

**Methodology Paper**

**Utilizing Diverse HTA Products in the  
Alberta Health Technologies Decision  
Process: Work in Progress**

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INSTITUTE OF  
HEALTH ECONOMICS  
ALBERTA CANADA

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# Methodology Paper

## Utilizing Diverse HTA Products in the Alberta Health Technologies Decision Process: Work in Progress

Ann Scott, BSc(Hons), PhD  
Christa Harstall, BSc MLS, MHSA

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Competing interest is considered to be financial interest, either direct or indirect, that would be affected by the research contained in this report, or creation of a situation where an author's and/or external reviewer's judgment could be unduly influenced by a secondary interest such as personal advancement.

Based on the statement above, no competing interest exists with the author(s) and/or external reviewer(s) of this report.

## Corresponding Author

Please direct any inquiries about this report to Christa Harstall, [charstall@ihe.ca](mailto:charstall@ihe.ca)

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## LIST OF ABBREVIATIONS

AETMIS	Agence d'évaluation des technologies et des modes d'intervention en santé (Quebec, Canada)
AH	Alberta Health
AHRQ	Agency for Healthcare Research and Quality (United States)
AHTDP	Alberta Health Technology Decision Process
ASERNIP-S	Australian Safety and Efficacy Register of New Interventional Procedures-Surgical
CADTH	Canadian Agency for Drugs and Technologies in Health (Canada)
CMS	Centers for Medicare & Medicaid Services (United States)
HTA	health technology assessment
IHE	Institute of Health Economics (Alberta, Canada)
INAHTA	International Network of Agencies for Health Technology Assessment
MAS	Medical Advisory Secretariat (Ontario, Canada)
MOHLTC	Ministry of Health and Long-Term Care (Ontario, Canada)
MSAC	Medical Services Advisory Committee (Australia)
NICE	National Institute for Health and Clinical Excellence (United Kingdom)
NIHR	National Institute for Health Research (United Kingdom)
OHTAC	Ontario Health Technology Advisory Committee (Ontario, Canada)
STE	Social and system demographics (S), technology effects and effectiveness (T), economic evaluation (E)

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## SCOPE AND OBJECTIVES

The Provincial Health Technology Assessment (HTA) Program at the Institute of Health Economics (IHE) is the provincial focus for HTA activities in Alberta and is funded by Alberta Health (AH) through a 5-year agreement. The Program conducts assessments on a range of topics for the Alberta healthcare system, promotes collaboration within the health sector, works to strengthen assessment processes, and explores various approaches for achieving the effective and efficient dissemination of its findings. HTA topics from the Alberta Technologies Decision Process (AHTDP), which is the provincial mechanism for introducing and diffusing publicly funded healthcare technologies, form a major part of the work undertaken by the Provincial HTA Program.

AH is seeking to enhance the timeliness, responsiveness, and flexibility of the AHTDP. To this end, AH will establish a process whereby provincial reviews of healthcare interventions will utilize one of a set of HTA products, each varying in scope and depth, to address the research question(s) of interest within a particular timeframe.

The Provincial HTA Program was asked to identify and describe a set of HTA products and to develop a framework for their use within the Decision Process. The framework will be used by AH to choose which HTA product is the most appropriate for addressing a particular policy question, with the aim of increasing the efficiency of the Decision Process. Thus, the objectives of **Section 1** of this report are:

1. To identify and describe a complement of HTA products for use in the AHTDP.
2. To develop a framework for using HTA products in the AHTDP based on the scope and research question(s) of the review and its timeline.

This project is concerned with describing a comprehensive set of HTA products, not the methods used to produce them. Consequently, this report will describe various products produced by HTA agencies and provide a summary of the basic elements of these products, but an in-depth analysis of, or comparison between, the various products in terms of their methodology is beyond its scope.

Rounds of consultation and feedback were undertaken with stakeholders in the Alberta HTA production process to refine and revise the framework and decision matrix developed in **Section 1** of this report. This process, together with the revisions made to the decision matrix and the additional tools created, are outlined in **Section 2** of the report.

The tools outlined in Section 2 were designed to assist policy makers in choosing the most appropriate type of HTA report for addressing a particular policy question, with the aim of increasing the efficiency of the AHTDP. These tools need to be further refined and evaluated within a structured pilot to determine whether they have a place within the AHTDP.

