

The European Observatory on Health Systems and Policies is a partnership between the World Health Organization Regional Office for Europe, the Governments of Belgium, Finland, Greece, Norway, Spain and Sweden, the Veneto Region of Italy, the European Investment Bank, the Open Society Institute, the World Bank, CRP-Santé Luxembourg, the London School of Economics and Political Science and the London School of Hygiene & Tropical Medicine.

This policy brief is intended for policy-makers and those addressing the issue of health technology assessment.

Policy brief

Health technology assessment
*An introduction to objectives,
role of evidence, and
structure in Europe*



by

Marcial Velasco-Garrido
Reinhard Busse



© World Health Organization 2005,
on behalf of the European
Observatory on Health Systems
and Policies

All rights reserved. The European
Observatory on Health Systems and
Policies welcomes requests for
permission to reproduce or translate
its publications, in part or in full
(see address on inside back cover).

The views expressed by authors or editors do not necessarily represent the decisions or the stated policies of the European Observatory on Health Systems and Policies or any of its partners.

The designations employed and the presentation of the material in this policy brief do not imply the expression of any opinion whatsoever on the part of the European Observatory on Health Systems and Policies or any of its partners concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Where the designation "country or area" appears in the headings of tables, it covers countries, territories, cities, or areas. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the European Observatory on Health Systems and Policies in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

The European Observatory on Health Systems and Policies does not warrant that the information contained in this policy brief is complete and correct and shall not be liable for any damages incurred as a result of its use.

Policy brief

Health technology assessment

An introduction to objectives, role of evidence, and structure in Europe

Health systems have developed at different speeds, and with differing degrees of complexity throughout the twentieth century, reflecting the diverse political and social conditions in each country.

Notwithstanding their diversity, all systems, however, share a common reason for their existence, namely the improvement of health for their entire populations. To attain this goal a health system undertakes a series of functions, most notably, the financing and delivering of health services.

Since available resources are limited, delivering health services involves making decisions. Decisions are required on what interventions should be offered, the way the health system is organized, and how the interventions should be provided in order to achieve an optimal health gain with available resources, while, at the same time, respecting people's expectations.

Decision-makers thus need information about the available options and their potential consequences. It is now clear that interventions once thought to be beneficial have, in the light of more careful evaluation, turned out to be at best of no benefit or, at worst, harmful to the individual and counterproductive to the system. This recognition has led to the emergence of a concept known as "evidence-based medicine", which argues that the information used by policy-makers should be based on rigorous research to the fullest extent possible (Ham et al. 1995).

This policy brief introduces the concept of "health technology assessment", which has been described as "the speciality of assistance to health policy-making" (Jonsson & Banta 1999) by means of evidence, describing what is

This policy brief is one of a series on health care issues by the European Observatory on Health Systems and Policies. This series is available online at: www.observatory.dk

meant by evidence. We then review the structures and institutions involved in health technology assessment at the European level.

What is health technology assessment?

Health technology assessment (HTA) has been defined as “a form of policy research that systematically examines the short- and long-term consequences, in terms of health and resource use, of the application of a health technology, a set of related technologies or a technology related issue” (Henshall et al. 1997). HTA is concerned with the medical, organizational, economic and societal consequences of implementing health technologies or interventions within the health system. By its nature, HTA is a multidisciplinary activity which systematically evaluates the effects of a technology on health, on the availability and distribution of resources and on other aspects of health system performance such as equity and responsiveness.

The origin of HTA lies in discussions that followed what was then seen as the uncontrolled diffusion of expensive medical equipment in the 1970s (Jonsson & Banta 1999). However, HTA is now much broader. It includes drugs, medical and surgical procedures used in health care, and the organizational and supportive systems within which such care is provided (Banta et al. 1978). The scope of HTA thus includes:

- the whole range of interventions which can be provided within the health system as it delivers health services;
- interventions applied to the system, that is, policies on organizing and financing the health system.

Health technologies can thus be seen as any actions whose aim it is to improve the performance of the health system in the achievement of its ultimate goal: health gain.

Policy-oriented

The declared purpose of HTA is to support the process of decision-making in health care at policy level by providing reliable information. In this respect, HTA has been compared to a bridge between the world of research and the world of decision-making (Battista 1996). This bridge is intended to allow the transfer of knowledge produced in scientific research to the decision-making process. In order to achieve this, HTA is committed to the work of collecting and analysing evidence from research in a systematic and reproducible way

and to make it accessible and usable for decision-making purposes, in particular by means of assessment reports. HTA shares these principles with evidence-based medicine (EBM) and clinical practice guidelines (CPG) and, together with them, builds a body of best practice initiatives (Perleth et al. 2001). However, in contrast to HTA, which is policy-oriented, EBM and CPG aim to support decision-making at individual clinical level and patient group level, respectively.

The policy orientation of HTA has several implications. Assessments are conducted in response to, or anticipation of, a need for reliable information to support a decision, that is, at the origin of an assessment there is a decision to be made. The types of decisions about which HTA can provide information are multiple and may be located at different levels of the health system and involve different actors (politicians, hospital managers, health civil servants, etc.). Assessments can be conducted in order to inform, for example, investment decisions (purchasing new equipment), or the shaping of the benefit catalogue (reimbursement of new services), as well as decisions concerning the organization of the service provision (implementation of rules for referral to specialists). The information needs are in accordance with the type of decision and the level of decision-making; they also vary depending on the actors involved. All these contextual factors determine the scope of the assessment, that is, which aspects of the technology or intervention are to be assessed, as well as the methodology to be applied, not least because of the financial or time constraints that may be imposed (Busse et al. 2002). For the purposes of HTA, the decision-maker's need for information is known as *the policy question*. Its various dimensions are illustrated in Box 1 (overleaf).

A policy question can be raised by the decision-maker her/himself. However, institutions undertaking HTA often proactively identify areas where information is likely to be needed in the future, perhaps through a process of horizon-scanning. Close cooperation between decision-makers and researchers is needed in order to clarify the underlying policy question and tailor the assessment to the decision-maker's information needs. The quality of this interaction is one of the main determinants of the value of evidence for policy-making (Innvaer et al. 2002).

