Institute for Health and Clinical Excellence (NICE)

\*Manages R&D programme on behalf of the Department of Health, commissioning assessments from academic departments (see Chapter 5).

\*\* Both assessment and appraisal under the auspices of the HAS.

The composition of the committees also varies across countries and may include representatives of patients, providers, payers, government or manufacturers, as well as clinical and methodological experts. For example, the NICE appraisal committee consists of representatives of the NHS, patients’ and carers’ organizations, academia and manufacturers of pharmaceuticals and medical devices (NICE, 2008). The German appraisal committee comprises representatives of providers and payers as well as patients (see Box 4.4). In France, different committees have different compositions (see Box 4.5). Generally, members of such committees have either a consultative role (typically manufacturers’ or patients’ representatives) or a full deliberative function (i.e. voting right).

**Box 4.4** *Assessment and appraisal in Germany*

The Federal Joint Committee (*Gemeinsame Bundesausschuss – G-BA*) was established in 2004 and is responsible for appraisal and decision-making concerning the technologies to be provided in the German SHI system, in both ambulatory care and the inpatient sector. In addition to coverage decisions, the G-BA is responsible for issuing directives on organizational aspects of health-care service provision and on quality assurance in health care. It gathers SHI representatives, providers, independent members and representatives of patients' associations in a consultative role. Depending on the specific decision, providers' representatives will be appointed to specific working groups, for example by the hospital association, the SHI-physicians' association or the SHI-dentists' associations. Patients' representatives also vary according to the specific issue under discussion. Working groups (e.g. disease management programmes, palliative care, drugs, prevention, rehabilitation) comprise the different actors in the same proportions represented in the plenary and issue decision recommendations to the G-BA.

The German Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen – IQWiG*) produces evidence assessments which – among others – are commissioned by the G-BA and discussed in its subcommittees. To date, IQWiG has produced reports on pharmaceuticals, procedures, organizational issues (service volume thresholds) and CPGs (as the basis for the development of disease management programmes), according to the decision-making priorities of the G-BA.

**Box 4.5** *Coverage and pricing in France*

In France three different institutions may be involved in the decisions relevant to shaping the benefit basket (i.e. coverage decisions). Decisions on coverage and pricing are largely related but are allocated to different committees.

A specific committee within the HAS advises the Ministry of Health on whether a device or a drug is to be funded by the public health-care system. A specific committee for drugs (*Commission de la Transparence*) consists of representatives of sickness funds, government and providers, as well as clinical and pharmacological experts. The committee for devices (*Commission d'Évaluation des Produits et Prestations*) consists of scientific experts and representatives of sickness funds, industry, government, users and patients (HAS, 2008). When a specific technology is approved for inclusion in the benefit basket, another committee (the governmental *Comité Économique des Produits de Santé – CEPS*) establishes the price of drugs and devices in negotiation with the manufacturers. Finally, the organization of health insurance providers ascertains the level of reimbursement (*Union Nationale des Caisses d'Assurance Maladie – UNCAM*).

**Table 4.3** *Assessment, appraisal and decision-making institutions in Switzerland*

Area	Assessment	Appraisal	Decision-making
Pharmaceuticals	Pharmaceutical Unit	Federal Commission of Pharmaceuticals (EAK)	Swiss Federal Office of Public Health (SFOPH)
Screening, prevention, medical procedures	Medical Technology Unit (MTU)	Federal Commission of Medical Services (ELK)	Swiss Federal Ministry of Home Affairs (EDI)
Laboratory analyses		Federal Commission of Analyses (ALK)	
Medical devices		Federal Commission of Medical Devices (MiGeLK)	

*Source:* personal communication, M. Züllig 2008.

In general, these committees generate two types of output. The first are policy recommendations that result from the appraisal process, these are more or less directive for the body with ultimate responsibility for the decision – e.g. the government. In France, the health ministry makes the final decision although the recommendation of the committees can be considered to be a preliminary decision. Similarly, in Switzerland the decision rests with the federal government and the process can be considered to be three steps from assessment to appraisal and decision (Züllig, 2008) (Table 4.3). Other countries generate the second type of output. Although the appraisal committee takes the actual decision per se, in some countries the decision might be subject to oversight and formal final approval by (e.g.) the health ministry. Appraisal committees with decision-making authority include NICE (Stevens & Milne, 2004), the German G-BA and the Pharmaceuticals Pricing Board in Finland (Zentner et al., 2005).

Decision-making criteria

In addition to the institutions outlined above, a plurality of criteria governs decisions according to the health-care sector involved or the specific technology of interest. Table 4.4 illustrates the criteria that guide coverage decisions in selected European countries (including NHS- and SHI-systems; systems with highly formalized coverage policy processes and those with little formalization). These criteria have been laid down in the legal frameworks that govern the general organization of health care, service provision and, in particular, coverage of technologies.

The legal frameworks for health-care systems frequently mention need, effectiveness, costs and cost effectiveness as the essential criteria to be observed in decisions about which technologies should be included in the benefit basket (Velasco Garrido et al. 2006). Criteria stated in laws are relatively vague, generally only mentioned in single words or short sentences and lacking clear definitions or specifications on how to implement them. The wordings of the criteria reflect the cultural traditions of the system and are sometimes difficult to translate, although they may indicate very similar things. For example, many categories do not explicitly mention safety although it is always a prominent criterion in all decision-making. Different countries might assume that this is covered under the criteria of utility, effectiveness, appropriateness or benefit. Detailed definition of criteria to guide decisions can be considered the first step towards explicit and transparent decision-making. However, information on how the criteria are operationalized, and whether and how they are weighted against each other, is still difficult to determine (Velasco-Garrido et al. 2006).

The pharmaceutical sector has the greatest number of explicit decision criteria. Several European countries (Austria, Belgium, Denmark, Finland, the Netherlands, Norway, Sweden, United Kingdom) have defined cost effectiveness as one of the relevant criteria for decision-making related to drugs (Zentner et al. 2005). Nevertheless, decision-making on coverage of the use of devices or on medical and surgical procedures is also guided by explicit criteria in many countries.

## **Conclusions**

We have drawn on a broad understanding of the term health technology in order to provide an overview of technology related decision-making in the health-care system. This shows the different types of decisions within which HTA has the potential to provide valuable input into policy-making (because of its multifaceted and multidisciplinary approach), at least from a theoretical point of view. A broad spectrum of decisions ranges from those dictating which technologies should be included in the health-care system, and how they should be used, to those related to the organization and management of the health-care system.

HTA has a higher profile in coverage decisions and several factors contribute to this greater visibility. As we have described here, the policy processes related to coverage are highly explicit and formalized in many countries. Such formal policy processes establish clear decision-making paths in which HTA is clearly integrated and enforced by law as an input to decision-making. In addition, decision-making on coverage presents the characteristics of a deliberative process



**Table 4.4** Criteria guiding coverage (funding + reimbursement + investing + planning) decisions in selected European countries

Service categories	D	DK	E	F	H	I	NL	PL	EW
Curative care									
Inpatient services	A; CE; Ex; N	B; N	C; E; N; S	N; E; S	C; E	A; N; B	C; E; N	ns	B; C; N
Outpatient	CE; Ex; N	B; N	C; E; N; S	N; E; S	C; E	A; E; N; B	C; E	ns	C; E; N
Rehabilitative care	CE; Ex; N	B; N	N	N	ns	A	A	ns	E; N
Long-term nursing care	C	N	N	N	ns	A; E; N; B	ns	ns	E; N
Ancillary services*	A; Ex	N	C; E; N	N	ns	C; E	ns	ns	E; N
Medical goods for outpatients									
Pharmaceuticals and non-durables	E; N	B; CE; N	B; N; U	C; E; I; S	N; S	C; E	B; CE; I	C	B; CE; E; N; S
Appliances and durables	E; U	U	CE; E; S;	E; U	ns	N; C	C	N; C	E; N; S

D: Germany, DK: Denmark, E: Spain, F: France, H: Hungary, I: Italy, NL: the Netherlands, PL: Poland, EW: England and Wales  
 \* Performed by medical, technical and paramedical personnel with or without medical supervision (e.g. laboratory tests, patient transportation).  
 Criteria: A: appropriateness; B: budget; C: costs; CE: cost effectiveness; E: effectiveness; Ex: expenditure; I: innovation-degree; N: need; S: safety; U: utility; ns: not stated.

in many cases. Deliberative processes stress the integration of scientific research on context-free and context-dependent issues with the views of stakeholders and the public elicited through consultation and participation (Culyer & Lomas, 2006). Thus, these deliberative processes may add to the visibility of HTA by engaging the public in the process. Finally, decision-making processes for coverage show an increasing degree of transparency (one of the conditions for a reasonable and fair decision-making process, Daniels & Sabin, 1997) through explicit sets of decision-making criteria, public reports that summarize the evidence and the publication, at least to some extent, of the rationale for specific decisions.

The acknowledgement that formal deliberative processes may increase not only the visibility of HTA but also its impact (see Chapter 6) does not imply that the role of HTA is of less value in decision-making processes that are less explicit than those on coverage. The value of HTA as an input for policy-making does not depend on its integration in formal appraisal and decision-making processes, rather it is rooted in its methodological approach.

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## Chapter 5

# Health technology assessment in Europe – overview of the producers

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### Introduction

Health technology assessment (HTA) has been defined as the structured analysis of a health technology, set of related technologies or a technology-related issue that is performed for the purpose of providing input to a policy decision (EUR-ASSESS 1997), where technology is a broad concept including drugs, devices, procedures and organizational approaches. In addition, HTA is characterized by a scientific approach to previously formulated questions, namely the analysis of data from research (i.e. the analysis of context-independent and context-dependent scientific evidence).<sup>6</sup> HTA also aims to strive for a high degree of transparency – its methods are explicit, well-documented and include explanations and justifications of the underlying assumptions behind methodological choices as well as disclosure of the reasons for considering (or not considering) some types of research or single pieces of evidence.

This definition implies that different kinds of research can be considered to be HTA as long as they are conducted with the explicit aim of supporting the policy-making process in the health-care arena and according to the principle of methodological soundness. In this context Banta speaks of HTA as: “a broad concept with many facets and vague borders” since the scope and contents of HTA reports differ from country to country (Banta, 2003). They can

<sup>6</sup> Concepts of context-independent and context-dependent scientific evidence proposed by Lomas et al. (2005) are introduced in Chapter 3.

have a wide focus (including clinical effectiveness, organizational issues and ethical concerns) or be limited to a single aspect of the technology (e.g. cost effectiveness). The methodological approaches include the systematic review of published research; collection and analysis of primary data – i.e. conducting primary research; and the synthesis and adaptation of secondary research to a particular context.<sup>7</sup> These variations reflect differences in the information needs of decision-makers, determined by the type of decision required and the context of the decision-making. For some decisions the information needs are determined by the requirements laid down in the regulatory frameworks governing the decision-making process (see Chapter 4).

In line with this broad concept, a diversity of organizations perform HTA in Europe in order to support decision-making in health care with evidence from research. These organizations have a common goal but other features differ, e.g. their activity portfolio, formal linkage to specific decision-making processes or location in the health-care system. Here we describe some of these differences encountered in Europe as well as some of the institutional developments of recent years. Acknowledging the limitations of any generalization or simplification,<sup>8</sup> this chapter sets out to describe through examples the various features of HTA agencies in Europe.

## **Emergence of HTA in Europe**

In the mid 1960s the concept of technology assessment developed in response to growing recognition that technology's prominent role in society includes unintended and potentially harmful consequences (Goodman, 2004). The term health technology assessment was most likely first used around 1967 by the United States Congress (Banta, 2003). The approach was institutionalized in the United States of America with the establishment of the congressional Office of Technology Assessment (OTA) in 1972-1973. The OTA's health programme started in 1975, fuelled by the emergence of technologies that evoked social, ethical, legal or political concerns such as contraception, organ transplantation and life-sustaining technologies (Goodman, 2004).

At roughly the same time – but initially independently of developments in the United States – some groups of European researchers started to focus on the policy implications of the implementation of medical technologies and their economic and social consequences (Jonsson, 2002). Thereafter, the driving factors for the development of HTA were: i) the recognition that the effects

<sup>7</sup> Some HTA reports mainly synthesize other HTA reports or systematic reviews of the evidence.

<sup>8</sup> It is beyond the scope of this chapter to provide a comprehensive description of the institutionalization of HTA in every European country. Comprehensive descriptions of the organization of HTA in particular countries have been published for example in the *International Journal for Technology Assessment in Health Care*: 16(2) (Spring 2000) and 20(1) (Winter 2004). Information on most of the European HTA agencies is also available on the INAHTA web site.

of new medical interventions needed to be assessed; ii) concerns about the effectiveness of many existing and established medical practices, and iii) concerns about the high costs of medical technology (Oliver et al. 2004; Banta, 2003).

In 1982 a hospital-based group, the *Comité d'Évaluation et de Diffusion des Innovations Technologiques* (CEDIT), was established in France to support Parisian hospitals on questions of technological innovation. University-based groups, such as the Swedish Center for Medical Technology Assessment (*Centrum för utvärdering av medicinsk teknologi* – CMT) started to produce ad hoc evaluations of drugs and devices in the early 1980s. However, neither of these organizations were formal national HTA programmes.

The first national agency for HTA in Europe, the Swedish Council on Technology Assessment in Health Care (*Statens beredning för medicinsk utvärdering* – SBU), was established with the purpose of informing the Swedish central government and county councils on the value of health technologies (Jonsson & Banta, 1994) (see Box 5.1).

The institutionalization of HTA in Sweden was soon followed by the establishment of other agencies and HTA funding programmes in France and Holland. Since then, the number of organizations or programmes mandated to support decision-making in health care has grown continuously, especially in western Europe. In the 1990s new agencies were established in Austria, Denmark, Finland, Norway, Spain and the United Kingdom (see Table 5.1).

The establishment of the HTA Programme in the United Kingdom was important for the development of HTA in Europe. After recognizing a need for the NHS to identify its research needs and ensure that knowledge from research is transferred to services, the NHS National Research and Development Programme – in which HTA has been most prominent – was established with solid funding in the mid 1990s (Stevens et al. 2003). Another important development was the establishment of the National Institute for Health and Clinical Excellence (NICE) in 1999. This has the mandate to provide guidance for best clinical practice supported by HTA. These developments were observed with great interest in the rest of Europe (Jonsson, 2002). Other countries (e.g. Belgium, Germany, Poland) also started HTA programmes during this time, partly in cooperation with university departments, leading to the creation of national agencies in the 2000s.

By early 2008, the association of publicly funded HTA agencies (International Network of Agencies for Health Technology Assessment – INAHTA) counted 46 members worldwide including 31 in European countries (INAHTA,



**Box 5.1** *Establishment of the SBU*

Several discussions, workshops and conferences took place during the years before SBU was established in Sweden in 1987. In 1979 the first European conference on HTA was organized in Stockholm with participants from all over Europe and from WHO and the OTA. This conference led to the establishment of different committees, in-depth discussions and study tours to the United States with the aim of finding out how a Swedish agency could be established, mandated, structured and organized to carry out comprehensive assessments of health technologies in their broad sense. In 1984 and 1985 two more high-level conferences gathered representatives (including the ministers) of the Ministry of Health and Social Affairs and of Finance, regional health authorities, medical profession, Medical Research Council, some major universities and governmental agencies in the field of health care. The incentives for establishing a national HTA agency were the:

- increasing costs of health care (10% of gross domestic product at that time);
- need to assess established practices and old routines in order to create space for (and speed up) the introduction of new, effective and cost-effective health technologies;
- politically sensitive, yet necessary, prioritization of costly but effective and cost-effective health technologies.

After these two high-level conferences the Minister of Health formally appointed a committee to lay out the details for the establishment of an agency. SBU began operations in 1987, funded entirely by the government.

SBU's mandate was to provide evidence-based information on matters of health technology to guide health policy and practice. It was made explicit that the agency should synthesize research findings and present this information in a manner understandable to both experts and the lay public. Also, the agency should focus not only on clinical aspects, but also on the economic, ethical and social implications of different technologies, procedures and programmes for preventing, diagnosing and treating disease. Its functions include effective dissemination of the findings from technology assessment. The agency should not have any regulatory function.

The Swedish Government appoints an executive director and a 10-member Board representing the scientific community in health care. The Board appoints a 15-member Scientific Advisory Committee representing different areas of knowledge: basic biomedical research, clinical medicine, nursing, epidemiology, economics, management, administration and the general public. It also prioritizes the areas of health care to be assessed – usually not specific technologies but rather major public health problems such as back pain, depression, alcohol- and drug-abuse, obesity, hypertension, asthma, dementia and chronic pain. All available technologies for prevention, diagnosis and treatment are identified and assessed for each area.

2008).<sup>9</sup> Organizational units which are not (yet) members of INAHTA, but that work on the principles of HTA and have similar mandates to current members (see Table 5.1) also contribute to European HTA activities. These include recently founded national agencies such as the Health Information and Quality Authority (HIQA) in Ireland or the Centre for Pharmacotherapy Development (*Lääkehoidon kehittämiskeskus – ROHTO*) in Finland, as well as units working in the production of evidence-based information with the purpose of informing decision-making processes at local and hospital levels, as in Denmark (besides the national agency) or Italy (where an HTA agency was established only in late 2007, see Box 5.2).

Since 2006, the European Network for Health Technology Assessment (EUnetHTA) has brought together well-established, long-standing regional and national HTA agencies and ministerial units and research groups involved in HTA-like activities from countries where no formal HTA agencies have yet been established. It has a total of 54 institutional partners from 29 European countries (all members of the European Union are represented with the exception of Slovakia and Bulgaria, as well as Iceland, Norway, Serbia and Switzerland). The groundworks for EUnetHTA were laid in two collaborative projects: EUR-ASSESS (1994-1997) and the European Collaboration for Health Technology Assessment – Assessment of Health Interventions (2000-2002), which brought together established HTA agencies and other institutions across Europe (cf. Banta et al. 1997; Jonsson et al. 2002).

The number of HTA agencies illustrates that HTA is a well-established institution in western European countries. In addition, countries in eastern Europe are showing a growing interest in formalizing HTA activities, as shown by their increasing involvement in international collaborative activities.

## **Features of European HTA agencies**

The organization of HTA activities varies considerably across European countries. This diversity reflects the different health-care and political systems with different mandates, financing mechanisms and roles in policy formulation. In addition to their common understanding of HTA, these institutions share some organizational features but to different degrees. This section provides an overview of HTA organizations based on the following characteristics: i) setting in which the organization operates; ii) funding; iii) types and scope of assessments conducted by the organizations; iv) activities other than the production of HTA reports; and v) their relation to decision-making.

<sup>9</sup> INAHTA was established in 1993. A brief history of this network has been described by Hailey and Menon (1999).

**Box 5.2** *HTA without an HTA agency: the Italian network*

Unlike many other European countries, Italy does not yet have a national HTA agency. However, having recognized the need to spread the culture of assessment, in 2003 the Ministry of Health started financing a project aimed at introducing HTA into the management process of the Italian health system (Ricciardi et al. 2005). For this purpose a network of organizations which have formally established, or are in the process of implementing, an HTA unit (i.e. organizations with at least some level of relevant expertise) has been established. The network comprises ten partner organizations including hospital-based HTA units in academic medical centres, research hospitals and regional and local health authorities (i.e. bodies responsible for the organization, management and delivery of health-care services). The aim of the network is to share methods and tools for the application of HTA logic to support decision-making and clinical practice mainly at the hospital level.

One of the network's primary goals is to identify an organizational and methodological standard from the best experiences of its partners which can be applied to the Italian national health service. For this purpose the competences, processes and organizational features of the partners have been analysed and compared to international benchmarks. In addition, the network is developing an accredited curriculum on HTA which will allow health-care providers to build professional HTA capacity in their own organizations.

During the project, organizations not originally involved in the network have shown great interest in participating in order to establish their own HTA units or committees at the management level of both hospitals and regional health authorities. This is both a confirmation of the need for an HTA structure as well as an indication of the network's preliminary success in disseminating HTA.

The specific characteristic of the Italian approach is its absolute decentralization, based on the subsidiarity principle resulting from the devolution of responsibilities for health-care provision to the regions (Amigoni et al. 2005). The HTA capacity – whether staff are organized within a formal HTA unit or as part of other departments – is integrated in the organizational structure of the institution it supports (i.e. hospital, local health administration). The structural closeness between assessors and managerial decision-makers (extending to clinicians in the case of hospital-based units) is expected to increase HTA's responsiveness to the contextual factors and increase its impact.

In 1997 the National Agency for Regional Health Care Services (*Agenzia Nazionale per i Servizi Sanitari Regionali* – ASSR) was created as a central institution under the Ministry of Health to support the development of regional health services and their coordination. In 2007, the ASSR was given the mandate to promote and support regional HTA activities, including the production of HTA reports for the Italian context and their diffusion to the regions and health authorities.

## Setting

In general we can differentiate between agencies that serve the population of a whole nation or a region (i.e. national or regional) and those that are integrated into single hospitals or hospital trusts (hospital-based HTA). The latter focus on hospital management decisions and clinical governance and are discussed in more detail below.

The target audience of most national and regional agencies comprises different levels of decision-making. On the one hand the agencies aim to support decision-making at the macro level, i.e. concerning the availability and coverage of health technologies as well as the organization of health service provision in the health-care system. These are decisions that affect large groups of people such as individuals covered by national health service systems (either central or regional) or the beneficiaries of sickness funds in monopsonistic or oligopsonistic social health insurance systems. At the same time, part of their work will primarily target the micro level of clinical decision-making, i.e. decisions made by providers in their clinical practices concerning the use of health technology. For example, a national agency such as SBU defines its target groups as the whole spectrum of professional caregivers, health-care administrators, planners and policy-makers as well as patients and their families (SBU, 2008). Regional agencies, as found in Spain, define the potential users of their output in similar ways although limited to their specific region. Despite the existence of national HTAs, local health authorities or organizations may also undertake their own assessments, as is the case in England where primary care trusts also have a responsibility to conduct local assessments (Elston & Stein, 2007).

The primary target audience for HTAs varies according to the particular topic, independent of the setting in which a particular agency or unit is located. For example, an assessment of an organizational technology (e.g. telemedicine or payment for performance) would target mainly the policy-makers at the corresponding health authority rather than health-care providers or patients. A broad target audience has implications for the functions of an agency. Different target audiences, for example decision-makers at the hospital and primary-care level (Andradas et al. 2008), may expect different outcomes from an HTA agency's work and require different strategies to disseminate the results. By elucidating the demands and expectations of potential target groups (as illustrated in Box 5.3), an agency can tailor its work to the context in which it delivers its products and achieve a higher impact in the health system by increasing awareness (Andradas et al. 2008). Awareness is considered to be the first step on the ladder to influence decision-making through HTA (see also Chapter 6).