## SECTION 1: INTRODUCTION

Health technology assessment (HTA) has been used by policy makers to inform decisions since the 1970s, but it has only reached ascendancy in the last two decades.<sup>1,2</sup> HTA is a form of policy research that seeks to inform decision making, in both policy and practice, by systematically examining the effects of a particular technology on the individual and society with respect to its safety, efficacy, effectiveness, and cost-effectiveness, and its social, economic, and ethical implications, and identifying areas that require further research.<sup>3,4</sup> A health technology, in this instance, is any intervention administered with the aim of improving the health status of patients or of populations.<sup>5</sup> HTA activities are currently undertaken in more than 26 countries, and the majority are publicly funded and administered by national or regional governments.<sup>6</sup>

Because the demand for health care far outstrips the resources available to provide it, decision makers are under great pressure to allocate resources appropriately. Thus, the purpose of HTA is to inform policy decisions and to facilitate the efficient allocation of healthcare resources.<sup>7</sup> While HTA has become a useful tool in this endeavour, it has suffered from the misplaced expectation that HTA, through the application of a scientific methodology, can remove the political difficulties inherent in health policy decision making.<sup>8</sup>

### Tensions between producing and using evidence to inform decisions

HTA is not defined by its methodology, but rather by its intent. Although the centrepiece of most HTAs is a systematic review of available research evidence, HTAs can also encompass other types of information gathering.<sup>9</sup> Systematic reviews are an established method for collating research evidence, but the typical timescale required to complete a methodologically rigorous and comprehensive review is often ill-suited to the decision-making windows available to policy makers.<sup>10</sup> In addition, even though high quality, synthesized evidence is necessary to ensure that the policy maker focuses on key elements of the question, policy decisions are also influenced by factors other than evidence, such as institutional constraints, interests, ideas and values, and external factors. Thus, other types of information, in addition to research evidence, are needed to inform policy judgements.<sup>11</sup> For example, a typical policy decision often requires the simultaneous consideration of clinical benefit, the quality of the clinical evidence, the price and budget impact, value judgements, and local evidence.<sup>12</sup>

Decision makers use HTA reports in a number of ways. They can be used instrumentally in the direct application of the findings to decisions about staffing, coverage, and funding, and the implementation or withdrawal of services and programs. HTA reports can also provide a conceptual framework for stimulating debate and orienting policies, or they can be used symbolically to justify or validate existing policies or positions.<sup>13</sup> But for HTAs to effectively inform or influence decisions, they must be timely.<sup>14</sup>

The paradox for decision makers is that the introduction of new technologies should be preceded by careful and detailed analysis, but public expectations and lobbying pressure can make it difficult for policy makers to conduct such thorough assessments.<sup>15</sup> In addition, in most healthcare systems the capacity to conduct HTAs is limited,<sup>16</sup> and policy makers must be careful to avoid lengthy assessments that could lead to inadvertent rationing by delay.<sup>17</sup> Although the use of horizon scanning may help reduce the need for urgent, detailed advice, the constant struggle to achieve a

workable trade off between rigour and relevance in HTA is an inevitable part of the decision-making landscape in health care.<sup>14</sup>

## **Evolution of HTA products to meet the needs of decision makers**

The inverse relationship between the comprehensiveness and methodological rigour of an HTA and the speed with which it can be produced has led to the development of an array of HTA products to meet a variety of stakeholder needs. The continuum of assessment products ranges from full HTAs with a rigorous approach at all stages to less detailed mini-HTAs and horizon scanning reports, which can be produced in much shorter timeframes by virtue of their less comprehensive methodology.<sup>18</sup> The shift in HTA toward the concept of “fitness for purpose” with respect to HTA products has occurred in response to the need for HTA to remain relevant and useful to its primary users, healthcare decision makers.<sup>17</sup> The need for greater contextualization of what were originally scientifically rigorous summaries of published clinical data forced a change in approach. Evidence bases were expanded to include sources such as qualitative literature, grey literature, and administrative and clinical databases. HTA also became more participatory, with input on the process and outcomes increasingly being sought from patients, clinicians, policy makers, and other key stakeholders. These changes affected various aspects of HTAs, including their timeframe and implementability. The methodological concessions required to achieve this flexibility caused great debate within the HTA community as it struggled to simultaneously maintain the quality and reliability of HTA products and to meet the responsiveness and relevance required by decision makers.<sup>17,19</sup> There is no single way to conduct HTAs that will meet the needs of all decision makers, and local constraints on the resources available for conducting HTAs can also influence their structure and methodology.<sup>20</sup>