Context-embedded

As already mentioned, the context in which HTA research is carried out determines the methods used and the extent and comprehensiveness of the assessment. The scope and level of detail of HTA vary considerably, depending upon who commissioned a study and why. It will not always be necessary to assess

Box 1: Contextual aspects of the policy question (Busse et al. 2002)

Who initiated the assessment?	Health policy-makers Health care managers, administrators
Who commissioned it?	Third-party payers Patients' advocate HTA institution
Why is an assessment needed right now?	New technology Changes in old technology New indications for old technology Structural/organizational changes Safety concerns Ethical concerns Economic concerns New problem calling for action
Which decision is the assessment going to support?	Investment decisions Market licensure Inclusion in/exclusion from benefit catalogue Planning of capacities Guidance on best practice Investment in further research Organization of service provision
Who represents the primary target audience for the report?	Political decision-makers Third-party payers Hospital managers/administrators Civil servants

all aspects of the intervention to the same level of detail, as some effects might already be known and some might be of no concern. For example, if a decision is to be made by a hospital to purchase a new medical device so as to participate in a new research field, organizational and economic aspects will be of greatest importance, whereas the effects on health will be of less concern, since this will be the subject of the intended research. It is therefore crucial to explain that context clearly, so that readers of HTA (other than those

who initiated and commissioned the study) can better assess whether the report is relevant to their own problems. The description of the context in which decision-making is taking place, which should help to define the policy question, is a key feature of HTA reports (Busse et al. 2002).

In order to give an evidence-based solution to the problems outlined in the policy question, the researchers undertaking the assessment will need to specify the policy question in terms of safety, efficacy, effectiveness, psychological, social, ethical, organizational, professional and economic aspects. These research questions determine how the rest of the assessment will be conducted, the aspects that will be evaluated and those that will not. A decisive step in the formulation of the research questions is the selection of the parameters that will lead the evaluation, that is, how the impact of the intervention on the selected aspects is going to be measured. For each of the aspects to be evaluated, relevant and valid parameters should be chosen, that is, parameters that measure what is intended to be measured, such as changes in quality of life, as measures of the impact on health.

Formulating research questions is a crucial part of the assessment, since they transpose the original decision-making problem, the policy question, into questions that can be answered by evaluating scientific evidence. Thus there should be a feedback loop to the commissioner(s) of the assessment in order to ensure that the research questions represent a useful “translation” of the policy question.

Methodologically sound

Once the research questions have been posed, the task of the HTA researchers is to retrieve, analyse and synthesize the available evidence, preparing it in a way that is useful for decision-makers (in other words, so that it responds to their information needs). The researchers will try to identify and collect the best available evidence that will allow them to give valid answers to the questions. They will summarize this evidence in a way that corresponds to the original policy question. In some cases it is appropriate to provide recommendations for policy-making, or to outline the policy options that result from the assessment.

As mentioned above, the product of the HTA process is the assessment report or HTA report. HTA reports are often technically very detailed, since they fulfil the function of making the process of formulating and answering the questions both transparent and reproducible, thus demonstrating the validity of the information contained in them. However, long technical reports with exhaustive discussions on the validity of evidence and on its generalizability are not very useful for decision-makers who expect brief summaries and clear recommendations

Box 2: Differences between “Executive Summary” and “Scientific Summary Report” (Busse et al. 2002)

Executive Summary	Scientific Summary Report
Addressed to (local) decision-makers (“executives”)	Addressed to the HTA and scientific community
Focuses on recommendations and conclusions	Stresses the context of the HTA and methodological aspects, in addition to conclusions and recommendations
Written in agencies’/ institutions’ official tongue(s)	Available in English
Quickly informs decisions	Allows for critical appraisal of relevance, quality and main findings of the assessment

(Innvaer et al. 2002). In order to achieve a greater relevance of HTA to decision-making, the European Collaboration for Health Technology Assessment (ECHTA) has recommended that HTA researchers additionally provide two kinds of short reports on their assessments, one tailored to the commissioners and decision-makers (executive summary) and one targeting the scientific community, each differing in content (Busse et al. 2002; see Box 2).

So far, we have been talking about the ability of HTA to support health decision-making by providing evidence. But what exactly is meant by the term evidence? In the following section we explain in some detail the notions of evidence and best evidence, as they are applied in the HTA community.

What is the notion of evidence in an assessment?

Evidence-based medicine has been defined as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients” (Sackett et al. 1996). As stated in the definition, the origin of this evidence-based approach can be seen in the application of clinical medicine delivered at an individual level. Pressure to base decisions on evidence has, however, been extended to other areas of health care, such as public health interventions and health care policy-making (Ham et al. 1995).

In this context, evidence is understood as the product of systematic observation or experiment. It is inseparable from the notion of data collection (McQueen & Anderson 2001). The evidence-based approach relies mainly on research, that is, on systematically collected and rigorously analysed data following a pre-established plan. Evidence is the result of a search for practical, useful knowledge (Banta 2003).

In addition, the definition of EBM introduces the concept of best available evidence, which implies a “hierarchy” of evidence. Since the evidence comes from research, it is important to consider:

- the hierarchy of research designs;
- the quality of the research execution.

Some research studies are considered to be better than others. Evidence from good research is considered to be better than evidence resulting from research of a lesser standard.

