Institutionalization of Health Technology Assessment

Report on a WHO Meeting

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ABSTRACT

The WHO Regional Office for Europe convened a meeting for the description and discussion of experience with and the options for institutionalizing health technology assessment (HTA) in different countries and health systems. In this context, institutionalizing meant promoting structures and processes suitable to produce technology assessments that will be powerful in guiding policy and clinical practice towards the best possible health and cost outcomes. The meeting also explored ways of integrating HTA activities with initiatives for quality assurance (QA). The recommendations stressed the legal role of HTA in the health care system and called for the provision of sufficient resources; the integration of methods of HTA and QA; cooperation, communication and networking among HTA institutions in different settings and countries; training and education in HTA with emphasis on the implementation of results by empowering decision-makers; and the further development of HTA methods and processes.

Keywords

TECHNOLOGY ASSESSMENT, BIOMEDICAL QUALITY ASSURANCE, HEALTH CARE POLICY MAKING ORGANIZATIONAL OBJECTIVES EUROPE
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Background and purpose of the meeting

A systematic approach the evaluation of the effects of medical technologies (Health Technology Assessment, HTA) is accepted internationally as an important means to increase evidence and information for decision-making in health care systems. HTA has been instituted through publicly or privately financed activities in Europe. HTA reports based on scientific studies are carried out by agencies or other institutions primarily designed to assist policy-makers at the system level (top-down). Results from clinical databases developed to assist health care providers in decision-making in daily work may also be used in the context of HTA (bottom-up approach). In order to achieve a comprehensive assessment of technologies, these HTA reports should be complemented by providers’ and users’ (e.g. purchasers, patients) assessments being performed in the daily circumstances of the health care delivery reality.

A number of European HTA collaborative projects and networks have been established since the 1990s (e.g. EUR-ASSESS, HTA Europe). The current European Collaboration in Health Technology Assessment (ECHTA) project aims at a closer cooperation and more standardization among European HTA agencies. The Quality of Health Systems Programme at the WHO Regional office for Europe has developed several projects and models on HTA at the clinical level in all European Member States for quality of care development purposes. Efforts to institutionalize HTA can build upon these experiences.

This symposium aimed at describing and discussing the experiences and options of institutionalizing HTA with respect to developments in countries and health systems. “Institutionalizing” hereby refers to promoting structures and processes suitable to produce technology assessments that will be powerful in guiding policy and clinical practice towards the best possible health and cost outcomes.

Building upon the results of two previous WHO meetings (“Reshaping Health Systems towards Health Outcomes” in Celle, Germany in December 1997 and “Experiences with Quality Management in an International Context” in Velen, 1998), this event was planned as a two-day meeting during which the following questions were addressed: What is the role of HTA in the framework of evidence-based health care? How are decisions in health care systems at different levels informed by HTA? What are the best ways of institutionalising HTA? How can experiences from different countries and health care systems be used in this process?

Representatives from health care management, health policy, private and public payers, providers, users and applied health services researchers in the field of HTA participated in and contributed to the meeting.

Executive summary

An international workshop jointly organized by the Hanover Medical School and the WHO Regional office for Europe, financially supported by the German Ministry of Health, discussed the experiences and options of institutionalising Health Technology Assessment (HTA). HTA is a multidisciplinary activity that systematically examines the consequences of the use of medical technologies in order to provide evidence-based input in decision-making in policy and practice. The workshop also explored ways of integrating HTA activities with quality assurance (QA)
initiatives with regard to the WHO quality of care development (QCD) concept. QCD has its focus on the development of information systems that enable providers, patients and payers to collect and compare (benchmark) biomedical outcomes, user wellbeing and costs using common, agreed quality indicators.

HTA and quality assurance/QCD could be of mutual benefit if used to gain a comprehensive picture of medical technologies or when barriers at the health care professional level impede implementation of findings and when there is evidence that effective technologies are used inappropriately or low quality. Important developments that may inform both QA and HTA but are not yet widely used are population-based disease and procedure registries (suitable for both HTA and QA), use of clinical and outcome indicators and methods to measure the appropriateness of use of health technologies.

It was recognized that HTA and QA should be embedded in an evaluation culture. Such a culture relies on the identification, implementation and evaluation of health care for defined indications and patients/population groups according to the best evidence on effectiveness, cost–effectiveness, appropriateness, availability and quality.