**Box 5.3** *Elucidating target audience's perspective to determine fields of work for an HTA agency*

The Unit for Health Technology Assessment of the Autonomous Community of Madrid was established in 2003. It is linked to the public Regional Health Service and the Regional Ministry of Health. Work was initiated by designing and conducting a Delphi study (April-June 2003) among decision-makers in the region in order to elucidate the demands and expectations of potential target groups. The principal aim of the study was to explore the demands, concerns and needs of decision-makers in the Madrid regional health-care system (including the policy-making level) as well as the clinical and management context in both the hospital and the primary-care setting. In addition, the survey aimed to increase awareness of the unit and offer its products and services to potential users.

The Delphi technique proceeded in two consecutive rounds. In the first round, a questionnaire was designed and developed on the basis of a review of the portfolio of services and products delivered by 26 Spanish and international agencies. The validated questionnaire was distributed to participants selected among relevant potential users of the products and services of the unit – namely managers and medical directors of both hospitals and primary-care units, as well as general directors of regional health departments. The initial panel involved 87 experts from 21 public hospitals (n=43), 11 primary-care centres (n=22), 8 regional health departments (n=8) and 6 private hospitals (n=14). The first round questionnaire included three open-ended questions regarding qualitative information about what kind of services an HTA unit should provide. Semistructured questions on 22 potential services and products provided by an HTA unit were evaluated using a five-point Likert scale ranking from “no interest” to “essential”. The questionnaire also enabled panellists' organizations to prioritize the five most important products. The second round drew on these responses and sought to reach consensus on the most important services and products to be offered by the unit.

Decision-makers participated extensively in the study (overall response rate: 83.9%) and were most interested in the monitoring of emerging technologies; appropriateness studies; and rapid reviews of the evidence. Overall, 9 out of 22 potential products were rated to be of high interest for more than 80% of all decision-makers, independent of the setting. The ranking (questions weighted according to the product assessment of each participant) identified economic evaluations of health technologies; the assessment of appropriate use of health technologies; and the elaboration of full HTA reports as the areas of highest priority. It is remarkable that the preferences included services traditionally seldom offered by HTA agencies such as appropriateness assessments; monitoring of emerging health technologies (service with the greatest overall interest) and the appraisal and development of clinical guidelines (although <80% of participants expressed interest in these).

**Box 5.3** *contd*

<i>Preferences and priorities for decision-makers in Autonomous Community of Madrid</i>					
<b>Product/service</b>	<b>Overall</b>	<b>Sector</b>			
		<b>Public</b>		<b>Private</b>	
		<b>Hospital</b>	<b>Primary health-care unit</b>	<b>Health department</b>	<b>Hospital</b>
Monitoring of emerging health technologies	97.1% [6]	91.9% [5]	95.5% [8]	87.5% [5]	100% [9]
Appropriateness assessment	95.9% [2]	100% [1]	95.5% [7]	- [-]	100% [1]
Rapid reviews	95.9% [4]	100% [3]	100% [2]	100% [8]	- [-]
Systematic reviews	93.1% [8]	89.2% [9]	95.5% [3]	100% [4]	83.3% [5]
Medical/surgical procedure assessment (clinical effectiveness)	91.8% [9]	97.3% [8]	95.5% [9]	- [-]	- [7]
Economic evaluations	90.1% [1]	91.9% [2]	90.9% [6]	87.5% [2]	- [2]
Drug assessment (clinical effectiveness)	86.3% [5]	100% [7]	100% [1]	- [6]	- [-]
Information system assessment	86.3%	-	81.8%	100%	100%
Full HTA reports	86.3% [3]	83.8% [6]	90.9% [4]	100% [1]	- [8]
Feasibility studies on technology introduction	81.7% [7]	81.1% [4]	86.4% [10]	- [9]	- [-]
HTA periodical publications	79.5%	-	90.9%	100%	100%
Clinical practice guideline quality assessment	78.1%	81.1%	-	-	83.4%
HTA methodological guidelines	78.1%	-	90.9%	-	100%
Organizational models' assessment	77.5%	-	-	-	100%
Collaboration on clinical practice guidelines development	71.2% [10]	- [10]	90.9% [5]	- [-]	83.4% [3]

The % refers to the percentage of decision-makers expressing high interest. The number in brackets shows the ranking achieved in the priority scoring. Values under 80% not shown.

*Source:* compiled from Andradas et al. 2008

Priority ranking represents an assessment of a product's importance for respondents own organizations, with a more practical approach to the necessities and demands of HTA products and services. In contrast, preference ranking represents the more generic understanding of what an HTA unit should be able to deliver.

**Box 5.3** *contd*

The areas of higher interest and priority varied among the participants depending on the sector in which they were working, as shown in the table above. Assessments of appropriate use were prioritized by public- and private-sector hospital decision-makers. Interestingly, classical full HTA reports (i.e. those aiming to provide a comprehensive assessment of clinical, economical, organizational and ethical aspects) ranked lower in the overall interest scale than reports focusing on either clinical or economical aspects alone. However, they were perceived to be of highest priority by the health departments/directorates staff. Unlike private providers and the managerial sector, public providers showed high interest in assessments of drugs and procedures.

In general, health-care providers in the public sector showed more interest in assessments relevant to clinical decision-making (assessments of drugs and procedures or of appropriate use; feasibility studies for introduction of innovation; appraisal and development of clinical guidelines). Providers in the private sector, as well as decision-makers at the managerial level of the public regional health services, showed a more systemic understanding of HTA (preferred assessments of organizational models, information systems, educational interventions, as well as dissemination and inter-institutional collaboration activities).

Overall this study revealed that there were considerable expectations of the HTA unit by the time of its inception in the Community of Madrid. The approach presented allows for a focus on the unit's work in terms of a specific set of products and services that consider the needs and expectations of potential users.

**Funding**

Two organizational features are common to all the HTA institutions considered in this chapter. First, all have a not-for-profit orientation. Second, their main source of funding is public money (direct, indirect taxation or tax-like contributions). Thus, they may be regarded as part of the public sector.

The main source of funding derives from each country's health-care accounts. This is true whether the health-care system is funded primarily through taxes or whether resources are generated mainly through employers' and individuals' contributions, as for social health insurance systems. In addition to funding from health-care budgets, some organizations draw financial resources from public research funds and even private sources (Mears et al. 2000; Martelli et al. 2007). For example, the *Haute Autorité de Santé* (HAS) in France is financed through governmental subsidies (10%), fees for accreditation activities (15%), contributions from social health insurance (31%), fees from the medical device industry (7%) and contributions from the pharmaceutical industry (34%) (by means of a tax on their promotional activities) (HAS, 2007).

The financial resources available to HTA agencies in Europe range from annual budgets of less than €1 million for most agencies with a regional jurisdiction, to over €10 million for national HTA programmes in the Netherlands, the United Kingdom and the *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (IQWiG) in Germany (see Table 5.1). Even after accounting for the population served by the agencies, the range of funding is still very broad (US\$ 0.02 to US\$ 0.89 per capita).

The variations in available funding can be explained to some extent by differences in the understanding of HTA. In some countries agencies' assessments are mainly secondary research (i.e. systematic reviews), usually produced in cooperation with academic researchers and clinical experts who act as consultants. In others, the HTA programme funds not only secondary research but also an important amount of primary research considered relevant for the health system. For example, the National Coordinating Centre for Health Technology Assessment (NCCHTA) does not conduct assessments but manages the NHS HTA Research and Development Programme. As shown in Box 5.4, this includes research based on primary and secondary data on issues relevant to the NHS. The programme spends an important amount of its resources on funding randomized controlled trials relevant for the evaluation of health technologies (Stevens & Milne, 2004). The Netherlands Organisation for Health Research and Development (*Nederlandse organisatie voor gezondheidsonderzoek en zorginnovatie* – ZonMw) also funds primary research on the cost effectiveness of health technologies.

### Types and scope of assessments

In its initial phase, i.e. before formal institutionalization, HTA's main foci were large, capital-intensive technologies and (to some extent) costly pharmaceuticals (Banta & Jonsson, 2006). In the first years of HTA in Europe, the few existing agencies concentrated mainly on the assessment of procedures and medical devices. For example, the first report issued by SBU in 1989 assessed the preoperative diagnostic routines and their use in Sweden (Arvidsson et al. 1989), focusing on the entire procedure rather than single diagnostic devices. The first report published by the Catalan Agency for Health Technology Assessment and Research (CAHTA) evaluated the procedure for ambulatory surgery (Espinàs et al. 1992).

The scope of HTA has widened rapidly and the number of assessments of other technologies, such as drugs or modes of care, has grown continuously. To date the majority of the European agencies have assessed (to different extents) devices, procedures, drugs and complex interventions. However, the assessment of procedures and devices continues to dominate overall output (Draborg et al.



**Table 5.1** HTA agencies and units in Europe

Agency	Country	Since	Scope	Annual HTA budget (US\$ million) <sup>a</sup>	Population served (million)	Per capita HTA budget	Permanent staff	Consultants
CEDIT	France	1982	Regional	0.34	11.0	0.03	11	variable
CMT	Sweden	1984	Regional	1.5	n.a.	n.a.	17	5-8
SBU	Sweden	1987	National	6.8	9.0	0.75	33	variable 300
LBI@HTA <sup>a</sup>	Austria	1990	National	0.93	8.0	0.12	10	variable
CAHTA <sup>b</sup>	Spain	1991	Regional	2.4	7.0	0.34	45	150
MTU	Switzerland	1992	National	n.a.	7.6	n.a.	6	60
OSTEBA	Spain	1992	Regional	0.3	2.1	0.14	5	40
AETS	Spain	1994	National	0.6	46.1	0.01	11	80
FinOHTA	Finland	1995	National	2.0	5.1	0.39	18	65
VSMTVA	Latvia	1995	National	0.05	2.3	0.02	8	variable
AETSA	Spain	1996	Regional	0.9	7.5	0.12	15	variable
NCCHTA	United Kingdom	1996	National	21.6	59.8	0.36	36	variable
DACEHTA <sup>c</sup>	Denmark	1997	National	3.8	5.4	0.7	15	variable
NHSC	United Kingdom	1998	National	1.2	50.0	0.02	7	variable
AVALIA-t	Spain	1999	Regional	0.35	2.7	0.13	7	variable
MTV-Aarhus	Denmark	1999	Regional	n.a.	n.a.	n.a.	n.a.	n.a.
DAHTA	Germany	2000	National	1.5	80.0	0.19	8	variable
ZonMw	Netherlands	2001	National	13.5	16.0	0.84	7	variable
MTV-Odense	Denmark	2001	Hospital	n.a.	n.a.	n.a.	n.a.	n.a.
A. Gemelli	Italy	2001	Hospital	n.a.	n.a.	n.a.	n.a.	n.a.
KCE	Belgium	2002	National	3.1	10.3	0.3	35	variable
NHS QIS <sup>d</sup>	United Kingdom	2003	Regional	0.8	5.1	0.16	15	variable
NOKC <sup>e</sup>	Norway	2003	National	4.0	4.5	0.89	30	100
ROHTO	Finland	2003	National	n.a.	5.1	n.a.	n.a.	n.a.
UETS	Spain	2003	Regional	0.8	6.0	0.13	10	variable
IQWiG	Germany	2004	National	17.0	80.0	0.21	70	variable
AHTAPol	Poland	2005	National	3.6	38.2	0.09	40	variable
HAS <sup>f</sup>	France	2005	National	1.0 (60.0) <sup>h</sup>	65.0	0.01-1.2	17	225
HIQA	Ireland	2007	National	n.a.	4.2	n.a.	n.a.	n.a.

Sources: INAHTA ([www.inahta.org](http://www.inahta.org)) and organizations' web sites.

<sup>a</sup>Formerly HTA Unit of the Austrian Academy of Sciences (created 1990); <sup>b</sup>Formerly COHTA; <sup>c</sup>Formerly DIHTA;

<sup>d</sup>Merger of former HTBS (created 2000) with other organizations; <sup>e</sup>Merger of former SMM (created 1998) with other organizations; <sup>f</sup>Merger of former ANAES (created 1989) with other committees; <sup>g</sup>No information on the public fraction of funding. Membership of INAHTA requires at least 50% of public funding; <sup>h</sup>HTA budget US\$ 1 million, whole budget including all activities 60,0

**Box 5.4** *NCCHTA – research to inform NHS decision-making*

The NCCHTA was established in 1996 to coordinate and manage the NHS Health Technology Assessment Programme funded by the English Department of Health's Research and Development Directorate. It works in three ways to identify the information needs of policy-makers, managers and health-care providers; support prioritization of research; commission research; and disseminate results (NCCHTA, 2008).

1. *Commissioned HTA*. Expert panels prioritize topics identified through consultation throughout the health services and by scanning the recommendations of previous research. Consequently, primary or secondary research is commissioned from academic or health service research organizations.
2. *Responsive HTA*. Stream funds research on topics proposed by researchers. They may propose pragmatic trials on an ongoing basis or submit proposals for specific calls for themes. The latter include primary research, systematic reviews and research on methodological issues.
3. *Call-off contract*. Supports NICE guidance. NCCHTA commissions reports from seven contracted academic departments in the United Kingdom. Academic groups commissioned to carry out assessments within the NICE process form the InterTASC collaboration which includes the Development and Evaluation Team at the Department of Public Health, Epidemiology and Biostatistics (University of Birmingham); the School of Health and Related Research (SchARR) at the University of Sheffield; and the Peninsula Technology Assessment Group (University of Exeter).

2005). There has also been a rapid shift from focusing mainly on therapeutic and diagnostic technologies (i.e. medical technologies) to assessments of screening, prevention or rehabilitation (Banta & Jonsson, 2006). However, the assessment of public health and health promotion interventions outside the health-care system (such as road traffic policies) has generally played a very limited role in the work of HTA agencies (Banta et al. 2002).

Drug assessments for regulatory purposes of reimbursement or pricing are performed mainly by bodies traditionally not considered HTA agencies (see below). However, IQWiG or the NCCHTA produce many pharmaceuticals assessments as they are commissioned by the decision-making bodies with jurisdiction in this field in Germany and the United Kingdom respectively. To date, the clinical aspects of technologies have dominated in the majority of assessments. Organizational and societal issues have not generally been assessed with the same depth, although they have received relatively greater attention from assessments in Europe than in reports from other parts of the world (Mears et al. 2000; Draborg et al. 2005).

### Activities of HTA agencies

The activities of European HTA agencies enable them to be classified into two main groups (see Table 5.2 for an overview of the activities of European HTA organizations).

1. Organizations that concentrate activities on the production and dissemination of HTA reports. These include the CEDIT (France); SBU and CMT (Sweden); NCCHTA (United Kingdom); *Ludwig Boltzmann Institut für HTA – LBI@HTA* (Austria); Medical Technology Unit – MTU (Switzerland); Agency for HTA (*Agencia de Evaluación de Tecnologías Sanitarias*) in Spain and the *Deutsche Agentur für HTA* (DAHTA). All were established during the 1980s and 1990s. DAHTA was officially established in 2000 but the project that led to its establishment produced the first HTA reports in the 1990s. Beside the assessment of established technologies, some of these organizations also participate in the identification of emerging technologies (see Table 5.2). The National Horizon Scanning Centre (NHSC) in the United Kingdom is specialized in the field of emerging technologies and forms part of the English HTA programme together with the NCCHTA.
2. Institutions with broader mandates that include (but are not limited to) the production of assessment reports on technologies. For example, the Belgian Health Care Knowledge Centre (*Federaal Kenniscentrum voor de Gezondheidszorg - Centre Fédéral d'Expertise des Soins de Santé – KCE*) (see Box 5.5) is mandated to support decision-making through its work in HTA, the development of clinical guidelines and health services research. Other agencies with broader mandates include the agencies of the Spanish autonomous regions (AETSA, AVALIA-t, CAHTA, OSTEBA, SCS, UETS), the Danish Centre for Evaluation and Health Technology (DACEHTA), the German IQWiG, or the Agency for Health Technology Assessment in Poland (*Agencja Oceny Technologii Medycznych – AHTAPol*).

In Norway, HTA agencies' activities have broadened as a result of several functions being merged into a single organizational unit. The Norwegian Knowledge Centre for the Health Services (*Nasjonalt Kunnskapssenter for Helsetjenesten – NOKC*) was established in 2004 as a result of the fusion of the former Norwegian Center for HTA (SMM), the HELTEF-Foundation for Health Services Research and the Scientific Unit of the Ministry of Health and Social Affairs. The NOKC is also responsible for monitoring health-care system user and staff satisfaction (NOKC, 2005) (see Box 5.6 for an illustration of its work).

**Box 5.5** *Belgian Health Care Knowledge Centre: HTA and health services research*

The KCE is an independent scientific institute established by federal decree from late 2002 with the mandate to support health and health services policy and decision-making in the Belgian health-care and health insurance systems. It issued its first scientific reports in 2004. It can be commissioned to analyse policy and research issues by the Public Health Committee of the Belgian Parliament; the Federal Ministry of Social Affairs, Public Health and the Environment; the Social Security; the National Institute for Health and Disability Insurance; as well as academic centres, hospitals and even private organizations and patients. The KCE formulates recommendations for policy but they are not binding. Although policy decisions may deviate from the recommendations, there is increasing consideration and uptake of KCE recommendations.

The KCE has a multidisciplinary scientific staff including social scientists, health economists, statisticians, epidemiologists and experts in public health, medical law and knowledge management. In addition, a pool of external (national and international) experts can be involved temporarily on specific projects. There is an established policy for transparency and disclosure of conflicts of interests for KCE personnel and external experts.

The scientific work of KCE is organized in four fields.

1. *Good clinical practice*. Analysis of clinical practice variations and issuing of recommendations which in turn can be applied as standards in quality assurance and performance feedback initiatives.
2. *HTA*. Assessment of the effectiveness and cost effectiveness of procedures, devices and drugs in order to support management of the introduction of innovations and the allocation of resources in the health-care delivery system.
3. *Health services research*. Covers needs assessment and the analysis of financial and organizational issues in health-care provision.
4. *Equity, patient behaviour and miscellanea*. Analysis of the impact of health-care reform on equity and access to the health-care system.

All fields focus mainly on the impact of interventions, ranging from clinical (preventive, diagnostic, therapeutic) to policy interventions (e.g. public health policy). For example, one report deals with the financial consequences of modifying the rules for medical liability. Another assesses the possible effects of co-payments on access to emergency medical services. Reports and recommendations from KCE act at different levels of decision-making (federal, regional, provider trusts, single providers), depending on the specific topic.

**Table 5.2** Overview of institutions performing HTA and their activities in selected European countries

Agency (country)	Since	HTA		
		HTA reports	Horizon scanning/ emerging technologies	Education
CEDIT (F)	1982	+	+	
CMT (S)	1984	+		
SBU (S)	1987	+	+	
LBI@HTA (A) <sup>d</sup>	1990	+	+	+
CAHTA (E) <sup>a</sup>	1991	+		+
MTU (CH)	1992	+		
OSTEBA (E)	1992	+	+	+
AETS (E)	1994	+	+	+
FinOHTA (SF)	1995	+		+
VSMITVA (LT)	1995	+		
AETSA (E)	1996	+	+	+
NCCHTA (UK)	1996	+		
DACEHTA (DK) <sup>b</sup>	1997	+	+	+
NHSC (UK)	1998		+	
AVALIA-t (E)	1999	+	+	+
DAHTA (D)	2000	+		
ZonMw (NL)	2001	+		
KCE (B)	2002	+		
NHS QIS (UK) <sup>e</sup>	2003			+
ROHTO (SF)	2003	+		+
UETS (E)	2003	+		+
IQWiG (D)	2004	+		
NOKC (N) <sup>f</sup>	2004	+	+	+
AHTAPol (PL)	2005	+		+
HAS (F)	2005 <sup>c</sup>	+	+	
HIQA (IRL)	2007	+		+

Sources: compiled from information on INAHTA and institutional web sites. <sup>a</sup>Formerly COHTA; <sup>b</sup>Formerly DIHTA; <sup>c</sup>Merger of former ANAES (created 1989) and other committees; <sup>d</sup>Formerly HTA Unit of the Austrian Academy of Sciences; <sup>e</sup>Merger of former HTBS (created 2000) and other organizations; <sup>f</sup>Merger of former SMM (created 1998) and other organizations

A: Austria, B: Belgium, CH: Switzerland, D: Germany, DK: Denmark, E: Spain, F: France, IRL: Republic of Ireland, LT: Latvia, N: Norway, NL: the Netherlands, PL: Poland, S: Sweden, SF: Finland, UK: United Kingdom

<b>Other activities</b>			
<b>Patient-tailored information</b>	<b>Quality assessment, accreditation</b>	<b>Health services research/ registries</b>	<b>Clinical practice guidelines/ consensus conferences</b>
+			
		+	+
		+	+
			+
	+	+	+
+		+	+
+		+	+
		+	+
+	+		+
	+		

**Box 5.6** *Expanding mandate of HTA institutions: the NOKC**Identification and introduction of new technologies in Norway*

New technologies are a major driver for increasing the health-care budget in Norway, as in most developed countries. The paths for introducing new technologies into the health-care system differ with the technology type. Reimbursement decisions for approved pharmaceuticals are based on evaluations of efficacy and cost effectiveness. Devices and procedures are introduced and financed through a diagnosis-related group system without any formal assessment (beyond CE approval for devices).

NOKC has supported decision-makers with information on new technologies on an ad hoc basis for several years. However, the lack of a system for identification and early assessment of new technologies is unsatisfactory. Such systems, known as horizon-scanning, operate in several countries (Canada, Australia, France, United Kingdom, Spain, Switzerland, Sweden, Denmark and the Netherlands), although their levels of activity and extent of use vary considerably. Institutions that are members of the International Information Network on New and Changing Health Technologies (EuroScan) perform early-warning activities, exchange experiences and share a common database on new and emerging health technologies.

Recently, NOKC has been mandated to develop such an early-warning system in order to inform decision-makers and health-care providers about new and emerging technologies that are likely to impact on the Norwegian health system. The system will serve two main objectives. First, to enhance the use of research evidence when new technologies are considered for implementation in individual hospitals. For this purpose a database of new technologies has been developed to enable Norwegian users to access resources from the EuroScan network and other international scanning initiatives. NOKC provides a short summary of selected technologies, and also updates or assesses new technologies at the request of providers.

The second objective is to identify those technologies that are likely to have a substantial impact on health, costs or the organization of health-care provision in Norway and thus require an in-depth HTA process that results in the development of national guidance or guidelines. The identification of emerging technologies results from a system that combines experiences from international networks (especially EuroScan but also incipient EUnetHTA activities in this field) with those of key national clinical experts (e.g. oncology experts as described below).

Either clinicians (who need a better evidence base before implementing a new technology) or the recently established National Council for Quality and Priority setting in Health Care prioritizes which technologies to assess.

The methods for early assessments basically follow those for HTA reports, although with a less extensive literature search, and often with limited information on both efficacy and safety. Important considerations are safety, efficacy, costs, ongoing trials and approval and implementation status.

