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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

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HANDBOOK ON HTA CAPACITY BUILDING

WORK PACKAGE 8

OCTOBER 2008

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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

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EUnetHTA Handbook on HTA Capacity Building

was developed by

Work Package 8

Systems to support Health Technology Assessment (HTA) in Member States with limited institualisation of HTA

Work Package 8 Lead Partner: CAHTA, Catalan Agency for Health Technology Assessment and Research, Spain

October 2008

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CATALAN AGENCY FOR HEALTH TECHNOLOGY ASSESSMENT AND RESEARCH

General information on the European network for Health Technology Assessment, EUnetHTA

Background

Health Technology Assessment (HTA) is increasingly used in European countries to inform decision- and policy-making in the health care sector. Several countries have integrated HTA into policy, governance, reimbursement or regulatory processes. Therefore, the EU and Member States in 2004 expressed the need for a sustainable European network for HTA.

EUnetHTA was established to respond to this need. The European Commission and Member States co-funded the three year project (2006–2008) with the aim to develop a sustainable network and information resources to inform health policy making[1,2,3] . The project, which was based on three prior projects, connected national HTA agencies, research institutions and health ministries and enabled an effective exchange of information and support to policy decisions[4] .

What is health technology assessment?

EUnetHTA used the definition of *health technology* offered by the ***International Network of Agencies for Health Technology Assessment (INAHTA)***: **"**Any intervention that may be used to promote health, prevent, diagnose or treat disease, or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures and organisational systems used in health care"[5] .

EUnetHTA defined *health technology assessment* (HTA) as "a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe effective, health policies that are patient focused and seek to achieve best value".

EUnetHTA aims and strategic objectives

The EUnetHTA project was established to create an effective and sustainable network for HTA across Europe that could develop and implement practical tools

to provide reliable, timely, transparent and transferable information to contribute to HTAs in Members States.

The strategic objectives of the EUnetHTA project were to:

- reduce duplication of effort in order to promote more effective use of resources
- increase HTA input to decision making in Member States and the EU in order to increase the impact of HTA
- strengthen the link between HTA and health care policy making in the EU and its member states
- support countries with limited experience of HTA.

Structure of EUnetHTA

The EUnetHTA Partnership involved 64 organisations: 1 Main Partner, 33 Associated Partners, and 30 Collaborating Partners. In total, 33 countries (Europe: 25 EU and 2 EEA countries (Norway, Iceland), Switzerland and Serbia; outside Europe: Australia, Canada, Israel, USA) participated in the project. The list of partners is accessible at: www.eunethta.net .

Management and leadership

EUnetHTA governance structure consisted of

- the Steering Committee which comprised the heads of each of the Associated Partners or representatives appointed by the head. The head of the Main Partner chaired the Steering Committee. The Steering committee mandated the the management of the network to:
- the Executive Committee representing the Main Partner and Work Package Lead Partners,
- the Secretariat under the leadership of the Main Partner which provided managerial support to the overall project and ensured ongoing contact to the DG SANCO.

Collaborating Partners participated in the work packages and received internal communication on a regular basis.

The modes of operation of the network were described in a standard operating procedures (SOP) manual, a communication strategy, and supported by virtual and face-to-face meetings, website (with the Members Only work area), regular e-newsletter and other types of communication tools. The Associated Partners agreed on 3-year work plan during the first Steering Committee meeting and project results were presented at the EUnetHTA Conference "HTA's Future in Europe", in journal articles and conference presentations.

Work Packages and major results

The scientific work in the EUnetHTA project took place in separately managed Work Packages (WPs), each led by a Lead Partner. The following major results were achieved:

- A well functioning network of partners and colleagues from HTA agencies, research institutions and health ministries (WP1 - DACEHTA/National Board of Health, Denmark)
- A well functioning Information platform and website (www.eunethta.net) (WP2 - SBU, Sweden and Co-Lead Partner – DIMDI, Germany)
- Internal evaluations that helped to adjust work plans (WP3 – NOKC, Norway)
- A comprehensive, evidence-based and validated common framework for HTA information (HTA Core Model) applied to two types of technology to produce generic Core HTAs a) on medical and surgical interventions (Drug Eluting Stents) and b) on_diagnostic technology (Multislice CT coronary angiography) (WP4 - FinOHTA, Finland)

- A handbook instructing in the use of the Core HTA Model (WP4 - FinOHTA, Finland)
- An Adaptation Toolkit (and a guidance document) composed of a series of checklists and resources which address the relevance, reliability and transferability of data and information from existing reports (WP5 - NCCHTA, UK)
- A book "Health technology assessment and health policy-making in Europe" (WP6 - DACEHTA/National Board of Health, Denmark)
- A web-based Stakeholder Open Forum, a Draft Stakeholder Policy and Discussion Topic Catalogue; (WP6 - DACEHTA/National Board of Health, Denmark)
- Web-based tools for information sharing on the monitoring of new promising technologies and information service on emerging technologies (WP7 – HAS, France, and Co-Lead Partner- LBI/HTA, Austria)
- A handbook on HTA capacity building (WP8 - CAHTA, Spain)
- A proposal for a permanent EUnetHTA Collaboration after two rounds of public consultation (WP1 - DACEHTA/National Board of Health, Denmark)

Based on best practice each Work Package developed the methods suitable for their purpose, which is described in WP-specific products. The Lead Partners were responsible for coordination within the WP, for bringing work forward, producing and reporting results, for sending management information reports to the Main Partner and for responding to internal evaluation questionnaires.

The next phase

Through a series of internal and public consultation rounds, the network developed a Proposal for the EUnetHTA Collaboration (published June 16, 2008) detailing the approaches for the future development of the network. A group of founding partners was established after this to implement the proposal for EUnetHTA Collaboration.

FOREWORD

A little fiction for a completed project

The 6 October, half past eight in the morning, and I'm in front of my first coffee of the day. I open the Financial Times as usual while I am having breakfast. I am an economist and I deal with stock market operations. Today my attention has been caught by article headlined "'Europe's Health". I read that "For Europe's citizens, a key concern should be the widespread discrepancies between countries in the take-up of innovative new medicines. Despite all the rhetoric about EU integration, when it comes to health and treatment, where people live has an enormous impact on the treatment they receive".

I think that the journalist is absolutely right and I ask myself what we can do in Europe to remove these discrepancies between countries. I find the answer in the following paragraph: "Reform requires far more systematic use of 'health technology assessments', which take a rigorous look at both the efficacy and the cost effectiveness of medical treatments". I had never heard of this concept that the journalist was mentioning, which seems to be the European approach in terms of health policy. So, I wondered whether it might be something worth having a look at.

As soon as I got to my office I sat in front of my computer and even before I read my email I looked for information about 'health technology assessment'. I could be dealing with an economic treasure! After visiting several web pages I found out that health technology assessment (HTA) was an idea from the seventies, but in Europe it was not until the eighties that the first units or institutions were created. I found a 2005 publication from the WHO European Observatory on Health Systems and Policies that identified a total of 29 institutions in 14 States. According to this publication, the nineties could be described as the decade when HTA was institutionalised in Europe since this was the period when HTA programmes were created in almost all the countries of the European Union, either through agencies or institutes, or by establishing university departments or units in governmental organisations.

At lunchtime that day I told another stock exchange dealer about this issue that I had discovered and I asked him if he thought there were any financial possibilities. He couldn't tell me, but he was especially interested in European policy on HTA and asked me if these evaluations really shared a common procedure, even with this large number of institutions. I couldn't give him an answer straight away but I said that I would continue investigating.

At home that night, when my children had gone to bed, I went back to the internet to find the answer for my colleague. I learnt that that the idea of sharing methodology globally came about almost at the same time as HTA, since 1985 saw the holding of the first congress of the International Society for Technology Assessment in Health Care (ISTAHC), now HTAi (Health Technology Assessment International). And it was at one of these congresses, in Sorrento in 1993, that six agencies decided to create the International Network of Agencies for Health Technology Assessment (INAHTA). The first steps were taken that same year and today it has 46 members from 24 countries. Next, I found a lot of information about European collaboration (I will explain it to my colleague tomorrow). This finding satisfied me. I was sure that HTA was definitely worth investing in. Soon I would start to look for investors.

The 7 October 2006, 12.30. I had lunch, like yesterday, with my colleague and in answer to his question, I told him that the diversity of structures had never been a barrier for collaboration, that the thing that had always led to international collaboration in the world of HTA was that the same methodology was shared and was of secondary importance to the people who received the results: the governments (national or regional), or the hospital management units, customers (if it is a private organisation), or the university in the form of scientific publications. I also told him that it was probably this ability to co-operate that allowed the European Commission, from DG SANCO, to keep on funding almost consecutive projects for more than ten years in order to co-ordinate efforts: EUR-ASSESS (1994-1997), HTA-Europe (1997-1999), ECHTA/ECAHI (1999-2001) and at present EUnetHTA (2006-2008).

I certainly did not want to tell him that I had decided to look for investors because he might have taken it over for himself, and that is why I brought the conversation round to terms of European health policy, which in fact is something that interests him. I talked to him about European collaboration. I told him that the goal of EUnetHTA is to develop a network of HTA organisations and so as to develop practical tools to avoid the duplication of reports and assure a better use of resources.

My colleague became very interested in the project and I went on to explain that EUnetHTA consists of 8 work-packages, and one of these foresees the publication of a handbook on HTA capacity building in 2008. When he heard this, he asked me for more information, but I insisted that he would have to wait two years (I had to remind him that it was 7 October 2006). The thing is that not only I but also my colleague would have to await the publication of this handbook with patience. We were convinced that diversity, or rather wealth, in the forms of organisation (governmental agencies, units or programmes of state or regional ministries, university departments, etc.) is the thing that makes it possible to give tools to those who want to have an organised structure that produces HTA, whether to start a new one or to increase or modify one that already exists.

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1 The author's position and workplace during the contribution to the handbook

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Norwegian Knowledge Centre for the Health Services

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State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania

Contents

SUMMARY

The Handbook on HTA capacity building aims to provide practical guidance and support on how to establish HTA not only in countries with limited HTA capacity but also for existing HTA agencies. This handbook is a main deliverable of Work Package 8 (WP8) of the European Network for Health Technology Assessment (EUnetHTA) project and it has been developed by a group of experts that are partners of WP8 and co-ordinated by the Catalan Agency for Health Technology Assessment and Research (CAHTA). Thus, it is the result of a collective effort searching for a practical tool to give guidance on the establishment of HTA activities. The handbook consists of seven chapters, each devoted to one specific field and a final chapter on conclusions and recommendations and another one on challenges and new future actions.

Chapter contents

Chapter 1 deals with the general background, objective, development and structure of the handbook. **Chapter 2** introduces concepts on HTA capacity building. Prior to institutionalising HTA there is a need for a solid commitment from politicians and key decision makers in the health system. Further, an appropriate organisational structure and an efficient institutional setup for HTA work needs to be identified (HTA agency or network model with a coordination mechanism, etc.). Sufficient investment funds should be estimated for establishing and sustaining HTA programmes. The success depends also on the quality and relevance of the HTA reports, an efficient information dissemination system and the willingness of the policy level to integrate HTA into the decision making. Finally, the national HTA concept should include an international network strategy. **Chapter 3** elaborates on central aspects to be considered prior to the implementation of an HTA project. All HTA organisations have the same aim but their scope depends on their resources, their liaisons and requirements. These organisations can work at local-regional, national or international level. **Chapter 4** summarizes the argument that collaboration either at national or international level plays an important role in the process for the institutionalisation of an HTA programme which is in fact a synthesis of a top-down and bottom up action and relies in the end on strong networking activities. Collaboration at national level is based on all types of institutions (Academia, Government, professional associations, hospitals, industry and patient associations) whereas internationally collaboration is largely with Academia and Governmental bodies. **Chapter 5** deals with the infrastructures relevant for an HTA organisation. In particular the human resources constitute a central element within the HTA organisation. Gathering the staff capable of working in this area is one of the most important difficulties that emerging and established HTA organisations are facing, whereas problems with facilities are playing a minor role. The teams in HTA organisations comprise various disciplines. Diverse models of contracting human resources that are needed are pointed out in the view of training and recruitment strategies. **Chapter 6** introduces the work process of assessing health technologies. The are three steps in the work process of the HTA organisation: identification of the technologies to be assessed, priority setting, and assessment of health technologies. Furthermore, the work process gives suggestions on the formulation of recommendations, the process and product quality assurance and components of an assessment. It also offers links to work much more in-depth in each of these processes. After that, **Chapter 7** gives an approach on aspects related to the communication and dissemination of HTA products and results. Visibility and dissemination, as active ways of communicating and transferring the HTA results and recommendations to intended audiences, are key steps to improving the prestige and credibility of HTA organisations and their activities.

Finally, there is a chapter on conclusions and recommendations that has been drawn up on the basis of each chapter presented in the handbook and also a chapter on challenges and new future actions.

Chapter 1

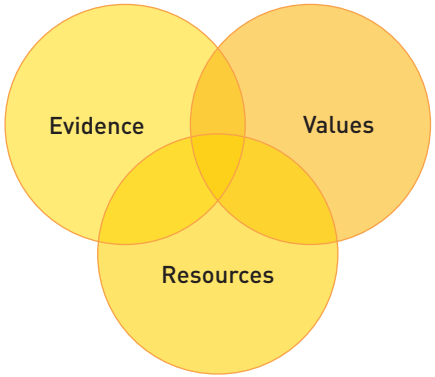
Introduction

N. Kubesch
Catalan Agency for Health Technology Assessment and Research

1.1 Introduction to HTA

Health care decisions have to be made explicitly and transparent for the public in times of limited resources. The increasing pressure on resources has led to a transition in health care decision-making and an obligation to consider evidence that is systematically generated through research (**Figure 1**)[6]. Muir Gray summarized the three factors where health care decision-making must be based on:

Figure 1. Muir Gray, Evidence Based Healthcare, 2003



A significant tool for evidence-based decision-making is Health Technology Assessment (HTA). Without consideration of the best available evidence the diffusion and use of health technology might be influenced by other social, financial and institutional factors. In order to be useful, HTA must deliver timely and relevant information that takes into account the actual requirement of the health care system. At the same time it promotes those innovations that provide value for money and disinvest in ineffective and obsolete technologies and interventions, protecting the basic principles of equity and choice[7].

The original approaches of HTA focused primarily on efficacy. An economic dimension, efficiency, has been gaining increasing attention and has been integrated in the HTA concept[8]. The European network for Health Technology Assessment (EUnetHTA) defined HTA as "*a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe effective, health policies that are patient focused and seek to achieve best value*[9].

Stakeholders who potentially benefit from HTA are those involved in decisions on funding and investment or planning of health care. According to an OECD survey, participating in both of these types of decision-making were mainly health care managers, academics/technical experts, and governmental officials followed by providers, politicians, industry representatives, and least involved patients/ consumer groups[10].

Even though the methods HTA uses should follow a degree of commonality, HTAs must be tailored to the needs of the particular situation to be useful. The context of the setting, such as political factors, decision-making processes, and cultural aspects influence the assessment process[11]. However, despite considerable differences amongst the settings in which HTA has been conducted, existing and upcoming HTA organisations can benefit from sharing their past and current experience. In particular with relevance to the institutionalization, which has been described as "promoting the structures and processes suitable to produce technology assessments that will be powerful in guiding policy and clinical practice towards the best possible health and cost outcomes"[12], upcoming and existing agencies can learn from each other as it appears they are or were facing common barriers [13].

1.2 HTA in Europe

Even though HTA is in the process of becoming established and institutionalized both in individual countries and internationally[14] the majority (70%) of the total number of countries in the European region, and more than a half of EU countries do not yet have formalised HTA yet (**Table 1**). The table shows the countries with and without HTA agencies that are members of the International Network of Agencies for Health Technology Assessment (INAHTA), which is regarded as an indicator of a considerable stage of the institutionalization process. INAHTA membership implies the agency is not-for-profit, funded at least 50% from public sources and has national /regional functions[15].

Table 1. HTA agencies in European Countries (Nov 2008)

EU Countries		EU Candidate Countries	Potential EU Candidate Countries	Other European Countries	
With formal HTA (n=13)	Without formal HTA (n=14)	Without formal HTA (n=3)	Without formal HTA (n=4)	With formal HTA (n=2)	Without formal HTA (n=14)
Austria	Bulgaria	Croatia	Albania	Norway	Andorra
Belgium	Cyprus	Macedonia	Bosnia-Herzegovina	Switzerland	Armenia
Denmark	Czech Republic	Turkey	Montenegro		Azerbaijan
Finland	Estonia		Serbia*		Belarus
France	Greece				Georgia
Germany	Ireland				Iceland
Hungary	Italy*				Kazakhstan
Latvia	Lithuania				Liechtenstein
Netherlands	Luxembourg				Moldova
Poland	Malta				Monaco
Spain	Portugal				Russia
Sweden	Romania				San Marino
United Kingdom	Slovakia				Ukraine
	Slovenia				Vatican

* Considerable activity in HTA but no INAHTA member agency

Three prior projects at the European level supported the development of co-operation among HTA institutions and the overall establishment of the field. **Table 2** provides an overview on the chronology of these projects including their main goals and conclusions, and a reference of the projects.

