

HTA AGENCIES AND DECISION MAKERS

An INAHTA guidance document

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Introduction

This document has been prepared to provide guidance on the interaction of health technology assessment agencies with the decision makers whom they inform through their assessments. The perspective taken generally reflects that of the member organizations of INAHTA, which are primarily concerned with informing decision makers in the public sector. However, many of the issues will also be applicable to the interaction of HTA with decision makers in other sectors.

HTA is

Health technology assessment is 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 policy making in health care. HTA contributes to answering questions from decision makers in areas and organizations related to health policy and/or practice.

What is HTA used for?

- Primary purpose: to inform decisions relating to national, regional or local health care systems. Such decisions may relate to the procurement, funding or appropriate use of health technologies and also to disinvestment in obsolete or ineffective technologies.
- Secondary purpose: to contribute to global knowledge on assessment of specific technologies – a library function. HTA provides source material for other research, guidelines etc.

Who and what does HTA inform?

HTA informs the following groups and individuals

Government agencies, parliaments

e.g. decisions on regulatory approval, reimbursement, public health programs

Health care professionals

e.g. decisions on adoption of technologies, practice guidelines

Hospital and other health care administrators

e.g. decisions on equipment procurement, availability of procedures, service delivery

Private sector insurance

e.g. decisions on scope and extent of coverage

Manufacturing industry

e.g. decisions on product development, marketing

Patients, carers and their representatives

e.g. decisions on guidance for treatment and support, access to services; shared decision making with health care professionals

General public, citizens

e.g. information for future decisions on health care

Those responsible for or associated with requests for assessments are the primary targets and the main focus for HTA. However, the influence of HTA on secondary decision targets through provision of information will often also be important.

HTA and decision makers

Decision makers who use HTA come from a variety of backgrounds.

- HTA will usually be only one of several kinds of information used by decision makers.
- Decision makers in many bureaucracies are generalists, without technical expertise.
- There is often volatility in the staffing of policy areas, with short-term appointments.
- Clinical groups and other target groups may have gaps in their knowledge of the assessment process and of government requirements.

Responsibilities

Implicit in the HTA process is the interaction between assessors and decision makers. There are two sides to the contract, and both have responsibilities.

Commonly, but not necessarily, the roles and responsibilities of the HTA agency and the decision maker will be separate, though there may be some areas of overlap.

HTA agency

An HTA agency should:

- conduct data collection and analysis competently
- present findings clearly and transparently
- address the questions that have been asked, and avoid inclusion of non-relevant material in its assessments
- ensure that assessors without detailed knowledge of clinical practicalities or other areas of expertise seek advice or guidance from appropriate sources
- respect the time frame negotiated with the decision makers and inform them of any significant changes and their impact on project completion
- follow up with decision makers on the findings and conclusions that were reached in assessments.

Decision makers

Decision makers should:

- make a commitment to the HTA process. They should see that they have an obligation to engage in the process. Requests for HTAs typically require commitment of public funds for the assessments and appropriate allocation of public funding in the areas on which the HTAs provided information.
- have a clear intention to make use of HTA material when this has been prepared and delivered.
- ensure that there is continuity of contact with HTA projects within the decision making structure.
- inform the HTA agency in a timely manner of any event likely to have an impact on the work in progress, and specifically on any need to adjust the approach or the established time frame.

Joint responsibilities

- Both the HTA agency and the decision maker must be clear on what the question is and how it will be addressed.
- Each party should make efforts to understand the way in which the other works. Decision makers should have some understanding of the methodology and other aspects of the assessment process. HTA agencies should obtain some understanding of the policy making process.
- There should be regular, appropriate contact between the decision maker and assessor.

Planning and prioritization

HTA agencies face pressures in determining their work programs. The number of technologies requiring evaluation outweighs available resources. Clients of the agencies present competing claims regarding the level of urgency to be given to their requests.

HTA programs must set priorities for the assessments that they undertake. Many agencies use guidelines or explicit criteria to set priorities for assessment.