**Box 5.6** *contd*

Decisions on the implementation of new technologies in hospitals are commonly taken locally at each hospital. The database supports these decisions as described above, either with evidence from international collaborators or with in-house NOKC assessments. However, the experience so far has demonstrated that, although local decision-making is important and needs to be strengthened, there is also a need for clinical policy decisions at the national level. Certain technologies have greater implications for health, cost or organization and call for a national approach in order to secure equal access, fair prioritization among patient groups or for other reasons. For example, local decision-making has produced substantial variations in access to high cost cancer drugs across the country. Therefore, a national process is under way to integrate early warning of new and costly technologies with decisions on implementation and coverage, overseen by the National Council for Quality and Priority setting in Health Care.

*Improving the quality of cancer guidelines*

Clinical cancer guidelines in Norway have been developed by a set of specialist groups comprising oncologists, surgeons, pathologists and others. These groups have not been supported in the implementation of an evidence-based approach so their recommendations have largely been based on expert advice and specialists' (non-systematic) knowledge of the scientific literature. The need for fair priority-setting that allows limited resources to be distributed among competing programmes has not been explicitly considered in the processes of guideline development. Furthermore, new and costly cancer drugs have been introduced unevenly, generating regional differences in access.

Against this background the Ministry of Health and Care Services decided to allocate resources to establish collaboration between the specialist groups, NOKC and the Directorate of Health and Social Services, with the aim of producing new and improved national cancer guidelines based on existing guidelines.

The collaboration has four main activities with the main goal that all cancer patients should have equal access to high-quality diagnosis and cancer treatment.

1. Establish national standards for diagnosis and treatment of most cancers, including palliative care.
2. Establish a formal process for early identification and assessment of new cancer technologies.
3. Identify costly technologies that will need special financing arrangements.
4. Establish a national cancer library within the electronic health library.

NOKC's main role has been to support the guideline development process with the systematic preparation of research evidence. It facilitates the use of existing HTA reports, Cochrane reviews and evidence-based clinical practice guidelines in the development process. After evaluating the existing evidence each group identifies technologies and proposes further questions that require an HTA process.



A third group comprises the institutions that perform quality assessment and promotion activities (such as the development and monitoring of quality indicators or the accreditation of providers) in addition to technology assessment functions. For example, the Irish HIQA is mandated with both assessment and quality monitoring tasks. This organization not only produces assessments to support the Irish Department of Health but is also responsible for setting standards for health and social care facilities (e.g. hygiene and infection control standards), and for inspecting such facilities. Also, the Health Technology Board for Scotland (HTBS) has been merged with other units to form NHS Quality Improvement Scotland (NHS QIS) which is responsible for the development and monitoring of standards of care.

In France, there has been an even greater concentration of activities under one institutional roof since HAS started its work in January 2005. This organization combines the former National Agency for Accreditation and Evaluation in Health Care (ANAES) and the committees responsible for assessing drugs, devices and procedures for reimbursement purposes. Accreditation tasks are not limited to health-care facilities and staff; they now also refer to quality assessment of health information web sites and certification of software aids for prescription.

Whether agencies have a broad or a narrow mandate, many are also involved in educational and training activities for professionals outside the agency. These include seminars, workshops, intensive courses and (in some cases) distance learning programmes (Jonsson & Chamova, 2000).

#### Relation to decision-making

HTA organizations are linked to policy decisions in varying degrees. This is largely dependent on whether there are formalized decision-making processes – most often present in service coverage and reimbursement (see Chapter 4). A formal linkage between the activities of an agency and the decision-making process has consequences for the work of an institution. Organizations with a high degree of explicit linkage mostly initiate their assessments at the request of the decision-making body, i.e. they have less influence on priority setting and the research agenda. For example, in Germany IQWiG (which is embedded in the formal decision-making process for reimbursement) may initiate projects on its own but to date has worked nearly exclusively on assessments commissioned by the Joint Federal Committee, the body responsible for decision-making. In contrast, agencies which are relatively removed from specific policy decisions mostly initiate their own assessments according to pre-established systems of topic identification and priority setting. In some cases, the institutions are

closely related to the regional or national health ministry. They are involved in less explicit decision processes and may impact on the organization and planning of health-care delivery and (most likely) investment decisions.

Formal involvement in the process as well as closeness to decision-makers can be advantageous for an institution – increasing its impact on the policy process. However, it may come at the cost of reduced power in agenda setting and a perceived lack of independence in the eyes of the public and health-care professionals. Some agencies have realized that being a department of the health ministry (or the equivalent) is not the appropriate organizational model. They have retained public funding but evolved into independent organizations (for example SBU or the Catalan HTA Agency) (Banta & Jonsson, 2006).

### **Special case of hospital-based HTA**

Hospital-based HTA units can be defined as in-house units that provide tailored advice to support managerial decisions and clinical governance at hospital level. The rationale is that their integration in the relevant organizational context means that they are best placed to achieve the transfer of evidence from research into managerial and clinical practice (Dopson & Fitzgerald, 2005). Hospital-based HTA can draw on the results of assessments made by national or international agencies, adding locally relevant information (i.e. economic consequences or organizational implications for the hospital) and adapting the product to the requirements of the context.

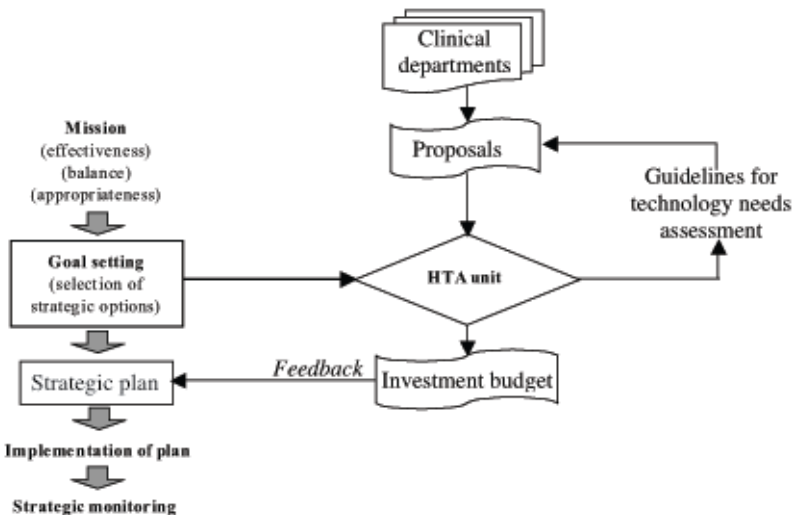
In Canada this model of HTA has been advocated as having a relevant impact in the management of technologies due to its high relevance for decision-makers' needs, the incorporation of local data, timeliness of assessments and formulation of policy in accordance with the context (McGregor & Brophy, 2005). In Italy, some university hospitals are developing a hospital-based approach following this model (see Box 5.7 for an illustration from the university hospital in Rome). The experience in Italy shows that the integration of an HTA unit within the structure of a highly complex organization also has a signalling effect on clinicians by contributing to the diffusion of the culture of assessment and evaluation, not least by involving local clinicians in the assessments. Denmark has similar activities at all university hospitals.

One of the first HTA organizations in Europe, the French CEDIT was established by the administration of the public and university hospital group of the Paris area (*Assistance Publique-Hôpitaux de Paris* – AP-HP) with the aim of supporting hospital managers in the management of technologies. CEDIT assesses technologies and provides advice on their implementation and use.

**Box 5.7** Hospital-based HTA: technology assessment unit in the Agostino Gemelli University Hospital

In 2001 the HTA unit at the A. Gemelli University Hospital in Rome was formally established to support the general directorate and different departments involved in the selection of technologies for the hospital (Catananti et al. 2005). The unit is located at the Medical Directorate of the University Hospital and comprises a multidisciplinary staff which is regularly supported by clinicians, engineers and economists from the respective hospital departments and institutes. The presence of an HTA unit is an attempt to overcome barriers that reduce the impact of the HTA message in practice. Material, organizational and scientific barriers are faced through organizational change supported by the top management team who provide skills and professional competencies in HTA (thus overcoming scientific barriers).

The unit is involved in a variety of aspects related to hospital management, participating in strategic and investment planning (see figure below), technology implementation support, assessment of activities, quality improvement, clinical governance activities and accreditation of services provided within the hospital. It evaluates the clinical, financial and organizational implications of introducing drugs, devices, procedures and management systems into the institution. The hospital-based approach probably allows better measurement of the real impact of health technology in the organizational context in which it is or will be delivered. The HTA unit has introduced a formal procedure – supported by an information and communication technology application system available on the hospital's Intranet – aimed at supporting the institution's investments in new technologies. By applying an ad hoc assessment grid designed to incorporate the hospital's strategic goals, the hospital management was able to produce a priority list incorporating a rational economic approach built on



**Box 5.7** *contd*

scientific evidence acceptable to clinicians. There has been increasing awareness and understanding of the usefulness of HTA principles and tools among hospital personnel since clinicians became more aware of HTA. The unit is embedded in the managerial-organizational structure of the hospital thereby ensuring that assessments take full account of the specific needs and constraints of the institution. The unit also fosters the development of technological innovation in the university hospital through partnerships with biomedical industries and is involved in teaching activities (including participation in the International Masters Programme in HTA and Management).

In addition to the embedded organizational approach of hospital-based units (or an agency for a hospital group), other approaches are being developed to support knowledge transfer to decision-making at hospital level. National and regional agencies have begun to offer support for hospital managers' decisions concerning the introduction and use of technologies. In Spain, the Andalusian Agency for Health Technology Assessment (*Agencia de Evaluación de Tecnologías Sanitarias de Andalucía* – AETSA) has developed a guide to support decision-making at provider level. This allows a structured approach to facilitate dialogue between clinical and managerial staff when negotiating applications for the incorporation of new technology (Briones et al. 1999).

In Denmark, a comparable tool (so-called mini-HTA) has been developed jointly by DACEHTA and the HTA units of the university hospitals in Aarhus, Copenhagen and Odense (DACEHTA 2005) – hospital managers and heads of department are asked to complete forms on financial, technical and patient-view aspects of the requested technology. This demonstrates that hospitals are looking for a flexible tool that is easily accessible and understandable for both health professionals and health-care managers (Ehlers et al. 2006). In Austria, the national agency (LBI@HTA) supports and coordinates an informal network of medical directors and quality managers with the aim of disseminating HTA information on topics relevant to these decision-makers.

### **Assessments for pharmaceutical regulation**

In addition to the HTA agencies and units described above, some European countries have specific public bodies that synthesize research findings in order to support decision-making concerning pharmaceuticals (see Box 5.8 for some examples). In general, these bodies are embedded in a formalized decision-making process, delivering assessments to the committees responsible

**Box 5.8** *Assessments for pharmaceutical reimbursement policies – examples from Europe*

*Ireland*

The Product Committee, based in the Department of Health & Children is responsible for the reimbursement of pharmaceuticals in the primary-care sector. The National Centre for Pharmacoeconomics (NCPE), funded by the same department, conducts reviews of published evidence, evidence submitted by manufacturers and its own pharmacoeconomic evaluations. Summaries of the assessments requested in the decision-making process are published online ([www.ncpe.ie](http://www.ncpe.ie)). In addition, NCPE performs educational activities to build pharmacoeconomic capacity.

*Norway*

The Norwegian Medicines Agency (*Statens Legemiddelverk* – NoMA) is responsible for regulation concerning pharmaceuticals, including market approval, reimbursement, pricing, surveillance and the regulation of pharmacy supply. To achieve reimbursement, manufacturers need to supply systematic reviews on effectiveness as well as evidence on cost effectiveness. The agency appraises the submitted evidence and the in-house department of pharmacoeconomics may perform additional assessments but no detailed assessment report is published.

*Portugal*

The National Authority of Medicines and Health products (*Autoridade Nacional do Medicamento e Produtos de Saúde* – INFARMED) is a governmental agency responsible for reimbursement decisions for pharmaceuticals. These are based on assessments of the therapeutic advantages and cost effectiveness of a drug. Assessments are performed by an internal department (*Observatório de Saúde* – Health Observatory) and include evidence submitted by manufacturers (i.e. pharmacoeconomic studies). The assessment reports are confidential.

*Sweden*

In 2002 the PBB was established as a governmental agency with the aim of basing reimbursement and pricing decisions on cost-effectiveness assessments. Reimbursement and pricing for new drugs is decided on the basis of assessments of evidence from clinical and pharmacoeconomic research submitted by the manufacturers and additionally retrieved by the PBB. In addition, the PBB is reviewing groups of drugs included in the covered drugs list before 2002 to assess the fulfilment of reimbursement criteria. To date, three groups of drugs have been reviewed (for migraine; asthma/chronic obstructive pulmonary disease; and diseases related to gastric acid) and have been published in English.

for appraising the fulfilment of reimbursement and pricing requirements for pharmaceuticals in the public health system (see Chapter 4 for more details). As these are oriented to policy- and decision-making, to a certain extent the assessment reports can be considered to be within the conceptual sphere of HTA. An overview of HTA in Europe would be incomplete without them but although they share a similar understanding of the notion of evidence with the aforementioned organizations they have some critical differences.

First, with some exceptions, assessment and appraisal are conducted following a manufacturer's application. Second, the manufacturer is required to submit evidence from research. The extent to which further evidence beyond this data is included in assessments varies from country to country (Zentner et al. 2005). The scope of the assessments is limited to therapeutic benefit, cost effectiveness and budget impact.

Another relevant difference is that many of these bodies do not publish full (i.e. detailed) reports of their assessments (Zentner et al. 2005). For this reason, some authors have estimated their degree of transparency to be low and warranting improvement (Sorenson et al. 2007; Hutton et al. 2006).

The most prominent difference appears to be that (unlike HTAs by independent agencies) there is not always clear separation between assessment and regulation since both the assessment unit and the regulatory committees are often gathered under the roof of a drug evaluation agency or a drug reimbursement authority. However, these assessments have a high impact on the final decision due to this formal and systematic linkage in the form of a regulatory body.

In summary, although they perform HTA-like activities these institutions clearly differ from HTA agencies and rather play the role of authorities within the state administration. In some countries there may be some degree of cooperation between HTA agencies and reimbursement bodies. This is the case in Sweden, where there is significant collaboration between the SBU and the Pharmaceutical Benefits Board (*Läkemedelsförmansämnden* – PBB), particularly in reviews of entire groups of drugs (Sorenson et al. 2007).

## **Trends and the next steps**

It has to be acknowledged that no two approaches to HTA in Europe follow an identical organizational model (Banta & Jonsson, 2006). This is unsurprising since these institutions are part of the respective health systems they serve, which in turn show great differences in most of their organizational aspects across Europe. We have documented this institutional diversity by describing some of the key characteristics of HTA organizations in Europe. This descriptive

exercise does not claim that some models are better at achieving HTA's ultimate goal of improved health systems. Furthermore, information on why a particular country has chosen a particular model is not available in an analytical form (Banta, 2003). A stakeholder analysis would most likely be required to understand these choices at the national level. Nevertheless, this exercise has allowed us to identify some tendencies that may be relevant for the continued development of existing and future institutions and indicates that the landscape of HTA in Europe is changing.

The scope of institutions involved seems to be expanding beyond the sole production of HTA reports. Newly created agencies have been mandated with tasks in health services research and quality standards development upon their inception. In addition, a growing tendency to concentrate HTA, health services research and quality assessment related activities under the same institutional roof (rather than dispersed among several organizations) can be observed in some countries. In our view, these developments reflect the recognition that the knowledge needed to manage the health-care system in an evidence-based manner transcends classical HTA reports – i.e. assessments on the consequences of technology introduction. As Fulop et al. argue, classical HTA reports are vital for the improvement of health services but evidence from research on the organization and delivery of health services (health services research) is at least as relevant (Fulop et al. 2003). This includes surveying the quality of care and conducting primary research on the needs and demands of patients and providers. The institutional proximity of these tasks to the culture of HTA may lead to a more rigorous approach in this field.

An increasing number of European countries have established institutions with a mandate to perform or coordinate HTA activities in the past decade. These agencies and units have been created at national, regional and local levels. The establishment of HTA units in regional or local health authorities, as well as their integration within the structure of health-care organizations such as hospitals, represents a process of decentralization. This emphasizes the need to contextualize evidence produced elsewhere in order to make it useful for local decision-making. Central HTA agencies have been quite successful in assessing the clinical effects and macroeconomic consequences of health technologies. However, they have been less effective in producing answers to other questions relevant to local decision-makers concerning impacts on their own organizations. With the increasing economic pressure on purchasers and providers, especially on hospitals (e.g. through DRG-payment systems), it may be an option for hospital trusts or large hospital facilities such as university hospitals to establish HTA intelligence within their own organizational structures.

The issues of cooperation and information sharing have been prominent since the early years of HTA and the need to formalize collaboration among a growing number of European institutions was recognized early. Since the 1990s, efforts to establish such a formal collaboration – EUR-ASSESS (Banta et al. 1997), HTA-Europe (Banta & Oortwijn, 2000), European Collaboration for Health Technology Assessment – ECHTA (Jonsson et al. 2002), EUnetHTA (Kristensen et al. 2006) – have led slowly but consistently to the formulation of a serious proposal for the longer-term institutionalization of a European HTA network. Thus, one of the next steps in the evolution of European HTA will be the establishment of a permanent and highly committed crossnational collaboration in a sustainable structure, to act upon the areas of HTA which would profit from a higher degree of centralization. Tasks could include the coordination of cross-border assessment projects; the facilitation of structured information exchange among partner institutions; and the transfer of know-how to nations, regions or settings wishing to build local capacity for evidence-based policy-making. Such a European HTA coordinating institution would not compete with local organizations but would complement national HTA efforts, allowing them to direct their resources to increase responsiveness to local decision-makers' needs and demands, for example by emphasizing the assessment of aspects that are highly dependent on local context.

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## Chapter 6

# **What are the effects of HTA reports on the health system? Evidence from the research literature**

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### **Introduction**

Health technology assessment (HTA) is both a scientific process and a health technology. As a scientific process it involves systematic literature searches; critical reviews of scientific and other studies; evidence syntheses and the formulation of conclusions; and recommendations on the assessed information and the context of decision-making. However, the ultimate value of HTA in a health system depends on its contribution to improved health status or increased efficiency rather than to increased knowledge. In this respect, HTA does not differ much from other health technologies and must be subject to the same rigorous standards of evaluation.

The effects of HTA can be only indirect and thus differ from other health technologies. For example, a drug to lower blood pressure would be assessed on its ability to lower blood pressure and to decrease the risk of stroke or other related outcomes. Information could also be derived about the drug's cost effectiveness or whether any legal or ethical problems might be associated with its use. Each of the evaluation criteria is relative and of varying importance but a consensus on use and usefulness can

eventually be achieved, as can a common understanding about the main objectives (and thus the outcomes and other factors to be evaluated) of such a drug.

In this chapter we begin by describing the rationale and the possible nature of HTA impact evaluation. A hierarchical model of HTA impact reports is used as a framework to structure the current body of knowledge concerning the impact of reports that were identified through a systematic review. We demonstrate the factors that might enhance or hinder the contribution of HTA and conclude with the lessons learned from the empirical literature.

### **Why and how should the impact of HTA be evaluated?**

What can be expected from an HTA report? The first indication can be gained by scanning these reports for statements regarding their overall goals as their function and possible impact depends on the binding character of their findings. This may vary according to the health-care system of a country, among other things. For example, the United Kingdom's National Institute for Health and Clinical Excellence (NICE) produces mandatory government guidelines. Its HTA recommendations are likely to have a different level of impact to those issued by organizations that are not directly integrated into the decision-making process, such as the German Institute of Medical Documentation and Information (DIMDI).

The disturbing finding is that HTA reports typically do not define their impact objectives, that is – the effects they would like to achieve (for example, to influence coverage decisions, support guideline formulation or change routine practice). This is not to say that HTA reports lack clearly defined objectives. However, the stated objectives or research questions are scientific, related to the technology being assessed rather than describing the expected role of the HTA itself. A report's stated objective may be: "to find out whether technology A is more effective than technology B" or "Is technology C adequate for solving health problem X?" In contrast, an HTA report does not include statements such as: "The results of the final report should form the basis for the decision on the reimbursement of the technology" or "One year after publication of the report, 90% of physicians should prescribe the drug that this HTA finds to be superior" (Gerhardus, 2006).

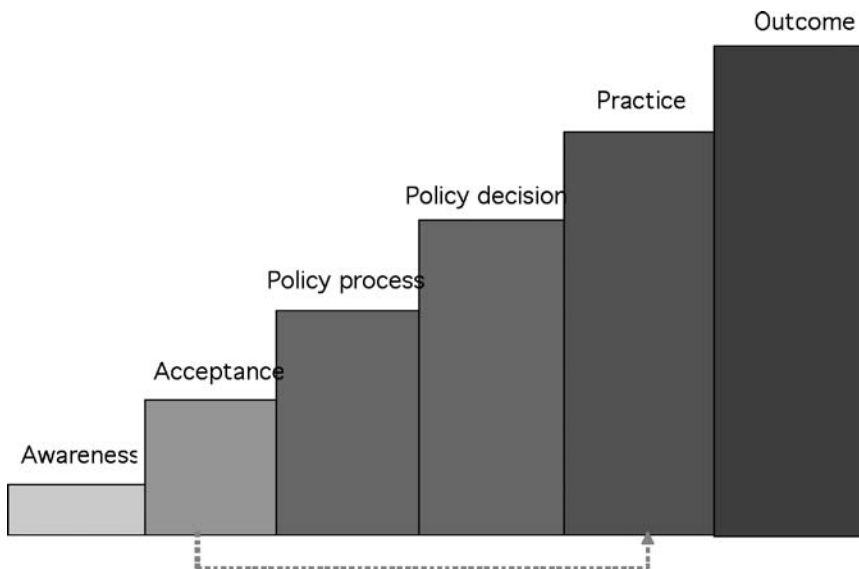
This demonstrates how HTA reports can produce different impacts. As with the effects of other health technologies, they can be conceptualized in a hierarchical order. For the purpose of this chapter we have adapted general models of research utilization developed by Gerhardus et al. (2000) and Landry et al.

(2001) to the HTA context. Other authors have proposed similar frameworks to assess the impact of outcomes research (Stryer et al. 2000) and the impact of health promotion (Nutbeam, 1998).

Our model includes six steps (see Fig. 6.1).

1. *Awareness*: the corresponding stakeholder must know that the HTA is a prerequisite for influencing a decision.
2. *Acceptance*: the report should also be useful in terms of validity, relevance and applicability and its findings acceptable.
3. *Policy process*: the policy process within which the HTA is used (e.g. reimbursement or guideline development) should explicitly utilize the HTA report.
4. *Policy decision*: the actual policy decision should be clearly influenced by the HTA's conclusions or recommendations.
5. *Practice*: the policy decision has to be implemented in practice, through clear and measurable changes in clinical practice.
6. *Outcome*: clinical practice must change before it is possible to begin to measure the true impact of an HTA, for example in terms of health or economic outcomes.

**Fig. 6.1** Hierarchical steps of the impact of HTA reports



In some situations HTA reports influence practice directly, without formal consideration in the policy process, in this case the third and fourth steps will be omitted.

