The ECHTA/ECAHI Project

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Egon Jonsson (Chairman)
David Banta
Chris Henshall
Laura Sampietro-Colom

Introduction

Health technology is an indispensable part of any nation's health care system. During the past 50 years all member states have increased their technological base for health care, both in terms of knowledge and by investments in equipment, devices and pharmaceuticals. This process has basically gone well. However, several problems have emerged related to the acquisition, diffusion and use of modern health technology. Also, concerns have been raised about the effectiveness and efficiency of already established procedures in health care.

Many innovations in medicine transform into applicable medical technology with potentially great benefits for patients. Although a new technology could prove to be more effective and cost-effective in comparison with established practices, it may face certain obstacles in finding a place in the practice of medicine, particularly if it carries high and clearly visible investment costs.

At the same time, the effectiveness and cost-effectiveness of many established medical technologies have never been assessed. In a sense, these technologies may block the market for other, better proven, innovations. Some estimates show that as many as 90% to 95% of the procedures used in health care have never been evaluated as to their relative cost-effectiveness.

In all countries, the medical profession has traditionally been left free to select technologies for diagnosing and treating patients. This has usually worked satisfactorily, due largely to the general sense of responsibility among the medical profession, accompanied by in-depth training and specialised skills applied in an environment of strong social control overseen by peers.

Nevertheless, the rapid growth of medical technology and the increasing volume of new knowledge from basic and applied clinical research have made it virtually impossible for even specialists to keep up with advancements in the field. Many inappropriate practices have crept into health care, while ineffective and obsolete technology may survive and be in frequent use despite overwhelming evidence of ineffectiveness or, even worse, of doing more harm than good. Examples of such poor investments are found in all member states.

Health technology assessment

There is, in principle, no such thing as a need for medical technology. What is needed is the end outcome of a technology, i.e. what it may do for health and quality of life. The traditional definition of medical technology, applied in the past mainly to equipment and devices, does not enable one to assess anything else than its technical features. Therefore, medical technology needs to be broadly defined. Furthermore, it is impossible to assess the value of a single drug, a medical device or a piece of equipment in pure isolation from other contributions to the end outcome for patients. All medical technologies form parts of a chain of measures in the process of prevention, diagnosis, treatment and rehabilitation. Hence, medical technology is defined generally as:

The equipment, devices and drugs and the medical and surgical procedures used in prevention, diagnosis, treatment and rehabilitation of disease as well as the organisational and support systems used in the delivery of health care.

Thus, technology assessment not only concerns machines and devices. It concerns all measures for preventing disease, such as programmes for mass screening of disease, and technologies for diagnosing disease, such as routine laboratory testing and the use of imaging techniques. It concerns technologies for treatment, such as bypass surgery, artificial lens operations, hip implants, the management of hypertension, diabetes and stroke and the indications for using different pharmaceuticals. It also concerns assessments of rehabilitation programmes, such as those used for alcohol and drug abuse. Finally it concerns the organisation and delivery of care since assessments, by definition, include issues about the use and diffusion of technology. Hence, it is in this context that we use the term “health technology assessment”.

Aim of health technology assessment

Governmental interest in health technology assessment has paralleled the growth in health care spending. It is important to emphasise that the main purpose of assessment is not to save money by denying services or to sacrifice the needs of the individual for some ”public good”.

The aim of health technology assessment is: to improve quality of care by promoting effective and cost-effective technology and protecting the patients from ineffective health interventions.

Health technology assessment in the member states

Nearly all of the European Union governments have established agencies for health technology assessment. Their purpose is to provide policy makers, the medical profession and the general public with syntheses of findings from research on the relative effectiveness and cost-effectiveness of different medical technologies. Several examples show that HTA has substantially impacted on both health policy making and clinical practice.

In general, these agencies are funded by the national health ministry or by local governments. Most of the agencies have no regulatory function, but are advisory bodies. In addition, many research institutions are involved in the field. In the UK, a major activity of the National Health Services research and development programme is aimed at ”assessments of the effectiveness, costs and broader impact of all procedures used by health care professionals to promote health and to prevent or treat illness”. This includes not only synthesising the evidence, but also commissioning primary research to help fill gaps in the evidence.

Different models are used at the operational level, especially in the methodology of synthesising evidence and in the dissemination of findings. Obviously, scientific evidence needs to be interpreted in the light of each country’s system for health care, its culture, demography, disease panorama, health care organisations, resources and wealth.

Collaboration at the European level

The Commission of the European Union is supportive of health technology assessment as a means of establishing best health practice in the member states.

During 1994 to 1997, the Commission funded a collaborative project called the EUR-ASSESS project, which aimed at:

1. Harmonising the methodology for assessments,
2. Exploring mechanisms for efficient dissemination of results,
3. Investigating the possibilities of linking the results of assessments to financing and reimbursement and
4. Developing a process for setting priorities in health technology assessment.

In 1997 to 1998 the EUR-ASSESS project was followed by the HTA Europe project, also supported by the Commission, which included the following aims:

1. Contribute to the effectiveness and cost-effectiveness of health care in Europe through improved HTA,
2. Contribute to the development of institutions for health care technology assessment in Europe,
3. Strengthen co-ordination of health care technology assessment in Europe,
4. Contribute to the development of methods of information transfer among European countries and
5. Furnish guidance to the European Commission concerning how to strengthen and aid co-ordination of HTA activities in Europe.

In 2000, the European Commission signed an agreement for a project aimed at developing a means of collaboration for health technology assessment activities in Europe.

The project, The European Collaboration for Assessment of Health Interventions and Technology (ECHTA/ECAHI) used six working groups to address subjects of importance for networking at the European level, namely:

1. To assess health promotion and disease prevention activities in terms of benefits, risks and economic, social and ethical implications as a complement to community health indicators.

2. To develop systems for routine exchange of information between programmes on:

    - Emerging technology issues
    - Priorities for future evaluation
    - Conduct and timing of ongoing evaluations, including findings from evaluations.

3. To identify possible joint assessments and to co-ordinate findings and existing resources within the community to support joint assessments.

4. To develop and disseminate best practice in undertaking and reporting assessments. To identify needs for methodological development.

5. To develop and co-ordinate education and support networks for individuals and organisations undertaking or using assessment of health interventions. To identify needs in the field and assist in the establishment of new provisions.

6. To identify and share successful approaches to link findings of assessments, their contribution to health indicators and health care decision-making.

All 15 member states of the European Union and observers from 8 other countries were involved in the project (about 110 medical and health policy experts in total). A Steering Committee representing all member states guided the project, and an Executive Committee was responsible for system design and integration. A key challenge for the working groups was to take full advantage of relevant expertise within Europe.

The main goal of the project was to promote European co-operation. The project intended to promote evidence-based health care in the European Community and explore opportunities to strengthen the network throughout the member states.

Findings of the ECHTA/ECAHI project

The main finding of the project is the need to establish a permanent Network mechanism, European Collaboration for Health Technology Assessment (ECHTA), built on the considerations and following recommendations of the six working groups:

- Identify and prioritise needs and opportunities for assessment of health interventions and technology (including those in the area of prevention).

- Gather and disseminate information (e.g. by way of a clearinghouse using an Internet portal providing access to information and advice).

- Enable and encourage collaborative work.

- Develop skills in health technology assessment (e.g. by developing a common framework for training and education in the field, including a Masters degree in health technology assessment).

- Help in further development of methodologies in assessments and “best practice” in assessments. The development of measures for community effectiveness is a particularly pressing task.

- Improve ways of communicating the results of health technology assessment to policy makers, clinicians, industry, patients and the general public to ensure effective implementation of results and realise health gains.

Co-ordinating role for the European Union

All member states of the EU are forced to balance biomedical advances and the promises of innovations with available resources for health care. Difficult choices must be made, and priorities must address the care of ageing populations, soaring costs of health care and public and professional demand for new medical technology – which may or may not substantially improve the quality of care.

Since knowledge is limited about the relative effectiveness of both new and established technologies in health care, there is a need for evidence-based, rather than opinion based, information about the medical, economic, social, ethical and organisational implications of the diffusion and use of health care technology. This need is shared by many parties including industry, researchers, clinicians, health policy makers, patients and the general public. These issues are by no means restricted to the technical capability of health technology. Rather, they are about value for money, equity, access and quality of care, including questions of financing and payment for health services.

Both medical technology and health technology assessment are international in scope. Few differences are found among countries as to the technological arsenal used by the health services. Furthermore, all agencies in the field of technology assessment use essentially the same sources to compile evidence, namely the body of international, scientific literature. The overall findings from systematic literature reviews, performed in any country in the EU, will apply to other member states, but some issues will remain country-specific. Health policy for investments in medical technology cannot be based on scientific evidence alone. Much of what is needed in health policy-making has not been, or cannot be, addressed by research. It goes without saying that governmental priorities, the ethical and social implications of technology and issues of cost-effectiveness cannot be dealt with by a co-ordinating mechanism at the EU level. These must be addressed by each individual member state.

No mechanism has yet been established within the European Union that could regularly and systematically support the decision-making processes with critical facts from the many health technology assessments performed in the individual member states. However, this is of increasing importance, considering the fact that the mere availability and diffusion of a technology may determine its use, rather than population needs, the appropriate indications for use or the true effectiveness of the technology.

Proposal

Many agencies and institutions within the European Union are currently working on assessment of different health care practices, interventions and technology, including evaluations of health care systems and structures.

The aim is to produce evidence-based information for health policy-making and practice. Such information focuses on effective and cost-effective procedures, technology and delivery of health

care, taking account of social and ethical issues. There is evidence of successful improvement from this work, both in terms of the cost and quality of health services.

The European Commission has funded several projects to stimulate collaboration in this field. The ECHTA/ECAHI programme is the latest of these. An informal network has been established among the people involved in this project, mainly to:

- Work together,
- Share information about finished, ongoing and planned evaluations in different countries,
- Share best practice in doing assessments,
- Share experiences and methodology for successful dissemination and implementation of the results into policy and practice, and
- Provide education and training in the field.

There is now a need to strengthen this collaboration and create a sustainable Network within the European Union.

The objective of the Network would be to assist the European Union, its member states and the candidate countries to plan, deliver and monitor health services effectively. Strong commitment and funding from the Commission would allow such a Network to achieve this objective.

The Network should involve those working actively on assessments in health care in Europe, focusing on those in the public sector, but welcoming those working in other settings.

The Network should be based on an agreed workplan, developed within the ECHTA/ECAHI project. A Steering Committee should oversee the Network and should be supported by a Secretariat, initially placed at an existing HTA agency in a member state. The Network should work closely with global collaborative efforts in the field, such as INAHTA (The International Network of Agencies for Health Technology Assessment

Summary Report

1. Introduction

Health technology assessment (HTA) seeks to inform health policy makers by using the best scientific evidence on the medical, social, economic and ethical implications of investments in health care. Technology is broadly defined to include the drugs, devices, medical and surgical procedures used in health care, as well as measures for prevention and rehabilitation of disease, and the organisational and support systems in which health care is provided.

Assessment includes:

1. Identifying evidence, or lack of evidence, on the benefits and costs of health interventions,
2. Synthesising health research findings about the effectiveness of different health interventions,
3. Evaluating the economic implications and analysing cost and cost-effectiveness and
4. Appraising social and ethical implications of the diffusion and use of health technologies as well as their organisational implications.

The HTA process helps identify best practices in health care, thereby enhancing safety, improving quality and saving costs.

For almost 20 years, European governments, especially in the member states of the European Union (EU), have been engaged in developing and supporting this field. HTA is seen by increasingly more policymakers as a key mechanism to assist in making difficult choices.

During the past 10 years, the European Union and the European Commission have gradually become more active in health care, especially with the acceptance of the Maastricht and Amsterdam treaties, which have given the Commission "competence" and legal responsibility, in the field of public health. Recent policy papers concerning health from the European Commission and other bodies of the European Union have highlighted the field of HTA as an important activity of the European Commission in the years to come. In particular, there have been several calls for a formal, established network of European HTA agencies and programmes to form the basis of a truly European programme in HTA. In particular, the European Commission's proposal for a health strategy of the European Community of May 2000, accepted with minor changes, stated this explicitly (p. 18): "The Commission intends to strengthen health technology assessment structures and mechanisms by supporting collaboration between the agencies involved in order to refine methodologies, promote joint working and help disseminate the results of studies effectively."

The population of the European Union (EU) enjoys essentially universal access to health care services, although this is guaranteed in very different ways among the member states, leading to a complex landscape of health care systems within the EU. Despite this diversity, member states face common challenges concerning their health care systems. Demographic developments, dissemination of new diagnostic and therapeutic technologies in health care (e.g. genetics) and growing expenditures in health services are common issues across the European Union. Decision-

makers in the member states (and also in the candidate countries and non-EU countries) are expected to contain costs while preserving universal access to high(est) quality health care. In this context, the common aim of HTA in the EU countries could be briefly described as to provide decision-makers with reliable information concerning the implications of health care interventions to allow scientifically based health policy-making.

The purpose of a formal network of HTA agencies and programmes would be to improve the results of HTA and to make these results more readily available at the country level for improving national, regional and local health policy and practice decisions.

During roughly this same 10-year period, the European agencies and programmes working in HTA have themselves developed such a network, generally with financial support from the European Commission. In connection with the EUR-ASSESS and the HTA-Europe projects, the ECHTA/ECAHI project is the third such project supported by the Commission. Each project contributed to the goals of establishing a formal network. Thus, the desires and needs of the European Union and of the member states concerning HTA have converged. The purposes of the network focus on co-ordinating the work in HTA, avoiding duplication of effort and sharing scarce financial and human resources in meeting critical assessment needs.

This report describes and analyses possible ways forward and considers several critical challenges that need to be faced during the next years within the field of HTA itself. It needs to be emphasised from the outset that principles of accountability and transparency are critical in the development of a European network for HTA.

2. The European Collaboration for Health Technology Assessment –Assessment of Health Interventions (ECHTA/ECAHI) and Its Aim and Objectives

Aim of the ECHTA/ECAHI project

To develop and strengthen the network(s) (of HTA organisations) in the EU by promoting co-operation between the various centres and activities concerned with assessments of health interventions in the member states.

Efforts to develop better co-ordination of HTA in Europe began with discussions among several European leaders in HTA, leading to the EUR-ASSESS project, which existed from 1994 to 1997 and led to a number of useful products. The participants of EUR-ASSESS concluded that an efficient system for sharing information and exchanging experiences among those involved in HTA across Europe was needed. From 1997 to 1999 the HTA-Europe project further explored this issue, while considering several other important issues for HTA in Europe. In its conclusions, the participants in the HTA-Europe project recommended the European Commission to assist in the establishment of a co-ordinating mechanism for HTA.

Continuing efforts toward better co-ordination of HTA in Europe, the European Collaboration for Assessment of Health Interventions-Health Technology Assessment (ECHTA/ECAHI) started to work in 1999 with the aim of developing a co-ordinating mechanism for assessing health interventions. Following the recommendations of EUR-ASSESS and HTA-Europe, the main task of the project was to design and implement a formal European network for HTA. All member states of the EU (with the important participation of Switzerland and Norway and observers from other countries) were actively involved in this effort through representatives of national and regional HTA agencies or through other individuals involved in assessment of health interventions, as not all countries yet have an institution for HTA. The project proposal was submitted to the former Directorate General V (DGV)[1] of the European Commission. After including assessment of health promotion and disease prevention interventions in the objectives of the project, the proposal was approved by the Health Monitoring Committee. The project began formally on 15 December 1999 and was completed on 15 October 2001.

As already stated, the ECHTA/ECAHI project aimed at further improving the co-ordination and co-operation in the field of assessment/evaluation of health care interventions among member states of the EU. The main objective of the project was the development of a system for continuous collaboration and exchange of information and experience in the field of assessment of health care interventions in the European Union. The project proposal stated that a model for formal networking in HTA should be developed.

The project was also intended to produce an overview of the process of HTA in Europe, focusing on key issues for HTA, e.g. assessment of health promotion and disease prevention, databases for HTA, methods for identification, prioritisation and conducting assessment, education and training of HTA doers (and users) and the use and impact of assessments in the health policy-making process.

Further, the advancement of HTA in Europe should be stimulated through the project by bringing together expertise and allowing exchange of experiences from the context of different health systems. In the setting of the project, countries in which the field of HTA is starting to be developed and/or to be institutionalised should also profit and learn from the diversity of the experiences of others.

3. Structure and Methods

The project was structured in six Working Groups each of which addressed issues of critical relevance for HTA in Europe and in which the identification of possibilities for closer collaboration and formal networking could be expected. The overall project was supervised by a Steering Committee in which all participant countries and regions were represented[2]. The Steering Committee included about 20 individuals. An Executive Committee was appointed to oversee the entire project between the meetings of the Steering Committee. Moreover, the Executive Committee was responsible to monitor the work of the subgroups, assuring the functioning of

[1] Directorate General V is now called SANCO (Santé et Consuments)
[2] Members of the Steering Committee, the Executive Committee, the Working Groups and the Secretariat are listed in Annex !

the project through directly interacting with the Working Groups. In addition, the Executive Committee was responsible for synthesising the work of the subgroups into a model for a formal European network, thus depending on the outcomes from the Working Groups. Formally, the project was carried out under the legal and financial responsibility of the Swedish Council for Technology Assessment in Health Care (SBU), which established a Secretariat to manage the project and administer the financial resources provided by the European Commission. The Secretariat kept records of the ongoing work and actively supported the Working Groups and the Steering Committee in administrative and organisational issues (e.g. organising meetings).

The Steering Committee first met in June 1999 before financial support was approved. In the first meeting the composition, objectives and preliminary work plans of the Working Groups were already outlined. This previous work allowed the project to immediately begin with its work after the Commission definitely approved financing for the project. The Steering Committee met on four occasions between June 1999 and October 2001. One of the meetings took place in the context of an international symposium held in Stockholm in May 2001. The symposium gathered representatives of HTA agencies, decision-makers and other potential users of HTA, and aimed at identifying, analysing and discussing current opportunities and future strategies to improve HTA co-operation. The potential benefits of further formal networking of HTA were also discussed at this meeting.

About 70–100 individuals from national or regional HTA agencies, universities and other bodies related to HTA and decision-making in health care, from all EU member states, plus the important participation of Switzerland and Norway, engaged themselves in one of the six different Working Groups. Each of the groups had a specified scope and specific objectives. However, all of the groups shared the primary aim of exploring the possibilities of improving co-operation and networking in HTA within the EU and the European Region. The specific aims and objectives of the Working Groups, as stated in the application for funding submitted to the DGV, are presented in the following table.

WG	***Aim***	**Objectives**
I	*To assess health promotion and disease prevention activities in terms of benefits, risks and economic, social and ethical implications as a complement to community health indicators*	• To analyse current initiatives to assess health promotion and disease prevention activities in European countries • To an overview beneficial health promotion and disease prevention activities • To examine the extent to which HTA has been implemented into health policy and health practice in relation to health promotion
II	*To develop systems for routine exchange of information between programmes on: emerging issues, priority setting and ongoing evaluations and their findings*	• To encourage further development of the existing network for emerging technology issues (EuroScan)· • To share information on methods and results on priority-setting activities • To consider ways of improving information sharing on ongoing assessments and HTA results· • To oversee the development and improvement of clearinghouse activities in all these areas· • To help assure that all HTA programmes benefit from clearing house activities • To help assure that the results of HTA are recognised as relevant and useable for health policy-making and practice

III	*To identify possible joint assessments and to co-ordinate findings and existing resources within the community to support joint assessments*	• To examine and evaluate experiences with joint assessments • To develop models for identifying assessment topics and the European network of institutions that can carry out joint assessments· • To consider strengths and weaknesses of proposed models
IV	*To develop and disseminate best practice in undertaking and reporting assessments and identify needs for methodological development*	• To identify HTA practices used by different agencies and institutions in Europe· • To reach consensus on needs for methodological development and improvement· • To develop general principles describing best practice in HTA • To develop methods and protocols of best practice in HTA for agreement and adoption by HTA programmes
V	*To develop and co-ordinate education and support networks for individuals and organisations undertaking or using assessment of health interventions and to identify needs in the field and assist in the establishment of new provisions*	• To identify available programmes and educational resources • To identify target groups • To conceptualise the needs of these groups and develop a curriculum • To assist in the development of new provisions • To participate in co-ordinating and supporting education activities in Europe • To develop a framework for support from the network to groups, institutions and countries in the process of entering the field of HTA
VI	*To identify and share successful approaches to link findings of assessments, their contribution to health indicators and to health care decision-making*	• To identify experiences of successful implementation of HTA in policy and practice in European countries· • To collect in-depth information on a sub-set of these experiences· • To analyse selected experiences to identify elements leading to success· • To reach conclusions concerning approaches to enhance the use of HTA in policy and practice • To evaluate and rank successful approaches in terms of impact or cost-effectiveness· • To disseminate the resulting information to health policy makers and the medical profession within the EU • To evaluate the impact in terms of improved health policy and practice in Europe

Each of the Working Groups made a working plan and selected the specific methods to achieve their objectives. Surveys, literature overviews and workshops (where Working Group members and potential users of HTA participated and exchanged experiences) represent the most common approaches chosen by the Working Groups to identify needs and opportunities for closer co-operation. Some of the groups contracted academic researchers to carry out research on special topics of interest for the group. Based on the findings of the research, the members of the six Working Groups worked out recommendations for further action aiming at the implementation of a new co-ordinating body for HTA at the European level. In general, each of the Working Groups undertook comprehensive research and exchange work, combining different methods to approach their objectives and producing outcomes that met the general aim of the ECHTA/ECAHI project.

4. Outcomes of the project

Outcomes of ECHTA/ECAHI

- A generally comprehensive overview of the field of HTA and identification of challenges in the areas addressed in the project.
- Proposal for a co-ordinating body for European HTA

4.1. Results from the Working Groups

The results of the ECHTA/ECAHI project are diverse in nature. First, findings of the research carried out by the Working Group members and the contracted researchers represent a comprehensive overview of the present situation of critical areas of HTA in Europe, e.g. education of HTA doers and users, identification of emerging technologies, priority-setting activities, exchange of information through databases, methodology for carrying out and reporting of assessments, joint assessments, assessments in the field of disease prevention and health promotion and impact of HTA in health policy-making. The elaboration of such a comprehensive overview has helped to identify present shortcomings in the areas mentioned.

The six Working Group reports present a rich body of knowledge and experience that can be summarised briefly as follows:

Working Group 1 considered HTA in relation to health promotion and disease prevention in Europe. The main task of the Working Group was to determine, to the extent possible, whether proven methods of prevention are available, whether HTA effectively deals with prevention activities in Europe and whether the results of HTA are used for decision making. A general literature review revealed more than 1000 systematic reviews dealing with the general field of disease prevention and control. These reviews have identified approximately 70 preventive interventions that have been shown by adequate studies to be efficacious/effective in a certain group in at least one country. Thus, the frequent assertion that prevention has not been assessed and that proven technologies are not available for implementation in the health systems of Europe does not appear to be supported by this evidence. To determine if HTA programmes are assessing prevention, a search of the HTA Database (formerly the INAHTA database) was carried out, revealing a considerable number of assessments, 11% of the assessments carried out, again refuting the common impression that HTA does not deal with such issues. Both reviews, the literature review and the review of the HTA Database, also revealed that studies of prevention generally deal with efficacy, with relatively little consideration of costs and cost-effectiveness and little consideration of ethical or other social issues.

To determine if HTA influences health policy and practice in the field of prevention, a special survey of all member states, plus Switzerland and Norway, was carried out, depending on members of the Steering Committee and the Working Group to assure adequate and timely responses. Usable data were obtained from all countries. Because of the large number of possible

interventions, eight were selected for consideration in the survey. An attempt was made to assure that the interventions selected covered a variety of population groups (children, women, etc.) and included cases where important interventions fall outside the responsibility of the health care system, since many important preventive actions do not in fact fall within the organised system of health care. The eight intervention areas were as follows:

- Genetic aberrations and congenital malformations
- Detection and treatment of hypertension
- Cigarette smoking/lung cancer
- Counselling and sexual behaviour
- Cervical cancer screening
- Colorectal cancer screening
- Detection of excessive drinkers
- Traffic injuries

These areas were all shown by thorough literature review to have one or more efficacious intervention. However, as noted above, relatively little economic, ethical or social information was found. The survey revealed a considerable number of completed assessments. However, assessments carried out on cigarette smoking, detection of excessive drinkers and traffic injuries were generally not carried out by HTA agencies (as shown in the HTA Database study), but were carried out by other groups (including government departments) outside the health care system. Assessments were generally used in policy-making, although such use seemed to be at a higher level in countries with well-established HTA programmes. It is also noteworthy that coverage of the eight areas by health policy varies greatly from country to country, with prevention policy apparently unsatisfactory in a number of countries surveyed, while France, the United Kingdom, the Netherlands, and Sweden have quite well-developed prevention policies that generally are based on HTA results.

Working Group 2 addressed several key issues in HTA. One important issue – of critical importance to those working in HTA and all those seeking evidence of efficacy, effectiveness and cost-effectiveness – concerned databases for HTA information. Using a variety of methods, the Working Group found that the existing databases are diverse in coverage, structure, search options, indexing and frequency of updating. The Cochrane Library, the HTA (formerly the INAHTA) Database and Medline are used by more than 90% of respondents who carry out HTAs. The HTA Database is considered to be a valuable information source for obtaining information on HTA results and ongoing HTA activities. However, examination of the HTA Database revealed several problems, e.g. low frequency of updating, lack of detailed information on study design, lack of English language abstract or executive summary and absence of links to the website of the agencies (some of the same problems were identified by Working Group 1 in its study of prevention reports in the HTA Database). The users of HTA considered that the HTA Database and the Cochrane Library provide useful information for clinical guideline development, research purposes and policy-making. However, the HTA information provided is alone insufficient for policy-making. HTA users found both databases not functional enough and missed structured information. The users also considered access to full HTA reports through a

single database to be very valuable, especially because it saved time. In this context, they considered a clearinghouse for the co-ordination of HTA information exchange as desirable.

The Working Group 2 also addressed two issues of critical importance in HTA: early identification/assessment and priority setting. The report on early identification focused on EuroScan, a collaborative network for the exchange of information on emerging technologies that has developed within the past 5 years. Membership of EuroScan is open to any agency which has a substantial programme for the early identification and assessment of emerging, new or changing health technologies; has an officially recognised role; and is a non-profit organisation and funded at least 50% by public sources. To date, EuroScan has produced the following outputs: a terminology for the activity, a set of prioritisation criteria, a comparative study of scanning models and a database on emerging health technologies. In addition, EuroScan has helped establish early warning systems in countries that did not have them. The main point concerning early identification and HTA is that these activities are a critical part of HTA and must be viewed within the HTA context. Specifically, Working Group 2 believes it is of greatest importance to include EuroScan activities in any European clearinghouse function.

The final issue addressed by Working Group 2 was priority setting, which was examined by literature review and a special survey of 35 HTA programmes in 17 countries. The study found that 14 of the 24 responding institutions have implemented a priority-setting procedure. However, these efforts are generally not very extensive. In addition, formal use of these procedures remains limited, and in general the priority-setting procedures are mainly implicit and not very transparent. A diverse range of procedures is used across European countries, and the criteria used also differ. Due to the different contexts in which HTAs are undertaken, no single procedure for priority setting can be recommended. The methods used range from qualitative models (e.g. consensus building) to quantitative models (e.g. Bayes approach). Criteria used include: number of people for which the technology is applicable, efficiency considerations, potential health impact, financial impact of applying the technology and variations in use. Social and ethical considerations are often not taken into account when setting priorities. Regarding the actors involved, decision-makers are often involved in the process (e.g. governments). Other external inputs come from physicians and national organisations (e.g. advisory bodies). Involvement of the public was mentioned only by three organisations, however, it was recognised that this group should play a more important role in setting priorities. The results of priority setting are used for commissioning or rejecting research projects. The recommendations made by EUR-ASSESS in 1997 are being used by the agencies, but no additional theoretical models have been published since that time.

Working Group 3 had the task to identify possible joint assessments and to co-ordinate findings and existing resources within the community to support joint assessments. The Working Group used a mix of methods: literature review, a special survey and a workshop. Those surveyed included both those working in HTA and those working in other fields of health research. In total, 110 questionnaires from 13 European countries were received. Data were collected from 13 HTA organisations and 82 non-HTA organisations dealing with other fields of health research. The differences between these two groups were fairly large, especially because those working in

HTA deal mainly with published literature while those in other fields deal more with collecting original data. Seventeen international HTA projects were identified; the participants gave detailed responses concerning problems and outcomes of these projects.

The most cited benefit from working in joint projects was to share and gain knowledge and experience (27%). Joining forces to solve common problems and enhancement of impact followed with 15% each. The most cited disadvantages were organisational and logistic problems (50%), especially those concerning European Commission bureaucracy and paperwork. HTA respondents mentioned differences in health system cultures as one of the main problems. Researchers working in both types of organisations are interested in taking an active role in future international joint assessments (92%).

HTA researchers considered that topics for joint assessment should be selected by a committee through a formal priority-setting process, acting at the European level (67%). In addition, respondents found that multinational joint assessments should be carried out within the existing informal European network of HTA agencies, giving non-experienced organisations from European non-EU countries the opportunity to participate.

Most of the HTA respondents considered it necessary to have a permanent co-ordinating body for HTA in Europe (72%) to give support in the development of joint projects. The organisational characteristics proposed were a virtual organisation (33%), followed by a central body situated in one country (28%). Finally, scientific quality and appropriate partners as well as balanced country participation were the main characteristics highlighted as principles to consider in an ideal multinational European and international joint project.

The review of papers published in peer-review journals show that the EU states are very active in multinational joint projects. This activity is not circumscribed only to the member states, since 53% of the identified publications include members from other non-EU countries. Furthermore, it was observed that the sponsorship of multinational joint projects by EU is quite low compared with the sponsorship by industry (18% vs. 46%). The funding contribution by EU toward HTA multinational joint projects is also low.

Working Group 4 had the task to develop and disseminate best practice in undertaking and reporting assessments and to identify needs for methodological development.

One task undertaken by Working Group 4 was to synthesise existing methodological toolkits and standard procedures from HTA agencies and other methodological literature into a document that describes what can be considered best practice in conducting and reporting HTA. A great deal of existing work on isolated methodological aspects is relevant to HTA, but little has been done on how to apply the individual methodological toolkits when conducting HTA. To fill this gap the Working Group produced a document to help guide those conducting and using HTA. The different steps undertaken when carrying out an assessment and writing an HTA report were reviewed, and a comprehensive methodological guide was provided for each of these points. It was particularly stressed that although not all steps and aspects of HTA can, or need to, be treated in a "systematic review" manner, a structured and transparent approach should be

warranted by the elaboration of the background information and formulation of research questions, and by the assessment of important aspects such as psychological, social or ethical implications. In addition, methodological gaps were identified in the field of assessment of psychological, social and ethical issues, and in the ways to assess community effectiveness.

The second main issue for Working Group 4 concerned how to actually improve methods used in HTA. In short, although "best practice" can be identified, many HTA agencies and programmes do not follow these methods. Discussions among Working Group members led to a consensus to develop a "Scientific Summary Report" that should be completed by those concluding an HTA. This would allow the reader to critically appraise HTA reports to evaluate their reliability.

The methodological guide includes a compilation of the methodological literature identified on specific topics relevant to HTA, a comprehensive list of databases useful for conducting assessments and a list of identified software resources helpful for data synthesis.

Working Group 5 had the task of developing and co-ordinating education and support networks for individuals and organisations undertaking or using assessment of health interventions, to identify needs in the field and to assist in the establishment of new educational provisions.

The work of the group depended on the results of a special survey of HTA training carried out in Europe. Data were collected from 46 European countries. The survey focused on existing education and training opportunities in the field of HTA and related disciplines. In the questionnaires, HTA-related courses were differentiated from HTA-courses, the latter including all or most dimensions of HTA ranging from diffusion of technology, through assessment methodology, to the use of HTA in policy-making. HTA-related courses referred to disciplines useful in HTA (e.g. clinical epidemiology, economic analysis, health policy, etc.).

In total, 145 courses were identified in 26 countries. Twenty-seven of the courses were university level HTA-courses, 85 were university level HTA-related courses. Forty-eight courses were continuing education courses, whereof 21 were HTA courses and 27 were HTA-related courses. While nearly all countries provide HTA-related courses, only 13 provide HTA courses at a university level. Regarding the EU-members (plus Norway and Switzerland) all countries provide either HTA-courses or HTA-related courses. Denmark, France, Germany, Italy, Spain, Sweden, Switzerland, the Netherlands and UK provide HTA-courses at the university level. No responses were obtained from Luxembourg. Regarding candidates to EU membership, only Estonia, Hungary and Poland identified HTA courses at the university level. Regarding the HTA courses, three Masters educational programmes were identified, one an international Master of Science programme in which five universities and five HTA agencies from Canada, Italy and Spain are involved, starting for the first time in September 2001. The other two Masters of Science in HTA are provided at a national level in UK (to be started in October 2001) and Spain (started for the first time in September 2000), the latter being organised as a cross-regional co-operation of several Spanish HTA agencies and the Iberoamerican Cochrane Centre. Other HTA courses (not Masters) were also identified.

Despite the limitations of the survey (e.g. concept of HTA course and HTA related course might be misunderstood, or reliability of data), it was found that education opportunities in HTA are increasing rapidly in Europe. The courses offered cover a great variety of contents and audiences, however, there are few programmes that cover the whole HTA process in a comprehensive manner.

Based on the results of the survey, Working Group 5 produced a second important outcome: a proposal for a European Master of Science degree in HTA (EMHTA). The long-term objective of such a degree is to generate a cadre of professionals who share a common understanding of HTA, being aware of the diversity but also of the common interest of the European countries, and who are able to conduct assessments both across and within European health care systems. The EMHTA would be a two-year programme, the first year being theoretically oriented on a part-time basis. The second year would have a practical orientation requiring full-time dedication.

Working Group 6 had the task to identify and share successful approaches to link findings of assessments, their contribution to health indicators and to health care decision-making. The Working Group focused on the users of HTA, exploring the links between HTA and decision-making. It commissioned two overview papers and held two workshops, one oriented to policy-makers and the other to hospital administrators.

The review of published literature showed that little information on the use of HTA has been published in academic papers. This type of information is more likely to be found in public reports or other sources that are not included in the common databanks used in academic research. Despite sparse published information, it was found that the Netherlands, the Scandinavian countries, United Kingdom and Spain are the countries where use of HTA in decision-making is more widespread.

The workshop with policy-makers found that the countries of the EU consider HTA in very different ways, ranging from informal approaches to systematic and structured ways to include HTA in the policy-making process. Despite health system differences, the participants identified similarities in the marketing and diffusion patterns of some health care technologies, and found that exchange of information on these topics is essential. In the discussion, issues of common interest were identified: role of patients, the community and the media, regional variations in policy and access to services, HTA and the legal system, HTA and the pharmaceutical sector, and demonstrating added value in quality of care resulting from HTA. Finally, the participants stressed the importance of involving decision-makers in the process of HTA from the beginning to enhance later implementation of the findings.

The workshop with hospital administrators identified the role of HTA in the elaborating guidelines and in the quality assurance of every day clinical practice. Although local and regional differences often permit only individual assessments, the value of exchange of experiences was identified by the participants. The main problems identified were financial coverage and keeping up to date. The participants agreed that a database containing information on implementation of HTA is needed. Electronic "notice-boards" were also proposed as a way to share knowledge and

ideas, specially concerning the areas of treatments and preventive interventions of unproven efficacy. Finally, it was suggested that users and doers of HTA should be brought together in future meetings.

An important outcome of both workshops was to form the nucleus of a network of policy-makers and another one of hospital administrators, with the aim of including additional members in the future. An "evidence-based medicine (EBM) implementation group" was formed also as an outcome of the second workshop. These initiatives are a response to the needs for exchanging experiences perceived by the participants in both workshops. The evaluation of the workshops showed that their major benefits were the opportunity to exchange knowledge, to learn from others and to establish networks. In general, the participants found the workshops to be a very positive experience.

The overall view of the Working Group reports is difficult to synthesise. The list of recommendations gives a view of the most pressing issues for HTA in Europe.

The main conclusion from the Working Group reports is that HTA is developing rapidly in Europe. It is improving its methods, access to its results is easier and these results are increasingly more often used in decision-making.

The most important result of the Working Group reports is the demonstration that those working in HTA in Europe are already members of what may become an effective network, prepared to undertake work on European topics with limited support and generally with no extra pay. In short, the network exists. It needs support. European developments in HTA cannot go very rapidly without support from the European Commission. Based on the Working Group reports and other inputs, a proposal for institutionalisation will be presented here.

4.2 Model for a co-ordinating body for HTA in Europe

In the late 1980s and early 1990s, national or regional governmental HTA agencies began to be established in some European countries as a response to the challenges posed by the increasing expenditures in health care, the need for health services that were more evidence-based, and the public demand for a high-quality medical care. Since then, HTA has continued to spread in Europe and has been consolidated in the countries that have been involved for the longest periods. Today, most of the countries of the European Union (plus Switzerland and Norway) have official HTA programmes at the national and the regional levels. The interest on HTA is now also spreading beyond the borders of the EU, and candidate states (such as the Baltic States, Cyprus, Hungary and Poland) are increasing their involvement and activities in HTA.

Early in the development of European HTA, those involved recognised the need for co-ordination of efforts at the European level. The first step taken in this direction was the EUR-ASSESS project, conducted between 1994 and 1997. The network formed during the EUR-ASSESS project has stimulated other European countries to become involved in HTA, and the network itself has continually expanded. The network has continually explored opportunities and possibilities for closer co-operation. The experiences gained on the basis of these projects have

demonstrated the value of collaboration at the European level, despite cultural differences and diversity of health care systems throughout Europe. Through improved communication and exchange within the network, efficiency in the field of HTA can be enhanced, and overall quality of HTA can be further improved. Through this work, gaps have been identified in the co-ordination of exchange activities among those involved in HTA at the European level. These shortcomings may have limited the overall efficacy of HTA at the European level.

The most important organisation concerned with this effort is the International Network of Agencies for Health Technology Assessment (INAHTA). INAHTA was formed in 1993 with the aim of facilitating information exchange and collaboration among HTA agencies. INAHTA presently has 37 members in 19 countries. Most INAHTA members are located in European Union countries. INAHTA membership is open to any organisation which:

– Assesses technology in health care
– Is a non-profit organisation
– Relates to a regional or national government
– Funded at least 50% by public sources

Since 1998, INAHTA has maintained an electronic database of published reports and ongoing studies by its member agencies. Each agency submits a standard form to the INAHTA Secretariat in Stockholm giving the title of the study and basic information, e.g. study design and methodology. Most INAHTA members also provide a structured abstract, and some make a full text version of the report available on line. The database, now called the HTA Database, was previously known as the INAHTA Database. It is available through the Internet and free of charge to all users. Other INAHTA activities include joint assessments (four joint assessments have been completed to date) and an Annual Meeting where HTA issues are explored and proposals for new INAHTA activities are considered. INAHTA is a membership organisation supported by modest dues from participating organisations. The membership dues alone, however, do not provide a sufficient financial base for rapid development of activities.

Based on the findings from their research, and on their knowledge of other activities such as those of INAHTA, the members of the Working Groups have elaborated several tasks, suggestions and recommendations aimed at achieving better collaboration and co-ordination of HTA in Europe. Together, these perspectives give an idea of how a permanent co-ordinating body could/should work, which functions and tasks it could/should accomplish and how it could/should relate to existing international collaborations in HTA, such as ISTAHC or INAHTA.

The design of this co-ordinating body is to be viewed as the main recommendation of the ECAHI-ECHTA project to the EU Commission.

4.2.1 Functions of the co-ordinating body

The proposed co-ordinating body is not to be viewed as a completely new agency, but as a needed tool to facilitate better functioning of the network, and to ensure efficiency and continuity of collaboration over time. The co-ordinating body (European Collaboration for

Health Technology Assessment, ECHTA) is intended to have a **value-added** function. In accord with the principle of subsidiarity, in which tasks in the European Union should be carried out at the appropriate level, ECHTA will only undertake tasks that are not being undertaken by other groups, including the national and regional HTA agencies. ECHTA is first and foremost a **service** organisation that is intended to support others' activities. An important part of its activities is to gather information on different aspects of HTA in Europe and to furnish this to members of the network and others to facilitate co-ordination.

The main overall objective is to improve the availability of assessment information to assist in implementing national and regional health policies. To serve this purpose, a European co-ordinating body for HTA should perform (at least) the following functions:

- Facilitate networking
- Co-ordination (e.g. identify needs for development of closer collaboration)
- Gather information
- Service functions

Facilitate networking

ECHTA should take an active role in promoting further networking in the field of HTA at the European level. The body could act in a way as a "coupling agent", bringing together those searching for potential co-operation or exchange partners for closer collaboration. Considering the amount and diversity of information that ECHTA would potentially be managing, it could be in an optimal position to identify actors at different levels willing to exchange experiences with others and bring them together. Information concerning actors interested in HTA is valuable for identifying common interests and opportunities for building more specific sub-networks (e.g. decision-maker networks).

For this purpose, ECHTA could act in two complementary ways: after identifying potential members of specific networks (e.g. decision-makers) ECHTA itself could actively initiate networking by, e.g. organising symposiums or workshops; in addition, ECHTA could act as a supporter of incipient specific networks (e.g. on education in HTA) by providing them with useful information regarding potential partners and by giving them organisational support.

Another way to facilitate networking involves the co-ordination of already established partnerships (such as bilateral relationships among HTA agencies) to make single efforts more efficient.

Another important function related to facilitation of networking is to assure continuous quality improvement in HTA. Without assurance of rigorous and valid methods and high quality products, information developed in one site will not be used in others, and HTA doers in one country will hesitate to collaborate with those in other countries. This project has developed several tools that can be used in such an effort, especially in Working Group 4 on best practice in HTA.

Co-ordinate and develop opportunities for closer collaborative work.

ECHTA will need a continuously updated overview of the field of HTA in Europe. Concentrating this function in one actor may help to identify gaps in each of the fields of European HTA in a timely fashion, and may allow ECHTA to make proposals on how to approach existing shortcomings (e.g. by identifying expertise). In this way, development of HTA can be supported in a more efficient way.

The term "co-ordination" should not be understood as "directing" or "controlling" the agenda for work. Partners in the network are committed to collaboration to improve the use of technology as well as the health of the European population. Just as the member states of the European Union have their own agendas, but co-operate in specific areas of endeavour, the HTA agencies and programmes will continue to work predominantly on issues of national and regional concern, while joining voluntarily in efforts to deal with problems at the European level, when this is appropriate.

Identifying opportunities for closer collaboration should be understood as a critical task of ECHTA, whose information can be very helpful when establishing the agenda of HTA in Europe, both in the sense of further methodological developments, and in the sense of identifying topics for which international joint assessments can be undertaken.

Collaboration with others, in particular INAHTA, also deserves mention. INAHTA has several years of experience in to co-ordinating HTA activities worldwide. Duplication of activities in the field of co-ordination should also be avoided. The fact that the INAHTA secretariat is located in Stockholm at SBU will facilitate this effort.

Gather information for monitoring

Co-ordination of HTA requires comprehensive and reliable information on HTA in the member states of the European Union, and elsewhere. Information concerning different aspects of the process of HTA and results of assessments should be gathered in a systematic way. In addition this information needs to be presented in a standardised manner to improve its usefulness for different actors. It should be emphasised here that to assure that the greatest amount of relevant and up-to-date information is collected, this function of gathering information needs to be carried out in a very active way. This means that ECHTA must take the role of an information seeker, keeping continuous contact with the members of the Network and regularly requesting relevant information from them. This may be the only way to achieve a comprehensive and up-to-date collection. The information gathered needs then to be presented in a standard structured way so that maximum of utility is achieved for the potential users. For some of the aspects listed below, a structured way of providing information has been already developed (e.g. Scientific Summary Report for reporting results). An important function of ECHTA will be to develop ways to structure information concerning other aspects for which no standards are yet available.

The information gathering function should cover (at least) the following fields:

1. Priority setting: Different priority setting procedures are being applied across Europe. Added value can be achieved by comparative research and by bringing together different methodological approaches in priority setting. In addition, preventive activities are often not a high priority for European governments. The European Commission can help assure that prevention and health promotion become a more prominent part of European health policy and HTA, in accord with the public health mandate of the European Union.

1.1 *Overview of the procedures:* HTA institutions should provide descriptions of their priority setting procedure including the following points: goals and responsibilities of actors involved in the priority setting procedure, general approach, methods used to identify assessment needs, criteria used to select technologies to be assessed, purposes for which results are used, results (priorities set), use of an evaluation procedure and contact details. This information should be fed back to the HTA agencies and programmes with a view toward improving their approaches to priority setting.

1.2 *Overview of the actors:* ECHTA should actively identify actors on different levels with an interest in priority setting. Information on their needs and their purposes should be recorded. On the other side, actors at different levels may have already formulated priorities. Information on existing priorities also needs to be gathered, since this can be helpful for both current HTA programmes and for setting future European priorities.

2. Planned and ongoing assessments and results from HTA: There is a need to avoid duplication of work in HTA, as this means inefficiency. When planning an assessment, knowledge about ongoing or finished projects is useful for HTA doers. However, information needs to be comprehensive and structured if it is to be helpful. HTA users also need access to structured information fitting to their needs, to account for the findings in their decisions.

2.1 *Planned and ongoing projects.* ECHTA should maintain regular contact with the members of the network to identify assessments being planned, being conducted or nearly completed. When reporting planned projects, agencies should state if they are willing to participate in collaborative projects, if others are planning assessments of similar topics. This could be helpful for identifying opportunities for joint assessments.

2.2. *Results from assessments:* ECHTA should regularly approach HTA agencies to keep an updated database on European HTA results. Structured information should be provided by HTA doers using the Scientific Summary Report (proposed by Working Group 4 in this project), this being a requisite for reports to be included in such a database. ECHTA should also ensure that links to agencies, including availability of full reports in electronic form, are provided together with the summary. The information gathered in this form could be forwarded to the HTA Database[3]. Alternatively ECHTA could itself improve the HTA Database, considering users' needs to assure that maximum benefit can be achieved. In this context, additional ways to structure information for actors other than HTA doers should be explored and adopted by consensus.

[3] Former INAHTA

3. **Educational resources:** Educational initiatives in HTA and related fields have been increasing rapidly in Europe. ECHTA should actively collect information on educational and training opportunities on HTA from the different actors involved in education (e.g. Universities, HTA agencies). A European catalogue of HTA educational opportunities should be compiled and made available for all those interested. The information should be presented in a structured way to allow better comparability. Such an overview can be helpful to identify educational needs and duplications. In addition, it is the basis for a future European Masters of Science in HTA, which may be co-ordinated by ECHTA.

4. **Implementation of HTA:** Besides results of HTA, decision-makers also need information on the results of implementation of HTA findings. European added value can be achieved by sharing experiences with the implementation of HTA. Information on this topic should also be gathered by ECHTA.

4.1 *Results of implementation:* A database including information on experiences with implementing HTA should be established.

4.2. *Actors:* ECHTA should try to actively identify actors involved in decision-making at different levels of European health care systems. This can be very helpful for building a network of decision-makers.

Information gathering is of critical importance for the success of a European HTA network. First, it is the basis for information exchange among members of the network. The information gathered and made available in a structured way represents a valuable and helpful tool for all those involved or interested in HTA. Second, it feeds ECHTA with the material needed for fulfilling its other functions: identifying needs for further development, identifying opportunities for closer co-operation and further networking and taking an advisory function.

Dissemination of the information collected also needs emphasis. It is certainly not enough to collect information and make it available on-line. The information needs to be actively disseminated and used in decisions in the network. **Feedback and evaluation** of the impact of the information will be helpful in assuring appropriate development and use of the information to be collected. Without doubt, the types and forms of information to be collected will be modified actively to help assure that it is both useful and used.

Service functions

The fourth task of ECHTA should be viewed as a provision of service. Although some of the services proposed here could be offered free-of-charge to actors different than the ones participating in the network, others could be offered on a fee basis. Services that could be offered by ECHTA are:

1. Access to information resources. In general, the information gathered by ECHTA should be made available to a wide range of potential "clients", e.g. via the Internet. Since the information resources built under ECHTA are only possible with the co-operation of the

network's members and other actors, it should be ensured that at least those providing information should have free access to the diverse areas of ECHTA's databank. Other potential users of this service may be patient and consumers groups, industry, professionals, etc. It should be further discussed on which basis potential users of the databank should have access to the information. An important point is that restrictive regulations could limit dissemination, and thus be counter-productive.

2. Advisory function. The expertise gathered under ECHTA should help those starting in the field of HTA. Providing technical support could be done in different ways. In close co-operation with the members of the network, ECHTA could develop printed guides on different aspects of the HTA process, e.g. as the one on methodological aspects developed during the ECHTA/ECAHI project, or the one on priority setting elaborated during the EUR-ASSESS project. These printed guides should have an orientative and practical character, presenting the minimum key elements to be considered when establishing, e.g. a new HTA programme, a priority setting procedure, an educational programme, etc. The utility of such guides has been shown, for example, with the case of the priority setting document from EUR-ASSESS. The aim of these documents should be to help and guide those lacking experience in this complex field. ECHTA would offer assistance to those within the European Union and to those likely to become members of the EU, tailored to their needs.

The potential functions of ECHTA are summarised in the following box:

Proposed Functions of ECHTA

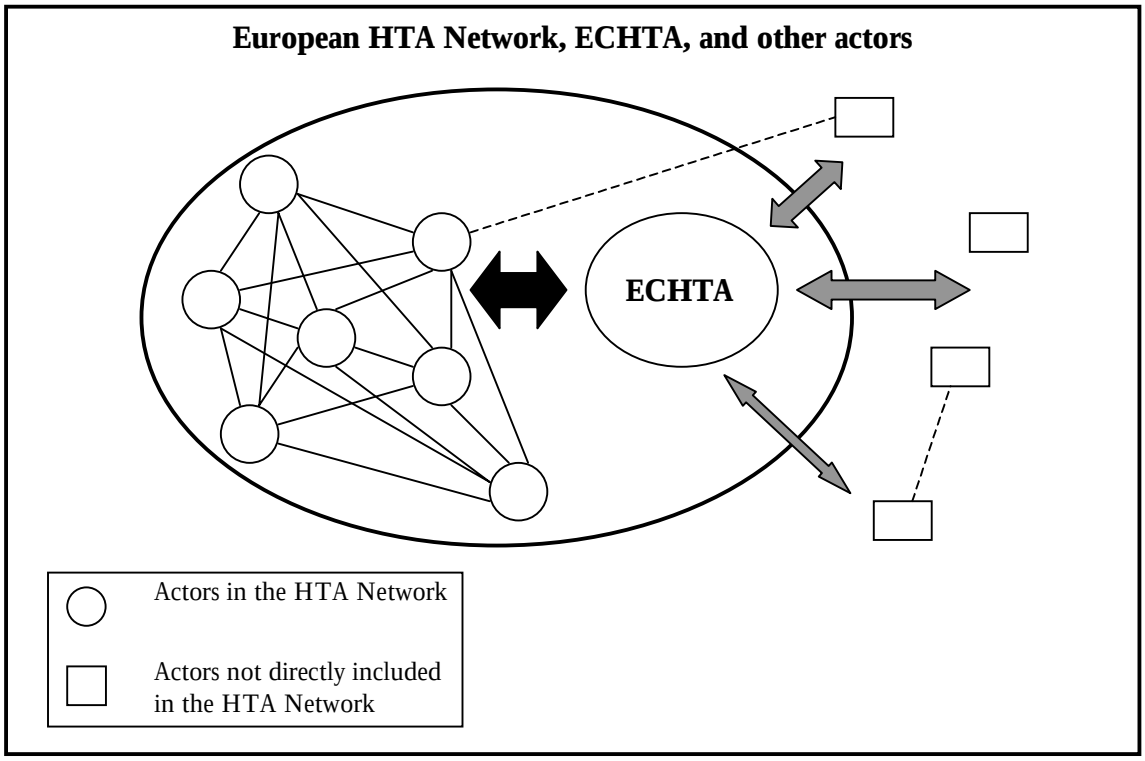
- Facilitate networking
  - Establishing links·
  - Co-ordinating networks
  - Administrative and organisational support of networks and sub-networks
- Identify
  - Opportunities for joint assessments
  - European priorities
  - Needs for methodological development
  - Educational needs
- Gather information
  - Actors
  - Methodology
  - Ongoing projects and results
  - Educational opportunities
- Services
  - Information exchange
  - Printed guides
  - Consultancy services

4.2.2 Structure of ECHTA

As mentioned above, a network of European HTA doers and programmes has already been established in Europe through previous projects, including, most importantly, the ECHTA/ECAHI project. An active body is needed now to accomplish critical functions for the network.

The network of HTA agencies is like a web. The single HTA agencies (national or regional) and collaborations already underway (e.g. EuroScan, HTA Database) represent the web knots. In the case of European HTA, the network has already been webbed to a considerable extent through the efforts made in three European projects. But a web is a delicate structure that needs to be continuously maintained. The European network currently lacks the means for continuous maintenance of the web. It requires continuous effort to strengthen the links between agencies and to assure that the structure is sustained functionally over time. The network also needs to expand by establishing new “knots” and the links between them. In addition, continuous attention must be given to the products. These are all tasks for the co-ordinating body for HTA in Europe.

The following figure depicts the position of ECHTA.



The proposed co-ordinating body for the European HTA network should have a more permanent character with stable financing. Up to now, the networking efforts in the field of HTA were in the context of time-limited projects. Now, to assure fulfilment of the functions mentioned above and to warrant continuity over time, a permanent co-ordination body is needed. Without funding to cover the activities inherent in a European programme of work, progress will be slow. It should be clear, however, that the European Commission would only cover activities related to the European level under the principle of subsidiarity. The member states would continue to support activities aimed specifically at their own needs, as is the case today in most countries of the European Union.

Important functions, such as organisational and administrative issues can be better accomplished in the context of a permanent institution. In addition, for a more effective functioning of the network it is necessary that at least some of the people working for ECHTA are dedicated to this task full time.

The following structures and considerations should form and inform ECHTA:

1. Steering Committee or Board: Each member state would need to be represented on this Steering Committee, as in the ECHTA/ECAHI project. The Steering Committee could be advisory, or it could actually direct ECHTA. The Steering Committee would probably need an Executive Committee in charge of close and continuous oversight of the work done in ECHTA.

2. Secretariat: A permanent Secretariat or administrative centre should undertake the administrative and organisational functions. The work of the Secretariat should encompass the different functions described for ECHTA and others that emerge later. The Secretariat could also repre-

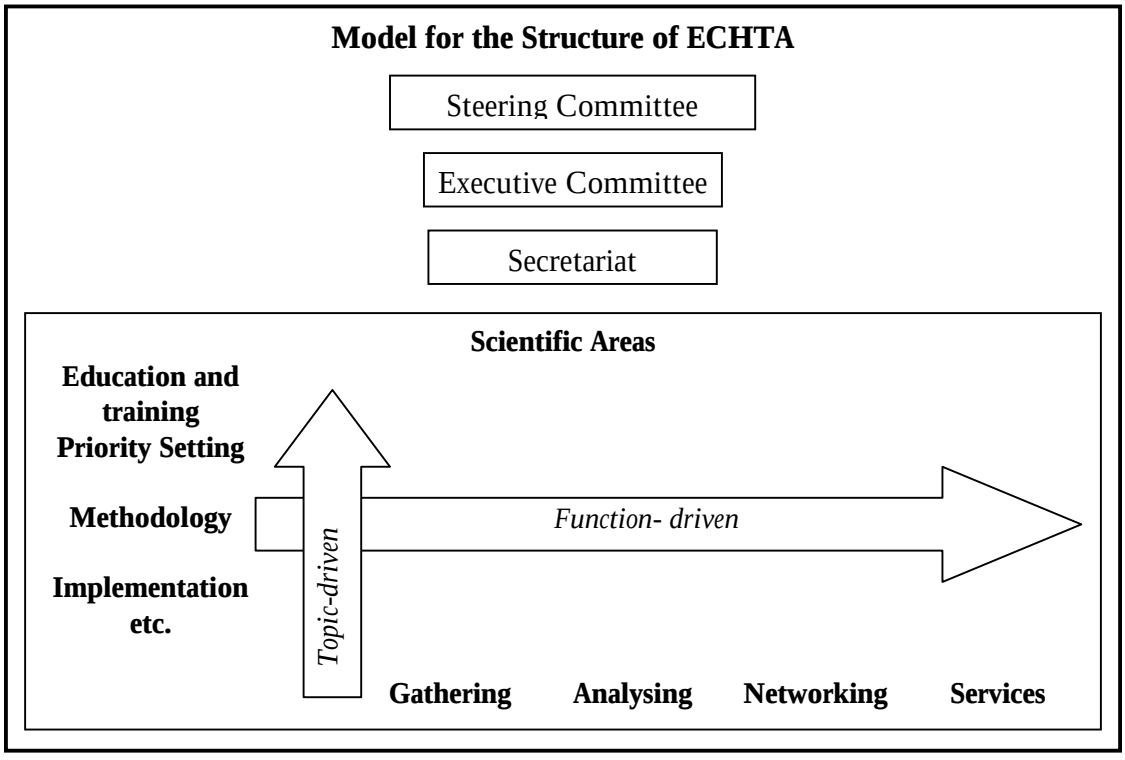
sent the contact point for those interested in HTA, searching for advice etc. Persons involved in the Secretariat should be dedicated to full-time work for the network. Special committees or Working Groups would assist the Secretariat in specific areas of endeavour. The Secretariat might be partially decentralised to different centres in different countries, although one administrative centre for overall co-ordination seems important.

A key task for the Secretariat is to assure full use of the relevant expertise and commitment of different programmes and individuals in Europe.

3. Scientific Areas: A range of scientific areas could be defined as the responsibility of ECHTA. Organisation and division of the areas needs further discussion. Here two possible models will be presented and are depicted in the figure. Both have limitations, and probably the most effective way would be to combine both approaches, taking into account the work already done, existing collaborations and expertise of different actors.

3.1 Topic-driven. Each of the Scientific Areas would be in charge of one relevant topic of HTA (education, priority assessment, methodology, implementation). The area would be responsible for the different functions described above concerning its topic. That means: gathering information on the topic and making it available in a structured way, identifying gaps and opportunities, helping networking and giving advice. This structure would be comparable to the one followed in the ECHTA/ECAHI project.

3.2 Function-driven. Alternatively, the Scientific Areas could be in charge of implementing one of the functions described above, independently of the topic. Four areas would be necessary, one in charge of gathering and structuring information, a second in charge of analyses, identification of shortcomings and opportunities, a third in charge of the network care and a fourth in charge of giving advice and delivering other services.



ECHTA should be provided with enough human and financial resources to fulfil the ambitious tasks described here. At least a part of the personnel should be exclusively dedicated to the network to assure efficient functioning. In addition, some grade of centralisation will be needed to assure efficacy of the network and would have to be accepted to ensure that the functions of the network are fulfilled. Centralisation concerns mainly organisational aspects, since the agenda of the network should be further developed in the context of the steering committee. It would take some time to build this institution and develop it as a fully effective body. Funding should be stable and assured during this period, with systematic evaluation of its functioning later.

4.2.3 Why should the EU support a European co-ordinating body for HTA?

The member states of the European Union have the responsibility for the organisation of health services and for the delivery of medical care. The Community has also a role to play in the health protection of EU citizens. Article 152 of the Treaty establishing the European Community allows the Community to take actions to complement the efforts of the Members States, adding value to their actions. This article also requires the Community to play an active role in this sector by taking measures that cannot be taken by individual states, in accordance with the principle of subsidiarity. In this context, as mentioned in the Introduction, a proposal for a Programme of Community Action in the field of public health for the years 2001–2006 has been presented by the Commission and is currently in the stage of second reading after amendments from the European Parliament have been included. This proposal is intended to form part of the European Community's Health Strategy.

The programme aims at supporting the member states in their efforts to improve the health of the population and to improve cost-effectiveness of their health systems. For achieving this purpose the Commission stresses the importance of having reliable and comparable information on health interventions. One of the pillars of this programme is the implementation of a comprehensive health information system, including among others, health indicators, information on health technologies and interventions (e.g. efficacy, costs), and quality standards and best practice criteria. This should help decision-makers when developing health policy, health professionals when improving the quality of care, and the general public when making their choices.

As stated in the proposal, to assure achievement of the objectives, the networking approach is preferred, since it allows for exchange of experiences and expertise among members, providing European added value. In addition, the candidate countries should be actively involved in the development and implementation of the programme.

The European HTA network and its co-ordinating body can contribute in many aspects toward fulfilling the objectives stated in the action programme, while being in line with the principles stated in it. The following table should help explain the relevant role HTA must play in the implementation of the action programme, and highlight the way ECHTA and its co-ordination can contribute toward achieving the programme objectives.

Health Technology Assessment (HTA) provides comprehensive, scientifically sound information on different aspects of health interventions, and has already been identified as a key tool for the management of limited resources in health care. HTA is also one of the approaches included in the concept of best practice, playing a role in identifying high quality care and in establishing quality standards. ECHTA will provide a comprehensive overview on results, procedures and actors, which can contribute to the European health information system proposed in the action programme. In addition, it will allow for effective exchange of valuable information and expertise for supporting decision-making in health care, aiming at providing high(est) quality of care while accounting for limited resources.

Thus, supporting the formalisation of the European HTA network and establishing its co-ordinating body can be considered one of the actions to take within the context of the action programme for 2001–2006 to enhance the health of EU citizens.

The Action Programme for 2001–2006* and European HTA		
**	**Principles of the Programme**	**European HTA and ECHTA**
P(1)	*[...] The Community should take into account people's right to receive simple, clear and scientifically sound information about their illnesses, available treatment and ways of improving their quality of life.*	• HTA provides scientifically based information on health interventions (preventive, diagnostic, therapeutic, organ-isational, etc.) • Results of assessments of different health interventions will be made available to many actors through ECHTA
P(17)	*[...] the programme should take into account the importance of education and training, networking and supporting the development of centres of excellence.*	• ECHTA will provide an overview of educational and training opportunities in the disciplines related to HTA and best practice, and help co-ordinate a European Master of HTA· • ECHTA will help effective management of the network of European HTA institutions and promote further networking of groups with specific needs and interests (e.g. decision-makers). • ECHTA will provide support to those starting or developing HTA programmes.
P(18)	*[...]To ensure sustainability and the efficient use of existing Community investment and capacity, established Community and national networks should be used to pull together expertise and experience from member states on effective methods for the implementation of public health interventions, quality criteria and disease prevention activities.*	• The European HTA network represents such a forum where expertise and experience in the assessment of effectiveness of health interventions, including health promotion and disease prevention can be gathered. • ECHTA can help identify European priorities for assessment of public health interventions and co-ordinate joint projects where assessment expertise from a wide range of actors can be gathered.
P(21)	*[...] the candidate countries should be actively involved in the development and implementation of the new programme.*	• The European HTA network has already started to involve candidate States, and has among its aims to further support the advancement of HTA in those countries.

P(22)	*[...]The programme can provide significant added value to promoting health in the Community through the support of structures and programmes which enhance the capabilities of individuals, institutions, associations, organisations and bodies in the health field by facilitating the exchange of best practice and training and by providing a basis for a common analysis of the factors affecting public health.*	• The European HTA network and ECHTA represent such a structure, which allows different actors (e.g. decision-making bodies, professionals, the general public, etc.) to enhance their capabilities, through access to scientifically sound information on a wide range of health interventions, on procedures for priority setting, on results of implementation, etc.· • ECHTA allows for a more efficient exchange of experiences and results in the field of HTA, and the information administrated by it can help further define best practice.
Art. 2.2a Objectives	*To improve information and knowledge for the development of public health, in order to optimise health status, strengthen efficient health systems, conduct effective health interventions and develop methods to tackle health inequalities.*	• HTA provides scientifically sound information on efficacy, effectiveness and cost-effectiveness of health interventions and has been accepted as one tool for the management of sparse resources in health care. • The information gathered by ECHTA, including results of HTA, can contribute to build such an information resource.
Art. 3.1a Community Actions	*[...] developing and using mechanisms for analysis, advice, reporting, information and consultation on health issues in accordance with best practice, in order to identify the most appropriate public health strategies.*	• ECHTA can help identify and disseminate best practice in many areas of HTA (e.g. priority setting, methodology, evidence-based decision making)· • Results of assessments, including those evaluating disease prevention and health promotion interventions, provide sound scientific information for supporting choices
Art. 3.2d Community Actions	*Support for and promotion of activities by the Community and the member states to define and determine good practice, sound guidelines for health and quality guidelines and minimum standards based on scientific data.*	• The European HTA network has already been supporting development of HTA in Europe, which is an approach in the direction of providing evidence based, high quality care. • ECHTA can better co-ordinate efforts for the further advancement of HTA and promote the development of such activities by giving expertise support.

Art. 3.2i Community Actions	*Encouraging education and vocational training in the field of public health.*	• The implementation of a European Masters of Science in HTA represents an educational initiative, which can be fostered in the context of the action programme.
AN 1.2.1.1 Specific Objectives and Actions	*Develop and operate a Community network or Community networks:(a) to undertake analysis and the preparation of reports on health status and on the impact of health determinants and policies including disease prevention and treatment, identify risk factors and gaps in knowledge and forecast trends for use in policy formulation, priority setting and resource allocation.*	• The HTA approach is a kind of policy analysis. HTA helps identifying knowledge gaps and supports policy formulation· • The European HTA network and ECHTA can play a critical role since they gather information on HTA efforts by wide range of actors, including policy-makers at different levels (e.g. regional, national).
AN 1.2.2. Specific Objectives and Actions	*Report on Community health status and identify trends giving rise to concern; report on the impact of selected activities, policies and measures and health determinants;Present reviews, advice and guidelines on health technologies, health interventions and quality and best practice.*	• The contribution of HTA to those aspects is widely accepted· • ECHTA will make available assessment results from different institutions, thus providing comprehensive reviews on health technologies and interventions. • ECHTA can co-ordinate efforts to assess impact of new activities and policies in the form of European joint assessments

* COM (2001) 302 final. Brussels 01.06.2001. The statements are listed in order of appearance in the proposal.

** P: Preamble, Art.: Article, AN: Appendix

5. Recommendations to the EU

Considering the results presented in this report, which represents a synthesis of the work produced during the ECHTA/ECAHI project, the following recommendations can be made:

The European Commission should establish a sustainable and properly funded co-ordinating body for an EU-wide network of Health Technology Assessment (ECHTA). This network should involve recognised organisations and agencies in the field of health technology assessment, which will enable and facilitate the co-ordination of assessments within the European Union. The Commission will thereby demonstrate the benefits of these activities and the risks of not implementing them in terms of quality of life, quality of care and cost of health care.

The overall goal is to promote best practice and appropriate use of human and financial resources in preventing disease and delivering health care. The following functions would be included in the tasks of ECHTA:

- To identify and prioritise needs and opportunities for assessment of health interventions and technology (including those in the area of prevention);
- To gather and disseminate information (e.g. by way of a clearinghouse using an Internet portal providing access to information and advice);
- To enable and encourage collaborative work;
- To develop skills in health technology assessment (e.g. by developing a common framework for training and education in the field, including a Masters degree in health technology assessment);
- To help in further developing the methodologies in assessments and "best practice" in assessments. The development of measures for community effectiveness is a particularly pressing task;
- To improve ways of communicating the results of health technology assessment to policy makers, clinicians, industry, patients and the general public – so as to ensure effective implementation of results and thereby realise health gains.

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This summary is based on the reports produced by each of the six Working Groups or contracted researchers and is to be viewed as a synthesis of the work and the results of the ECHTA/ECAHI project. Although citations are omitted in the text, the summary report continuously refers to the work of the Working Groups.

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Appendix 1. Participants in ECHTA/ECAHI

Steering Committee

Chair
Prof. Egon Jonsson
The Swedish Council on Technology
Assessment in Health Care, SBU
Stockholm, Sweden

Prof. Kjell Asplund
Chair, Board of Directors
The Swedish Council on Technology
Assessment in Health Care, SBU
Stockholm, Sweden

Dr. José Asua
Basque Office for Health Technology Assessment, Osteba
Dept. Health Basque Government
Vitoria-Gasteiz, Spain

Prof. David Banta
ECHTA/ECAHI Project
Stockholm, Sweden

Dr. Sergio Bellucci
Director TA-Program
Swiss Science Council
Bern, Switzerland

Prof. Dr. Finn Børlum Kristensen
Danish Centre for Evaluation and Health
Technology Assessment, DACEHTA
Copenhagen, Denmark

Dr. Reinhard Busse
European Observatory on Health Care Systems
Madrid Hub at Escuela Nacional de Sanidad
Madrid, Spain

Prof. Michael Drummond
Universtiy of York
Center for Health Economics
York, United Kingdom

Prof. Karen M. Facey
Health Technology Board for Scotland
Glasgow, United Kingdom

Dr. Pedro Koch
Swiss Federal Office of Social Security
Medical Technology Unit
Bern, Switzerland

Prof. Lycourgus Liaropoulos
University of Athens, Department of Nursing
Center for Health Care Management and Evaluation
Athens, Greece

Dr. José M. Martín-Moreno
Spanish Agency for Health Technology
Assessment, AETS
Instituto de Salud "Carlos III"
Madrid, Spain

Prof. Yves Matillon
The National Agency for Health
Technology Assessment, ANAES
Paris, France

Dr. Berit Mørland
The Norwegian Centre for Health
Technology Assessment, SMM
SINTEF Unimed
Oslo, Norway

Ass. Prof. Carlos Gouveira Pinto
Technical University of Lisbon Instituto
Superior de Economia e Gestao
Lisbon, Portugal

Dr. Risto Roine
Assessments of Technologies
Helsinki and Uusimaa Hospital Group
HUS, Finland

Dr. Alric Rüther
German Agency for HTA at the German Institute
for Medical Documentation and Information,
DAHTA@DIMDI
Cologne, Germany

Dr. Carlo Favaretti
Azienda Provinciale per i Servizi Sanitari, APSS
Trento, Italy

Prof. Dr. John Gabbay
National Coordinating Centre for Health
Technology Assessment, NCCHTA
University of Southampton
Southampton, United Kingdom

Prof. James Goldberg
The National Agency for Health
Technology Assessment, ANAES
Paris, France

Dr. László Gulácsi
HCOHTA
Debrecen, Hungary

Mr. Charlie Hardy
Department of Health and children
Planning and Evaluation Unit
Dublin 2, Ireland

Dr. Chris Henshall
Department of Trade and Industry, Office
of Science and Technology
Director of Science and Engineering Base Group
London, United Kingdom

Prof. Katrien Kesteloot
University of Leuven
University Hospitals
Leuven, Belgium

Mr. Andrzej Rys'
Jagiellonian University
Institute of Public Health
Krakow, Poland

Dr. Laura Sampietro-Colom
Catalan Agency for Health Technology
Assessment, CAHTA
Barcelona, Spain

Dr. Virpi Semberg
Finish Office for Health Care Technology
Assessment, FinOHTA/STAKES
Helsinki, Finland

Mrs. Miriam Ines Siebzehner
Israel Center for Health Technology Assessment
The Gertner Institute
Tel Hashomer, Israel

Dr. Jose A. Valverde Albacete
Andalusion Agency, for Health Technology
Assessment, AETSA
Sevilla, Spain

Dr. Menno van Leeuwen
Health Council of the Netherlands
The Hague, The Netherlands

Dr. Claudia Wild
Institute of Technology Assessment of
the Austrian Academy of Science
HTA Unit of the ITA
Vienna, Austria

Observers

Dr. Richard Alderslade
WHO
Regional Office for Europe
Copenhagen, Denmark

Dr. Andrei Biskop
Leningrad Oblast Regional
Cardiology Center
St. Petersburg, Russia

Dr. Hans-Peter Dauben
German Agency for HTA at the German Institute
for Medical Documentation and Information,
DAHTA@DIMDI
Cologne, Germany

Ms. Raquel Lucas
Ministry of Health
Lisboa, Portugal

MSc. Andreas Mallouppas
University of Cyprus
Biomedical Research Foundation
Nicosia, Cyprus

Dr. José Pereira Miguel
Instituto de Medicina Preventiva
Faculdade de Medicina de Lisboa
Lisboa, Portugal

Dr. Josep Figueras
European Observatory on Health Care Systems
Copenhagen, Denmark

Dr. Danguole Jankauskiene
Independent Agency of Health Technology Assessment
Vilnius, Lithuania

Dr. Finn Kamper-Jørgensen
Danish Institute for Clinical Epidemiology
Copenhagen, Denmark

Mr. Christoph Künzli
Swiss Federal Office of Social Security
Medical Technology Unit
Bern, Switzerland

Dr. Krzysztof Landa
National Center for Quality Assurance in Health Care
Evidence Based Activities
Krakow, Polen

Dr. Peter Lepes
National Inst for Medical Information
and Library of Medicine
Budapest, Hungary

Ass. Prof. Maj-Inger Nilsson
Pharmacia & Upjohn
Brussels, Belgium

Dr. Joan Pons
Catalan Agency for Health Technology
Assessment, CAHTA
Barcelona, Spain

Ms. Elettra Ronchi
OECD-DSTI-BU
Co-ordinator Health and Biotechnology Activities
Paris, France

Prof. Tore Scherstén
The Swedish Council on Technology
Assessment in Health Care, SBU
Stockholm, Sweden

Mr. Niels Würgler Hansen
Danish Centre for Evaluation and Health
Technology Assessment, DACEHTA
Copenhagen, Denmark

Dr. Maya Züllig
Swiss Network on Health Technology Assessment
Bern, Switzerland

Former Representatives

Dr. Christian Behles
DIMDI
Köln, Germany

Dr. Eduardo Briones
Andalusian Agency for Health
Technology Assessment, AETSA
Sevilla, Spain

Dr. José Conde-Olasagasti
Spanish Agency for Health
Technology Assessment, AETS
Instituto de Salud "Carlos III"
Madrid, Spain

Dr. Alicia Granados
Institute Catalá de la Salut
Barcelona, Spain

Dr. Gunnar Griesewell
Bundesministerium für Gesundheit
Bonn, Germany

Dr. Hervé Maisonneuve
WEBSURG/IRCAD
Strasboug, France

Dr. Antoni Parada
Catalan Agency for Health Technology
Assessment, CAHTA
Barcelona, Spain

Dr. Manuela Mota Pinto
Ministry of Health
Lisboa, Portugal

Prof. Harald Schweim
German Institute for Medical Documentation
and Information, DIMDI
Köln, Germany

Dr. Raymond Wagener
Inspection Générale de la Sécurité Sociale, IGSS
Luxembourg, Luxembourg

Members of the Working Groups

Working Group 1

Chair
Prof. David Banta
ECHTA/ECAHI Project
Stockholm, Sweden

Vice-Chair
Dr. Evridiki Hatziandreu
Social Security Institute, IKA
Athens, Greece

Members

Dr. Hans-Peter Dauben
German Agency for HTA at the German Institute for Medical Documentation and Information,
DAHTA@DIMDI
Cologne, Germany

Prof. Fred Paccaud
University of Lausanne
Institute of Social & Preventive Mededicine, IUMPS
Lausanne, Switzerland

Prof. Olav Helge Førde
University of Tromsø
Institute of Health Research
Tromsø, Norway

Dr. Emilia Sanchez
Catalan Agency for Health Technology Assessment, CAHTA
Barcelona, Spain

Dr. Marlène Laeubli Loud
Swiss Federal Office of Public Health, SFOPH,
Health Policy Division Research and Education,
Bern, Switzerland

Dr. Therese Stutz Steiger
Swiss Federal Office of Public Health, SFOPH
Health Policy Division Research and Education
Bern, Switzerland

Dr. Sven-Olof Isacsson
Department of Community Medicine
Malmö University Hospital
Malmö, Sweden

Working Group 2

Co-Chair
Dr. Jose Asua
Basque Office for Health Technology Assessment, Osteba
Department of Health, Basque Government
Vitoria-Gasteiz, Spain

Co-Chair
Prof. Kerstin Hagenfeldt
SBU/Karolinska Hospital
Stockholm, Sweden

Members

Ms. Malene Fabricius Jensen
Danish Centre for Evaluation and Health
Technology Assessment, DACEHTA
Copenhagen, Denmark

Dr. Alessandro Liberati
Mario Negri Institute
Milan, Italy

Dr. Wija Oortwijn
University Medical Centre Nijmegen
Department of MTA
Nijmegen, The Netherlands

Dr. Berit Mørland
The Norwegian Centre for Health
Technology Assessment, SMM
SINTEF Unimed
Oslo, Norway

Dr. Sergio Bellucci
Director TA-Program
Swiss Science Council
Bern, Switzerland

Prof. Rachid Salmi
ISPED
Victor Segalen University
Bordeaux, France

Mr. Wilf Higgins
Hospital Planning Office
Department of Health and Children
Dublin, Ireland

Prof. Andrew Stevens
The University of Birmingham
Department of Public Health and Epidemiology
Birmingham, United Kingdom

Dr. Gabriel HM ten Velden
Health Council of the Netherlands
The Hague, The Netherlands

Working Group 3

Chair
Dr. Laura Sampietro-Colom
Catalan Agency for Health Technology Assessment, CAHTA
Barcelona, Spain

Co-Chair
MSc Virpi Semberg
Finnish Office for Health Care Technology Assessment, FinOHTA/STAKES
Helsinki, Finland

Members

Prof. Kjell Asplund
Chair, Board of Directors
The Swedish Council on Technology Assessment in Health Care, SBU
Stockholm, Sweden

Dr. Ruth Barrington
Chief Executive Officer
Health Research Board
Dublin, Ireland

Dr. Dolors Estrada
Catalan Agency for Health Technology Assessment, CAHTA
Barcelona, Spain

Dr. Karin Faisst
University of Zürich
Institute of Social and Preventive Medicine
Zürich, Switzerland

Dr. James Kahan
RAND Europe
Leiden, The Netherlands

Dr. Inge Kjonniksen
The Norwegian Centre for Health Technology Assessment, SMM
SINTEF Unimed
Oslo, Norway

Dr. Aldo Marotto
University of Padova
Padova, Italy

Dr. Ruairidh Milne
National Coordinating Centre for Health Technology Assessment, NCCHTA
University of Southampton
Southampton, United Kingdom

Dr. Alric Rüther
German Agency for HTA at the German Institute for Medical Documentation and Information, DAHTA@DIMDI
Cologne, Germany

Mr. Saffan Stilven
Danish Centre for Evaluation and Health Technology Assessment, DACEHTA
Copenhagen, Denmark

Dr. Bertrand Xerri
The National Agency for Health Technology Assessment, ANAES
Paris, France

Working Group 4

Chair
Dr. Reinhard Busse
European Observatory on Health Care Systems
Madrid, Spain

Vice-Chair
Dr. Jacques Orvain
The National Agency for Health
Technology Assessment, ANAES
Paris, France

Members

Prof. Michael Drummond
University of York Centre for Health Economics
United Kingdom

Dr. Felix Gürtner
Swiss Federal Office of Social Security
Medical Technology Section
Bern, Switzerland

Mr. Torben Jørgensen
Secretariat of Regional Management
Odense University Hospital
Odense, Denmark

Dr. Albert Jovell
Catalan Agency for Health Technology
Assessment, CAHTA
Barcelona, Spain

Dr. Matthias Perleth
University of Medicine Hannover
Department of Epidemiology, Social Medicine
Hannover, Germany

Dr. Alric Rüther
German Agency for HTA at the German Institute
for Medical Documentation and Information,
DAHTA@DIMDI
Germany

Dr. Claudia Wild
Institute of Technology Assessment
of the Austrian Academy of Science
HTA Unit of the ITA
Vienna, Austria

Associate
Dr. Marcial Velasco
University of Medicine Hannover
Department of Epidemiology, Social Medicine
Hannover, Germany

Working Group 5

Chair
Prof. Dr. Finn Børlum Kristensen
Danish Centre for Evaluation and Health Technology Assessment, DACEHTA
Copenhagen, Denmark

Vice-Chair
Prof. Dr. John Gabbay
National Coordinating Centre for Health Technology Assessment, NCCHTA
University of Southampton
Southampton, United Kingdom

Members

Dr. Gerd Antes
The German Cochrane Centrum
Freiburg, Germany

Prof. Dr. Mona Britton
The Swedish Council on Technology Assessment in Health Care, SBU
Stockholm, Sweden

Dr. Eduardo Briones
Andalusian Agency for Health Technology Assessment, AETSA
Seville, Spain

Dr. Gerard L. Engel
Association of University Hospitals
Utrecht, The Netherlands

Dr. Pedro Gallo
Catalan Agency for Health Technology Assessment, CAHTA
Barcelona, Spain

Prof. Bengt Jönsson
Stockholm School of Economics
Centrum for Health Economy
Stockholm, Sweden

Prof. Lycurgos Liaropoulos
University of Athens, Department of Nursing
Centre for Health Care Management and Evolution
Athens, Greece

Dr. Alessandro Liberati
Mario Negri Institute
Milan, Italy

Prof. Marjukka Mäkelä
Finnish Office for Health Care Technology Assessment, FinOHTA/STAKES
Helsinki, Finland

Mr. Bo Nordby Jensen
The School for Medical Laboratory Technologist
Aarhus, Denmark

Ass. Prof. Carlos Gouveia Pinto
Technical University of Lisbon Instituto Superior de Economia e Gestao
Lisbon, Portugal

Dr. Heiner Raspe
Medical University of Lübeck
Institute for Social Medicine
Lübeck, Germany

Dr. Aidan Synnott
Beaumont Hospital
Dublin, Ireland

Associated Members

Dr. Bernard Burnand
University of Lausanne
Institute of Social- and Preventive Medicine
Lausanne, Switzerland

Dr. Krzysztof Landa
National Center for Quality Assurance in Health Care
Evidence Based Activities
Krakow, Poland

Dr. Audrone Piestiniene
Assistant to the Minister of Health
Vilnius, Lithuania

Mrs. Miriam Ines Siebzehner
The Getner Institute Israeli Center for HTA
Tel Hashomer, Israel

Working Group 6

Chair
Dr. Chris Henshall
Office of Science and Technology
Department of Trade and Industry
London, United Kingdom

Vice-Chair
Dr. Pedro Koch
Swiss Federal Office of Social Security
Medical Technology Section
Bern, Switzerland

Members

Dr. Georg Carl von Below
Swiss Medical Association
Bern, Switzerland

Dr. Albert Boer
Standing Committee for Health Insurance
Amstelveen, The Netherlands

Dr. José L Conde-Olasagasti
Spanish Agency for Health
Technology Assessment, AETS
Instituto de Salud "Carlos III"
Madrid, Spain

Mr. Andrew Dillon
National Institute for Clinical Excellence, NICE
London, United Kingdom

Dr. Bernhard Gibis
National Association of Statutory
Health Insurance Physicians, NASHIP
Department of Health Technology Assessment
Cologne, Germany

Dr. Roberto Grilli
National Agency for Regional Health Care Services
Roma, Italy

Mr. Charlie Hardy
Department of Health and children
Planning and Evaluation Unit
Dublin, Ireland

Prof. Lycurgos Liaropoulos
University of Athens, Department of Nursing
Centre for Health Care Management and Evolution
Athens, Greece

Dr. José M Martín-Moreno
Spanish Agency for Health
Technology Assessment, AETS
Instituto de Salud "Carlos III"
Madrid, Spain

Dr. Risto Roine
Assessment of Technologies
Helsinki and Uusimaa Hospital Group
HUS, Finland

Prof. Tore Scherstén
The Swedish Council on Technology
Assessment in Health Care, SBU
Stockholm, Sweden

Prof. Odd Søreide
University of Oslo
Department of Surgery
Oslo, Norway

Dr. Maya Züllig'
Swiss Network on Health Technology Assessment
Bern, Switzerland

Suppl.
Dr. Christian Gawlik
National Association of Statutory
Health Insurence Physicians, NASHIP
Department of Health Technology Assessment
Cologne, Germany

Executive Committee

Chair
Prof. Egon Jonsson
The Swedish Council on Technology
Assessment in health care, SBU
Stockholm, Sweden

Prof. David Banta
ECHTA/ECAHI Project
Stockholm, Sweden

Dr. Laura Sampietro-Colom
Catalan Agency for Health Technology
Assessment, CAHTA
Barcelona, Spain

Dr. Chris Henshall
Office of Science and Technology
Department of Trade and Industry
London, United Kingdom

Secretariat

Ms. Julia Chamova
International Communications Manager
Network Coordinator, INAHTA
SBU, Sweden

Ms. Margareta Nordwall
Administrative Coordinator
ECHTA/ECAHI Project
SBU, Sweden

Dr. Mats Halldin
Working Group 1 Coordinator
ECHTA/ECAHI Project
SBU, Sweden

Mrs. Melinda Öjermark
Consultant
ECHTA/ECAHI Project
SBU, Sweden

Working Group 1
Health Promotion and Disease Prevention

To assess health promotion and disease prevention activities in terms of benefits, risks and economic, social and ethical implications as a complement to community health indicators

Working Group Members

David Banta (Chair)
Evridiki Hatziandreu (Vice-Chair)
Hans-Peter Dauben
Olav Helge Førde
Marlène Läubli Loud
Sven-Olof Isacsson
Fred Paccaud
Emília Sanchez
Therèse Stutz Steiger

Executive summary

This report deals with preventive technology, health technology assessment (HTA) and health policy in the European Union (plus Norway and Switzerland). The report has been developed by Working Group 1 of the ECHTA/ECAHI project, to assess health promotion and disease prevention activities in terms of benefits, risks and economic, social and ethical implications as a complement to community health indicators.

The ECHTA/ECAHI project is funded by the European Commission's Community Health Monitoring Programme (HMP), one of whose pillars is to establish community health indicators. Community health indicators are intended to allow monitoring the health status of the population of the European Union, to facilitate evaluation of health system performance and to enable international comparisons.

In fact, standard community health indicators do not tell a great deal about health system performance. The health system generally does not have a great influence on the most common comparable indicators of health, such as overall mortality and life expectancy, which are quite similar in all European Union Member States. One of the basic goals of Working Group 1 was to test and perhaps demonstrate an alternative or complementary method: examining the use of proven preventive technologies in the European Union as a measure of health policy and health system performance.

Public health, prevention and health promotion activities, including screening, are priorities for the European Union's health activities. Obviously, preventing disease is of importance to the general public, to the health systems of Europe and to health policy makers. When disease can be prevented and health promoted or enhanced, the entire society of Europe profits. Furthermore, public health and prevention is a major task for the public sector in all European Union Member States.

Health technology assessment (HTA) has developed during the last 25 years as an aid to decision-makers in determining health policy and practice. In its early years, HTA dealt mainly with large, visible, expensive technology. But more recently, HTA has turned toward the evaluation of a wider range of health technologies, including those in prevention. This report will give some insights into how far this process of evaluation has gone and how useful the evaluations of prevention are or could be.

It is often said that there are relatively few proven interventions in the prevention field. The report of the Working Group has demonstrated that this impression is not correct. It is an easy task to develop a list of more than 70 interventions that have been found effective by systematic review of the scientific literature. Such a list is presented in this report, without a detailed evaluation of each intervention, taken from systematic reviews carried out in the United States, Canada, the United Kingdom, the Netherlands and other countries. Few interventions in the area of health promotion have been tested – and of these, only a few were found to be efficacious.

On the other hand, evaluation of cost-effectiveness is difficult, because the needed studies have not been done in most cases. As for broader assessments of ethical and social implications of preventive technologies, these are almost entirely lacking.

Much of this evidence, whether dealing with effectiveness, cost-effectiveness or other issues, may not be entirely reliable because of the poor quality of many of the original studies and the gaps in available information.

The health technology assessment agencies, members of INAHTA, have developed a large database of their own studies, including those in the area of prevention. The Working Group examined the INAHTA's HTA Database to determine how useful it might be in the evaluating prevention. The database has many assessments in the area of prevention, and most of these are systematic reviews. Therefore, as a source of information immediately available, the HTA Database is certainly useful. On the other hand, it could be improved in a number of ways, some of which will be discussed in the body of this report. It will be noted here, however, that almost all of the interventions assessed by HTA agencies concern technologies provided by the health care system, not considering interventions or strategies under the jurisdiction of government agencies or other sectors not associated with the ministries of health.

The Working Group also wished to gain an idea of how much HTA is used in the Member States of the EU in the field of prevention and if these assessments had affected policy and practice. In fact, there are several indications, including the results of the survey carried out by the Working Group, that the potentials of prevention are not realised in European countries because of lack of effective policies. The survey was organised to further explore this problem. Because of the large number of apparently effective preventive interventions, the Working Group decided to focus on 8 technologies. Those technologies were the following, selected from the longer list because they cover a wide range of topics and considerations:

Genetic aberrations and congenital malformations
Detection and treatment of hypertension
Cigarette smoking/lung cancer
Counselling and sexual behaviour
Cervical cancer screening
Colorectal cancer screening
Detection of excessive drinkers
Traffic injuries

The Working Group did not choose these cases randomly, and they are not necessarily representative. Furthermore, there are other good examples that could have been used. In this sense, this effort must be considered a pilot project.

An exhaustive literature review was carried out in the case of these 8 areas, focusing on systematic reviews. As can be seen, some of the areas are broad, and could be addressed by several different technologies, while a few (e.g. cervical cancer screening) are rather discrete. In summary, there is

little doubt that each of these areas has one or more effective technologies that could be implemented with benefits to the population of most European countries.

The literature review showed some serious shortcomings. While information on efficacy is often available, this literature is not always of the best quality. Relatively little information on other assessment dimensions is found. Specifically, and in terms of this project, cost and cost-effectiveness information is skimpy. When it is available, it is often of poor quality. Systematic reviews in the area of prevention seldom give information on cost or cost-effectiveness. When they do, they generally point to the poor quality of the information and the analysis.

Ethics is another important area not often the subject of detailed assessment. Ethics are seldom mentioned in the literature concerning prevention (with a few exceptions such as prenatal screening and screening for familial breast cancer). And systematic reviews, despite acknowledging the importance of ethical issues in assessment, seldom mention this area.

The15 Member States of the European Union (and several autonomous provinces of Spain, plus Norway and Switzerland) were then surveyed to determine:

1. If HTAs had been carried out in the particular country covering each of the 8 areas;
2. If HTAs carried out had had discernible effects on health policy;
3. If there was, in fact, a formal health policy dealing with that prevention area in the particular country and, if so, of what type; and
4. The actual extent of use of interventions in each area in each country.

The survey revealed that considerable assessment has been done in all of the 8 areas and that these assessments generally had a policy impact. Of the 8 areas, the one with the least policy attention is colorectal cancer screening. Policies, however, often consisted of statements from policy sources or professional bodies without backing from legislation, regulation, or special payment provisions. The Working Group is not convinced that formal statements without other actions are effective at the country level. The survey attempted to gather information on actual extent of use of preventive and health promotion activities in the 8 areas, but specific information comparable across countries was generally not found. Some countries do have good information to show that implementation of prevention policies has dramatically affected the situation in some areas, indicating that other countries could adopt such policies with benefits to their populations.

The activities of the Working Group have clearly shown that there is an extensive array of proven preventive technologies that should be available to the European public. The actual implementation of these technologies is, however, generally disappointing. European countries and the European Union need to devote more attention to preventive strategies in Europe.

Introduction

Since passage of the Maastricht and Amsterdam Treaties, the European Commission has had explicit competence in the field of public health, which includes prevention. Disease prevention and health promotion activities are a priority for European health policy and for the European Union Member States. However, Member States need to know which possible activities in this area are effective and cost-effective to make the necessary policies and investments necessary to implement disease prevention and health promotion activities. Health technology assessment (HTA) can furnish such information.

There are some indications that HTA is not fully used in Europe in the area of disease prevention and health promotion, but little is known about this subject on the whole. There is a need to describe the present situation concerning the assessment and use of selected disease prevention and health promotion activities in Europe.

The main aim of this part of the project is to promote links between health policy, HTA and prevention and health promotion.

At the same time, this project falls under "community health indicators". In general, it is difficult to correlate specific societal actions, including health care system interventions, with standard health indicators. However, the Working Group will present one alternative that shows promise: to examine the use of proven technologies in the health care system. If effective technologies are not widely applied, the health care system cannot be performing optimally to produce health. This observation applies to disease prevention and health promotion activities as well as to all other technologies.

Objectives

The objective of Working Group 1, as stated in the contract with the European Commission, is as follows:

To assess health promotion and disease prevention activities in terms of benefits, risks and economic, social and ethical implications as a complement to community health indicators.

The Working Group defined these tasks as methods to meet the objective:

- Carry out an overview and analysis of completed and ongoing assessments of disease prevention and health promotion activities in European countries, focusing on assessments carried out by national and regional European HTA programmes and agencies
- Carry out an overview of disease prevention and health promotion activities to develop a list of proven technologies in this area, focusing on efficacy and (perhaps) cost-effectiveness

- With the assistance of the Steering Committee partners, determine the extent that HTA has been implemented into health policy and health practice in each of the Member States
- Run one or more workshops to explore the implications of the findings
- Report to the project Steering Committee on this work and consider how to encourage better use of HTA in determining available prevention and health promotion activities within the EU Member States

Methods and results

The Working Group was made up of 10 experts in the field of disease prevention and health promotion, including a co-ordinator from the Swedish Council on Technology Assessment in Health Care (SBU), who in addition to data collection and analysis, performed an in-depth study of the HTA Database (Working Group members are shown in Appendix 3). The Chairman of the Working Group supervised the implementation of the tasks, designed the country survey, shared in analysis of the literature and the results of the surveys and drafted the final report and executive summary. The Working Group met three times during the course of the project: on 17 June 2000 to discuss the tasks and objectives of the Group; on 21 October 2000 to review materials already developed, to adopt a work plan and to define tasks to be carried out; and on 21 April 2001 to review and critique a draft final report, including the results of the various tasks that had been carried out.

The tasks carried out were the following:

1. To review synthesis reports in prevention carried out by others to develop a possible list of interventions to be examined;
2. Based on these reports, to select a sub-set of interventions for detailed examination;
3. To search the literature for systematic reviews in the area of prevention so as to characterise the field and its evidence base in general;
4. To analyse the database of the International Network of Agencies for Health Technology Assessment (INAHTA) to examine its utility as a source of assessment information concerning disease prevention and health promotion;
5. To survey the Member States of the EU other interested countries, to learn if they used HTA in their health policies toward prevention, if relevant assessments had been carried out and if the extent of use of HTA was in fact represented in the extent of use of the relevant interventions;
6. To discuss all these materials to arrive at overall conclusions and recommendations.

These tasks were in fact carried out. The major problem encountered by the Working Group was the extensive set of interventions that have been found to be effective (see below). Therefore, a sub-set of only 8 interventions was fully examined. These interventions were chosen from the longer list of effective interventions because they raised a wide range of issues and dealt with a variety of health problems. Furthermore, several of the conditions could not be approached effectively through the health care system alone, giving opportunities to consider cross-sectional

co-ordination. Therefore, this is in part a pilot study, demonstrating what could be done throughout all prevention and health promotion activities, or, indeed, throughout all health care.

The 8 selected areas were as follows:

Genetic aberrations and congenital malformations
Detection and treatment of hypertension
Cigarette smoking/lung cancer
Counselling and sexual behaviour
Cervical cancer screening
Colorectal cancer screening
Detection of excessive drinkers
Traffic injuries

Extensive literature documentation was collected in these 8 areas, and the survey concerned these 8 areas. Little cost-effectiveness literature on these issues was found, however, nor did the literature search find many analyses of ethics and social consequences.

The lack of cost-effectiveness information cannot be explained by a lack of general expertise and information on costs and cost-effectiveness analysis. In general, economists and analysts agree that the assessment of prevention is conceptually no different from the assessment of other health technologies (US Prevention Services Task Force, 1996; Banta and Luce, 1993, p. 157; Russell, 1986). A number of excellent texts and guidelines are available laying out good practice in cost-effectiveness, as well as giving a basis for determining the excellence of a particular study (Drummond et al, 1987; Drummond et al 1997; Warner and Luce 1982; Gold et al, 1997; Luce and Elixhauser, 1990). Furthermore, several books and articles have discussed the issue of cost-effectiveness of prevention (Cohen and Henderson, 1986; Russell, 1986; Banta and Luce, 1993).

Others have observed the lack of literature on cost-effectiveness of prevention. Banta and Luce (1983) were perhaps the first to identify this weakness in the literature, commenting, after a complete review of cost-effectiveness literature "… in the main, the hard evidence supporting the cost-effectiveness of many otherwise attractive preventive programmes is disappointingly small." The US Prevention Services Task Force (1996, p. xci) commented, concerning the cost-effectiveness of prevention: "Cost-effectiveness studies are currently available on many health care services … A much larger group of services remains for which cost-effectiveness is not yet established. Information on costs and outcomes is inadequate for many interventions. For others, the cost-effectiveness analyses have not been done, or their quality is insufficient to provide conclusive evidence. Finally, the variation in cost-effectiveness methodology often makes it difficult to take cost-effectiveness results at face value." A report from the United Kingdom makes a similar observation, noting the disappointing lack of comparable studies of cost-effectiveness of preventive interventions (NHS Centre, 1995).

Russell (1986) asked the question, is prevention better than cure? Many people, especially those working in the field of public health, often seem to think that it is, by definition. Could this assumption explain the lack of studies and analyses concerning cost-effectiveness? Russell's answer

to the question is that prevention cannot be considered generally superior to cure. Any preventive intervention must be assessed as rigorously as a treatment technology.

Studying the cost-effectiveness of prevention does raise some special methodological problems. For example, in some cases, such as health education intended to change disease rates for in the future, the link between intervention and outcomes may be difficult to establish. Furthermore, cost-effectiveness, by its nature, tends to focus on benefits that can be quantified and to ignore such issues as reduced or increased anxiety and social benefits and harms such as a more or less equitable distribution of medical or health care (Banta and Luce, 1983). Analysing costs raises some of the same problems, especially the issue of investing now for benefits in the future, which may make a proposed programme look expensive for the gains, especially if benefits are discounted to their present value. Preventive programmes today are often oriented to changing the behaviour of individuals; their effectiveness rests on who takes advantage of them, and often the highest risk groups do not (Banta and Luce, 1983). This, in fact, is one of the ethical issues in prevention that deserves more attention. Preventive programmes may actually increase gaps in health status if those most at risk, such as the poor or certain ethnic groups, do not use such services.

Nonetheless, some programmes have been found to be very cost-effective, even resource saving. For example, the childhood vaccines such as measles, pertussis, poliomyelitis and rubella have all been found to be money-saving for society (Banta and Luce, 1993). The adult vaccines for influenza and pneumococcus have been found to be cost-effective in well-done studies (OTA, 1984; OTA, 1981). As noted in this report, screening for hypertension (followed by effective treatment) has been shown to be cost-effective.

In summary, disappointingly few high quality studies of the cost-effectiveness of prevention and health promotion have been carried out. Since the expected outcome of such programmes is clear – improved health – and the methods are available, this lack is difficult to understand. As Banta and Luce (1993, p. 150) noted, " … the sheer volume of the cost-effectiveness prevention literature continues to lag behind both treatment and diagnostic technologies."

Other types of assessment information, such as that concerning ethics and social consequences, are generally lacking in the field of prevention and health promotion. Concerning ethics, a number of general sources are available on justice and/or medical ethics (United Nations, 1999; Heitman, 1998; Hall, 1997; Engelhard, 1996; Swedish Commission, 1993; Jensen and Mooney, 1990; Rawls 1971), and there are sources that discuss the ethics of screening in general (Ewatt, 2000), or access to screening services by minority group members (Gotay and Wilson, 1998). However, only in a few specific areas, such as genetic advances (Clarke 1990; WHO, 1996), including screening for familial breast cancer (Steel et al, 2000), prenatal screening (Geniats, 1996) and HIV screening and counselling (Belcher et al, 1998; Schrappe and Lauterbach, 1998) were any references found related to ethics.

Heitman (1998) has presented a comprehensive discussion of ethical issues in health technology assessment, along with a useful bibliography. She points out a general problem: "there is a limited consensus on the fundamentals of ethical analysis." Concerning prevention, she apparently finds

little that is different from the ethics of treatment. She focuses especially on the "technological imperative and rescue medicine" that may lead to inappropriate action. She notes, "Particularly as health systems work to de-emphasise the role of rescue medicine in favour of prevention and early treatment, much more outcomes research is needed on preventive technologies and the long-term effects of preventive and primary care."

Screening programmes raise particular ethical issues, since screening involves testing persons who have no symptoms of the condition being searched for. As Eddy (1991, p. 1) says, "Most persons who are screened will receive no benefit because they do not have the target condition. But many persons will suffer risks, and all will face some inconvenience, anxiety, personal cost and sometimes discomfort … This fact places a special burden on any individual or group that wants to recommend a screening test. They must determine that screening can in fact deliver benefits and that the potential benefits outweigh the harms and justify the costs."

Dehlholm and Olsen (1992) have presented a good analysis of the ethical and psychological aspects of screening. They emphasise that authorities offer screening tests to the population for specified conditions. The individual is put into a choice situation without a basic understanding of the possible consequences of accepting or rejecting the offer. As Eddy noted, the harms from screening can be considerable, including the physical consequences of false positive and false negative results, psychological consequences such as anxiety and stigmatisation and the consequences of having a condition that cannot be treated (Eddy, 1991). This puts an ethical burden on those who wish to propose a screening programme. Ewatt (2000) agrees with this view, emphasising the importance of careful assessment of screening.

Given the lack of information on cost-effectiveness and ethical and social issues, material presented below will deal mainly with the issue of efficacy/effectiveness.

A workshop involving more than the Working Group was not held for pragmatic reasons, mainly involving time. However, the Steering Committee of the project, plus the audience of a special programme based on the project held in Stockholm on 17 May 2001, were introduced to the conclusions of the Working Group.

Findings of specific studies and surveys

The European Commission's Health Monitoring Programme (HMP) was established in 1997 with the objective "to contribute to the establishing of a Community health monitoring system", in order to:

"4. Measure health status, its determinants and the trends therein throughout the Community
5. Facilitate the planning, monitoring and evaluation of Community Programmes and action, and
6. Provide Member States with appropriate health information to make comparisons and support their national health policies."

One purpose of developing such information, as stated by the Commission, is to enable international comparisons.

One of the pillars of the Programme is “Establishment of Community Health Indicators”. The ECHTA/ECAHI project was funded under this pillar.

As part of its work under the health indicator area, the Working Group reviewed a report to the Commission “Design for a Set of European Community Health Indicators” being developed under the same programme and with similar timing (see reference list).

Overall, the draft report is a rather comprehensive introduction to available health indicators, including many indicators that are routinely available. Unfortunately, the indicators presented also very well reflect some of the problems with existing indicators. One is that they are often not available, that is, they are not routinely collected. Another is **their lack of utility**.

The fundamental reason that routinely collected data are not very useful for monitoring trends, evaluating policies, or enabling international comparisons is that routinely collected information is seldom sensitive to actions within the health care system. Health is the result of many factors, including genetics, life style, environment and health care (which is probably the least important of these). Health outcome, while most important, is difficult to use practically; process indicators are much easier. If process indicators can be clearly linked to outcomes, their use for monitoring is more practical and probably more useful. Therefore, international comparisons are difficult to make and to interpret using existing health indicators.

Schaapveld et al (1995) carried out a useful review of variations in health between the 12 countries of the European Union. The conclusions of the review are also applicable to Eastern and Central Europe. Clearly, it is difficult to make overall conclusions on outcomes of care. Comparable data on outcomes are only generally available for mortality. Standardised mortality rates do not vary greatly in Western Europe. Although mortality in Eastern Europe is higher and has even risen, it is difficult to attribute this to any factor or set of factors with any precision, since socio-economic factors and the environment have deteriorated at the same time that the health care system has come under severe pressures. It is known, at any rate, that the link between health services and mortality is limited, especially in developed countries with the high prevalence of chronic disease. The greatest predictor of health is probably the numbers and percentage of the elderly population.

Disease-specific mortality is interesting, but difficult to interpret. For example, cardiovascular mortality varies greatly from country to country, with a rate twice as high in Ireland as in France (Schaapveld et al). The rate of cancer deaths varies greatly as well, with higher rates in Northern Europe than in Southern Europe. It requires a great deal of specific knowledge to interpret such differences. At the same time, few investigators have shown an interest in examining these differences. It would be worthwhile funding more investigations of disease-specific mortality.

An approach called "avoidable mortality" or "mortality amenable to medical intervention" (causes of death that could have been prevented with existing medical technology or changes in

behaviour) has been used to analyse the experience of different countries in Europe. Holland (1991, 1988) has published a large set of cross-national comparisons, and the OECD now routinely publishes disease-specific years of life lost (OECD, 1993), although relatively few countries submit such information.

The Working Group was unable to identify much recent information using this approach, but the report developed by the EC Working Group up to 1984 (Holland, 1991) shows the potential value of the concept very well. The avoidable causes of death used by the EC Working Group included several mortality indicators related to the survey carried out as part of this study: malignant neoplasms of the cervix uteri; respiratory diseases; asthma; hypertensive and cerebrovascular disease; malignant neoplasms of the trachea, bronchus and lung; cirrhosis of the liver; and motor vehicle accidents. For example, Sweden was found to do very well on almost all of these indicators (Westerling and Smedby, 1992). Given the age of this data, it will not be described further.

An excellent review of this subject was carried out by Mackenbach et al (1990), who critically examined 11 aggregate data studies from the literature, mostly dealing with European countries in the period 1950 to 1984. The levels of mortality from "amenable causes" were generally low and death rates from those causes had declined rapidly. This was felt to reflect an increased effectiveness in health care services. Charlton and Velez (1986) reported similar findings for six countries.

Perhaps the fact that deaths from amenable causes are low in the European Union explains the relative sparse literature using this approach in recent years. However, it is worth noting that considerable differences were found within countries, a finding that deserves follow-up. As can be seen, it is also useful when comparing European Union countries with countries from other areas, including Eastern Europe.

Boys et al (1991) compared trends in mortality from conditions amenable to medical care in four Eastern European nations and two Western European nations (as well as two North American nations). The investigators found that a divergence in the trends for all cause mortality between Eastern European and Western nations occurred about 1970, when the rates of Western countries declined steadily, but those in Eastern Europe remained fairly static. In the age group 0–64 mortality from causes considered amenable to medical care fell less quickly in Eastern Europe than in the West. At the same time, mortality from non-amenable causes rose in Eastern European countries in the late 1960s compared with substantial declines in such mortality in the West. The authors concluded, "Non-amenable causes of death seem to be the principal, but not exclusive, reason for lack of improvement in trends in all cause mortality in Eastern Europe from 1970." Environmental safety is an especially high priority in Eastern Europe, but personal health related behaviour, including smoking, alcohol consumption and healthy diet was also considered important. At the same time, "enhancements in the quality and efficiency of direct health services" were considered important.

Velkova et al (1997) also examined the East-West life expectancy gap in Europe. “Amenable causes accounted for 11–50% of the differences in mortality between the Eastern Europe and

Western Europe in men and 24–59% of the difference in women. Cardiovascular disease was especially significant in the differences. The authors concluded that reducing differences in effectiveness of medical care might be more important than is generally assumed.

Other studies of avoidable mortality have focused on this issue in Sweden (Westerling et al, 1996; Westerling, 1992; Westerling and Smedby, 1992). For example, Westerling (1992) found that deaths from preventable and treatable diseases both declined over time (in the case of preventable diseases only after lung cancer was excluded). Death rates increased for some avoidable causes, especially for the category of diseases of the lungs: pneumonia, chronic bronchitis, emphysema and malignant neoplasms of the lung.

Finally, Simonato et al (1998) examined avoidable mortality in 21 European countries between 1955 and 1990. Reductions in mortality were greater for causes amenable to improved medical care. Smaller reductions were found for causes amenable to secondary prevention in women and for primary prevention in men (especially tobacco-related causes of death). The greatest future reduction could be from primary and secondary prevention, especially control of cigarette smoking in men, improved diet and reduction of occupational exposures. For women, further implementation of screening programmes for breast and cervical cancer were singled out as the area of greatest potential. Simonato et al concluded that avoidable mortality is an indicator of the adequacy of health care resources or quality and availability of medical interventions across geographic units, social classes and time. The negative result for primary prevention was felt to be a consequence of limited public health activities in Europe.

Such analyses as these led Tugwell et al (1986) to propose the “technology assessment iterative loop”. In this model, assessment begins with determining the current levels of morbidity and mortality for specific conditions. Then the modifiable burden of disease is determined, based on having health technology that has the potential to provide accurate diagnosis and efficacious prevention, cure, or palliation. Resources should then be made available to assess these potential technologies, or for those that are already known to be effective, to assure the development and diffusion of applications of these technologies in the primary, secondary and tertiary care levels of the health system.

A problem with this entire approach, however, is that except for mortality, little comparative information from country to country, region to region, or hospital to hospital is available. Health care has important implications for morbidity (occurrence of disease and its effects) and quality of life, but essentially no data are available that allows comparison between and among countries. OECD has begun to collect data on "life expectancy in good health", but as noted above, relatively few countries report such data and methods are not standardised, so it is difficult to reach conclusions.

Another problem with most proposed health indicators is their **responsiveness**. That is, is it based on an understanding of factors of disease and the possibilities of intervention? One must ask of a health indicator, is it evidence-based? To be useful, a health indicator must be influenced by a particular intervention, and there must be evidence that in fact the intervention does have health effects. The field of health technology assessment (including evidence-based health care)

has been working for more than two decades to find out what is worth doing and what is not worth doing. Most documents on health indicators, including the one reviewed here, make no acknowledgement of these efforts. Any indicator based on one or more health care actions or intended to be used in comparing health systems needs to be carefully examined in the light of available evidence on (at least) efficacy/effectiveness.

Examining proposed indicators for their utility and validity could help in making statements about **priority** indicators. One goal would be to make a relatively short list that could be used to examine quality of health care. International comparisons would also be more reliable and valid.

Other possibilities that have only recently been considered are to use disability-adjusted life years (DALYs) (Hollinghurst et al) or quality-adjusted life years (QALYs) to compare countries. However, such approaches would need careful validation.