Table 2. Previous EU-funded HTA projects

EUR-ASSESS (1994-1997)		
Reference: Banta D et al (1997). Report from the EUR-ASSESS Project. Int J Technology Assessment in Health Care, 13: 133-340	**Main goal**: Improved co-ordination in the field of HTA in Europe	**Main Conclusion**: The project recognized the "value in bringing those involved in HTA in different countries together, and asked that "each country should have at least one organisation (or a co-ordinating body) that can serve as contact point for technology assessment activities, including priority setting, dissemination, and implementation".
HTA Europe (1997-1999)		
Reference: Banta D, Oortwijn W, eds. (2000). Health Technology Assessment in the European Union. Int J Technology Assessment in Health Care, 16: 299-635	**Main goal**: "Contribute to the effectiveness and cost-effectiveness of health care in Europe through improved HTA."	**Main Conclusion**: "It would be beneficial for the healthcare system of European Union countries for the European Commission to assist the establishment of a co-ordinating mechanism for HTA at the European level."
ECHTA/ECAHI Project (1999-2001)		
Reference: Jonsson E et al. eds. (2002) European collaboration for health technology assessment: developing an assessment network. Int J Technology Assessment in Health Care, 18: 213-455	**Main goal**: The project aimed at "developing a means of collaboration for HTA activities in Europe".	**Main Conclusion**: "There is now a need to strengthen this collaboration and create a sustainable co-ordinating body within the EU."

Subsequent to the abovementioned projects the EUnetHTA project started in January 2006. EUnetHTA is an answer to the call of the European Commission that indicated that *"HTA has become a political priority and there is an urgent need for establishing a sustainable European network for HTA"*[16] *The* EUnetHTA project overall purpose is to establish an effective and sustainable European Network for Health Technology Assessment that informs policy decisions, and to connect public national HTA agencies, research institutions and health ministries, enabling an effective exchange of information and support to policy decisions by Member States. These aims are expected to be achieved by means of eight separately managed Work Packages (WPs) that the project consists of: Co-ordination (WP1), Communications (WP2), Evaluation (WP3), Common Core of HTA (WP4), Adapting existing HTAs from one country into other settings (WP5), Transferability of HTA into health policy (WP6), Monitoring emerging/new technology development and prioritization of HTA (WP7), and Systems to support countries with limited institutionalization (WP8).

This last WP8 is dedicated to supporting the building of HTA capacity in Europe. Within the framework of this package an international survey on HTA organisations[13] was conducted aiming to gain knowledge of the current state of HTA agencies worldwide including those countries without formal HTA or else, with still limited institutionalisation of HTA[17].

1.3 Objectives of this handbook

This handbook, the main deliverable of WP8, aims at providing practical guidance on how to establish HTA in countries with limited HTA capacity. Furthermore, it aims at giving practical support for already existing HTA agencies in the institutionalisation process. The handbook addresses stakeholders at multiple levels (macro, meso, micro) who potentially have an interest in HTA capacity building such as:

- health care administrations (local, regional, national, international),
- public and private health care providers,
- health care industry,
- health care payers,
- health care researchers
- other stakeholders,

And also to those who wish to improve structures and processes in established HTA agencies. Although the Handbook was developed within a European context, we consider it to be globally relevant and applicable since its recommendations are based on international data.

1.4 Development of this handbook

Apart from the Catalan Agency for Health Technology Assessment (CAHTA), which was responsible for the co-ordination of the development, 16 external researchers from 13 different countries contributed to this handbook. Among them seven are from a formal HTA agency and thus are knowledgeable about processes and structures of formal agencies. The remainder of the contributors are actively involved in the process of establishing formal HTA in their countries and for that reason contributed the handbook's sensitivity to the obstacles in the institutionalisation process that these countries are facing.

The observations and recommendations in this handbook are based on a combination of findings from an international survey on HTA organisations[13], other relevant literature, discussions at workshops and the opinions and experiences of the authors, who are experts and stakeholders on HTA.

1.5 Structure of this handbook

Chapter 2 deals with concepts of HTA capacity building. The chapter elaborates central aspects to be considered prior to the implementation of an HTA agency followed by a presentation of a step-wise approach to implementing HTA. **Chapter 3** outlines the potential activities considering the various levels in which the HTA agency might operate. **Chapter 4** deals with the organisational and legal framework of HTA agencies. It discusses the environment where the organisation is operating, considering various factors. **Chapter 5** considers fundamental structures of an HTA agency such as Human Resources and Facilities. The requirements of the human resources for HTA in terms of profiles and training, and the various options of contracting personnel are pointed out. Subsequently, **Chapter 6** introduces to the work process of HTA. The first three steps of the work process in HTA, which are the identification of the technologies to be assessed, the setting of the priorities and the assessment process itself are outlined in this section. **Chapter 7** proceeds with the HTA process and gives practical guidance on how to develop a strategy for disseminating the products. Also, this section explores the assessment of the impact that the products may have. **Chapter 8** concludes some recommendations that can be drawn from each specific chapter and **Chapter 9** deals with challenges and new future actions.

Chapter 2

Building of national HTA capacity

M. Raab

Swiss Network for Health Technology Assessment

2.1. Moving from sporadic assessment to formal HTA

Even though a formal HTA programme might not be in place in a given country, decision-making about the adoption of new technologies may be part of the operational routine of health authorities and health service providers[18,19].Decisions, however, are frequently based on unilateral industry information, particular interests of individuals or 'gut feelings'. At best, decisions take into account experience generated in other countries or selective expert advice. The challenge is to shift to a decision-making process that follows modern principles such as Evidence Based Medicine (EBM), cost effectiveness and patient centred services[20,21].Moving to a formalised and systematic HTA programme requires a solid commitment from governmental authorities and a designated and motivated team of professionals that take charge of the HTA development plan. The establishment of one formal 'HTA Agency' should not necessarily be the sole focus when targeting the creation or upgrading of national 'HTA capacity'. Quite often the establishment of a structured HTA network integrating existing national institutions and steered by an HTA commission (or HTA co-ordination board) is a more appropriate solution[22].

2.2 Preparatory considerations prior to launching an HTA programme

The following aspects are recommended for consideration prior to the formulation of an action plan leading to HTA capacity building ('HTA programe'):

Preparing the ground

The entire venture of building up HTA capacity needs considerable advocacy work and discussion among relevant national or subnational stakeholders, such as ministries, health administrations or insurance funds[23]. The objectives, the potential benefits and resources required should be clearly stated in a project document. This will help ex-ante in the lobbying work for general political support and in obtaining funds.

A selected group of committed professionals (task force) with a clear mandate from the competent governmental authority to build up HTA capacity should serve as a catalyst for the intensified discussion and planning. Ideally, the task force members are already part of an existing institution dealing with aspects of typical HTA work. Targeted advocacy and consensus building needs to be conducted among the identified stakeholders, potential financing bodies, potential users of policy recommendations and research institutes interested in HTA related issues.

Human resources development

Given the probable shortage of national HTA specialists, one of the key foci of any HTA project will be the identification of suitable professionals and HTA training opportunities. The results of the international survey of HTA organisations[13] identified the shortage of specialised (HTA) staff as the single most important barrier to the establishment of HTA capacities. The issue of recruitment and development of HTA specialists is further discussed in chapter 5.

HTA is a developing concept in many countries of Europe and the wider international community. Its complex nature combines a variety of activities, which have been so far carried out separately and independently from each other. The interdisciplinary

nature of HTA[22,24] should, right from the beginning, be emphasised in the formulation of the mission statement or statutes of an HTA agency. Besides professionals from medical disciplines, public health specialists, psychologists, biomedical engineers and economists should form part of the core HTA staff team. Client, and/or patient-centeredness is a key feature of modern HTA and a relatively new approach in many countries.

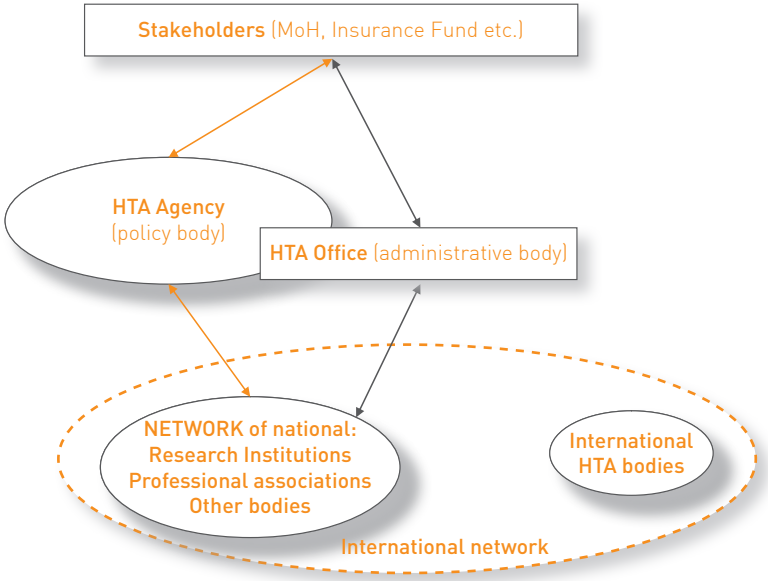
Integrating various disciplines

2.3 Implementation Alternatives

International experience shows that setting up national HTA structures in the meaning of an 'HTA Agency' may be a time-consuming process and involves a variety of stakeholders, scientific research capacity and considerable financial resources to function. Additionally, with the increasing importance of international networking, the recent development of a European network of HTA (EUnetHTA), and an increasingly complex and multidisciplinary HTA framework, large administrative structures at governmental level may not be able to work effectively in the long run. Therefore, the setting up of a national 'HTA Agency' should be considered as one model beside other alternatives[22].

A decentralised network of research groups working on the various aspects of HTA and embedded in European or international HTA networks with a national HTA board to co-ordinate their work could be an implementation alternative to the 'HTA agency' option. Switzerland, for example, operates a 'network mode'. This experience could help to assess the suitability of a similar network model for any country aspiring to build up national HTA capacity. **Figure 2** illustrates the possible configuration and organisation of national HTA work: An HTA Agency with a governmental mandate fulfils the role of a policy body. It commissions specific HTA reports and functions as a clearing house between academia and the 'end-users' (health ministries, private health providers, health insurances, etc.) Alternatively, an HTA agency sets the overall frame for assessment work and serves as a platform for national HTA work. In this model, the policy setting and the clearinghouse function would have to be assigned to existing professional institutions.

Figure 2: Sample Organigram for a national HTA model



2.4 A phased approach towards establishing an HTA programme

Since there is no single clear-cut pathway of building up national HTA capacity and formalising HTA work, a step-wise model approach to develop an HTA model that is adapted to the national specific circumstances is presented below[25]. This model approach provides an implementation framework and an orientation plan to set up an 'HTA project'. It was developed by the Swiss Centre for International Health on the basis of longstanding implementation experience in various national settings.

Step 1: Identification, sensitisation and training of key stakeholders.

An important initial activity is the sensitisation of key stakeholders, the clarification and discussion of the HTA concept (HTA, EBM, guidelines, cost benefit of medical procedures, etc.). International HTA experts should be contracted to train selected actors from relevant national institutions on up-to-date HTA methodologies and key concepts. On-site visits to other countries where HTA programmes have successfully been established are recommended and are instrumental in building professional networks and in shaping the national HTA concept.

Preparatory work should also include a literature review with regard to international experience in building up HTA capacity. Highly recommended are the guidelines and handbooks created in the frame of the EUnetHTA activity. Of particular relevance are the documents of WP4 (content independent HTA topics), WP5 (HTA adaptation toolkit) and WP6 (HTA and policy making).

Step 2: Carry out HTA and EBM situation analysis

An inventory of current (national) activities related to guideline development and HTA should be developed and current experience reviewed. The country's expertise in the various fields relating to the subject will be identified and contacted. Additionally, contacts to relevant national research institutions should be made in order to identify those which in turn will participate in the HTA process. This could be done in a series of workshops or working meetings where all important actors and representatives of HTA/EBM relevant institutions are invited. At the same time their needs in terms of training, networking (e.g. participation in international conferences and networks), and capacity building will be identified. This step will help to identify members for the HTA task force.

Step 3. Gain international HTA experience and acquire key HTA expertise

The team of experts to participate in the site visit and/or short term training will be identified and an itinerary and curriculum should be developed. Together with the results of the situation analysis, the site visit/training will give an opportunity to discuss together with international experts and define and fine-tune the institutional setup of an HTA agency or an HTA commission. Together with international experts the trainees will also identify additional training requirements and develop curricula.

Step 4. Institutional set-up of the HTA commission and making it operational

The resource materials collected and generated through the situation analysis and the review of European and international experience will be used to facilitate the institutional set-up of the HTA agency or the HTA commission. Tasks in this step will be: defining terms and tasks for the HTA institution, defining organisational set-up and institutional arrangements, developing job descriptions, setting up specific sub commissions, developing SOP's (Standard Operation Procedures) and defining technical equipment needs, including access to international information and data bases. This step will also identify financing mechanisms for the functioning of the HTA commission. A critical component in this step should also be to set up professional communication structures to encourage and facilitate the consensus building process, necessary for the adoption of Clinical Procedure Guidelines (CPG's) and HTA reports.

Step 5. Setting up relevant processes and identification of priority areas in HTA

Priority areas for guideline development and HTA reports should be developed based on agreed criteria (e.g. magnitude of expected gain in health status, international experience, best evidence, acceptability of new guidelines, etc.) involving relevant experts, policy-making bodies and end-users. The process needs to be standardised in order to continually identify areas of need for HTA reports and guideline development and the necessary review mechanisms. The initial HTA work 'products' should be carried out with supervision and backstopping of international experts.

Step 6. Translate research process into policy advice

In the beginning of the HTA work a close dialogue with the 'clients' of the HTA reports should be held in order to get feedback on the utility, relevance and user friendliness of the produced HTA reports. The measure of success should be the effects that the HTA reports produce on the policy level. A feedback mechanism should be instituted to obtain routine feedback on the 'usefulness' and impact of the HTA reports.

Step 7. Review lessons learnt and strategic planning

The programme management will review project achievements in terms of structures, products, networks, etc. towards the end of a set pilot period to capitalise on the initial work experience, identify its strengths and weaknesses and use this information to develop with key partners on the policy level a five year strategic plan for further national development of the HTA programme and the strengthening of its structures.

Final remarks

Establishing an effective HTA programme that guides key policy decisions for a national health care system is a challenging task. The basis for this task is a solid commitment from politicians and key decision-makers in the health system to integrate HTA findings and recommendations into key decision-making on the policy level. Further, an appropriate organisational structure and an efficient institutional set-up for HTA work need to be identified. This does not necessarily signify the establishment of a dedicated HTA Agency. There are good examples of network models with a co-ordination mechanism (e.g. 'HTA office') which could be appropriate for many countries. Ultimate success also depends on the quality and relevance of the HTA reports, an efficient information dissemination system and the willingness of the policy level to integrate HTA into decision-making. Sufficient investment funds should be made available to train professionals in HTA work. Funding for the recurrent operational costs of the established HTA structure should be identified and secured on a long term basis. HTA work is no longer done in national isolation. The national HTA concept should include an international network strategy right from the beginning.

Chapter 3

Aims and scope

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3.1 Aims

Since its inception in the middle of the 1970's, HTA has emerged as a crucial tool in the decision-making process performed by the different stakeholders inside a specific healthcare system. HTA examines the short and long-term consequences of the applications or use of technology but, as a characteristic point of the HTA process, it has to take the context into account. HTA is part of the health system and, therefore, reflects its history, its culture, its wealth, and many values and preferences[8].

The growth and development of HTA reflected the demand for well-founded information, based on sound scientific knowledge, to support decisions in the development, uptake and diffusion of health technology. HTA can play a valuable role in healthcare decision-making, but the process must be transparent, timely, relevant, in-depth and usable[10].

According to the World Health Organisation, the ultimate purpose of HTA and healthcare quality initiatives are improvement of health at individual and population level[12]. The EUR-ASSESS project made it clear that the goal of HTA is to provide input that helps to decision-making in policy and practice. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawn from a variety of methods. The essential properties of HTA, according to this project, are the orientation to decision-making and its multidisciplinary and comprehensive nature[1].

