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For more information contact:

Health Technology Assessment Unit
Alberta Heritage Foundation for Medical Research

Suite 1500
10104 – 103 Avenue
Edmonton, Alberta
Canada T5J 4A7

Tel: 780 423-5727
Fax: 780 429-3509

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David Hailey

Don Juzwishin

AHFMR
ALBERTA HERITAGE FOUNDATION
FOR MEDICAL RESEARCH

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Risk Management for Health Technology Assessment Programs

Prepared by:
David Hailey, Don Juzwishin

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Director, Health Technology Assessment
Alberta Heritage Foundation for Medical Research
1500, 10104 – 103 Avenue NW
Edmonton, Alberta, Canada T5J 4A7

Tel: 780-423-5727
Fax: 780-429-3509

www.ahfmr.ab.ca

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PREFACE

Health technology assessment (HTA) is now well established as a tool to assist decision makers in making informed choices on which health care technologies to pay for and on how they ought to be used. Decision makers can benefit from the synthesis of information and analysis provided through HTA. It forms a valuable component of the various types of information and relationships that influence decisions in health care. The thousands of HTA reports that are now readily available worldwide are an excellent source of objective information on health care technologies.

However, although HTA generally has a positive image and is well regarded, there are potential risks for programs that carry out assessments. We do not dispute the gains made through HTA, but in this paper we consider issues related to identification and management of risks associated with the operation of HTA programs.

Published information on risks to HTA programs is quite scarce, perhaps in part associated with a reluctance to discuss situations in which things have gone wrong. In developing this paper, we have drawn from our experiences in working with HTA in Alberta and elsewhere. We have given our impressions of risks to HTA programs and approaches to managing these risks, but note that evidence supporting our statements and opinions is usually not available. Although our intent is to develop an overview as a guide to HTA managers, this paper should be regarded as a vehicle for further discussion on these issues. We hope it may stimulate debate and further development of the directions we outline.

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RISK MANAGEMENT

The process of risk management has been considered at length in the context of many types of organizations. A university risk management strategy mentions that *"Dynamic enterprise will inevitably create new risks. Risk management is about ensuring that all significant relevant risks are understood and prioritised as part of normal management practices. Information on risk must be organised in a way that is useful for management purposes and enables decisions to be taken based on the knowledge of risk versus reward"*.[1]

Health technology assessment (HTA) is one of the mechanisms contributing to risk management in a broader sense, as discussed by Leiss [2]. Information from HTA feeds into and informs various regulatory, policy, and administrative processes. As noted by Leiss, Kaplan and Garrick proposed that *risk is a multi-dimensional entity comprising the answers to three questions: What can go wrong? How likely is it? and What are the consequences?* The answers to these questions effectively amount to an assessment of risk [3].

The framework published by the Treasury Board of Canada notes that the common concept in all definitions of risk is uncertainty of outcomes. Where definitions differ is in how they characterize outcomes. Some definitions describe risk as having only adverse consequences, whereas others are neutral. Also, *"…there is considerable debate and discussion on what would be an acceptable generic definition of risk that would recognize the fact that, when assessed and managed properly, risk can lead to innovation and opportunity"*[4].

Some major elements of the risk management process are conveniently summarized in the diagram included in a UK publication (Figure 1) [5]. The main stages are identifying, assessing, addressing, and reviewing and reporting risks, each stage being integrated with a communication and learning process.

Figure 1: The risk management process

Source: Reference 5

THE HTA CONTEXT

HTA programs exist to provide specialized advice to inform decision makers who are involved in health care. Particular tasks of HTA programs are as follows:

- Review, analysis, and synthesis of data from the published literature and from other sources
- Reaching conclusions, and often making recommendations, on clinical, economic, and other aspects of health technologies
- Disseminating assessment findings to decision makers, including those in government, health care delivery organizations, and health care professions

HTA programs therefore combine detailed technical or scientific analysis and interaction with various players in the health care sector to provide a particular type of policy advice. The tangible products of the programs are typically technical reports of varying complexity and format, customized to match the decision maker's needs. The influence of the HTA programs is determined in part not only by the quality of these technical information products, but also by how effectively the products are disseminated and by broader relationships between organizations external to the HTA program. Such relationships have been considered in a previous Alberta Heritage Foundation for Medical Research (AHFMR) publication on elements of effectiveness of HTA programs [6].