In summary, the literature indicates that the field of health indicators is not very well-developed. The Working Group questions the value of collecting and analysing long lists of indicators that cannot in fact help in international comparisons, or even in comparisons within one country. The approach of "amenable mortality" or "avoidable mortality" has promise, but has not been widely implemented or studied. In its survey of practices of Member States, the Working Group seeks to illustrate an alternative to conventional health indicators: this approach **would define a set of evidence-based practices and then compare countries on the extent of their implementation of these practices**.

Survey of systematic reviews

The Working Group examined a large number of systematic reviews in the field of health promotion and disease prevention. It is often said that evidence is lacking in this field. In fact, although evidence is never "sufficient", the evidence on prevention and health promotion is far more extensive than such statements would lead one to believe. One document produced in the United Kingdom found more than 1,100 systematic reviews relevant to prevention while examining only a limited number of problems: cancer, coronary heart disease and stroke, accidents, mental health, education, social care and social welfare, and crime, drugs and alcohol (University of York, 2000). Similarly, the US Prevention Services Task Force (1996) has examined the evidence for efficacy of more than 70 preventive interventions, mostly in the areas of screening and counselling, examining more than 6,000 citations to the scientific literature to arrive at conclusions concerning efficacious interventions. However, the US effort focused on clinical prevention and did not pay a great deal of attention to activities that can prevent disease and promote health that lie outside the health care system.

The Working Group did not attempt to develop a comprehensive list of systematic reviews, since such a list becomes rapidly out-of-date. However, some representative articles are cited in the sections of the report that follows.

Identification of a list of efficacious practices

The Working Group reviewed a number of synthesis reports on prevention to identify interventions that others have suggested are efficacious, based on their systematic reviews of the scientific literature. In these cases, the Group did not make an independent attempt to verify the evidence, but accepted the analyses of the groups making the reports referenced. The list given here indicates the rather long list of interventions that have been found efficacious (University of York, 2000; US Prevention Services Task Force, 1996; Schaapveld et al, 1995; Canadian Task Force,1994; Eddy, 1991;OTA, 1991).

A caution: the fact that an intervention appears on the list does not mean that all forms of the intervention are efficacious for all individuals. In most cases, studies examine specifically designed interventions in certain population groups. Timing, such as whether the intervention should be given every year or every two years, is another important variable, as is age of those to receive the intervention. Before implementing such a list, it would be necessary to examine each proposed intervention in detail, taking into account such factors as the prevalence of the disease or problem in the specific population.

Furthermore, efficacy is not the only factor in deciding if a particular intervention should be implemented. Costs are a key factor in the policy arena. But these reviews have generally not reviewed the issue of costs, most importantly because of the lack of good data.

The NHS Centre for Reviews and Dissemination (1995) has carried out a literature review that, to an extent, supplements the one presented in this report. The report examines the evidence about the effectiveness of interventions to reduce variations in health. While a great deal of evidence has been collected relevant to effectiveness, the report notes, “Very few studies explicitly considered the cost-effectiveness of the intervention used (see above). Even basic data on the cost of interventions were rarely given. Without such information, it is difficult … to make rational decisions about which interventions to support. Research to collect and report basic cost data should be strongly encouraged.”

The report also notes that acceptability is sometimes a problem, especially when different ethnic backgrounds are offered the same intervention (NHS Centre, 1995).

A group associated with the US Prevention Task Force searched the cost-effectiveness literature on 30 clinical interventions in the area of prevention. The authors present useful critiques of the quality of the existing literature on effectiveness, burden of disease and cost-effectiveness, as well as pointing to gaps in available information. Specifically, they point to the small number of high quality cost-effectiveness analyses (Coffield et al, 2001; Maciosek et al, 2001).

The group ranked the priority of the 30 interventions based on estimated burden of disease and cost-effectiveness in the US population. The highest ranked services, in order, were providing tobacco cessation counselling in adults; screening older adults for undetected vision impairments; offering adolescents an anti-tobacco message or advice to quit; counselling adolescents on alcohol and drug abstinence; screening adults for colorectal cancer; screening young women for

chlamydial infection; screening adults for problem drinking; and vaccinating older adults against pneumococcal disease.

The Cochrane Database of Systematic Reviews, the NHS Economic Evaluation Database, and other sources were also searched for studies of the cost-effectiveness of prevention. Relatively few references were found.

Therefore, the list illustrates that a fairly large number of interventions have been shown to work (to be efficacious) in one or more populations under defined circumstances. However, the Working Group had the opinion that few of these could be considered proven by several controlled trials with a long-term follow-up of appropriate end-points. Also, as noted, few references dealing with studies of economics or ethical considerations were found.

Furthermore, few of the interventions fall within the area of health promotion.

It also seems apparent that many preventive interventions in widespread use have not been shown to be efficacious. This is another reason that prevention deserves more attention.

"Efficacious" interventions

Amniocentesis or chorionic villus sampling for all pregnant women 35 years or older
Blood pressure measurement – periodically for all children and adults
(alternative: only in high risk)
Childhood immunisation – see widely accepted schedules
- diphtheria, pertussis, tetanus
- measles, mumps, rubella
- polio (OPV)
- hepatitis B
- varicella
- Hib

Chlamydial infection screening – all sexually active woman periodically
Cholesterol measurement – periodically in adults (alternative: only in those with risk factors)
Dental health assessment – everyone periodically
Depression screening – everyone as part of routine visit to physicians
Diabetes screening – periodically in adults
Examination for anaemia – all pregnant women
Examination for Hepatitis B infection – all pregnant women
Folic acid for all pregnant women
Functional status assessment – everyone periodically (more often in elderly)
Hearing screening for children – all children before age 1
Hearing test – all elderly people periodically
Height and weight screening – periodic measurement for everyone
Hypothyroidism screening of newborns
Ocular chemoprophylaxis for newborns
Phenylketonuria screening of newborns

Postexposure prophylaxis for selected infectious diseases – after exposure
Screening for congenital hip problems for newborns
Screening for D (RH) incompatibility – all pregnant women
Screening for Down Syndrome – serum multiple marker testing for all pregnant women (if adequate counselling and follow-up available)
Screening for family violence – alertness, routine questions for everyone (if suspected)
Screening for high blood pressure – all pregnant women
Screening for neural tube defects – all pregnant women if adequate counselling and follow-up available
Screening for rubella – all pregnant women (or immunisation without screening)
Screening for sickle cell disease and thalassemia in all pregnant women in the appropriate ethnic group
Screening for skin problems and scoliosis – all children
Screening for undescended testes in all male newborns
Serological testing for syphilis – all pregnant women
Sexual abuse of children – alertness of health care workers
Testing for asymptomatic bacteriuria – all pregnant women
Tuberculosis screening – alertness of health care providers
Vision examination – all elderly people periodically
Vision screening for children
– all children for amblyopia before age 1
– all children before entering school
Vitamin K for all newborns

Cancer screening
Cervical cancer screening – all women sexually active every 1–3 years
Colon cancer screening – periodically for all adults 50 or older
Mammography breast cancer screening – women 50–70 every 1–2 years

Adult immunisation
Hepatitis B – all young adults
Influenza – all individuals 65 years or older
Pneumococcal – all individuals 65 years or older
Tetanus-diphtheria booster – everyone periodically

Education and Counselling
Alcohol drinking pattern and counselling – all adolescents and adults periodically
Alcohol use – all adolescents and adults periodically
Appropriate use of medications – all adolescents and adults periodically
Bicycle helmet – after history of use of bicycle or motorcycle
Breast feeding – all pregnant women
Counselling about osteoporosis – all postmenopausal women
Counselling about sudden infant death syndrome – all pregnant women
Counselling concerning sunlight – everyone periodically

Counselling on contraception – all adolescents and young adults
Counselling on prevention of dental problems – everyone periodically
Counselling to prevent motor vehicle injuries – everyone periodically
CPR training for parents/caretakers
Drug use history and counselling – all adolescents and adults
Exercise – exercise is beneficial, counselling not established
General nutrition (include weight control) – all adults and children
Home safety/injury prevention – adolescents and adults periodically
Lap-shoulder belts – adolescents and adults
Poison control phone numbers
Safe storage of drugs, toxic substances, firearms and matches
Sexual history and counselling (HIV) – adolescents and adults periodically
Smoke detector – all adults at least once
Smoking cessation – for all smokers
Stress management – all adults periodically

Discussion of the eight chosen interventions

As indicated above, the Working Group chose 8 "target" interventions or problem areas. In some cases, possible interventions were extensive and cross-sectional. In each case, the evidence was examined to determine what interventions had been found to be efficacious.

Genetic aberrations and severe congenital malformations

Genetic aberrations and congenital malformations cause a great deal of distress and cost to those afflicted, to parents and other relatives and to society at large. The main approach to such problems is screening either while the foetus is in utero or shortly after birth. The detection of genetic conditions or other problems in utero provides the opportunity to inform prospective parents of the likelihood of giving birth to an affected child. Parents may be counselled about the consequences of the abnormality and can make informed decisions about optimal care for the newborn or about elective abortion. The most common chromosome abnormality is Down syndrome, which occurs in about 1 of 1,000 live births. Expert groups recommend screening for Down syndrome for all pregnant women who are aged 35 years and older or otherwise at high risk for chromosome abnormalities. Another common problem is neural tube defects. Screening is recommended for all pregnant women who have adequate counselling and follow-up services available. Daily multivitamins with folic acid to reduce the risk of neural tube defects are recommended for all women who are planning or capable of pregnancy to prevent neural tube defects. Other recommended foetal screening includes screening for different hemoglobin-opathies, depending on expected prevalence in the population. Screening for a common genetic disorder, cystic fibrosis, is possible, but there is no consensus as to its desirability. Recommended neonatal screening includes screening for phenylketonuria, hypothyroidism and various hemoglobinopathies. With neonatal screening, the goal is to begin treatment very early in the course of the infant's disease.

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Detection and treatment of hypertension

Studies have shown a strong relationship between blood pressure and the risk of coronary heart disease and stroke. Drug treatment of hypertension decreases the risk of fatal and non-fatal stroke, cardiac events and total mortality. Non-pharmacological intervention – salt restriction, alcohol reduction, stress management, physical exercise – for controlling blood pressure have only small effects compared with drug therapy, although salt restriction may be the most efficacious of these alternatives. Weight reduction stands out as showing modest but important effects. For some high-risk groups, such as diabetes, trials have shown that intensive lowering of blood pressure reduces the risk of cardiovascular events more effectively than less intensive programmes. Intensive programmes of hypertension detection and treatment following protocols both reduce cardiovascular mortality but also narrow social class mortality differences. Anti-hypertensive drug therapy is effective in treating those at high risk of stroke, especially the elderly. Case finding for hypertension is particularly useful when linked with professional training, protocols and reminders, given to both patients and doctors.

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Cigarette smoking / lung cancer

Cigarette (tobacco) smoking is associated with lung cancer, laryngeal cancer, oral cancer, cancer of the urinary bladder, other cancers, and chronic bronchitis and chronic lung disease. In addition, cigarette smoking is associated with coronary artery disease and other health problems. Reducing cigarette smoking contributes to a lower incidence of these conditions in the population. Taxation and similar fiscal measures raise cigarette prices and reduce cigarette smoking. Control of advertising is an effective method to reduce cigarette smoking, especially when coupled with an increase in the level of counteradvertising. Restricting access to minors can reduce cigarette smoking if coupled with education on the effects of smoking. Some evidence shows that community interventions help prevent smoking in young people. Workplace tobacco policies can reduce tobacco consumption and worksite environmental tobacco smoke exposure. A total ban on cigarettes in the workplace coupled with monetary incentives to quit has been shown to improve cessation rates substantially. Health education programmes providing information together with personal support can be used to change behaviour across all socio-economic groups. National media campaigns targeted at smokers can result in small reductions in the prevalence of smoking. Free telephone quit lines, as part of an anti-smoking campaign, can improve quit rates. School-based programmes that use social reinforcement techniques have been shown to prevent the uptake of smoking among children. Encouragement and advice by physicians and other health professionals during routine visits are effective in promoting smoking cessation. Training health professionals increases the degree to which they offer anti-smoking interventions and their effectiveness in doing so. Nicotine replacement therapy is effective as well. Free telephone quit lines and other methods of counselling can help those who wish to quit smoking.

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Counselling and sexual behaviour

Sexual behaviour is related to the acquiring of sexually transmitted diseases, including HIV/AIDS, syphilis, gonorrhoeaand chlamydial infection. Counselling has been shown to influence behaviour and can reduce infection rates. For example, some interventions targeted toward women are efficacious for increasing condom use during sexual intercourse. However, programmes targeted toward adolescents have shown only small effects on intentions and behaviour of students.

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Cervical cancer screening

Cervical cancer is one of the greatest causes of death in women. Cervical cancer screening followed by treatment can reduce mortality and morbidity rates in women. Cervical cancer screening is likely to be most effective if women are screened every 2 years starting at age 18 (or within a year of first sexual intercourse) and ending at age 70, with a systematic approach to monitoring the screening programme. Human papilloma virus (HPV) testing is more sensitive than cytology for high-grade cervical intraepithelial neoplasia (CIN) but has lower specificity, especially in young women, and is currently not recommended as a routine. Cancer screening attendance increases with interventions targeting either the physician or the patient. Special efforts must be made to reach social and ethnic groups that do not participate fully in screening programmes.

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Colorectal cancer screening

Colorectal cancer is one of the most important causes of death and morbidity in adult men and women and is the first cause of cancer deaths in non-smokers. Colorectal cancer screening using faecal occult blood tests followed by identification and removal of lesions can reduce mortality from colorectal cancer. Annual screening is more effective than biennial screening. Colonoscopic

surveillance should be offered to patients with long standing ulcerative colitis. Cancer screening attendance increases with interventions targeting either the physician or the patient.

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Preventing Traffic Injuries

Traffic accidents are one of the major causes of mortality and morbidity in Europe, especially among adults. A wide variety of measures can reduce accidents and injuries from accidents. Area-wide traffic schemes, such as speed limits and “traffic calming”, have resulted in some reduction of road accidents and pedestrian injuries. Guard rails and crash cushion (impact attenuators) can reduce the rate and severity of accidents. Graduate driver-licensing systems and night-time curfews reduce young driver crashes. Wearing seat belts reduces the risk of serious injury in road traffic accidents. Child car seat restraints reduce car occupant injuries. Incidence and severity of head injury are lower in cyclists wearing helmets. Hospitals with up-to-date equipment and medical staff trained in trauma care have lower case-fatality rates among accident victims. Remedial interventions with drink-driving offenders can reduce recidivism and subsequent alcohol-related crashes. Random screening for drinking can substantially reduce crash fatalities and injuries.

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Detection of excessive drinkers

Excessive drinking is associated with a wide variety of health conditions including various cancers (mouth, larynx, oesophagus and others), liver disease, diseases of the pancreas and with accidents. Brief interventions in primary care, including assessment of alcohol intake and provision of information and advice, may be used to reduce alcohol consumption in those with consumption levels above recommended levels. Remedial interventions with drink-driving offenders can reduce recidivism and subsequent alcohol-related crashes. Random screening for drinking can substantially reduce crash fatalities and injuries.

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The survey concerning the eight target intervention areas

In its meeting in October 2000, as already stated, the Working Group selected the 8 intervention areas. The Working Group was aware that some of the areas are rather broad. However, it wished to move out of the usual definition of preventive interventions as discrete procedures addressed to a particular disease. In fact, much of the future success of prevention will be in "softer" areas such as counselling addressed to behaviour change. This breadth of intervention makes the survey instrument slightly difficult to deal with. The hope of the Working Group was that meaningful responses could be acquired by this method. In this sense, the survey is a pilot study.

Responses were received from all EU Member States, plus Switzerland and Norway, and the Spanish provinces of Catalonia, Andalusia, the Basque Country and Galicia. The overall responses are presented in Tables 1–3.

Table 1 shows the identified HTAs in each of the 8 areas surveyed. As can be seen, the number of assessments is lowest in the cases of counselling for sexual behaviour and screening for colorectal cancer. The highest number of assessments was found in the case of screening for genetic aberrations and severe congenital malformations. In summary, this is a rather impressive number of assessments. Why the low number of assessments in two cases? This could be related to the personal nature of these two areas and the cultural meaning of interventions in these areas.

Table 1: Completed HTAs

	Malform.	Hyper-tension	Smoking	Sexual Behaviour	Pap Smear	Colo-rectal Cancer	Traffic Injuries	Alcohol
Austria	Y	N	N	N	N	N	N	N
Belgium	N	N	N	N	N	N	N	N
Denmark	Y	Y	Y	N	Y	Y	Y	Y
Finland	Y	Y	Y	N	Y	Y	Y	N
France	Y	Y	Y	Y	Y	Y	Y	Y
Germany	Y	N	N	N	Y	N	N	N
Greece	Y[1]	N	N	–	Y	N	Y[1]	Y
Ireland	Y	Y	Y	N	Y	N	Y	Y
Italy	Y	Y	Y	N	Y	Y	N	Y
Luxembourg	N	N	N	N	N	N	N	N
The Netherlands	Y	Y	–	–	Y	Y	Y	Y
Norway	Y	Y	N	N	N	N	N	N
Portugal	Y	N	Y	Y	N	Y[1]	N	N
"Insalud"	N	N	Y	N	N	N	N	N
Andalusia	N	N	N	N	N	N	N	N

	Malform.	Hyper-tension	Smoking	Sexual Behaviour	Pap Smear	Colo-rectal Cancer	Traffic Injuries	Alcohol
The Basque Co.	N	N	Y	N	N	N	Y	N
Catalonia	Y	Y[1]	N	N	N	N	N	Y
Galicia	Y	N	Y	Y	N	N	N	Y
Sweden	Y	Y	Y	Y	Y	Y	Y	Y
Switzerland	Y	N	Y	Y	Y	N	Y	N
The UK	Y	Y	Y	Y	Y	Y	Y	Y

Footnotes: "Insalud" is the health service under the Spanish National Health System, excluding those of the seven autonomous regions with devolved power in health care.
Y[1] = Professional society or original research
– = No information submitted

At the same time, considering the results of the HTA Database study, it is known that the HTA agencies have done little assessment with regard to traffic injuries and alcohol. This means that evaluation is being carried out, but not in the HTA agencies. Since these evaluations also have influenced policy (see Table 2), there may be no reason to be concerned about this situation. However, the term “health technology assessment” is now favoured over “health care technology assessment”, while HTA agencies seem in fact to be largely confined to health care technology.

Overall, Table 1 shows that countries with well-established HTA programmes such as Sweden, the United Kingdom, Denmark and the Netherlands are involved in the evaluation of prevention and health promotion. Likewise, countries including Austria, Belgium and Luxembourg have not (yet) effectively institutionalised HTA, so it is not surprising that they have generally not carried out HTAs or related evaluation research in prevention.

The number of assessments by country varies from 0 in the cases of Belgium, Luxembourg and Andalusia (and 1 in Spain Insalud and Austria) to a high of 8 in the United Kingdom and Sweden.

Table 2 shows the respondents estimations of the impact of the HTAs identified on health policy. Again, impact varies rather widely, but in countries with well-established HTA agencies, including France, the United Kingdom, Sweden and the Netherlands, impact seems generally satisfactory. In short, established HTA programmes seem to have established links with policy-makers.

Table 2: HTAs used for policy-making

	Malform.	Hyper-tension	Smoking	Sexual Behaviour	Pap Smear	Colo-rectal Cancer	Traffic Injuries	Alcohol
Austria	N	X	X	X	X	X	X	X
Belgium	X	X	X	X	X	X	X	X
Denmark	N	N	N	X	Y	N	Y	Y
Finland	Y	N	N	X	Y	Y	Y	X
France	Y	Y	Y	Y	Y	Y	Y	Y
Germany	N	X	X	X	Y	X	X	X
Greece	N	X	X	–	N	X	Y	Y
Ireland	Y	Y	Y	X	Y	X	Y	Y
Italy	Y	N	Y	X	Y	Y	X	Y
Luxembourg	X	X	X	X	X	X	X	X
The Netherlands	Y	Y	–	–	Y	Y^2	Y	Y
Norway	Y	N	X	X	X	X	X	X
Portugal	Y	X	–	N	X	N	X	X
"Insalud"	X	X	N	X	X	X	X	X
Andalusia	X	X	X	X	X	X	X	X
The Basque Co.	X	X	Y	X	X	X	–	X
Catalonia	N	X	X	X	X	X	X	Y
Galicia	Y	X	Y	Y	X	X	X	Y
Sweden	Y	N	N	Y	Y	Y	Y	Y
Switzerland	N	X	Y	Y	Y	X	Y	X
The UK	–	N	Y	Y	Y	Y	Y	Y

Footnotes: "Insalud" is the health service under the Spanish National Health System, excluding those of the seven autonomous regions with devolved power in health care.
Y^2 = In preparation
– = No information submitted
X = No completed HTAs

Table 3 indicates which countries have formal policy in each of the 8 areas and the type of policy. Respondents made many interesting extra comments in response to the questions in this area. A number of countries have explicit health plans or prevention plans that should form a basis of health policy. Examples include the Danish Governmental Programme on Public Health and Health Promotion; the Health Plan for Catalonia; the Galician Plan About Drugs (including alcohol); and the Italian National Health Plan. Some countries also have plans dealing with specific problems examined in this report. For example, Portugal has a National Road Law and Code that covers a number of aspects related to public health, including driving, parking and mandatory use of seat-belts (however, use of child seats and seatbelts in the backseat is low, as it is in most countries that reported the data). Portugal also has an Alcohol Action Plan approved in 2000. Sweden has a White Paper on Swedish Road Safety Policy since 1997 that has a number of strong elements in it, including mandatory seat belts, mandatory lights on while driving, speed

limits and mandatory helmets for motorcyclists. The United Kingdom has periodically up-dated reports laying out preventive policies in different areas examined in this report.

Table 3: Formal policies

	Malform.	Hyper-tension	Smoking	Sexual Behaviour	Pap Smear	Colo-rectal Cancer	Traffic Injuries	Alcohol
Austria	Y[5]	Y	N	N	Y	Y[5]	Y	N
Belgium	Y	N	N	Y[4]	Y[6]	N	Y	N
Denmark	Y[4]	N	Y	Y	Y	N	Y[4]	Y[4]
Finland	Y[6]	Y[4]	Y	N	Y	N	Y	N
France	Y[3]	Y	Y[3]	Y[3]	Y[3]	Y	Y[3]	Y[3]
Germany	Y[5]	N	N	Y[4]	Y[5]	N	Y	N
Greece	Y[6]	N	Y	–	N	N	Y	Y
Ireland	Y[6]	Y[4]	Y	Y[5]	Y	N	Y	Y[4]
Italy	Y[3]	Y[5]	Y[3]	Y	Y	Y[4]	Y	Y
Luxembourg	N	N	Y	Y	Y	N	Y[4]	Y
The Netherlands	Y	Y[5]	–	–	Y	N	Y	Y
Norway	Y[6]	N	Y	N	Y[6]	N	Y	Y
Portugal	Y[5]	Y[4]	Y[4]	Y	Y[4]	N	Y	Y
"Insalud"	N	N	N	N	Y[6]	N	N	N
Andalusia	Y	Y[6]	Y	Y[6]	N	Y[4]	Y[4]	Y[4]
The Basque Co.	Y[3]	Y	Y[3]	Y[6]	Y	N	Y	Y[6]
Catalonia	Y	Y[6]	Y	Y[4]	Y	N	Y	Y
Galicia	Y	Y[4]	Y[4]	Y[4]	Y[4]	N	Y[4]	Y[4]
Sweden	Y	Y[4]	Y	Y	Y[4]	N	Y	Y
Switzerland	Y[6]	Y[6]	Y	N	Y[5]	N	Y	Y
The UK	N	Y[4]	Y[4]	Y[4]	Y[4]	Y[4]	Y	N

Footnotes: "Insalud" is the health service under the Spanish National Health System, excluding those of the seven autonomous regions with devolved power in health care.
Y[3] = Several types of policy actions
Y[4] = Policy statements
Y[5] = Formal payment decisions
Y[6] = Policy statements and formal payment decisions
– = No information submitted

Table 3 also presents information on policy actions that have been made that are compatible with these plans. As can be seen, frequently the only formal policy is a statement from the government or from prominent professional bodies. Respondents gave examples of follow-up action, such as laws mandating random screening of drivers for alcohol, formal organised screening programmes, or special payment provisions. The Working Group felt that such follow-up action is generally necessary and that policy statements with no further policy action have questionable impact.

At the same time, differences from country to country must be acknowledged here. Countries such as the United Kingdom and Sweden, with their universal health care systems have fewer potential policy instruments than other countries. As shown in Table 3, the most common action beyond policy statements is making special payment provisions. Generally speaking, this would mean that the service would be entirely free to the population. Sometimes, special incentives are available for providers who offer the service. This option is probably not available in Sweden and the United Kingdom.

France stands out in having strong prevention policies in all of the areas examined, generally laws and regulations, often backed by special payment provisions. For example, in the area of sexual behaviour, a law and regulations deal with this subject, and special payment provisions are also made. The policy includes pieces on television promoting condom use, family counselling and abortion rights. Traffic is highly regulated in France, with ever-stronger laws and attempts to identify and improve dangerous spots on the roads. Drinking is highly regulated by laws and regulations, professional guidelines are available to guide clinical practice, and special clinics have been set up to help drinkers. Hypertension screening is the subject of special payments, the rate of screening is above 50%, and new initiatives are expected to bring it even higher.

Almost all countries have policies concerning congenital abnormalities that include prenatal screening and the option of abortion. In Ireland, abortion is not available, and the national policy focuses on provision of folic acid to all pregnant women.

Most countries, even those with formal policies, note relatively low levels of **screening for hypertension**. For example, in Italy, it is reported that fewer than 40% of those with hypertension know about their condition. In Norway, only "opportunistic" screening is carried out. However, this is an area of concern, and a number of countries are taking action to remedy the situation.

Most countries have strong policies dealing with **cigarette smoking**. Policies towards cigarettes have also been shown to be effective in a number of countries. In Sweden, for example, smoking rates have fallen to 19% of adults. In the Basque Country, the rate of smoking has been reduced, many smokers are trying to quit, the number of cigarettes smoked by each smoker has been reduced, low nicotine cigarettes are smoked more frequently, and passive exposure to cigarette smoke has been greatly reduced. In Denmark, smoking continues to be widespread, although the number of smokers has been reduced. However, 43% of smokers have stated they would like to quit smoking, so the goal is to offer all smokers smoking cessation assistance during the next 20 years. In general, the prevalence of cigarette smoking is falling in Europe, except that a numbers of countries report distressingly high rates of smoking among young people.

Counselling concerning sexual behaviour is commonly a subject of policy in Europe, but little information is available concerning the effects of such policies. This area is also in the process of change. For example, the Italian AIDS Project 1998–2000 has been approved by the national government. The document emphasises counselling to reduce sexually transmitted diseases, including health education in schools and national and local advertising to increase condom use. The United Kingdom reports a very active effort in this area.

Almost all countries have policies concerning **Pap smear testing for cervical cancer** and rates of screening seem relatively high in almost all countries. In Ireland, a decision was recently made to establish a national, population-based screening programme. Only Greece and the Andalusian Province of Spain report no formal policies in this area.

As can be seen, few countries have policies dealing with **colon cancer screening**. The situation may be changing. In France, the United Kingdom and the Netherlands, for example, pilot programmes are being carried out to determine whether a national programme should be implemented or how it should be made more effective. In Denmark an assessment is underway that might lead to a change in policy. On the other hand, the possibility has been assessed in some countries, including Sweden, Ireland and Italy, where it was decided not to develop a positive policy toward screening.

Many countries have strong policies dealing with **traffic injuries**. A particular area of traffic injuries of interest is random screening of drivers for alcohol intoxication, which is done in (at least) France, the Netherlands, Norway, Ireland, Catalonia, Belgium, Germany and Sweden. New laws for this purpose are being considered in Portugal and Switzerland.

Another common policy is requiring seat belts while driving. Countries that report this policy include Greece, Catalonia, Portugal, Norway, Sweden, and Belgium.

A number of countries are in the process of strengthening their policies concerning traffic injuries and deaths. For example, in Switzerland, The Federal Road Department closely follows recommendations based on analyses carried out by the Swiss Council for Injury Prevention and is in the process of proposing legal changes that are expected to inaugurate random alcohol testing among drivers as well as daytime head and tail lights on all moving automobiles. In Italy, The National Plan for Traffic Safety, the Transport General Plan, the Highway Code and the National Health Plan all contribute to the implementation of policies that include improvements in the road network, use of safety devices such as seat belts and safety helmets, alcohol and drug use, speed limits, traffic education and monitoring of traffic accidents and their causes (nonetheless the rates of accidents and traffic injuries is still rising, which is considered to be a very serious problem).

It is interesting that activities concerning cigarette smoking and traffic injuries generally do not fall under ministries of health. Why is it that policies are generally stronger here than in those areas, which fall within health care?

Finally, policies toward **alcohol use** are found in most countries. However, respondents generally felt that, outside the area of screening drivers, policies are weak in this area. This area is gaining increasing attention. For example, in Italy the National Health Plan 1998–2000 includes targets for reducing drinking and a recent law on alcohol strengthens services available to those with a drinking problem. Portugal, too, has recently created an inter-ministerial commission to strengthen and improve the “fight against alcoholism”.

Respondents were asked to estimate the effects of the 8 policy areas, since data are generally not available, or not available in a form that allows comparison between countries. However, they were not able to give accurate figures on the actual implementation of the policies and their effects. The information received was too fragmentary to be presented. Where appropriate, it has been mentioned above. A common statement was “nobody knows” the extent of use. Another common estimate of effectiveness or implementation of prevention programmes was “very low”.

The Working Group carried out an extensive literature review seeking reliable, comparable data on use of the preventive interventions in European countries. Little was found. The most interesting literature was from the MONICA project, which includes populations in Denmark, Finland, France, Germany, Italy, Spain, Sweden, Switzerland and the United Kingdom (Dobson et al, 1998). The main problem with this data is that it related to the 1980s, not the present. During that period, the prevalence of cigarette smoking in men declined in almost all populations, but the picture for women was very mixed, with both increases and declines both within countries and across Europe. The prevalence of hypertension declined in most of the European populations studied, probably related to effective treatment (but not screening), but the picture was again quite inconsistent.

Overall, little is known about the implementation of preventive methods in Europe, and even less is known about their effectiveness. A very worthwhile activity would be to mount European studies evaluating the effects of policies toward prevention in selected areas.

Study of the HTA Database

The International Network of Agencies for Health Technology Assessment (INAHTA) was formed in 1993 to foster communication between different HTA agencies. INAHTA presently has 37 members in 19 countries. Most INAHTA members are located in European Union countries. INAHTA membership is open to any organisation which:

- Assesses technology in health care
- Is a non-profit organisation
- Relates to a regional or national government
- Is funded at least 50% by public sources

Since 1998, INAHTA has had an electronic database of published reports and ongoing studies by its member agencies. The database is produced through a collaboration between the INAHTA secretariat in Stockholm and the NHS Centre of Reviews and Dissemination in York (CRD). Details from current projects and publications from INAHTA agencies, such as title of the study and study design, are required from the INAHTA agencies and sent to CRD by the INAHTA secretariat every 6 months. The agencies are also encouraged to submit abstracts directly to CRD, including author, language of publication, methodology, results, sources searched, type of interventions, author's objective and conclusions, etc. Many of the publications records on the HTA Database contain a web link (URL) to the full text paper or an executive summary.

The database, previously referred to as the INAHTA database, is now called the "HTA Database". The HTA Database is available through the INAHTA website (www.inahta.org) and the CRD website (www.york.ac.uk/inst/crd) free of charge, as well as through the Cochrane Library. HTA database records are also available on the TRIP database of evidence-based medicine (www.tripdatabase.com).

In June 2001, the HTA Database consisted of 2139 unique entries from INAHTA agencies, consisting of 1388 completed reports and 751 ongoing projects.

The issues for this report were the following:

1. The extent to which INAHTA agencies have examined preventive technology;
2. The utility of the HTA Database in identifying these studies;
3. The methods used in HTA studies of preventive technology;
4. The overall utility of the HTA Database in identifying useful studies of preventive technologies;
5. The general usefulness of INAHTA agency reports in assessing preventive interventions.

To address these issues, the HTA Database was searched using 29 search terms, defined as related to prevention (see Appendix 2). Even if this search claims to reach completeness, there might be publications missing due to the search terms used. Other search strategies could have been used, such as truncation (e.g. "prevent") and even further or other search terms. Since the field of prevention is very extensive, it was crucial but difficult to find a distinct definition in order to limit the possibility of individual interpretation. In addition to an analysis of the utility of the HTA Database, this study, however, is aimed at giving an overview of the prevention field and to show what the members of INAHTA have produced so far in this matter.

The analysed publications of the HTA Database were moreover, only those produced by INAHTA members (which is about 95% of the content of the database).

The search resulted in 753 "hits", including overlaps, projects and publications that were to be excluded at a later stage, based on additional review of the content. A protocol was developed to identify reports focused on prevention, as defined in this report. A serious problem for this study was that "prevention" was often checked as a key word (all terms in the entire text of the database record/abstract were included in the scope of the search). In many cases, these reports were actually on treatment, with some on rehabilitation. The decision was made, in consultation with the Working Group, to exclude these articles since they were dealing with tertiary prevention, following the definitions. The scope for this study comprised articles related to primary and secondary prevention. Therefore, each report had to be examined to assure that it was actually on the subject of prevention.

Under the protocol, two investigators independently examined the titles of all reports identified by the database as related to prevention. In principle, if the word "prevention" appeared in the title of the report, it was included in the analysis. All disagreements were resolved by discussion. In questionable cases, the abstract was examined by both investigators, and each report was

characterised as in the case of the title. In cases where there was no abstract, other information, such as a full text report, often available only from the INAHTA agency, was examined.

The categorisation of the 753 reports was as follows:

Overlaps	182
Exclusions (not prevention)	256
Ongoing projects	159
Completed projects	156

Therefore, the conclusion is that the HTA Database includes 156 reports on prevention, about 11%of all reports. In answer to the first question above (the extent to which INAHTA agencies have examined preventive technology), the INAHTA agencies have certainly dealt with preventive technology. Is 11% (156 reports out of 1388) about the right percentage? The reader will have to judge.

In answer to the second question (the utility of the HTA Database), the search process allows rapid identification of a report on a specific subject, such as smoking cessation. It is difficult to use in a study such as this. In particular, the search words are overlapping, aimed at completeness rather than uniqueness.

Concerning the study design/method (the third question), the information reported by the INAHTA members indicated that the 156 reports had the following study designs:

Consensus statement:	4
"Cost-effectiveness analysis":	1
"Cross-sectional study design":	1
"Evaluation":	1
Expert panel:	4
"Literature review":	1
"Non-systematic review":	4
Overview:	4
Primary research/RCT:	6
"Review":	25
"Spreadsheet model":	1
Systematic review:	70
No design information:	34

Assuming that those using the database would be first interested in systematic reviews (and possibly primary research), 76 reports seem of high interest (perhaps together with 25 "reviews", which could be regarded as either systematic reviews or even other methods less systematic). Since the systematic review is the accepted standard for carrying out synthesis, it is disappointing that only about one half of the reports report this method. However, this might be more due to insufficient methodological information provided by the agencies than the actual methods used

in the reports. Since neither the INAHTA secretariat nor the CRD personnel form critical appraisals, this issue is largely dependent on the agencies.

It is also disappointing that 34 entries give no design information, i.e. the study design was neither clearly stated in the title of the report, the abstract in the database, or the executive summary, nor explicit in the full text report. This hampers the usefulness of the database. In discussing this issue with several people working in HTA agencies, they confirmed that they first look for a systematic review on a specific subject. If there is no systematic review, other information from a non-systematic review may still be useful. In those cases, the full report is sought from the agency that has produced the report.

In making a determination of possible utility in an individual case, it would be useful if the report information from the INAHTA agencies included a structured abstract. This was the result of this parameter:

Abstract available in the HTA Database:	111
Only record with basic information available:	45

Finally, the answers to the fourth (the overall utility of the database) and fifth (the usefulness of reports) questions above can only be judgements. The HTA Database seems quite useful for identifying HTAs carried out by INAHTA members dealing with prevention. An analyst undertaking a specific study can quickly determine what studies have been completed and can generally learn something about their study design. In many cases, the abstract will give enough information to judge if acquiring the entire report is worthwhile. On the other side, however, in many cases the analyst will not be able to judge the usefulness of the study because the database may lack information on study design or may not have an abstract. Therefore, the HTA Database could definitely be improved.

If database information is scarce, an alternative option is to obtain information through the website of the INAHTA agency where the report has been produced, or alternatively to search for the report itself. About one third of the publications were hypertext-linked, which is highly beneficial to the search process.

Concerning executive summaries available through the Internet (from the website of the INAHTA agencies) the result was similar to the availability of database information:

Electronic summary in English:	105
No electronic summary in English:	10
No information found:	41

Not surprisingly, the availability of full text reports was more limited (all free of charge through website or pdf-file):

Full text electronic report in English:	65
No full text electronic report in English:	75
No information found:	16

Some of the INAHTA agencies do not have an English website (see above). This is the fact concerning e.g. ANAES of France, the Dutch CVZ and AETSA of Spain, all relatively well-established members of INAHTA.

Another observation was, that the website addresses of the different reports were sometimes not correct (maybe not updated), which requires the user to experiment with other search paths when searching the articles. Furthermore, the search engine of many agencies' websites did not perform satisfactory. The result of a search was too dependent to the skills and experience of the user.

The answer to the fifth question depends in part on the subject on which one is seeking information. The table gives information on specific subjects of assessment.

Table 4: Subjects of INAHTA reports on Prevention and Health Promotion (156 reports)

Alcohol abuse		1
Cardiovascular disease		8
Childhood- and pre-school health		8
Communicable disease		20
HIV	1	
Immunisation	14	
Urinary tract infection	2	
Other	3	
Diabetes mellitus		4
Drug abuse		3
General prevention		11
Health education/health promotion		8
Hypertension		1
Maternal child health		4
Mental health		3
Neonatal screening		5
Occupational/environmental health		5
Osteoporosis		9
Prenatal screening		6
Screening, cancer		38
Breast	11	
Breast and prostate	1	
Cervix	9	
Colorectal	4	
Ovary	2	
Prostate	11	
Screening, general		18
Smoking		4

Concerning the overall usefulness of the HTA Database for assessing prevention technologies, it can be observed that several subjects have been examined a number of times. Particularly

"popular" subjects include screening for cervical, breast and prostate cancer and osteoporosis (including screening). Obviously, these are subjects that are of high importance in different countries. The danger is unnecessary repetition of assessments. Such subjects would be good candidates for collaborative international assessments.

The small number of reports in areas of importance is surprising. For example, only three reports deal with mental health and only four with diabetes mellitus.

It also noteworthy that the subjects for assessment are almost entirely interventions used within health care. Until a few years ago, the term “health care technology assessment” was the predominant name for the field. However, “health technology assessment” has gradually displaced this name. Does the field actually merit this name? As has been seen in the survey of European countries, technologies related to health, but outside of health ministries, such as interventions to discourage smoking (taxes, etc.) and to prevent traffic injuries and deaths (road design, checking drivers for alcohol level) are assessed, and these assessments do affect policy. However, as shown here, these assessments have not been carried out by INAHTA agencies. One conclusion is that the idea of assessment seems to have spread to other sectors of government, which is a beneficial outcome.

The first observation on the HTA Database is that it is quite difficult to search for reports on an issue such as prevention. However, that is not necessarily a drawback, since the indexing and search process was not set up for this purpose. Rather, the purpose is to allow the person searching to quickly identify articles on a particular subject. For that purpose, the search process might be quite functional. In fact, in a study carried out by Working Group 2 in this project, those working in European HTA agencies stated that the HTA Database was the most useful database in their work regarding information on ongoing HTA projects and HTA results. Presumably, whenever an agency is undertaking an assessment, one of the first steps is to check the HTA Database to see what is available.

However, it is not clear that inter-sectoral co-operation and communication is effectively carried out, since HTA reports reviewed on the problem areas and excerpts of reports furnished as part of the survey seldom note the activities of other sectors of government. It may be that inter-sectoral co-operation is an issue that needs more attention.

Otherwise, the study has identified several problems, not so much with the database itself, but with the assessments. It is surprising that the method of systematic review was explicitly reported in only about 50% of assessments of prevention. The final observation is that the information requested from the INAHTA agencies is necessary for the potential user to determine if the report should be acquired, but this information is often lacking or inadequate. This indicates considerable scope for improvement in the HTA Database.

Discussion

As demonstrated in this report there is a substantial literature on benefits of specific interventions in disease prevention and health promotion, although there are problems with the quality of much of this literature. Not only have clinical trials been carried out, but also there are literally hundreds of systematic reviews to guide policy and practice. The activities of this Working Group have certainly met the objective of demonstrating that fact.

However, cost-effectiveness literature is limited, with spotty coverage. It is not possible to make definitive statements about cost-effectiveness of prevention in general. Some interventions have been shown to be cost-effective. However, the often-heard statement that prevention is a superior intervention, the "primacy of prevention", has little support from the literature. For some problems, prevention is very effective and cost-effective, but in other cases, there is no effective preventive intervention known, while treatment may be quite effective and cost-effective.

As previously noted, there is generally little ethical and social analysis in the literature dealing with prevention outside the field of screening. In addition, access to preventive services by certain social and ethnic groups has received some attention.

The Working Group identified one issue that has received little attention: medicalisation. Screening programmes assume that the benefit from the screening more than balances the side effects. One of the side effects of screening is that people put faith in the medical system that can be quite misplaced. The Working Group feels that, in general, it is better for individuals to have control of their own health. This is another argument that the evidence concerning screening needs to be quite sound before a screening procedure would be desirable. Furthermore, with doubts on cost-effectiveness and ethical implications, screening programmes need to be carefully scrutinised, which they are not, in general. However, it should be noted that some countries, notably the United Kingdom and the Netherlands, are paying special attention to the implications of screening programmes.

It should also be noted that commercial interests are growing in screening programmes. Industrial companies produce screening methods and a screening infrastructure is developed concerning different screening methods. There are therefore strong forces in favour of more screening in European societies. Commercially-driven screening may in fact be developing too fast, while other preventive interventions may diffuse too slowly. This issue deserves more attention.

A related issue is that of "opportunistic" screening, where the physician carries out a screening test during a patient visit, compared to organised screening programmes, mandated and funded by government. **The Working Group strongly favours organised screening programmes for a number of reasons, including quality assurance and cost-effectiveness of such screening.** The Working Group feels strongly that opportunistic screening should be discouraged, and should certainly not be a method of organising national screening programmes.

The report also demonstrates that, although prevention is a more frequent topic for HTA than earlier, HTA agencies have generally not focused on prevention, with some prominent exceptions, and have dealt very little with health promotion. The lack of assessments dealing with non-health system interventions by INAHTA agencies is striking. Likewise, counselling is an uncommon topic for assessments by agencies.

The number of assessments carried out by government departments and agencies not part of the ministry of health or of the HTA agencies is striking. For example, the transportation ministries of several countries have examined strategies to reduce traffic injuries. Therefore, inter-sectoral co-operation may need more attention.

The Working Group acknowledges the substantial amount of assessment literature in this field, including assessments by HTA agencies. The Swedish Council on Technology Assessment in Health Care, the United Kingdom HTA programme, and various efforts in the Netherlands are examples of the increasing examination of prevention and health promotion in recent years.

The policies toward prevention vary dramatically in the Member States of the European Union. In the case presented in this report, links between assessment and prevention have often been identified, especially in the United Kingdom, the Netherlands, France and Sweden. An overall generalisation is that countries with an established HTA activity, especially one that has had time to mature, have assessed prevention more systematically and have used assessment more consistently in establishing prevention policies.

The activities described in this report give preliminary evidence that it is possible to monitor effectiveness of health systems by examining the implementation of proven interventions. It is surprising that a number of proven interventions have not been implemented in European countries. At the same time, another project has shown the widespread use of unproven preventive interventions, such as screening for prostate cancer and routine use of ultrasound in pregnancy (Banta et al, 2001).

Thus, it seems apparent that many opportunities exist to improve health in Europe through prevention. Why have these not been used more consistently?

Naturally, the Working Group is aware that health systems in Europe are quite diverse, with different histories, cultures and social backgrounds. While almost all of the populations of the Member States that are the object of this study are covered for health care, arrangements for such coverage vary dramatically from countries with an almost totally public national health service to countries with a substantial private sector for payment and largely private provision of health services. Since public health is largely a public responsibility, it is probably true that a largely public system would generally pay more attention to the development of public health and prevention services.

Only a few countries have made prevention an obviously high priority as part of its health services. In Sweden, the United Kingdom, France and the Netherlands, prevention is considered an important part of national health policy (Banta et al, 2001). It can hardly be an accident that

these same countries have actively implemented HTA programmes and policies, and have linked health policy, including policies toward prevention, to HTA.

The field of HTA has shown that it can assess health technologies in a sound and timely fashion. However, as already mentioned, few existing HTA programmes in Europe have made prevention a relatively high priority for its assessments.

Recommendations

To the Steering Committee for consideration for a recommendation from the entire project:

The European Union and the European Commission should encourage HTA in the area of prevention and public health both in the Member States and at the European level. While such a general move is already underway, special attention to prevention and health promotion is both appropriate and important given the competence of the EU in public health in Europe. Links between HTA, evaluation research and prevention could be fostered by numerous means, such as supporting conferences and meetings, fostering education programmes in HTA and evaluation research as an integral part of all public health activities, funding special HTAs in the area of public health and so forth. Given that existing knowledge is not being well-applied, an urgent need is to develop means of assuring the implementation of effective preventive strategies. One possible strategy is intensive networking, with the aim of demonstrating problems and needs and connecting existing evidence to these needs.

Specific recommendations on prevention

1. HTA agencies need to pay more attention to disease prevention and health promotion in their assessment activities. In the opinion of the Working Group, they need to make closer links with government public health research and evaluation units and health education/promotion evaluation publications to increase their knowledge and understanding of the evidence gained through such research. In particular, since screening and other activities addressed to individuals are reasonable well-covered in assessment, they need to consider strategies addressed to the broader community, such as community prevention and action related to health promotion. An example might be speed limits to prevent injuries from vehicle-pedestrian accidents.

2. A complementary method to conventional health indicators could be to define a set of evidence-based interventions and then to establish comparisons between countries basing on the extent to which those interventions are legally covered, implemented, made accessible to the population, utilised and provided with high quality. The interventions assessed here could serve as an example for such indicators.

3. HTA agencies also need to broaden the scope of the assessments. Side effects, intended effects (both positive and negative) of prevention tend to be ignored or minimised in assessments of prevention. Cost and cost-effectiveness considerations are seldom covered in formal HTAs of prevention technologies, and when they are, the methods used and data presented are often of poor quality. This is particularly important given that many efficacious strategies may not be

feasible from a cost or cost-effectiveness point of view. Likewise, ethical and social implications are seldom discussed in any depth. This is also clearly important, especially from the standpoint of equity and access by different groups in society.

4. While a considerable amount of assessment in the area of prevention has been carried out, far more could be done. Furthermore, HTA agencies could help assure that health promotion is also assessed. The potential for such activities has not been fully realised in most (if not all) European countries. Countries need to foster such assessment activities and assure linkages between health policy and assessment so that preventive interventions are fully implemented in accord with the evidence showing their value (or apparent lack of value). Furthermore, implementation deserves special attention in this field, since lip service and formal statements without real action seem common in European countries.

5. The European Commission could help this effort in a number of ways, including fostering HTA programmes and activities, publicising the results of HTA and evaluation research (particularly in the field of prevention and health promotion) and by encouraging links between HTA, evaluation research and policies towards prevention. Funding comparative studies of policies and their implementation and effects in European studies could be a particularly useful activity.

Definitions

Public Health is the art and science of preventing disease, prolonging life and promoting health through organised community efforts. It is made up of systematic efforts to identify health needs and to organise comprehensive health services with a well-defined population base.

Public health policy usually refers to specific actions taken by governments, at national, regional, or local levels, to improve the health of populations groups. Public health policy may be defined in laws and regulations, but also includes other actions, such as decisions on what health care has to pay for or encouraging media information concerning health and disease.

Prevention is made up of actions aimed at averting the establishment or development of a health problem. This includes interventions undertaken by health care providers, but also includes other measures, such as promoting seat belts or anti-smoking campaigns in the mass media. In a broad sense, it includes all measures that promote health or limit the progression of disease at any stage of its course.

It is usual to speak of “primary prevention”, “secondary prevention” and “tertiary prevention”.

Primary preventive services intended to prevent or delay the onset of disease. Mass vaccine programmes or laws requiring seat belts when driving are examples.

Secondary preventive services efforts to detect disease or condition before it is clinically recognisable to avoid or delay further progression. Examples include screening for cancer or hypertension.

Screening is the application of a test to detect a potential disease or condition in a person who has no known signs or symptoms of that disease or condition.

Tertiary preventive services attempts to reduce the impact of already existing disease on the quality of a person's life by maintaining or improving his or her ability to function. Examples include specialist treatment of severe heart disease or physical and mental rehabilitation.

Health promotion is actions aimed at promoting the conditions for well being, including health education, health protection and the prevention of disease and ill health. One important part of health promotion is counselling and health education.

Health education includes providing health information to individuals and groups, aiming to facilitate or enable behavioural change. In a broader sense, health education is aimed at an inculcation of a sense of responsibility for one's own health and a shared sense of responsibility for avoiding injury to the health of others.

NOTE: Sources consulted in developing these definitions included the following:

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Andalusia (Spain): Eduardo Briones, Andalusian Agency for Health Technology Assessments, AETSA.

Austria: Claudia Wild, HTA-unit of the Institute of Technology Assessment, ITA.

The Basque Country (Spain): José Asua, Basque Office for Health Technology Assessment, OSTEBA

Belgium: Katrien Kesteloot, University Hospital of Leuven

Catalonia (Spain): Emília Sanchez, Catalan Agency for Health Technology Assessment, CAHTA

Denmark: Helga Sigmund and Olaf Corry, Danish Centre for Evaluation and Health Technology Assessment, DACEHTA

Finland: Risto Roine, Finnish Office for Health Care Technology Assessment, FinOHTA

France: James Goldberg, l'Agence Nationale d'Accréditation et d'Evaluation en Santé, ANAES

Galicia (Spain): Maria Luisa López García, Galician Agency for Health Technology Assessment, AVALIA-T

Germany: Hans-Peter Dauben, German Agency for HTA at the German Institute for Medical Documentation and Information, DAHTA@DIMDI

Greece: Evridiki Hatziandreu and Athanasios Lopatatzidis, Social Security Institute, IKA

Insalud (Spain): José Martín-Moreno, Spanish Agency for Health Technology Assessment, AETS

Ireland: Charlie Hardy, Department of Health and Children

Italy: Carlo Favaretti, Health Care Service Trust, Trento

Luxembourg: Gerard Holbach, Ministry of Health

The Netherlands: Menno van Leeuwen, Health Council of the Netherlands

Norway: Olav Helge Førde, Institute of Health Research University of Tromsø

Portugal: José Pereira Miguel, Institute of Preventive Medicine, University of Lisbon

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The United Kingdom: Muir Gray, National Screening Committee, Institute of Health Science, University of Oxford

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Appendixes

1. Prevention Survey
2. HTA Database report
3. Members of the Working Group

Appendix 1

Dear

We are writing you on behalf of the European Collaboration for Health Intervention Assessment (the ECHTA project), supported by the European Commission. As a member of the Steering Committee for ECHTA, you are our entry contact for your particular country.

As you are aware, ECHTA is examining a number of areas related to coordination of health technology assessment (HTA) in the European Union. One of the subjects for ECHTA is the consideration of HTA and policy-making toward prevention and screening in the EU countries (Working Group 1). Our aim is to examine the links between HTA and policy-making in this field through selected cases. In the survey to follow you will find the cases of prevention and screening selected by the ECHTA Working Group on Prevention.

Our request is that you complete the survey on each of the cases. We realize that you will probably not have all the information necessary to complete the survey. What we ask you to do is to coordinate a collection of information. Perhaps some parts of the survey, or all of it, will need to be sent to one or more experts in your own country. We will not try to define how you will carry out this task. We only ask that you try to assure that the information is as accurate as possible.

We need this information within about two months. Please return the survey forms completed to Mats Halldin at SBU, P.O. Box 5650, S-11486 Stockholm or by e-mail to Halldin@sbu.se

We will follow up with you to see when you are able to send the information. Please let us know if you need any sort of assistance in completing the survey. We look forward to working with you on this important subject.

Thank you.

David Banta, M.D., M.P.H.
Chairman, Prevention Working Group

Mats Halldin, M.D.
Coordinator, Prevention Working Group

Egon Jonsson, Ph.D.
Director, ECHTA

Genetic Aberrations and Congenital Malformations

The basic method of preventing genetic aberrations and congenital malformations is screening of the fetus in utero or of the child shortly after birth. The screening allows informed parental choice between elective abortion in the case of in utero screening or optimal care of the child after birth in both cases. Conditions screened for include Down syndrome, neural tube defects, hemoglobinopathies, cystic fibrosis, phenylketonuria and congenital hypothyroidism. In addition, provision of folic acid for pregnant woman prevents some cases of neural tube defects. Such interventions certainly can reduce the burden of some genetic and congenital problems in society and also improve therapy in other cases.

1. Have there been any technology assessments of screening for genetic aberrations and congenital malformations done in your country by government or government-appointed bodies? By others? Assessments of folic acid supplementation?

__Yes
__No

If yes, please give details (sponsor, name of the report, publisher, availability, etc).

2. If any assessment has been done, is there an indication that it has been used for policy-making purposes?

__Yes
__No

Please give details.

3. Is there a formal, national policy toward reducing the burden of genetic aberrations and congenital malformations in your country?

__Yes
__No

If yes, what type of policy action has been taken?

__National law
__Formal regulation
__Statements in official health policy document(s)
__Formal payment decisions
__Policy positions by professional organizations and groups

Please give details.

Genetic Aberrations and Congenital Malformations

4. What is the extent of actual use of screening for genetic aberrations and congenital malformations in your country?*

__Above 50% __Below 50%

Please give any figures that are available on this subject (attaching copies of tables or other materials is quite satisfactory). Other comments, such as “very low”, are also very acceptable.

5. If there is any report on this subject in your country such as a national evaluation of a screening program, please send a copy, if possible. If not possible, please summarize the results briefly.

*Above 50% refers to the extent of screening, depending on recommendations of international and local groups.

Screening and Treatment of Hypertension

Intensive programmes to identify hypertension and assure its effective treatment clearly reduce mortality from cardiovascular problems such as coronary artery disease (heart attacks) and stroke. Early treatment of hypertension by such measures as weight reduction may be effective. Drug therapy is generally quite successful in controlling high blood pressure.

1. Have there been any technology assessments of screening and treatment of hypertension done in your country by government or government-appointed bodies? By others?

__Yes
__No

If yes, please give details (sponsor, name of the report, publisher, availability, etc).

2. If any assessment has been done, is there an indication that it has been used for policy-making purposes?

__Yes
__No

Please give details.

3. Is there a formal, national policy toward hypertension screening and treatment in your country?

__Yes
__No

If yes, what type of policy action has been taken?

__National law
__Formal regulation
__Statements in official health policy document(s)
__Formal payment decisions
__Policy positions by professional organizations and groups

Please give details.

Screening and Treatment of Hypertension

4. What is the extent of actual use of hypertension screening in your country?*

__Above 50% __Below 50%

Please give any figures that are available on this subject (attaching copies of tables or other materials is quite satisfactory). Other comments, such as “very low”, are also very acceptable.

5. If there is any report on this subject in your country such as a national evaluation of a screening program, please send a copy, if possible. If not possible, please summarize the results briefly.

*Above 50% refers to the extent of screening, depending on recommendations of international and local groups.

Reducing Cigarette Smoking

Reducing cigarette smoking contributes to lowered mortality and morbidity from a number of conditions. Many measures can reduce cigarette smoking, including: raising cigarette prices; controlling cigarette advertising; national media campaigns; restricting access to cigarettes, especially for minors; community intervention programs; workplace programs; individual counseling; health provider advice and provision of nicotine replacement therapy.

1. Have there been any technology assessments concerning reducing cigarette smoking done in your country by government or government-appointed bodies? By others?

__Yes
__No

If yes, please give details (sponsor, name of the report, publisher, availability, etc).

2. If any assessment has been done, is there an indication that it has been used for policy-making purposes?

__Yes
__No

Please give details.

3. Is there a formal, national policy toward reducing cigarette smoking in your country?

__Yes
__No

If yes, what kind of policy action has been taken?

__National law
__Formal regulation
__Statements in official health policy document(s)
__Formal payment decisions
__Policy positions by professional organizations and groups

Please give details.

Reducing Cigarette Smoking

4. What is the extent of use of cigarettes among adults in your country?

__Above 50% __Below 50%

Please give any figures that are available on this subject (attaching copies of tables or other materials is quite satisfactory). Other comments, such as “very low”, are also very acceptable. Please indicate if the figures have changes in recent years.

5. If there is any report on this subject in your country such as a national evaluation of a screening program, please send a copy, if possible. If not possible, please summarize the results briefly.

Counseling and Sexual Behavior

Sexual behavior is related to the acquiring of sexually transmitted diseases, including HIV/AIDS, gonorrhea and chlamydia. Counseling has been shown to influence behavior and can reduce infection rates. Counseling of adolescents has not been shown to be associated with much behavior change, however.

1. Have there been any technology assessments of counseling and sexual behavior done in your country by government or government-appointed bodies? By others?

__Yes
__No

If yes, please give details (sponsor, name of the report, publisher, availability, etc).

2. If any assessment has been done, is there an indication that it has been used for policy-making purposes?

__Yes
__No

Please give details.

3. Is there a formal, national policy toward counseling on sexual behavior in your country?

__Yes
__No

If yes, what type of policy action has been taken?

__National law
__Formal regulation
__Statements in official health policy document(s)
__Formal payment decisions
__Policy positions by professional organizations and groups

Please give details.

Counseling and Sexual Behavior

4. What is the extent of counseling concerning sexual behavior among at risk groups in your country?*

__Above 50% __Below 50%

Please give any figures that are available on this subject (attaching copies of tables or other materials is quite satisfactory). Other comments, such as “very low”, are also very acceptable.

5. If there is any report on this subject in your country such as a national evaluation of a screening program, please send a copy, if possible. If not possible, please summarize the results briefly.

*Above 50% refers to the extent of counseling, depending on recommendations of international and local groups.

Pap Smear Screening for Cervical Cancer

Pap smear testing is an accepted screening method for identifying early cervical cancer. It has been assessed in many countries and shown to contribute to early identification and treatment of cervical cancer. Death rates from cervical cancer have been shown to drop dramatically with effective implementation of such screening.

1. Have there been any technology assessments of cervical cancer screening done in your country by government or government-appointed bodies? By others?

__ Yes
__ No

If yes, please give details (sponsor, name of the report, publisher, availability, etc).

2. If any assessment has been done, is there an indication that it has been used for policy-making purposes?

__Yes
__No

Please give details.

3. Is there a formal, national policy toward Pap smear screening in your country?

__Yes
__No

If yes, what type of policy action has been taken?

__National law
__Formal regulation
__Statements in official health policy document(s)
__Formal payment decisions
__Policy positions by professional organizations and groups

Please give details.

Pap Smear Screening for Cervical Cancer

4. What is the extent of actual use of Pap smear testing in your country?*

__Above 50% __Below 50%

Please give any figures that are available on this subject (attaching copies of tables or other materials is quite satisfactory). Other comments, such as “very low”, are also very acceptable.

5. If there is any report on this subject in your country such as a national evaluation of a screening program, please send a copy, if possible. If not possible, please summarize the results briefly.

*Above 50% refers to the extent of screening, depending on recommendations of international and local groups.

Colorectal Cancer Screening and Early Treatment

Colorectal cancer screening using fecal occult blood tests followed by identification and removal of lesions can reduce mortality from colorectal cancer. Annual screening is more effective than biennial screening. Cancer screening attendance increases with interventions targeting either the physician or the patient.

1. Have there been any technology assessments of colorectal cancer screening done in your country by government or government-appointed bodies? By others?

__Yes
__No

If yes, please give details (sponsor, name of the report, publisher, availability, etc).

2. If any assessment has been done, is there an indication that it has been used for policy-making purposes?

__Yes
__No

Please give details.

3. Is there a formal, national policy toward colorectal cancer screening in your country?

__Yes
__No

If yes, what type of policy action has been taken?

__National law
__Formal regulation
__Statements in official health policy document(s)
__Formal payment decisions
__Policy positions by professional organizations and groups

Please give details.

Colorectal Cancer Screening and Early Treatment

4. What is the extent of actual use of colorectal cancer screening in your country?*

__Above 50% __Below 50%

Please give any figures that are available on this subject (attaching copies of tables or other materials is quite satisfactory). Other comments, such as “very low”, are also very acceptable.

5. If there is any report on this subject in your country such as a national evaluation of a screening program, please send a copy, if possible. If not possible, please summarize the results briefly.

*Above 50% refers to the extent of screening, depending on recommendations of international and local groups.

Preventing Traffic Injuries

A wide variety of actions can reduce accidents and injuries from accidents. Effective actions include: traffic schemes, such as "traffic calming"; guard rails and crash cushions; wearing seat belts; child car seat restraints; random screening of drivers for drinking and remedial interventions with drunk-driving offenders; and well-trained and equipped medical emergency facilities.

1. Have there been any technology assessments of the prevention of traffic injuries done in your country by government or government-appointed bodies? By others?

__Yes
__No

If yes, please give details (sponsor, name of the report, publisher, availability, etc).

2. If any assessment has been done, is there an indication that it has been used for policy-making purposes?

__Yes
__No

Please give details.

3. Is there a formal, national policy toward prevention of traffic injuries in your country?

__Yes
__No

If yes, what type of policy action has been taken?

__National law
__Formal regulation
__Statements in official health policy document(s)
__Formal payment decisions
__Policy positions by professional organizations and groups

Please give details.

Preventing Traffic Injuries

4. Please give any figures that are available on the subject of preventing traffic injuries (attaching copies of tables or other materials is quite satisfactory). Other comments, such as “very low activity”, are also very acceptable.

5. If there is any report on this subject in your country such as a national evaluation of prevention efforts, please send a copy, if possible. If not possible, please summarize the results briefly.

Detection of Excessive Drinkers

Excessive drinking is associated with a wide variety of health conditions including various cancers (mouth, larynx, esophagus and others) and with accidents. Brief interventions in primary care, including assessment of alcohol intake and provision of information and advice, may be used to reduce alcohol consumption in those with consumption levels above recommended levels. Remedial interventions with drink-driving offenders can reduce recidivism and subsequent alcohol-related crashes. Random screening for drinking can substantially reduce crash fatalities and injuries.

1. Have there been any technology assessments of effectiveness of detecting excessive drinkers done in your country by government or government-appointed bodies? By others?

__Yes
__No

If yes, please give details (sponsor, name of the report, publisher, availability, etc).

2. If any assessment has been done, is there an indication that it has been used for policy-making purposes?

__Yes
__No

Please give details.

3. Is there a formal, national policy toward detection of excessive drinkers in your country?

__Yes
__No

If yes, what type of policy action has been taken?

__National law
__Formal regulation
__Statements in official health policy document(s)
__Formal payment decisions
__Policy positions by professional organizations and groups

Please give details.

Detection of Excessive Drinkers

4. What is the extent of attempts to identify excessive drinkers in your country?*

__Moderate to High __ Low

Please give any figures that are available on this subject (attaching copies of tables or other materials is quite satisfactory). Other comments, such as “very low”, are also very acceptable.

5. If there is any report on this subject in your country such as a national evaluation of a screening program, please send a copy, if possible. If not possible, please summarize the results briefly.

*Above 50% refers to the extent of screening, depending on recommendations of international and local groups.

INAHTA Reports

Selection of search words (hits – projects – hits included in the report)

1. "Behavior" (12 – 2 – 0)
2. "Behaviour" (17 – 0 – 0)
3. "Campaign" (1 – 0 – 0)
4. "Counseling" (11 – 1 – 3)
5. "Counselling" (22 – 3 – 0)
6. "Health Behavior" (0)
7. "Health Behaviour" (1 – 0 – 0)
8. "Health Campaign" (0)
9. "Health Information" (5 – 1 – 0)
10. "Health Promotion Disease Prevention" (0)
11. "Health Promotion" OR "Disease Prevention" (16 – 1 – 14)
12. "Health Protection" (0)
13. "Immunisation" (0)
14. "Immunization" (11 – 3 – 6)
15. "Medical Care" (12 – 0 – 2)
16. "Prevention" (193 – 24 – 53)
17. "Preventive Program" (0)
18. "Preventive Programme" (0)
19. "Promotion" (21 – 2 – 2)
20. "Promotional Item" (0)
21. "Promotion of Health" (1 – 0 – 0)
22. "Screening" (161 – 41 – 75)
23. "Wellness" (1 – 0 – 0)
24. "Wellness Program" (0)
25. "Wellness Programme" (0)
26. "Wellness" AND "Program" (0)
27. "Wellness" AND "Programme" (0)
28. "Wellness" OR "Program" (200 – 78 – 0)
29. "Wellness" OR "Programme" (68 – 3 – 1)

Total number of hits: 753

Overlaps: 182
Excluded: 256
Projects: 159

Included: 156

Footnote: In June 2001 the HTA Database consisted of 2139 INAHTA articles – 1388 completed reports and 751 projects. The database is updated every six months.

INAHTA report examination

Summary (156 reports in total)

Abstract available from the HTA Database: 111
Only record with basic information available: 45

Study design information from the HTA Database:

- Consensus statement: 4
- "Cost-effectiveness analysis": 1
- "Cross-sectional study design": 1
- "Evaluation": 1
- Expert panel: 4
- "Literature review": 1
- "Non-systematic review": 4
- Overview: 4
- Primary research/RCT: 6
- "Review": 25
- "Spreadsheet model": 1
- Systematic review: 70
- No design information*: 34

Interventions (not always indicated):

- Diagnosis: 5
- Diagnosis, prevention and treatment: 2
- Diagnosis, screening and treatment: 1
- Drug therapy: 1
- Education: 1
- Genetic testing: 1
- Health Education: 2
- Health Promotion: 4
- Immunization: 1
- Mental Health Promotion: 3
- Prevention: 11
- Screening: 53
- Treatment: 4
- Treatment and prevention: 2
- Vaccination: 2

Electronic summary in English: 105
No electronic summary in English: 10
No information (found): 41

Full text electronic report in English: 65
No full text electronic report in English: 75
No information (found): 16

Full text electronic report access: 65 free of charge (website/pdf-file)
Hypertext-linked: 49

Only printed English full text reports: 33

Summary of languages of full text reports (exclusively, or in English as well): Catalan (7 reports), Danish (4), Dutch (18), Finnish (2), French (19), German (3), Norwegian (1), Spanish (17), Swedish (8).

Study design information by:

Title: 42
INAHTA abstract: 57
Abstract: 17
Full text report: 6
No design information*: 34

Included by:

Title: 128
INAHTA abstract: 25
Abstract: 2
Full text report: 1

Remarks (*):

"No design information", means that the study design was neither clearly stated in the title, the record/abstract of the HTA Database, or the executive summary of the report, nor explicit in the full text report.

Total: 156

Appendix 3

Working Group 1

Chair
Professor David Banta
ECHTA/ECAHI Project, Paris, France

Vice-Chair
Dr. Evridiki Hatziandreu
Deputy Governor, Social Security Institute (IKA), Greece

Members

Dr. Hans-Peter Dauben
German Agency for HTA at the German Institute for Medical Documentation and Information, DAHTA@DIMDI, Germany

Professor Olav Helge Førde
Institute of Health Research University of Tromsø, Norway

Dr. Marlène Laeubli Loud
Swiss Federal Office of Public Health, SFOPH, Health Policy Division Research and Education, Switzerland

Dr. Sven-Olof Isacsson
Department of Community Medicine, Malmö University Hospital, Sweden

Professor Fred Paccaud
University of Lausanne Institute of Social and Preventive Medicine, IUMPS, Switzerland

Dr. Emília Sanchez
Catalan Agency for Health Technology Assessment, CAHTA, Spain

Dr. Therèse Stutz Steiger
Swiss Federal Office of Public Health, SFOPH, Health Policy Division Research and Education, Switzerland

Coordinator
Dr. Mats Halldin
The Swedish Council on Technology Assessment in Health Care, SBU, Sweden

Footnote: The members from Norway and Switzerland participated on self-pay basis.

Working Group 2
Clearing House Function and Emerging Technologies

To develop systems for routine exchange of information between programmes on:
Emerging technology issues, Priorities for future evaluations, and
Conduct and timing of ongoing evaluations including findings from evaluations

Working Group Members

Kerstin Hagenfeldt (Co-Chair)
José Asua (Co-Chair)
Sergio Bellucci
Malene Fabricius Jensen
Wilf Higgins
Alessandro Liberati
Berit Mørland
Wija Oortwijn
Rachid Salmi
Andrew Stevens
Gabriel HM ten Velden

Executive Summary

Introduction

There is a need for – and benefits could be derived from –international collaboration and sharing experiences in the field of health technology assessment (HTA). All member states are faced with increasingly difficult choices and priorities. For example, only a fraction of existing health technology has been formally evaluated, and many new technologies appear every year. Resources for HTA are, however, limited so that priorities for HTA have to be set, whether explicitly or implicitly. The aim should be to identify those assessments that offer the greatest benefits in relation to their costs, and thus maximise the benefit derived from investments in HTA.

HTAs are based on evidence from many different sources of information. To avoid duplication of HTA activities, the first step is usually to search for information on HTA results and ongoing and planned HTA projects. Therefore, it is important for agencies to stay up-to-date with the information in the field.

Objectives

The objectives of Working Group 2 were:

1. To encourage the further development of the existing network for emerging technology issues (the work of EuroScan);
2. To share information on methods and results on priority setting activities;
3. To consider how to improve the sharing of information on ongoing HTAs and the results of HTAs;
4. To oversee the development and improvement of clearinghouse activities in all these areas;
5. To help assure that all HTA programs benefit from the clearinghouse activities; and
6. To help assure that the results of HTA are recognised as relevant and useable for health policy making and health care practice.

The final two objectives (5 and 6) were the responsibilities of other working groups of the ECHTA project, so they will not be included in this part of the report. Furthermore, with regard to objective 1, EuroScan (European Information Network on New and Changing Health Technologies) is reported separately as the EuroScan Report. Thus this summary focuses only on objectives 2, 3 and 4.

Methods

Working Group 2 contracted two experts for commissioning research regarding Objective 2 on priority setting (Wija Oortwijn, PhD, University of Nijmegen, The Netherlands) and Objective 3 on sharing of information on HTA activities (Malene Fabricius, Information Specialist, DACEHTA, Denmark). Both experts included recommendations for clearinghouse functions

of priority setting for HTA and exchange of information on HTA activities (Objective 4) in their reports. The full reports describing the results of the work commissioned follow this summary.

The methods used to address Objective 2 on priority setting for HTA in Europe" were: a) an inventory of existing and possible new methods for priority setting for HTA through a Medline search for the years 1992–2001; b) a survey sent to 35 HTA agencies in 17 European countries followed by an in-depth telephone interview with 5 of the survey respondents.

The methods used to address Objective 3 on the exchange of information on HTA activities were: a) a literature study searching the following databases: The HTA Database, the ISTAHC database, Medline, HealthStar, the Cochrane Library and Embase; b) a survey sent to 35 HTA agencies in 17 European countries followed by a second survey sent to 8 users of HTA in 7 European countries.

Results and conclusions

The main results and conclusions addressing Objective 2 on priority setting for HTA are:

- The recommendations of EUR-ASSESS are used by the agencies.
- There is an increasing interest in priority setting for HTA, but no additional new theoretical models have been published since the EUR-ASSESS report on priority setting. Some new developments on techniques for determining the ranking of priorities are available.
- There is an increased use of priority setting procedures. Unfortunately, formal use of these procedures remains limited, and in general the procedures are mainly implicit and not very transparent.
- Social and ethical considerations are often not taken into account when setting priorities, and involvement of the public remains limited and must be improved.
- Due to the various contexts in which HTAs are undertaken, no single procedure for priority setting can be recommended.
- Added value can be achieved by comparative research among countries and by bringing together a wide variety of different national methodological approaches. The possibility to exchange experiences with different actors involved in priority setting for HTA is of main importance to improve the (cost-) effectiveness of the health care system.

The main results and conclusions addressing Objective 3 on exchange of information on HTA activities are:

- Information about already completed and ongoing HTA projects can improve the HTA process by means of a quicker production period – not least when the HTA deals with a new or emerging health technology.
- At present, there is wide variation in existing databases –in coverage, structure of information, indexing, search options and frequency of updating.
- Of the databases studied, the HTA Database (formerly the INAHTA database) is considered to be the most valuable information source for obtaining information on

HTA results and ongoing HTA activities. This database could be improved regarding structure of information, information on study design, frequency of updating and updating discipline of agencies.

- It is better to improve the existing database (the HTA Database) than to create a new one.
- Sixty percent of the agencies provide information to the HTA Database.
- Closer and more formal co-operation between the doers of HTA is necessary to assure that the information on HTA activities is collected, structured and distributed in the best possible, systematic way.
- Added value can be achieved by discussing and exchanging information on different methodologies used when developing HTA projects. In addition, closer co-operation between the different databases can help increasing the knowledge of HTA activities among health care actors in Europe.

Recommendations on clearinghouse activities

The function of a clearinghouse concerning priority setting for HTA should include:

- Identifying actors on different levels (European, national, regional or local) with an interest in HTA and priority setting.
- Provide (potential) users of priority setting procedures with examples of possible purposes for which priority setting for HTA could be used.
- Collect information about the purpose of the actors with an interest in priority setting.
- Develop an overview of descriptions of existing procedures. From these procedures, contact information of initiators should be provided to get more information or guidance, and a summary of the key elements should also be provided.
- Provide overviews of priorities of different actors (results of priority setting procedures: European and national policy concerns and results of HTA programmes).
- Develop a service (framework) to help those who wish to develop a priority setting procedure for HTA (minimum or desirable standards for priority setting procedure) focusing on: a) the involvement of policy makers and researchers, b) the involvement of the public/ consumers, c) formal criteria, d) use of evidence and e) improving general approaches.

The function of a clearinghouse related to the exchange of information on ongoing HTA projects and HTA results should include:

- Collect and distribute information on HTA methods, processes and results.
- Participate in organising future developments of the HTA Database. Close collaboration with existing HTA networks (e.g. INAHTA) is necessary and important.
- Assist the agencies in developing standards for structuring the descriptions of ongoing HTA projects and results. This includes standardised abstracts, keywords and information on methodology.
- Develop methods for facilitating the collection of information on HTA activities from European HTA agencies.

- Distribute information on HTA activities in accordance with the needs of different actors in the field of HTA.
- Initiate collaboration with existing organisations and networks including HTA programs and agencies in Europe who are currently non-members of INAHTA.
- Initiate further co-operation between existing databases and other information sources.

The function of a clearinghouse with regard to new or emerging technologies (EuroScan activities) should consider the following:

At present, the access to the information in the EuroScan database is limited only to the members of this network: nine European HTA agencies and one Canadian HTA agency. It is of uttermost importance for the future of European HTA work, especially with regard to an early warning system, that steps are undertaken to include these EuroScan activities in a European clearinghouse function for HTA. Other existing networks, with a connection to non-EU countries (such as INAHTA), should also be closely linked to the clearinghouse.

Priority Setting for HTA (Objective 2)

W.J. Oortwijn, PhD.

Introduction

There is a need for – and benefits could be derived from – international collaboration and sharing experiences in the field of health technology assessment (HTA). All member states are faced with increasingly difficult choices and priorities. For example, only a fraction of existing health technology has been formally evaluated, and many new technologies appear every year. Resources for HTA are, however, limited so that priorities for HTA have to be set, explicitly or implicitly. The aim of setting priorities for HTA should be to identify those assessments that offer the greatest benefits in relation to their cost, and thus maximise the benefit derived from investments in HTA (Henshall et al, 1997).

Priority setting for HTA focuses on reducing the uncertainty regarding the benefits and cost of applying a technology. The HTA itself can involve primary and/or secondary research. Priority setting requires consideration of the potential outcomes of assessment and also the issues that assessments are likely to address (research questions). This means that priority setting can be used to identifying questions for HTA, as performed by the National Co-ordinating Centre for HTA (NCCHTA) in the United Kingdom. In addition, priority setting can also be used to set research priorities for HTA or to reject projects if financial resources are insufficient.

Commissioning research on the basis of a priority setting procedure is done, e.g., in the United Kingdom, the Netherlands and the Basque country in Spain. Since 1996, the Basque Office for HTA (Osteba) has developed a priority setting procedure based on the model proposed by the Institute of Medicine (IOM). This model uses seven criteria, seven steps, a Delphi process and Nominal Group techniques with multidisciplinary teams. The priority setting procedure of Osteba focus on the most appropriate choice of issues to be assessed within Osteba and on topics for commissioning research.

Priority setting for HTA can indicate a substantial uncertainty or lack of data necessary to make decisions. Policy makers and health professionals are the most important users of HTA results (Jacob and McGregor, 1997). For example, policy makers and health professionals may decide not to stimulate diffusion of a new technology when an assessment is identified as a high priority due to considerable uncertainty. The results of HTA are of importance to the policy maker mainly as a means of allocating scarce resources and controlling health care expenditures. Priority setting for HTA could also be used to stimulate the introduction of appropriate health technologies or to abandon ineffective health technologies. These purposes aim to make judgements about the importance of health technologies for the health service.

Priority setting is of interest of payers of health care services because they want to finance cost-effective care for the population. In Belgium, priority setting for HTA has been used for selection and financing of prevention (screening) programs (e.g. diabetes and mammography) by insurance organisations. With regard to implementation, experience from several countries suggests that policy makers are more likely to take an interest in, and act upon the findings of HTAs if they have been involved in discussions about which health technologies should be assessed (Henshall et al, 1997). The involvement of policy makers can create a climate to design the assessment in such a way that the results provide enough information for answering a policy-oriented question. In the Netherlands priority setting for HTA has been used to commission HTAs which will provide information about whether a health technology should be reimbursed as a provision of the benefit package. Thus, highest priority might be given to assessments of health technologies creating new and possibly avoidable cost pressures in the health care system. Last, but not least, priority setting for HTA is of interest to patient and consumers. Patient and consumers want the highest quality of care for the individual patient. All stated purposes of priority setting for HTA address the problems of ineffective and cost-ineffective health care, and therefore impact on the health care system has a whole. Identifying the assessments that offer the greatest benefits in relation to their cost will ultimately improve the (cost-) effectiveness of the health care system. An example of the influence of priority setting for HTA on the health care system is shown in Box 1.

Box 1. Antibiotic prescription in primary care in the Basque country

Identification:
The issue of antibiotic prescription in primary care was one of the 104 topics proposed by clinicians and policy makers following an open call for topics to be prioritised by the Basque Office for Health Technology Assessment (Osteba) in 1996 (Rico & Asua, 1996).

Classification:
Using a modified Delphi method with a multidisciplinary panel of 67 members, the topics were classified according to their relevance, using average scores on a 1 to 10 scale. After an "in and out" system the topic of antibiotic prescription was placed on the 8th place on a list of the 12 most relevant topics.

Prioritisation:
A discussion panel of ten experts ranked the 12 best-classified topics, using the Nominal Group technique. Seven explicit criteria (previously weighted) were used and priority scores were calculated for each topic. After prioritisation, the topic of antibiotic prescription was listed as 2nd. The most relevant issue was health care of terminally ill.

Commissioned research:
After a call for commissioning research in July 1997, a team of pharmacists, general practitioners, one microbiologist and epidemiologist, performed the HTA regarding antibiotic prescription in primary care and produced a draft report which was submitted for peer review in 1999.

Products:
In July 2000 the report "Appraisal of the variability and suitability of prescribing antimicrobials in primary health care in the Basque country" was published (Rotaeche et al, 2000).

Dissemination:
In total, 1120 issues of the final report were sent to policy makers, libraries of health centres, research and epidemiological units, quality improvement units, primary care co-ordinators, primary care pharmacists, and health centres.

Impact:
A number of relevant activities have been developed on different levels of the Basque health care system, to improve the prescription of antibiotics in primary care:

– Policy makers decided to stimulate interventions for appropriate prescription of antibiotics
– Workshops were held with primary care pharmaceutics and clinicians
– Several health centres' co-ordinators produced leaflets for general practitioners

An impact assessment study measuring changes in the prescription of antibiotics will be made after 2 years of the implementation of the described activities.

There is also evidence of ineffectiveness in how health systems operate within their local frameworks and priorities. Resources should be used for effective interventions in the context of national or local priorities. According to World Health Organisation (WHO) determining priorities for a health system depends on several different criteria (technical, ethical and political) and is subject to modification due to different aspects such as experience in implementation and the reaction of the public (WHO, 2000).

To avoid unnecessary and wasteful duplication of work in priority setting between member states and regions, it is important that there is co-operation among the organisations doing the work. Some important international HTA activities have been initiated in recent decades, e.g. the International Society of Technology Assessment in Health Care (ISTAHC), the International Network of Agencies for Health Technology Assessment (INAHTA), and the EUR-ASSESS project (Banta, 1997) and HTA-Europe project (Banta & Oortwijn, 2000). In the EUR-ASSESS project (1994–1997) the subject of priority setting for HTA was studied. An analysis of the process of setting priorities is given in the report on priority setting, and the report offers some practical guidance to help those wishing to set priorities for HTA to develop a system suited to their particular needs and circumstances (Henshall et al, 1997). The subject of priority setting for HTA is further elaborated in Working Group 2 "Developing systems for the routine exchange of information between programs" of the ECHTA project. The duration of the actual work of Working Group 2 is 16 months, which started on March 1, 2000. The members of Working Group 2 are listed in Appendix 1. This report describes the results regarding how different agencies are setting priorities for health technology assessment.

Objective, Scope and Methods

Objective and scope

As stated above, one of the objectives of Working Group 2 focuses on priority setting for HTA. The objective is defined as "to share information on methods and results of priority setting activities". These activities are concerned with priorities for HTA and not with priorities for research in general or for health care. Health technology assessment is an important tool in the identification of priorities for health care, but this report is not concerned with the identification of priorities for health care.

Currently priority setting is regarded as a separate, but closely related, phase that follows early identification. Early identification is another aspect studied in Working Group 2. The objective focusing on early identification is "to encourage the further development of the existing network for emerging technology issues". The aim of this network, called EuroScan, is to support national agencies and HTA organisations in developing and running systems in early identification of health technologies to provide useful information to health planners and policy makers. The development of early warning systems is part of the EuroScan activities, which are described separately (EuroScan, 2001).

To achieve the objective of the priority setting part of the ECHTA project the following aspects were studied: the present state of priority setting activities regarding HTA in Europe, the usefulness of the different priority setting procedures and the use and usefulness of the EUR-ASSESS report concerning priority setting published by Henshall et al in 1997.

Methods

The workplan focusing on priority setting, which was discussed and approved by the Working Group, contains the following activities:

1. Description of the present state of priority setting for HTA in Europe. For this purpose the literature on priority setting in HTA was reviewed during the whole project. The literature search was based on a MEDLINE search of the years 1992–2001 using societal criteria, priority setting and health technology assessment as key words. The literature between 1984 and 1992 was reviewed in the EUR-ASSESS report on priority setting (Henshall et al, 1997), which was used in this report.

2. Updating a survey done as part of the EUR-ASSESS project in 1995. The survey aimed to retrieve information about the usefulness of the different systems for priority setting and the use and usefulness of the EUR-ASSESS priority setting report. In June 2000 a pilot survey was developed, which was finalised in August 2000 after approval of the Working Group. The survey focused on the guiding principles for setting priorities, responsibility for setting priorities, methods for selecting technologies, criteria for selecting technologies, impact in practice and parties of influence on the priority setting process. The survey contained 11 questions focusing especially on priority setting. These questions were the same (n=5) or based on the questions of

the EUR-ASSESS survey sent in 1995, which contained 8 specific questions regarding priority setting. For example, the organisations were asked to send copies of written descriptions of the methods used for setting priorities. The purpose of the survey was to determine how many organisations are doing formal priority setting for HTA and what methods they are using.

The survey and the results are presented in Appendix 2. In August 2000 the survey was sent to 35 organisations from 17 countries in Europe (all European Union (EU) countries plus Switzerland and Norway). These organisations are the European (EU) respondents of the survey sent as part of the EUR-ASSESS project (Henshall et al, 1997), INAHTA members in Europe and additional agencies of non-EU members (Switzerland and Norway). A list with full names of the organisations is given in Appendix 3. Of these organisations a total number of 23 organisations from 12 countries are a member of INAHTA. A reminder was sent 1 month after the first invitation (August 2000) to those organisations that did not respond. At the end (October 2000) organisations from almost all countries respond (24 out of 35 HTA organisations (69%) from 14 out of 17 countries). The respondents included almost all organisations with a substantive activity in HTA. From the responding agencies 18 organisations (75%) are INAHTA member. Organisations from Ireland, Italy and Portugal (n=3) did not respond. Health technology assessment in these three countries is limited to some studies and analyses, although there is a growing interest in HTA (Banta & Oortwijn, 2000). From the respondents 20 organisations can be described as agencies with a national function, of which 8 are a national HTA agency. The other four respondents were organisations with a regional function (see Table 1, Appendix 2).

Based on the results of this survey a limited number of more in depth personal telephone interviews were planned with some of the respondents of this survey. The interviews provide more insight in the priority setting procedures of the agencies and the usefulness of the EUR-ASSESS report on priority setting. The interview focuses on priority setting for HTA as part of a European clearinghouse, priority setting for HTA on different levels (local, regional, national, European), use and usefulness of the procedure and benefits of the EUR-ASSESS report on priority setting.

The selection criteria for the in-depth interviews were:

1. Division of countries (northern Europe and southern Europe): One of the problems is that from the ‘southern’ European countries (Greece, Italy, Spain and Portugal) only organisations in Spain had implemented priority setting procedures and Italy and Portugal did not respond at all.

2. Long versus short history in HTA (included in the EUR-ASSESS survey versus no/little experience with priority setting).

3. Number of FTE dedicated to priority setting (small (<2 FTE) versus large number (>2 FTE)).

4. Use of explicit versus implicit priority setting procedure.

Regarding the duration of interviews (about 1 hour) we decided to interview 5 organisations (around 15% of the survey sent). Based on the selection criteria the following organisations were contacted:

Basque Office for Health Technology Assessment – Osteba (Spain): long history in HTA, 0.5 FTE, explicit procedure

LCM – Alliance Nationale des Mutualites Chretiennes (Belgium): long history in HTA, 3 FTE, implicit procedure

National Co-ordinating Centre for Health Technology Assessment – NCCHTA (United Kingdom): short history in HTA, 6 FTE, explicit procedure.

Netherlands Organisation for Scientific Research – Council for Medical and Health Research-MW-NWO (the Netherlands): short history in HTA, 3–4 FTE, combination of procedures

Norwegian Centre for Health Technology Assessment – SMM (Norway): short history in HTA, 0.5 FTE, implicit procedure.

The interviews took place in the end of March and the beginning of April 2001. Two persons (from Osteba and MW-NWO) were face-to-face interviewed, and the other three persons were interviewed by telephone. An (anonymous) analysis of the interviews is presented in Appendix 4.

Results

Process of health technology assessment

Health technology assessment is analysis of the implications (for example societal, economic, ethical, legal) of health technology, and is intended to influence decision making (Banta & Luce, 1993). The objective of HTA is to support appropriate use of existing and new health technologies in terms of safety, effectiveness, efficiency, accessibility and equity, providing input to decision making in policy and practice. The ultimate goal is to improve the quality and cost-effectiveness of health care.

The process of HTA is rather complex, consisting of the following interdependent phases:

1. Identification and priority setting: monitoring new and existing health technologies, and selecting those in need of assessment;
2. Testing: conducting the appropriate data collection and analysis;
3. Synthesis: collecting and interpreting existing information and integrating it with the results of the former phase;
4. Dissemination and implementation: providing the synthesised information to the appropriate persons, and translating knowledge into policy and practice.

Identification and prioritisation of health technologies are of main importance for a health system. Health technologies can have desirable and undesirable effects on health services and patients, and

therefore they need to be assessed. Most developed countries struggle to control the steadily growing amount of new, and in many cases expensive health technologies, which are sometimes not effective or cost-effective. In the eighties it was felt that too early an introduction of new technologies might increase health service variations and contribute to ineffectiveness, inefficiency and inequity in health care. To date, only a fraction of existing health technology has been formally evaluated, and many new technologies appear every year. A more rational process of identifying and setting priorities can help to ensure that the maximum benefits in relation to their cost are realised for a health system. The aspects of identification and early warning systems are described in the report of the EuroScan group (EuroScan, 2001). Early warning activities can list suggestions for technologies to be studied within a HTA programme. Because resources to undertake evaluations fall far short to those needed to cover all technologies, priorities have to be set. The present state of setting priorities for HTA in Europe is described in the following section.

Present state of setting priorities for HTA in Europe: theoretical considerations and practical approaches

Priority setting is about making choices, but also about defining alternatives among which choices have to be made. Priority setting for HTA attempts to focus on those assessments, which generate the highest potential benefits given the available resources. Priority setting is therefore an integral part of the HTA process (Oortwijn, 2000).

The aim of setting priorities for HTA is to identify those assessments that offer the greatest benefits in relation to their cost, maximising the benefits derived from investments in HTA. To achieve an optimal allocation of HTA resources it is important that the results of HTAs are based on suitable societal criteria. Although priority setting for HTA is generally acknowledged to be worthwhile, relatively little attention had been paid to the theoretical principles of priority setting for HTA including how to use societal criteria. The question of how to set priorities for HTA was studied in the EUR-ASSESS project, which ran from 1994 until 1997. In the report on priority setting an analysis of the process of setting priorities is given and the report offers some practical guidance to help those wishing to set priorities for HTA to develop a system suited to their particular needs and circumstances (Henshall et al, 1997). A brief overview is given of the theoretical considerations of priority setting for HTA.

Theoretical considerations

Priority setting for HTA in general involves the following elements:

1. Identifying problems of concern or relevance to decision-makers
2. Translating these problems into potential assessments
3. Setting priorities between these assessments
4. Communicating the priorities to those responsible for commissioning and undertaking assessments
5. Monitoring and reviewing the assessments and priorities for assessments.

When organising a priority setting procedure various aspects should be considered. The context in which priorities must be set is important and therefore no uniform procedure for priority setting for HTA can be prescribed. For example, national priority setting procedures may define the relative importance of major research areas, while priority setting within one organisation can focus predominantly on the role of different research programs in line with the aims of the organisation. Often decisions are made without formally considering the published evidence. Furthermore, overriding the priorities or interests of stakeholders may bypass a formal priority setting process. In addition, the nature of the organisation(s) funding the proposed HTA and the reviewers commenting on the feasibility of the project are important.

Another contextual factor is the health care systems in which an organisation operates. The health care system influences the way HTA is organised and implemented in each country. In the European Union countries have different health care systems, which have evolved over time, with different social and cultural preferences. Some countries have an actual public agency for HTA (for example, Sweden, Spain and France). Other countries implemented HTA mainly in relation to payment for health care through insurance companies and sickness funds (for example, Switzerland and the Netherlands (Banta & Oortwijn, 2000). Different health care systems influence the priority setting procedure for HTA regarding the actor who is responsible for, and has interest in, identifying priorities for HTA. The health ministry or other government departments, the health insurance system, health care delivery system, an HTA agency or a combination may be the responsible actor(s) for publicly funded HTA programmes (Henshall et al, 1997; Banta & Oortwijn, 2000). The particular division of responsibilities may influence the priority setting procedure. For example, health care financing organisations could be interested in cost containment, while health care providers are more interested in rapid diffusion of effective new health technologies.

Priority setting procedure

The development of a practical procedure for setting priorities itself involves six steps:

1. Clarifying goals and responsibilities;
2. Choosing a general approach, method, and criteria for prioritisation;
3. Establishing advisory mechanisms and relations with external bodies;
4. Establishing arrangements to support and manage the procedure;
5. Defining a time table and cycle of activity; and
6. Evaluating and developing the procedure.

Variations in procedures

Approaches to priority setting can vary in the extent to which the procedure is explicit and systematic, the extent to which external input and advice is accepted or actively sought, the relative weight given to the views of decision makers and researchers, the extent to which the procedure is transparent, and the effort and resources devoted to the procedure (Henshall et al, 1997).

In the article of Singer et al (2000) six interrelated domains for priority setting for new health technologies (in cancer and cardiac care) were identified. These domains are: the institutions in which the decisions are made, the people who make the decisions, the process of decision making, the factors they consider, the reasons for the decisions, the process of decision making and the appeals mechanism for challenging the decisions. These domains are comparable with the steps of priority setting described above.

From a publication of the Working Group on Priority Setting of the Council on Health Research for Development (COHRED) in Geneva (2000) it can be concluded that no additional theoretical models regarding priority setting for HTA have been published recently. They also stated that past and current processes have been focused on expert-driven research agendas, emphasising scientific quality. This approach can lead to a disproportionate distribution of assessment over different speciality areas. In addition, this approach often does not lead to a reflection of the needs of the health care system (Oortwijn, 2000). The methods for setting priorities still range from qualitative methods such as consensus building to the use of quantitative formulations and prioritisation matrices, with a reference to the EUR-ASSESS report on priority setting. In the cases where a qualitative model was applied, it was often a Delphi model.

However, there are some new developments regarding some elements in the priority setting procedure. In a recent article of Vella et al (2000) the nominal group technique (consensus technique) was considered as a feasible and reliable technique for determining priorities among health professionals (clinicians). The procedure did not lead to a rank order of priorities but a list of suggested topics into three tiers (strong, moderate, weak support). They state that this procedure is more democratic and transparent than the traditional procedures used by research funding bodies, although this might be discussed.

The use of quantitative models and decision analytical approached in determining priorities is also developing. For example, Claxton and Posnett (1996) described a framework for setting priorities for research based on Bayes theorem and economic principles. They conclude that the framework could be of use for setting priorities between research proposals. The disadvantage of the framework is that it only focuses on the concept of efficiency (Oortwijn, 2000). Farrar et al (2000) studied discrete choice modelling in priority setting. This technique can be used for estimating cost per unit of benefit ratios for competing clinical interventions. The aim of the study was focused on the benefit gained from clinical service development, which should reflect the preferences of health professionals in the hospital. This approach to use discrete choice modelling needs further work to address methodological issues. Another approach, which is used to support health decision-making, is multiple-criteria decision making, taking into account the preference of decision-makers. A multiple-criteria decision making approach includes several methods and models that help and guides decision-makers in discovering their most desired solution to the problem. This approach has been successfully applied in the health care field: the approach was used to analyse the process of purchasing health technology in a University hospital in Rio de Janeiro (Nobre et al, 1999).

Variations also exist regarding the criteria used in a priority setting procedure. In most cases the criteria number of patient, (potential) effectiveness and cost of technology are used as the leading criteria. One method to retrieve information about benefits from health care is needs assessment, which depends on a measure of epidemiology and on (cost-)effectiveness of care. The purpose of needs assessment is to gather information about change beneficial to the health of the population (Stevens and Gillam, 1998), which is a long-term exercise. The use of needs assessment in priority setting has been criticised. For example Petrou (1998) stated that prioritising healthcare services on the basis of need could lead to inefficient use of resources.

In addition, the Working Group of the COHRED has identified that the use of composite indicators (such as the QALY – quality adjusted life years and the DALY – disability adjusted life years) has increased throughout the world, also in priority setting for HTA. This is mainly due to the ability of such factors to compare a broad range of diseases and their attractiveness for cost-effectiveness analysis. The use of QALY for decision-making purposes has been discussed. Composite measures such as the QALY include more information than the one-dimensional measures such as life expectancy (all years lived are considered equal regardless of disability) and healthy life expectancy (years lived with disability are disregarded). However, doubts exist whether QALYs and DALYs are an adequate measure of health or burden because both measures value life as a function of health status (Arnesen and Nord, 1999; Mooney and Wiseman, 2000). In addition, Arnesen and Nord (1999) stated that any attempt to summarise information about quality of life and length of life in one figure run into conceptual as well as methodological problems. They propose that the DALY protocol as developed and under revision by the WHO should focus on these problems.

As stated in the EUR-ASSESS report on priority setting it is still safe to conclude that a priority setting approach should reflect some estimates of the benefits and costs of (possible) assessments. The estimates of the benefits should be based on explicit criteria and information about costs should be based on (a combination of qualitative and) quantitative data. The method for determining priorities should be transparent and should be credible for those who asked to use it (Henshall et al, 1997).

Practical approaches in European countries described in the literature

The results of the EUR-ASSESS subgroup on priority setting showed that only four publications describe a procedure for priority setting for HTA (Henshall et al, 1997). Of these procedures, only the procedure described by Donaldson and Sox (1992), the so-called IOM (Institute of Medicine) model, has partly been used in the prioritisation procedure of the Basque Office for Health Technology Assessment (Osteba) (Henshall et al, 1997; Rico & Asua, 1996). In addition, the Catalan Agency for Health Technology Assessment and Research (CAHTA) used an adapted version of the IOM model in their priority setting procedure of 2000 (CAHTA, 2000; Aymerich 2001). In the EUR-ASSESS report on priority setting four procedures were described: a labour intensive, consultative system of the NHS Health Technology Assessment Programme (United Kingdom), the application of the IOM model in the Basque Office for Health Technology Assessment (Osteba, Spain) and two examples of a pragmatic procedure (Catalan Agency for

Health Technology Assessment (now Catalan Agency for Health Technology Assessment and Research, Spain), and Health Insurance Council (now Health Care Insurance Board, the Netherlands). These, and other new initiated, experiences could be of use to other organisations that wish to set priorities. Although there is some experience with priority setting, it appeared that the feasibility of the theoretical methods has been insufficiently evaluated, precluding firm conclusions about their usefulness. In the Netherlands an attempt has been made to apply the theoretical principles for priority setting in a real world setting and evaluate this procedure (Oortwijn, 2000). From 1988–2000 the Health Insurance Council administered the Fund for Investigative Medicine, which is one of the most important HTA programmes in the Netherlands. From 2000 the Council for Medical and Health Research administers this Fund. The Fund aims to commission research that provide information for evidence-based policy making at the national level and also to promote evidence-based use of the relevant health technologies at the practice level. Research proposals submitted to the Fund were examined with regard to their policy relevance using societal criteria. These criteria were: actual burden of disease, potential benefit for the individual patient, number of patients, direct costs of the intervention per patient, financial consequences of applying the intervention over time, and additional aspects, with an impact on health policy. Two procedures for setting priorities between research proposals were compared: an experimental procedure and a conventional procedure based on subjective overall judgements. In the experimental procedure the judgement was based on objective information provided in the research proposals. Three algorithms for scoring and weighing were explored as well. The experimental procedure led to different ratings of the research proposals compared to the conventional procedure. This result strengthens the arguments for more explicit and transparent procedures for setting priorities for HTA (Oortwijn, 2000).

Practical approaches in non-European countries described in the literature

Israel has also initiated a priority setting procedure, which focuses on using HTA for priority setting in health care (Shani et al, 2000). In the Israeli procedure societal criteria were used to evaluate different technologies, including number of patients and health and financial impact of the intervention under study. A consensus method (Delphi model) was used to rank the technologies. A public National Advisory Committee was appointed by the Minister of Health to make the actual decisions, also based on consensus. The process led to a list of priorities for inclusion in the basis list of health services provided to the public.

In Canada some HTA agencies are involved in priority setting for HTA. For example, the Alberta Heritage Foundation for Medical Research (AHFMR) and the Canadian Co-ordinating Office for Health Technology Assessment (CCOHTA), which are both a member of INAHTA, are active in priority setting. The primary aim of AHFMR is to provide objective information to support health care decisions and policy making. The HTA unit of AHFMR undertakes assessments upon requests or by initiating HTAs themselves. Criteria used for selecting requests are: purpose of request, impact of the technology (costs and effects), availability of technology, variation in use, timeliness of assessment, whether research was done before and feasibility of assessment (Alberta Heritage Foundation for Medical Research, 2000). CCOHTA performs HTA studies regarding health technologies of national concern. Topics for assessment can be

suggested by different sources such as board members, CCOHTA's advisory committees, CCOHTA's staff and the general public. Criteria used for determining priorities for HTAs are: availability of data, scope of CCOHTA, appropriateness of CCOHTA to conduct study, cost of the project, legal aspects, health impact, timing of assessment, controversiality of health technology. The final topics are approved by the Board and are based on the criteria mentioned and priority decisions for the coming year (CCOHTA website, 2000).

Since the publication of Donaldson and Sox (1992), priority setting is visible in the USA. However, in most cases in concerns priority setting for (biomedical) research, such as the National Institutes of Health (NIH) (National Institutes of Health, 1998). Since we are focusing on priority setting for HTA, these activities are not further described.

Several developing countries have attempted priority setting exercises for determining essential national health research: Benin, Caribbean countries, Guinea, Kenya, Nicaragua, The Philippines, South Africa and Thailand (The Working Group on Priority Setting of the Council on Health Research for Development, 2000). However, no elements and application of priority setting procedures within these countries were described. Although these attempts focus on health research, the priority setting procedure is similar to the steps proposed in the EUR-ASSESS report on priority setting (Henshall et al, 1997). The procedure was applied by the INCLEN (International Clinical Epidemiology Network) to discuss international efforts in malaria control and ways in which they could best contribute to these efforts through research and capacity building malaria (Fraser, 2000). The procedure used by INCLEN is comparable to the procedure applied by the Dutch Health Insurance Council in 1998 (Oortwijn, 2000), although the criteria used were mainly related to the strategic plan of the INCLEN.

Practical approaches used in Europe, results from the survey and interviews

Fourteen of the responding 24 agencies have implemented a priority setting procedure in their organisation (Table 1). One organisation (NICE) filled in that they have not implemented a priority setting procedure but mentioned the Medical Clinical Innovations Group run by the UK Department of Health. With this organisation in mind they responded to the survey. Nine organisations answered that they have not implemented a priority setting procedure (yet). No organisation mentioned another institution/organisation in their country involved in priority setting.

People dedicated to priority setting

The preliminary results show that there are not many people involved in priority setting (Table 3). Most of the agencies (n= 8) have less than 2 people on a full-time basis (FTE) dedicated to priority setting. One organisation (NCCHTA) stated that they have around 6 people working on a full-time basis on priority setting. Some people found it hard to estimate the FTE due to the fact that priority setting procedure is not a continuing process. The person who is mainly responsible for the priority setting procedure is the director of the organisation or the head of the department (Table 4).

Identification of health technologies in need of assessment

The methods used for identifying health technologies in need for assessment are mainly a review of technologies entering or about to enter service delivery, review of existing health care practices and expert opinions (Table 5). It should be noted that most organisations (n=12) mentioned more than three methods.

Criteria for selecting health technologies

The criteria for selecting health technologies are quite diverse, but it is obvious that social, ethical and legal aspects are not mentioned often (Table 6). Most agencies (n=10) use more than 8 criteria for setting priorities between health technologies. The following criteria were mentioned most often: number of people for which the technology is applicable; efficiency considerations (cost-effectiveness); potential effectiveness for the individual patient (health impact); financial impact of applying the technology and variations in use. Results from Working Group 3 of the ECHTA project (Joint assessments) show that the following criteria were mostly used in determining international joint projects: large number of people affected; new technology; emerging technology. Similar to the results of the survey, the use of ethical consideration got the lowest priority of the nine criteria mentioned.

Overall nature of priority setting procedure

The overall nature of the procedure is mainly implicit and not very transparent. A lot of organisations (n=11) use external input (Table 7). Most organisations (n=10) involve the view of the decision-maker, but the view of the researcher (performing HTA) is only involved in three organisations. This is an important result, since the perspective of decision-makers and researchers need to be combined to ensure that priorities address questions of importance to policy (Oortwijn, 2000).

Parties of influence

Most organisations (n=12) indicated three or more actors, which have an influence on the priority setting procedure. Health technology assessment is a form of policy analysis implying that policy makers must have a strong input to determine priorities. The results show that the involvement of the government is obvious (n=14). In addition, physicians (n=10) and national organisations (advisory councils) (n=10) are mentioned as the parties which have remarkable influence (Table 9). Maybe this is related to the fact that the main emphasis of HTA has been on expensive diagnostic and therapeutic procedures (Banta & Oortwijn, 2000). The role of the public/consumer was mentioned only by three organisations. It has been recognised that this situation needs to be changed. In the phase of identifying technologies in need of assessment, the experiences of consumers could be of great value (Banta & Oortwijn, 2000).

Written description of the priority setting procedure

From the organisations that implemented a priority setting procedure (n=14) 10 organisations indicated that they have a written description of the procedure used. Although we have asked to send the description, we received a written description only from CAHTA (Spain) and NWO (The Netherlands). One organisation (AETS, Spain) referred to their website (Table 10), which updated their priority setting exercise of 1998. After consulting the persons to be interviewed we

received written description of the priority setting procedure of Osteba and NCCHTA and some additional information about the procedure from NWO-MW, SMM and LCM. No (additional) information was found on the websites of the organisations, which stated that they have a written procedure. Possibilities for joint assessments can be identified if the different organisations share information about the priority setting procedure used. A written description (in English) of the procedure used can be of great value for sharing information on priority setting for HTA in different countries.

Use of priority setting results in practice

Results of priority setting procedures are of increasing interest to different actors involved in HTA (Banta & Oortwijn, 2000). The results of the priority setting procedures are often used (n=12). The results are used for several purposes such as selection and financing of screening programs (LCM, Belgium) and for rejecting projects if there are not enough financial resources (FinOHTA, Finland). Most organisations use the results for commissioning research (Osteba, Spain; AETS, Spain; CAHTA, Spain, AETSA, Spain; Health Council, the Netherlands, NWO, the Netherlands; NCCHTA, United Kingdom and NICE, United Kingdom). Although the organisations stated that the results are used, no reference was made to publications (Table 8). This last finding implies a need for information sharing regarding the use of priority setting results in practice.

Usefulness of the EUR-ASSESS report concerning priority setting

The usefulness of the EUR-ASSESS report is underlined by seven organisations. However, eight organisations do not think that the report is a useful technical tool to guide the priority setting procedure (Table 11). Therefore, only one organisation (AETS) has used it for developing a system (Table 12). The main reasons for the limited usefulness were that the information given is too general (n=2) and that the organisations already had implemented a procedure (n=5). In addition, most respondents of the interviews argued that the EUR-ASSESS report on priority setting gives general guidance to those who wish to set priorities, but its usefulness could be improved (Appendix 4). The overall picture of the survey shows, however, that most organisations use similar recommendations as those of the EUR-ASSESS report on priority setting with regard to guiding principles, methods used for identifying health technologies in need of assessment and criteria used for selecting health technologies (Tables 2, 5 and 6).

Utility of different priority setting procedures

As recommended in the EUR-ASSESS report on priority setting 'those responsible for HTA programmes should evaluate the process and outcome of priority setting to establish whether, and if so, how it has affected the topics assessed and the value for money achieved from investment in HTA' (Henshall et al, 1997). Although priority setting for HTA is acknowledged to be worthwhile, relatively little attention had been paid to the evaluation of the few available procedures (Oortwijn, 2000). The evaluation of the priority setting procedure developed and used by the Health Care Insurance Board in the Netherlands is one of the first examples for determining utility of priority procedures. In addition, some qualitative indications of the utility of different procedures are published as well. For example, Vella et al (2000) stated that the

nominal group technique (consensus technique) was considered a feasible and reliable technique for determining priorities among health professionals (clinicians).

Discussion / Conclusions

Not every possible research effort can be undertaken, indicating that decisions have to be made about how to allocate resources available for HTA. Priority setting for HTA focuses in those assessments, which generate the highest potential benefits given the available resources. Priority setting is therefore an integral part of HTA (Oortwijn, 2000). Priority setting requires consideration of the potential outcomes of assessment, and also the issues that assessments are likely to address (research questions). This means that priority setting can be used to identifying questions for HTA and to set research priorities for HTA or for rejecting projects if there are not enough financial resources. In addition, priority setting for HTA can indicate a substantial uncertainty or lack of data necessary to make decisions of allocating scarce resources and controlling health care expenditures. Priority setting for HTA could also be used to stimulate appropriate introduction of health technologies or to abandon ineffective health technologies. These purposes will improve maximising health gain for a given level of health care expenditure. The involvement of policy makers can create a climate to design the assessment in such a way that the results provide enough information for answering a policy-oriented question. Identifying the assessments that offer the greatest benefits in relation to their cost will ultimately improve the (cost-) effectiveness of the health care system.

The most general observation of this study concerns the increasing interest in priority setting for HTA, although no additional (new) theoretical models have been published since the EUR-ASSESS report on priority setting. However, some new developments address certain elements in the priority setting procedure, focusing mainly on techniques for determining the ranking of priorities.

A second observation concerns the increased use of priority setting procedures throughout the world. Unfortunately, formal use of these procedures remains limited. Most organisations have implemented a priority setting procedure, but the overall nature of the procedure is mainly implicit and not very transparent. A key element to improve the usefulness and generalisability of priority setting for HTA is to focus on transparency in the priority setting procedure. The results of the survey show that most of the priority setting procedures of the organisations surveyed reflect the variations in procedures (theoretical considerations) as described in the EUR-ASSESS report on priority setting. The EUR-ASSESS report offers some practical guidance to help those wishing to set priorities (Henshall et al, 1997), but some of the respondents of the survey and the interviews judge the guidance as too general. The main reason for the limited usefulness is that most organisations already had implemented a priority setting procedure. However, written descriptions were received from only 2 of the 10 organisations, which stated that they have a written procedure. In addition, the results of the survey show that most of the organisations use similar recommendations as those of the EUR-ASSESS report with regard to guiding principles, methods used for identifying health technologies in need of assessment and criteria used for selecting health technologies.

The utility of the different priority setting procedures is mostly unknown since the feasibility of the procedures has been insufficiently evaluated. In addition, due to the various contexts in which HTAs are undertaken no single procedure for priority setting can be recommended.

A third important observation is that social and ethical considerations are often not taken into account when setting priorities. Although the need for more comprehensive HTA is recognised, not much has been done (Reuzel & de Wilt, 2000). Ethical and social aspects are of main importance when determining whether the results of HTA are relevant for policy.

