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Managing external risks to health technology assessment programs

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Objectives: The aim of this study was to develop a guide to identifying and managing risks for health technology assessment (HTA) programs and to obtain opinions on this topic from HTA agencies.
Methods: The risks and approaches to their management were compiled, drawing on experiences from HTA programs and the risk assessment literature. Opinion on this classification was obtained from members of the International Network of Agencies for Health Technology Assessment (INAHTA).
Results: Twenty-one risks for HTA programs were identified under the categories Formulation of HTA Questions, Preparation of the HTA Product, Dissemination, and Contracting. For each risk area, potential consequences and suggested management approaches were outlined. Responses from ten HTA programs indicated substantial agreement regarding the risks that had been identified and on the importance of risk management for their own operations.
Conclusions: Prudent management of HTA programs should take into account the risks related to external factors.

Keywords: Health technology assessment, Risk assessment, Program management

Health technology assessment is well established as a tool to assist decision makers in making choices on which healthcare technologies to pay for and on how they ought to be used. However, although HTA generally has a positive image, there are potential risks for those organizations that carry out assessments. Management of risk associated with the provision of scientific advice for policy making has been discussed in terms of broad principles applicable to government departments (5;6), but there has been little information to date on risk issues applying more specifically to HTA.

The issue of risks for organizations that perform HTA arose during a review of a Canadian provincial HTA program run by the Alberta Heritage Foundation for Medical Research (AHFMR). As part of the management process for the program, we saw a need to consider potential risks associated with its operation and approaches to dealing with these. We decided to develop a brief guide as an aid to management and considered three categories of risk:

We are most grateful to those members of the International Network of Agencies for Health Technology Assessment that provided opinions and information on risks for health technology assessment programs.

A. Risks to the HTA program that are generated externally. Many of these risks will be related to the nature of the HTA program and to its products. For example, a program could produce high quality reports but find that there is little uptake of the advice provided. This finding might lead to a loss of confidence on the part of those funding the program.

B. Risks to organizations, individuals, and the general community that may be caused by the HTA program. These risks may be related to the influence of the program's products. For example, advice provided by an HTA report might mislead decision makers.

C. Risks to the program that are generated internally. These risks include a range of matters associated with program governance, management, and operation. They will, in general, not be specific to HTA programs. In some cases, the categories may overlap, as some risks could be influenced by both internal and external factors.

In this article, we discuss matters related to the external risks for HTA programs. Information on internal risks (Category C) is available from AHFMR (1).

Table 1. Risks Associated with Formulation of the HTA Question

Area of risk	Features	Possible consequences	Possible management approaches
Inadequate definition of the problem.	Unclear on purpose of work, policy implications. Uncertain resource implications.	Client dissatisfaction	Dialogue with organization/ person requesting the HTA. Refine focus of the assessment through discussions.
Inappropriate question.	Question outside mandate of the HTA program. Unnecessary duplication of earlier work.	Adverse perceptions of the program.	Deny support for project; advise on alternative sources of advice. Provide information on material that is already available.
Reaction to declined requests.	Request for HTA refused, or accepted only in a limited way.	Loss of good will, adverse perception of program	Formulate and apply consistent criteria for refusal of requests. Where possible, provide some assistance even if an HTA is not feasible or desirable.
Scope of assessments: technologies considered, questions addressed.	Suggestions that HTA program resources should be applied to other things.	Adverse perception of agency.	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.	Adverse impact on HTA program environment. Delays with other projects.	Negotiate realistic time frame; consider partial assessment, more limited analysis as interim step.

HTA, health technology assessment.