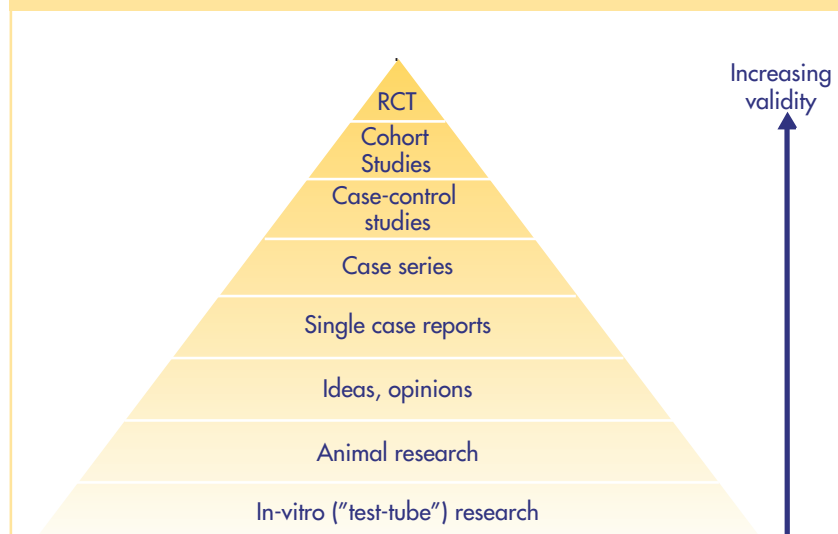
HTA assesses the potential effects of an intervention on health outcomes. In the evaluation of effects (for example, reducing mortality from a specific cause), evidence from experiments is considered to be superior to evidence from non-experimental observations, and among experiments, some study designs (for example, those including an explicit comparison group) are considered to be better than others, thus ranking higher in the hierarchy of research design. The underlying rationale of this hierarchy involves considerations of “internal validity” (see Figure 1, overleaf). Internal validity tells us how likely it is that an observed effect of an intervention is in fact attributable to that intervention. Put simply, when we observe an effect following an intervention, there are two possible explanations:

1. The observed benefit has really been caused by the intervention itself, for example, a reduction in mortality is fully attributable to the intervention.
2. The observed benefit seems to be caused by the intervention but in fact other factors are responsible, and the intervention itself does not have any benefit (or even produces harm). These factors may be chance, errors in collecting or interpreting the data (“bias”) or the effect of additional variables (“confounding”).

Assessing research

The more internal validity a research design has (the higher it is in the hierarchy of evidence), the more we can be sure that an observed effect is truly

Figure 1: Hierarchy of research designs for evidence-based medicine (based mainly on internal validity)



attributable to the intervention. As we move down the hierarchy, the likelihood increases that the findings from the study will be misleading. The design highest in the hierarchy is the “randomized controlled trial” (RCT)¹ where there is an adequate number of participants.

The extent to which the information provided by a study has clinical or policy relevance has been defined as the “non-methodological quality” of the evidence (Lohr & Carey 1999). For instance, animal or test-tube research usually has high internal validity, undoubtedly contributes to the understanding of physiology and pathophysiology, and serves in the development of diagnostic and therapeutic interventions. However, the findings cannot be extrapolated to individuals and so cannot be used to assess the benefit as measured by, for example, reductions in mortality. Thus, as shown in Figure 1, these types of research rank low because the non-methodological quality of their evidence is very poor.

1. In RCTs, at least two groups are defined, for example, one to receive the intervention and another to receive a placebo. Assignment of participants to each group is randomized in order to minimize the effects of selection bias or confounding.

The extent to which research findings have clinical or policy relevance is also related to their degree of “external validity” (the generalizability to the reference population). To achieve a high level of internal validity, RCTs usually follow strict protocols for the selection of participants and the delivery of interventions. However, as a consequence of this, their external validity can be reduced as the participants and intervention delivery may not be truly representative of the population to whom the results should be applied (Britton et al. 1998). This can happen for a number of reasons:

- Often, only a very small proportion of the patients with a condition are considered to be eligible for a trial.
- Important subgroups of the population are often systematically and unjustifiably excluded, such as ethnic minorities, the elderly and/or women.
- Participants in research studies differ systematically from those eligible subjects who refuse to participate.
- Research is often conducted in health care settings not representative of the usual health care setting.

Whereas these problems may also limit the external validity of non-randomized research studies, they are more likely to be relevant in RCTs (Britton et al. 1998).

A more elaborate hierarchy of research designs for the assessment of interventions has been developed by the United States Task Force on Community Preventive Services. With it the authors have introduced the concept of suitability for assessing the effectiveness of interventions (Briss et al. 2000), which goes beyond the internal validity of the research designs used. This approach is particularly interesting because it argues that the RCT is not always the most appropriate (or feasible¹) research design. It recognizes that other study designs – in particular, well-designed cohort studies which are able to draw on large numbers and cover long time spans – can produce data which are not obtainable from RCTs. Additionally, it provides a detailed systematization, in the form of an algorithm, of the different kinds of research designs that can be used to evaluate the effectiveness of an intervention (Figure 2, overleaf).

The way in which an intervention has effects on health is referred to as its “directness”. The causal pathway between an intervention and an outcome can

1. Large RCTs are expensive and, when conducted in several centres (multi-centric), require a high degree of coordination and organization.

Figure 2: Algorithm of study design and levels of suitability
(adapted from Briss et al. 2000)