- A review of priority setting frameworks found that there was variability in the methods used by agencies. Use of quantitative rating approaches and consideration of the expected costs and benefits of proposed assessments were uncommon.¹
- The most common criteria applied by agencies in determining priorities were the clinical and economic impact of the technology, disease burden, budget impact, availability of relevant evidence from HTA or similar agencies and expected level of interest (from governments, health professionals and patients).¹
- Decision makers should also consider the performance and availability of alternative technologies, and availability of adequate clinical competency and supporting infrastructure.²

Application of such criteria in setting priorities is highly desirable, but the nature of decision makers and their interaction in the process needs to be considered.

Organizations with a high degree of explicit linkage with government programs mostly initiate their assessments at the request of the decision-making body, i.e. they have less influence on priority setting and the research agenda.³

In other situations, the HTA agency may have a variety of decision makers as clients. There may be a need to consider how the different clients are placed in terms of their possible influence on the HTA program as well as their influence on future use of health technologies. Issues to address include:

- Are the criteria used in setting priorities well formulated and widely known?
- Were the decision makers involved in determining the criteria? Do they accept them?
- How are the criteria applied? By the agency alone, by the agency on the advice of others (e.g. expert committees), in consultation with the decision makers?
- Are there overriding imperatives? (If the health minister requests something directly is the agency going to say 'No'?)

However the criteria are applied, situations will arise where competing proposals for HTAs will have similar or identical ratings. Choices will still have to be made. Discussion with the decision makers concerned will likely be needed, and negotiations may be sensitive. Topics for discussion might include:

- whether the decision maker has further information, or further thoughts, on the importance and urgency of the topic (both can fluctuate rapidly within policy areas)
- whether a less detailed response, for example through preparation of an interim rapid HTA, would help meet the decision maker's needs.

After priorities have been established and agreed, the process still has to be managed by the HTA agency as:

- priorities are likely to change
- further requests for assessment need to be handled together with tasks that are in progress
- progress in dealing with topics must be kept under review - there may be delays in completing ongoing assessments.

Issues such as these require continuing dialogue between the HTA agency and the decision maker.

Assessment preparation

Formulation of the question

Formulation of the question(s) to be addressed by an HTA will often require negotiation between the agency and the decision maker at the start of the assessment process.

Decision makers should be involved at an early stage. Matters for discussion include:

- the question that the decision maker wants the HTA to answer, which needs to be clearly defined
- context - how the HTA will be used by the decision maker, and the types of decision that it is likely to influence
- scope of the assessment – which aspects will need to be included in the HTA, or excluded, and why
- urgency and content – how quickly the report can be prepared, in what detail and with what level of certainty.

In all of this there is a trade-off between the decision maker's requirements, level of detail in the report, time and resources, and (possibly) availability of data.

There may be a need to refine the original question to clarify what is needed by the decision maker and how the HTA can help.

The perspective of the decision makers (requesters) is important but may not be sufficient. After consultation with different stakeholders, the aspects that require assessment may exceed the scope of the initial request. By increasing the scope of an assessment, the HTA agency may obtain results that can be used by other stakeholders. On the other hand, decision makers may be reluctant to broaden the scope of an assessment beyond the area of immediate policy interest. Also, widening the scope of a project will typically require more resources and more time. Neither of these will necessarily be available to the agency.

There may be pressure to meet urgent policy needs, with the HTA being required to “catch the moment of decision”. Points to consider include:

- The urgency of the decision maker's request has to be kept in context, and may change.
- If a full answer to the question is unlikely in the time available, this needs to be established early and clearly.
- Interim advice, including rapid assessments, may be a useful option. Further points are included in a previous INAHTA paper.⁴