There are many other forms of research produced by HTA agencies, including coverage with evidence development and comparative effectiveness reports and research. These represent a shift from the perception of HTA as merely a data collection process toward HTA as actively shaping the evidence base it seeks to assess. Comparative effectiveness research is a term that is used differently by different groups.<sup>21</sup> Comparative effectiveness research encompasses the commissioning of pragmatic, head-to-head clinical trials, whereas comparative effectiveness reviews are essentially systematic reviews or HTAs that compare alternative healthcare interventions using existing data derived from either published medical literature or administrative and clinical databases. As the name suggests, comparative effectiveness is generally focused on the “real world” use of technologies, with an emphasis on effectiveness rather than efficacy.<sup>20-24</sup> Coverage with evidence development or conditional reimbursement is a process that makes a technology available for a defined period within the context of a structured research study. These studies share many similarities with comparative effectiveness research. The safety and effectiveness data collected during the study are used for subsequent review and re-evaluation of the technology. Such programs have been trialed in Australia, Canada, the Netherlands, Spain, the United Kingdom, and the United States.<sup>20,25,26</sup> However, comparative effectiveness research and coverage with evidence development will not be discussed further in this report as the former has yet to be clearly defined from the provincial perspective in Alberta and the latter is not currently within the remit of the Provincial HTA Program in Alberta.

## **Fitting the method to the question**

Ideally, assessments should be conducted at the critical point before policy makers need them, but often the window of opportunity for producing a timely evaluation is very short and decision makers

may have already made their decision before the results of a lengthy review become available. In these situations, a “quick and dirty” assessment might be needed to provide at least some evidence on which to base a decision.<sup>27</sup> While rapid reviews are sometimes used to inform policy decisions, they are also often used as interim advice or as a scoping mechanism for deciding when a full review is needed.<sup>10,14</sup> As reports generated in a short timeframe have a greater chance of providing inappropriate advice than more comprehensive, externally refereed publications, sometimes a mix of different HTA methods used in parallel will, between them, yield a useful knowledge base for decision makers.<sup>27</sup>

The approach taken in an HTA should generally reflect the question being asked.<sup>28-31</sup> Because policy makers often need to assess the implications of a technology at several points in its lifecycle, assessments are increasingly being seen as part of an ongoing, iterative process rather than as providing a final definitive answer to a particular question.<sup>29</sup> The type of HTA product used to answer a particular question is dependent on a number of factors, including the focus of the evaluation, the characteristics of the technology, the context and political environment, the evidence base, the decision timeframe, and the resources available.<sup>30,31</sup> Optimizing the usefulness of HTA input in the decision-making process will mean finding the best fit between the information needed by decision makers and the products and capacity of the HTA organizations at their disposal.

## METHODS

### General approach and inclusion criteria

An Information Paper level report was considered the most appropriate approach for addressing the objectives within the timeframe allotted. Information Papers are reports that focus on methodological or policy issues and have variable timelines depending on the complexity of the issues identified (Appendix 1.A). The two main objectives of the report were:

1. To identify and describe a complement of HTA products for use in the AHTDP.
2. To develop a framework for using the HTA products in the AHTDP based on the scope and research question(s) of the review and its timeline.

These objectives were addressed by dividing the topic into three separate, but linked, segments as follows.

1. ***Inventory of HTA products offered by HTA agencies***

A systematic literature search was conducted to identify systematic reviews, HTAs, or narrative reviews detailing the types of products produced by HTA agencies worldwide. This listing was used as a benchmark to identify shortcomings, if any, in the product line of the IHE Provincial HTA Program and to formulate a list of current best practice HTA products for use in the Decision Process.

2. ***Inventory of criteria or questions used for priority setting***

A systematic literature search was conducted to:

- a. identify studies of any design detailing the criteria or questions used to determine which HTA product is used by healthcare decision makers to inform a given policy question;

- b. identify systematic reviews, HTAs, or narrative reviews detailing the criteria or questions used by healthcare decision makers to set priorities for HTA research.