A fourth observation focuses on the role of the public/consumer in priority setting. It has been recognised that the involvement of consumers and/or the public has been limited and that this situation needs to be changed. In the phase of identifying technologies in need of assessment, the experiences of consumers could be of great value (Banta & Oortwijn, 2000). For example, in the UK, consumers are involved in direct consultation focusing on identifying questions for HTA.

Recommendations

Recommendations to the European Commission

As stated during the Conference on Health in 1991 (Noordwijk, the Netherlands), the European Commission could provide opportunities to encourage closer national collaborations to confront common challenges, they should stress the importance of choices and indicate that closer co-operation and collaboration among Member States is both desirable and necessary. It would be beneficial for all health systems in Europe to have a co-ordinating mechanism for HTA at the European level (Banta & Oortwijn, 2000).

Member States should work together to identify common problems. The European Commission should consider that health policy choices and priorities are important topics, which should regularly appear on the agenda of the Council of Ministers for Health (RVZ, 1999). European added value can be achieved by comparative activities between countries and by bringing together a wide variety of different national methodological approaches, including (methods for) priority setting. Exchange of HTA information and the possibility to exchange experiences with different actors involved in priority setting for HTA are of main importance to improve the (cost-) effectiveness of the health care system. Therefore, priority setting for HTA should be an integrated part of a European clearinghouse for HTA. The European Commission could emphasise these intentions by means of supporting such a clearinghouse for HTA. The respondents of the interviews (n=5) all favour a European clearinghouse for HTA (Appendix 4).

Recommendations for the function of priority setting as part of a European clearinghouse for HTA

1. The clearinghouse function should identify actors on different levels (European, national, regional or local) with an interest in HTA and priority setting.

Health technology assessment is undertaken by a number of actors for different purposes in different institutional contexts. This will influence the approach taken in a priority setting procedure. Therefore, it is recommended to have an overview of actors who are (interested in) setting priorities for HTA on the different levels in health care. The needs of different actors who wish to set priorities should be the key issue of the function of priority setting as part of a clearinghouse for HTA. Although different actors on different levels have different goals for setting priorities, it is possible to provide general guidance for developing a priority setting procedure (see Recommendation 6).

2. The clearinghouse function should provide (potential) users of priority setting procedures with examples of possible purposes for which priority setting for HTA could be used.

Priority setting requires consideration of the potential outcomes of assessment, and also the issues that assessments are likely to address (research questions). This means that priority setting can be used to identifying questions for HTA and to set priorities for HTA (commissioning research) or to reject projects if financial resources are insufficient. For example, in the Netherlands priority setting for HTA has been used to commission HTAs, which provide information relevant for the regular financing of the health care system. Thus, highest priority might be given to assessments of health technologies creating new and possibly avoidable cost pressures in the health care system. In addition, priority setting for HTA can indicate a substantial uncertainty or lack of data necessary to make decisions of allocating scarce resources and controlling health care expenditures. Priority setting for HTA could also be used to stimulate appropriate introduction of health technologies or to abandon ineffective health technologies. Priority setting for HTA is also of interest to patients and consumers. Patients and consumers want the highest quality of care for the individual patient. All these purposes of priority setting for HTA address the problems of ineffective and cost-ineffective health care, and therefore impacts on the health care system has a whole. Identifying the assessments that offer the greatest benefits in relation to their cost will ultimately improve the (cost-) effectiveness of the health care system.

3. A task of the clearinghouse function should be to collect information about the purposes of the actors with an interest in priority setting.

The different purposes will influence the priority setting procedure taken. Hence, it is recommended to provide this information to those who are interested in priority setting for HTA.

4. The clearinghouse function should develop an overview of descriptions of existing procedures in priority setting. In addition, contact information of initiators should be provided to get more information or guidance about the priority setting procedure:

A. The clearinghouse function should provide an overview of written descriptions of existing priority setting procedures. In addition, contact information (and links to websites of the

organisations) should be provided to obtain more information about the specific procedure. It is recommended that people with experience in priority setting should help those with little or no experience in priority setting.

Practical examples from the survey include:

- Agencia de Evaluación de Tecnologías Sanitarias (AETS) in Spain.
  AETS produced priority lists in 1998 and 1999. A summary of the identification and prioritisation of health technologies is available at website: www.isciii.es/aets (in Spanish and English).
- Agencia de Evaluación de Tecnologías Sanitarias de Andalucía (AETSA) in Spain.
  AETSA has a written procedure on the priority setting procedure, in Spanish only. Limited information is available at website: www.csalud.junta-andalucia.es/AETSA (in Spanish only).
- Basque Office for Health Technology Assessment (Osteba) in Spain.
  The initial procedure of Osteba is published in English (Osteba, 1996). The evolution of the procedure during the years 1996–2000 is published in Spanish only (Asua, 2000). Appendix 4 presents a brief description of the Basque procedure. Osteba does not have their own websiite since they are part of the Department of Health of the Basque Government. The website of the Department of Health is http://www.euskadi.net/sanidad (in Spanish only).
- Catalan Agency for Health Technology Assessment and Research (CAHTA) in Spain.
  Reports about the procedure performed in 1996, 1998, 2000 are available in English (Granados, 1995; CAHTA, 1998, CAHTA, 2000, Aymerich, 2001). The priority setting procedure of 1998 and a summary of the identification and prioritisation phase of the latest procedure (2000) are available at website: www.aatm.es (in English and Spanish).
- National Co-ordinating Centre for Health Technology Assessment (NCCHTA) in the United Kingdom.
  The priority setting procedure is described in detail at the website of NCCHTA: http://www.NCCHTA.org (in English). The procedure of NCCHTA is briefly described in Appendix 4.
- Netherlands Organisation for Scientific Research (NWO-MW) in the Netherlands.
  The procedure of NWO-MW has been described in a public report, including application forms. The report is only available in Dutch. A summary of the procedure is available at the website of NWO-MW: www.nwo.nl (in Dutch only). The priority setting procedure is briefly presented in Appendix 4.
- Norwegian Centre for Health Technology Assessment (SMM) in Norway.
  The procedure of SMM is described in Norwegian, and is mainly used internally. SMM has described some of their procedures in English (for example use of systematic surveys in priority setting) See also Appendix 4 for a brief presentation of the priority setting procedure of SMM.
- Swedish Council on Technology Assessment in Health Care (SBU) in Sweden.
  In 1989 SBU published a report about priority setting for HTA in English (Johnsson et al, 1989). The working process of SBU is briefly presented at the website of SBU: http://www.sbu.se.

One recommendation in the EUR-ASSESS report on priority setting focused on transparency of the procedure (Henshall et al, 1997). Therefore, it is recommended to ask all organisations to provide the clearinghouse with a written description of their procedure.

B. The clearinghouse function should provide for each of these written descriptions a summary of the key elements, which is easily accessible:

– goals and responsibilities of actors involved in the priority setting procedure
– general approach (explicit and systematic, implicit, external input, views of policy makers and researchers, transparency)
– methods used for identifying health technologies in need of assessment
– criteria used for selecting health technologies
– purpose(s) for which results are used
– evaluation procedure

5. The clearinghouse function should provide overviews of priorities of different actors (results of priority setting procedures).

– European policy concerns

In addition, when establishing a clearinghouse function for all Member States, the priorities of the European Union should be taken into account. The following priority themes for the coming 5 years (2000–2005) were selected: health promotion, education and training, health monitoring, cancer, drugs, aids and other communicable diseases, pollution related disease, rare diseases and injury prevention) (RVZ, 1999). Working Group 3 of the ECHTA project studied the health topic areas on which international joint projects were undertaken. Although the results are difficult to compare, it appears that many joint efforts have been undertaken in cancer research (Overheads Working Group 3 of Seville meeting). It is recommended to take the EU priorities as a starting point for priority setting on a European level. The EU priorities could be a starting point for collaboration in international joint projects. A task of a clearinghouse could be to study how these priorities could play a role in priority setting on different (national and local) levels.

– National policy concerns

Also, national priority setting procedures may define the relative importance of major research areas. Sharing of information on priorities developed in different countries could be of benefit for the different HTA programs (Banta & Oortwijn, 2000). It recommended that all countries involved in a clearinghouse describe their national priorities as determined by their government.

The information that will result from recommendations 1 through 5 should be provided by means of an accessible database of the clearinghouse focusing especially on priority setting for HTA.

– Results from HTA programmes

The clearinghouse should ask those responsible for HTA programmes to share information on priorities and discuss opportunities for joint working on expensive assessment of joint interest, and the division between programmes of assessments or components of assessments whose results can be shared. This recommendation was part of the recommendation section of the EUR-ASSESS report on priority setting (Henshall et al, 1997).

6. The clearinghouse function should develop a service (framework) to help those who wish to develop a priority setting procedure for HTA (minimum or desirable standard for priority setting procedure).

Key elements should focus on:

– Involvement of policy makers and researchers

Those who wish to establish a priority setting procedure should be clear about how priorities for assessment are identified, who is responsible for particular elements in the priority setting procedure and whom they are expected to involve in the procedure.

The perspectives of decision-makers (from different levels) and researchers should be combined in setting priorities. Researchers need to be aware of health policy issues and policy makers need to be made aware of assessment (im)possibilities (Oortwijn, 2000). This interaction could improve the likelihood that results of an HTA provide enough information for answering the policy-oriented question.

– Involvement of the pubic/consumers

The role of the public/consumers remains limited. It has been recognised that this situation needs to be changed. In the phase of identifying technologies in need of assessment, the experiences of consumers could be of great value (Banta & Oortwijn, 2000). It is recommended to involve different stakeholders in the process of priority setting for HTA. It should be noted that an assessment which is not responsive to stakeholder concerns, would not be useful or used, and could be viewed as irrelevant or as inappropriate (Rossi et al, 1999).

– Formal criteria

A priority setting procedure depends on the context in which priority must be set. Therefore, no universally applicable list of criteria can be presented. The literature describes mainly the following broad categories of criteria, which can be used as guidelines when developing a priority setting procedure:

– number of people affected
– expected health impact (predicted effectiveness)
– economic consequences (investment costs, total economic impact)
– impact on health policy (regulatory decision, controversiality, ethical concerns) (Oortwijn, 2000).

– Use of evidence

Often decisions are made without formally considering the published evidence (Henshall et al, 1997). When applying an explicit and transparent procedure successfully all necessary information should be available. Collecting, collating and disseminating information is therefore necessary (link to HTA database). Gathering and exchanging information, and improving dissemination of findings will lead to more effective and efficient priority setting procedures. If data are missing, ways should be studied, such as statistical procedures to estimate the most likely figures, to retrieve the information needed. If there is no information at all, subjective judgements from experts could be used. Sensitivity analyses are recommended for assessing problems of uncertainty regarding the data.

– (Improving) general approaches

All countries involved should exchange information about the development, use and evaluation of their priority setting procedures. It is recommended to use explicit and transparent procedures to improve usefulness and generalisability. Hence, it is recommended that the countries involved provide the clearinghouse with an electronically accessible version of their priority setting procedure. It is recommended that the clearinghouse should (further) develop explicit priority setting procedures in the future. More transparent and explicit procedures can help organisations that wish to set priorities to improve the relevance of their research. Some developments in decision-analytical approaches are challenging (Oortwijn, 2000; Fraser, 2000; Nobre et al, 1999; Claxton & Posnett, 1996). It is recommended to study the potential of decision-analytical approaches in more detail. The network of the clearinghouse could be used to develop a more common standard for priority setting for HTA.

7. A clearinghouse function for priority setting should be well organised.

It is important to know what people with an interest in priority setting for HTA need to present the information in the most efficient way. This implies that the clearinghouse should have a minimal staff and resources for data collection, for updating a website, for giving advice, for secretariat services etc. It is recommended that people involved in the ECHTA project continue to develop the clearinghouse function for priority setting. Existing European networks (e.g. EuroScan) should become part of the clearinghouse. Other existing networks with connections to non-EU countries (e.g. INAHTA), should be closely linked to the clearinghouse function for priority setting.

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Appendixes

1. Participants of Working Group 2
2. Survey on priority setting and results of survey
3. Full names of organisations and contact persons to which survey was sent
4. Analysis of interviews

Appendix 1 – Participants of Working Group 2

Jose Asua (Co-chair)
Basque Office for Technology Assessment (Osteba)
Vitoria-Gasteiz, Spain

Kerstin Hagenfeldt (Co-chair)
SBU/Karolinska Hospital
Stockholm, Sweden

Malene Fabricius
Danish Centre for Evaluation and Health Technology Assessment,
DACEHTA (formerly DIHTA)
Copenhagen, Denmark

Wija Oortwijn
University Medical Centre Nijmegen
Nijmegen, The Netherlands

Sergio Belluci
Swiss science Council/Technology Assessment
Bern, Switzerland

Wilf Higgins
Hospital Planning Office, Department of Health and Children
Dublin, Ireland

Alessandro Liberati
Mario Negri
Milan, Italy

Berit Mørland
Norwegian Centre for Health Technology Assessment (SMM)
Oslo, Norway

Rachid Salmi
Université Victor Segalen Bordeaux
Bordeaux, France

Andrew Stevens
The University of Birmingham, Department of Public Health and Epidemiology
Birmingham, United Kingdom

Gabriel ten Velden
Health Council of the Netherlands
The Hague, The Netherlands

Appendix 2 – Survey on priority setting and results of survey

Dear Sir, Madam,

With this letter we request your participation in a survey about priority setting and databases on health technology assessment (HTA). All member states are faced with increasingly difficult choices and priorities. There is also evidence of ineffectiveness in how health systems operate within their local frameworks and priorities for HTA. To avoid unnecessary and wasteful duplication of work in HTA between member states and regions, it is important to have access to information, especially access to HTA projects, that have been or are being carried out at other HTA agencies. The survey consists of two parts: one focusing on priority setting for HTA and one focusing on databases on HTA4. The part focusing on priority setting involves an update of the survey done as part of Subgroup on Priority Setting for HTA of the EUR-ASSESS project in 1995. The final product, a report offering guidance to those who wishes to set priorities, was published in a special issue of the International Journal of Technology Assessment in Health Care in 1997; 13(2). We send this survey to all (European) respondents to the survey performed in the EUR-ASSESS project, and a few additional relevant European HTA agencies.

This survey is being conducted as part of the European Collaboration for Health Technology Assessment (ECHTA) project. It was decided in the Working Group on Developing Systems for the Routine Exchange of Information between Programs to prepare a survey on priority setting processes and use of databases in different HTA agencies.

The Working Group contracted Wija Oortwijn (University of Nijmegen, the Netherlands) and Malene Fabricius (DIHTA, Denmark) to conduct the survey. The purposes of this survey are:

1. To gain insight in the present status of priority setting activities by different organisations;
2. To retrieve information about the use and usefulness of the EUR-ASSESS report concerning priority setting;
3. To collect information on the evaluation of different systems for priority setting;
4. To collect information on the use and usefulness of existing databases on HTA;
5. To collect information on methods of dissemination in relation to databases;
6. To evaluate the usefulness of the Health Technology Assessment (HTA) database (formerly the INAHTA database)

Based on the results of this survey we intend to perform a limited number of more in depth personal telephone interviews with some of the respondents of this survey. The results of the survey, the interviews and a literature review will be used to help to strengthen HTA-activities by promoting co-operation between established centres and activities of HTA in the European Member States. This can be done by sharing information on methods and results on priority setting activities, by improving the sharing of information on ongoing HTAs and results of

4 In this report only the part of the survey concerning priority setting (Part A) is presented. The part on databases (Part B) is presented separately in a report on databases.

HTAs and by overseeing the development and improvement of clearinghouse activities in all of these areas.

We kindly ask you to return the survey to Malene Fabricius by the 1st of September 2000, at the latest. For this purpose you can use the enclosed envelope.

Thank you for your assistance.

Kind regards,
on behalf of all members of the working group,

Information Specialist Malene Fabricius
DIHTA
Amaliegade 13, P.O Box 2020
1012 Copenhagen K, Denmark

Dr. Wija Oortwijn
University Medical Centre Nijmegen
Department of MTA, 253
6500 HB Nijmegen, The Netherlands

ECHTA Project

Working group on developing systems for the routine exchange of information between programs

SURVEY

on

Priority setting and databases on health technology assessment in different countries

This survey is about priority setting and databases on health technology assessment (HTA) and therefore consists of two parts. Concerning the part on priority setting this survey involves an update of the survey done as part of Subgroup on Priority Setting for HTA of the EUR-ASSESS project in 1995. The survey as a whole will be used to help to strengthen HTA activities by promoting co-operation between established centres and activities of HTA in the European Member States.

General Information

1. Name of Organisation:

_____

_____

2. Name and email address of Person(s) completing the survey:

_____

_____

3a. Has your organisation implemented a priority setting procedure for health technology assessment (HTA)?

☐ NO ----> Do you know of an organisation (and responsible person) in your country that sets priorities for HTA?

If yes, please write the name(s) below.

_____

_____

☐ YES

3b. Does your agency use databases to collect information on HTA activities carried out at other HTA agencies or HTA programs ?

☐ NO ----> Could you please state the reasons why your agency does not use databases ?

_____

_____

☐ YES

If you have answered NO on both questions 3a and 3b, please return this survey to Malene Fabricius. Please use the enclosed envelope.

If you have answered question 3a with YES, please turn to the following page and answer part A of the survey.

If you have answered question 3b with YES, please turn to page 8 and answer part B of the survey.

Part A: Priority setting for health technology assessment

4. In a general sense, what are the guiding principles (goals), which takes your organisation into account regarding priority setting for health technology assessment?

☐ Needs-assessment

☐ Containing health care costs

☐ Generating evidence base

☐ Promoting the appropriate introduction, diffusion, and use of new and existing health technologies

☐ Abandon ineffective health technologies

☐ Maximising health gain for a given level of health care expenditure

☐ Lowering mortality rates

☐ Other(s) _____

_____

_____

5. How many full-time equivalents (FTE) of your organisation are involved in analysing and in setting priorities for health technology assessment?

_____ FTE

6. Is there a person in your organisation who is responsible in working on priority setting?

☐ NO

☐ YES ----> ☐ Director of organisation

☐ Head of department

☐ Senior researcher

☐ Other(s) _____

_____

7. Which methods are used for identifying technologies in need for assessment?

- ☐ Reviewing general health policy or problems
- ☐ Reviewing demands being placed on the health system by the public
- ☐ Political priorities
- ☐ Review technologies entering or about to enter service delivery
- ☐ Review existing health care practices (variations)
- ☐ Monitoring international scientific literature (scanning evidence base)
- ☐ Expert opinion
- ☐ Delphi method/ group judgement
- ☐ Other(s) _____

8. Which criteria are used for selecting health technologies for assessment?

- ☐ Severity of the disease
- ☐ Number of people for which the technology is applicable
- ☐ Efficiency considerations (cost-effectiveness)
- ☐ Potential effectiveness for the individual patient (health impact)
- ☐ Potential costs of application per patient
- ☐ Financial impact of applying the technology
- ☐ Controversy
- ☐ Variations in use
- ☐ Social and ethical considerations
- ☐ Scientific quality
- ☐ Availability of data
- ☐ Health policy implications
- ☐ Legal
- ☐ Other(s) _____

9. The overall nature of the priority setting procedure is:

- ☐ Explicit and systematic
- ☐ Implicit (subjective)
- ☐ One in which, external input and advice is accepted or actively sought
- ☐ One in which, views of decision-makers (who will use the assessments) are involved
- ☐ One in which, views of researchers (who will undertake assessments) are involved
- ☐ Transparent

10. Have results of the priority setting process actually been used in initiating assessments?

- ☐ NO
- ☐ YES, please describe how _____

_____

_____

11. Which parties influence the priority setting process?

- ☐ Government
- ☐ National Organisations (for example advisory councils)
- ☐ Research Councils
- ☐ Research Organisations
- ☐ Physicians
- ☐ Public/Consumers
- ☐ Insurance Companies
- ☐ Funding Organisations
- ☐ Other(s) _____

_____

_____

12. Has your organisation a written description of the procedure used?

☐ NO

☐ YES, could you please return it with this survey?

13. Is the EUR-ASSESS report, which was published in 1997, a useful technical tool to guide the priority setting process?

☐ YES

☐ NO, please describe why not _____

_____

_____

_____

_____

14. Has your organisation changed their priority setting procedure as a consequence of the EUR-ASSESS report on priority setting?

☐ YES, please describe how _____

_____

_____

_____

_____

☐ NO, please describe why not _____

_____

_____

_____

_____

Thank you very much for completing this part of the survey.

Results of Survey

Table 1. Organisations to which survey was sent (A list with full names of the organisations is given in Appendix 3).

Organisations	Country	INAHTA member	Responded	Regional (R) or national (N) function; national agency (NA) [5]	Involved in priority setting
ITA	Austria	Yes	Yes	N	No
CUL, School of PH	Belgium	No	Yes	R	No
AZ-BUV	Belgium	No	No	R	-
Ministry Pub. Health	Belgium	No	Yes	N	Yes
LCM	Belgium	No	Yes	N	Yes
MTV-enheden	Denmark	No	Yes	N	No
DIHTA [6]	Denmark	Yes	Yes	N, NA	Yes
DSI	Denmark	Yes	No	N	-
FINOHTA	Finland	Yes	Yes	N, NA	Yes
ANAES	France	Yes	Yes	N, NA	Yes
CEDIT	France	Yes	No	N	-
DIMDI	Germany	Yes	Yes	N, NA	No
CHESME	Greece	No	Yes	N, NA	No
Hospital Planning Office	Ireland	No	No	N	-
Azienda Provinciale	Italy	No	No	R	-
IGSS	Luxembourg	No	Yes	N	No
SMM	Norway	Yes	Yes	N, NA	Yes
National School PH	Portugal	No	No	N	-
Osteba	Spain	Yes	Yes	R	Yes
AETS	Spain	Yes	Yes	N, NA	Yes
CAHTA	Spain	Yes	Yes	R	Yes
AETSA	Spain	Yes	Yes	R	Yes
CMT	Sweden	No	No	N	-
SBU	Sweden	Yes	Yes	N, NA	Yes
FSIOS	Switzerland	Yes	No	N	-
SWISS/TA	Switzerland	Yes	Yes	N	No
CVZ	The Netherlands	Yes	No	N	-
Health Council	The Netherlands	Yes	Yes	N	Yes
NWO	The Netherlands	Yes	Yes	N	Yes
TNO PG	The Netherlands	Yes	Yes	N	No
NHS CRD	United Kingdom	Yes	No	N	-
NCCHTA	United Kingdom	Yes	Yes	N	Yes
NHSC	United Kingdom	Yes	Yes	N	No
NICE	United Kingdom	Yes	Yes	N	No [7]
NHS Dept. of Health	United Kingdom	No	No	N, NA	-

[5] Regional function (R): Decisions based on HTA are mainly focusing on own region (county, province, autonomous region); National function (N): Results of HTA study are mainly focusing on whole country; National agency (NA): Agency is established as national agency (Banta & Oortwijn, 2000).
[6] Per 1 April 2001 the Danish Centre for Evaluation and Health Technology Assessment.
[7] NICE does not have a priority setting procedure but is closely linked to the priority setting procedure of the Medical Clinical Innovations Group run by the UK Department of Health.

Table 2. Guiding principles (goals)

Organisations	Needs assessment	Containing hc costs	Generating evidence base	Appropriate introduction etc.	Abandon ineffective health technologies	Maximising health gain	Lowering mortality rates	Others
AZ-BUV								
Ministry Pub. Health [8]		X	X [9]	X	X			Produce feedback to hospitalsElaborate best practice by physicians
LCM	X	X		X		X		
DIHTA	X			X	X	X		
DSI								
FINOHTA	X	X	X	X	X	X	X	
ANAES	X	X	X	X				
CEDIT								
Hospital Planning Office								
Azienda Provinciale								
SMM				X	X	X		
National School PH								
Osteba		X		X	X	X		
AETS			X	X	X	X		
CAHTA	X	X	X	X	X	X	X	
AETSA	X	X		X				
CMT								
SBU				X	X	X		Guarantee best practice
FSIOS								
CVZ								
Health Council	X		X	X	X	X		
NWO		X	X	X	X	X	X	
TNO PG								
NHS CRD								
NCCHTA	X	X	X	X	X	X		
NICE [10]				X	X	X		
NHS Dept. of Health								

[8] The procedure focuses on analysing health procedures in the department of health, and includes not really priority setting.
[9] Elaborate best practice by physicians.
[10] They are not having a priority setting procedure themselves. They have filled out the questionnaire for the Medical Clinical Innovative Group, run by the UK Department of Health.

Table 3. FTE's involved in analysing and in priority setting for HTA

Organisations	< 1 FTE	1-2 FTE	3-5 FTE	5-7 FTE	7-9 FTE	> 9 FTE	Other
AZ-BUV							
Ministry Pub. Health		2					
LCM			3 [11]				
DIHTA		1,5					
DSI							
FINOHTA		1					
ANAES							Unknown
CEDIT							
Hospital Planning Office							
Azienda Provinciale SMM	0.5						
National School PH Osteba							No answer
AETS		1					
CAHTA	0.5-1 [12]						
AETSA	0 [13]						
CMT							
SBU	< 0.1						
FSIOS							
CVZ							
Health Council			4				
NWO			3-4				
TNO PG							
NHS CRD							
NCCHTA				Around 6			
NICE							Unknown
NHS Dept. of Health							

[11] More or less 3.
[12] It is difficult to calculate how many full-time equivalents are involved since they work intensively on priority setting every two years. Many people collaborate on it, but not fulltime.
[13] It was a one-time exercise.

Table 4. Person(s) responsible for setting priorities

Organisations	Director	Head of Dept	Senior Researcher	Other(s)	No answer	No one
AZ-BUV						
Ministry Pub. Health				X[14]		
LCM		X				
DIHTA	X					
DSI						
FINOHTA		X				
ANAES					X	
CEDIT						
Hospital Planning Office						
Azienda Provinciale						
SMM	X			X[15]		
National School PH						
Osteba			X			
AETS	X	X				
CAHTA	X	X		X[16]		
AETSA						X
CMT						
SBU	X		X			
FSIOS						
CVZ						
Health Council	X					
NWO	X	X[17]				
TNO PG						
NHS CRD						
NCCHTA			X	X[18]		
NICE						X
NHS Dept. of Health						

[14] Answer focuses on analysing databases: 3 members of the Institute of National Health Assurance; 3 members of the health department and subtracting out of universities.
[15] The Board.
[16] Scientific Committee and CAHTA researchers.
[17] Co-ordinator-HTA.
[18] We have a team, part of whose role is to serve priority setting expert panels.

Table 5. Methods used for identifying health technologies in need of assessment

Organisations	General health problems	Demands by public	Political priorities	Technologies entering hc system	Review existing health care practices	Scanning evidence base	Expert opinion	Delphi method	Other(s)
AZ-BUV									
Ministry Pub. Health					X				
LCM	X			X	X		X	X	
DIHTA	X	X	X	X	X	X	X		
DSI									
FINOHTA	X			X	X		X	X	
ANAES	X			X	X		X		
CEDIT									
Hospital Planning Office									
Azienda Provinciale									
SMM	X		X	X	X				
National School PH									
Osteba	X	X	X	X	X	X			
AETS	X	X	X	X		X	X		
CAHTA	X	X	X		X	X	X	X	
AETSA			X		X		X		
CMT									
SBU	X	X	X	X	X		X		
FSIOS									
CVZ									
Health Council	X			X	X	X	X		
NWO				X		X	X	X	
TNO PG									
NHS CRD									
NCCHTA			X			X	X	X	
NICE			X	X	X				
NHS Dept. of Health									

Table 6. Criteria used for selecting health technologies in need of assessment

Organisations	Severity	Number	Efficiency	Health impact patient	Potential costs	Financial impact	Controversy	Variations	Social/ ethical aspects	Scientific quality	Availability data	Health policy	Legal aspects	Others
AZ-BUV														
Ministry Pub. Health				X [19]		X		X				X	X	
LCM	X	X	X			X		X	X			X		
DIHTA	X	X	X	X	X	X	X	X	X	X	X	X		
DSI														
FINOHTA	X	X	X	X	X	X	X	X	X	X	X	X		
ANAES	X	X	X			X	X	X		X	X	X		
CEDIT														
Hospital Planning Office														
Azienda Provinciale														
SMM	X	X	X	X			X	X	X	X	X	X		
National School PH														
Osteba	X	X	X					X	X					X [20]
AETS	X	X	X	X	X	X	X		X	X		X		
CAHTA	X	X		X	X	X		X	X	X		X	X	
AETSA	X	X		X		X					X			X [21]
CMT														
SBU	X	X	X	X	X	X	X	X	X					
FSIOS														
CVZ														
Health Council		X	X	X		X	X	X	X	X	X	X	X	
NWO		X	X	X	X	X	X	X			X			
TNO PG														
NHS CRD														
NCCHTA	X	X	X	X		X				X	X	X		X [22]
NICE		X	X	X	X			X						
NHS Dept. of Health														

[19] More or less.
[20] Potential impact of the assessment in reducing variability in use and cost and improve the social and ethical considerations.
[21] Feasibility of project.
[22] Burden of disease and rate of diffusion.

Table 7. Overall nature of priority setting procedure

Organisations	Explicit and systematic	Implicit	External input	View of decision makers involved	View of researcher involved	Transparent	Other
AZ-BUV							
Ministry Pub. Health		X					
LCM		X	X	X			
DIHTA			X	X	X	X	
DSI							
FINOHTA	X[23]	X[24]	X				
ANAES			X	X	X		
CEDIT							
Hospital Planning Office							
Azienda Provinciale							
SMM		X	X	X			
National School PH							
Osteba	X						
AETS	X			X		X	
CAHTA	X						
AETSA		X	X	X	X		
CMT							
SBU		X	X	X			
FSIOS							
CVZ							
Health Council			X	X			
NWO	X[25]	X[26]	X			X	
TNO PG							
NHS CRD							
NCCHTA	X		X	X[27]		X, as far as possible	
NICE		X	X	X			
NHS Dept. of Health							

[23] Depends on case.
[24] Depends on case.
[25] Criteria are explicit.
[26] Weighting of the individual criteria is usually implicit.
[27] Implicitly via expert groups.

Table 8. Use of results in initiating assessments

Organisations	Results are used	Results are not used	No answer
AZ-BUV			
Ministry Pub. Health		X	
LCM	X[28]		
DIHTA	X[29]		
DSI			
FINOHTA	X[30]		
ANAES		X	
CEDIT			
Hospital Planning Office			
Azienda Provinciale			
SMM			X
National School PH			
Osteba	X[31]		
AETS	X[32]		
CAHTA	X[33]		
AETSA	X[34]		
CMT			
SBU	X[35]		
FSIOS			
CVZ			
Health Council	X[36]		
NWO	X[37]		
TNO PG			
NHS CRD			
NCCHTA	X[38]		
NICE	X[39]		
NHS Dept. of Health			

[28] The results are used for selection and financing of prevention (screening) programs (e.g. diabetes and mammography).
[29] The results are used by involvement of broad stakeholder board (DIHTAs 22 persons board).
[30] The results are used for rejecting projects if there are not enough financial resources.
[31] The results define an important part of the Osteba work programme and the topics for the commissioned research projects.
[32] The results have led to the production of 170 technical notes on health technologies according to the need for an assessment report and the need for evaluative research (full HTAs).
[33] Every two years a priority setting procedure takes place in CAHTA. After this procedure there is a public call of all prioritised topics.
[34] In 1997, six project areas were prioritised, and are still being developed.
[35] Successive voting in different groups and committees.
[36] Results are used in the Working Programme for the Health Council: annually updated.
[37] Within broader topics to select specific questions for HTA-research, and to select HTA-research proposals with sufficient relevance for policy.
[38] We commission all our HTAs only after they have been prioritised.
[39] The results are used since the MCIG determine the HTA programme of NICE.

Table 9. Influencing parties

Organisations	Government	National org.	Research councils	Research org.	Physicians	Public/ consumers	Insurance companies	Funding org.	Others
AZ-BUV									
Ministry Pub. Health	X				X			X	
LCM		X			X		X		
DIHTA	X	X	X	X	X			X[40]	
DSI									
FINOHTA	X		X						
ANAES	X	X			X				X[41]
CEDIT									
Hospital Planning Office									
Azienda Provinciale									
SMM	X		X		X			X	
National School PH									
Osteba	X	X							
AETS	X	X						X	
CAHTA	X		X	X	X				
AETSA	X	X						X	X[42]
CMT									
SBU	X	X			X	X			
FSIOS									
CVZ									
Health Council	X								X[43]
NWO	X	X		X	X	X	X		
TNO PG									
NHS CRD									
NCCHTA	X	X			X	X			X[44]
NICE	X	X			X				
NHS Dept. of Health									

[40] INAMI: to adapt the existing nomenclature.
[41] Sickness fund.
[42] Hospital managers.
[43] 8 Experts committees of the Health Council.
[44] Other health care staff, including our medical clinicians, policy makers and managers; researchers and experts in the given technologies; own research staff.

Table 10. Written description of the procedure used

Organisations	Yes	No	Description was sent	Description was not sent
AZ-BUV				
Ministry Pub. Health		X		
LCM		X		
DIHTA	X			X
DSI				
FINOHTA		X		
ANAES		X		
CEDIT				
Hospital Planning Office				
Azienda Provinciale				
SMM	X[45]			X
National School PH				
Osteba	X			X
AETS	X			X[46]
CAHTA	X		X[47]	
AETSA	X[48]			X
CMT				
SBU	X			X
FSIOS				
CVZ				
Health Council	X			X
NWO	X		X	
TNO PG				
NHS CRD				
NCCHTA	X			X
NICE		X[49]		
NHS Dept. of Health				

[45] In Norwegian language.
[46] Link to website (www.isciii.es/aets) was given.
[47] There is a description of the priority setting procedure for the years 1996 and 1998 and also one for the year 2000, which procedure changed substantially. The last report was sent.
[48] In Spanish.
[49] At least he is not aware of a written procedure.

Table 11. Usefulness of EUR-ASSESS report on priority setting for guiding a priority setting procedure

Organisations	No answer	Yes	No, because ....
AZ-BUV			
Ministry Pub. Health			X
LCM			X, The information provided is mostly not specific enough (topics too general, and health policy is very much of institutional character per country and is influenced by many other things than HTA alone.
DIHTA	X		
DSI			
FINOHTA		X	
ANAES			X
CEDIT			
Hospital Planning Office			
Azienda Provinciale			
SMM			X, SMM was established in 1998, and had not been aware of this report in due time.
National School PH			
Osteba		X	
AETS		X	
CAHTA			X, Because the first priority setting procedure was already done taking into account the EUR-ASSESS report conclusions.
AETSA		X	
CMT			
SBU		X	
FSIOS			
CVZ			
Health Council			X, The present procedure has proven itself to be quite satisfactory. It does not deviate essentially from the EUR-ASSESS report.
NWO		X	X, Only part of it is applicable to our specific situation.
TNO PG			
NHS CRD			
NCCHTA		X	
NICE			X, Not used it.
NHS Dept. of Health			

Table 12. Change of priority setting procedure due to the EUR-ASSESS report on priority setting

Organisations	Yes, because…	No, because…	No answer
AZ-BUV			
Ministry Pub. Health			X
LCM		X, see answer table 11.	
DIHTA		X, DIHTA was formed in 1997.	
DSI			
FINOHTA		X	
ANAES		X	
CEDIT			
Hospital Planning Office			
Azienda Provinciale			
SMM		X, see answer table 11.	
National School PH			
Osteba		X, They had already an explicit method for prioritisation.	
AETS	X, Used a base for a priority setting procedure for HTA		
CAHTA		X, The first ps was done, taking into account the EUR-ASSESS report conclusions	
AETSA		X, the ps procedure was already in place when the report was available.	
CMT			
SBU		X	
FSIOS			
CVZ			
Health Council		X, see answer table 11.	
NWO		X, She is in charge with this process since 1999.	
TNO PG			
NHS CRD			
NCCHTA		X, They already had an established system and contributed anyway to EUR-ASSESS.	
NICE			X, Not sure
NHS Dept. of Health			

Appendix 3 – Full names of organisations and contact persons to which survey was sent

1	Dr. Claudia Wild *HTA Unit of the Institute of Technology Assessment (ITA)* *Austria*
2	Prof. dr. Katrien Kesteloot *School of Public Health* *Catholic University Leuven (CUL)* *Belgium*
3	Mr. J. Beeckmans *AZ-VUB* *Belgium*
4	Ms. A. Simoens *Ministry of Public Health* *Belgium*
5	Dr. R. van den Oever *LCM - Alliance Nationale des Mutualites Chretiennes* *Belgium*
6	Bodil Wahlstrøm *MTV-enheden* *Denmark*
7	Dr. Finn Børlum Kristensen *Danish Centre for Evaluation and Health Technology Assessment (formerly the Danish Institute for Health Technology Assessment (DIHTA))* *Denmark*
8	Mr. Jürgen Erler-Rohde *Danish Institute for Health Services Research and Development (DSI)* *Denmark*
9	Dr. Virpi Semberg *Finnish Office for Health Care Technology Assessment (FINOHTA) Stakes* *Finland*
10	Dr. B. Xerri *L'Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES)* *France*
11	Dr. Elisabeth Féry-Lemonnier *Comité d'Evaluation et de Diffusion des Innovations Technologiques Assistance (CEDIT)* *France*
12	Dr. Ruther Dauben *German Institute for Medical Documentation and Information (DIMDI)* *Germany*
13	Professor L. Liaropoulos *Center for Health Services Management and Evaluation (C.HE.S.M.E)* *Greece*
14	Mr. Wilf Higgins *Hospital Planning Office* *Department of Health and Children* *Ireland*
15	Director General, MD Carlo Favaretti *Azienda Provinciale per i Servizi Sanitari* *Italy*
16	Dr. Gerhard Holbach *Inspection Générale de la Sécurité (IGSS)* *Luxembourg*
17	Dr. Berit Mørland *Norwegian Centre for Health Technology Assessment (SMM)* *Norway*

18	Dr. Joao Pereira *National School Public Health, Nova University, Lisboa* *Portugal*
19	Dr. José Asua *Basque Office for Health Technology Assessment (OSTEBA)* *Spain*
20	Dr. Setefilla Luengo *Agencia de Evaluacion de Tecnologias Sanitarias (AETS)* *Spain*
21	Marta Aymerich *Catalan Agency for Health Technology Assessment (CAHTA)* *Spain*
22	Dr. Eduardo Briones *Agencia de Evaluación de Tecnologías Sanitarias de Andalucia (AETSA)* *Spain*
23	Prof. dr. Jan Persson *Centrum för utvärdering av medicinsk teknologi (CMT), Linköping* *Sweden*
24	Dr. Helena Dahlgren *Swedish Council on Technology Assessment in Health Care (SBU)* *Sweden*
25	Dr. Pedro Koch *Medical Technology Unit* *Federal Social Insurance Office Switzerland (FSIOS)* *Switzerland*
26	Dr. Sergio Belucci *Swiss Science Council/Technology Assessment (SWISS/TA)* *Switzerland*
27	MD Albert Boer *Health Care Insurance Board (CVZ)* *The Netherlands*
28	Dr. Gabriel HM ten Velden *Health Council of the Netherlands* *The Netherlands*
29	Dr. Jetty Hoeksema *Netherlands Organization for Scientific Research* *Council for Medical and Health Research (MW-NWO)* *The Netherlands*
30	Dr. Taeke van Beekum *TNO Prevention and Health (TNO-PG)* *The Netherlands*
31	Prof. dr. Jos Kleijnen *NHS Centre for Reviews and Dissemination (NHS CRD)* *United Kingdom*
32	Dr. J. Gabbay *National Coordinating Centre for Health Technology Assessment (NCCHTA)* *United Kingdom*
33	Prof. dr. A. Stevens *UK Horizon Scanning Center (NHSC)* *United Kingdom*
34	Dr. Rod Taylor *National Institute for Clinical Excellence (NICE)* *United Kingdom*
35	Ms. T. Lamont *Research and Development Directorate - NHS Department of Health* *United Kingdom*

Appendix 4 – Analysis of interviews

Introduction

The general questions, which were discussed in the interviews, were:

- What do you think of priority setting for HTA as part of a (European) clearinghouse? [clearinghouse]
- What is your view with regard to priority setting for HTA on different levels (local, regional, national, European level)? [level of priority setting]
- Please could you walk me through your priority setting procedure? [priority setting procedure]
- What are the benefits of the EUR-ASSESS report on priority setting for HTA? [EUR-ASSESS]

The terms between brackets are used as headings in the analyses of the interviews described below.

Results

Clearinghouse

All respondents mentioned that they are in favour of a European clearinghouse. Their arguments were as follows:

"A European clearinghouse is useful, and it would be beneficial to provide the existing priority setting procedures to other people who wish to set priorities for HTA. A clearinghouse, which provides a guide for setting priorities for HTA is fine. A guide could provide, for example, three theoretical procedures for setting priorities from which people could choose to implement or use for building their own procedure.

The clearinghouse should contain descriptions of the priority setting procedures of different HTA agencies (for example 5-10 agencies). A format in which this could be presented is a matrix with on the horizontal axes the criteria used and on the vertical axes the different agencies using the criteria. A checklist with phases and criteria could be of use to state what kind of aspects is important in setting priorities for HTA."

"A European clearinghouse for priority setting could be beneficial for those who wish to set priorities. Providing information about how to set up a general framework for priority setting is possible and a list with common (national) priorities could be of interest for joint assessments. However, two reservations should be taken into account when developing a clearinghouse function for priority setting:

- In general priority setting depends often on local policy imperatives, which differ per country.

- In some countries the priority setting procedure cannot be described entirely open due to confidential information which is needed to ensure fair competition between applicants of research proposals.

A clearinghouse function for priority setting should guide those who wish to set priorities. The people with experiences in priority setting should help those with little or no experience in priority setting. Sharing experiences is beneficial for all people involved in priority setting for HTA."

"There is a need for a clearinghouse, mainly when it concerns exchange of information and the possibility to exchange experiences with different actors involved in priority setting for HTA."

"It is beneficial to offer information about priority setting procedures of different organisations in different countries. In addition, collaboration between different countries has added value. It would be beneficial to start joint projects between countries, which would like to encounter the same problems. One reservation should be made about the timing of assessments. In many cases the results of assessments are not available in time. Therefore, the respondent recommends guidelines for the procedure of HTA and implementation of results (translating research into practice)."

"It would be an advantage to have relevant information regarding HTA available at one place (clearinghouse). A clearinghouse for all functions of HTA is a great challenge, but it should be noted that all actors involved in HTA have different wishes and are performing HTA differently. A clearinghouse needs to study whether different aspects of HTA could be standardised. Regarding priority setting for HTA, it would be beneficial to get information about ongoing and finished HTA projects (link to INAHTA database) and about emerging health technologies (link to EuroScan). In addition, advice about how to retrieve information for a specific question would be necessary ("If I have this or this question, where can I go to get this information?")."

All respondents thought that the clearinghouse should be well organised, in which the role of INAHTA is emphasised:

"The clearinghouse should have a minimal staff and resources. At least a database expert should be dedicated to the clearinghouse: someone who knows where the information can be found, and who can give advice. The clearinghouse should not contain scientific documents only because of their limited practical value. It is important to know what people need in order to present the information in the most efficient way."

"The responsibility for a clearinghouse is a difficult issue. It would be beneficial to take the organisation of INAHTA as an example. It is necessary to have a permanent secretary for the clearinghouse, which is comparable to the INAHTA secretariat. The INAHTA network functions extremely good, and this kind of network could be used as an example for initiating joint assessments."

"The clearinghouse will need strong leadership as in INAHTA. A barrier for membership of INAHTA is the high membership fee."

"A clearinghouse should be well organised. It certainly will need resources for data collection, for updating a webpage, secretariat etc. It is recommended that people involved in the ECHTA project continue to develop the clearinghouse. Existing European networks (such as EuroScan) should become part of the clearinghouse. Other existing networks, with a connection to non-EU countries (such as INAHTA), should be closely linked to the clearinghouse."

Level of priority setting

Most respondents are not in favour of one single uniform procedure for setting priorities on different levels. The needs of different actors who wish to set priorities should be the key issue in the clearinghouse function for priority setting:

"For a regional or national HTA agency priority setting for HTA should be local, although the information provided at this level could be useful on a supranational level. However, a guide or tool should be 'soft', not demanding. It is known that different systems on different levels have different scopes, responsibilities and goals. This implies that no single procedure can be developed, which is valid and applicable for different actors who wish to set priorities."

"It will not be possible to recommend one single uniform priority setting procedure for all different levels. There is a difference between the procedure itself and the content of the procedure. The procedure will depend on the purpose for which the procedure will be used. For example, priority setting for commissioning research proposals or for commissioning research regarding health problems will need a different approach. In addition, different actors can have a different perspective on the same issues. Therefore, different levels will require different criteria, which can be weighted differently. However, it can be useful to have a set of common criteria in a kind of toolkit, which are applicable on all levels."

"It is not possible to have a general framework for setting priorities on different levels. It is known that the health care system is influenced by different cultural values. The respondent is in favour of an open system, which is applicable to different actors on different levels. It is important to respect the autonomy of those who wish to set priorities. In addition, it is important to have an accessible system where people can retrieve information that can be used in real practice. Information about and guidance of priority setting for HTA needs to be flexible. The information should be offered in accordance with the need of the actors involved."

"It appears that different actors such as clinicians and health administrators have different tasks regarding priority setting. It would be beneficial for different actors on different levels to have general guidance and examples of real world experiences with priority setting. It is stated that the clearinghouse should recommend the development of open and clearly described priority-setting procedures. In addition, the clearinghouse should provide clearly described examples of existing priority setting procedures on different levels. To provide useful information, different actors

need to be asked what they need for setting priorities since countries and their actors differ in how much they are involved in HTA."

"Although different actors on different levels have different goals for setting priorities, it is possible to provide general guidance for developing a priority setting procedure. Minimal requirements for setting up a procedure, as well as minimal requirements regarding the content of the procedure should be recommended in the clearinghouse function."

EUR-ASSESS

Most respondents argue that the EUR-ASSESS report on priority setting gives general guidance to those who wish to set priorities, but its usefulness could be improved:

"The report on priority setting for HTA would have been more beneficial when it focused more on what is happening in the real world. "Policy makers do not believe in theories". To have a real impact on health policy researchers, assessors and clinicians should work together."

"The EUR-ASSESS report can be seen as a toolkit."

"The EUR-ASSESS report gives a general oversight of priority setting for HTA. The usefulness of the report could be increased if it presented more details on how priorities in different contexts were set and the results of these different procedures. It is important to ensure a dynamic priority setting procedure. A requirement for a dynamic procedure is to involve all relevant actors."

"The EUR-ASSESS report has benefits, which focus on the general guidance provided to develop a priority setting procedure. The general guidance provided by EUR-ASSESS should be reflected in a clearinghouse function for priority setting."

"It is difficult to determine benefits of EUR-ASSESS for those people who wish to set priorities. If the EUR-ASSESS report will be (partly) used in the clearinghouse, it should be more specific."

Description of priority setting procedures (in alphabetically order)

A brief description of the organisations of the persons that have been interviewed is given below:

Basque Office for Health Technology Assessment - Osteba (Spain)

Osteba has applied the model of the Institute of Medicine (IOM, 1992) to develop their priority setting procedure in 1996. The IOM model uses seven criteria, seven steps, a Delphi process and Nominal Group techniques with multidisciplinary teams. The priority setting procedure of Osteba focus on the most appropriate choice of issues to be assessed within Osteba and on topics for commissioning research. Osteba thought that the IOM-model was, at that time, the less complicated and most theoretically grounded model for setting priorities for HTA. The procedure of Osteba is not externally validated, but they have discussed the procedure internally every time they need to set priorities. Based on the discussions the procedure has been adapted in some extent, and this is described in (Spanish) publications. The priority setting procedure of Osteba is dependent on the political system.

The initial procedure of Osteba has been published in English ("The prioritisation of Evaluation Topics of Health") in 1996. The evolution of the procedure during the years 1996-2000 is published in Spanish ("Priorizaci•n de necesidades de evaluci•n en el Pa•s Vasco". Universidad Complutense de Madrid. Instituto de Salud Carlos III). Osteba does not have their own website, since they are part of the Department of Health of the Basque Government. The website of the Department of Health is [http://www.euskadi.net/sanidad]. Only abstracts of full reports are available on this website, which is provided in Spanish only. Reports will be available in PDF-format soon.

LCM – Alliance Nationale des Mutualites Chretiennes (Belgium)

LCM is the biggest health insurance organisation in Belgium (4,5 million insured; 45% of the total). The priority setting procedure of LCM is needs led. It is focused on suggestions for HTA, which matter to different actors, for example industry, clinicians or consumers/patients. The organisations, which propose topics (specific health technologies), provide necessary information about several relevant aspects such as number of patients, prevalence figures, costs and effects. LCM does not use real decision rules for determining which topic should be assessed first. LCM judges the proposed topic implicitly, mainly with regard to the number of people affected and the effects on health. Most topics proposed are considered for a feasibility study. The results of the feasibility study are disseminated to a specific committee. There are several committees depending on the topic under study (for example a technical, pharmaceutical, scientific, health care committee). The procedure of applying the health technology to one of these specific committees is well described. The advice of the committee is sent to the Overeenkomstencommissie. This Overeenkomstencommissie is committee of insurers and health professionals, which judges whether implementation of the health technology fits within the health care budget. The Overeenkomstencommissie advises the Minister, who makes the final decision whether or not the health technology will be funded.

LCM co-ordinates the whole track: from organising the trial and advising the Minister. One of the main advantages of the LCM procedure is its flexibility and publicly open character. Information about LCM can be found at their website: http://www.cm.be (in Flemish only).

National Co-ordinating Centre for Health Technology Assessment – NCCHTA (United Kingdom)

The priority setting procedure of NCCHTA (HTA Programme) is described in detail at the website of NCCHTA: http://www.NCCHTA.org. The HTA Programme is a national research programme established and funded by the Department of Health Research and Development Programme.

In summary, the procedure starts with the identification of important gaps in the NHS knowledge base about health technologies. NCCHTA uses an open channel (for example direct consultation of people, systematic reviews and horizon scanning) to solicit ideas for primary and secondary research (systematic reviews) on health technologies. From up to 1500 suggestions received by the HTA programme each year, around 40 will be the subject of commissioned research. The HTA Programme has three expert advisory panels, which prioritise topics 3 times a year.

The prioritisation of the topics includes three steps:

- The suggestions received are sorted and sifted according to research criteria by the panel senior lecturer and researcher (whether or not suggestions have a researchable question, whether it is related to HTA or not and if it has been covered by current HTA or not). Each advisory panel will decide upon the topics for which a vignette should be written (between 5-8 topics per panel) by NCCHTA;

- The vignettes, which are summaries of the importance of the health problem, current evidence base and cost of the intervention, are presented to the advisory panel. Each panel should recommend about three topics to the Prioritisation Strategy Group

- The Prioritisation Strategy Group makes the final decision about which topics will be advertised for commissioning research (consensus meeting).

After the prioritisation process the topics are advertised (inter)nationally. Invitations are sent to submit outline proposals for primary research and full proposals for secondary research. Applicants are guided by commissioning briefs, which are developed for each priority area. All proposals received are subject to a peer-reviewed process. The HTA Commissioning Board reviews the proposals mainly regarding scientific quality, and makes recommendations to the Prioritisation Strategy Group. The role of the Prioritisation Strategy Group is to formulate the best combination of the priority of the area and the quality of the proposal. Finally, the HTA Commissioning Board decides about commissioning research on the basis of consensus.

This procedure is the new procedure of NCCHTA: Since 2000 the procedure has changed in response to changes in the organisation of quality improvement in the NHS, including the

establishment of NICE. The most important changes are that the procedure is more flexible, speedy and responsive, and that a new product – the Rapid Reviews – has been added.

Netherlands Organisation for Scientific Research – Council for Medical and Health Research-MW-NWO (the Netherlands)

MW-NWO administers the Health Care Efficiency Research Program since 1999. The Dutch Health Insurance Council administered this programme (which was called the Fund for Investigative Medicine) from 1988 until 1999. The purpose of the programme is to finance research proposals (HTAs), which focus on diagnostic or therapeutic health technologies and the organisation of health care. The HTAs should contribute to an efficient use of the health technology in practice. In other words the results of the HTA should provide information relevant for the regular financing of the health care system.

Different actors are involved in the priority setting procedure of the Health Care Efficiency Research Program. Review of research proposals focuses on the relevance for policy and the scientific quality. Policy relevance of the research proposals is assessed by the Committee Health Care Efficiency Research (Commissie Doelmatigheidsonderzoek). A scientific committee judges the scientific quality of the proposals (Commissie Beoordeling Wetenschappelijke Kwaliteit). Actors involved in the Committee Health Care Efficiency Research are representatives from different parties: physicians, insurance companies, researchers, consumers, and policy makers. Policy relevance is determined by different criteria such as relevance of the policy problem for the Netherlands, incidence and prevalence figures, practice variations, potential health effects and cost-effectiveness, possibilities for implementing the results of the study, and cost of the study itself. It has been recognised that often little evidence is available regarding the criteria described. Often applicants estimate the figures required.

The final decision about funding research proposals is made by the Committee Health Care Efficiency Research on the basis of both policy relevance and scientific quality of the proposal. The evaluation of the procedure from last year shows that the applicants often underestimate the description of the policy problem. Often the relation between the aims of the proposed research and the policy problem stated is not clear. This implies that the involvement of researchers and policy makers (those who will use the results of the study) in the formulation of the research proposal as well as in a priority setting procedure is of great importance.

The procedure itself has been described in a public report, including application forms. The report is only available in Dutch. MW-NWO intends to translate the procedure into English. The application form for submitting proposals is available in English. In addition, some of the referee reports are also available in English.

A summary of the programme can be found at the website of NWO: http://www.nwo.nl (in Dutch).

Based on discussion within the Committee Health Care Efficiency Research and other external advisors (for example advisory councils such as the Health Care Insurance Board (College voor

Zorgverzekeringen) and Advisory Council on Health Research (Raad voor Gezondheidsonderzoek) the procedure for next year will change to some extent.

Norwegian Centre for Health Technology Assessment - SMM (Norway)

SMM was established and is funded by the Ministry of Health. It is organised at an independent research foundation. SMM is not commissioning research, but they perform assessments themselves in co-operation with interdisciplinary expert groups. The secretariat of SMM (12 persons) is performing about 5-10 health technology assessments per year. Topics for assessments can be suggested by different sources. The assessments are based upon systematic reviews. The main task of SMM is to critically review the scientific basis of health technologies regarding costs, risks and benefits (see website SMM).

The Ministry of Health is the most important actor who is proposing health technology questions (for example: what is the value of PET scan in cancer?). Next to the Ministry, the Board of SMM (5 persons), the secretariat and a scientific panel (consisting of about 60 people with different backgrounds such as clinicians, ethicists, HTA researchers) propose questions to be assessed. Criteria used for determining priorities are practice variation, uncertainties with respect to clinical effect, number of patients, interest of public and availability of data. From the priority criteria practice variation is the most important. The secretariat gathers relevant information regarding the health technology by means of databases (such as Medline) and by asking additional information (for example about the patient group, whether the technology is emerging or not, cost of technology). After collecting this information, the secretariat will prioritise the issues and provide a list with issues to be discussed within the Board. The secretariat does not use explicit decision rules for determining priorities. The Board approves the final topics for the coming period.

The procedure of SMM is described in Norwegian, and is mainly used internally. SMM has described some of their procedures in English (for example use of systematic surveys in priority setting), and they are willing to translate their priority setting procedure into English as well. The priority setting procedures of SBU and NCCHTA have been studied when developing the SMM procedure. Since its development in 1998, the priority setting procedure of SMM is discussed internally. SMM wishes to develop a more organised and formal procedure. A summary of the procedure can be found on the SMM website: http://www.sintef.no/smm (in Norwegian and English).

Part on Databases on HTA activities (Objective 3)

Malene Fabricius Jensen

Introduction

Following the establishment of several new health technology assessment (HTA) agencies and programmes in Europe during the past decades, the volume of information on HTA activities has been increasing heavily. The EUR-ASSESS and HTA Europe projects have shown that further collaboration on HTA activities in general is needed, and that activities on more effective information sharing would be beneficial to HTA agencies in the process of carrying out HTAs (Banta 1997; Banta & Oortwijn 2000).

Health technology assessments are based on evidence from many different information sources. To avoid duplication, HTA activities usually commence with a search for information on HTA results and ongoing or planned HTA projects. It is important for agencies to stay up-to-date with information on HTA results and ongoing/planned HTA projects carried out at other agencies.

As part of meetings its objectives, the ECHTA Working Group 2 studied the aspects of "Developing systems for the routine exchange of information between HTA programs". The work covered 16 months, starting March 1, 2000, and the members of the Working Group are listed in Appendix 1.

This report presents the results regarding the use and usefulness of current HTA databases.

Objective, scope and methods

Objective and scope

The objective of this part of the ECHTA project is to consider how to improve the sharing of information on HTA results and ongoing HTA projects/activities and to consider if further clearinghouse activities are needed on how to improve the exchange of information among HTA programs in Europe.

To achieve the objective on sharing information about HTA results and ongoing HTA projects, the following aspects were studied:

- the use and usefulness of existing databases on HTA results and ongoing HTA projects/activities from the view of HTA agencies in Europe and HTA user representatives; and
- the methods of dissemination used by HTA agencies regarding these databases.

Definition

An HTA database or an HTA information source is a database containing information on HTA activities, HTA projects and HTA results.

Other information sources and databases used in the process of carrying out an HTA are not included in this study.

Methods

Prior to the first Working Group meeting in June 2000, Malene Fabricius Jensen had drawn up a working plan describing the actual work to be done. The working plan, focusing on databases of HTA activities was discussed and approved by the Working Group. The plan included the following activities:

Literature study

A literature study on databases of HTA activities has being carried out by searching the following databases: the HTA Database, the ISTAHC database, the Cochrane Library, Medline, HealthStar and EMBASE combining the terms "hta" or "health technology assessment" or "health care technology assessment" or "hcta" or "mta" or "medical technology assessment" or "technology assessment, biomedical" with the terms "database" or "information source" or "information resource".

Survey – HTA agencies

In August 2000, a survey was sent to the 35 agencies from 17 countries in Europe (all European Union countries plus Norway and Switzerland). A reminder was sent 1 month after the first invitation. The survey is presented in Appendix 2. The objective was to collect information on databases containing HTA information, to study the use and usefulness of these databases and to study the agencies' methods of dissemination in relation to the databases.

The survey contained 7 questions, 5 of which related to each of the following databases:

- The Cochrane Library
- EMBASE
- HealthStar[50]
- The Health Technology Assessment (HTA) database (formerly the INAHTA database)
- The ISTAHC database
- Medline (PubMed)

The questions focused on the following aspects:

- HTA-relevant content (information on HTA results and ongoing HTA projects)

[50] By April 2nd, 2001 HealthStar will no longer be updated, and records will be transferred to other U.S. National Library of Medicine (NLM) databases (Knecht 2001).

- Study design
- Search options
- Frequency of updating
- Overall impression
- Suggestions for improvement

Furthermore, the respondents were asked to indicate the strengths and weaknesses of the HTA Database (formerly the INAHTA database), based on their actual experience with the database at the time of filling out the questionnaire (August 2000).

The final 2 questions of the questionnaire related to the dissemination activities of the HTA agencies in relation to databases and the frequency of providing information to the databases.

Additional information of the databases

Additional information on the databases has been collected either by visiting the websites of the databases or by contacting the producers of the databases. The objective has been collecting additional information on the following aspects:

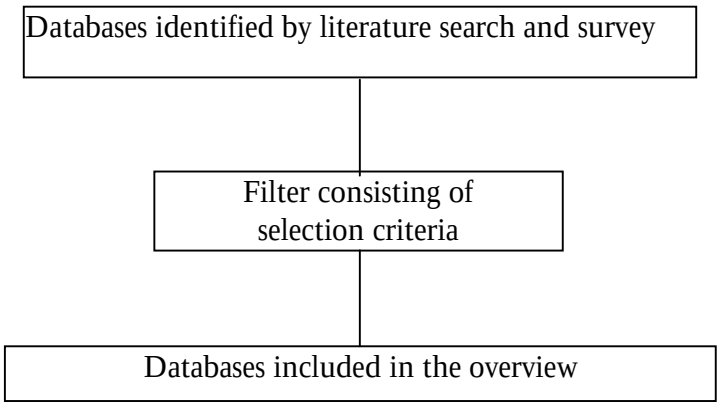
- What is the purpose of the database?
- How is the information/content collected and updated?
- How is the database accessed (free of charge or by subscription, Internet and/or CD-ROM?)?
- Is there integration/co-operation with other databases?

Selection criteria

A filter of selection criteria has been set up to identify the databases to be included in the overview:

- Does the database contain information on HTA results and/or ongoing HTA projects?
- Is information on study design included?
- Search options - e.g. is field searching and/or fulltext searching possible?
- Is the database easy to access?
- Is the information updated with acceptable frequency?

Fig. 1. Selection of databases to be included in the overview



Based on the results of the literature review and the survey, the selection process illustrated in Fig. 1 was used to overview the databases useful for information exchange on HTA activities.

Usefulness of databases: perspectives from HTA users

The users of health technology assessments were surveyed to study the use and usefulness of the HTA databases from the HTA users' point of view. The following selection criteria were used:

1. short versus long history of HTA in the country,

2. clinical/university versus administrative/political setting.

As part of the questionnaire sent to the HTA agencies, the respondents were asked to provide the name of a user of HTA within their country. Eight respondents provided names of users of health technology assessments from the following countries:

- Belgium - long history of HTA, administrative/political setting
- Finland - short history of HTA, clinical/university setting
- Greece - short history of HTA, clinical/university setting
- Norway - short history of HTA, clinical/university setting
- Spain - long history of HTA, administrative/political setting
- Spain - long history of HTA, clinical/university setting
- The Netherlands - long history of HTA, administrative setting
- United Kingdom - short history of HTA, administrative setting

Based on the selection criteria, 8 persons from the countries mentioned above (representing about 40% of the countries) were contacted during April-May 2001.

The survey (Appendix 5) includes the databases in the final overview, and the following aspects have been studied from the HTA users' point of view:

- use of the databases
- use of HTA information in the databases as an input for activities such as clinical decision making, clinical guideline development, policy making, research purposes
- usefulness regarding relevance, validity/reliability and structure of the database information
- suggestions for improving the databases as regards HTA information

Results

Exchange of information on HTA results and ongoing projects described in the literature

The establishment of INAHTA in 1993 has improved the exchange of information between HTA agencies (Hailey 1999) – e.g. by collecting and distributing lists with information of publications and ongoing projects. In 1999 this led to co-operation with the NHS Centre of

Reviews and Dissemination in making free electronic access to the information through the HTA Database on the Internet.

The U.S.-based agency ECRI (Emergency Care Research Institute) has established a database (IHTA - International Health Technology Assessment Database), which includes information on completed and ongoing HTA projects, published information on emerging technologies etc. (Coates 1993; Coates 1994). The input for the database comes from member agencies of ECRI and existing information sources (databases, websites etc.). Access to IHTA requires a subscription – e.g. via ECRI or DIMDI (German Institute for Medical Documentation and Information).

HTA publications are included in several databases and information sources - whose subject coverage often focuses on subjects other than HTA results and projects (e.g. Medline and Embase, which both focus on clinical medicine) - but yet no single gateway to information sources of HTA information exists, and especially ongoing research can be difficult to identify (Glanville 2000).

Most of the existing HTA information sources are searchable in English only, and there seems to a publication bias towards English publications in the existing databases. A few initiatives have been made to overcome these problems:

INAHTA agencies are asked to provide English titles and abstracts of the records, which are sent to the HTA Database, so that non-English publications and project descriptions are included in the HTA Database. INAHTA has also initiated translation of the titles of member agencies' reports and projects into Spanish (Parada 1999). This database is available via the INAHTA website. Also the Índice Médico Español (IME), which is the Spanish Index Medicus, includes journal literature about HTA.

A recent study has shown that health care purchasers in the U.S. and the United Kingdom have difficulties in finding, interpreting and critically appraising HTA information (Milbank Memorial Fund 2000). Even though HTA information is valued, few health care purchasers use it when making decisions. When (or if) they search for HTA information and other clinical effectiveness information, it tends to be in a very sporadic and unsystematic way. Often they tend to rely on health care professionals to analyse and interpret the information instead. Five factors seem to influence their limited use of HTA information: they seem to be more concerned about costs rather than the quality of health care services; they have little or no access to HTA information; they find it difficult to search the databases; they have insufficient training in using, interpreting and appraising the data; and weak skills in translating research evidence into practice also plays a role. To improve this situation, the study suggests that HTA information should:

- be produced by a credible agency or organisation;
- be based on the same standards and methodologies;
- include executive summaries for the lay audience and the academic audience;
- be timely and up-to-date; and
- be peer-reviewed.

The establishment of a clearinghouse for health technology assessment - including a function for exchange of information on HTA results and projects - can help overcome these problems by reviewing the HTA reports and providing a "stamp of credibility" of those HTA reports that meet a set of criteria.

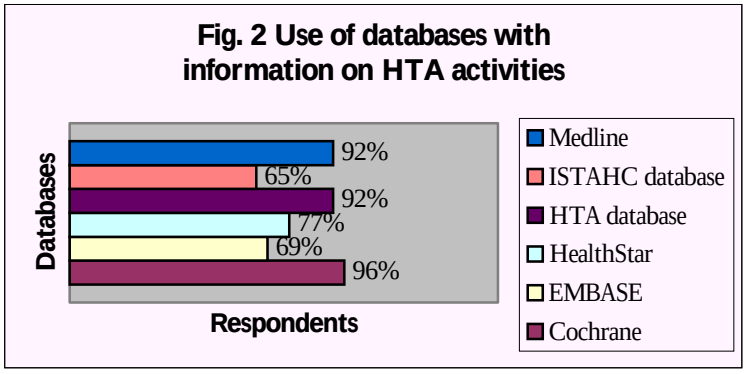
The existing initiatives of collecting and distributing information regarding the agencies' HTA activities seem to depend more or less on personal contacts and voluntary co-operation between the HTA agencies. This means that the users of this information have to search for the information in a range of different sources, which vary in coverage, structure of information and frequency of updating.

Present use of HTA databases by European HTA agencies

In total, 24 (69%) of the 35 organisations responded (Appendix 3, table 1). The responding organisations represent 14 European countries. Only Ireland, Italy and Portugal did not respond. The organisations to which the questionnaire was sent are listed in Appendix 4, including the names of the responding persons.

Databases are useful sources for obtaining information about HTA results and ongoing projects and are used by 83% (20/24) of the surveyed HTA agencies in Europe (Appendix 3, tables 1-2).

The databases used to collect information on HTA activities are shown in Fig. 2



The Cochrane Library, the HTA Database and Medline are all used by more than 90% of the 24 agencies (Fig. 2).

Of the respondents, about 38% use other databases as a supplement to the databases shown in Fig. 2. These databases are often local databases within the agencies or other national databases. Some of the databases are bibliographic databases, such as Pascal and IME: Índice Médico Español (Spanish Index Medicus). These databases include information on published studies only. Also IHTA (International Health Technology Assessment Database) is mentioned by a few respondents. IHTA is included in the overview because of its focus on health technology assessment.

The results of the literature study and the survey to the HTA agencies are presented in Appendix 3, tables 3-8 and summarised in Fig. 3.

Fig. 3 Overview of databases (as of August 2000) identified by literature review and survey to HTA agencies. Arranged by selection criteria

	The Cochrane Library	**EMBASE**	**HealthStar**	**The HTA Database**	**IHTA**	**ISTAHC**	**Medline (PubMed)**
HTA information	Good coverage (the HTA database is one of the databases in the Cochrane Library)	Poor coverage	Good coverage	Good coverage	Good coverage	Good coverage	Medium coverage (parts of HealthStar are included)
Study design	Good	Poor	Medium	Poor	Medium	Poor	Good
Search options	Medium	Good	Good	Medium	Medium	Poor	Good
Accessibility	Subscription (Internet, CD-ROM)	Subscription (Internet, CD-ROM)	Free (Internet)	Free (Internet) Subscription (part of the Cochrane Library)	Subscription (Internet). Free access for ECRI members	Free (Internet, CD-ROM)	Free (Internet)
Frequency of updating	Quarterly	Weekly (internet) Monthly (CD-ROM)	Weekly	Every 6 months (request from INAHTA secretariat to members). Information sent directly to publisher is added in between	Monthly	Quarterly	Weekly (HealthStar citations on a monthly basis)
Comments and suggestions for improvements (based on comments in survey to HTA agencies)	• Difficult to search for study design • Should include more information on the content of HTA reports • Should include fulltext or links to fulltext on Internet	• Published studies only • Should include links to fulltext on Internet	• Should include ongoing studies also· • Try to ensure that HTA agencies submit abstracts to this database	• More focus on methodological terms • Should increase frequency of updating· • Should include information from HTA agencies outside INAHTA • Try to ensure that all records have an abstract or executive summary in English • Not possible to save and run strategies in HTA database only		Should improve: • Search options (e.g. field searching)· • Frequency of updating· • Links to fulltext	• Should include more HTA reports with links to fulltext

The HTA agencies dissemination activities related to databases

The frequency of updating is the most frequently stated disadvantage of some of the databases, among them the HTA Database. One of the reasons seems to be a "lack of updating discipline from INAHTA agencies", but also "inconsistency of the detail information of the projects" is a problem. Often the agencies include no abstract or executive summary in English in the records, nor a link to this information in English at the agencies' own websites.

Regarding the organisations updating discipline, 54% of the respondents provide information regarding ongoing HTA activities, and 65% provide information on HTA results to the HTA Database. Information about ongoing projects and HTA publications are requested from the agencies by the INAHTA secretariat twice every year, but the agencies are also encouraged to send in the information on a regular basis. Of the responding agencies 60% provide this information on a regular basis, 13% upon request only.

About 20% of the agencies also provide this information to the Cochrane Library, HealthStar and ISTAHC. Only 15% provide the information to Medline (Appendix 3, tables 13-14).

Use and usefulness of databases: perspectives from HTA users

Despite the small number of participants in the survey regarding views of the HTA users (8 persons were surveyed, 6 persons responded - Appendix 6, table 1), the results indicate, that both the Cochrane Library and the HTA Database provide relevant and reliable information for activities regarding clinical guideline development, research purposes and policy making (Appendix 6, tables 3 and 5). However, the information and results from the HTA projects included in these 2 databases do not alone provide sufficient information for health policy making (Appendix 6, table 9).

The results of the survey emphasise, that the quality of both the Cochrane Library and the HTA Database could be increased by standardising the structure of information and by establishing links to fulltext reports (Appendix 6, tables 3,5 and 10).

There seems to be limited or no use of other databases included in the survey. 2 respondents use Medline, none of the respondent use HealthStar or The International Health Technology Assessment (IHTA) database to locate information on HTA projects or results.

Having access to a collection of HTA projects and reports (in the HTA Database) from international HTA organisation is very valuable, because "it saves the user navigating through many different databases", which is a very time-consuming process. The importance of exchanging information between HTA programs is underlined by all the respondents, and information exchange at an international level is preferable (Appendix 6, table 11). The respondents are in favour of establishing a clearinghouse for HTA, including a function of co-ordinating the activities regarding exchange of HTA information. The clearinghouse could provide access for both doers and users of HTA to information on completed, ongoing and planned HTA activities, presented in a structured and standardised way (Appendix 6, table 12).

Overview of existing databases useful for finding information on HTA activities

Based on the literature, the selection criteria and the results from the surveys to European HTA agencies and HTA user representatives, the following databases are identified as being useful for information exchange on HTA activities:

- The Health Technology Assessment (HTA) Database
- The Cochrane Library
- Medline
- HealthStar (Health Services Technology, Administration and Research)
- The International Health Technology Assessment (IHTA) database

Looking at the overall nature of the databases included in the study, **the HTA Database is regarded as the most important source of information on HTA activities,** followed by the Cochrane Library and Medline.

Few databases have a specific HTA information purpose

The HTA database is regarded as "the only specific HTA database". It gives "a comprehensive list of INAHTA agency reports, many of which are not published", and it is a strength that it "includes all sorts of projects, not only systematic reviews". Also the quality of the reports and the credibility of the INAHTA member agencies are important factors. *The Cochrane Library* is considered to be the best information source regarding systematic reviews, and it also has high coverage of HTA information since the HTA Database is included in the Cochrane Library. *HealthStar* has been focusing on health services research including clinical aspects (emphasising the evaluation of patient outcomes and the effectiveness of procedures, programs, products, services and processes) and non-clinical aspects (emphasising health care administration, economics, planning and policy) of health care delivery. HealthStar will not be updated after April 2nd, 2001. The periodical literature in HealthStar will then be included in Medline; books, book chapters and conference papers will be included in NLM's online catalogue LocatorPlus (http://locatorplus.gov); and meeting abstracts (including abstracts from the annual meetings of ISTAHC (International Society of Technology Assessment in Health Care and the Cochrane Colloquium annual meetings) will be searchable via the NLM Gateway (http://gateway.nlm.nih.gov). Forthcoming literature will be indexed and included in the NLM databases following these criteria (Auston 2001). *Medline* is the largest of the included databases (approx. 10 mill. records by January 2001), but regarding information on HTA activities, it is a disadvantage, that only HTA results published in report series or journals are indexed.

The International Health Technology (IHTA) Database focuses on HTA information, mainly from English speaking countries, and a small part of the database refers to ongoing HTA projects.

Lack of information on study design

Many of the records in *the HTA Database* are lacking information on study design. One of the respondents suggests, that "the agencies submit their abstracts, according to standards that focus on methodological terms". Also *the Cochrane Library* and *the International Health Technology*

(IHTA) Database could be improved by including more detailed information about study design. It could be considered to include study design as a separate search option in more databases.

Large variations in search options

The search options in *Medline (PubMed)* are splendid, the records are indexed with structured keywords: Medical Subject Headings (MeSH) and very complex searches are possible. In *HealthStar*, searches can be performed via the NLM Gateway by using Medical Subject Headings (MeSH), but the user interface is different from Medline (PubMed), and it must be noted that by April 2nd, 2001 HealthStar will no longer be updated as a separate database. Also the records in *The International Health Technology (IHTA) database* are indexed with Medical Subject Headings (MeSH) of the U.S. National Library of Medicine (NLM). It must be considered as a weakness though, that the complexity of the index structure is not accessible upon searching. This means that hierarchical searches (top-down) in the tree structure of MeSH terms are not possible. Regarding *the HTA Database*, it is considered as a weakness, that it is "not possible to save and run search strategies in the HTA Database only"[51]. The searching is difficult and there is "no possibility to collect/mark hits from multiple pages and see full records". The records in *the Cochrane Library* can be searched by using Medical Subject Headings (MeSH), but the respondents don't find searching the database very user friendly. A study by Wilson et al. (2001) about medical directors' views of the Cochrane Library concludes that searching and indexing should be improved together with the layout and interface of the database.

Information needs to be updated more frequently

The most frequently mentioned aspects to be improved regarding information on HTA activities were the frequency of updating (together with the information on study design). The HTA database is updated every 6 months, the Cochrane Library is updated on a quarterly basis only, which is one of the main disadvantages together with the search options of both databases.

Link to fulltext publications is recommended

Having searched the databases and located relevant HTA publications, it would be an advantage if links to fulltext publications were included in the database records. Often the full publication has to be accessed, because only part of the information is included in the databases. Many of the HTA agencies publish fulltext versions of their publications on the agencies' websites, and the inclusion of links to fulltext publications, e.g. in the HTA Database is increasing. Also, the Cochrane Library and Medline would be improved by enhancing access to fulltext publications.

Discussion / conclusions

Keeping up-to-date on international HTA activities is widely recognised among HTA agencies and important for reducing the duplication of health technology assessments (Banta 1997).

[51] In 2001 the user interface of the NHS CRD databases has been changed. The 3 databases HTA database, DARE and NHS EED are still searched by using the same search screen. The HTA database can be chosen as the one database to be searched, and it is now possible to save and run search strategies in the HTA database only.

Information about already completed and ongoing HTA projects can improve the HTA process by means of a quicker production period - not least when the HTA is dealing with a new (or an emerging) health technology (Hailey 2000). Hence, it is important to know which information sources to consult to determine if part of the HTA has already been carried out, or is part of another ongoing project elsewhere.

Wide variations in existing databases

The present state of the existing databases containing information on HTA activities is characterised by wide variations - both in coverage, structure of information, indexing, search options and frequency of updating. For the non-frequent user of electronic information sources, it is difficult to find out which information is available at the different databases. Among the databases included in this study, the HTA Database (formerly the INAHTA database) is considered to be the most valuable information source for obtaining information on HTA results and ongoing HTA activities. It includes information about HTA results published both as journal articles and as HTA publications, published and distributed by the HTA agencies. Many of these HTA reports would have been very difficult to locate, if they had not been indexed in the HTA Database. The inclusion of descriptions of ongoing HTA projects is also an important factor. However, the HTA Databases has a small volume of information compared to other bibliographic databases, such as Medline and the Cochrane Library. In addition, the information is collected from a small number of informants, depending much on personal contacts and voluntary co-operation between informants.

Overlap between findings in the HTA Database and other databases

A study by Royle & Bidwell (1999) shows that the indexing of INAHTA reports in major, bibliographic databases is 50% for the Cochrane Library, 14% for Embase, 53% for HealthStar and 21% for Medline. It should be noted that the HTA Database was not included in the Cochrane Library at the time when the study by Royle & Bidwell was performed.

Some of these databases co-ordinate their information: studies in the HTA Database are included in the Cochrane Library, and many of the findings in HealthStar are included in Medline (PubMed). There seems to be an overlap between IHTA and other bibliographic databases such as Medline, HealthStar, the HTA Database. However, IHTA includes fulltext articles, published in the journal "Health Technology Trends", produced by ECRI (Emergency Care Research Institute) in the U.S. The major difference between the HTA Database and these databases are the inclusion of descriptions of ongoing HTA activities in the HTA Database. Not only is it possible to find information on completed assessment of health technologies, information on ongoing assessments of health technologies can also be obtained from the HTA Database.

A conclusion that can be drawn from this study is that a need exists for the HTA Database with information on completed, ongoing and planned HTA projects. The HTA Database fulfils many of the needs of both HTA “doers” and HTA users concerning easy access to accurate and timely information on HTA activities. Closer and more formal co-operation among the doers of HTA is

necessary to assure that information on HTA activities is collected, structured and distributed in the best possible, systematic way. The variations in the structure of HTA descriptions in the databases make it difficult to compare and interpret the results of health technology assessments. Added value can be achieved by discussing and exchanging information on the different methodologies used when developing HTA projects, including how to structure the information provided to the databases.

Information on HTA results and ongoing HTA projects is provided from a range of different databases, information sources and websites - if available at all electronically. Due to the various objectives and target groups of the existing databases, closer co-operation between these databases can help increase the knowledge of HTA activities among health care actors in Europe.

Added value can be achieved for both doers and users of HTA information by co-ordinating the exchange of information on HTA activities in a clearinghouse setting. The clearinghouse function regarding exchange of information on HTA activities should provide information on HTA methods, processes and results; information on dissemination and implementation activities and methods, and information on the impact of HTA results on health care policy and practice in different countries.

A clearinghouse for HTA could play an active role in strengthening the network within the field of HTA, by

- providing access to evidence based information…
- based on systematic methods…
- presented in a standardised and structured format…
- to the right persons…
- at the right time

whether the information is to be used for research purposes, clinical guideline development, clinical decision making or health policy making in the European countries.

Recommendations regarding the function of an European clearinghouse for HTA related to the exchange of information on ongoing HTA projects and HTA results

1. The clearinghouse should collect and distribute information on HTA methods, processes and results

The ideal process of HTA includes identification, prioritisation, assessment, dissemination, implementation, decision making, impact and information on further research based on the results. To avoid duplication of work within the European HTA field, and to provide the decision makers with timely and accurate information, it is essential for the HTA agencies to have access to

- information on ongoing and planned HTA projects and HTA results,

- information regarding methodologies and
- information regarding the processes of dissemination and implementation.

Currently, this information is collected and distributed in different ways within the member countries of the European Union.

Besides the information on HTA projects and HTA publications produced by the member agencies of INAHTA, the information is often collected and distributed in an unstructured way. To help strengthen the existing collaboration between HTA agencies, it is recommended that systems for collecting and providing information on all these aspects are established.

2. Improvement and further development of the HTA Database are recommended rather than establishing a new database for HTA projects and results.

This study has underlined the quality and importance of the HTA Database (formerly the INAHTA database). The clearinghouse should participate in organising future developments of the HTA Database

Improvements of the HTA Database - suggestions:

- more standardised and structured descriptions of studies(see item 3)
- inclusion of links to websites of (all) involved agencies/institutions
- inclusion of expected deadline of ongoing projects
- inclusion of link to fulltext version of all HTA reports
- inclusion of information on dissemination, implementation, decisions and further research following the HTA results/report
- inclusion of date of last update of information
- increase the frequency of updating (see item 4)
- possibility of accessing the database in other languages than English

International input is essential for the development of European HTA results, and close collaboration with existing HTA networks (e.g. INAHTA) is important.

INAHTA "co-funds" the NHS Centre for Reviews and Dissemination (NHS CRD) in York, UK for producing and updating the HTA Database. The NHS Centre for Reviews and Dissemination in York, UK has a number of employees with experience in database structure and database updating procedures etc. It is necessary to stress that further development of the HTA Database, as recommended by this study, would require resources independent from INAHTA. Close collaboration between the secretariat of the clearinghouse and NHS CRD could be beneficial for developing procedures to help assure that the information is collected, managed and disseminated in the best possible way.

3. The clearinghouse should assist the agencies in developing standards for structuring the descriptions of ongoing HTA projects and results

The information on HTA projects and results in the HTA Database (INAHTA database) is structured in different ways, and not all relevant information is available in all records. For a systematic comparison of projects, it is necessary to structure information in the database in the same way. This includes standardised abstracts, keywords and information about methodology of study (according to recommendations/output from ECHTA Working Group 4). A common understanding of methodology is necessary in comparing and understanding the results of HTA projects.

Development of a filter of minimum requirements for project descriptions to be included in the database is recommended. The clearinghouse should initiate the discussion and development of such a filter.

4. The clearinghouse should develop methods for collecting information on HTA activities from European HTA agencies.

Non-compliance from the agencies in submission of data to the HTA Database (INAHTA database) is influencing the updates of the information in the HTA Database. The recent update in January 2001 of the HTA Database had a response rate of 73% of the requested INAHTA member agencies (HTA Database Update 2001).

One method of improving the frequency of updating could be to develop an electronic form for submitting information. Another could be to develop an electronic reminder system for updating the information. Developing electronic forms/systems to be used by the agencies when submitting and updating information regarding their HTA projects and publications would:

- encourage the agencies to provide the information on a regular basis
- give the same structure to the information in all records
- help automate some of the routine procedures regarding updating the database – e.g. the program/system could send out a reminder to the agency when it is time to update.

The database could be updated more frequently since all the records would not need to be updated at the same time. The frequency could be determined with regard to the duration of each project.

In return for project descriptions submitted by the agencies, the clearinghouse might provide a systematic analysis – a critical appraisal – of the project descriptions. The analysis should follow the criteria for inclusion in the database (according to item 3). A similar function has been developed for the inclusion of studies in the Database of Abstracts of Reviews of Effectiveness (DARE), which is produced by The NHS Centre for Reviews and Dissemination in York, UK.

5. The clearinghouse should distribute information on HTA activities in accordance with the needs of the different actors in the field of HTA.

Different actors need different information. It is recommended that the clearinghouse develop methods for structuring the distribution of information according to the needs of the different target groups. One method could be to develop structured abstracts of HTA reports for different target groups – e.g. HTA agencies, health policy makers, health care professionals and the general public. Another method could be to develop an e-mail notification service to provide both doers and users of HTA with information on new and updated HTA activities. It is recommended to study the informational needs of the different target groups in more detail.

6. The clearinghouse should initiate collaboration with HTA programs and agencies in Europe that are currently non-members of INAHTA.

Information on ongoing, planned and completed HTA projects produced by non-members of INAHTA (at regional and local levels of the European Union countries, as well as HTA activities in the European countries outside the European Union) is often difficult to locate. By collecting and distributing this information – e.g. by inclusion in the HTA Database - the knowledge of European HTA activities would be increased, and duplication of HTA work could be reduced. 7. The clearinghouse should initiate further co-operation between existing databases and information sources regarding exchange of information on HTA activities.

To increase the knowledge of HTA, it is important that information on HTA activities is available through several sources. The co-operation between the HTA Database (INAHTA Database) and well-established bibliographic databases, such as the Cochrane Library, Medline and EMBASE should be facilitated. Also co-operation with other databases such as the International Health Technology Assessment Database (IHTA) and the ISTAHC database should be initiated.

Access to information sources concerning new and emerging technologies (e.g. the EuroScan database), priority setting etc. should be provided by the clearinghouse – for example by establishing and updating an Internet portal for information sources on HTA activities. The portal should provide an overview with an up-to-date description of the databases and links to the databases. Closer integration between, e.g. the EuroScan database and the HTA Database should be initiated, for example, by linking the descriptions of emerging technologies in the EuroScan database to descriptions in the HTA Database of HTA projects (and reports) that eventually will follow.

Where possible, the clearinghouse should establish access for HTA agencies to the databases requiring subscription, by making arrangements with the producers and providers of the databases.

Knowledge of database structures, indexing and searching principles etc. are essential for organising the collaboration among databases. Therefore, at least one person on the clearinghouse staff (or secretariat staff) should have a library and information science background. Also co-operation with, e.g. the members of the ISTAHC Special Interest Group on Information

Resources (SPIG-IR) would be beneficial. 8. The clearinghouse should initiate collaboration with existing organisations and networks

Initiatives to facilitate international collaboration among actors of HTA have increased in recent decades. EUR-ASSESS, HTA Europe, INAHTA (International Network of Agencies for Health Technology Assessment), ISTAHC (International Society of Technology Assessment in Health Care), the Cochrane Collaboration, the WHO Programme on Health Technology and PAHO (Pan American Health Organization) are a few of the organisations and networks involved in the field of HTA. Collaboration with these organisations and networks will bring added value to users of the European clearinghouse by exchanging information and experiences on methods, processes and results and by co-ordinating future activities.

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Appendix 1 – Participants of Working Group 2

Jose Asua (Co-chair)
Basque Office for Technology Assessment (Osteba)
Vitoria-Gasteiz, Spain

Kerstin Hagenfeldt (Co-chair)
SBU/Karolinska Hospital
Stockholm, Sweden

Malene Fabricius
Danish Centre for Evaluation and Health Technology Assessment,
DACEHTA (formerly DIHTA)
Copenhagen, Denmark

Wija Oortwijn
University Medical Centre Nijmegen
Nijmegen, The Netherlands

Sergio Belluci
Swiss science Council/Technology Assessment
Bern, Switzerland

Wilf Higgins
Hospital Planning Office, Department of Health and Children
Dublin, Ireland

Alessandro Liberati
Mario Negri
Milan, Italy

Berit Mørland
Norwegian Centre for Health Technology Assessment (SMM)
Oslo, Norway

Rachid Salmi
Université Victor Segalen Bordeaux
Bordeaux, France

Andrew Stevens
The University of Birmingham, Department of Public Health and Epidemiology
Birmingham, United Kingdom

Gabriel ten Velden
Health Council of the Netherlands
The Hague, The Netherlands

Subject: survey on priority setting and databases on HTA

Appendix 2 – Survey on priority setting and results of survey[52]

Dear Sir, Madam,

With this letter we request your participation in a survey about priority setting and databases on health technology assessment (HTA). All member states are faced with increasingly difficult choices and priorities. There is also evidence of ineffectiveness in how health systems operate within their local frameworks and priorities for HTA. To avoid unnecessary and wasteful duplication of work in HTA between member states and regions, it is important to have access to information, especially access to HTA projects, that have been or are being carried out at other HTA agencies. The survey consists of two parts: one focusing on priority setting for HTA and one focusing on databases on HTA. The part focusing on priority setting involves an update of the survey done as part of Subgroup on Priority Setting for HTA of the EUR-ASSESS project in 1995. The final product, a report offering guidance to those who wishes to set priorities, was published in a special issue of the International Journal of Technology Assessment in Health Care in 1997; 13(2). We send this survey to all (European) respondents to the survey performed in the EUR-ASSESS project and a few additional relevant European HTA agencies. This survey is being conducted as part of the European Collaboration for Health Technology Assessment (ECHTA) project. It was decided in the Working Group on Developing Systems for the Routine Exchange of Information between Programs to prepare a survey on priority setting processes and use of databases in different HTA agencies.

The Working Group contracted Wija Oortwijn (University of Nijmegen, the Netherlands) and Malene Fabricius (DIHTA, Denmark) to conduct the survey. The purposes of this survey are:

1. To gain insight in the present status of priority setting activities by different organisations;
2. To retrieve information about the use and usefulness of the EUR-ASSESS report concerning priority setting;
3. To collect information on the evaluation of different systems for priority setting;
4. To collect information on the use and usefulness of existing databases on HTA;
5. To collect information on methods of dissemination in relation to databases;
6. To evaluate the usefulness of the Health Technology Assessment (HTA) database (formerly the INAHTA database)

Based on the results of this survey we intend to perform a limited number of more in depth personal telephone interviews with some of the respondents of this survey. The results of the survey, the interviews and a literature review will be used to help to strengthen HTA-activities by promoting co-operation between established centres and activities of HTA in the European Member States. This can be done by sharing information on methods and results on priority setting activities, by improving the sharing of information on ongoing HTAs and results of HTAs and by overseeing the development and improvement of clearinghouse activities in all of

[52] Only the part of the survey regarding HTA databases is included in this report. Part on priority setting is presented in the priority setting report by W.J. Oortwijn.

these areas. We kindly ask you to return the survey to Malene Fabricius by the 1st of September 2000, at the latest. For this purpose you can use the enclosed envelope.

Thank you for your assistance.

Kind regards,
on behalf of all members of the working group,

Information Specialist Malene Fabricius
DIHTA
Amaliegade 13, P.O Box 2020
1012 Copenhagen K, Denmark

Dr. Wija Oortwijn
University Medical Centre Nijmegen
Department of MTA, 253
6500 HB Nijmegen, The Netherlands

ECHTA Project

Working group on developing systems for the routine exchange of information between programs

SURVEY

on

Priority setting and databases on health technology assessment in different countries

This survey is about priority setting and databases on health technology assessment (HTA) and therefore consists of two parts. Concerning the part on priority setting this survey involves an update of the survey done as part of Subgroup on Priority Setting for HTA of the EUR-ASSESS project in 1995. The survey as a whole will be used to help to strengthen HTA activities by promoting co-operation between established centres and activities of HTA in the European Member States.

General Information

1. Name of Organisation:

_____

_____

2. Name and email address of Person(s) completing the survey:

_____

_____

3a. Has your organisation implemented a priority setting procedure for health technology assessment (HTA)?

☐ NO ----> Do you know of an organisation (and responsible person) in your country that sets priorities for HTA?

If yes, please write the name(s) below.

_____

_____

☐ YES

3b. Does your agency use databases to collect information on HTA activities carried out at other HTA agencies or HTA programs?

☐ NO ----> Could you please state the reasons why your agency does not use databases?

_____

_____

☐ YES

If you have answered NO on both questions 3a and 3b, please return this survey to Malene Fabricius. Please use the enclosed envelope.

If you have answered question 3a with YES, please turn to the following page and answer part A of the survey.

If you have answered question 3b with YES, please turn to page 8 and answer part B of the survey.

Part B: Databases for Health Technology Assessment

In this survey "HTA database" is defined as a database containing information on HTA activities. The term does not include databases used in the process of carrying out an HTA.

1. Which of the following databases does your agency use to find information on HTA results and ongoing HTA activities? (please mark Ö as many as relevant)

The Cochrane Library
(http://www.update-software.com/cochrane/cochrane-frame.html)

EMBASE
(http://www.elsevier.nl/inca/publications/store/5/2/3/3/2/8/)

HealthSTAR
(http://www.nlm.nih.gov/pubs/factsheets/healthstar.html)

The Health Technology Assessment (HTA) database (formerly the INAHTA database)
(http://144.32.228.3/htahp.htm)

The ISTAHC database
(http://www.istahc.org/en/database.html)

Medline
(http://www.ncbi.nlm.nih.gov/entrez/query.fcgi)

Other (please specify name and www-link to description if available)
_____

Other (please specify name and www-link to description if available)
_____

2. How would you characterise the usefulness (regarding HTA information) of the databases (marked in question 1) concerning the following aspects?
(please mark on the scale of 1-5, 1 being "inadequate" and 5 being "excellent")

The Cochrane Library					
HTA relevant content	1	2	3	4	5
information on study design	1	2	3	4	5
search options	1	2	3	4	5
frequency of updating	1	2	3	4	5
overall impression	1	2	3	4	5

In what ways do you think the Cochrane Library could be improved regarding information on HTA activities?

_____

EMBASE					
HTA relevant content	1	2	3	4	5
information on study design	1	2	3	4	5
search options	1	2	3	4	5
frequency of updating	1	2	3	4	5
overall impression	1	2	3	4	5

In what ways do you think EMBASE could be improved regarding information on HTA activities?

_____

_____

HealthSTAR

HTA relevant content	1	2	3	4	5
information on study design	1	2	3	4	5
search options	1	2	3	4	5
frequency of updating	1	2	3	4	5
overall impression	1	2	3	4	5

In what ways do you think HealthSTAR could be improved regarding information on HTA activities?

_____

_____

The HTA Database (formerly the INAHTA database)

HTA relevant content	1	2	3	4	5
information on study design	1	2	3	4	5
search options	1	2	3	4	5
frequency of updating	1	2	3	4	5
overall impression	1	2	3	4	5

In what ways do you think the HTA Database could be improved regarding information on HTA activities?

_____

_____

The ISTAHC database

HTA relevant content	1	2	3	4	5
information on study design	1	2	3	4	5
search options	1	2	3	4	5
frequency of updating	1	2	3	4	5
overall impression	1	2	3	4	5

In what ways do you think the ISTAHC database could be improved regarding information on HTA activities?

_____

_____

Medline

HTA relevant content	1	2	3	4	5
information on study design	1	2	3	4	5
search options	1	2	3	4	5
frequency of updating	1	2	3	4	5
overall impression	1	2	3	4	5

In what ways do you think Medline could be improved regarding information on HTA activities?

_____

_____

Other (please specify name of database) _____

HTA relevant content	1	2	3	4	5
information on study design	1	2	3	4	5
search options	1	2	3	4	5
frequency of updating	1	2	3	4	5
overall impression	1	2	3	4	5

In what ways do you think the database could be improved regarding information on HTA activities?

_____

_____

Other (please specify name of database) _____

HTA relevant content	1	2	3	4	5
information on study design	1	2	3	4	5
search options	1	2	3	4	5
frequency of updating	1	2	3	4	5
overall impression	1	2	3	4	5

In what ways do you think the database could be improved regarding information on HTA activities?

_____

_____

3. How relevant are the listed databases as information sources regarding information on health technology assessment?

(Please mark the databases you use - starting with 1 as being most relevant)

The Cochrane Library	☐
EMBASE	☐
HealthStar	☐
The HTA Database	☐
The ISTAHC database	☐
Medline	☐
Other _____	☐
Other _____	☐

4. Information on current HTA projects and publications carried out at the INAHTA member agencies are included in The Health Technology Assessment (HTA) Database. If you are using the HTA Database, we would like your opinion on the advantages and disadvantages of the HTA Database.

What do you regard as the strengths of the HTA Database ?

_____

_____

What do you regard as the weaknesses of the HTA Database ?

_____

_____

5. As a supplement to the results of this survey sent to the INAHTA member agencies, we plan to send a survey to users of health technology assessments.

Do you know of a user of health technology assessments in your country, who is using databases of HTA activities ? If so, please write the person's name, institution and address below. Thank you.

_____
_____

Dissemination of information on HTA activities (in relation to databases)

Does your agency disseminate information on own HTA activities to the editors/producers of the following databases? (please mark √ as many as relevant)

	Ongoing HTA activities	HTA results
The Cochrane Library	☐	☐
EMBASE	☐	☐
HealthStar	☐	☐
The HTA Database	☐	☐
The ISTAHC database	☐	☐
Medline	☐	☐
Other _____	☐	☐
Other _____		

Does your agency provide the information on own HTA activities to the databases on a regular basis or upon request only?

	Regular basis	Upon request only
The Cochrane Library	☐	☐
EMBASE	☐	☐
HealthStar	☐	☐
The HTA Database	☐	☐
The ISTAHC database	☐	☐
Medline	☐	☐
Other _____	☐	☐
Other _____	☐	☐

Thank you very much for completing part B of the survey on HTA databases

If you like to contribute any additional comments that you may have regarding the survey, setting priorities for HTA, databases on HTA or any other topic of interest, please write it down in the space below.

Thank you very much for all your help.

Please return the survey by the 1st of September, 2000 to Malene Fabricius by using the enclosed envelope. Thank you.

Appendix 3– Results of survey sent to HTA agencies

Table 1 Surveyed organisations, response and use of databases

Organisation	Country	INAHTA member	Responded	Uses databases
ITA	Austria	Yes	Yes	Yes
CUL, School of Public Health	Belgium	No	Yes	No
AZ-BUV	Belgium	No	No	-
Ministry Pub. Health	Belgium	No	Yes	No
LCM	Belgium	No	Yes	Yes
MTV-enheden, Aarhus	Denmark	No	Yes	Yes
DIHTA [53]	Denmark	Yes	Yes	Yes
DSI	Denmark	Yes	No	-
FINOHTA	Finland	Yes	Yes	Yes
ANAES	France	Yes	Yes	Yes
CEDIT	France	Yes	No	-
DAHTA@DIMDI	Germany	Yes	Yes	No
CHESME	Greece	No	Yes	Yes
Hospital Planning Office	Ireland	No	No	-
Azienda Provinciale	Italy	No	No	-
IGSS	Luxembourg	No	Yes	Yes
SMM	Norway	Yes	Yes	Yes
National School PH	Portugal	No	No	-
Osteba	Spain	Yes	Yes	Yes
AETS	Spain	Yes	Yes	Yes
CAHTA	Spain	Yes	Yes	Yes
AETSA	Spain	Yes	Yes	Yes
CMT	Sweden	No	No	-
SBU	Sweden	Yes	Yes	Yes
FSIOS	Switzerland	Yes	No	-
SWISS/TA	Switzerland	Yes	Yes	No
CVZ	The Netherlands	Yes	No	-
Health Council	The Netherlands	Yes	Yes	Yes
MW-NWO	The Netherlands	Yes	Yes	Yes
TNO PG	The Netherlands	Yes	Yes	Yes
NHS CRD	United Kingdom	Yes	No	-
NCCHTA	United Kingdom	Yes	Yes	Yes
NHSC	United Kingdom	Yes	Yes	Yes
NICE	United Kingdom	Yes	Yes	Yes
NHS Dept. of Health	United Kingdom	No	No	-

[53] Per April 1st, 2001 Danish Centre for Evaluation and Health Technology Assessment

Table 2 Use of databases

Respondent	The Cochrane Library	Embase	HealthStar	HTA database	ISTAHC	Medline	Other	Other
ITA	x		x	x	x	x	DARE	NHS EED
CUL								
AZ-BUV								
Min.Pub.Health								
LCM	x		x			x		
HTA unit, Aarhus	x	x	x	x	x	x	CRD Databases: DARE, NHS EED, HTA	SBU alert
DIHTA	x	x	x	x	x	x	DIHTA's project database	
DSI								
FINOHTA	x		x	x		x	DARE	NEED
ANAES	x	x	x	x		x	Pascal	www.clearinghouse.gov, www.clinicaltrials.gov
CEDIT								
DAHTA@DIMDI	x	x	x	x	x	x	i.e. IHTA (ECRI)	Note [54]
CHESME		x				x	WHO database www.who.org	HealthGate www.healthgate.com
Hosp. Plan. Off. Azienda Provinc.								
IGSS	x			x	x	x		
SMM	x	x		x		x		
Nat. S. Pub Health								
Osteba	x	x	x	x	x	x	NHS CRD databases	www.controlledtrials.com
AETS	x		x	x	x	x		
CAHTA	x	x	x	x	x	x	IME-Spanish Index Medicus	SciSearch
AETSA	x	x	x	x	x	x		
CMT								
SBU	x	x	x	x	x	x		
FSIOS								
SWISS/TA								
CVZ								
Health Council	x	x	x	x	x	x		
MW-NWO	x	x	x	x	x	x		
TNO PG	x	x	x	x	x	x		
NHS CRD								
NCCHTA	x	x	Note[55]	x		x	Wide variety of sources.	
NHSC	x			x			Note [56]	
NICE	x	x	x	x	x	x		
NHS DOH								

[54] For each topic the databases are selected out of a pool of 100 biomedical databases as specified in a SOP, using the grips retrieval system
[55] Now part of MEDLINE
[56] individual agency sites such as CCOHTA, SBU, ASERNIP-S ect.

Table 3 Use and usefulness of the Cochrane Library

Aspects are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent".

Respondent	HTA relevant content	Study design	Search options	Frequency of updating	Overall impression	Suggested improvements
ITA	1	5	4	4	3	
CUL						
AZ-BUV						
Min.Pub.Health						
LCM	3	4	3	2	3	
HTA unit, Aarhus	4	4	3	3	4	
DIHTA	5	5	4	3	4	
DSI						
FINOHTA	2	5	3	3	3	
ANAES	3	4	2	3	3	Search options and indexing.
CEDIT						
DAHTA@DIMDI	4	5	2	3	3	Search facilities, HTA-links, updates, full text or executive summary in HTA database.
CHESME						
Hosp. Plan. Off.						
Azienda Provinc.						
IGSS	3	5	3	4	4	
SMM	5	5	5			Frequency of updating.
Nat. S. Pub Health						
Osteba	4	4	4	3	4	Frequency of updating and contents of the HTA reports.
AETS	3	1	1	2	3	Frequency of updating.
CAHTA	5	5	3	3	5	
AETSA	4	5	4	5	5	Faster updates of INAHTA reports.
CMT						
SBU	4	4	4	2	4	
FSIOS						
SWISS/TA						
CVZ						
Health Council	4	5	4	4	4	
MW-NWO	4	4	4	4	5	
TNO PG	4	4	3	4	4	
NHS CRD						
NCCHTA	4	4	3	3	5	More reviews, cost data, cost-utility analyses.
NHSC	5	4	5	5	5	
NICE	5	5	4	4	5	
NHS DOH						

Table 4 Use and usefulness of EMBASE

Aspects are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent".

Respondent	HTA relevant content	Study design	Search options	Frequency of updating	Overall impression	Suggested improvements
ITA						
CUL						
AZ-BUV						
Min.Pub.Health						
LCM						
HTA unit, Aarhus						We don't search Embase ourselves. The State and University Library in Denmark does it for us.
DIHTA	3	3	3	5	3	
DSI						
FINOHTA						
ANAES	3	4	5	5	4	
CEDIT						
DAHTA@DIMDI	3	1	4	4	4	Full text or link to full text.
CHESME			4	5	4	
Hosp. Plan. Off.						
Azienda Provinc.						
IGSS						
SMM						
Nat. S. Pub Health						
Osteba	3	2	4	4	3	Including more HTA reports.
AETS	4	3	4	5	4	
CAHTA	5	4	5	5	5	
AETSA	3	2	2	3	3	
CMT						
SBU	3	2	4	4	4	
FSIOS						
SWISS/TA						
CVZ						
Health Council	3	2	4	4	3	
MW-NWO	4	4	3	4	4	
TNO PG	3	3	2	3	3	
NHS CRD						
NCCHTA	3	2	4	4	3	Better indexing – it is "over-indexed" with keywords used which are not really justified.
NHSC	4	4	3	4	3	
NICE	3	3	5	4	4	
NHS DOH						

Table 5 Use and usefulness of HealthSTAR

Aspects are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent".

Respondent	HTA relevant content	Study design	Search options	Frequency of updating	Overall impression	Suggested improvements
ITA	4	2	4		5	
CUL						
AZ-BUV						
Min.Pub.Health						
LCM	4	4	4	4	4	
HTA unit, Aarhus			3			
DIHTA	5	3	3	5	3	
DSI						
FINOHTA	4	3	3	3	3	
ANAES	3	2	5	3	3	
CEDIT						
DAHTA@DIMDI	2	2	3	4	2	
CHESME						
Hosp. Plan. Off.						
Azienda Provinc.						
IGSS						
SMM						
Nat. S. Pub Health						
Osteba	4	4	4	3	3	
AETS	4	2	2	3	3	
CAHTA	5	3	5	5	5	Trying that all HTA agencies submit its abstracts to the database, according to standards that focus on methodological terms.
AETSA	4	3	4	4	4	
CMT						
SBU	3	3	3	3	3	
FSIOS						
SWISS/TA						
CVZ						
Health Council	3	2	3	3	3	
MW-NWO	4	4	4	4	4	
TNO PG	3	2	3	3	3	
NHS CRD						
NCCHTA						N/A – now in Medline and NLM catalogues, but meeting abstracts are currently lost.
NHSC	3	3	3	3	3	
NICE	3	3	5	4	4	
NHS DOH						

Table 6 Use and usefulness of The HTA Database (formerly the INAHTA database)

Aspects are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent".

Respondent	HTA relevant content	Study design	Search options	Frequency of updating	Overall impression	Suggested improvements
ITA	5	2	2	3	4	
CUL						
AZ-BUV						
Min.Pub.Health						
LCM						
HTA unit, Aarhus	5	3	4	3	4	
DIHTA	5	4	3	4	4	Possible to save and run strategies
DSI						
FINOHTA	5	5	1	1	2	
ANAES	5	4	3	2	3	To increase the frequency of updating.
CEDIT						
DAHTA@DIMDI	5	3	2	2	3	Abstracts for projects and executive summaries in English, links to full text.
CHESME						
Hosp. Plan. Off.						
Azienda Provinc.						
IGSS	5	4	4	3	4	
SMM	4-5	4-5	4-5	4-5	4-5	
Nat. S. Pub Health						
Osteba	5	4	4	3	4	Increasing the frequency of updating.
AETS	4	2	2	1	2	
CAHTA	5	3	2	3	5	Note [57]
AETSA	5	4	5	4	4	More effort in the structured abstracts, peer reviewed?
CMT						
SBU	3	3	3	3	3	
FSIOS						
SWISS/TA						
CVZ						
Health Council	4	2	4	3	3	
MW-NWO	5	4	5	4	5	
TNO PG	4	4	3	3	4	
NHS CRD						
NCCHTA	5	5	5	4	5	
NHSC	4	2	3	3	3	
NICE	5	4	4	4	4	
NHS DOH						

[57] Trying that all HTA agencies submit its abstracts to the database, according to standards that focus on methodological tems - and that all those HTA agencies that do not belong to the INAHTA submit their reports to the INAHTA database

Table 7 Use and usefulness of The ISTAHC database

Aspects are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent".

Respondent	HTA relevant content	Study design	Search options	Frequency of updating	Overall impression	Suggested improvements
ITA	5	1	2	1	2	
CUL						
AZ-BUV						
Min.Pub.Health						
LCM						
HTA unit, Aarhus	5	1	2		2	
DIHTA	5	2	2	3	3	Field searching, links to full text when possible.
DSI						
FINOHTA						
ANAES	5	2	3	2	4	
CEDIT						
DAHTA@DIMDI	4	3	2	2	2	
CHESME						
Hosp. Plan. Off.						
Azienda Provinc.						
IGSS	5	4	4	4	4	
SMM						
Nat. S. Pub Health						
Osteba	3	3	2	2	3	Improving the search options and frequency of updating.
AETS	4	2	2	1	2	
CAHTA	4	3	1		3	
AETSA	4	3	3	3	3	
CMT						
SBU						
FSIOS						
SWISS/TA						
CVZ						
Health Council	5	2	3	3	3	
MW-NWO	4	3	2		3	
TNO PG	4	3	3	3	3	
NHS CRD						
NCCHTA	5	2	1	2	3	Search options poor.
NHSC						
NICE	5	4	3-4	4	4	
NHS DOH						

Table 8 Use and usefulness of Medline

Aspects are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent".

Respondent	HTA relevant content	Study design	Search options	Frequency of updating	Overall impression	Suggested improvements
ITA	5	4	5	4	5	
CUL						
AZ-BUV						
Min.Pub.Health						
LCM	4	4	4	4	4	
HTA unit, Aarhus	4		5	4	4	
DIHTA	3	5	5	5	4	
DSI						
FINOHTA	2	3	5	5	3	
ANAES	5	5	5	4	4	
CEDIT						
DAHTA@DIMDI	3	3	5	5	4	
CHESME	4	4	5	5	4	
Hosp. Plan. Off.						
Azienda Provinc.						
IGSS	3	4	4	5	4	
SMM						
Nat. S. Pub Health						
Osteba	3	3	4	5	4	Including more HTA reports.
AETS	2	1	4	4	4	
CAHTA	5	4	5	5	5	
AETSA	3	3	3	4	4	
CMT						
SBU	3	3	3	3	3	
FSIOS						
SWISS/TA						
CVZ						
Health Council	3	2	5	5	4	
MW-NWO						
TNO PG	2	3	4	3	3	
NHS CRD						
NCCHTA	4	3	4	5	4	
NHSC	3	4	4	4	3	
NICE	5	5	5	5	5	
NHS DOH						

Table 9 Use and usefulness of other databases

Aspects are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent".

Respondent	Database	HTA relevant content	Study design	Search options	Frequency of updating	Overall impression	Suggested improvements
ITA	DARE	5	2	2	3	5	
CUL							
AZ-BUV							
Min.Pub.Health							
LCM							
HTA unit, Aarhus							
DIHTA							
DSI							
FINOHTA	DARE	4	5	1	1	3	
ANAES	PASCAL	2	3	1	2	2	
CEDIT							
DAHTA@DIMDI	IHTA	4	3	3	4	3	
CHESME	Healthgate	2	2	3	4	3	
Hosp. Plan. Off.							
Azienda Provinc.							
IGSS							
SMM							
Nat. S. Pub Health							
Osteba	NHS CRD	4	4	3	4	4	
AETS							
CAHTA	IME	3	1	2	1	3	It is useful to know the Spanish medical literature.
AETSA							
CMT							
SBU							
FSIOS							
SWISS/TA							
CVZ							
Health Council							
MW-NWO							
TNO PG							
NHS CRD							
NCCHTA	SCI	4	2	3	5	4	Better indexing by study design (eg. RCT or systematic reviews.
NHSC							
NICE							
NHS DOH							

Table 10 Use and usefulness of other databases

Aspects are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent".