Some authors argue that such models oversimplify by implying a direct linearity that does not accord with the rather complex reality. They have also questioned whether the impact of HTA reports goes beyond the mere delivery of information on concrete technologies. The enlightenment model (Weiss, 1979) suggests that a more important contribution of HTA reports might be shifts in categories and perspectives, or in structuring the dialogue between stakeholders. Thus, the main impact of an HTA of blood pressure lowering drugs would not be the concrete result (i.e. drug A is more effective than drug B) but rather the level of methodological standard the HTA accepts (e.g. only randomized controlled trials) or the criteria used to assess the technologies (e.g. patient-centred outcome parameters [stroke] instead of surrogate parameters [blood pressure]). Clearly these effects are even more indirect, and more difficult to evaluate, as they influence the health system as a whole and not only one single technology. Another approach, the process model (Weiss, 1979), focuses on the degree of stakeholder participation in the assessment process and the HTA's influence on the technology it evaluates. Other possible uses of HTAs have been discussed elsewhere (Gerhardus, 2005a; Hailey, 2003; Lehoux & Blume, 2000).

There are various reasons for measuring the use of HTA reports. It is essential to identify factors that enhance or hinder their impact and thus support better targeting and the development of dissemination strategies. It can also assist with prioritizing future research. Supervising institutions may request such assessments in order to justify the use of resources. However, Hailey (2003) warns against using an HTA impact assessment as a measurement of the performance of an HTA agency and making its financing completely dependent on the results. There are always many other factors that influence decision-making processes.

In this chapter we have aimed to gather the current body of knowledge and experience regarding the impact of HTA reports and the factors that might enhance or hinder HTA's contribution. Systematic review techniques have been used to search relevant published and (as far as possible) unpublished literature (see Box 6.1).

### **Contribution of HTA**

The results of the literature review are presented by the impact objectives they investigated. Factors that enhanced or hindered the impact were sorted into

**Box 6.1** *Systematic review: method*

In January 2007, we updated earlier systematic reviews of the literature (Gerhardus & Dintsios, 2005; Gerhardus, 2005a), searching for documents from 1990 onwards using seven electronic databases and the reference lists of the studies included. Often this kind of research is not published in journals or indexed in electronic databases so we additionally e-mailed the members of the European Network for Health Technology Assessment (EUnetHTA) and the International Network of Agencies for HTA (INAHTA) to request information on any of their own unpublished investigations.

We included empirical documents that dealt with measuring HTA's impact (or non-impact) on decision-making or with factors that enhance or hinder its impact. All documents that met the inclusion criteria were written in English or German, though language was not an exclusion criterion.

Electronic database indexing is not very elaborate for a topic such as HTA impact. The search strategy was based on search terms like "health policy", "impact", "effects", "evaluation", "health-planning" or "decision-making" that were combined with "health technology assessment" and its synonyms. The search yielded 5664 results. After screening titles and abstracts, 51 documents were selected and ordered as full text, 8 of which were included. The e-mails to EUnetHTA and INAHTA, as well as personal contacts, resulted in 48 documents of which 19 additional documents were included. From the earlier searches (Gerhardus & Dintsios, 2005; Gerhardus, 2005a), 33 documents were selected. In total, the review comprised 60 documents.

contextual factors; factors related to the process of creating a report; and factors related to the subject, content and quality of a report.

Awareness: knowledge of HTA reports

Nine studies investigated the awareness of HTA reports among their target groups (Axelsson et al. 2006; Bodeau-Livinec et al. 2006; Dixon et al. 2003; Harrison, 2005a & 2005b; Howard, 2004a & 2004b; Sigmund et al. 2004a & 2004b). In all but one of these studies (Bodeau-Livinec et al. 2006), questionnaires were sent to health-care managers and/or practitioners. Four studies conducted interviews and/or focus group discussions (Bodeau-Livinec et al. 2006; Dixon et al. 2003; Sigmund et al. 2004a & 2004b). Most respondents knew the reports and guidances, although awareness differed between professional groups. Shorter versions of the reports were much better known than the corresponding full reports.

With one exception (Bodeau-Livinec et al. 2006), all studies originated from countries with tax-funded health systems (NHS systems) and respected and



influential institutions for HTA and guidance formulation. In the survey-based studies, response rates ranged between 40% and 85%. The surprisingly high response rate (>60%) in most studies may indicate very active interaction between the HTA agencies and their target groups therefore it cannot be assumed that the degree of knowledge of HTAs stated in the questionnaires can be expected in other settings. In addition the validity of the answers (i.e. if respondents actually knew the guidances they claimed to know) was not tested. This can be a problem, as demonstrated in an earlier study by Drummond et al. (1997) in which decision-makers were asked if they were aware of any studies on a list of eleven references. The list included two fictitious studies in order to check whether responses were swayed by awareness of the purpose of the survey. Approximately 20% of the respondents reported knowing the two fictitious studies, whereas between 10% and 60% recognized the nine real studies. Close to 20% of those pointing to the two fictitious studies said that they changed their advice or actions based on their findings.

Another study which investigated changes in practice found no correlation between the relatively high degree of awareness and a rather modest impact on practice (Axelsson et al. 2006). This accords with the literature (Grimshaw et al. 2004) demonstrating the challenges in changing clinical practice through, for instance, clinical guidelines and other quality improvement efforts.

#### Acceptance: attitudes towards HTA reports

Nine studies investigated acceptance of the HTA reports (Bodeau-Livinec et al. 2006; DACEHTA, 2003 [for a shorter abstract-version see Sigmund et al. 2004b]; Dixon et al. 2003; Harrison, 2005a & 2005b; Howard, 2004a & 2004b; Sigmund et al. 2004a; Wathen & Dean, 2004). These used questionnaires and semistructured interviews, administered in person or by phone. Most of these studies also looked at the correlation between acceptance of the reports and their recommendations, and actual changes in behaviour. The degree and patterns of acceptance varied broadly.

The recommendations in two studies were almost unanimously accepted. This led to no major changes in practice as the report was perceived as merely stating the obvious and a ceiling effect had already been reached (Harrison, 2005b; Howard, 2004b). One study found that the recommendations of a report divided a group of anaesthetists. No relevant changes in practice were noted as the group that practised in accordance with the recommendations was doing so already and the report results were not enough to convince the group that opposed them (Howard, 2004a). Acceptance was quite heterogeneous for four technology appraisals in the South West Region of the United Kingdom's NHS too: health-care managers reacted very positively but hospital doctors

were more sceptical. It was thus unsurprising that practitioners did not change their behaviour following the HTA reports (Dixon et al. 2003).

#### Policy: impact on health policy process

Five studies (Bonsel et al. 1990; Mitton & Hailey, 1999; Stemerding & van Berkel, 2001; Van den Heuvel et al. 1997; Van Rossum, 1991) used an explicit qualitative approach to assess decision-making processes through in-depth interviews, personal experiences, document analyses and discourse analyses. The choice of methods enabled more differentiated insights. Several of these studies showed that HTA reports were controversial and heavily discussed by stakeholders with diverging interests. One study showed that two HTAs substantially changed the mode of operation of the technologies but had no impact on coverage decisions (van den Heuvel et al. 1997).

These studies illustrate that decision-making is a very complex process. It is not sufficiently understood if the perspective concentrates only on the final decision. Therefore, it can be misleading to judge HTA reports' impact only by comparing their recommendations and the corresponding policy decisions. This runs the risk of ascribing an impact even in cases where the HTA report (or its content) is not even known to the decision-maker. The probability of drawing the wrong conclusions diminishes when the first two steps of our model (knowledge and acceptance) are assessed together with the other steps.

#### Policy: impact on health policy decisions

Fourteen studies looked at HTA's impact on health policy and decisions at the national level (AHFMR, 2001 & 2002; Boer, 1999; Gerhardus, 2005b; Gibis & Rheinberger, 2002; Hailey et al. 2000; Hailey, 1993; Jacob & Battista, 1993; Jacob & McGregor, 1997; Rawlings, 2002; Shani et al. 2000; Sigmund et al. 2004a & 2004b; Smith et al. 1994). Some were carried out by staff members of HTA units, often without detailed descriptions of the methodology or operationalized definitions of HTA impact. Others used interviews, document analysis and questionnaires, individually or in combination. The impact was assessed mainly by comparing the recommendations of HTA reports with subsequent decisions on reimbursement, installation or prioritization of the corresponding technologies. One study used the relevance of policy documents to quantify the degree of HTA impact (Jacob & McGregor, 1997).

The majority of studies found at least 70% of HTAs to have impacted on policy. Some found the impact highly variable, depending on the different professional groups and types of hospitals (e.g. Sigmund et al. 2004a). Four studies focused on HTA-informed decisions at hospital level (Bodeau-Livinec et al. 2006;

**Box 6.2** *Impact of HTA reports on policy and practice: results from a nine country project*

The project assessed HTA availability and impact on three screening procedures (mammography, antenatal ultrasound, prostate specific antigen – PSA) across nine European countries. The methods used included document analysis, data from health service or epidemiological research and interviews with stakeholders and experts.

Out of 27 potentially available HTA reports (one report on each technology in each country) 12 reports were identified. However they were not equally distributed as they originated from 5 countries, no reports were available in the other 4 countries.

According to the influence on policy, HTA reports were judged to have had “high” (8x), “probably low” (2x) and “low” (2x) impacts. The influence on practice was judged to be less: “high” (3x), “probably low” (2x), “low” (4x) and “not specified” (3x).

Four countries had an HTA report on PSA screening but none recommended it. In all cases the policy followed the recommendation although opportunistic screening was still observed in practice. In contrast, among the five countries without HTA reports three offered reimbursement, one offered it under certain conditions and one did not offer it at all.

Publications are listed in Table 6.1 together with Banta & Oortwijn, 2001.

Ehlers et al. 2006; Finohta, 2007; McGregor, 2006). The reports came from national agencies and units within hospitals or hospital networks and most were used for decisions on new treatments and for purchasing. All studies noted a strong impact on these decisions.

Results from a nine country project on the impact of HTA reports on policy and practice are presented in Box 6.2.

#### Practice: impact on clinical practice

Seventeen studies investigated HTAs’ impact on health practice (Axelsson et al. 2006; Britton & Jonsson, 2002; Brickwood, 2004; Brorsson & Arvidsson, 1997; Catchpole, 2004; Cullum et al. 2004; Dixon et al. 2003; Harrison, 2005a & 2005b; Howard & Harrison, 2004; National Cancer Director, 2004; NICE, 2006a–f; Sigmund et al. 2004a & 2004b; Smith et al. 1994; Walley, 2004; Wathen & Dean, 2004). Most studies investigated the impact of NICE guidance.

The studies assessed whether NICE HTA had a notable impact on the dissemination of pharmaceuticals and procedures by using routine data, often complemented by data from sales and manufacturers. The conclusions were mostly derived by comparing the trends before and after NICE guidance was

issued. Prescription rates in different age groups were applied as a proxy to estimate appropriateness of treatment.

The most sophisticated approach has been described in the report of Cullum et al. (2004; for a shorter article version see Sheldon et al. 2004) in which routine data on prescriptions and procedures from Hospital Episode Statistics (HES) or the Prescription Pricing Authority (PPA) were evaluated by interrupted time series analysis. For eight guidance decisions, samples of patient records (790 on average) were drawn to assess changes in the appropriateness of prescribing patterns. These findings were complemented by questionnaires and semistructured interviews with NHS managers and providers to identify factors that enhance or hinder the impact of the guidance.

The findings on the impact of NICE guidance differed between the studies. One study concluded that practice basically reflected the recommendations of the six NICE appraisals evaluated (NICE, 2006a–f) but the impressions of other authors were mixed. One author found little impact (Brickwood, 2004) but others suggested that about half of the guidance decisions had had an impact. One study noted an unexpectedly large regional variation in the use of cancer drugs that could not be explained by case-mix or cross boundary flows (National Cancer Director, 2004). The study by Cullum et al. (2004) confirmed the high degree of regional variation and found NICE guidance to have a much smaller impact on medical devices and procedures than on pharmaceuticals.

In Sweden, Britton and Jonsson (2002) and Brorsson and Arvidsson (1997) evaluated the impact of HTAs from the Swedish Council on Technology Assessment in Health Care (SBU). They used available data on rates in prescriptions, procedures and sales or collected their own quantitative data. Britton and Jonsson (2002) found that five out of seven reports had an impact, that of the remaining two was unclear. Within their multi-centre prospective study Brorsson and Arvidsson (1997) discovered declining rates for three routine preoperative tests following the recommendations of an HTA report. However, the decline of routine tests was less pronounced than expected.

Studies that compare trends before and after an occurrence (such as the release of an HTA report) have a structural drawback – it is not entirely possible to disentangle the contribution of other contextual factors. Brorsson and Arvidsson (1997) reported that cutbacks decided prior to the HTA report, as well as budget restrictions, might have contributed to the observed changes.

Outcome: impact on health and economic parameters

Four studies aimed to assess outcome parameters. Smith et al. (1994) found that two assessments “probably” changed the health status of patients. In one

case the impact was “possible”, for three assessments it was “not known” and for two “too early to be assessed”. Three studies from Canada used modelling of hypothetical cost reductions. One study found that the costs of creating the reports were estimated to be only 7% of the projected savings (Jacob & Battista, 1993). Following the recommendations would create savings of between 16 and 27 million Canadian dollars (Jacob & McGregor, 1997) or about 3.1 million Canadian dollars annually (McGregor, 2006).

#### Other contributions from HTAs

HTAs can achieve objectives and contributions beyond the impacts described above. This body of research focuses on *how* HTAs are used rather than *to what extent*. In part this implies wider frameworks on the possible role of HTA, recurring on the enlightenment and the process model (Weiss, 1979). Some studies relied mainly on document analysis and personal observations or authors’ experiences (Blancquaert, 2006), complemented by data on usage (Wild, 2007); others used questionnaires (AHFMR, 2002 & 2003; Ehlers et al. 2006; Gerhardus, 2005b; Hailey, 2004a & 2004b).

HTA was used to identify gaps in applications, support decisions on appeals, define adequate patient-centred outcomes and create research questions. Blancquaert (2006) found that four Canadian HTA units’ reports on genetic topics were quite successful at increasing awareness of evidence-based concepts among geneticists as well as fostering and structuring discourse in this field. However, none of the four reports had any direct impact on decision-making.

Similarly, Ehlers et al. (2006) and Wild (2007) found that HTAs supported and structured the dialogue between different professional groups. Wild (2007) also noticed effects on knowledge and discourse in the public sphere, improved involvement in the process among different stakeholders as well as the promotion of conditional coverage schemes. Gerhardus (2005b) found that HTAs were used for consensus documents, guidelines and information for patients.

### **Factors that enhance or hinder the impact of HTA**

The impact (positive or negative) of an HTA report depends on many factors. These can be structured into contextual factors that act independently of a specific HTA; factors related to the process around an HTA report; those concerning the content, quality or format of the reports; and those related to the technologies.

The complexity of the decision-making processes makes it difficult to analyse the relevance of isolated factors within rigid study designs. Thus, although most of the studies included in this review present their viewpoints, only four (AHFMR, 2002 & 2003; Cullum et al. 2004; Gagnon et al. 2006) operated with explicit, predefined lists of factors. A comprehensive list is offered in Table 6.1 in the Appendix to this chapter. The following section focuses on the factors that are mentioned more often and appear to be more influential.

### Contextual factors

Many publications demonstrate that HTA conclusions or recommendations have a higher likelihood of being implemented when they are used in a defined policy process with regulation in place that demands that policy decisions will be followed (e.g. Banta & Oortwijn, 2001). One example is England and Wales where the consideration of NICE guidance has been institutionalized within the decision-making process. Equally important, and most likely interlinked, is a growing culture of technology assessments. It has become increasingly accepted that stakeholders in some health systems demand evidence from rigorous studies. Other health systems give greater value to experience – either personal or via authorities. Firm and long-standing beliefs are likely to resist evidence-based information and the implementation of HTA recommendations is substantially jeopardized if there is strong external pressure from stakeholders, especially patient groups (Walley, 2004; Wathen & Dean, 2004).

### Factors related to HTA report process

The acceptance of an HTA is strongly dependent on the reputation of the HTA agency involved – its scientific capacity and its independence from the policy decision-making body. It is also advantageous if agencies, authors and users collaborate closely in the production of an HTA. Local anchorage of the HTA agency was also claimed to be beneficial for the implementation of recommendations and easy access through a user-friendly dissemination strategy helps to increase awareness. By contrast, an evaluation of screening programmes (Banta & Oortwijn, 2001) confirms that reports published after the implementation of the technology are usually too late to produce a sustainable influence on its dissemination. Therefore, it is crucial that HTA reports are timely.

### Factors concerning content, quality or format of HTAs

Reports that presented conclusive evidence had more impact than those with weak evidence bases. User-friendliness, transparency and compact

presentation of information were correlated with an increased acceptance of HTA recommendations. In contrast, HTA recommendations which appeared to contradict the practical experiences of clinicians were very unlikely to be accepted.

#### Factors related to technologies

HTA's contribution was stronger for emerging technologies than for established ones. One study (Cullum et al. 2004; Sheldon et al. 2004) found that HTAs assessing pharmaceuticals had more impact than those assessing medical devices. This is probably related to the higher degree of regulation and formal policy decision processes related to the former. Decision-makers were also more receptive to HTA reports when the technology was connected to a high budget impact.

### **Contribution of HTA: lessons learnt from empirical literature**

Many studies documented the considerable impact of HTA reports. Reports were known by a high percentage of their target groups although acceptance varied. The same applied to the ascribed impact on policy decisions. However, the vast majority of the included studies were carried out in countries with national health systems and a strong, often institutionalized, position for HTA, e.g. England, Wales, Sweden or Canada. Thus, it cannot be taken for granted that the same applies to other health systems. The location of the studies might also partly explain why the influence on practice seemed so much lower than on health policy. In these health systems HTA agencies and decision-makers at the policy level interact closely. Practitioners have more distance and more autonomy from the system. They are also more directly affected by HTA reports as they consider medical decision-making to be their domain and area of expertise. It is generally challenging to change clinical practice by external interventions (Grimshaw et al. 2004).

It is equally interesting to note the type of impact that was discovered. Too often HTA's impact is assessed exclusively on its influence on reimbursement decisions. The review showed a much more heterogeneous contribution. HTA reports also inform stakeholders, structure dialogues and sensitize recipients to outcome parameters.

## Managing the contribution of HTA

The review reveals that the contribution of HTA reports needs to be managed at different levels. The health system needs to institutionalize the role of HTA by integrating it within the decision-making process. Reports that are only informative are very likely to be overlooked. However, the review also showed that many recommendations were accepted at the policy level but never implemented. This requires shifts in the culture of decision-making at clinical level. Collaborative approaches have been found to be successful in enabling ownership and minimizing the risk that relevant aspects are overlooked. Clearly, explicit impact objectives are important for the production of targeted HTA reports.

## Monitoring the contribution of HTA

The methodology for assessing the impact of HTA has evolved enormously over the past years. The scope of what are considered to be its impacts has broadened and the methodology and indicators of impact have been refined.

The basis for successful management is information. Valid feedback on their impact is necessary in order to manage the contribution of HTA reports. Therefore, monitoring of the impact of HTA reports should become a standard element of the quality assurance portfolio of any commissioning agency.

## **Impact objectives**

There is a saying that if you do not know where you want to go you should not be surprised to find yourself in a place you did not expect. So far, HTA reports have been written without explicit statements about what they aim to achieve. Prior description of these goals allows for targeted and efficient planning from the outset.

## **Further research**

Further research is necessary to consider how to develop and test theoretical frameworks. Successful HTA impact assessment requires the involvement of different disciplines and will face the continuing challenge of optimizing the compilation and integration of their results.



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**Table 6.1** *Included studies – impact*

Publication	Objectives	Factors	Results
AHFMR, 2002 & 2003	<p>External consultants evaluated the impact of the products of the HTA units of the Canadian province of Alberta</p> <p>a) 2000-2001 (2002)</p> <p>b) 2001-2002 (2003)</p>	<p>Enhancing: products that present conclusive evidence; communication networks for informing stakeholders; high quality HTA product; appropriately written for target audience; reputation and credibility of HTA unit.</p> <p>Hindering: barriers external to requesters' organization (lobbying by advocacy groups); delivery timing of products; missing link between research and practice.</p>	<p>a) 8/10 products had e.g. influence on: policy and resource allocation decisions; information and education; clinical decisions; changes in programmes; impetus for further research projects.</p> <p>b) HTAs used for: funding decisions; identifying gaps in applications; supporting decisions on appeals; adopting best practices; expanding scope of practice; selecting patient outcomes; selecting research questions and interventions.</p>
Axelsson et al. 2006	<p>Evaluated awareness and the impact on practice of an HTA and its "popular" version on tobacco cessation activities, disseminated by the Swedish HTA agency (SBU) to dentists and dental hygienists.</p>	<p>Enhancing: easy access; easy to understand; easy to apply.</p>	<p>Short popular version much better known than full report. In 2003, 66% of dentists and 90% of dental hygienists claimed to know popular version; 25% of each group also knew the HTA. Participants' knowledge of first report had not changed since first evaluation (dentists; 22%, dental hygienists; 30%). No change in number of patients receiving cessation support between the two studies (2001, 2003). Limited impact on practice but better among dental hygienists in both studies.</p>
Banta & Oortwijn; Faist et al.; Favaretti & De Pleri; Gray; Jonsson et al.; Mousiama et al.; Perleth et al.; Vermeulen et al.; Wild; all 2001	<p>With special focus on role of HTA, comparative 9-country analysis evaluated decisions at policy and practice levels around 3 screening technologies (mammography, prostate-specific antigen [PSA], ultrasound in pregnancy).</p>	<p>Enhancing: HTA institutionalized in decision-making process; established culture of assessment; recommendations not associated with budget cuts; proven efficacy and efficiency of preventive intervention.</p> <p>Hindering: strong impact of interest-groups (industry, patients) on decisions; strong beliefs of physicians that procedure (screening) has a benefit although it is not recommended; policy-makers not familiar with purpose, scope and role of HTA.</p>	<p>Identified 12 HTAs in 9 countries, each with 3 screening technologies (27 potentially available). Impact varied between technologies: assessments on breast cancer screening often influenced policy and practice; assessments of other screening methods had limited influence. In sum, influence on policy was high (8), probably low (2) and low (2). Influence on practice was high (3), probably low (2), low (4) and not specified (3).</p>

**Table 6.1** *contd.*

<b>Publication</b>	<b>Objectives</b>	<b>Factors</b>	<b>Results</b>
Blancquaert, 2006	Evaluated influence of Canadian HTA agency (AETMIS) and its HTAs on policy-making, practice and structuring discourses and decisions in Canada.	<p>Enhancing: collaborative projects; continuous exchange between all stakeholders; mutual trust.</p> <p>Hindering: low priority of topic; diverging understanding of role of HTA (limited to assessment or appraisal).</p>	Four assessed reports had no direct impact on decision-making but some on laboratory practice. Had greater impact on structuring dialogues between science, practice and policy. Increased awareness of evidence-based medicine among geneticists.
Bodeau-Livinec et al. 2006	French CEDIT is located within a network of 39 teaching hospitals in and around Paris.  Study assessed (i) awareness and perception of HTAs among users and (ii) impact of 13 HTAs on the implementation of innovations within the network.	<p>Enhancing: valid scientific and relevant information; regulation; connection between recommendations and funding; good scientific reputation of CEDIT.</p> <p>Hindering: recommendations not known; suboptimal fitting between recommendation and situations; time lag between request and recommendation; HTA finished after innovation was implemented; CEDIT perceived as being too close to the decision-making department (felt lack of independence).</p>	<p>(1) HTA recommendations perceived as useful (clear, well-drafted) when timely.</p> <p>Varying awareness of how CEDIT operates. Often incomplete but respondents believed to be informed about what is relevant to them.</p> <p>(2) 7/13 HTAs had very strong or strong impact; 1 had no impact; 3 had impact that was difficult to ascribe as addressees were also involved in the project; 2 were difficult to ascribe because of external factors.</p>
Boer, 1999	Author describes impact of Dutch Investigative Medicine Program on health policy decisions.	<p>Enhancing: providers involved in evaluation studies; institutional establishment of studies in decision-making process.</p> <p>Hindering: evaluations make large demands on costs and time.</p>	Total of 78 decisions on basis of 53 finished projects: decisions on coverage (38); indications (15), funding (12), planning (9), others (4).
Bonsel et al. 1990	Authors assessed impact of an HTA/study on liver transplantation on health services in the Netherlands.	<p>Enhancing: information gap in a controversial topic; targeted request; independent source of information; budget relevance</p>	Report influenced decision on reimbursement of liver transplantation.