HTA may often find itself at the intersection of forces in the marketplace. For example, aspects of innovation, research and development (R&D), first to market, and battling for market share may come into conflict with evidence considered by HTA that shows lack of effectiveness or cost-effectiveness. HTA may therefore be seen as a "barrier" to a revenue stream and return on investment. This situation can cause some interesting dynamics to be played out by those attempting to discredit the HTA program for this reason. There is also the opposite effect of an institution, funder, or insurance company wishing to not innovate because funds may not be available to provide a health care intervention that is shown to be effective but extremely costly. Lack of resources may constrain the opportunity, and the advice provided by HTA may not be welcome.

Assessments may also be unwelcome to health care professionals who have adopted certain technologies for which HTA has been unable to identify evidence of effectiveness. There may be a pecuniary incentive involved or a wish for reassurance from use of a service that is perceived as causing no harm to clients. Challenging these practices creates a tension between those who create and comment on the evidence and those who use the technology. In such situations, it

may be that an individual HTA product is the target for criticism, rather than the HTA program as a whole.

HTA programs have risks to manage that come from many quarters for reasons that may be driven by "perverse" incentives. This conflict in objectives can sometimes be seen in government programs. On the one hand, governments attempt to stimulate the creation of wealth through R&D and innovation, but this attempt may conflict with the responsibility of a publicly funded health care system that pays only for interventions that are effective. This is not to suppose that the creation of wealth is more or less important than the funding only of effective health care interventions, but to recognize that in a complex society, mutually exclusive and conflicting objectives will arise.

Risks for HTA Programs

In the broadest terms, there are two sorts of risks associated with an HTA program – ***those that affect the performance and viability of the program itself and those that the program may impose on external organizations or individuals as a result of its work***. These two sorts of risks may intersect and sometimes come into conflict.

For the purposes of this paper, risks are formulated as falling into three categories:

Category A. *Risks to the HTA program that are generated externally.*

> Many of these risks will be directly related to the nature of the HTA program and to its products. For example, an HTA program could produce outstanding reports but find that there is little uptake of the advice provided. This may lead to a loss of confidence on the part of those funding the program.

Category B. *Risks to organizations, individuals, and the general community that may be caused by the HTA program.*

> Again, these risks will generally relate to the nature of the HTA program and will be a function, among other things, of the level of influence of the program's products. For example, advice provided by an HTA product might mislead decision makers or might be provided too late to influence a decision.

Category 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—many other sorts of programs will also have to deal with such issues. For example, maintaining a staff with core competencies in critical appraisal methods would be essential for maintaining the effectiveness of the HTA program.

In some cases, the categories may overlap, in that some risks could be influenced by both internal and external factors.

Publicly available information on risks associated with HTA programs have 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 US Office of Technology Assessment has perhaps been the most clearly documented [7]. 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 [8]. As well as pressure on the programs themselves through effects on budgets and efficiency, there are implications for decision makers through possible impediments to the free exchange of scientific information.

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 [9], but there has been little information to date on risk issues applying more specifically to HTA.

Identifying and Addressing External Risks for HTA Programs

Areas in the HTA process, as outlined in HTA Initiative #9, include formulation of the question, preparation of the HTA product, collaboration and contracting, dissemination, governance, and program impact [6]. All of these areas will in some way be associated with areas of risk for the HTA program.

The following tables summarize possible areas of risk, potential consequences, and approaches to address them**.** Risks to the HTA program that are generated externally are identified as *A* and risks to others caused by the program as *B*.

As mentioned earlier in the paper, the material in the tables is based on our experiences in working with HTA programs. The experiences of others may differ: other risks may be apparent for some programs, whereas certain items in the tables may be seen as being of less significance. Various areas of risk that are identified in the tables will be associated with potential benefits to the HTA program, providing examples of the positive aspects of HTA. Program managers must balance perceived risks with potential benefits and opportunities.

FORMULATION OF THE HTA QUESTION

Appropriate formulation of the question to be addressed by the HTA is an important task.

The decision maker will need to be clear on what parts of the question of interest are likely to be usefully addressed by HTA and to what extent. Those in the HTA program will need to confirm that the proposed task is within their mandate and competence and that the nature of the request is matched by the resources available. Both parties will need to reach agreement on the timelines for the assessment, perhaps balancing detail sought in the HTA with the urgency of the forthcoming decision and the time that will be needed for assessment. There should also be an appreciation that the HTA will not necessarily be able to provide a definitive answer to the question, perhaps because of data limitations.

An unsuccessful formulation of the appropriate question may be the first chink in the armour of a successful form of policy advice. The opportunity arising from the decision maker and the HTA program taking the time to effectively interrogate the question and to identify the approaches and options sets the stage for a shared understanding of the risk each incurs by undertaking the project.