Possible difficulties associated with formulation of the HTA question

Area of difficulty	Features	Possible approaches
Inadequate definition of the question(s).	Unclear on purpose of work, policy implications. Uncertain resource implications.	Dialogue with organization/person requesting the HTA. Refine focus of the assessment through discussions.
Inappropriate question.	Question is outside mandate of the HTA program. Unnecessary duplication of earlier work.	Deny support for project; suggest alternative sources of advice. Provide information on material that is already available. Apply consistent criteria for refusal of requests.
Scope of assessments: technologies considered, questions addressed.	Suggestions that HTA program resources should be applied to other topics or forms of analysis.	Keep under review; provide information to show HTA products are consistent with the program's mandate and address relevant issues.
Unrealistic time frame.	Too little time for assessment, having regard to other work, resources available, data available.	Negotiate realistic time frame; consider partial assessment, more limited analysis as interim step.
Lack of understanding of how the technology may be used in the local context.	Uncertainty on relevance of some studies from other countries or regions to the local health system.	Use local experts to define the scope of the technology and to provide a clearer idea of current and future uses

Preparation of the HTA report

Guidance on several points is given in the INAHTA checklist for health technology assessment reports.⁵

Level of analysis/presentation

Keep in mind the needs and competencies of those who are asking the question(s).

Education and mentoring of HTA users who often do not have science backgrounds is an ongoing essential activity. These people may turn over – in and out of influential positions – at a great rate. They also have many issues competing for their attention, meaning that long, technical HTA documents are less useful to them. HTA outputs must be moulded for this audience.

Background material not directly relevant to the question may ‘get in the way’.

Summary

The executive summary in an HTA report is crucial for providing effective input to decision makers. The summary should include information on:

- what has been asked
- what the technology does
- briefly, what was done in the assessment
- the main findings
- conclusion/suggestions.

Long summaries may be skipped. If possible, keep the executive summary to no more than two pages.

As far as possible the summary should be presented in plain language so that those without specialist knowledge related to the technology and its assessment can readily understand what has been done.

Plain language should also be used in summaries of assessments that are prepared for consumers. These should also be kept to short documents but with sufficient information to describe the technology and important outcomes of the review.

Conclusions and recommendations

Frequently, judgements will have to be made in the absence of definitive data on the performance of a technology. The nature and basis of such judgements should be made explicit. The reader of an HTA report should be given a clear account of what has been done, what has been assumed and what has not been done.⁵

The ability or requirement to include recommendations in a report depends on the mandate of the HTA organization. Recommendations can bring a clear focus to the conclusions of a report and, under favourable circumstances, lead into dissemination/

implementation processes. Not all agencies will have a mandate to make explicit recommendations, but the conclusions of the assessment should be clear to the reader.⁵

If recommendations are included, they must flow from the evidence reviewed. Also, a realistic position must be taken on the context of the question that has been addressed and the position and capability of the organization at which the recommendations are directed. For example, HTA agencies should avoid making recommendations that include unrealistic suggestions for expenditures or changes to the health system.

Possible inclusion of explicit direction in an HTA report needs to be weighed against political and administrative realities. Inclusion of policy options in a report is problematic because policy formulation has many inputs of which HTA will be only one. HTA agencies are unlikely to be fully aware of all the issues being considered by policy makers, or their perceived relative importance.

It may be useful in presenting findings to link the level of available evidence with the conclusions and recommendations in the assessment. An evidence assessment matrix can be a helpful in summarising the body of evidence for each research question that has been addressed. The matrix shown in Appendix 1 includes the evidence base, consistency, clinical impact, generalizability and applicability.⁶

Available data on a health technology will often be limited, for example because of the absence of good quality trials. The HTA report should put such shortcomings in an appropriate context for decision makers, for example by:

- indicating what further data are needed
- suggesting how these might be obtained
- advising whether or not conditional use of the technology is warranted, with use linked to further local data collection or formal audit.

Merely concluding that “more research is needed” is a message that is unlikely to be appreciated. It may give the impression that the HTA was not worthwhile.