It is expected that the literature addressing point 2a will be limited or non-existent. Therefore, literature on priority setting criteria (2b) was also included because of the expected overlap between the two sets of criteria. The criteria (2a and 2b) used by the major publicly funded HTA agencies in the following countries were also collated.

- Canada - the Canadian Agency for Drugs and Technology in Health (CADTH)
- United States - the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS)
- United Kingdom - the National Institute for Health and Clinical Excellence (NICE) and the National Institute for Health Research (NIHR) HTA Programme
- Australia - the Medical Services Advisory Committee (MSAC)

These organizations were chosen because: they are publicly funded HTA agencies with similar mandates; they represent a broad geographical distribution; and they have considerable health policy relevance within their respective jurisdictions. Within Canada, the provinces of Ontario, Quebec, and Alberta have strong HTA programs. Therefore, the criteria used by the provincial HTA agencies in Ontario and Quebec were also examined for context.

Priority setting strategies for horizon scanning were not included because horizon scanning usually precedes HTA and is often used as a means of identifying potential topics for such assessments.<sup>32</sup>

### 3. *Framework for using various HTA products in the Decision Process*

Using the information from points 1 and 2, a draft framework was created to guide government policy makers in determining which HTA product to choose for a given policy question.

## Background information

Additional relevant published material, in the form of letters, conference material, commentary, editorials, and abstracts, was included as background information, where appropriate.

## Literature search strategy

A systematic literature search was conducted by the IHE Research Librarian to identify relevant literature published in English from root to November 2009 (Table 1). The search was developed and carried out prior to the study selection process. The reference lists of retrieved articles were also reviewed for potential studies that may have been missed in the database searches. All issues of the *International Journal of Technology Assessment in Health Care*, published from January 1997 to December 2009, were handsearched for additional articles. Google.com was also searched for grey literature. The electronic literature searches and handsearches were subsequently updated in March 2011.

**Table 1: Search strategy used to identify relevant articles**

Database	Edition/ Date Searched	Search Terms
<b>Core Databases</b>		
MEDLINE (includes in process and other non-indexed citation) OVID Licensed Resource	January 1950 to March 15, 2011	<ol style="list-style-type: none"> <li>1. (hta* OR assessment* OR mini-hta OR appraisal*).ti.</li> <li>2. technology assessment*.mp,jw. OR hta.tw.</li> <li>3. 1 AND 2</li> <li>4. decision*.ti.</li> <li>5. priori*.tw.</li> <li>6. polic*.ti.</li> <li>7. resource allocation.mp.</li> <li>8. Decision Making/</li> <li>9. horizon scanning.tw.</li> <li>10. OR/4-9</li> <li>11. 3 AND 10</li> <li>12. (products OR mini OR mini-hta OR full OR rapid* OR short* OR vary OR variety OR variation* OR quick* OR brief* OR accelerate* OR expedite* OR speed*).ti.</li> <li>13. (systematic review* NOT "rapid AND systematic review").ti. AND 2</li> <li>14. (3 OR 13) AND 12</li> <li>15. 14 OR 11</li> </ol>
CRD Databases (DARE, NHS EED and HTA)	January 1990 to March 15, 2011	<ol style="list-style-type: none"> <li>1. hta*:ti OR (technolog*:ti AND assessment*:ti)</li> <li>2. decision*:ti</li> <li>3. prior*</li> <li>4. polic*:ti</li> <li>5. decision AND making</li> <li>6. horizon AND scanning</li> <li>7.#2 OR #3 OR #4 OR #5 OR #6</li> <li>8. #1 AND #7</li> <li>9. products:ti OR mini:ti OR mini-hta:ti OR full:ti OR rapid*:ti OR short*:ti OR vary:ti OR variety:ti OR variation*:ti OR quick*:ti OR brief*:ti OR accelerate*:ti OR expedite*:ti OR speed*:ti</li> <li>10. #1 AND #9</li> <li>11. #8 OR #10</li> </ol>
EMBASE (Ovid Interface)	Week 1, 1980 to Week 10, 2011	<ol style="list-style-type: none"> <li>1. (hta* OR assessment* OR mini-hta OR appraisal*).ti.</li> <li>2. technology assessment*.mp,jx. OR hta.tw.</li> <li>3. 1 AND 2</li> <li>4. decision making/</li> <li>5. priori*.tw.</li> <li>6. decision*.ti.</li> <li>7. resource allocation.mp.</li> <li>8. horizon scanning.tw.</li> <li>9. polic*.ti.</li> <li>10. OR/4-9</li> <li>11. 3 AND 10</li> <li>12. (products OR mini OR mini-hta OR full OR rapid* OR short* OR vary OR variety OR variation* OR quick* OR brief* OR accelerate* OR expedite* OR speed*).ti.</li> <li>13. (systematic review* NOT "rapid AND systematic review").ti. AND 2</li> <li>14. (3 OR 13) AND 12</li> <li>15. 11 OR 14</li> </ol>