Respondent	Database	HTA relevant content	Study design	Search options	Frequency of updating	Overall impression	Suggested improvements
ITA	NHS EED	4	2	2	3	4	
CUL							
AZ-BUV							
Min.Pub.Health							
LCM							
HTA unit, Aarhus							
DIHTA							
DSI							
FINOHTA	NEED	4	5	1	1	3	
ANAES	www.clearinghouse.gov	3	5	3	2	3	Search and update to be developed.
CEDIT							
DAHTA@DIMDI							
CHESME	WHO database	2	2	2	4	2	
Hosp. Plan. Off.							
Azienda Provinc.							
IGSS							
SMM							
Nat. S. Pub Health							
Osteba	www.controlledtrials.com	3	4	4	3	4	Giving more details about reports.
AETS							
CAHTA	SciSearch	5	3	5	5	5	
AETSA							
CMT							
SBU							
FSIOS							
SWISS/TA							
CVZ							
Health Council							
MW-NWO							
TNO PG							
NHS CRD							
NCCHTA	Cancerlit	4	5	3	4	4	
NHSC							
NICE							
NHS DOH							

Table 11 Relevancy of databases regarding HTA information

Aspects are marked on a scale of 1-5, 1 being "most relevant" and 5 being "less relevant".

Respondent	The Cochrane Library	EMBASE	HealthSTAR	The HTA Database	The ISTAHC database	Medline	Other	Other
ITA	2		1	1	2	1	DARE: 1	NHS EED: 2
CUL								
AZ-BUV								
Min.Pub.Health								
LCM	3		1			2		
HTA unit, Aarhus	1	4	5	2	6	3		
DIHTA	4	6	2	1	2	5		
DSI								
FINOHTA	5		4	1		6	DARE: 2	NHS EED: 3
ANAES	2	4	3	5		1		www.clearinghouse.gov: 6
CEDIT								
DAHTA@DIMDI	4	3b	8	1	5	2	IHTA: 3a	SciSearch: 7
CHESME	2					1	WHO: 4	Healthgate: 3
Hosp. Plan. Off. Azienda Provinc.								
IGSS	4			1	1	3		
SMM	2			1				
Nat. S. Pub Health								
Osteba	2	8	3	1	7	4	NHS R&D: 6	mRCT: 5
AETS	1		4	2	3	5		
CAHTA	2	5	4	3	6	1	IME: 7	SciSearch: 8
AETSA	2	5	4	1	6	3		
CMT	1		3	Included in Cochrane		2		
SBU								
FSIOS								
SWISS/TA								
CVZ								
Health Council	2	3	4	5	6	1		
MW-NWO	1	3	3	4	4	5	OCE/HEED: 5	
TNO PG	1	6	5	2	3	4		
NHS CRD								
NCCHTA	2	4	5	1	6	3	To many to list	
NHSC	1	4	5	2		3		
NICE	1	4	4	1	4	1		
NHS DOH								

Table 12 Strengths and weaknesses of the HTA Database

Respondent	Strengths	Weaknesses
ITA	Insight into current projects	Language barriers - Spanish, Scandinavian languages.
CUL		
AZ-BUV		
Min.Pub.Health		
LCM		
HTA unit, Aarhus		
DIHTA	International coverage.	Language coverage, the lack of "updating discipline" from HTA agencies, the inconsistency of detail information of the projects.
DSI		
FINOHTA	Content extensive, structured abstracts.	User interface poor, difficult searching, no possibility to collect hits from multiple pages and see full records, no saving possibility.
ANAES	Full text documents.	Update frequency.
CEDIT		
DAHTA@DIMDI	Overview of international HTA activities and projects.	Update frequency, offer no abstract or executive summary.
CHESME		
Hosp. Plan. Off.		
Azienda Provinc.		
IGSS	Complete, very suitable, correct interface.	
SMM	Very relevant for an HTA agency.	
Nat. S. Pub Health		
Osteba	The quality of the reports and the credibility of the agencies members of INAHTA. The importance of the information given and the accuracy of reports.	Frequency of updating.
AETS	It is the only HTA specific database.	Access online – not CD-ROM, small volume of information.
CAHTA	To search in a unique database, the most HTA reports of most the INAHTA agencies.	Not all the HTA agencies are rigorous in order to submit their abstracts to the database.
AETSA	Completeness, including all sorts of projects, not only systematic review, very useful for beginners.	Depending on information sent by agencies.
CMT		
SBU		
FSIOS		
SWISS/TA		
CVZ		
Health Council	Possibilities for exchange of reports and for sharing information.	Variation of usefulness.
MW-NWO		
TNO PG	It provides into the agencies programmes, including ongoing projects.	It depends to much on the voluntary contributions of individuals (including…
NHS CRD		
NCCHTA	Comprehensive list of INAHTA agency reports, many of which are not published.	
NHSC	Awareness of research activities in particular areas, inclusive , wide-range of agencies included links to own sites for whole HTA report in some cases.	Very hard to keep up to date, some data is old, no details of methodologies employed. Lack of complete information on individual reports which leads to time, often wasted, in trying to obtain complete reports.
NICE		
NHS DOH		

Table 13 Dissemination of information on HTA activities (in relation to databases)

	The Cochrane Library		EMBASE		HealthSTAR		The HTA Database		The ISTAHC database		Medline		Other	
Respondent	HTA activities	HTA results	HTA activities	HTA results	HTA activities	HTA results	HTA activities	HTA results	HTA activities	HTA results	HTA activities	HTA results	HTA activities	HTA results
ITA						x	x	x		x		x		
CUL														
AZ-BUV														
Min.Pub.Health														
LCM														
HTA unit, Aarhus													DIHTA	DIHTA
DIHTA						x	x	x						
DSI						x								
FINOHTA							x	x						
ANAES									x	x				
CEDIT														
DAHTA@DIMDI							x	x					IHTA	IHTA
CHESME														
Hosp. Plan. Off.														
Azienda Provinc.														
IGSS														
SMM							x	x						
Nat. S. Pub Health														
Osteba		x				x	x	x		x		x		
AETS		x					x	x	x	x				
CAHTA		x				x	x	x						
AETSA							x	x						
CMT														
SBU						x	x[58]	x						
FSIOS														
SWISS/TA														
CVZ														
Health Council							x	x		x				
MW-NWO														
TNO PG							x	x						
NHS CRD														
NCCHTA		Note[59]						x				x[60]		
NHSC		x[61]						x					Note[62]	
NICE								x						
NHS DOH														

[58] Included in Cochrane.
[59] Occasionally if reviews can be converted into Cochrane forms.
[60] HTA monograph series is indexed.
[61] Via York.
[62] NICE website disseminates information.

Table 14 Dissemination of information on a regular basis or upon request

	The Cochrane Library		EMBASE		HealthSTAR		The HTA Database		The ISTAHC database		Medline		Other	
Respondent	Regular basis	Upon request only	Regular basis	Upon request only	Regular basis	Upon request only	Regular basis	Upon request only	Regular basis	Upon request only	Regular basis	Upon request only	Regular basis	Upon request only
ITA							x							
CUL														
AZ-BUV														
Min.Pub.Health														
LCM														
HTA unit, Aarhus													DIHTA.dk	
DIHTA					x		x							
DSI					x									
FINOHTA							x							
ANAES									x					
CEDIT														
DAHTA@DIMDI							x						IHTA	
CHESME														
Hosp. Plan. Off.														
Azienda Provinc.														
IGSS														
SMM							x							
Nat. S. Pub Health														
Osteba	x	x		x	x		x	x		x	x	x		
AETS	x						x		x					
CAHTA	x				x		x							
AETSA							x							
CMT														
SBU					x		x							
FSIOS														
SWISS/TA														
CVZ														
Health Council							x		x					
MW-NWO														
TNO PG							x	x						
NHS CRD														
NCCHTA		x		x		x	x			x		x		
NHSC [63]														
NICE														
NHS DOH														

[63] Never had a request yet. We would provide to anybody if asked.

Appendix 4 Name of surveyed HTA organisations and responding persons – Part B on databases

1	Dr. Claudia Wild *HTA Unit of the Institute of Technology Assessment (ITA)* *Austria*
2	Prof., dr. Katrien Kesteloot *School of Public Health, Catholic University Leuven* *Belgium*
3	Information Specialist, Librarian *AZ-VUB* *Belgium*
4	Mr. Etienne Pelfrene *Dept. Social Affairs & Public Health, Ministry of Health* *Belgium*
5	Dr. Robert van den Oever *LCM - Alliance Nationale des Mutualites Chretiennes* *Belgium*
6	Ms. Bodil Wahlstrøm *MTV-enheden, Aarhus University Hospital* *Denmark*
7	Inf. Spec. Malene Fabricius Jensen *Danish Institute for Health Technology Assessment (DIHTA)* *Denmark*
8	Librarian Ilse Schødt *Danish Institute for Health Services Research and Development (DSI)* *Denmark*
9	Mr. Kristian Lampe *Finnish Office for Health Care Technology Assessment (FINOHTA) Stakes* *Finland*
10	Dr. B. Xerri *L'Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES)* *France*
11	Information Specialist, Librarian *Comité d'Evaluation et de Diffusion des Innovations Technologiques Assistance (CEDIT)* *France*
12	Dr. Alric Rüther & Dr. H-P. Dauben *German Agency for HTA at the German Institute for Medical Documentation and Information (DAHTA@DIMDI)* *Germany*
13	Prof. L. Liaropoulos *Center for Health Services Management and Evaluation (C.HE.S.M.E)* *Greece*
14	Information Specialist, Librarian *Hospital Planning Office, Department of Health and Children* *Ireland*
15	Information Specialist, Librarian *Azienda Provinciale per i Servizi Sanitari* *Italy*
16	Dr. Danielle Hanse-Koenig *Direction de la Sante, IGSS* *Luxembourg*
17	Information Advisor Berit Kolberg Rossiné *Norwegian Centre for Health Technology Assessment (SMM)* *Norway*

18	Information Specialist, Librarian *National School of Public Health, Nova University, Lisboa* *Portugal*
19	Documentation manager, Dr. Iñaki Gutierrez-Ibarluzea *Basque Office for Health Technology Assessment (OSTEBA)* *Spain*
20	Documentation Chief, Dr. Antonio Hernandez-Torres *Agencia de Evaluacion de Tecnologias Sanitarias (AETS)* *Spain*
21	Documentalista Antoni Parada Martinez *Catalan Agency for Heatlh Technology Assessment (CAHTA)* *Spain*
22	Dr. Eduardo Briones *Agencia de Evaluación de Tecnologías Sanitarias de Andalucia (AETSA)* *Spain*
23	Information Specialist, Librarian *Centrum för utvärdering av medicinsk teknologi (CMT)* *Sweden*
24	Information Scientist Viveka Alton / Dr. Helena Dahlgren *Swedish Council on Technology Assessment in Health Care (SBU)* *Sweden*
25	Information Specialist, Librarian Medical Technology Unit *Federal Social Insurance Office Switzerland (FSIOS)* *Switzerland*
26	Dr. Sergio Belluci *Swiss Science Council/Technology Assessment (SWISS/TA)* *Switzerland*
27	Information Specialist / Librarian *Health Care Insurance Board (CVZ)* *The Netherlands*
28	Dr. Gabriel HM ten Velden *Health Council of the Netherlands* *The Netherlands*
29	Dr. H.L. Hoeksema *Netherlands Organization for Scientific Research, Council for Medical and Health Research (MW-NWO)* *The Netherlands*
30	Dr. Take Van Beekum *TNO Prevention and Health* *The Netherlands*
31	Information Services Manager *Julie Glanville* *NHS Centre for Reviews and Dissemination (NHSCRD)* *United Kingdom*
32	Information Scientist Pam Royle *National Coordinating Centre for Health Technology Assessment (NCCHTA)* *United Kingdom*
33	Ms. Claire Packer *National Horizon Scanning Center (NHSC)* *United Kingdom*
34	Dr. Rod Taylor *National Institute for Clinical Excellence (NICE)* *United Kingdom*
35	Information Specialist / Librarian *Research and Development Directorate NHS* *Department of HealthUnited Kingdom*

Appendix 5 Survey sent to users of HTA results

Subject: survey on databases on health

Dear name of respondent,
With this letter we ask for your participation in a survey about databases on health technology assessment (HTA). All member states are faced with increasingly difficult choices and priorities. To avoid unnecessary and wasteful duplication of work in HTA between member states and regions, it is important to have access to information, especially access to HTA projects that have been or are being carried out at other HTA agencies.

In August 2000, a survey was sent to European HTA agencies, to study their use and usefulness of databases on HTA information. In addition, the agencies were asked to provide the name of a person within their country, who is using databases on HTA results and ongoing projects.

Your name has been provided by **name of agency**, and we kindly ask for your participation in this survey, which is being conducted as part of the European Collaboration for Health Technology Assessment (ECHTA) project.

The purposes of this survey are:

- to collect information on the use and usefulness of existing databases on HTA from the HTA users' point of view;
- to evaluate the usefulness of the Health Technology Assessment (HTA) database (formerly the INAHTA database).

The results of this survey, the survey sent to the European HTA agencies, and a literature review will be used to help to strengthen HTA-activities by promoting co-operation between established centres and activities of HTA in the European Member States.

We kindly ask you to return the survey to Malene Fabricius by e-mail (mfj@sst.dk) or by fax (+45 33 48 75 37) by the 15th of May 2001, at the latest.

Thank you for your assistance.

Kind regards,
on behalf of all members of the working group,

Information Specialist Malene Fabricius
Centre for Evaluation and Health Technology Assessment (formerly DIHTA)
P.O.Box 2020
Amaliegade 13
DK-1012 Copenhagen K
Denmark
Tel. +45 33 48 74 35
Fax +45 33 48 75 37
E-mail mfj@sst.dk

ECHTA Project

Working group on developing systems for the routine exchange of information between programs

SURVEY

on

Databases on health technology assessment

This survey is about the use and usefulness of databases on health technology assessment (HTA).

The survey will be used to help to strengthen HTA activities by promoting co-operation between established centres and activities of HTA in the European Member States.

General Information

1. Name of person completing the survey:

_____

_____

2. Name and address of institution:

_____

_____

3. Do you use databases to collect information on HTA activities carried out at HTA agencies or HTA programs ?

☐ NO ----> Could you please state the reasons why not?

_____

_____

☐ YES

If you have answered NO on question 3, please return this survey to Malene Fabricius by e-mail (mfj@sst.dk) or by fax +45 33 48 75 37.

If you have answered YES on question 3, please turn to the following page and answer the questions.

Databases for Health Technology Assessment

In this survey "HTA database" is defined as a database containing information on HTA activities. The term does not include other databases used in the process of carrying out an HTA.

The databases included in this survey have been identified as useful for collecting information on HTA results and ongoing HTA activities by analysing the results of a survey sent to European HTA agencies in August 2000, and by a literature review.

4. Which of the following databases do you use to find information on HTA results and ongoing HTA activities ? (please mark Ö as many as relevant)

The Cochrane Library
(http://www.update-software.com/cochrane/cochrane-frame.html)

HealthSTAR
(http://gateway.nlm.nih.gov)

The Health Technology Assessment (HTA) database (formerly the INAHTA database)
(http://144.32.228.3/htahp.htm)

International Health Technology Assessment (IHTA) database
(http://www.dimdi.de)

Medline
(http://www.ncbi.nlm.nih.gov/entrez/query.fcgi)

5. Do you use the Cochrane Library for any of the following activities?
(please mark √ as many as relevant)

clinical decision making ☐

clinical guideline development ☐

policy making ☐

research purposes ☐

other (please specify) ☐

_____

_____

6. How would you characterise the usefulness (regarding HTA information) of the Cochrane Library concerning the following aspects?
(please mark on the scale of 1-5, 1 being "inadequate" and 5 being "excellent")

The Cochrane Library

- relevancy as input for activities
  stated in question 5 ☐1 ☐2 ☐3 ☐4 ☐5
- validity/reliability of information ☐1 ☐2 ☐3 ☐4 ☐5
- structure of information ☐1 ☐2 ☐3 ☐4 ☐5
- overall impression ☐1 ☐2 ☐3 ☐4 ☐5

In what ways do you think the usefulness of the Cochrane Library could be improved regarding HTA information?

_____

_____

_____

5. Do you use HealthStar for any of the following activities?
(please mark √ as many as relevant)

clinical decision making	☐
clinical guideline development	☐
policy making	☐
research purposes	☐
other (please specify)	☐

_____

_____

6. How would you characterise the usefulness (regarding HTA information) of HealthStar concerning the following aspects?
(please mark on the scale of 1-5, 1 being "inadequate" and 5 being "excellent")

HealthStar

• relevancy as input for activities stated in question 7	1	2	3	4	5
• validity/reliability of information	1	2	3	4	5
• structure of information	1	2	3	4	5
• overall impression	1	2	3	4	5

In what ways do you think the usefulness of HealthStar could be improved regarding HTA information?

_____

_____

_____

5. Do you use The Health Technology Assessment (HTA) database for any of the following activities?
(please mark √ as many as relevant)

clinical decision making	☐
clinical guideline development	☐
policy making	☐
research purposes	☐
other (please specify)	☐

_____

_____

6. How would you characterise the usefulness (regarding HTA information) of The Health Technology (HTA) database concerning the following aspects?
(please mark on the scale of 1-5, 1 being "inadequate" and 5 being "excellent")

The Health Technology Assessment (HTA) database

• relevancy as input for activities stated in question 9	1	2	3	4	5
• validity/reliability of information	1	2	3	4	5
• structure of information	1	2	3	4	5
• overall impression	1	2	3	4	5

In what ways do you think the usefulness of The Health Technology Assessment (HTA) database could be improved regarding HTA information?

_____

_____

_____

5. Do you use the International Health Technology Assessment (IHTA) database for any of the following activities?
(please mark √ as many as relevant)

clinical decision making	☐
clinical guideline development	☐
policy making	☐
research purposes	☐
other (please specify)	☐

_____

_____

6. How would you characterise the usefulness (regarding HTA information) of the International Health Technology Assessment (IHTA) database concerning the following aspects?
(please mark on the scale of 1-5, 1 being "inadequate" and 5 being "excellent")

IHTA database

• relevancy as input for activities	1	2	3	4	5
stated in question 11	1	2	3	4	5
• validity/reliability of information	1	2	3	4	5
• structure of information	1	2	3	4	5
• overall impression	1	2	3	4	5

In what ways do you think the usefulness of the International Health Technology Assessment (HTA) database could be improved regarding HTA information?

_____

_____

_____

5. Do you use Medline (PubMed) for any of the following activities?
(please mark √ as many as relevant)

clinical decision making	☐
clinical guideline development	☐
policy making	☐
research purposes	☐
other (please specify)	☐

_____

_____

6. How would you characterise the usefulness (regarding HTA information) of Medline (PubMed) concerning the following aspects?
(please mark on the scale of 1-5, 1 being "inadequate" and 5 being "excellent")

Medline (PubMed)

• relevancy as input for activities stated in question 13	1 2 3 4 5
• validity/reliability of information	1 2 3 4 5
• structure of information	1 2 3 4 5
• overall impression	1 2 3 4 5

In what ways do you think the usefulness of Medline (PubMed) could be improved regarding HTA information?

_____

_____

_____

5. How relevant are the listed databases as information sources regarding information on health technology assessment?
(Please mark the databases you use - starting with 1 as being most relevant)

The Cochrane Library	☐
HealthStar	☐
The HTA Database	☐
IHTA database	☐
Medline (PubMed)	☐

Information on current HTA projects and publications carried out at member agencies of the International Network of Health Technology Assessment (INAHTA) is included in The Health Technology Assessment (HTA) Database (formerly the INAHTA database). If you are using this database, we would like you to answer the following questions in addition to the answers given in questions 9-10:

6. Do the descriptions of the HTA results and projects in the database provide you with sufficient information for decision making?

☐ NO---->Please specify

_____

_____

_____

☐ YES

5. What do you regard as the strengths of the HTA Database ?

_____

_____

6. What do you regard as the weaknesses of the HTA Database ?

_____

_____

7. Do you find it important to exchange information on HTA results and ongoing HTA projects between HTA agencies?

YES, (please mark √ as many as relevant and specify below):

☐ at a national (incl. regional and local) level

☐ at an European level

☐ at an international level

_____

_____

☐ NO - please specify:

_____

_____

5. Do you think that the establishment of an European (or international) clearing house could be beneficial in co-ordinating the exchange of information on HTA activities ?

☐ YES - please specify:

_____

_____

☐ NO - please specify:

_____

_____

Thank you very much for completing this survey.

If you would like to contribute with any additional comments, please write it below:

_____

_____

_____

_____

_____

Please return the survey to Malene Fabricius by e-mail (mfj@sst.dk) or by fax +45 33 48 75 37 by the 15th of May, 2001 at the latest.

Appendix 6 Results of survey sent to users of HTA results

The survey was sent to 8 users of HTA results from a administrative/political setting or a clinical/university in 7 European countries.

In Table 1 the name and organisation of the surveyed persons are listed, indicating whether they responded to the survey, whether they come from a administrative/political or a clinical/university setting, and whether they use databases.

Table 1. Name and organisation of surveyed users of HTA results

Respondent	Organisation	Country	Setting	Responded	Uses databases
Dr. Jean-Paul Dercq	Ministry of Social Affairs, Public Health and the Environment, Brussels	Belgium	Administrative/ political	No	-
Dr. Olli-Pekka Ryynänen	University of Kuopio	Finland	Clinical/ university	No	-
Dr. Mary Geitona	Dept. of Health Economics, National School of Public Health, Athens	Greece	Clinical/ university	Yes	No
Prof. Olav H. Førde	Institutt for Samfunnsmedi-sin, University of Tromsø	Norway	Clinical/ university	Yes	Yes
Director, Dr. Alfredo Rodríguez-Antigüedad Zarranz	Departemento di Sanidad del Gobierno Vasco, Vitoria-Gasteiz	Spain	Administrative/ political	Yes	Yes
Marta Roqué & Miren Fernandez (on behalf ofDirector Xavier Bonfill)	Iberoamerican Cochrane Center, Barcelona	Spain	Clinical/ university	Yes	Yes
Dr. Rob van der Sande	Raad vor Gezondheidsonderzoek – RGO, The Hague	The Netherlands	Administrative/ political	Yes	Yes
Information Specialist Ruth Frankish	National Institute for Clinical Excel-lence (NICE)	United Kingdom	Administrative/ political	Yes	Yes

Table 2 Use of databases

The following databases have been included in the survey:

- The Cochrane Library
- HealthStar
- The Health Technology Assessment (HTA) database (formerly the INAHTA database)
- The International Health Technology Assessment (IHTA) database
- Medline (PubMed)

Respondent	The Cochrane Library	HealthStar	HTA database	IHTA database	Medline	Doesn't uses databases
Dr. Jean-Paul Dercq						
Dr. Olli-Pekka Ryynänen						
Dr. Mary Geitona						x
Prof. Olav H. Førde	x		x			
Director, Dr. Alfredo Rodríguez-Antigüedad Zarranz	x		x			
Marta Roqué & Miren Fernandez	x		x			
Dr. Rob van der Sande	x		x		x	
Information Specialist Ruth Frankish	x		x		x	

Table 3 Use and usefulness of the Cochrane Library

Aspects regarding relevancy, validity/reliability, structure of information, overall impression are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent"

Respondent	Used for clinical decision making	Used for clinical guideline development	Used for policy making	Used for research purposes	Used for other activities	Relevancy of database for stated activities	Validity/ Reliability of information	Structure of information	Overall impression	Comments
Dr. Jean-Paul Dercq										
Dr. Olli-Pekka Ryynänen										
Dr. Mary Geitona										
Prof. Olav H. Førde			x	x		2	3	3	3	
Director, Dr. Alfredo Rodríguez-Antigüedad Zarranz		x	x	x		5	5	3	4	
Marta Roqué & Miren Fernandez	x	x		x		3	4	5	4	x[64]
Dr. Rob van der Sande			x			2	4	4	4	
Information Specialist Ruth Frankish	x	x		x		5	3	4	4	

[64] It's a good resource to identify HTA reports, but it would be more useful if all reports were in full text or at least with objectives and an abstract. Information is presented non-homogeneously. A link to full text of reports (not just to the HTA web) would be necessary. Drawback of Cochrane Library is the incompleteness of thesaurus coding

Table 4 Use and usefulness of HealthStar

Aspects regarding relevancy, validity/reliability, structure of information, overall impression are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent"

Respondent	Used for clinical decision making	Used for clinical guideline development	Used for policy making	Used for research purposes	Used for other activities	Relevancy of database for stated activities	Validity/ Reliability of information	Structure of information	Overall impression	Comments
Dr. Jean-Paul Dercq										
Dr. Olli-Pekka Ryynänen										
Dr. Mary Geitona										
Prof. Olav H. Førde										
Director, Dr. Alfredo Rodríguez-Antigüedad Zarranz										
Marta Roqué & Miren Fernandez										
Dr. Rob van der Sande										
Information Specialist Ruth Frankish										

Table 5 Use and usefulness of the HTA Database

Aspects regarding relevancy, validity/reliability, structure of information, overall impression are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent"

Respondent	Used for clinical decision making	Used for clinical guideline development	Used for policy making	Used for research purposes	Used for other activities	Relevancy of database for stated activities	Validity/ Reliability of information	Structure of information	Overall impression	Comments
Dr. Jean-Paul Dercq										
Dr. Olli-Pekka Ryynänen										
Dr. Mary Geitona										
Prof. Olav H. Førde			x		x[65]	3	2	2-3	3	
Director, Dr. Alfredo Rodríguez-Antigüedad Zarranz		x	x	x		3	3	4	3	
Marta Roqué & Miren Fernandez	x	x		x		5	5	3	4	x[66]
Dr. Rob van der Sande			x			2	4	4	4	
Information Specialist Ruth Frankish	x	x		x		5	3	3	3	

[65] Teaching

[66] It's a good resource to identify HTA reports, but it would be more useful if all reports were in full text or at least with objectives and an abstract. Information is presented non-homogeneously. A link to full text of reports (not just to the HTA web) would be necessary. Drawback of The HTA database is the incompleteness of thesaurus coding

Table 6 Use and usefulness of The IHTA database

Aspects regarding relevancy, validity/reliability, structure of information, overall impression are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent"

Respondent	Used for clinical decision making	Used for clinical guideline development	Used for policy making	Used for research purposes	Used for other activities	Relevancy of database for stated activities	Validity/ Reliability of information	Structure of information	Overall impression	Comments
Dr. Jean-Paul Dercq										
Dr. Olli-Pekka Ryynänen										
Dr. Mary Geitona										
Prof. Olav H. Førde										
Director, Dr. Alfredo Rodríguez-Antigüedad Zarranz										
Marta Roqué & Miren Fernandez										
Dr. Rob van der Sande										
Information Specialist Ruth Frankish										

Table 7 Use and usefulness of Medline

Aspects regarding relevancy, validity/reliability, structure of information, overall impression are marked on a scale of 1-5, 1 being "inadequate" and 5 being "excellent"

Respondent	Used for clinical decision making	Used for clinical guideline development	Used for policy making	Used for research purposes	Used for other activities	Relevancy of database for stated activities	Validity/ Reliability of information	Structure of information	Overall impression	Comments
Dr. Jean-Paul Dercq										
Dr. Olli-Pekka Ryynänen										
Dr. Mary Geitona										
Prof. Olav H. Førde										
Director, Dr. Alfredo Rodríguez-Antigüedad Zarranz										
Marta Roqué & Miren Fernandez										
Dr. Rob van der Sande			x			4	4	4	4	
Information Specialist Ruth Frankish	x	x		x		4	3	-	3	

Table 8 Relevancy of databases regarding HTA information

(1 being most relevant, 5 being less relevant)

Respondent	The Cochrane Library	HealthStar	HTA database	IHTA database	Medline	Doesn't use databases
Dr. Jean-Paul Dercq						
Dr. Olli-Pekka Ryynänen						
Dr. Mary Geitona						x
Prof. Olav H. Førde	2		1			
Director, Dr. Alfredo Rodríguez-Antigüedad Zarranz	1		2			
Marta Roqué & Miren Fernandez	2		1			
Dr. Rob van der Sande	3		2		1	
Information Specialist Ruth Frankish	1		2		3	

Table 9 Do the descriptions of the HTA results and projects in the HTA Database provide you with sufficient information for decision making?

Respondent	No,	because	Yes,	Doesn't use database
Dr. Jean-Paul Dercq				
Dr. Olli-Pekka Ryynänen				
Dr. Mary Geitona				x
Prof. Olav H. Førde	x	Not in relation to health policy		
Director, Dr. Alfredo Rodríguez-Antigüedad Zarranz			x	
Marta Roqué & Miren Fernandez	x	It allows only to identify interesting or promising reports		
Dr. Rob van der Sande	x	Most of our work concerns national priorities of HTA. Choices being made depend on more than information about HTA results and projects.		
Information Specialist Ruth Frankish	x	You need to get hold of the full publication most of the time; it is just part of the information that goes into any report		

Table 10 Strengths and weaknesses of the HTA Database

Respondent	Strengths	Weaknesses	Doesn't use the database
Dr. Jean-Paul Dercq			
Dr. Olli-Pekka Ryynänen			
Dr. Mary Geitona			x
Prof. Olav H. Førde	Easy access to systematic reviews	The methods are not standardised	
Director, Dr. Alfredo Rodríguez-Antigüedad Zarranz	-	-	
Marta Roqué & Miren Fernandez	A good data warehouse, up to date. It saves the user to navigate through many different databases	Not enough user-friendly. Information should be presented in a more homogeneous format.	
Dr. Rob van der Sande	Only HTA projects	Is it all there is?	
Information Specialist Ruth Frankish	Coverage of all HTA reports from international organisations; great to have it collated all in one place	-	

Table 11 Do you find it important to exchange information on HTA activities between HTA organisations?

Respondent	Yes,	At the following level(s)			No,	because	No answer
		National	European	International			
Dr. Jean-Paul Dercq							
Dr. Olli-Pekka Ryynänen							
Dr. Mary Geitona							x
Prof. Olav H. Førde	x			x			
Director, Dr. Alfredo Rodríguez-Antigüedad Zarranz	x			x			
Marta Roqué & Miren Fernandez	x			x			
Dr. Rob van der Sande	x	x	x				
Information Specialist Ruth Frankish	x	x	x	x			

Table 12 Clearinghouse function for information exchange

Respondent	Beneficial,	because	Not beneficial,	because	No answer
Dr. Jean-Paul Dercq					
Dr. Olli-Pekka Ryynänen					
Dr. Mary Geitona					x
Prof. Olav H. Førde	x				
Director, Dr. Alfredo Rodríguez-Antigüedad Zarranz	x				
Marta Roqué & Miren Fernandez	x	It could be as beneficial like the National Guidelines Clearinghouse in the US, that even allows comparison of different guidelines (by source, level of evidence, etc)			
Dr. Rob van der Sande	x	For our work as an advisory body it is important to know about other research in the European region.			
Information Specialist Ruth Frankish			x	Information is already collated in the HTA Database; feel that there would be no benefit in creating another collection of information	

EuroScan and European HTA

European information network on new and changing health technologies

Compiled by: Claire Packer, Sue Simpson, Andrew Stevens and Gabriël ten Velden on behalf of EuroScan

Executive Summary

The early identification, prioritisation and assessment of new and emerging health technologies are essential parts of the health technology assessment process. Early warning systems allow the assessment of health innovations to be sufficiently timely to make a real difference in policy making, particularly in relation to reimbursement or funding where resources for health care are limited. The objectives of this report are to share information on the methods used for early identification, prioritisation and assessment, to describe the current collaboration between agencies working in the field of early warning (EuroScan), to develop an understanding of the potential for future collaboration and to consider the options for wider dissemination of information and participation in a European HTA clearing-house function. To address these objectives we report on EuroScan's activities and progress to date, summarise the findings of a comparative analysis of member agency systems and develop scenarios for future collaboration and information sharing. Finally we discuss the relative merits and constraints of these scenarios.

EuroScan's critical developments have been to:

- Establish a common terminology, classification and understanding of the activity.
- Exchange information on the working and context of each agency,
- Identify, evaluate and monitor the quality of sources of information concerning new and changing health technologies.
- Share and develop methods for the early assessment of new and changing health technologies.
- Pilot the exchange of information and early assessments of significant new and emerging health technologies.
- Establish a web-based common database of significant new and changing health technologies.
- Publish and disseminate the results of these activities, including arranging a European meeting of members from interested HTA agencies.

The comparative analysis of the structure and processes of the individual early warning systems found some common features including similar coverage and definition of new and emerging health technologies and similar sources used for the identification and prioritisation of innovations. In addition, all the units working on early identification and assessment are small and all are financed from public sources and are independent of commercial concerns. Although all the units use clinical experts within their processes their involvement differs. Other differences between the systems include the type of host organisation for the unit, the range of activities undertaken and the principal target group.

The EuroScan collaboration intends to consolidate the use of the early warning database within the work of individual agencies, promote the value of the collaboration to others with an interest in the work and develop a research programme to evaluate activities and gain a greater understanding of the determinants of diffusion and impact of innovation in health care. Scenarios for future collaboration and information sharing are presented and range from maintenance of the 'status quo' to the institution of a formal centralised permanent international system with standardised outputs. Mechanisms for information sharing both within and external to the collaboration are also explored.

Recommendations

1. Consolidation of the EuroScan collaboration

The EuroScan network is an evolving collaboration that requires further consolidation. Currently EuroScan is a semi-formal network with funding from membership fees supporting a scientific secretariat. For the next 3-year period EuroScan recommends that the collaborative network continues to work as a semi-formal system (as set out in scenario 2: level 1) and explores the potential of working towards a semi-formal collaboration with some additional central funding (scenario 2: level 2).

2. Consolidation of the EuroScan information exchange and database

Further consolidation of EuroScan's information sharing function is recommended. Confirmation of information on emerging health technologies from multiple sources increases the efficiency of early identification and assessment activities, has the potential to avoid duplication and improves reliability. It is recommended that the current EuroScan database be consolidated with access, in the short to medium term, being limited to EuroScan members.

3. Expansion of the EuroScan collaboration

Expansion of the membership of EuroScan should be encouraged and promoted, and wider use of the information database investigated. It may be possible to provide restricted access to selected fields of the database to non-members in the future, but some issues such as technical feasibility and ownership of the information will need careful exploration, piloting and time to implement. Although some EuroScan member agency assessments are made publicly available and could be considered for inclusion in a central European clearing-house function, it is not feasible at this time for confidential outputs or the pilot EuroScan database to be included.

4. Exploration of links with other HTA organisation and networks

At present, EuroScan recommends that the collaboration continue to operate as a separate expert group focusing on early warning activities with active links into other HTA activities. However, in the future, stronger links into European and non-European HTA networks (such as INAHTA) should be considered and, where necessary, a closer working arrangement investigated.

1. Introduction

1.1 The development and diffusion of new pharmaceuticals, diagnostics, clinical procedures and medical equipment is advancing at an accelerating speed [1]. The supply of fragmented scientific information about, and increasing public awareness of, medical innovations puts pressure on policy makers and health planning systems especially where restrictions on healthcare funding are in place. Policy-makers and medical professionals have for some time expressed an interest in information systems that can prioritise innovations early in their life cycle, according to their potential for impact, and provide systematic and timely reports about important, emerging health technologies and their anticipated clinical efficacy and impact on health services [2]. Such assessments are an early and integral part of health technology assessment (HTA) and are of particular relevance to national and regional health policy-makers. The development of systems for early identification and assessment of innovations in a number of countries offers great potential for a collaborative HTA network in Europe.

1.2 Collaboration is desirable in HTA in general, but is essential in early identification and assessment. It is desirable in HTA for reasons of the shared purpose and methods as well as the potentially infinite workload. Collaboration is essential in early identification and assessment for two reasons: firstly, such activities are relatively novel and their methods need to be developed rapidly. Secondly, because the principal method for such activity involves confirmation of information from multiple sources [3,4,5,6], this inevitably benefits from co-ordinated activities in different countries. As such any collaboration both avoids duplication and increases the reliability of the output thereby increasing value for money, both by increasing output and by reducing the total workload.

1.3 Early identification and assessment of new and emerging health care technologies is also called early warning or horizon scanning. An early warning system (EWS) generally has five main components:

- the identification of emerging health technologies and new applications of existing technologies,
- filtration and prioritisation to identify those technologies with the potential to have a significant impact in the future
- the assessment of the impact of these technologies and
- the dissemination of the resulting information
- the monitoring of assessed technologies.

2. Objectives of the Report

i. To share information on the methods used for early warning and to share results of these activities.

ii. To describe the current European collaboration (EuroScan) and to develop an understanding of the potential for further development of the collaborative network.

iii. To consider the options to improve the sharing of information within EuroScan and with other interested HTA organisations.

iv. To explore EuroScan's potential for participation in a European clearing-house for information relating to HTA.

3. Methods

To address the objectives listed above the following methods have been employed:

i. A review and summary of EuroScan's activities and progress to date including a comparative analysis of member agency systems and methods used for the identification, filtration, prioritisation and early assessment of new and emerging health care technologies and an overview of the development of an early warning database.

ii. An appraisal of progress towards the goals set out in EuroScan's initial action plan.

iii. The development of scenarios for future collaboration of agencies interested in early warning activities, the dissemination of information and a clearing-house function.

iv. A discussion of the relative merits and constraints of these scenarios leading to a preferred option.

4. Results

4.1 Background and the Development of EuroScan

4.1.1 Early warning systems have been part of the regular approval processes in a few European countries for some years [7]. More recently systems have developed in many other countries and are now in place in France, the Netherlands, Norway, Spain, Sweden, Switzerland and the United Kingdom and after a recent feasibility study about to be established in Denmark. Countries outside Europe with functioning systems include Canada and Australia. A survey in 1998 among INAHTA members showed that 30% of agencies had continuing and structured early warning activities [8].

4.1.2 The feasibility and benefits of an international network of national horizon-scanning systems has been discussed for some years. In January 1995, the Danish Hospital Institute organised a meeting entitled "International Collaboration Concerning Monitoring of Emerging Medical Technologies (MEMT)". Fourteen participants from Denmark, Finland, France, Luxembourg, the Netherlands, Sweden and the UK attended and discussed national experiences concerning MEMT and the possibility for a European collaboration. A number of options for a MEMT-system were discussed. The next major developments took place in 1997 at an international workshop "Scanning the Horizon for Emerging Health Technology" in Copenhagen. This was supported by the Danish Institute for Health Technology Assessment, the Swedish Council on Technology Assessment in Health Care and the European Commission DG

V as part of the "HTA Europe" project. It attracted twenty-seven policy makers and researchers from twelve countries.

4.1.3 The major findings from the Copenhagen workshop concerning collaboration were focused on the obvious value of exchanging information and experience [9,10]. Other areas of interest for future international collaboration were stated as:

- identifying and prioritising emerging technologies,
- developing methods for assessment early in the lifecycle of the technology,
- learning more about the attributes that are important in the diffusion of emerging technologies and
- using this knowledge as a basis for determining the focus of future work.

Further collaboration among organisations working with early warning systems was strongly recommended.

4.1.4 At the Copenhagen workshop it was agreed that collaboration should develop as a gradual process with representatives from different countries starting by sharing information, establishing a "mail-box" and gradually advancing the co-operation to higher levels. It was recommended that the initial collaboration should focus mainly on the exchange of information on the safety and efficacy of the new technologies.

4.1.5 Following an agreement in Copenhagen a small working group was established with representatives from Denmark, the Netherlands, Spain, Sweden and the United Kingdom plus associated representatives from Canada and Switzerland.

4.2 Current Position of EuroScan

4.2.1 The European Information Network on New and Changing Health Technologies (EuroScan) developed from the working group and is a collaborative network of health technology assessment agencies for the exchange of information on new drugs, devices, procedures, processes and settings in health care. EuroScan has regular meetings and has by-laws outlining the groups' mission statement and formal membership structure; aims and objectives; and an action plan.

Aims

4.2.2 The members of EuroScan aim to share and evaluate key information on selected emerging health technologies or new applications of existing ones in order to address their effects and the anticipated short and long term consequences of their use for health care and society. EuroScan also aims to support national agencies and HTA organisations in developing and running systems to provide information to health planners and policy makers on important new and changing health technologies. Additionally a research programme is being developed to investigate questions of mutual interest.

Structure

4.2.3 EuroScan comprises Members, an Executive Committee and a Secretariat (see Appendix I). The Executive Committee of EuroScan is made up of representatives from member agencies that, on a permanent basis, undertake substantial early warning activity. There is an elected Chair, Vice Chair, Registrar, Treasurer and a North American Advisor. Although Executive Committee members are employed by or represent a member agency they are nominated for the Executive Committee based on their personal experience. The Secretariat is currently based at the National Horizon Scanning Centre at the University of Birmingham in the United Kingdom.

Membership

4.2.4 Membership of EuroScan is open to any agency which:

- has a substantial programme for the early identification and assessment of emerging, new or changing health technologies;
- has an ongoing, officially recognised role in relation to regional or national government;
- is a non-profit organisation
- is at least 50% funded from public sources.

4.2.5 Currently EuroScan has ten member organisations:

- Agencia de Evaluacion de Tecnologias Sanitarias (Madrid, Spain) (AETS)
- Assistance Hôpitaux Publique de Paris, Committee for Evaluation and Diffusion of Innovative Technologies, France (CEDIT)
- Basque Office for Health Technology Assessment (Osteba)
- Canadian Co-ordinating Office for Health Technology Assessment (CCOHTA)
- Danish Institute for Health Technology Assessment (DIHTA)
- Federal Social Insurance Office of Switzerland (FSIOS)
- Health Council of the Netherlands (GR)
- National Horizon Scanning Centre (NHSC), UK
- Norwegian Centre for Health Technology Assessment (SMM)
- Swedish Council on Technology Assessment in Health Care (SBU)

EuroScan Action Plan and Progress

4.2.6 To meet its aims and objectives EuroScan developed a long-term action plan. The plan includes some activities that fall outside the remit and control of EuroScan member agencies but which are vital for continuing international collaboration. The major tasks for EuroScan in the first 2–3 years of activity have been to:

	Task description	Progress
Task 1	Establish a common terminology, classification and understanding of the activity	Complete
Task 2	Identify, evaluate and monitor the quality of sources of information concerning new and changing health technologies	Ongoing
Task 3	Share methods for the early assessment of new and changing health technologies	Complete
Task 4	Pilot the exchange of information on significant new and emerging health technologies	Complete
Task 5	Establish a common database of significant new and changing health technologies	To be completed by summer 2001
Task 6	Publish and disseminate the results of these activities including arranging a European meeting of members from interested HTA agencies	2 international seminars complete; further planned.
Task 7	Identify areas for further research in this field	Current
Task 8	Based on these experiences design and implement a permanent system	Ongoing

4.3 EuroScan Outputs

Terminology and understanding of the activity

4.3.1 EuroScan members have been able to learn from the experiences of other members and the systems they work within to gain a broader understanding of early warning activities. A common terminology has been deliberated upon and agreed.

4.3.2 An early warning system (see paragraph 1.3) focuses on technologies that are:

- **new** (a technology in the phase of adoption that has only been available for clinical use for a short time and is generally in the launch or early post-marketing stages) or

- **emerging** (a technology that is not yet adopted by the health care system; pharmaceuticals will usually be in phase II or phase III clinical trials or perhaps pre-launch; medical devices will be prior to marketing, or within 6 months of marketing, or marketed but <10% diffused or localised to a few centres) or

- represent a **change** in indication or use of an existing technology, or

- part of a **group** of developing technologies that, as a whole, may have an impact.

4.3.3 EuroScan has developed preliminary prioritisation criteria used by member agencies to select technologies that may require further assessment:

- there are major uncertainties regarding health benefit or cost effectiveness, or
- there may be some health benefit if the technology diffuses widely,

(a technology that is an innovative therapy for a disease or disorder with no satisfactory standard treatment; or a new, potentially more effective therapy, measured by relevant outcomes, than standard treatment; or a new therapy with significantly fewer known side effects or long term adverse effects than the standard treatment), or

- there is a potential for inappropriate diffusion or use of the technology, or
- there is likely to be a major cost impact if the technology is widely diffused because of moderate to high unit costs and/or patient numbers and/or service re-organisation requirements, or
- there are other major impacts such as staff retraining needs, or
- there are significant legal, ethical, political, environmental or social issues with regards to the use of the technology.

Comparative analysis of systems

4.3.4 A grid comparing the structure and processes of the individual early warning systems has been compiled by the collaboration with the aim of describing the state of development in each country and identifying any common elements between systems. This analysis was conducted to both help those agencies with established systems and to provide guidance to agencies contemplating setting up new systems.

4.3.5 Common elements of early warning systems found were:

- The units working on early warning activities are small (between 1–5 staff). All are financed from public sources and are independent of commercial concerns.

- Coverage and definition of new and emerging health technologies are similar, except where an agency's remit is limited, such as CEDIT – non-pharmaceuticals only.

- Sources used for identification and prioritisation are principally the same but may have different relative importance.

4.3.6 Differences within the systems include:

- The type of host organisation for the unit – from part of a government organisation or independent organisations to University departments subcontracted to provide information.

- All agencies use clinical experts within their processes but in different ways. The Federal Social Insurance Office of Switzerland and the Norwegian Centre for Health Technology Assessment use experts for the initial identification and filtration of technologies, others such as the UK National Horizon Scanning Centre for prioritisation prior to assessment, and others such as the Swedish Council on Technology Assessment in Health Care both for prioritisation and to write early assessments.

- Programme activities and dissemination of the results – from identification, prioritisation and a brief early assessment only, through to a full appraisal of the technology.

- Major target groups – from Government ministers and officers to insurance organisations and the wider public.

4.3.7 Planned developments and future objectives common to many agencies include:

- to become more stable with regards funding and staff
- to ensure activities become more transparent
- to ensure activities become more integrated with policy-making within and between countries
- to develop wider access to early assessment reports (on the world-wide web)
- to continue to develop collaboration between relevant agencies in each country working with similar issues

Collaboration

4.3.8 The EuroScan collaboration has not only ensured that there is a forum for discussion on early warning activities and systems for members but has encouraged interest in such activities and helped in the development of systems in countries who were not already undertaking early warning. The pilot study for the establishment of a Danish early warning system described below (Box 1) illustrates the value of international exchange of information on new health care technologies.

Box 1: Collaboration on identification and prioritisation

A pilot study initiated by the Danish Institute for HTA and carried out by the Centre for Applied Health Services Research and Technology Assessment (CAST) at the University of Southern Denmark explored the different steps involved in an EWS. The pilot study focussed on the identification, filtration, prioritisation and early assessment of new health care technologies with a view to determining the most appropriate methods for use in the establishment of a Danish EWS.

The study initially involved consultation with members of EuroScan to gain information on new health care technologies that members had previously identified. In December 1999, a letter requesting information on the names of the technologies, their application, and the estimated time-horizon for the introduction of the technologies, was sent to EuroScan members. Information on over 200 technologies, that on average would emerge within 0–5 years, was obtained from individual members. This initial list of technologies was reviewed by members of a committee advising the project, and added to where appropriate, resulting in a list of categorised technologies representing Danish clinical specialities.

For the purpose of the pilot study a filtration method was tested on technologies in the areas of oncology, neurology, immunology, rheumatology, medical imaging and robot-surgery. A list of around 80 technologies was sent to clinical experts to solicit their opinions on the novelty of each

technology, the likely timing of its introduction and the potential impact on the Danish health care system. The survey had a response rate of 78%. This filtration method resulted in a reduced list of new health care technologies thought to be important for further consideration and assessment in Denmark.

Information exchange

4.3.12 All members contribute to the exchange of key information on significant emerging, new or changing health technologies at least twice a year. They are also required to provide a copy of relevant, published and, where possible, confidential reports on these health technologies. In the identification and assessment of new and emerging technologies members sometimes work with commercially sensitive data which places constraints on the dissemination of findings. EuroScan members make available such information to other members with the condition that its use is restricted and confidential to the level that it is in the host agency[67].

4.3.13 EuroScan members have exchanged information in a variety of formats. The most informal being direct individual contact between members either verbally or by email. Individual agency reports, bulletins and briefs have been exchanged or made available as appropriate and a formal exchange of work in progress and current concerns including exchange of information about important new and emerging technology made on several occasions.

Box 2: Examples of technologies on which information has been exchanged

Pharmaceuticals

Tenecteplase: single bolus thrombolytic therapy for acute myocardial infarction
Entacapone: adjunctive use in patients with advanced Parkinson's disease
Dendritic cell vaccination for the treatment of advanced melanoma
Memantine for Alzheimers and vascular dementia
Apligraf for venous leg ulcers

Devices

Gastrointestinal miniprobe endosonography
Cardiac pumps in treating chronic heart failure
Digital mammography
Brachytherapy for prostate cancer
Ventricular pacing and resynchronisation for heart failure

Procedures

Neuronavigation in neurosurgery
Deep brain stimulation for Parkinson's disease
New techniques for breast biopsiesLiving donor liver-transplantation
Islets of Langerhans allotransplantation and autotransplantation

[67] If a report is confidential within an early warning agency and cannot be made freely available EuroScan members may use the report for background information but undertake not to circulate it outside their agency or reference it

Programmes

Prenatal screening
Screening for colorectal cancer
Screening for hereditary hemochromatosis by genetic methods

Database

4.3.14 A pilot dynamic database of key information about selected health technologies that members can access and update in 'real-time' is in the final stages of development.

4.3.15 The EuroScan database contains information provided by member agencies on selected new and emerging health technologies that may have a significant impact on health services in the next 5 years (see Box 3 for sample entry).

4.3.16 There are some restrictions on the database's content in order for it to be manageable and relevant to early warning activity. A technology will not be included in the database if it is too early in development, is not considered to be relevant for the network at this time, is not considered to be new, or there is a relevant recent HTA report concerning the technology.

Box 3: An example of an entry in the EuroScan database

Dendritic cell (DC) vaccination for the treatment of advanced melanoma

Technology – description: Current treatment approaches for advanced melanoma have low response rates and severe side effects (e.g. chemotherapy). Most of the chemotherapy protocols are performed on an inpatient basis. DC vaccination provides significant health benefits because: partial and complete responses are induced in 26% of patients, responses are long lasting, there are no significant side effects and therapy is performed on an outpatient basis
Technology – stage of development: Investigational – phase III
Technology – type: Vaccine
Technology – use: Therapeutic
Target group (indications of use): Advanced malignant melanoma
Numbers of patients: 1–3 per 100,000 population in Switzerland per year.
Setting for technology use: General hospital, outpatient basis
Licensing, reimbursement and other approval: Approved by the ethical committee, University or Zurich Hospital. No licensing approval of reimbursement status.
Company or developer: Non-profit, non-company supported

Area of possible impact
Uncertainty of benefit: Unknown or uncertain
Health Impact: Major
Cost impact: Moderate
Potential for cost savings: Moderate
Appropriateness of diffusion: Unknown
Ethical, social, legal, political or environmental impact: Minor. New treatment with low side effect profile on an outpatient basis, stimulation of the patients immune system to fight cancer instead of toxic chemotherapy.

Alternative or complementary technology: Substitution technology
Current technology: Chemotherapy
Diffusion: About 200 new stage IV patients in Switzerland per year, slow diffusion because of restriction of technology to treat advanced disease.
Unit cost and price: CHF 20,000.- (Euro 13,150) per patient per 6 vaccinations.
Infrastructure requirements: Dedicated clinical and cell culture facilities, 2 medical doctors, 1 laboratory technician for up to 30 patients/year.
Economic consequences: Cheaper than chemotherapy
Risks and safety: Very good risk and safety profile, no serious side effects (follow up 4 years).
Clinical effectiveness: Short term effectiveness: Complete and partial response rate in phase I/II trial: 31%
Economic evaluation: see analysis of the "Abteilung Medizinische Oekonomie"
Ongoing research: New innovative small phaseI/II studies Randomized control multicenter trial.
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Nestle FO: Vaccination of Melanoma Patients with Peptide- or Tumor Lysate- Pulsed Dendritic Cells: A Follow-up. Dendritic Cell Symposium, 6th International Symposium on Dendritic Cell Therapy, Brisbane/Australia, May 25, 2000.

Source agency: Switzerland
Date on database: 1/12/2000

External Dissemination

4.3.17 Wide dissemination of the work on methods for early warning and reports on the experiences and progress of EuroScan members in establishing systems within their own countries are an important output of the EuroScan collaboration. The EuroScan website (www.bham.ac.uk/publichealth/euroscan) provides information on the aims and proposed activities of the collaboration, membership details for organisations wishing to apply to join the collaboration and a copy of the by-laws. The website will continue to develop as EuroScan evolves.

4.3.18 Conferences to which EuroScan has made a formal contribution:

- 15th ISTAHC Annual Meeting; Emerging Health Technologies Seminar – Edinburgh, Scotland, June 1999.

- 16th ISTAHC Annual Meeting; EUCOMED (European Confederation of Medical Devices Manufacturers) Symposium – The Hague, The Netherlands, June 18th, 2000.

- Early Assessment of Health Technologies Symposium: Do the Risks Justify the Benefits? In collaboration with CCOHTA – Ottawa, Canada, October 2000.

4.3.19 Relevant Member Publications

The International Journal of Technology Assessment in Health Care (Vol 14 no. 4 1998) included a special section on Early Identification and Assessment of Emerging Health Technology edited by Per Carlsson (Sweden) and Torben Jørgensen (Denmark) with contributions from member organisations including:

- An Early System for the Identification and Assessment of Future Health Care Technology: The Dutch STG Project by David Banta and Annetine Gelijns.

- Basis for Decisions on Emerging Health Technology: A Danish Feasibility Study by Torben Jørgensen and Lars Grupe Larsen.

- Which are the Best Information Sources for Identifying Emerging Health Care Technologies? An International Delphi Study by Glenn Robert, John Gabbay and Andrew Stevens.

- The Identification of New Health Care Technologies by the Health Council of the Netherlands by Gabriël ten Velden.

- Early warning of New Health Care technologies in the United Kingdom by Andrew Stevens, Claire Packer and Glenn Robert.

- The Early Experiences of a National System for the Identification and assessment of emerging Health Care Technologies in Sweden by Per Carlsson, Henric Hultin and Johanna Törnwall.

4.4 Future Plans

The EuroScan collaboration has the following intentions: firstly, that the exchange of early assessments and the use of the early warning database will be evaluated, consolidated and become entirely routine for EuroScan members. This will mean that the work they do for themselves and for other EuroScan members will not be separate activities. Secondly, that the value of this system will support other EU members such that they will either be attracted to join the collaboration or that they can become users of its outputs. Thirdly, EuroScan is developing a research programme partly to evaluate its own activities and partly to inform a deeper understanding of the determinants of diffusion and impact in it's member countries.

5. Scenarios for Future Collaboration and Information Sharing

5.1 The development of a mechanism for the support and collaboration of cross-national HTA activity has created a valuable framework and given stability to early warning systems within Europe. The development and marketing of new health technologies is an international activity and many countries have shared concerns about new technologies that have the potential to make a substantial impact on their health services. Each country is exposed to varying levels and quality of information on new and emerging health technologies at different stages of development. EuroScan membership enables this information to be combined adding considerable value to

each member's work as members corroborate findings, share experiences and add new insights. The existing collaboration is an evolving product that will continue to develop. EuroScan members have drawn up a number of potential scenarios for future areas of collaboration, information sharing and a clearing-house function.

Collaborative Network Scenarios

5.2 There are a number of scenarios that describe the level at which a future collaborative network could operate:

Scenario 1 – An informal collaboration involving primarily information exchange on an 'ad hoc' basis by a group of individuals or organisations that have a shared interest in early warning activities with no obligation on any members to contribute other than that of goodwill. No common funds exist. This represents a reduction in current collaboration and information sharing.

Scenario 2 – A funded, semi-formal collaboration

Level 1 – A semi-formal system with funding from membership fees to support a Secretariat and part-time research worker. A web-based database of information provided by members on selected new and emerging health technologies is supported by the Secretariat. There is an obligation for members to submit information every 6 months. The main joint outputs of this collaboration are on developing methodologies for early warning activities and potentially some international research activity. There is no joint reporting. This represents the situation of the current EuroScan collaboration.

Level 2 – A semi-formal collaboration (as Level 1) with additional funding from central sources. Funders in addition to members would have some say on output. Members would contribute in a semi-informal way being contracted to produce a number of reports with a local focus. The stability of funding will allow for a number of permanent members of staff and increased opportunities for more integrated research, selected membership-wide reports and guaranteed maintenance of a database and website. This scenario would facilitate the further development of the current database and possibly the institution of a Europe-wide filtration and prioritisation process with selection of technologies of common concern. A joint programme for development of methods and research in the field of early warning is optional.

Scenario 3 – a formal centralised early warning system. This system would have a permanent central staffing to identify, filter and prioritise new and emerging technologies and produce reports in a standardised format. It would have a steering group with representatives from member countries who would set the work programme.

Information Sharing and clearing-house function

7.2 Information on new and emerging health technologies and early warning activities is already shared within EuroScan (4.3.12). Individuals and organisations who are not members of

EuroScan have access to the general pages of the EuroScan website but are restricted to reports on new and emerging technologies that are publicly available and are, as such, at the end of the early warning process.

7.3 It is expected that the EuroScan web-based database will be the main vehicle for sharing information within the collaboration in the future. However, access to the database is limited to members of EuroScan. This is for a number of reasons including the database's stage of development, ownership of the information in the database and the nature of the information i.e. confidential, commercially and politically sensitive data. There are a number of options for future access to the database:

Level 1 – Keep the EuroScan database maintained and hosted by the EuroScan Secretariat. Options for access to information:

1. Keep the current status: with members having full access (on subscription) and non-members having no access.
2. Allow non-members to have access (on payment) to selected non-confidential fields on the database.
3. Allow non-members to have access (free) to non-confidential fields on the database.
4. Allow non-members to have full access (on payment) to all fields on the database.
5. Allow non-members to have full access (free) to all fields on the database.

Level 2 – Incorporate the EuroScan database into any future central European HTA clearing-house and allow full access (on payment or free) to non-confidential fields on the database.

6. Discussion

6.1 Members of EuroScan have collaborated to develop a common understanding of early warning activity, shared information on methods used for early identification and assessment, shared results of early warning activities and developed a pilot web-based database of important technologies. Common elements of member agency systems include the coverage and definition of new and emerging health technologies, the sources used for identification of these technologies and the filtration and prioritisation criteria used to select the most significant technologies.

6.2 Collaboration in early warning activities will continue to be important. The corroboration of findings from individual member agencies avoids duplication of effort, increases reliability of output, increases efficiency within systems and assists agencies with limited resources. The benefits of collaboration are currently gained without losing local sensitivity or compromising timeliness and agencies continue to control their own outputs and means of dissemination of findings.

6.3 Increased collaboration is seen as a positive step forward in any HTA activity, however, there may be some difficulties associated with this in early warning activities. Problems that have been identified include questions over the ownership of information, the potential legal difficulties caused by the exchange of commercially sensitive information (particularly with regard to

pharmaceuticals) and the management of large quantities of information. There are also disadvantages inherent in developing a collaboration faster than members are comfortable with. EuroScan has developed in a structured yet semi-formal way where goodwill has played a large part in its success. This goodwill may be compromised by enforced development plans or targets. It should also be recognised that the EuroScan collaboration is still evolving and that the full potential of this collaboration has not yet been reached.

6.4 Support of the proposed Scenario 1 is a retrograde step and would reduce the current level and potential for information sharing. There would also be no capacity for maintenance of a database and further developmental work. Scenario 2: level 1, relates to the present EuroScan system. It is sensitive to the systems of member organisations, the circulation of outputs is limited and commercially sensitive information can be respected. The collaboration does have some insecurity in the way in which it is funded but there is some potential for development, particularly of the database, and for joint research.

6.5 The addition of central funding; Scenario 2: level 2, would facilitate the further development of the database and possibly a Europe-wide filtration and prioritisation process with identification of technologies of common concern. The obligation of member agencies to undertake core activities and to disseminate results would be similar to the current system with some preservation of local sensitivity. Concerns with the development of this scenario include the reliance on external funding, diminishing local sensitivity, reduced control as to the direction of the collaboration and potential loss of goodwill.

6.6 Scenario 3 would provide a centralised system within Europe with standard outputs. Appreciation of differences in health care systems and issues in different countries would be lost, as would control over the selection of technologies for early assessment. The system would only be able to assess a limited number of technologies and individual countries would still need their own systems to assess locally important topics not selected for scrutiny by the central system. The timeliness of reports may also suffer and the contribution of non-European countries may be restricted. 6.7 There is potential for access to the EuroScan database to be widened in the future to allow access for non-members. This would entail either restricting the amount of potentially sensitive information entered into the database or allowing access to restricted database fields for non-members. Some of the problems with this option include the time required to administer the system and questions over the ownership of the information. The number of agencies contributing to the database is expected to be limited compared to the numbers who may be interested in access. It is also hard to envisage how this function could be separated from the EuroScan Secretariat function and incorporated without further work into a European clearinghouse.

6.8 A further consideration is EuroScan's relationship with INAHTA (the International Network of Agencies for Health Technology Assessment). INAHTA is a global network spanning 35 non-profit, governmental institutions from 18 countries (2001). All EuroScan members are also members of INAHTA. INAHTA was established in 1993 with the aims of accelerating exchange and collaboration among HTA agencies; promoting information sharing and comparison; and

preventing unnecessary duplication of activities. These aims are common to both networks. A difference is that INAHTA generally collaborates on traditional HTA, whereas EuroScan focuses on the early identification and early assessment of new or emerging health technologies. This activity requires specific methodology and specialised staff.

7. Recommendations

7.1 Consolidation of the EuroScan collaboration

The EuroScan network is an evolving collaboration that requires further consolidation. Currently EuroScan is a semi-formal network with funding from membership fees supporting a scientific secretariat. For the next 3-year period EuroScan recommends that the collaborative network continues to work as a semi-formal system (as set out in scenario 2: level 1) and explores the potential of working towards a semi-formal collaboration with some additional central funding (scenario 2: level 2).

7.2 Consolidation of the EuroScan information exchange and database

Further consolidation of EuroScan's information sharing function is recommended. Confirmation of information on emerging health technologies from multiple sources increases the efficiency of early identification and assessment activities, has the potential to avoid duplication and improves reliability. It is recommended that the current EuroScan database be consolidated with access, in the short to medium term, being limited to EuroScan members.

7.3 Expansion of the EuroScan collaboration

Expansion of the membership of EuroScan should be encouraged and promoted and wider use of the information database investigated. It may be possible to provide restricted access to selected fields of the database to non-members in the future, but some issues such as technical feasibility and ownership of the information will need careful exploration, piloting and time to implement. Although some EuroScan member agency assessments are made publicly available and could be considered for inclusion in a central European clearing-house function, it is not feasible at this time for confidential outputs or the pilot EuroScan database to be included.

7.4 Exploration of links with other HTA organisation and networks

At present, EuroScan recommends that the collaboration continue to operate as a separate expert group focusing on early warning activities with active links into other HTA activities. However, in the future, stronger links into European and non-European HTA networks (such as INAHTA) should be considered and, where necessary, a closer working arrangement investigated.

Appendix 1 – EuroScan Membership

Chairman	Dr Gabriël ten Velden	Health Council of the Netherlands
Vice Chair	Professor Andrew Stevens	National Horizon Scanning Centre, England
Registrar	Dr Julian Schilling	Federal Social Insurance Office of Switzerland
Treasurer	Dr Per Carlsson	Swedish Council on Technology Assessment in Health Care
North American Adviser	Dr Jill Saunders	Canadian Coordinating Office for Health Technology Assessment
Head of Secretariat	Dr Claire Packer	National Horizon Scanning Centre, England
Members	Dr José Asua	Basque Office for Health Technology Assessment
	Ms Karla Douw	Danish Institute for Health Technology Assessment
	Ms Anne-Florence Fay	Assistance Hôpitaux Publique de Paris, Committee for Evaluation and Diffusion of Innovative Technologies
	Dr Setafilla Luengo	Agencia de Evaluacion de Tecnologias Sanitarias
	Dr Berit Mørland	Norwegian Centre for Health Technology Assessment
Researcher	Dr Sue Simpson	National Horizon Scanning Centre, England

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Working Group 3
European Joint Assessments

To identify possible joint assessments and to co-ordinate findings and existing resources within the community to support joint assessments

Working Group Members

Laura Smpietro-Colom (Chair)
Virpi Semberg (Co-Chair)
Kjell Asplund
Ruth Barrington
Dolors Estrada
Karin Faisst
James Kahan
Inge Kjonniksen
Aldo Mariotto
Ruaridh Milne
Alric Rüther
Staffan Stilvén
Bertrand Xerri

Abstract

Background: Health care decision-makers throughout Europe constantly face similar uncertainties about health care and are in need of reliable information. Scientific information and health care decision making must come into closer collaboration. International Joint Health Technology Assessments collaboration is one tool for that, since it promotes synergies, avoids duplication of effort and is the most efficient way to produce the rigorous and comprehensive information needed. However, the success of joint assessments depends on several factors that need to be explored to improve the effectiveness and impact of future international joint assessments.

Objectives: 1) to examine and evaluate experiences with joint assessments; 2) to develop models for identifying assessment topics and the European network of organisations that can carry out joint assessments; 3) to propose principles for carrying out joint assessments.

Methods: a) Workshops with representatives from 10 European Union countries (Denmark, Finland, France, Germany, Italy, Ireland, The Netherlands, Spain, Sweden, United Kingdom) plus Norway and Switzerland; b) Survey by means of a questionnaire addressed to key informants with past experience in multinational European Joint Projects working in the fields of Health Technology Assessment (HTA), health services research, health economics, bioethics and clinical research; c) Literature review on European Joint Projects in Medline, Embase and Health STAR databases from 1995 to 2000. Inclusion criteria: an article published in English; two or more authors from the countries mentioned above. Analysis: univariate analysis was performed for the survey and literature review. Additionally, open questions of the survey were analysed and classified by two independent reviewers. In case of disagreement, final classification was reached through consensus.

Results: Survey. 110 questionnaires from 13 European countries were analysed. Respondents work in 13 HTA organisations and 82 non-HTA organisations. Past international joint projects used workshops as the main tool of communication (80%), and scientists acted as searchers and collectors of (64%) in both types of organisations. As regards methodology, while HTA scientists mainly used secondary research in their work, non-HTA scientists used primary research. The most cited benefit was to share and gain knowledge and experience (27%), and organisational and logistic problems were the most frequently mentioned problems (50%), especially those affecting European Union bureaucracy and paperwork. HTA respondents identified differences in health system cultures as one of the main problems. Researchers working in both types of organisations expressed interest in participating in future international joint assessments (92%), taking an active role. In this case, 83% of HTA respondents prefer to synthesise/analyse data while 80% of non-HTA respondents prefer to collect data. Additionally, the organisations are willing to devote human resources to this task, and HTA organisations are also willing to share economic responsibilities with the European Union in project funding (60%). Regarding topic selection, most of the respondents prefer that experts and scientists select the topics through a formal priority-setting process (67%), using a high number of patients/people potentially affected in Europe as a main prioritisation criteria (39% to 49%). Proposed models for the topic selection process range from using Internet to applying traditional research techniques, e.g. the Delphi

method. Multinational joint assessments should be carried out by the existing informal European network of agencies for HTA, but allowing for the participation of other non-experienced HTA organisations, mainly from European non-EU countries. Most of the HTA respondents expressed interest in having a permanent co-ordinating body for HTA in Europe (13/18) to support the development of projects. The preferred organisational characteristics are a virtual organisation (33%), followed by centralisation in one country (28%). Finally, scientific quality, appropriate partners and balanced country participation were the main characteristics highlighted as the principles to consider in an ideal multinational European and international joint project.

Literature Review. 1666 articles were identified. When inclusion criteria were applied, 765 articles were finally reviewed. The median number of authors was 7 (range: 2 to 65). The most frequently identified body of work concerned clinical research (67%). Primary research was the main methodology used (98%). The United Kingdom ranks first, in absolute numbers, as the country that collaborates most in multinational European joint projects (n=500) and leads in papers published (n=200). The principal promoters of multinational European joint projects are hospitals (75%), while industry is the main sponsor (46%). The EU has financed only 18% of the multinational European joint projects that are published. HTA organisations have sponsored 42 of the studies identified. In these cases, primary research was the methodology most frequently used (91%), and clinical research and health services research are the areas mainly studied (60% and 12% respectively). Regarding country participation, the United Kingdom (29%) and Spain (17%) are more represented in this subset.

Conclusion: International joint health technology assessments have several strengths, weaknesses, opportunities and threats. Enthusiasm to co-operate and the availability of a wide range of expertise among scientists are two of the most important strengths. Additionally, the informal network of HTA agencies that has already been collaborating for several years offers an invaluable opportunity for future collaboration at the European level. However, certain weaknesses and threats should be considered when planning for future international collaborative assessments. The two most relevant weaknesses are the difficulty of project management and the lack of adequate funding. The most important challenge faced by European scientists is dealing with official EU procedures.

Recommendations to the EU: In light of our study, three main recommendations can be made: a) to explicitly support a formal European collaboration in HTA, b) to improve the organisation and logistics of European collaboration in HTA, and c) to increase financial resources for multinational European collaboration in HTA.

Executive summary

The need for reliable and rigorous information for health decision-making is a good reason to promote the development of multinational European Joint Health Technology Assessments (EJHTA).

EJHTA promotes synergy, avoids duplication of effort, provides comprehensive information and is an efficient way to produce information. However, little is known about the factors that

make an international joint project succeed or fail. This information is of key importance when planning for future joint assessments.

Workshops, a survey and a literature review were the three methods used in this study. Representatives from 10 EU member states (Denmark, Finland, France, Germany, Italy, Ireland, The Netherlands, Spain, Sweden, United Kingdom) plus Norway and Switzerland participated in the workshops. The survey was carried out by means of a questionnaire sent to key European scientists experienced in international collaborative assessment projects. The literature review includes all the publications from 1995 to 2000 related to European international joint projects.

Although workshops have been frequently used means of communication in past international joint assessments (80%), they consume considerable time and economic resources. Although face-to-face contact is extremely important, new communication tools (e.g. videoconferences) should be promoted.

The main benefit associated with EJHTA is the increased knowledge and experience of participants (27%), which probably impacts positively on their organisations.

The main problem identified in relation to performing EJHTA is project management, i.e. organisation and logistics (50%) with European Union administrative procedures being frequently mentioned as a major challenge. Insufficient financial support was the second most frequently reported problem (24%).

Most respondents are willing to actively participate in future international joint assessment projects (92%).

All types of organisations are willing to invest human resources in international joint assessments (HTA organisations=39%; non-HTA organisations=41%). Furthermore, HTA organisations are quite willing to share financial responsibilities with the EU in developing EJHTA (60%).

A formal priority-setting process for selecting topics in a need of EJHTA is reported (67%). The most important prioritisation criterion identified is a large number of people/patients potentially affected in Europe (39% to 49%).

Scientific quality, appropriate partners and balanced country participation were reported as the main principles to consider for an ideal multinational EJHTA project.

Most of the HTA respondents are interested in having a permanent co-ordinating body for HTA in Europe to give support in developing multinational EJHTA projects (13/18=72%). However, there is a need to clarify the type of HTA body that best fits the needs and preferences of European HTA organisations.

The United Kingdom ranks first, in absolute numbers, as the country that collaborates the most in multinational European joint projects (n=500) and is the nation that leads in published papers (n=200). Adjusted for the number of inhabitants, Luxembourg appears to rank first in

both cases. However, the most appropriate adjusting factor would be the number of health scientists or health universities, but these data are not readily available.

While the principal promoters of multinational European joint projects are hospitals (75%), industry is the main sponsor (46%). The EU has financed only 18% of the multinational European joint projects published between 1995 and 2000.

The ratio between the funding effort of HTA organisations and the EU is 2:1, i.e. for every two studies sponsored by an HTA organisation, one is co-sponsored by the EU. A redistribution of EU economic resources from primary health research to HTA research is advisable.

The informal network of HTA agencies that has already been operating for several years offers an invaluable opportunity for future collaboration at the European level.

In light of our study, three main recommendations can be made: a) to explicitly support a formal European collaboration in HTA, b) to improve the organisation and logistics of European collaboration in HTA, and c) to increase financial resources for multinational European collaboration in HTA.

Introduction

Technology, science and health uncertainties are international. Decision-makers throughout Europe constantly face similar turbulence in health care. To succeed, they need to find the right information at the right time. Scientific information and both clinical practice and health policy must come into closer collaboration. Health Technology Assessment is a means for achieving this result. However, isolated and fragmented HTA efforts addressed to answer these uncertainties often lead to an inefficient information production process. Moreover, it can lead to a situation where decision-makers gain access to non-comprehensive information, which might bias one's knowledge of a complex health care reality.

Since one of the major sources of new knowledge is fusion, i.e. bringing together people with different ideas to work on the same issues[68], International Joint Assessments-Projects (IJA-P) emerge as a powerful tool to produce new and relevant knowledge. Moreover, since Health Technology Assessment (HTA) is context-dependent, International Joint Assessments-Projects make it possible to identify national and regional variations regarding health priorities, epidemiology, health care organisation and social values[69]. This is highly important in a multinational European Union (EU) in order to highlight the idiosyncrasy of each nation, which is a sine qua nom condition to reinforce the credibility of the results achieved by the project and allow them to be used by decision-makers from the different European nations. Additionally, the identification of differences in health care settings and their influence on health outcomes could be benchmarked, helping to point out the differences that are worth maintaining or rejecting.

[68] Davenport TH, Prusak L. Working Knowledge: how organisations manage what they know. Boston, Massachussetts: Harvard Business School Press, 1998.
[69] International Collaboration: beyond the harmonization of scientific standards. Editorial. Informatiu CAHTA. October-December 1997. Number 12

International Joint Assessments/Projects generate useful information, promote synergy, avoid duplication of effort and are generally the most efficient way to produce necessary and comprehensive data on health to assist the health care decision making process. Additionally, the interaction among different partners creates scientific networks and enhances the knowledge and experience that would improve human capital among the participating organisations.

There has been active, informal collaboration for several years among the European HTA organisations. However, this informal working network has never been formally recognised by any official European bodies. Moreover, it has not established a systematic approach to carry out multinational European joint projects. At this point, to identify the advantages and disadvantages of international collaboration it is necessary to successfully proceed with future HTA international collaborating projects.

Objectives

- To examine and evaluate experiences with joint assessments
- To develop models for identifying assessment topics and the European network of organisations that can carry out joint assessments
- To propose principles for carrying out joint assessments
- To consider strengths and weaknesses of proposed models

Methodology

Three types of methods have been used to achieve the aims of the subgroup:

a) Workshops with subgroup members

b) Survey

c) Literature review on European Joint Projects

a) Workshops with subgroup members

Subgroup participants belong to 10 countries from EU states plus Norway and Switzerland. The names of representatives from each country are listed below:

Country	Participants	Organisations
Denmark	Staffan Stilvén	Danish Institute for Health Technology Assessment (DIHTA)
Finland	Virpi Semberg (Co-Chair)	Finnish Office for Health Care Technology Assessment (FinOHTA)
France	Bertrand Xerri	L'Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES)
Germany	Alric Rüther	German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information (DAHTA@DIMDI)
Italy	Aldo Mariotto	Health Authority n.6. Pordemone
Ireland	Ruth Barrington	Health Research Board
Norway	Inge Kjonniksen	The Norwegian Centre for Health Technology Assessment (SMM)
The Netherlands	James Kahan	RAND Europe
Spain	Laura Sampietro-Colom (Chair) Dolors Estrada	Catalan Agency for Health Technology and Research (CAHTA)
Sweden	Kjell Asplund	Swedish Council on Technology Assessment in Health Care(SBU)
Switzerland	Karin Faist	Institute for Social and Preventive Medicine
United Kingdom	Ruairidh Milne	National Co-ordinating Centre for Health Technology Assessment (NCCHTA)

Two workshops were held, the first in June 2000 in The Hague (The Netherlands) and the second in April 2001 in Barcelona (Spain). The discussions in these workshops have been used to complement the information generated by the survey and the literature review.

b) Survey

Objective: To gather opinions and perceptions from experienced people in international joint projects.

Design: A cross-sectional study was carried out using a questionnaire designed to obtain general information on European Joint Assessments and health-related Projects. Appendix 1 presents the questionnaire. The questions were classified in 4 sections:

1. Experience from past IJA-P (questions 3 through 7)

2. Interest in future IJA-P (questions 8 through 10)

3. Propositions for future IJA-P (questions 11 through 17)

4. Issues for future research (question 18)

Geographic Scope: The geographic scope of the study covered the 10 EU state members plus Norway and Switzerland.

Subjects: Subjects of interest were professionals working in the field of HTA, health services research (HSR), health economics (HE), bioethics (BE) and clinical research (CR). The selection criteria were: a) key informants; b) past experience in European joint projects; c) working in public and private organisations. The reasons for including non-HTA professionals were to gather as much information as possible on the limitations and potentials perceived by experienced people working on international projects.

Sampling technique: Systematic non-probabilistic (convenience sampling). A database was created specifically to identify subjects who followed the inclusion criteria. The International Network of Agencies for Health Technology Assessment (INAHTA) database and other HTA sources were used to identify European HTA scientists who have worked on international projects. Additionally, the BIOMED I website was used to identify researchers in the different health and healthcare-related fields. All researchers/scientists identified were classified by country, and the database was sent to subgroup participants as a guide to identify potential respondents to the questionnaire. Representatives from each country were also asked to identify key people in the private sector who could answer the questionnaire since most of the researchers identified through publicly available sources were working in public organisations. The representative from each country selected the participants and sent the questionnaires. Each representative used different follow-up techniques to retrieve as many questionnaires as possible.

Analysis: The analysis was carried out by CAHTA. A univariate analysis was performed for closed questions. The unit of analysis was each respondent (i.e. each questionnaire). Open questions were analysed and classified by two independent reviewers. When disagreement was present, final classification was reached through consensus. After an aggregate analysis of all questionnaires, a stratified analysis by respondents working in HTA organisations and those not working in HTA organisations was carried out.

c) Literature review

The literature review was commissioned to the Iberoamerican Cochrane Centre.

Objective: To identify and describe the maximum number of scientific projects in biomedical and health fields in which at least two European Union state members had participated (plus Switzerland and Norway).

Inclusion Criteria:

1. Subjects: Any completed biomedical or scientific health project or paper with the main researcher being European and which involved at least two participating European countries: Switzerland, Norway, or any EU member (Belgium, Germany, France, Italy, Luxembourg, The Netherlands, Denmark, Ireland, United Kingdom, Greece, Spain, Portugal, Austria, Finland and Sweden).

2. Period of the study: The project, or the paper, had to be published between 1995 and June 2000.

3. Language: The project or paper had to be published in English.

Study selection: 1666 records were recovered through the search strategy mentioned above. A qualified technician conducted a critical review of the paper records obtained, taking into account the inclusion criteria mentioned above. The studies were labelled either as "included", "excluded" or "doubtful". Hard copies of the doubtful studies were obtained to determine their final classification. Appendix 2 describes the search strategy and process of study selection.

Data Collection: A data extraction sheet was created, which followed some of the questions included in the questionnaire (see Appendix 3). The sheet included the following variables: project format, project title, publication year, number of investigators, first investigator, the first author's country, study group/s, number of study group/s, speciality, length of the project, starting year of the project, ending year of the project, participating countries, promoter, sponsor, study setting, topic, study methodology, study subjects, non European Union (EU) countries. All data were entered in a database created for that purpose.

Analysis: A univariate analysis was performed for closed questions.

Results

1. Results from the survey

110 questionnaires from 13 countries were received and analysed (Denmark, Finland, France, Germany, Ireland, Italy, Norway, Spain, Sweden, Switzerland, The Netherlands, United Kingdom, Hungary). The respondents to the questionnaires were working in 95 organisations across Europe, from which 13 organisations were identified as HTA organisations and 82 as non-HTA organisations (e.g. hospitals, units inside the government)

1.1. Basic characteristics of past international joint projects

Topic

Considering HTA and non-HTA organisations together, respondents (n=104) reported 270 International joint projects performed in the past. Of these, information on the topic covered was reported in only 228 questionnaires: some respondents only wrote an acronym (n=29) without any additional information, and the rest did not respond to the item.

After grouping by health topic area, we observed a wide diversity of topics, with up to 28 categories, roughly corresponding to the usual clinical specialities. On the other hand, the most frequent area reported was HTA (17%), with public health in second place (see Figure 1).

Figure 1. Question 3: Topic of most recent IJA-P in the past (n=104)

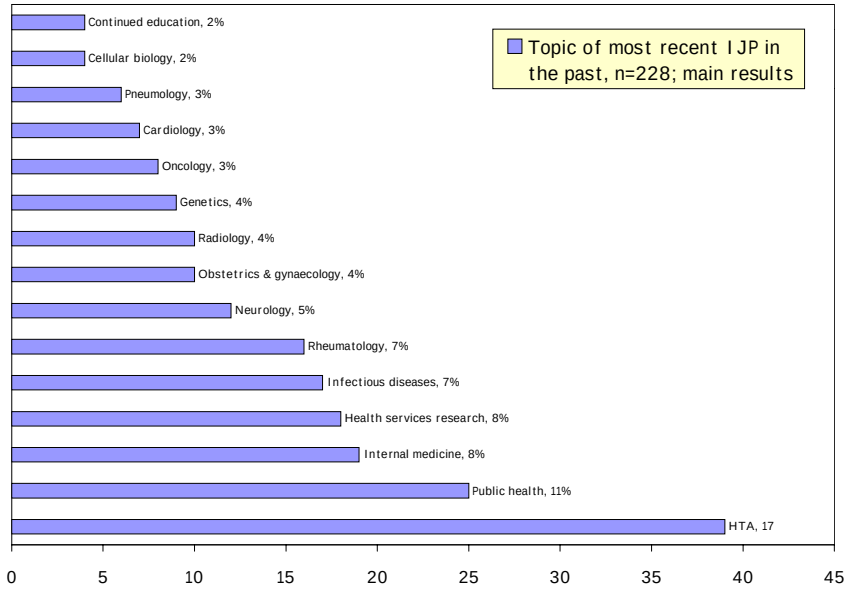
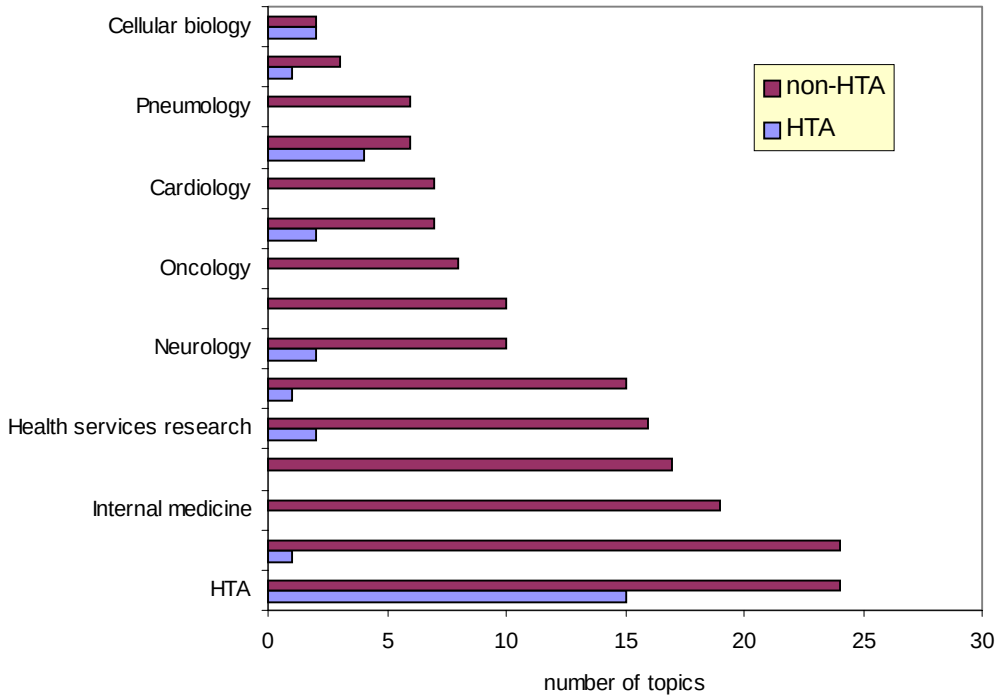


Figure 1 shows the absolute number of projects and their percentages. We included only health topics with more than three past projects. The remaining categories and the absolute number of projects performed in the past, but not shown in Figure 1, are as follows: Pharmacology and therapeutics (3), Otorhinolaryngology (3), Quality of life (3), Ophthalmology (2), Intensive Medicine (2), Biocomputing/information systems (2), Ethics (2), New emerging technologies/ rare diseases (2), Geriatrics (1), Paediatrics 1), Nuclear Medicine (1), Psychiatry and mental health (1) and Stomatology/maxillo-facial (1).

Table 1b, Appendix 4, presents each of the projects according to the 28 categories and type of organisation (HTA and non-HTA).

Figure 1a. Question 3: Topic of most recent IJA-P in the past (17 HTA and 87 non-HTA)



When results are broken down by type of organisation (HTA [n=17] vs. non-HTA [n=87]) (see Figure 1a), we found several frequent topics covered only by non-HTA organisations. Of these, Internal Medicine, Infectious diseases, Obstetrics and Gynaecology, Cardiology and Pneumology are the most relevant. The opposite does not occur with any topic, i.e. that only HTA organisations developed it. Of all projects classified as HTA projects (39), 62% belong to non-HTA organisations.

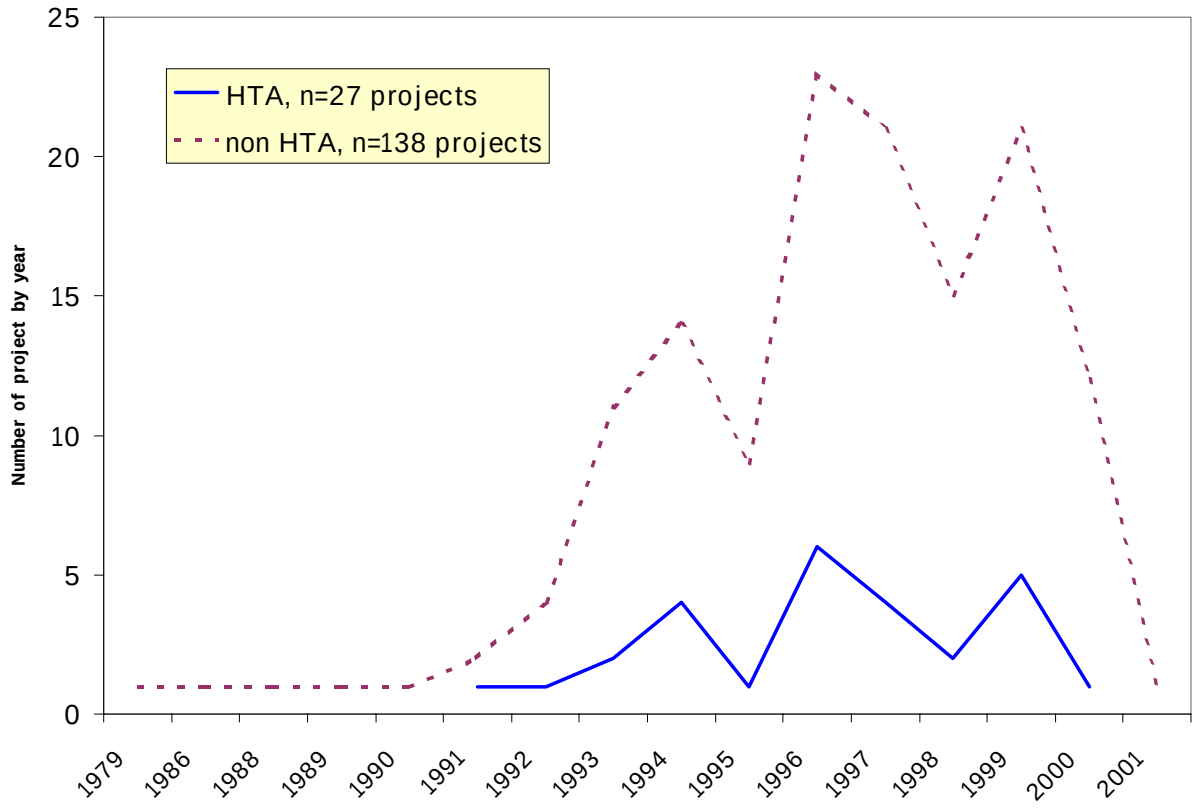
The remaining topics of most recent international joint projects developed exclusively by non-HTA organisations are as follows: Geriatrics, Paediatrics, Nuclear medicine, Psychiatry and mental health, Stomatology/maxillo-facial, Quality of life, Biocomputing/information systems and Ethics.

Starting year

Considering HTA and non-HTA organisations together, respondents (n=165), as shown in Figure 2, reported that 1996 was the year when most projects started.

The HTA organisations reported information on the starting year for 61% of past projects (27/44). After 1996, the most frequent starting years are 1997 and 1999. As regards non-HTA organisations, the starting year was reported for 62% of the projects (138/223), with one project starting 22 years ago (1979).

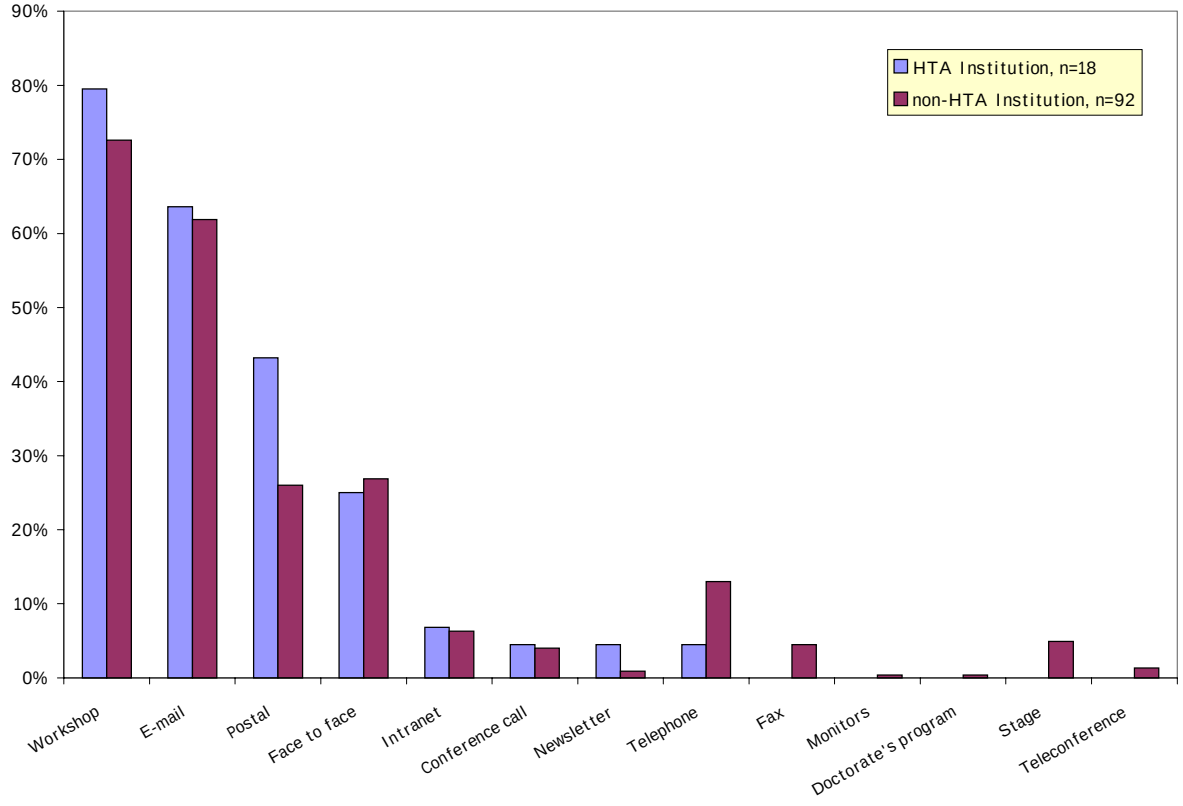
Figure 2. Question 3: Starting year of past IJA-P (n=165)



Tools of co-ordination

Up to 13 different methods of co-ordination for past projects were found (see Figure 3). Workshops are the most frequent, used in the past by nearly 80% of the members of HTA organisations, with e-mail and mail next. In the non-HTA group, workshops were also the most frequent (73%), although mail was not as frequent as in the HTA group. The use of in-site stages, fax and teleconferencing was higher in non-HTA organisations, although barely reaching 5%. Newsletters were more frequent in HTA organisations. Monitors and doctorate programmes are similar in both types of organisations.

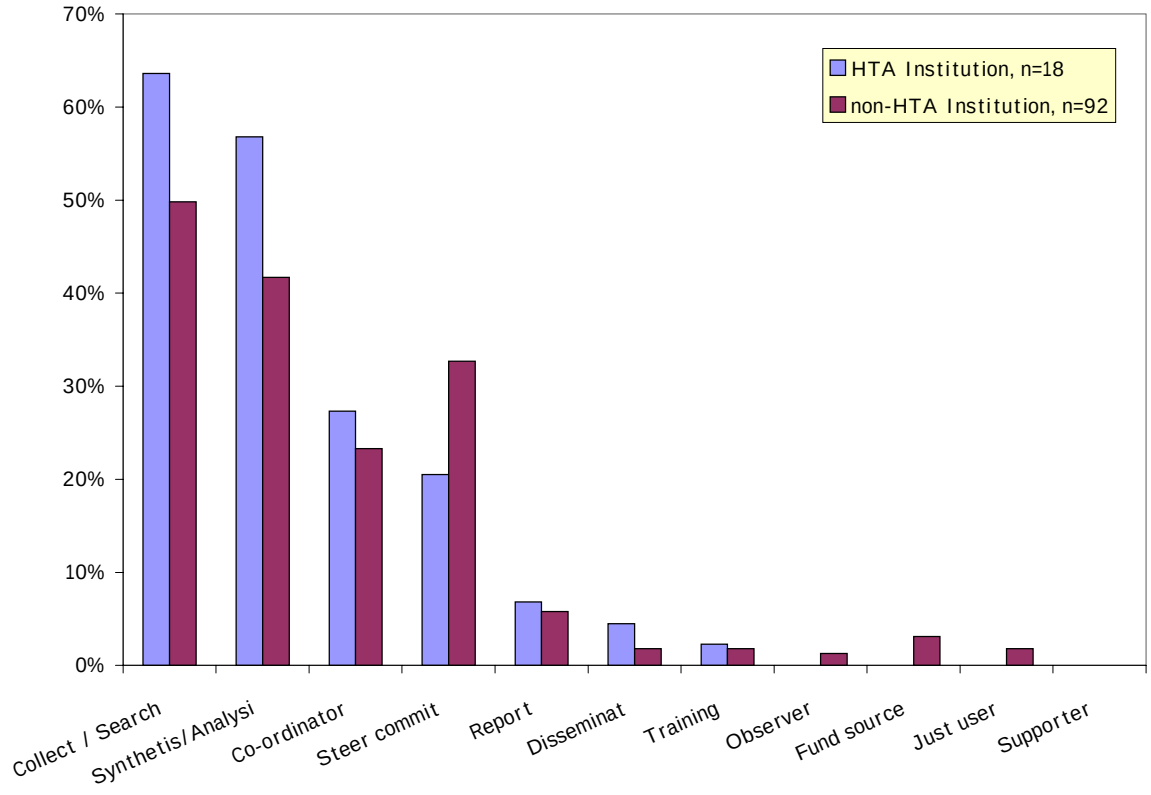
Figure 3. Question 3: Tools used in the co-ordination of past IJA-P



Role of participants

We identified eleven different ways of participating in past projects (see Figure 4). Members of HTA organisations collected data or searched for evidence in 64% of the cases; over 50% actively synthesised evidence or analysed data. Co-ordination and serving on steering committees were also mentioned as frequent tasks. The situation among non-HTA organisations was similar, with a higher percentage on steering committees (33%); the categories of observer, funding source and user were found only among this group. No participant reported playing the role of supporter of the results.

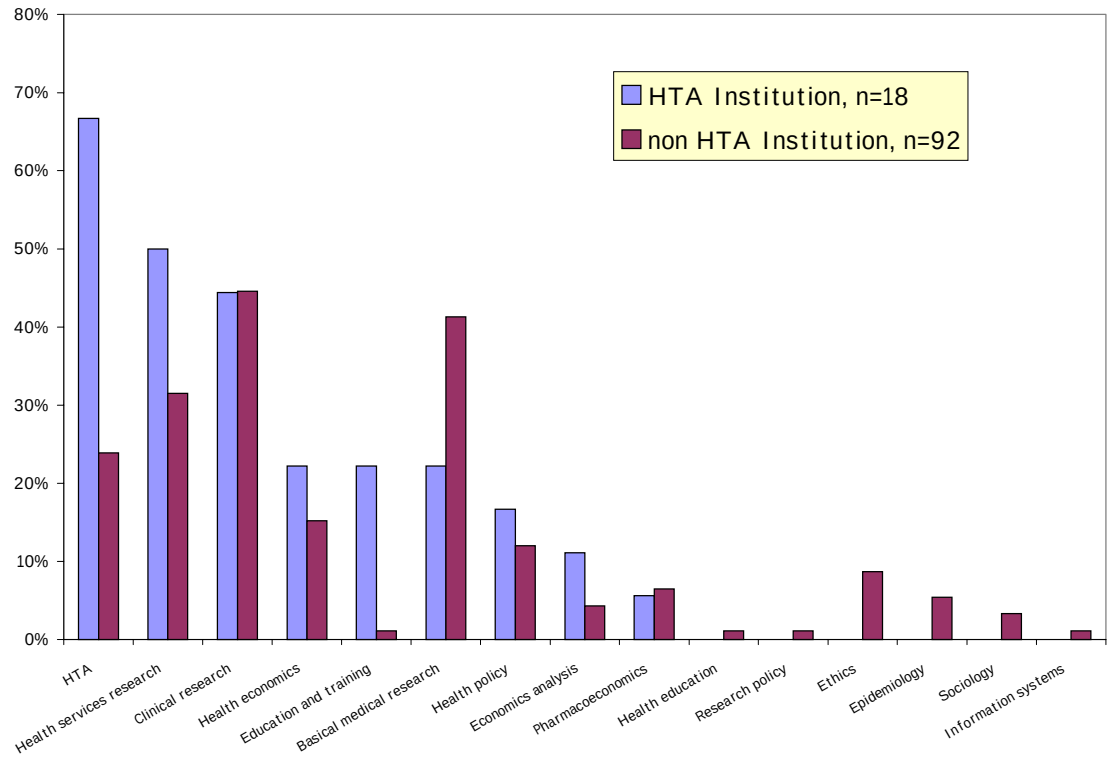
Figure 4. Question 3: Role in past IJA-P



Topics

Regarding the 15 topics covered by past international joint projects (see Figure 5), 45% of the participants in the non-HTA group were involved in Clinical research and 41% in Basic medical research. In the HTA organisation group, the order of the main topics changes, with 67% of the participants doing HTA research and 59% doing Health services research (both meso and micro). Additionally, while 22% of the participants from HTA organisations worked in the field of Education and training, practically none of the non-HTA organisations did. The opposite is true for areas such as Ethics, Epidemiology in public health and Sociology, with projects on those topics by 9%, 5% and 3% of the participants respectively from non-HTA organisations, in contrast to none from HTA organisations. In other areas, e.g. Health education, Research policy or information systems research and development, the trend is similar in both types of organisations.

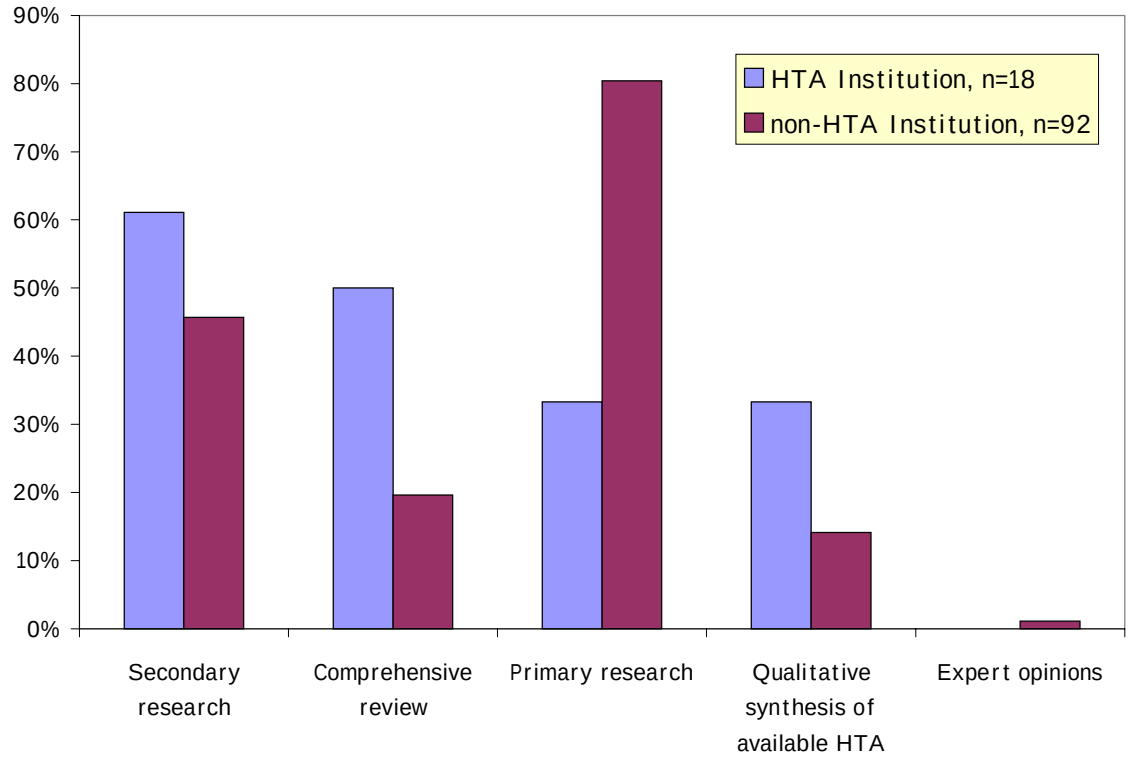
Figure 5. Question 4: Topics of past IJA-P



Methodology used

The methodology used in past international joint projects is described in Figure 6. In the group of HTA organisations, 61% had used Secondary research in the past, although 50% also used comprehensive review. The other two methodologies, Primary research and Qualitative synthesis of available HTA, were used by one third of the members of these organisations. Except for Primary research, used in the past by most participants from non-HTA organisations (80%), the rest appeared in a smaller proportion, but with secondary research still ahead of the others. In both groups, consideration of Expert opinion is practically zero.

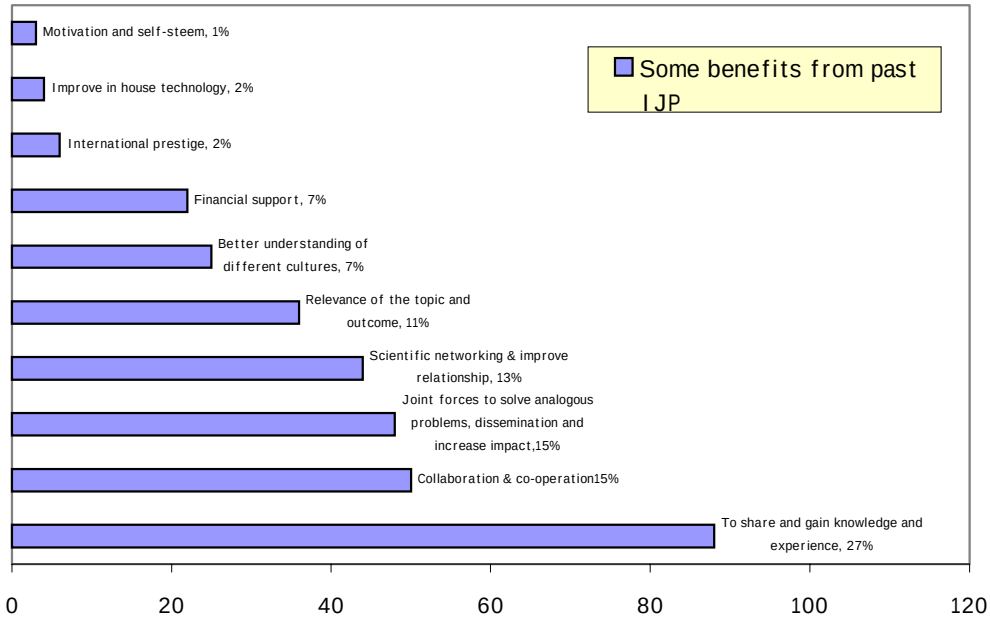
Figure 6. Question 5: Methodology used in past IJA-P

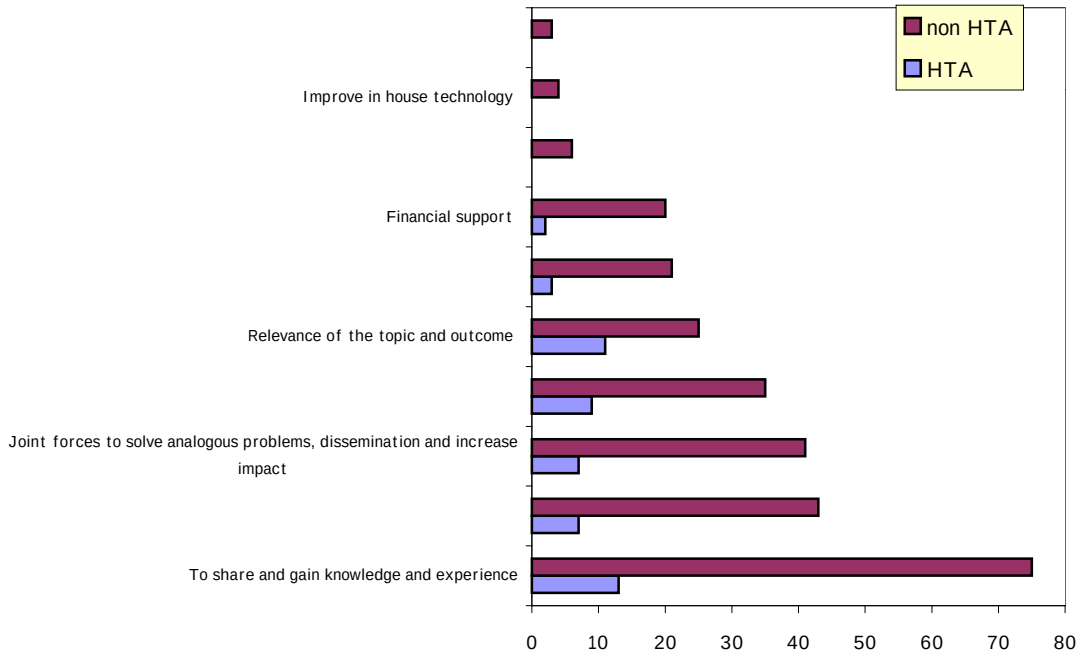


Benefits

Only 87 of 110 respondents answered this question. They mentioned 325 types of benefits, which were structured into 10 categories (see Figure 7). Of these, sharing and gaining knowledge and experience was the most frequently mentioned (27%), followed by other benefits, e.g. Joint forces to solve analogous problems, Dissemination and increase impact or Collaboration and co-operation (with 15% each). Other aspects were far less valued, e.g. motivation and self-esteem (1%), or International prestige, and Improvement of in-house technologies (2% each).

Figure 7. Questions 6/6a: Some benefits from past IJA-P (n=87)





When data are broken down by type of organisation, (HTA [n=16] vs. non-HTA [n=71]) (see Figure 7a), the three least frequent benefit categories, international prestige (6), improve in-house technology (4) and motivation and self-stem (3) were only considered by members of non-HTA organisations. The most widely considered benefit of participating in an IJA-P, i.e. to share and gain knowledge and experience, also received the highest consideration among HTA organisations. Here, however, benefit related to the relevance of the topic and outcome is more important than collaboration and co-operation, which ranked second in the pooled analysis.

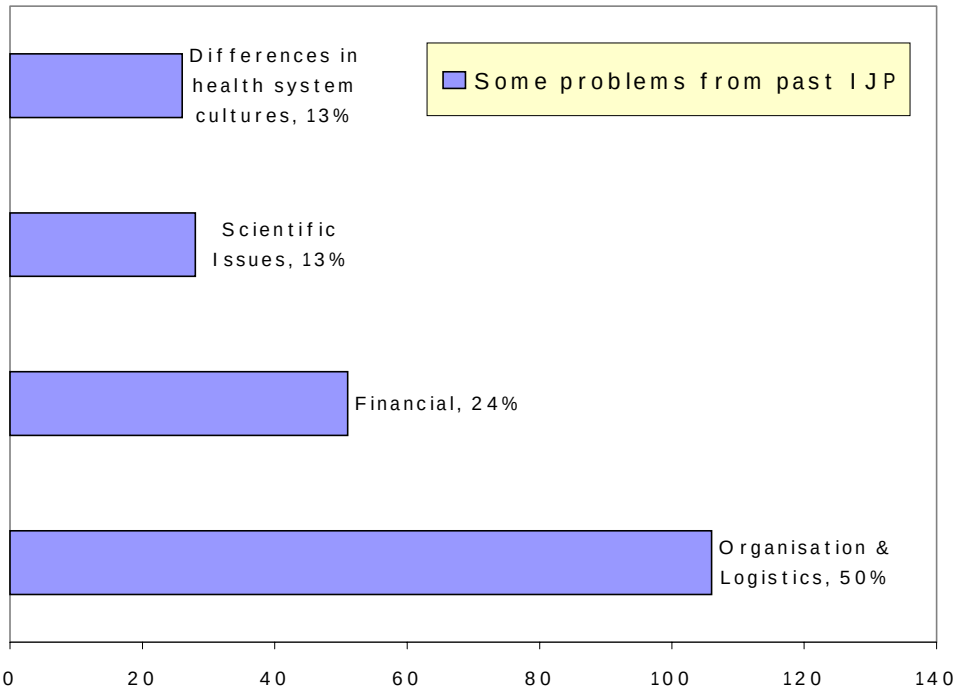
Table 7b, Appendix 4, shows how the respondents perceive the benefits of having participated in an IJA-P, presenting the 10 categories by type of organisation (HTA and non-HTA).