Table 2. Risks Associated with Preparation of the HTA Product

Area of risk	Features	Possible consequences	Possible management approaches
Not meeting time lines, report takes too long to complete.	Nonavailability of data. Internal delays in assessment. Competing work program demands.	Poor perception of program. Potential for advice to be sought from other sources. Decisions taken without HTA input, possible adverse consequences.	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.	Leaves program open to criticism from wide range of external organizations and individuals. May have adverse consequences for decisions on the technology.	Ensure that high quality is maintained in preparation of HTA products. 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.	Client dissatisfied; adverse comment from other organizations and individuals. Potential for inappropriate influence on decisions.	As above; responsibility lies with the HTA program.
HTA products are characterized as being closed to public scrutiny.	Complaints of not having opportunity to participate in scoping or review of HTA products.	HTA findings criticized by interested parties.	Seek input and advice of stakeholders in problem definition.
Imperfect HTA product review process.	HTA material is 'leaked' during review process, criticism of program before the product is released. Reviewers unduly delay responses or inadequately address scope and content of product.	Loss of ability to maintain credibility or momentum on the project. Possibly decisions are taken on the basis of the draft material. Adverse influence on timelines. Reduced assurance of product quality.	Ensure request for external review clearly identifies the requirement for confidentiality. Indicate that report is draft only, not necessarily reflecting program's position on the technology. Use alternative reviewers. Exclude inappropriate feedback.
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; or patient groups.	Dissatisfaction with the product, criticism of HTA program. Potential to disadvantage some organizations or individuals.	Ensure that technical quality of report meet required standards and that processes used are transparent. Seek consultation with interested parties. Consider sensitivities when finalising report.
HTA report viewed as serving certain interests.	For example, a perceived wish from government agencies to ration use of technologies.	Credibility of HTA product and program may be compromised.	Ensure HTA report is of high quality and transparent with regard to its purpose, approach and conclusions.

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Table 3. Risks Associated with Dissemination of the HTA Product

Area of risk	Features	Possible consequences	Possible management approaches
Wrong message accompanies the HTA product.	Covering summary gives inaccurate information, omits important findings, or provides misleading emphasis.	Credibility of HTA program may be adversely affected. Critical, possibly damaging reaction from external parties that are aware only of the summary. Inaccurate summary may distort influence of the HTA, potentially contributing to inappropriate decisions.	Pay close attention to content and presentation of dissemination messages, with involvement of authors of the HTA product. Follow-up inappropriate dissemination message with a clarifying statement, ensuring that this is widely distributed.
Ineffective dissemination to primary target for assessment.	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. Misunderstood or ignored HTA message might contribute to inappropriate decisions.	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.
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.	Expense and loss of program efficiency should interested party seek to take the matter before the courts. Effective decision making is hindered by impediments to provision of assessment information.	Ensure HTA process has been transparent and of high quality. Clear communication with interested parties.
Inappropriate targeting of recipients.	Dissemination to individuals or organizations that have little or no interest in the particular HTA topic. Message to targets is inappropriate in terms of language used, detail provided.	HTA product, information perceived as unhelpful; future products that are more relevant to targets might be ignored.	Keep under review organizations and persons that are to be targeted for dissemination of a particular assessment. Ensure that dissemination plan is developed and followed.

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Publicly available information on risks associated with HTA programs has mostly related to Category A situations. Several well-established HTA programs have disappeared over the years, partly as a result of pressures arising from some of the areas of risk outlined below. The abolition of the U.S. Office of Technology Assessment has perhaps been the most clearly documented (4). More recent examples are provided by the disappearance of the British Columbia Office for Health Technology Assessment, the Scottish Health Purchasing Information Centre, and the Health Technology Advisory Committee of the Minnesota Department of Health.

Pressures on HTA programs through legal procedures have been discussed with reference to situations in which manufacturers sought to prevent the publication of assessment material and to potential restrictions arising as a result of international trade treaties (3). As well as pressure on the HTA programs through effects on budgets and efficiency, there are implications for decision makers because of possible impediments to the free exchange of scientific information.

METHODS

We considered information from the risk assessment literature and a report on elements of effectiveness for HTA programs (2). Drawing on this material and on our experiences with health technology assessment, we compiled a list of external risks that might be faced by HTA programs. Risks were addressed for the program areas of Question Formulation, HTA Product, Dissemination and Contractors. We also outlined possible consequences of these risks and options for dealing with them (1).

To obtain other perspectives on the issues we had identified, we sought opinions from members of the International Network of Agencies for Health Technology Assessment (INAHTA). INAHTA agencies were sent details of the AHFMR classification and a short questionnaire seeking their opinions on the suggested areas of risk and approaches to these, and information on their own experiences.