Grey Literature Resources		
CADTH <a href="http://www.cadth.ca">http://www.cadth.ca</a>	March 15, 2011	Browsed site for information on priority setting
NIHR HTA <a href="http://www.hta.ac.uk">http://www.hta.ac.uk</a>	March 15, 2011	Browsed site for information on priority setting
OHTAC / MAS <a href="http://www.health.gov.on.ca/english/providers/program/oh tac/ohtac_mn.html">http://www.health.gov.on.ca/english/providers/program/oh tac/ohtac_mn.html</a>	March 15, 2011	Browsed site for information on priority setting
AHRQ <a href="http://www.ahrq.gov/clinic/techix.htm">http://www.ahrq.gov/clinic/techix.htm</a>	March 15, 2011	Browsed site for information on priority setting
NICE <a href="http://www.nice.org.uk/guidance/index.jsp?action=byType&amp;type=6">http://www.nice.org.uk/guidance/index.jsp?action=byType&amp;type=6</a>	March 15, 2011	Browsed site for information on priority setting
Google	March 15, 2011	HTA decision-making OR priority OR priorities OR prioritization OR resource-allocation Reviewed first 100 results

**Note:** “\*” is a truncation character that retrieves all possible suffix variations of the root word e.g. surg\* retrieves surgery, surgical, surgeon. Searches separated by semicolons were entered separately into the search interface.

## Study selection and data extraction

Study selection was conducted by one reviewer. Articles were excluded that, on the basis of their abstract, clearly did not meet the inclusion criteria. Copies of the full text of potentially eligible studies were retrieved. In some cases, when the full text of the article was retrieved, closer examination revealed that it did not meet the inclusion criteria specified by the review protocol. Consequently these papers were not used to formulate the evidence base for the report. However, relevant information contained in these excluded papers was used to inform and expand the review discussion.

Relevant data were extracted by one reviewer. The methodological quality of the included studies was not formally assessed, but any aspects of the design or conduct of a study that may have introduced bias were discussed narratively.

## Expert review

Input on the proposed approach was sought from AH and the other HTA partners at the HTA Partners meeting on December 3, 2009. AH asked for the mega-analyses published by the Medical Advisory Secretariat (MAS) of the Ontario Ministry of Health and Long-Term Care (MOHLTC), the Health Technology Inquiry Service reports conducted by CADTH, and comparative effectiveness reports to be considered in the Information Paper.

## RESULTS

### Objective 1 - Inventory of HTA products offered by HTA agencies

#### Description of included studies

Five potentially relevant articles were identified,<sup>19,33</sup> three of which represented duplicate publications of a single study.<sup>34-36</sup>

The Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S) conducted a comprehensive scoping survey in March 2007 that evaluated several aspects of the preparation of rapid reviews.<sup>34-36</sup> First, a 17-question survey was sent to the 46 member agencies of the International Network of Agencies for Health Technology Assessment (INAHTA), as well as four non-member HTA agencies (NICE, the Malaysian HTA Program, the Singapore Health Authority, and the Agostino Gemelli University Teaching Hospital). The survey questions focused on aspects of the rapid review process, including administration, research strategies, product composition, and the use of peer review and external experts. Second, a systematic search of various electronic databases was conducted from root to March 2007, in conjunction with a handsearch of articles published in the *International Journal of Technology Assessment in Health Care* from January 1998 to March 2007, to identify articles that reported on rapid review methodology, content, or quality.