With regard to training and education in HTA, it is important to consider the relatively small number of experts currently active in the field and – in contrast – the large number of new and existing technologies to be evaluated. Successful HTA programmes require an appropriate education and training strategy targeted at expertise, organization and staff qualification.

A number of recommendations for the German Ministry of Health and for other European countries were developed. These are related to the legal role of HTA in the health care system and the provision of sufficient resources; integration of methods of HTA and QA; cooperation, communication and networking of HTA institutions in different settings and countries; training and education in HTA with emphasis on the implementation of HTA results by means of “empowerment” of decision-makers; and on the further development of HTA methods and processes.
### Introduction

Health technology assessment (HTA) according to Banta is defined as a multidisciplinary activity that systematically examines technical performance, safety, clinical efficacy and effectiveness, cost, cost–effectiveness, organizational impact, social consequences, as well as legal and ethical aspects of the application of a health technology. The term derives from the political and social debates about environmental and social consequences of technologies in the 1960s and 1970s. Health technologies according to the former U.S. Office of Technology Assessment “are the drugs, devices, procedures, and the organizational support systems within which health care is delivered”. Given this broad context, HTA is not defined by a set of methods, but by its intention. The goal of HTA is to provide input to decision-making in policy and practice and to ensure value for money.

Although HTA has made much progress during the last decade, it is still in its early days in Germany. The same holds true for quality assurance (QA), which emphasises the importance of ownership and self-evaluation from a bottom-up perspective. HTA aims at linking evidence to decision-making in health care following a top-down approach. Few attempts have been made so far to link both concepts to the benefit of both. It is hypothesized at the outset of this workshop that efforts both in HTA and QA may not only benefit from each other but also make up complementary pieces in the larger puzzle of the health care system (Fig. 1).

![Fig. 1. Relation between HTA and QA](image)

HTA and quality assurance could be used complementarily in order to gain a comprehensive picture of medical technologies when barriers at the health care professional level impede implementation of findings and when there is evidence that effective technologies are used inappropriately or are provided at low quality. Thus, HTA should acknowledge the potential of quality initiatives, including guidelines, and QA may benefit from HTA, since quality also refers to provision of effective and cost-effective care.
Overview of major topics discussed in the meeting
(See also programme as Annex 3)

Health technology assessment for overall policy-making

Of the 51 European countries, health technology assessment (HTA) has only been introduced in western and northern Europe. The European Commission has recently stressed the increasing importance of HTA and there are growing links between HTA and policy-making. Within the context of evaluation of health care interventions, regulation of drugs, devices and procedures, coverage of new and established technologies, planning and regulation of investments, payment of services, quality assurance, consumer information, and education and training, HTA plays a functional role in supporting decision-making at the different levels of health policy, management and practice.

Many European countries are at various stages of institutionalization of HTA. Some countries have a long-standing tradition, such as the United Kingdom or Sweden (where an HTA agency has been established since 1987), while others only recently started systematic HTA activities. The diversity of the organization of HTA in different countries with regard to mission, structure, financing, priority setting and impact on decision-making was demonstrated using examples of four well known HTA agencies from Spain, Finland, Canada and the Netherlands. It is often difficult to assess impact of HTA on clinical practice as well as on policy decisions because of insufficient resources for this task. This is also true for maintaining external relations and communication. The need for and usefulness of international collaboration and networking was stressed as well.

Although evaluations of many individual technologies exist, they are not always applied in the context of systems. Thus, one of the key issues is the need to adopt a “systems of care” context and to extend HTA to the assessment of whole systems. How this is approached in Europe was shown for Switzerland, the United Kingdom and some central and eastern European countries.

Switzerland serves as an example of a predominantly insurance-based health care system. By legislation, a basic benefit package is defined that ensures efficacious, appropriate and efficient health care. Advisory committees exist for drugs, devices, equipment and laboratory analysis. New procedures are assessed by the Federal Social Insurance Office Switzerland (FSIOS). FSIOS carries out its tasks according to an HTA manual to ensure a standardized approach to the evaluation of medical technologies. Exemption rules for experimental technologies exist and usually no simple “yes/no” decisions are made. The Swiss Network on HTA (SNHTA) and the International Network of Agencies for HTA (INAHTA) also play an important role.