Respondents were also asked to mark the single most important benefit. Only 69 of the 87 respondents to this item did so. Again, to share and gain knowledge and experience was considered the most important benefit. This ranking is the same when data are broken down by type of organisation (HTA [n=18] vs. non-HTA [n=51]). Table 7c (Appendix 4) shows all major benefits according to the 10 above-mentioned categories by type of organisation (HTA vs. non-HTA).

Problems

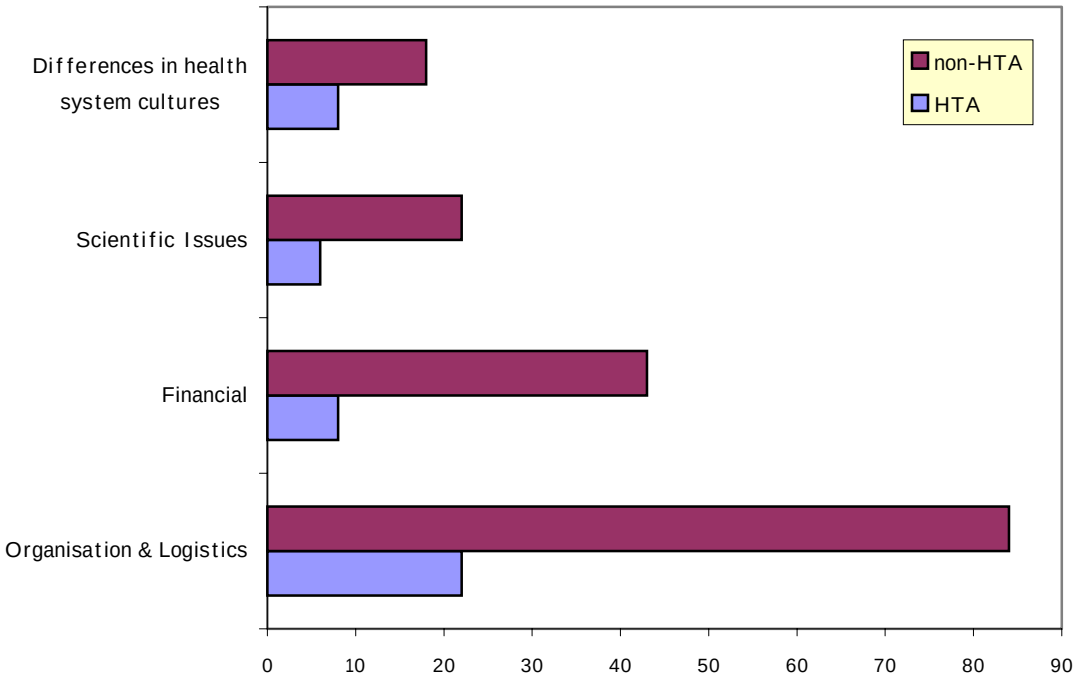
This item was answered by 87 of 110 participants, and 211 problems were cited. The most frequently cited problems were those related to Organisation and Logistics, although a fourth pointed at Financial problems (see Figure 8).

Figure 8. Questions 7/7a: Some problems from past IJA-P (n=87)



When data related to problems are broken down by type of organisation (HTA [n=16] vs. non-HTA [n=71]) (see Figure 8a), and despite the lower number of participants from HTA organisations, the most frequent type is the same as observed in the pooled analyses. Table 8b, Appendix 4, shows the problems encountered by respondents when participating in an IJA-P according to their four categories by type of organisation (HTA and non-HTA).

Figure 8a. Questions 7/7a: Some problems from past IJA-P (16 HTA and 71 non-HTA)



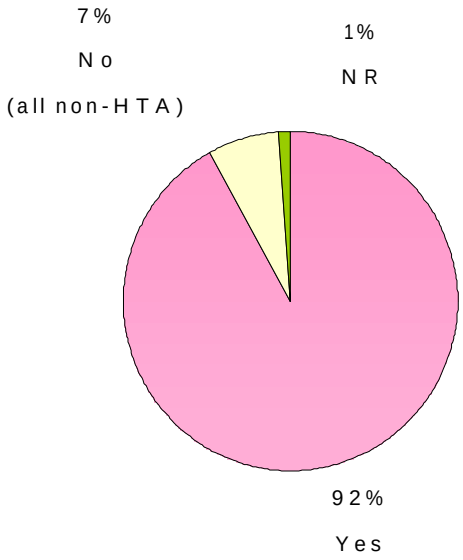
Of the four categories we found, the one related to organisation and logistics was again considered most important among the 60 persons who specifically picked up one among the others. When breaking down the data according to type of organisation (HTA [n=11] vs. non-HTA [n=49]), and despite the low number of participants, differences in health system cultures, which ranked fourth in the list of problems, is in first place among HTA organisations. Table 8c, Appendix 2, shows the most important problems reported by the respondents as a result of their participation in an IJA-P according to the four categories by type of organisation (HTA and non-HTA).

1.2. Interest in future IJA-P

Participation

As for the respondents' interest in participating in future international joint projects, 92% of those surveyed answered affirmatively to this item, i.e. their organisation would be interested in taking part in an international joint project. Of the 7% who responded negatively, all belonged to non-HTA organisations. Figure 9 reflects the ratio of negative answers, summarised in Table 9a, Appendix 4.

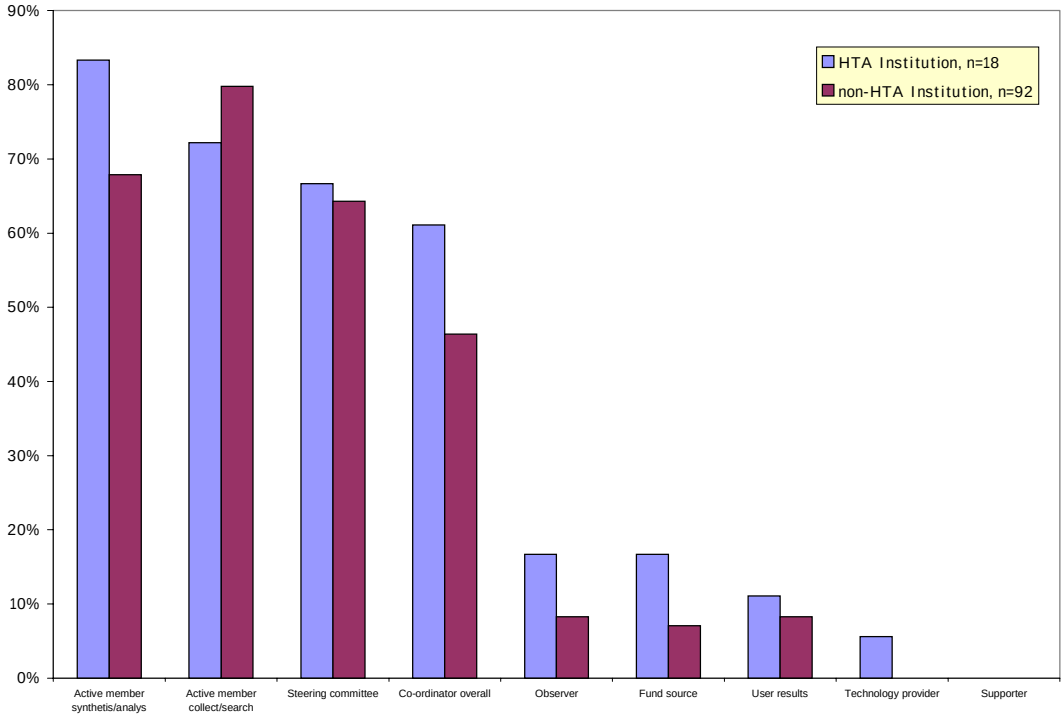
Figure 9. Question 8: Interest in participating in future IJA-P



Preferred role

In HTA organisations, 83% of the surveyed persons prefer to participate as active members synthesising evidence or analysing data. The most frequently stated task as an active member involved collecting data or searching the evidence. The roles of observer, funding source, user of results or technology provider were played far less by their members, despite being nearly double that of members from non-HTA organisations. In these, collecting data or searching the evidence exceeded synthesising evidence or analysing data (80% vs. 68%), as expected in this type of organisation. Additionally, co-ordination of tasks is more frequent in HTA organisations than in non-HTA organisations (see Figure 10).

Figure 10. Question 9: Preferred role in future IJA-P



Type of resources organisations are willing to devote to IJA-P

As for the type of resources organisations are willing to devote to international joint projects, of the 6 alternatives offered (see Figure 11), 39% of the surveyed persons from HTA organisations were quite favourable toward the human resources contribution, as were respondents from non-HTA organisations. Regarding the economic aspects, the situation is not as clear, with nearly one fourth of the surveyed persons least willing to contribute economically. This percentage, however, is lower than among non-HTA organisations. Collaboration through technical assistance, in the case of HTA organisations, is quite favourable, in contrast to non-HTA organisations.

Figure 11. Question 10: Types of resources that organisations are willing to devote IJA-P

	Least %		**Little %**		**Some %**		**Good bit %**		**Most %**	
	HTA*	NonHTA**	HTA	NonHTA	HTA	NonHTA	HTA	NonHTA	HTA	NonHTA
Dedicated human resources	–	2	6	2	11	15	39	31	39	41
Financial support	22	33	28	18	28	13	11	3	–	5
Technical assistance	6	5	6	12	28	27	17	23	28	14
Space + laboratory facilities	–	–	–	–	–	–	–	1	–	–
Administrative help	–	–	–	–	–	–	–	–	–	1
Consultancy	–	–	–	–	–	1	–	–	–	1

* HTA Organisation, n=18

** Non-HTA Organisation, n=92

The other collaboration initiatives identified in the open answers to this item (space and laboratory facilities, Administrative help and Consultancy) fared very poorly (1%) and only in non-HTA organisations.

1.3. Propositions for future IJA

Criteria for use

Of the nine selection criteria for future international joint project topics, described in question 11 (see Figure 12), 44% of those surveyed in HTA organisations viewed "a large number of patients potentially affected in Europe" and "controversial technology" as the most important. One third of those surveyed viewed criteria such as Costly technology or Variations in clinical use of a health technology in Europe to be somewhat important, while they viewed Lacking or modest research evidence or Established technology being inappropriately used to be even more important. Overall, Ethical concerns are least considered.

Figure 12. Question 11: Criteria for future IJA-P topic selection

	Least %		**Little %**		**Some %**		**Good bit %**		**Most %**	
	HTA*	NonHTA**	HTA	NonHTA	HTA	NonHTA	HTA	NonHTA	HTA	NonHTA
A large number of patients/people potentially affected in Europe	–	2	–	1	11	13	(44)	26	39	(49)
Costly technology	–	4	–	8	33	22	33	38	22	11
Controversial technology	6	6	–	9	(11)	29	(44)	(17)	17	21
Lacking or modest research evidence	11	8	6	6	28	21	17	17	(33)	30
Emerging technology	–	3	11	5	22	25	39	31	22	20
New technology	–	2	11	6	28	22	28	(38)	28	18
Established technology being inappropriately used	6	4	6	10	28	20	22	24	(33)	24
Variations in clinical use of a health technology in Europe	–	6	6	9	(33)	23	33	26	22	17
Ethical concerns	17	8	22	12	33	24	22	17	–	14

* HTA Organisation, n=18

** Non-HTA Organisation, n=92

In the open answers to item 11, according to some of the respondents, other criteria were identified that should be used when selecting topics. The criteria, and their percentages, are: Equity (5.6% good bit by HTA), Medical education (1.1% most by non-HTA), Legislation (5.6% some by HTA), Unknown biology of disease (1.1% most by non-HTA), Orphan topics (1.1% some and 2.2% most by non-HTA), Variability of health care system structures in different countries (1.1% most by non-HTA) and Aging (1.1% most by non-HTA).

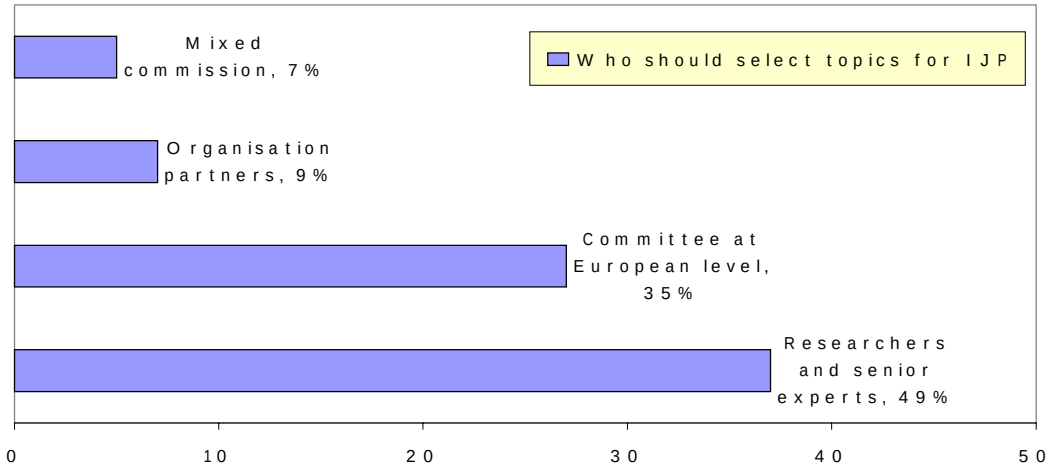
In the case of non-HTA organisations, the criterion "A large number of patients /people potentially affected in Europe" is viewed as most important, with nearly 50% of the surveyed persons in this group. Of those surveyed from non-HTA organisations, 38% viewed New

technology as an important criterion for topic selection. Other criteria, such as Emergency technology were also found to be important, but less frequently than in HTA organisations. In this group, the least considered were Controversial technology and Ethical concerns.

Who should select topics

Only 70/110 persons answered this item. The different options fell into four categories (see Figure 13). Nearly one half of those surveyed considered that researchers and experts are the ones to select topics for international joint projects. Of the other three alternatives, a Committee at the European level was considered by 35%.

Figure 13. Question 12: Criteria for future IJA-P topic selection



When data are broken down by type of organisation (HTA [n=12] vs. non-HTA [n=58]) (see Figure 13a), HTA respondents believed that a Committee at the European Level should be in charge of selecting IJA-P topics, in contrast to most non-HTA participants, who believed that researchers and senior experts should do it.

Figure 13a. Question 12: Whou should select topics for IJA-P (12 HTA and 58 non-HTA)

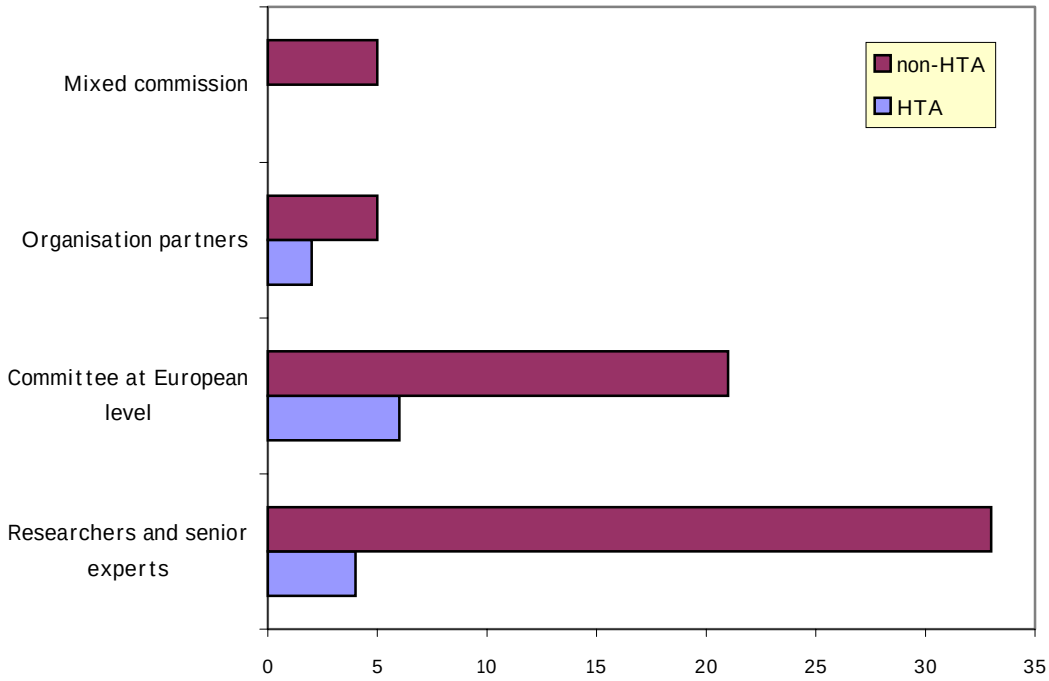
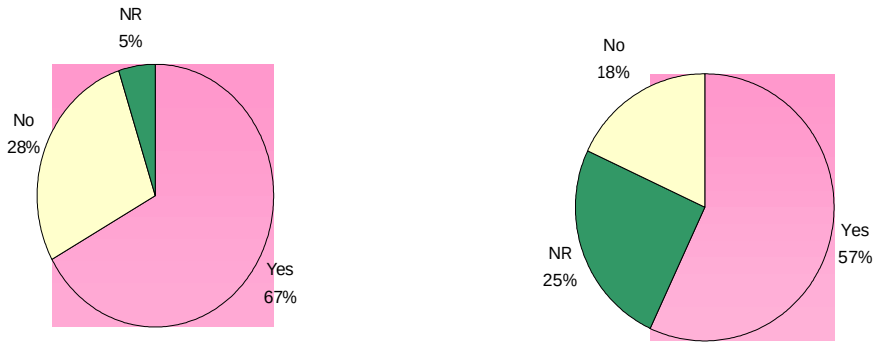


Table 13b (Appendix 4) shows the responses of the participants, by type of organisation, regarding responsibility to select IJA-P topics.

Willingness to have a formal priority setting process at the European level to select topics for IJA-P

In HTA organisations, 67% of the respondents indicated that a formal priority-setting process should be established at the European level to select topics for joint HTA; 28% responded negatively and 5% did not respond (see Figure 14).

Figure 14. Question 13: Willingness to have a formal priority setting process at the European level to select topics for IJA-P in HTA (NR= no response)



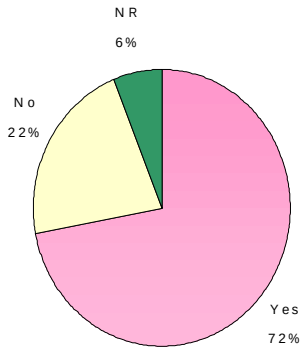
Question 13 was to be answered only by respondents from HTA organisations. Of the remaining participants, however, 31 gave adequate responses, and the rest did not (n=61). Of the latter, their answers have been considered and appear in the figure on the right. Of these, 57% said that a formal priority-setting process is necessary, 18% responded negatively and 25% did not respond.

Table 14a (Appendix 4), shows the reasons for and against, by type of organisation (HTA vs. non-HTA).

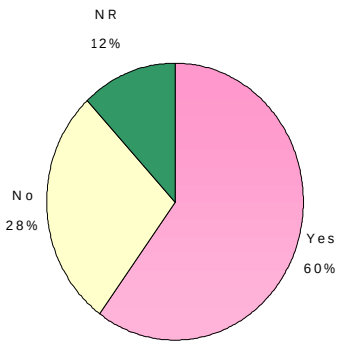
Willingness to have a permanent co-ordinating European office for HTA

In HTA organisations, 72% considered it necessary to have a European office to co-ordinate international joint projects on HTA, while 22% considered it unnecessary (see Figure 15). Rigidity was one of the reasons mentioned against it. A few respondents mentioned alternatives, e.g. flexible systems, such as networks, to deal with topics and resources acceptable to the involved countries. Many reasons were given in support of a European co-ordination office, the most frequent being to guarantee continuity and improve co-ordination. Other reasons included improvements in efficiency, dissemination and impact, the promotion of synergy, and recognition that HTA is a field that requires an international approach.

Figure 15. Question 14: Willingness to have a permanent co-ordinating European office for HTA (NR= no response)



HTA Organisation, n=18



Non-HTA Organisation, n=50

The responses from non-HTA organisations (which were not allowed initially) have also been considered, and are shown in Figure 15 (right figure). Sixty percent of the non-HTA organisations considered it necessary to have a European co-ordination office; 28% did not, and 12% did not respond. The reasons for and against, by category and type of organisation, appear in Table 15b (Appendix 4).

Preferred organisational characteristics of an HTA co-ordinating body

Of the different characteristics proposed by respondents from HTA organisations, 33% prefer a virtual organisation and 28% prefer a centralised body in a single country. It should be noted that 28% did not express an opinion, and 5% preferred one organisation in each country.

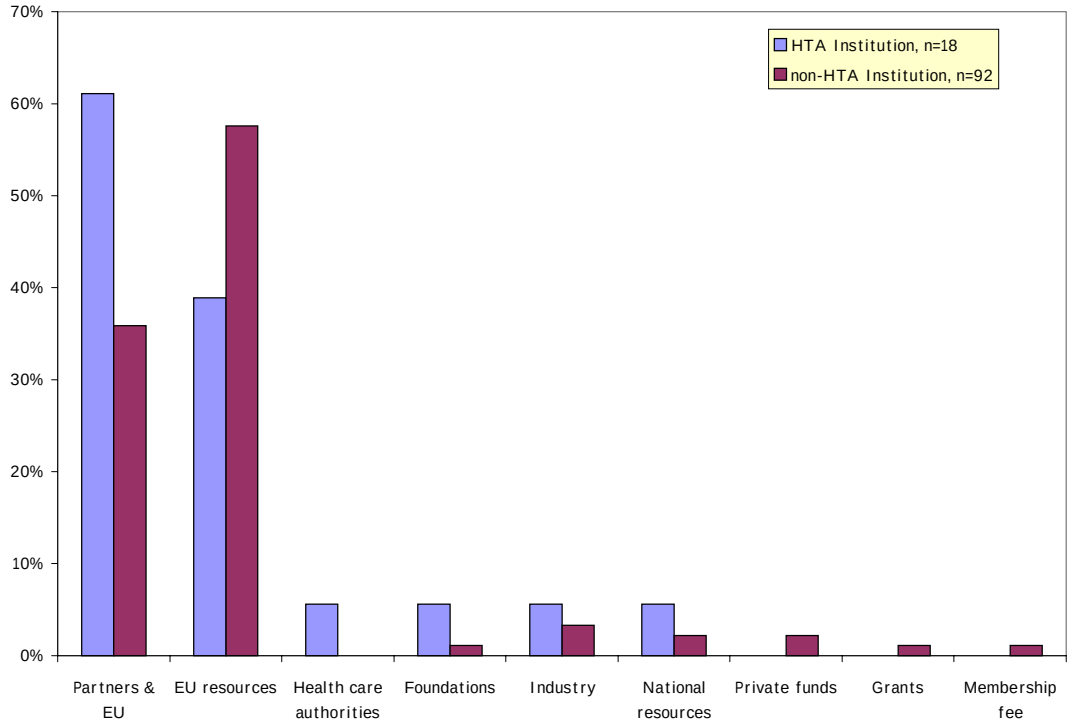
As with items 13 and 14, this question was to be answered only by those working in an HTA organisation. Only 32 gave adequate responses, hence, non-HTA answers were also considered, with 36% preferring a virtual organisation.

Some suggested that the decision should be made by consensus and closely linked to clinicians.

Funding sources preferred

In HTA organisations, 60% of the surveyed persons consider that funding of international joint projects should come from the partners and the European Union (see Figure 16). Other funding sources, such as Private funds, Competitive grants or Membership fees from interested partners are not contemplated. Other alternatives, such as Health care authorities, Foundations, Industry or National resources were proposed by only 5% of the respondents respectively. Contrary to this more participatory view by HTA-organisation members, nearly 60% of non-HTA members say that international joint projects should be funded only by the European Union, and only one third believe that projects should be co-funded by EU and the involved organisations. The only funding source not listed by non-HTA organisations was Health care authorities.

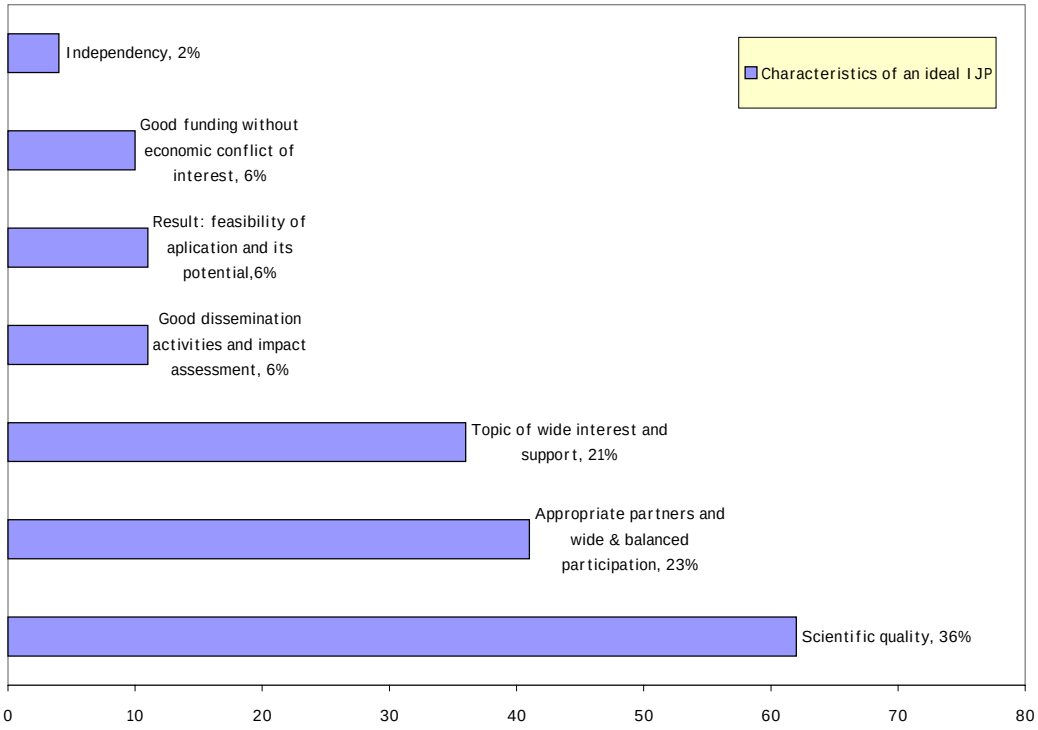
*Figure 16. Question 16: Funding sources preferred for future I*JA-P



Characteristics of ideal international joint projects

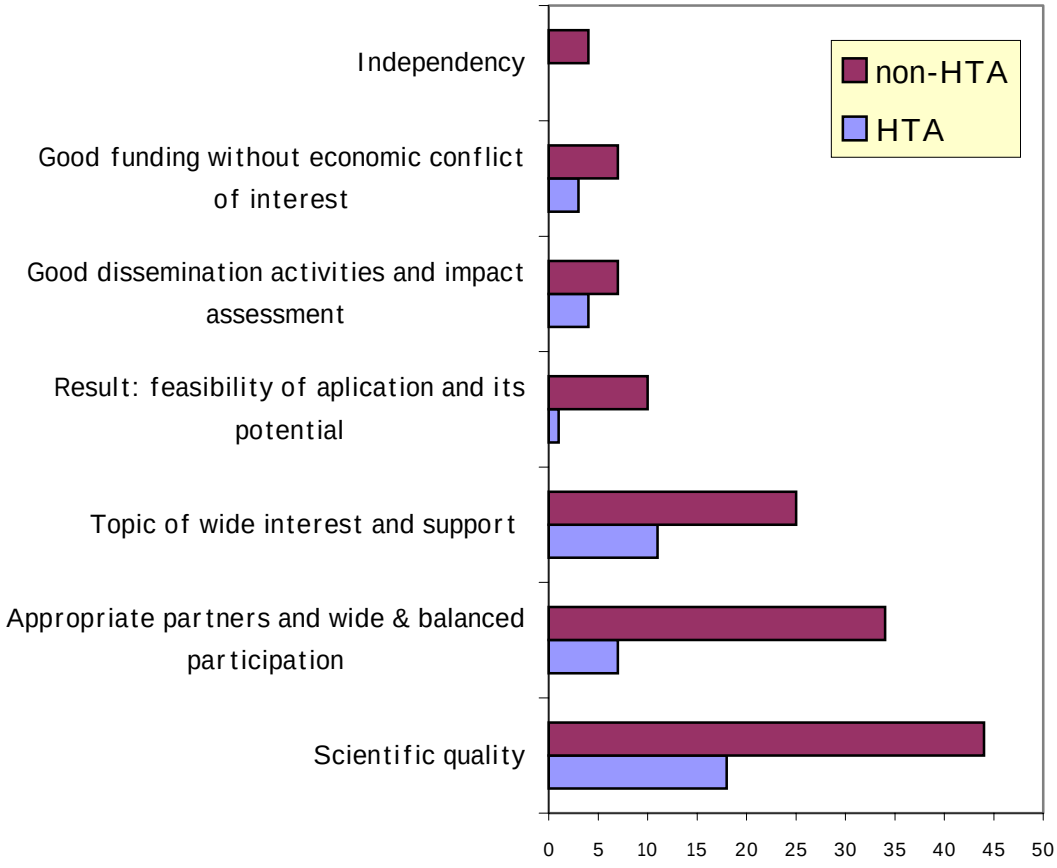
Only 70 participants responded to this question. Up to 175 aspects were cited as ideal characteristics, and they have been classified into seven categories (see Figure 17). Scientific quality, appropriate partners and wide and balanced participation were the most common characteristics. Others, such as independence, were far less common (2%).

Figure 17. Question 17: Characteristics of an ideal IJA-P (n=70)



When data are broken down by type of organisation (HTA [n=14] vs. non-HTA [n=56]) (see Figure 17a), both types report that scientific quality is the feature that an ideal IJA-P should have to be credible and supported by both the participants and external organisations. However, appropriate partners and wide, balanced participation is more important to HTA respondents than is wide interest and support. Table 18b (Appendix 4) gives the ideal characteristics, as grouped into seven categories, by type of organisation to which the respondents belong (HTA vs. non-HTA).

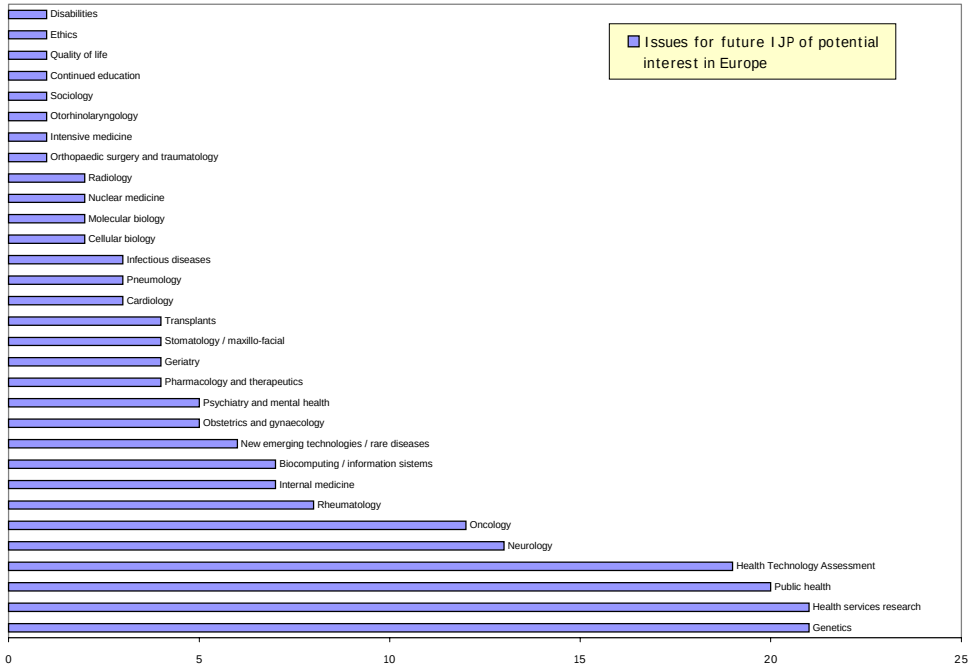
Figure 17a. Question 17: Characteristics of an ideal IJA-P (14 HTA and 56 non-HTA)



1.4. Issues for future IJA-P of potential interest in Europe

This question was answered by 73 respondents who mentioned 185 issues classified into 31 categories. Of these, Genetics, Health service research, and Public health are the most frequently mentioned, followed by Health technology assessment, Neurology and Oncology as the next most frequently mentioned (see Figure 18).

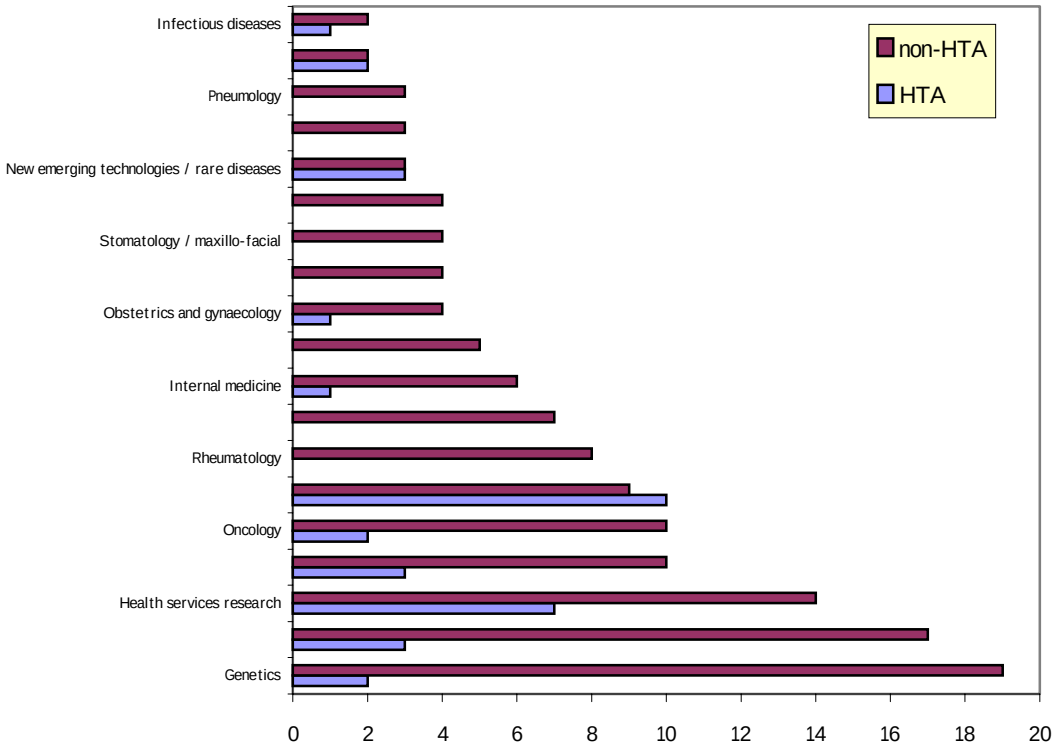
Figure 18. Question 18: Issues for future IJA-P of potential interest in Europe (n=73)



In addition, other issues for future international joint projects were identified: Nuclear medicine (2), Orthopaedic surgery and traumatology (1), Intensive medicine (1), Quality of life (1), Cellular biology (2), Molecular biology (2), Radiology (2), Otorhinolaryngology (1), Sociology (1), Continued education (1), Ethics (1) and Disabilities (1).

When data are broken down by type of organisation (HTA [n=15] vs. non-HTA [n=58]) (see Figure 18a), several issues are mentioned frequently in the global appraisal for future IJA projects of potential interest in Europe, but are not supported by participants from HTA organisations, i.e. Rheumatology, Biocomputing/information systems, Geriatrics, Stomatology/ maxillo-facial, Transplants, Cardiology and Pneumology. Pharmacology and therapeutics, new emerging technologies/rare diseases receive equal ratings. Obviously, only the respondents associated with HTA organisations prefer HTA-related topics.

Figure 18a. Question 18: Issues for future IJA-P of potential interest in Europé



The issues for future IJA projects of potential interest in Europe as stated by the respondents appear in Table 19b (Appendix 4), classified by type of organisation (HTA vs. non-HTA), grouped into 31 categories.

Finally, Table 20, Appendix 4, shows other observations by respondents regarding IJA-P.

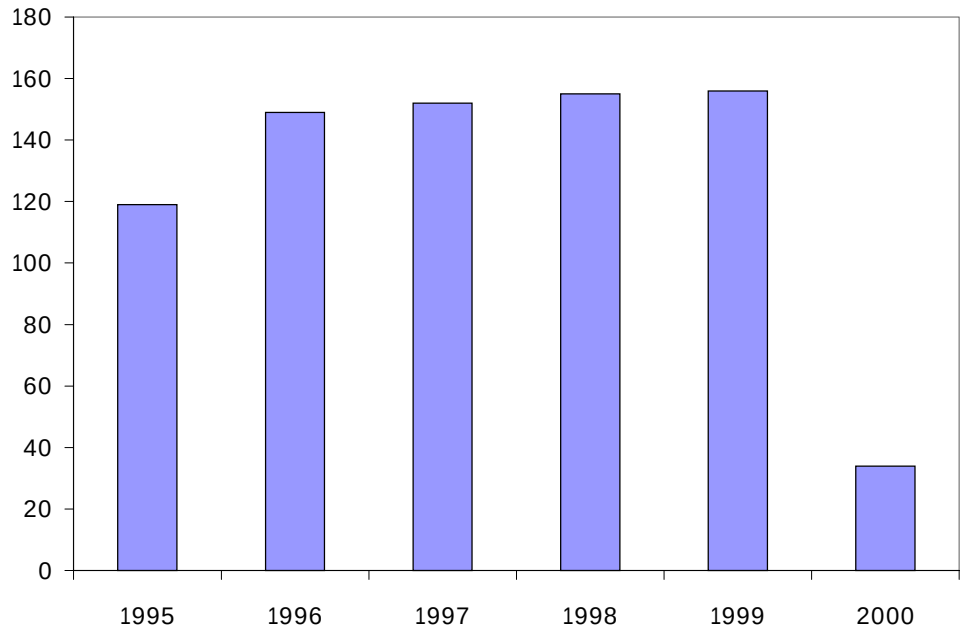
2. Results from literature review

2.1. Aggregate analysis

Main characteristics

In total, 765 articles were reviewed. The distribution of the year of publication appears in Figure 19. A quantitative jump is observed from 1995 to 1996, although the trend between 1996 and 1999 is stable. The records in 2000 were searched until June. The delay in updating the abstract database is a reason for the low number of articles found in the last year searched.

Figure 19. Year of publication



The median number of authors in the papers reviewed was seven (range from 2 to 65), although 56% of the articles named one or more working groups or scientific organisations as author, considering them as a single, unique author. The median project length was 2 years (ranging between 1 and 33), whereas the median time lapse from project completion until publication was 3 years (ranging between 1 and 15).

The most frequent topic of research identified was clinical research (66.7%). Less frequent were health services research (11.8%), basic research (11.0%), evaluation of health technology (7.7%), pharmacoeconomy (0.9%), health economy (0.7%), sociology (0.5%) and ethics (0.1%). The most common settings for these studies were: hospitals (38.7%) and ambulatory care (37.0%), with community (13.1%), laboratory (12.7%) and university (0.5%) quite far behind.

The methodology mainly used by projects was primary research (97.5%). Only 6 projects (0.8%) used secondary research. Three projects were high-quality reviews and two others were low-quality reviews. Based on the methodology used, the median project length was 2 years (ranging

from 1 to 33) for primary research and 1 year (ranging from 1 to 19) for secondary research. Data on project length are not available for low and high quality reviews or for reports.

Country participation

The rank of nationality of the first author is shown in Figure 20. When absolute numbers are considered, the UK leads with a frequency of 27% followed by Holland with 13%. It is important to note that these two countries along with Germany represent 50 % of all reviewed papers. This figure also shows the level of participation of each EU member state in the articles reviewed. As shown by the figure, the United Kingdom, Holland, Germany and France have a higher level of participation. In general, the median number of participants from EU states is five (ranging from 2 to 17); while the median number of total participating countries in different projects is seven (ranging from 2 to 57). This indicates that many of the studies were done in conjunction with non-EU countries (53%). Figure 20 b shows the order of countries when absolute numbers are adjusted for population in each country.

Figure 20. Country participation in published EJP

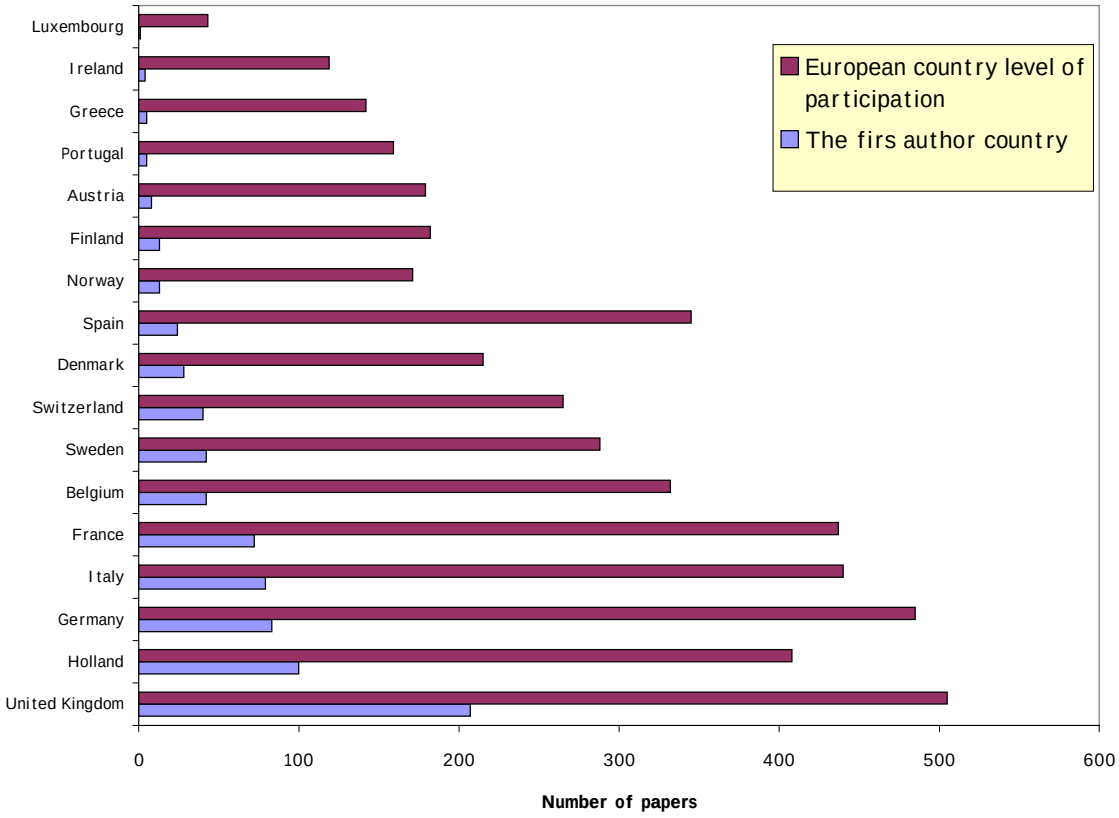
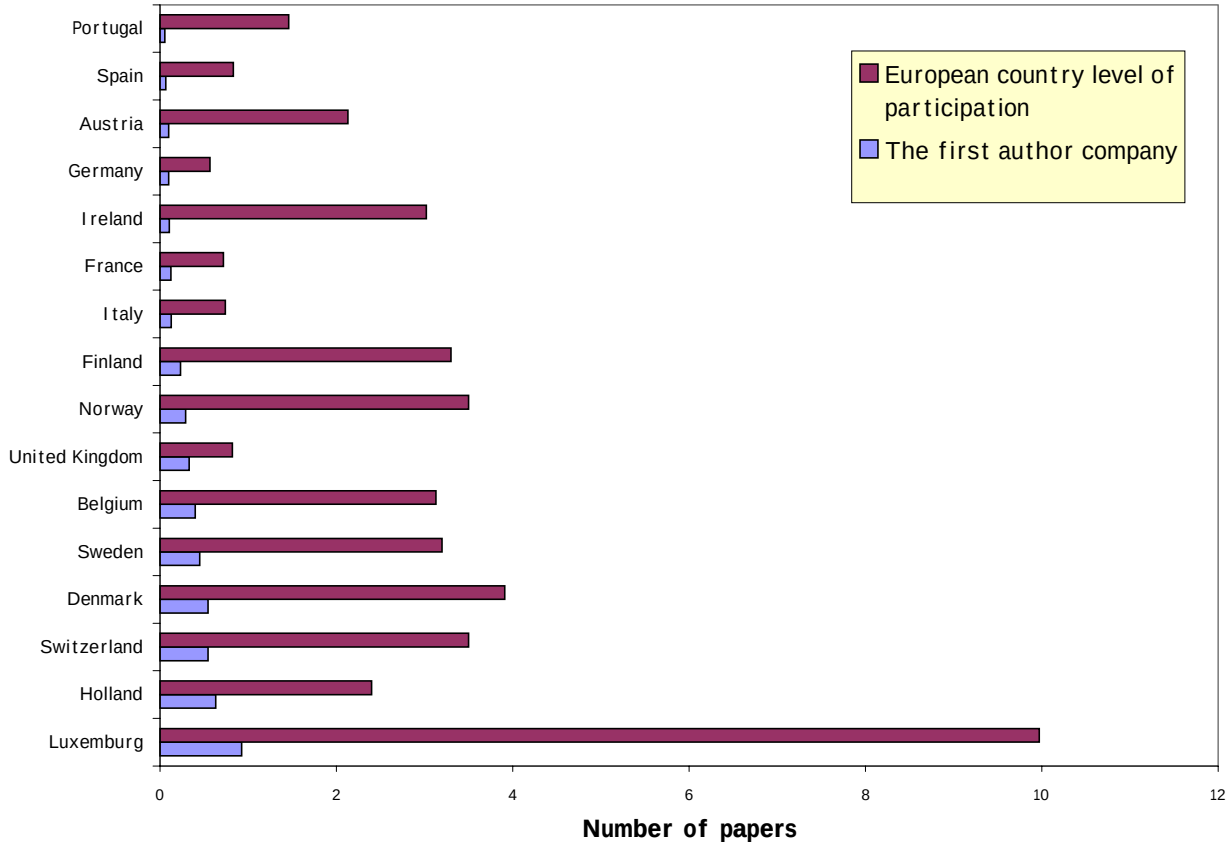


Figure 20a. Country participation in published EJP. Adjusted by country population (1999).



When looking at the continents that collaborate with European projects (EJP), the United States (USA), and European non-EU countries are the ones that collaborate the most. (Figure 21 shows the results.) When individual countries from different continents are considered, again the USA and Poland (as a European non-EU country), rank first. Other details of level of collaboration with other European non-EU countries are presented in Figure 22.

Figure 21. Intercontinental collaboration

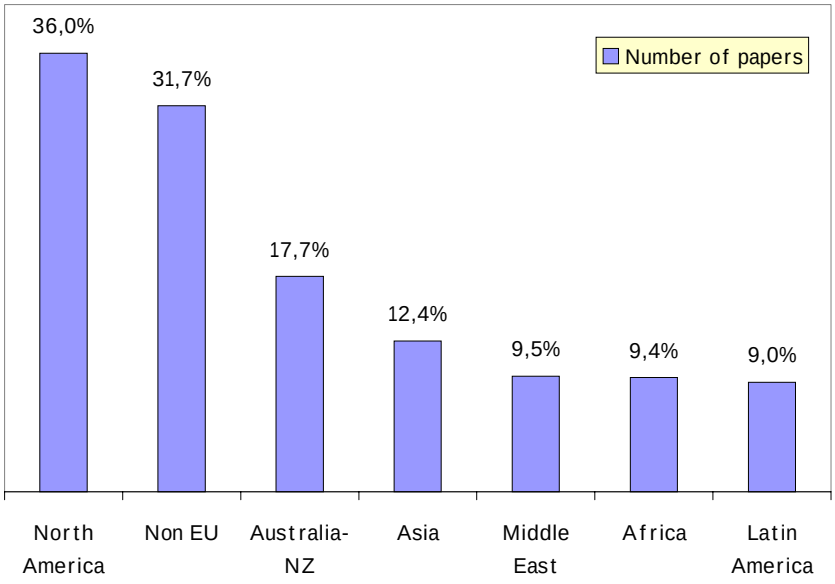
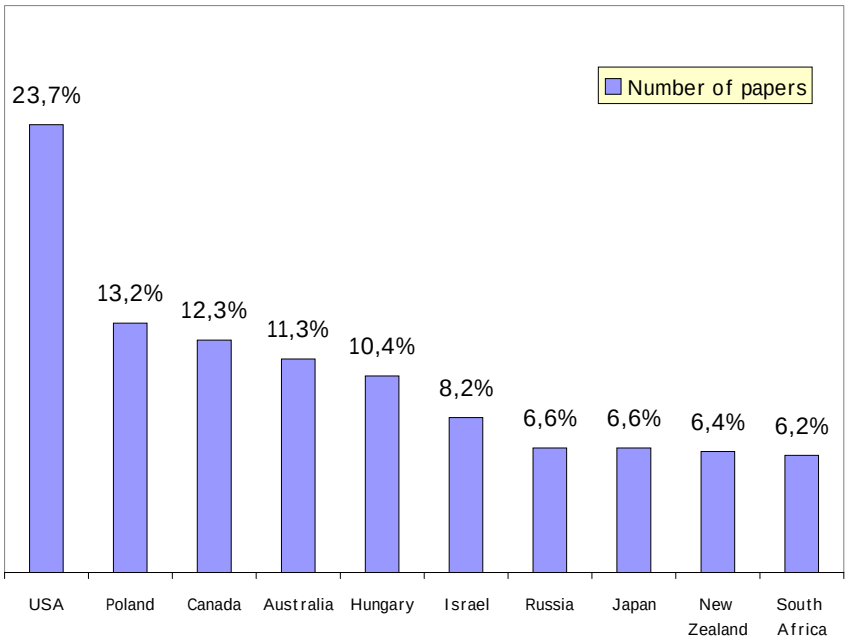


Figure 22. Country partners (European non-EU)



Promoters and sponsors

A detailed description of the promoters and sponsors of the studies can be found in Figure 23. Generally, the principal promoters of European joint projects are hospitals (75%). Universities also represent important participants (39%). Other organisations represent a heterogeneous group of entities (Medical and health societies, foundations, organisations as EU or WHO, etc). Table 1 shows the level of participation from the EU and WHO as a promoters and sponsors of European joint assessments. As regards sponsoring, industry participates economically in 46% of the published European Joint projects. Table 1 (Appendix 5) shows a list of the names of the sponsor industries.

Figure 23. Promoters and sponsors

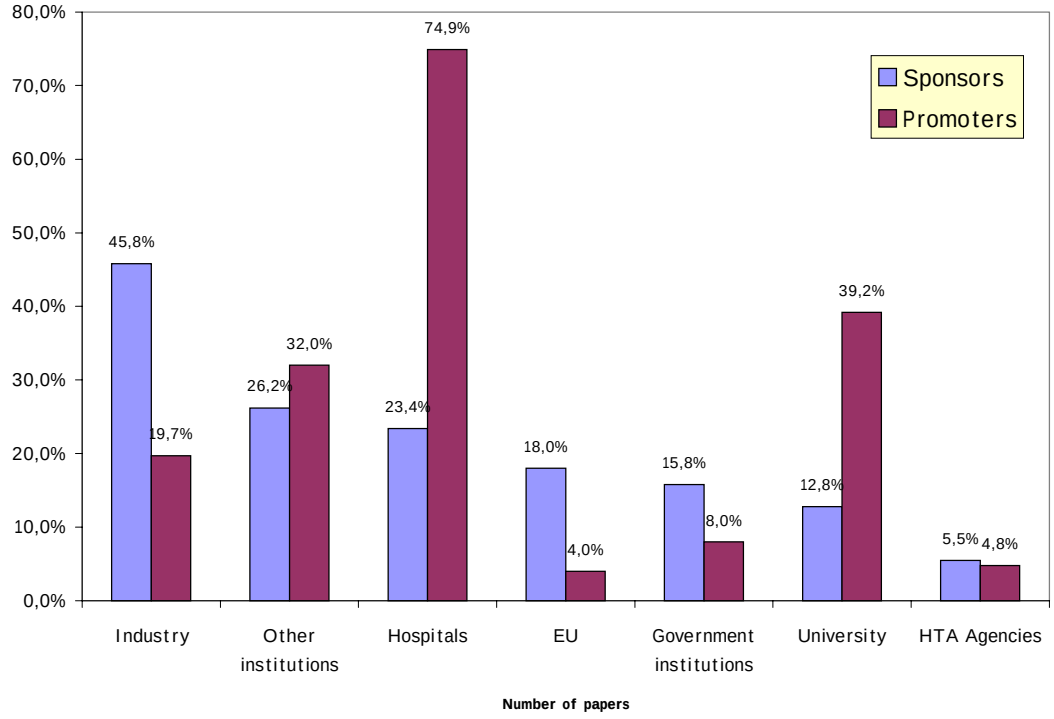


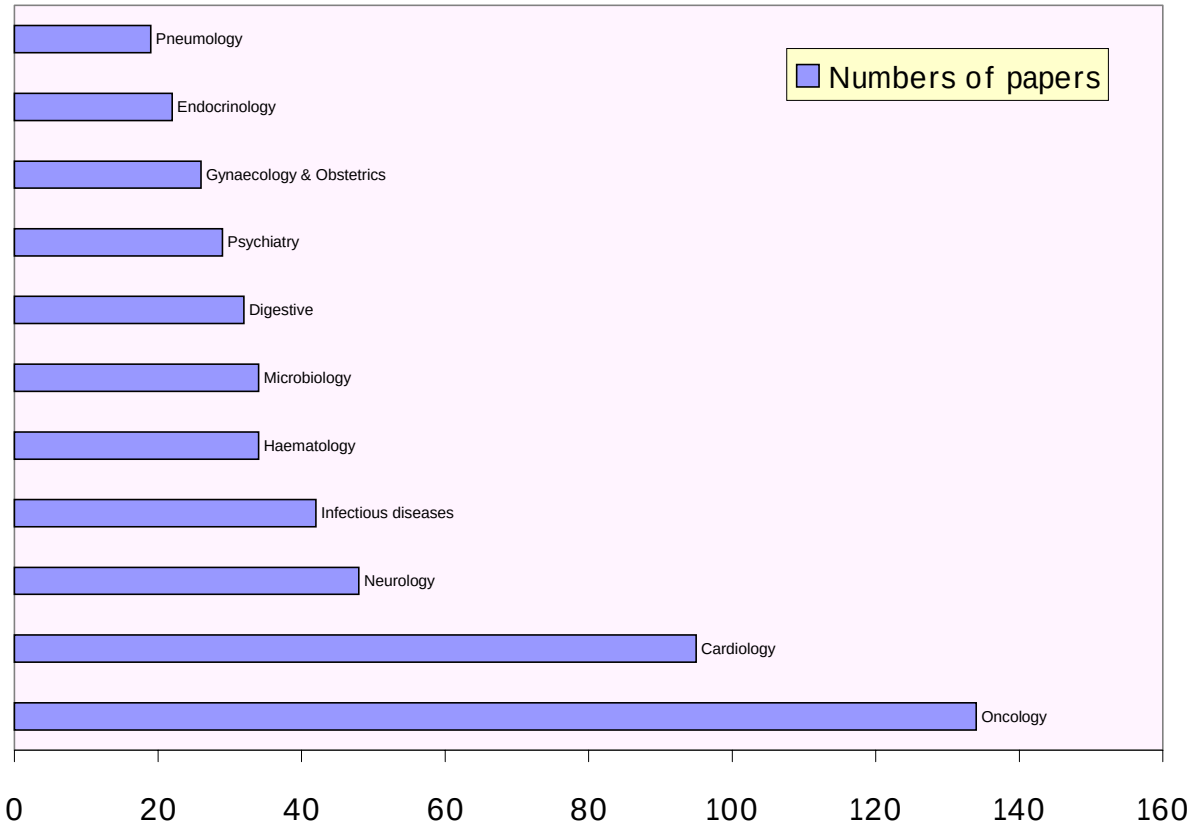
Table 1. Participation of EU and WHO as promoters and sponsors of EJP.

	Promoter, n(%)	**Sponsor, n(%)**
EU	3 (0,4)	137 (18)
WHO	23 (3)	31 (4)

*(%) refers to the total number of papers (n=765)

Figure 24 indicates that the medical specialities studied most in European joint projects are Medical Oncology and Cardiology. The other prominent specialities studied also appear in Figure 24.

Figure 24. Top ten health topic areas



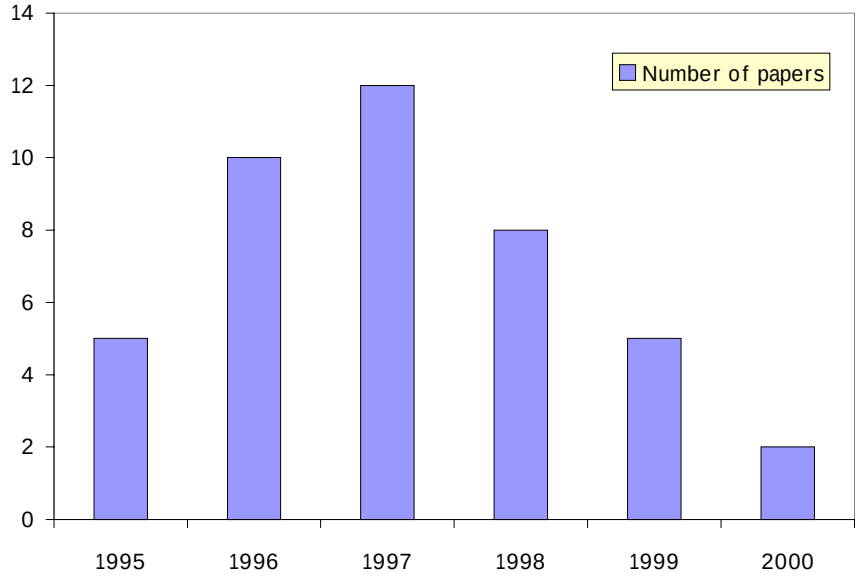
2.2. Stratified analysis

The stratified analysis presents a comparison between studies sponsored by HTA organisations vs. others.

Forty-two studies were identified as having an HTA organisation as their sponsor. These articles were analysed using the same variables included in the aggregate analysis.

A distribution of the year of publication appears in Figure 25. A quantitative jump is evident from 1995 to 1996, although the trend is steady between 1996 and 1997. There is a progressive drop thereafter. The search for records in year 2000 was continued until June. The delay is due to abstract database updating.

Figure 25. HTA Agencies as sponsor. Year of publication



The median number of authors in the papers reviewed was nine (range from 1 to 65), although in 60% of the reviewed papers, the articles named one or more working groups or scientific organisations as study authors, considering them as a single, unique author.

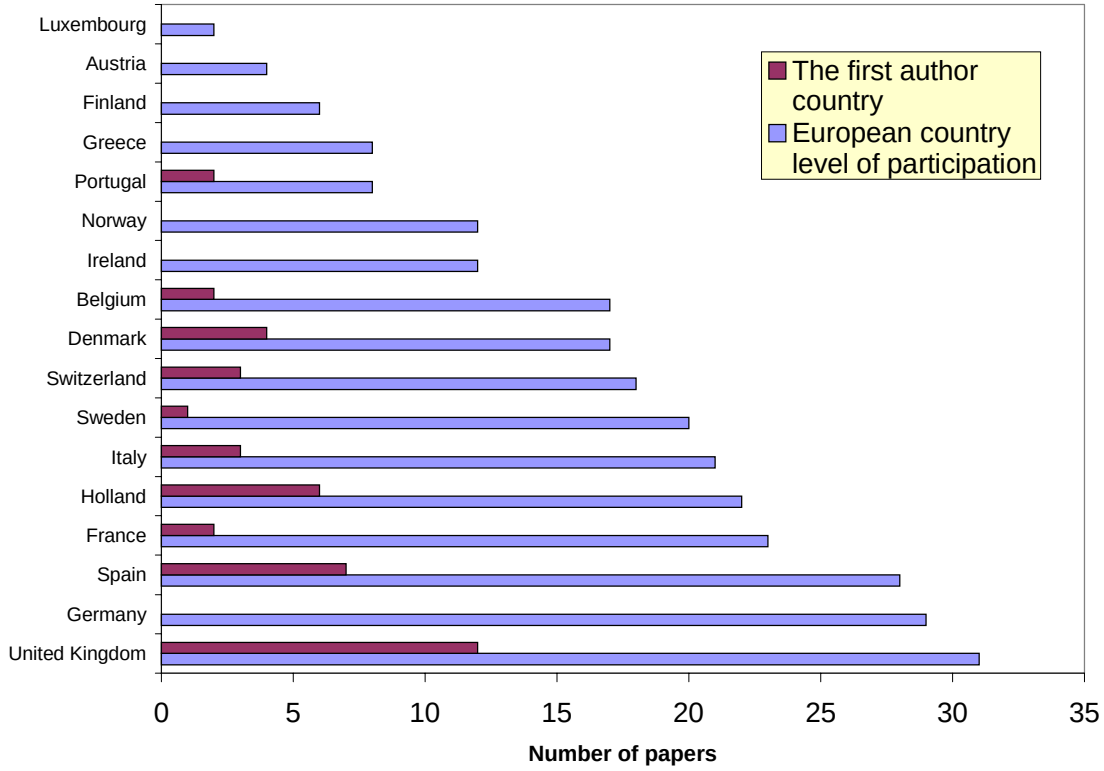
The median project length was 2 years (ranging between 1 and 20), whereas the median time lapse from project completion until publication was 3 years (ranging between 1 and 7). Primary research was the methodology most frequently used (90.5%), while only 3 projects (7.1%) are based on secondary research and one project was a high-quality review.

The most frequent topic of research identified was clinical research (59.5%). Less frequent were; health services research (12%), basic research (16.6%) and the evaluation of health technology (7.1%). The most common settings where these studies were carried out were hospitals (43.0%) and ambulatory care (35.7%); trailed by community (28.6%) and laboratory (12.0%).

Country participation

The rank of nationality of the first author can be seen in Figure 26. The UK leads with 28.5% followed by Spain with 17% of the published papers. This figure also shows the level of participation of each EU member state in the articles reviewed. As shown by the figure United Kingdom, Germany and Spain are the countries with higher level participation. In general, the median number of participants from EU states is 7 (ranging from 2 to 15); while the median number of total participating countries in different projects is 8 (ranging from 2 to 28). This indicates that many of the studies were done in conjunction with non-EU countries (59.5%).

Figure 26. HTA Agencies as sponsor. Level of participation of European countries and country of first author



Looking at regions that collaborate with European projects, USA and European non-EU countries are the ones who collaborate most. Figure 27 shows the results. When individual countries from different continents are considered, the USA and Australia rank first. Other details concerning the level of collaboration with other European non-EU countries appear in Figure 28.

Figure 27. HTA Agencies as sponsor. Intercontinental collaboration

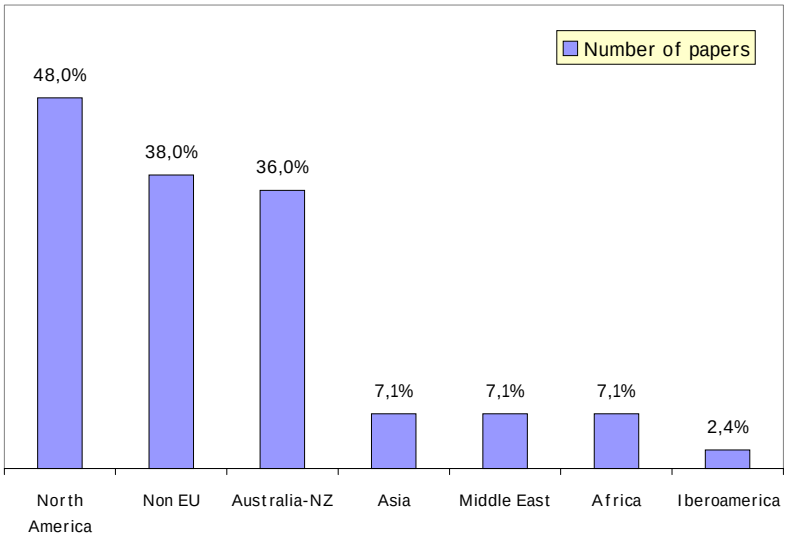
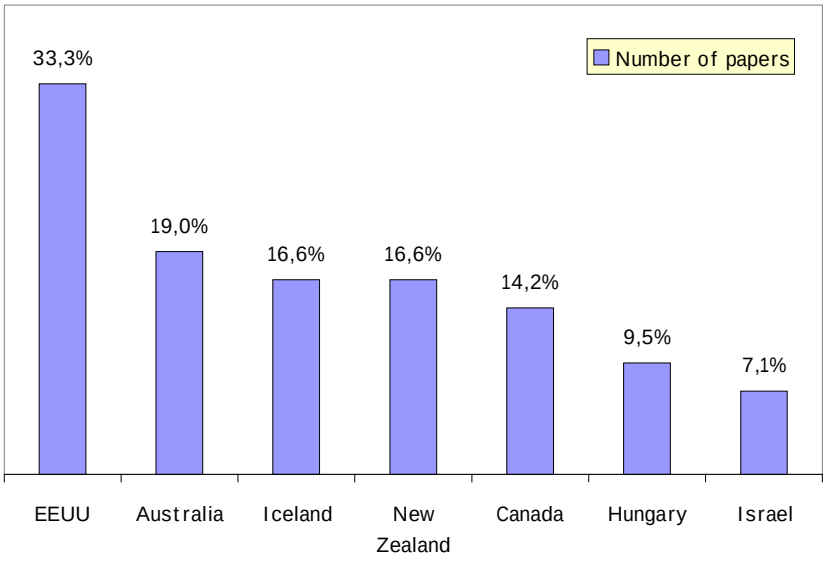


Figure 28. HTA Agencies as sponsor. Most frequent European non-EU countries participants



Promoters and sponsors

A detailed description of the promoters of the studies can be found in Figure 29. Generally, the principal promoters of European joint projects are hospitals (81%). Universities are also important participants (59.5%). Other organisations represent a heterogeneous group of entities (Medical and health societies, foundations, organisations as EU or WHO, etc). Table 2 shows the level of participation from the EU and WHO as a promoters and sponsors of European joint assessments. As regards sponsoring, HTA organisations receive economic help from other organisations, i.e. co-sponsorship. Government organisations help to co-sponsor 76% of European Joint Assessments. Figure 30 shows the results.

Figure 29. HTA Agencies as sponsor. Promoter's study

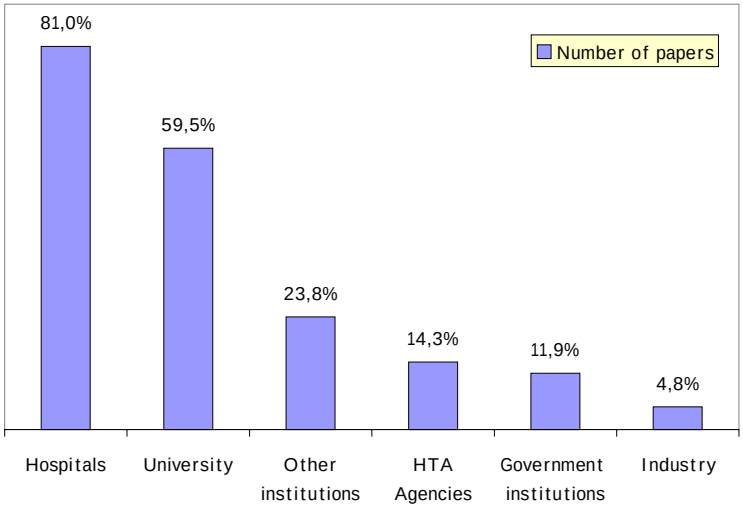


Figure 30. HTA Agencies as sponsor. Participation of other sponsor organisation

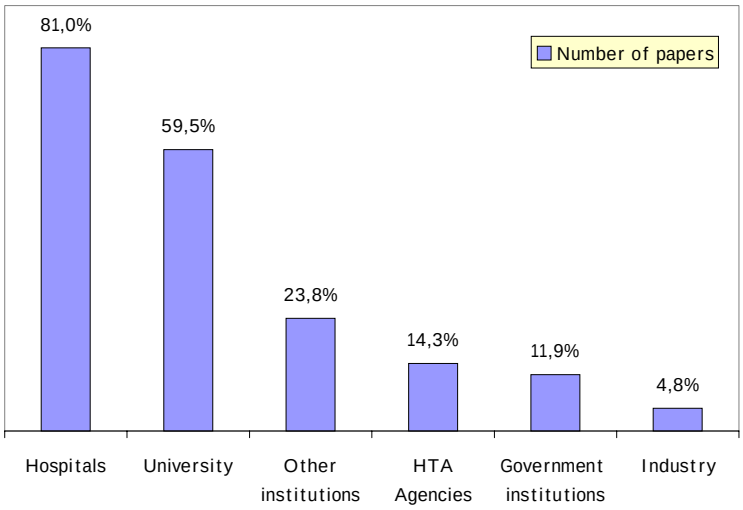


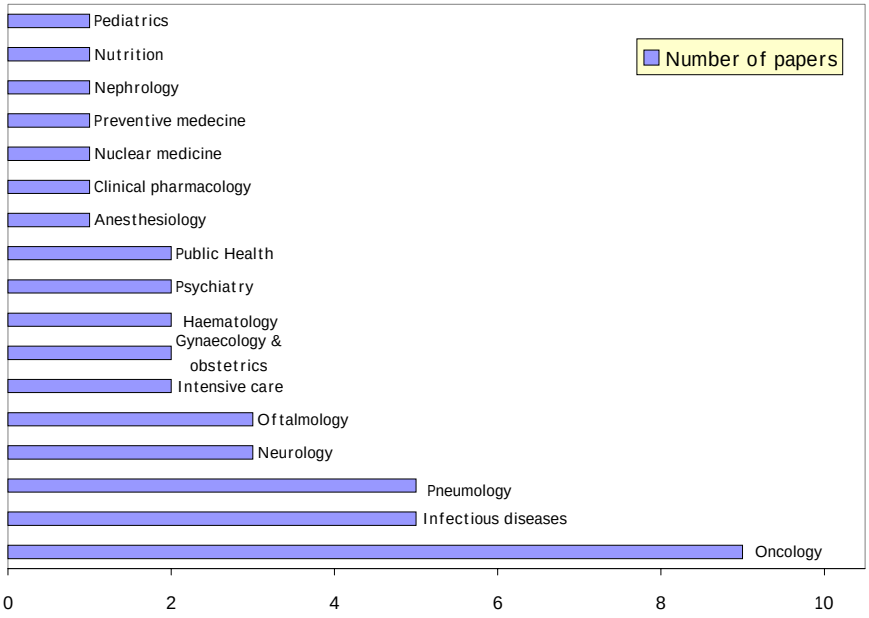
Table 2. Level of participation of EU and WHO in studies sponsored by HTA organisations.

	Promoter, n(%)	**Sponsor, n(%)**
EU	1 (2.4)	10 (24)
WHO	1 (2.4)	2 (5)

*(%) refers to the total number of papers (N=42)

As shown in Figure 31, the more-studied medical specialities in European joint projects sponsored by HTA organisations were Medical Oncology, Infectious diseases and Pneumology. Other specialities studied are shown in Figure 31.

Figure 31. HTA Agencies as sponsor. Medical specialities studied in European Joint Projects



The distribution of different specialities by topic is presented in Table 3.

Table 3. Distribution of the papers by topic and medical specialities

Medical Specialities	Basic Research N	Clinical Research N	Health Services Research N	Health Technology Assessment N
Medical Oncology	1	6	2	0
Infectious	0	5	0	0
Pneumology	0	4	1	0
Neurology	0	3	0	0
Ophthalmology	0	0	2	1
Intensive Medicine	0	0	0	2
Gynaecology & obstetrics	0	2	0	0
Haematology	1	1	0	0
Psychiatry	1	1	0	0
Public Health	2	0	0	0
Anaesthesiology	0	1	0	0
Clinical Pharmacology	0	1	0	0
Nuclear Medicine	0	1	0	0
Preventive Medicine	0	1	0	0
Nephrology	1	0	0	0
Nutrition	1	0	0	0
Paediatrics	0	0	1	0
Total	7	26	6	3

3. Results from the workshops. Possible mechanisms for developing joint European assessments and projects

3.1. Prioritisation

A formal, transparent structure for priority setting should be developed. A bottom-up system in topic selection is preferred. Regarding the profile of the participant in the priority setting process, a mixed composition is preferred, because of the broad variety of topics, interests and necessities. HTA agencies, the research community, the interest groups (patient organisations, etc) and citizens should be consulted about the most effective HTA assessments to be conducted at the European level and funded by the EU. Different systems can be used to organise the process, e.g. a list of issues could be published on the Internet to be scored by each party. Another option would be to carry out a topic selection process using the Delphi method. When selecting a topic, the possibility of a long time lag should be recognised.

3.2. Financing and contract

Several funding modalities are proposed: a) for projects selected as top-(from EU)-down projects, the EU should provide total funding, b) for bottom-up projects, the EU and the countries participating should co-fund the project.

Regarding the contract, there should be one leading contractor with an agreed minimum of partners from other member states. The partners in the project should have an official document from the EU that formally recognises their participation.

Management of economic resources should be delegated, to the extent possible, to the leading contract agency. However, it is necessary to allow for the option of sub-budgets managed by the individual, participating HTA organisations.

3.3. Proposal

Participation from candidate European non-EU countries should be encouraged when these countries have expertise and research capacity. However, motivated EU member states are preferred to comprise the team of project initiators. If the process works, it should be open for other European non-EU countries with strong (national) interests in the topic selected.

The review of the proposal should be transparent and carried out by experts selected from EU and European non-EU countries. Since one of the problems identified by respondents of the survey is the inadequate selection of peer-reviewers, i.e. reviewers are not knowledgeable on the topic, one of the proposals raised was to also send the proposal to experts for review, and receive their response via a sealed letter.

Finally, the selection of topics should be need-directed as regard health systems. Ethical, socio-cultural and economic issues should be stressed in the proposals since these areas are not well developed in multinational European Joint Assessments.

3.4. Logistics

Dedicated human resources are needed from each partner to carry out a multinational joint assessment. Additionally, easier EU procedures for obtaining funds and managing projects should be encouraged.

In cross-national communication and project development, it is preferable to use a combination of effective tools (e.g. workshops, e-mails, videoconferences), which should be adequately funded.

A physically small co-ordinating office could help improve co-ordination. However, a clear definition of its responsibilities must be agreed on.

Discussion

Present state of participating in multinational European joint assessments and other health related projects

Literature review and INAHTA database search

As shown by the results of the literature review in the health care field, EU members carry out considerable activity in multinational joint health care projects inside Europe. This activity is not circumscribed only to the member states, since 53% of the publications identified include members of other non-EU countries, mainly in North America (Canada and USA) and Europe

(Poland and Hungary). This fact enables the transfer of knowledge and experiences to and from other non-EU countries and continents, enriching the final results of these international projects.

The United Kingdom is the EU country with the highest participation in European multinational joint projects, ranking first in absolute numbers regarding the nationality of the first author. However, when the figures are adjusted for population the country order changes considerably, with Luxembourg being the country showing the most publications based on first author. However, it is not completely appropriate to adjust the number of publications based on the number of inhabitants. The best way to proceed would have been, for example, to adjust by the number of health scientists working in each country. Since this information is unavailable, we consider the absolute number to be the best proxy.

The fact that United Kingdom has a high number of publications with first author may be due to its long and strong tradition of obtaining funds from the government and the drug industry for health care research. Another possible explanation for its leading position may be its long tradition in research education, its good level of scientists, and their good co-ordination. However, it should be noted that this ranking refers to published articles in peer-review journals. Therefore, had we included the "grey literature", this result might have been different. Nevertheless, some countries are far from the first positions both in terms of participation and the author, e.g. Luxembourg, Ireland, Greece, Portugal, Norway, Austria and Finland. This could suggest that an increase in European resources aimed to develop and consolidate stronger research capabilities should be addressed to those end-range countries. The development of research capabilities facilitates multinational European joint assessments and the dynamics of working. Another interesting result is that in terms of the first author of a paper, most countries rank quite far behind the U.K., although some of them have a high level of participation in IJA-P (e.g. Germany, Italy, France, Holland and Spain). This could suggest that the systematic lack of leadership by some of the non-English speaking countries could be due to a language limitation. English is currently the most used scientific language, making it difficult for scientists from non-English speaking countries to act effectively as a leader in international projects. In fact, this has been one of the limitations related to IJA-P and often cited by the respondents to the survey. Language limitations also raise other types of problems, such as higher translation costs in disseminating the results of the assessments/projects to non-English-speaking countries. Although this presents a difficult obstacle, it could stress the need for strengthening international relationships since the greater the need to work globally the higher the incentives to learn/improve English. It is important to note that a review concerning the quality of the studies has not been carried out. Therefore, a large number of studies published by a country does not necessarily mean here that all these studies have been performed within accepted parameters for quality.

While hospitals and universities have been the greatest promoters of studies, health care industry has been the main sponsor. The EU also sponsors European research. However, its contribution to the total volume of published studies is quite low (18%) compared to industry (45.8%). While funds from industry are welcomed and help develop R&D, an excessive level of investment from this sector could lead to a situation where industry sets the agenda concerning what is deemed

appropriate and needed research at the European level. More investment from the EU is needed to guarantee independent, need-directed research in Europe. Another possibility to manage this situation would be to increase the dialog between European bodies in charge of research, industry and scientists to assess their interests.

Studies sponsored by HTA organisations/agencies receive some economic support from the EU. The ratio between the funding effort of HTA organisations/agencies and the EU is 2:1, i.e. for every two studies sponsored by an HTA organisation, one is co-sponsored by the EU. Since the budgets of HTA organisations are generally low, more financial support from the EU is necessary. Since resources for research are limited, it might be suggested to redistribute them from primary research in biomedicine to HTA research, as primary or secondary, to assist European HTA organisations.

As shown by the INAHTA database search, currently only one joint HTA project deals with a specific topic/technology (Hearing Impairment among Adults, HIA-Project). Four European HTA organisations from four Nordic countries (Finland, Sweden, Denmark and Norway) plus an expert adviser from the U.K. are carrying out this project. No other effort for developing a study on a specific topic has been attempted by the European HTA agencies. However, at the international level, i.e. where non-European countries are also involved, there are four specific studies ("Bone densitometry measurements and treatments for osteoporosis", "Positron Emission Tomography", "Screening for prostate cancer" and "Telemedicine"). These studies have had the participation of most of the European HTA organisations and were performed under the International Network of Agencies for Health Technology Assessment (INAHTA). Specifically, 19 people from 9 European HTA agencies or organisations[70] have taken an active part as contributors or reviewers in the development of these projects. None of the projects received funding from the EU.

Apart from the low number of international joint health technology assessment studies on specific topics/technologies, to our knowledge, two European projects on generic HTA issues have been carried out by several HTA organisations which have been partly funded by the EU (EUR-ASSESS 1994–96, HTA-EUROPE 1997–99). These projects attempted to harmonise methodologies and pathways to improve the dissemination and impact of HTA results in Europe and to understand the approaches, priority setting and health policy role of HTA in the different EU member states (plus Switzerland and Norway).

The survey

The results from the survey show that HTA organisations have also been involved in the research of other disciplines when performing international joint projects, e.g. health services research and clinical research. This might be due to the different priorities and interests in each country, leading to the type or approach of the assessment performed. On the other hand, 24% of the joint projects performed by non-HTA organisations address HTA, which may also be a sign of

[70] TELEMEDICINE: 1 from FinOHTA; 2 from CAHTA(reviewers); 2 from the Austrian Academy of Science (reviewers). PET: 2 from OSTEBA, 1 from AETSA(Spain), PROSTATE CANCER: 1 from SBU, 2 from OSTEBA, 1 from Norway (reviewer), 1 from UK (reviewer), BD:2 from OSTEBA, 2 from CAHTA, 1 from CRD, 1 from SBU, need to include European agencies for HTA-reviewers.

the interest in HTA from different disciplines and organisations. Due to the global interest in HTA, the promotion of interaction between HTA groups and other research groups should be emphasised in the EU research policy.

Secondary research has been the methodology used most by HTA organisations to perform assessments, and is currently the most widely used method among them. However, as shown in the survey, primary research is growing as an activity conducted by HTA organisations. One explanation could be that published evidence does not always answer the questions asked to HTA organisations by decision-makers. Hence, HTA organisations perceive the need to produce, or finance the production of, primary data. This point is indirectly raised by the results from the literature search, showing that HTA mainly sponsors primary research as opposed to secondary research or a high quality review.

Since the evidence from published studies does not always present the information necessary to answer the uncertainties that have triggered an assessment, primary research should be promoted and financially supported as another important methodology tool in performing HTA.

Level of involvement

Those involved in European joint projects have played an active role mainly in searching/ collecting and synthesising/analysing data, which indirectly indicates their willingness to participate in such studies. Compared to non-HTA organisations, HTA organisations have performed considerable work in dissemination and training activities. This is natural due to basic mission of HTA organisations: to work on the creation of a culture of evaluation in different health systems and to disseminate the results of their assessments. Dissemination of the results and promoting the implementation of the assessment results are essential elements in the HTA process. However, to date, little is known about the effect of these efforts even though dissemination efforts have increased and use different formats and strategies.

Communication tools

Workshops and e-mail were the main tools used in the co-ordination of projects. Workshops consume time and money, e-mails are obviously far cheaper and a less time-dependent way to communicate. Advanced tools can effectively minimise the inconvenience of communication based on e-mail, e.g. desktop video-conferencing and multimedia computing that transmits sound, video and text. However, communication technology does not eliminate the need for personal meetings. It has been observed that when people meet in person, it is easier to work using communication technologies1.

The EU should recognise the value of both face-to-face and electronic contacts and provide opportunities for both. Funding for acquisition of this type of technology could be included as a separate portion of the total amount allocated by the EU. This probably high, short-term investment could lead to long-term savings in future projects.

Benefits and problems

International joint projects are perceived to have numerous benefits. These benefits deal mainly with the creation of scientific/technical networks; the transfer of knowledge and experience and cross-cultural fertilisation and understanding of other cultures; a source of funding for research; and a way to increase the efficiency of projects (throughout synergies). Funding and promotion of cross-national projects among the member states should increase in the EU to help minimise physical and cultural borders.

Problems from international joint projects are also mentioned. Bureaucracy and paperwork is the most frequently reported limitation (e.g. 'bureaucracy and paper work' 'too much time consumed in administration' 'spending too much time in bureaucracy'), along with the lack of appropriate management and co-ordination of the overall project and between teams (e.g. 'co-ordination was poor', 'ineffective management' 'time consuming meetings'). There is a need to reduce administrative complexity in European projects. If not, researchers may tend to look for funds outside Europe, which could direct European research efforts toward areas without priority within the EU. Additionally, much remains to be done toward improving partner co-ordination. The uneven effort by different participants and the need to make up for others' undone work have been mentioned as a problem in international joint projects (e.g. 'uneven effort' 'making up for others 'undone work'). This situation can threaten future joint efforts if the issue is not correctly presented and addressed from the outset of a project. One way to manage this situation could be to plan in advance for the possibility to engage external resources to appropriately support a project, if needed.

A problem often mentioned is the need for adequate funding, which draws resources from the participant organisations (e.g. 'difficulties to get funding', lack of complete cost coverage by most EU programs', 'inadequate funding'). Inadequate funding relates both to under-funding of global projects, and almost complete lack of funding for disseminating and implementing the results. More timely delivery of economic resources is also a need.

Easier administrative procedures and improvement of both project management skills and sufficient funding must be arranged if Europe wants to remain in the forefront of science and research.

To date, there has been little European multinational collaboration concerning medical ethics, cost-effectiveness and socio-cultural aspects of health technologies. In these areas, development of methodology and practical applications are urgently needed. European HTA collaboration should take a leading role in this development.

Existing opportunities for European joint assessment projects

An informal European network for EJA already exists

Europe is in a very good position to implement European joint assessment projects. There is a European dimension for HTA. Currently, 22 organisations from 10 countries formally work with HTA in Europe. These organisations have been working as an informal European HTA

network for the past 7 years, through day to day exchange of information and collaboration in partially EU-funded projects. Both the human resources and the willingness exist to carry out high-quality HTA work in Europe. Additionally, many countries in Europe have carried out, or are interested in developing, HTA activities even though some have not yet established a formal organisation for HTA (e.g. Portugal, Greece). The EU should encourage national bodies to develop HTA organisations in countries where formal resources are not yet available.

A willingness to actively participate in EJA projects

The survey results show that scientists want to actively participate in projects. They are willing to devote time toward collecting/searching and analysing data. Additionally, organisations are keen to dedicate human resources and technical assistance to EJA projects.

It is worth noting the large number of European multinational health-related projects identified through the review of the literature during the past 5 years. This also indicates the existence of human assets and willingness to participate in multinational joint projects.

Most of the scientists in HTA organisations who have worked in multinational joint assessments have expressed a willingness to participate in future international joint assessment projects. However, a small percentage of scientists working in non-HTA organisations declined to do so – the main reason being the organisation's loss of money in this type of activity, which supports one of the most frequent problems associated with international projects, i.e. inadequate funding.

Although private-public partnerships have been promoted by the EU in some research activities, it appears that scientists prefer to work in projects that are free from potential conflicts of interest. A clear statement based on the process described in the agreement between partners, and reporting of the results (positive or negative), could overcome the potential distrust between public and private partners. The CONSORT (Consolidated Standards of Reporting Trials) Statement could serve as a guide to develop a collaboration form.[71]

Most HTA organisations are also willing to invest economic resources in international joint projects, sharing the cost with the EU, while non-HTA organisations are more prone to ask the EU for money. Sharing economic responsibility has benefits, because it makes partners more responsible, but usually, as mentioned by some respondents to the survey, sharing of costs could draw resources, which are generally scarce, from a single HTA organisation. Active participation (e.g. in funding) in a multinational joint assessment project could lead each individual country to carry out a more active dissemination strategy of the results. Additionally, if there is added value for a country to carry out the project, then sharing the funding of the assessment project could itself be cost-effective.

The interest in HTA expressed by scientists working in HTA organisations and other types of organisations suggests there is a good opportunity that deserves to be promoted by the EU. However, any actions should be linked to adequate funding. Regarding the source of funds, an

[71] Mother D et al. The CONSORT Statement: Revised recommendations for improving the quality of reports of parallel-group randomized trials. JAMA 2001; 285(15):1987-1991.

adequate balance in the percentage of resources invested from each organisation could be established, taking into account the origin of the research proposal. In other words, if the proposal comes from the EU (top-down), the EU should invest a highest percentage of funds. However, if the proposal comes from a group of interested countries (bottom-up), these countries should invest a greater share than the EU.

Possibilities for future European joint assessment

A formal priority-setting process selecting topics for assessment is needed

Most respondents to the survey agree on the need to establish a formal priority-setting process among the EU countries to identify joint assessments. Due to the cultural and health policy diversity among member states, this process should be built on considering national priorities, on reaching a consensus among country partners and on raising the selected topic(s) with the EU.

A set of explicit criteria to implement such a process is mentioned, with some respondents suggesting the use of quantitative models, e.g. those used by the NIH (USA). The existence of a priority-setting process for selecting topics to be assessed could ensure that assessments are carried out on issues of common interest and European relevance, while duplication of assessment activities will be prevented. The results from the priority-setting process could act as a consultation arm, or be formally accepted by the EU, considering that the topics chosen are in line with European Union research priorities. In summary, since methods for priority setting already exist, the EU should support the development of a formal priority-setting process for selecting topics for European Joint Assessment Projects.

A range of options has been mentioned regarding who should take part in the Priority Setting Committee. These range from a group of well-known scientists to the participation of all stakeholders, including members of the European Parliament and citizens. Scientists could be the most informed people to guide and address issues that need to be further explored or assessed. However, the involvement of all the interested parties, i.e. those with other types of interest and knowledge needs, could decrease the bias toward a scientifically interesting topic of weak, short-term, social and political relevance. Therefore, based on these considerations, the best priority-setting process will consult all interested parties.

Specific generic criteria to use when selecting health technologies/clinical topics for assessment have been selected by respondents working in both types of organisations (i.e. HTA organisations and non-HTA organisations). The three most commonly mentioned were: 1) large number of patients/people potentially affected in Europe; 2) lacking or modest research evidence and 3) established technology that is used inappropriately. These criteria could guide the selection of topics to be funded at the European level. It should be noted that little assessment or research activity is targeted at accepted, well-diffused, but inappropriately used, technologies.

A set of criteria should be met by a project to guarantee the credibility of a multinational joint assessment

The credibility and transfer of results from EJA projects depend on meeting a set of criteria. Several criteria have been identified to guarantee European-wide credibility of the results of any project. The criteria most frequently mentioned are: solution-oriented problem/need, relevant and opportune, transparent process, good scientific quality, competent and qualified partners, no economic conflicts of interest, balanced cross-country representativeness, practical feasibility and the possibility to evaluate impact.

An adequately funded resource for constant co-ordination is needed

From the results of the survey, it seems that a generally accepted way to improve current informal European networking of HTA projects would be the formal establishment of a sustainable European resource for co-ordinating European joint assessment projects. This type of resource could serve as the organiser and supervisor of the priority setting process as well as the supporter of any multinational joint project developed at European level. Almost an equal number of respondents prefer developing this resource on a virtual basis and having a physically established European co-ordinating body; it was also proposed to rotate the leadership of co-ordinating body. Obviously, any type of action toward this aim should be supported by financial resources. However, the main limitation of this finding is that the responses come from a few HTA scientists in Europe, i.e. those who have worked on past European Joint Assessments. Deeper research on this issue is needed. However, these results can guide further actions to determine the predisposition and needs of European HTA organisations regarding access to a European HTA co-ordinating body.

Possible mechanisms for developing joint European assessment and projects

The development of the prioritisation process should take into account the three main pillars of the new EU Health Policy (health promotion, health monitoring and rapid reaction to health threats). These are the priorities for the development of health policy at European level agreed and accepted by the Governments of the member states. Logically, priority should be given to HTA projects linked to these priorities. However, the organisation of an explicit and transparent priority setting process is a time-consuming and expensive task that should be led by a single organisation. The availability of a European HTA co-ordinating office can help in this task.

A way to more efficiently manage economic resources provided by the EU would be to pass them on, to the extent possible, to the participating HTA organisations. Obviously, this would require good supervision of the activities by the main contracting organisation.

The existence of a formal contract between the EU and each participating HTA organisation will probably improve the final quality of the project, since everyone will feel a greater responsibility for the final product. Additionally, it is important for each HTA organisation to have its work formally recognised by the EU. This could have a positive impact at the national level among the bodies funding bodies for health assessments and projects.

The scientific community in the European Union should open its borders to European non-EU scientists. Among the reasons supporting this proposal are: 1. European non-EU countries have similar health and health care problems as the EU countries; 2. It will likely improve the final project outcome since new inputs and perspectives will be available.

Although the provision of dedicated human resources is the ideal situation for carrying out an international joint assessment, it could be difficult to achieve for some organisations with few senior staff. To overcome this situation, more involvement of junior scientists should be promoted, providing them with adequate training to increase the researcher base.

Finally, European grants (from BIOMED and other programmes) are linked to very complicated administrative systems that most scientists find cumbersome and frustrating. The EU procedures are usually much more intricate and resource-consuming than the administrative systems used for handling national grants, whether from private or public sources. It appears reasonable that EU should explore much simpler and translucent systems from some member countries that could be used as models for its own process for handling of grants.

Conclusion

SWOT analysis of European Joint Assessments

Based on the information collected from the literature review, the search in the INAHTA database, the survey and the discussions with participants during the workshops, the conclusions are presented as a SWOT analysis (Strengths, Weaknesses, Opportunities and Threats). The internal factors from the European joint assessment (EJA) projects are included under strengths and weaknesses, and the external factors are included under opportunities and threats. As scientists working with HTA, we can try to influence factors generated by the project but we cannot usually influence the factors generated by the outside world (e.g. economic, social, political factors). Within the project, scientists have to put more effort and emphasis on the strengths while trying to minimise and be aware of the weaknesses. Opportunities from the outside world should be utilised and threats recognised to develop the necessary actions.

Please note that the issues that appear in the following sections are not listed in order of importance.

Strengths

Enthusiasm to co-operate

Various ranges of expertise available

Perspectives from different health care systems

Willingness to invest dedicated human resources and technical assistance

Willingness to share economic responsibilities in project development.

Weaknesses

Uneven leadership and country participation

Unsuccessful co-ordination

Difficult management of IJA projects

Dissemination and implementation of results tends to remain insufficient

Adequate funding is often uncertain and insufficient, and does not cover the entire project up to publication

Complicated and resource-consuming handling of EU grants

Too little emphasis on medical ethics, cost-effectiveness and socio-cultural aspects in the past EJA projects

Language difficulties

Opportunities

HTA is an issue of interest for many non-HTA organisations and disciplines (e.g. clinical research, health economists, health services researchers)

Wide acceptance of collaboration in European joint HTA projects can be noticed in many European HTA agencies

Informal network for collaboration for HTA in Europe already exists

Interest in HTA activities can be found even in countries without a formal HTA programme

The results of EJA projects can be utilised in all European countries, even where HTA activity not established

Collaboration with other non-European countries and other continents

Commonly expressed need for international collaboration in HTA

Most HTA respondents are willing to have a co-ordinating European body for HTA

Threats

EU procedures are intricate and may tend to discourage European scientists from participating in EU projects in favour of joining non-EU studies

Funding is not adequate and does not cover all the project elements

Not enough co-sponsorship from the EU, which can lead to a decapitalisation of HTA organisations.

Weak percentage of EU funding to health-related projects versus the percentage devoted by industry, which could lead to a research agenda set by industry

HTA's potential/possibilities and possible benefits are not fully known in most of the EU member states and in European non-EU countries

HTA's potential as an informative decision making tool is not fully assimilated by the EU

The participation of health policy makers and health authorities in European Joint Assessments is weak, which is probably why they do not fully recognise the value of HTA collaboration

General limitations

Several limitations should be highlighted from both the survey and the literature review.

The number of respondents to the questionnaire from the different participant countries varies. Spain reports the highest number of responses (35), while The Netherlands reports the lowest (1). If cultural differences exist regarding the questions to be answered, bias may have been introduced into the results of the study. Furthermore, the percentage of participants from private organisations was very low compared to the participation of people from public organisations. Probably, the interests from private organisations differ considerably from the ones shown here.

Although this study shows industry to be the main sponsor of European joint projects, the figure obtained here is probably underestimated since the origin of funds is not often referenced in the publications.

The classification of topics has reflected the judgement of the respondents. In other words, the classification of a project into a clinical speciality or into another non-clinical area (e.g. methods for studying a rheumatology problem) is based on the respondents' criteria. We do not have information on how they classified each topic. This could introduce a misclassification bias. When looking at the past topics of IJA projects, HTA studies rank first (17%) followed by public health (11%) and clinical specialities. However, these results should be viewed with caution since the answers may reflect the characteristics of the organisation where the respondent works (HTA organisation vs. non-HTA organisation). In other words, those working in HTA organisations could have indicated HTA as a topic of past IJA projects, while scientists in non-HTA organisations may have based their answers on research topics (e.g. rheumatology).

A list of different health technologies/clinical conditions have been identified by the respondents as potential issues for future European joint assessment projects. However, it is not possible to use them as definitive areas of future actions since they reflect their individual interest. Although the sample surveyed is not small (N=110) and includes scientists from different countries, the results still have poor external validity since we have used a convenience sample that is not representative of all scientists working in European joint projects. However, the identified topics could give some picture of topics of interests among the scientific community.

Finally, there is a limitation in the literature review that could have led to underestimating the total number of European joint assessment projects identified. The only way to identify the country of the first author in a database search is to use the field ".in" (institution field). This field should include the name of the institution and the country where it is located. However, there is no homogeneous practice to introduce this information or the guidelines to proceed. Furthermore, many authors do not specify this information when papers are submitted. This is a limitation that should be taken into account in this study, but presently there is no means to overcome it.

Recommendations to the European Union

Need for explicit support for formal European collaboration in HTA

Due to the global interest in HTA by different types of organisations and disciplines, the promotion of interaction among HTA organisations and other scientific groups should be emphasised by EU research policies to assure continuation of high standards in European health care research.

Currently, there is a high level of collaboration among both EU countries and European non-EU countries. This collaboration should be promoted and supported by the EU since it enriches the final results of the project.

European resources for developing and consolidating stronger research capabilities should be increased in European countries with low participation.

Improved organisation and logistics for European collaboration on HTA

The European Commission should support measures known under the recent Framework Programmes as "accompanying measures" to help HTA agencies join together to build HTA capacity at a European level.

The existing informal HTA network in Europe should be given a formal status. Clarification is needed regarding the type of European HTA co-ordinating body that best fits the needs and preferences of European HTA organisations. The work processes and the mechanisms of interaction between a new HTA co-ordinating resource, other European HTA organisations and other resources available internationally (e.g. INAHTA) should be developed.

The EU should encourage national bodies to develop HTA organisations in those countries where formal resources for HTA activities are not yet available.

Funding and promotion of cross-national projects through EU state members should increase to help transcend the physical and scientific borders within the EU.

The EU should support a formal priority-setting process to select topics for European Joint Assessment Projects.

Administrative complexity needs to be reduced in European projects, or researchers may tend to seek funds outside of Europe. This could result in directing European research efforts toward areas that do not have a high priority inside the EU.

The EU should recognise the value of both face-to-face and electronic contacts, and provide opportunities for both. Funding for acquisition of all types of communication technology should be included as a separate portion of the total amount allocated by the EU.

Increase financial resources

Greater investment from the EU is needed to guarantee needs-directed health research in Europe.

Greater economic support to HTA organisations from the EU is needed to develop multinational European Joint Assessments.

The origin of a research proposal should be a determining factor as regards the source of funds and the funding ratio. For example, when a proposal originates from the EU (top-down), more of the funding should come from the EU.

The economic resources allocated should cover the total scope of the project, from its design stage to, and including, dissemination of the results (e.g. translation costs into European minority languages).

Appendix 1 – Assessments Questionnaire

ID # |__|__|__|

The answers to this questionnaire are voluntary, and confidentiality is guaranteed.
Please, fill in the questionnaire with capital letters.

1. *Name of the organisation*: _____

2. *Type of organisation*

HTA Agency[72] …… ❑1
Governmental organisation, but non-HTA agency[73] .. …❑2
Teaching Hospital …….....…..…❑3
Non-teaching Hospital …… ❑4
University …….....❑5
Industry, field (specify)…….....❑6
Private HTA organisation ..……...❑7
Other (specify) _____

K Experiences from the past International Joint Projects

3. *Name the topic of most recent international joint projects in which yourself or your organisation has participated in the past. How was the project co-ordination done?. Also briefly describe your / your organisation´s role in the project. (eg. Osteoporosis treatment(1994) – e-mail & workshops – collecting & analysing data & funding).*

Name of the topic and year(s)	Way co-ordination was done*	Role in the project**

* Some examples of co-ordination strategies: Postal, e-mail, intra-web, face to face, workshops …

[1] Non-profit organisations whose main activity is health technology assessment
[73] Units inside governmental organisation that carry out technology assessment activities but that are not considered an Agency themselves.

** Some examples of roles in the project: as an active member of the working group collecting data or searching the evidence; as an active member of the working group synthesising evidence or analysing data; as a member of the steering committee/group; as an observer; as a funding source; just as an user of the results; just as a supporter of the results; others (specify)

4. *Check the topics of international joint projects you or your organisation have been involved in (you can tic more than one)*

4a Basic medical research .....…….. …… ❑
4b Clinical research .....…… ❑
4c Health services research (meso/micro)…….. ❑
4d Health economics (general) .....…… ❑
4e Pharmacoeconomics ……. ❑
4f Economics Analysis for Medical devices …….. ❑
4g Sociology .....……. ❑
4h Health Policy (macro) .....…… ❑
4i Ethics .....…… ❑
4j Health Technology Assessment[74] …….. ❑
4k Other (specify) _____

5. *What kind of methodology has your organisation mainly used in the past when performing a joint international joint project? (you can tic more than one)*

5a. Primary research[75] …….....…. ❑
5b. Secondary research[76] ……..... ❑
5c Qualitative synthesis of available HTA reports ….....…. ❑
5d Comprehensive review [77] ……..... ❑
5e Other (specify) _____

For questions 6 and 7, some examples of issues to consider are: general management of the project, outcome of the project (i.e. mesurable benefit to your nation or related outcome), equality of the participation (i.e. equitative share of tasks), relevance of the topic addressed, others (specify)

6. *List below some <u>benefits</u> of the international joint projects your/your organisation has been involved in.*

1._____

2._____

3._____

[74] Health technology assessment: a structured analysis of a health technology, a set of related technologies, or a technology-related issue that is performed for the purpose of providing input to a policy decision (EUR-ASSESS definition)
[75] Primary research: collecting field data
[76] Secondary research: using available data and performing quantitative synthesis through analytical techniques such us meta-analysis, decision analysis
[77] Comprehensive review: when using in the qualitative synthesis information from HTA documents as well as other information obtained from other non-HTA sources and of different quality.

4._____

5._____

6a. *From the list above, identify the most relevant for you/your organisation.*

_____

7. *List below the <u>problems</u> in the international joint projects you/your organisation has been involved in.*

1. _____

2. _____

3._____

4._____

5._____

7a. *From the list above, identify the most relevant for you/your organisation.*

_____

Interest in Future International Joint Projects / Assessments

8. *Is your organisation interested in participating in international joint projects?*

No ❑ Why not? _____
_____

Yes ❑

→ 9. What is the role your *organisation* would like to have in international joint projects?

9a. As an active member of the working group (collecting data).. ❑
9b As an active member of the working group (analysing data) .. ❑
9c As a co-ordinator of the overall project…….. ❑
9d. As a member of the steering group ….....…… ❑
9e. As an observer …….....….…….. ❑
9f. As a funding source …….....….…….. ❑
9g. Just as an user of the results …….....…….. ❑
9h. Others (specify) _____

10. *What kind of resources is your organisation willing to put into international joint projects? .Indicate your willingness on the scale (most preferred - least preferred).*

	most	good bit	some	little	least
10a. Dedicated human resources .....….....	❑	❑	❑	❑	❑
10b. Financial support[78] .....…….	❑	❑	❑	❑	❑
10c. Technical assistance ….....… ……	❑	❑	❑	❑	❑
10d. Other (specify) _____	❑	❑	❑	❑	❑

K Propositions for the future International Joint Projects / Assessments

11. *What criteria should be used when selecting topics for international joint projects? Indicate the importance on the scale (most important – least important).*

	most	good bit	some	little	least
11a. A large number of patients/people potentially affected in Europe....	❑	❑	❑	❑	❑
11b. Costly technology [79] …….....	❑	❑	❑	❑	❑
11d. Controversional technology ……..….….....	❑	❑	❑	❑	❑
11e. Lacking or modest research evidence ….....	❑	❑	❑	❑	❑
11f. Emerging technology …….....	❑	❑	❑	❑	❑
11g. New technology …….....	❑	❑	❑	❑	❑
11h. Established technology being inappropriately used.....	❑	❑	❑	❑	❑
11i. Variations in clinical use of a HT in Europe..……....	❑	❑	❑	❑	❑
11j. Ethical concerns …….....	❑	❑	❑	❑	❑
11k. Other (specify) _____	❑	❑	❑	❑	❑

12. *Who should select topics for international joint projects?*

_____

For questions 13&14&15 answer only if you work in a HTA organisation. Otherwise go

13. *Should a formal priority setting process be established at the European level to select topics for joint HT assessment?*

No. ❑ *Why not?* _____

Yes ❑ *Explain briefly a potential priority system.* _____

_____

[78] Apply for both, those organisation who has no human resources but still want to participate and those others who want to contribute with financial support additionally to other type of resources.

[79] Costly technology: high investment costs/ high maintaining costs/ very common low ticket technology)

14. *Should there be a permanent co-ordinating office/ body in Europe to manage internbational joint HT assessments and disseminate results?*

Yes ❑ *Why?* _____

_____

No ❑ *Why not?* _____

15. *Which organisational characteristics should the co-ordinating office/body has?*

15a. Virtual …… ❑

15b. Centralised in one country …….. ❑

15c. Others (specify) _____

16. *How should an international joint project be financed?*

16a Membership fee from interested partners ……. ❑

16b European Union resources ……. ❑

16c Both of the above ……... ❑

16d Others (specify) _____

17. *What characteristics should have the 'ideal' international joint project to be both credible and supported by the partners in the project as well as by external organisations?*

_____

_____

K Issues for future research

18. *List issues for future international joint projects of potential interest in Europe, on what grounds and how to accomplish the research*

1. a. Issue: _____
1. b. Why? _____
1. c. What methodology? _____

2. a. Issue: _____
2. b. Why? _____
2. c. What methodology? _____

3. a. Issue: _____

3. b. Why? _____

3. c. What methodology? _____

4. a. Issue: _____

4. b. Why? _____

4. c. What methodology? _____

5. a. Issue: _____

5. b. Why? _____

5. c. What methodology? _____

19. Please, write below any other observation you would like to make regarding international joint projects. If needed attach separate notes.

_____

_____

_____

THANK YOU VERY MUCH FOR YOUR COLLABORATION!!!

If you want to receive the results of this study, please fill in the following information:

Name and surname of the respondent: _____

Address: _____

Phone: _____

Fax: _____

E-mail: _____

Appendix 2 – Search Strategy and Process Study Selection

1. Search Strategy

Medline, Embase and Healthstar data bases were searched by an archivist.
The search strategy was as follows:

Search strategy in Medline and Health Star

1. exp Multicenter studies/
2. (multicent$ adj10 (study or trial)).ti,ab.
3. Multicenter study.pt.
4. 1 or 2 or 3
5. (europ$ adj25 (study or trial)).ti,ab.
6. transnational or international or multinational or collaborat$).ti,ab.
7. 5 or 6
8. 4 and 7
9. (United States or US or USA or canada or brazil or mexic$ or new zealand or australia or japan or hong kong or china or argentina or egypt or Southafrica).in.
10. 8 not 9
11. limit 10 to yr=1995-2000
12. limit 11 to la=english

Search strategy in Embase

1. Multicenter study/
2. (multicent$ adj10 (study or trial)).ti,ab.
3. 1 or 2
4. (europ$ adj25 (study or trial)).ti,ab.
5. (transnational or international or multinational or collaborat$).ti,ab.
6. 4 or 5
7. 3 and 6
8. (United States or US or USA or canada or brazil or mexic$ or new zealand or australia or japan or hong kong or china or australia or argentina or egypt or Southafrica).in.
9. 7 not 8
10. limit 9 to yr=1995-2000
11. limit 10 to la=english

2. Process study selection

After a manual review, 680 records were excluded from the study. The reasons for their exclusion were:

a) In 389 of the records, only one country among those accepted originally appeared as the sole participant

b) About 232 records were duplicated in the database
c) In 59 records, the main author was not from one of the countries included in the study.

Out of the remaining 986 records, 893 fulfilled a priori the inclusion criteria whereas 153 were considered "questionable". After conducting a posterior review, 93 of these records were excluded whereas other 60 were included.

As a result, 953 records (893+69) identified met the inclusion criteria. 907 (95%) hard copies were obtained, through biomedical libraries in Barcelona and other Spanish cities as well as from different telesearching services. Upon performing another review of the complete papers, 140 out of 907 (15%) records were excluded, leaving 765 (85%) studies as the subject of analysis.

The causes for the latter exclusion of 140 papers in that new selection process were:

a) In 80 papers, only one European country participated in the study
b) In 29, the first author was not from a EU country
c) In 13 papers, the participant countries could not be identified
d) In 4 papers, the language of publication was not English
e) 5 papers were previously reported in different journals
f) 5 studies of papers were unfinished
g) 2 papers came from countries not of interest
h) One paper reported a study on animals

In one paper, the first author's origin country was not identified

Appendix 3 – Literature Review

1. Questionnaire (please fill in capital letters)

Identification number | | | | |

Project Format

1. Report
2. Abstract
3. Article

Project Title

Publication Year

Number of Investigators / Authors

First Investigators / Authors

The First Authors's Country

Germany	Austria	Belgium	Denmark	Spain
☐	☐	☐	☐	☐

Finland	France	Greece	Luxembourg	Italy
☐	☐	☐	☐	☐

Ireland	Holland	Portugal	United Kingdom	Sweden
☐	☐	☐	☐	☐

Norway	Switzerland
☐	☐

Study Group/s

Number of Study Groups

Health Speciality

Duration of the Project (months)

Start of the Project

End of the Project

Participating Countries

Number of european countries ☐☐☐

Number of countries ☐☐☐

Germany	Austria	Belgium	Denmark	Spain
☐	☐	☐	☐	☐

Finland	France	Greece	Luxembourg	Italy
☐	☐	☐	☐	☐

Ireland	Holland	Portugal	United Kingdom	Sweden
☐	☐	☐	☐	☐

Norway	Switzerland
☐	☐

Study's Promotor

(the entity that initiated the project)

Health technology assesment (HTA) entities (non-profit Organisations) ☐
Governmental organization, but non-HTA specifically ☐
Teaching Hospital ☐
Non-teaching Hospital ☐
University ☐
Industry (specify) ☐
Others (specify)_____

Sponsor's Study

(the entity that provided the funds for the study)

Health technology assesment (HTA) entities (non-profit Organisations) ☐
Governmental organization, but non-HTA specifically ☐
Teaching Hospital ☐
Non-teaching Hospital ☐
University ☐
Industry (specify) ☐
Others (specify)_____

Study Setting

Community	Laboratory	Ambulatory
☐	☐	☐

University	Hospital	Others (specify)
☐	☐	☐

Topics

Basic medical research ☐
Clinical research ☐
Health services research ☐
Health economics ☐
Pharmacoeconomics ☐
Economics Analysis for Medical devices ☐
Sociology ☐
Health Policy ☐
Ethics ☐
Health Technology Assessment ☐
Others (specify)_____

Study Methodology

Primary research
Secondary research(using available data and performing quantitative synthesis through analytical techniques such as meta-analysis) ☐
Qualitative synthesis of available HTA reports ☐
High quality descriptive (without stadistic analysis) review ☐
Low quality descriptive (without stadistic analysis) review ☐
Others (specify) _____

Study Subjects

(You can tic more than one)

Biological material ☐
Fetus ☐
Breast-fed baby ☐
Children ☐
Adults ☐
Elderly ☐
Both sex ☐
Men ☐
Women ☐
Healthy people ☐
Sick people ☐
Others (specify)_____

Num Identification ☐☐☐

Non Communitary Countries

EUROPE

SPECIFICY_____

EEUU

CANADA

IBEROAMERICA

SPECIFICY _____

AFRICA

SPECIFICY _____

ASIA

SPECIFICY _____

AUSTRALIA

NEW ZELAND

MIDDLE EAST

SPECIFICY _____

2. Definition of questionnaire variables

Identification number

Every paper is numbered for easy identification purposes. The number is located in the upper right corner of the first page.