Of the 50 surveys sent out, 22 were returned with useable data, representing a 44% response rate. The survey and study defined rapid reviews as HTA products that contained the elements of a comprehensive literature search and took less than 6 months to complete. However, a definition of what constituted a “comprehensive” literature search was not provided. Full reviews (comprehensive HTA reports or systematic reviews) were defined as reports that took longer than 6 months to complete. It is possible that the products produced by some HTA agencies did not fit these definitions, making it difficult for some organizations to appropriately answer some of the survey questions. In addition, the authors of the report noted that some response categories were not well defined, which may have resulted in different interpretations among respondents. For example, the question relating to the search strategy did not provide a definition for the “many databases” and “restricted databases” options. In addition, questions about whether products examined “economic factors” or utilized “quality assessment” did not provide options for respondents to describe the degree of analysis involved, so important information on these aspects was not captured. Unfortunately, the survey asked about the quality appraisal of studies included in rapid reports but not in full reviews, which limited the information obtained on this aspect of HTA reports. Although the organizations that received the survey represented a diverse international population of HTA agencies, the survey was only provided in English, and it was noted that questions were misinterpreted by respondents whose first language was not English.<sup>34</sup> Despite these flaws, the ASERNIP-S environmental scan represents the most up-to-date information on the types, structure, and methodology of rapid review products produced by the HTA community.

To support planning for a new HTA agency in Madrid, Spain, Andradas et al. (2008)<sup>33</sup> searched multiple websites in 2003 for products and services offered by leading HTA agencies who were members of the INAHTA. A review of published literature on HTA activities, projects, and strategic development was also conducted, although the search strategy was not provided. The products of 26 HTA agencies from 15 different countries were analyzed. However, this review was not exhaustive as only those agencies with significant experience were targeted. Although the information in this

report was superseded by the ASERNIP-S report,<sup>34</sup> the focus of the study was not solely on rapid review products. Consequently, it was included because of the information it provided on other HTA products.

Grant and Booth (2009)<sup>19</sup> combined joint experience with scoping searches of the literature to construct a typology of reviews, which described the most common types of reviews currently undertaken in the fields of health and health information. Details of the search strategy used were not provided. Fourteen review types were analyzed and described in terms of the methods used to search, appraise, synthesize, and analyze the research evidence. While an analysis of the different methods of conducting a review are not within the scope of this report, the Grant and Booth (2009)<sup>19</sup> study was included because it provided a useful summary of the various review types available and their advantages and limitations.

### **Inventory of HTA products**

There is currently no universally agreed upon description or methodology for rapid review products. These products defy definitive categorization because of their heterogeneous timelines, components, search strategies, and methodologies,<sup>34</sup> which reflects a common imperative of methodological flexibility in addressing the needs of policy makers. Thus, characterising review types by the labels applied by their authors can lead to confusion because of the considerable variation in the use of terminology, and the often subtle differences in methodology between the different review types.<sup>19</sup> Categorizing reviews by production aspects such as the time taken to complete them is also not ideal because these are a function of extrinsic factors, such as the resources and expertise available and the quantity and quality of the evidence, which often have little to do with the type of methodology used.<sup>19,34</sup> Grant and Booth (2009)<sup>19</sup> overcame the problem of review categorization by quantifying each review type with respect to the methods used to search, appraise, synthesize, and analyze the research evidence (Appendix 1.B).

The ASERNIP-S report<sup>34</sup> categorized HTA products as either rapid or full reviews according to the time taken to complete them. Of the 22 HTA agencies that responded to the survey, 18 produced a rapid review product. The components of these products are summarized in Appendix 1.C. Although not theoretically ideal, time to completion can be a useful variable for categorizing report types from a user’s perspective because decision makers routinely have to make decisions within a highly time-constrained environment. For this reason, the IHE HTA product line table (Appendix 1.A) lists products by level of methodological rigour and time to completion. Melding the results from the ASERNIP-S report<sup>34</sup> and the IHE product line table yields a picture of how the IHE HTA products compare to other HTA agencies worldwide (Table 2). The IHE product line was born out of a desire to address all questions raised, without exception. Given the limited resources available, the only way to achieve this was to employ the “fitness for purpose” principle, whereby diverse products are offered to fulfill various needs. As a result, the IHE product line covers the range of rapid review products offered by other HTA agencies. It also includes additional report types such as comparative effectiveness reports and Information Papers, which focus on methodological, policy, or human resource issues.

