Chapter 6

Work process

H. Vondeling
Centre for Applied Health Services Research and Technology Assessment,
University of Southern Denmark.

C. Tufanaru
National School of Public Health and Health Services Management,
Bucharest, Romania

D. Atanasijevic
Ministry of Health, Belgrade, Serbia.

K. Meiesaar
University of Tartu, Department of Public Health, Tartu, Estonia
6.1 Introduction

The structure of this chapter reflects the steps that can be distinguished when HTA is regarded as a process or system\textsuperscript{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\textsuperscript{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\textsuperscript{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\textsuperscript{39}, which partly uses the framework developed by Hailey\textsuperscript{37}.

6.2 Identification of technologies for assessment

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\textsuperscript{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. 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 states that HTA programs may use guidelines or explicit criteria to set priorities for assessment. The results of the international survey on HTA organisations 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. 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 similar results were reported.

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 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.  

### 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. 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. 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. 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.  

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. 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. 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. Recommendations

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. 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, 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.
When provided, recommendations can in principle be formulated for all actors involved. In practice, as documented by the international survey on HTA organisations, 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. 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, 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, 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 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. 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, 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.

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. In practice, the international survey on HTA organisations 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.

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