3.2 Scope

Whereas the aim can be seen as common for any HTA organisation, its scope may vary. HTA is a broad concept with many facets and vague borders, differing between countries both in its foci and methods. Particular societal groups have their role in the development of HTA (policy-makers, insurers, clinicians, epidemiologists and health service researchers, industry, and lay public). These differences in HTA from country to country might hamper its development, continentally and internationally. HTA has largely developed indifferent ways in different countries, so it is not so strange to find no uniform stage of development of HTA agencies. Many parameters explain this diversity such as resources, the culture, the main type of technology assessed, the type of reports produced and the health system and socio-economic environment in which the organisation will have to fulfil its aim.

An HTA process can function at different levels and depending on this, the attributes of HTA can vary

3.2.1. Local-regional, National and International levels

An HTA process can function at a local, regional, national and also international level. Depending on the level the attributes of HTA can vary, from micro to macro assessments. In the *local-regional* level, the HTA organisation will respond to HTA questions emerging mainly from the local authorities and decision-makers, patient groups or associations, health care institutions as well as health insurance providers and other stakeholders. The main concerns in this case can include the acquisition, use (appropriateness, over or under utilisation), cost (as well as charges), payments from insurers at levels associated with a particular technology.

The HTA organisation, especially in small countries, will function within the *national* context as well, and it is at this level that much of the international literature published on HTA is focused. In this case the HTA organisation will provide HTA information to the government, to the national health system, to policy makers, other stakeholders, and to patient associations or groups, healthcare institutions and health insurers. In this framework the HTA organisation will have to develop a liaison with other national organisations involved in tasks that are related to HTA work, as well as international healthcare institutions and HTA agencies. The HTA organisation will also have to liaise with academic and healthcare institutions and establish scientific co-operation in the local context. In addition, there must be liaison with the various patient groups and associations as well as other social and research bodies that will provide input to the HTA organisation as regards socio-economic factors that will have to be accounted for within the context of an HTA procedure. On this macro level the impact of healthcare technologies addresses issues related to the impact of new technology on national healthcare cost (budget impact) and the effect of technology on resource allocation among different and competitive health programmes or among healthcare and other socially important sectors.

At national level the HTA organisation will provide information to the government, national health system and policy makers, among others

Results from the international survey on HTA organisations[13] showed that most HTA organisations work at national level and, probably as a consequence of networking, most of them also work at international level (**Table 3**).

Table 3. Type of working level in HTA organisations (N=41)

Type of working level	N	%
Local-regional	5	12.1
National	12	29.3
Local-regional and national level	1	2.4
International	1	2.4
National and international	8	19.5
Local-regional, national and international level	14	34.2

* Multiple choice question which allows to select more than one correct answer. Cases with missing values were excluded from the analysis;

International co-operation and information exchange is important for HTA organisations established in small countries without institutionalised HTA

The generation and provision of sound and useful HTA information is a task that demands a significant amount of resources. This is the reason for the present trend to further develop and implement *international* co-operation and promotion of information exchange. International liaison co-operation and information exchange is particularly important for HTA organisations established in small countries without institutionalised HTA. Such organisations must develop an international profile that will facilitate their work through information exchange with larger and more competent HTA organisations and institutions.

In Europe, thanks to the support of the EU and regional and state governments, a more congruent approach is being made to reducing differences between the different HTA agencies operating at local, regional and national level. More widespread co-ordination, especially through EU-funded projects, began in 1994 and is still continuing with EUnetHTA.

HTA organisations should benefit from International institutions such as: WHO, INAHTA, HTAi, Cochrane Collaboration among others

Especially for those newly established HTA organisations, EUnetHTA will provide an excellent opportunity for the exchange of HTA reports with member states. The HTA organisation will greatly benefit from the "core" information that will be provided by the network about the effectiveness of technologies and shared among member states. The HTA organisation will also benefit from the aim of the network to monitor emerging health technologies to identify those that will have the greatest impact on health systems and patients and support countries without institutionalised HTA activity. Also, it is likely that some features of best practice, coming from national experiences, can be generalised to apply to local models or emerging HTA programmes.

The HTA organisation should also aim at benefiting from activities taking place under the auspices of international organisations such as WHO, INAHTA, HTAi, Cochrane Collaboration, Euroscan, GIN, The Joanna Briggs Institute, Campbell Collaboration, etc (see Annex 1).

At the European level, there is an agreement among member states to encourage and formalise networks to meet the European goals instead of turning to a pan-European body. Although EU member states want to maintain their sovereignty in health policy, they favour a more formal co-ordinating mechanism for HTA in the EU. Some explicit statements have been produced in the main EU treaties such as the Maastricht and Amsterdam Treaties [8].

3.2.2. Activities

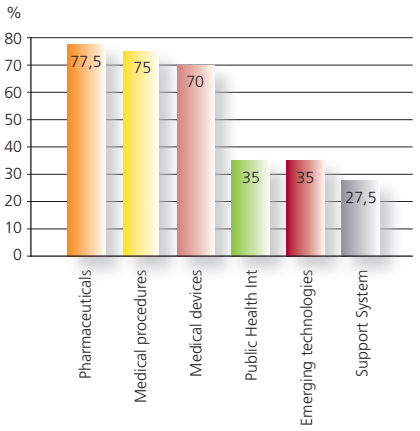
Surveys have shown that at present, the activities of HTA organisations vary[13,26]. HTA can be used in many ways to support policy making. Among these different roles are:

1. Supporting the decisions of healthcare product companies regarding product development and marketing or investors concerning venture capital funding, acquisitions and divestitures.
2. Supporting regional and national allocation decisions for healthcare resources (planning and priority setting).
3. Providing information for regulatory decisions on market approval of a technology.
4. Helping healthcare payers and providers determine which technologies should be included in health benefits plans and helping them formulate coverage (whether or not to pay) and reimbursement (how much to pay) policies.
5. Helping managers of hospital healthcare networks, and other healthcare organisations, make decisions regarding technology acquisition or adoption.
6. Informing clinicians, providers, and patients about the proper use of healthcare interventions for particular health problems (for instance practice guidelines and disease-management programmes).
7. Reporting gaps in scientific knowledge and health services research[27]

The international survey of HTA organisations[13] showed that 80.5% of the HTA organisations worked on HTA as main line of activity, followed by 'performing or doing research' (63.4%). Fewer than 50% of the organisations were developing activities related with health policy (48.4%), clinical practice guidelines (36.6%) and healthcare quality assessment and patients' safety (29.3%). Some HTA organisations perform their activities and conduct assessments via in-house committees with important participation by their own staff; others co-ordinate independent reviews by external bodies such as university research institutions or expert groups.

Models vary across countries in their HTA processes. While the most comprehensive ones cover all health services, many if not most models restrict their scope to procedures only, drugs only, or services requiring major capital investment[28]. In general and around the world, the approaches developed for drugs are more well-established and systematic than for other technologies. When the international survey on HTA organisations[13] asked about the type of health technology assessed for HTA organisations, as **Figure 3** summarises, the most frequently assessed were pharmaceuticals, medical procedures and medical devices. Assessments related to public health interventions, emerging technologies and support systems are still less developed. In particular, there should be further exploration of applying the principles and methods of HTA to preventive measures[10].

Figure 3. Types of HT assessed in HTA organisations (N=41)*



* Multiple choice question which allows to select more than one correct answer to be selected.

An HTA organisation should inform policy makers, government and other stakeholders

An HTA organisation should inform policy makers, government and other stakeholders through development of systematic literature reviews, promotion or commissioning research to fill the gap between knowledge and practice, and to promote what has been called a "culture of evaluation". The organisation may include horizon scanning in its activities aiming at detecting/assessing new technologies with a potentially strong impact in health care.

The main activities of a newly established HTA organisation that functions within a regional or national context with limited resources, would be low burden activities, namely, provision of brief reports, adaptation of "core" reports from EUnetHTA within the national context, and processing of information that is available through international networks in general, for production of national guidelines or provision of answers to specific questions. It may be possible to find evidence from the most frequent HT assessed by well established HTA organisations. Newly established organisations could adapt this evidence to their countries and healthcare systems. The EUnetHTA adaptation toolkit may well be used to facilitate this procedure. The organisation may gradually expand its activities and areas of interest as long as its know-how and resources gradually increase.

The operation of a successful model of HTA at local levels would require the development of both an empowered organisational unit (at regional or national level) and a process for helping the implementation of the results of HTA and, as crucial step in its development, the building of capacity to support both types of activities. Additional expertise and skills will be required for both providers of HTA evaluations and for the commissioners and users of HTA[28].

3.2.3. Main products of HTA organisations

As has been said, HTA is broad in both its methods and its applications. It can encompass assessment of safety, efficacy, effectiveness, cost, and cost-effectiveness, as well as organisational, social, ethical and legal implications and can be applied to drugs, devices, procedures and the organisational and support systems within which healthcare and health services are delivered. Some models of HTA organisation are pro-active, determining priorities by a mix of seeking emerging issues and horizon-scanning for new technologies; others, on the other hand, are reactive and rely on submissions from interested parties[28].

Most HTA organisations or programmes have been limited to the synthesis of existing evidence, although some are able to generate new evidence or to fund new research or to establish indicators (together with guidelines) and assess providers' quality performance. However, performing primary research is not a common activity in most HTA organisations.

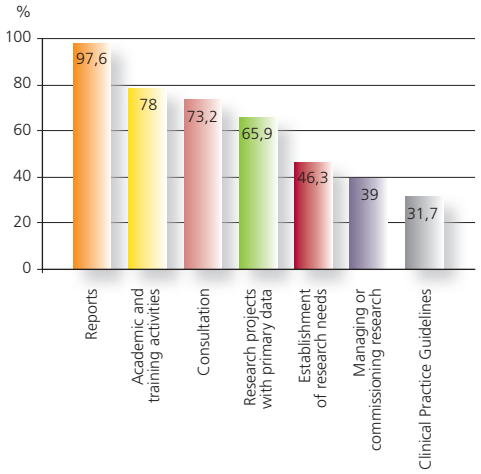
The final products of the activities developed by HTA organisations could be included in two general categories:

1. as advisory body with guidance to provide structured evidence-based advice about which technologies are appropriate and should be introduced. That is performed through reports (extended, brief, and patients' versions), clinical practice guidelines, consultations etc.
2. as a mandatory role with capacity to enforce its recommendations. In this case there might be a political commitment to require health services managers and providers to carry out the recommendations in agreement or, even more effectively, through the funds required to implement them. As some authors have mentioned, more stakeholder involvement is needed to improve the HTA process and the implementation of decisions and related policy[10].

Timing of the HTA process can affect the application of its evidence and recommendations. Decision-makers need timely information and that may collide with a comprehensive and in-depth evaluation. Some HTA organisations have introduced rapid reviews or fast-track procedures to facilitate the assessment process and reports on emerging technologies. As **Figure 4** summarises, reports of different length (quick response, technical query or assessment reports) are the most frequent products of HTA organisations.

An HTA organisation needs to develop guidelines where needed, especially on the management of different technologies. It also needs to provide answers to questions within a procedure of quick response. Finally, the organisation may also need to provide education and conduct commissioned research. The delivery of high-quality scientific evidence based HTA products should be the outcome of the effort of newly established HTA organisations. This will help them establish themselves as a valid source of evidenced based information within the local context. Using the experience of established organisations in this aspect might be of significant assistance in this effort.

Figure 4. Types of products and services in HTA organisations (N=41)*



Final remarks

Newly established HTA organisations in countries without any institutionalised HTA will have to develop gradually, starting from activities that do not require a large amount of resources. The acknowledgement of the quality of the results produced by this work, together with other related factors, may lead to increased funding and other resources, enabling the organisation to expand its activities. Its development must run alongside health policies and those, in most countries, are emphasising measurement, accountability, value for money and evidence-based policies and practices.

Networking, at regional, national and international level, can be very helpful for newly established HTA organisations with limited resources by avoiding repetition of HT assessments made previously by other HTA organisations. The form or type of the final products of newly established HTA organisations will be influenced by the local culture as well as by factors that determine the type of HTA questions (e.g. existence or otherwise of academic activity, existence or otherwise of research or not, level of healthcare etc.).

Chapter 4

Organisational and Legal framework

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The purpose of this chapter is to describe and discuss the aspects related to the organisational profile, legal framework and collaboration mechanisms for establishing an HTA organisation.

4.1. Profile of the organisation

The HTA organisational profile depends on different dimensions such as the type of technology assessed, linkage with policy decision, source of funding, regulatory role etc.

The types of technologies under analysis affect the overall appraisal process, which can be more complex if the focus is on biomedical devices, pharmaceuticals, organisational change etc. rather than just on one of them. Furthermore, the kind of technology (e.g. a focus on health policy campaigns) can influence the multidimensional nature of the assessment, thus making the process more articulate in term of expertise and knowledge involved, and in terms of human resources and costs. The degree to which the assessment is linked with policy decisions is also another dimension that defines the profile of the HTA organisation. First, the policy decision can be at national/regional level. Furthermore, the elements that make a "linkage" high or low can be: The strength of the final recommendation of HTA activities on final decisions, the relationship with the commissioner, the regulatory role.

Different elements define the profile of the HTA organisation

HTA organisations can have a direct regulatory role provided by law or their recommendations can be used by the commissioner to give rules. In this case the commissioner decides the strength of regulation and the linkage could be defined as low.

Moreover, organisations with a low degree of linkage to policy decisions, would initiate an assessment on request from manufacturers and any health care providers, whereas organisations with a high degree of linkage to specific policy decisions would initiate assessment by themselves or on request from a public commissioner. The source of funding can provide information about the public or private nature of the organisation, and the relation with the regional or national government, and tells us about the independence of the assessment. Those agencies whose main source of funding is public are usually founded under the auspices of the government, be it regional or national.

Beside the agency model, HTA activities can also be started and/or organised by the approval of a governmental programme funded on a standing or temporary basis, which can also be a first step in the institutionalisation process. Chapter 2 contains a proposed strategic plan to build up systematic HTA capacity.

Not-for-profit agencies typically include hospitals or institutions set up as trusts that, in principle, are financed and seen as an integrated part of the public health services. They usually have a subordinate role within the health care system and were

established primarily to complement public funded services. Thus these agencies are either entirely government funded or mainly government funded, sometimes with some private contribution. For-profit or private HTA agencies are mainly funded by the private sector. They are either entirely privately funded or mainly privately funded with some government contribution.

Not-for profit or for-profit profile agencies

Results from the international survey on HTA organisations[13] showed that all the organisations which answered the question about their profile, were not-for profit and they were either governmental institutions or universities (**Table 4**).

This is confirmed by the EUnetHTA WP8's review of HTA organisations' characteristics[29] which, notably, highlights the governmental organisational profile as the most widespread. With regard to this, countries with low institutionalisation of HTA willing to establish formal HTA activities at macro level, this being national or regional, could maybe more profitably refer to a governmental model, implemented as a unit within the national/regional Department of Health or an independent agency. This model is followed by many countries with well established programmes in HTA, such as the UK, France, Spain and Canada. Data from the international survey on HTA organisations[13] show that the initiative in the establishment of the HTA agency comes in 52.5 % of cases only from Government, in 15.0% of cases only from researchers and in 7.5% only from decision-makers. The initiative comes from mixed groups in 12.5% of cases. These figures give a key role to the governmental/political area (**Table 5**).

Table 4. Type of profile of HTA organisations (N=40)*

Profile of the organisation	N	%
Governmental agency**	17	42.5
Academia/University	13	32.5
Compulsory health care insurance (public)	2	5.0
Other private company	2	5.0
Professional association	1	2.5
Private medical insurance	0	0
Other	5	12.5

* Multiple choice question which allows more than one correct answer to be selected. Cases with missing values were excluded from the analysis; **One out of 17 agencies declared its profile as being a Governmental agency + Academia/ university.

Table 5. Initiative in the establishment of HTA organisations (N=41)*

Initiative in the establishment	N	%
Government	25	61.0
Only Governmental	21	52.5
Governmental + (decision makers** or health researchers)	3	7.5
Governmental + decision makers + health researchers	1	2.5
Health researchers	12	29.3
Only health researchers	6	15.0
Health researchers + decision makers	1	2.5
Decision-makers	10	24.4
Only decision-makers	5	7.5
Other	2	4.9

* Multiple choice question which allows more than one correct answer to be selected. Cases with missing values were excluded from the analysis; ** Decision-makers include health professionals, patient associations, health care managers and professional organisations.