Table 1: Risks associated with formulation of the HTA question

Area of risk	Specific features	Possible consequences	Approaches and options
Inadequate definition of the problem	Unclear on purpose of work; unclear policy implications. Uncertain resource implications.	A. Client dissatisfaction	Dialogue with organization/ person requesting or proposing the HTA; clarify/ refine the focus of the assessment through iterative discussions. Clearly define use to which HTA information will be put.
Inappropriate question	Question outside mandate of the HTA program. Unnecessary duplication of earlier work.	A. Adverse perceptions of the program	Deny support for project; advise on alternative sources of advice. Provide information (commentary) on the material that is already available.

Table 1: Risks associated with formulation of the HTA question (cont'd)

Area of risk	Specific features	Possible consequences	Approaches and options
Reaction to declined requests	Request for HTA refused, or accepted only in a limited way.	A. Loss of good will; adverse perception of agency	Formulate and apply consistent criteria for refusal of request. Make these available as appropriate. Where possible, provide some assistance to the requestor even if preparation of assessment is not feasible or desirable.
Scope of assessments: technologies considered, questions addressed	Suggestions that HTA program resources should be applied to other things.	A. Adverse perception of agency	Keep under review; where necessary, provide information to show HTA products are consistent with the program's mandate and address issues that are important to the health care system.
Unrealistic time frame	Too little time for assessment in regard to other work, resources available, data available.	A. Adverse impact on HTA program environment. Delays with other projects.	Negotiate realistic time frame; consider partial assessment, more limited analysis as interim step.

PREPARATION OF THE HTA PRODUCT

Having formulated the HTA question with the client, the HTA program develops a work plan to produce its advice. One set of risks at this stage may arise through changes in the scope of the project or in the time expected for completion. Open dialogue and engagement between the HTA program and the client are the best remedies for avoiding unnecessary risk and consequences in these areas.

A further set of risks will be associated with the conduct of the HTA, for example, with the approaches used for data identification, data extraction, and analysis. These risks should be largely within the control of the HTA program and will be minimized through following best standards of HTA practice, as summarized by the International Network of Agencies for Health Technology Assessment [10], and using a transparent approach in assessment. Error in the HTA product is probably the greatest risk of all for an HTA program.

There are also potential risks through the product review process. External review of a report is generally regarded as a measure that improves its quality and credibility [10]. However, difficulties may arise through use of inappropriate reviewers, delays in review, and feedback that is not relevant to the HTA product or the question that it addresses.

It is not uncommon for findings from HTA projects to run counter to preferred positions or opinions of various players in the health care system. There will be risks to the HTA program arising from such situations. Risks will be reduced through ensuring that the HTA product meets accepted standards of practice, as referred to earlier, and that there is appropriate consultation with health care professionals and other potentially interested parties. Although this is an area of risk, it is also an area of great opportunity for HTA programs. HTA findings that run contrary to established policy or practice may provide an incentive for change in areas where the risks and benefits of technologies are not established or are contrary to the best interests of society. Ignoring the findings of HTA products may expose various parties to future risks.

Table 2: Risks associated with preparation of the HTA product

Area of risk	Specific features	Possible consequences	Approaches and options
Not meeting timelines, report takes too long to complete	Non-availability of data Internal delays in assessment. Competing work program demands. Timeline unreasonable (see "Formulation of the HTA Question," above).	A. Dissatisfied client. Poor perception of agency. Potential for advice to be sought from other sources. B. Delay might mean that decisions are taken in absence of 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.	A. Leaves agency open to criticism from wide range of external organizations and individuals. B. Incorrect analysis and conclusions may have adverse consequences for decisions on the technology and on subsequent use and outcomes	Ensure that high quality is maintained in preparation of HTA products, consistent with guidelines on HTA practice. Where necessary, undertake prompt correction of product and dissemination of any 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. Presentation/style of the HTA report limits accessibility to audience.	A. Dissatisfaction with HTA product by client. Adverse comment from wide range of organizations and individuals. B. Potential for too limited or inappropriate influence on decisions.	As above; responsibility lies with the HTA program.
HTA products are characterized as being closed to public involvement or scrutiny	Complaints of not having opportunity to participate in scoping or review of HTA products.	A. Findings of HTA product come under criticism by interests affected by the findings.	Seek input and advice of stakeholders in problem definition.