As an example of a predominantly tax-based system, the United Kingdom National Health Service (NHS) has adopted an increasingly important research and development policy since 1991 with emphasis on evidence and a scientific basis for interventions. In 1999, the National Institute for Clinical Excellence (NICE) was established which has three main areas of responsibility: appraisal of evidence; judgements on impact, feasibility, priority, costs; and guidelines/guidance. NICE is embedded in and plays an important role in the relations between the Department of Health, the NHS, HTA and QA. Science and decision-making are separated in this system. Although it is too early to assess the impact of such a central system, it is clear that mechanisms exist to ensure a role for HTA in a central, tax-based system.
The countries of central and eastern Europe such as Croatia, where systems are in transition, have just begun to establish HTA capacity since no structures exist yet. They tend to adopt and adapt existing models and affordability remains one of the key issues. Considering the gap between east and west in avoidable deaths, the key question is the extent to which health care contributes to population health. HTA can lead to increased efficiency with regard to allocation of coverage, reimbursement, funding, regulation, patient education and facility planning. It is therefore desirable to foster the culture of evaluation. This, however, needs resources and assistance. First steps may comprise the establishment of core groups at the government level, communication with stakeholders, and the creation of data warehouses and networks. With regard to costs of care and the ageing population, it is concluded that modern health care systems cannot afford not to have HTA.

**HTA in health care delivery**

Developing a culture of measuring by using several tools, such as quality indicators, basic information sheets and appropriate software, but also increased accountability, may establish self-assessment and self-regulation as integral part of the daily work in clinical practice. Clinical databases that focus on low-cost common technologies versus high technology; correlation between output and content; bottom-up/top-down synergy; driven by professions not by industry; increase equity and access to emerging technology may be especially helpful in this regard. The development of an appropriate information system enabling providers, patients and payers to collect and compare (benchmark) quality indicators in terms of biomedical outcomes, user wellbeing and cost is needed for this purpose. This approach is part of the WHO quality of care development (QCD) concept. The feasibility of such information systems has been tested and an internet server has been set up at the WHO Regional Office for Europe in Copenhagen enabling health care providers and health care institutions in different countries to compare and benchmark their results. Similarities between HTA and QCD refer to scope, evaluation and implementation taking into account utilization, outcomes and costs of health care. According to the WHO concept of the development of quality in health systems, all components of health technology systems, organizations, processes, procedures, devices and drugs should be subject to assessment, comparison and continuous improvement.

The combination of top-down and bottom-up approaches of HTA can be mutually beneficial in maximizing the benefit of health services. Issues for further development are: reaching users and beneficiaries effectively; a need for common European terminology; and more transparent and systematic methods for observational studies. It should be recognized that HTA can inform and advise but not replace choices, decisions and actions made by politicians, professionals, payers and users. There is a need to distinguish between maximum possible effect of technology (efficacy) from actual provider performance (effectiveness).

Important developments that may inform both QA and HTA are population-based disease and procedure registries, use of clinical and outcome indicators and methods to measure the appropriateness of use of health technologies.

In principle registers are systematic and comprehensive collections of diagnosis – and/or procedure related patient data. They provide detailed and periodically updated information on individuals. In the context of technology assessment two different types of registries are of outstanding relevance: population-based disease registries and procedure-related evaluation registries. The former aim at the registration of all cases of the target disease within a defined population and within a defined period of time. Data are collected on the demographic
characteristics of the patients, disease-related data and relevant outcomes. The latter record all medical procedures of a certain type (e.g. arthroplasties, transplantation, cardiac catheterization, in-vitro fertilizations). In addition to the categories of data mentioned above, information relating to the procedure itself (e.g. indication algorithms, technical details, peri- and post-procedural care) are collected. Table 1 shows at which stages data from registries may yield valuable input to the HTA process. To avoid “data death”, a model project has recently been initiated in Denmark that aims at the integration of several databases and registries for use in HTA.