Project title

Specifies only the first few words of the title.

Number of authors

The number to be entered is that referred to after the title in the first page. Sometimes the author refers to a research group together with some individual authors. The research group will be considered as a single author to avoid counting an important number of authors who are generally referred to as group members at the end of the paper. If one specific group appears as the author, the number of authors will be assumed to be one. The first author will be that to whom all correspondence is addressed.

1st Author

Refers to the first author mentioned; if a group signs the abstract, the first author will be the person to whom all the correspondence is addressed.

Group(s) of study

It refers to a group of researchers that work together continuously and are considered a specific group based on the pathology which they study (e.g. pain group, lung cancer group, chronic bronchitis group, etc). They are referred to as "group" or "team". In occasions, a group of researchers get together to develop a study and refer themselves according to the project's title (e.g. INTERSEPT, PROSPECT, etc).

Different groups can intervene in a project, for example, the pain group can work in conjunction with the lung cancer group. If a group is mentioned in a publication, the group's name shall be noted and the total number of groups shall be numbered.

Speciality

According to the medical thematic of the paper it is classified in one determined specility .

Length of the project

It is specified in months.

Participant countries

Only the specified countries will be considered.

European num

The number of countries from the EU, Switzerland and Norway that participate in the study shall be noted.

Study num

Total number of countries that took part in the study.

Promoter and sponsor

They can be mentioned in the section of Methods. They may appear in small characters in the first page or at the end of the discussion.

Usually, the promoter appears as the publication's signatory whereas the sponsor is acknowledged at the end. Unless specified otherwise, the promoter and the sponsor will be considered as a same individual.

When a project is funded by the European Economic Community (EEC), WHO, Foundations, Institutes, or private organisations, it will be mentioned under "other" and will be specified.

Setting of the study

The study will include both the primary care and the ambulatory hospitals (or outpatient) care.

When a study is conducted within more than one setting, it will be mentioned under "others" (e.g. a case-control study, in reference to inpatient cases and community controls).

Subject of the study

Studies about secretions, cells, genes,...humans and biological studies about bacteria, viruses, etc, will be included in basic medical research.

Clinical research: studies about healthy and ill individuals will be included.

Health services research: studies related to quality of life, patients' satisfaction, etc. will be included.

Health economy: cost-effectiveness studies, cost analyses, cost-minimization studies, cost-benefit studies, cost-utility studies, all related to health subjects.

Pharmacoeconomy: cost-effectiveness studies, cost-assessment, cost-minimization studies, cost-benefit studies, cost-utility studies, all related to drugs.

Economic analysis and evaluation of medical equipment: Studies about health equipment efficiency.

Sociology: legal and ethic subjects, etc.

Health politics: studies directed to establish/define health politics such as equity studies, financing systems (DRGs,...), coverage, comparative descriptions of health systems characteristics (models, types of organizations, financing,...), description of politics of adaptation directed to specific health topics (i.e. financing politics for drugs in Europe)

Health technology assessment: about diagnosis and treatment methods, etc.

Methodology of the study

Primary research: process of obtaining data through an intervention. It includes the use of available databases.

Secondary research: use of available data obtained from reports and publications, with statistical analysis or meta-analysis.

Qualitative synthesis of available reports in health evaluation agencies.

High quality descriptive review: a rigorous methodology has been conducted (with a description of inclusion and exclusion criteria, and/or search strategy, and/or inclusion of a study quality scale) but it has been impossible to make a statistical analysis.

Low quality descriptive review: the methodology is not rigorous and a statistical analysis has not been made.

Subjects

Biological material: human secretions (sputum, sweat, saliva), human excrements, cells, genetic materials...humans, viruses, bacteria.

Foetuses: intrauterine life

Infant: from delivery to one year old

Children: from one to 14 years old

Adolescents: from 14 to 18 years old

Adults: from 18 to 64 years old

Elderly: 65 years old and older

Both sexes: when men and women participate in the study

Male: only men participate in the study

Female: only women participate in the study

Healthy: people without pathologies

Ill: people with pathologies

Others (specify): when the individual can not be classified under any of the above mentioned

Appendix 4

Tables 1b. Question 3: Topic of most recent international joint projects in the past

Cellular biology [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
Vaccines development	Animal studies
Cyclophilins	Alterations of extracellular

Cardiology (Non HTA Organisation) [Q3-TOPIC]
Cardiovascular disease
Myocardial infarction treatment
European secondary prevention in MI patients
Evaluation of care for myocardial infarction
Antianginal treatment
Diagnosis of myocardial viability
Euroheart surveys esc

Pharmacology and therapeutics [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
Drugs development	Development of analgesics
	Roadside detection of drug in drivers

Genetics [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
DNA Vacatopy	Brain genes
Computational genetics	Genetic susceptibility to lung cancer in non smokers
	High throughput DNA sequence
	Human gene
	Ethical issues in obstetrics
	Chromosome 6 mapping
	Multigenes

Geriatrics (HTA Organisation) [Q3-TOPIC]
Formation in geriatrics assessment

Ophthalmology [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
Effectiveness of cataract surgery	Effectiveness of cataract surgery

Paediatrics (Non HTA Organisation) [Q3-TOPIC]
Ways of reducing sudden infant death syndrome

Otorrhinolaryngology [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
Hearing impairment	Hearing impairment among adults
Hearing impairment among adults	

Internal medicine (Non HTA Organisation) [Q3-TOPIC]
Role of inhibin and activin in new improved immunoassays
Somatostatin in digestive fistulas
Telematic tools for diagnosis & treatment
Prevention of portal hypertension
Sclerotherapy
Variceal haemorrhage
Polycystic kidney disease
Appropriateness 1996-1999
Physical exercise for low back pain
Acute promyelocytic leukemia
Allergic diseases
Diabetes
Study of laboratory workers
Matrix components in diabetic nephropathy and other glomerular diseases
Stress safety in CAD diagnosis, diabetic ketoacidosis
Diagnostic data base on jaundice computer-base
Vasculitis treatment (ECSYSVAS trial)
Vasculitis treatment (AVERT)
Rehabilitation of chronic back pain in Sweden and Germany

Intensive medicine [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
Intensive care	EURICUS I. Organization ICU

Nuclear medicine (Non HTA Organisation) [Q3-TOPIC]
Positron emission tomography (PET)

Neurology [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
Epilepsy and risks	Neurodegenerative disorders
Treatment of epilepsy	Histamine receptor antagonists in Alzheimer's disease
	Prosencephalia
	Brain repair
	Development of an anxiolytic agent
	International stroke trial
	Role of metabotrophic receptors in brain function
	Hereditary ataxias
	Post-operative cognitive dysfunction
	Stroke units

Obstetrics and gynaecology (Non HTA Organisation) [Q3-TOPIC]
International perinatal studies + HIV
Prenatal screening in Europe
Antenatal care in Europe
Reproductive health
Hormone therapy
Hormone therapy
Antenatal care
Screening ahead/neonatal hearing
Impairment hear / Genetics of hearing
Down syndrome

Oncology (Non HTA Organisation) [Q3-TOPIC]
Gastric cancer
Breast cancer screening
Cancer Research
Prostate cancer screening
Ovarian cancer screening
Cancer and brain disease. Characterization and therapy assessment by quantitative MR spectroscopy
Cervix cancer
TiO_2 cancer

Pneumology (Non HTA Organisation) [Q3-TOPIC]
Asthma frequency & etiology
Asthma & allergy
European acute respiratory distress syndrome
Risk factors adult asthma
Severe asthma
Follow-up of adult asthma

Psychiatry and mental health (Non HTA Organisation) [Q3-TOPIC]
Unmet needs in mental health

Radiology [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
Teleneuromedicine	Electrical impedance tomography
Teleneuromedicine	Magnetic resonance
Telemedicine	Assessment of Telemedicine
Validation of telematic applications	3D Ultrasound
	WHO-Steering group of medical imaging
	Sequencing cDNAs Euroimage

Rheumatology [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
Effectiveness of technologies for osteoporosis	Strontium for osteoporosis
	Male osteoporosis
	Treatment of osteoporosis
	Osteoporosis & Asthma
	Treatment of osteoporosis
	Osteoporosis & corticoids
	Osteoporosis
	Bone mineral density & fractures in osteoporosis
	Osteoporosis: epidemiology & identification
	Rehabilitation for musculoskeletal disorders
	Physiotherapy for lateral epicondylitis
	Osteoporosis
	Rheumatic arthritis
	European vertebral osteoporosis study
	Rehabilitation comparison CH, SE, UK, D, ongoing

Public health [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
Airways group	Air pollution health effects
	Falls
	Human frontiers science
	Winter mortality, survey Europe
	Winter mortality. Finland
	Winter mortality. Russia
	Winter mortality. Iakutsk
	Women and tobacco
	Passive smoking at the work place
	Smoke free class competition
	Women against tobacco
	The smoking prevention
	Smoke free healthy cities
	Educational strategies tobacco
	Impairment of driving ability by drug use
	Early warning
	WHO/Europe Multicentre study on suicidal behaviour
	WHO task force on hopelessness and stress related morbidity
	WHO Suicide prevention: Multisite on suicidal behaviour (SUPREMISS)
	European review of suicide & violence epidemiology (EUROSAVE)
	Child and adolescent selfharm in Europe (CASE)
	Reaching young Europe
	Work incapacity and reintegration (comparison of 7 countries)
	Epidemiological laboratory for surveillance in rural Ethiopia

Health technology assessment [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
EURASSESS	EURASSESS – HTA
HTA – Europe	HTA – Europe
HARMET	ECHTA – ECAHI
Ulysses	AGREE
ASTEC	EURASSESS. Priority setting group
EURASSESS	EURASSESS
INAHTA	EU – Outcomes in medicine
HTA Europe	EUROSCAN HTA. Euro indications
AGREE	Evaluation of quality of guidelines
ASTEC	Teleplans HTA Summary
HTA Europe	CPP Guidelines implementation
Nordic HTA, Hearing loss	AGREE – Guidelines evaluation
HTA Europe	Assessment, hearing
EURASSESS	ECHTA
Steering group	ECAHI
	Standarization of surgery. HTA Methodology
	Reviews of HTA in Ireland
	EURASSESS
	European guidelines assessment project (AGREE Collaborative group)
	Guideline project of the council of Europe
	Joint guideline project of the Scottish intercollegiate guidelines network (SIGN) ant the German
	HTA
	Guideline implementation
	Appropriateness

Stomatology / maxillo-facial (Non HTA Organisation) [Q3-TOPIC]
Oral health, fluoride toothpaste & fluorosis

Health service research [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
Hospital admission case-mix system for elderly patients – ACME PLUS	Health Service Reform
Preoperative in elective surgery	Telematic tools for quality assurance in health
	Implementing quality programs
	Preoperative evaluation
	Expert quality in health care
	Appropriateness of care
	Women health services Book
	Pharmaco-economics & Europe
	Economic evaluation methodology
	Evaluation of oral health care systems in Europe
	Finding the Bayesian added value of the technologies in diagnosis of jaundice
	Comparison with that of EU use of technology on jaundice
	ANCA standardisation
	Rationing in medicine
	Health economics
	WHO-Collaboration

Continued education [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
International education programs	Continuing medical education
	Competence Assessment
	Equip tools Book

Quality of life (Non HTA Organisation) [Q3-TOPIC]
Quality of life / Generic activities
Quality of life instruments
Development of HRQOL instrument

Infectious diseases (Non HTA Organisation) [Q3-TOPIC]
Vaccine TBC
Molecular epidemiology antigen tuberculosis
New strategies control tuberculosis
Vaccine tuberculosis
Molecular epidemiology tuberculosis
Novel approaches for the control of fungal disease
Mycology
New targets for antifungal therapy
Urosepsis
Infected lung
Protein C & severe sepsis
Communication in AIDS
Communication in AIDS
HIV infection in women + children
Vertical transmission of hepatitis C + outcome in child
Meta-analysis of international studies on HIV transmission + breastfeeding
GMENT Group on HIV Infection in pregnant women + children

Biocomputing/ information systems (Non HTA Organisation) [Q3-TOPIC]
EXPERT
Intelligent decision mapping med. record

Ethics (Non HTA Organisation) [Q3-TOPIC]
Parental visiting in neonatal units
Ethical decisions in neonatology

New emerging technologies/ rare diseases [Q3-TOPIC]	
HTA Organisation	Non HTA Organisation
Biomedical simulators	Future of biosensors

Tables 7b. Question 6: Some benefits from past international joint projects your/your organisation has been involved in

Scientific networking & improve relationship [Q6-BENEFITS]	
HTA Intitution	Non HTA Organisation
Consensus HTA language	Gain know-how
To obtain more support at HTA for authorities	Gain contacts
Scientific networking	Improvement of the relationship with supplier
Common use of resources	Better relationship among colleagues
Establishing contact / links with other researchers	Involvement & interaction with European research leaders
Better understanding of other approaches to HTA	Knowledge of other researchers
Insights into the scientific basis for dissemination and implementation of HTA results	To create a working group at national level
Description of the genetic diversity of the HTA Systems in populations of Europe	Meeting and identifying new colleagues
Strengthen international links	Network building
	Building up close links across countries + developing networks
	Contact with other individuals in the research area
	Communication with European colleagues
	Improved interacting with other investigations
	Personal relation ships
	New contacts
	Networking
	Develop international connection
	Contact network
	Learning to know experts in the field
	Possibilities to meet other researchers
	Sharing of resources
	Increased technology available in collaboration
	International contacts
	Networking
	Similar exchanger experiences
	Networking
	Networks
	Development of close links with our colleagues in EU
	Contact with science Euro leaders advanced information
	Getting to know colleagues abroad
	Creation of scientific network
	Identifying new research partners
	Contacts with other researchers
	Creation of contact network
	Networking

To share and gain knowledge and experience [Q6-BENEFITS]	
HTA Organisation	Non HTA Organisation
To share information & experience	Learning from the exchange
Learning from other new techniques/methods	Share information
Extension of clinical research	Staff training
Quality control / Accommodation schemes	Share of scientific data
Exchange of know with international peers	Exchange of know-how
Learning methodology by discussions	Impetus for improved patient care
Develop methodology	Improvement in scientific knowledge
Broaden score	Training for post-doctoral fellows
Exchange of expertise	Share scientific information at the edge of the field
Increased competence	New methodologies applied
Understanding of other conditions for EU research	Exchange of results
Knowledge of meta-analysis and it drawbacks	Transfer of technology
Publications	Changing experiences with other countries
	Developing a methodological framework
	Increased quality of the work
	Stricter quality control
	To learn from other organisations and people
	Improvements of the methods
	Exchange of information
	Developing management protocols based in evidence
	Understanding rates, risk factors of mother-to-child transmission of HV, hepatitis C, etc: for developing policy
	Recognition of the importance of randomized trials
	Epidemiological training (PhD project)
	Application of local piloted methodology
	Broaden one's mind
	Learning new things
	Exchange of ideas
	Transfer of own expertise
	Shared knowledge
	Collaborating to improve methodology
	Getting expert guidance to junior researchers
	Information about the latest studies in the field
	Methodological ideas
	New tools for headline assessment
	Share mutual interest and learn from the other partners

To share and gain knowledge and experience [Q6-BENEFITS]	
HTA Organisation	Non HTA Organisation
	Complementing clinical and methodological expertise
	Sharing of knowledge
	New competencies
	Increased information flow
	Increased access to resources
	Sharing experience
	Exchange of methods
	Exchange of information and materials
	Exchanging information
	Cross-checking the quality of data
	Exchange information
	Insight new methodology
	Acquisition of new knowledge
	Knowledge about rules/guidelines etc in other countries
	Improving HSR skills in other countries as well as our own
	State of art
	Quality control
	Learning new methods and views
	Drawing on experiences made by other centres
	Extending our knowledge & understanding in the field of suicidology
	Developing proper methodologies
	New clinical knowledge
	Information acquisition
	Learning from international group experiences
	Being able to use international experiences
	Discussion own projects on an international level
	Exchange of methodological knowledge
	Expand scientific knowledge
	Teachings training
	Overcome cultural barriers
	Broader and deeper competence
	Simulating young doctors
	Respect for handling data
	Capacity 3 research training
	Cross-cultural fertilization
	Advance in scientific knowledge
	Facilitate technology development
	Training of scientific fellows

Collaboration & co-operation [Q6-BENEFITS]	
HTA Organisation	Non HTA Organisation
Co-operation	Collaboration between groups
International collaborations /exchange	General management of the project
Sharing of the work-load between partners	Exchange of co-workers
Increase of collaboration with European laboratories	Collaborative research
Access to data	General management of the project
General management of the project	General management of the project
	Joint publications
	Fostering co-operation in other areas
	Increasing the level of international publications
	Equitative share of tasks
	International co-operation between research groups
	Steering research activities
	To participate preparing and publishing papers in journal of high impact factor
	Participation in trials
	Co-ordination
	Ownership and co-ordination with project partners
	Matching consensus for treatment guidelines
	High profile publications (Lancet)
	Collaborative projects (site visits)
	European workshops
	Data for publications
	Medical tourism
	Management of European Projects
	Logistic support
	Sabbatical from home
	More quickly process of data
	Joint publications in quality journals
	This way new innovative ideas and solutions may be found, as well as spin off projects and products generated
	Committed and qualified consortium members may actually establish a continuum of R&D activities and co-operation in the field
	Collaboration
	Exploration opportunities
	Established new collaboration
	Exchange of young researchers
	Publications in high quality journals
	Human resources
	International co-operation
	Documenting process
	Experience of organising, recruiting, international planning

Improve in house technology (Non HTA Organisation) [Q6-BENEFITS]
Gain technology
New technologies acquisition
Acquisition of hardware
Budget for equipment and for research

Motivation and self-steem (Non HTA Organisation) [Q6-BENEFITS]
Motivation of the team members
Increase self-steem
The willingness and enthusiasm of participants

Relevance of the topic and outcome [Q6-BENEFITS]	
HTA Organisation	Non HTA Organisation
Outcome of research	Relevance of the topic addressed
Relevance of the topic	Outcome of the project
Outcome of the project	Introduction of new safe & more effective treatments for portal hypertension
Relevance of the topic addressed	Outcome of the project
Results of the project important for our health care	Relevance of topic
Fits with international needs	Participation in more relevant research projects
Cultural benefits	Definitive basis for health care Planning + improving diagnosis and therefore avoidance + treatment
Development of a vaccine in Allergy	Benefit to UK health
Validation of cord blood transplantation	The establishment of definitive answer to project objectives
Outcome of the project	R&D can be related to the background interest and activities of the participating organisations
Producing "evidence" / Cochrane reviews	Scientific results
	New diagnostic procedures
	New biomedical technologies
	Development of new methods of measuring MRS parameters of medical relevance
	Development of harmonised procedures for assessing instrumental performance
	Development of appropriateness standardisation and quality assurance Procedures
	Multicentre reviews and evaluation of drug pharmacokinetis, using MRS
	Relevance of the topic addressed since very important public health issue
	Developing new strategies
	Development of standardised methods (1) photographic (2) data collection
	Collection of baseline data
	Establishing objectively the added value contribution of technology to diagnosis
	Creation of a test battery for research purpose
	International publications
	Promote international standardization

Financial support [Q6-BENEFITS]	
HTA Organisation	Non HTA Organisation
Funding for research	Funds obtained
Obtaining grants for postdoctoral students	Economical support for basic research
	Possibility to get money for research & contracts
	Financial support for basic research
	Freedom to use funding for salaries
	Financial resources
	Economic income to do research
	Funding
	Increase local funding
	Fund source for research
	Funding overheads
	Resources to help data analysis
	Resources to help publications
	Money
	Funding for national project parts
	Needs for resources
	Funding from the commission makes it possible to be more involved in research type activities
	Funding
	Support for basic research
	Adequate budgets for research instead of resource-poverty; ability to compete on equal terms

International prestige (Non HTA Organisation) [Q6-BENEFITS]
Acknowledgement in the specific market
Marketing of our own research
International prestige in basic research & influence
Get achnowledgment for R&D projects done
Where results may be disseminated jointly or by each partner nationally depending on their situation
Rapid transmission of information

Joint forces to solve analogous problems, dissemination and increase impact [Q6-BENEFITS]	
HTA Organisation	Non HTA Organisation
Synergies	Joint forces to solve analogous problems
Synergies	Synergism
Joint patient data, samples	To create of bank of data useful for sub-analysis
Compilation in Ireland of international data base of define data quality controlled 13000 cases from 23 countries	Scientific synergy
Avoid duplication of effort	Large study populations
International agreement on the results for a specific topic	Increased variability
Agreement on a relevant topic	Increased outcome/impact
	Studying a larger number of cases
	More diffusion of the results
	To have a more comprehensive joint of view
	With more external validity
	And to collaborate with other groups to tackle problems we do not have the ability to undertake on our own
	Large sample organization from multiples sites
	The assembly of a large up-to-data data set
	Improved potential recruitment base
	We would have been unable to complete without large scale collaboration
	More data available
	Market for results
	Possibility in a larger scale to perform R&D
	Where results may be disseminated jointly or by each partner nationally depending on their situation
	Rapid transmission of information
	Development of synergies between teams
	Increase in statistical power
	Larger number of subjects
	Confrontation of different exposures
	Reinforcement of results
	Better research (larger sample size, etc)
	Scientific data collection and dissemination
	Easier to address a national problem if the same is tome for other countries
	Sharing the task of producing data
	Increase quality
	Possibility to perform large scale clinical trials
	Creation of data bank
	Creation of renal histology bank
	Creation of serum bank
	Gaining insight in different health care systems
	Larger numbers-higher statistical power

Collaboration & co-ordination & results in different countries [Q6-BENEFITS]	
(HTA Organisation	Non HTA Organisation
Outcomes in different contexts	Methods & performance in different contexts
Comparing outcomes / data among ? countries / health system	Multidisciplinary approach
A wider perspective to the topic being addressed	Gathering state of the art in different contexts
	Knowledge of problems of implementation in other countries
	Comparative international analyses
	Compilation of existing systems in Europe
	Interaction with different research cultures
	Understanding other countries problems /solutions
	Evidence obtained on causes and means needed to prevent winter excess mortality in different regions
	Comparative data on treatment practices
	Homogeneity of risk factors and associated risks across Europe
	Conduct studies across health care systems
	Increase critical size of research tem
	Comparison of data sets in different countries
	Better understanding of the international environment
	Exploitation of different exposure circumstances
	International comparison
	Comparative evaluation of MRS measurement on advanced clinical equipment
	Quantifying differences among countries
	Getting data for comparison with own
	General benefits from collaboration w. international experts

Tables 7c. Question 6a: The most relevant benefits for your/your organisation

cientific networking & improve relationship [Q6a-RELEVANT BENEFITS]	
HTA Organisation	Non HTA Organisation
The role of dissemination	Involvement & interaction with European research leaders
Description of the genetic diversity of the HTA Systems in populations of Europe	Acquisition of emerging information/trends
	Workshops
	Communication with European colleagues
	Improved interacting
	New contacts
	Networking
	Develop international connection
	Learning to know experts in the field
	Networking
	Networking
	Getting to know colleagues
	Creation of scientific network
	Contacts with other researchers
	Creation of contact network
	Networking

To share and gain knowledge and experience [Q6a-RELEVANT BENEFITS]	
HTA Organisation	Non HTA Organisation
Sharing information and experiences	Gain know-how = knowledge
Learning methodology	Share of scientific data
	Exchange of know-how
	Impetus for improved patient care
	Improvement in scientific knowledge
	Share scientific information at the edge of the field
	New methodologies applied
	Improvements of methods
	Shared knowledge
	Methodological progress
	New tools for headline assessment
	Involvement of R&D organisations, health care organisations and users, commercial companies and it suppliers in a R&D project is a very fruitful forum to learn, to share interest and opinions, to understand he situation in the field, constraints included and to disseminate results
	New competencies
	Increased access to scientific resources
	Cross-checking the quality of data
	Insight into new methodology
	Being able to use international experiences
	Broader and deeper competence
	Capacity 3 research training
	Cross-cultural fertilization
	Facilitate technology development

Collaboration & co-operation [Q6a-RELEVANT BENEFITS]	
HTA Organisation	Non HTA Organisation
Co-operation	Collaborative research
Collaborations with resulting spin-off	General management of the project
Increase of collaboration	Steering research activities
Exchange of know with international peers	To participate preparing and publishing papers in journals of high impact factor
	Publications
	Workshops
	Collaboration
	Human resources
	International co-operation
	Co-operation
	Joint work

Improve in house technology (Non HTA Organisation) [Q6a-RELEVANT BENEFITS]
New technology acquisition

Motivation and self-steem (Non HTA Organisation) [Q6a-RELEVANT BENEFITS]
Motivation (of the Spanish team members)?

Relevance of the topic and outcome [Q6a-RELEVANT BENEFITS]	
HTA Organisation	Non HTA Organisation
Outcome of the project	Introduction of new safe & more effective treatments for portal hypertension
Outcome of the project	Outcome of the project
International needs are fulfilled	Participation in more clinically relevant projects
Outcome of project	Definitive basis for health care Planning + improving diagnosis and therefore avoidance + treatment
Doing Cochrane reviews	Scientific results
	Development of new methods of measuring MRS parameters of medical relevance
	Development of harmonized procedures for assessing instrumental performance
	Development of appropriateness standardization and quality assurance procedures
	Multicentre reviews and evaluation of drug pharmacokinetis, using MRS
	Developing new strategies
	Development of standardised methods
	International. Standardization

Financial support (Non HTA Organisation) [Q6a-RELEVANT BENEFITS]
Funds obtained
Freedom to use funding for salaries
Funding

International prestige (Non HTA Organisation) [Q6a-RELEVANT BENEFITS]
Acknowledgement in the specific market
International prestige and influence

Joint forces to solvea analogous problems dissemination and increase impact [Q6a-RELEVANT BENEFITS]	
HTA Organisation	Non HTA Organisation
Synergies	Synergism
Sharing of the work-load	To create of bank of data useful for sub-analysis
Avoid duplication of effort	Increased outcome
International agreement on the results for a specific topic	Large sample organization from multiples sites
	Increase in statistical power
	Larger number of subjects
	Sharing the task of producing data
	Larger numbers-higher statistical power
	Implications for health policy
	Broadening of research goals

Collaboration & co-ordination & results in different countries (Non HTA Organisation) [Q6a-RELEVANT BENEFITS]
Comparative international analyses
Understanding other countries problems/solutions
Evidence obtained on causes and means needed to prevent winter excess mortality in different regions
The establishment of definitive estimates of risk applicable across Europe
Better understanding of the international environment
Exploitation of different exposure circumstances
Comparative evaluation of MRS measurement on advanced clinical equipment
General benefits from collaboration w. international experts

Tables 8b. Question 7: Some problems from past IJP your/your organisation has been involved in

Organisation & Logistics [Q7-PROBLEMS]	
HTA Organisation	Non HTA Organisation
Bureaucracy and paper work	Too much travelling
Communication	Own organisation (bureaucratic) are not prepared to this sort of work
Leadership	Not enough administrative assistance
Much bureaucracy	Not enough technical assistance
Fluency in Anglosaxon language and culture	Too much time consuming in administration
Nt all partners/participants deliver their part	Spending too much time in bureacracy
Participants do not devote enough time and energy for the project	Bad coordination
Meetings are costly to arrange	Lack of collaboration, too much individualism
Much more time-consuming than national HTA activities	
Difficulty to organize processes at the international level	Amount of administrative tasks - bureaucracy
Acceptance of central projects for countries	Communication delays
Bureaucracy	Delays in making decissions
Difficulties in interpreting EU rules	Not enough collaboration between teams
Bureaucracy load	Burocratic overbooking
Difficulties in maintenance contacts with some countries (Eastern Europe	Coordination
Difficulties in recruiting partners	Different agendas
Organisation	Coordination was poor
Communication	Bureacratic management of the project
Non-equitative share of tacks	Administrative requirements
Lengthy & slow process	Time consuming preparing the research project
Poor coordination / management (repetition of tasks non clear tasks to be performed)	Difficulties to be recognized as principal contractor
Language problems	To stablism a coordination at national level
	To continue supporting a net work
	Complex management
	Complex bureaucracy
	Difficulties in communication
	Some countries not accomplishing the compromises
	Managerial complexity
	USA predominance
	poor management
	Unwilling management is N of sites >10
	Obtaining ethics approval in so many centers
	Lack of support for local input
	Preparing cost statements for each centre

Organisation & Logistics [Q7-PROBLEMS]	
HTA Organisation	Non HTA Organisation
	Not always possible to avoid duplicate work
	Various commitments of partners
	Slowliness of projects
	Slow (EU)
	Overhead of being in context
	Responsibility of weak partness
	Practical arrangements time consuming
	Very tight schedules
	Making up for others' undone work
	Incompatibility of software
	Poor planning
	EU project management bureaucracy
	All project partners may not be well committed to the work
	Accepted project plans are not always good work plans for performance of actual work
	Information systems design and software engineering are tasks that are not easily shared between the partners
	Time
	Administrative delays
	Heavy administrative work = bureaucracy
	Laborous administrative procedures = bureaucracy
	Organizational problems
	Administration problems = bureaucracy
	Lack of efficient intercenter coordination
	Usually: adiministrative problem = bureaucracy
	Too many documents with too many details
	Time consuming meetings
	Ineffective management
	In reality coordination of projects requires extensive input and time commitment at all levels within an organisation. Funding is never adequate. Projects are subsidized by other contracts?
	Breach of agreement by participants causing money losses
	Inadequate control of contractor by financial agents
	The comission's bureaucratic control procedure a kafkian experience
	Problems with multiple ethical committee aprovals
	Difficulties to retrieve data, serum and histology from some participants
	Some countries do not have sufficient numbers of patients
	None, wich is not astonishing in view of the practice oriented approach of the organisation (not aiming at long-term research cooparation)
	Work load
	Diverging expectations concerning project conduct and results
	Lack of competence by some participants
	No clear leardership of the project
	Difficulties of meeting to solve problems
	Longterm commitment

Scientific Issues [Q7-PROBLEMS]	
HTA Organisation	Non HTA Organisation
Representativeness of participants	Not well defined common goals
Complexity of the project (primary research)	Objectives not clear
Impact of the outcome of the project	Methodology not according the objectives
Commissions assessing proposals are not experts in the fields	Objectives not very ambitious
Heaviness	Refereeing of EU proposals by non-experta in the field (difficulties getting assessing to go to Brussels) with quixotic results
Small impact of the results internationally or non-mesurable	Poor agreement on aims and priorities
	The cumbersome way in which funding is obtained
	The need to ensure recognitition for all participants in publications
	Slow data delivery from some groups
	Inadequate help with analysis due to no possibility of extension
	Statistical problem with meta-analysis
	Management of missing data
	Review process emphasizes political rather than scientific issues
	Difficulties to do advanced research project
	Ownership of results and intellectual property rights
	Inadequacy of work programme to current R&D key problems
	Inadecuacy of evaluation criteria to real-life innovation practice
	Difficulty to attract good foreign post-doctors
	No major problems were found during the project, wich actually achieved the proposed goals and international recognition. However, after the end of the Project, the network was not given the opportunity of effectively transferring (to the clinical level) the results of these successful and costly efforts.
	Data management
	Generating a critical mass of interdiscipline on both sides
	Lack of unified purpose

Financial [Q7-PROBLEMS]	
HTA Organisation	Non HTA Organisation
Under financing of projects	Funding
Insufficient funding to do all the work	Conflict of interests
Meetings are costly to arrange	Labour and economic arrangements
Low cost-effectiveness of the HTA process	Delay in recovering the investment throug the funds
Delay in financing	Funding
Politics of resource (funds) sharing	Flexibility in money handling
Lack of full financement	No budget for data collectors in some studies
Expensive traveling	Differential funding across countries
	Expenditures increased
	Local fund-raising in support of concerted actions withdrawal from research support by national health services, destabilizing the clinical concerted action as a research platform
	Expense
	Poor resourcing
	Lack of tenure for researchers onprojects
	Heavy bureaucracy of funding
	Low level of overheads
	Uncertainty as to funds available due to variable exchange rates
	Falling euro
	Difficulty in arranging financial control
	Funding enough funds to support time work
	Lack of funding
	Difficulties to get funding
	Costly (EU)
	Complex financial matters
	Complex processes in funding applications
	Difficulties to get funding
	Personnel funding
	Conflict between EU and national explotation strategies
	Lack of complete cost coverage by most EU programs
	Lack of further funding to expand the project beyond the projected timeline
	Difficulty in keeping time-table of established schedule due to delay in receiving funds
	Problem of financing with UE
	In reality coordination of projects requires extensive input and time commitment at all levels within an organisation. Funding is never adequate. Projects is subsidized by other contracts?
	EU programs are limited to 3 years, an avenue to allow continuation of a project would be helpful where appropriate
	Delay by EU or contractor of disbursements
	Bias from industry or administration
	Lack of local resources
	Insufficient financial support nationally
	Insufficient financial support internationally
	Funding
	Financial
	No resources for primary research
	Longterm commitment and funding
	Inadequate funding

Differences in health system cultures [Q7-PROBLEMS]	
HTA Organisation	Non HTA Organisation
Different languages	Language
Diferents objectius de cada agència i # mandaaats	Different clinical setting
Diferents propietats en cada context geogràfic	Differences in patient population
Cultural differences	Cultural differences
Different background and cultures	Health services organisation differences
Language problems	Limitation in writing in English
Different traditions in HTA	Different mortality coding systems in different countries
Context differences	Cultural differences with regard to attitudes to deadlines
	Different culture
	Differences in the styles of working
	Cultural differences
	Different local environments
	Legislative constraints
	Lack of european identity
	Shortage of facilities or expertise in Ireland
	Differences in monetary as well training resources
	Different economic resources
	Different systems cultures

Tables 8c. Question 7a: The most relevants problems from past IJA-P your/your organisation has been involved in

Organisation & Logistic [Q7a-THE MOST RELEVANT PROBLEMS]	
HTA Organisation	Non HTA Organisation
Lack of devotion	Own organizations are not prepared to this sort of work (bureaucratic)
Bureaucracy load	Not enough administrative assistance
	Not enough technical assistance
	Too much time consuming in administration
	Spending too much time in bureaucracy
	Bad coordination
	Lack of collaboration too individualism
	Not enough collaboration between learns
	Excessive burocracy
	Different agenda
	Coordination was poor
	Time consuming preparing the research project
	Managerial complexity
	Poor management
	Management difficulties
	Ineficiency for our group to deal with Bussels bureaucracy
	Practical arrangements time consuming
	Very tight schedules
	Informations systems design and software engineering are taks that are not easily shared between the partners
	Administrative delays
	Organizational problems
	Ineffective management
	Breach of agreement by participants causing money losses
	The comission's control procedure
	Diverging expectations concerning project conduct and results
	Difficulties of meeting to solve problems
	Longterm commitment and funding
	Generating a critical mass of interdiscipline on both sides
	Lack of competence of the organization in managing the project

Scientific issues [Q7a-THE MOST RELEVANT PROBLEMS]	
HTA Organisation	Non HTA Organisation
Impact of results	Objectives not very ambitious
Commissions evaluating proposals are not experts in the field	Inadequacy of work programme to current R&D key problems
	Difficulty to attract good foreign post-doctors
	All = no major problems were found during the project, wich actually achieved the proposed goals and international recognition. However, after the end of the Project, the network was not given the opportunity of effectively transferring (to the clinical level) the results of these successful and costly efforts.
	Longterm comittment amb funding
	Generating a critical mass of inter interdiscipline on both sides
	Lack of unified purpose

Financial [Q7a-THE MOST RELEVANT PROBLEMS]	
HTA Organisation	Non HTA Organisation
Underfinancing of projects	Funding
Not enough funding for the work delivered	Funding
Lack of full financement	The cumbersome.... = the cumbersome way in which funding is obtained + lack of tenure for researchers onprojects
	Heavy bureaucracy (especially financial reports)
	Difficulty with financial control
	Funding
	Funding
	Lack of complete cost coverage by most EU programs
	Lack of futher funding to expand the project beyond the projected timeline
	Problem of financing with UE
	Lack of local resources
	Insufficient financial support nationally
	Financial
	No resources for primary research
	Longterm comittment and funding
	Generating a critical mass of inter interdiscipline on both sides

Differences in health system cultures [Q7a-THE MOST RELEVANT PROBLEMS]	
HTA Organisation	Non HTA Organisation
Different languages	Health services organisation differences
Cultural differences	Different mortality coding systems in different countries
Different background	Different culture
Context differences	Different local environment

Tables 9a. Question 8: interest in future IJA-P

why not? (Non HTA Organisation) [Q8-INTEREST]
The company is loosing time and money, which perhaps will never be recovered
Tremendous bureaucracy/paperwork
Poor scientific benefit obtained in previous joint projects
At present time lack of available time of senior staff
Missing time and money
Transaction costs are generally too high. Collaborations is too cumbersome if the tasks are not well-defined. It may be possible to work together if the number of participating partners does not exceed two.
Takes resources out of our organizations without providing benefits

Tables 13b. Question 12: Who should select topics for IJP?

Researchers and senior experts [Q12 SELECT]	
HTA Organisation	Non HTA Organisation
Consensuated after rotating by all possible partners	Managing director
Those involved is doing research and those using the results of that research	A group of scientists
Scientific committee / independent / transparent	Scientists based (on public / Government demand)
Physicians' doing research in the field	Scientific community
	People knowing the aims of the project
	Researchers
	Scientific
	Experts in basic sciences & in th e clinical manifestations of the diseases
	A board made up of senior academics & research council members should do a connectation exercise
	People with expert advice available but no biassing personal interest to serve
	Those writing to participants
	Individual principal investigators willing/able to lead
	Scientific comments
	Investigators
	A international working group
	University research group, professional working groups
	Potential participants, informed by policy needs
	Researchers
	International peer-reviews
	Panels of scientifics only
	Referees of major scientific journals + health managers
	Steering committees (taking into account opinion of stakeholders)
	Steering committees (with stakeholders)
	International scientific working groups
	HRB (Health Research Board)
	Decision makers i.e. those who decide to apply the technology
	Experts in the field
	Steering group
	International steering groups
	The researchers
	Policy makers and members together
	The researchers jointhy with policy makers
	Investigators

Organisation partners [Q12 SELECT]	
HTA Organisation	Non HTA Organisation
HTA organisation and those formal HTA networks (INAHTA)	HTA experts groups
Joint decision by the HTA agencies included	Politicians & scientists
	HTA organisations
	International boards (primary researchers, HTAS) the area involved (EU)
	The organisations involved

Mixed commission (Non HTA Organisation) [Q12 SELECT]
Both researcher and agencies
A mixed commission of eurodiputees and experts
A large number of patients/people potentially affected in Europe
Committee with organisation by the study promotors + clinics + experts in health technology
Each country - users -usees fed with comparative added value/cost survey data on HT

Committee at European level [Q12 SELECT]	
HTA Organisation	Non HTA Organisation
Directorates of EU of coordinating office of European HT agencies.	Management committee at european level
Groups of experts after taking into account former criteria at the European level	Experts committee
A committee consisting of representations from participants nations	Panel of experts
This should be derived from a priority process where all countries are asked	International organisations
A coordinating office including representatives of health organisations in Europe	European union through working groups of experts
International bodies, such us EU will advise from experts	EU organisation
	Expert panels with relevance research experience
	Panel of experts
	Professional representatives from all countries
	EU parliament up on recommendation of experts
	Expert committees, named by their research knowledge on experience in policy
	International expert boards formed from national authorities, including HTA authorities, and experts and representatives from user organisations, HC professionals organisations and it suppliers and product developers
	Experts in the same hold and experts of a differents field (they should be cominced of the relevance)
	International panels of experts
	Internationally recognized scientists
	Appropriateness, efficient EU organization(s) and multidisciplinary Advisory Group
	An international committee of experts after and accureate analysis of what's actually needed and can have an impact
	International research organisation (like our own: EUVAS: www.vasculitis.org
	Internationally composed advisory board including: scientific community, providers, payers, consumers politicians
	Organisations like European Society of cardiology and it's working groups
	A panel of investigators by the EU

Tables 14a. Question 13: Should a formal priority setting process be established at the European level to select topics for IJA-P?

Why not? [Q13-FORMAL PROCESS]	
HTA	Non HTA
Por las dificultades del contexto	There is no competence at European level
Wouldn't work, it must be topics already prioritised i individual countries	To restricted
Danger of system fossilization	I do not think a "top down" approach would work well
Difficult to handle – Not more formal than a discussion i.e in INAHTA or similar organization	Due to very different social & organisational arrangements in various countries, an informal process would probably reflect potencials better
	It should be dynamic process
	Current approaches for priority setting are adequate
	It would be too politically oriented
	Too difficult – almost impossible for political reasons
	It may be difficult to prioritise, as agreement of criteria for priorities may not be possible. However, agreement on topics of clear importance might be reached. Also, the door should be left open to submissions to do HT assessment of other areas where a proposer makes a good argument for it

Why yes? [Q13-FORMAL PROCESS]	
HTA	Non HTA
Those listed in Q#11 & equity	Committee with governmental and social representatives from each country
Type of criteria in question #11	Priorities according to health impact on the population
Assign weighs to each of the selected criteria to prioritise and assess each topic according to these criteria, to finally have a ranking	Open process including consultation with researchers, and others
Adapting the process to each context, optimising resources, sharing HTA	Delphi for selecting topics Explicit criteria and National group adapted method
International board with representative from HTA agencies and including consumer interests	Similar to one used by NHS, HTA
Prelisted topics + rating system (scoring)	Need encourage research in specific fields represented
Each lab should send patients to a Committee who will select the topics and transmit them to European committee	It would be interesting to have such system as a consultation arm
Avoid duplication	Economic interest for the community & scientific priority
This should be set up jointly	Scientific basics
Committee of experts looking at fields requiring further research	Although the process should allow further inputs “in itinere” according to specific needs
A group of multidisciplinary health related professional should rise topics for research on the base of explicit criteria select those most frequently named	Taking into account what can have most impact on health and in most countries
	Quantitative criteria based (as the OTA system)
	Quantitative model (such as the USA’s one)
	Problems of importance, too many people’s projects with possible large gains
	Survey of competing technologies added values ranked by frequency of use, in each country by common agreed protocol
	Ref. Oortwijn WJ et al. The use of societal criteria in priority
	Organisations propose special priority areas to the EU
	Sets of criteria formulated by committees comprising internationally acknowledged experts in relevant fields
	Most impact on health profiles of the European citizens
	It is a knowledge producing process in itself
	Areas in which Europe could play a leading role. Specific topics of common interest

Tables 15b. Question 14: Should there be a permanent co-ordinating office/body in europe to manage IJA-P and disseminate results?

Why not? [Q14-PERMANENT OFFICE]	
HTA	Non HTA
Wouldn't work, dissemination very much a local process (at country level)	It would be difficult to effectively do this coordination
A flexible system with countries being coordinators (depending on topics + resources)	Unecessary bureaucracy
Danger of system fossilizations	Too remote
Not more formal than a network of interested cooperating organizations	Top down approach tends to produce bureaucracy rather than productivity
	Informal communication about possible projects within INAHTA is probably sufficient
	This is already done within EU programmes
	Too rigid, many limitations linked to it
	There are already too many control bodies
	No need for additional offices to increase bureaucracy
	Becomes enevitabely too bureaucracy
	Too much bureaucracy
	it is probably much better if plurality governs that process

Why yes? To assure continuing and improve coordination [Q14-PERMANENT OFFICE]	
HTA	Non HTA
Care should be taken to avoid similar initiatives in different countries	It is only way to follow the situation year after year
Someone needs to specifically concentrate on this topic	To avoid dispersions
Past experiences of joint international HTA have shown that strong coordinating support is need	To maintain the overall process
The projects should be sent at any moment	To improve coordination
Because it is necessary to exchange information and experiences, coordinate HTA work to avoid duplications and address a same topic from different perspectives, to make a commont lobbying front in the European health market	Coordination lack of resources in each country
	Deadlines are bore. A board should be able to decide at any time
	As facilitator body
	To allow harmonization of procedures and efforts with health authoritites and health care services/providers active at the National level
	To act as focal point and resource centre to coordinate research
	As facilitador body
	There would be added value in coordinating efforts, likely to help prevent unnnecessary repetition
	Yes for coordinating, no for managerial (which would fail acceptance)
	Provided financial resources are provided we need manpower to coordinate
	This is the only way to maintain a continuation in areas with a longstanding interest

Why yes? To improve efficiency [Q14-PERMANENT OFFICE]	
HTA	Non HTA
It would be cost-effective	Help desk
Paper-work	Economy of scale
To do the job	Sounds efficient
	To use the limited resources in the best possible way without destroying the enthusiasm and local initiatives necessary

Why yes? To promote synergies [Q14-PERMANENT OFFICE]	
HTA	Non HTA
Synergies	To facilitate the experts of researchers
To join eforts, if applicable	
To facilitate knowledge on existing collaborative research	

Why yes? To improve dissemination & impact [Q14-PERMANENT OFFICE]	
HTA	Non HTA
They have greater impact	To strengthen coordination influence
Because it is necessary to exchange information and experiences, coordinate HTA work to avoid duplications and address a same topic from different perspectives, to make a commont lobbying front in the European health market	Dissemination currently inadequate in most countries
	To disseminate results
	Consistency
	Dissemination is vital: a central source & the latest evidence would be valuable
	Dissemination and ineffective procedures except to usees

Why yes? Global issue of interest [Q14-PERMANENT OFFICE]	
HTA	Non HTA
Because it is a global issue that needs an international approach (sample size resource)	Common interest, we are all inmerse in same biomedical system
To identify	
The existence of an European office favours the creation of an European culture	

Tables 18b. Question 17: what characteristics should have the "ideal" IJA-P to be both credible and supported by the partners in the project as well as by external organisations?

TOPIC OF WIDE INTEREST AND SUPPORT [Q17-IDEAL IJA-P]	
HTA ORGANISATION	(Non HTA Organisation)
Consensus in topic selection	Basic science project should be founded on scientific interest and not by economical profit
Relevance	Wide support from different countries
Relevant	Addressing a relevant issue
Opportune	Politically (in a broad sense) relevant for the European citizens
Justified	A clear research subject of general interest
Of interest to all partners	
Main characteristics would be relevance of the topic	Social importance and demand
Research question must be relevant to all those participating	Relevant issue
Solid decision	Projecte de recerca rellevant
Be pragmatic on needs oriented to a transparent process	Wide benefit
Relevance	Based on population important
	Focused on priority in terms of health resource allocation
	Address priority areas
	Economic priority
	Scientific impact
	Linked to actual problems
	Problem-solving oriented
	Relevance to health
	Being problem solving oriented and being formally choosen
	Relevance to funding
	The project should deal with a major human and socio-economic problem.
	Accessibility for everybody
	Accessibility for everybody
	Relevant topic
	Clearly defined policy relevant question
	Address an important topic

Scientific quality [Q17-IDEAL IJA-P]	
HTA Organisation	Non HTA Organisation
Explicit method	Scientific credibility
Good methods	Solid scientific project
Adequate working plan	Have a good project
Robustness	Scientific quality
Methological standards	Well designed
Original	Scientifically sound
Well designed	Original plan of work
Adequate coordination among partners	Scientific quality
Quality of the work	Quality
High-quality of the review process plus well-written and succinct summary / recommendations	Originality
Transparency	Scientific quality
Rigorous methodology	Appropriateness methods
Scientifically validated	Appropriateness methods and analysis
Well planned	Clear objectives
Strong rationale	Good collaboration
Explicitness of full process, including identification of HTA to assess, and methodolgy	Other than to ensure work is going according to plan
Use of high quality methods	Well focused research question
Ethically OK	Peer reviewed support of submitted projects
	More involvement of citizen and their needs
	Clear scope
	Timetable
	Specific
	Time-planned smart
	Realistic workplan to achieve the planned results
	Good and innovative ideas behind
	Direct and working communication means
	Credible rationale
	Strong scientific methodology
	Scientific excellence
	Evidence based
	Clear aims
	Objectives
	Common agreed evidence-gathering protocol
	Agreed assessment protocol with clinical trial of protocol in each country
	Clinical research of high standard needing collaboration from many organisations
	High level scientific support
	Agreed upon by multidisciplinary advisory board
	Sound methodology; extensive peer review process
	Scientific originality
	Outstanding study design
	Added scientific (not necessarily political) value and stable funding
	Method and material of high scientific standard
	...and with a sound and cost effective methodology
	In a methodologically sound maner

Good funding without economic conflict of interest [Q17-IDEAL IJA-P]	
HTA Organisation	Non HTA Organisation
EU financing (total or partial)	Non economical interest
Adequate funding	Adequately funded
Funding	Adequate funding, no interference from funders
	Lots of money
	Economically
	Lack of conflict of interest
	Adequate financing

GOOD DISSEMINATION ACTIVITIES AND IMPACT ASSESSMENT [Q17-IDEAL IJA-P]	
HTA ORGANISATION	NON HTA ORGANISATION
Implementable, measurable results	Measurable
Constant publicity and correct dissemination	Reported and disseminated both academically and commercially
Disemination activities	Evaluated
Impact assessment plan	Dissemination of information on project
	Publication of activities and findings
	Responsive communication
	Feed back from users and usees

APPROPRIATE PARTNERS AND WIDE & BALANCED PARTICIPATION [Q17-IDEAL IJA-P]	
HTA Organisation	Non HTA Organisation
Expertise of partness	Balanced (country) participation
Multidisciplinary	Experience in the field
With the participation of the highest possible number of countries	The best participants possible
With a clear leader	Recognized leading group and partners
Not bureaucratic	Strong scientific background
Multidisciplinary	Research leaders
Cross-country representativeness	Network of participating centers
	Supported by dedicated and expert investigators
	Multidisciplinary
	Credibility
	In the specific case of research project, quality of the participants
	Experienced researchers
	Directed by renowned researchers and carried out in centres implied in research.
	Large number of partners
	Requiring multinational action
	There must be added value to justify the added problems of multinational research, access to adecuate patient pool, informative contrast in practice etc.
	Professional partners
	Competitive and qualified partners
	Skillful project management and coordination
	Leading character of the project manager
	High level of competence
	Multidisciplinary partnership
	Possible image best for organisations and countries
	Roots in established national scientific groups
	Well recognised and respected membership
	Good leadership
	Participation open to all countries
	Dedicated acknowledged leaders in the research field must participate personally
	The project should be headed by a steering group comprising experts in the field (not civil servants)
	Adaquate announcement and call for participation period
	Creativity and complementary competences among collaborators
	Organized to solve major health issues for most countries
	Multi-country comparisons built-in and with a sound and cost-effective methodology
	It should be important at the European level at both opportunity and competence

RESULT: FEASIBILITY OF APLICATION AND ITS POTENTIAL [Q17-IDEAL IJA-P]	
HTA Organisation	Non HTA Organisation
To allow members from basic research to provide supports for applications	Project including credible possible future applications
	A relevant potential benefit in health care and technology
	Lots of results
	Real benefit from being international
	Achievable
	Realistic
	Good project results
	Immediate or sufficient guarantee of immediate results
	Strong transferabely of results and products
	Practical feasibility

Independency (Non HTA Organisation) [Q17-IDEAL IJA-P]
Not involving politicians
A good understanding of the political prerequisite
Fully independant from interest in the topic
Independence from governments

Tables 19b. Question 18: Issues for future HTA-P of potential interest in europe , justification (Why?) and methods .

Cellular biology	Why	Methods [Q18-FUTURE]
	HTA Organisation	
Role of chimiokines and their reception	Role in grafts	Biochemical characterisation
Quality control - accreditation schemes in biology		Pilot study

Molecular biology	Why	Methods [Q18-FUTURE]
	HTA Organisation	
Role of glyc an heterogeneity in glycoproteins	For recombinant glycoproteins	Biosynthesis of glycans
Characterisation of new proteins	Postgenomic research	Biochemical characterisation

Cardiology	Why	Methods [Q18-FUTURE]
	Non HTA Organisation	
Cardiac diseases	Social impact	Multidisciplinary
Variations in invasive cardiac test	Costly, indications uncertain	Standardised observational data sets with outcome
Medico-legal implications of testing in coronary artery disease	High economic impact	Multicenter study

Orthopaedic surgery and traumatology	Why	Methods [Q18-FUTURE]
	Non HTA Organisation	
Effectiveness of hip / knee prosthesis	Data currently very scarce	RCTS, Data bases

Pharmacology and therapeutics	Why	Methods	Pharmacology and therapeutics	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Instituion		
New anti-bacterial compounds	Resistance to antibiotics is increasing	Peptides characterisation and synthesis	New drugs	High cost and moderate benefit	Analysis of the evidences
Anti-inflammatory compounds	Sepsis is always important	Identification of inhibition of adhesion	Appropriateness antibiotic prescription	---	---

Genetics	Why	Methods	Genetics	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
Genetic testing	Potential impact on health care ethics	Qualitative synthesis of reports	Development of methods for the genetic characterisation of cancer	Possibility to design more specific treatments	---
Genomics and HTA	Emerging technology that will change the organization and caractheristics of health care delivey	Qualitative research	Genomic/proteomics analysis and pathology	---	---
			Pharmaco/toxico-genetics	---	---
			Genetic susceptibility to oral diseases	Wide prevalence among the population	Combination of basic and clinical research
			Genetic determinants of development	Possibility in intrauterine diagnosys	Experimental embryology - genetics
			Genomics	Health implications	Actual and developing technology
			Proteomics	Health implications	Actual and developing technology
			Genetic therapy	Emergent, controversial, ethical concerns	---
			Genotype phenotype relation	No single country in Europe has adequate clinical resource	
			Applications of Genetic research	Benefit from large data bases	Clinical research

Genetics	Why	Methods	Genetics	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
			Gene Therapy	Efficiency not clear, ethical problems	---
			Predictive genetic test's	Social implications	---
			Functional genomics	New frontier of molecular biology	New technologies for gene expression studies and mutation identification
			Genomics	Thousands of genes to be discovered	---
			Proteonics	Thousands of proteins to be discovered	---
			Genetic counseling	To increase possibilities of prevention	---
			Psychiatric genetics	Major health problems	Genetic epidemiology, genomics
			Murine models of genetic disorders	Need to understand the basis of the disorders	Transgenesis
			Gene therapy of mendelian disorders	Technology development	Vival and non-viral vectors; gene correction methodology

Geriatry	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
Becoming old	---	---
Ageing	21 century "disease"	Basic science
Better care for the elderly	Priority of EU	Different methods
Ageing	Universal problem	Laboratory (genetics)

Internal medicine	Why	Methods	Internal medicine	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
Genetic and environmental aspects of allergy	Medical social economic importance	Research - networks	Development of fast clinical immunoassays	Need of more and more efficient diagnostic tools	---
			Drug-induced & autoimune disease	----	---
			Ethiology and pathogenesis of primary vasculitis	A small but expensive group of patients / Epidemiology / gene-technology	Knowledge can target treatment, cut cost and improve quality of life
			Improve treatment of vasculitis	As above	RCT'S to identify better treatments
			Improve diagnosis of primary vasculitis	Earlier and more precise diagnosis increases survival	Improve and standardize anca testing using gene technology products
			Atherosclerotic disease	No. 1 killer in Europe	Pan European approach with human behaviour involved

Intensive medicine	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
Severity scores and organ system failure in ICU	To define prognostic factor and predict survival	Collecting prospectively data + statistical analysis of 16.000 patients

Nuclear medicine	Why	Methods	Nuclear medicine	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
Forecasting PET use and impact in oncology	It is a new technology pushing to widespread in the health care systems	Patterns of use and intention to use, cost analysis, effectiveness analysis	Positron emission tomography (PET)	Recently implemented in Spain	obtention and collection of data from those diseseases that are more clinically relevant

Neurology	Why	Methods	Neurology	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
Alzheimer disease: therapy and rehabilitation	Burden of disease and uncertainty	---	Immunological & Neurobehavioral in development	Uncertainly + unknown + controversial	Epidemiology + basic sciences + clinicians
Prophylaxis of epilepsy with AED In high risk patients	Relevant issue, controversial (frequency incorrect) management	Randomized clinical trial (treatment vs. no treatment)	Neuroprotective therapy in neurodegenerative disorders	Heath benefit	Genetherapy, stem cells
Registries of rader neurological disoders (ej. ALS)	Only large numbers of patients may be required to address questions regarding ecology screening of patients living in well defined areas	---	Mechanisms of neuronal death	Ageing	Biochemistry, trophic factor treatment, molecular
			Neurodegenerative diseases	Incidence in population	Multidisciplinary
			Neurodegenerative diseases	Social impact	Multidisciplinary
			Brain development	Relation with possibles ways of regeneration	Experimental embryology
			Neurosciences	It is one of the largest unknown areas	---
			Brain ageing	--	Basic research
			Stroke	--	Basic research
			Treatment of Stroke	Variability of treatment, epidemiology relevance, costs	On site evaluation of practice

Obstetrics and gynaecology	Why	Methods	Obstetrics and gynaecology	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Institutin		
Mammography screening	Controversial results. Costly	Systematic review	Development of prenatal diagnostics (unexpensive methods)	Need of tools for detecting an increasing number of genabnormalities	---
			Osteoporosis treatment	Relevant and non-solved	RCT
			Pre-natal diagnosis involving biopsies of the embtyo	Ethical concerns	---
			Hormone replacement therapy	Profound the importance to all women during, on average, 30 years of their life	Prospective cohort study with repeated exposure measurements

Oncology	Why	Methods	Oncology	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
Screening for colorectal cancer	Cost, acceptance, epidemiology	Quantitative, qualitative reviews	Cancer research	Clinical, biological, social relevance of the disease	---
PET in oncology	Expanding technology - wide variations	Systematic review, context analysis	Opportunistic screening for prostate cancer	Differences according to health system	Patterns of care analysis
			Palliative chermotherapy in advanced cancer	Variations	Patterns of care in depth interviews
			Cancer research	Social interest	Basic + applied science
			Population based cancer screening	High variability	---
			Variations in cancer outcomes	Public health importance, inconsistent data collection	Standardised data on stage treatment and outcome for populations
			Toxic environment & cancer	Bad methodology - wrong ideas circulating	---
			Evaluation of screening for cancer	Heavy burdens of cancer	Variable according to cancer
			Early diagnosis and therapy follow-up in cancer	---	MRI/MRS
			Cervix cancer screening	Great potential benefit, but role HPV testing unclear	Randomized intervention trial

Otorhinolaryngology	Why	Methods [Q18-FUTURE]
HTA Organisation		
Tonsillectomy	It is still being probably over-used	Sist. Review + country patterns of use

Pneumology	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
Epidemiology of acute lung injury	Prevalent disease (90 cases/100.000) inhabitants/year + high mortality	Creatine and ALI network
Definition and pathogenesis of acute lung injury	Homogeneize diagnosis criteria for futures trials	Consensus conference. Delphi study
Acute lung Injury Sepsis and blood coagulation	Difficulties to obtain BAL samples and pathology	Bank of biological data + basic research of cell mechanisms

Psychiatry and mental health	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
Psychiatric diseases	Incidence in population	Multidisciplinary
Treatment of major depressions	Rising prevalence / indemnity costs	RCTS
Handling of depression	Variability of treatment, epidemiological relevance, costs	On site evaluation of practice
Mental retardation	Very complex pathology	Genomics
Psychosomatic disorders	Very common in the population	Genomics - genetic epidemiology

Radiology	Why	Methods [Q18-FUTURE]
HTA Organisation		
Assessment in telemedicine	There are many initiatives, but few xxxxxxxxxx	Rigorous impact assessment. Cost-effectiveness
Diagnostic imaging	Expensive, may be introduced without sufficient evaluation	Joint rigorous research

Reumatology	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
Osteoporosis treatment	Relevant and non-solved	RCT
Osteoporosis	Social Impact	Bone mass measurement. Biomedical markers of bone turnover. Genetic markers
Paget's disease of bone	Laking of new data	Biochemical marken of bone turnover genetic studies. Therapeutic approaches
Post-transplantation bone disease	Clinical impact. New area of research	
Hepatic osteodistrophy	Short sample studies	Bone mass measurement. Hormonal determinations
Epidemiology of osteoporosis: risk factors personal impact	Environmental/lifestyle causes not well identified; big ageing problem	Epidemiology
Osteoarthritis, spine	There is no treatment & avoidance is the key	---
Prevention of osteoporotic fractures	Rising health / economic burden	Multicenter RCT

Public health	Why	Methods	Public health	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
Patient education programs	Participation	Qualitative, systematic reviews	Food contamination	Everybody exposed + thigh risk + unknown	Chemistry + Environment + Epidemiology
Prevention technology	Poorly assessed and with high cost effectivenes potential	Systematic reviews + qualitative research	Education of youngsters	---	---
Public health projects	---	---	Drug abuse in its cultural context	---	---
			Growth sustainable and preservation of nature	---	---
			Climatic effects in health	Very larges cause of illness & death	Epidemiology, surveys, lab.
			International variations in obesity, diabetes, diet	Increasing public health burden or obesity, diabetes	Cross-sectional comparative data
			Prevention of injuries	Major cause of dealth for all ages	Quasi - experimental studes
			Prevention / treatment of alcohol / substance abuse	Raising problem	Quasiexperimental studes
			Women and tobacco	There are no gender specific studies. The reasons for taking up smoking are different among women and men; health effects are also higher and set in earlier no so it seems	A gender specific research project on tobacco use and gender way to help women/girls quit tobacco smoking
			Evidence base for judgement of drugged driving	Increasing phenomenon - international guidelines lakcing	Analysis of published data

Public health	Why	Methods	Public health	Why	Methods [Q18-FUTURE]
	HTA Organisation			Non HTA Organisation	
			Measurement of fluorosis on teeth at age 8 having measured the ingestion at age 2	Baseline has been conducted in 7 countries	Outcome should be measured to complete knowledge. X photographic study
			Mehods of measuring fluoride	No standardisation - different methods in different places	Identify centers doing work, document methods swap samples. Make recomendation, apply new teck.
			Suicide research and prevention	More people die from suicide than from traffic accidents, AIDS and drugs combined and 8-10 times as many make suicide attempts	Collecting and analyzing data to be able to work out plans for prevention of suicidal behaviour, the main being aim to increase awareness of the problem of suicide and enhance suicidological research. An exemple:When the WHO/EURO Multicentre study on Parasuicide began in t he late 80'ies, 16 centres participated; in the following years 2 centres dropped out because of lack of funds. Today 25 centres are participating
			Selenium supplementation and cancer risk	Intriguing evidence of substantial benefit that needs further scientific documentation	Randomized intervention trial

Public health	Why	Methods	Public health	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
			Smoking	Too many people struct	A unified policy and better tools to stop smoking
			Commiunity interventions	Lacking evidence	Epidemiological
			Alcoholism	Increasing most in ther east	Better than taxation

Health Technology Assessment	Why	Methods	Health Technology Assessment	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
Define and diffuse an evaluation outline of diagnostic tests and applied to specific technologies	Revision	---	Outcomes of medical. Procedures	Public interest	Several
Database of systematic reviews of diagnostic test	Because it doesn't exist and great for such info	---	Can we assess HT in Europe in a timely schedule	Information available offer too late	Series of case studies
HTA reports and assessment of emerging technologies	To reduce overlapping work between HTA agencies	Secondary research	Bringing users along to adopt HT assessments	---	Participation in assessment from the beginning, workshops, observer agreements with feeback
Common electronic network on HTA reports	To facilitate for decision-makers, professionals and consumers	Internet	Assessment of scope for technology in the various diseases	Allows assessment of need for new technologies and cost / benefit posibilities	Similar methods
Educational programs on HTA and EBM	Great need in most European countries	Courses and internet-based	The effect of applying HTA in political/administrati on decisions	We need to know why HTA is not used much more	---
Meta-evaluation (assessment of HTA reports)	To explore differences in quality and results	Quantitative and qualitative research	Prioritzation of health care a financial	Emerging without sound evidence	Qualitative as well as social

Health Technology Assessment	Why	Methods	Health Technology Assessment	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
Effective methods for implementation of HTA results	Poor scientific backing	Primary research	Drug trials combined with health economy	Always needed	RCT
Priority setting	According to Agencies, priorities differ significantly	Priorisating process	Prioritising RCTS	Address crucial needs	Epidemilogy, appropiateness, C-E
Variations of methods of HTA	According to assessment body, methods are different	Education on techno assessment - rigourous choice of methods			
Systematic reviews	---	Cochrane reviews			

Stomatology / maxillo-facial	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
	Wide prevalence among the population	Combination of basic (microbiological and molecular biology) and clinical research
Genetic susceptibility to oral diseases	Wide prevalence among the population	Combination of basic and clinical research
Dental caries in adults	Problem off virtually entire population	Standardised EU survey
Periodental disease	Comparable data are few (off 15% pop)	Assess intervention in practose

Health Services Research	Why	Methods	Health Services Research	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
Finance of health care	Relevance, cost, democracy, context specific	Qualitative	Role of primary care inside health system	Different experiences (countries)	International comparison of health outcomes
Waiting list but management	Cost, social concern, organisation	Quantitative, qualitative, health Policy Research	Evaluation new health care services (hospital at home, call centre)	We introduce changes (reforms) with low evidence	Systematic review of evidences
Setting priorities in health care	Resources are limited	Diverse, but should be applied to all the population	Ways of citizen participation in health decision	Priority of EU	First qualitative and latter quantitative
Needs analysis in the treatment of diseases	Associated to ageing	Diverse	Changing from acute to integrated care	Economical and sociological need	---
Waiting list prioritisation (in a sub-strudy of the first issue)	---	Qualitative research / conjoint analysis	Quality in health care	Public interest	Not procedsses xxx structures exept for underdevelopped countries
Cost-effectiveness analysis of the prioritised technologies in order to help establishing care priorities	---	Economic evaluation methods	Priority setting	Cost of health care	Several
It in health care	Organisational and economic impact	Comprehensive HTA	Variations in use of HT	Ethical political issue	Descriptive study
			Overuse + underuse of care	Equity concerns	Criteria develoment, descriptive study interaction
			Effects of reduced resources for health care on people health and wellbeing	---	---
			Equity in health and health care	---	---
			Cost of competing imaging modalities	High economic impact	Multicenter-Multidisciplinary study
			Waiting-lists management	Risk of delay	Primary research - multicentric
			Political and administration decision process in health care	We don't know much about it	
			Appropiate care in central Europe	Community experience	Appropiateness method

Sociology	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
Social values	Relevance, cost, democracy, context specific	Qualitative

Continued education	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
Distance learning	Information technologies, medical devices, cost	Qualitative

Quality of life	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
Does technology improve quality of life?	---	---

Transplants	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
Living donor organ transplantation	Shortage of donors. Ethics	International conference, primary research
Stem cells from adult organs and tissues	Possibility of cell regeneration and easy sources	Cellular biology methods - cell therapy
Embryo-stem cells	Extreme potentiality	Establishment of cell lines
Stem cell research	Basic research needed. Application	Not clear

Infectious diseases	Why	Methods	Infectious diseases	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
Genetic testing	Potential impact on health care ethics	Qualitative synthesis of reports	Infections diseases	Social impact	Multidisciplinary
			Lung infections	Prevalent disease with high mortality and morbidity	Local pulmonary treatment using a combination of perflouro + antibiotics

Biocomputing / information sistems	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
Bioinformatics	Loss of international leadership of the E.U.	As appropriate emphasis in human resources
Information technology in health	High cost and wide variation in application	Identify centres of excellence
Variation of electronic patient record usage	---	---
Co-operation (electronic) between primary and secondary care	---	---
Organisational aspects of health information systems and networks	Need to manage new technology products and legacy systems in the changing health care organisational environment	Multidisciplinary approach needed: social sciences, organisational sciences, human computer interaction issues, health sciences health informatics
Conceptual basis of health information systems	Theories and frameworks needed to manage design, development and installation of health information systems.	

Ethics	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
Ethics of technology developments	---	---

Disabilities	Why	Methods [Q18-FUTURE]
Non HTA Organisation		
Disabilities	Commond and growing in many countries	Systematic review, scope of resources available

New emerging technologies / rare diseases	Why	Methods	New emerging technologies / rare diseases	Why	Methods [Q18-FUTURE]
HTA Organisation			Non HTA Organisation		
New pharmaceutical treatments	Costly, information need whether to adopt or not	Systematic reviews of available data	New technologies	Public interest	Several
All emerging technologies	Information needed rapidly	Systematic reviews	Staff levels of new technologies, casemix, etc	Staffing costs are biggest then capital	---
Developing methods to proactively emerging technolog	There is lacks of consensuated methodology	Workshops, qualitative research	Rare diseases	Small number	---

Tables 20. Question 19. Other observation you would like to make regarding IJA-P (N=25)

Observations [Q19-OBSERVATIONS]	
HTA Organisation	Non HTA Organisation
Potential "users" of the results should be recruited at each participating country, as well as health care professionals leaders in their fields, at least as project's assessors	Reduce burocracy
It is necessary to make compatible computers systems communication across-countries	Make sure good projects are supported, but assure funds whenever a project is judged possitively
Worked at the nordic Cochrane Centre until 97 and has since then been director of public health, so my answers stand for my personal opinions and are not on behalf of the Cochrane Collaboration or my present organization	Increasing the money in the subjects of study and stimulating the creation of multidisciplinary consortiums inside and outside Europe
	Bureaucracy in the IV framework projects has been a major reason for me to avoid joining other EC-funded international projects
	As they stand, 20 research projects involves far too much useless paperwork
	This should be minimized; control of expenditures is necessary but should also be more agile and flexible.
	Most Universities find it very hard to comply will all the regulations, deadlines, etc, imposed by XXX in administering the funds.
	We need a strong support of the national research agencies to promote and help preparing projects at international level and specifically in the EU.
	There is a strong desire among basic scientists to from the EU S budget it a EURO-NIH. Until the budget is increased 10 fold, thair onslamp bus result of matening the EU's science effort of poor relevance or unfocussed as well as of sub-US quality.
	The only way this problem can be addressed is by a combination of political determination at the top to make it flow and a radical restructuraction of the assessment process, especially avoiding the need for assessors to travel: they are too busy or they are useless!
	Difficult questionaire to complete as not specific and broad.
	Not quite clear what you wish to gain from this (2) topics or (3) above are somewhat epidemiologicaly but highly relevant to future demand for health technologies
	The conclusion of the ECAS study is that there needs to be an on-going case/control monitor of SIDS cases across Europe to determine effectiveness of education programs & monitor risks associated with new facts in baby care. We have not been able to secure support for such effort under any EC programme
	Our experience of one HT grant is that the funding is totally adequate, and as such the project is not feasible as planned
	A lot of hot air is produced while impact on topics
	Those started by key own initiative and done outside EU bureacracy have been most fruitful anual cost-effective
	We should not restrict the co-operation to cover only European countries
	Researcher involved shall be qualified properly

Observations [Q19-OBSERVATIONS]	
HTA Organisation	Non HTA Organisation
	Is life-blood for research in Ireland – gives experience of good research, familiarity with leaders in the field, opportunity to work with them, experience success and develop confidence to undertake further research: develops leadership
	Because of pressure of time I did not sit at scientific committes for specific technologies but on the steering group
	Local resources for the research progam must be provided from the EU (like the pharmaceutical companies do)
	Health care spending as a proportion of GDP is high in all industrialized countries. Therefore, one would expect that there is generlly enough funding around for health technology research. Both provision and finance of health care as well as preferences differ a lot from country to country. The people are best served if one finds local solutions. There is a point, however, with the integration of the EU, antitrust for instance, or the regulation of pharmaceuticals. To the extent that health care regulation refers to the European level, there is a case for international collaboration
	International collaboration should not be considered an end in itself. Hence, funding from the EU should be possible when there is not scientific rationale for a more complicated (and expensive) international collaboration
	Money is needed to provide time for interested persons to work with things. A will is not sufficient
	Please do not forget the world outside the European Community

Appendix 5

Table 1. Sponsor Industries

Ab Hassle
Abbott
Abelló
Advanced Cardiovascular Systems
Aga Ab
Alimenterics Inc
Alliance Pharmaceutical Corporation
Raritan
Angen Ltd
Astra
Bard
Basf Pharma
Baxter Health-Care
Bayer
Bellco
Bioceram Sapphire Implants
Bio-Technology General Corp
Boehringer Ingelheim
Boehringer Mannhein
Braun
Bristol Myers Squibb Co;
British Biotech
British Sugar
Byk Gulden
Cell Pro Inc
Cell Therapeutics Inc
Centocor
Centre For Mollecular and Vascular Biology (Belgium)
Chemical Ltd
Chemische Industrie Katwije
Chiron Diagnostics Inc
Ciba-Geiby Ltd
Cobe Bct Inc
Cochlear Ag
Cor Therapeutics Inc
Cordis (Johnson And Johnson)
Cr Bardinc
Crbard (Usci) Inc
Cricket Graph
Debat
Debiopharm
Edap-Technomed
Eisai Ltd
Ethicon Endosurgery
Fidia Pharmaceutical Company
Fujisawa Gmbh
Fujisawa Pharmaceutical Co Ltd
Galderma
Genetech Inc
Gensia Inc
Gist Beciades
Glaxo Wellcome
Grmicro Ltd
Grünewtital Gmbh
Gynecare Inc
Hanssen
Hoechst Marion Roussel
Hoffman-La Roche
Howmedica Europe
Iaterpharmacia
Ici UK
Incstar
Innogenetics and Roche Diagnostics
Innothera
Janssen
Johnson & Johnson
Jungenson and Wettre
Knoll Ag
Koshst
Laboratories Fournier
Lederle Cyanamid Inc
Lilly
Lofarma
Ludbeck
Manchester Comparative Reagens

Marquette Electronics Inc
Masterpharma Pharmaceutical Company
Med Tronic
Medical Affairs
Mediolanum Farmaceutics Spa
Merck Sharp and Dohme
Merieux
Miles-Arles
Morris Plains
Neovals
Novartis
Novo Nordisk
Nutricia Research
Nycomed Imaging As
Ohmeda Inc
Organon International
Ortho Diagnostics
Pall Corporation
Par Astatal Insurance Company
Parke-Davis
Perstorp Pharma
Pfizer
Pharma Inc
Pharmaceuticals
Pharmacia and Upjohn
Pharmacia Biotech
Picturetel Corp
Plc Medical Systems
Promonta Lundbeck Company
Protein Technologies International;
Honeyvine Grainn
Rhône Poulenc
Rhöne-Poulenc Rorer
Roche
Roussel Uclaf
Roverts Laboratories
Rtho Biotech Mgi
Sandoz Pharma
Sanofi
Sanofi Bio Industries
Schering Plough
Schwarz Pharma
Scl Bioscience Services Ltd
Seqvus Pharmaceutical Inc
Serono Diagnostic S.A.
Servier
Shering Ag
Shering Plough
Shering-Ploug Spa
Sigma-Tau
Skield Diagnostics
Smith Beecham Pharmaceuticals
Smithkline Beecham
Solvay Pharmaceuticals
Squibb
St Jude Medical And Bard
Syntex
Synthelabo Spa
Takeda Pharma
Teaneck Nj (USA)
Ucb Pharma Sector
Upjohn
Uriach
Vascular Solutions Inc
Virus Inc
Wellcome
Yamanouchi
Zambon
Zeneca
Zeneca-Pharmaceuticals.
Zenela Spa
Zoetermees

Glossary

This glossary only includes terms that need to be clarified for the understanding of the reader.

Health Technology Assessment: a structured analysis of a health technology, a set of related technologies or a technology-related issue that is performed for the purpose of providing input to a policy or health care decision.

Primary research: implies the collection of field data.

Secondary research: using available data and performing quantitative synthesis through analytical techniques such us meta-analysis or decision analysis.

Comprehensive review: when a exhaustive search of the literature is performed and HTA documents as well as other type of information from non-HTA sources, being or not being of different quality, are considered in the review.

Working Group 4
Best Practice in Undertaking and Reporting HTA

To develop and disseminate best practice in undertaking and reporting assessments. To identify needs for methodological development

Working Group Members

Reinhard Busse (Chair)
Jacques Orvain (Co-Chair)
Michael Drummond
Felix Gurtner
Torben Jørgensen
Albert Jovell
Jim Malone
Matthias Perleth
Alric Rüther
Claudia Wild
Marcial Velasco (Associate)

Chapter 0. Introduction

Health technology assessment (HTA) is a multidisciplinary activity which systematically examines the technical performance, safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organisational implications, social consequences, legal and ethical considerations of the application of a health technology (EUR-ASSESS 1997). HTA activity has been continuously increasing over the last few years. A number of HTA agencies and other institutions (termed in this report "HTA doers") across Europe are producing an important and growing amount of HTA information. The objectives of HTA vary considerably between HTA agencies and other actors, from a strictly political decision making-oriented approach regarding advice on market licensure, coverage in benefits catalogue or investment planning to information directed to providers or to the public. Although there seems to be broad agreement on the general elements that belong to the HTA process, and although HTA doers in Europe use similar principles (Mears et al. 2000), this is often difficult to see because of differences in language and terminology.

In addition, the reporting of the findings from the assessments differs considerably. This reduces comparability and makes it difficult for those undertaking HTA assessments to integrate previous findings from other HTA doers in a subsequent evaluation of the same technology. Transparent and clear reporting is an important step towards disseminating the findings of a HTA, thus standards which ensure high quality reporting may contribute to a wider dissemination of results.

The EUR-ASSESS methodological subgroup already proposed a framework for conducting and reporting HTA (EUR-ASSESS 1997) which served as the basis for the current working group.

New developments in the last 5 years necessitate revisiting that framework and providing a solid structure for future updates. Giving due attention to these methodological developments, this report describes the current "best practice" in both undertaking and reporting HTA and identifies the needs for methodological development. It concludes with specific recommend-ations and tools for implementing them, e.g. by providing the structure for English-language scientific summary reports and a checklist to assess the methodological and reporting quality of HTA reports.

Specifically, this report is structured as follows: Chapter 1 states the objectives of the report. Chapter 2 briefly describes the methods applied and the material used by the working group. Chapter 3 characterises the HTA process which served as an outline for structuring the information of this report. Chapters 4 and 5 identify and describe "Best practice" in undertaking and reporting HTA. Chapter 6 presents the conclusions, which include a checklist for assessing quality and relevance of an HTA report, and place particular emphasis on identifying methodological gaps and needs for further development. Finally, Chapter 7 presents some recommendations.

Chapter 1. Objectives of the working group and this report

In the overall framework of the ECHTA project, the objectives of the working group and this report are as follows:

- To develop best practice in undertaking assessments
- To develop best practice in reporting assessments
- To disseminate best practice in undertaking assessments
- To disseminate best practice in reporting assessments
- To identify needs for methodological development

The report addresses the first two objectives in chapters 4 and 5; the two objectives of disseminating this best practice are addressed both by writing this report and through providing the structure for a scientific summary report and a checklist for assessing the quality of HTA reports. The final objective is addressed in Chapter 6 of this report.

When reading the report, several caveats should be kept in mind:

- The report tries to outline current "best practice" covering all (possible) aspects, ordering them in a logical sequence and using an understandable terminology for the concepts. Actual practice regarding completeness, sequence and terminology of HTA doers will, however, vary, which does not per se constitute "bad practice".

- While the report serves to identify "best practice," the strength of the evidence to identify certain practices as "best" varies. In this respect, the degree to which they can be recommended also varies – this is clearly indicated in the text. The report makes recommendations, e.g. for methodological development, which are summarised at the end.

Chapter 2. Methodology applied by the working group

As mentioned, the EUR-ASSESS methodological subgroup proposed a framework for conducting and reporting HTA (EUR-ASSESS 1997), which served as the point of departure for the current working group. In its two formal meetings in June 2000 and January 2001, the working group decided to provide a methodological framework based on existing guidelines from HTA agencies and other institutions to enhance comparability among European HTA. In the discussion, particular importance was given to the need for a structured way of reporting, especially stressing the need for a structured/standard summary, to make HTA findings from European agencies and other institutions more available to the HTA community. In addition, specific issues which the group felt were underrepresented thus far (e.g. the HTA process, the use of qualitative methods, factors responsible for differences between efficacy and effectiveness) were identified as requiring special attention.

Considering the recommendations and consensus reported in discussion papers from the INAHTA Annual Meeting 2000 at Loosdrecht on a similar issue (Hailey 2001, personal communication), guidance documents and tool kits from different institutions involved in HTA

were examined and summarised into an outline. Putting emphasis on freely available documents, the following tool kits and guidelines were identified via personal searches/ contacts of the working group members and a search of the websites of European and other HTA institutions and were taken into account for elaborating the methodological framework (in chronological order):

- EUR-ASSESS Project Subgroup Report on Methodology: Methodological guidance for the conduct of health technology. Int J Technol Assess Health Care 1997;13(2):186-219 (EUR-ASSESS 1997).

- Various reports from the NHS R&D HTA Programme, UK, 1998-2001 (for details see Appendix A1).

- Guía para la elaboración de informes de evaluación de tecnologías sanitarias. Agencia de evaluación de tecnologías sanitarias, Madrid, Spain, 1999 (Imaz-Iglesia et al. 1999).

- Development and Evaluation Committee Guidelines. The Wessex Institute for Health Research and Development, Southampton, UK (DEC undated [2000]).

- West Midlands Development and Evaluation Service (DES) Handbook. Department of Public Health and Epidemiology, University of Birmingham, UK, DPHE Report No 8, 2000 (Burls et al. 2000).

- Guide d'Analyse de la littérature et gradation des recommandations. Agence Nationale d'Accréditation et d'Évaluation en Santé, Paris/ France, 2000 (Durocher et al. 2000).

- Undertaking Systematic Reviews of Research on Effectiveness. CRD's Guidance for Carrying Out or Commissioning Reviews. CRD Report 4, NHS-CRD, University of York, UK, 2000 (Khan et al. 2000).

- Guide to the Technology Appraisal Process. National Institute for Clinical Excellence, UK, 2000.

- German tool kit and checklist for the conducting and appraisal of HTA reports. German Scientific Working Group on Technology Assessment for Health Care, last updated 2000.

- Funding for new medical technologies and procedures: application and assessment guidelines. Medicare Services Advisory Committee, Canberra, 2000 (MSAC 2000).

- Health Technology Assessment Handbook. Danish Institute for Health Technology Assessment, Copenhagen, Denmark, 2001 (Kristensen et al. 2001).

In addition, based on working group members' experience and reference lists, specific guidance and key references for the identified specific issues – and for gaps which became obvious while drafting this report – were identified and selected for inclusion into the report. To achieve a consensus process, a core group drafted a first version of this report in April 2001 for discussion among the other working group members (Mike Drummond, Felix Gürtner, Torben Jørgenson,

Albert Jovell, Alric Rüther, Claudia Wild) and others. This final version reflects the amendments, comments and discussion.

The authors are indebted to Wendy Wisbaum (European Observatory on Health Care Systems) for providing English-language editing.

Chapter 3. Methodological framework for conducting HTA

3.1 Characteristics of HTA

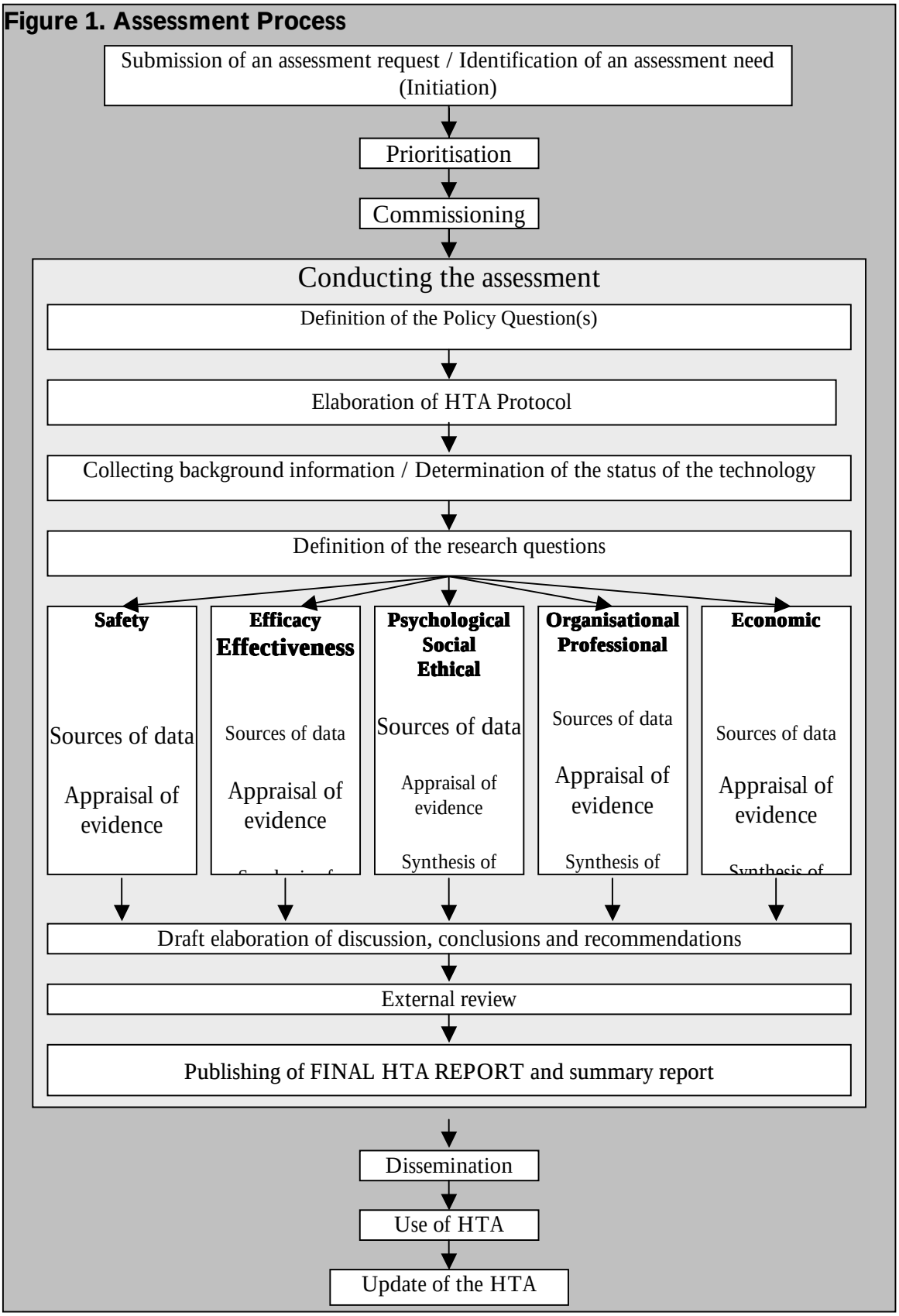
Health technology assessment, a multidisciplinary activity which systematically examines the technical performance, safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organisational implications, social consequences, legal and ethical considerations of the application of a health technology (EUR-ASSESS 1997), has to take into consideration all aspects which might be influenced by the technology and those influencing the technology. In this context, health technology is a broad concept which includes drugs, devices, procedures and the organisational and support systems within which health care is delivered.

As with Evidence Based Medicine (EBM) and Clinical Practice Guidelines (CPG), HTA belongs to the group of best practice activities in the health care sector (European Commission 1999). These kinds of activities are characterised by a systematic and structured way of answering questions by evaluating and synthesising available evidence. Even though certain institutions (e.g. ANAES, NICE) use all three approaches, they differ in some aspects. The primary audience of HTA consists of decision makers at the policy level, while other activities aim at the clinical level (EBM, CPG). In addition, the sources of information and the methods used are broader in HTA than in the other approaches. It is now accepted that the characteristics of HTA are: a clear formulation of the problem, an explicit methodology and a wide scope on the technology, i.e. not only dealing with safety or efficacy/effectiveness (EUR-ASSESS 1997). Besides a systematic methodology, the strength of HTA relies on transparency of the process and in the reporting which also improves the usefulness and generalisability of the findings.

3.2 Process of HTA

When performing health technology assessments, all European doers seem to follow a similar process. Nevertheless, the way assessments are initiated, priorities are set, and reports are commissioned and later disseminated may differ substantially among agencies and other institutions (which is outside the scope of the current report). Although the aim of this report is not an analysis of the whole HTA process, it has to be pointed out that the way the different steps are undertaken influences the elaboration of the HTA report, which can be seen as a step in the overall assessment process and represents the deliverable product of the assessment (Fig. 1). The “HTA Report Box” is the scope of this report.

Figure 1. Assessment Process



After a report is commissioned, the first step to be taken is the definition of the policy question, if that has not been clearly formulated during the prioritisation and/or commissioning process. The next step consists of the gathering of background information (part of which may have already been collected during the prioritisation process). When collecting background information, possibly after (re-)contacting the commissioner, the researcher will be able to decide which aspects of the problem (e.g. efficacy, ethical considerations etc.) should be further assessed. Concise research questions will be posed and the methodology will be outlined.

In HTA, the five columns reflecting the main types of outcomes should all be considered relevant; thus, they are presented in a parallel way. However, it seems plausible to start with assessing safety first, then efficacy and so on, as subsequent aspects of the assessment might not be needed if previous ones already provided a negative answer. To illustrate, for instance, if the technology shows a safety deficit or proves to be not efficacious at all, evaluation of further aspects will not be necessary.

Chapter 4. "Best practice" in undertaking HTA reports

The EUR-ASSESS Subgroup proposed a framework with the following elements to be included in a HTA report (Box 1).

Box 1. Content of a HTA (modified from EUR-ASSESS 1997)

- Policy Question (4.1)
- Background Information on: target group, target condition, technology (technical aspects, diffusion, and current practice) (4.3)
- Research Questions (4.4)
- Findings & Methodology (4.5/ 4.6)
  - Safety
  - Efficacy / Effectiveness
  - Psychological, social and ethical considerations
  - Organisational and professional implications
  - Economic issues
- Policy conclusions and recommendations (4.8)

For each of the aspects of the HTA, it is important that the sources of data, the methods for searching and gathering data, and their synthesis are clearly stated. If some aspects are not being addressed, the reason for omission (e.g. sufficient data available from other HTA reports) should also be included.

The following sections will provide a general methodological framework, in terms of what could be considered best practice, following the structure shown in Fig. 1 and Box 1. Other important issues concerning the HTA process, like the review process, updates of the HTA and possible

conflicts of interest cannot be clearly ordered in the structure proposed in Fig. 1 and will therefore be considered afterwards.

4.1. Policy question

HTA is policy-driven research, aimed to support decision-making. Thus, the commissioners' scope of the problem has to be clearly documented in the report. Ideally, the policy question should be worded with close co-operation between the commissioners and the researchers.

The policy question reflects the context in which the assessment was carried out. This context is defined by the following aspects (Box 2).

Box 2. Aspects included in the policy question

Question	*Examples*
• Who initiated the report? • Who commissioned it?	• Policy makers • Health care providers • Third party payers • Patients' advocate
• Why is an assessment needed right now?	• New technology • Changes in old technology • New indications for old technology • New findings • Structural/ Organisational changes • Safety concerns • Ethical concerns • Economic concerns
• Which decision is it going to support?	• Investment decisions • Market licensure • Inclusion in/Exclusion from benefits catalogue • Planning of capacities • Guidance on best-practice • Investment in further research
• Who represents the primary target audience for the report?	• Political decision makers • Third party payers • Hospital managers/administrators • Clinicians • Citizens / Patients

The context in which the research is carried out may lead to some financial or time constraints which determine the methods used and the extent/comprehensiveness of the assessment. The scope and level of detail of HTA vary considerably depending on who commissioned a study and why. Therefore, it is crucial to clearly explain that context, so that readers of HTA (other than those who initiated and commissioned the study) can better assess whether the report can be also relevant for their own problems. The scope of the assessment and its recommendations are determined by the policy question.

The policy question should be clearly stated in the HTA protocol (cf. section 4.2) and in both the technical report, i.e. the detailed document (cf. section 5.3) and the scientific summary report (cf. section 5.2). The questions listed in Box 2 should be answerable when reading any of these documents.

4.2 HTA protocol

As soon as the policy question is clear, a HTA Protocol should be developed to define how the whole assessment is going to be carried out. A HTA Protocol is not a Systematic Review Protocol, as this usually refers only to one of the possible aspects to be reviewed in the assessment. A HTA Protocol has to be understood as the elaboration of the plan for both undertaking the whole process of the assessment and for writing the HTA Report. The utilisation of such a protocol should be seen as an important component for achieving best practice in undertaking and reporting HTA. HTA Protocols are sometimes referred to as Project Plans (DEC 2000).

In a simplified way, the development of a HTA protocol can be divided into two phases, with the first one at the beginning of the assessment. Here, the problem will be stated and the way of gathering the background information will be defined. While synthesising the background information, the research questions will be posed. Then the protocol should be completed by stating:

- which aspects of the problem are going to be assessed,
- how each aspect will be addressed, i.e. which and how data sources will be searched and used,
- which methodology for the appraisal will be followed, and,
- what kind of synthesis of evidence is planned.

In this regard, a HTA protocol should include guidelines on when and how to undertake a systematic review of one or more of the aspects (if no standing operating procedures exist for such a decision within the commissioning agency or the institution undertaking the HTA). Additionally, it will most likely state timelines and division of competencies within the group of persons involved. The HTA protocol should document the way the whole process explained in Fig. 1 was carried out.

4.3 Background information

After defining the policy question, the HTA doers need to gather information about the target condition, the target group and the technology to be assessed.

The background information helps translate the policy question into a research question. The process of gathering background information is intimately related to the definition of the research questions, which can only be stated satisfactorily after the background information is reviewed.

Most of the agencies and other institutions recommend preliminary research to address the background issues. If a literature search is conducted, it is strongly recommended that it be carried out separate from the systematic literature search done later to address the research question(s). The scope of this first search is to learn the epidemiology, natural history and clinical presentation of the condition, possible target group(s) (see section 4.3.1) and background information on the technology, e.g. technological characteristics (see section 4.3.2). Review articles (not necessarily systematic) and textbooks can be helpful in giving an idea as to the condition and treatment alternatives.

Further information sources, such as routinely collected data, expert contacts, guidelines on diagnosis and management, patient opinions (e.g. websites of associations of persons suffering from the condition), or information from manufacturers of the technology are also valuable for an idea about the status of the technology. Previous HTA reports are another important source of background information.

Key steps and sources of data for the elaboration of background information are summarised in Box 3.

Box 3. Key steps in finding background information (DES; Burls et al. 2000)

- Perform this parallel with defining research question
- Search for and record information on the:
    - Nature of the health problem or disease
    - Epidemiology and burden of the disease
    - Treatments for the disease (alternatives)
    - Current practice
    - Technology status
- Sources:
    - Research literature (search strategies targeting “reviews,” “prevalence,” “incidence,” etc.)
    - Routinely collected data (on utilisation, costs, etc.)
    - Guidelines
    - Special sources (disease registers, organisations of affected people, experts, manufacturers) [some of those sources are accessible through the www]
    - Other HTA reports (searchable in INAHTA database, or in the websites of HTA agencies)

The elaboration of the background information does not necessarily imply systematic research, as other approaches may deliver sufficient information for elaborating the research questions[80]. However, for the transparency of the HTA, the approach(es) and sources used when elaborating the background information should be documented.

4.3.1 Condition and target group

The essential information needed to understand the nature of the health problem or disease and its consequences should be provided. The target group(s) to which the assessment refers should also be clearly stated. In this step of the assessment, the following questions concerning the condition and the target group should be addressed (Box 4).

Box 4. Questions to be addressed as background information on condition and target group (Adapted from DES; Burls et al. 2000)

Questions	*Example*
• Condition(s)	• Health problem • Disease
What are the mechanisms of disease?	• Causes • Pathology
What is the course and prognosis of the condition?	• Clinical presentation • Stages • Time course
What are the consequences? (Outcomes)	• Physical disabling • Psychological consequences • Death
Treatment alternatives and current practice	• Drugs • Surgical • Current service provision
• Target group(s) (epidemiology, burden of disease)	• Patients • Healthy subjects (for prevention)
• How many people are affected?	• Incidence • Prevalence
• Who is affected?	• Age • Gender • Social factors • Risk factors

[80] When drafting the full report, these sections of the background sections should be revisited to check whether they need any amendments due to the identified evidence. This could, for example, be the case if a technology is highly effective for an indication originally not included in the assessment.

These issues should be addressed briefly and clearly, keeping in mind that not all HTA readers are experts in the given field. The background information serves also to clarify and explain the concepts which are going to be used in the assessment on safety, efficacy, effectiveness and the other relevant outcomes. The description of the appropriate outcomes and how they are measured is therefore an important issue too.

4.3.2 Technology

It is best practice to concisely describe the following aspects of the technology (Box 5), keeping in mind that the technology assessed may be a drug, a device (therapeutic/diagnostic), a community intervention, a medical aid, a procedure, an organisational process, a support system or a combination of these.

Box 5. Questions to be addressed as background information on the technology

Question	*Aspects / examples*
• How does it work? What kind of intervention is it?	• If a device, explain technical characteristics, functioning • If a community/system related intervention, explain its crucial features
• What are the requirements for its use?	• Setting for use/implementation • Special measures needed for use/implementation • Qualification required • Maintenance
• What is the status of the technology?	• Diffusion/distribution • Patterns of use • Current indications for use • Current utilisation • Costs • Regulatory status • Manufacturers and market shares

The description of the technology should be concise and understandable, with particular emphasis on those aspects of the technology that directly affect the safety, efficacy or effectiveness (e.g. doses of drugs, material in implants, image characteristics of diagnostic devices, etc.). Technical details of the technology, which have no influence on the outcomes, do not need to be described in detail.

A description of the status quo of the technology can be considered an important part of the assessment. Current practice, indications (if given) for use of the technology, frequency of utilisation and associated costs should be described here. Some of these issues are directly related to the point where the technology is on the learning curve of the technology[81].

Sometimes these issues may not need serious consideration, depending on the status of technology (e.g. utilisation patterns if assessment is prior to approval for use).

4.4 Research Question(s)

Formulating the research question(s) means specifying the policy question in terms of safety, efficacy, effectiveness, psychological, social, ethical, organisational, profes-sional and economic aspects. These aspects may be able to be addressed with available evidence and data, but they either have not yet been sufficiently answered or have answers that are not accessible and/ or appropriate for the use of decision-making.

The research questions can also be drawn from previous HTAs that were unable to answer them because of lack of evidence, and which stated that further research was required.

The research questions have to specify the target group, the (disease) condition and the aspects of the technology that are going to be assessed. Thus, formulation of the research questions is closely related to the gathering of background information. The examined guiding documents agree that both steps have to be taken in parallel.

The formulation of the research questions also implies defining the outcomes of interest for the assessment. The outcomes of interest for the evaluation are different for the different aspects of the assessment. Some of them may be easier to define than others. Safety, efficacy and effectiveness of an intervention should be always measured with health related outcomes. These should be patient-related (e.g. quality of life, mortality, morbidity). Outcomes for the assessment of psychological, social and ethical considerations are, for example, satisfaction or acceptance. Organisational and professional implications can be addressed with system-related outcomes, such as length of stay or required personnel. Finally, for the economic issues, costs and cost in relation to outcomes (cost-effectiveness, cost-utility, cost-benefit) are the main categories of interest. Box 6 provides examples of outcomes for the different aspects.

[81] Methods to statistically assess the learning curve have been gathered and evaluated by Ramsay et al. 2001.

Box 6. Examples of outcomes for different aspects of HTA

Aspect of assessment	*Outcomes*
Safety	• Mortality directly related to the use of technology • Morbidity/disability directly related to the use of technology
Efficacy/Effectiveness	• Change in overall/ condition-specific mortality • Change in morbidity/ disability/ disease-free interval • Change in quality of life • Change in quality-/disability-adjusted life years (QALYs/DALYs)
Psychological/ Social/ Ethical	• Compliance • Acceptance • Satisfaction • Demand • Preferences • Information/patient advice requirements
Organisational/ Professional	• Utilisation of service • Change in the treatment location • Change in length of hospital stay • Change in required personnel, material inputs (e.g. hospital beds) and organisational structure • Training requirements
Economic	• Costs and changes in cost compared to current practice (if applicable) • Cost-effectiveness, cost-utility, cost-benefit

The research question(s) drive(s) how the rest of the assessment is going to be conducted, the aspects which will be evaluated and those which will not. The inclusion and exclusion criteria for literature or other sources of data to be reviewed in the assessment also depend on the formulation of the research questions. The documents and recommendations reviewed all agree that this is a crucial part of the assessment, as other aspects (e.g. methodological) of the evaluation flow from it. If possible and where relevant, there should be a feedback loop to the commissioner(s) to ensure that the research questions a useful "translation" of the policy question(s).

The research questions need to be formulated in an understandable and answerable way, and should be limited in number (Box 7).

Box 7. Characteristics of research questions

- Clearly worded
- Answerable
- Limited in number
- Address meaningful outcomes
- Address other relevant treatment alternatives

4.5 Answering the questions / General methodology

Once the research question(s) have been formulated, the next step is to answer them. As shown in Fig. 1, there are some general methodological steps which apply to all aspects of the HTA (i.e. safety, efficacy/effectiveness, psychological/social/ethical, organisational/professional, economic). Most of the methodology has been developed under the scope of systematic reviews on efficacy/effectiveness; however, some principles of this methodology are applicable to other aspects. These common principles are discussed in sections 4.5.1 to 4.5.3. Specific methodological considerations concerning each aspect of the assessment are then addressed in section 4.6.

The common methodology for addressing the different aspects can be summarised in three steps (Box 8).

Box 8. General methodological steps for addressing each aspect of assessment

- Searching for sources of information (4.5.1)
- Selecting and evaluating information (application of inclusion and exclusion criteria)/ appraising the evidence (4.5.2)

1. Synthesising the obtained data (4.5.3)

4.5.1 Sources of information.

For different aspects of the assessment, different sources of data may be useful or appropriate. Sources of data do not always have to be published literature. Databases, registries of routine data or even one's own primary research[82] may be also appropriate, depending on the aspect being assessed.

One or more of the aspects of the current assessment may have been already addressed by other HTA reports. A first approach to answer the question(s) can thus be the search for previous HTA reports, even if one or more should have been already identified during the search for background information[83]. Search for HTA reports has to be systematic and also clearly documented. Identified HTA reports should also be critically appraised (see 4.5.2).

[82] Own primary research refers here to primary research conducted within the assessment to address some aspects of it, e.g. a survey to assess the satisfaction after a treatment.
[83] Appendix 2 provides further information on different databases for identifying HTA reports or systematic reviews.

Systematic reviews may already cover some of the aspects and answer some of the questions posed. This may be the case for aspects like safety, efficacy, effectiveness or economic evaluation. Thus, a search for this kind of research has to be an integral component of all searches.

If primary scientific literature is going to be used, the principles of the systematic primary literature search, developed for example by the Cochrane Collaboration, can be applied to all aspects of the assessment, and not only to efficacy/effectiveness. To identify the evidence, a search strategy has to be developed, based on the research questions and to some extent, on inclusion and exclusion criteria (e.g. study design). Key words related to the condition, the technology, types of publication etc. will be combined, forming the search strategy to obtain the biggest number of hits. It is recommended that the language of publication not be used as a search criterion, as relevant literature in other languages will be missed (see also section 4.5.2).

A systematic approach can be also applicable for psychological/social/ethical[84], organisational/ professional or economic issues if literature is going to be used. Search strategies and databases searched will differ, depending on the aspect, and, as a result, they should be documented separately.

If other sources of information or evidence are used, a systematic approach should be followed. The strategies used to identify them, the way in which the information was obtained etc., should also be documented.

The documentation of the information sources is of utmost importance for the transparency of a HTA report. Both sources which provided useful information and those which did not should be included in the documentation (DIHTA; Kristensen et al. 2001).

Box 9. Documentation of the sources (DIHTA; Kristensen et al. 2001)

2. Which sources have been consulted?
3. Which period did the performed search cover?
4. How was the search performed? (Strategies, key words, search criteria)
1. When was the search conducted?

4.5.2 Inclusion and exclusion criteria/ Appraisal of the evidence.

The selection of the literature which will be definitely included to answer the research questions is a process with consecutive steps to be taken, as summarised in Fig. 2.

With the systematic literature search, a big number of hits will be obtained. Applying selection criteria (inclusion and exclusion criteria) to the titles and abstracts of articles, these will be separated into relevant and not relevant. This first selection refers more to relevance than to quality of studies. Studies considered to be relevant will be ordered, but not all ordered studies

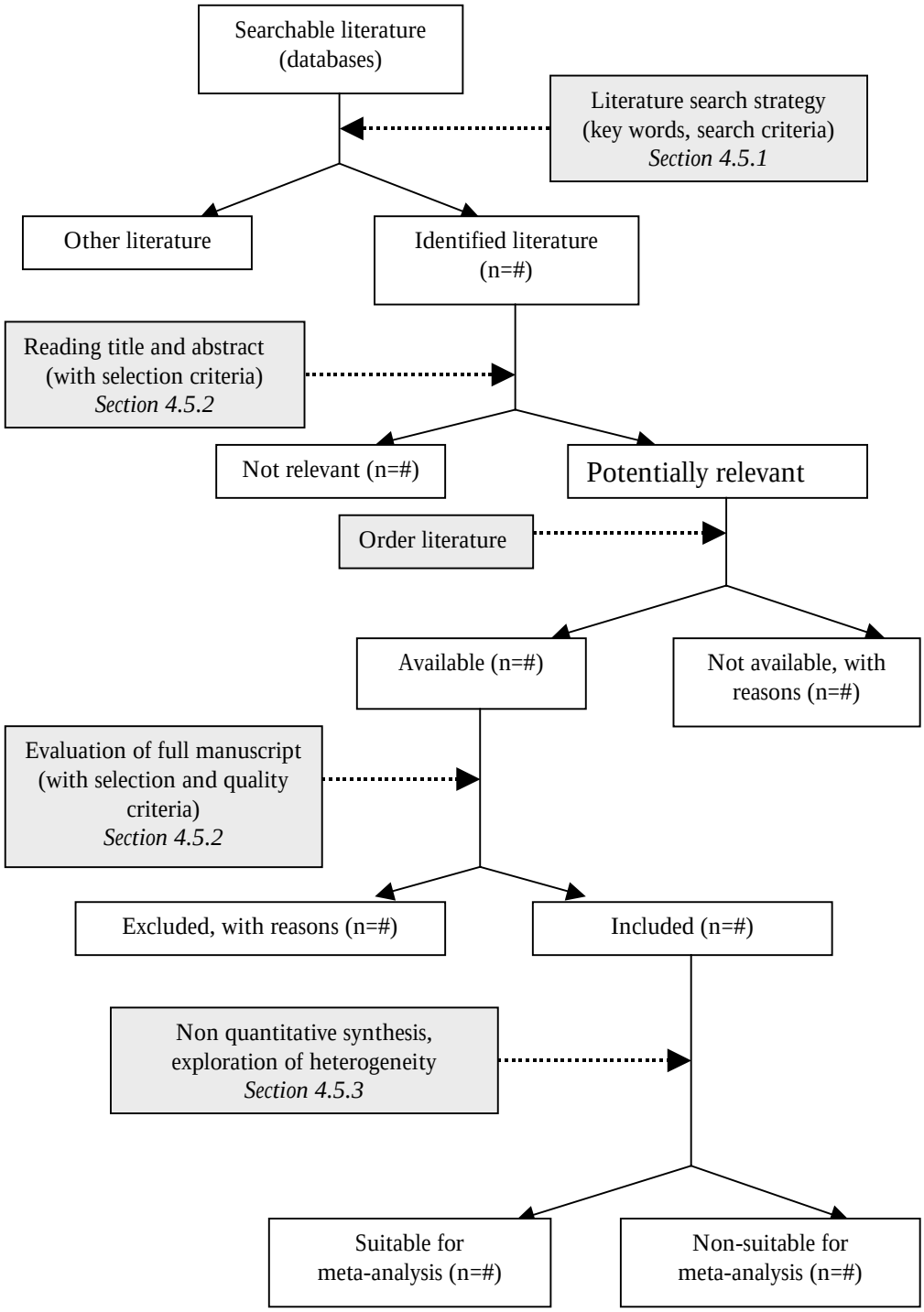
[84] This systematic approach can be applied when outcomes such as acceptance or satisfaction are being addressed. However, if more general philosophical issues are being assessed, the systematic approach may not be possible at all, as disciplines may be involved which, for example, do not have databases such as those of the medical literature.

will be actually retrieved (e.g. delayed delivery). The available studies will then be critically appraised for quality. Those which fulfil the defined quality standards will be definitively selected for inclusion in the synthesis. It is recommended that this process be reported in an understandable and transparent way, e.g. by using Fig. 2 as a guide.

It is also recommended that two reviewers select the literature to be included, however, this may not always be possible. When reporting on the methodology, it should be stated whether this step was performed by one or more reviewers, and how contradictions were handled.

Inclusion and exclusion criteria should be defined for all kinds of evidence, and not only for the literature on efficacy and effectiveness. Selection criteria should be developed in a prospective way to avoid bias when selecting the evidence. Inclusion and exclusion criteria flow from the background information, the research questions and the availability of evidence. They refer to patients being treated, outcomes being measured, aspects of the technology being studied, etc. Selection criteria also may refer to study design or other methodological issues. Those criteria (may) differ for each of the aspects being assessed. For instance, when assessment of efficacy issues is based on RCTs, study design will be an inclusion criterion. However, if, for example, routine register data are used to assess safety, the size and follow-up time of the register might be the selection criterion (Box 10).