Table 2: Risks associated with preparation of the HTA product (cont'd)

Area of risk	Specific features	Possible consequences	Approaches and options
Public involved in production/review of HTA products	Delays in completion and dissemination of product. Further demand on program resources. Possible attention to issues that are not relevant to the question being addressed by the HTA.	A. Criticism of the program for not delivering results. B. Potential adverse effects on the decision-making process.	Balance transparency and accessibility of the HTA process, and benefits from involvement of the public, with practicalities of meeting client's requests in a timely fashion.
Imperfect HTA product review process	HTA material is "leaked" during an external review process; criticism is levelled at the agency before the product is released. Reviewers are not considered experts in their field or limited perspectives are sought in the review. Reviewers unduly delay responses or do not adequately address scope and content of product.	A. Loss of ability to maintain credibility or momentum on the project. B. Possibly decisions are taken on the basis of the draft material. A. Possible loss of credibility for the product if review is inadequate. A. 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, subject to change, not necessarily reflecting program's position on the technology. Use an appropriate and consistent process to identify reviewers. Use alternative reviewers. Exclude inappropriate or irrelevant feedback.
Analysis and findings of the report are contrary to established policy or practice	Findings not consistent with position of government authority; contrary to current or proposed clinical practice; or to position of technology manufacturer; or to interests of patient groups.	A. Dissatisfaction of the product, criticism of agency. B. Potential to disadvantage some organizations or individuals.	Ensure that data extraction, analysis, presentation of report meet required standards and that processes used are transparent. Seek consultation/discussion with interested parties. Consider significant sensitivities when finalizing and disseminating report.

Table 2: Risks associated with preparation of the HTA product (cont'd)

Area of risk	Specific features	Possible consequences	Approaches and options
HTA reports viewed as serving certain interests	For example, might be perceived wish from government agencies to cut costs, ration use of certain technologies.	A. Credibility of HTA product and program may be compromised.	Ensure technical quality of the HTA report is excellent and that it is transparent in its purpose, methodology, and conclusions.

DISSEMINATION OF THE HTA PRODUCT

Dissemination is an integral and challenging part of the HTA process. Moving beyond the tangible products of an HTA program, the next clear determinant of its effectiveness is the process by which decision makers are informed and influenced. These two elements—HTA products and their dissemination—form the primary areas for determining effectiveness of an HTA program [9]. To be useful, the HTA product must be adopted by the client, and perhaps other parties, and used to inform a policy or decision.

Risks from ineffective dissemination are that the key messages from the HTA product will be ignored or misunderstood. As with preparation of the HTA product, discussed previously, there are also risks associated with effective dissemination if the message is in some way contrary to the perspective of those with interests in the technology.

Table 3: Risks associated with dissemination of the HTA product

Area of risk	Specific features	Possible consequences	Approaches and options
Wrong message accompanies the HTA product	Covering summary or message gives inaccurate information, omits reference to important findings, or provides misleading degrees of emphasis on particular issues.	A. Credibility of HTA program may be adversely affected. Critical, possibly damaging reaction from external parties who are aware only of the summary. B. Inaccurate summary may distort or divert influence of the HTA, potentially contributing to inappropriate decisions.	Pay close attention to content and presentation of dissemination messages, with direct involvement of the authors of the HTA product. If necessary, follow up any inappropriate dissemination message with a clarifying statement, ensuring that it is widely distributed.
Ineffective dissemination to primary target for assessment	Process may not take sufficient account of changes to personnel, organization. Message in HTA product may not be framed in a way that is accessible to the primary target. Contact with the primary target is indirect; opportunity not taken to explain HTA findings and conclusions.	A. HTA program perceived as not immediately helpful to needs of primary target. B. Misunderstood or ignored HTA message might contribute to inappropriate decisions on support for and use of the technology.	Detailed follow-up with the primary target, if feasible (presentation of findings; discussion of uptake of the HTA advice or findings). Formal documentation of action and responses.

Table 3: Risks associated with dissemination of the HTA product (cont'd)

Area of risk	Specific features	Possible consequences	Approaches and options
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.	A. Expense and loss of program efficiency should interested party seek to take the matter before the courts. B. 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 or the product. Message to targets is inappropriate in terms of language used, detail provided.	A. HTA product, information perceived as unhelpful; future products that are more relevant to targets might be ignored.	Keep under close review the organizations and persons that are to be targeted for dissemination of a particular assessment. Ensure that dissemination plan is developed and followed and that the message is accurate, balanced, and clearly worded.
Inefficient use of dissemination media	Delays or difficulty in accessing media. Distortion of message from an assessment.	A. Poor image of the HTA program. B. Potential to mislead those who may be interested in the technology.	Active review of media use, preferably by media specialists; close scrutiny of material that is to be disseminated. Where necessary, follow up message.
External perception that HTA results have not been disseminated	Possible criticism from those who have made little effort to obtain HTA information or from those associated with decisions that run contrary to the findings of the HTA.	A. Good standing and credibility of the program are damaged.	Make appropriate use of dissemination media and specialists (as above). Maintain, and make available where necessary, records of dissemination action. Follow up with those who are dissatisfied to clarify and resolve problem.