Table 6.1 *contd.*

Publication	Objectives	Factors	Results
Brickwood, 2004	Assessed impact of NICE guidance on drug sales of 8 pharmaceuticals.	Not assessed	More impact on secondary than primary care. Impact varied between administrative regions.
Britton & Jonsson, 2002	Authors evaluated impact of 7 HTAs of the Swedish HTA agency (SBU) on medical practice (practitioners and patients).	Enhancing: extensive dissemination; inclusion of recognized experts in assessment process.  Hindering: intensive media coverage arguing against recommendations.	Impact from 5/7 reports; unclear for 2 reports.
Brorsson & Arvidsson, 1997	In 7 hospitals authors evaluated impact of an HTA of the Swedish HTA agency (SBU) and a related consensus conference on preoperative routines.	Enhancing: consensus conference as disseminator and intermediary of recommendations; threat of budget restrictions.	Over 2 years use of the 3 preoperative tests declined: a) 47% to 41%; b) 26% to 21%; c) 61% to 52%. However, substantial potential for further reduction remained. Considerable variation between hospitals.
Catchpole, 2004	Described impact of NICE guidance on drug sales for one pharmaceutical company in the United Kingdom.	Not assessed	NICE guidance increased sales rates of 3/7 drugs evaluated.

**Table 6.1** *cont'd.*

Publication	Objectives	Factors	Results
Cullum et al. 2004	Assessed dissemination, implementation and impact of 12 NICE guidances in health-care organizations.	<p>Enhancing:                      unambiguous, clear practice recommendations; robust research evidence base; support from relevant professional groups; good fit with national priorities; minimal costs associated with implementation, where costs are high – good fit with national priorities; Trusts have clear strategies to support implementation of NICE guidance.</p> <p>Hindering:                      disagreement with results or methodology used by NICE in arriving at its recommendation; lack of implementation skills and experience; extra investment or resources required – lack of funding; low level of evidence; too complex.</p>	<p>Implementation of NICE guidance varied heavily by Trust and by topic. Impact much smaller on medical devices and procedures than pharmaceuticals.</p>
Sheldon et al. 2004	Investigated acute and primary care trusts in England and Wales.	Work commissioned by National Coordinating Centre for Research Methodology (NCCRM).	<p>Stakeholders had great confidence in validity of HTA reports. Reports well-known at hospital level and in health administration. Utilization lower in hospitals. Higher impact in somatic than in social/psychiatric administrations and hospitals.</p>
DACEHTA, 2003	Impact of Danish HTA agency (DACEHTA) evaluated by international external evaluators and consulting firm.	<p>Enhancing:                      national strategy for HTA; work of high quality, validity, credibility; short, rapid, focused reports; stakeholders actively involved in HTA process; links between DACEHTA, regional HTA units and National Board of Health.</p> <p>Hindering:                      Lack of timeliness; lack of strategies for implementation of conclusions; comprehensiveness of reports; perception of DACEHTA as restrictive.</p>	<p>56% of S&amp;W Region's respondents and 8% from outside had used a S&amp;W report before. Agreement with quality, usefulness and influence was high among managers but lower among hospital doctors.</p>
Sigmund et al. 2004b			<p>b) Routine data showed no impact in the 4 case studies. Partly because it was difficult to show as rates generally accorded with earlier recommendations.</p>
Dixon et al. 2003	South & West NHS Executive commissioned study to assess awareness, acceptance and changes in patterns of purchasing or clinical practice due to impact of HTAs from South & West Development and Evaluation Committee (S&W DEC) in the South & West Region and the NHS.	<p>Enhancing:                      reliability and authoritative; knowledge of system; reputation of people involved in analysis; quality of information.</p> <p>Hindering:                      clinicians more sceptical than purchasers.</p>	



**Table 6.1** *contd.*

Publication	Objectives	Factors	Results
Ehlers et al. 2006	Danish HTA agency (DACEHTA) developed a tool – mini-HTA – to support decisions on health technologies in hospitals. Article evaluates if and how mini-HTAs are used.	<p>Enhancing: interdisciplinary assessment; flexible and open form and use of tool; involves users in HTA planning process; timeliness; quality.</p> <p>Hindering: evidence base insufficient; lack of quality control; felt increase of administrative burden of implementing new technologies.</p>	<p>Mini-HTAs used for budget planning, approval of new treatments and purchasing by 55% of hospital authorities, 66% of hospital management sections and 27% of department management teams.</p> <p>Mini-HTAs supported dialogue and transparency.</p>
Finohta, 2007	Finnish HTA agency (Finohta) assessed impact of a rapid review on newborn hearing screening in maternity wards.	<p>Enhancing: compulsory adoption of new statute from Ministry; right timing of report; involved stakeholders actively in HTA process; HTA replying to an ongoing question.</p>	<p>14/24 hospitals adopted screening or were planning to do so; 6 hospitals emphasized that rapid review had strong impact on their decision.</p>
Gagnon et al. 2006	Study conducted to detect factors at institutional, organizational and professional levels that affect uptake of 3 HTAs in hospitals in Catalonia.	<p>In general: factors vary with type of technology</p> <p>Factors identified as relevant:</p> <p>degree of collaboration between HTA agency and hospitals; distance between hospital and HTA agency; economic factors; peer influence and collegial control; level of specialization (for medical technologies); degree of professional autonomy (for medical technologies); degree of formalism (for administrative technologies); patients' interests.</p>	<p>Not assessed</p>
Gerhardus, 2005b	Examined impact of 33 HTA reports commissioned by the German governmental HTA agency.	<p>Hindering: Consideration of HTA reports by governmental HTA agency not institutionalized in decision-making process.</p>	<p>4/37 HTA reports had impact on decision-making, 1 on health care, 2 were used for guidelines.</p> <p>Enlightenment model: HTA authors entered positions in health system; HTA now a prerequisite for decision-making in Germany.</p>
Gibis & Rheinberger, 2002	Assessed impact of 20 HTA reports commissioned by social insurance system.	<p>Enhancing: HTA reports requested as basis for decision-making.</p>	<p>All 20 HTA reports had impact on decision-making.</p>

**Table 6.1** *cont'd.*

Publication	Objectives	Factors	Results
Hailey, 2004a	Former staff member evaluated impact of products (2002-2003) of Canadian province of Alberta's HTA unit regarding coverage decision; capital funding; referral for treatment; programme operation; guideline formulation; influence on routine practice; indications for further research.	Hindering: spread of products over 4 printed series is confusing and not helpful for dissemination.	1/19 assessed products had no obvious impact. All other were at least considered by decision-makers. Recommendations were accepted in 6 cases; 1 was linked to changes in practice; 6 to other types of impacts.
Hailey, 2004b	Tested simple instrument for assessing impact of HTA reports internationally.		21 HTA agencies reported on impact of 56 (purposefully selected) HTA reports. Only one HTA report had no apparent impact.
Hailey et al. 2000	Authors assessed whether 20 rapid HTAs (Technotes) have influenced policy decision-making in Canadian province of Alberta.	Not assessed	14/20 reports had impact on decisions; 4 reports delivered background information but no direct influence on decisions; 2 reports had no impact.
Hailey, 1993	Author analysed effect of 26 HTAs undertaken by Australian advisory bodies on health-care policy and practice in Australia.	Enhancing: request of assessment by governmental agencies or national bodies; timeliness of data and recommendation; political credibility; acceptance through various publications; assessments of new technologies (before introduction); parallel primary data collection.  Hindering: volatility in policy; personnel changes in assessment agencies; vulnerability of assessment organizations due to uncertain funding.	From 26 assessed HTA reports: major influence on policy and practice (8); direct but limited influence (4); minor or uncertain influence (7); useful but marginal (3); no obvious policy impact (6); inappropriate influence (1).

**Table 6.1** *contd.*

Publication	Objectives	Factors	Results
Harrison, 2005a; Harrison, 2005b	NICE commissioned external consultant to assess felt degree of impact and barriers to implementation of a NICE guidance a) by primary care trusts (PCTs). b) by Human Fertilisation and Embryology Authority (HFEA) clinics.	Enhancing: government pressure; external pressure. Hindering: PCT has competing priorities; lack of guidance on social criteria.	a) 81/88 had read the guideline, all were aware of recommendations. 64/88 responded that guidance had moderate or high impact. All aim at implementing guidance. b) All respondents had read guideline. Agreed to main recommendations. No changes as practice was in accordance before publication of guidance.
Howard, 2004a; Howard, 2004b	NICE requested external consultant to assess knowledge, acceptance and compliance of/with two guidelines among targeted groups of practitioners for: a) devices for guiding CVC placement. b) debinding agents for management of difficult wounds.	Hindering: a) lack of training in use of ultrasound in CVC placement; little or no access to technology necessary to implement guidance; lack of funding; practitioners not sharing recommendations. b) guidance matched existing practice – no need for changes.	a) 150/172 responders had read guideline. Only 4 of remaining 22 were unaware of recommendations. Respondents polarized about recommendations – resulted in low rate of change. Attitude towards recommendations correlated well with stated practice. b) 63/72 responders had read guideline. Remaining 9 were unaware of recommendations. Acceptance high but only minor impact on practice.
Howard & Harrison, 2004	NICE requested external consultants to identify sources to monitor impact of NICE and to measure actual changes in utilization in 28 disease areas.	Hindering: external factors such as agreements with industry.	12/28 "reasonably implemented within the expectations of guidance"; 12 under implemented. Utilization above guidance for 4 reports (2 had large confidence intervals).
Jacob & Battista, 1993	External consultant commissioned to review impacts on decisions and cost of 10 HTAs from Quebec Council on Health Care Technology Assessments (CETS).	Enhancing: reputation of institution (scientific expertise, political independence); reports tailored to local conditions; perceived limitation of resources.	8/10 assessed reports influenced health-care technology decisions. Degree of impact varied. Costs for creating reports estimated to be only 7% of money saved by following recommendations.

**Table 6.1** *cont'd.*

<b>Publication</b>	<b>Objectives</b>	<b>Factors</b>	<b>Results</b>
Jacob & McGregor, 1997	Evaluated impact of 21 reports (16 topics) of the CETS on policy decisions and on costs in 1995.	Enhancing: evaluations commissioned by decision-makers; goal is cost reduction; recommendations in line with other sources. Hindering: technology has low economic relevance.	18/21 reports influenced decisions; 3 had no impact.  Cost-minimization studies created savings between 16 and 27 million Canadian dollars.
McGregor, 2006	Canadian McGill University Hospital created an in-hospital HTA unit. Assessed impact of 18 HTAs.	Enhancing: HTA requested by user; policy advice (appraisal located close to the user); timeliness; user-friendliness. Hindering: concept of quality adjusted life years (QALYs) not understood/accepted by user.	Recommendations of all 18 HTAs completely accepted. Budget impact estimated to be annual saving of about 3.1 million Canadian dollars.
Mitton & Hailey, 1999	Assessed impact of HTA on efficiency of hyperbaric oxygen treatment and question of installing an additional unit in the Canadian province of Alberta.	Not assessed	Adopted recommendation not to install second unit in province of Alberta.
National Cancer Director, 2004	The National Cancer Director analysed variations in usage of 16 cancer drugs between the 34 cancer networks in England following appraisals from NICE.	Reasons for variations in usage: variations in human and logistic resources; variation in preferences of individual physicians; involvement in clinical trials; variations in planning capacities.	Usage of cancer drugs increased generally following positive appraisal from NICE. Variation lessened over time. Variation could not be explained by case-mix or cross boundary flows. Usage correlated between NICE evaluated drugs and with comparators.
NICE NHS 2006a–f (partly overlapping with Walley 2004)	Reports describe national trends on use of technologies associated with recommendations in NICE guidances.	Not assessed	Practice mainly followed recommendations of 6 NICE appraisals.
Rawlings 2002	Assessed impact of NICE-guidance on one drug (trastuzumab) in England.	Hindering: Lack of forward planning for implementation at local level; lack of resources, low awareness of guidance among professionals and patients; no clear lines of responsibility or accountability at local level.	Responding chief executives of local planning authorities confirmed that guidance was implemented locally.

Table 6.1 *cont'd.*

Publication	Objectives	Factors	Results
Shani et al. 2000	Investigated HTA's contribution as a tool to support Ministry of Health's priority setting of health technologies in Israel.	Enhancing: transparent decision-making process; neutral committee with public representatives; perceived scarcity of resources in health services.	70% of recommendations adopted; 30% were discussed.
Sigmund et al. 2004a	Examined impact of national and regional Danish HTAs.	Not mentioned	Considerable but variable impact. National HTA reports had stronger impact than regional.
Smith et al. 1994	Authors analysed influence of 8 selected HTAs on policy and practice in Australia.	Enhancing: relevance of topic; assessments have clear objectives in evaluation; dissatisfaction with current practice. Hindering: highly emotional topic; assessment not timely; only vague idea about assessment objectives.	Influence on: Policy: yes (6); partial (1); not known (1). Practice: yes (2); probably (2); partial (1); doubtful (1); too early to assess (2). Health status: probably (2); possibly (1); not known (3); too early to assess (2).
Stemerding & van Berkel, 2001	Authors analysed and evaluated process of development and implementation of serum screening in Dutch maternity care. Used theoretical framework to describe process of introduction of new technologies in terms of social learning processes.	Hindering: dual-track pattern of promotion (by medical community) and control and regulation of implementation of new technologies (by political decision-makers); timeliness (NHC advice published after 7 years).	NHC advice led to political judgement in which State Secretary for Health, Welfare and Sport rejected NHC recommendations (proposal for national serum screening programme and a pilot study). Resulted in rejection of serum screening as form of population screening. Conversely, medical community understood NHC's advice to be support for broadening practice of serum screening.
Van den Heuvel et al. 1997	Investigated impact of 4 HTAs on health policy and its implementation in the Netherlands.	Enhancing: HTA deals with operational issues, on "how" a technology should be implemented. Hindering: HTA deals with issues of high ethical relevance, on "if" a technology should be implemented; technology introduced before HTA.	2 HTAs had impact on implementation of technologies but not decision; 2 HTAs had no impact.

**Table 6.1** *contd.*

<b>Publication</b>	<b>Objectives</b>	<b>Factors</b>	<b>Results</b>
Van Rossum, 1991	Investigated impact of 3 HTAs on health policy and its implementation in the Netherlands.	<p>Enhancing: inclusion of relevant decision-makers in assessment process.</p> <p>Hindering: specific vested interests of stakeholders; differing perspectives on relative weight of outcome parameters (e.g. QALYs); insufficient consideration of ethical and social aspects.</p>	Recommendations of 1 HTA were followed; recommendations of 2 were not.
Walley, 2004	Author deals with NICE's advice (4 reports) on drugs for treating psychiatric or neurological conditions and the advice's impact on policy decision-making and practice in the United Kingdom.	<p>Enhancing: regulations foresee compulsory implementation of recommendations within certain timeframe; credibility of HTA agency.</p> <p>Hindering: strong lobbying from patients' and commercial interest groups; politically conflicting technologies; lack of transparency in decisions.</p>	In some cases assessment recommendations were reversed in appraisal process, possibly due to political pressure. (Final) results from appraisals were implemented.
Wathen & Dean, 2004	Study focused on attitudes to NICE guidance (5 technical appraisals) and changes in prescribing patterns among general practitioners (GPs) in one area of England.	<p>Enhancing: cost savings; pressure from local pharmaceutical advisers.</p> <p>Hindering: resistance from patients; concerns over deterioration in patients' symptoms; concerns over adverse effects; not convinced of effectiveness; better options than this drug; own practical experiences contradict recommendations; budget impact.</p>	Very moderate increase in prescribing of 4 drugs and 1 complete rejection of NICE guidance. NICE guidance in isolation had little impact on GPs' prescribing patterns.
Wild, 2007	Evaluated impact of HTA reports on the utilization rates of technologies in Austria. HTA's impact was considered in the sense of the enlightenment model.	<p>Enhancing: institutionalization of HTA; HTA's reputation in administration and politics; involvement of health-care providers.</p>	<p>4 HTA reports had impact on utilization rates of technologies evaluated.</p> <p>Enlightenment model: impact on discourses, critical awareness in population, promotion of conditional coverage.</p> <p>Not achieved: HTA as a prerequisite for reimbursement.</p>

## Abbreviations

AETMIS	Agence d'évaluation des technologies et des modes d'intervention en santé
AHFMR	Alberta Heritage Foundation for Medical Research
BPI	British Pharmaceutical Index
CEDIT	Comité d'évaluation et de diffusion des innovations technologiques
CETS	Conseil d'évaluation des technologies de la santé (since 2000 – AETMIS)
CVC	central venous catheter
DACEHTA	Danish Centre for Evaluation and Health Technology Assessment
ECG	electrocardiogram
Finnohta	Finnish Office for Health Technology Assessment
GP	general practitioner
HES	Hospital Episode Statistics
HFEA	Human Fertilisation and Embryology Authority
HPA	Hospital Pharmacy Audit
NHC	National Health Council
NHS	National Health Service
NICE	National Institute for Clinical Excellence
PACT	prescribing analysis and cost
PCA	Prescription Cost Analysis
PCT	primary care trust
SBU	Swedish Council of Technology Assessment in Health Care
S&W DEC	South & West Development and Evaluation Committee

## Chapter 7

# Needs and demands of policy-makers

*Gerardo Atienza Merino, Leonor Varela Lema*

### **Introduction**

Health technology assessment (HTA) has been conceived as a systematic and multidisciplinary analysis of the consequences of the introduction, dissemination and use of health techniques intended to support the decision-making process, by furnishing information of high scientific quality. Hence, HTA has been defined as “the bridge between evidence and policy making” (Battista & Hodge, 1999) and also as “the speciality of assistance to health policymaking” (Jonsson & Banta, 1999).

Evidence-based scientific information produced by researchers can be used by managers and health policy-makers to orient the decision-making process, in turn generating new research needs and financing for these investigations. Such activity has grown (see Chapter 5) but HTA scientific evidence is still not incorporated routinely into the decision-making process.

The gap between the production of scientific evidence and its use to inform the decision-making process has been acknowledged (Gagnon et al. 2006). Many researchers are sceptical about the extent to which scientific evidence is used and many decision-makers are sceptical of the utility of scientific research. Little is known about the expectations of decision-makers regarding HTA information and the constraints that affect utilization. There is no clear idea of the needs of policy-makers that will enable feasible and timely information on a given health policy process, thus (in many situations) researchers produce scientific evidence that cannot always be applied in the process.

The purpose of this chapter is to analyse how decision-making and knowledge-transfer processes take place and to assess policy-makers’ demands and



expectations regarding scientific evidence in general and HTA in particular. We carried out a systematic review of the available literature in order to identify barriers and facilitators to the use of HTA evidence in decision-making and summarized the strategies proposed to improve HTA utilization.

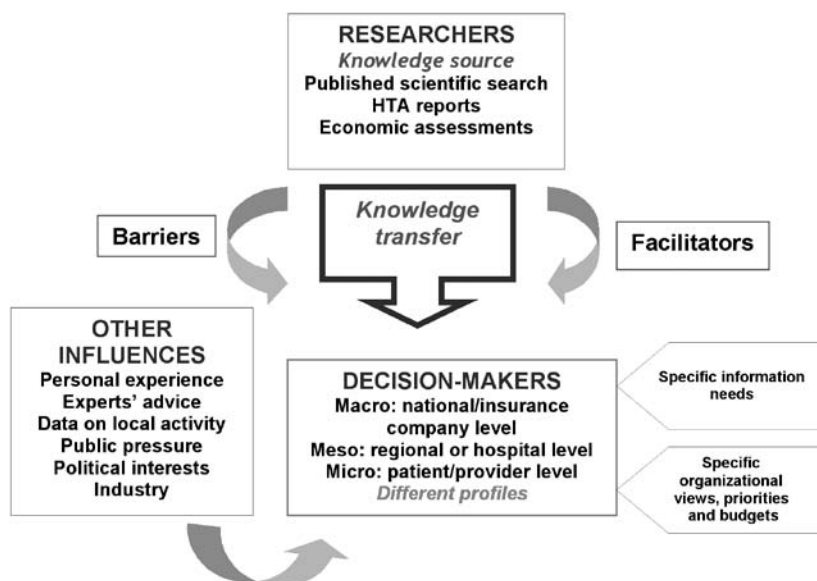
## **Decision-making process**

In any health-care system, the decision-making process is a complex set of interactions among a wide variety of stakeholders. It constitutes an important consequence of the successful use of scientific evidence and the implementation of the recommendations so obtained (OECD Health Project, 2005).

In general, different bodies participate in drawing up health policies. Scopes of action range from the micro- (decisions at patient or provider level) to the meso- (regional health authority or hospital level decisions) and macro-level (decisions at national or insurance company authority level), with different organizational views, priorities and budgets. So, depending on the level of responsibility, decision-makers will have to take account of different inputs from law-makers, politicians, stakeholders and society (for example, beneficiaries and casualties of health policies); the feasibility of particular legal, administrative and financial aspects; and questions of timing, adequacy, consistency, fairness or equity. Attention should be drawn to the potential influence from decision-makers' personal experience as well as the opinions of key stakeholders of the health system (e.g. patients, expert groups, private industry, mass media). In the European context, public pressures may arise from comparisons with neighbour countries that are commonly drawn in public debates – especially concerning decisions on coverage.