Table 1. Importance of registries for HTA

<table>
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<tr>
<th>Stage</th>
<th>Disease registry</th>
<th>Procedure related registry</th>
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<tr>
<td>Estimating burden of Illness</td>
<td>+++ (incidence/prevalence of target condition)</td>
<td></td>
</tr>
<tr>
<td>Efficacy</td>
<td></td>
<td>+ (if delivery of procedure is bound to trial conditions)</td>
</tr>
<tr>
<td>Needs assessment</td>
<td>++ (incidence/prevalence of target condition)</td>
<td>+++ (identifying ability to benefit)</td>
</tr>
<tr>
<td>Community effectiveness</td>
<td></td>
<td>+++ (if delivery of procedure is not limited by trial conditions)</td>
</tr>
<tr>
<td>Efficiency</td>
<td>++ (incidence/prevalence of target condition)</td>
<td>++ (size of benefit in different target groups)</td>
</tr>
<tr>
<td>Implementation</td>
<td>+++ (incidence/prevalence of target condition)</td>
<td>+++ (size of benefit in different target groups)</td>
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A framework for the use of clinical and health outcome indicators for HTA purposes in the United Kingdom using internet technology was demonstrated. This framework functions as a whole systems approach to outcomes assessment with some 150 clinical and health outcome indicators with attached data tables, maps and graphs showing geographical and institutional comparisons. Health outcome overviews show the relationship between health outcomes, health interventions and resource use for a number of diseases and clinical areas, the relationship between the indicators and health outcome objectives, and the relationship between the indicators and the NHS Performance Assessment Frameworks. Further activities include reports on development and evaluation of indicators, and case studies to follow up indicator findings, reports on statistical and other methods used.

Variation in the use of health technologies often leads to the initiation of HTA or QA measures respectively. Methods to study such variations include pharmacoepidemiological studies. Where controlled trials remain the best means of evaluating drugs under controlled and optimal conditions, pharmacoepidemiological studies evaluate how a medication is applied or performs under highly variable conditions in the heterogeneous population for which it was intended. The main sources of data for these studies are prescription databases, which allow evaluations of patterns of drug use, and record-linkage studies, which can investigate associations between drug use patterns and some outcomes. Pharmacoepidemiological techniques have been used to evaluate effectiveness, safety, and health economic outcomes in large populations. However, standards for effective doses and for effective length of time of treatment must be defined.

The use of drugs and technology in diabetes care illustrates the importance of such databases. The St Vincent Declaration Diabetes Action Programme (1989) endorsed by all European ministers of health sets targets for reducing complications from diabetes and improving the quality of diabetes care. In Germany alone, there are about 4 million people with diabetes, of
which the majority are older patients with type II diabetes. For type II diabetes a lot of interventions are not evidence based (e.g. blood glucose self-monitoring) and population data on blindness and amputation rates indicate no improvement over the last 12 years. Although there is evidence that optimal management, teaching programmes and weight reduction could lower the need for oral anti diabetics and improve outcomes, the use of such drugs has been increased considerably in the last decade, leading to substantial unnecessary expenditures.

On a systems level, indicators of the impact of evidence on the performance of health care systems have been further developed in the WHO World Health Report 2000, which focused on the analysis of overall performance of health care systems with regard to goal attainment (Fig. 2), performance (Fig. 3) and functions of health systems. The key question was “What do you get for what you put in?” in light of evidence that not every country is getting the maximum possible return for the resources used.

Fig. 2. Framework for goal attainment according to World Health Report 2000

<table>
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<th>Health</th>
<th>Level</th>
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<tr>
<td>Responsiveness</td>
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<td>Fairness in financing</td>
<td></td>
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<tr>
<td>Distribution</td>
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\[
\begin{array}{c}
\text{Quality} \quad \text{Equity} \\
\hline
\text{efficiency}
\end{array}
\]

Fig. 3. Performance measurement using health system resources and goal achievement according to World Health Report 2000

Goal achievement

\[
\begin{array}{c}
\text{Maximum achievable} \\
A \quad \text{B} \\
\text{Minimum possible}
\end{array}
\]

Health system resources

Functions of health systems include stewardship, resource generation, financing, revenue collection, fund pooling, purchasing, provision of services, personal health services and non-personal services. The following key policy transitions were postulated based on the health report: from rigid regulation to strategic stewardship; from segmented revenue collection to solidarity based pre-payment; from limited to broad fund pooling, from inertial and unstructured to active purchasing, from unregulated to explicit service provision. These goals may be achieved by empowerment of decision-makers, improving performance, relation of goals to functions and structured approaches to evidence-based information of decisions.
Research and development and training in HTA