CONTRACTORS AND COLLABORATORS

HTA programs will often seek to expand their capacity to provide HTA products through working with other organizations or individuals. Collaboration with others can range from obtaining expert advice and information exchange to joint projects in which expert assessors external to the program are authors of HTA products. There are also likely to be inputs from organizations and individuals who provide advice or services to the HTA program on a contractual basis without active collaboration.

The use of such relationships can offer substantial benefits through enhancing the capability of the HTA program. However, their use introduces a new set of dynamics that must be managed to minimize the risk to the program and its clients.

Management of the HTA program requires that risks, consequences, and opportunities be properly balanced. Areas that may demand attention are the appropriate formulation of the contract or agreement, acceptable quality and timeliness of deliverables, and confidentiality of some types of information.

Table 4: Risks associated with contractors and collaborators

Area of risk	Specific features	Possible consequences	Approaches and options
Definition/form of contract	Contract does not fully meet the needs of HTA program. Contract imposes unreasonable obligations on the contractor/collaborator.	A. Loss of good will, adverse external perception of agency procedures. B. 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 ongoing review (applies also to items below).
Deliverables overdue or uncompleted	Contractor does not meet agreed deadlines. Contractor does not meet agreed obligations under statement of work.	A. Completion of HTA product may be prejudiced; adverse perception of agency.	Appropriate HTA product management, communication with contractor, eventual decision on whether remedial internal action may be needed or another contractor engaged.
Deliverables of unacceptable quality	Contractor's output does not meet acceptable technical standards.	A. As above; risk of unacceptable delay, consequent adverse perception. B. Potential adverse effects on subsequent decisions on the technology if the work is accepted without correction.	As above.

Table 4: Risks associated with contractors and collaborators (cont'd)

Area of risk	Specific features	Possible consequences	Approaches and options
Separate, – non-approved publication	Contractor publishes findings, other material, without approval from the HTA program.	A. Loss of credibility for the agency. B. Material may inappropriately influence decisions (e.g., may not reflect position of the HTA agency).	Suitably monitor implementation of contract. Where necessary, issue statements to clarify situation.
Unapproved provision of data to third parties	Contractor provides confidential material obtained under the terms of the contract to other persons, without approval from the HTA program.	A. Loss of credibility for the agency. B. Material may inappropriately influence decisions (e.g., may not reflect position of the HTA agency).	Implement any penalty provisions in contract. Seek return of data from third party. Advise client of situation, as appropriate.
Undeclared or unacceptable interests in the technology or issue that is being assessed	Contractor/collaborator has financial or other interests in the technology or its use.	A. Risk of accusation of conflict of interest. B. Potentially, could contribute to bias in the findings of the HTA product.	Close communication and definition/declaration of interests when the contract is drawn up. Clear statement in the HTA product of any perceived interests.

OTHER SORTS OF RISK

The preceding summaries have identified some areas of potential risk to HTA programs associated with interaction with external factors. These summaries are not definitive; other risks—wild cards—may arise. Also, some risks may arise through a combination of factors identified earlier.

In an earlier formulation of risk assessment considered at AHFMR, some details of which are given in Appendix A, a type of risk identified was that *"Stakeholders, policy makers or vested interests may wish to interfere or influence the independence of the scientific process or findings and interpretation of a health technology assessment."* Such a risk may be very real, and persistent, but is not always easily related to the elements in the HTA process that have been considered previously.

As noted in an earlier paper in this series [6], 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. Data related to the operation of HTA programs could be used selectively, and inappropriately, to undermine their operation. HTA programs and the people who manage them must operate in an imperfect environment, with "bounded rationality" 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.

INTERNALLY GENERATED RISKS FOR HTA PROGRAMS

Some general points on internal factors related to program efficiency were considered in HTA Initiative #9 [6]. These factors fell within three categories in the "resources chain" of elements of program effectiveness: governance, resources, and staff and structure. Details of areas that might be associated with risk are shown in Table 5.