4.2. Relationships and collaborating mechanisms in the process of establishment and/or implementation

Collaboration mechanisms in the establishment process

In order to establish and institutionalise a formal HTA activity in a country with a low HTA capacity, it is essential to rely on a positive "environment" embedding the future organisation. At national level the environment includes the political, social and healthcare systems' actors and groups that would have a role and an interest in HTA and in the different technologies assessed: health professionals and their associations, producers, health and hospital trusts and their operators, citizens' and patients' associations, experts, researchers and universities (see Chapter 2.2). A proper stakeholder analysis would highlight any resistance and barriers for the formalisation of HTA[30].The kind of collaborations needed would vary, depending on the country's range of stakeholders and on the different influence they wield. Although this applies to any country, regardless of its healthcare and financing system, it is notably relevant for those countries with a federal structure, or for countries on the road towards federalism. Indeed, the number of relationships to deal with becomes tangled, as does the number of possible collaborations, making it necessary to find partnerships and connections between central and regional future HTA agencies (in the case of a number of regional organisations). For each step of the HTA process[31] (priority setting, assessment, appraisal, dissemination and implementation of results/recommendations) it is important to define roles and tasks, and provide clear mechanisms aimed at involving stakeholders and communicating, to allow this complex network to work efficiently.

Data from the international survey on HTA organisations[13] show that collaboration at national level would imply collaborative projects on the one hand with other HTA agencies or individuals through HTA reports and other products of collaboration or, on the other, with individuals/organisations (by means of contracts in order to provide information/advice on specific topics) or by means of provision of services related to the production or dissemination of HTA products.

There are different collaborating mechanisms that the organisation can set up in the establishment/implementation of HTA activities. Co-operation, communication and networking among HTA institutions at different levels and in different countries will help the implementation of HTA activities. Collaboration involving staff of an HTA programme will range from expert opinion/advice and information exchange, to joint projects in which external assessors or other experts are co-authors of an HTA. This relationship/collaboration can be at different levels: local, regional, national and international.

Collaboration at international level

Collaboration at international level (**Table 6**) is based on communication and networking among HTA institutions or through HTA Agencies networks. This kind of co-operation could also help countries where the need for HTA exists and the interest in developing this activity has been officially expressed.

Table 6. Type of international collaboration in HTA organisations (N=38)*

Type of international collaboration	N	%
Academia / University	31	81.6
Governmental agency	25	66.0
Professional associations	9	24.0
Hospital	5	13.2
Industry	2	5.3
Patient associations	1	2.6
Other	2	5.3

* Multiple choice question which allows more than one correct answer to be selected. Cases with missing values were excluded from the analysis

Thus the collaboration at international level is essential. In this sense there are several networks and international organisations within the field of HTA. There are several studies and projects[29,32] which show the importance of encouraging international communication and collaboration.

The two main organisations that promote collaborative work and educational activities through an international network of contacts are:

HTA international

Health Technology Assessment International, founded in 2003, is a membership organisation that is run for individual members but also welcome organisational members. It is the only international professional society focusing specifically on HTA and embracing those who perform and use it, coming from academic institutions, health care systems, industry, business, the voluntary sector, or government.

HTAi' s aims for its first five years are:

- To build a thriving international society serving as a primary professional and scientific forum for all those who undertake and use HTA in health care systems, business, government, academic institutions and consultancies
- To run annual international meetings addressing the needs of members from all groups interested in health care technologies

- To distribute an international journal on HTA, in collaboration with the publishers of the journal
- To support the exchange of information, scientific methods, expertise and ideas through other meetings, groups, information services, educational activities and other programmes of work
- To consolidate and develop HTA as a useful means of informing health policy
- To position the society as a respected partner for international health policy oriented organisations
- To develop and manage responsive, professional and accountable systems for the governance and administration of the Society www.htai.org

INAHTA

International Network of Agencies. INAHTA was established in 1993 and now has 46 member agencies from 24 countries. INAHTA's mission is to provide a forum for the identification and pursuit of interests common to HTA agencies. Since its foundation INAHTA has facilitated the adoption of methods and common health assessment procedures. INAHTA aims to avoid duplication of project themes across its HTA agencies through the exchange of information on the project's initial phases and the assessment results. In addition, INAHTA promotes dissemination and seeks to achieve the greater impact of assessment results developed in collaboration www.inahta.org.

EUNETHTA

The European network for Health Technology Assessment. EUnetHTA has been established since 2006 and co-ordinates the efforts of 27 European countries, including 25 Member States of the European Union in evaluating health technology in Europe. The network is led by the Danish Centre for HTA (DACEHTA) in Copenhagen and is co-financed by the European Commission and contributions from network members. The objective of the Network is to connect public national/regional HTA agencies, research institutions and health ministries, creating a European network for HTA along with practical tools ensuring timely and effective production, dissemination and transfer of HTA results into policy advice to the Member States and the EU. Reports and information on EUnetHTA activities involving are available on the EUnetHTA website.

Both HTA international and INAHTA hold an annual meeting. Other networks and organisations that are involved in HTA activities are reported in **Annex 1.**

Apart from participation in European main research projects as mentioned above under EUnetHTA (see chapter 3), newly-established organisations could gain international collaboration through direct contact with agencies or researchers. Sometime in the starting phase (see "step by step" approach in chapter 2.4) these relationships should be useful for obtaining practical guidance. Furthermore, it will be relevant to establish permanent international collaboration, which will help to avoid duplication and to accelerate work, as in the recent proposal for future EUnetHTA collaboration.

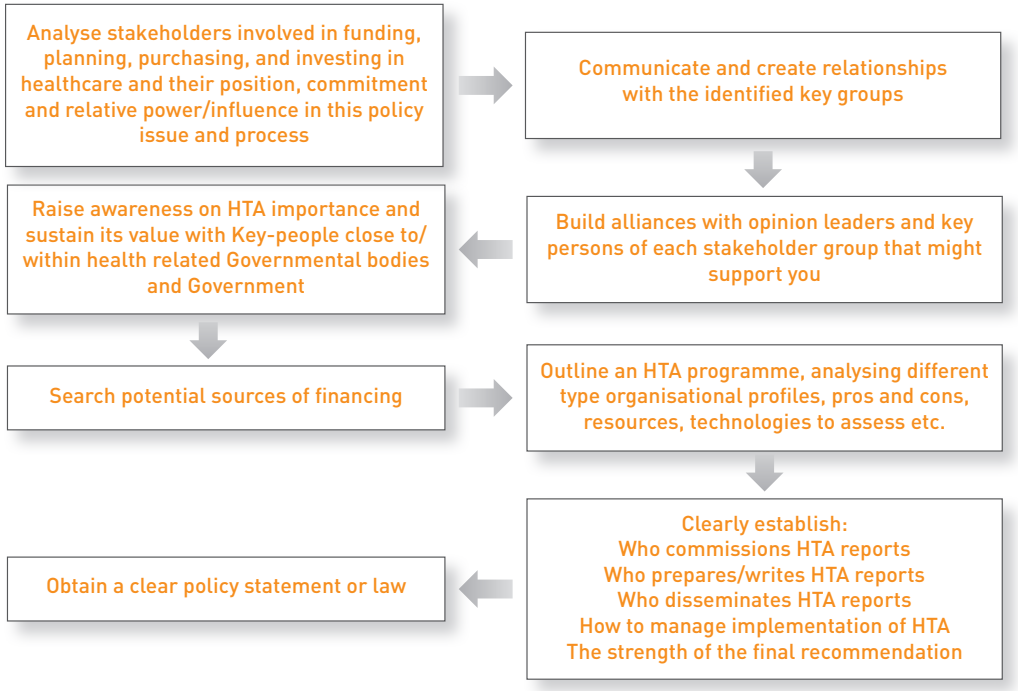
4.3. Achievement of legal support

Data from the international survey on HTA organisations[13] showed that 28 HTA agencies out of 39 respondents (around 72%) can rely on an HTA supporting policy act enacted by the government. The achievement of legal support, that is a policy statement or an ad hoc law providing for the institution of a new body or giving HTA functions to an existing organisation, is an important step in formalising HTA activities. The organisation's remit and the strength of its recommendations/results should be clearly defined to avoid hindering the effectiveness of the process and leading to duplication of efforts and unnecessary resource use. An unambiguous definition of the organisations' or offices' spheres of activity is important to prevent overlaps.

In developing the legal framework the differences in regulation of medical devices and drugs both at national and European level have to be considered, together with the legal profiles of regional and local health authorities and of providers (kind of contract, agreement, and so on).

The achievement of legal support can be facilitated by following some steps aimed at creating a positive attitude among interested stakeholders (**Figure 5**)

Figure 5. Steps to achieve legal support in the establishment of HTA organisations



Final remarks

The process of institutionalising a national HTA programme is a synthesis of top-down and a bottom-up action and relies on strong networking activities. It should always imply the involvement of all relevant stakeholders, together with action on decision-makers at the central level since they can set off the regulatory framework for the institutionalisation of HTA and provide the financial resources for funding the future agency. A bottom-up process can be activated by creating a positive interest among context's various actors and involving expertise at meso and micro level. Those activities are based on building a network which includes producers, health professionals, clinicians, decision-makers, patients' associations etc. A first purpose is communicating HTA benefits for individuals and the whole population. A second aim is to improve understanding of the importance of HTA as a means to rationalise the provision of healthcare at any level. Moreover, two-way communication is needed that helps to elicit stakeholders' points of view and perspectives on HTA and to embed them, as far as possible, in the final organisational profile given to the future HTA agency.

The action should also include international collaboration, which plays an important role. Newly established HTA organisations or those in the process of becoming an HTA agency should co-operate at national level by establishing a central body with a legal mandate for co-ordination and priority-setting, decentralising HTA research itself as well as funding, creating a platform for information exchange on HTA, ensuring multidisciplinary of HTA, and establishing some kind of formal links with health policy. The international collaboration should include participation in joint projects, cross-national issues should be given high priority and an exchange of information, and project reports and other HTA background material should be improved

Chapter 5

Structure

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This chapter discusses the relevant infrastructure for the viability of an HTA organisation. Predominantly, the subject of human resources, including training and recruitment strategies as well as the necessary facilities, will be considered.

5.1 Human Resources

The Availability of human resources depends on various parameters

The diversity of the subjects that an HTA organisation is confronted with requires a considerable availability of human resources for multidisciplinary teams. The majority (78.6%) of the participants in the international survey on HTA organisations[13] considered "Engaged staff" as an important aspect in the establishment of an HTA organisation[13]. Nevertheless, the availability of human resources within an HTA organisation depends on various parameters, such as financial resources.

Recruiting "trained Staff" is a frequently experienced barrier

Furthermore, as the results of the international survey on HTA organisations[13] suggest, the recruitment of appropriate human resources is a critical issue. Gathering "trained staff" was the most frequently experienced barrier in both establishment (63.6%) and in daily work (51.3%). Practical solutions to these barriers and advice will be given in the following sections.

Required profiles and number of the personnel

Quality is based on structures and processes

According to the Donabedian trilogy[33], quality is based on structures and processes. Taking this analogy into the present context, the quality of an HTA report depends on the procedures and analytical methods used by the appropriate expert personnel (processes) that work in an environment with the appropriate facilities (structures).

Human resources should be adequate to cope effectively and efficiently in the various areas of HTA activities

Therefore the availability of experienced assessors is of utmost importance for the viability of an HTA organisation or programme[37], However, the extent of the required Human Resource profiles will depend mainly on the available resources, human and financial, that obviously determine the ability of the organisation to undertake certain HTA activities.

The scope of the HTA mandate determines the number and profile of the required human resources

Owing to the multidisciplinary nature of HTA, human resources should be adequate in order to cope effectively and efficiently in various areas of activities. HTA-related skills include for instance: 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, priority setting, legal, social and ethical aspects, and others[34]. One of the tasks of personnel working in HTA is collecting and synthesising clinical and economic data, which form the basis for evidence-based decision-making. HTA specialists should be able to perform literature searches, assessing and avoiding the several types of bias (e.g. publication bias, language bias, retrieval bias, reporting bias), synthesising the evidence (may be qualitative, quantitative [meta-analysis] or formal decision-analysis) and publishing the results (both paper versions and online electronic versions).

The results from the international survey on HTA organisations[13] reveal that the majority of the participating organisations had "Clinical specialists" (71.1%) in their organisations followed by "Economists" (68.4%) and "Information specialists" in third place (65.8%), (**Table 7**)

Besides the professionals listed in **Table 7**, HTA organisations had dentists, pharmacists, physiotherapists, lawyers, chemists, nutritionists and engineers (mainly biomedical engineers) in their teams.

Also, information specialists are a significant part of the HTA team as they can assist the entire HTA process and can often help afterwards through their involvement in dissemination.

The required number of human resources is highly dependent on the legal mandate given to the HTA programme. The scope of the mandate will determine the number and profile of the required human resources to start the HTA programme. A vital limiting factor will be the available resources for hiring this minimum number of human resources.

Data from the international survey on HTA organisations[13] has shown that "Health service researchers" formed part of the teams in only 52.6% of the organisations but they were in terms of the quantity the most employed professionals. (**Table 7**).

Table 7. Background of the professionals in HTA organisations

	HTA organisations according to number of staff				
			None*	1- 5*	>5*
Background	N**	Median (range)	N (%)	N (%)	N (%)
Clinical specialist	38	1 (0-8)	11 (28.9)	23 (60.5)	4 (10.6)
Economist	38	1.5 (0-11)	12 (31.6)	20 (52.6)	6 (15.8)
Information specialist	38	1 (0-12)	13 (34.2)	23 (60.5)	2 (5.3)
Social scientist	38	1 (0-10)	18 (47.4)	17 (44.7)	3 (7.9)
Health service researcher	38	1.5 (0-43)	18 (47.4)	13 (34.2)	7 (18.4)
Public Health specialist	38	0.5 (0-12)	19 (50.0)	15 (39.5)	4 (10.5)
Epidemiologist	37	0 (0-9)	19 (51.4)	16 (43.2)	2 (5.4)
Statistician	38	0 (0-7)	20 (52.6)	17 (44.7)	1 (2.7)
Nurses/nursing scientist	37	0 (0-29)	22 (59.5)	12 (32.4)	3 (8.1)
General practitioner	37	0 (0-8)	23 (62.2)	13 (35.1)	1 (2.7)
Media professional	37	0 (0-28)	24 (64.9)	11 (29.7)	2 (5.4)
Psychologist	37	0 (0-6)	28 (75.7)	8 (21.6)	1 (2.7)

* None: number of HTA agencies that did not have any specialist professional working in the organisation; 1-5: number of HTA agencies that had from 1 to 5 specialist professionals working in the organisation; >5: number of HTA agencies that had more than 5 specialist professionals working in the organisation. **Number of respondents replying to each category

Relationship of the Human Resources with the Organisation

Covering the human resources exclusively by core personnel might be difficult for small and young agencies

Depending on the activities that the organisation chooses to include in its practice, there must be a basic structure with core personnel working on a full-time regime. However, considering that the main barrier in the establishment of the HTA organisation is to find staff trained in running HTAs, covering the human resources needs exclusively by core personnel might be difficult particularly for small and young agencies. For that reason ad-hoc hired experts relative to the subject of the project or study could assist the core staff. Contracting external collaborators for projects co-ordinated and controlled by the HTA organisation eases the performance of specific assessments. It provides the possibility of involving leading experts for special HTAs and eliminates the need to maintain a group of assessors[37]. The extent of such involvement ranges from contributions to the performance of HTA to consulting activities.

Contracting external researchers might be less flexible in terms of time constraints and availability

Although this option appears to be of help in particular to small units, complications might arise from contracting external researchers since they might be less flexible in terms of time constraints, and the availability of suitable experts that could be contracted for particular HTAs is not guaranteed. However, the most important disadvantage of involving external collaborators is that the HTA organisation depends on them, since the permanent staff of the organisation may not themselves be capable of adequately judging the quality of the final product[37].

The following table provides information on the relationship of the personnel working for HTA organisations. External personnel formed an important part of the staff: 75% of the organisations involved "Collaborating researchers" that worked occasionally and on a non-for-profit basis for the organisation (**Table 8**)[13].

Table 8. Types of personnel working in HTA organisations

Profile	HTA organisations according to number of staff				
Internal staff	N**	Median (range)	None* N (%)	1- 5* N (%)	>5* N (%)
Administrative staff	37	2 (0-200)	2 (5.4)	26 (70.3)	9 (24.3)
Research assistant[a]	34	1 (0-100)	15 (44.1)	14 (41.2)	5 (14.7)
Trainee	35	1 (0-20)	16 (45.7)	16 (45.7)	3 (8.6)
External staff					
Collaborating researcher[b]	36	8 (0-150)	9 (25.0)	8 (22.2)	19 (52.8)
Advisor	33	5 (0-100)	13 (38.2)	6 (17.6)	15 (44.2)
Associated researcher[c]	35	0 (0-50)	18 (51.4)	8 (22.9)	9 (25.7)

[a]**Research assistant:** those who help researchers with a technical task (e.g., writing scientific reports, co-ordinating research activities, etc.); [b]**Collaborating researchers:** those that may collaborate occasionally not-for-profit with your organisation; [c]**Associated researchers:** those who from time to time collaborate with your organisation earning money as freelance; *None: number of HTA agencies that did not have any specialist professional working in the organisation; 1-5: number of HTA agencies that had from 1 to 5 specialist professionals working in the organisation; >5: number of HTA agencies that had more than 5 specialist professionals working in the organisation. **Number of respondents replying to each category

As the results of the international survey on HTA organisations[13] suggest, the majority in the participating HTA organisations have full time permanent staff, both in terms of the frequency (97.4%), and of quantity, since 73.7% of them have more than five full time workers (**Table 9**)[13].