The study by Andradas et al. (2008)<sup>33</sup> identified 22 products produced by leading HTA agencies, including traditional products such as HTA reports, systematic reviews, and economic evaluations. They also described other distinct products and services such as rapid reviews; monitoring of emerging technologies; development of clinical practice guidelines; development of HTA methodological guidelines; and assessment of clinical practice guideline implementation. The IHE

Provincial HTA Program does not conduct horizon scanning because, in Canada, this falls within the purview of the national HTA agency, CADTH. The IHE HTA Program produces internal guidance on HTA methodology, contributes to methodological development within the HTA community through information papers and reports,<sup>14,21,37-41</sup> and develops clinical practice guidelines.<sup>42</sup> While these activities indicate that the depth and breadth of products and services offered by the IHE Provincial HTA Program are on par with those offered by other HTA agencies, they are outside the scope of this report and will not be discussed further.

The MAS of Ontario's MOHLTC does not conduct rapid reviews. They conduct assessments of single technologies, which are produced within 16 weeks, and mega-analyses that take approximately 24 weeks to complete (Pers. Comm. Dr Leslie Levin, Head, MAS, MOHLTC, Ontario, Canada). Mega-analyses blend evidence-based analysis and expert opinion to examine multiple technologies as part of a process of care rather than in isolation.<sup>43</sup> The description suggests that these reports share some similarities with comparative effectiveness reports, but they were not added to the product list because it is unclear how, or if, they differ from a full HTA.

The Health Technology Inquiry Service of CADTH produces expedited summaries of research evidence that range from a list of references to a best-evidence synthesis.<sup>44</sup> These products are roughly equivalent to the QwikNotes and TechNotes listed in the IHE product line table (Appendix 1.A).

**Table 2: Comparison of IHE HTA products with products from other HTA agencies (adapted from Cameron et al. (2007)<sup>34</sup>)**

Review Element	<1 month		1 to 3 months			3 to 6 months		>6 months	
	Other HTA agencies* n=2	IHE QwikNote <sup>§</sup>	Other HTA agencies n=17	IHE TechNote	IHE STE Report	Other HTA agencies n=16	IHE CompNote	Other HTA agencies n=13	IHE HTA report
Comprehensive database search <sup>†</sup>	X	X	X	X <sup>‡</sup>	✓	✓	✓	✓	✓
Include grey literature	X	X	✓	✓	✓	X	✓	✓	✓
Includes non-randomized controlled trials	✓	✓	✓	Topic dependent	✓	✓	✓	✓	✓
Includes case series studies	X	✓	✓	Topic dependent	Topic dependent	✓	Topic dependent	✓	✓
Formal quality assessment	X	X	✓	X	✓	✓	X	NR	✓
Clinical outcomes	✓	X	✓	✓	✓	✓	✓	✓	✓
Economic factors	X	X	✓	Topic dependent	✓	✓	✓	✓	✓
Social issues	X	X	✓	Topic dependent	✓	X	Topic dependent	✓	✓
Input from external experts	X	X	✓	✓	✓	✓	✓	✓	✓
Peer review	X	X	X	X	✓	✓	✓	✓	✓

\*For other HTA agencies, the component was considered a standard part of the HTA product if more than 50% of the survey respondents indicated that it was.

<sup>†</sup>The term “comprehensive” was not defined in Cameron et al. (2007).<sup>34</sup> For IHE HTA reports, the search conducted for an HTA report was considered the gold standard in terms of comprehensiveness and was the benchmark against which all other searches were compared.

<sup>‡</sup>Although the search strategy is as comprehensive as that of an HTA report, it is listed as less comprehensive because it is routinely limited by publication date.

<sup>§</sup>QwikNotes are based on study abstracts only.

HTA - health technology assessment; IHE - Institute of Health Economics; NR – not reported because the question was not included in the survey; STE - Social and system demographics (S), technology effects and effectiveness (T), economic evaluation (E)

## Strengths and limitations of the various IHE HTA products

A QwikNote is a form of scoping review that lists the abstracts of potentially relevant studies, thereby providing a preliminary assessment of the potential size and scope of the existing literature. They do not include a synthesis of the study results or an appraisal of the methodological quality of the included studies. Consequently, their findings cannot be used to inform policy directly because their limited rigour and duration and lack of quality assessment increases the risk that conclusions will be based on the quantity of studies rather than their quality.<sup>19,45</sup> However, providing a list of abstracts can be of assistance in determining whether a further assessment is needed, and many HTA agencies use such briefing papers or “vignettes” for that purpose.<sup>9,46-48</sup>