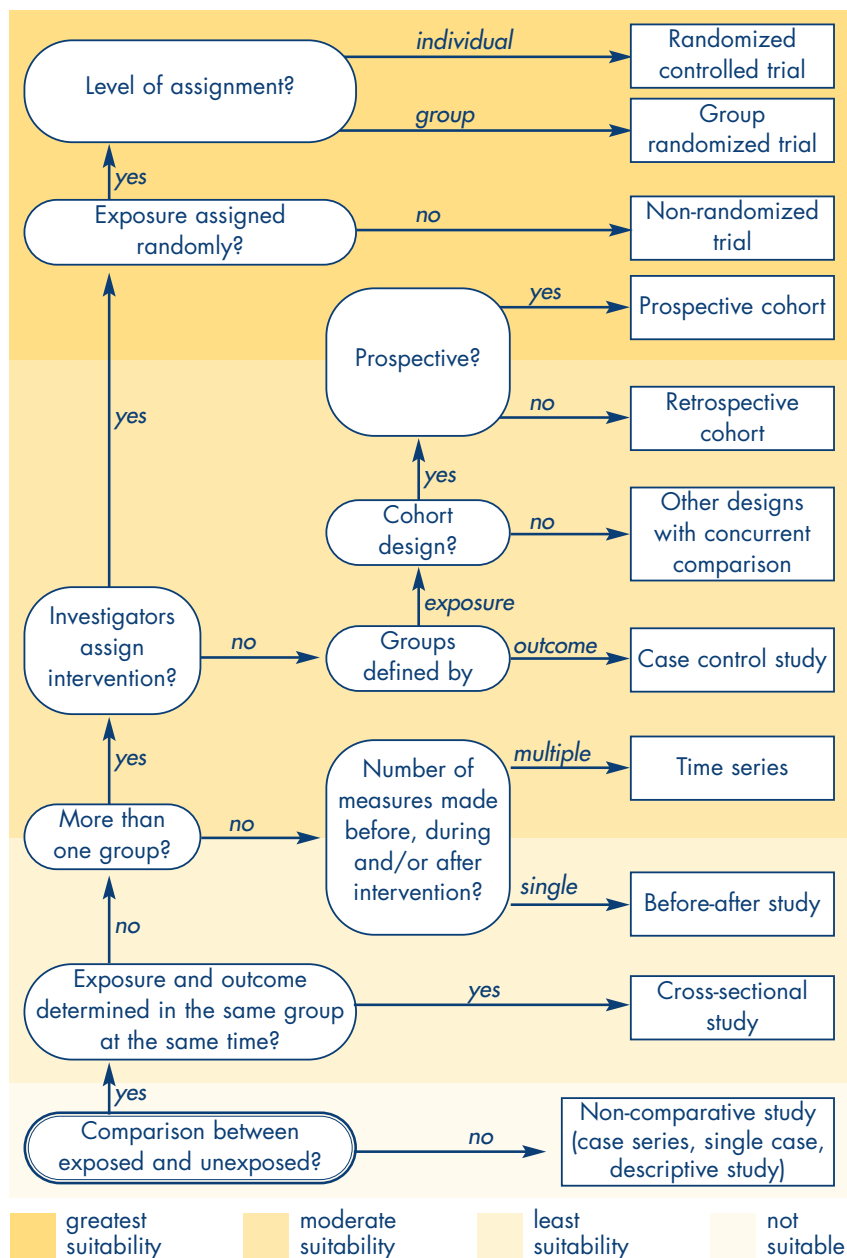
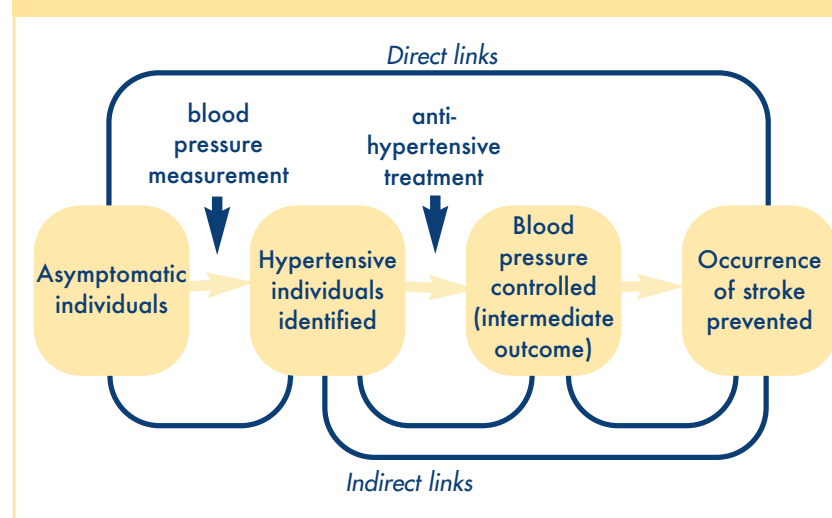


Figure 3: Example of causal pathway showing direct and indirect links between an intervention and its health effects (Woolf et al. 1994)



be represented graphically, as in Figure 3. The representation makes it possible to differentiate between direct and indirect paths connecting an intervention (for example, blood pressure measurement) and its expected health effects (for example, reduction in strokes). Evidence that a link is direct is considered to be better than evidence that a link is indirect. When there is only evidence on indirect links available, it is better to have evidence for all the single indirect steps in the causal chain than only for some of them. A direct link can be established in a single study, but for the establishment of a complete chain of indirect links several studies are needed. Directness is thus also related to the kind of parameters used to measure the effect of an intervention.

The results from research are usually published in scientific journals, so searching for the best evidence is usually seen as synonymous with searching the literature for results of studies (that is, for publications).¹ The approaches shown

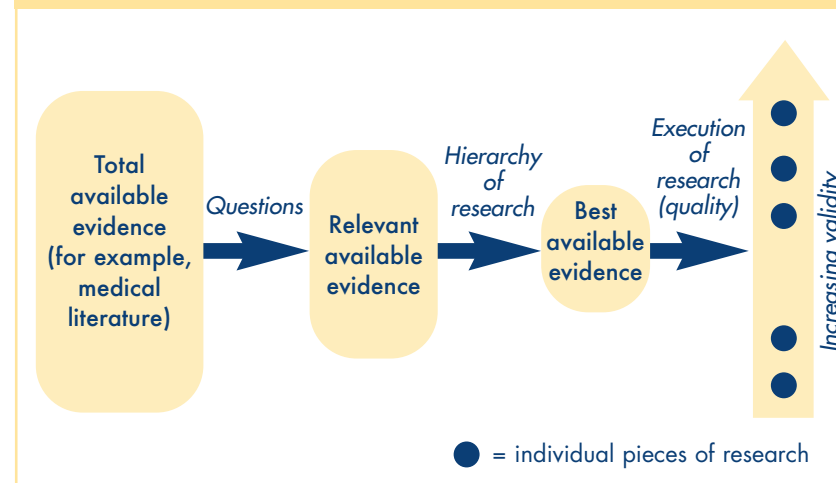
1. Although it is desirable (and sometimes necessary) to search in evidence from sources other than the published literature, this is not always possible because of resource constraints. Many systematic reviews and assessments focus mainly on published results. Most of the work carried out on the classification and appraisal of evidence has been concentrated on evidence available in published form, and particularly on the benefits from interventions.