Training and Recruitment Strategies

With regard to training and education in HTA, it is important to consider that a relatively small number of experts are currently active in the field, in contrast with the large number of new and existing technologies to be evaluated. Successful HTA programmes require an appropriate education and training strategy targeted at expertise, organisation and staff qualification[12].

Participants in the international survey on HTA organisations[13] reported on their solutions for overcoming the barrier of lack of trained personnel in the establishment. Providing training for staff, endeavour in recruitment of trained staff, and collaboration with universities and hospitals were considered useful for overcoming this barrier (**Table 10**).

Relatively, there is a small number of experts in contrast to the number of new and existing technologies to be evaluated

Table 9. Information about the staff in HTA organisation

	HTA organisations according to the staff				
	N**	Median (range)	None*	1- 5*	>5*
Full time permanent staff[a]	38	8 (0-380)	1 (2.6)	9 (23.7)	28 (73.7)
Part time permanent staff	37	2 (0-20)	14 (37.8)	14 (37.8)	9 (24.4)
Temporary[b]	37	1 (0-18)	16 (43.2)	12 (32.5)	9 (24.3)
Internship[c]	37	0 (0-40)	21 (56.8)	13 (35.1)	3 (8.1)
Fellowship[d]	37	0 (0-35)	25 (67.6)	8 (21.6)	4 (10.8)
Freelance[e]	36	0 (0-6)	29 (80.6)	6 (16.7)	1 (2.7)
Visiting researcher[f]	37	0 (0-6)	33 (89.2)	3 (8.1)	1 (2.7)

[a]**Permanent staff**: contracted for at least 3 years; [b]**Temporary:** contracted for a specific project or for less than 3 years; [c]**Internship:** students / recent graduates not paid or paid very little for their work; [d]**Fellowship:**In training earning money from a research project; [e]**Freelance:** working for the organisation with a service contract; [f]**Visiting researcher:** researchers from other organisations in a stay; *None: number of HTA agencies that did not have any specialist professional working in the organisation; 1-5: number of HTA agencies that had from 1 to 5 specialist professionals working in the organisation; >5: number of HTA agencies that had more than 5 specialist professionals working in the organisation. **Number of respondents replying to each category

Table 10. Solution to Gathering trained staff in the establishment of HTA organisations (N=14)*

Barrier	Solution to Barriers in the Establishment
Gathering trained staff	- Provision of training for staff a. Provision of informal training for new or existing staff (by means of staff of the agency or external experts) b. Provision of or support for official/ accredited training courses (e.g. master's degree courses) - Intensive efforts to recruit trained staff - Collaboration with universities and hospitals

*Number of respondents replying to this category

Internal training for the organisations' staff and the support of external training are essential for maintaining trained personnel.

Respondents who reported barriers to experience in daily work provided data on how they intended to overcome them. Participants considered both the provision of internal training for the organisations' staff and the support of external training as essential for sorting out the problem of lack of trained personnel. The international survey on HTA organisations[13] revealed two different recruitment strategies followed by the participants: the search for already experienced trained staff and secondly, the hiring of new staff members and training them once they are employed (**Table 11**).

Training and particular attention to the recruitment of staff were considered relevant to the establishment of a new organisation and also later during daily work.

Table 11. Solution to Gathering trained staff in daily work of HTA organisations (N=20)*

Barrier	Solution to Barriers in Daily Work
Gathering trained staff	- Internal training of existing or new hired staff (partly by external experts) - Support of or contributing to external training programmes - Intense endeavours in searching for trained staff

*Number of respondents replying to this category

Training and education should be targeted to specific expertise levels

Training and education in HTA should be through effective educational means that should be targeted to specific expertise levels according to the organisation and staff qualifications. It is therefore important to distinguish between career researchers who need full technical skills; temporary researchers, who may need training in specific skills; commissioners, who need implementation skills; and the work force, who need awareness[12].

The HTA training and education agenda consists of two broad strands: training to understand/implement HTA findings (evidence-based policy and practice), and training to conduct HTA[12].

HTA recommendations are essential for the implementation of the technology

Any training and education strategy of human resources should include: health care institutions, professional associations, industry, product manufacturers, academic institutions, health care reimbursement/funding agencies, policy-making institutions/agencies, and legal aspects.

It is no longer just the implementation of findings that is important, but increasingly it is also the integration of HTA recommendations into the implementation of the technology that is essential. To date, it has been recognised that there is

a need to educate individuals so that they will be able to understand the information (recommendation) provided by HTA and be amenable to implementing the findings, adapting and translating more complex findings for application in their local circumstances[12].

HTA as field is in the process of becoming established and institutionalised

The 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. In general, HTA as a field is in the process of becoming established and institutionalised both in individual countries and internationally[34]. 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.) but not in HTA itself. Most countries also have short courses in HTA, but these are provided on a very ad-hoc basis, aimed at a postgraduate audience. Likewise the supply of training in HTA at the undergraduate level is virtually undocumented[34].

An important part of HTA training includes clinical research methodology, epidemiology, and health economics. Other components include:

- The skill of critical and systematic literature review, which includes the 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 tailored options for practical policy-making[34]

5.2 Facilities

Organisations consider "Facilities" a less important barrier

In both the establishment of a new HTA organisation and during daily work "Facilities" appeared to be a barrier of less importance for the organisations compared to others such as "Staff", "Funding", or "Impact on target groups". The "Facilities" barrier, which included for instance building and personal computers, was ranked in last place. Problems related to facilities occurred in the establishment (13.6%) and in the daily work (12.8%) of the organisations. The only solution mentioned by the participants in the international survey on HTA organisations[13] was related to a problem with the building and involved approaching potential stakeholders.

The following table provides an impression of the facilities that the participating HTA organisations have. All organisations have "Individual" and "Shared offices" (each 100%), almost all have "Personal computers" (94.7%), and the majority a "Library" (67.5%), a "Staff/common room" (79.5%), and a "Meeting room" (77.5%) (**Table 12**).

Table 12. Facilities and equipment in HTA organisations

	HTA organisations according to number facilities/equipment	
Offices	**0-20 offices**	**>20 offices**
Individual offices	30 (81.1)	7 (18.9)
Shared offices	33 (89.2)	4 (10.8)
Other facilities	**Without**	**With**
Free offices	29 (74.4)	10 (25.6)
Training rooms	23 (59)	12 (41.0)
Staff/common room	8 (20.5)	28 (79.5)
Library	13 (32.5)	25 (67.5)
Own reception	25 (61.0)	12 (39.0)
Meeting room	9 (22.5)	28 (77.5)
Personal computers	2 (5.3)	34 (94.7)

In terms of databases, the International survey on Information Management Units[35] showed that the HTA Database, MEDLINE/PubMed and the Cochrane library were considered the key sources for information for HTA (**See Annex 2**)

Furthermore, it is of the utmost importance to allocate sufficient resources to allow the analysis of the impact of HTA on clinical practice and policy decisions, as well as resources that will facilitate the maintenance of external relations and communication.

Final remarks

The needs of different organisations are different depending on a large number of variables originating from the financial, legal and cultural backgrounds in which they operate.

We therefore provide very general recommendations:

- It can be recommended to employ core permanent staff and additionally engage external collaborators and advisors, which should also increase the multidisciplinarity of the teams. For the development of internal and external staff, co-operation at national level as well as the integration in international networks of collaborating HTA organisations is suggested.
- Facilities appeared to be of less importance for the survey participants. It must be mentioned here that the result might be influenced by memory bias. However, it must be guaranteed that the HTA organisation has sufficient access to the necessary databases.
- Vital elements of an HTA organisation or programme are:

- Flexibility to collaborate and network with other HTA Agencies.

Chapter 6

Work process

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6.1 Introduction

The structure of this chapter reflects the steps that can be distinguished when HTA is regarded as a process or system[36]. The first three steps, identification, priority setting, and assessment, are covered in this chapter. The dissemination and implementation steps are covered in chapter 7.

A starting point is the identification of new health technology, new indications of well-documented existing technologies, or existing technologies with a poor evidence base. This is followed by priority setting for assessment, carrying out the assessment, with or without the formulation of recommendations, and dissemination and implementation of the findings in policy and practice.

The process of HTA as defined above has a close relationship to what Hailey has termed the 'assessment chain'

The process of HTA as defined above has a close relationship to what Hailey[37] has termed the 'assessment chain', in which he distinguished three steps: the formulation of the HTA question, production of the HTA report, and dissemination and measurement of the (in)direct impact of the HTA report. Hailey combined the 'assessment chain' with the 'resource chain' to arrive at an overall description of the requirements for the effectiveness of HTA programmes. The latter include the roles of governance, resources, staff and structure, and collaborative and contracted inputs. We recognise that these elements have a close relation to how the working process can be organised in new HTA agencies, which is reflected in our approach to the subject. In addition, as about twenty percent of HTA agencies host an Early Warning/Horizon Scanning System[38], some attention will be paid to the working process in these organisations as well. A general introduction on the working processes in Early Warning/Horizon Scanning Systems is provided by Murphy et al[39], which partly uses the framework developed by Hailey[37].

6.2 Identification of technologies for assessment

When the identification of new health technologies is defined as part of the activities of an Agency, the process of identification needs to be linked to the methods employed in the remainder of the HTA process

The need for an HTA agency to have a process in place for identification of new health technologies is highly dependent on whether or not there is a specific source of requests for assessments (e.g. the Ministry of Health) and whether or not there is an agreement on the number of assessments to be carried out per year. If (some of) the assessments can or should be carried out at the discretion of the Agency, then the process of identification will have to be linked to the methods employed in the remainder of the HTA process. Regarding the methods for identification, most experience has been gained by Horizon Scanning/Early Warning Systems. In this context, Robert et al[40] provide a baseline list of sources, and recommend, on the basis of an international Delphi study, an approach for identifying new health technologies that uses, wherever possible, resources which are available on the Internet. In addition, other sources such as expert opinion are recommended for inclusion.

Usually, the process will be such that Agency staff carry out the identification activities, repeatedly scanning a limited number of websites and other sources. This requires a critical attitude and trained appraisal skills to preliminarily assess the validity and quality of the information. To streamline the process of identification a reporting format should be developed, e.g. based on the format developed by Euroscan, which is the European Information Network on New and Changing Health Technologies (for more information see http://www.euroscan.bham.ac.uk, and for a specific example of the Euroscan format see Appendix 4 of the article by Hagenfeldt et al[41]. Information specialists play a particularly important role here, and they in turn can seek support by joining the HTAi Interest subgroup on Information Resources. More information on this issue can be found at the HTAi Vortal, available at http://216.194.91.140/Vortal.

6.3 Priority setting of technologies for assessment

Hailey[37] states that HTA programs may use guidelines or explicit criteria to set priorities for assessment. The results of the international survey on HTA organisations[13] showed that a little more than half of the agencies use an explicit process for priority setting. In this effort, agencies can draw upon a recent review on this issue[42]. The authors reported that a majority of all agencies that have a priority-setting procedure in place use a panel or committee to provide advice regarding priorities. In one agency, two approaches were used. In this particular agency, requests submitted by macro level decision-makers are prioritised at Ministry level, and other requests are submitted directly to the agency and prioritised by its Board Members. In all cases, committees contained representatives from healthcare system funders, health professionals, and researchers. Advice from a Board of Directors was used in a number of systems, sometimes in conjunction with a committee. Other mechanisms to provide advice on priority setting were e.g. the use of a stakeholder group (a volunteer group that includes clinicians, researchers, third party payers, consumers of beneficiary programmes, and health care industry professionals), and a prioritisation strategy group (composed of clinicians, medical advisors, and researchers). In the international survey on HTA organisations[13] similar results were reported.

The general approach to priority setting should reflect the goals of the agency, the resources available and the preferred way of working of those who need to be involved

Overall, there are many different ways to organise a priority-setting process, and there is no best way to do this. As a consequence of a situation in which no single 'state-of-the-art' procedure can be identified, it has been recommended by the EUR-ASSESS Priority Setting Subgroup[43] that the general approach to priority setting should reflect the goals of the programme, the resources available and the preferred way of working (e.g. informal or formal, procedure-based) of those who need to be involved (EUR-ASSESS 1997). It is of course of paramount importance for starting Agencies to be sensitive to the priorities of the main regional or national stakeholders, to secure the relatively rapid production of a series

of assessments that are deemed to be useful. Agencies that contemplate establishing a Horizon Scanning system (HSS) are referred to an overview of specific priority setting processes and mechanisms for HSS[44] .

6.4 The assessment process

As outlined in paragraph 6.1, the HTA process involves several steps. As a starting point, it is desirable to have an explicit understanding of the purpose of the assessment and who the intended users of the assessment are. The specifications of the professionals in the agency who are involved in the process should be clarified just as their exact roles, including a list of authors of the review and personnel providing technical or administrative support[45, 46]. In the assessment process, different agencies may differ in their approach, but in virtually all assessments the aspects of safety and efficacy/effectiveness are included and, increasingly, also considerations on cost-effectiveness, and organisational implications are addressed. In general, the nature and scope of the assessment at hand affects the judgment whether the organisation is appropriate to conduct the assessment; and for each case the organisation should determine the extent to which it will devote its resources to conducting the complete assessment, or commissioning selected components of the assessment and performing the other parts in-house[45,47]. Agencies can be characterised as applying a 'light' or a 'heavy' model in this respect, indicating to which extent activities are carried out in-house[48] . What is important is that an agency should clearly define its scope of activities and on that basis either select technologies for assessment or await other agencies' assessment, with or without subsequent adaptation to a local context. In all cases, there should be a clearly defined agreement on the process of assessment, e.g. on using a predefined template, and including quality criteria. Just as with priority setting, there is no single correct way to describe a technology in need of assessment, but it has been suggested that an initial plan should specify at least the following elements: health care problem; patient population; technology; practitioners or users; setting of care; and properties or impacts or health outcomes to be assessed[45] .

It is desirable to assemble all of the evidence relevant to a particular technology and to collect new primary data if the existing evidence will not adequately address the assessment problem. In practice, however, the ability of most HTA Agencies to undertake new primary data collection is limited and many organisations only use evidence from published sources[45,47]. For evidence interpretation organisations should use an explicit and systematic approach to classify and critically appraise the quality of the available studies, firstly for determining which studies should be included in the synthesis and secondly for grading the evidence[45,47]. The EUnetHTA project has resulted in a number of specific products to facilitate the HTA process. Firstly, WP5 has prepared tools to assist in the selection and prioritisation of technologies for assessment. Secondly, WP4 has

developed an HTA Core Model, which is a framework tool for comprehensive analysis of the elements to be included in a robust HTA. The model embraces nine thematic domains for assessment, which are:

1) current use of the technology (implementation level);
2) description and technical characteristics of the technology;
3) safety;
4) effectiveness;
5) costs, economic evaluation;
6) ethical aspects;
7) organisational aspects;
8) social aspects;
9) legal aspects.

Each domain consists of specific building bricks of information, which are called assessment-elements. Each element defines a question that should be answered as part of an HTA. The structure and the use of the HTA Core Model will be presented in a handbook that will provide instruction on the practical application and further development of the model. Thirdly, WP5 has developed an 'adaptation toolkit', aimed at assisting Agencies to adapt HTA reports from other countries, regions or settings for their own use by assessing the report's relevance, reliability and transferability. For this purpose, the toolkit consists of a series of checklists, questions and information about additional sources. An instruction manual will present the tools and how to use them. More detailed information on each product can be found on the EUnetHTA website (http://www.eunethta.org).

6.5.Recommendatons

Although the terms *findings* and *recommendations* are sometimes used interchangeably, they have different meanings: *findings* are the results or conclusions of an assessment; *recommendations* are the suggestions, advice, or counsel that follow from the findings[47]. In addition, the term *advice* is occasionally used, which can be regarded as intermediate between findings and recommendations.

Some HTA Agencies have a mandate to make explicit recommendations[37,] for other Agencies the formulation of recommendations is a facultative component of assessment, and for yet other Agencies the formulation of recommendations is explicitly excluded from an assessment.