There is an interdependence of producing evidence and establishing a culture of evaluation and this should be reflected in the HTA activity cycle. Such an evaluation culture relies on identification, implementation and evaluation of health care for defined indications and patients/population groups according to the best evidence on effectiveness, cost-effectiveness, appropriateness, availability and quality. Elements of establishing an evaluation culture comprise adoption of the concept of best practice/evidence-based health care; establishing of formal links between health policy decisions and HTA or systematically derived evidence; and integration of HTA into market admission, regulatory procedures (e.g. coverage) and health care management. Necessary steps are: on a political level, the set-up of a legal basis for HTA (e.g. Switzerland) including independence and funding; on the management/corporate level, integration of HTA into contracting/negotiations are crucial; capacity-building should aim to provide training, career opportunities, and establishing centres of excellence.

Another important issue is the timely provision of evidence for decision-making (Fig. 4). At the time of the introduction of a new technology clinical evidence is often sparse and little is known about the use of established technologies (appropriateness, quality).

Elements of a comprehensive HTA programme comprise: independent evaluation capacity; horizon scanning; explicit criteria and responsiveness to demands of decision-makers; collecting and synthesizing data; dissemination of results; implementation (+ disinvestments of less cost-effective technologies); evaluation of impact; feedback.

Producing evidence, i.e. collecting and synthesizing clinical and economic data, forms the basis for evidence-based decision-making. Evidence comes from clinical trials, observational studies, systematic reviews (e.g. from the Cochrane Collaboration), HTAs, clinical practice guidelines, drug trials and other studies. The validity of the scientific evidence is usually ranked according to levels of evidence scales, which rank systematic reviews highest and expert opinions and case studies lowest. Various methods of assessing the quality of studies exist, but no consensus has been achieved so far on this. Other crucial steps to producing evidence include literature searches, assessing and avoiding the several types of bias (such as publication bias, language
bias, retrieval bias), synthesis of the evidence (may be qualitative or quantitative, hence meta-
analysis or formal decision-analysis) and publication of results (both paper versions and online
electronic versions). The major issues to date are to improve access to evidence, filling methodological gaps and accept this type of work as research.

With regard to training and education in HTA, a number of issues should be kept in mind: the relatively small number of academics and other experts currently active in the field; the large number of new and existing technologies which need evaluation; the manner in which many of these technologies continue to change and develop; and the limited funding available for primary research. It is highly unlikely that any single European country could mount a fully comprehensive HTA programme. Successful HTA programmes require an appropriate education and training strategy. Training and education in HTA through effective educational means are targeted at expertise, organization and staff qualification. It is therefore important to distinguish between career researchers who need full technical skills; temporary researchers who may need training in specific skills; commissioners who need implementation skills and the work force, who needs awareness.

A recent survey of training and education (T&E) in HTA showed among others a variety of technologies used; varied by type of organization; variety of levels of interest in HTA; different purposes of T&E; gaps between existing expertise and organizational need. HTA education and training remains relatively underdeveloped in most countries at the start of the present decade. The HTA training and education agenda consists of two broad strands: training to understand/implement HTA findings (evidence-based policy and practice); training to conduct HTA.

Any training and education strategy should include: health care institutions; professional associations; industry, product manufacturers; academic institutions; health care reimbursement/funding agencies; policy-making institutions/agencies. It is no longer just the implementation of findings that are important, but increasingly it is also the integration of HTA into the implementation of the technology which is essential. To date, it has been recognized that there is a need to educate individuals so that they will be able to understand the information (directive) provided by HTA and be amenable to implementing the findings; adapt and translate more complex findings to be applied in their local circumstances.

The concept of T&E in HTA is still evolving, since the recipient community is quite heterogeneous, including different disciplines and perspectives. The quality and breadth needs to be continuously refined.