above allow for a broad classification of the available evidence on the effects of an intervention into different levels of quality (that is, validity + relevance). This broad approach can be used to limit the types of studies that are taken into account when evaluating an intervention. So, with the help of the hierarchy of research designs, one can set a threshold concerning the types of research to be considered in the evaluation. For example, in the systematic reviews undertaken by the Cochrane Collaboration, the threshold for inclusion is usually that there is a well-conducted RCT. In the past, these reviews have not taken into account evidence from other study designs as these were considered to pose too high a risk of bias that could produce misleading results, although a broader perspective is now being taken by many reviewers. In contrast, the approach of the United States Task Force sets the threshold for inclusion according to the presence of a comparison group. As a consequence, studies that include any kind of explicit comparison group are considered to be suitable (and thus are included), whereas studies that do not include any kind of comparison (for example, case description) are excluded from the review (see Figure 2). Thus, the way such thresholds are applied determines the interpretation of statements such as “no evidence was found”, “there is no conclusive evidence”, etc., which often appear in systematic evaluations of interventions.

Furthermore, within the same level of validity of evidence in a given hierarchy (for example, “moderate suitability” or “RCT”), there are also differences in the internal validity, due to differences in the execution of the study. For example, an RCT that has a large number of patients who prematurely leave the study (lost to follow-up), or in which there is failure to avoid bias, may have a very limited validity. The limitations to internal validity can be so important that, even though the design places the study at the highest level in the hierarchy, the results have to be considered as lower level evidence due to the execution of the study. Well-conducted cohort studies, in which measures were taken to avoid the influence of bias or confounding, may provide a level of internal validity comparable to RCTs.

Several tools have been developed to assess and grade the quality of execution of single studies, following the same rationale as the hierarchy of research designs (that is, higher quality = higher internal validity = higher level of evidence). A recent review identified 67 ways to assess and/or grade the quality of different study designs, most of which have been developed for assessment of the quality of RCTs (West et al. 2002). One can thus order a group of studies with the same design according to the quality of their execution, again generating a hierarchy. This approach makes it possible to organize the available evidence in a way that will facilitate drawing conclusions and making recommendations.

Figure 4: Simplified process of selection and organization of the evidence



Summarizing research

When assessing the effects on health of an intervention, HTA researchers follow the principles presented here to make choices about the kind of evidence they consider, that is, which will answer their research questions in order to give advice to decision-makers. In a very simplified way, Figure 4 shows the process of selection and organization of the evidence, as it takes place in HTA (or in the conducting of systematic reviews).

The group of studies selected as the best available to answer the questions is called the “body of evidence”. A body of evidence is characterized by a combination of the factors discussed above, that is, the hierarchy of research design, the directness of the evidence and the quality of execution. In addition, other factors such as the number of studies, the size of the effect and the homogeneity/consistency of results across the group of studies are also relevant when judging the strength of the evidence. The challenge is to judge the evidence from different studies (saying, for example, “there is strong evidence that ...”) in order to give answers to the research questions and, in the end, to the policy questions (saying, for example, “thus it is strongly recommended to ...”). Several approaches have been developed to standardize the way researchers make their judgements about the strength of the evidence which will underlie their recommendations. A recent review has identified 40 different systems to rate the strength of the evidence, which differ in the combination of the factors for the

standard of evidence and the weight given to each when rating the strength of evidence derived from a group of research pieces (West et al. 2002).

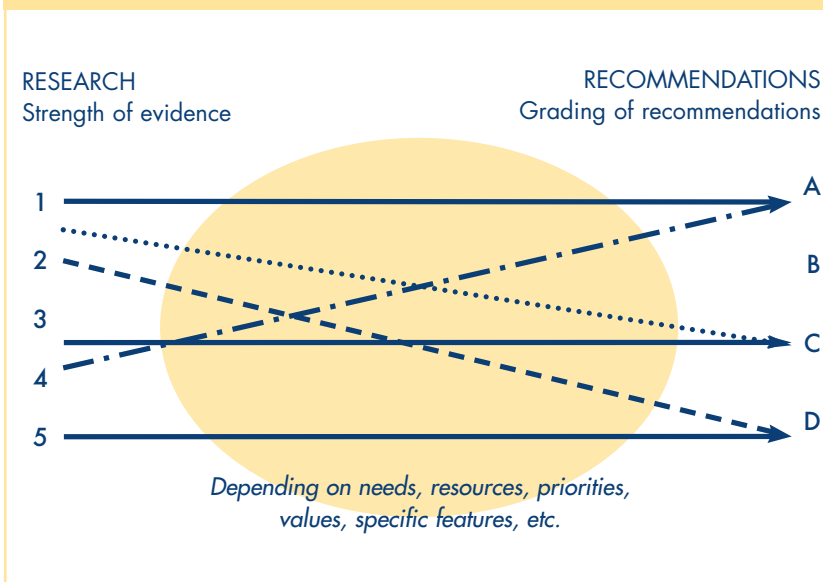
Besides rating the strength of evidence, these systems also establish a link between the strength of the evidence and the grade of recommendation, which is to be understood as the strength of the recommendation. Strong evidence on the effects of an intervention (positive or negative) allows for strong recommendations for or against the use of it. Weak evidence only supports weak recommendations. There are several systems to standardize the process of grading the strength of recommendations, typically using letters (for instance A, B, C, etc.) to describe the strength of a recommendation (West et al. 2002). In general the strength of recommendations is related to the strength of evidence and the different systems to grade recommendations take into account, to different extents, the standard, directness, amount and consistency of the evidence, as well as the size of the effect, reflecting the traditional criteria for assessing causality in epidemiology. Since interventions may have both positive and negative effects at the same time, more advanced systems for grading recommendations try to make explicit the trade-offs between harms and benefits (GRADE Working Group 2004). Therefore, in the language of recommendations, the letters do not always mean the same and the “strength” of “strong evidence”, and thus of “strong recommendations”, varies according to the system used. It is thus necessary that, whenever such a system is used in HTA reports, the authors provide enough information for the reader to interpret the grading of recommendations used (Busse et al. 2002).