Fig. 2. Flow diagram of literature selection process (Adapted from CRD 2000)



Box 10. Issues addressed in inclusion and exclusion criteria

2. Patient characteristics (e.g. age, gender)
3. Condition characteristics (e.g. stage of disease)
4. Technology aspects
5. Methodological issues (e.g. number of patients, length of follow-up, study design)
6. Outcomes measured
1. Publication type

Depending on the aspects being assessed, selection criteria may be narrower or wider. The selection of the literature or other sources has to be transparent, thus, the explicit stating of these criteria should be mandatory in a HTA report. Inclusion and exclusion criteria have to be documented in both the technical report and the scientific summary report. They have to be explained (especially if they might not seem to be justified) and they have to be compatible with the research questions.

Every effort should be made to include relevant evidence independent of the language available. This means that language should be used very cautiously as a selection criterion. Rather, potentially relevant studies published in languages not familiar to the HTA doers should be ordered. Possibly, tables or other pieces of information will indicate the relevance of the study and justify a translation. If the HTA doers are not able to handle potentially relevant publications in unfamiliar languages, these studies should be explicitly listed and their number later taken into account when discussing the results. This is important because the selection of literature/information sources based on language of publication may lead to bias in conclusions or results (Egger & Smith 1998).

Once the literature is ordered, the available references will be checked again for their relevance by carefully evaluating the full document. At this point, some studies will be excluded because they are not actually deemed relevant to the research questions, even though they were identified as relevant when the abstract was read.

The quality and relevance of all sources of data need to be critically assessed. Again, most of the work done here refers to the critical appraisal of the medical literature referring to efficacy and effectiveness (primary and secondary research), for which different checklists[85] have been developed. Some doers have adapted these checklists and provide them in their guidance documents (ANAES [Durocher et al. 2000], German Toolkit 2000, MSAC 2000). However, every source of evidence should be appraised under the scope of validity, e.g. if a source of routine data, such as registry of side-effects, is going to be used, the quality and validity of the retrieved data should also be critically appraised and discussed. There are no standards or guidelines on how quality of sources of information other as the medical literature should be appraised. The tools and criteria developed for the medical literature are not applicable to other sources of information, so there is a gap here that needs to be addressed in the future.

[85] In Appendix 4, validated appraisal tools for different study designs are collected.

Hierarchies of study design have been developed, referred to as levels of evidence, where RCTs or meta-analysis from RCTs are usually classified as the highest level of evidence, as they are the study design less likely to provide biased results[86]. The inclusion threshold for studies can rely on those hierarchies; however, it may depend on the average quality of all the evidence (e.g. if no RCTs have been done, other kinds of studies may be included). For certain aspects, e.g. psychological/social/ethical considerations, the existing hierarchies may not be applicable at all.

Besides hierarchies of evidence, several quality checklists have been developed to assess the quality of studies (Moher et al. 1999a). Although standard quality assessment instruments/checklists/ scores exist, such as the validated Jadad-Score (Jadad et al. 1996), some agencies recommend developing specific instruments for each assessment, as some quality issues are closely related to special aspects of the technology being assessed. The criteria should cover both generic and specific methodological aspects. Generic methodological aspects refer to study characteristics which if present, for example, indicate good quality of a study independent from the subject being studied (e.g. concealment of allocation). Specific methodological aspects refer to characteristics, which if present, for example, indicate good quality of the study for evaluating the specific question (e.g. length of follow up needed to assess relapses varies with the condition/intervention) (Box 11).

Box 11. Quality items/criteria

1. Generic methodological issues (e.g. study design, allocation of concealment, prospective, randomisation, drop-out-rate, etc.)

2. Specific methodological issues (e.g. length of follow up, methods for assessing outcomes, ways of applying technology, etc.)

This step should be reported in a transparent way. For each study, how or whether it fulfils the different quality items should be documented. An overall score that synthesises all the items might be also used, and if so, the way the score is constructed should be explained. If a score is used, studies not reaching a defined threshold score will be excluded. However, since different overall scores may lead to different thresholds for excluding studies, possibly resulting in unexplained differences in the results of meta-analyses, a detailed checklist with ratings of the different quality items (component scale) should be used (Jüni et al. 1999).

Some criteria for appraising quality may be so-called “knock-out” criteria, which means that studies not fulfilling them will be automatically excluded, even if they fulfil all other quality criteria. If knock-out criteria are being used, which they are and why they were chosen should be clearly stated. Studies originally retrieved which do not fulfil the quality criteria will be excluded; documentation of excluded studies should be provided, along with the reasons for exclusions (Box 12).

[86] A comprehensive hierarchy of levels of evidence for different kinds of interventions has been developed by the Centre for Evidence Based Medicine at the Oxford University. This is provided in Appendix 6.

Box 12. Transparency in Quality Assessment

- Document and explain quality criteria and items included in assessment
- If a score is used, describe how it is constructed
- List retrieved studies which were not included with reasons for exclusion

1. Fully report results of quality assessment (tabulation)

A good approach for reporting the quality assessment is the use of tables, as recommended by the DES, where quality items assessed are listed and the degree to which studies meet the criteria is documented. These tables could be completed with a statement about whether a study was subsequently included or excluded. The use of such tables allows readers of HTA to assess and decide on the quality of the studies themselves (Fig. 3).

Fig 3. Quality assessment presentation (example) (DES 2000)

	Prospective	*Concealment*	*Follow-up sufficient*	*Included in assessment*
Study 1	Yes	Yes	Yes	Yes
Study 2	Yes	No	Yes	Yes
Study 3	No	No	No	No
Study 4	No	Yes	Yes	No
Study 5	Yes	Yes	No	Yes
Study 6	Yes	No	No	Yes

4.5.3 Non-quantitative and quantitative synthesis

The next step to be taken is the extraction of the relevant data for the assessment from included studies and its synthesis in a way that allows comparison among studies. Data to be extracted is mainly determined by the research questions. It is strongly recommended that customised extraction sheets be used. As with the selection of studies, the process of data extraction should be done by more than one person; however, this is not always possible. The way the data were extracted should be reported.

The information will then be synthesised and presented in a clear and understandable way. This should be done for all aspects assessed. A clear methodology has been developed for the quantitative synthesis of data on efficacy and effectiveness of therapeutic interventions, and, to some extent, for therapeutic interventions. For the synthesis of data concerning other kinds of technologies or other aspects of the assessment, a methodology is being developed but no clear standards are yet available. If no quantitative synthesis can be made, the narrative way of summarising information can be used.

In HTA, synthesis should be transparent. A way to enhance transparency, even if synthesis is narrative, is the use of evidence tables. These tables are commonly used to summarise medical literature, but they can also be applied to other sources of information. The information cont-

ained in evidence tables may vary depending on what kinds of studies are being used and also on the scope of the assessment. The rationale for such tables is to present in a structured way the sources of information/data, the issues concerning their validity and quality, and their results (Box 13).

Box 13. Elements to include in evidence tables

- Reference, year
- Study type and design issues (if not a study, characteristics of the data source, e.g. registry of routine data)
- Setting
- Patient characteristics, subgroups
- Interventions, characteristics of the intervention
- Outcomes measured and methods
- Results
- Overall quality score, if used

2. If appropriate, statement as to whether study was included in meta-analysis

If such kinds of tables are used, readers can easily compare sources and results and make their own judgements about their validity.

To include all the information needed in the tables, different tables may be constructed for study design issues, patient characteristics, results, etc. A standard way of constructing evidence tables has not been identified, mainly because this depends on the assessment problem. However, all results and characteristics of the included studies, which may have influenced the results or which are relevant for the generalisability of results, should be presented in a way that enables easy comparison between included studies.

When recommending the use of evidence tables to summarise study characteristics and study results as the best way to synthesise the evidence in a non-quantitative form (which always precedes a quantitative synthesis), agencies and other institutions coincide. In a non-quantitative synthesis, consistency of results throughout studies or heterogeneity among studies (e.g. differences among patients or relevant details of the intervention) can be explored. Furthermore, lack of valid or relevant evidence can also be identified. In the non-quantitative synthesis of information, explicit criteria for validity and quality of the studies have to be followed. Thus, the non-quantitative synthesis is closely related to the appraisal process (section 4.5.2).

An important issue here is also identifying possible duplicate publications of results. Studies may be reported several times and it is often difficult to detect which reports refer to the same trial (Cochrane Collaboration [Clarke & Oxman 2000]). These issues may only be clarified by contacting the principal investigators of the studies in question. In addition, results of studies may be reported in a fragmented way in several publications, referring to different outcomes, different patient groups or different lengths of follow-up (so called “salami-publication”). Sometimes it can be very difficult to assess how and to which extent publications of the same studies overlap. This is especially a problem in trials of rare diseases which may lead to repeat

publications of sequential case series. Again, the principal investigators of the trials should be contacted directly to clarify overlap between study populations.

The decision as to whether a quantitative synthesis can be performed and if so, which results can be pooled into what comparisons, will be made from the results of the non-quantitative summary of the available evidence. If significant heterogeneity among studies or lack of validity of results are identified, a quantitative synthesis may not be indicated.

There are different methods for performing a quantitative synthesis for HTA doers[87]. However, the most extended one is the use of meta-analysis. Box 14 gives an overview of the factors that should be taken into consideration when choosing a method of meta-analysis.

Box 14. Factors to consider when using Quantitative Synthesis (meta-analysis)* (adapted from QUOROM statement [Moher et al. 1999b] and Egger et al. 2001)

3. Why does the meta-analysis approach seem possible and appropriate?
4. Which studies are being included in meta-analysis and why?
5. Which comparisons are going to be made and why?
6. Which outcome measures are chosen and why?
5. Which summary statistics (OR, RR, WMD, etc.) are chosen and why?

6. • type of data (e.g. binary, continuous)
7. • consistency of treatment effects across trials
   • ease / plausibility of interpretation of summary estimate

8. Which weighting method is used?

   • reliability when sample sizes are small
   • reliability when events are rare
   • degree of imbalance in allocation ratios among groups

9. Is heterogeneity explored? Possibilities to consider heterogeneity:

   • meaning of a meta-analysis depending on degree of disagreement between studies
   • use of random effects model
   • accounting for variations in treatment effects (e.g. meta-regression, stratified analysis)

10. Is the presence and possible effect of publication bias taken into account?
11. Is a sensitivity analysis carried out?

* Some of the issues listed should have been already specified in the review protocol; however, after the qualitative approach of the evidence, it may be necessary to modify some of these. Modifications should be clearly stated and justified.

[87] A comprehensive review on quantitative synthesis methods is found in: Systematic reviews of trials and other studies (Sutton et al. 1998). An up-to-date review of the methods of meta-analysis of binary and continuous results is available in Egger et al. 2001.

In addition to assessing the problem of publication bias, robustness of results of a meta-analysis should be tested. This is done through a sensitivity analysis which enables an assessment of how sensitive results are to changes in included studies (e.g. studies of lower quality, or studies suspect of double publication) or in statistical methods of synthesis (random effects model, fixed effects model).

Certain types of modelling are other tools for quantitatively summarising information (AETS; Imaz-Iglesia et al. 1999). The use of models has usually been discussed as a part of the economic analysis; however, it also constitutes a way of comparing different options by quantifying their final results. By quantifying the results of different alternatives, the decision regarding which to choose can be simplified, as the more favourable way will be identified by the means of an overall score.

In addition, the use of modelling can be useful for other purposes, many of which aim at providing more information than "just" a quantitative synthesis of available evidence (Box 15).

Box 15. Uses of modelling (Adapted from EUR-ASSESS 1997)

- Include different sources of evidence in a structured way
- Generalise results to other settings and extrapolate data from studies to populations

9. Include several aspects which influence the final outcomes

There are different methods for modelling, such as decision-trees, Markov-models or threshold analyses (Sloan 1995, Gold et al. 1996). The use of mathematical models implies some assumptions, which have to be explained. A model needs to be fed with probabilities (e.g. of having an illness, of suffering an event), which will be taken from different sources (e.g. meta-analyses, single studies, experts opinions), thus having different grades of validity. Therefore, the sources of data which feed the model have to be transparently stated. The results of models should be carefully interpreted, taking into account the validity of the data introduced in them and the assumptions made. A sensitivity analysis, conducted by varying the values from particular variables or by modifying the underlying assumptions, should always be made to explore how these influence the final results of the model. A comparison of results with other approaches or other models should also be made (Box 16).

Box 16. Modelling

10. Why has the modelling approach been chosen?
11. What kind of modelling method is used? Why?
12. Variables used (Which ones? Why? Sources?)
13. Assumptions being made (e.g. pathways)
14. Sensitivity analysis
13. Comparison with other models' results

The different methods of quantitative synthesis provide complementary information and do not substitute each other.

4.6 Specific methodological considerations

In the following sections, methodological considerations concerning sources of information, outcomes or ways to synthesise will be addressed for specific aspects of an assessment.

4.6.1 Safety

Assessing safety implies a wide scope to identify all possible harm caused through the use of a technology and should be based on all available data for assessing adverse outcomes of an intervention (MSAC 2000). In its guidelines, the MSAC recommends reporting all possible harm related to the use of a technology in the form of a summary table. Outcomes relevant to safety may be adverse effects, morbidity or mortality caused by the use of the technology.

Data sources for outcomes related to safety are the medical literature and routinely collected data (e.g. from regulatory authorities such as the FDA, from clinical databases, from quality assurance projects).

Although severe adverse effects of a technology may lead to a reduction in efficacy or effectiveness (e.g. because of less survival) in an RCT designed to assess those aspects, this study design, first, is not always able to identify all possible harm caused by the use of the technology. In RCTs, only what was looked for will be seen. Second, the reporting of RCTs in regard to quality and quantity of safety (adverse effects and laboratory-determined toxicity) is currently largely inadequate (Ioannidis & Lau 2001); thus, it is extremely important to carefully examine the reasons why subjects leave the study, as the presence of adverse effects might have been an exclusion criteria.

Other study designs, such as observational studies, have an important role in identifying infrequent but serious adverse effects. This is because these designs can provide reliable evidence about adverse effects when the outcome of interest is rare among those not exposed, the excess risk among the exposed is large or there are no obvious sources of bias likely to account for the observed association (MacMahon & Collins 2001). As a result, these study designs should also be considered when assessing safety. Also, as case reports of adverse effects of a technology may be useful when describing its safety, the MSAC recommends a special literature search for such a publication type.

Routinely collected data can complement the ones obtained from the literature. The quality and validity of these data are variable. Often these databases are generic and may not contain enough information. However, they have advantages, such as bigger size or coverage over long periods of time.

The different sources of data on safety should be documented, taking into consideration their quality and validity. Presentation through tables is transparent and may be helpful in summarising the different data.

When discussing the safety of a technology, the way adverse effects are caused should be described. Harm may be device dependent or related to the application of the technology. The

occurrence of adverse effects may be also operator or setting dependant (e.g. learning curve of surgeons), which also need to be also taken into consideration and discussed. Timing (short-term, long-term) and severity of adverse effects should be considered, too. Another important aspect of safety is the identification of differences in risk among different groups of patients.

When possible, quantification of harm into quality- or disability-adjusted life years (QALYs, DALYs) should be made (DEC 2000). Safety can be summarised as frequency of adverse effects, relative risk or as the number needed to treat to produce one episode of harm (NNH)[88]. Sometimes it may not be possible to calculate frequency, and, in this case, harmful effects should then be listed.

4.6.2 Efficacy and effectiveness

Efficacy of a health technology refers to its performance under ideal circumstances, such as study conditions. Effectiveness is the extent to which the technology works in day-to-day practice (see Box 17).

Box 17. Definitions of "efficacy" and "effectiveness"

Efficacy	*Effectiveness*	*Source*
the ability of a particular medical action in altering the natural history of a parti-cular disease for the better, under ideal conditions	the ability of a particular medical action in altering the natural history of a parti-cular disease for the better, under actual conditions of practice and use	Cochrane 1971
the probability of benefit to individ-uals in a defined population from a medical technology applied for a given medical problem under ideal circumstances of use.	the benefit of a technology under average conditions of use	U.S. Congress 1978
maximum achievable benefit	achieved benefit	Williamson 1978
Can it work? Does the manoeuvre, procedure, or service do more good than harm to people who fully comply with the associated recommendations or treatment?	Does it work? Does the manoeuvre, procedure, or service do more good than harm to those people to whom it is offered?	Sackett 1980
what works under carefully controlled conditions, such as randomised clinical trials	what works in day-to-day clinical practice	Rettig 1997

[88] Currently known as Number Needed to Harm (NNH).

The accepted methodology for assessing efficacy is to conduct a systematic review following the principles of the Cochrane Collaboration. It is also accepted that reviews are based on the findings of RCTs. Many areas of health care, however, have not been and often cannot be evaluated with RCTs, and, in these cases, assessment based on other study designs is justified. Besides this fact, another problem concerning RCTs is that the patients included in them do not necessarily represent the assessment's target population. Even if the clinical characteristics were the same, however, they are different because patients included in RCTs gave consent to participate in the trial, and differences among those who choose to participate and those who choose not have been observed. Thus, effects observed in a RCT represent an "ideal world" and do not necessarily have to be observed in the target population, or the "real world" (DIHTA; Kristensen et al. 2001).

Before conducting a systematic review, the need for it should be carefully assessed. At this point of the assessment, when the research questions have already been clearly formulated, a search for systematic reviews which could contain answers for those questions should be made.

An important source of this kind of literature is the Cochrane Library (see Appendixes). Search filters to identify systematic reviews have been developed and may be useful (CRD; Khan et al. 2000 and at http://www.york.ac.uk/inst/crd/revs.htm). If systematic reviews on efficacy are found which may be suitable for answering the questions of the current assessment, their quality and relevance have to be assessed, to decide if they can be included in the assessment. Checklists to critically appraise systematic reviews have been developed and are summarised in Box 18.

Box 18. Key issues in assessing systematic review articles (adapted from Oxman et al. 1994, Greenlagh 1997)

- What are the review questions? Are they relevant for the current research questions?
- Which sources were searched? How were they searched?
- Are selection criteria explicit and appropriate?
- What criteria were used to assess study quality?
- How were the data extracted?
- How were the data synthesised?
- Are the results of the review transferable to my context?
- Should the review be updated?

If an identified systematic review contains all information needed to assess efficacy, undertaking a new one might not be justified. An existing systematic review of good quality may only need to be updated.

If there is no relevant or usable secondary research, a systematic review is justified. When conducting a systematic review, a review protocol has to be formulated. The questions, the outcomes to be measured, the inclusion and exclusion criteria for studies, the search strategy and the planned analyses should be prospectively stated. Some of those points (e.g. the research questions) have already been defined in the HTA protocol, but others (e.g. inclusion/exclusion criteria) need to be refined when undertaking the review. The review protocol can be seen as a

part of the HTA protocol. Comprehensive methodological guidelines already exist on how to conduct systematic reviews of primary research[89].

In contrast to these guidelines, little consensus exists in regard to how to measure effectiveness, especially "community effectiveness". Tugwell et al. (1984) have proposed that the latter should be calculated as "efficacy x diagnostic accuracy x health professional compliance x patient compliance x coverage". More systematically, one could differentiate between factors influencing the access to a procedure and factors influencing the actual process of the procedure. Regarding the former, important variables relate to the health care system (e.g. availability of health insurance, inclusion of service in benefits catalogue, geographical access), providers (e.g. appropriate/ inappropriate indication for service, which may be influenced by payment system) and patients (e.g. felt need for service, availability of information). Regarding the latter, important variables mainly relate to providers (especially technical quality of service) and patients (especially compliance) (Busse 1998). "Effectiveness" is thus the result of a complex interrelationship of efficacy with system-, provider- and patient-related variables. Many of these variables are the outcomes explored under different aspects of the assessment (especially psycho/social/ethical considerations and organisational/professional implications) and a solid estimation of "community effectiveness" is therefore possibly better placed in the conclusions section which brings together the evidence from the various strands.

4.6.2.1 Therapeutic interventions

In the slightly differing models which define levels of evidence, RCTs are always seen as the most valid approach for evaluating therapeutic interventions. However, evidence from RCTs will not always be available. Furthermore, RCTs may not always be suitable for the evaluation of some therapeutic interventions (e.g. if randomisation is not ethically justifiable). In such cases, the HTA doers will have to use evidence from other kinds of study designs. Optimised standard search procedures have been developed to find RCTs[90] and thus other search strategies may be needed if other study designs are to be included.

As mentioned above, when assessing efficacy and effectiveness of therapeutic interventions, health-related outcomes (e.g. mortality) should be used. Using physiolo-gical or biochemical outcomes (= "surrogate" outcomes) should be avoided as far as possible as they may not correlate with the health-related outcomes. Thus, if surrogate outcomes are used, the underlying assumptions have to be clearly stated and results should be regarded carefully. Reliance on surrogate outcomes may be harmful and even lethal (Gotzsche et al. 1996).

The methodology of meta-analysis has been mainly developed for combining the results of RCTs on therapeutic interventions and is comprehensively described elsewhere[91]. However, the meta-analytical approach can also be applied to other study designs, such as observational ones.

[89] Systematic reviews of trials and other studies (Sutton et al. 1998); Undertaking systematic reviews of research on effectiveness (Khan et al. 2000).
[90] Optimal procedures are described in the manuals listed in Appendix 3 or are available at http://www.york.ac.uk/inst/crd/revs.htm.
[91] Cochrane Reviewers Handbook 4.1.1 (Clarke & Oxman 2000).

As already mentioned, the main steps of a meta-analysis include pooling results, testing heterogeneity, carrying out a sensitivity analysis and testing for publication bias. A meta-analysis should only be conducted after the adequacy of statistically combining results has been assessed by means of a non-quantitative synthesis. Results of meta-analysis of therapeutic studies should be graphically presented using the forest plot, including confidence intervals.

The discussion of the results of a meta-analysis is an essential element, and should not be too superficially addressed. Here, the effects of a possible publication bias or of heterogeneity among studies should be addressed. In addition, the relevance and generalisability of results for the questions of the HTA should also be considered, taking into account the characteristics of patients and settings involved in the studies pooled in meta-analysis.

4.6.2.2 Diagnostic interventions

There are two kinds of technologies which aim at identifying conditions of patients: *diagnostic tests* and *screening tests. Screening* is the detection of disease in an asymptomatic population, whereas *diagnosis* is the confirmation of the presence or absence of disease in a symptomatic patient (CRD; Khan et al. 2000). The evaluation of both follows similar principles.

For the assessment of diagnostic and screening tests, a hierarchical model can be followed (Box 19).

Box 19. Evaluation of efficacy and effectiveness for diagnostic interventions (Adapted from Fryback & Thornbury 1991, Flynn & Adams 1996)

"Level"	*Typical measures*
• Technical efficacy	• Physical parameters describing technical performance of the test (e.g. image quality)
• Diagnostic accuracy efficacy	• Sensitivity (% of positives among ill) • Specificity (% of negatives among healthy) • Accuracy (% of correct diagnoses) • Likelihood ratio (likelihood for a given test result in a patient with the target disorder compared to the likelihood of the same result in a patient without the target disorder; details at http://cebm.jr2.ox.ac.uk/docs/likerats.html)
• Diagnostic thinking efficacy/ effectiveness	• Post-test odds/ probability compared to pre-test odds/ probability in target population • % of cases in which test is judged "helpful" to making diagnosis
• Therapeutic effectiveness	• % of cases in which test is judged "helpful" in planning therapy

	• % of therapeutic procedures avoided due to test <<< information
• Health-related effectiveness (Patient outcomes)	• Mortality/morbidity avoided with test • Changes in quality of life through use of test

This hierarchy does not represent a hierarchy of levels of evidence (see Appendix 6), but a hierarchy of outcomes evaluated. Each level requires establishing evidence on the prior level. For the evaluation at each of the stages, studies belonging to different levels of evidence can be conducted.

In HTA, the evaluation of diagnostic technologies should be based on patient related outcomes, as they represent the actual effects of such tests in the health of patients. However, such evidence is not always available and efficacy of the technology is assessed based on test accuracy, sensitivity, specificity or likelihood ratios, which can be seen in this context as "surrogate parameters" for the real effect on the outcomes of the patients. When assessing any of these parameters, it is crucial that the diagnostic technology is evaluated against the "gold standard" (which is not in every case well established). The diagnostic technology should be ideally evaluated in a patient sample that includes an appropriate spectrum of patients with the target condition plus a representative group of individuals without the disease (Flynn & Adams 1996). Both the positively and the negatively tested patients should be compared with the diagnostic gold standard, i.e. not only those who are tested positively (though, depending on the invasiveness of the gold standard, this might raise ethical issues). Ideally, the allocation of positively and negatively tested persons to the gold standard technology should be randomised and the examiners blinded regarding the result obtained with the diagnostic technology.

For the quantitative synthesis of studies on diagnostic tests, several methods have been proposed. The choice of the method depends mainly on homogeneity of results, type of outcome (binary, continuous) and variation in diagnostic thresholds. Nevertheless, all available meta-analytical methods summarise results of diagnostic accuracy.

Most frequently, studies on diagnostic accuracy use different study populations, different settings and different cut-points (diagnostic thresholds). For this situation, the method of Littenberg and Moses (SROC curves) has been proposed as standard approach (Irwig et al. 1994, 1995, Egger et al. 2001). In SROC curves, the area under the curve represents the accuracy of the test to diagnose the condition. This approach is attractive since it is easy to calculate and presents the results in a graphically appealing way. Another approach can be to pool the LR of the studies into a summary LR. This approach should be used only in cases of homogeneity of study results. There is still an ongoing debate as to which is the most suitable statistical method to pool test-accuracy studies. Thus, a good approach is to use several methods and test the sensitivity of the summary results to the method chosen (CRD; Khan et al. 2000).

When assessing a diagnostic test or strategy, outcomes deriving from misclassification / misdiagnosis of patients can also be considered as harm (MSAC 2000).

4.6.2.3 Health care organisation and system related interventions

Organisational, financial or regulatory interventions can also be considered as health technologies. As defined by the EPOC Group[92], different types of interventions, such as professional (e.g. educational program on prescription), financial (e.g. co-payment), organisational (e.g. changes in medical record system) and regulatory (e.g. licensure) are included here. These interventions are not to be confused with organisational, professional and economic implications of introducing or applying a health technology (cf. sections 4.6.4 and 4.6.5).

For the evaluation of professional, financial, organisational or regulatory interventions, the HTA doers need often to be more flexible in their inclusion criteria for studies. Transparency in the selection process is of utmost importance as generalisibility/ transferability to other settings will be highly context-dependent. Box 20 lists available study design by their methodological strength (with the weakest designs towards the lower left, marked in grey).

Box 20. Study designs used for assessing health care organisation and system related interventions (adapted from Busse 1998)

	Cross-sectional	Longitudinal	
	1 point of measurement	2 points of measurement	Regular/continuous measurement
Experimental designs – often not feasible for evaluating health care organisation and system related interventions			
Researcher has control over intervention and allocation of subjects/ institutions/ areas etc. into at least 2 groups; randomisation possible		classical experiment (randomised controlled trial = RCT)	
Researcher has control over intervention and allocation of subjects/ institutions/ areas etc.into at least 2 groups; randomisation not possible	post-test only with non equivalent groups – *weak design*	control group design with pre- and post-test/controlled before and after study	time series with non-equivalent control group/ cohort study
Quasi-experimental designs – feasible for evaluating health care organisation and system related interventions			
Natural experiment (i.e. intervention not determined by researcher) with randomised allo-cation of subjects/ institutions etc. into at least 2 groups through researcher		quasi-RCT – *theoretically possible and desirable but de-facto hardly ever used; requires 1. a dialogue between health politicians and researchers and 2. enough time before the intervention to prepare evaluation*	
Natural experiment with non-randomised allocation of subjects/ institutions etc. into at least 2 groups	post-test only with non equivalent groups – *weak design*		
Natural experiment without prior allocation of subjects/ institutions etc; control group existing		*case-control study – not ideal but a com-promise if pre-intervention measurements were not possible*	
Simple, methodologically weak designs			
Intervention but no control group	one-group post-test only design	one-group pre-test-post-test design	simple interrupted time series – *acceptable if at least three data points before and three after the intervention*

[92] Effective Practice and Organisation of Care Review Group, within the Cochrane Collaboration, which is elaborating some guidelines on how to review such kind of interventions. The guidelines from this group can be found at http://www.abdn.ac.uk/hsru/epoc/down.hti.

Effectiveness of such interventions can be measured using patient health outcomes, but usually other, more process-related outcomes are measured (e.g. number of drugs prescribed, number of patient-physician contacts).

4.6.2.4 Preventive interventions

Preventive interventions intend to avoid having a target condition appear in a target group. They may be implemented at an individual level, making them comparable to therapeutic interventions (e.g. use of aspirin to prevent stroke), and thus evaluated using the same methodology (see section 4.6.2.1). Others, such as screening programmes, are more diagnostic and have to be implemented at a community-level; these have to incorporate the considerations listed both for diagnostic interventions (see section 4.6.2.2) and for organisational and system related interventions (see section 4.6.2.3). Other community-based interventions include health promotion programs or public health strategies aiming at the population or environmental factors (e.g. fluoridation of drinkable water). Common methodological problems when assessing these kinds of interventions are the need for a long-follow-up time (e.g. several years), the use of big observation units (e.g. regions, communities, etc.) instead of individuals, and the difficulty of establishing clear causal relationships between intervention and outcomes.

Regarding the process and methodology of evaluating preventive technologies, the "Current methods of the Third U.S. Preventive Services Task Force" (Harris et al. 2001) can be regarded as "best-practice". Building upon previous work (especially Battista & Fletcher 1988), the Taskforce uses two "analytic frameworks" to map out the specific linkages in the evidence that must be present for a preventive technology to be considered effective. The frameworks make explicit the populations, technologies (e.g. counselling, diagnostic or therapeutic interventions), intermediate and health outcomes to be considered in a review. Most often evidence is only available for individual components of a whole chain of technologies of interventions necessary for a preventive technology to be effective.

In its paper, the Task Force also describes issues such as literature search and abstraction, assessing magnitude of benefits and harms as well as translating the evidence into recommendations including the codes and wording of statements (see Appendix 6).

4.6.3 Psychological, social and ethical considerations

The assessment of the impact of the use or no-use of a technology in terms of psychological, social and ethical benefits or harm is an important part of HTA. Effectiveness of an intervention is influenced by the way it is experienced by those to whom it is directed, by the way they value it, etc. (e.g. if there is no acceptance, compliance will be reduced and thus effectiveness too). Such aspects should therefore also be included in a structured way in a HTA.

Psychological effects of a technology refer to a range of possible subjective effects, such as fear, anxiety, feeling labelled, satisfaction, etc. caused by the use of the technology by the individual. Under social effects of a technology, changes in equity or access to care produced by the implementation of a technology can be addressed. The introduction of a technology may, for example, improve the lot of the rich or middle-class while not touching the poor, so that the

poor become relatively more disadvantaged. Addressing ethical implications of a technology refers more to the exploration of all possible effects of technology on values (e.g. the use of a technology may foster judgements: for example, discrimination of handicapped life through the use of pre-natal diagnostic tests).

The way to approach these issues in HTA depends on the degree of available knowledge. For some of these aspects, information may already be available in the form of studies. The scientific approach for addressing these topics has been included in the field of the so-called "Qualitative Research," involving areas of knowledge such as psychology or the social sciences. Following a rigorous methodology, these approaches allow important variables and effects of the technology from the point of view of the patients and the society to be explored and described. Now, some work is being done to enable the inclusion of qualitative research in a systematic way when assessing health care[93].

Evidence on these topics can be available to some extent from the medical literature and optimal search strategies, similar to the ones used to identify RCTs, which are being developed now to allow systematic search of studies using the methods of qualitative research in Medline[94]. Comprehensive databases exist for social sciences, which also include literature on psychological and sociological aspects of health interventions (e.g. PsycINFO, Sociological Abstracts[95]). If such a literature search is done, the origin of the data and the strategies followed to find the evidence should be clearly stated. Literature found should then be assessed for their validity, quality and transferability. Some criteria for appraising qualitative research used in health care research have been proposed and are summarised in Box 21; however, debates on this are still ongoing.

Box 21. Sets of criteria for assessment of studies using qualitative research methods (updated from CRD; Khan et al. 2000)[96]

I. (Popay et al. 1998)

1. A primary marker: is the research aiming to explore the subjective meanings that people give to particular experiences of interventions?
1. Context sensitive: has the research been designed in such a way as to enable it to be sensitive/flexible to changes occurring during the study?
2. Sampling strategy: has the study sample been selected in a purposeful way shaped by theory and/or attention to the diverse contexts and meanings that the study is aiming to explore?
3. Data quality: are there comparisons of different sources of knowledge/understanding about the issues being explored?

[93] For instance, in 1998 the Cochrane/Campbell Qualitative Methods Group (CQMN) was established, which focuses on including qualitative research in systematic reviews and developing methods to search for and critically appraise such studies. This group is also developing some methodological checklists for qualitative research (accessible at http://www.salford.ac.uk/iphrp/cochrane/homepage.htm).

[94] Grant MJ. Searching for qualitative research studies on the Medline database. Presented at the Qualitative Evidence Based Practice Conference, Coventry, 14th-16th May 2001.

[95] For more see Appendix 2.

[96] A further checklist, based on Giacomini & Cook 2000a/b, is provided in Box A4-12 (appendix 4).

4. Theoretical adequacy: do the researchers make explicit the process through which they move from data to interpretation?
5. Generalisability: if claims are made to generalisability, do these follow logically and/or theoretically from the data?

II. (Mays & Pope 1996)

- Adequate description: Is sufficient detail given about the theoretical framework of the study and the methods used? Is the description of the context for the study clear? Is there an adequate justification and description of the sampling strategy? Is the description of the fieldwork clear?
- Data analysis: Are procedures for analysis clearly described? Is the analysis repeated by more than one researcher? Are findings from quantitative research used to 'test' qualitative findings? Is there evidence that the researchers have looked for contradictory observations?

1. Link to theory: Is the study design and sampling strategy theoretically grounded? Does the link to theory inform the analysis and any claims for generalisability? Is sufficient original evidence provided to support relationship between interpretation and evidence?

III. (BSA Medical Sociology Group 1996)

2. Are research methods appropriate to the question being asked?
3. Is there a clear connection to an existing body of knowledge/wider theoretical framework?
4. Are the criteria for/approach to sample selection, data collection and analysis clear and systematically applied?
5. Is the relationship between the researcher and the researched considered and have the latter been fully informed?
6. Is sufficient consideration given to how findings are derived from the data and how the validity of the findings was tested?
7. Has evidence for and against the researcher's interpretation been considered?
8. Is the context for the research adequately described and accounted for?
9. Are findings systematically reported and is original evidence reported to justify a relationship between evidence and conclusions sufficient?
1. Are the researchers clear about their own position in relation to the research topic?

IV. (Mays & Pope 2000)

2. Triangulation (comparison of results from two ore more different methods)
3. Respondent validation (comparison of investigator's account with those of research subjects to establish level of correspondence)
4. Clear exposition of methods of data collection and analysis
5. Reflexivity (discussion of the ways the researcher and research process have shaped collected data)
6. Attention to negative cases
1. Fair dealing (incorporation of a wide range of perspectives)

In the sense of levels of evidence, no hierarchy of study designs in qualitative research has yet been proposed. In fact, the use of more than one of the methods available in one study (triangulation of methods) is seen as a sign of high quality in a study (Mays & Pope 2000).

If no evidence from the literature is available, the HTA doers may need to conduct primary research by themselves, to include the patient perspective when assessing a technology. Some of the methods which can be applied for this purpose are participant observation, individual interviews, focus group discussions, Delphi method or future workshops[97]. If such primary research is going to be conducted within the HTA, expertise is needed in the use of this methodology, highlighting the multidiscipli-nary nature of HTA. The criteria exposed in Box 21 are also applicable to primary research.

Another source of data can be surveys or questionnaires about some aspects, e.g. satisfaction, acceptance. These sources may give more representative data, but they may only be useful to map phenomena which are already known (DIHTA; Kristensen et al. 2001). The knowledge gained through qualitative research can be complemented with quantitative approaches.

However, time and financial constraints may not allow such a comprehensive approach to address psychological or social aspects, and the HTA doers may use other sources of information like patient organisation websites to gain knowledge about the perspective of the patients or make some assumptions about the possible psychological/social implications and the ethical considerations of a technology. Such an approach can be considered as a "document analysis", which is part of the methodological tool kit available in qualitative research. Thus, it should also be systematic. It is important to clearly state the sources of data, methods used, and assumptions made when approaching these aspects, to maintain the principle of transparency and warrant that all positions are represented. Furthermore, HTA doers have to be careful not to rely on their own moral stance (EUR-ASSESS 1997).

In summary, assessment of psychological, social and ethical considerations refers to the inclusion of the public perspective in a structured way in HTA. These aspects determine public preferences about technologies and thus, their assessment could also be considered a tool of HTA[98].

4.6.4 Organisational and professional implications [99]

The scope of a HTA report should also include organisational and professional changes induced by the technology and predict their further consequences, especially if the background information indicates important implications (cf. Section 4.3). For instance, the use of a new surgical procedure may imply training of staff, but also reduce hospital length of stay, the need

[97] A comprehensive review of qualitative methods is found in: Qualitative research methods in health technology assessment: a review of the literature (Murphy et al. 1998). Some of these methods are also described in the Handbook of DIHTA (Kristensen et al. 2001).

[98] A review on methods for assessing public preferences is included in: Eliciting public preferences in HTA: a systematic review (Ryan et al. 2001).

[99] The issues discussed here, i.e. impact and effects of the technology under consideration on organisational and regulatory issues should not be confused with the issues discussed in 4.6.2.3, i.e. efficacy and effectiveness (in terms of health outcomes) of organisational interventions.

for hospital beds, and potentially the cost for treating patients with this condition. (This may or may not lead to conclusions and/or recommendations for reducing the number of hospitals beds, or alternatively, for using for patients with other indications.)

Organisational issues to be assessed may, for example, address changes in:

2. utilisation of service (for example, if the introduction of a pharmaceutical therapy reduces or even replaces surgical interventions),
3. change in the treatment location (for example, if a traditional in-patient treatment, by means of the new technology, can be performed as an out-patient procedure),
4. training/ qualification requirements (for example, if the application of a health technology – in contrast to its alternatives – presuppose the skills of a special medical expert),
5. channels of co-operation/ communication (for example, if the effective use of a health technology presuppose extra communication between hospital and general practice), and
1. job satisfaction (for example, if a new procedure presuppose such a high throughput that the physicians have insufficient time for following the patients' progress).

As an organisation is a social interaction, within given frames, between persons who have one or more common ends but also individual goals and aspirations, it is useful to start analysing organisational issues by identifying the stakeholders and their interests (for a review of stakeholder analysis see Brugha & Varvasovsky 2000).

An assessment of such issues gives the first picture of the technology's (potential) organisational impact. It may be relevant then to assess – often even to propose and then assess – a strategy for implementing the technology. Some stakeholders may be very interested in promoting diffusion of the technology, whereas others display resistance to change.

Evidence from available studies may have addressed organisational changes induced by a health technology. Often results from such studies are not directly transferable due to for example social or cultural differences, but issues identified, and methods applied to assess them may be relevant and useful. Therefore, in addition to a critical survey of literature, doers often have to collect data from the organisation in which the technology is considered implemented.

Observational studies and individual interviews may be applied, but more often methods used for this data collection are:

2. questionnaires, mainly concerning existing technologies, for factual issues, when the doer knows what kind of information is needed,

3. focus group interviews, mainly concerning existing technologies, when only some of the issues are known to the doer, and others are searched for (Morgan 1993),

4. structured group processes such as future workshop or Delphi method (especially when trying to identify and evaluate future changes of organisational structure and processes, or when trying to predict reactions of people involved in the implementation.

Recommendations of manufacturers and current legislation may be consulted to establish which changes are needed as well.

4.6.5 Economic issues

Assessments of economic issues in HTA implies first collecting information on resource consumption from the use of the technology (costs). The next step will be to conduct an analysis comparing costs to other outcomes, such as efficacy or effectiveness.

Most of the existing guidelines focus on the second aspect; Baladi (1996) provides a useful guide on the identification of resources, the measurement of resources, cost valuation and dealing with possible bias in estimating costs. DIHTA also provides helpful hints for HTA doers (Kristensen et al. 2001).

Generally, there are different types of costs which need to be taken into account depending on purpose and perspective (Box 22). For all of them, the importance of measuring physical units first, before multiplying them with unit costs/ prices to obtain total costs cannot be over-emphasised in order to help interpret results regarding their transferability to other settings – not only from one country to another (Drummond et al. 1992) but also within one country across different providers (Coyle & Drummond 2001). If the data have been collected alongside a clinical trial, protocol-driven costs should be identified and excluded to make the results useful for HTA (Rittenhouse 1997).

Box 22. Types of costs in an economic analysis (modified from DIHTA; Kristensen et al. 2001)				
Perspectives			Types of costs	Examples
Societal Perspective	Health care payer	Hospital	Direct costs	Health care staff, medicine, tests, capital costs (equipment and buildings), inpatient stay (hotel), outpatient visits, overhead costs (e.g. food, light, heat), possibly research and education
		Ambulatory care	Direct costs	Visits with general practitioner, ambulatory specialist, physiotherapist etc., prescription drugs (the share paid by the health care payer), screening programmes
			Direct costs (possibly in other sectors)	Rehabilitation, home care and nursing care at home, social arrangements
			Direct costs (for the patient and family)	User payment (medicine, dentist), cost for travelling, time costs due to patients time used for the treatment, family or friends (unpaid) use of time of the patient
			Lost production in the society	The patient's temporary absence from work due to illness, reduced working capacity due to illness and disablement, or lost production due to an early death
			Future health care costs	Future unrelated health care costs caused by curing the patient with the present treatment

The types of costs and the perspectives used in the analysis should be clearly stated in the report. Data on costs may be obtained from different sources; thus, the evidence used to calculate the costs has to be stated and assessed for quality.

After calculating costs, economic evaluation is necessary to put these into relation with the other outcomes. Depending on the purpose and availability of data, different types of economic evaluations are available (Box 23).

Box 23. Types of economic analysis (DIHTA; Kristensen et al. 2001)	
Type of economic analysis	• When should the specific type of analysis be chosen?
Cost-minimisation analysis	• If the compared technologies are equally effective, then it is only necessary to collect data about costs
Cost-effectiveness analysis	• If the effectiveness of the compared technologies are different (e.g. the difference in costs have to be weighted against the difference in effectiveness) • If activities with the same aim and measure of effectiveness are compared
Cost-utility analysis	• If health-related quality of life is an important health outcome • If activities across specialities or departments in the health care sector have to be compared

Cost-benefit analysis	• If non-health effects also are of importance (e.g. the treatment process itself, utility of information) • If only one technology is assessed (net-benefit) • If there is a wish that individual lives are valued in monetary units • If activities across society have to be compared

Guidelines on economic evaluation are numerous, though they are not tailored for use within the context of HTA (e.g. Canadian Co-ordinating Office for Health Technology Assessment 1997, Drummond et al. 1997a, 1997b, Gold et al. 1996, Guyatt et al. 1986, O'Brien et al. 1997). The EUROMET project, i.e. the "European Network on Methodology and Application of Economic Evaluation Techniques", reviewed the contents of guidelines for economic evaluation of medical technolo-gies from Australia, Canada, France, Germany, Italy, Spain, Switzerland and the United Kingdom regarding stated purpose, comparator, study design, time horizon, perspective, data sources, cost measurement, outcome measurement, discounting and sensitivity analysis (von der Schulenburg & Hoffmann 2000). The recommendations in guidelines regarding discounting only were recently compared by Smith and Gravelle (2001).

The EUROMET group also developed a consensus on a framework for European guidelines which is useful in the context of HTA (von der Schulenburg & Hoffmann 2000). Box 24 summarises the main issues for economic evaluation in HTA.

Box 24. Economic evaluation (based on the EUROMET consensus; von der Schulenburg & Hoffmann 2000)

- Study frame: clearly stated research question, identification of target population, explanation of choices and assumptions made etc.
- Analytical technique: choice to be explained
- Study perspective: societal perspective if the study does not require a narrower perspective
- Selection of alternatives: description and justification of choice; recommendation to use currently most effective or efficient alternative
- Data collection: to be described in detail; must include systematic review of literature; various types of studies and data sources are suitable
- Costing: all relevant direct and indirect costs should be identified, collected and reported; physical units should be reported separately from costs of resources; use of average values only if marginal data are not available
- Outcome measurement: primary outcome measures to be reported clearly; if values for health states are used, individual utilities should be distinct from modelling society's valuation

- Time frame: long enough to capture all effects; modelling can be used to estimated long-term costs and outcomes if real data are unavailable; shortening of time horizon has to be justified and possible bias estimated
- Discounting: necessary if costs and consequences occur at different times; use of standard rate (5%) plus national recommendation
- Sensitivity analysis: should be conducted to test robustness of results to a variation of assumptions, cost and outcome parameters and discounting rate
- Equity: values and preferences important but more valid indicators are needed

4.7 Discussion of methods and results

The discussion is an important part of a HTA. When addressing the different aspects of the assessment, part of the discussion will be possibly already carried out, as a part of the appraisal process and the non-quantitative synthesis (see sections 4.5.2 and 4.5.3). However a structured summary discussion should be always included in an assessment as a separate section. This section should include following parts (Box 25).

Box 25. Discussion

- Methodology of the assessment
- Evidence used (quality, validity, generalisability)
- Assumptions made
- Discrepancies and uncertainties identified
- Expected changes (in technology, in evidence)

The methodology followed to address the different aspects and its appropriateness for assessing those aspects should be discussed (e.g. meta-analysis, modelling). Possible limitations of the approaches used should be discussed with special attention to their influence on the results. The evidence available should also be discussed. Possible sources of bias from the type of evidence used (e.g. study design issues) and their possible influence on the findings should be discussed. Discrepant findings from different sources of information (e.g. if a meta-analysis and a large RCT with discrepant results were included) and the way that the discrepancies were handled should be also addressed. The areas where weak or no evidence is available should be presented, pointing out areas in which future research is needed. It is important to state the degree to which objectives and questions posed at the beginning of the assessment were fulfilled with the chosen approach.

When different outcomes were used, the possible interrelations among them should be addressed in the discussion.

For the issue of generalisability, in addition to the characteristics of the participants in the studies, the identified practice differences between studies and actual practice should also be discussed. Furthermore, identified upcoming changes in the use of the technology or in the evidence (e.g. identified ongoing studies) which could influence the findings of the assessment should also be addressed.

In the discussion, relationships among the findings on the different aspects assessed should be explored, trying to find the ways in which they may influence each other, and discussing how the different findings may be transferable to the real setting in which the assessed technology will be and/or is being implemented. It is also important to discuss which aspects may have an influence on the implementation of the technology and on its effectiveness in the real settings.

In summary, the discussion should point out the limitations (from the method used, from the evidence/lack of evidence) of the assessment and their possible effects on the findings. The discussion can be seen as a needed previous step to formulating conclusions and/or recommendations.

4.8 Conclusions and recommendations

The conclusions of the assessment aim primarily at providing answers to the research questions. They should be brief, clear and explicit, highlighting the most relevant aspects so they can be easily understood and used.

Derivation from the evidence found in the assessment should also be clear; in this respect, the NHS recommends to report conclusions always starting with: “Based on the evidence…”.

Conclusions are often the most read part of an assessment, so they should contain a summary of the most relevant findings taking into consideration the issues of the discussion (Box 26).

Box 26. Conclusions

- Related primarily to the research question(s)
- Summarise quality/origin of the evidence
- Summarise evidence on all aspects assessed
- Give size of effect (benefit/adverse)
- Highlight differences among groups of patients (if found)
- Highlight variations of effect with varying characteristics of technology (if found)
- Discuss applicability of evidence for national/local context and “community effectiveness”
- Point out fields where further research is needed

Note: There are good reasons, although there is no consensus yet, to view the estimation or calculation of the community effectiveness of the technology as an issue for this section as it not confined to the efficacy/effectiveness dimension but needs to take into account psychological/social/ethical, organisational/professional and economic considerations. For example, if a technology with a high efficacy has low or absent acceptance in the population, or if professional

training requirements are extremely high, then the community effectiveness will be very low or even zero.

An important aspect of the conclusions is to clearly point out the fields in which further research is needed (e.g. because no or weak evidence was found). This has to be seen as a major relevant finding of a HTA.

The elaboration of recommendations depends on the original policy questions and objectives of the assessment, as well as on the policy of the HTA commissioners (e.g. the NHS-CRD HTA-Programme explicitly prohibits making recommendations about policy or about clinical care), so this is a facultative component of an assessment. If recommendations are given, the audience of focus should be clear (e.g. for decision makers, clinicians). Recommendations have to be consistent with the findings of the assessment and take into account the kind of evidence they rely on. The gradation of recommendations using hierarchies, which consider the quality of the underlying evidence, represents the best practice when giving recommendations. There are different gradation scales, so the HTA doers have to state which one was used and the way it is constructed[100].

Besides recommendations for the policy-makers, clinicians, etc., recommendations referring to the need for further research or further aspects to be assessed should be made, if such needs were identified.

4.9 Other relevant issues

The following issues should also be taken into account when undertaking a HTA. A transparent HTA should include statements on all of these, as they are important when assessing the quality of the work and, to some extent, might be helpful in interpreting its results.

4.9.1 Review process

Agreement exists that some kind of external review is needed before publication and dissemination of the assessment. Undergoing such a review is seen as a quality attribute of HTA reports, although no clear best practice could be identified among the different models of review[101]. The review processes of different institutions should be evaluated in order to make further recommendations on this issue. For the purpose of future evaluation, it would be very helpful to always clearly state whether an external review was done or not, and, if so, to document the comments from reviewers and the way in which they were incorporated (if so) to the final report (Box 27).

[100] In Appendix 6, scales for gradation of recommendations related to levels of evidence and quality of data (internal validity) are given.

[101] Review models range from individual reviewers giving comments on the report to a comprehensive review process, including institutional boards and consensus finding approaches.

Box 27. Review process

- Did the report undergo an expert review before publication?
- Who reviewed the report (disciplines)? Were there possible conflict(s) of interest?
- Were the comments from reviewers incorporated into the final report? How?
- How many comments were usable? How many were not usable?

Ideally, a preliminary version of the report should be reviewed by experts in the methodology and in the field which is being evaluated. The aim of the experts' review is to assure the quality, accuracy and validity of the report. The external review process is also seen as a way to improve acceptance of the report among professionals (German Toolkit 2000). Within ANAES, for example, the review process takes place in two stages. The draft report may first be reviewed by a panel of experts who did not participate in the working group. Afterwards, the report is always reviewed by the Agency's Scientific Committee. This committee is nominated by the government from a list of representatives of the different health care providers.

4.9.2 Updating of assessment

The validity of the findings of a HTA is limited, and, as a result, it is generally accepted that updating is an important component in the process of HTA. However, it seems to be difficult to determine when a HTA report should be updated. Some institutions (NICE/DES) use a set of different criteria to decide how long a report is valid, and when it needs to be updated. Depending on how the assessment was conducted it might be very difficult to give an exact expiration date for the report. It seems much more important to provide information about the updating process itself, and not about when. In the report, it should be made clear whether an update is planned, and, if so, how the need of an update is going to be identified (e.g. periodical literature search, hearings, etc). Box 28 shows an example of the way DEC decided on an update.

Box 28. Identification of the need for update (DEC 2000)

- New Evidence: Screening searches can be regularly made (e.g. annually if rapid change is expected) to assess whether new evidence relevant to the problem has appeared.
- Controversy: If interested parties communicate disagreement with report after publication, revision may be indicated.
- Interest: If interest is communicated by the public, update may be undertaken.

The update timing depends on expected changes in the evidence for the technology (e.g. ongoing relevant trials which could not be included, but were already identified). It could also be indicated when there are organisational or regulatory changes which may influence utilisation or even effectiveness.

An update is typically made through the original search strategy again, for the period of time subsequent to the original assessment. Original selection criteria should be applied to the

literature found. If there have been many changes, the original search strategy, selection criteria and approach may no longer be acceptable, making a full new assessment necessary.

To provide an assessment with a expiration date does not seem to make much sense, as the need for an update may present itself earlier or later, and to determine this in a prospective way does not seem possible. It is of much more interest to provide information on the mechanisms used to identify the need for update. As with the review process (see section 4.9.1), documentation of the updating process can be helpful for the future evaluation of different approaches. Information about updating the HTA should include the following aspects (Box 29).

Box 29. Update of HTA

- Is an update planned?
- How will the timing / the need for the update be assessed?
- If an update need is identified, how should the update be conducted?

If a standard institutional policy on updating exists, which is always the same, this does not necessarily need to be always reported, as it may be enough to refer to the source in which the process is described.

Chapter 5. "Best practice" in reporting HTA

The reporting of an assessment should include at least three kinds of documents:

1. "Abstract",
2. "Scientific Summary Report" and
3. "Technical Report".

Besides the "Scientific Summary Report", the doers (or commissioners) of the assessment may also publish other summaries targeted at specific audiences (e.g. an "Executive Summary" aimed at decision-makers or a "Patient Information"), with different lengths and content. In general, the common structure of reporting scientific work should be followed: "Objectives/Questions", "Methods to answer those questions", "Answers found/ Results" and "Discussion/ Conclusions." The three types of documents mentioned will differ above all on length and target audience.

In terms of making these documents available for a wide audience, it is now best practice (as practised by most HTA institutions, even though the toolkits/ guidelines do not mention this) to place them freely available in the internet (usually, in pdf-Format). It is however still necessary to print executive summaries, patient information etc. to reach the desired target audience.

In the following sections, the main characteristics of these three documents will be described, with special attention to the concept of "Scientific Summary Report".

5.1 Abstract

Recommendations already exist on how to write a structured abstract for the INAHTA databank (http://agatha.york.ac.uk/htahp.htm). The "Abstract" has to be written in English. In its present form, it is usually too short to contain all aspects of interest when assessing the relevance and quality of a HTA report. The aspects to be included in the "Abstract" are listed in Box 30.

Box 30. Data to be included in English structured abstract (AETS; Imaz-Iglesia et al. 1999)

- **Title:** first title in English, then original title in brackets
- **Author/s:** according to Vancouver style
- **Organisation:** organisation commissioning the report
- **Contact person:** name and address
- **Date:** month and year of publication
- **Language:** language(s) of publication
- **Abstract:** specify whether summaries other than structured abstract are included and their language (e.g. "patient information summary in Dutch")
- **Publication type:** report, clinical practice guideline
- **Pages**
- **References:** number of references cited
- **ISBN:** International Standard Book Number.
- **Technology type:** e.g. screening, diagnostic, therapeutic, organisational
- **Subject index terms:** it is recommended to use terms from Index Medicus, indicating the Major Descriptors with *. State which terms are Non MeSH: e.g. *Aortic Aneurysm – epidemiology; *Stents; Blood Vessel Prothesis; Kharkov Stent (Non MeSH)
- **Objectives:** general and specific objectives
- **Methods:** Data sources: Data used and sources. Criteria for study inclusion: Inclusion and exclusion criteria used. Primary data collection: Specify whether primary data were collected. Secondary data analysis: Specify whether secondary data (e.g. clinical registers) were used. Literature review and integration of evidence: Sources of literature and other sources of data used. Method of synthesis: (non-quantitative, meta-analysis, modelling, economic evaluation)
- **Results:** Main results
- **Recommendations:** if given
- **Peer review process:** Specify: Yes / No / Internal / External / Both

5.2 Scientific Summary Report (and other summaries)

Although HTA reports are primarily addressed to local agents (decision makers, clinicians etc.), their findings may also be of interest for the international scientific/HTA community (one of the underlying assumptions of the ECHTA project). Those readers need to be able to assess the relevance and quality of previous HTA reports when they are considering previous HTA knowledge in their assessment. Up to now, only the technical reports ("full" HTA report) contain (and not always) all the information needed to assess their quality and relevance.

Usually those technical reports are written in the official tongue(s) of the commissioning/writing agency. For Europe, (but also for other parts of the world) this means that a large amount of

HTA knowledge is currently being produced in languages other than English, making them difficult to access for the European and international audience (which often restricts itself to English and the national language).

Aside from the abstract, the Executive Summary may be, if at all, the only part of a report written in a language (usually English) other than the official tongue(s) of an agency, representing the only information easily accessible for the scientific community and the "rest of the world". However, not all HTA doers and agencies provide English summaries of all their publications.

Besides language, another difficulty of validly assessing relevance and results arises from the fact that an (good) Executive Summary is (should be) actually addressed to local decision makers ("executives"), stressing a summary of conclusions and recommendations, as these are the kinds of information sought by local decision makers. Methodological aspects of the assessment are usually underrepresented in the Executive Summary, as they are not of much interest to the target audience.

Only a comprehensive and structured summary available in English could warrant that all information needed to assess the relevance of a report can be found. This could be termed "Scientific Summary Report", to distinguish this kind of summary from the well known "Executive Summary", as they actually differ in their purpose and content (Box 31).

Box 31. Differences between "Executive Summary" and "Scientific Summary Report"

Executive Summary	**Scientific Summary Report**
• Addressed to local decision makers ("executives") • Focuses on recommendations and conclusions • Written in agencies'/institutions' official tongue(s) • Quickly informs decisions	• Addressed to the HTA and Scientific Community • Stresses the context of the HTA and methodological aspects, in addition to conclusions and recommendations • Available in English • Allows for critical appraisal of relevance, quality, and main findings

The Scientific Summary Report is a comprehensive summary of a HTA technical report, available in English and structured around five main questions (Who?, Why?, What?, How? and What are the findings?) to allow for a quick assessment of the report's relevance, quality and main findings to determine its further consideration. Additionally, both methodological and contents-oriented key words should be included to help to identify the report in database searches. The target audience of such a Scientific Summary Report is mainly other researchers undertaking HTA/other HTA doers.

All questions listed in Box 32 should be addressed in the Scientific Summary Report (though not necessarily in this order). The length should be enough to warrant that all items are covered sufficiently and adequately.

Box 32. Elements to be addressed in the Scientific Summary Report	
Question	Aspects
• Who?	• Who initiated the HTA? • Who commissioned it? – statement on conflict of interest • Who conducted it? – statement on conflict of interest • Who paid for it? – statement on conflict of interest • To whom is it addressed? Who will receive it?
• Why?	• Why was the HTA commissioned/conducted? • Why right now? • What decision(s) is it going to inform?
• What?	• What technology or which aspects of a technology are going to be assessed? Which aspects are relevant to the outcomes? • For what target group? • For what target condition? • What outcomes were considered and why? • What are the questions to be answered in the assessment?
• How?	• Was a HTA protocol followed? How was the assessment approached? Which aspects were assessed? • Sources and synthesis of background information? • Was safety assessed? How was the evidence/data identified? Which were the sources? How were data sources/studies selected (inclusion/exclusion criteria)? How was quality of data/studies appraised? What data were extracted and why? How were the results synthesised? • How was the efficacy/effectiveness assessed? How was the evidence/data identified? Which were the sources? How were data sources/studies selected (inclusion/exclusion criteria)? How was quality of data/studies appraised? What data were extracted and why? Was a qualitative review conducted? How was it conducted? Was a meta-analysis conducted? What comparisons were made? What effect measures were used? What pooling method was used? How was heterogeneity accounted for? Was publication bias assessed and taken into account in the analysis? Was a sensitivity analysis done? • Were psychological/social/ethical considerations assessed? How was the evidence/data identified? Which were the sources? How were data sources/studies selected (inclusion/exclusion criteria)? How was quality of data/studies appraised? What data were extracted and why? How were the results synthesised? • Were organisational/professional implications assessed? How was the evidence/data identified? Which were the sources? How were data sources/studies selected (inclusion/exclusion criteria)? How was quality of data/studies appraised? What data were extracted and why? How were the results synthesised? • Was an economic evaluation conducted? What were the alternatives which were compared? What perspective was assumed? What were the underlying assumptions? What kind of analyses was made and why?

	• Did the HTA undergo an external review process before publication?
Results	• What are the main findings of the research?
Conclusions/ Discussion	• Relate results to questions posed • For which aspects of the assessment are there information lacking/uncertain? • Discuss transferability issues of results
Recommendations	• If recommendations are given and graded, what gradation scale was it used?
Update	• Is an update of the report planned? • What criteria will be used to decide on it?
General aspects	• Key words • Bibliographic info

The Scientific Summary Report could improve the dissemination and use of HTA findings among the HTA community, preventing duplication of work when assessing a technology.

As already mentioned, other summaries addressed to other groups (e.g. executives, patients) may be elaborated. For such summaries, no recommendation or standards are given here. The way in which such summaries are elaborated should be left up to the commissioning institutions, as they better know their needs.

5.3 Technical Report

The technical report should include comprehensive information on all issues covered under Chapter 4. The questions listed in Box 30 also apply to the technical report; however, as there are no space limitations, information should be more comprehensive.

The technical report can be seen as the deliverable product of the assessment. The steps undertaken, tools used (e.g. protocols), and evidence included and excluded should be documented in this comprehensive report. There are different elements that can be included in the technical report to enhance transparency and comprehensive-ness in an understandable way (Box 31).

The description of the methods followed cannot limit itself to the methodology of a systematic review of the literature on efficacy/effectiveness. Instead, it refers much more to the methodology used to conduct and write the whole HTA report, referring to methods used to approach the (HTA protocol) and methods used to assess each of the aspects. Generally, the methodology part should be as detailed as to allow other researchers/ doers to replicate exactly was has been done. If a HTA protocol was used, this, along with the extent to which it was followed, should be documented. The HTA protocol can also be included as a part of the appendixes.

The same is true for the documentation of the sources. All sources (e.g. medical literature, databanks, experts opinions) used to obtain information on the different aspects should be documented in a structured way.

Background information can be accompanied by a glossary, which helps non-specialists understand the terms being used. Such a glossary is strongly recommended when the issues under study are highly specialised.

The results for each aspect should be presented in a structured way, using evidence tables. Sometimes, graphical presentation (e.g. forest-plot by meta-analysis) can be very helpful for understanding the results of a synthesis.

Another important issue which should be included in the technical report is a clear statement on possible conflicts of interest. Who performed the report, who commissioned it, and who financed it should be clearly stated. A description of relations and possible conflicts of interests of the HTA doers, commissioners and financiers of the assessment have to be transparently documented in the full HTA report (Box 33).

Box 33. Statement on Conflict of Interest

- Who performed the report?
- Who financed it?
- Who commissioned it?
- Are there any conflicts of interest for the performers, commissioners or payers?

The declaration of conflict(s) of interest makes the reader aware of the possibility of judgements which are influenced by the motives of the persons involved. Although some of these aspects (e.g. who commissioned the report) might also be addressed under the policy question, a separate statement on conflict of interest is strongly recommended. The importance for doing this should not be underestimated, as possible distrust and/or perceived bias is an important barrier for the credibility of studies (Hoffmann & von der Schulenburg 2000).

The way of organising the technical report depends on the assessment and, as a result, no standard is recommended. However, a general structure is given as an example which may be altered depending on the needs of the HTA doers – or the specifications of the commissioners – for each assessment (Box 34).

Box 34. Structure example for a HTA technical report
(in brackets the section of this report where further explanation is given)

- Title
- Authors
- Statement on Conflict of Interest
- Policy Question *(Section 4.1)*
  Who commissioned the assessment?, Why?, What decision(s) is it supporting?
- Methodology of the HTA report
  HTA-Protocol *(Section 4.2)*
  Review process *(Section 4.9.1)*
  Sources of data* *(Section 4.5.1)*
  Appraisal of data/studies (inclusion/exclusion criteria)* *(Section 4.5.2)*
  Method of synthesis* *(Section 4.5.3)*
- Background Information *(Section 4.3)*
  Target Condition, Target Group, Outcomes of Interest, Technology aspects
- Research questions *(Section 4.4)*
- Results**

Safety *(Section 4.6.1)*
Efficacy/effectiveness *(Section 4.6.2)*
Psychological/social/ethical considerations *(Section 4.6.3)*
Organisational/professional implications *(Section 4.6.4)*
Economic issues *(Section 4.6.5)*

- Discussion *(Section 4.7)*
  Methodology of the assessment
  Quality of evidence / Types of evidence (studies/data)*
  Uncertainties / lack of information*
  Generalisability, applicability of findings*
- Conclusions *(Section 4.8)*
- Recommendations *(Section 4.8)*
- Appendixes***
  Documentation of sources (search protocols, key words used, etc.)
  Selection process documentation
  Tables of evidence for included studies (including study characteristics, quality, and results)
  Excluded studies with reasons for exclusion
  Reference lists (included, excluded, other references used)
  Tables of evidence from other sources of data included (e. g routine registers)
  Appraisal tools used
  Levels of evidence / grading of recommendations used
  Glossary
  Update Plan

*For each of the aspects of the assessment.
**Results can be presented with the help of tables and graphics.
***Information contained in Appendixes can also be included in the body of the report. This is up to HTA doers, who should choose the most comprehensible way to report their work.

Chapter 6. Conclusions

The members of the Working Group 4 of ECHTA have reached the conclusion that an improvement in the methodology currently employed by European HTA agencies and other institutions is best served by providing this report on current "best practice" and an instrument for assessing the quality of reports, rather than prescribing a rigid methodology. Particular emphasis should be given to the reporting of findings to enhance comparability and allow for a better cross-border dissemination of results.

During its work, the working group identified several methodological gaps and needs:

- Considerable work has been done on isolated methodological aspects relevant to HTA, but is little done on how to apply the individual methodological tool kits when conducting HTA. Only a few of the identified documents provided methodological guidelines for carrying out HTA; most of the reports focused on specific issues.

- Transparency of the entire HTA process has to be achieved, which is warranted by clear reporting and explanations of all steps undertaken in the assessment. To date, transparency has

been concentrated on the evaluation of efficacy/effectiveness or in economic evaluations, while other important aspects of HTA have not been handled in a very systematic way.

- Other aspects of HTA are not being treated in a structured way at present. These range from the elaboration of the background information and formulation of research questions, to the assessment of important aspects such as psychological, social or ethical implications. A systematic approach might not be possible (or needed at all) for all aspects, but a structured and transparent approach should be warranted.

- Further research needs to be conducted to shed light on how underrepresented aspects can be better approached and included in HTA. Some aspects of HTA can be assessed with the help of qualitative research. However, no clear standards exist on how to include this in HTA. Further work should be done in this field.

- The systematic review on efficacy of therapeutic interventions has been accepted as the core of HTA. Methodological guidance concentrates mostly on such aspects, distracting from a balanced approach to all aspects. However, with expanding work of the Cochrane Collaboration and similar groups, it can be expected that the HTA doers will not need to carry out systematic reviews on efficacy by themselves all the time, as they will be able to use this work.

- Currently, no methodology is available to project or even calculate the community effectiveness of a technology even if the evidence on efficacy is of the highest level. This is an urgent need, as the main function of HTA is to provide sound evidence on effectiveness, taking system-, provider- and patient-orientated issues into account. The identified gap might possibly be dealt with through methodological advancement of modelling techniques.

- Some work is being done to develop systematic reviews of diagnostic, preventive community-based and health system-related interventions; however, the methodological debate is still open.

- Important issues of an assessment, such as the review process or update process are being conducted in different ways, but further evaluation of different alternatives is needed to identify what could be “best practice”.

- No appraisal tool exists to assess the quality of HTA reports. The working group therefore proposes such an instrument, see Box 35.

Box 35. Proposal for a Checklist/ Criteria to assess the quality of HTA reports		
Criterion		Questions
A	*Basic information*	• Are the authors of the report stated? • Is/Are any possible conflict(s) of interest stated? • Is there any information about who financed the report? • Was the report externally reviewed?
B	*General methodological aspects of the assessment*	• Was there a stated HTA report protocol? Was it followed, if not why not? • Is the scope of the assessment specified? Is there an explanation given for aspects not being assessed? • Are there clear research questions posed? • Are sources of information used for each aspect stated? Is it described how was the information for the different aspects gathered? • Are selection criteria for the different kinds of information used stated? • Are validity/quality criteria for appraisal of information clearly stated for each aspect? • Were evidence tables used?
C	*Description of the context of the assessment*	• Is the reason why the HTA was conducted stated? • Is the timing of the HTA explained (e.g. inappropriate extension of indication)? • Is what decision(s) the HTA is intended to support stated? • Is there any information given of who has commissioned the HTA?
D	*Background information*	• Were conditions, target group, relevant interventions or comparisons between interventions and relevant outcomes appropriately defined?
E	*Data about the status quo of the technology*	• Are patterns of utilisation, diffusion, indications, time trends adequately described? • Is an analysis of the regulatory status of the technology provided (e.g. market admission, status in other countries)?
F	*Technical description of the technology*	• Is there any consideration of when and how technical characteristics affect the outcomes? • Description of additional influencing factors (e.g. qualification requirements of staff, quality assurance, risks)?
G	*Safety*	• Are sources of data stated? • Are selection criteria for material stated? • Is there a transparent assessment of validity/quality of data? • Are the results transparently presented?
H	*Efficacy / effectiveness*	• Is the literature search done in a systematic way and documented accordingly (including search strategies, data sources and years)? • Are inclusion / exclusion criteria for primary studies defined? • Are included studies checked for quality and validity? • Is there a description of data extraction of included studies? • Is there a listing of excluded studies with reasons for exclusion given? • Are the results properly documented (e.g. tables, graphs, meta-analysis plots)? • Do the conclusions match the results?

I	*Psychological, social, and ethical considerations*	• Are psychological/social/ethical implications of the technology under consideration adequately discussed? • Are sources of data stated? • Are selection criteria for material stated? • Is there a transparent assessment of validity/quality of data? • Are the results transparently presented? • Are assumptions made, clearly stated?
J	*Organisational and professional implications*	• Were organisational and regulatory issues discussed (e.g. responsibility, necessary investments, financing, regulation, personnel, need, demand)? • Are the methods used for assessing these aspects stated?
K	*Economic evaluation*	• Is there a proper documentation of the methods used (see above)? • Is the perspective of the economic evaluation clarified (e.g. social insurance, societal)? • Are assumptions (e.g. for discounting rates, sensitivity analysis) justified? • Are issues of transferability (e.g. prices, cost structures, remuneration) across countries or settings adequately discussed?
L	*Discussion of generalisability / applicability of the findings*	• Are aspects of the generalisability of the results discussed (e.g. for populations not included in clinical trials or in different settings)? • Are aspects of the transferability of the results to different settings discussed (with regard to epidemiology, diffusion, structure of health care delivery, reimbursement, access)?

Chapter 7. Recommendations

• While some of the methodological gaps identified in Chapter 6 are relatively minor and could be solved through research efforts by individual HTA agencies or other institutions, others are of such magnitude or require consensus to be meaningfully filled (e.g. the issue of community effectiveness) that they should be addressed at a European level.

• To overcome two of the main barriers in European collaboration in HTA (i.e. the non-availability of structured reports and the language barrier), the use of a Scientific Summary Report, as described in this paper, should be viewed as a sign of "Best Practice in Reporting HTA". For all assessments conducted within Europe, such a Scientific Summary Report should be available in the working languages of the EU, but at least in English.

• A European HTA Database could be built using the Scientific Summary Reports of European HTA reports to facilitate accessibility to the HTA findings to the European scientific community. To promote the use of such a summary, its use could be a requisite for reports of assessments which receive EU funding.

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Appendixes

A1. Toolkits and methodological guidance documents

- Table A1-1. Toolkits on HTA
- Table A1-2. Methodological toolkits on specific topics

A2. Sources of information

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A4. Appraisal checklists

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- Box A4-13. Complete list of the Users' Guide

A5. Software for data synthesis

A6. Levels of evidence and grades of recommendations

NB: All websites cited in appendixes 1, 2, 3 and 5 were available as of late April 2001 while the ones in appendixes 4 and 6 were available as of mid July 2001.

A1. Toolkits and methodological guidance documents

Table A1-1. Available toolkits for HTA which refer to the whole assessment process.

Reference	Source	Language	Comments
Burls A, Cummins C, Fry-Smith A, Gold L et al. West Midlands Development and Evaluation Service Handbook. West Midlands Development and Evaluation Service (DES), 2000.	http://www.bham.ac.uk/WMidsDES/	English	Description and methodological guidance of all steps undertaken when performing an assessment for the DES. Provides comprehensive guidance on how to elaborate background information and research questions, on how to report appraisal and selection of the data and on how to summarise the evidence found in a non-quantitatively way.
DEC. DEC Guidelines. Wessex Institute for Health Research and Development, Development and Evaluation Committee, undated [2000].		English	Description of the process of assessment for the DEC ("rapid HTA"), with special focus on the costs aspects.
Imaz-Iglesia I, Gonzalez-Enriquez J, Alcaide-Jimenez JF, Conde-Olasagasti JL. Guía para la elaboración de informes de evaluación de tecnologías sanitarias. Agencia de Evaluacion de Tecnologias Sanitarias (AETS) Informe de Evaluacion de Tecnologias Sanitarias No. 19, 1999.	http://www.isciii.es/unidad/aet/caet.html	Spanish	Description of the process of HTA and elaboration of HTA reports, including an overview of methods of synthesis of evidence and a comprehensive list of sources of data.
Kristensen FB, Hørder M, Poulsen PB (eds.). Health Technology Assessment Handbook. Danish Institute for Health Technology Assessment (DIHTA), 2001.	http://147.29.115.214/publikationer/docs/Metodehaandbog/MethodologyHandbook180601.pdf or via http://www.dihta.dk	English	Provides an overview of qualitative research methods, measurement of quality of life, methods to address the organisational aspects and economic evaluation methods which can be applied in HTA.
MSAC. Funding for new medical technologies and procedures: application and assessment guidelines. Medicare Services Advisory Committee (MSAC), 2000.	http://www.health.gov.au/haf/msac	English	Description of the assessment process and elaboration of HTA reports.

Table A1-2. Methodological toolkits on specific topics. The documents listed here refer only to some aspects of HTA.

Reference	Source	Language	Comments
Baladi J-F. A guidance document for the costing process. Canadian Co-ordinating Office of Health Technology Assessment (CCOHTA), 1996.	http://www.ccohta.ca/newweb/pubapp/pdf/costing_e.pdf	English (French)	Deals with the identification of resources, the measurement of resources, cost valuation, possible bias in estimating costs, and proposes a reporting format for these issues.
Canadian Co-ordinating Office for Health Technology Assessment. Guidelines for economic evaluation of pharmaceuticals: Canada. Canadian Co-ordinating Office of Health Technology Assessment (CCOHTA), 1997.	http://www.ccohta.ca/newweb/pubapp/pdf/peg_e.pdf	English (French)	Focuses on the economic evaluation of drugs, giving also guidelines for reporting economic analyses.
Clarke M, Oxman AD (eds.). Cochrane Reviewers Handbook 4.1.1 [updated Dec 2000]. The Cochrane Library, Issue 1/ 2001.	http://www.cochrane.org	English	Comprehensive methodological guidance on how to conduct systematic reviews and meta-analyses of RCTs of therapeutic interventions.
Durocher A, Pazart L, Dosquet P, Moquet MJ et al. Guide d'analyse de la littérature et gradation des recommendations. Agence Nationale d'Accréditation et d'Évaluation en Santé (ANAES), 2000.	http://www.anaes.fr/ANAES/anaesparametrage.nsf/HomePage?ReadForm	French	Focuses on literature search and appraisal, including a set of checklists and literature appraisal criteria for different types of medical literature.
Egger M, Smith GD, Altman DG. Systematic reviews in health care. Meta-analysis in context. London: BMJ, 2001.		English	Comprehensive and updated review of methods for meta-analyses of binary and continuous results.
Flynn KL, Adams EJ. Assessing Diagnostic Technologies. U.S. Department of Veterans Affairs (VATAP) Technology Assessment Program Report No. 1, 1996.	http://www.va.gov/resdev/ps/pshsrd/mdrc.htm#HealthCareTechnologyAssessment	English	Provides methodological guidance on how to conduct systematic reviews on accuracy of diagnostic tests.
Harris RP, Helfand M, Woolf SH et al. Current Methods of the U.S. Preventive Services Task Force: A Review of the Process. Am J Prev Med 2001;20(3S):21-35.	Via http://www.ahcpr.gov/clinic/ajpm.htm	English	Detailed description of process and methods applied by the Third U.S. Preventive Services Task Force for assessing preventive technologies including useful analytic frameworks, its principles for making recommendations etc.

Khan KS, Ter-Riet G, Glanville J, Sowden AJ, Kleijnen J (eds.). Undertaking Systematic Reviews of Research on Effectiveness. CRD's Guidance for Carrying out or Commissioning Reviews. NHS Center for Reviews and Dissemination (CRD). Report No 4, 2000.*	http://www.york.ac.uk/inst/crd	English	Comprehensive methodological guidance on conducting systematic reviews of literature referring to effectiveness of therapeutic interventions and to some extent of diagnostic interventions.
Billingham LJ, Abrams KR, Jones DR. Methods for the analysis of quality-of-life and survival data in health technology assessment. Health Technol Assess 1999;3 (10).**	http://www.hta.nhsweb.nhs.uk/fullmono/mon310.pdf	English	
Lewsey JD, Leyland AH, Murray GD, Boddy FA. Using routine data to complement and enhance the results of randomised controlled trials. Health Technol Assess 2000;4 (22).**	http://www.hta.nhsweb.nhs.uk/fullmono/mon422.pdf	English	
Murphy E, Dingwall R, Greatbatch D, Parker S, Watson P. Qualitative research methods in health technology assessment: a review of the literature. Health Technol Assess 1998;2 (16).**	http://www.hta.nhsweb.nhs.uk/fullmono/mon216.pdf	English	Comprehensive review of qualitative research methods applicable in HTA.
Ramsay CR, Grant AM, Wallace SA, Garthwaite PH, Monk AF, Russell IT. Statistical assessment of the learning curves of health technologies. Health Technol Assess 2001;5 (12).**	http://www.hta.nhsweb.nhs.uk/fullmono/mon512.pdf	English	
Ryan M, Scott DA, Reeves C, Bate A et al. Eliciting public preferences for health care: a systematic review of techniques. Health Technol Assess 2001;5 (5).**	http://www.hta.nhsweb.nhs.uk/fullmono/mon505.pdf	English	Review of methods to include the public preferences perspective on HTA.
Sutton AJ, Abrams KR, Jones DR, Sheldon TA, Song F. Systematic reviews of trials and other studies. Health Technol Assess 1998;2 (19).**	http://www.hta.nhsweb.nhs.uk/fullmono/mon219.pdf	English	Comprehensive methodological guidance on conducting systematic reviews of literature. Presents a comprehensive overview of different meta-analytic approaches.

*Other methodological documents on how to conduct systematic reviews are collected in the CRMD Cochrane Reviews Methodology Database available at http://www.update-software.com/ccweb/cochrane/cdsr.htm.

**Besides the documents listed here, the Health Technology Assessment Series of the NHS includes further methodological reviews on more specific topics concerning HTA. A complete list of them is available at http://www.hta.nhsweb.nhs.uk/htapubs.htm.

A2. Sources of information

In the following tables a selection of sources of information and literature is presented. The tables were elaborated with information obtained from the Handbooks of AETS, DES, DIHTA and own research. The sites listed below are only a selection of providers (free or for fee) of access to the mentioned databases. Many of the databases may be also available in CD-ROM or online, through databases providers (e.g. http://www.silverplatter.com, http://www.ovid.com, http://www.dialog.com, http://www.fiz-karlsruhe.de/stn.html) It is recommended to consult documentation specialist for further details on access and use of the different databases.

Table A2-1. Sources of HTA reports and systematic reviews.

Name of the Source	**Available at**	**Comments**
INAHTA Members	http://www.inahta.org	Provides access to HTA agencies members of INAHTA. Many HTA Agencies allow online-retrieving of their HTA reports.
HSTAT Health Services/Technology Assessment Text	http://text.nlm.nih.gov	Includes the technology assessments and evidence reports of the Agency for Health Care Policy and Research/ Agency for Healthcare Research and Quality.
HTA Database	http://agatha.york.ac.uk/htahp.htm	Abstracts of publications and projects from INAHTA members and other organisations.
ISTAHC Database	http://www.istahc.org/en/database.html	Includes abstracts, journal citations, meeting programs, post conference courses and articles related to health technology assessment.
Cochrane Database of Systematic Reviews	http://www.update-software.com/ccweb/cochrane/cdsr.htm	Systematic reviews elaborated by members of the Cochrane Collaboration.
DARE Database of abstracts of reviews of effectiveness	http://agatha.york.ac.uk/darehp.htm	A collection of structured abstracts and bibliographic references of systematic reviews assembled by the NHS Centre for Reviews and Dissemination (NHS CRD).
TRIP Database	http://www.tripdatabase.com	Allows searching in evidence based medicine related databases, including guidelines.
HSRProj Health Services Research Projects in Progress	http://igm.nlm.nih.gov	Database of ongoing research and projects referring to health services research including health technology assessment and the development and use of clinical practice guidelines (will be replaced by NLM Gateway later in 2001).

Table A2-2. Bibliographic sources

Name of the Source	**Available at**	**Comments**
General		
MEDLINE	Usually available at university libraries or through Internet: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi	Covers the whole field of medical information, including dentistry and medical psychology. If using optimised search filters, systematic reviews can also be found.
NLM Gateway	http://gateway.nlm.nih.gov	Contains MEDLINE plus citations of monographs (LOCATORplus) and meeting abstracts, e.g. those of the ISTAHC meetings (previously available via HealthStar). The Gateway will, from late 2001, also include all unique journal citations which are currently available at AIDSLINE, BIOETHICSLINE and other databases not relevant to HTA.
HealthSTAR	All citations are available through NLM Gateway: http://gateway.nlm.nih.gov	Focused on the clinical (e.g evaluation of patient outcomes, effectiveness of procedures, programs, products, services, and processes) and the non-clinical (health care administration, economics, planning, and policy) aspects of health care delivery (specific database was dismantled early in 2001 as information is now available through the NLM Gateway).
EMBASE	http://www.embase.com	Covers the whole field of medical literature, including health policy, management and pharmacoeconomics.
UNCOVER Database	http://uncweb.carl.org	Provides access to multidisciplinary journals (English speaking).
Science Citation Index	http://www.isinet.com/isi/products/index.html#sdb	Provides access to bibliographic information, author abstracts, and cited references found in technical and science journals.
Specific		
AIDSLINE	Currently accessible through GratefulMed: http://igm.nlm.nih.gov	Acquired immunodeficiency syndrome (AIDS) and related topics (to be replaced by NLM Gateway).
AIDSDRUGS/ AIDSTRIALS	http://www.actis.org/	Clinical trials of substances being tested for use against AIDS, HIV infection, and AIDS-related opportunistic diseases.
BIOETHICSLINE	Currently accessible through GratefulMed: http://igm.nlm.nih.gov	Ethics and related public policy issues in health care and biomedical research (to be replaced by NLM Gateway).
CANCERLIT	http://cancernet.nci.nih.gov	Literature related to cancer.

DIRLINE	http://dirline.nlm.nih.gov	Focuses primarily on health and biomedical information resources including organizations, government agencies, information centers, professional societies, voluntary associations, support groups, academic and research institutions, and research facilities and resources.
CINAHL Cumulative Index to Nursing and Allied Health Literature	http://www.CINAHL.com	Database of information concerning nursing, physiotherapy and related topics.
AMED Allied and Comple-mentary Medicine Database	http://www.bl.uk/services/stb/amed.html	Covers topics related to complementary medicine physiotherapy occupational therapy, rehabilitation and palliative care.
PsycINFO Psychological Abstracts	http://www.apa.org/psycinfo	Literature on psychology, medicine, education and social science.
ASSIA (Applied Social Sciences Index and Abstracts)	http://www.bowker-saur.co.uk/products/catalog/a_and_i/assia_plus_c.htm	Includes abstracts and references from literature on social science applied to medicine and health care system.
Social Science Citation Index	http://www.isinet.com/isi/products/index.html#sdb	Provides access to bibliographic information, author abstracts, and cited references found in social science journals.
Sociological Abstracts	http://www.silverplatter.com/catalog/soci.htm	Covers sociological aspects of medicine and health among many others including interdisciplinary research in social sciences issues.
NHSEED NHS Economic Evaluation Database	http://agatha.york.ac.uk/nhsdhp.htm	Database of economic evaluations studies of health care interventions.
ECONLit	http://econlit.org	Database of general economic literature, including health economics and technological change.
ECONbase	http://www.elsevier.nl/homepage/sae/econbase/menu.sht	Database of general economic literature, including health economics topics.
HEED Health Economics Evaluation Database	http://www.ohe-heed.com	Contains information on studies of cost-effectiveness and other forms of economic evaluation of medicines and other treatments and medical interventions.
Grey literature/Ongoing Research		
SIGLE System for Information on Grey Literature	http://www.fiz-karlsruhe.de/stn/Databases/sigle.html	Covers many research fields including health, social science and economics. Limited to Europe.
Conference Papers Index	http://www.csa1.co.uk	Abstracts of conference papers. Multidisciplinary.

Registries of trials and other ongoing research		
CCTR Cochrane Register of Controlled trials	http://www.update-software.com/ccweb/cochrane/cdsr.htm	Includes RCTs and other controlled studies identified by contributors to the Cochrane Collaboration. It includes many sources not included in MEDLINE or other bibliographic databases.
Controlled Trials (USA)	http://clinicaltrials.gov	
Glaxo Wellcome register	http://ctr.glaxowellcome.co.uk	
Meta-register of controlled trials	http://www.controlled-trials.com	
UKCCCR registry of cancer trials	http://www.ctu.mrc.ac.uk/ukcccr/	
NTIS National Technical Information Service	http://www.ntis.gov	Contains information about ongoing research on different fields
NNR National Research Register	http://www.doh.gov.uk/research/nrr.htm	Set of databases containing information on ongoing research of interest for the NHS.

*Table A2-3. Other sources of data/information**

Name of the Source	**Available at**	**Comments**
WHO World Health Organisation	http://www.who.org	Access to multiple health statistics.
FDA Food and Drug Administration	http://www.fda.gov	US Approval Agency for medical devices and drugs, contains information on safety for different medical technologies.
OECD	http://www.oecd.org	Access to the OECD Health Data Database, which can be useful for the elaboration of the background information.
CORDIS Community Research and Development Information Service	http://www.cordis.lu	Information about research and development activities within the EU.
EUROSTAT European Union Statistics Office	http://europa.eu.int/en/comm/eurostat/eurostat.ht	Statistical service of the EU.
WHO, Regional Office for Europe	http://www.who.dk/country/country.htm	Contains epidemiological information on European countries.

*The sources cited here aim at providing a general idea of sources other than the literature. Statistical agencies, ministries, epidemiological registers, manufacturers and professional, consumers and patient associations at the national, regional or local level are not listed here but are also useful sources of information, which the HTA doers can consider when under taking an assessment.

A3. Search filters

In this section a selection of websites is presented where validated search strategies are available.

Source	**Available at**	**Search filters provided for**		
		Database	**Software**	**Topics**
University of Rochester, USA	http://www.urmc.rochester.edu/Miner/Educ/Expertsearch.html	MEDLINE CINAHL	Ovid	diagnostic devices, aetiology, harm, prognosis/natural history, therapy, meta-analysis/systematic reviews and qualitative research
NHS CRD, UK	http://www.york.ac.uk/inst/crd/search.htm	MEDLINE CINAHL	Ovid Silverplatter	meta-analyses and systematic reviews
Oxford University, UK	http://wwwlib.jr2.ox.ac.uk/caspfew/filters	MEDLINE CINAHL EMBASE PsycInfo	Ovid Silverplatter	aetiology, diagnostic, prognosis and therapy
BMJ Publishing Group, UK	http://www.evidence.org/what-is-ce/search-strategy-appraisal.htm	MEDLINE	Ovid	systematic reviews, RCTs, cohort studies

A4. Appraisal checklists

This section presents a selection of checklists for appraisal of the medical literature. More checklists and appraisal tools have been developed by other authors and also by HTA institutions. This thus not a comprehensive collection but an example. Except for the one in box A4-8, all the checklists presented here have been originally published in the JAMA series "Users' guide to the medical literature" (complete list in Box A4-14).

Internet source of checklists: http://www.cche.net/principles/content_all.asp

Box A4-1. Checklist for an article about therapy (Guyatt et al. 1993, 1994)

I. Are the results of the study valid?
Primary Guides:
- Was the assignment of patients to treatments randomised?
- Were all patients who entered the trial properly accounted for and attributed at is conclusion?
- Was follow up complete?
- Were patients analysed in the groups to which they were randomised?

Secondary Guides:
- Were patients, health workers, and study personnel "blind" to treatment?
- Were the groups similar at the start of the trial?
- Aside from the experimental intervention, were the groups treated equally?

II. What were the results?
- How large was the treatment effect?
- How precise was the estimate of the treatment effect?

III. Will the results help in the clinical practice?
- Can the results be applied to my patient group?
- Were all clinically important outcomes considered?
- Are the likely treatment benefits worth the potential harms and costs?

Box A4-2. Checklist for an article about diagnostic tests (Jaeschke et al. 1994a, 1994b)

I. Are the results of the study valid?
Primary Guides:
- Was there an independent, blind comparison with a reference standard?
- Did the patient sample include an appropriate spectrum of patients to whom the diagnostic test will be applied in clinical practice?

Secondary Guides:
- Did the results of the test being evaluated influence the decision to perform the reference standard?
- Were the methods for performing the test described in sufficient detail to permit replication?

II. What were the results?
- Are likelihood ratios presented or data necessary for their calculation provided?

III. Will the results help in the clinical practice?
- Will the reproducibility of the test result and its interpretations be satisfactory in my setting?
- Are the results applicable to my patient group?
- Will the results change management of the patient all?
- Will patients be better off as a result of the test?

Box A4-3. Checklist for an article about harm (Levine et al. 1994)

I. Are the results of the study valid?
Primary Guides:
- Were there clearly identified comparison groups that were similar with respect to important determinants of outcome, other than the one of interest?
- Were the outcomes and exposures measured in the same way in the groups being compared?
- Was follow up sufficiently long and complete?

Secondary Guides:
- Is the temporal relationship correct?
- Is there a dose response gradient?

II. What are the results?
- How strong is the association between exposure and outcome?
- How precise is the estimate of the risk?

III. Will the results help in the clinical practice?
- Are the results applicable to my patient group?
- What is the magnitude of the risk?
- Should it be attempted to stop the exposure?

Box A4-4. Checklist for an article about prognosis (Laupacis et al. 1994)

I. Are the results of the study valid?
Primary Guides:
- Was there a representative and well-defined sample of patients at a similar point in the course of the disease?
- Was follow up sufficiently long and complete?
- Did the patient sample include an appropriate spectrum of patients to whom the diagnostic test will be applied in clinical practice?

Secondary Guides:
- Were objective and unbiased outcome criteria used?
- Was there adjustment for important prognostic factors?

II. What were the results?
- How large is the likelihood of the outcome event(s) in a specified period of time?
- How precise are the estimates of likelihood?

III. Will the results help in the clinical practice?
- Were the study patients similar to my patient group?
- Will the results lead directly to selecting or avoiding therapy?
- Are the results useful for reassuring or counselling patients?

Box A4-5. Checklist for a review article (Oxman et al. 1994)

I. Are the results of the study valid?
Primary Guides:
- Did the overview address a focused clinical question?
- Were the criteria used to select articles for inclusion appropriate?

Secondary Guides:
- Is it unlikely that important, relevant studies were missed?
- Was the validity of the included studies appraised?
- Were assessments of studies reproducible?
- Were the results similar from study to study?

II. What are the results?
- What are the overall results of the review?
- How precise are the results?

III. Will the results help in the clinical practice?
- Are the results applicable to my patient group?
- Were all clinically important outcomes considered?
- Are the benefits worth the harms and costs?

Box A4-6. Checklist for a clinical decision analysis (Richardson & Detsky 1995a, 1995b)

I. Are the results of the study valid?
Primary Guides:
- Were all important strategies and outcomes included?
- Were all of the realistic clinical strategies compared?
- Were all clinically relevant outcomes considered?
- Was an explicit and sensible process used to identify, select and combine the evidence into probabilities?
- Were the utilities obtained in an explicit and sensible way from credible sources?
- Was the potential impact of any uncertainty in the evidence determined?

Secondary Guides:
- Were objective and unbiased outcome criteria used?
- Was there adjustment for important prognostic factors?

II. What were the results?
- In the baseline analysis, does one strategy result in a clinically important gain for patients? If not, is the result a toss-up?
- How strong is the evidence used in the analysis?
- Could the uncertainty in the evidence change the result?

III. Will the results help in the clinical practice?
- Do the probability estimates fit my patients' clinical features?
- Do the utilities reflect how my patients would value the outcomes of the decision?

Box A4-7. Checklist for clinical practice guidelines (Hayward et al. 1995, Wilson et al. 1995)

I. Are the recommendations valid?
Primary Guides:
- Were all important options and outcomes included?
- Was an explicit and sensible process used to identify, select, and combine evidence?

Secondary Guides:
- Was an explicit and sensible process used to consider the relative value of different outcomes?
- Is the guideline likely to account for important recent developments?
- Has the guideline been subjected to peer review and testing?
- Were the results similar from study to study?

II. What are the recommendations?
- Are practical, clinically important, recommendations made?
- How strong are the recommendations?
- What is the impact of uncertainty associated with the evidence and values used in the guidelines?

III. Will the recommendations help in the clinical practice?
- Is the primary objective of the guideline consistent with your objectives?
- Are the recommendations applicable to your patients?

Box A4-8. Checklist based on the "Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument" (June 2001; available at www.agreecollaboration.org)

1. Are the overall objectives of the guidelines specifically described?
2. Are the clinical questions covered by the guideline specifically described?
3. Are the patients to whom the guideline is meant to apply specifically described?
4. Does the guideline development group include individuals from all the relevant professional groups?
5. Have the patients' views and preferences been sought?
6. Are the target users of the guideline clearly defined?
7. Has the guideline been piloted among end users?
8. Were systematic methods used to search for the evidence?
9. Are the criteria for selecting the evidence clearly described?
10. Are the methods for formulating the recommendations clearly described?
11. Have the health benefits, side effects and risks been considered in formulating the recommendations?
12. Is there an explicit link between recommendations and the supporting evidence?
13. Has the guideline been externally reviewed by experts prior to its publication?
14. Is a procedure for updating the guideline provided?
15. Are the recommendations specific and unambiguous?
16. Are the different options for the management of the condition clearly presented?
17. Are key recommendations easily identifiable?
18. Is the guideline supported with tools for application (e.g. a summary document, a quick reference guide, educational tools, patients' leaflets, computer support)?
19. Have the potential organisational barriers in applying the recommendations been discussed?
20. Have the potential cost implications of applying the recommendations been considered?
21. Does the guideline present key review criteria for monitoring and/ or audit purposes?
22. Is the guideline editorially independent from the funding body?
23. Have conflicts of interest of guideline development members been recorded?

Box A4-9. Checklist for an article reporting variations in the outcomes of health services research (Naylor & Guyatt 1996a)

I. Are the recommendations valid?
- Are the outcome measures accurate and comprehensive?
- Were the comparison groups similar with respect to important determinants of outcome, other than the one of interest, and were residual differences adjusted for in the analysis?

II. What are the recommendations?

III. Will the recommendations help you in caring for your patients?
- How will the recommendations help you?

Box A4-10. Checklist for a clinical utilisation review (Naylor & Guyatt 1996b)

I. Are the criteria valid?
- Was an explicit and sensible process used to identify, select, and combine evidence for the criteria?
- What is the quality of the evidence used in framing the criteria?
- Was an explicit and sensible process used to consider the relative values of different outcomes?
- Are the judgements of the clinical experts who established the criteria reproducible?
- If the quality of the evidence used in originally framing the criteria was weak, have the criteria been prospectively evaluated in an implementation study and shown to improve patient outcome?

II. Were the criteria applied appropriately?
- Did the process of applying the criteria meet scientific standards?
- What is the impact of uncertainty associated with evidence and values on the criteria-based ratings of process of care?
- Could the uncertainty in the evidence change the result?

III. Can you use the criteria on your own setting?
- Have the criteria been field-tested for feasibility of use in diverse settings?
- Are the criteria up-to-date?

Box A4-11. Checklist for an article about health-related quality of life measurements (Guyatt et al. 1997)

I. Are the recommendations valid?

Primary Guides:
- Have the investigators measured aspects of patients' lives that patients consider important?
- Did the HRQL instruments work in the way they are supposed to?

Secondary Guides:
- Are there important aspects of HRQL that have been omitted?
- If there were tradeoffs between quality and quantity of life, or an economic evaluation, have they used the right measures?

II. What were the results?
- What was the magnitude of effect on HRQL?

III. Will the recommendations help in the clinical practice?
- Will the information from the study help me inform my patients?
- Did the study design simulate clinical practice?

Box A4-12. Checklist for qualitative research in health care (Giacomini & Cook 2000a, 2000b)

I. Are the results valid?
- Were participants relevant to the research question and was their selection well reasoned?
- Were the data collection methods appropriate for the research objectives and setting?
- Was the data collection comprehensive enough to support rich and robust descriptions of the observed events?
- Were the data appropriately analysed and the findings adequately corroborated?

II. What were the results?
- How evocative and thorough is the description?
- How comprehensive and relevant are the theoretical conclusions?
- What major and minor concepts does the theory entail, and how well-defined are they?
- What are the relationships between the conceptual categories, are these dynamics clearly described, and do they make sense?
- Are the concepts adequately developed and illustrated?
- Where does the empirically-generated theory fit in relation to existing theory and beliefs in the field?

III. How do the results help in the clinical practice?
- Does this study help to understand the context of the clinical practice?
- Does this study help to understand the relationships with the patients and their families?

Box A4-13. Checklist for an economic analysis article (Drummond et al. 1997, O'Brien et al. 1997)

I. Are the results of the study valid?
- Did the analysis provide a full economic comparison of health care strategies?
- Were the costs and outcomes properly measured and valued?
- Was appropriate allowance made for uncertainties in the analysis?
- Are estimates of costs and outcomes related to the baseline risk in the treatment population?

II. What were the results?
- What were the incremental costs and outcomes of each strategy?
- Do incremental costs and outcomes differ between subgroups?
- How much does allowance for uncertainty change the results?

III. Will the results help in the clinical practice?
- Are the treatment benefits worth the harms and costs?
- Could my patients expect similar health outcomes?
- Could I expect similar costs?

Box A4-14. Complete list of the User's Guides

Oxman AD, Sackett DL, Guyatt GH. Users' guides to the medical literature. I. How to get started. Evidence-Based Medicine Working Group. JAMA 1993;270:2093-5.

Guyatt GH, Sackett DL, Cook DJ. Users' guides to the medical literature. II. How to use an article about therapy or prevention. A. Are the results of the study valid? Evidence-Based Medicine Working Group. JAMA 1993;270:2598-601.

Guyatt GH, Sackett DL, Cook DJ. Users' guides to the medical literature. II. How to use an article about therapy or prevention. B. What were the results and will they help me in caring for my patients? Evidence-Based Medicine Working Group. JAMA 1994;271:59-63.

Jaeschke R, Guyatt G, Sackett DL. Users' guides to the medical literature. III. How to use an article about a diagnostic test. A. Are the results of the study valid? Evidence-Based Medicine Working Group. JAMA 1994a;271:389-91.

Jaeschke R, Guyatt GH, Sackett DL. Users' guides to the medical literature. III. How to use an article about a diagnostic test. B. What are the results and will they help me in caring for my patients? Evidence-Based Medicine Working Group. JAMA 1994b;271:703-7.

Levine M, Walter S, Lee H, Haines T, Holbrook A, Moyer V. Users' guides to the medical literature. IV. How to use an article about harm. Evidence-Based Medicine Working Group. JAMA 1994;271:1615-9.

Laupacis A, Wells G, Richardson WS, Tugwell P. Users' guides to the medical literature. V. How to use an article about prognosis. Evidence-Based Medicine Working Group. JAMA 1994;272:234-7.

Oxman AD, Cook DJ, Guyatt GH. Users' guides to the medical literature. VI. How to use an overview. Evidence-Based Medicine Working Group. JAMA 1994;272:1367-71.

Richardson WS, Detsky AS. Users' guides to the medical literature. VII. How to use a clinical decision analysis. A. Are the results of the study valid? Evidence-Based Medicine Working Group. JAMA 1995a;273:1292-5.

Richardson WS, Detsky AS. Users' guides to the medical literature. VII. How to use a clinical decision analysis. B. What are the results and will they help me in caring for my patients? Evidence Based Medicine Working Group. JAMA 1995b;273:1610-3.

Hayward RS, Wilson MC, Tunis SR, Bass EB, Guyatt G. Users' guides to the medical literature. VIII. How to use clinical practice guidelines. A. Are the recommendations valid? Evidence-Based Medicine Working Group. JAMA 1995;274:570-4.

Wilson MC, Hayward RS, Tunis SR, Bass EB, Guyatt G. Users' guides to the Medical Literature. VIII. How to use clinical practice guidelines. B. what are the recommendations and will they help you in caring for your patients? Evidence-Based Medicine Working Group. JAMA 1995;274:1630-2.

Guyatt GH, Sackett DL, Sinclair JC, Hayward R, Cook DJ, Cook RJ. Users' guides to the medical literature. IX. A method for grading health care recommendations. Evidence-Based Medicine Working Group. JAMA 1995;274:1800-4.

Naylor CD, Guyatt GH. Users' guides to the medical literature. X. How to use an article reporting variations in the outcomes of health services. Evidence-Based Medicine Working Group. JAMA 1996a;275:554-8.

Naylor CD, Guyatt GH. Users' guides to the medical literature. XI. How to use an article about a clinical utilization review. Evidence-Based Medicine Working Group. JAMA 1996b;275:1435-9.

Guyatt GH, Naylor CD, Juniper E, Heyland DK, Jaeschke R, Cook DJ. Users' guides to the medical literature. XII. How to use articles about health-related quality of life. Evidence-Based Medicine Working Group. JAMA 1997;277:1232-7.

Drummond MF, Richardson WS, O'Brien BJ, Levine M, Heyland D. Users' guides to the medical literature. XIII. How to use an article on economic analysis of clinical practice. A. Are the results of the study valid? Evidence-Based Medicine Working Group. JAMA 1997;277:1552-7.

O'Brien BJ, Heyland D, Richardson WS, Levine M, Drummond MF. Users' guides to the medical literature. XIII. How to use an article on economic analysis of clinical practice. B. What are the results and will they help me in caring for my patients? Evidence-Based Medicine Working Group. JAMA 1997;277:1802-6.

Dans AL, Dans LF, Guyatt GH, Richardson S. Users' guides to the medical literature: XIV. How to decide on the applicability of clinical trial results to your patient. Evidence-Based Medicine Working Group. JAMA 1998;279:545-9.

Richardson WS, Wilson MC, Guyatt GH, Cook DJ, Nishikawa J. Users' guides to the medical literature: XV. How to use an article about disease probability for differential diagnosis. Evidence-Based Medicine Working Group. JAMA 1999;281:1214-9.

Guyatt GH, Sinclair J, Cook DJ, Glasziou P. Users' guides to the medical literature: XVI. How to use a treatment recommendation. Evidence-Based Medicine Working Group and the Cochrane Applicability Methods Working Group. JAMA 1999;281:1836-43.

Barratt A, Irwig L, Glasziou P, Cumming RG, Raffle A, Hicks N, Gray JA, Guyatt GH. Users' guides to the medical literature: XVII. How to use guidelines and recommendations about screening. Evidence-Based Medicine Working Group. JAMA 1999;281:2029-34.

Randolph AG, Haynes RB, Wyatt JC, Cook DJ, Guyatt GH. Users' guides to the medical literature: XVIII. How to use an article evaluating the clinical impact of a computer-based clinical decision support system. Evidence-Based Medicine Working Group. JAMA 1999;282:67-74.

Bucher HC, Guyatt GH, Cook DJ, Holbrook A, McAlister FA. Users' guides to the medical literature: XIX. Applying clinical trial results. A. How to use an article measuring the effect of an intervention on surrogate end points. Evidence-Based Medicine Working Group. JAMA 1999;282:771-8.

McAlister FA, Laupacis A, Wells GA, Sackett DL. Users' guides to the medical literature: XIX. Applying clinical trial results B. Guidelines for determining whether a drug is exerting (more than) a class effect. Evidence-Based Medicine Working Group. JAMA 1999;282:1371-7.

Hunt DL, Jaeschke R, McKibbon KA. Users' guides to the medical literature: XXI. Using electronic health information resources in evidence-based practice. Evidence-Based Medicine Working Group. JAMA 2000;283:1875-9.

McAlister FA, Straus SE, Guyatt GH, Haynes RB. Users' guides to the medical literature: XX. Integrating research evidence with the care of the individual patient. Evidence-Based Medicine Working Group. JAMA 2000;283:2829-36.

McGinn TG, Guyatt GH, Wyer PC, Naylor CD, Stiell IG, Richardson WS. Users' guides to the medical literature: XXII. How to use articles about clinical decision rules. Evidence-Based Medicine Working Group. JAMA 2000;284:79-84.

Giacomini MK, Cook DJ. Users' guides to the medical literature: XXIII. Qualitative research in health care A. Are the results of the study valid? Evidence-Based Medicine Working Group. JAMA 2000a;284:357-62.

Giacomini MK, Cook DJ. Users' guides to the medical literature: XXIII. Qualitative research in health care B. What are the results and how do they help me care for my patients? Evidence-Based Medicine Working Group. JAMA 2000b;284:478-82.

Richardson WS, Wilson MC, Williams JW, Moyer VA, Naylor CD. Users' guides to the medical literature: XXIV. How to use an article on the clinical manifestations of disease. Evidence-Based Medicine Working Group. JAMA 2000;284:869-75.

Guyatt GH, Haynes RB, Jaeschke RZ, Cook DJ, Green L, Naylor CD, Wilson MC, Richardson WS. Users' guides to the medical literature: XXV. Evidence-based medicine: principles for applying the users' guides to patient care. Evidence-Based Medicine Working Group. JAMA 2000;284:1290-6.

A5. Software for data synthesis

A selection of useful software for the synthesis of data is here provided. The list was elaborated with information obtained from the CRD Report No. 4, Egger et al. 2001 and from "Netting the Evidence" (http://www.shef.ac.uk/~scharr/ir/netting):

Software	Available at	Comments
Epi Meta	http://www.cdc.gov/epo/dpram/epimeta/epimeta.htm	Meta-Analysis
Meta	http://www.fu-berlin.de/gesund/gesu_engl/meta_e.htm	Basic meta-analysis procedures, based on DOS
Meta-Analyst	Available on request from: Dr J Lau, New England Medical Center, Box 63, 750 Washington St, Boston, MA 02111, USA. e-mail: joseph.lau@es.nemc.org	Basic meta-analysis procedures, based on DOS
EasyMA	http://www.spc.univ-lyon1.fr/~mcu/easyma/	DOS based, performs basic procedures, standard and cumulative MA
Meta-Test	http://www.cochrane.org/cochrane/sadt.htm	Meta-analysis of diagnostic test data, based on DOS
Metaxis	http://www.update-software.com/metaxis/metaxis-frame.html	Commercial package
Review Manager	http://www.cochrane.org/cochrane/revman.htm	Manages the whole systematic review process
Clinical decision making	http://www.ccc.nottingham.ac.uk/~mczwww/tltp/decis.htm	Decision making trees
StatsDirect	http://www.statsdirect.co.uk	Statistical package for epidemiology and health research
EpiInfo	http://www.cdc.gov/epiinfo	Statistical package for epidemiology

Meta-analyses may also be performed with comprehensive statistical packages such as SAS or STATA, for which meta-analytic procedures are available.

A6. Levels of Evidence and Grades of Recommendations

Table A6-1. Levels of Evidence (Centre for Evidence Based Medicine, Oxford - version May 2001)

Level of Evidence	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	Differential diagnosis/ symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval‡)	Individual inception cohort study with > 80% follow-up; CDR† validated in a single population	Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts††	All or none case-series	Absolute better-value or worse-value analyses ††††
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs.	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§§ only	Exploratory** cohort study with good††† reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Source: Centre for Evidence Based Medicine, Oxford, UK. http://cebm.jr2.ox.ac.uk/docs/levels.html
SR Systematic Review
RCT Randomised controlled trial

*By homogeneity we mean a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a "-" at the end of their designated level.

†Clinical Decision Rule. (These are algorithms or scoring systems which lead to a prognostic estimation or a diagnostic category.)

**An appropriate spectrum is a cohort of patients who would normally be >tested for the target disorder. An inappropriate spectrum compares patients already known to have the target disorder with patients diagnosed with another condition.

‡See note #2 above for advice on how to understand, rate and use trials or other studies with wide confidence intervals.

§Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it.

††An "Absolute SpPin" is a diagnostic finding whose Specificity is so high that a Positive result rules-in the diagnosis. An "Absolute SnNout" is a diagnostic finding whose Sensitivity is so high that a Negative result rules-out the diagnosis.

‡‡Good, better, bad and worse refer to the comparisons between treatments in terms of their clinical risks and benefits.

§§By poor quality cohort study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders.

§§§Split-sample validation is achieved by collecting all the information in a single tranche, then artificially dividing this into "derivation" and "validation" samples.

***By poor quality prognostic cohort study we mean one in which sampling was biased in favour of patients who already had the target outcome, or the measurement of outcomes was accomplished in <80% of study patients, or outcomes were determined in an unblinded, non-objective way, or there was no correction for confounding factors.

****Good follow-up in a differential diagnosis study is >80%, with adequate time for alternative diagnoses to emerge (eg 1-6 months acute, 1 - 5 years chronic)

†††Good reference standards are independent of the test, and applied blindly or objectively to applied to all patients. Poor reference standards are haphazardly applied, but still independent of the test. Use of a non-independent reference standard (where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference') implies a level 4 study.

††††Better-value treatments are clearly as good but cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and the equally or more expensive.