**Conclusions from the working groups**

Two working groups were set up, one on developing recommendations in regard to Germany in particular and Europe in general and a second on institutionalization of HTA. Representatives of the German Ministry of Health, the Sickness Funds, the National Association of Social Health Insurance Physicians and the German Medical Association expressed their perspectives on HTA. On the part of the government, it was stated that although much has been achieved, a number of issues need to be solved. These include rapid response to demands for HTAs, identification of needs, and international collaboration and networking. Sickness funds as users of HTA need better information to help define a basic benefit package and guidance on when and how health care interventions should be provided. HTA tools have become a method of integrating
knowledge. There is also a potential for community effectiveness research. The National Association of Social Health Insurance Physicians (NASHIP) adopted HTA in 1997 with the establishment of a “Department of Health Technology Assessment”, the first such institution in the German insurance-based health care system. NASHIP has some experience as both a producer and as a user of HTA. From this experience it is essential to have timely, accurate and complete information from HTA available. The Scientific Advisory Board of the German Medical Association (GMA), which represents more than 350 000 physicians, has a longstanding tradition in formulating statements concerning medical technologies. These range from recommendations to legally binding standards. An important area of work is ethical considerations as related to new medical technologies (e.g. xenotransplantation). Thus, the GMA uses HTA as an important tool for developing recommendations. However national harmonization and integration of federal, professional and science policy regarding HTA are needed.

Working Group I

The first working group addressed the following issues: health care system, HTA awareness in Germany, HTA experience, and current situation regarding linkage of HTA to health policymaking.

Existing legislation seems to be sufficient as related to HTA but it is important to promote awareness of HTA at different levels (government, scientific community, management, hospitals). At the political level, possibilities to raise awareness of HTA and to keep it high on the agenda should be pursued. The German HTA project may ultimately lead to the possibility for funding and setting up an HTA society and should therefore be helpful in integrating the scientific and medical community. International networks such as INAHTA, ECHTA (Germany involved), and activities of the EU and WHO should be involved especially with regard to sharing resources. This includes also participation in joint projects. Cross-national issues should assume high priority. Coordination of HTA activities is important, since there are several interested parties involved. A central body should be established that has authority, e.g. for coordination, or for setting priorities on the basis of advisory board efforts. HTA research itself should be decentralized, also funding of HTA. An information exchange platform for HTA for all interested parties should be created. It is recommended by WHO (see World Health Report) that each country should have access to HTA and to develop mechanisms for HTA. Leadership, however, is important, which stresses the need for a coordinating body. HTA in Germany should be multidisciplinary and linked to health policy.

Working Group II

The second working group discussed the issue of how to integrate HTA and quality development under consideration of the peculiar tasks of each of the approaches. HTA and quality development could be regarded as complementary parts (see Fig. 5). HTA deals with the question of what is the right thing to do, and depends on the social, ethical and legal conditions. Quality documentation deals with the questions: do we do it right? How can we do it better? HTA should be made first on the basis of clinical and statistical databases (e.g. mortality data, patient registries). Then continuous quality development should be used to identify problems, document quality and identify new problems. HTA and QCD can in fact be integrated into one framework. Example: HTA on multiple sclerosis and beta interferon in Denmark led to the development of clinical practice guidelines which are evaluated using a database and have already been revised due to scientific research results.
HTA should include recommendations on necessary databases and quality development measures accordingly. Evaluation of clinical practice guidelines must be included when new guidelines are developed. Staff participation is mandatory for the acceptance of and commitment to quality measures. Professional acceptance is also necessary, e.g. by ensuring ownership (Fig. 6). It is important to assess whether people who need and are likely to benefit from a health care intervention indeed receive the intervention. This has not yet been done. A risk of HTA is that those who enter clinical trials are a sub-set of those who receive care, themselves being a sub-set of those with disease; hence they are possibly not representative.

The ultimate purpose of quality development and HTA is improvement of health. Institutionalization may then be referred to as an implementation process which highlights this as an ethical obligation of all professionals, policy-makers and managers.
**Conclusions and recommendations**

In the context of evaluation of health care interventions HTA refers to regulation of drugs, devices and procedures; coverage of new and established technologies; planning and regulation of investments; payment of services; quality assurance; consumer information; and education and training. The meeting aimed at developing recommendations for the German Ministry of Health, but also for other European countries on the basis of the description and discussion of experiences in institutionalizing HTA. “Institutionalizing” was referred to as promoting structures and processes suitable for producing technology assessments with the power to guide policy and clinical practice towards the best possible health and cost outcomes. This also includes thorough consideration of quality development activities. The meeting should therefore be considered as a starting point for a fruitful collaboration between WHO and the international HTA network. One overall conclusion of the meeting was that there should be a right to effective health care for all. Efforts in HTA and quality assurance (QA) could be considered as complementary and should be linked to contribute to the aim of more effective health care.