Table 5: Internally generated risks for an HTA program

Governance		
Issue	**Possible measure**	**Nature of risk**
Mandate or specifications for program	High-level documentation, general availability. Operational strategies and work plans for local manager. Consistent reporting of activities, providing a match between the mandate and what was delivered.	Program operates outside its mandate.
Values	Publicly articulated. Consistency with mandate.	Agreed values are not maintained (e.g., on transparency in the HTA process).
Interaction with HTA program management and staff	Formal meetings. Open opportunity for interaction. Documented decisions on program.	Communication between the program and governance is too limited or inappropriate. Lack of appreciation of HTA requirements, nature and appropriateness of tasks.
Support for generating program resources	Continuity of program budget. Availability of resources for new initiatives. Endorsement and approval for external funding.	Insufficient support to ensure resources are provided to meet program tasks and requirements.
Availability of resources at an appropriate level for program	Comparison with historical levels. Identifying new opportunities and challenges in meeting methodological and topic requirements.	As above, under Governance.
Allocation to program components	Relate to estimates for work program components.	Inadequate assessment and allocation of resources needed.
Management of program components	Local measures of outputs and impact vs. costs.	Inefficient management of program resources.

Table 5: Internally generated risks for an HTA program (cont'd)

Governance		
Staff and structure		
What it takes to produce an acceptable HTA product	Technical competence. Writing ability. Awareness of other issues in the health system. Availability of data and other backup.	Inadequate appreciation of technical requirements.
Experience and competence of assessment staff	Exposure to HTA tasks, HTA and related literature. Adequate qualifications. Appropriate training and continuing learning. Aptitude for communication and consultation.	Competence and ability not maintained at an adequate level.
Morale and stability of HTA program staff	Conditions of employment. Acceptance of mandate and values of the organization. Workload and work scope. Capacity to communicate and collaborate. Professional recognition.	Staff dissatisfaction, consequent inefficiencies and turnover.

Staff stability within the HTA program may be a challenge. Because of the specialized nature of the work, training and professional advancement for those undertaking assessments will be an important issue for HTA programs. Risks may arise through competencies not being developed or maintained and through isolation of assessors from contact with their peers and the mainstream of HTA. Consequent decreased efficiency and effectiveness of the program might occur. Meaningful linkage and collaboration between the policy and/or decision makers requesting the HTA product also adds to staff morale and sense of accomplishment.

As with any other program, turnover of skilled staff is an issue to be considered and managed. Limitations on professional opportunities and training may contribute to turnover. On the other hand, some movement of assessment staff is to be expected as their expectations and horizons change and they seek other opportunities outside the program. Turnover of staff presents opportunities through introduction of new perspectives and a possible increase in the external network of professional contacts.

ASSESSING RISKS: BALANCING EXTERNAL RISKS AND BENEFITS

The material presented so far has focused on identifying and addressing risks. How should risks be assessed? Various approaches might be applied to quantify the degree of risk from an event and its probability. Some details contemplated previously within AHFMR are shown in Appendix A.

Likelihood and severity of risk, especially external risk, is likely to vary over time and according to the topics and activities in the current work program of the HTA program. Individual HTA programs may well be able to identify priority areas that will demand first call when risks are being considered. Decisions made within programs will typically balance the magnitude and probability of risk with the expected degree of benefit and opportunity associated with a particular project.

Overall, it may be useful to use a checklist for each product on a routine basis, as an aid to reviewing current or potential areas of external risk and action to avoid or minimize these risks. A possible checklist is shown in Figure 2, in which 20 areas of risk identified in Tables 1–4 are listed, grouped by question formulation, HTA product, dissemination, and contractors. 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. All areas of risk may need some consideration in each of the project phases. Risk level might simply be scored on a three-point scale, based on judgements by HTA program management of the magnitude and probability of both risks and benefits associated with the project.

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. Further elaboration would be possible, for example, through links to the checklist to record an action taken, but a simple approach would more likely be used.

A corresponding list for internally generated risks would be less easy to formulate on a project-by-project basis. The sorts of risk identified in Table 5 are more appropriately managed through continuous review and program administration.

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 (discussed in some of the risk assessment literature) to meet the risks that surround it and maintain its purpose and output. External risks to the program have to be balanced by the benefits achieved by competently conducted, transparent, and well-disseminated assessments of health care technology. 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 will decline, in turn generating the major risk of becoming irrelevant and dispensable.

Figure 2: Potential HTA risk checklist

Title of project:……..