Table A6-2. "Traditional" EBM hierarchy of reseach design/ quality of evidence

I:	Evidence obtained from at least one properly randomized controlled trial.
II-1:	Evidence obtained from well-designed controlled trials without randomization.
II-2:	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
II-3:	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
III:	Opinions of respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

Table A6-3. Grades of Recommendations (Centre for Evidence Based Medicine, Oxford - version May 2001)

A	consistent level 1 studies
B	consistent level 2 or 3 studies *or* extrapolations from level 1 studies
C	level 4 studies *or* extrapolations from level 2 or 3 studies
D	level 5 evidence *or* troublingly inconsistent or inconclusive studies of any level

"Extrapolations" are where data is used in a situation which has potentially clinically important differences than the original study situation.

Source: Centre for Evidence Based Medicine, Oxford, UK. http://cebm.jr2.ox.ac.uk/docs/levels.html

Table A6-4. Recommendation grid and standard recommendation language (based on Third U.S. Preventive Services Task Force)

Quality of evidence	**Net benefit**			
	Substantial	**Moderate**	**Small**	**Zero/ Negative**
Good	A	B	C	D
Fair	B	B	C	D
Poor	I			
A	… *strongly recommends* that clinicians routinely provide [X] to eligible patients. (… found *good evidence* that [X] *improves important health outcomes* and concludes that *benefits substantially outweigh harms.*)			
B	… *recommends* that clinicians routinely provide [X] to eligible patients. (… found *at least fair evidence* that [X] *improves important health outcomes* and concludes that *benefits outweigh harms.*)			
C	… *makes no recommendation* for or against routine provision of [X]. (… found *at least fair evidence* that [X] *can improve health outcomes* but concludes the *balance of the benefits and harms is too close* to justify a general recommendation.)			
D	… *recommends against* routinely providing [X] to asymptomatic patients. (… found *at least fair evidence* that [X] is *ineffective or that harms outweigh benefits.*)			
I	… concludes that the *evidence is insufficient* to recommend for or against routinely providing [X]. (Evidence that [X] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.)			

Source: Harris RP, Helfand M, Woolf SH et al. Current Methods of the U.S. Preventive Services Task Force: A Review of the Process. Am J Prev Med 2001;20(3S):21-35

Working Group 5
Education and Training

To develop and co-ordinate education and support networks for individuals and organisations undertaking or using assessment of health interventions.
To identify needs in the field and assist in the establishment of new provisions.

Working Group Members

Finn Børlum Kristensen (Chair)
John Gabbay (Vice-Chair)
Gert Antes
Eduardo Briones
Mona Britton
Bernard Burnand
Gerard Engel
Pedro Gallo
Carlos Gouveia Pinto
Miriam Ines Siebzehner
Bengt Jönsson
Krzysztof Landa
Lycourgus Liaropoulous
Alessandro Liberati
Marjukka Mäkelä
Bo Nordby Jensen
Audrone Piestiniene
Heiner Raspe
Aidan Synnott

HTA Education and Training in Europe

K. Douw[1], H. Vondeling[102], L. S. Bakketeig[103]

1 Background

The Centre for Applied Health Services Research and Health Technology Assessment (CAST) at the University of Southern Denmark carried out a survey on HTA education and training in the European Union from May 2000 to May 2001. The study was part of a European Union supported project, the European Collaboration for Health Technology Assessment (ECHTA). Broadly conceived, the ECHTA project aims at stimulating HTA in Europe. The overall project consists of six Working Groups and has been co-ordinated by SBU in Stockholm, Sweden. Working Group 5, on education and training, is co-ordinated by the Centre for Evaluation and Health Technology Assessment (CEHTA) in Copenhagen, Denmark, in co-operation with the National Co-ordinating Centre for Health Technology Assessment in Southampton, United Kingdom. For the specific task of the survey, the University of Southern Denmark has acted as a subcontractor for the Centre for Evaluation and HTA.

The content of the survey builds on a report on HTA in Europe which states that although the need for training in HTA is increasing in the EU, no inventory of training and education opportuneities in HTA is available, either nationally or internationally (Banta and Oortwijn, 1998). However, the report continues, it is possible to receive training in HTA in most countries of the European Union. This training is mostly in the different disciplines working in HTA (medicine, epidemiology, economics, etc.) and not in HTA itself. Most countries also have short courses in HTA, but these are provided on an ad-hoc basis and target a postgraduate audience. Likewise, the supply of training in HTA at the undergraduate level is virtually undocumented. For example, according to the report, of all HTA agencies in Europe, only one (CAHTA in Barcelona) is collaborating to develop a university-based Master of Science (MS) programme in HTA.

Beyond the European Union, the lack of an inventory of training and education opportunities in HTA was also recognised by the International Society for Technology Assessment in Health Care (ISTAHC). In late 1999, the ISTAHC Secretariat in Montreal, Canada commissioned researchers at Montreal University to survey HTA training. They developed and distributed a survey among ISTAHC's worldwide membership (then over 1000 members), including European members. Preliminary results indicated that 124 courses (HTA courses and HTA-related courses combined) were being provided in 25 countries. Among these were 12 countries in Europe, mostly in Western Europe (Erickson and Lehoux, 1999). These data indicate that HTA education and training are available in a minority of European countries, if Europe is regarded as a geographical entity. In addition, the survey data indicated that there seems to be a recent

[102] Centre for Applied Health Services Research and Health Technology Assessment (CAST), University of Southern Denmark, Odense, Denmark
[103] Centre for Evaluation and Health Technology Assessment, Copenhagen, Denmark

explosion of HTA courses, with about half of the courses identified starting in 1999 (or within the next 3 years).

The results of this survey (referred to as the "ISTAHC Survey" in this report) provided a first impression of the supply of education and training in Europe. The present project aims at providing a more comprehensive overview. More specifically, its objective has been to identify – via a network approach based on a survey – training programmes and educational resources in the area of health technology assessment in Europe.

2 Methods

2.1 International co-operation, co-ordination and planning

For our work in Europe we built on the survey that ISTAHC had carried out among its membership. This entailed that the ISTAHC Survey served as the principal framework for data collection. The associated database was used to store any new data. At a later stage, we also co-ordinated our activities with a complementary survey from INAHTA (INAHTA Secretariat, 2000).

An initial plan for data collection, among other issues focusing on the content and layout of the ISTAHC Survey, was presented by CAST during the inaugural meeting of Working Group 5. (Held during the ISTAHC Annual Meeting in The Hague, the Netherlands, June 2000.) The discussion resulted in a number of proposals for adaptation of the ISTAHC Survey to the needs of the European Survey, which were subsequently addressed by the Project Team at CAST (see section 2.3). In addition, a brief manual and accompanying letter were developed. The results were discussed with the Chair and Co-Chair of Working Group 5 (Prof. Dr. F.B. Kristensen and Prof. Dr. J. Gabbay, respectively), and subsequently pre-tested in Denmark among university affiliates involved in teaching in HTA. The results gave rise to few additional layout changes, which were discussed with CEHTA staff before distributing the survey. A first interim-report (January 2001) served as an input for discussion with Members of the Steering Group in February 2001 in Seville, Spain. A second interim-report (early March 2001) was presented and discussed during a meeting of the Members of Working Group 5 in Copenhagen in mid-March 2001. Data-collection was completed by the end of April, and a revised concept-report was sent to the Chair and Co-Chair of the Working Group, whose comments served as a final input for the report.

2.2 Inclusion of countries

It was felt that both the anticipated growth of the European Union and the prospect of growing multilateral co-operation in Europe in general justified a broad inclusion of countries. As a result, with the exception of Andorra and Vatican State, all countries that fit with the geographical definition of Europe were included. Some other countries were included as well, e.g. Israel was included as it was represented in ECHTA as an observer-country. Likewise, a number of states in the Caucasian region of the former Soviet-Union were included. Overall, the survey includes 48 countries. These countries are subdivided in three groups:

- European Union Countries (and Switzerland, Norway) (n=17)
- Candidate countries for the European Union (n=12)
- Other countries in Europe (n=19)

For the purpose of this report, which is funded by the European Union, it is relevant to distinguish European Union countries as a group. Norway and Switzerland have been added because there are close ties between HTA-Agencies in European Union countries and those in Norway and Switzerland, respectively, as exemplified in previous EU funded reports on HTA (Banta and Oortwijn, 1998). The candidate countries for the European Union are a group of countries that will be subject to EU regulations in a few years from now, inclusive any new EU initiatives with regard to HTA. The remainder of countries is considered as a group of 'other countries', with a more distant relation to the European Union. These countries are therefore considered as a group too. The three groups of countries are made-up of the following members:

European Union countries (and Switzerland, Norway)

Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom (including England, Scotland, Wales and Northern Ireland).

Candidate countries for the European Union

Bulgaria, Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovenia, the Slovak Republic.

Other countries

Albania, Armenia, Belarus, Bosnia and Herzegovina, Croatia, Georgia, Iceland, Israel, Kazakhstan, Kyrgyzstan, Liechtenstein, Macedonia, Moldova, Russia, Tajikistan, Turkey, Turkmenistan, Ukraine, and Yugoslavia (including Serbia and Montenegro).

2.3 Content of the survey

2.3.1 General set-up

The original ISTAHC survey includes a limited set of questions at the level of an individual course, including:

- the title
- the organising institution, including information on e.g. an e-mail/ Web site and the name of a contact person
- the frequency
- the length
- the target group
- the contents
- the level, e.g. specified by educational requirements for enrolment

- the teaching methods applied, e.g. lectures, mono- or multidisciplinary exercises, and work in small groups.

One of the main points that were raised by Members of Working Group 5 during a discussion on the content of the ISTAHC Survey was that the survey did not provide enough room for informants to fill out the questions of the survey in case they were not affiliated with a university or in case they were not personally involved in teaching. As it was considered to be important to cover as wide a target group as possible, the Project Team at CAST was invited to consider this issue. As a result, to allow for relevant information to be filled out by informants who are not directly involved in teaching HTA (as requested in the ISTAHC Survey), and in order to provide names of potential informants, the European Survey includes two questions on these issues. In order to maintain compatibility with the ISTAHC Survey, it was decided to combine these questions as 'part 1' of the Questionnaire, preceding the virtually unchanged text of the ISTAHC Survey, which was decided to be presented as 'part 2' of the European Survey.

The resulting set of questions was compared to those listed in a report on Danish training courses in HTA and HTA-related disciplines by Møller and Jørgensen (1999). This report is probably the first to document the supply of training in HTA on a national basis. Compared to the Danish report, which is quite comprehensive, the ISTAHC survey covers all relevant issues, except perhaps the costs of the courses. As prices are easily outdated, it was decided not to include this information.

2.3.2 Types, scope and content of courses included in the survey

Types of courses/target groups

The ISTAHC Survey distinguishes undergraduate and graduate training courses. Undergraduate training in HTA is subdivided in training for MDs and other disciplines. In addition, the survey leaves a blank space for other types of HTA courses, e.g. as part of International Summer Schools. Another question focuses on HTA courses as part of continuing education.

Scope and content of HTA courses versus HTA-related courses

The motivation for distinguishing HTA courses versus HTA-related courses in the survey could perhaps be related to a report by Banta and Oortwijn (1998). In this report the authors indicate that an important part of HTA training includes clinical research methodology, epidemiology, and health economics. The authors add that such training is widely available in Europe. Other parts, not that easily available, include:

- the skill of critical and systematic literature review
- the making of synthesis of evidence of the medical, social, ethical, and economic implications of the diffusion and use of technology
- the multidisciplinary skill of drawing conclusions and presenting options tailor made for practical policy-making.

Therefore, it can be argued that courses that should be primarily included in the survey are those, that meet the criterion of being comprehensive in scope. This concept is operationalised in the survey in the form of a description of an HTA course as: 'an HTA course includes all or most dimensions relevant to HTA, ranging from the diffusion of technology in health care, to methods and the use of HTA in policy making.'

This is contrasted with HTA-related courses, which are also included in the survey. These courses are described as: 'clinical epidemiology, evidence-based medicine, clinical trials, health services research, meta-analysis, economic (cost-effectiveness) analysis, consensus conferences, technology management, decision-making, policy making/analysis, legal, social and ethical aspects, others'.

This approach resulted in the identification of 124 courses in the ISTAHC Survey, of which only 20 had a title including the words 'Health Technology Assessment'. The remaining courses were offered using 49 different titles, covering courses that are sometimes wide and sometimes narrow in scope (Erickson and Lehoux, 1999). Based on this approach and the associated results, the European Survey has focussed on courses that present HTA as a broad, multidisciplinary activity, irrespective of the course title. Furthermore, the survey has distinguished between university level courses, including undergraduate- and postgraduate courses, and continuing education courses.

Continuing education courses are described as courses outside a regular university curriculum, usually aimed at specific groups of participants with a completed education.

Based on these considerations, the contents of the European Survey were agreed upon by all those involved. The version of the Survey that has been distributed, the manual and the introductory letter are included in annex 1.

2.4 Data collection

2.4.1 A combination of methods

The main method of data collection was by distributing the European Survey to potential informants. It was attempted to identify key informants in every country included in the survey in order to produce reliable and comprehensive information. Two main strategies were followed. One was to identify informants through existing networks in HTA. In countries without personal links to HTA-networks an Internet strategy was developed to identify potential informants. Whenever the Internet sites contained information on education and training in HTA directly, this was included. Both methods of data collection were supported by telephone calls or other means of acquiring information such as fax and e-mail. The complementing strategies are described in more detail below.

2.4.2 Identification of key informants by means of HTA networks

Three main entrances were used to access available networks in HTA in Europe. These include European ISTAHC members, INAHTA, and the members of Working Group 5 of the ECHTA programme. The results on the individual European ISTAHC members had been made available to the research team by the ISTAHC Secretariat. In order to avoid duplication with the ISTAHC

Survey, only the institutional members of the European ISTAHC members were approached to fill out the European Survey.

European members of INAHTA

Members of the International Association of Health Technology Assessment Agencies (INAHTA) were identified, as far as the associated institutes are located in Europe, and addressed both to identify key informants and to fill out the survey. At a later stage, the results of the INAHTA survey were made available to the Project Team to complement data collection on the basis of the European Survey.

Late 1999, the INAHTA membership included 32 organisations, representing 18 countries, of which 11 are in Europe. The latter include 1 in Austria (ITA), 4 in Spain (AETS, AETSA, CAHTA, OSTEBA), 2 in France (ANAES, CEDIT), 3 in the Netherlands (CVZ, GR, TNO), 2 in Denmark (DIHTA, DSI), 1 in Finland (FINOHTA) 1 in Germany (DIMDI), 1 in Norway (SMM), 1 in Sweden (SBU), 2 in Switzerland (FSIOS, SWISS-TA), and 3 in the UK (Horizon Scanning Centre, NCCHTA, NHSCRD).

Participants in the ECHTA programme: Members of Working Group 5

During the June 2000 meeting of Working Group 5, several members offered to collect information on the country level, e.g. in Israel, whereas other members provided us with the names of potential informants in their country and/or abroad. The latter was requested because the Working Group did not include representatives of all countries that were included in the survey. As a particularly important example, the Polish member of the Working Group provided us with the names of attendees of a conference on HTA in Poland, which was organised in the fall of 2000, mainly targeting an Eastern-European audience.

In addition, the members of the Working Group filled out the Survey on an individual basis. The members of the Working Group are included in annex 2.

Members of the Project Team

The professional network of the Project Team (Norwegian, Dutch) was also used to identify potential informants outside those identified by the members of the Working Group.

Despite this combination of sources of potential informants, a number of countries, in particular Eastern-European countries, were underrepresented in the Survey. To address this issue, a number of additional data collection strategies were developed.

Conference of the Association of Schools of Public Health in Europe

In October 2000, the Association of Schools of Public Health in the European Region (ASPHER) organised its 12th annual conference in Århus, Denmark. A large number of Eastern European delegates were expected to be attending the meeting. ISTAHC's president, Prof. D. Banta, was invited speaker, and HTA was a subject of a parallel session. Prof. Banta and a

member of the Project Team used the occasion to call for assistance to fill out the survey, in particular to obtain information on Eastern European countries. A number of delegates showed interest and provided us with valuable information.

Internet

The Internet strategy was focused on identifying the Deans of European universities with Medical and/or Health Sciences Faculties, who were accessed through the TEMPUS network and the ASPHER website in countries like Bosnia and Herzegovina, Turkey, Albania, Slovenia and Romania. We sent a letter to all informants who were accessed other than through the HTA-network, asking them which professionals to approach in their country in order to provide an overview of HTA courses.

2.4.3 Distribution of the European Survey

The European survey has been distributed as an e-mail file in two different formats, in Word and as a PDF-file, to ensure that the survey could be opened in any type of software environment.

Non-responders received a reminder after 3 weeks. Incompletely filled-out questionnaires were completed by additional data collection by telephone, fax, or e-mail or by contacting members of the Working Group.

3 Results

3.1 Structure

The results of the project are presented in three different ways. Firstly, in paragraph 3.2 the data of the ISTAHC Survey, the European Survey and the INAHTA Survey have been integrated to allow for an overall impression of the status of HTA education and training in Europe. This paragraph also presents the results for different groups of countries as defined in paragraph 2.2, European Union-countries, candidate EU-membership countries, and other countries.

The results of the European Survey are presented in paragraph 3.3. Emphasis is put on the organisational context and geographical distribution of HTA courses, HTA-related courses and continuous education courses.

Annex 3 presents some personal comments of respondents, identifying a need for collaboration in the development of training and education in HTA.

3.2 General overview of education and training in HTA in Europe

Response rates

The ISTAHC Survey was distributed to its over one thousand membership in 1999, of whom 570 were located in the countries included in the European Survey. The response rate has not been reported.

The INAHTA Survey was distributed to its 32 member organisations (late 1999 data), representing 18 countries, of which 12 were in countries included in the European Survey. Twenty-nine members responded (85%).

The European Survey would ideally have included 48 countries. As no informants were identified in Liechtenstein and Macedonia, the survey was distributed to a total of 91 informants in 46 countries. One reminder was sent. The overall response rate was 50%. In the group of European Union countries the response rate was 60%, compared to 68% in the group of candidate countries, and 42% in the group of other countries.

3.2.1 General results

HTA and HTA-related courses

The final results of the ISTAHC Survey as documented in the database showed that 125 courses (either HTA- or HTA-related) are provided in 14 European countries. These countries include Denmark, Finland, France, Germany, Hungary, Italy, the Netherlands, Poland, Portugal, Spain, Sweden, Switzerland, the Netherlands, the United Kingdom, and Israel (ISTAHC survey database, 2000).

The INAHTA Survey results illustrated that 79% of the INAHTA agencies provide training and education. Seventy-one percent of the agencies provide training in HTA.

The European Survey identified 145 courses (either HTA or HTA-related) in 26 countries. Compared to the ISTAHC commissioned Survey, additional countries include predominantly Eastern-European countries. A breakdown of this number shows that 27 of the 145 courses are provided as university level (both undergraduate and graduate) HTA courses, 85 courses can be categorised as university level HTA-related courses, and 48 are continuous education courses. Of these latter 48 courses, 21 are HTA courses, whereas 27 are HTA-related courses. Fifteen of the continuing education courses are also provided as university level courses.

The results of the combination of the ECHTA-, INAHTA- and ISTAHC survey are summarised in Table I.

Table I Results per country on HTA training and education

Country	University level courses		Continuing Education courses	
	HTA	HTA-related	HTA	HTA-related
Armenia	–	+	–	+
Austria	–	+	+	–
Belgium	–	–	–	+
Bulgaria	–	+	–	–
Bosnia and Herzegovina	–	+	–	–
Croatia	–	+	–	–
Cyprus	–	–	–	–
Denmark	+	+	+	+
Estonia	+	+	–	+
Finland	–	+	+	+
France	+	+	+	+
Germany	+	+	–	+
Greece	–	–	–	–
Hungary	+	+	–	+
Ireland	–	+	–	–
Israel	+	+	+	–
Italy	+	+	+	–
Kyrgyzstan	–	+	–	–
Latvia	–	–	+	–
Lithuania	–	+	–	+
Moldova	–	+	–	–
Norway	–	+	–	–
Poland	+	+	+	–
Portugal	–	+	–	+
Romania	–	+	–	–
Russia	–	+	–	–
Slovenia	–	+	–	+
Spain	+	+	+	+
Sweden	+	+	+	+
Switzerland	+	+	+	–
The Netherlands	+	+	+	+
The Slovak Republic	–	+	–	–
The United Kingdom	+	+	+	+
Ukraine	–	–	–	–
Yugoslavia	–	–	–	–

Table I shows that 13 countries provide HTA courses at university level. Nearly all countries provide HTA-related courses. Thirteen countries provide HTA as a continuing education course. Thirteen countries supply HTA-related continuing education courses. Nearly all countries provide university level, HTA-related courses. Six countries provide HTA and HTA-related courses both as university level courses and as continuing education courses. These countries are Denmark, France, Spain, Sweden, the Netherlands, and the United Kingdom. In 4 countries, neither HTA nor HTA-related courses are provided. These countries include Cyprus, Greece, Ukraine, and Yugoslavia. No response was received from Albania, Belarus, Czech Republic, Georgia, Iceland, Kazakhstan, Luxembourg, Tajikistan, Turkey and Turkmenistan.

3.2.2 General results per group of countries

Table II and III provide a breakdown of results presented in table I in accordance with the definition of each groups of countries, starting with HTA and HTA-related courses in the European Union, Norway and Switzerland.

Table II HTA and HTA-related courses in the European Union plus Norway and Switzerland

Country	University level courses		Continuing Education courses	
	HTA	HTA-related	HTA	HTA-related
Austria	-	+	+	-
Belgium	-	-	-	+
Denmark	+	+	+	+
Finland	-	+	+	+
France	+	+	+	+
Germany	+	+	-	+
Greece	-	-	-	-
Ireland	-	+	-	-
Italy	+	+	+	-
Norway	-	+	-	-
Portugal	-	+	-	+
Spain	+	+	+	+
Sweden	+	+	+	+
Switzerland	+	+	+	-
The Netherlands	+	+	+	+
The United Kingdom	+	+	+	+

Table II shows that eight countries in the European Union countries reported to provide HTA courses at the university level (as does Switzerland). Ten countries report to provide HTA courses as continuing education courses. Six countries in the European Union provide HTA and HTA-related courses, both as university level courses and as continuing education courses. Belgium, Greece, Portugal, and Norway do not provide HTA courses. Of these, Greece is the only country that provides neither HTA courses nor HTA-related courses, as defined in the methods section. No information has been obtained on Luxembourg.

Table III HTA- and HTA-related courses in candidate EU-membership countries

Country	University level courses		Continuing Education courses	
	HTA	HTA-related	HTA	HTA-related
Bulgaria	-	+	-	-
Cyprus	-	-	-	-
Estonia	+	+	-	+
Hungary	+	+	-	+
Latvia	-	-	+	-
Lithuania	-	+	-	+
Poland	+	+	+	-
Romania	-	+	-	-
Slovenia	-	+	-	+
Slovakia	-	+	-	-

Table III indicates that three countries in the group of EU-membership countries provide HTA courses at the university level. Eight countries reported to provide HTA-related courses at the university level. These HTA-related courses include courses in health economics, health policy and management, evidence-based medicine and clinical epidemiology. Two countries provide HTA courses as continuing education courses. No information has been obtained from the Czech Republic and Malta.

HTA- and HTA-related courses in other countries

A third group of countries, that is non-EU member countries and non-candidate EU-membership countries, mainly consists of Eastern European countries, and the new independent states. Israel is included, because it is represented in ECHTA as an observer country. Israel is the only country in this group that provides HTA courses, both as university level courses and as continuing education courses. All countries, except Ukraine and Yugoslavia, reported to provide HTA-related courses at the university level. These included courses in quality of care, medical informatics, health policy, finance and management, research methods, and evidence based medicine.

No response was received from Albania, Belarus, Georgia, Iceland, Kazakhstan, Tajikistan, Turkey, and Turkmenistan. As indicated earlier, no informants were identified in Liechtenstein and Macedonia.

3.3 Results of the European Survey

In paragraph 3.3.1 the information that was obtained on HTA courses is presented according to the type of course, in general and per group of countries. Paragraph 3.3.2 illustrates the areas in which HTA-related courses are provided.

3.3.1 HTA courses

The survey identified 15 countries that provide HTA courses. A first categorisation of these courses can be made on the basis of the organisational context of their provision. At least ten different settings can be distinguished:

1. International Master of Science in HTA
2. National Master of Science in HTA
3. Internet based distance learning course
4. Part of MSc in Public Health or Health Sciences
5. PhD course
6. HTA in combination with a clinical area
7. Introductory course
8. Summer- and Winter school in HTA
9. HTA methodology
10. Part of a Health Economics course

Master of Science in HTA

Three Master's programmes in HTA have been identified. One Master of Science programme is international in scope, whereas national MSc's in HTA are provided in the United Kingdom and Spain.

The international MSc in HTA and Management is provided by the Ulysses international consortium. The Ulysses international consortium consists of five universities and five HTA agencies in Europe (Spain and Italy) and in Canada (Quebec and Ontario). The European HTA agencies include the Catalan Agency for HTA and Research (CAHTA) in Barcelona, Spain, and in Italy the Agency for Regional Health Care Services (ASSR), and the Public Health Agency of the Lazio Region (ASP) are represented. Both these organisations are located in Rome. The HTA agencies in Canada include Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) in Montreal and the Institute for Clinical Evaluative Services (ICES) in Ottawa. The Master's program consists of four two-week modules organised in different cities (Montreal, Rome, Barcelona and Ottawa) and a training period up to 8 months within an HTA and Management Agency or University. A research- or policy analysis project is to be completed during the programme. The total of 8 topics covered in the modules are: HTA principles and practice, HTA methods, health policy analysis, institutional management, clinical decision making, and ethical, socio-cultural and legal issues. The MSc program in HTA and Management will start in September 2001 and will be organised every second year. The total course programme will take 450 hours.

The Spanish MSc in HTA is organised by the Galician Health Service together with the University of Santiago de Compostela. Nearly all the Spanish HTA agencies (CAHTA, OSTEBA, AETS), and the Iberoamerican Cochrane Centre contribute to the programme. The programme started for the first time in September 2000 and will be organised every second year. The total number of course hours is 500.

The third Master of Science education in HTA will be provided in the United Kingdom at the University of Birmingham, starting in October 2001. The MSc in Birmingham will be provided once a year. The total number of course hours will be 300.

Internet based distance learning course

An Internet-based distance learning-course is provided by the Catalan Agency for HTA and Research (CAHTA) in collaboration with the Open University of Catalonia. The course addresses managers, professionals and graduates interested in assessment, health service management, and evidence based medicine. The course started for the first time in 2000, will be organised twice a year, is provided in Spanish, and the duration is 60 hours. The course program focuses on 4 themes: introduction into the evaluation of health care services, health care decision analysis, systematic review of scientific evidence, and efficiency and equity analysis.

HTA as part of a MSc in Public Health or Health Sciences

HTA-courses are provided as a part of a Masters in Public Health or Health Sciences in the Netherlands, Spain, Switzerland, Denmark and Germany. The HTA-elements of these programmes vary in duration from one day in Switzerland and the Netherlands, to 20 hours in Spain.

PhD course in HTA

A PhD course is provided at the University of the Basque Country in Spain.

HTA in focus

Some courses in HTA are identified with a specific focus, either a clinical area or a target group. Courses in HTA in combination with a specific clinical area are provided by CAHTA. One course focuses on palliative medicine and another on diagnostic imaging. The courses will be provided at the end of 2001, and the duration will be 30 hours.

Courses for a specific target group include a course in Poland for policy makers: HTA – Grounds for Reimbursement policy, organised by the National Centre for Quality Assessment in Health Care. HTA for physicians is a continuing medical education course organised by the Nijmegen University Medical Centre, the Netherlands.

Introductory courses in HTA

Introductory courses in HTA are provided in Poland at the undergraduate and graduate level by the National Centre for Quality Assessment in Health Care. One of the courses addresses how to teach HTA and EBM. Introductory courses in HTA are furthermore organised in Denmark, Israel, Latvia, and the Netherlands. The course in Latvia was recently organised by the Health Statistics and Medical Technology Agency in close collaboration with the Swedish Council for HTA.

Summer school in HTA and the Nordic Winterschool in HTA

A summer school in HTA and the Nordic Winterschool in HTA are provided in Denmark. The summer school was organised in 2000 and addressed Danish researchers and health care professionals working with HTA projects. The Nordic Winterschool used the same principle. The courses build on actual HTA projects submitted by the participants. The Nordic Winterschool is a collaboration of the HTA agencies in Denmark, Finland, Sweden and Norway and addresses participants from throughout Scandinavia.

HTA methodology

A course in HTA methodology is provided at the graduate-level and as a continuing education course by the Galician Health Service together with the University of Santiago de Compostela in Spain.

Part of a Health Economics course

Elements of HTA are provided in combination with courses in health economics at the Institute of Public Health at the University of Tartu in Estonia, and at the Budapest University of Economics in Hungary.

Finally, two other types of activities were distinguished that have a distinguished educational feature but are tailored towards individuals: fellowships and subsidies of post-doctoral positions in HTA.

Fellowships

Fellowships (either HTA or HTA-related) are offered in Spain (AETSA, CAHTA, OSTEBA), France (ANEAS), Sweden (SBU), the UK (University of Birmingham), and Israel (ICTAHC).

Post-doctoral positions in HTA

In Denmark, the Danish Institute for HTA funds three three-year post-doctoral positions in HTA as of early 2001. These post-doctoral posts are integrated in universities across the country.

In summary, a wide variety of HTA courses can be distinguished in Europe. When taking a bird's-eye view of HTA courses in Europe, a concentration of activities can be identified in Spain. Three HTA agencies in Spain provide HTA courses in their respective regions. Furthermore, there is an HTA agency at the national level. These agencies collaborate cross-regionally in a national Master of Science in HTA. In general, Spain shows a high level of collaboration in HTA and HTA-related courses at the university level and in continuing education for health care professionals. There is collaboration in training and education between HTA agencies, health services, universities, and quality of care institutions. Furthermore, one of the regional Spanish HTA agencies takes part in an international consortium, which provides an international MSc in HTA.

Another cross-national collaboration in Europe has been identified in the Nordic region. The HTA agencies of Denmark, Sweden, Norway, and Finland have recently established a Nordic Winterschool in HTA.

Other initiatives for collaboration are undertaken by SBU in Sweden, providing assistance in courses in HTA and Evidence Based Medicine in e.g. Russia and Latvia.

In Poland the NCCQA can be mentioned in this context, which in recent years twice organised an international workshop on HTA specifically directed towards Eastern European- and Baltic countries.

Types of HTA courses in three groups of countries

Table IV Types of courses in three groups of countries in Europe

	Type of HTA course	EU-countries	Candidate EU-countries	Other countries
1	International Master of Science in HTA	X		
2	National Master of Science in HTA	X		
3	Internet based distance learning course	X		
4	Part of a MSc in Public Health or Health Sciences	X		
5	PhD course in HTA	X		
6	HTA in focus	X	X	X
7	Introductory course in HTA	X	X	X
8	Summer- and Winter school in HTA	X		
9	HTA methodology	X		
10	HTA as part of a Health Economics course	X	X	

Table IV illustrates that in the group of European Union countries all types of HTA courses are provided. The types of courses are provided in different countries within the European Union, and vary in frequency and duration. In the group of the candidate EU-countries, Poland provides a course in HTA focused on reimbursement for health care decision-makers. Introductory courses in HTA are provided in Latvia, and Poland. HTA as part of a Health Economics course is provided in Hungary and Estonia. In the group of other countries none of the countries except Israel provides HTA courses. More specifically, Israel provides a course in HTA with a focus on management and an introductory course in HTA.

3.3.2 HTA-related courses

The INAHTA Survey showed that the HTA agencies most often provide training in literature searching, systematic literature reviews, EBM, and health economics.

In the European survey, 85 HTA-related university level courses have been identified. The areas in which they are provided are listed in Table V. Table V shows that the combination of courses in the areas of evidence based medicine, health care management and policy and financing, and clinical epidemiology make up for half of the supply of HTA-related courses.

Table V Areas in which HTA-related university level-courses are provided

Areas		% (n=85)
1	Evidence Based Medicine	20
2	Health Care Management, Policy and Financing	14
3	Health Economics	14
4	Clinical epidemiology	12
5	Health Statistics/informatics	8
6	Research methods	7
7	MSc in Public Health, Health Sciences	6
8	Quality of Care	5
9	Literature searching	2
10	Systematic literature reviews	2
11	Critical Appraisal	2
12	Ethics in health care	1
13	Other	7

Continuing Education courses

In total 48 continuing education courses have been identified. Continuing education courses are defined as courses outside a regular university curriculum, usually aimed at specific groups of participants with a completed education (medical doctors, nurses, administrators, government employees, other health professionals). Twenty-one of these CE-courses are HTA courses. In 14% of these courses HTA is combined with evidence-based medicine.

Twenty- of the CE-courses are HTA-related courses and can be categorised in a number of areas (see Table VI).

Table VI Areas in which HTA-related continued education courses are provided

Areas		% (n=27)
1	Evidence Based Medicine	26
2	Health Economics	22
3	Systematic Reviews	19
4	Other	15
5	Clinical epidemiology	11
6	Critical Appraisal	4
7	Literature searching	3

Teaching methods

More than fifty percent of the respondents reported which kind of information technology is used in training and education in HTA and HTA-related courses. The Internet is used frequently, as well as other use of computers. Videotapes, videoconferences, and CD-ROM were used occasionally in training and education. More than fifty percent of the respondents reported on the teaching methods that are used in training and education in HTA and HTA-related courses. The majority of the respondents most frequently used traditional lectures, and student participation. The majority of respondents occasionally used invited speakers, internships, and problem-based learning.

Of the teaching methods employed distance-learning courses can be regarded as a special case with regard to learning methodology, the use of new communication technology and course organisation (Geiger et al., 2000). However, no further information is yet available from the Spanish distance learning course in HTA.

4 Conclusions and discussion

Conclusions

Perhaps the most obvious conclusion allowed by the European Survey is that the supply of education and training in HTA in Europe is increasing rapidly. Many courses have only recently been organised, or will be organised for the first time in the near future. This confirms the results provided by the ISTAHC Survey (Erickson and Lehoux, 1999). In general, HTA as a field is in the process of becoming established and institutionalised both in individual countries and internationally. This can be regarded as the fruit of the effort of many dedicated individuals and

organisations, including ISTAHC, INAHTA, national societies for health technology assessment, universities and research institutes with HTA units, etc.

Nevertheless, notwithstanding the rapid increase in the supply of education and training in HTA, only a minority of all European countries currently participate in this development. In particular, countries in the European Union are well represented. Within the European Union, the traditional north-south division has more or less vanished with Spain, in particular, as the main example of what can be achieved. Education and training in HTA is scarce in EU-candidate membership countries, with exceptions in Poland, Hungary, Estonia and Latvia, while education and training in HTA is virtually absent in the remainder of countries covered by the survey, except for Israel. Responding to the survey, many countries in Central and Eastern Europe, including members of the Russian Federation and the new states of the former Yugoslavia often expressed the wish to become more involved in HTA.

Concerning the content of HTA education and training, it can be concluded that a great variety of courses exist for a correspondingly large variety of audiences. Overall, the pattern is scattered on both the international and, in most cases, the national levels.

Teaching methods in both HTA and HTA-related courses are still largely traditional. The role of the Internet, as a means of communication between teachers and students is increasing, but the Internet's potential for integration in teaching methods remains largely untapped.

Besides the growing supply of education and training in HTA, the survey shows that the supply of HTA-related courses is increasing even more rapidly, with courses in evidence-based medicine as the most prominent subject. This may reflect the impact of the Cochrane Collaboration, with increasing numbers of Cochrane Centres around the world.

Discussion

Methods

The European Survey was based primarily on a network approach. More specifically, we have applied a 'snow-ball sampling' method, which generally relies on previously identified members of a group to identify other members of population (Fink, 1995). This method is recommended when a population listing is unavailable and cannot be compiled.

In the case of the European Survey, this condition was fulfilled in most countries, in particular in the group of candidate EU membership countries and the group of 'other countries'. In these countries, in particular in Central and Eastern Europe, several informants were identified whose information might not have been included using alternative survey methods.

When, as a supplementary strategy to the 'snow-ball sampling' method, the Internet was used to identify additional potential informants in the latter countries, this was often difficult due to the relative scarcity of English language sites in these countries. Although the Internet is becoming

extremely important as a source of information in the industrialised world, this may not yet be the case in Central Europe, Eastern Europe and beyond.

Results: quantity and quality

In Group I (EU countries plus Norway and Switzerland, information was obtained from all but one of the 17 countries (94%). Only from Luxembourg was no information obtained. The response rate of informants was 60%. The main sources of information in this group were HTA agencies and universities involved in HTA.

In Group II, uniting the EU candidate membership states, information was obtained from 10 of the 12 countries (84%). Neither Malta nor the Czech Republic provided us with any information. The response rate of informants was 68%. A combination of sources of information was represented in this group, including both HTA agencies and other agencies and institutions.

In Group III, the 'other countries', information was obtained from 9 countries (n=19, 47%). Information is lacking from Albania, Belarus, Georgia, Iceland, Kazakhstan, Tajikistan, Turkey, Turkmenistan, Liechtenstein and Macedonia. The response rate of informants was 42%. The sources of information represented in this group had only in exceptional cases a direct relation to the field of HTA. The concept of HTA was largely unknown in most countries comprising Group III.

Based on both the percentage of countries represented, the response rate of informants, the specificity of data sources and general reactions to the Survey, we conclude that at the level of groups of countries, the quality of data is likely to be highest in Group I, followed by Group II and Group III.

The quality of results in Group I has benefited most from the fact that the European Survey built on the ISTAHC Survey, and that results of the INAHTA Survey were made available to the Research team. The results in Group I have the highest probability of being representative given the acceptable representation of countries and response rates of informants and the relatively high share of specific HTA information sources (HTA agencies and universities).

Clearly, the results of the European Survey should be interpreted with caution in Group II, and even more so in Group III. The latter group represented less than half of the countries, it was difficult to identify informants and the specificity and response rates of informants were both rather low compared to the other groups.

At the level of individual countries, the reliability of data presented in this report could be checked for Denmark only, as only in this country a thorough nation-wide survey on education and training in HTA has recently been reported (Møller and Jørgensen, 1999). This publication, serving as a 'gold standard' indicated that the method applied in the European Survey provided nearly identical results with regard to HTA courses, but that the national publication was much more elaborate in the reporting of HTA-related courses. This finding may indicate that the results of the European Survey are only informative with respect to HTA courses. However, as it

is impossible to generalise from a single EU country to all countries in the survey, we feel that it is appropriate to state that considerable uncertainty and variability is likely with regard to the quality of data within and between individual countries.

Explanation of the HTA concept

Some difficulties have been reported concerning the distinction between 'HTA courses' and 'HTA-related' courses'. In one case it was explicitly reported that the distinction was unclear. In a few other cases the answers provided by respondents indicated an unintended interpretation of HTA courses, e.g. exclusively referring to physical examples of technology applied in clinical practice. One solution to this problem might have been to include a more elaborate definition of HTA, e.g. as provided by Banta in the EUR-ASSESS report (Banta et al., 1997). On the other hand, a longer manual would perhaps have induced non-response due to the longer time needed to complete the survey.

A related factor that may have influenced the results on the coverage of HTA courses is variability in the content of the concept of HTA, which can be related to cultural differences. The members of Working Group 5 explicitly pointed to the possibility that what is considered an HTA-related course in one country, could be considered as an HTA course in another country. The responses to the Survey did not directly reveal this factor, but if the results reflect different cultural understandings of what an HTA or an HTA-related course consists of, this may have led to either an under- or an over representation of HTA courses. A recommendation to avoid this in future surveys is to secure a common understanding of the concept of HTA. Education and training may achieve this.

The future of education and training in HTA in Europe

The prospects for education and training in HTA in the European Union are good. International collaborative structures aimed at organising HTA courses at different levels have been established in different parts of Europe, and one of these is actively supported by the EU (Dr. P. Gallo, personal communication, March 2001). Relevant initiatives have also been identified on a national basis, e.g. in Spain and the UK, and may serve as examples for other countries. Of the individual countries, perhaps Spain sets the standard of what can be achieved. Key characteristics may be the presence and collaboration of four, mostly regional, HTA agencies and the presence and collaboration with a Cochrane Centre. Spain provides a wide range of courses for a wide variety of target groups.

Likewise, prospects for the future development of education and training in HTA in candidate membership countries for the EU are good. Some of these countries, e.g. Poland and Slovakia, are already successfully making the transition to a market economy, and in some Eastern Europe countries, e.g. Poland, Hungary, Estonia and Latvia, HTA courses have been set up. Some of these countries, e.g. Latvia, collaborate successfully with more wealthy neighbours (in this case Sweden-SBU) to support the development of local HTA structures. Other countries with favourable geographical positions may follow this example, anticipating a future stimulating role of the EU in establishing HTA in the respective countries after having become regular EU

members. Both these 'pre-accession' countries and other Central and Eastern European countries have consistently expressed a need for co-operation with their Western European neighbours to "catch up".

The prospects for education and training in HTA in the group of 'other countries' are less clear. However, as data were scarce in most of these countries, perhaps a focussed effort could be organised to elucidate the supply of HTA education and training in greater detail. A likely explanation is, however, a (nearly) complete lack of supporting structures. An indication of this situation is the high level of interest that many countries in this group expressed in collaborating in the field of HTA. Fulfilling the needs of the countries in both Group II and Group III may very well be among the most important tasks for the European HTA community.

5 Recommendations

To stimulate the further development of education and training across Europe:

1 A clearinghouse for information on training and education in HTA needs to be established.

2 A distance-learning programme in HTA needs to be developed that is tailored to countries in Group II and, in particular, to countries in Group III.

3 Central and Eastern European countries should be adopted by EU neighbours in a concerted action.

4 In several EU countries, INAHTA member agencies, local universities and (if present) the local Cochrane Centre could play a stimulating role in this effort.

5 Priorities need to be set with regard to the development of courses for both doers' and ' users' of HTA at different levels.

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Appendixes

Appendix 1

European Survey – Questionnaire

Personal information

Please fill in the following information:*

Your name (and degrees): _____

Your position: _____

Organisation: _____

(include e-mail/web-site address if available): _____

* - Please fill in the computerised version of the questionnaire!

Questionnaire Part 1

Do you know of any institutions and professionals, other than yourself, providing a university level course in the area of Health Technology Assessment in your country? (please tick 'YES' or 'NO')

☐ YES (Please fill out table 1 below and then continue with Question 2)
☐ NO (Please continue with Question 2)

Table 1 Institutions and contact persons for providing university level courses in Health Technology Assessment

Institution and City	Course title	Contact person (please include e-mail/Web site address if available)

2 Are you, or is the organisation you are affiliated with, involved in teaching university level courses in Health Technology Assessment? (Please tick 'YES' or 'NO')

☐ YES (please continue with Questionnaire Part 2)

☐ NO (please return this Questionnaire. You do not have to continue with Questionnaire Part 2)

Questionnaire part 2

1) During the next 3 academic years, do you or does your organisation expect to teach a university level course in HTA?

☐ YES

☐ NO (continue with question 2)

If yes, please fill in the following tables and þ check appropriate boxes. Include anticipated starting date for courses currently being developed.

Course Title and Course Elements	Academic Level				Frequency					
	Undergrad MDs	Other Undergrads	Graduate	Other(specify)	Once a year	Twice a year	Every 2 years	Other (specify)	Total Course Hours	Offered Since(month/ year)
	☐	☐	☐		☐	☐	☐			
	☐	☐	☐		☐	☐	☐			/
	☐	☐	☐		☐	☐	☐			/
	☐	☐	☐		☐	☐	☐			/
	☐	☐	☐		☐	☐	☐			/
	☐	☐	☐		☐	☐	☐			/

2) During the next 3 academic years, do you or does your organisation expect to teach an HTA-related university level course?

☐ YES (please fill in the following tables)

☐ NO (continue with question 4)

Course Title	Academic Level				Frequency					
	Undergrad MDs	Other Undergrads	Graduate	Other(specify)	Once a year	Twice a year	Every 2 years	Other (specify)	Total Course Hours	Offered Since(month/ year)
	☐	☐	☐		☐	☐	☐			
	☐	☐	☐		☐	☐	☐			/
	☐	☐	☐		☐	☐	☐			/
	☐	☐	☐		☐	☐	☐			/
	☐	☐	☐		☐	☐	☐			/
	☐	☐	☐		☐	☐	☐			/

3a) How often do (will) your courses utilise the following information technologies?

Information Technologies	Never	Occasionally	Frequently
Internet (group discussion, literature searches, etc.)	☐	☐	☐
Other use of Computers (discussion, assignments, etc.)	☐	☐	☐
Videotaped presentation	☐	☐	☐
Live videoconference	☐	☐	☐
CD-ROM	☐	☐	☐
Other (specify)		☐	☐

3b) How often do (will) your courses utilise the following teaching methods?

Information Technologies	Never	Occasionally	Frequently
Traditional lectures	☐	☐	☐
Student Discussion/ Presentations	☐	☐	☐
Practicum /internship (e.g participation in an HTA project)	☐	☐	☐
Invited speakers	☐	☐	☐
Problem-based learning	☐	☐	☐
Other (specify)		☐	☐

4) Do you give continuing education courses in the area of HTA?

☐ YES ⇒ What authority grants credits for these courses? _____

☐ NO ⇒ Go to Question 6

5. Please indicate the subject, the participant group, the duration and the frequency of these courses :

Course Title	Participant group				Frequency					
	MDs	Nurses	Administrators	Other Health Professionals	Once a year	Twice a year	Every 2 years	Other (specify)	Total Course Hours	Offered Since(month/ year)
	☐	☐	☐		☐	☐	☐			/
	☐	☐	☐		☐	☐	☐			/
	☐	☐	☐		☐	☐	☐			/

6. May we contact you for more information? ☐ YES ☐ NO

7. Additional comments: _____

Thank you for your time

Manual to the Questionnaire

Please fill out the computerised version of the questionnaire!

This questionnaire is made up of two parts. The purpose of part 1 of the questionnaire is to obtain as much information as possible on HTA in your country. The most adequate way to achieve this is to approach the right persons in each country that can provide an overview of the supply of HTA or HTA-related courses. In part 1, we therefore kindly ask you to list names of institutions or professionals, other than yourself, that provide HTA or HTA-related courses. Part 2 focuses on the provision of HTA or HTA-related courses by yourself or by colleagues in your organisation.

What defines an HTA or HTA-related course?

An HTA course is multidisciplinary in nature and includes all or most dimensions relevant to HTA, including for example safety, efficacy, economic or financial aspects, and ethical, legal and social aspects of the use of a particular healthcare technology. In addition, issues such as the diffusion of technology in health care and the use of HTA in policy-making could be included in HTA courses in the broad sense of the word.

HTA-related courses have a more narrow focus than HTA courses (monodisciplinary) and include e.g. clinical epidemiology, evidence-based medicine, clinical trials, meta-analysis, economic evaluation, consensus conferences, technology management, decision-analysis, policy analysis, etc.

Manual to Questionnaire Part 1

1 Do you know of any institutions and professionals, other than yourself, that provide a university level course in the area of Health Technology Assessment in your country?

Yes:

It would be most helpful if you could provide us with the names of both the institution, the course title, and the name, e-mail address and/or website of a contact person, but if you only have partial information or a name and telephone number please fill in table 1 too. The Project Team will follow up on this.

No:

If you do not know of any institutions and professionals, other than yourself, that provide a university level course in the area of Health Technology Assessment in your country, please continue with question 2.

Manual to Questionnaire Part 2

Question 1 During the next three academic years, do you or does your organisation expect to teach a university level course in HTA?

For a description of HTA courses, see page 1 of this manual.

If you answer 'no', please continue with Question 2.

Question 2 During the next three academic years, do you or does your organisation expect to teach an HTA-related university level course?

For a description of HTA-related courses, see page 1 of this manual.

Question 3a How often do (will) your HTA courses utilise the following information technologies?

Question 3b How often do (will) your HTA courses utilise the following teaching methods?

Occasionally is defined as one or two times each course. Frequently is defined as at least three times each course.

Question 4 Do you give continuing education courses in the area of HTA?

Continuing education courses are defined as courses outside a regular university curriculum, usually aimed at specific groups of participants with a completed education. Examples of authorities that grant credits for these courses include Physician Societies and General Practitioner Societies.

Question 5 Please indicate the subject, the participant group, the duration and the frequency of these courses.

Other health professionals may include e.g. GPs, physiotherapists, dentists, etc.

Question 6 May we contact you for more information in the future?

If you allow us to contact you again, for example in case new courses are under development, this would be helpful when updating the survey.

Question 7 Additional comments

Feel free to add any comments on the Questionnaire, or to elaborate on any of your answers.

Introductory letter to the survey

University of Southern Denmark
Centre for Applied Health Services Research
and Technology Assessment
Winsløwparken 19, 3rd floor
DK-5000 Odense C, Denmark

Dear Sir, Madam,

We would like to ask your collaboration for a questionnaire on Health Technology Assessment[104] (HTA) training and education in your organisation and your country. Enclosed you find a two-part Questionnaire on these issues. This survey on HTA education and training is part of a new European Union supported programme supporting HTA activities in Europe (the European Collaboration for Health Technology Assessment). The overall programme is co-ordinated by the Swedish Council on Technology Assessment in Health Care (SBU) in Stockholm. The group on HTA education and training is co-ordinated by the Danish Institute for HTA (DIHTA) in Copenhagen. All organisations involved are non-profit. The results of the survey will be made publicly available and are aimed at a better match of supply and demand in the field of HTA education and training in Europe. In addition, the information will be helpful for the HTA community in identifying needs for co-ordination and/or support for educational provisions.

It could be that you or the organisation that you are affiliated with is not involved in HTA or HTA training and education. In that case we would still appreciate your co-operation, because maybe you know other professionals or institutions that could be of help for us. Please return the questionnaire before the 6th of March. To assist in correctly filling out the Questionnaire, we enclose a brief manual. If any questions remain or if you have any additional remarks, please do not hesitate to contact the EU Survey Project Team. Thank you very much in advance for your co-operation.

Yours sincerely, on behalf of the European Survey Project Team,

Karla Douw
HTA researcher
tel + 45 65 50 30 86,
fax + 45 65 91 82 96, e-mail: kdo@cast.sdu.dk

[104] 1HTA is research that examines short and long term consequences of the application of a health care technology (e.g. clinical, economical, societal, ethical, and legal consequences) with the aim of providing input to a policy decision. It concerns health care technologies in a broad sense, for the purpose of prevention, diagnosis, treatment and rehabilitation and in all phases (future, new, and widespread technologies).

Appendix 2 – Members of Working Group 5

Chair
Prof. Dr. Finn Børlum Kristensen
Centre for Evaluation and Health Technology Assessment
Copenhagen, Denmark

Vice-chair
Prof. Dr. John Gabbay
NCCHTA
University of Southampton, Southampton

Pedro Gallo, MD, MSc, PhD
CAHTA
Barcelona, Spain

Heiner Raspe, MD
Medical University of Lübeck
Institute for Social Medicine
Lübeck, Germany

Prof. Dr. Mona Britton
Swedish Council for Health Technology Assessment (SBU)
Stockholm, Sweden

Prof. Lycourgus Liaropoulous
Center for Health Care Management and Dev.
University of Athens, Department of Nursing
Athens, Greece

Gert Antes
Director, Deutsches Cochrane Zentrum
Freiburg, Germany

Dr. Aidan Synnott
Beaumont Hospital
Beaumont Road
Dublin, Ireland

Alessandro Liberati
Mario Negri
Milano, Italy

Dr. Eduardo Briones
Andalusian Agency, AETSA
Sevilla, Spain

Prof. Bengt Jönsson
Stockholm School of Economics
Centrum för hälsoekonomi
Stockholm, Sweden

Prof. Marjukka Mäkelä
FinOHTA
Helsinki, Finland

Associate Professor Carlos Gouveia Pinto
Instituto Superior de Economia e Gestao
Technical University of Lisbon
Lisbon, Portugal

Bo Nordby Jensen
Hospitalslaborantskolen i Århus
Århus, Denmark

Dr. Gerard Engel
Association of University Hospitals
Utrecht, The Netherlands

Associated Members:
Dr. Bernard Burnand
Institute of Social- and Preventive Medicine
University of Lausanne
Lausanne, Switzerland

Krzysztof Landa, MD
National Center for Quality Assurance in Health Care
Krakow, Poland

Dr. Audrone Piestiniene
Assistant to the Minister of Health
Vilnius, Lithuania

Miriam Ines Siebzehner, RN, MA, MPA
Israeli Center for HTA
The Getner Institute
Tel Hashomer, Israel

Appendix 3

Personal Comments of Respondents

Kyrgyzstan - Institute of Health Care management and Public Health

Does expect to teach HTA university level course in next 3 years

Austria – Institute for Technology Assessment

On university level, EBM/Cochrane courses are still rare in Austria, but will be offered/attended more in the future. Since there is no university level education for public health or health economics there is 'no place' to fit in for HTA. But: HTA-courses will gain importance as training tools for hospital managers, for health/social insurance-managers, for ministry members.

Armenia - National Institute of Health, School of Health Care Management and Administration, Yerevan

Will be glad to participate and contribute HTA initiatives.

Lithuania - State Health Care Accreditation Service, Vilnius

I would like to teach a university level course in HTA. I would like to know if it possible to teach both courses. The Faculty of Medicine in Vilnius is also interested in the participation in this program. I had a talk with the Head of Department.

Cyprus - University of Cyprus, Nicosia

The University of Cyprus does not have medicine or related subjects and hence does not offer any courses. HTA is carried out by the Biomedical Research Foundation, but we do not provide courses. We try to evaluate technology from an engineering-user view-point. The area of HTA is new to Cyprus and no real work is being done on this issue. When purchasing equipment we use international standards and specifications and try to rely on the work of other bodies. We do not do any of our own. Even the Cyprus standards adopt the IEC ones.

Scotland - Health Technology Board for Scotland, Glasgow

The HTA board was set up 6 months ago. The organisation is in the stage of recruiting appraisal staff. At the moment I have no information for the survey. I would be grateful if you could consider us for future involvement in your European work.

Yugoslavia - Institute of Public Health Novi Sad, Novi Sad

We are very interested in collaboration with ECHTA, so we kindly ask you for more information about HTA or HTA-related courses (who and when can organise them in our region, how to

supply financial resources etc.). We would be very pleased if you should inform us about that. We will appreciate for your co-operation.

Ukraine – Odessa State Medical University, Social Medicine and Health Care Management Department

Thank you for possibility to take part in European program on the Effectiveness control of medical technology. We need more information about the project and its participants. Please advise.

Training and Education in HTA in Europe – translating recommendations into practice

Introduction

Education in HTA has been receiving increasing attention for several years. It seems apparent that sufficient educational resources are not available. An indication of this is that HTA agencies themselves are increasingly involved in education, although this is not their primary mandate. This constitutes a need to identify the needs for HTA training, relevant target groups and existing training and education programmes in Europe. Support networks are particularly critical for those who are attempting to start HTA in countries where the field is new, for example in Eastern Europe. Another imperative seems to be the need for co-ordination of existing efforts in the field.

Working Group 5 on training and education in Europe was established as one of six working groups under the ECHTA project umbrella to address problems and suggest solutions.

The objectives of Working Group 5 are:

1. To identify available programs and educational resources
2. To identify target groups
3. To conceptualise the needs of these groups and develop a curriculum
4. To assist in the development of new provisions to address shortcomings
5. To participate in co-ordinating education and support activities in Europe
6. To develop a framework for support from the network to groups, institutions, countries in the process of entering the field of HTA

The first two objectives and part of the third objective were addressed by conducting a survey on training and education activities in HTA in Europe, i.e. the Working Group 5 survey report "Training and Education in Europe".

The remainder of the objectives, and what could be called the objectives with a less analytic but a more operational focus, are addressed in this document by suggesting ways to implement the recommendations given as a result of the survey.

The survey

Working Group 5 decided to survey training and education activities in Europe. A questionnaire was developed based on the ISTAHC questionnaire to insure compatibility with ISTAHC[105] data.

[105] International Society for Technology Assessment in Health Care

Furthermore an agreement on data sharing was made with ISTAHC and INAHTA[106] . ISTAHC had conducted a similar survey a year earlier, and INAHTA had, parallel to Working Group 5, conducted a complementary survey on training and education offered by the HTA agencies themselves.

The (preliminary) results of the Working Group 5 survey are described in Part 1 "HTA Education and Training in Europe" by Douw, Vondeling and Bakketeig. This paper provides valuable information on training and education activities in Europe.

Supply of training and education in HTA

According to the survey, the supply of education and training in HTA is rapidly increasing. However, approximately half of all European countries (WHO definition) do not supply HTA courses, and the overall picture is rather scattered and with large variations in supply and quality - even within the European Union. Spain is without doubt the spearhead in Europe with an impressive supply of courses, while in contrast practically no courses are offered in Central and Eastern Europe, with the exceptions of Poland, Hungary, Estonia and Latvia (the two latter possibly due to Swedish support).

Parallel to the increase in supply of HTA courses, an even more rapid increase can be observed in the supply of HTA-related courses[107].

Content of courses

The content of courses varies greatly both within and among countries, and with few exceptions the picture must be characterised as scattered and poorly co-ordinated.

Teaching methods are largely traditional, and the integrative potential of the Internet seems to be more or less unexplored.

Translating recommendations into practice

Based on the survey report, on discussions in Working Group 5 and the results of a workshop in Copenhagen, March 2001, the working group agreed on seven recommendations on how to improve the supply, quality and co-ordination of training and education in HTA in Europe.

1. A common methodological framework for training and education in HTA in Europe should be developed.

[106] International Network of Agencies in Health Technology Assessment

[107] An HTA course is multidisciplinary in nature and includes all or most dimensions relevant to HTA, including, e.g. safety, efficacy, economic or financial aspects, and ethical, legal and social aspects of the use of a particular healthcare technology. In addition, issues such as the diffusion of technology in health care and the use of HTA in policy-making could be included in HTA courses in the broad sense of the word.

HTA-related courses have a narrower focus than HTA courses (monodisciplinary) and include, e.g. clinical epidemiology, evidence-based medicine, clinical trials, meta-analysis, economic evaluation, consensus conferences, technology management, decision-analysis, policy analysis, etc.
Definitions from the survey material

2. A common European curriculum as a basis for training and education in HTA at the university level should be developed.

3. A clearinghouse for information on training and education in HTA needs to be established.

4. A distance-learning programme in HTA needs to be developed that is tailored to economies in transition.

5. Central and Eastern European countries should be adopted by their EU neighbours and friends in a concerted action.

6. In several EU countries, INAHTA Agencies, local universities and professional organisations could explore this line of co-operation.

7. Priorities need to be set with regard to the development of courses for both 'doers' and ' users' of HTA at different levels.

Re 1+2) A basic HTA course and a European Master of Science in HTA

The survey concludes that a great variety of courses exist, and that the overall pattern is scattered at both the international and national levels.

The more work we do across borders, the more we utilise the work done in other countries. The more we put these results into our own national contexts, the more we need a common understanding of HTA at a fundamental and basic level – not only to ensure that we can communicate across borders, but also to ensure that the quality of the work we do lives up to certain agreed upon standards.

The way we teach HTA has importance for the way we utilise the skills taught. Hence, the tasks vested in Working Group 5 constitute an opportunity to promote a high international standard of training and education in HTA, an opportunity to promote a common international understanding of training and education and an opportunity to ensure a high level of compatibility.

A means to this end is to suggest the development of a common and agreed upon methodological framework for training and education in HTA in Europe; a methodological framework that can be used in introductory-level courses and in university-level courses. Such a methodological framework could be used as a general recipe for what an HTA course must consist of – a common denominator that should apply to all HTA courses. Such a core content course should be developed in terms of minimum demands, and hence by thinking in ways of learning objectives. To ensure methodological compatibility, it is recommended, that the development of such a basic course builds on key elements of a future European Master of Science (MSc) in HTA (see below).

Another means is to develop a common curriculum for a European Master of Science degree in HTA. **An outline for such a European Master of Science in HTA is presented in Part 3 of the Working Group 5 report, i.e. "Towards a European Master of Science in Health Technology Assessment".**

The short term objective of a European Master in HTA is to provide for training in HTA that draws on the present skills and courses in HTA of universities and HTA agencies across Europe. This base can be used to further develop core skills that are increasingly common to several nations in the European Union. The programme allows students to train mainly in their own countries, but encourages short term exchange with other European countries by providing courses within the network to suit this purpose.

The long-term objective of EMHTA is to generate a cadre of professional health technology assessors that is able to share a common European understanding of HTA, that is aware of both the individual characteristics and common interests of European countries and their historical and cultural roots, and that can systematically and competently refer to and conduct valid and appropriate assessments within and across European health systems.

Briefly stated: The *short-term purpose* is to guarantee that the scope and level of competencies are equivalent across Europe. The *long-term purpose* is to guarantee that the scope covers the most relevant HTA issues in Europe and EU health-related policies.

One way to introduce a European Master of Science in HTA would be through a pilot programme in several countries experienced in HTA. Building on experiences from a pilot programme, the MSc in HTA could be implemented more broadly at the European level.

To assure the quality of a European MSc programme in HTA, the document suggests the establishment of a European HTA Education Board comprised of, e.g. skilled educators, health technology assessors and professionals with knowledge of HTA at the European level.

Re 3) A clearinghouse on training and education in Europe

General co-ordination of training and education initiatives in Europe must be considered a first priority. It seems an obvious conclusion to suggest the establishment of European clearinghouse for training and education.

This suggestion is targeted at both content and supply aspects of training and education in Europe. First, such a clearinghouse would help promote compatibility among the variety of European initiatives on training and education. Second, a clearinghouse could function as a valuable instrument in supporting the growing supply of training and education, especially in Central and Eastern Europe.

The establishment of a clearinghouse for education and training should be carefully co-ordinated with the general recommendations for co-ordination and clearinghouse facilities suggested by the ECHTA project.

Re 4) A distance learning programme

Concerning the development of a distance learning programme, it is important not to duplicate work already done. Hence, it is suggested to await the results of the ISTAHC distance learning project.

Re 5+6) Supporting HTA in Central and Eastern Europe

The survey clearly shows that important target groups are "HTA newcomers" from the Central and Eastern European countries. There seems to be a specific need both in terms of the content and supply of training and education in these countries.

Content

Only a couple of Central and Eastern European states provide HTA courses, and the provision of HTA-related courses also seems to be scarce. Therefore, efforts to promote HTA training and education cannot be separated from initiatives to support the provision of HTA-related courses. It seems premature to focus exclusively on "genuine" HTA courses if the basis for these multidisciplinary courses only exists to a modest degree. This calls for a broad-based approach to the needs of these countries.

Supply

The supply of training and education seems very much to correlate with the level of the organisation of the HTA efforts in general. Hence, efforts to promote training and education in Central and Eastern Europe should be carefully co-ordinated with the general support to HTA initiatives in this region.

In general, it could be suggested to follow a two-track strategy; on one hand supporting the bottom-up efforts to provide the necessary supply of HTA and HTA-related courses, and on the other hand supporting the top-down efforts to build local structures for HTA. Both, but especially the latter, should be done in close co-operation with the general effort to promote HTA in Central and Eastern Europe.

"Adoption"

The survey itself and comments given in the questionnaires express need from the Central and Eastern European countries for co-operation with HTA experienced countries.

The survey shows that the "adoption" of HTA newcomers by experienced countries, agencies etc. has had a positive effect on the number of training and education activities. To date, this "adoption" has been relatively unorganised and based on the initiatives of specific individuals and/or agencies.

A network based on the suggested clearinghouse for training and education could provide a basis for well co-ordinated support to HTA newcomers. It is, however, recommended to highly

involve the WHO European Regional Office in the general support to Central and Eastern European countries, and perhaps WHO could even assume a co-ordinating role. It should, however, be emphasised that such a network/clearing house should function complementary to – and as a co-ordinated strengthening of – the bilateral relationships between countries, agencies etc, and not as an alternative. The aim should not be to transfer the valuable bilateral relationships into another structure, but instead to ensure that the efforts are well co-ordinated – especially among the countries experienced in HTA.

Re 7) Development of courses for users of HTA

The survey clearly shows that only a few of the programmes offered distinguish between courses for "doers" and courses for "users" of HTA. The survey also shows that even if the supply of HTA courses is increasing rapidly, the courses targeted at "users" have not been a priority in this process. Clearly, this represents an important shortcoming and requires attention.

It is suggested that a two-track strategy be used to address this shortcoming.

First, the communication of HTA and HTA results from "doers" to "users" should be a priority and an important and necessary element of any education and training in HTA. Very often "users" (and especially decision makers at the political and administrative levels) do not possess the necessary skills to interpret an HTA report, and very often "doers" do not possess the necessary skills to communicate HTA results to decision makers.

Second, the introductory courses in HTA should be offered to decision makers at all levels, prioritising the "user approach" for appraisal of HTA results. Such courses should be viewed not only as part of a training and education strategy, but should be considered an implicit element in the overall promotion of HTA.

Towards a European Master of Science in Health Technology Assessment

1. Introduction and objectives

As documented by the ECHTA Working Group 5 survey on education and training in health technology assessment (HTA) in Europe (1), there is an obvious need for better training in HTA. A potential way to secure better training in HTA is to organise a European Master of Science (MSc) programme in HTA. The time is right for such an initiative, not only because the need for such an educational programme has been identified by the survey referred to above (1), but also because HTA in Europe has evolved into a thriving community, with increasing individual, local and national needs for collaboration, exchange of knowledge and construction of a common core of knowledge to serve a future generation of assessors in policy and practice. These factors, in combination with the survey results, suggest that there is both a need and a basis for developing a European MSc in HTA.

Notwithstanding the lack of a European MSc in HTA, initiatives have been employed to establish an international MSc programme in HTA (the Ulysses Project). However, within the EU this effort is limited to Spain and Italy. Although two national MSc programmes in HTA have recently been established, in Spain and the United Kingdom, each of these has its own focus and fits into its respective national health care system.

In light of these data and the discussions that followed, the ECHTA Working Group 5 and the ECHTA Steering Committee reached a common view on how to attain both the short-term objective of improving education and training facilities in HTA in the European Union and the long-term objective of creating a cadre of health technology assessors in member states with a common European understanding.

It was agreed that a European Master of Science degree in Health Technology Assessment (EMHTA) can be realised by building on a network model. The degree will be conferred by a network of institutions (universities and HTA agencies) that each run part of a Master of Science educational programme.

The short-term objective of EMHTA is to provide training in HTA that draws on the present skills and courses in HTA of universities and HTA agencies across Europe, which can be used as the basis for developing core skills that are increasingly common to several nations in the European Union. The programme allows students to train mainly in their own countries, but encourages short-term exchange with other European countries by providing courses within the network to suit this purpose.

The long-term objective of EMHTA is to generate a cadre of professional health technology assessors that is able to share a common European understanding of HTA, that is aware of both

the individual characteristics and common interests of European countries and their historical and cultural roots and that can systematically and competently refer to and perform valid and appropriate assessments within and across European health systems.

Briefly stated: The short-term purpose is to guarantee that the scope and level of competencies are equivalent across Europe. The long-term purpose is to guarantee that the scope covers the most relevant HTA issues in Europe and EU health-related policies.

Furthermore, a European Master of Science programme in HTA will constitute a bottom-up approach to the general co-ordination of HTA and hence be a valuable contribution to the overall objective of the ECHTA project.

The ideas about the content and structure of the programme, as presented in section 2 below, build on the findings of a survey on HTA education and training in Europe (1). It recognises that a 'European' Master of Science programme in HTA should have a European component. In formulating these requirements the present document has benefited largely from a document published by the Association of Schools of Public Health in the European Region (ASPHER) on the issue of the establishing a European Master of Science programme in Public Health (2).

The content of any educational programme should bear a close relationship to the defined acquisition of knowledge and skills of the students at the conclusion of training. In the case of the European MSc programme in HTA, at the end of their training the graduates should:

1. Share a basic understanding of HTA, being aware of significant affinities and differences among European countries and their historical and cultural roots.
2. Consider European perspectives in their approach to any HTA issue, when appropriate.
3. Be able to support decision-making across health systems in the European Union
4. Be able and ready to systematically and competently refer to information on health technology and health policy issues that are relevant at the level of the European Union.

To achieve this purpose, a proposal is presented for a general structure of the programme. This is followed by a description of core principles for European degrees and how to achieve a European dimension in the programme. Then the issues of assuring quality and recognition of European degrees are addressed. Finally, an outline is provided of the role and organisation of the network of organisations involved in realising the programme.

2. General structure and content of a European Master of Science in Health Technology Assessment

2.1 Introduction

The 2-year programme is divided into a first year that has a theoretical orientation requiring only a part-time effort by the students, and a second year that has a practical orientation requiring a full-time effort. A starting point is to use the European Credit Transfer System (ECTS) to describe the workload of the programme. The assumption is that one credit is approximately

equivalent to a student workload of 25 to 30 hours, a full academic year is then equivalent to 60 ECTS.

2.2 Main general areas in the first year (core areas)

The student workload should be about 630 hours, 21 ECTS, achieved by 210 contact hours.

The EMHTA covers 5 main areas (compulsory courses), described below. A European dimension should be incorporated into each of these courses.

Course structure:

1. HTA principles and practice

Introducing HTA as a process or system, as a multidisciplinary policy oriented science, assessing one or a combination of relevant aspects of technologies. Introducing HTA as an international activity, but emphasising the European Union. Introducing the European Union, its institutions and its diversity in the health field.

2. Introduction to public health, epidemiology and biostatistics

Introduction to public health, history of public health in Europe, historical trends in major causes of morbidity and mortality, and differences within Europe in major determinants of morbidity and mortality.

Introduction to basic epidemiology and statistics, types of data and data presentation, descriptive statistics, frequency distributions, mean, median and normal distribution and its properties, probability theory, sampling inferential statistics, inferences on means and proportions, analysis of categorical data, correlation and regression and assessment of risk.

3. Introduction to health economics with an emphasis on economic evaluation of health care programmes

Introduction to health economics emphasising the significance and relevance of health economics in the present health environment in the EU. Introduction of basic concepts in economics: scarcity, choice, opportunity cost, supply, demand, markets, public goods and non-market provision. Overview of economic evaluation; framework for and outline of economic evaluation methods: cost-minimisation analysis, cost-effectiveness analysis, cost-benefit analysis. The identification, quantification and valuation of costs. The determination, measurement and valuation of outcomes, including monetary benefit evaluation (willingness-to-pay approaches) and health-related quality of life measurement and valuation. Introduction to uncertainty, sensitivity analysis, decision analysis and equity in the finance and delivery of health care.

4. Methodological basis of HTA

Methods for identifying technologies, priority setting for assessment, testing (primary data collection), synthesis (including clinical appraisal, narrative and systematic reviews, meta-analysis) and formulation of recommendations, dissemination and implementation of assessments (guidelines, audits, consensus conferences etc.). Primary data collection and the subsequent steps include the following aspects of a technology: safety, efficacy, effectiveness, ethical, legal, social, educational, organisational and wider cultural aspects, where appropriate emphasising the context of the European Union. Methods for the study of the diffusion of technology, distinguishing adoption and use.

5. Introduction to health policy

Policies towards research and development in the health field, towards clinical experiments, and towards publication of research results; policies towards market approval, towards education, training, certification and accreditation; planning policies, policies towards cost containment, e.g. including budgets, investment controls and payment policies; policies towards dissemination and implementation of assessments and policies towards consumer information.

It is proposed to consider what type of concrete ways could be used in each area to introduce an effective European dimension in the objective/content of the courses (see section 4).

The student workload for each of these five core modules should be at a minimum of 90 hours (equivalent to 2 full weeks or to 3 ECTS credits). Therefore, a minimum 15 ECTS credits will be devoted to the main areas including the study of the European component.

2.3 Advanced modules

Each institution will offer its own advanced courses in each of the five main areas of HTA; the exact content of these courses has yet to be defined. Each student should choose at least two of the five advanced courses in the main areas of HTA; this component of the MSc programme in HTA may represent up to a maximum of 6 ECTS credits.

The structure of the first year is illustrated in Table 1.

Table 1. Structure of a European Master of Science Programme in HTA (first year)

Compulsory courses (level 1) and elective courses (level 2)			
Modules/Course title	Contacthours	Student workload	ECTS Credit
1 HTA Principles and Practice (I and II)	30 (30)	90 (90)	3 (3)
2 Public health, epidemiology and biostatistics (I and II)	30 (30)	90 (90)	3 (3)
3 Health economics andeconomic evaluation (I and II)	30 (30)	90 (90)	3 (3)
4 Methodological basis for HTA (I and II)	30 (30)	90 (90)	3 (3)
5 Health Policy (I and II)	30 (30)	90 (90)	3 (3)
Total	150 (150)	450 (450)	15 (15)

2.4Thesis (second year)

As writing a thesis constitutes an important part of the learning process and should remain close to the interests of the students and the availability of material etc., it is important to leave room for variation and then to organise a review mechanism which will guarantee that it meets the general purpose of the European MSc in HTA. To some extent, the thesis should demonstrate the competence acquired in the "European dimension". The thesis should represent 60 ECTS credits (one-year full-time), with 30 to 60 contact hours.

3. Core principles for European degrees

Suppliers of HTA courses in Europe have a diverse history and purpose, distinguishing universities and HTA agencies, some of which function under governmental auspices while others are more free-standing. Likewise, the periods and styles of training vary widely, as (likely) do the standards of training. It can be expected that universities and HTA agencies that are interested in (the development of) a curriculum of a MSc in HTA will only participate enthusiastically if this does not require radical changes to the models of teaching, or rules for assessment and examination of students. Changes in the scope of subjects taught must retain an adequate focus on general health technology assessment training, while ensuring that the European dimension, as outlined below, is satisfied. Conforming to this line of reasoning, the proposed first step in the development of European degrees based on this resource is to concentrate on ways to develop good quality and relevant training that fits in with current practice. Universities and other legitimate degree-giving bodies would retain responsibility for the award of qualifications.

Institutions that participate in a network may be best suited to develop a European curriculum. If HTA agencies are involved, universities should be consulted to secure quality issues, and the universities and other legitimate degree-giving bodies should retain the responsibility for the award of qualifications that are valid both in individual Member States and throughout the European Union.

Adding a substantial European dimension to successful HTA courses through, e.g. strengthening core modules, sharing optional modules within and across institutions, exchanges and joint projects/thesis, will enhance learning opportunities for students and could lead to useful collaboration among staff.

4. Defining the European dimension

Two kinds of knowledge are necessary for a training programme to be deemed European. First, since health technology assessment respects no boundaries, especially in an area with free movement of capital, technology and, increasingly, of labour, it is important to have some understanding of health technology assessment problems in countries other than the student's country of origin. This pertains to the European level and recognising that the institutions of Europe, most notably but not exclusively the European Union, have an increasingly important

effect on health, health technology and health policy. Second, some understanding of the cultural diversity within Europe is needed and will be best acquired if students spend some time in countries other than their home countries, e.g. by attending courses or course modules in different countries.

Where feasible, it is best for a general introduction to the European content to be embedded in teaching of general health technology assessment principles and practice (course 1). It is suggested to establish a European HTA Education Board to define the content of the European dimension (see sections 5, 6, 7 and 8).

5. Guaranteeing quality

As mentioned earlier, it is suggested to establish a European HTA Education Board. The main tasks vested in this board will be to ensure the quality of the programme(s) and to approve the European HTA degree. The board must include skilled educators and health technology assessors, including professionals with knowledge of health technology assessment at the European level. The board could be organised as a sub-committee of a future European Network for HTA. Furthermore it is imperative to ensure close co-ordination between such a board and the ISTAHC committee on education.

It is envisaged that designation of the Master of Science in HTA as an approved European degree will give significant recruitment and marketing advantages to those universities that are approved by the European HTA Education Board.

It is important to ensure that approved courses provide relevant and good quality training. In practical terms, this means that there must be mechanisms in place that ensure scrutiny of quality and content of teaching.

The peer review process as employed by the Association of Schools of Pubic Health in the European Region (ASPHER) could be used as a template for this purpose at the level of the educational programme as a whole. For individual courses, modules or the thesis, an ad hoc review of documents by external reviewers selected within the network may be more appropriate. In a way this process will then be analogous to the well-established review of papers submitted to a periodical.

6. Recognition of European degrees

It is important for the process of recognition of degrees to be transparent and fair. The aim is not to restrict access to such degrees, but to ensure that approved programmes are relevant and of high quality.

The process of approval should involve a preliminary application and interim approval only when the Board is satisfied that the programme can meet the criteria. Full approval would be given only when feedback from the first students is available and would be renewed on a 5-year basis.

Membership of the network will not in itself guarantee that the programme will be immediately approved as meeting the requirements for designation as a European degree.

It is important to maintain an appropriate balance between the European dimension of the programme and its scientific content since the Master of Science must meet both national requirements and European requirements. It is therefore suggested that, as a target, the content of European dimensions should represent at least 20 % of the learning time in a European degree. This percentage is inspired by and identical to a similar norm in a European Master of Science in Public Health (2). It should be noted that it constitutes a yardstick to be assessed by reviewers of each programme.

In summary:

- Students register in the institution where they want to spend most of their study time, called the "host institution".
- The degree is delivered by the institution in which the student is registered, following its own regulations. These will be examined by the European HTA Education Board and will be made explicit about the parts of the programme which have to be done in other institutions.
- Some learning activities have to be taken in any of the other participating institutions and perhaps even outside these institutions. The learning activities have to be recognised as “European” in part or in total by the Board.
- The degree is validated by the European HTA Education Board on the basis of the principles defined in this agreement: i.e. a minimum of 20 % of “European” dimension in the general HTA curriculum.

7. Role and organisation of a network of pilot programmes

The first stage of development of the MSc programme is to identify universities and HTA agencies that wish to ‘host’ European degrees. Each participating institution should agree:

1. To accept students from other universities in the network for one or a range of courses, and
2. To accept students for project or dissertation study from other institutions in the network.

In addition, ‘host’ institutions may wish to form partnerships on a bilateral basis with universities outside the network who wish to provide opportunities to take individual courses or for project study, but which do not at this stage wish to be part of the network.

An incremental development scenario is suggested, starting with the organisation of one or more ‘European modules’ to be offered to the students choosing to follow this curriculum. Based on a credit system whereby the students can have these courses recognised as part of their national educational scheme or a possible, future European Master of Science certificate, these modules

should add up to the student's normal curriculum, until meeting the prerequisites for the European Master's education. The use of the European Credit Transfer System (ECTS) is suggested.

8. Recommendations

8.1 Recommendations for participating institutions in the network

Each institution should prepare and submit its specific and individual proposals for its own (series of) modules (including placements and thesis) for which the specific objectives will show a European dimension.

The learning material and sources of information should be recorded by the contributing institutions in a database and made accessible to all partners.

Each institution should nominate a contact person to the European HTA Education Board to address the "European dimension" in the EMHTA. This contact person assists and supervises its implementation within the programme.

Each institution should develop a series of examples of various ways to implement the general recommendations of the European HTA Education Board on the European dimension of the course modules

8.2 Recommendations at the level of the network

The network should compile the advantages and disadvantages, conditions and obstacles for exchanges of students, teachers and learning material.

The network should refine the European Credit Transfer System to allow the system to support a quality monitoring system that goes beyond its present administrative value.

The network should facilitate the exchange, storage and retrieval of national and/or regional information on HTA issues including course material specifically covering the European dimensions.

8.3 Recommendations for the tasks of the European HTA Education Board

A register of courses submitted by institutions will be organised and maintained by the European HTA Education Board and made accessible to everyone (submitted, reviewed, recommended, recognised).

The European HTA Education Board formulates recommendations on the European dimension of the compulsory and elective course modules

The European HTA Education Board formulates minimum requirements for assessing language skills of candidates and specifies entrance criteria.

8.4 Recommendations to the European Union

The European Union could financially support the establishment of a European HTA Education Board and could provide means to enable the institutions that collaborate in the network to develop coherent and high-quality teaching material and courses.

9. References

1. Douw K, Vondeling H, Bakketeig LS. HTA education and training in Europe. Centre for Applied Health Services Research and Technology Assessment (CAST), University of Southern Denmark, Odense, Denmark, 2001.

2. A European Union Programme for promoting the development of a European Union perspectives in the training programmes in public health. Second phase, 97-99. Final report. ASPHER, May 1999.

Working Group 6
HTA in Policy and Practice

To identify and share successful approaches to link findings of assessments, and their contribution to health indicators and to health care decision-making

Working Group Members

Chris Henshall (Co-Chair)
Pedro Koch (Co-Chair)
Georg Carl von Below
Albert Boer
José L Conde-Olasagasti
Andrew Dillon
Bernhard Gibis
Roberto Grilli
Charlie Hardy
Lycurgos Liaropoulos
José M Martín-Moreno
Risto Roine
Tore Scherstén
Odd Søreide
Maya Züllig

Summary

In line with the EUR-ASSESS report on priority setting, Working Group 6 decided to focus on the users of HTA, exploring the links between HTA and decision-making. The members of Working Group 6 agreed on a pragmatic approach to assess the impact of HTA in European health care systems and discussed the practicalities of organising workshops to involve decision-makers at the health policy-making level and leaders at the hospital level.

Approaches

Working Group 6 approached the objectives in two ways.

First, two groups of academic researchers were contracted:

- One to carry out a systematic literature review of published papers addressing the linkage of HTA to decision-making.
- One to identify and map decision-making bodies throughout European health care systems. The effort aimed to explore the role of HTA in these institutions and provide a list of potential users of HTA, which would allow networks of decision-makers to be established.

Second, decision-makers at two different levels were identified: the health policy-making level and the hospital level (hospital leaders). The group focused on decision-makers who already use (or attempt to use) HTA to inform and support their decisions. These individuals were identified mainly through contacts from Working Group members and through research undertaken by a third contracted academic researcher.

The individuals identified were invited to participate in the one of the two workshops dedicated to their decision-making level. The aim of the workshops was to gather first-hand information on the role of HTA at different levels of decision-making. The workshops also offered the opportunity to explore the need for a network of decision-makers and to take the first steps towards its establishment. The workshops followed a structured design that included an evaluation tool.

Results

1. The overview of the published literature shows that in general the type of information the Working Group focused on is not published in academic papers, but in Federal registers and gazettes, which are not part of the traditional academic database such as Medline or Embase. The overall result of the report was that the usage of HTA has reached different stages in European health care systems, but even for countries with long tradition of using and implementing HTA, concrete examples of the impact HTA are sparse.

2. A consistent amount of information providing a promising start on behalf of the anatomy of decision-making in Europe was gathered in the second report. Since the published literature does

so far not focus on the anatomies of health care systems and particularly not in a comparative way it was necessary to conduct interviews with knowledgeable people of European health care systems. This aim was achieved best for the countries the authors had in-depth knowledge and in a lesser extent for those countries, where additional information had to be gathered via interviews.

3. The first workshop gathered 15 health policy-makers from ten European countries. In a combination of countries presentations and the presentation of case study it became quite obvious that countries indeed consider HTA very differently, given that the social structure has tremendous influence on how HTA can be used in policy making. The participants decided to enhance contacts through an informal network via e-mail or protected web-areas.

4. In the second workshop, 28 people discussed topics related to hospitals and HTA, including financial coverage. Furthermore, they proposed to establish databases on successful implementation and an electronic notice board to share ideas and general communication among health care professionals in hospitals. An implementation group was formed to develop a structure for the implementation databases.

Conclusions and recommendations

Decision-making structures are exposed to HTA only to a very limited extent. HTA is not yet sufficiently rooted in European decision-making structures despite the efforts of predecessor programmes, e.g. EUR-ASSESS. Although HTA reports may be excellent from an academic and research perspective, this does not automatically translate into an impact for the reports. Raising the impact of HTA through input by decision-makers is of paramount importance.

™ Inclusion of the HTA users' perspective (health policy-makers, hospital leaders, patients' organisations, industries) from the very beginning of the assessment will considerably raise the understanding of the decision-making process and philosophy and the acceptance and implementation of the findings.

™ Further in-depth research on the structure of European health care systems with respect to their decision making anatomy to identify decision nodes where HTA can contribute relevant information. Ideally this would be undertaken with the support of knowledgeable representatives from all European countries, i.e. European Union and observer countries.

™ Further stimulation and support of informal networks of decision makers via the implementation of a clearinghouse which facilitates notice boards, contact databases and meetings.

Introduction

A remarkable amount of money was spent in recent years on HTA in Europe, both on a national and on the European level. While HTA seems to offer a plausible way to improve the outcomes in daily health care delivery, the experiences of HTA users and the assessment of the impact of HTA in European health care systems have not been the focus of European HTA programs. To integrate a user perspective, the ECHTA initiative included a Working Group comprised of HTA producers and users. The objectives of Working Group 6 were consequently as follows:

Objectives

- To outline current initiatives among users of HTA in European countries to improve transfer of HTA findings to policy and practice.
- To identify groups of users (e.g. hospitals, guideline developers) who might benefit from networking to share experience.
- To test the value of networking through one or more workshops.
- To recommend future action and structures to support users of HTA in Europe.

Methods

The members[108] of Working Group 6 and their co-chairs Chris Henshall and Pedro Koch, representing eleven European countries and all experts in the area of implementation , met on three occasions: June 18, 2000 in The Hague; March 2 and 3, 2001 in Athens and informally June 3, 2001 in Philadelphia. Their methods and proceedings were revised and approved by the Steering Committee of ECHTA/ ECAHI: June 18, 2000 in The Hague, January 13, 2001 in Seville and May 18, 2001 in Stockholm.

To achieve the above-mentioned goals, the Working Group undertook two principal measures:

1. The first measure was intended to gather relevant information on the anatomy of European health care systems and on the impact of HTA in Europe to date. This information was sought by outsourcing contracts to academic researchers.

2. The retrieved information was used as a basis for second measure, which aimed at the establishment of decision-maker networks. This was undertaken by the conductance of workshops.

Contracted work

The first contracted report aimed at the mapping of decision-making institutions throughout European health care systems. The identification of these decision-making bodies was thought to be of importance regarding a) the role of HTA in these institutions, b) the identification of

[108] Members of Working Group 6: Appendix 1

decision makers who can contribute experiences with HTA and finally c) networks of decision makers. This research project was conducted by Matthias Perleth and Marcial Velasco.

The second report aimed to identify systematically published literature on the use of HTA in European health care environments. An elaborate search strategy was used to identify all articles dealing with the influence and role of HTA in European decision making environments. Additionally, grey literature and literature and languages other than English were provided by members of the Working Group to avoid an (English) language bias. Michael Drummond and Marco Barbieri conducted this second report.

The methodology of the reports is attached in the appendixes 2 and 3.

A third research area concerned the penetration of HTA at the hospital level. Melinda Öjermark of Sweden investigated this area to identify hospitals which already have experience with HTA and can contribute examples of successful implementation[109].

Workshops

To gather first hand information in addition to the academic research projects, two workshops were organised and focused on decision makers at all levels in European health care systems, emphasising the national level (organised by Andrew Dillon and Bernhard Gibis). A second workshop concentrated on experts who use HTA in the hospital setting (by Tore Scherstén and Odd Søreide). The participants of the workshop were identified through research work of the academic groups and through personal contacts of Working Group 6 members. Both workshops followed a structured design and comprised an evaluation tool which enabled an outcome control. Further information regarding participants and structure is attached in appendixes 6 and 7.

Results and Outcomes

Contracted work

1. HTA use at system/government level[110]

In their report, Matthias Perleth and Marcial Velasco gathered information sufficient to provide a promising start towards describing the anatomy of decision-making in Europe. Since the published literature to date does not focus on the anatomies of health care systems, particularly in a comparative way, it was necessary to conduct interviews with people knowledgeable about European health care systems. This aim was achieved best in the countries where the authors had in-depth knowledge and to a lesser extent in countries where additional information had to be gathered via interviews. For the first time, decision points in European health care systems were systematically identified which can be targeted to familiarise decision makers with the HTA instrument. The report also identified how medical technologies, i.e. medical devices,

[109] Hospital List: Appendix 4
[110] Summary: Appendix 5

pharmaceuticals and procedures, are regulated in the various European health care systems. In addition, factors influencing decision-making were presented.

It became clear through the report that national and very often cultural features of the various European health care systems demand different approaches for the implementation and usage of HTA. In general (exceptions apply such as France, the Netherlands and Switzerland) countries with an insurance-based social health care system such as Germany are adopting HTA considerably later than government-run health care systems such as in Great Britain, Spain and the Scandinavian countries.

Furthermore, the work presented a useful basis for identifying participants for the Health System Policy Makers' workshop.

2. Evidence of HTA impact on policy level

Michael Drummond and Marco Barbieri retrieved in their work an overview of the published literature on the usage of HTA in European health care systems. Generally, the type of information the Working Group focused on is not published in academic papers. Given this fact, the report did not deliver the information which was needed for the proceedings of the Working Group. However, since decision-making processes are often conducted within the health care system bureaucracy, these decisions are often published in Federal registers, which are not part of the traditional academic database such as Medline or Embase. The overall result of the report was that the use of HTA has reached different stages in European health care systems whereas Great Britain, the Netherlands, Spain and the Scandinavian countries have the longest tradition of using and implementing HTA. Even for these countries, concrete examples describing the impact of HTA are sparse.

Workshops

1. Workshop for Health System Policy Makers using HTA[111]

Working Group 6 succeeded in gathering nine health system policy makers from seven European countries, beside themselves. Including Working Group 6 members, 15 people from 10 European countries who were knowledgeable about their respective health care system and who had at least some experience in conducting and/or implementing HTA met in Stockholm May 18, 2001. Given the short time frame it was felt that the issue of HTA is of considerable interest for decision makers when approached directly and in a structured way.

During the presentations of countries and case studies it became obvious that countries indeed consider HTA very differently, given that the social structure has tremendous influence on how HTA can be used in policy making. From informal approach to very structured approach, every style was present. Although the health care structures the participants are working in were different, many similarities about the diffusion and marketing of various health care technologies

[111] Summary: Appendix 6

were identified. The exchange of this information was deemed essential in an increasingly multi-national research and industrial environment.

In a first step to establish and enhance contacts, an informal network via e-mail or protected web-areas was regarded as an appropriate way and measure to achieve this goal. This is thought to serve as a nucleus around which more in-depth collaboration can evolve. If required, further meetings can be scheduled to promote personal contacts.

In the evaluation questionnaire, the two benefits mentioned most often were:

1. Learning from others' experience
2. Contacts/networking

All judged the workshop to be suitably structured to achieve its stated objective. Mailing, mailing lists or personal contact were considered more appropriate for continuing contact than meetings which are difficult to schedule and often time- and cost-intense. Most fruitful subjects for collaboration were: enabling discussion of issues, including upcoming questions and improving uptake of HTA, and sharing experiences. Continuing these workshops was viewed to be of high to very high interest for all of them, personally and for their organisations.

2. Workshop 2 for Hospital leaders using HTA[112]

Fifteen Hospital leaders from eight European countries accepted the invitation to Zurich May 28, 2001, representing Austria, Finland, Germany, Norway, Spain, Sweden, Switzerland and United Kingdom. Together with four attendants from SBU and Working Group 6 members, 28 people gathered to discuss on hospitals and HTA on six practical presentations.

They focused on basic details, e.g. ensuring that at least one person per hospital receives all reports on financial coverage and assuring a link between HTA and quality assurance in everyday practice, showing that HTA is the basis for the latter. Even though their reference populations differ, and some case study work is therefore uniquely local, they pointed out that some universal elements exist.

As a result, they proposed to establish an implementation database on successful implementation and an electronic notice board for sharing ideas and general communication among health care professionals in hospitals. An implementation group was formed to develop a structure for the implementation database.

In the evaluation questionnaire, again, contacts/networking and to learn from others experience were the two most named benefits expected. Also, the workshop was considered suitably structured to achieve its stated objective. Meetings and network were regarded much more appropriate for continuing contact than mailing, mailing list or personal contact. Besides the proposed database and notice board, the most fruitful subjects for collaboration were the

[112] Summary: Appendix 7

exchange of HTA results and experience and information about specific themes, e.g. unproven treatments and prevention.

Discussion

HTA as an instrument which can lead through better information to better outcomes in real health care environments has gained considerable attention in the academic world. The work undertaken by academic researchers shows that decision-making structures are exposed to HTA to only a limited extent. This may have two possible explanations: First, HTA plays a major role, but this is not well published or not published in the traditional databases, and the wrong measures were used by the Working Group. Second, HTA has in fact not reached most of the decision-making institutions in European health care systems.

Since the Working Group used different strategies to avoid "publication bias" by conducting a primary study (Perleth and Velasco) and conducting the workshops, the members of the Working Group felt that HTA is not yet sufficiently rooted in European decision-making structures despite the efforts of predecessor programs, e.g. ECHTA or EUR-ASSESS. The following two points are deemed important to illustrate the specific obstacles which should be avoided to gain a realistic view of the use of HTA in Europe:

1. HTA use at system/government level

Few publications address this field of interest, and common knowledge seems difficult to acquire, even for good researchers. Outlining what's going on among users of HTA in Europe seems to require a real familiarity with the health system discussed, e.g. Germany and Spain, the home countries of the two researchers, are portrayed in a much more functional way. Indeed, they succeeded in identifying health system policy makers who benefited greatly from sharing experience. The Working Group found it necessary to acquire a more in-depth view of other health care systems to identify possible users of HTA. In principal, "scanning" health care systems for decision nodes is an appropriate task for subsequent programmes.

2. Evidence of HTA impact on policy level

Again, it appears that – in addition to some language bias – structured information on the use of HTA in Europe simply is not readily available. The most striking example is that experienced researchers failed to find "the" HTA implementing agency in Switzerland, but found a smaller agency instead because it happened to have published something that met the inclusion criteria. This again shows that using published information is not the appropriate way to gather information about the impact of HTA, at least in the European context. To some extent, it is surprising that the impact of HTA as a "return on investment" has not been the focus of European HTA programmes so far. To assess the "outcomes" of HTA, it is not enough to count the number of reports posted on the Internet, but one must follow up on how they are adopted by the decision-making community. This goal is best achieved by integrating representatives of decision-making bodies in HTA programmes such as ECHTA to facilitate direct collaboration among the producers and users of HTA reports.

Workshops

The positive perception of the workshops by the decision makers indicates the overall need for networking and exchanging experiences. Since all of the participants face similar challenges in a multi-national health care market, it was regarded as crucial to share knowledge and learn from each other in an informal way on a European level. All participants considered HTA to be useful, but all too often not customised for the needs and legal requirements of the respective health care systems. In particular, the hospital workshop clarified that decision makers do not experience a scarcity of information on a particular health technology but a lack of validated and customised information. To the contrary, information is produced at an unprecedented speed, and HTA producers have so far obviously not delivered the message to decision makers that their reports are of better quality and more valuable than other sources of information.

Raising the currently minute impact of HTA the "user" perspective in these reports can result in further insight and measures to make HTA reports more useful for decision makers. Health care decisions are made in a specific socio-cultural and economical context, which differs considerably between the European countries. The input of decision makers is of paramount importance in order to take advantage of existing HTA reports from individual countries. Although from an academic and research point of view HTA reports can be excellent, this does not automatically mean that the reports will impact on the health care system. One of conclusions from the decision-maker workshop was that early involvement of the "customers" of an HTA report considerably enhances the later adoption and implementation of the results.

This aim of increasing the impact of HTA can be fostered on a European level by supporting networks of HTA users and integrating them in ongoing HTA initiatives, both on a national and on a European level.

Working Group 6 established two working groups of decision makers, one focusing on the health care system level and another focusing on the hospital level. This may be viewed as a starting point for a further initiative to establish networks of decision makers on a European level. In a pragmatic way, these two initiatives are considered to be self-sustaining. However, to maximise the impact of the first encounters, additional efforts on a European level are deemed necessary.

Conclusions and recommendations

Decision-making structures are exposed to HTA only to a very limited extent. HTA is not yet sufficiently rooted in European decision-making structures despite the efforts of predecessor programmes, e.g. EUR-ASSESS. Although HTA reports may be excellent from an academic and research perspective, this does not automatically mean that these reports have an impact. The input of decision makers is of paramount importance for enhancing the impact of HTA.

™ Including the perspectives of HTA users (health policy-makers, hospital leaders, patient organisations, industry) from the very beginning of an assessment will considerably raise the

understanding of the decision-making process and philosophy and the acceptance and implementation of the findings.

™ Further in-depth research is needed on the structure of European health care systems with respect to their decision-making anatomy to identify decision nodes where HTA can contribute relevant information. Ideally this would be undertaken with the support of knowledgeable representatives of all European countries, i.e. European Union and observer countries.

™ Further stimulation and support is needed for informal networks of decision makers via the implementation of a clearinghouse, which facilitates notice boards, contact databases and meetings.

Appendixes

Appendix 1 – Members of Working Group 6

Chair
Dr. Chris Henshall
Director, Science and Engineering Base Group
Office of Science and Technology
Department of Trade and Industry
Albany House, 94–98 Petty France
London SW1H 9ST, UK

Chair
Dr. Pedro Koch
Medical Technology Unit
Federal Social Insurance Office Switzerland, FSIOS
Effingerstrasse 20
CH-3003 Berne, Switzerland

Dr. Georg Carl von Below
Quality Assurance
Swiss Medical Association FMH
Elfenstrasse 18
CH-3006 Berne 16, Switzerland

Dr. Albert Boer
Ziekenfondsraad, Box 396
NL-1180 BD Amstelveen, The Netherlands

Dr. José L Conde-Olasagasti
The Spanish Agency for HTA, AETS
Instituto de Salud "Carlos III"
Sinesio Delgado 6, Pabellón 3
ES-28029 Madrid, Spain

Mr. Andrew Dillon
Chief Executive
National Institute for Clinical Excellence, NICE
90 Long Acre
London WC2E 9RZ, UK

Dr. Bernhard Gibis
NASHIP, National Association of
Statutory Health Insurance Physicians
Department of HTA
Herbert-Lewin-Strasse 3
D-50931 Cologne, Germany

Dr. Roberto Grilli
Senior Executive
Regional Agency for Health Care
Agenzia Sanitaria Regionale Emilia-
Romagna, viale Aldo Moro, 38
IT-40127 Bologna, Italy

Mr. Charlie Hardy
Department of Health and children
Planning and Evaluation Unit
Hawkins House, Poolberg st.
Dublin 2, Ireland

Prof. Lycurgos Liaropoulos
Centre for Health Care Management and
Evolution, University of Athens,
Department of Nursing
123 Papadiamantopoulou Str.
GR-11527 Athens, Greece

Dr. José M. Martin-Moreno
Director, The Spanish Agency for HTA, AETS
Instituto de Salud "Carlos III"
Sinesio Delgado 6, Pabellón 3
ES-28029 Madrid, Spain

Dr. Risto Roine
Chief physician, Assessment of technologies
Helsinki and Uusimaa Hospital Group
P.O.Box 100, FI-00029 HUS, Finland

Prof. Tore Scherstén
The Swedish Council on Technology
Assessment in Health Care, SBU
Box 5650, SE-114 86 Stockholm, Sweden

Prof. Odd Søreide
SMM/Norwegian Centre for HTA
P.O. Box 124 Blindern
N-0314 Oslo, Norway

Dr. Maya Züllig
Medical Technology Unit
Federal Social Insurance Office Switzerland, FSIOS
Effingerstrasse 20
CH-3003 Berne, Switzerland

Appendix 2 – Methodology of HTA Use at System/

Government Level, Mathias Perleth and Marcial Velasco

"For this review, we used several existing reviews of the European health care systems and of HTA in Europe. These include among others journal articles, monographs, the final reports from the HTA Europe project, the ASTEC project, a recent OECD synthesis report (covering only some European countries), the WHO Health Care in Transition series and our own results from previous research. Personnel working in HTA related agencies or at the institutions taking coverage decisions were contacted. If possible, a telephone interview was carried out. If not possible, a questionnaire was sent by e-mail and the experts were asked to send a written answer.

Data from the different sources are extracted into summary tables. Country boxes contain more detailed information about the way coverage decisions are taken in some European countries."

Appendix 3 – Evidence of HTA Impact on Policy Level,

Michael Drummond and Marco Barbieri

"A systematic literature review have been performed searching the following databases:

- Medline (1966–2001)
- EMBASE (1980–2000)
- CINAH (1981)
- HMIC databases (King's Fund, DH-Data and HELMIS) (1981–2001)
- EconLit (1981–2001)
- Sociological Abstracts. Science Citation Index (1981–2001)
- Social Science Citation Index (1981–2001)
- Index to Scientific and Technical Proceedings (1990–2001)
- DARE (Database of Abstracts of Reviews of Effectiveness) (all to date)
- NHS Economic Evaluation Database (all to date)
- HTA Database (all to date)

The search strategies performed for each database are reported in Appendix 1. Title and abstracts (where available) of the publications identified were used to assess a paper's potential relevance to this review. Inclusion criteria and exclusion criteria were the following:

Inclusion criteria:

- English language
- Studies that consider the history and development of HTA in European countries
- Studies that consider the impact of HTA on clinical decision-making

Exclusion criteria:

- Non-English language
- Studies considering HTA in non-European countries
- Studies based on individual clinical practice
- Conference abstracts

Several items of grey literature identified by members of the Working Group were also considered. In addition a search of the grey German literature regarding HTA and decision-making has been performed (Gibis B.). Full transcripts of all the papers deemed potentially relevant were then obtained."

Appendix 4 – List of Hospital Participants

Austria
Dr. Robert Gfrerer
Medical University Clinic Graz
Auenbruggerplaz 15
8020 Graz, Austria

Finland
Prof. Dr. Martti Kekomäki
Chief Administrative Physician
Helsinki and Uusimaa Hospital Group
P.O. Box 100
FI-00029 Hus, Helsinki, Finland

Prof. Dr. Lauri Nuutinen
Oulu University Hospital
Hallintokeskus
FIN-90221 Oulu, Finland

Germany
Prof. Dr. Franz Porzsolt
AG Klinische Ökonomik
Universitätsklinikum Ulm
89075 Ulm, Germany

Norway
Mr. Arnt Jakobsen
Medical Director
Rikshospitalet
0027 Oslo, Norway

Mr. Tore Nepstad
Chief Operating Officer
Haukeland University Hospital
5021 Bergen, Norway

Prof. Jan Olofsson
Haukeland University Hospital
5021 Bergen, Norway

Spain
Dr. Jordi Colomer
Hospital Valle Hebron
1 vall O'Hebron
119129 Barcelona, Spain

Dr. Joan Escarrabill
Hospital de Bellvitge
Barcelona, Spain

Dr. José Expósito-Hernández
Medical Director, Servicio Andaluz de Salud
H. U. Virgen Nievas
Avda. Fuerzas Armadas, 2
ES-18014 Granada, Spain

Sweden
Dr. Jan Adolfsson
Oncologic Center, M8:01
Karolinska Hospital
SE-171 76 Stockholm, Sweden

Prof. Jörgen Nordenström
Department of Surgery
Huddinge University Hospital
SE-141 86 Stockholm, Sweden

Switzerland
On behalf of Prof. Szucs: Dr. Silvia M Ess
Department of Medical Economics
University Hospital Zurich
Raemistrasse 100, 8091 Zürich, Switzerland

On behalf of Prof. Szucs: Matthias
Schwenkglenks M.A.
Department of Medical Economics
University Hospital Zurich
Raemistrasse 100, 8091 Zürich, Switzerland

Dr. Jean-Blaise Wasserfallen
Centre Universitaire Hospitalier Vaudois
Medical Direction BH-08
CH-1011 Lausanne, Switzerland

United Kingdom
Prof. Sir Miles Irving
Head of Audit and Clinical Effectiveness
Newcastle Hospitals NHS Trust
Freema Hospital, Newcastle upon Tyre
NE7 7DN Newcastle upon Tyre, UK

Appendix 5 – Summary of HTA Use at System/

Government Level, Mathias Perleth and Marcial Velasco

In most European countries, the health care services covered for those eligible for public services and social insurance represent only a part of all possible and practicable health care benefits. The scope of services covered is often outlined in health or social legislation approved by the respective Parliaments. In general, these legal norms only establish a rough framework within which the care is provided ("basic package"). At this level of decision-making the role of HTA seems to be very limited.

The implementation of the principles stated in such laws implies the definition of a more detailed package of services actually being covered, here referred to as "actual basic package". All European countries define some kind of actual basic package of benefits, which are covered by the social insurance or the national health services.

Two approaches to defining the actual basic package can be identified at this level of decision-making: explicit or implicit. Positive or negative lists of drugs and service catalogues (frequently connected to fee-for-service payment) are ways of explicitly defining the items covered. Planning of services represents an implicit way of defining coverage which follows the rationale "not supplied = not covered". Both ways of defining benefit packages coexist in many countries of the European Union. There seems to be an increasing relevance of HTA at this level of decision-making. Bodies, such as planning authorities or "coverage commissions" are to some extent legally obliged to consider effectiveness and cost-effectiveness data in their decisions, and thus are likely to consider and commission HTA. In some countries, a third level of coverage decision-making can be identified, namely single-case decisions. Benefits explicitly or implicitly not included in the actual basic package may be covered in single cases. Decisions at this level are taken by the payers under advice of their "medical services / inspections". Through those advisory bodies HTA may also take an increasing role in decision-making.

In some countries, single-case decisions can be brought to social courts that thereby become actors in the definition of benefit packages. The role of HTA in social court decisions, however, needs further discussion.

Appendix 6 – Summary: Workshop on HTA for policy makers

A seminar on HTA for policy makers was held in Stockholm on 18 May 2001. Andrew Dillon, Executive Director of NICE chaired the meeting. Sixteen participants from eleven countries participated in the seminar, representing government HTA agencies, national social insurance agencies, government social welfare authorities, private health insurance agencies, and ministries of health.

The objectives of the workshop were to share examples of:

- Successful HTA implementation
- Effective working practices
- Limitations in the use of HTA:
    - To identify where HTA adds value
    - To identify shortcomings of HTA

The workshop was structured into three parts. Firstly, brief country presentations from a number of national-level agencies were given (Germany, Scotland, Switzerland, Catalonia, Spain, Austria) and served as an introduction to the issue of HTA and decision-making. A set of similarities and differences was identified, in general issues around decision-making were familiar to all participants, however, handling and problem solving was different due to the different health care systems participants came from. Secondly, to focus in a pragmatic way on the implementation of a new technology, a case study of a particular technology was presented. Thirdly, a brief overview was given of NICE.

Key issues which arose in discussion included:

- the role of patients groups, the community and the media
- regional variation in policy and access to services
- re-evaluation issues
- HTA and the legal system
- HTA and the pharmaceutical sector
- demonstrating added value in quality of care resulting from HTA (“what is it good for?”)

The meeting was the first of its kind, and all participants expressed interest in a continued contact. It was agreed that the group would form the nucleus of a networking group on policy making and HTA, to include others in the future. Email contact for sharing of information was identified as an initial means of maintaining the network.

Some issues of future interest which were identified included:

- HTA 'tailored to demand'
- publication and dissemination of results (language problem)
- involving patients in decision-making

Interest was expressed on a constant exchange of experiences and on the organisation of meetings, which are dedicated to themes such as the three above mentioned. It was strongly felt that HTA has to be tailored to the needs of decision makers and closer co-operation of producers and users of HTA is necessary to maximise the impact of HTA.

Appendix 7 – Summary: Workshop for Hospital Leaders Using HTA

The ECHTA/ECAHI Working Group 6 (dealing with HTA in policy and practice) held a workshop in Zürich, Switzerland, May 28, 2001. The workshop was entitled "HTA and hospitals" and took place in Zürich University Hospital, 9:00 a.m. – 3:00 p.m.

The chairman, Pedro Koch, opened the workshop and announced it as being the first on HTA linked to hospitals. The workshop should therefore be considered as a first step towards building an informal network among interested parties.

Six presentations from different hospitals throughout Europe were held during the day. These were University Hospital of Lausanne, Switzerland (Jean-Blaise Wasserfallen); Hospital de Bellvitge, Barcelona, Spain (Joan Escarrabill); Huddinge University Hospital, Sweden (Jörgen Nordenström); Virgen de las Nieves University Hospital, Granada, Spain (José Expósito-Hernández); and Newcastle Hospitals NHS Trust, UK (Sir Miles Irving). Finally, Franz Porzsolt, University Hospital of Ulm, Germany presented the Bressanone System.

The main conclusions from the presentations dealt with implementation of HTA in hospitals and the importance of having financial coverage when doing it, especially regarding new technologies. It was also considered important to have an agreement within the professional society when implementing new technologies to ascertain enough impact.

Other presentations encompassed educational issues in EBM and different strategies to assess health technology. Important items mentioned in this latter aspect concerned structured methodologies and improved communication between clinicians and managers.

Regarding guidelines, it was considered important but difficult to keep them up to date, and it was emphasised that HTA plays a major role in this regard. Furthermore, it was stated that access to the data was not the obstacle, but rather the implementation of it.

The presentation of the Bressanone System dealt with, e.g. measurable effects of EBM on the quality of health care services. The combination of "internal evidence" gained at universities and hospitals and "external evidence" (what other people know) was pointed at when doing HTA.

After the presentations Pedro Koch concluded the workshop by emphasising the importance of remaining critical, and that implementation leading to investment is easy, compared to implementation leading to divestment. Finally he stressed not to reinvent the wheel by constructing new databases for implementation, as there are associations like INAHTA, ISTAHC, and the Cochrane Collaboration with already existing databases (even if their main purposes are not implementation issues).

A programme or, again, a database for implementation of HTA findings was nevertheless considered crucial. Is was also suggested to set up an electronic "notice-board" as a fundament for sharing ideas and general communication between health care professionals in hospitals.

Furthermore, it was decided to keep the two different workshops of Working Group 6 (policy makers and HTA versus hospitals and HTA) separated, at least for the time being.

Finally, an "EBM implementation group" was formed. The group was proposed to consist of five persons: Chris Henshall, UK; José Expósito-Hernández, Spain; Robert Gfrerer, Austria; Franz Porzsolt, Germany; and Risto Roine, Finland. One task for this group was to present a proposal on how to set up a (or use an existing) database for implementation. Chris Henshall will speak to the Chairman of the ECHTA/ECAHI project, Professor Egon Jonsson, about financial items in this concern.

Concerning future meetings, it was suggested to bring the "users" (hospitals and GPs) and the "doers" (those producing HTA reports) together to have synergies. No decision was made concerning date for next meeting.

Pedro Koch closed the workshop at 3:00 PM, and thanked all participants for contributing to a promising future collaboration in the field of HTA and hospitals.