The principles described here have been developed in the context of the assessment of the impact on health of individual clinical and public health interventions. They are, however, transferable to assessment of the effects on health of organizational or system interventions. The assessment of the evidence concerning the consequences of an intervention on, for example, responsiveness or equity follows the same principles, differing in terms of the outcomes measured (for example, patient satisfaction). In HTA, for each of the aspects of the assessment, the standard and relevance of available evidence need to be assessed. The underlying rationale is always the same: are the research findings valid? Are they relevant to the assessment questions? How strong is the body of evidence?

Good evidence = strong recommendation?

The identification of a strong body of evidence for the effectiveness of an intervention does not, however, lead inevitably to the formulation of strong recommendations for or against its use, since the evidence of the effectiveness

Figure 5: Relation between strength of evidence and grading of recommendations (Council of Europe 2001)



of health technology is only one part of the picture. For this reason, evidence-based statements, such as those gathered in supranational clinical practice guidelines (for example, the ones by the European Society of Cardiology), are to be understood as what – in the light of evidence of the highest quality – can be considered the most effective management of a specific condition, whereas judgements concerning the extent to which these “recommended” interventions should be available in a particular health system are left to health policy-makers (Schwartz et al. 1999). These clinical recommendations consider (for the most part) only benefits and harms of the interventions.

The other parts of the picture, such as the impact on the organization of the system, on the resources available, on responsiveness and on equity, also play a determinant role in the decision for or against the introduction or the implementation of a technology. So, even with strong evidence of benefit for health from an intervention, the recommendations derived from a technology assessment may be against its implementation, since under consideration of other factors like the burden of disease, needs and priorities, cost and cost-effectiveness issues, barriers to implementation, special features of the system, cultural issues, values, etc., the implementation can appear to be improper (Figure 5).

There is, for example, strong evidence of the effectiveness of adding nicotine replacement treatment (NRT) to smoking cessation strategies, almost doubling long-term success rates (Silagy et al. 2004). However, in Germany this therapy is not covered by the statutory health insurance system, since it is considered to be a so-called “lifestyle” drug (that is, a drug whose primary aim is the improvement of quality of life and whose use is primarily motivated by personal choice and not by illness). Obviously, other factors, such as the perception of what is an illness or the anticipated financial consequences for the health system, have played a major role in this decision, eclipsing other arguments such as clinical effectiveness. In other countries, NRT is covered at least partially by the health system. This case illustrates the importance of an explicit exposition of the different parts of the picture, their evidence basis, and the weight given to each.

Health technology assessment should explicitly take such factors into account, again following the principles of evaluating the validity and relevance of the available evidence. For the assessment of these other factors, however, the highest place in the hierarchy of evidence will be taken by research designs other than the RCT, since this study design is not appropriate to answer the relevant questions concerning these other factors. Indeed, the epidemiological approach is not always the appropriate method to answer many of the questions concerning the wide variety of aspects that play a role in health care decision-making. Evidence obtained with research approaches other than the epidemiological method, such as empirical, social or political science, needs thus to be considered in an assessment. Non-epidemiological research might be particularly appropriate to obtain evidence on aspects such as preferences, compliance, barriers to implementation, etc., which affect the intervention in question, and thus need to be taken into consideration when formulating recommendations on an intervention in a particular context.

The notion of evidence recently agreed by consensus for use within the WHO Regional Office for Europe – “findings from research and other knowledge that may serve as a useful basis for decision-making in public health and health care” (WHO Regional Office for Europe 2004) – emphasizes the potential relevance and validity of different study designs and research forms. It goes one step further, also acknowledging the value of evidence obtained with methods that – within the scope of some scientific discourses – are not considered to be scientific (for instance, public opinion surveys). The evidence-based approach requires that these “other kinds of evidence”, as well as evidence from research, are submitted to a systematic critical appraisal of their validity prior to the formulation of recommendations.

Health technology assessment in Europe – institutions and projects

The beginning of HTA in Europe can be dated back to the late 1970s, when interest in the economic aspects of health technologies started to grow, and the first scientific activities in the evaluation of health interventions in terms of HTA can be identified (Jonsson 2002). In Europe, the first institutions or organizational units dedicated to the evaluation of health care technologies were established in the 1980s, initially at regional/local level in France and Spain. The first national agency for HTA was established in Sweden in 1987. The late 1980s and the 1990s can be described as the era of institutionalization of HTA in Europe. Since then, in almost all countries of the European Union, programmes for HTA have been established through either the foundation of new agencies or institutes, or the establishment of HTA departments or units in universities or in other existing governmental and non-governmental bodies (see Box 3, overleaf).

Several reviews of the development and institutionalization of HTA in Europe have been conducted, each with different focuses and levels of comprehensiveness (Banta & Oortwijn 2000; Gulacsi 2001; Oliver et al. 2004). The result is a varied picture. The heterogeneity of HTA institutions in Europe reflects the variety of traditions and socioeconomic contexts of European health care systems. There are agencies for HTA with national mandates and those with regional ones. There are HTA institutions conceived to support decisions only at the level of investment in equipment for hospitals and those expected to give advice about policies concerning the organization of the whole health care system. HTA might be directly committed and funded by governments (national or regional) or by non-governmental organizations spending publicly collected money. The bodies performing HTAs are mainly funded by financial resources from the health care system or from the research and development budget.