**Recommendations in detail.**

1. Since HTA and QA are related to decision-making on different levels of health care, a legal role in each health care system for HTA should be defined and adequate resources should be provided to allow access to HTA and to develop mechanisms for HTA. It is essential for decision-making to have timely, accurate and complete information from HTA available.

   This includes:
   - on a political level, the set-up of a legal basis for HTA including independence and funding;
   - on the management/corporate level, integration of HTA into contracting/negotiations;
   - capacity building should aim to provide training, career opportunities, and establishing centres of excellence.

   Sufficient resources should be allocated:
   - to allow for an analysis of impact of HTA on clinical practice as well as on policy decisions;
   - for maintaining external relations and communication.

2. Quality assurance methods should be used when barriers at the health care professional level impede implementation of HTA findings and when there is evidence that effective technologies are used inappropriately or are provided at low quality.

3. According to the WHO concept of the development of quality in health systems, all components of health technology systems, organizations, processes, procedures, devices and drugs should be subject to assessment, comparison and continuous improvement. Important developments that may inform both QA and HTA but are not yet widely used are population-based disease and procedure registries (suitable for both HTA and QA), use of clinical and outcome indicators and methods to measure the appropriateness of use of health technologies. Future activities should ensure that these data sources are utilized in HTA and QA. Conversely, HTA should include recommendations on necessary databases and quality development measures accordingly.
4. More cooperation in the scientific community as well as collaboration and exchange of information with other countries is needed. HTA programmes should take part in international activities and networks.

Cooperation on a national level includes:
- coordination of the interested parties;
- establishment of a central body with a legal mandate for coordination and priority-setting;
- decentralization of HTA research itself as well as funding;
- creation of a platform for information exchange on HTA for all interested parties;
- ensure multidisciplinarity of HTA;
- establishment of formal links to health policy.

International networking includes:
- participation in joint projects;
- cross-national issues should be given high priority;
- exchange of information, project reports, and other materials.

5. Training and education in HTA should be targeted at expertise, organization and staff qualification. Any training and education strategy should include health care institutions, professional associations, industry, product manufacturers, academic institutions, health care reimbursement/funding agencies, and policy-making institutions. Implementation of HTA results should also be based on empowerment of decision-makers by means of training and education.

6. Issues for further development in HTA include:
- reaching users and beneficiaries more effectively (implementation and impact research);
- developing a common European terminology and methodology for HTA and QA;
- more transparent and systematic methods for integrating observational studies, registry data, etc.
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SCOPE AND PURPOSE

The systematic approach to evaluate the effects of medical technologies (Health Technology Assessment, HTA) is accepted internationally as an important means to increase evidence and information for decision-making in health care systems. HTA has been instituted through publicly or privately financed activities in Europe. HTA reports based on scientific studies are carried out by agencies or other institutions primarily designed to assist policy-makers at the system level (top-down). Results from clinical databases designed to assist health care providers in decision-making in the daily work may also be used in the context of HTA (bottom-up approach). In order to achieve a comprehensive assessment of technologies, these HTA reports should be complemented by providers’ and users’ (e.g. purchasers, patients) assessments being performed in the daily circumstances of the health care delivery reality.

A number of European HTA collaborative projects and networks have been established since the 1990s (e.g. EUR-ASSESS, HTA Europe). Efforts to institutionalize HTA can build upon these experiences.

This meeting aims at describing and discussing the experiences and options of institutionalizing HTA with respect to developments in countries and health systems. “Institutionalizing” hereby refers to promoting structures and processes suitable to produce Technology Assessments that will be powerful to guide policy and clinical practice towards the best possible health and cost outcomes.

It builds upon the results of the WHO Conferences on “Reshaping Health Systems towards Health Outcomes” in Celle, Germany in December 1997 and on “Experiences with Quality Management in an International Context” in Velen, 1998.