Possible areas of difficulty associated with HTA report preparation

Area of difficulty	Features	Possible approaches
Not meeting time lines, report takes too long to complete.	Non-availability of data. Internal delays in assessment. Competing work program demands. Potential for advice to be sought from other sources, action taken by decision makers without HTA input.	Dialogue with client. Provide interim results where appropriate.
Errors in the HTA product.	Miss relevant/significant material in review, inadequate search strategy, etc. Errors in analysis.	Ensure that high quality is maintained in preparation of HTA products. Have explicit internal and external validation processes. Use clinical and other expert input throughout the project. Where necessary, make prompt correction of product and disseminate amendments.
Misleading elements in HTA product.	Conclusions do not follow from the data and analysis. HTA does not adequately address the question that has been asked.	As above; responsibility lies with the HTA program.
Findings of the report are contrary to established policy or practice.	Findings not consistent with, e.g., positions of government authority, current clinical practice, technology manufacturer, patient groups.	Ensure that technical quality of report meets required standards and that processes used are transparent. Seek consultation with interested parties. Consider sensitivities when finalizing report.

Follow up of the HTA report - Dissemination

The influence that an HTA report will have is highly dependent on the dissemination process (knowledge transfer) – getting the message to the decision maker. The HTA agency should aim to generate some reaction from decision makers to the material and advice that have been provided.

Dissemination requires follow-up of the report by the HTA agency, but it is desirable to build in consideration of dissemination needs from the start of an HTA project. There should be contact with the primary clients (decision makers) early in the assessment process and while the project is in progress. It is necessary to maintain a dialogue.

Points to consider include:

What is to be said - messages to accompany the report

Material in the executive summary is important. Information on how well a technology works and whether it is safe will be picked up by many target groups. The message from economic evaluation may be more difficult to impart. There is the question of what parts of a possibly complex assessment should be disseminated widely.

What is the pathway for decision making?

It will be helpful for the HTA program to have an awareness of the machinery for decision making on the technology topic in question, and the roles of those persons who provide contacts for the agency. Assessors should be aware of the level at which decisions on a health technology are to be taken. This should be known by the assessors at an early stage of the HTA process.

Many decisions on use of or support for health technologies involve the use of committees of persons with technical expertise and/or officials from government agencies.

Methods of communication

Mail-outs and presentations in journals are relatively inefficient and may not be timely, although publication in relevant journals may be a good conduit to the appropriate audience. Use of the Internet offers advantages of speed of transmission, and potential for dialogue. A mixed strategy may be appropriate, using several approaches, but will tend to be demanding of resources and expertise.

- In some health systems, for example in Malaysia, knowledge brokers have an important role in the dissemination of an HTA report. Brokers will take an HTA product forward to the Ministry and other decision makers.
- In Finland, individual hospital districts report to a Board. HTA recommendations are made to the Board, not the districts, and the Board makes the decisions.
- The Ambassador Program concept was developed in Sweden by SBU to help initiate changes in clinical practice. Well-known local opinion leaders, often physicians in clinical practice, disseminated SBU reports and also served as representatives of their County Councils in influencing clinical practice.⁷ Activities of the ambassadors included arrangement of local workshops within their counties for disseminating information about reports. The Ambassador Program approach has also been used in Alberta with an initial focus on management of chronic, non-cancer pain.⁷
- A monitoring system initiative by AETMIS in Québec, described in Appendix 2, uses telephone interviews with requesters and users to obtain reactions to HTA reports and intended action on the technologies that have been assessed.

Possible areas of difficulty associated with HTA dissemination

Area of difficulty	Features	Possible approaches
Ineffective dissemination to primary target .	Contact with the primary target is indirect. Insufficient account taken of changes to personnel, organization. Message in HTA product may not be framed in a way that is accessible to the target. HTA program perceived as not immediately helpful to needs of primary target.	At the beginning of the HTA project, make sure that primary target is aware of the evaluation process. Detailed follow-up with the primary target, if that is feasible (presentation of findings; discussion of uptake of the HTA advice or findings). Formal documentation of action and responses.
Wrong message accompanies the HTA product.	Covering summary gives inaccurate information, omits important findings, or provides misleading emphasis.	Pay close attention to content and presentation of dissemination messages, with involvement of authors of the HTA product. Follow-up any inappropriate dissemination message with a clarifying statement, ensuring that this is widely distributed.
Inappropriate targeting of recipients.	Message to targets is inappropriate in terms of language used, detail provided. Dissemination to individuals or organizations that have little or no interest in the particular HTA topic.	Ensure that dissemination plan is developed and followed. Keep under review organizations and persons that are to be targeted for dissemination of a particular assessment.
Analysis and findings are contrary to commercial interests.	HTA report may not support position taken by the manufacturer of a technology. HTA findings may suggest action that could be challenged under the provisions of international treaties.	Ensure HTA process has been transparent and of high quality. Clear communication with interested parties. Seek legal advice if necessary.