The elaboration of recommendations, to policy makers, health care providers, researchers, patients, and insurance companies, is a facultative component of an assessment

The most important factors for recommendations to have a high impact, at least potentially, are: the general reputation and credibility of the Agency, involvement of stakeholders, timeliness and quality of the assessment

When provided, recommendations can in principle be formulated for all actors involved. In practice, as documented by the international survey on HTA organisations[13], recommendations are most often formulated to address policy makers, health care providers, researchers, patients, and insurance companies If recommendations are given, the target audience for the recommendations should be clear, recommendations must be consistent with the *findings* of the assessment and there should be an explicit link between evidence and recommendations[47]. The gradation of recommendations using hierarchies, which consider the quality of the underlying evidence, represents the best practice when giving recommendations; there are different grading scales[49], so the HTA organisation has to state which one was used and the way it is constructed.

In cases where recommendations are excluded from an assessment, for example in England and Wales, this goes together with distinguishing the terms 'assessment' and 'appraisal'. An assessment is then regarded as the scientific evaluation of a technology while 'appraisal' stands for the process of interpreting the evidence, leading to the policy advice or perhaps even to the actual policy ('guidance') based on the assessment. As an ultimate consequence of this distinction, it has been suggested that an assessment that includes recommendations should not even be called an HTA.

When formulated, HTA Agencies consider a number of factors of importance for recommendations to have a high impact, at least potentially. The most important of these factors, supported by about 60% of respondents in the international survey on HTA organisations[13], are the general reputation and credibility of the Agency and the involvement of stakeholders, closely followed by the timeliness and quality of the assessment, respectively. Ideally, when recommendations are aimed at changing practice, the most important criterion for assessing impact of recommendations is whether or not clinical practice variation has been reduced (in the desired direction) and patient outcomes have improved after the recommendations were published. However, this may be difficult to measure. Alternative, more feasible 'Intermediate' impact indicators may include e.g. changes in uptake of recommendations in clinical practice guidelines, changes in health care resource allocation (e.g. by changing reimbursement decisions), and documented changes in the adoption and utilisation rate of specific technologies.

6.6 Process and product quality assurance

It goes without saying that process and product quality assurance is extremely important in HTA and needs formal and explicit methods, techniques and instruments that are recognised as valid by the HTA community. Quality assurance in general needs to be the responsibility of the governance structure of any Agency, for which Hailey[37] provides a number of suggestions specific to the functioning of HTA Agencies. Further development of these suggestions can be based on publications focusing on e.g. process measures of health care quality[49] Analogous, indicators of the quality of the process

underlying the production of an assessment could be that the assessment is produced in time and stays within budget. Indicators of product quality could be formulated in terms of the clear and coherent presentation of the best available evidence in an assessment

6.6.1 Process quality assurance

In many programs, according to Hailey[37] most assessments are carried out in-house. Another option is to use external contractors to prepare an assessment. There may also be arrangements where the staff in an HTA programme actively collaborates with external workers in the preparation of assessments. As a minimum, there will need to be some co-ordinating and contracting function within an HTA programme if the assessment is to be undertaken externally. Advantages of external contracting include the possibility of using leading experts in a field and of avoiding the demands of maintaining a group of assessors. Disadvantages may include lack of flexibility when there are time constraints, and lack of availability of suitable expert persons for a particular task.

Depending on the organisation of the assessment (in-house or (partly commissioned) there are different options to organise the quality assurance process

6.6.2 Product quality assurance

In case of in-house produced assessments, product quality assurance can be achieved by organising external expert peer-review of the product. In cases of mixed internally/externally produced products, local Agency staff should not be involved in product quality assurance. It should be ensured that sufficient external experts, either regionally or nationally, are available for independent peer-review; otherwise a peer-review process should be organised using foreign experts. In case of externally produced products either the HTA staff has to be capable of assessing its quality or the staff have to organise external expert peer-review processes. A checklist developed by Hailey for INAHTA members is helpful in the process[46]. In practice, the international survey on HTA organisations[13] showed that about 90% of the agencies have internal review procedures in place, 79% of the agencies use external reviewers, and only 41% of the agencies use a checklist. The authors of the survey concluded that quality management systems are underdeveloped in most agencies. Both new and existing agencies are recommended to improve on this practice.

Final remarks

There is a considerable amount of information and expertise available to assist new Agencies in establishing work processes.

There are many possibilities for organising appropriate working processes, so the information in this chapter can be regarded as enlightening without being prescriptive.

HTA processes are complex and dynamic, a key for success of HTA staff is to be flexible with a commitment to lifelong learning.

Chapter 7

Disseminating HTA products

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Chapter 7 discusses communication and dissemination of HTA products. Dissemination as an active way of communication and transferring HTA reports and their recommendations to intended audiences, are key steps to improve the prestige, the visibility and the credibility of HTA organisations and their activities. At the same time, both are crucial to increase the capacity of supporting decision-making processes with evidence-based knowledge. Dissemination and communications activities that increase HTA organisations' visibility should not be neglected. On the contrary, according to the HTA organisation's mission, resources and staff, they should be planned and implemented according to the right identification and prioritisation of stakeholders and target audiences, and an accurate selection of the methods and means for reaching them.

HTA organisations aim to produce good-quality information and analyses to effectively support decision-making processes in health care systems. HTA reports can or must try to foster changes in the health care setting by promoting interventions of proven benefit and discouraging ineffective interventions, through a more evidence-based approach[50,51]. However, producing "good quality information and analyses" to reach these goals is not enough.

Only producing good quality information and analysis does not implies to be successful in HTA

HTA organisations cannot expect that just because HTA results are based on quality evidence-based methods they will exclusively convince the target groups to move to changed clinical practice[52]. Being realistic, on many occasions HTA reports are just another information source to support informed decision-making, but not the only one. Information generated by HTA organisations is competing in an environment full of information flows with news coming from different and multiple sources, which can mean an important barrier to HTA recommendations being assessed properly.

A preliminary basis in the communication field is that someone who comes into contact with information may not feel attracted by it. At the same time, the information may not be correctly interpreted or agreed on. The information may not even be relevant for the person at the moment of deciding what to do or even changing the opinion or point of view. When dealing with changing people's behaviour or minds there are "no magic bullets", so more than one intervention is called for, but no single intervention is always effective for changing behaviour[51]. In spite of this, multifaceted interventions tend to be more effective, but may be more expensive [53]. Thus, if the HTA organisations want to reach their aims successfully, they should be aware that the knowledge being produced should be made public and visible, and should be communicated and disseminated by means of different strategies.

Although the best way of being visible is informing effectively the decision making processes, dissemination activities must be encouraged and developed systematically to make HTA results present when decision makers act

If we accept that visibility can be defined as the capacity to be seen by others, it is logical to think that efficient communication of the results, together with appropriate dissemination of the HTA products, are essential elements to increase the visibility of the HTA organisations, without denying that a high level of visibility can be reached when the HTA results are useful and have an impact on decision-making.

HTA practitioners have recognised that dissemination activities are a key process that needs to be intensified. Why and how particular approaches should be adopted are still under debate[53,54,]

7.1 Methods or activities to increase visibility of HTA reports

Dissemination can be defined as any process by which information is transmitted (made available or accessible) to intended audiences or target groups[5,54] It is also an active targeted communication of results tailored for specific stakeholder groups, as a logical first step before implementing HTA research.

For instance, the most visible indicators of HTA organisations are traditional products such as reports and newsletters in printed or electronic formats, but even outputs such as HTA-derived products (clinical practice guidelines, seminars, methodological guidelines, patient leaflets) could be included[37].

The results of the international survey on HTA organisations[13] showed that most HTA organisations had a formal procedure to disseminate their products (75%) most often using the website (92.3%), participation and organisation of academic, scientific and training activities (84.6%) and electronic and printed versions of reports (79.5%). However, the survey did not take into account whether dissemination of the HTA products was being planned and it did not even take into account if the results of this dissemination were assessed.

Some HTA organisations even have highly skilled staff in dissemination and communication, and plan the release of new HTA results systematically and carefully. It is also acknowledged that asking agencies in countries with limited institutionalisation of HTA to adopt this kind of model, at lest in the initial phase, cannot be a realistic approach. Limited resources such as trained staff or budget, and the pressure of other priorities such as producing HTA products or responding to other demands, are obstacles to conducting complex dissemination strategies.

Certainly, there are few studies that deeply assess the efficacy of dissemination[55,56,57,58,59] strategies, as they focus much more on analysing some aspects related to the implementation of HTA results or on the analysis of its impact. However, some things should be taken into consideration and steps taken to apply them if possible. Thus, disseminating HTA results is a way of supporting the implementation of research that should not be neglected by any HTA organisation, always according to its scope, audience and resources.

As mentioned above, the most tangible HTA products are reports or newsletters. HTA reports present results and conclusions extracted from previous analyses and syntheses of different pieces of information. HTA reports can be either confidential or public and therefore the type of dissemination of the products will depend very much on this.

To be successful, different strategies and actions to be performed should be taken into account and carried out at the same time, which increases the possibility of the information reaching the target public.

One of the best ways of being visible is by providing the HTA organisation with an exclusive visual identification programme (logo, templates) to create a brand for rapid identification of the organisation and to raise awareness among target audiences. Designing and maintaining an updated and independent web site will be another immediate step to be taken. If this is not possible, a solution could be to try to get a section on the ministry or university web site. The web site operating 24 hours a day, 365 days a year, is a central contact point and a platform of all the HTA documents that the organisation posts in its electronic format. They are always accessible for any user at any time. At this point the organisation can use several methods and means to announce the publication of reports and to raise interest in them (email alerts, press notes, portal ads, and Really Simple Syndication (RSS) channels. Writing press releases or establishing personal contact with journalists to explain the results of the HTA is another key activity to foster public interest in the HTA results.

As mentioned before, publishing HTA reports, in printed or electronic format, is the most common traditional procedure used to disseminate HTA results. As wide dissemination based on printed materials can be expensive, electronic media are powerful tools to help to disseminate HTA reports at a low cost. In addition, the electronic format allows the organisation, starting from a full and finished HTA report, to use the information to make other products (scientific, structured abstracts, brief reports, evidence-based synopses) in a flexible manner, adapting its message to the different types of public.

Scientific communication of HTA results for scientists should be boosted as it is an indication of its quality, and because of its possible specific impact on the main specialists and opinion leaders.

Publishing the results in suitable peer review journals according to the target audience, to show that HTA reports go beyond simple technical government reports, is another strategy to reinforce the prestige and external consideration of the quality of the information produced by HTA organisations. In this vein, the fact of publishing HTA reports as papers in open access journals that provide access to free full text articles which can reach wider audiences and increase visibility, implies the possibility of taking advantage of other things; for instance it is worth mentioning that the HTA organisations can have the copyright of the information, being able to use it in different formats and media and in other languages, without concerning themselves with copyright infringement. It is important to add that most open access journals are indexed in the main medical databases, and they are increasing their impact factor.

However, publishing, printing and electronic formats are not the only ways to disseminate the HTA results. Any relation with the stakeholders and decision-makers means the possibility of publishing the HTA results in a personalised manner. The public verbal presentations of the results, and the involvement of different actors and experts and target publics, are other strategies that should be frequently used. Thus, encouraging influential local and national policy-makers and opinion-

leaders to read and know the benefits of the HTA conclusions and results. Meetings with key relevant policy-makers or experts to discuss summarised results and conclusions can be a valid resource, by strengthening personal relations with key relevant policy-makers, experts and journalists and creating networks to get interaction. Thus, organising and participating actively in local, regional, national and international workshops, conferences or courses on methodological aspects related to the HTA discipline to create a critical mass capable of interpreting the results and benefits of HTA, and evidence-based approaches and maintaining permanent contact with experts and networks to interact with them, should be another regular dissemination strategy to be applied.

7.2. Targeting the right message to the right usrs

As has been mentioned, there is a poor understanding and study of the factors that may influence the applicability of HTA research findings to make informed decisions.

Tailoring target audiences is one methodology for identifying common groups according to their homogeneity to send out HTA messages. Their position, responsibilities, behaviour, attitudes, needs, expectations, perceptions or geographical origin can be special characteristics that should be identified and analysed. Moreover, they can act as incentives or barriers to adopting HTA recommendations.

Different actions and strategies should be considered and carried out as an integrated plan

The international survey on HTA organisations[13] showed that the main target groups to whom they addressed the recommendations were public health care providers (82.5%), policy makers (77.5%) and health professionals (77.5%) (**Table 13**)

HTA organisations should try to identify different audiences and groups for adapting the key messages that should be conveyed to them and select the most appropriate and efficient channels for successful dissemination. Identifying different individuals or organisations that play a major role because of the influence they can have on other targeted users (opinion-leaders) is a key process for success, especially for major opinion leaders, individuals or organisations whose opinion has a great influence on the target audiences, acting as prescribers or influencers, because they can support or encourage the refusal or adoption of the HTA recommendations[54].

Table 13. Main target people of HTA organisations (N=40)*

Main target people	N	%
Public health care providers	33	82.5
Policy makers	31	77.5
Health professionals (general practitioners and specialists)	31	77.5
Professional associations	25	62.5
Health related professionals	23	57.5
Health service researchers	21	52.5
Researchers	17	42.5
Compulsory health care insurances (public)	17	42.5
Pharmaceutical/ Devices industry	15	37.5
Patient groups / Carers	15	37.5
Private health care providers	11	27.5
Media	9	22.5
General Public	8	20.0
Private Medical Insurance	5	12.5
Consumer associations	4	10.0

* Multiple choice question which allows more than one correct answer to be selected. The question was measured by a ranking from 1 to 15; The category "Most frequent user" was obtained by grouping the answers from 1 to 5.

It should also be taken into account that the number of categories referred to in table 13 is increased if we add other actors such as the industry in technologies, medical products and drugs. It is also important to note that we are not dealing with a homogeneous public, not even in their level of training and knowledge. Their profiles may differ, as they work in different settings and with different degrees of responsibility (management, health policy, research, clinical practice, primary care or specialised at local, regional or national level), which means a high complexity level for any approach that could be proposed.

The prioritisation and selection of the public is also influenced by the limited available resources that can be devoted to this activity, which means that the suitability of dissemination strategies of the results should be assessed.

Moreover, all the analyses or research that can be done before disseminating HTA results and recommendations will help us to identify barriers and incentives to adopt them or not. Relevant aspects concerning the target audience, results and relevant information, media, leading opinions in the setting, messages sent and different points of view of stakeholders are some of the options that should be studied and analysed.

Finally, the message or messages that are transmitted should be developed and modulated in a suitable manner. It should be noted that communication with the different stakeholders might be symmetric, if the recipient also knows "what we are talking about" as he/she knows the method assessed or the methods that we used for the analysis, or asymmetric, something that happens when the recipient is not an expert in the subject, as is the case of policy makers. Thus, it is useful to plan presenting the information in different formats and/or languages that can be interpreted correctly by different types of public, always making clear the main idea that we want to put across as a result of our assessment. The linguistic and narrative aspects should not be told in detail. A poor transformation of the results into the written text can represent a fault and a discredit for the report and also for the message that is intended to be sent. Therefore, the same rigour and professional level that are developed in the HTA report should be applied in the writing and final dissemination.

Final remarks

Dissemination activities are very important for obtaining adequate visibility of the HTA organisation and its products.

The dissemination process should be planned as carefully as possible, and consideration of it should start at the beginning of the development of public HTA reports, and not at the end of the report.

There is no "magic bullet" for disseminating HTA results. Different actions and strategies should be considered and carried out as an integrated plan.

Identifying HTA target audiences is also a key process in dissemination activities, especially when selecting key relevant stakeholders or opinion leaders.

Formal and complex dissemination strategies need extra resources (staff, budget)

Learning from experienced HTA organisations can be an efficient strategy to implement, increase and improve dissemination methods and activities.

Do not neglect the capacity of information technologies to communicate, especially the new ones that are under the concept of Web 2.0 or Social Web such as blogs, RSS and wikis among others that may be relevant to making communication more dynamic and raising interest in the HTA results.

Chapter 8

Conclusions and recommendations

What are the main aspects to be considered in the implementation of an HTA programme?