Finally, the decision-making process is also conditioned by issues of concern to the majority of countries in the current socioeconomic environment, including financial restraints, population ageing, public and industry pressures and so forth. In the European Union, Member States supranational agreements and legislation related to the delivery of services as well as jurisprudence from European courts may add other factors that must be taken into account, with the potential for generating additional pressures in the decision-making process. Fig. 7.1 provides an illustration of the decision-making process.

Multiple sources of information are available to decision-makers, not only scientific research papers and HTA reports but also personal experiences, advice from clinical experts and data on local activity and economic information (Mitton & Patten, 2004). Researchers' evidence is translated into health policies in several different ways, with distinctions between instrumental, conceptual and symbolic use (Pelz, 1978). Most stakeholders and health policy-

**Fig. 7.1** *Decision-making process*

makers use HTA reports instrumentally – available evidence serves to guide the implementation of services and programmes (Hivon et al. 2005). Nevertheless, knowledge of the factors that exert an influence on the use of evidence by managers and policy-makers, and the effectiveness of proposed interventions to improve such use, have been little developed (Innvaer et al. 2002).

The absence of a methodological procedure that shapes the decision-making process has been seen as a barrier to the efficient implementation of HTA (Oddone-Paolucci et al. 2006). The recommendations of the forum organized by WHO's Regional Office for Europe (2003) reflect that it is essential to clarify the roles of the different participants implicated in the public health decision-making process. Furthermore, priorities for the generation of scientific evidence should be determined by the needs of decision-makers rather than those of the scientific and academic communities.

### **Knowledge-transfer process**

Knowledge transfer has been defined as:

a process by which relevant research information is made available and accessible for practice, planning, and policy-making through interactive engagement with audiences and supported by user-friendly materials and a communications strategy that enhances the credibility of the

organization and, where relevant, reinforces key messages from the research (Program in Policy Decision-Making, 2007).

**Box 7.1** *Knowledge-transfer strategy*

What should be transferred? (the information or the message)

To whom should the research knowledge be transferred? (the audience)

Through or by whom is the information to be delivered? (the messenger)

How is the information transferred? (the mechanism)

What effect has it caused? (the assessment)

*Source:* Lavis et al. 2003

Lavis et al. (2003) proposed an appropriate knowledge-transfer strategy that could be drawn up by answering the questions listed in Box 7.1 and discussed in more detail below.

*What should be transferred?* Researchers must transfer actionable messages to policy-makers, based on scientific evidence and not on a single research paper or the results of a single study. The messages must be clear, convincing and linked to the decisions that policy-makers have to confront.

*To whom should the research knowledge be transferred?* The target audience must be specified. The message must be purpose-designed for the groups at which it is targeted and the contexts in which they live or work. Five possible target audiences can be discerned in the health-care sector: (i) general public; (ii) patients or end-users; (iii) health-care staff; (iv) managers and local health decision-makers; and (v) managers and regional or national health decision-makers.

*Through or by whom is the information to be delivered?* The success of knowledge transfer depends on the credibility of the messenger responsible. For instance, persons linked to academic posts or opinion leaders could meet this criterion.

*How is the information transferred?* The mechanism used to transfer the information must be interactive wherever possible. Accordingly, face-to-face meetings or conventions are useful for health-care staff; managers and public policy-makers prefer briefings or workshops. Lavis proposes four different formats for presenting written information (Lavis et al. 2003):

1. **Headline:** information is summarized in a short, catchy headline.
2. **One-sentence:** to highlight the importance of the scientific evidence or its implication in the decision-making process.

3. One-paragraph: must have four sentences that cover: (i) importance of the topic studied; (ii) scientific evidence on the subject; (iii) differences between what is being done and what could be done if the decision-making process were to be conducted on an informed basis; and (iii) what should be done, and to whom, in order for the change to take effect.
4. Full-text: drafted to cover each and every point raised in version 3 and providing all the references for the statements and conclusions reached.

*What effect has it caused?* The assessment should take account of the designated goals of knowledge transfer that must be specific to the target public to whom the message is addressed. For example, a change in clinical practice would be an appropriate objective for health-care staff. Managers and public policy-makers could be charged with introducing a specific matter into government plans, informing on health policy alternatives or showing another side of a particular topic.

In the transfer of knowledge, attention should be drawn to the relatively recent appearance of knowledge brokers. These are intermediaries tasked with presenting and disseminating health-care research among policy-makers and other stakeholders, in a useful and accessible form. However, knowledge brokering still needs to develop its own methodology and the role of these agents may call for further in-depth assessment (Haines et al. 2004; Van Kammen et al. 2006).

### **Use of HTA in the decision-making process: demands and expectations of health policy decision-makers**

The primary bibliographic search identified two published systematic reviews that examined decision-making in health care. Innvaer et al's systematic review (2002) included 24 studies that reported the results of 2041 interviews carried out with health policy-makers. Lavis et al. (2005) included 7 studies with health-care managers and 10 studies with health-care policy-makers. These reviews had 17 studies in common.

We carried out a more exhaustive search of the main electronic bibliographic databases from 2002 onwards (see Box 7.2). The aim was to identify the additional needs and demands of health policy decision-makers regarding scientific evidence in general (and HTA in particular) and the strategies that would improve their use in the decision-making process.

As a result of this specific systematic search, we included 10 papers that assessed the decision-making process. These had been either published subsequently to, or not included in, the earlier reviews but were nonetheless deemed noteworthy

**Box 7.2** *Methodology of systematic review**Search strategy*

Specific bibliographic search strategies were developed for the following databases for the period from 2002 to December 2006: MEDLINE, EMBASE, ISI Web, The Cochrane Library and the NHS Centre for Reviews and Dissemination. References from included studies and review articles were scanned.

The main terms used in the search strategy were: decision-making, organizational; policy making; health policy; public policy; health services research/\*utilization; technology assessment, biomedical; and evidence-based medicine.

*Selection criteria*

A study was eligible for inclusion if: i) it was an original collection of data; ii) participants included managers or health policy decision-makers; iii) decision-making process had been evaluated by means of surveys and/or interviews; and iv) results included perceived facilitators and/or barriers.

*Data collection and analysis*

Two researchers independently evaluated each citation to determine whether it met the inclusion criteria. Articles that did not meet these criteria were thought to provide useful background information. No papers were excluded on language grounds but all those finally included were written in English.

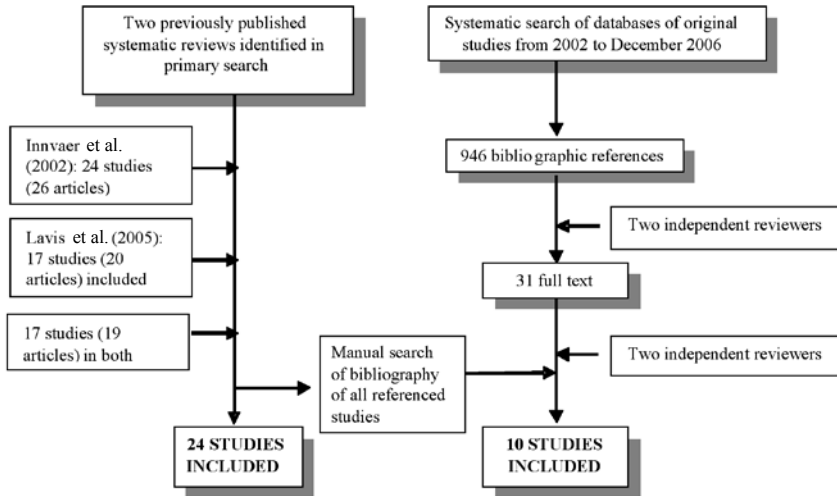
(see Fig. 7.2). The characteristics of all included studies (including year of publication, country, scope and data collection) are summarized in Table 7.1 in the Appendix at the end of this chapter.

**Facilitators and barriers**

Innvaer et al's systematic review (2002) questioned health policy-makers on the use of scientific evidence in health policy decision-making. These authors identified the factors most commonly cited as facilitators of the use of evidence in the decision-making process:

- personal contact between researchers and policy-makers (13);<sup>10</sup>
- timeliness and relevance of research (13);
- inclusion of a summary and clear recommendations (11);
- high-quality research (6);
- research that reaffirmed current health policy or supported policy-makers' own interests (6);

<sup>10</sup> Number of studies reporting the factor out of the 24 included in the paper by Innvaer et al. (2002).

**Fig. 7.2** Selection of studies for systematic review

- social pressure or demand for research by end-users (4); and
- research that included effectiveness data (3).

In contrast, the most commonly cited barriers were:

- absence of personal contact between researchers and policy-makers (11);
- research that lacked timeliness and/or relevance (9);
- mutual distrust, including researchers' perception of ingenuousness in health policy and policy-makers' perception of scientific ingenuousness (8);
- existence of power and budget struggles between researchers and policy-makers (7);
- low-quality research (6); and
- political instability or high turnover among policy-making staff (5).

Lavis et al's (2005) systematic review included studies based on interviews, surveys and case studies undertaken with health-care managers and policy-makers. In addition, they conducted their own interviews and reviewed web pages in which managers and policy-makers were their target of choice. These authors reported that the following factors exerted the most positive influence to encourage policy-makers to use research:

- interaction between researchers and health-care policy-makers (6)<sup>11</sup>
- timing and timeliness of research (4)

<sup>11</sup> Number of studies reporting the factor out of total of 17 included in the paper from Lavis et al. (2005).

- trust in researchers (3)
- involvement of health-care staff in the research process (3)
- creation of policy networks or structured mechanisms in which researchers and policy-makers worked together (2).

Lavis et al. (2005) reported the barriers to an informed decision-making process to be:

- policy-makers' negative attitudes towards scientific evidence (3);
- lack of skills and expertise among administrators and decision-makers (3);
- lack of support from management and front-line staff (3);
- lack of perception of the relevance of the research, use of technical vocabulary or scientific jargon (2); and
- publication for an exclusively research-oriented or academic audience (2).

In chronological order, Dobbins et al. (2001) was the first of the 10 papers not included in the above reviews. They performed a cross-sectional follow-up study of public health decision-makers in Ontario (Canada) to ascertain the degree of influence exerted on the decision-making process by five systematic reviews. They observed that the position of the policy-maker was the best predictor of the use of such kinds of research summary: programme managers and directors were the most important audience. Other influential factors were expectations of the review's future use, along with the perception that the review was simple to use and that there were sufficient skills to assess it. Dobbins et al. (2004) also conducted an assessment of systematic reviews by means of a telephone survey of health policy-makers in Ontario. They observed that most rated the executive summary as the most important part of the review for the purposes of health policy decision-making. Accordingly, the authors consider it extremely important that summaries are drafted with great care to ensure that the key research messages and their implications for health policy and practice are included and presented in a succinct, readily readable and easily understandable manner.

Sorian and Baugh (2002) conducted a telephone survey of a total of 292 American health policy-makers in order to study the different (formal and informal) methods of acquiring information about health policy. Participants agreed that the large amount of health information that they usually received and the limited time available to read it resulted in an extremely selective reading-habit (only 27% of the material received read in detail; 53% scanned superficially). Timeliness was the main incentive for reading information. Disincentives arose

when reports were perceived to be of little relevance; excessively long; used abundant technical jargon; or were excessively theoretical and prone to biases. Information presented succinctly, in a readily readable and easily understood form, was rated very positively. Moreover, the format of the information was important for decisions about whether or not to read a document – short, bulleted paragraphs were preferred to large blocks of type and the incorporation of figures or charts to illustrate key points was viewed as extremely helpful. Lastly, trust in the source of evidence was also a key consideration.

In England, Weatherly et al. (2002) examined the use of scientific evidence in local health policies developed through Health Improvement Programmes. They circulated a questionnaire to the 102 individuals responsible for coordinating these programmes and also conducted a series of semistructured interviews. They observed several barriers to the use of scientific research: lack of time and resources at the local level for interpreting the evidence; lack of availability; existence of excessive information; difficulty in synthesizing the information; and impossibility of adopting the proposals.

Mitton and Patten (2004) undertook a participatory action-research project in the Calgary Health Region in Canada. This included interviews and focus groups with health policy-makers both before and after the drawing-up and implementation of a health programme. The first barrier detected was the need for a cultural change among policy-makers in order to be able to introduce scientific evidence in the decision-making process. Other barriers were: lack of time; lack of support structures or adequate skills to make use of the evidence within the decision-making process; and the difficulty of applying the evidence in the local context.

In 2004, the Pan American Health Organization (PAHO, 2005) carried out a study focusing on the relationship between research results and the decision-making process in the health field, as well as the gap between knowledge and practical application. PAHO researchers identified a central group of health policy-makers in each country and conducted a series of interviews and surveys, with the following conclusions.

- Policy-makers need “more research that reports in a condensed and integrated manner”. There is an excessive flow of health information – a range of sources on any given topic and a diversity of results on any given problem. Yet, information is sparse on other areas.
- Information must have a multidisciplinary approach and be evidence-based, bearing in mind that policy-makers are a target group for scientific evidence.



- It is essential that research results be transformed into useful information for daily practice, i.e. information for policy-makers must be “a practical tool”, adapted to the decision-making level (national, regional or local).
- Time is a critical factor for health policy-makers. This requires summarized publication formats, figures and readily readable content.

Hivon et al. (2005) conducted a study to examine how HTA reports were used and identify existing limitations on accessing and using scientific knowledge. They held a series of semistructured interviews with health-care staff, health administrators and patients’ associations in various regions of Canada. Limitations on the use of HTA were classified as: organizational, i.e. attributable to work structure and organization; scientific, i.e. due to the scientific level of the end-user, to materials; or linked to the lack of material, financial or human resources. Within the organizational limitations – and focusing on the interviews conducted with health administrators – the authors emphasize that the use of HTA may be limited by the absence of long-term planning or the personal interests of policy-makers. In addition, the paucity of internal communication is perceived as a limitation on the circulation and use of information within the organizations. For the scientific limitations, they stress the lack of managers with the skills to comprehend scientific evidence. Material limitations such as lack of time and lack of financial, material and human resources are important barriers to integrating HTA in routine decision-making.

Aaserud et al. (2005) carried out a study to examine which factors are perceived as barriers to the use of research in the decision-making process in developing countries. Their results highlight the importance of interaction among researchers, policy-makers and other stakeholders. The authors consider that individual level interactions are useful but the most effective are observatories that are created to bring together the producers and end-users of research. For example, WHO’s Evidence-Informed Policy Networks (EVIPNet) (Hamid et al. 2005) is intended to strengthen ties between research and the decision-making process in countries with low to medium income levels.

Gagnon et al. (2006) used a series of interviews with physicians and other stakeholders in a study undertaken in Catalonia, Spain. They observed that the involvement of end-users and local adaptation of recommendations are important facilitators for the use of HTA in the decision-making process.

Lastly, Sarriá Santamera et al. (2006) undertook a study based on a series of interviews with the 13 members of the American Evidence-based Practice Center (EPC). They aimed to identify the characteristics of its reports that fostered their consideration in the decision-making process. Set up by the Agency for Healthcare Research and Quality (AHRQ), the EPC’s stated aim is

to draw up and disseminate evidence-based information among health policy-makers. The authors concluded that an assessment report should be deemed a success only when it is used in the decision-making process. This is achieved when it is both excellent (meeting the academic standards) and useful (meeting the needs of health policy-makers). The existence of a productive interaction between analysts and policy-makers (i.e. between science and health policy) is also a key factor.

Box 7.3 and Box 7.4 summarize the most important facilitators and barriers enumerated in the primary and secondary (systematic reviews) research included in this review.

The gap observed between the production of scientific evidence and its use in the decision-making process has been attributed to the existence of important differences in the characteristics of scientists and policy-makers, including different mentalities and goals, attitudes toward information, languages or distinct perceptions of time. Innvaer et al. (2002) postulated the theory of the existence of “two communities” – one comprising researchers, the other composed of health-care managers or policy-makers – each with opposite perceptions of both themselves and the other group. According to this theory, scientists see themselves as rational, objective people who are open to new ideas. They view policy-makers as individuals who are action orientated and yet indifferent to scientific evidence and innovations. For their part, policy-makers see themselves as responsible, pragmatic persons while researchers are naïve, removed from practical reality and immersed in their own jargon.

The results of Innvaer et al’s systematic review support the existence of these two separated communities. The most commonly identified facilitator for the use of scientific evidence was personal contact between researchers and decision-makers. The principal barriers were lack of contact and the existence of mutual distrust between them. However, Innvaer’s systematic review fails to clarify what type of research policy-makers use. It is conceivable that they use only the research that supports their own ideology or health policy programme.

Two-way communication between these two groups would enhance responses to health policy issues. Usually, research is not the sole determinant of a clinical decision or health policy and therefore decisions about specific patients should combine scientific evidence with information on their clinical condition and preferences. Health policy decisions need to consider resources and costs in addition to the evidence on effectiveness. Furthermore, scientific evidence influences the decision-making process in accordance with available evidence, the number of competing considerations and the culture and context of the decision-makers (Clancy & Cronin, 2005). Innvaer et al. (2002) considered that

**Box 7.3** *Facilitators of the use of research evidence in policy-making*

*Researchers and policy-makers*

- Personal contact and interaction among researchers, policy-makers and other stakeholders.
- Trust in researchers.
- Greater involvement of managers, decision-makers and health-care staff in the research process.
- Creation of policy networks.

*Scientific evidence*

- Timing, timeliness and relevance of research.
- High-quality research and trust in the source of evidence.
- Research that reaffirms existing policy or supports the interests of policy-makers.
- Social pressure or demand for research by end-users.
- Expectations of future use.
- Policy-makers' perception that the review is easily understandable and that they have sufficient skills to assess it.
- Recommendations adaptable to the local context.

*Research presentation format*

- Existence of executive summary and clear recommendations.
- Inclusion of effectiveness data.
- Use of short, bulleted paragraphs and incorporation of figures or charts to illustrate key points.

the aim of two-way communication would be to ensure that research afforded adequate support to policy-makers in the decision-making process and not that researchers assumed the role of policy-makers.

In something akin to parody, Choi et al. (2005) also characterize the two communities. They liken the principal function of managers and health policy-makers to putting out fires as they are interested solely in solutions that are applicable to a wide variety of problems and in reading “bullet points”. For their part, scientists are assumed to speak a private language that requires translation in order to be understood by persons without a scientific background or even

**Box 7.4** *Barriers to the use of research evidence in policy-making**Researchers and policy-makers*

- Lack of personal contact.
- Mutual distrust.
- Researchers' perception of ingenuousness in health policy and policy-makers' perception of scientific ingenuousness.
- Power and budget struggles between researchers and policy-makers.
- Instability or frequent changes among health policy-makers.
- Negative attitude towards scientific evidence among policy-makers.
- Policy-makers who lack the tools and skills to interpret scientific evidence.
- Lack of support for management and front-line staff.
- Lack of time and human, material and financial resources.
- Difficulty of applying evidence in the local context.

*Scientific evidence*

- Absence of timeliness and relevance of research.
- Low-quality research and reports that are biased or not objective.
- No perception of relevance of research.

*Research presentation format*

- Reports overly long, theoretical or abounding in technical jargon.
- Publication of research exclusively for an academic audience.
- Absence of availability of information.

by scientists in other fields. These authors suggest solutions such as: providing new incentives to encourage scientists and policy-makers to work together; using knowledge brokers (translational scientists); making organizational changes; defining research in a broader sense; redefining the starting point for knowledge transfer; expanding accountability; and, finally, acknowledging the complexity of policy-making.

## Strategies and proposals for improvement

The systematic reviews and papers included in this review identify a number of issues relevant to the utilization of scientific research knowledge in the decision-making process. For example, barriers to the implementation, timeliness or transfer of results to target groups, or the credibility of the messenger and the message. Yet, ongoing dialogue between researchers and policy-makers emerges as one of the key factors. The question is how to promote appropriate collaboration between scientists and policy-makers, i.e. how to favour the facilitators while eliminating (or at least diminishing) existing barriers. The solutions may well go far beyond simply establishing personal contact between scientists and policy-makers or requesting the former to produce timely and relevant assessments.

A new, more deliberative, appropriate and cooperative way of working together must be developed by bridging the gap between researchers and policy-makers. According to the findings of the evidence reviewed, a series of actions that target either or both communities simultaneously can be recommended in order to overcome the barriers and obstacles identified and to foster a better use of research results in the decision-making process.

### Actions for researchers and policy-makers

- Improve collaboration and ensure close, personal, two-way communication.
- Consolidate mutual trust.

### Actions for researchers

- Promote research which includes results on effectiveness (identifying not only the benefits but also any expected risks and costs of the technology assessed) and highlights the uncertainty of the estimates.
- Foster the synthesis of research results and their integration with information of real usefulness to health policy-makers. Translate this to the local context as far as possible.
- Incorporate the views of research policy-makers, ensure that research is perceived as timely and of high quality and advocate for it to be relevant to health policy and the demands of the public.
- Include representatives of the various health-system stakeholders in the drawing-up of recommendations in order to enhance their acceptability.
- Avoid becoming embroiled in power and budget struggles and be aware of the high turnover of managers and health policy-makers.

- Take policy-makers into account in the format, presentation and dissemination of scientific evidence by introducing take-home messages, brief summaries of the research, graphic communication and clear health-policy recommendations.
- Enhance accessibility to the formats outlined above, and systematic full-text reviews, via quality electronic databases in which health-care managers and policy-makers can search for information by using key words.

#### Actions for policy-makers

- Instigate cultural change and acquire the necessary training and skills in order to introduce scientific evidence into the decision-making process.
- Health-care managers and policy-makers should have greater involvement in systematic reviews and be furnished with adequate support to enable health-care staff to participate in these. This would increase the acceptability of the assessment reports and improve their impact.
- Health managers and policy-makers should make regular assessments of the availability of scientific evidence an integral part of the development of public health policy.
- Create health policy networks or observatories that promote the joint efforts of researchers and health-care managers.

### Conclusions

The findings of this systematic review reaffirm the existence of a gap between researchers and decision-makers. The review also identifies several strategies for improving the transfer of knowledge and communication between these two communities. There appears to be higher probability that decision-makers will use scientific evidence when it is of high quality; deals with questions that they consider relevant; and involves them in the generating process – from the formulation of questions to the presentation of results.

Most of the research in this field has been carried out in north America. Research on the factors that enhance or limit the use of scientific information (such as HTA) to inform public policy-making among European decision-makers is sparse and involves only a few countries of western Europe. Although it is likely that decision-makers' pressures and constraints are similar in countries with comparable socioeconomic situations, it is well-known that decision-making environments are context sensitive.

In November 2004, country delegations at the Ministerial Summit on Health Research in Mexico City backed calls to establish mechanisms to support the use of research evidence in policy and practice; as did the World Health Assembly in May 2005. Thus, there is a need for research to elucidate whether there are specific barriers and/or facilitators for the transfer of scientific knowledge to decision-makers in the European context and in general around the world. A research-based framework and more research would help the policy-HTA-policy loop to work better. Further European Union projects could focus on this topic and support direct country assessments (including country maps of decision-making bodies, description of the processes, identification and interviews of policy-makers, identification of best practice examples for the transfer of information between the two communities).