The meeting is planned as a two-day event during which the following questions should be addressed: What is the role of HTA in the framework of evidence based health care? How are decisions in health care systems, on the different levels, informed by HTA? What are the best ways of institutionalizing HTA? How can experiences from different countries and health care systems be used in this process?

Representatives from health care management, health policy, private and public payers, providers, users and applied health services researchers in the field of HTA will be both contributors to and audience of the meeting.
Annex 2

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Annex 3

PROGRAMME

Friday, 30 June 2000

08.30–09.00  Registration

09.00–09.30  Welcome/opening remarks (Dr F. W. Schwartz)
             Opening (Dr H. Schweim)
             Scope and purpose of the meeting (Dr I. Kalo and Dr M. Perleth)

09.30–10.00 Health care technologies and medical interventions: introducing a
             framework for integrating different approaches to HTA
             (Dr M. Perleth)

SESSION 1: HTA FOR OVERALL POLICY-MAKING

10.00–10.30 HTA in the context of licensing technologies and coverage decisions: a
               European perspective (Dr D. Banta)

10.30–11.00 Coffee break

11.00–12.30 Structuring, financing, organizing and ensuring independence of
              institutionalized HTA
              Dr J. Asua (Spain)
              Dr R. Roine (Finland)
              Dr J. Sanders (Canada)
              Mr G. ten Velden (Netherlands)

12.30–14.00 Lunch

14.00–15.30 HTA in the context of policy-making in different health care systems
              (introduced by Dr D. Banta: HTA Europe experience)
              • Switzerland – predominantly insurance-based (Dr P. Koch)
              • United Kingdom – predominantly tax-based (Dr D. Woods)
              • Greece – mix of insurance-based and tax-based
                (Dr E. Hatziandreu)
              • What can transition systems in central and eastern Europe
                learn from western experience (Dr S. Oreskovic)

15.30–16.00 Coffee break

SESSION 2: HTA IN HEALTH CARE DELIVERY

16.00–17.30 Institutionalization of HTA in the context of health care planning and
             health care delivery – Evidence from comparisons
             (Introduced by Dr I. Kalo)
             Bottom-up: Steering provider performance (e.g. benchmarking, peer
             review, dissemination of outcome information, development of
             guidelines) (Dr E. Jakubowski)
Registers and outcomes measurement  
(Dr D. Lühmann & Dr S. H. Sando)

A framework for the use of clinical and health outcomes indicators for HTA purposes  
(Dr A. Lakhani)

Variation in the use of health technologies (over- and under-use)  
*Dr J. Donoghue: Pharmacoepidemiology as a tool for HTA  
Dr M. Berger: Use of drugs and technology in diabetes care*

Discussion and conclusion

Saturday, 1 July 2000

09.00–09.30  
*Indicators of the impact of evidence on the performance of health care systems (Dr D. Evans)*

SESSION 3: RESEARCH & DEVELOPMENT AND TRAINING IN HTA

09.30–10.00  
*Report from the recently held WHO Workshop on appropriateness in health care (Dr E. Jakubowski)*

10.00–10.30  
*Interdependence of producing evidence and establishing a culture of evaluation: the HTA activity cycle (Dr M. Perleth)*

10.30–11.00  
*Producing evidence: collecting and synthesizing (Dr G. Antes)*

11.00–11.30 Coffee break

11.30–12.00  
*HTA in the context of prepurchase evaluation and procurement (Dr D. Watson)*

12.00–12.30  
*Training and education in HTA: needs and achievements (Dr A. Szczepura)*

12.30–14.00 Lunch

SESSION 4: PARALLEL WORKING GROUP SESSIONS

14.00–15.30  
*Introduction to working groups:  
What do users expect from HTA? Perspectives from Germany  
Dr A. Rüther (DIMDI/Ministry of Health)  
Dr C. Straub (Sickness Funds)  
Dr B. Gibis (National Assoc. of Social Health Insurance Physicians)  
Dr Winter (German Medical Association)*

15.30–16.00 Coffee Break

16.00–17.30  
*Working Group I: Developing recommendations  
• in regard to Germany  
• in regard to Europe in general*

*Working Group II: Institutionalization of HTA:  
Top-down and bottom-up approaches – combining HTA and quality development*

SESSION 5: CONCLUSIONS AND COMMITMENTS

17.30–18.00  
*Summing up and closure (Chairperson)*