Measuring the influence of HTA

A further area for consideration when addressing relationships between HTA agencies and decision makers is the influence of HTA reports. Information on the influence of HTA reports and other products is a useful aid to management of an HTA program. Such information can help to identify factors that determine the impact of an assessment, and support better targeting and the development of dissemination strategies.³

Overall, the influence of HTA reports is a key indicator of the output and performance of the agency. Supervising institutions may request reports on the outcomes of HTA in order to justify the use of resources.

Nature of HTA impact

In principle, there will be interest in the impact of an HTA:

1. on policy or administrative decisions
2. on subsequent administrative action
3. ultimately, on delivery of health care and on health status.

The target (decision makers) will be working within a framework determined by policy, administrative arrangements and organizational structure. Together, these will contribute to the context in which decision making is carried out, with input from the HTA.

Much of the focus on HTA impact has been on point 1, linked to the need for effective dissemination from the HTA agency.

With point 2, subsequent administrative action will be dependent on the availability of effective administrative machinery and the willingness of the decision maker to make use of it. The HTA agency may well be more remote from this process, and other influences on the decision maker can become more significant.

With point 3, consequent changes to health care and/or health outcomes related to a health technology may have a tenuous link to the HTA. Influence of an HTA on subsequent action and outcomes within a health care system will be dependent on actions of many individuals and organizations, and outside the immediate influence of the HTA program. There is an inherent difficulty in determining how third parties actually use the specialised HTA information that has been provided.⁸

The influence of HTA can also be considered in the context of the HTA/policy cycle, with a technology being assessed throughout its lifetime. An HTA report may be associated with policy change and implementation, leading to a change in practice. Subsequent use and performance of the technology is monitored and, where appropriate, reassessed with preparation of a new HTA report. Through this process HTA contributes to the making of informed policy choices. In practice, resource constraints will place limitations on the numbers of health technologies that can be followed up in this way by HTA organizations.

Measurement of influence

Measurement of HTA influence beyond that of information linked to the dissemination process is demanding of time and resources. In some cases, HTAs inform government decisions within a well-defined framework. However, frameworks are often less definite and impacts can be broader, longer term and harder to measure. A study of the impact of HTAs in Québec⁹ was one of the most detailed to date, but such a level of analysis is likely to remain uncommon. Perceived relevance of recommendations and intention to adopt recommendations can be used as a proxy for influence (see Appendix 2).

The INAHTA impact framework provides a basic approach to collecting information on HTA influence.¹⁰ It was developed with an appreciation that for routine collection of impact data there will be a limit to the amount of information that can be included, and that for the information to be widely used it must be readily accessible and clearly presented.

The framework provides for a four-level opinion by the agency and external sources on the impact of an assessment (no apparent influence, consideration of HTA by decision maker, HTA informed decisions, and HTA was a major influence on decisions). Indications of impact include acceptance of HTA recommendations/conclusions, demonstration that a technology met specific program requirements, HTA material was incorporated into policy or administrative documents, or used as reference material, and HTA was linked to changes in practice.

The publication on *HTA and Health Policy-Making in Europe*³ includes a proposed six-step model for considering HTA impact. The steps are awareness of the HTA by relevant stakeholders; acceptability of the report; explicit utilization of the HTA by the policy process; clear influence on the policy decision by the HTA's conclusions or recommendations; implementation of policy decision through clear and measurable changes in clinical practice; and impact of an HTA in terms of health or economic outcomes. A limitation, as indicated above, is that the final two steps will be subject to multiple influences.