The results of HTA are used, with varying levels of impact on decision-making, to plan capacities, to shape the benefit catalogue or to reorganize service provision. However, regardless of geographical and political variations, European HTA researchers share a common body of principles and methods, particularly the intention to support decision-making and the aspiration to provide the best available evidence on the different aspects of a technology or intervention. The means to achieve best available evidence might differ slightly: some agencies limit themselves to performing reviews of results from existing research; others also design primary collection and adequate analysis of data relevant to the policy questions. With regard to the kind of technologies evaluated by European HTA agencies, preventive and health promotion interventions are still under-represented. This is especially true for those preventive activities taking

Box 3: Year of foundation of agencies, institutes or departments for HTA*

Year of establishment/ starting HTA activity	Organization	Country/ region
1982	CEDIT Comité d'Evaluation et de Diffusion des Innovations Technologiques Assistance Publique Hôpitaux de Paris	France
1984	CMT Center for Medical Technology Assessment	Sweden
1987	SBU Swedish Council on Health Technology Assessment in Health Care	Sweden
1987	TNO The Netherlands Organization for Applied Scientific Research	Netherlands
1988	– National Fund for HTA	Netherlands
1989	ANAES (formerly ANDEM) National Agency for Accreditation and Evaluation in Health	France
1990	ITA Institute of Technology Assessment, Austrian Academy of Sciences	Austria
1991	CAHTA (formerly COHTA) Catalan Agency for Health Technology Assessment and Research	Spain
1992	OSTEBA Basque Office for Health Technology Assessment	Spain
1992	SFOPH Swiss Federal Office of Public Health	Switzerland
1992	TA-SWISS Swiss Science and Technology Council/Technology Assessment	Switzerland
1994	AETS Agencia de Evaluación de Tecnologías Sanitarias	Spain
1995	FinOHTA Finnish Office for Health Technology Assessment	Finland
1995	HSMTA Health Statistics and Medical Technology Agency	Latvia
1996	AETSA Andalusian Agency for Health Technology Assessment	Spain

Box 3: cont.

Year of establishment/ starting HTA activity	Organization	Country/ region
1996	NCCHTA National Coordinating Centre for Health Technology Assessment	UK
1997	DACEHTA (formerly DIHTA) Danish Center for Evaluation and Health Technology Assessment	Denmark
1998	DSI Danish Institute for Health Services Research	Denmark
1998	NHSC National Horizon Scanning Centre	UK
1998	SMM Norwegian Center for Health Technology Assessment	Norway
1998	– Federal Committee of Physicians and Sickness Funds (since 2004: Federal Joint Committee)	Germany
1999	MTV-Aarhus Unit for Health Technology Assessment – Aarhus University Hospital	Denmark
1999	NICE National Institute for Clinical Excellence	UK
2000	DAHTA German Agency for Health Technology Assessment	Germany
2000	HTBS Health Technology Board for Scotland	UK
2001	HunHTA Unit of Health Economics and Health Technology Assessment	Hungary
2001	MTV-Odense Unit for Health Technology Assessment – Odense University Hospital	Denmark
2002	UETS Unit for Health Technology Assessment – Madrid Region	Spain
2003	FKG Federaal Kenniscentrum voor de Gezondheidszorg/Centre Fédéral d'Expertise des Soins de Santé	Belgium

*This overview is not intended to be exhaustive; it reflects developments up to 2004.

place outside the health care system (for example, road traffic policies), or those targeting the community rather than individuals (Banta et al. 2002).

Since the beginning of HTA activities, efforts have been made at international level to share experiences. The first meeting of the International Society for Technology Assessment in Health Care (ISTAHC, today called HTAi: www.htai.org) in 1985 makes evident the beginning of international networking in the field of HTA.

At European level three projects have been conducted which should be mentioned here, since they have contributed to the development of cooperation in HTA and to the establishment of a culture of evidence-based decision-making in European Union countries. These projects were all funded by the European Commission, which has recognized the value of HTA.

The results of the *EUR-ASSESS project* were published in 1997 (Banta et al. 1997) and this was the first step towards standardization of methods for priority-setting concerning the technologies to be evaluated, and standardization of the methods for undertaking HTAs. Furthermore, the project highlighted methods to disseminate findings from HTA research.

The network established in the EUR-ASSESS project was strengthened in the course of the *HTA Europe project* (Banta & Oortwijn 2000). The aim of this was to provide an overview of the implementation of HTA in the European Union, as well as an inventory of the institutions involved in HTA and results of their work.

The third project, the *European Collaboration for Health Technology Assessment (ECHTA)*, can be seen as the successful result of the two previous efforts. In this project, several established agencies and individual researchers in the field of HTA explored the possibilities of institutionalizing HTA at European level and sharing efforts in ongoing assessments as well as in education in the field of HTA (Jonsson et al. 2002). The formulation of best practice guidelines for undertaking and reporting HTAs (Busse et al. 2002) is one of the most prominent outputs of this latter project.

The network of individuals and organizations which have been established through these projects is still functioning informally and is able to serve as the core of a future European HTA network. Meanwhile, HTA has been recognized by the EU's health ministers to be an area of importance for EU-wide cooperation.

In addition to existing informal networking, the Regional Office for Europe of the World Health Organization has launched the Health Evidence Network (HEN), an Internet-based resource, whose aim is to provide evidence-based answers for questions posed by decision-makers (www.euro.who.int/HEN). The HEN provides concise and standardized reports on available evidence on topics currently under discussion in the countries of the European region, such as reduction of hospital beds or the implementation of disease management programmes.

Networking in the field of HTA, however, is not limited to Europe. The International Network of Agencies for Health Technology Assessment (INAHTA), which was established in 1993, currently comprises 42 HTA organizations from 21 countries (www.inahta.org), and provides access to a database of HTA reports and ongoing assessments which dates back to 1988. Furthermore, INAHTA has facilitated joint assessments, including one on PSA-screening for prostate cancer (Schersten et al. 1999), in which several HTA agencies have shared the work on the assessment of a technology.

Conclusion

Health technology assessment can provide a unique input into the decision-making processes of the health system. In accordance with its broad concept of technology, the principles and scope of HTA can be applied in order to assess the potential consequences not only of medical interventions but also of organizational interventions, and even of health care reform, since the latter can be considered an intervention in the health system. The thorough assessment of the potential effects on health, and of the consequences for the health system, the economy and the society in which a technology is to be introduced or excluded, the acceleration or slowing down of its diffusion, or of the different options for reform, is what HTA can offer to decision-makers. To fulfil this task properly, evidence from different research traditions will have to be considered in an assessment.

Authors: The authors of this policy brief are Marcial Velasco-Garrido and Reinhard Busse, both of the Department of Health Care Management, Technische Universität Berlin, Germany. Professor Busse is also one of the research directors of the European Observatory on Health Systems and Policies.