Before establishing an HTA programme different aspects should be considered:

1- **Preparing the ground** with advisory work, discussion among relevant stakeholders and estimation of sufficient funds

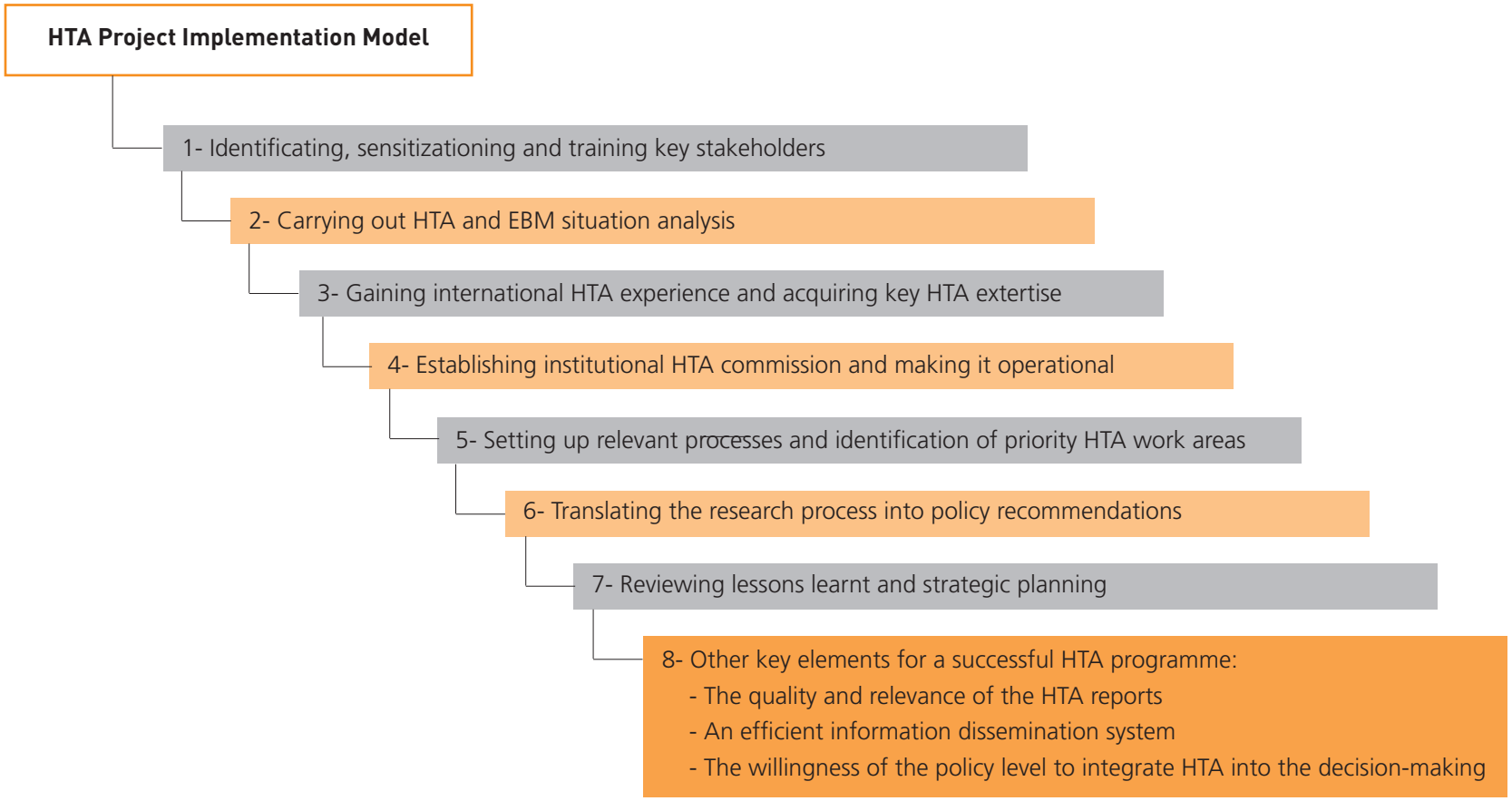
2- **Identifying suitable professionals and HTA** training opportunities

3- **Integrating various professional disciplines, not only** professionals from medical disciplines but also public health specialists, psychologists, biomedical engineers and economists should form part of the core HTA staff team.

4- **Analysing the current scene relevant to HTA**, such as institutions, regulations, financing system, publications, other HTA agencies, etc.

5- **Networking and communication** for identifying national and international partners and collaborators

This step-wise HTA project implementation model*[2] could be adapted to the specific national circumstances (see chapter two)



2 This step-wise HTA implementation model is based on Swiss HTA Implementation Model (see chapter 2)

What should be taken into account when the new HTA organisation has been established?

The needs of different organisations regarding structure are different depending on a large number of variables, ranging from the financial and legal and cultural background at which they operate.

Once the new agency has been established, different aspects **should be** taken into account:

1- **Be sensible to their specific setting needs** (stakeholders, decision makers, patients associations, healthcare institutions and health insurance providers)

2- **Establish liaisons** with, at least, other national organisations, with academic and health care institutions and with patients' groups and associations in order to obtain necessary inputs about HTA work, scientific information and socio-economics factors

3- **Be benefited from the 'core' information** provided by the European HTA network about the effectiveness of technologies and shared among member states and also to benefit from the emerging HTA network

4- **Look out for high quality products** in order to establish them as scientific evidence referents in their context

5- **Ensure financial sources** for funding the future HTA agency. An HTA organisation requires moreover, sufficient resources that allow analysis of the impact of HTA on clinical practice and policy decisions, as well as resources that facilitate the maintenance of external relations and communication

6- **Active action on decision makers** and involvement of all relevant stakeholders

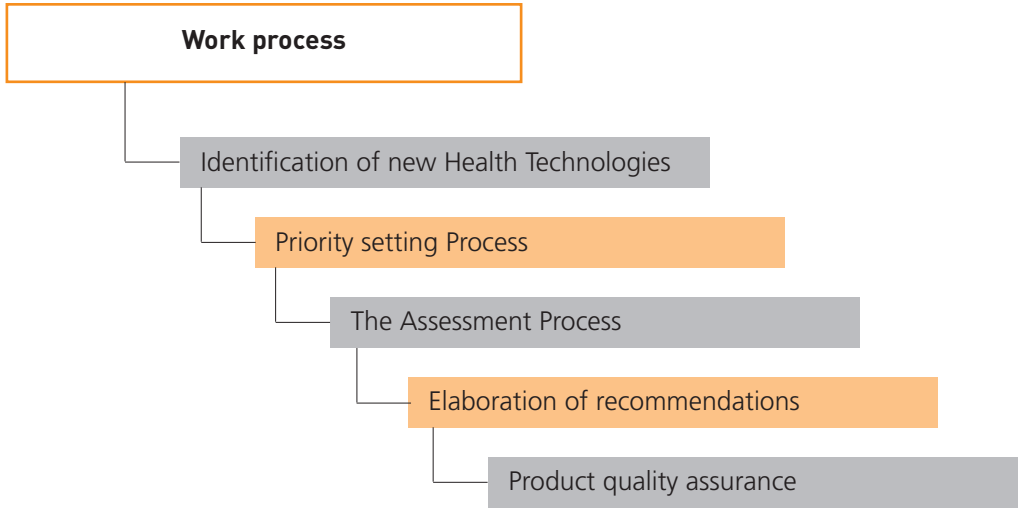
7- **Have multidisciplinary teams,** that will ensure a continuous professional development which is necessary for the evolution of the HTA organisation. A core permanent staff, completed by additionally engaged external collaborators and advisors, can serve the multidisciplinarity and increase the capability of the organisation to serve the various subjects that has to be explored

8- **Co-operate at national level** by means of establishing a central body with some key functions such as: legal mandate for co-ordination, priority-setting, decentralizations of HTA research, funding, creation of a platform for information exchange on HTA, ensuring of multidisciplinarity of HTA and establishment of formal health policy links

9- **Look for international collaboration:** International collaboration should include participation in joint projects and an exchange of information, such as project reports on other HTA background material

10-**Achieve legal support.** The achievement of legal support is top-down and bottom action that relies on strong networking activities

It is recommended that each agency should clearly define its scope of activities and on that basis either identify and/or select technologies for assessment or await other agencies' assessment of specific technologies, with or without subsequent adaptation to a local context.



Identification of new Health Technologies: When the identification of new health technologies and/or new indications of existing technologies is defined as part of the activities of an Agency,

- a publication[40] provides a baseline list of resources and a recommended approach, using resources available on the Internet whenever possible. The EuroScan format could be adopted for reporting purposes.
- The process of identification needs to be linked to the methods employed in the remainder of the HTA process (priority setting, assessment, etc).

Priority setting Process: There are many different ways to organise a priority setting process, and there is no best way to do this. The general approach to priority setting should reflect:

- The goals of the agency
- The resources available
- The preferred way of working of those who need to be involved

In practice, it is suggested that a panel or committee should be established to provide advice on priorities. The Committee could, among other things, include representatives of healthcare system funders, health professionals and researchers.

The Assessment Process: The assessment process involves several steps that need to be defined:

- professional characteristics of Agency personnel involved
- skills-mix availability and division of labour
- whether or not to carry out the assessment as a full in-house or (partly) commissioned project
- the scope of the assessment (e. g. including safety, efficacy/effectiveness, and cost-effectiveness of a health technology)
- other relevant aspects of the assessment methods including the issue of primary data collection or a limitation to secondary sources

For evidence interpretation, it is suggested that HTA organisations should use an explicit and systematic approach to classify and critically appraise the quality of the available studies. EUnetHTA WP4, 5 and 7 have resulted in useful tools for this purpose.

Elaboration of recommendations: The elaboration of recommendations to policy makers, health care providers, researchers, patients and insurance companies is a facultative component of an assessment.

When these are given, the recommendations should be clear and consistent with findings if the assessment and there should be an explicit link between evidence and recommendations. The most important factors for recommendations to have a high impact, al least potentially, are:

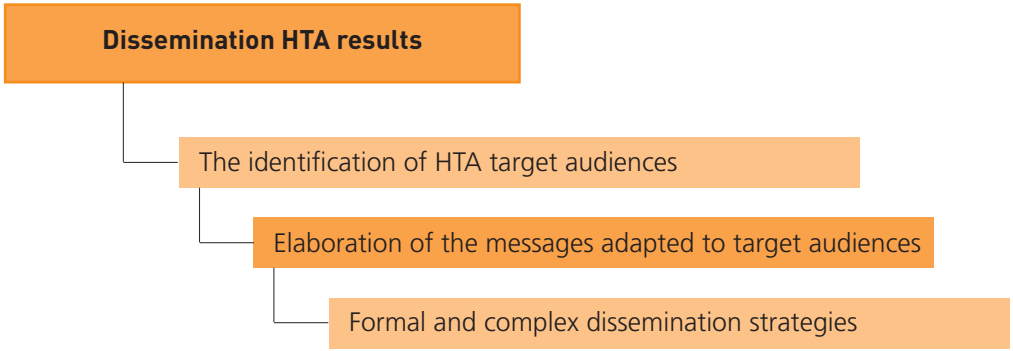
- the general reputation and credibility of the Agency
- involvement of stakeholders
- timeliness
- quality of the assessment

Product quality assurance: Quality assurance of assessment reports is a responsibility of the governance structure of any agency. Depending on the organisation of the assessment (in-house or (partly) commissioned) there are different options to organise the quality assurance process. For example, an in-house prepared assessment should be peer-reviewed by independent external reviewers, whereas an assessment that was commissioned can be peer-reviewed by internal agency staff. The checklist developed by Hailey[46] for INAHTA members is recommended for this purpose.

Why is the dissemination so important?

Dissemination and communication activities are very important for adequate visibility of the HTA organisation and its products in national health care systems.

There are no "magic bullets" for dissemination HTA results. Different actions and strategies should be considered and carried out as an integrated plan which should include:



The dissemination process should be planned as carefully as possible, and should first be considered at the beginning of the development of public HTA reports and not at the end of the report.

Chapter 9

Challenges and new future actions

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Advances in science, the rising expectations and the ageing of populations are powerful drivers for increasingly complex and costly health interventions. The stewardship and management of health systems in the future will therefore require even stronger guidance by relevant and timely information and advice provided from independent assessment work that reflects the dynamics of the technology and the health-care system. And, the ways in which health-care decisions are made require greater clarity, transparency and to be more favourable to the incorporation of evidence.

The beginning of the 21st century has lifted HTA from an academic niche to a prominent and visible position. Meanwhile, numerous national health ministries, the European Commission and the World Health Organisation have all proposed HTA as an indispensable coping strategy to appropriately confront the influx of new technologies and rising costs. In general, HTA as a field is in the process of becoming established and institutionalised both in individual countries and internationally. Even though the momentum for the continued evolution of HTA has been set in motion, several challenges as well as activity fronts require further attention and follow-up.

Setting up HTA structures and establishing effective HTA programmes that guide key policy decisions is a challenging task. There are no standard models or pathways so the "one fits all" principle is not useful because of the wide differences between countries/regions (cultures and values, health systems, labour organisations, public priorities, governance, etc.) In this handbook some approaches have been proposed while comparison with the experience of other HTA organisations may give some indications based on shared experiences, but each country (region, province, provider, etc.) must find its own way, its own most efficient possible alternative in its health and organisational context. Organising international advisory committees to help countries with low institutionalisation to start is another possible strategy.

On the other hand, the complexity of HTA has increased, partly because of its evolution through distinct phases. As proposed by Battista[60], HTA focus has shifted from a single machine to comparing technologies' impacts on disease conditions (clinical outcomes) to service delivery approaches (delivery modes). However, this author argues that the theoretical foundation for the field remains underdeveloped and it is time for HTA to bring together many more aspects of conceptual and theoretical works from other fields. This will strengthen the foundation of HTA and help to overcome many challenges that await the further development of HTA. Battista summarises them around three research themes which will be discussed throughout this chapter: adapting HTA to an evolving analysis object; translating HTA results into policy, management, and practice decisions; and evaluating processes and organisational models of HTA.

The first theme, the expanding breadth of the technologies to be evaluated, questions whether we can use the same tools to assess these different technologies. At the same time it brings particular attention to the context of policy making, which draws HTA closer to the political environment in which decisions are made, rather than remaining distant from it and, in some cases real trade-offs may have to be made between relevance and autonomy for HTA organisations[61]. Other areas of potential research relate to the expansion of the concept of health together with information technologies that have reduced the status of the expert.

Methodological research and development also needs to be undertaken to improve the relevance and validity of HTA findings. It is worth mentioning the need for health services research approaches to enact policies that deliver more equitable and efficient health outcomes (e.g. determining which subgroups might benefit most from an intervention)[10]. This is especially true for increasingly complex technologies such as tissue engineering, the integration of qualitative and quantitative research within assessments or the emerging field of "omics". In fact, complex innovations such as those on biotechnology field challenge current assessment techniques and decision making.

It also highlights the need for educational and training programmes in HTA and related areas in order to have trained personnel, coming from different disciplines but having a common "language", performing HTA in co-operation. This requirement is reinforced if we take into account that gathering trained staff has been pointed out as the most frequently experienced barrier in both the establishment and also in the daily work of an HTA organisation. Although the supply of education and training in HTA in Europe has increased rapidly, only a minority of all European countries had been involved in this development[61] at the beginning of the present decade. The existing training in the majority of European Union countries is mostly in the different disciplines working in HTA (medicine, epidemiology, economics, etc.) as well as short courses in HTA provided on a very ad-hoc basis and aimed at a postgraduate audience. Likewise the supply of training in HTA at the undergraduate level is virtually undocumented. An ongoing survey within EUnetHTA project (worpackage 8) will give us more data on the current situation and possible actions for the future.

Appropriate policies and laws need to be put in place to anchor and mandate the use of HTA for investment, reform and reimbursement decisions. These policies and laws prescribing the use of HTA need to be coupled with clear regulations for adequate financing and independence from industry/manufacturers when performing HTA. It is recognised, however, that collaboration with the industry/ manufacturers is necessary in order to obtain clarifications and unpublished or required evidence. The promotion of stricter regulatory frameworks for biomedical and medical devices would also enhance HTA activities.

HTA can deliver information ranging from highly technical matters such as efficacy and cost-effectiveness, through analyses of the equity, social, ethical and organisational impact of technologies. However, the question of how and where, along the line from assessment (the objective analysis of the impact of technology) to appraisal (the interpretation of objective analysis) to decision making, the full breadth of perspectives on new technology should come into play remains an open one, and will vary among health-care systems[10,62]. Besides, the coming of molecular medicine with its individualised and gene-based therapies will exacerbate the lack of clinical evidence from RCTs, and prompt the necessity of supplementing RCT efficacy evidence with real-world evidence of effectiveness and cost-effectiveness[63].