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Table 4. Risks Associated with Contractors

Area of risk	Features	Possible consequences	Possible management approaches
Definition/form of contract.	Contract does not fully meet the needs of HTA program. Contract imposes unreasonable obligations on the contractor/collaborator.	Loss of good will, adverse external perception of program procedures. Delay in meeting client's requirements; adverse influence on decisions.	Close communication with the contractor; clear internal appraisal of nature and scope of contract. Keep contract procedures, contractors, under on-going review.
Deliverables overdue or uncompleted.	Contractor does not meet deadlines or agreed obligations.	Completion of HTA product may be prejudiced; adverse perception of program.	Appropriate HTA product management, communication with contractor, eventual decision on whether remedial action may be needed, or another contractor engaged.
Deliverables of unacceptable quality.	Contractor's output does not meet acceptable technical standards.	Risk of unacceptable delay, consequent adverse perception. Potential adverse effects on subsequent decisions if the work is accepted without correction.	As above.
Unapproved provision of data to third parties.	Contractor provides material obtained under the terms of the contract to other persons, without approval from the HTA program.	Loss of credibility for the program. Material may inappropriately influence decisions, may not reflect position of the HTA program.	Implement any penalty provisions in contract. Seek return of data from third party. Advise client of situation, as appropriate.
Unacceptable interests in the technology.	Contractor has financial or other interests in the technology or its use.	Risk of accusation of conflict of interest. Potentially, could contribute to bias in the HTA findings.	Close communication and declaration of interests when the contract is drawn up. Clear statement in the HTA product of any perceived interests.

HTA, health technology assessment.

RESULTS

Specification of External Risks

Twenty-one external risks to HTA agencies were identified. These are shown in Tables 1–4, with brief details of specific situations, possible consequences, and management options.

Opinions from Other Agencies

Ten INAHTA agencies provided opinions and information on this topic. Their responses to the survey are summarized in Tables 5 and 6. Responses shown in Table 5 indicated that risk management is an issue of interest for most of the agencies. Also, there was a substantial measure of agreement regarding risks and approaches to their management. Three of the responding agencies advised that they were using the AHFMR paper to assist with their own risk management processes. Responses given in Table 6 reflect the varying experiences of individual HTA programs. Again, these were generally consistent with the issues explored in the AHFMR guide.

DISCUSSION

We suggest that the information in Tables 1–4 on risks, possible consequences, and management options may be helpful to those responsible for the operation of HTA programs. Circumstances will be different for each organization, but the results from the survey suggest that this classification has features that are widely applicable. Although the agencies that provided information differ in their structures, mandates, and resources, their responses indicated a substantial level of support for the outline of risks that had been developed and for risk management.

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Table 5. Responses from Ten HTA Agencies on Risk Management Issues

Question	Responses	Comments
1. Do you feel that your program, service, or agency is adequately prepared to deal with a broad spectrum of risk?	Yes: 2 No: 2 Unsure: 6	Of agencies responding "Unsure," three mentioned structures they used to face up to different risks
2. In our paper, we specified 20 areas of risk for HTA agencies; do you agree with the areas of risk and approaches that were identified for:		
A. *Question formulation*	Yes: 9 Partly: 1	"There is also a risk that person/institution etc. posing the question in fact has an agenda." (Partly) "The HTA question must attempt to meet the needs of the health service . . . . An excellent HTA which answers a question which isn't seen as relevant is counter-productive." "A very important area which we don't think has been taken seriously enough among HTA doers or users." "Especially transparent handling of prioritization and reaction to declined requests important; unrealistic time frame most common!"
B. The HTA product	Yes: 10	
C. Dissemination	Yes: 7 Partly: 2 No: 1	"In the dissemination process the message may be altered somewhat due to biases within the messenger. . . when opinion leaders are involved they may act more as stakeholders when they are on their own or when some time has passed after the assessment." (Partly) "We do not feel that 'risk' is the most relevant description here." (No)
D. Contractors	Yes: 9 Partly: 1	"Most hazardous area, in our opinion. Unacceptable quality by external experts is hard to foresee. Separate, non-approved publications have appeared in the past, as has unapproved provision of data to the press." (Yes) "Contractors may also promise too much in delivering in time." (Partly)
3. Do you feel that developing an explicit risk management strategy could be helpful to your service, program, agency?	Yes: 8 No: 1 Unsure: 1	"Basically no, because we have tools and procedures to handle certain situations." (No) "Not sure if an explicit risk management strategy is needed, or if an internal process which incorporates many of the risk management concepts outlined in the report would be more beneficial. Either way, risk management should be recognized and incorporated in the agency's HTA processes." (Unsure)
4. Other comments		"Not all areas of Question 2 are relevant for our institution, especially in relation to the client perspective." ". . . we do have a risk register for each HTA, and also . . . an organizational risk register." "You have described the risks as falling into three categories . . . we feel that these categories are at very different 'levels' as 1) and 3) deals with 'ourselves' - our agency, our staff etc, while category 2) may be of quite another serious matter if our conclusions mislead decisions taken in the health care."