In summary, there is a need for ongoing dialogue between researchers and policy-makers in order to consolidate mutual trust. This will improve the use of scientific evidence in the decision-making process.

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**Table 7.1** *Included studies – needs and demands*

<b>Authors</b>	<b>Year<sup>1</sup></b>	<b>Country</b>	<b>Scope</b>	<b>Data collection</b>
Aaserud et al. 2005.	2005*	Norway	RCT collaborators and WHO drug information officers, regulatory officials and obstetricians in 12 low and lower-middle income countries.	Survey, group interview and observations.
Boyer & Langbein, 1991.	1991*	USA	Congress members and their staff.	Structured telephone interviews.
Burns et al. 2000.	1999	UK and USA	Non-medical health authority purchasers, public health physicians, GPs, public officials from 11 USA states, private sector purchasers and consultants.	Semistructured telephone interviews.
Caplan, Morrison & Stambaugh, 1975; Caplan N, 1977.	1973–1974	USA	Upper-level decision-makers in the exclusive branch of the US federal government.	Personal interviews, open-ended and structured.
Dobbins, Cockerill & Barnsley, 2001.	2001*	Canada	Medical and associate medical officers of health, programme directors and programme managers who were responsible for making decisions about public health practice in Ontario.	Telephone surveys and self-administered questionnaires.
Dobbins et al. 2004.	2004*	Canada	Programme managers, directors, epidemiologists, medical officers of health, provincial consultants and local board of health members from five technical review groups to update the Mandatory Programs and Services Guidelines.	Telephone surveys.
Eyles et al. 2000.	1998–1999	Canada	Key informants holding different positions within the five health regions, Department of Social Services and various sectors. All regions, all sectors and management levels.	Semistructured and open-ended interviews and focus groups.
Florio & DeMartini, 1993.	1990	USA	Local planning committees and government employees in two rural communities in Pacific Northwest.	Personal, semistructured interviews.

Table 7.1 *contd*

Authors	Year <sup>i</sup>	Country	Scope	Data collection
Gagnon, Sanchez & Pons, 2006.	2006*	Spain	Head of service or department of each speciality (endocrinology, ophthalmology and orthopaedic surgery) and key informants representing decision-makers, professional associations and hospital administrators.	In-depth semistructured interviews.
Gerhardus, Kielmann & Sanou, 2000.	1999	Burkina Faso	Ministry of Health officials.	Semistructured interviews.
Glaser & Taylor, 1973.	1967–1968	USA	Principal investigators, other staff members, administrators and persons most likely to be utilizers.	Personal interviews.
Harries, Elliott & Higgins, 1999; Elliott & Popay, 2000.	1994–1995	UK	Lead policy-makers, GPs and researchers in nine different case studies at local level in the NHS.	In-depth interviews.
Hilderbrand, Simon & Hyder, 2000.	1998	Pakistan	Decision-makers from government, central Ministry of Health, planning commission and provincial health authorities.	Open-ended in-depth interviews.
Hivon et al. 2005.	2001–2002	Canada	High-level representatives of the three different viewpoints (administrators, health-care providers and patients) from each jurisdiction of the six Canadian HTA agencies.	Face-to-face or telephone interviews.
Ibbotson et al. 1993.	1991	UK	District general managers, directors of public health and directors of planning/commissioning in UK district health authorities or commissioning consortia.	Structured and open-ended postal questionnaires.
Lavis, Farrant & Stoddard, 2001.	2000	Canada	Policy-makers in health and employment sectors of all three levels of Canadian government and executive directors of ten Canadian non-governmental organizations.	Structured, semistructured and open-ended telephone interviews.

Table 7.1 *cont'd*

Authors	Year <sup>1</sup>	Country	Scope	Data collection
Lavis, Farrant & Stoddard, 2001.	2000	Canada	Policy-makers in health and employment sectors of all three levels of Canadian government and executive directors of ten Canadian non-governmental organizations.	Structured, semistructured and open-ended telephone interviews.
Lavis et al. 2002.	2000	Canada	Key informants of policies under study in two Canadian provinces, directors of research units.	Face-to-face semistructured interviews and surveys.
McNeece, DiNitto & Johnson, 1983.	1983*	USA	Directors in community mental health centres in Florida and North Carolina.	Structured and open-ended postal questionnaires.
Mitton & Patten, 2004.	2004*	Canada	Senior decision-makers (managers and clinicians) in a single health authority in Alberta.	In-depth interviews and focus groups.
Moodley & Jacobs, 2000.	2000	South Africa	Key informants in relevant roles.	Semistructured interviews.
Oh, 1997; Oh & Rich, 1996.	1996*	USA	Federal, state and local policy-makers at different levels dealing with finance and services.	Structured interviews.
PAHO, 2005.	2004	Different countries of the Americas	Members of the Executive Committee of PAHO, health managers and health policy consultants of ten American countries.	In-depth interviews, questionnaires and surveys.
Patton et al. 1977.	1977*	USA	Three key informants from each of the 20 studies: a project officer, the decision-maker (government level) and the evaluator.	Open-ended interviews.
Ross, 1995.	1995*	Australia	Seniors managers in Federal Department of Health, Housing and Community Services.	Open-ended and structured interviews.
Rudat, 1998.	1998*	UK	Health authorities.	Telephone interviews.

Table 7.1 *cont'd*

Authors	Year <sup>1</sup>	Country	Scope	Data collection
Sairiá Santamera et al. 2006.		USA	Research centre directors and project managers of the Evidence-based Practice Center network, Agency for Healthcare Research and Quality staff and representatives from partner organizations, both governmental entities and scientific organizations.	Semistructured interviews.
Sorian & Baugh, 2002.	2000–2001	USA	State-based health policy-makers randomly selected from all 50 states.	Telephone surveys.
Soumerai et al. 1997.	1993–1994	USA	Medicaid drug programme administrators, directors or policy analysts, pharmacy consultants and legislators.	Questionnaires, open-ended telephone interviews and semistructured telephone interviews.
Sunesson & Nilsson, 1988.	1984–1985	Sweden	Social workers, management directors, local and national politicians in 15 Swedish cities and communes.	Interviews.
Trostle, Bronfman & Langer, 1999.	1994–1995	Mexico	Researchers and policy-makers from different institutions and levels of responsibility.	Open-ended interviews.
van de Vall & Bolas, 1982.	1969–1971	Netherlands	Researchers and policy-makers responsible for incorporating research results.	Semistructured surveys.
Weatherly, Drummond & Smith, 2002.	2002*	UK	Lead responsible for coordinating development of Health Improvement Programmes in each of the 102 health authorities in England.	Mail questionnaires and semistructured telephone surveys.
Weiss & Bucuvalas, 1980.	1980	USA	Federal, state and local official decision-makers in upper-level positions.	Personal interviews, both open-ended and structured.
Weiss, 1993.	1982	USA	Experienced public and private sector managers.	Structured, semistructured and open-ended questionnaires combined with a controlled experiment.

<sup>1</sup>: Year conducted or published\*



## Chapter 8

# Future challenges for HTA in Europe

*John-Arne Røttingen, Ansgar Gerhardus, Marcial Velasco Garrido*

### Introduction

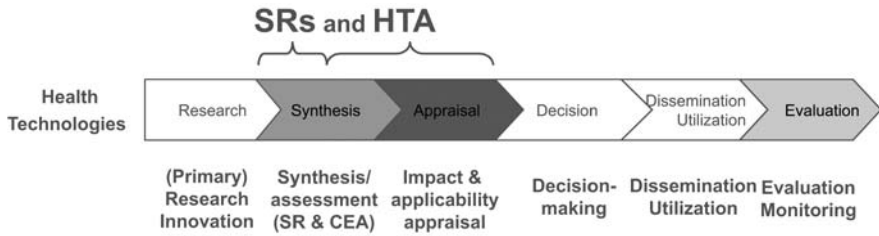
The health sector plays an important part in the economy and constitutes almost 10% of the gross national product in many European countries. It has an even higher political profile – through its role and value in society and, especially, its impact on the public's perception of the success or failure of government. Health policy-making is therefore challenging, needing to balance different interests and make the best use of the available resources.

Modern health care is largely based on knowledge developed gradually within the sector. Over the last 50 years knowledge generated by findings from scientific research has played an increasing role in defining what health care is and should be. Consequently, knowledge management is one of the key aspects of health-care management. Often, this is defined as the explicit and systematic management of vital knowledge and its associated processes of creation, organization, diffusion, use and exploitation (Skyrme, 2001). These processes of managing knowledge constitute an important value chain in the health sector (see Fig. 8.1).

Health technology assessment (HTA) is a tool for knowledge management and therefore also a tool for those who develop policies and other decision-makers. HTA is defined and explained thoroughly in Chapter 3. It comprises two main elements. The first synthesizes and assesses research evidence (particularly from clinical epidemiology and health economics). This often includes a systematic review of research on effectiveness and often also a health economic evaluation of the cost effectiveness (CEA) of the technology in question. The second element integrates this with other knowledge (often through deliberative mechanisms)



**Fig. 8.1** Knowledge value chain in the health sector



including evidence from social sciences, professional experience and values (the appraisal process). As described in Chapter 4, in some countries the appraisal process also includes the formal decision-making. However, it is not generally an integral part of HTA.

Most HTA is a tool for critically evaluating, synthesizing and presenting knowledge. It is about collecting information rather than reaching a decision. Decision-making should build on an HTA report but not be driven directly by the assessment itself. Decisions about health technologies are often related to whether or not a technology should be used and, if so, how it should be utilized in the system. However, the complete value chain is fulfilled only if the implementation of the technology is rigorously monitored and evaluated.

Chapter 6 presents a model that analyses the impact of HTA in the health system (see Fig. 6.1). It comprises six levels:

1. awareness
2. acceptability
3. policy process
4. policy decision
5. practice
6. outcomes.

Levels 1 and 2 are very much related to the strategies for disseminating the HTA reports, their technical quality and how they are made. Levels 3 and 4 relate to how the HTA reports are used in policy-making. Levels 5 and 6 address how the policy decisions, or possibly the HTA reports themselves, lead to better clinical decisions and practices and whether this improves patient outcomes.

In this chapter we build on the knowledge value chain model and the impact assessment framework to address the following questions.

- Do the HTA community and its organizations deliver what they promise?
- What kind of decisions are, and should be, based on HTAs?

- How does the HTA community deliver when assessed within a quality framework?

We discuss the challenges raised by these questions with the aim of identifying how HTA agencies in Europe may collaborate to tackle them. Finally, we describe how HTA may be integrated with other efforts to support and improve the quality of a health system.

### **Is HTA what it claims to be?**

Although it may be defined in several ways, the HTA community seems to have reached a common understanding of what it is and what it should be. The following questions are useful for assessing whether HTA is what it claims to be.

- What kind of methods and approaches are being used?
- What types of technologies are being assessed?

We present some findings from research that has analysed HTA reports by addressing these two questions and contrast them with definitions of HTA and health technology. We emphasize that this is based on specific ideas reflected in the definition of HTA rather than other approaches for synthesizing research evidence.

The International Network of Agencies for Health Technology Assessment (INAHTA) defines HTA as a: “multidisciplinary field of policy analysis that studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology”. Is this multidisciplinary nature reflected in the HTA reports? For example, do they include social, organizational and ethical issues? The answers are largely negative. An analysis of 188 HTA reports produced by 6 Canadian agencies between 1995 and 2001 shows that only 17% addressed ethical and/or social issues (Lehoux et al. 2004). A review of 433 HTA reports published between 1989 and 2002 from 11 agencies in 9 different countries reached a similar conclusion (Draborg et al. 2005). The reports addressed effectiveness (95%), cost effectiveness (53%) and acceptability issues for patients and organizations (25%-27%). A more recent report found a somewhat more positive result when assessing 382 full HTA reports published by 41 INAHTA member agencies between 2000 and 2005 (Lee & Sinding, 2007). Among these, 38% included organizational and/or patient-related issues.

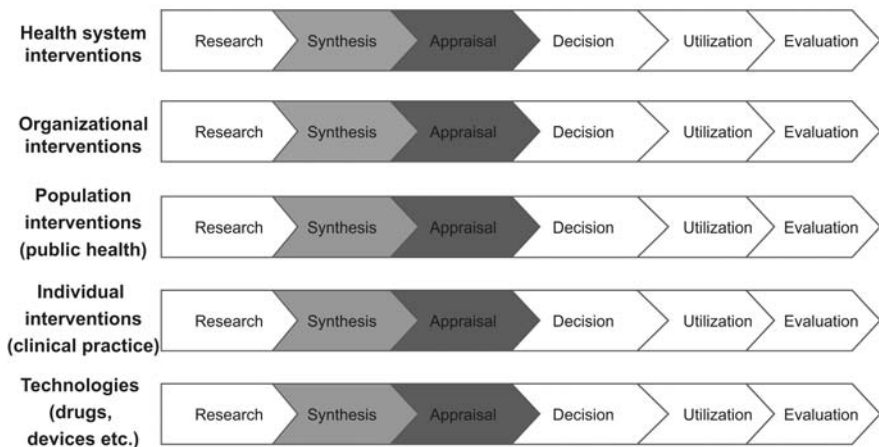
A recent survey of 223 HTA reports published by 9 different agencies – Canada (5), United Kingdom (2), Denmark (1), USA (1) – in 2003–2006 also reached

disappointing conclusions (Lavis et al. 2007). Approximately 50% of the HTA reports were only systematic reviews of effectiveness; another 40% were a combination of a systematic review and an economic evaluation. Only 5% were true, full HTA reports addressing organizational, social and ethical issues. In conclusion, most HTA reports seem only to include scientific evidence on effectiveness and cost effectiveness. They seldom include the scientific or colloquial evidence necessary for the assessments of sociopolitical factors that are essential for the appraisal process. In other words, most so-called HTA reports are pure systematic reviews and CEAs rather than full HTA reports. Thus, there remains a gap between what HTA actually is and what the HTA community claims it to be.

In order to examine the use of HTA it is necessary to define the technologies that are being investigated. The INAHTA defines health technology as: “prevention and rehabilitation, vaccines, pharmaceuticals and devices, medical and surgical procedures, and the systems within which health is protected and maintained”. Thus, single technologies such as drugs, diagnostics and devices; individual clinical interventions (both prevention and treatment) including procedures; public health related population-based interventions; organizational interventions related to delivery of care; and health systems’ interventions on governance and financial mechanisms should be subjected to HTA (Fig. 8.2). However, this is ambitious and may not yet be the reality.

A recent review of 433 HTA reports from 5 countries found that the majority focus on the assessment of clinical technologies or interventions (Draborg et al. 2005). Another survey analysed 223 HTA reports from 5 countries. This found the subjects to be clinical topics (75%), public health interventions

**Fig. 8.2** Different levels of health-care technologies/interventions



(5%), delivery arrangements (of clinical interventions) (15%) and governance or financial arrangements (only 5%) (Lavis et al. 2007). The overall picture is that HTA first and foremost covers health technology in its narrowest sense, rather than the broader meaning contained within the INAHTA definition. This confirms our earlier assertion that there is a gap between the actual focus of HTA reports and what the HTA community wishes them to address.

If Fig. 8.2 is viewed as a two-dimensional model then the HTA community mostly occupies the lower left. If its ambitions are to be met then it must expand both horizontally (to the right) and vertically (upwards). If HTA is to be something more than systematic reviews and CEAs then the inclusion of sociopolitical issues is a prerequisite for horizontal expansion and will also increase policy relevance. However, it must be reflected in the method tool box and methodologies used and in the competence and experience of the researchers involved. Policy analysis involves skills and mindsets other than clinical epidemiology and health economics.

Vertical expansion, especially to the two upper levels, is another matter. This requires consideration of research designs other than those that are typically used to assess clinical effectiveness (controlled trials). Traditionally, this is the domain of those concerned with health services and health policy and systems rather than clinical and epidemiological researchers. However, the rigorous and transparent way of synthesizing research evidence within the framework of systematic reviews or HTAs should clearly be striven for and implemented for such questions. It is debatable whether such efforts should be labelled HTA – the term may alienate health services and systems researchers. It may be that a stronger emphasis on *policy analysis* of clinical technologies in HTA may provide opportunities for increased use of systematic research syntheses in *analyses of policies* (different policy options) and a common term such as evidence or knowledge synthesis may be more pragmatic.

## **HTA and decision-making**

HTA is a tool and a resource for informed decision-making. The impact assessment framework (Chapter 6) suggests that HTA must be followed by a policy process in order to produce an impact on health service processes and patient outcomes. But what kinds of policy processes are needed? Is it reasonable to bypass these processes?

Given that most HTA reports address clinical interventions, we focus on policy decisions related to health programmes, services or technologies, i.e. which interventions to allow, fund, cover, provide or use. We do not address decisions on how to deliver, manage, finance and govern health care. Health policy-

making is often used as a term to cover all of these issues. However, we refer to these in *sensu stricto* and apply the term clinical policy to the former and health policy to the latter.

Clinical policy-making has different instruments and can be carried out at different levels in the health system, i.e. macro- (international, national or regional), meso- (institutional) and micro- (clinical) levels. Chapter 4 describes in more detail how HTA is linked to different decision-making processes in Europe. We discuss the different instruments for clinical policy-making to emphasize how HTA may feed into those processes where it is currently little used. We have identified the following clinical policy-making instruments at the macro level.

- Regulation: i.e. market approval/licensing process, formal and legally based permission to use a technology.
- Reimbursement/coverage: i.e. decision whether to fund a technology.
- Guidance: i.e. recommendation on whether or not to use a technology.
- Guidelines: i.e. descriptions of the best options for diagnosing and treating a condition.

### Regulation

Drugs and devices are regulated at the European level. The clinical efficacy and safety of drugs are assessed but devices are evaluated only in terms of their technical qualities. Neither clinical interventions and procedures nor diagnostic technologies (except when considered a device) are regulated. HTA is not used at all in any of the regulatory processes. The drug regulatory approval process includes a comprehensive and systematic assessment but this can be considered only a partial or rudimentary HTA due to its limited focus on safety and efficacy. Also, as it is not made publicly available it does not adhere to the transparency criterion adopted by most HTA agencies. It should not necessarily be an aim to include HTA in the regulatory processes if one of the other clinical policy instruments is used, based on HTA.

### Reimbursement

Health policy within Europe is a national responsibility. Decisions on reimbursement are made at national or subnational (regional) level or confined to the population covered by the relevant insurance scheme. The use of HTA in these processes varies substantially. Several countries have HTA-like processes for drug reimbursement issues but these are seldom carried out by HTA agencies

(Hutton et al. 2006). Many countries would most likely benefit from stronger internal and intercountry coordination in order to align HTA processes, as discussed in greater detail below.

### Guidance

England and Wales have set up a system in which national legally binding recommendations are issued on the use of single technologies. The National Institute for Health and Clinical Excellence (NICE) holds this authority and builds its guidance on HTA reports from a set of coordinated academic centres. However, these reports are not full HTAs since they generally cover clinical and cost effectiveness. The appraisal part of the process is integrated in the decision-making process. In contrast to most reimbursement systems, these binding recommendations create a challenge since the organizations that are responsible for paying for the technologies do not formulate the guidance.

### Guidelines

National or professional clinical practice guidelines are useful tools for improving and assuring the quality of clinical practice. In most settings clinical guideline processes do not normally build on full HTA reports. However, the assessment of research evidence overlaps substantially on both methods and approaches, e.g. based on systematic reviews and inclusion of clinical expertise. This warrants better collaboration and coordination. Guidelines are useful because (in contrast to HTA reports) they must make a recommendation for clinical action, even on questions for which there is little, no or even conflicting evidence.

Investment decisions and decisions about local use of technologies are taken at the meso- and micro level. Although it is often not practicable to conduct a full HTA, it can be beneficial to carry out mini-HTA processes or utilize existing HTAs, systematic reviews or CEAs. This is increasing and some mini-HTAs also include locally relevant assessments of organizational, professional and/or legal issues.

We have described how HTA may be used in clinical policy-making. Our second question is whether full HTAs should be used directly to inform clinical decisions for individual patients, i.e. whether it is reasonable to bypass the policy process and consider HTA reports mainly as an information source for clinicians. Both the United Kingdom and Sweden produce HTA reports partly with this aim in mind. Sweden has a long and solid track record for HTA and reports often cover broad topics such as diagnostic methods and various treatments of a condition. In these cases there may be little difference between

an HTA and a clinical guideline on the same disease. In other settings HTA reports include recommendations for clinical practice and are thus more like guidelines.

Nevertheless, we still conclude that full HTA reports should not be made with the primary aim of informing clinical decisions directly. Their format does not seem appropriate for bringing information to clinicians. HTA reports should rather be used for making the clinical policies that inform clinical decisions. If the appraisal segment is conducted appropriately and includes clinical expertise it should be viable to build on the HTA to make funding decisions, recommendations or guidelines that are all rooted in best evidence and in a deliberative process that includes the major interest groups. It may be a waste of resources and opportunities to make the fairly large investments necessary to perform HTA without ensuring that it is reflected in policy-making. Clinical decisions should be made by clinicians within the paradigm of evidence-based practice/medicine (EBP/EBM), by utilizing systematic reviews and HTA reports and by recognizing and utilizing clinical policies and their different instruments.

We conclude that HTA is a tool for clinical policy-making rather than clinical decision-making. As reported elsewhere (Sorenson et al. 2008), HTA mainly addresses single technologies or clinical interventions. Organizational and service management issues have been investigated for single technologies (especially screening programmes) but HTA needs to continue the expansion of its methodological perspectives to include organizational, ethical and social issues more systematically and more frequently. In addition, and due to this current major focus on clinical interventions, HTA has not yet fully developed its capacity as a tool for health policy-making related to issues such as service delivery, management, financing and governance of the health-care system. However, the HTA paradigm should also be explored and developed in relation to questions such as health-care reform. This may contribute to more evidence informed health policies.

### **Assessing HTA within a quality framework**

Different frameworks are used when developing performance or quality indicators and when describing the quality of the health system (Donabedian, 1966; Shaw & Kalo, 2002; Murray & Evans, 2003), but they have very similar dimensions. It is often stated that HTA itself should be assessed according to some criteria. By building on the dimensions of quality of care, we have therefore identified a parallel set of dimensions that we will use to discuss some challenges for HTA (Table 8.1).

**Table 8.1** *A quality framework for HTA*

<b>Health-care quality</b>	<b>HTA quality</b>
Responsiveness	Relevance
Effectiveness	Applicability
Safety	Validity
Availability	Timeliness
Coordination	Accessibility
Efficiency	Efficiency
Equity	Equity

### Relevance

HTA needs to address the right topics, i.e. the technologies or interventions relevant to clinical policy-makers. So who should lead decisions on which HTA reports to perform: researchers, HTA agencies or policy-makers? Policy-makers' needs automatically become part of the process when new technologies are mandated to be evaluated in relation to clinical policy-making processes, e.g. regulation and reimbursement. In other cases, their needs have to be identified through specific mechanisms and this is challenging. Horizon scanning and early warning mechanisms have been set up and the EuroScan network works to identify and assess new emerging technologies (see Box 5.6 in Chapter 5). However, more clinical policy-making should be related to assessing technologies and interventions that are already in use within the health service in order to increase quality, improve prioritization and identify opportunities for disinvestment. HTA needs to address such topics and therefore needs mechanisms to identify them.