Acknowledgements: The authors would like to express their gratitude to David Banta, Martin McKee, Nina Rehnqvist and Markus Wörz for their reviews and their invaluable comments on the manuscript.

References

Banta D (2003). Considerations in defining evidence for public health: the European Advisory Committee on Health Research, World Health Organization Regional Office for Europe. *International Journal of Technology Assessment in Health Care*, 19:559–572.

Banta D, Behney CJ, Andrulis DP (1978). *Assessing the efficacy and safety of medical technologies*. Washington, Office of Technology Assessment.

Banta D et al., eds. (1997). Report from the EUR-ASSESS Project. *International Journal of Technology Assessment in Health Care*, 13:133–340.

Banta D, Oortwijn W, eds. (2000). Health technology assessment in the European Union. *International Journal of Technology Assessment in Health Care*, 16:299–635.

Banta D et al. (2002). Health promotion and disease prevention as a complement to community health indicators. *International Journal of Technology Assessment in Health Care*, 18:238–272.

Battista RN (1996). Towards a paradigm for technology assessment. In: Peckham M, Smith R, eds. *The scientific basis of health services*. London, BMJ Publishing Group.

Briss PA et al. (2000). Developing an evidence-based guide to community preventive services – methods. *American Journal of Preventive Medicine*, 18(1S):35–43.

Britton A et al. (1998). Choosing between randomised and non-randomised studies: a systematic review. *Health Technology Assessment*, 2(13).

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

Council of Europe (2001). *Developing a methodology for drawing up guidelines on best medical practices* (Recommendation (2001)13 and explanatory memorandum). Paris, Council of Europe.

GRADE Working Group [Atkins D et al.] (2004). Grading quality of evidence and strength of recommendations. *British Medical Journal*, 328:1490–1494.

Gulacsi L (2001). Health technology assessment in Central and Eastern Europe. *Eurohealth*, 7:34–36.

Ham C, Hunter DJ, Robinson R (1995). Evidence based policymaking. *British Medical Journal*, 310:71–72.

Henshall C et al. (1997). Priority setting for health technology assessment: theoretical considerations and practical approaches. *International Journal of Technology Assessment in Health Care*, 13:144–185.

Innvaer S et al. (2002). Health policy-makers' perceptions of their use of evidence: a systematic review. *Journal of Health Services Research and Policy*, 7:239–244.

Jonsson E (2002). Development of health technology assessment in Europe. *International Journal of Technology Assessment in Health Care*, 18:171–183.

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

Jonsson E et al., eds. (2002). European collaboration for health technology assessment: developing an assessment network. *International Journal of Technology Assessment in Health Care*, 18:213–455.

Lohr KN, Carey TS (1999). Assessing “best evidence”: issues in grading the quality of studies for systematic reviews. *Joint Commission Journal on Quality Improvement*, 25:470–479.

McQueen D, Anderson LM (2001). What counts as evidence: issues and debates. In: Rootman I et al., eds. *Evaluation in health promotion: principles and perspectives*. Copenhagen, World Health Organization, pp. 63–82.

Oliver A, Mossialos E, Robinson R (2004). Health technology assessment and its influence on health-care priority setting. *International Journal of Technology Assessment in Health Care*, 20:1–10.

Perleth M, Jakubowski E, Busse R (2001). What is “best practice” in health care? State of the art and perspectives in improving the effectiveness and efficiency of the European health care systems. *Health Policy*, 56:235–250.

Sackett DL et al. (1996). Evidence based medicine: what it is and what it isn't. *British Medical Journal*, 312:71–72.



Schersten T et al. (1999). *Prostate cancer screening: evidence synthesis and update (INAHTA Joint Project)*. Vitoria-Gasteiz, Spain, Osteba (Basque Office for Health Technology Assessment, Health Department of the Basque Government).

Schwartz PJ et al. (1999). The legal implications of medical guidelines – a task force of the European Society of Cardiology. *European Heart Journal*, 20:1152–1157.

Silagy C et al. (2004). Nicotine replacement therapy for smoking cessation. *The Cochrane Database of Systematic Reviews*, Issue 3, Article No. CD000146. DOI: 10.1002/14651858.CD000146.pub2.

West S et al. (2002). *Systems to rate the strength of scientific evidence*. Evidence Report/Technology Assessment No. 47. Rockville, Agency for Healthcare Research and Quality.

WHO Regional Office for Europe (2004). *Evidence policy for the WHO Regional Office for Europe*. Copenhagen, (<http://www.euro.who.int/document/eni/evidencepolicy.pdf>, last accessed: 11.03.2005).

Wolf SH et al. (1994). Methodology. In: Canadian Task Force for the Periodical Health Examination. *The Canadian Guide to Clinical Preventive Health Care*. Ottawa, Canada Communication Group Publishing, pp XXV–XXXVIII.



The European Observatory on Health Systems and Policies supports and

promotes evidence-based health policy-making through comprehensive and rigorous analysis of health care systems in Europe. It brings together a wide range of policy-makers, academics and practitioners to analyse trends in health care reform, drawing on experience from across Europe to illuminate policy issues.

The European Observatory on Health Systems and Policies is a partnership between the World Health Organization Regional Office for Europe, the Governments of Belgium, Finland, Greece, Norway, Spain and Sweden, the Veneto Region of Italy, the European Investment Bank, the Open Society Institute, the World Bank, CRP-Santé Luxembourg, the London School of Economics and Political Science, and the London School of Hygiene & Tropical Medicine.

More information on the European Observatory's country monitoring, policy analyses and publications (including the policy briefs) can be found on its web site at: www.observatory.dk

WHO European Centre for Health Policy
Rue de l'Autonomie 4
1070 Brussels
Belgium

Please address requests about
publications to:
Publications
WHO Regional Office for Europe
Scherfigsvej 8
DK-2100 Copenhagen Ø
Denmark

for copies of publications:
publicationrequests@euro.who.int
for permission to reproduce them:
permissions@euro.who.int
for permission to translate them:
pubrights@euro.who.int