HTA, health technology assessment.

Likelihood and severity of risk are likely to vary over time and according to the topics that are being assessed. It may be useful to use a checklist for each HTA product on a routine basis, as an aid to management of current or potential areas of external risk. We have suggested that, for each area of risk, provision is made to record the risk level, with a date for further review, for three phases of the HTA project: planning, product preparation, and dissemination (1).

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Table 6. Responses by Ten HTA Agencies to the Question "What Is the Riskiest Situation Your Agency Has Encountered?

Specific situations
• . . .there was a period of uncertainty about the HTA work program as the new structure and processes . . . [of the HTA agency] . . . were developed.
• When members of an expert group engaged by us published a paper in the Lancet offsetting our report and the time for publication was very close to the time for publication of our assessment.
• Periodic turnover in top level management has created a knowledge vacuum in understanding and appreciation of the value of HTA at the top. This vacuum has created instability and uncertainty in the future of the HTA program and inconsistent support in global HTA activities, which are essential to program operations.
• An external expert who was unable to handle a large project, in a situation where we were unable to discontinue the contract. Patch-up by our own workers . . . was ill received but saved the product.
• . . . first HTA report . . . was carried out to support decision makers on the regional level. However, they turned out to be not trained enough to make use of the HTA results. Although the regions still were in the process of clarifying, the Government overruled all considerations by simply ordering the new very expensive drug . . . .
More general concerns
• The most sensitive area for us is the product itself.
• Making "rapid reviews," which are taken for "more than they are."
• Mismatch between funder expectation and product that could be delivered by a responsible HTA agency.
• Analysis and findings of the report are contrary to established policy or practice; unrealistic time frame.
• Funding uncertainty.

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Risk level might be scored on a three-point scale, based on judgments of the magnitude and probability of both risks and benefits associated with the project. HTA managers may also wish to develop a list of remedial responses to the risk they have identified and its level, and subsequently monitor their performance in relation to it. Remedial response may be in point form, identifying two or three initiatives to mitigate the risk. A checklist might be useful as a management tool to keep areas of risk under review while an HTA project is in progress. It could also form the basis for reporting on risk management for an HTA program.

The summaries of risks we have presented are not definitive; other risks (wild cards) may arise. A further type of risk identified in the AHFMR review was that vested interests may wish to influence the independence of the process or findings and interpretation of an assessment. Such risks are not always easily related to the elements in the HTA process that have been considered here. HTA programs must operate in an imperfect environment that includes parties with interests that may be inimical to HTA. Open communication between the HTA program and its clients will help to decrease such difficulties, though it is unlikely to eliminate them. Some risks and adverse influences will be largely beyond the control of the program.

Policy Implications

Risks to HTA programs need to be recognized and appropriately managed if these sources of policy advice are to remain viable. However, a balance has to be struck between prudent identification and management of risks and maintaining the benefits from the HTA process. An HTA program will need to incorporate a degree of resilience to meet the risks that surround it and maintain its purpose and output. Risks to the program have to be balanced by the benefits achieved by competently conducted, transparent, and well-disseminated assessments. If an HTA program becomes overly concerned about risk, at the expense of the benefits it is producing, then its output will suffer and its influence decline, in turn generating the major risk of becoming irrelevant and disposable.

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