		Project stage					
Program activity	**Area of risk**	**Planning**		**Product preparation**		**Dissemination**	
		Risk level	**Review date**	**Risk level**	**Review date**	**Risk level**	**Review date**
Question formulation	Problem/topic definition						
	Assessment scope						
	Decline or modify request						
	Time frame						
HTA product	HTA quality						
	Consultation—expert advice						
	Public/external involvement						
	Misleading information						
	Sensitivity regarding findings						
	Product review						

		Project stage					
Program activity	**Area of risk**	**Planning**		**Product preparation**		**Dissemination**	
		Risk level	**Review date**	**Risk level**	**Review date**	**Risk level**	**Review date**
Dissemination	Summary message						
	Dissemination to primary target						
	Sensitivities from other parties						
	Secondary dissemination—targets						
	Use of dissemination vehicles						
Contractors	Form of contract						
	Timelines for deliverables						
	Quality of deliverables						
	Confidentiality						
	Unacceptable interests						

CONCLUSIONS

The effective management of the risks associated with conducting HTA requires the careful mediation of expectations on the part of the client, governance structure, stakeholders, and staff resources. The tables in the preceding sections should provide HTA managers with useful checklists that indicate risks, possible consequences, and approaches to effectively navigate turbulent waters. This work is a "project in progress" and as the effort to effectively utilize science to inform questions of effective delivery and funding of health care continues to develop, new risks, consequences, and responses will need to be addressed.

APPENDIX A: RISKS IDENTIFIED FOR AHFMR

In an internal review of the AHFMR HTA program undertaken in 2003, 30 areas of risk were identified. Most of these areas had types of risk associated with them that seemed applicable to the AHFMR program.

Using the approach detailed earlier in this paper, 18 of the areas of risk identified in this previous work seemed associated with organizations and issues external to the HTA program. Fourteen were mainly Category A, four were Category B, and three Category C areas had strong Category A implications.

The remaining 11 areas appear to be associated with Category C risks, related overwhelmingly to the internal operation of the AHFMR program and supporting components within the Foundation. These are important issues, but not specifically associated with HTA—they would apply equally to many other types of organization.

The areas and types of risk that were identified in the 2003 review follow, with comments on their context and possible wider relevance.

Category A: Risks to the HTA program that are generated externally

Area of risk	Types of risk	Comments
Risks to independence, autonomy	Stakeholders, policy makers, or vested interests may wish to interfere or influence the independence of the scientific process or findings and interpretation of an HTA assessment.	A key area; mentioned at end of tables in earlier section. Interference with dissemination might be added to the types of risk.
Risks to reputation, “brand,” “identity,” "goodwill"	Conducting a methodologically poor quality, untimely, or irrelevant HTA.	The types of risk are very pertinent and are covered in previous sections. The area of risk seems almost too broad to be useful, tending toward a definition of Category A.
Risks for, associated with co-funders	Not being informed of a controversial or contested HTA being conducted.	Appears to be linked mostly to issues in the domain **“**Contractors and Collaborators**”** in an earlier section. Type of risk points to the need for adequate communication and disclosure.

Category A: Risks to the HTA program that are generated externally (cont'd)

Area of risk	Types of risk	Comments
Risks from or associated with university and/or hospital infrastructures	A joint publication between a university and AHFMR HTA or with a health region may become contested as a result of a methodological disagreement, scheduling, or interpretation of results. Accusation of interference in academic autonomy.	This overlaps with the next item. Risk through delays may also be an issue. Covered in earlier sections.
Risks from agreements entered into	Misunderstanding between a contractor and the HTA unit on the expectations of a deliverable.	This overlaps with the next item. Risk through delays may also be an issue. Covered in earlier sections.
Risk from the loss or minimization of intellectual capital (people, trade secrets, statutory protected trademarks, patent, copyright)	Loss of employees to competing firms.	These points may need clarification. There is a risk through divulging information given in confidence (e.g., by a manufacturer); resembles one example in the "Category C with Category A Implications" examples given in table below. Otherwise, this risk seems to be at the margin for an HTA program that is fully transparent. There could be an issue about intellectual property, but relatively minor. Loss of employees is more of a Category C issue, considered elsewhere.
Risks from and for reviewers: recruitment, retention	Risk from breach of privacy or confidentiality of a report under review.	Not entirely clear if the "area" refers to reviewers or assessors. Risks through being unable to recruit or retain reviewers might need to be addressed. Rates of compensation for reviewers might need consideration, for example. Type of risk comment is pertinent, included in previous section.

Category A: Risks to the HTA program that are generated externally (cont'd)

Area of risk	Types of risk	Comments
Regulatory risks (e.g., NAFTA, FAA)	Misrepresenting the bureau of biologics in Health Canada or the FDA position of health care technology. Employees from other countries breaching education or employment restrictions.	It is not clear what the focus of the area of risk is here, beyond the need to accurately reflect content of regulatory provisions in assessments. A possible area of risk may be perceived threats through the courts, as canvassed in a 1999 article 8. The issue is then more about what decision makers do with HTA findings. The type of risk example about employees given here appears to be Category C.
Risks from the global environment: shifts in the economy, cultures of similar agencies, competition for resources	Loss of employees to other agencies.	An issue not addressed under type of risk is potentially reduced funding because of shifts in the economy, etc. This might well have consequences for the work program and require careful management. Loss of employees is more of a Category C issue, as given below.
Risks from and for committees; e.g., Technology Commercialization review	Maintaining credible and dependable memberships of advisory committees.	Responses were in terms of AHFMR-appointed committees and internal procedures. However, these committees and others external to AHFMR might generate risk through inappropriately framing and/or disseminating recommendations and discussion material.
Risks associated with an inability to deliver due to staff or other interruptions	Timelines on projects are not met.	Always a significant concern; addressed in previous section.