### Applicability

If the appropriate topics are addressed, then these technologies need to be analysed by way of an appropriate set of questions. This is defined by whether the HTA report is actually used by the policy-makers and thus responds to their needs. The core HTA model described in Chapter 3 is based on previous work and aims to encompass these needs. Some domains are general, others are more contextual, and we have tried to order them by increasing context-dependence (of course this varies with the issues within each domain).

- Technical characteristics
- Safety
- Clinical effectiveness



- Cost and cost effectiveness
- Current use and state of the health problem
- Ethical analysis
- Organizational aspects
- Social aspects
- Legal aspects.

As described above, a majority of HTA reports do not cover the last few of these domains. This impedes applicability since policy-makers need sociopolitical analyses (including ethical considerations that are relevant to their specific setting) before making decisions.

### Validity

The technical, methodological or product quality of HTA reports, how the methods have been used and the processes carried out – all are of crucial importance. They determine whether an assessment is acceptable to policy-makers and, more importantly, the end users of their clinical policies, i.e. clinicians and patients. This requires HTA agencies and other institutions performing HTA to be scientifically independent from policy-makers and government. They must ensure transparency by being open to review, criticism and debate and based on publicly available documents and material. This may be threatened by increasing use of clinical policy-making based on often inaccessible industry submissions. If these are used it is necessary to ensure full public disclosure of such submissions and all their content. More common taxonomies, definitions, methods and processes between HTA institutions will also contribute to increasing the technical quality of HTA reports. Additionally, HTA reports need to be updated. A recent review of 100 systematic reviews indicated that new evidence had changed the conclusions of about 25% over a two-year period (Shojania et al. 2007). Therefore, all HTAs should include information on ongoing or planned research and a sell-by date to indicate when each needs to be updated.

### Timeliness

An HTA report should be ready when needed but timeliness represents a true challenge. As Buxton remarks: “it is always too early to evaluate until suddenly it is too late” (Buxton, 1987). This is particularly a challenge for new technologies. HTA researchers argue for more evidence to be available before conducting a review, whereas policy-makers are under pressure from industry,

professionals and patient groups to make rapid decisions. One approach is to produce assessments rapidly when the need is identified, e.g. rapid reviews, alerts. Another is to produce HTA reports before the demand has been defined, e.g. through horizon scanning mechanisms (above) or by international collaboration to create a broad base of HTA reports that may address later needs. Both approaches may challenge the technical quality of the HTA report. Rapid reviews are challenging due to time constraints, given that the reports have to be done in a short time, e.g. weeks or months. The early warning approach may be troublesome because good evidence is often lacking when a technology is introduced to the market. An alternative approach is to view HTA as a tool for identifying research needs and thereby helping policy-makers to demand new evidence. The coverage with evidence development mechanism that has been introduced, among others, in the United States and the only in research status used by NICE are clinical policy instruments that utilize such an approach.

#### Accessibility

This relates to the total availability and accessibility of HTA reports. Overall there is a large international capacity for producing HTA. However, lack of coordination means that the total number of technologies and interventions assessed in HTAs is not as high as it could be. All published HTA reports should be readily available through the international HTA database but there are delays between publication dates and dates of public availability. In addition, the database needs to have more user-friendly indexing, browsing and searching capacities. Language can be an issue when reports come from different countries. A potential agreement to write common core information and evidence tables in English is a prerequisite for international use of existing reports. This will facilitate the local adaptation described in more detail in Chapter 3. The content of HTA reports also needs to be more accessible for policy-makers. International efforts to standardize the summaries of findings, executive summaries and policy-maker friendly front ends should be exploited more systematically.

#### Efficiency

Is HTA a good investment? Are HTA reports good value for money? These questions are related to three issues. Firstly, whether HTA reports have an impact on decision-makers, policies, practices and outcomes. This is addressed in Chapter 6. Secondly, whether each individual report is produced in an efficient manner. This is difficult to assess since all HTA projects need to balance resources, time and quality. However, it may be useful to establish

international benchmarking mechanisms for resource use and the timeframes within which HTAs are produced, with the aim of comparing and learning from each other. Thirdly, whether the total amount of resources available within the HTA community is utilized efficiently. We think not, mainly because there is far too much duplication of work. This poses an important challenge for the international HTA community and for its funders and users. We return to this issue below.

### Equity

This relates to fair distribution and may be addressed by considering four issues concerning HTA reports.

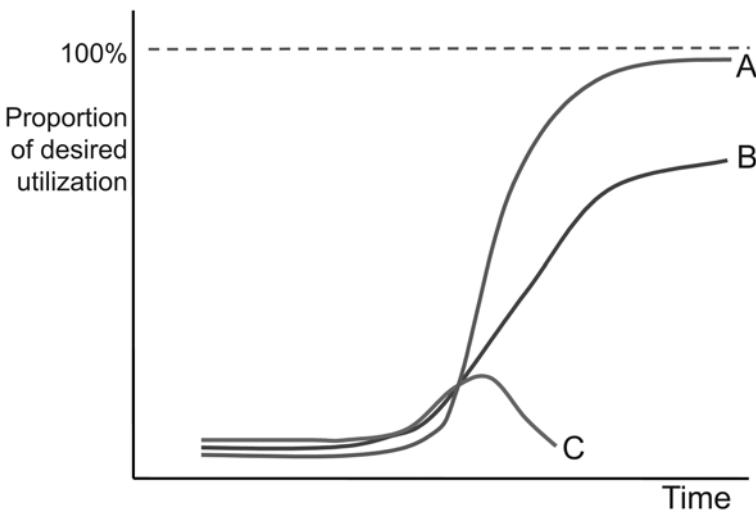
1. Are they carried out on a fair distribution of technologies and interventions, e.g. are commercial technologies covered better than other interventions, or are treatment options covered better than preventive measures? This is important since the HTA process itself may prioritize a topic.
2. Do they address potential inequalities? This relates to the distribution of effectiveness and whether some interventions may have a more positive impact on particular social groups. This can increase social inequalities even when the net benefit is positive.
3. Do they address topics that are relevant for vulnerable groups, such as the homeless, alcohol abusers and drug users? Or questions related to global health challenges and poverty-related diseases such as HIV/AIDS, tuberculosis, malaria and tropical diseases?
4. Is there capacity to utilize and produce HTAs in all settings where they are needed? We are thinking particularly of the middle-income states of eastern Europe and the low- and middle-income countries on other continents. In a recent review of organizations that support the use of research evidence, Dr Hassan Mshinda from Tanzania noted during a site visit: “If you are poor actually you need more evidence than if you are rich” (Moynihan et al. 2008).

We believe that the HTA community should address the ways in which equity and fairness could be improved in each of the above.

Some of these issues concerning aspects of the quality of HTA have been emphasized by others (Sorenson et al. 2008). The overall quality of HTA reports may be judged by assessing their impact. We reiterate the conclusion in Chapter 6 that such assessments demand that HTA reports have clear impact objectives. We also suggest that the quality of HTA may be assessed by sets of performance indicators adjusted to the different settings and built on the dimensions presented here.

However, the overall aim of HTA is to aid clinical policy-making in formulating informed decisions for practitioners so that the appropriate technologies and interventions are implemented. Rogers's model of diffusion of innovations may illustrate this (Fig. 8.3) (Rogers, 1962). The aim is that rejected technologies do not spread (C) while those that are valued positively diffuse efficiently and soon achieve the desired level of utilization (A). The probable normal situation has slow diffusion and an inadequate level of implementation (B). Monitoring the degree of implementation of technologies in this manner is another option for evaluating the quality of HTA.

**Fig. 8.3** *Not too early, not too late: effective implementation of innovations*



Source: Adapted from Rogers, 1962

### **Opportunities for stronger collaboration in Europe**

We have identified some challenges related to the content, quality and impact of HTA. Some are connected to how the process is carried out in different settings and some are related to how HTA is connected to clinical policy-making. Others are linked to how the overall HTA community and clinical policy-making processes perform in Europe. These are challenges associated with the coordination of regulatory, reimbursement/guidance and guideline processes and with the validity, timeliness, accessibility, efficiency and equity of HTA processes. Stronger collaboration within and between the HTA community and HTA agencies in Europe has been identified as a potential mechanism for addressing these latter challenges.

Collaboration can mean different things and take place at different levels (see Fig. 8.4). The first (lowest) level of collaboration is to share information on a voluntary basis and is the current situation within most of the HTA community. Methods and processes are presented at meetings and in papers, allowing others to discuss, adopt and use them. HTA reports are placed on a common database to allow others to utilize them in their local settings. International HTA organizations (INAHTA, Health Technology Assessment International – HTAi) have agreed a few general principles for presentation and quality.

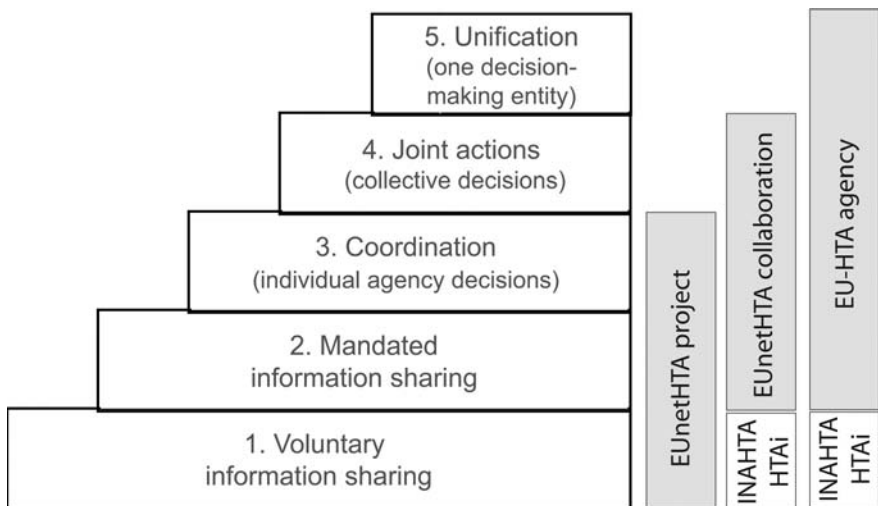
The second level is a more committed or mandated sharing of information. All collaborators agree to place protocols, reports and other material in a common information system in a timely manner.

The third level constitutes true coordination where e.g. common methods and processes for conducting and reporting HTAs are developed collaboratively and potential topics for HTA are shared and discussed. However, the formal decision-making power related to prioritizing topics and the ways of conducting assessments still lies within each individual participating HTA institution.

At the fourth level all (or a subset of) HTA agencies agree to make some collective decisions and work jointly. This may be by setting up one common mechanism e.g. for priority setting of topics and the production of the HTA report.

The fifth and final (highest) level of collaboration is what we call unification – methods, processes and products are common and there is one decision-

**Fig. 8.4** Staircase of collaboration



making<sup>12</sup> entity that, for example, decides on topics and coordinates the production of HTA reports, i.e. a European HTA agency.

We argue that stronger and more committed collaboration is necessary to address the challenges described and therefore call for an escalation to at least the second level of collaboration. The third and fourth levels imply some form of harmonization or standardization and would increase information sharing although not all activities need to be harmonized or unified. Some challenges can be tackled by mandated information sharing, others need coordination and joint actions and probably only a few require unification.

A good, common information system for HTA in Europe could improve the quality and efficiency of the individual HTA agencies, as well as the output of the entire HTA community. Such a system could include information on:

- new emerging technologies;
- suggested and selected topics for HTA;
- assessments in progress, with protocols;
- previews of HTA reports prior to publication;
- final HTA reports with additional material;
- clinical policy decisions taken in different settings and based on HTA;
- uptake/degree of implementation of technologies;
- monitoring the effectiveness of technologies in routine practice (registries, phase IV studies);
- resources and tools for conducting HTA.

An HTA core model and an adaptation tool kit have been developed as major deliverables in the EUnetHTA Project, through a process of collaboration across various HTA agencies (see Chapter 3). If, and when, HTA institutions implement these approaches then the potential for utilizing HTA reports from other countries will increase.

The plan for the permanent EUnetHTA Collaboration now being developed includes an information system and common methods as two of its five key functions.

1. Providing the contact point for the HTA community in Europe.
2. European HTA information and communication system.

<sup>12</sup> Decision-making refers here to the aspects concerning the processes of conducting the assessment and not to decisions taken by the clinical policy-makers. An HTA report made in a unified system does not imply that the same clinical policy decision (e.g. on reimbursement) is taken in all the countries where core HTA information is used for producing national HTA reports and to inform decision-making.

3. Developing and improving common processes for performing and reporting HTA.
4. Providing information on emerging/new technologies and facilitating new evidence generation.
5. Facilitating the establishment and continuous development of HTA institutions.
6. Piloting processes for production of HTA core information.

In addition, many stakeholders have an ambition to produce HTA core information jointly. This could be used as a starting point for national (or regional) HTA processes and would greatly increase capacity by removing the need to start from scratch. However, core information is not a full assessment and does not remove the necessity for the production of a national (or regional) HTA report. The production of HTA core information should become a joint global effort but the appraisal of that information; assessment of its sociopolitical consequences; and production of a full HTA report should be effected within the relevant clinical policy-making jurisdictions and settings. Often, this will be through deliberative mechanisms that include relevant stakeholders.

Current plans for the permanent EUnetHTA Collaboration do not include common decision-making processes concerning which technologies to prioritize for assessment. This is partly due to the issue of relevance (see above). HTA reports must respond to the needs of clinical policy-makers in the setting where the HTA is carried out. The harmonization of clinical policy-making in Europe would act as a driver for HTA harmonization but this is unlikely as health is seen as a national responsibility. However, increasing patient mobility between countries will be a driver for more explicit decisions on the health care to which citizens are entitled and their quality of care. This may lead to stronger coordination within Europe.

Still, new technologies emerge at more or less the same time across different countries, therefore there is a potential for better coordination (not harmonization) of clinical policy-making processes in Europe. This is particularly true for those related to reimbursement and guidance, at least for technologies that share a common approval process, such as drugs and devices. A common evidence base would clearly be useful. One solution might be a harmonized system for producing core HTA information in a timely and efficient manner, organized through a permanent EUnetHTA collaboration or a common European HTA agency. However, the production of prioritized core information and its adaptation for national clinical policy-making processes would remain the responsibility of national or regional HTA agencies.

**Table 8.2** *Qualities of the HTA community and the Cochrane Collaboration: a comparison*

	HTA community	Cochrane Collaboration
Relevance	++	+
Applicability	++	+
Validity	+	++
Timeliness	+	-
Accessibility	-	++
Efficiency	-	+++
Equity	-	+

Does collaboration work? That it *may* work is demonstrated by looking at other international communities within the field of evidence synthesis, most notably – The Cochrane Collaboration. The Cochrane Library now includes more than 5000 titles of systematic reviews (either completed or protocols) following a tremendous effort by a very well-coordinated community. We compare the different qualities of the HTA community and the Cochrane Collaboration in Table 8.2.

We score Cochrane higher on validity (common methodology, reviews updated); accessibility (large number of reviews, common format, user friendly database); efficiency (division of labour, avoids duplication of work); and equity (started to address needs of low- and middle-income countries). The HTA community has higher scores for relevance (policy-makers set priorities); applicability (addresses broader sets of questions, more domains); and timeliness (new interventions assessed more rapidly). This table demonstrates that the HTA community and the Cochrane Collaboration complement each other. It also suggests that there is a potential for more extensive collaboration between the two communities which in reality already overlap at the individual and institutional levels.

The HTA community should also improve its cooperation with organizations that produce clinical practice guidelines, many of which are organized in the Guideline International Network (G-I-N). The production of clinical guidelines is one instrument of clinical policy-making but, as discussed above, guidelines are seldom based explicitly on HTA. However, as they build on the same scientific evidence, the two processes should be better coordinated within countries to avoid duplication and to increase the capacity to produce both guidelines and HTA reports.

At the start of this chapter we noted that HTA reports rarely address health policy relevant topics related to health system issues such as delivery, management,



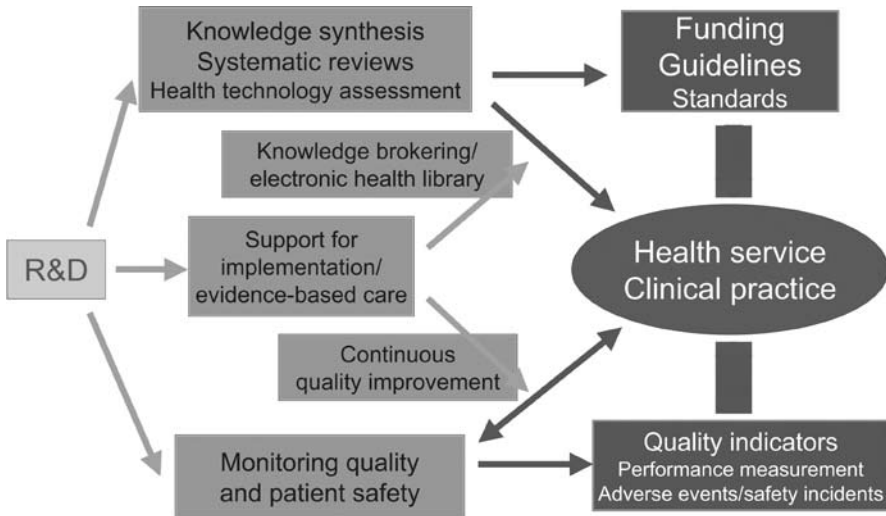
financing and governance. HTA agencies and organizations may develop such a stream of work, but who has been responsible for synthesizing the research evidence in these areas? A recent survey indicates that it is a heterogeneous mix of organizations, several linked to government (Moynihan et al. 2008). The publisher of this book – the European Observatory on Health Systems and Policies – is one such organization. However, there is no common international organization (such as INAHTA, HTAi, G-I-N, Cochrane Collaboration) for organizations engaged in this field of research synthesis. The international HTA organizations may explicitly include this within their remits and invite relevant organizations to join. Alternatively, such an organization may emerge to act as an important counterpart and collaborator for the HTA community and possibly to improve the policy analysis component of HTA reports (we have demonstrated that often this is weak or lacking).

An international organization (Alliance for Health Policy and Systems Research – AHPSR) and an international programme (Evidence-Informed Policy Network – EVIPNet) are both linked to WHO. They focus on research synthesis in low- and middle-income countries: AHPSR on health policy; EVIPNet on both health and clinical policies. We have stated that the HTA community should increase its assistance in addressing the needs of developing countries. One way of achieving this may be dialogue and collaboration with organizations such as AHPSR, EVIPNet, WHO and others such as the International Clinical Epidemiology Network (INCLIN) and The Cochrane Collaboration. Stronger European collaboration would increase the capacity to collaborate with these communities.

### **HTA integrated in the health system**

We began by stating that HTA is a tool for knowledge management. We have described how it is part of the knowledge value chain in the health sector; how HTA is, or should be, linked to clinical policy-making processes; and how mechanisms for monitoring and evaluation are needed to complete the value chain. In sum, HTA should be an integral part of the health system. The settings and roles of the different organizational structures determine how this should be done. Chapter 5 shows how HTA reports increasingly are produced within organizations with a broader mandate than HTA alone. We illustrate this by describing briefly the different roles of the Norwegian Knowledge Centre for the Health Services (NOKC) (Fig. 8.5).

The NOKC is mandated to conduct knowledge synthesis for all types of health-care related interventions (all levels in Fig. 8.2). This is produced in various formats: HTA reports, systematic reviews, cost-effectiveness analyses

**Fig. 8.5** Role of HTA in the health system: a Norwegian example

and other forms of evidence synthesis needed for health policy decisions and clinical policy-making, e.g. reimbursement issues and guideline development. NOKC also plays a role in monitoring the quality of care by measuring patients' experiences through regular surveys and by developing and producing performance indicators. It includes the National Unit for Patient Safety which builds on existing incidence reporting systems and supports the health system in improving patient safety.

In addition, NOKC supports quality improvement in the health service by utilizing approaches from leading institutions in this field, e.g. the Institute for Healthcare Improvement in the United States. In this manner, NOKC links the ideas of evidence-based practice with the outcomes, quality improvement movements and, more recently, the patient safety movement. To facilitate the use of best evidence in both policy-making and clinical practice, an electronic health library available to all health professionals has been established. Also, universities and regional colleges are supported in their efforts to include evidence-based practice, patient safety and quality improvement in their programmes.

Many institutions that conduct HTA have a similarly broad mandate to inform and support decisions within the health services (see Chapter 5) and improve the quality of care. These include institutions such as the *Haute Autorité de Santé* (HAS), France; Catalan Agency for Health Technology Assessment and Research (CAHTA), Spain); Health Information and Quality Authority (HIQA), Ireland; and NHS Quality Improvement Scotland (NHS QIS).

Their main role is to act as knowledge brokers within the health system, supporting the health service by collecting, analysing and disseminating useful knowledge. This is achieved by synthesizing and presenting evidence (push efforts); making policy-makers aware of this information and enabling them to utilize it by responding to their needs (pull efforts); and by establishing relationships and partnerships with policy-makers, including professional organizations (exchange efforts) (Lomas, 2000).

By serving as a link between the research community and health and clinical policy-makers, HTA agencies may also have an important role not only in retrospectively assessing evidence but also in identifying what evidence is needed. Prospective HTAs may be an important way forward – focusing on what evidence will be required to make decisions, what exists and what is lacking, and describing the types of evaluative studies required. This answers critiques that label HTA as backward looking and a barrier to innovation. It will certainly be necessary to collaborate across countries in order to set up systems that plan and initiate such important and necessary evaluative studies in a coordinated manner and therefore this is also included in the plans for the EUnetHTA Collaboration.

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Health care policy-makers throughout Europe seek to improve the health status of their citizens through the delivery of health services. Health policy thus aims at improving the performance and health outcomes within sustainable health systems.

Health technology assessment (HTA) contributes to the formulation of such health policy by providing evidence-based information to those who make policies and decide on the coverage and usage of health technologies. However, establishing links between HTA and policy-making poses challenges to both producers and users of HTA – and there is a potential to improve the responsiveness of HTA to the needs of policy-makers to achieve the desired goal for HTA of a larger policy input role.

This book gives an overview of the relationship between HTA and health policy in Europe by:

- examining how HTA contributes to policy processes;
- summarizing the crucial components of good HTA;
- analysing HTA-policy links and processes in different health systems, and classifying common characteristics of the relations;
- exploring the impact of HTA on health care and health policy; and
- focusing on needs and demands for HTA as well as challenges and potential for improving the role of HTA at different policy levels.

This book seeks to transmit the value and potential of HTA to a wider audience beyond the decision-making and health care management arena and, by so doing, aims to increase the awareness and the application of HTA activities and evidence-based decision-making.