Difficulties with HTA findings

The HTA process will often reach conclusions and deliver messages that are unpopular in some quarters. Health technologies may not meet the expectations of their proponents, on the basis of available evidence. Definitive answers sought by policy makers may not be deliverable in the absence of data and presence of complicating or confounding factors.

Reaction to unwelcome findings may create risks for the HTA agency, which must operate in an imperfect environment. Open communication between the HTA agency and its clients will help to decrease such difficulties, though it is unlikely to eliminate them.¹¹

Decision makers representing health professionals, such as physician groups, may have gaps in their knowledge of some aspects of assessment, including economic analysis, and of administrative arrangements such as approaches to reimbursement determination and other regulatory requirements. This can also be the case for consumer (patient) groups and politicians. An example is the strong public response by consumers, health

professional and politicians in Australia to a decision to reject government funding of an HPV vaccine. Misunderstanding of the decision making process, and of cost-effectiveness assessments were among the factors that led to criticisms of the decision.¹²

Appendix 1: Body of evidence assessment matrix

Component	A Excellent	B Good	C Satisfactory	D Poor
Evidence base	Number of studies sorted by methodological quality and relevance to patients			
Consistency	Consistency of study results – homogeneous or heterogeneous findings			
Clinical impact	Potential clinical impact – precision, size, clinical importance of primary outcomes			
Generalizability	Generalizability of the evidence to the target population			
Applicability	Conclusions about net clinical benefit of technology in context of clinical practice			

Based on NHMRC 2007 ⁶

Appendix 2: Current Québec initiative: Measuring the outcomes of HTA¹³

Since 2007, AETMIS has implemented a routine monitoring system to measure some outcomes of the HTA process and products.

Six months after publication, requesters (representatives of the organization that made the request) and users (representatives of the organizations targeted by the recommendations) are invited to participate in a 15-minute semi-structured telephone interview. This data-gathering strategy allows collection of quantitative and qualitative data.

Outcomes that are measured are:

- dissemination of the report by requesters and users
- satisfaction of requesters regarding services
- satisfaction of requesters and users regarding reports
- utility of the knowledge produced
- utilisation of knowledge produced in the reports :
- relevance of recommendations
- intention to adopt recommendations.

For each question, interviewees are invited to comment. These qualitative data are very revealing. This monitoring system does not measure the actual impact or influence of a report, which can take a certain time to occur. It measures the reactions of the primary target towards the report, and their intention of action. For AETMIS, it promotes continuous learning and also challenges established processes. It has resulted in improvements in our HTA design, processes, products and services, helping sustain requesters' and users' ownership and use of results.

Examples of qualitative results and action taken to improve the HTA process

Barriers	Corrective actions
<p>At the Ministry level, high turnover of people in charge of files, so those receiving the final HTA were not aware of :</p> <ul style="list-style-type: none"> • the context of the request • discussions during HTA process • some utilization of preliminary HTA results in the decision process. 	<ul style="list-style-type: none"> • Increase interactions with requesters during the evaluation process. • Keep a systematic record of interactions during the HTA process • Sign a memorandum of understanding between AETMIS and the requester, which clearly identifies persons in both organizations to assure communication.
<ul style="list-style-type: none"> • Misunderstanding of HTA process and methodology: • Requesters questioned consultation of stakeholders, leading to their non-acceptance of recommendation 	<ul style="list-style-type: none"> • Upon submission of HTA plan, explain and discuss: <ul style="list-style-type: none"> • scope • schedule • study limitation, process and methodology.
<ul style="list-style-type: none"> • Lack of understanding of results by requesters: • lack of time to read the HTA report • lack of HTA expertise. 	<ul style="list-style-type: none"> • Give oral presentation explaining final results to requesters. • Develop improved communication tools.
<ul style="list-style-type: none"> • Different interpretation of the same recommendation by requesters and various users. 	<ul style="list-style-type: none"> • Initiate joint meetings with requesters and users to discuss recommendations.

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