Category B: Risks to organizations, individuals, and the general community that may be caused by the HTA program

Area of risk	Types of risk	Comments
Risks to the provincial government from AHFMR actions	Findings of an HTA may be contested or contrary to current policy or practice of the provincial government. Risk of breach of confidentiality or privacy of patient in the care of a health region or Alberta Health and Wellness.	The general point is covered in an earlier section. The area seems too narrowly defined here—there may be "risks" to other sectors, e.g., health care professionals and manufacturing industry. The "risk" element of this one needs to be carefully balanced by the potential benefits. Breach of confidentiality seems to fall more under other areas of risk, as in the next item and some under category C.
Risks from situations demanding confidentiality	Breach of confidentiality with patient information, a confidential report being circulated for review.	Covered in a previous section. May have Category A consequences.
Risks from products we produce or endorse or support	Risk of accusation of conflict of interest or making claims beyond the methodological strength of the evidence.	Covered in an earlier section. Making claims beyond the evidence is a valid point, but HTA programs may legitimately be making inferences where evidence is very sparse.
Risks from services we provide or endorse or support	Risk of accusation for false or incorrect information.	Type of risk is Category A; Category B risk would be incorrect information leading to harm in some way.

Category C: Risks to the program that are generated internally

Area of risk	Types of risk	Comments
Risks flowing from the enabling legislation	No data	Potentially, this area might be very broad.
Financial risks (e.g., endowment investment performance, grant payments, internal systems/controls)	Risk of accusation for undertaking HTAs that are irrelevant, unnecessary, or not valued	Main area of risk appears more related to internal financial management. Type of risk example perhaps fits better in Category A, referred to in previous section.
Risks from the workplace (e.g., health, safety, environment, loss, employee welfare and treatment)	Risk of turnover of staff due to dissatisfaction with work or the environment	Inefficient operation associated with staff dissatisfaction might also be noted as a risk.
Risks from association with, reliance on, suppliers of goods (e.g., equipment) and services (e.g., computer services)	Risk of dependency on expertise outside of the organization	A common dilemma for many organizations.
Risk from the provision of insurance, indemnity, or other liability relief to others	No data	This point is hard to follow. It might refer to indemnifying the individual assessor, etc.
Risk from systems or use of systems: software, hardware, Internet, intranet, technology	Computer viruses	Might consider regular updates/briefings about potential problems associated with electronic systems. Common to many organizations.
Risks from and for human resources: recruitment, training, retention, succession	Risk from employee leaving	Discussed in previous section.
Risks from and for applicants: recruitment, selection, retention, transition	Breach of confidentially during a recruitment or selection	A matter common to many organizations.

Category C: Risks to the program that are generated internally (cont'd)

Area of risk	Types of risk	Comments
Risks from exposure to contracts (e.g., long-term leases, employment contracts)	No data	A matter common to many organizations.
Risks from theft or other crime	Risk of theft in the work area	A matter common to many organizations.
Risks associated with travel	Risk of travel on business	A matter common to many organizations.
Risks to personal property including know-how, people contacts, copyright	Risk of infringement of copyright	The area seems very broad; copyright infringement (of HTA products) may not be a significant problem for an HTA program.

Category C with Category A implications:

Risks to the program that are generated internally that may lead to adverse external perceptions of the program

Area of risk	Types of risk	Comments
Risks for, associated with trustees	Not being informed of a controversial or contested HTA being conducted	Most of this area seems to fall under Category C, being associated with the relationship between an HTA program and its governance, canvassed in HTA Initiative #9. But there are Category A implications if criticism becomes external to the program in some way.
Risks associated with conducting business off-premises: while travelling, at home, including loss of computer records	Risk of e-mail records being breached, risk of hard copy of confidential documents being lost or stolen	Essentially internally generated but with obvious Category A implications, possibly also Category B. Potentially very critical, even with a "transparent" HTA program.
Risks associated with records management	Loss of records or the "chain of evidence" with HTA projects	At one level, leads to inefficiencies through need to repeat work, etc. Clear potential also for Category A.

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