Also, in relation to the scope, HTA can be seen increasingly as a tool for promoting the introduction of cost-effective and promising technologies and not merely as an instrument for cost containment or gate-keeping. In that sense, the following actions or activities could be implemented:

- Proactive identification of technologies that will improve healthcare quality and reduce costs; HTA could be an important tool for improving the efficiency of the health service
- Need for greater convergence between health priorities and innvoation
- Monitored introduction of promising technologies where public and private sectors share risks[64,63] ("coverage with evidence" approaches to funding new medical technologies as a way of bridging currents gaps in evidence)
- Application of HTA to innovations (those technologies in phase I and II of clinical trials, not still being emerging technologies) in order to see their future potentialities, i.e. develop and apply those methodologies aimed at reducing the gap between the innovation generation and its market release (there are some current experiences such as the MATCH project in Scotland for home care technologies [http://www.cs.stir.ac.uk/~kjt/research/match/main/aboutus.html] or the Inno-HTA in Europe dealing with HTA-methodology for innovative healthcare technologies [http://www.inno-hta.eu/]
- Shifting of HTA to the point where health technologies are incorporated, i.e. the hospital
- Application of HTA to patient safety related interventions is another future claim that should not be overlooked

On the other hand, an HTA organisation might promote social debate and the interrelationships among different stakeholders related to the technology under assessment. For example, the challenge can be viewed in terms of creating HTA exchange forums with industry/manufacturers, clinicians, patients/public to set priorities, complete assessments and translate those assessment results into policy and decision-making

New technologies enter global markets swiftly and in large numbers. No single country can shoulder the amount of HTA work required. Therefore, an enhanced co-ordinated international strategy will become more important in the future even though the debate about how to formalise it raises questions on its geographic scope, its organisational structure (network or agency), etc. Strong and effective international collaboration requires further efforts in terms of unified assessment methods and quality and reporting standards. Internet-based repositories for HTA relevant literature (such as handbooks) and databases for HTA reports necessitate further development and capacities for continued updating[65].

The international collaboration is especially relevant for those countries without institutionalised HTA since it offers the opportunity of learning from others' experiences and takes advantage of the work already done in HTA. Nevertheless, the assessment of transferability of the evidence in HTA obtained from other HTA organisations is one of the main pitfalls, and also a challenge, while adapting the assessment data from other contexts. It also requires an important standardisation of country-specific methods [66]

In fact, there is need to undertake, to adapt or to interpret HTA on an international level for several other reasons apart from the increasing interest in networking and collaboration in the field of HTA. One of the main issues impeding this is the lack of generalisability of clinical and most economic data. There are problems when generalising from data collected in clinical trials alongside regular practice; there is also lack of generalisability of economic data over time or from place to place. Specifically, transferability deals with the latter issue but most often experts have to face up to all these issues at the same time. Several analytic strategies have been proposed to deal with issues of transferability (modelling approaches, analysing data from multinational clinical trials and systematic reviews of economic evaluations) but there is still a need to resolve several methodological issues, especially in relation to the conduct, reporting and use of economic evaluations.

When there is no evidence at all or it is impossible to adapt it to other healthcare contexts, performing or commissioning primary research to answer the assessment question is an activity that some organisations can afford; but it becomes a challenge for others, in terms of the appropriate methods to apply, the availability of trained staff or the resources required. The ability of most HTA organisations to undertake new primary data collection is limited and many of them only use evidence from published sources[47].

Assessments related to public health interventions, emerging technologies and support system are still less developed in comparison to pharmaceuticals, medical procedures and medical devices. In particular, there should be further exploration of applying the principles and methods of HTA and economic evaluation to preventive measures.

Related to the work process several other challenges are identified. Firstly, the development of priority setting mechanisms that are transparent and flexible, and that suit the needs of those who have to use them. There is a need to focus HTA strategically to meet national needs ("needs-led" prioritisation of HTA topics as opposed to "user led" prioritisation) including the capacity to disinvest from ineffective treatments. Since HTA is also about assessing already existing technologies in existing indications and a lot of everyday practice is not based on sound evidence, current practices must also be challenged[63]. So there is a need for innovative methodologies to identify and prioritise topics for HTA. Speciality mapping can make a positive contribution to the policy agenda, with several research and policy gaps being fed into existing prioritisation channels[67].

Secondly, co-operation and communication amongst HTA producers, users and other stakeholders is essential to ensure more comprehensive assessments of a wider set of technologies, reduce potential duplication and ensure that assessments are in line with decision makers' priorities. Such models of co-operation also need to reflect the local HTA production capabilities and institutions[10,68].

Besides there is a need for the development of efficient Internet search strategies for identification of new health technologies, for new indications of existing technologies, and for existing technologies for which the evidence-base is limited or when there is suspicion that the technology does more good than harm.

Balance between validity and opportunity in the production of assessments in a way that secures timely and high-quality products that actually serve decision-making in policy and practice is of great importance as well. This necessity for timely assessments for decision-making has led to the development of alternative evaluation processes and products such as rapid reviews, fast-track procedures or mini-HTA[69].There is a need to evaluate if these new developments are equally valid and reliable as traditional HTA reports or, at least, to know their main weaknesses.

The involvement in the HTA process of those clinicians who use or know the technology under evaluation is another challenging strategy for some HTA organisations. In fact, greater stakeholder involvement can facilitate improved implementation of decisions and policy, and manage uncertainty[10]. Moreover, some countries/regions have structured their HTA processes to be "advisory" to doctors and health care services whereas in others there is a link to the funding decision. But it is unclear whether this separation of advice from funding is more effective than the direct application of HTA to coverage decisions[63]. Also, there is a need to manage the inevitable tensions that arise when HTA directly influences funding decisions.

The most important future action may be to systematically and periodically evaluate the functioning of HTA organisations. Given HTA's focus on evaluation, it would be particularly misguided to exempt the HTA organisation and HTA processes themselves from evaluation[70]. Process and product quality assurance is extremely important in HTA and needs formal and explicit methods, techniques and instruments that are recognised as valid by the HTA community. Quality assurance in general needs to be the responsibility of the governance structure of any organisation, for which Hailey[37] provides a number of suggestions specific to the functioning of HTA organisations. However, there are some significant challenges in assessing effectiveness of HTA programmes. Some form of standards or guidelines exist for reports and other products, or for aspects of managing human and financial resources. But other aspects of an HTA programme are less easy to address through a potentially "objective" effectiveness appraisal process. A possible approach could be comparison with the experience of other HTA organisations but given the organisational diversity of HTA programmes and the varied contexts within which they work such strategies are limited at best. Nevertheless, identifying determinants of success for HTA organisations will create a "public good" available to all HTA organisations as they continue organisational learning and development[61] Finally, an obvious difficulty for HTA programmes is that many aspects of their effectiveness are determined by other parties.

Other possible work process actions include the application of Modern Knowledge Management methods to enhance the efficiency and overall performance of HTA programmes; the implementation of rapid learning strategies in the evaluation process (ways in which computerised medical information can be used to inform health care decision making from bedside to national HTA efforts[63]; or to the consideration of patient/public opinions and preferences in the HTA process (patient-based HTA). Nevertheless, methodologies on measures of patient preferences need to be better understood and defined by users and producers of HTA. A subsequent challenge will be to incorporate such information in the

decision effectively[10]. By asking patient-oriented questions in HTA and better involving patients throughout the entire process, we can promote patient empowerment, and as such make patients more capable to play a more active role in health-care decision making[71].

Relative to visibility, HTA practitioners have recognised that dissemination activities are a key process that needs to be intensified. Although dissemination activities are considered a key process in HTA, why and how particular approaches should be adopted are still under debate. In fact, some argue that the best visibility is to be able to demonstrate that the HTA assessments or products have an impact on policy and decision-making. But firstly, there is a need to develop a more cohesive framework for analysing the extent to which HTA has contributed to making rational choices, including its influence on decisions, use and diffusion of technology and, health outcomes, access and efficiency[10].

Whereas the technologies that HTA must consider are evolving rapidly, the need to translate HTA results into policy, management, and practice decision is an enduring theme from the field's earliest days. The limitations of the diffusion model adopted at the very beginning were rapidly identified but the challenge of implementing more effective alternatives remains unfinished work for HTA organisations and their partners, as more people recognise that evidence-based decision-making is a social process, not a technical task[72].Moreover, the challenge for many policy makers is to develop policy instruments that lead not only to the optimum levels of diffusion our use, but also encourage development of technologies that match priorities[10]. The knowledge brokering has been proposed as a strategy seeking to establish networks that allow in effectively knowledge exchange and learning among stakeholders[68].

Publishing the results in suitable peer review journals according to the target audience, to show that HTA reports go beyond simple technical government reports, is one of several dissemination activities. Moreover, it is a strategy to reinforce the prestige and external consideration to the quality of the information made by HTA organizations but it becomes itself a real challenge for HTA practitioners.

Besides, HTA should seek to have impact over all possible stakeholders and not only be oriented to health providers and insurers but also to patients/public, policy and decision-makers as well as scientific societies and professional organisations, academia, advocacy groups, the media, etc. Although decision-making processes and how evidence is used have received much analytic attention, the next step is field testing interventions to increase the impact of HTA results in decision-making at these different levels: macro (policy makers), meso (institutions) and micro (practitioners and patients)[60]. In the end, the responsibility of achieving an optimum use of evidence and HTA in decision making must be shared amongst stakeholders including policy makers, decision makers, innovators and producers of evidence.

Finally, some challenges that even go beyond HTA capacity building: the need for greater convergence of multiple different perspectives (disciplines, international scientific societies, etc.) in the improvement and sustainability of health-care systems; whether to have a process of harmonisation of healthcare systems (healthcare services portfolio, cross-border policies, coverage, etc.); and the need for a secure and long-term investment for developing a culture of evidence-based medicine and policy to ensure the development of analytical capacity and expertise. In this sense, new partnerships (amongst, for example, government, industry, public R&D organisations, and insurance institutions) that invest in such research may help share the cost burden[10].

In conclusion, for decision-makers at all levels in rapidly changing health care systems, reflecting on the future of HTA is critical in an environment that is increasingly dominated by cost-effectiveness, evidence-based medicine and changing ideas of accountability.

Annex

Annex I. Current networks and organisations involved in HTA activities

Organisation	Aim/objective	Contact
EUROSCAN. The International Information Network on New and Changing Health Technologies	It based on the collaboration of HTA agencies sharing and assessment information relevant to new or emergent health technologies or the new application of already existent health technologies, to assess their effects and long/short-term health and their social outcomes	http://www.euroscan.bham.ac.uk/
Health Evidence Network	Network of technical members and financial partners, involving United Nations agencies with a mandate related to health, organisations working with evidence-based health policy and health technology assessment, other institutions and governments	www.euro.who.int/HEN
Guidelines International Network (G I N)	International not-for-profit association of organisations and individuals involved in the development and use of clinical practice guideline. G-I-N seeks to improve the quality of health care by promoting systematic development of clinical practice guidelines and their application into practice, through supporting international collaboration	www.g-i-n.net
Cochrane Collaboration	The Cochrane Collaboration is an international not-for-profit and independent organisation, dedicated to making up-to-date, accurate information about the effects of healthcare readily available worldwide. It produces and disseminates systematic reviews of healthcare interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions	www.cochrane.org
The Campbell Collaboration	The Campbell Collaboration was founded on the principle that systematic reviews on the effects of interventions will inform and help improve policy and services. Through its reviews and annual Colloquiums, the Collaboration strives to make the best social science research available and accessible. Campbell reviews provide high quality evidence of "what works" to meet the needs of service providers, policy makers, educators and their students, professional researchers, and the general public.	www.campbellcollaboration.org
The Joanna Briggs Institute	Established in 1996, the Joanna Briggs Institute (JBI) is now a growing, dynamic international collaboration involving nursing, medical and allied health researchers, clinicians, academics and quality managers across 40 countries in every continent. It offers resources designed to meet the needs of service providers, health professionals and consumers by connecting the best available international evidence to the point of care.	http://www.joannabriggs.edu.au

Annex II. Information sources used by information specialists

Information sources		n (units)	%
Health bibliographic databases		23	100
	Health Technology Assessment (HTA) Database	23	100
	MEDLINE/Pubmed	23	100
	The Cochrane Library	23	100
	Database of Abstracts of Reviews of Effects (DARE)	22	95.7
	NHS Economic Evaluation Database (NHS EED)	20	87.0
	EMBASE	17	73.9
	CINAHL	15	65.2
	Web of Knowledge (ISI)	15	65.0
	PsycInfo	11	47.8
	Local or regional databases	11	47.8
	BIOSIS	8	34.8
HTA reports		22	95.7
Search engines		22	95.7
Grey literature		21	91.3
Monographs or books		14	60.9
Clinical administrative databases		5	21.7

Note: Percentages do not sum to 100% due to multiple responses possible for each respondent

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Glossary*

Clinical Practice Guideline. A systematically developed statement to assist practitioner and patient decisions about appropriate health care for one or more specific clinical circumstances. The development of clinical practice guidelines can be considered to be a particular type of HTA; or, it can be considered to be one of the types of policymaking that is informed or supported by HTA.

Clinical trial. A carefully controlled and monitored research study on human subjects or patients evaluating one or more health interventions (including diagnostic methods and prophylactic interventions). Each trial is designed to answer specific scientific questions.

Consensus conference. A consensus conference is a chaired public hearing with an audience from the public and with active participation of 10-15 lay people (sometimes called the jury or the panel) and a corresponding number of different experts. The experts may be from different disciplines and/or from different schools within a discipline. The conference lasts three days for the active participants plus the time for preparation. The purpose is to produce an informed debate on a limited subject presented in the form of six to seven main questions to the conference.

Cost benefit. A comparison of alternative interventions in which costs and outcomes are quantified in common monetary units

Clinical Effectiveness. The extent to which a specific intervention, procedure, regimen, or service does what it is intended to do under ordinary circumstances, rather than controlled conditions. Or more specifically, the evaluation of benefit to risk of an intervention, in a standard clinical setting, using outcomes measuring issues of importance to patients (e.g. ability to do daily activities, longer life, etc.)

Early warning. A stable unit with reliable connections and sources which aims to: identify new technologies that have the potential to make a large impact on health services, filter and prioritise these technologies to select those most likely to have a significant impact and make an assessment of likely impact in terms of health, service and financial impact.

Effectiveness. The benefit (e.g. to health outcomes) of using a technology for a particular problem under general or routine conditions, for example, by a physician in a community hospital or by a patient at home.

Efficacy. The benefit of using a technology for a particular problem under ideal conditions, for example, in a laboratory setting, within the protocol of a carefully managed randomised controlled trial, or at a "centre of excellence

Efficiency. The extent to which the maximum possible benefit is achieved out of available resources.

Emerging health technology. 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 a change in indication or use of an existing technology

Epidemiology. The study of the distribution and determinants of health-related states or events in specified populations.

Evidence Based Medicine. The use of current best evidence from scientific and medical research to make decisions about the care of individual patients. It involves formulating questions relevant to the care of particular patients, systematically searching the scientific and medical literature, identifying and critically appraising relevant research results, and applying the findings to patients.

Dissemination. Any process by which information is transmitted (made available or accessible) to intended audiences or target groups.

Health Services research. An interdisciplinary field of inquiry that examines the impact of the organisation, financing and management of health care services on the delivery, quality, cost, access to and outcomes of such services.

Health Technology (HT). Any intervention that may be used to promote health, prevent, diagnose or treat disease, or for rehabilitation or long-term care. This includes pharmaceuticals, devices, procedures and organisational systems used in health care.

Health Technology Assessment (HTA). Health technology assessment (HTA): the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care. HTA is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods.

Horizon scanning. The systematic identification of technologies in development that could have important effects on health care, and which might be considered for Health Technology Assessment.

(Formal) HTA agency. Not-for-profit agency with national functions funded by at least 50% from public sources.

Capacity Building. The process by which individuals, organisations, institutions and societies develop abilities (individually and collectively) to perform functions, solve problems and set and achieve objectives.

Glossary*

HTA organisation:

1. Option: An organisation operating to provide relevant information facilitating evidence based decision-making in health care.
2. Option: An organisation operating to provide policy decision-makers, health care providers and payers with information that supports their work.

HTA programme. A system of services, opportunities, or projects, usually designed to meet a social need (http://www.thefreedictionary.com/program)

Impact assessment. A particular type of evaluation that aims to determine whether and to what extent a programme causes changes in the desired direction among a target population or in an environment (Rossi and Freeman 1993). Impact assessment implies an estimation or measurement of the effects of a research programme, project or activity and thus requires a comparative analysis of the before and after or of a control and participant group.

Institutionalisation of HTA. The promotion of the structures and processes suitable to produce technology assessments that will be powerful in guiding policy and clinical practice towards the best possible health and cost outcomes.

Meta-analysis. Systematic methods that use statistical techniques for combining results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome. This combination may produce a stronger conclusion than can be provided by any individual study. (Also known as data synthesis or quantitative overview.)

Stakeholders. Parties who are affected by or have a vested interest in the success of a project or initiative. Potential stakeholders in HTA are for instance: health care providers, health care payers, Government, patients and patients advocacy, medical devices and pharmaceutical industry, and academia.

Standard Operation Procedure (SOP):

In the context of clinical research, SOPs are defined by the International Conference on Harmonisation (ICH) as **"detailed, written instructions to achieve uniformity of the performance of a specific function"** in order to guarantee safety and efficiency of the clinical research.

Visibility. In general, visibility is the capacity to be seen by others. It is also a way of giving publicity or communicating the produced results.

*This glossary contains data from the *INAHTA glossary,* descriptions formulated by Work Package 8 of the *EUnetHTA* project and from The Canadian Public Health Association.