Rapid reviews products, such as TechNotes and CompNotes, although scientifically rigorous, explicit, and systematic, are limited in their breadth or depth by the shortcuts employed to produce them within a shorter timeframe than full HTA reports.<sup>19</sup> The speed at which they are produced will depend on the urgency of the request, the resources available, and the extent to which the systematic review process is modified.<sup>45</sup> These aspects are highly variable both within and between HTA organizations.<sup>34</sup> Several techniques are used to shorten the timescale, including carefully focusing the question, using broader or less sophisticated search strategies, conducting a review of reviews, restricting the amount of grey literature included, limiting data extraction, conducting a cursory synthesis of the evidence, and omitting quality appraisal.<sup>19,45</sup> However, these steps may result in publication bias. The lack of quality assessment may cause results from poorer quality research to be over-represented, while the limited synthesis can mean that inconsistencies or contradictions in the research are missed. Documenting the methodology and highlighting its limitations, while helpful, does not completely offset the increased risk of bias.<sup>19,45</sup> In addition, the short timeframes for rapid review products do not allow time for reformulating the question or the inclusion criteria when the findings are inconclusive or the question is incorrectly framed.<sup>19,45</sup>

HTA reports include a systematic review component and, thus, attempt to identify, appraise, and synthesize all of the relevant research evidence on a topic in a systematic, thorough, and reproducible manner. They are currently considered the most comprehensive method of knowledge synthesis in HTA. The main limitation of systematic reviews can be a lack of applicability or relevance if the studies included are restricted to a single study design, which limits their ability to inform more complex questions about how and why a particular intervention works.<sup>19,45</sup> In addition, because their literature search methods and analyses are so comprehensive, HTA reports are the most resource intensive of the HTA products.

The STE reports (Appendix 1.A) are hybrid reports that use a methodology similar to that of an HTA report, but they are typically executed in less than a third of the time. While STE reports share many of the characteristics of an HTA report, some depth of analysis is lost and important issues may be missed in the attempt to synthesize and interpret results within the shorter timeframe. STE reports contain separate analyses on social and system demographics (S), technology effects and effectiveness (T), and economic evaluation (E). Depending on the questions posed, one section of the report (S, T, or E) may receive more emphasis than the others, which is reflected in the comprehensiveness and complexity of the analysis. This leads to variations among the STE reports in the methodological approach and the timeline, which can be extended to accommodate these requirements. STE reports, in general, are far more resource-intensive than an HTA because more personnel are required to complete STE reports within the short timeline.

## Objective 2a – Inventory of criteria used to fit the HTA product to the policy question

Only two references<sup>45,49</sup> were identified that contained information on methods or criteria used for determining which HTA product should be chosen for a particular policy question.

The United Kingdom Government Social Research service stated that Rapid Evidence Assessments, which take 2 to 6 months to produce, are appropriate in the following situations.<sup>45</sup>

- When there is uncertainty about the effectiveness of a policy or service and there has been some previous research.
- When a policy decision is required within months and policy makers want to make an evidence-based decision.
- When evidence of the likely effects of an intervention is required at the policy development stage.
- When there is a significant volume of research on a subject but questions still remain unanswered.
- When a map of evidence in a topic area is required to determine whether there is any existing evidence and to direct future research needs.
- As a starting point to answer a particularly pressing policy concern, provided that once the immediate question is answered the review will form the basis of a more detailed assessment.

The second reference, from the Danish Centre for Evaluation and Health Technology Assessment,<sup>49</sup> stated that rapid assessments are inappropriate when the technology is likely to be implemented on a large scale or when the topic is broad or involves important fundamental issues. Rapid reviews, in contrast, are better suited to questions that are narrow in scope and concern a specific problem or technology. Often rapid review products highlight the need for a more in-depth assessment. It was noted that in making the choice between review products, it is necessary for policy makers to balance the need for quality and comprehensiveness with the timing of the decision.<sup>49</sup>

### Criteria used by major publicly funded HTA agencies

Of the six organizations reviewed, only NICE made any mention of when a particular type of HTA product is used.<sup>50</sup> The NICE Single Technology Appraisal process takes 34 weeks instead of the 51 weeks required to produce a Multiple Technology Appraisal. As the names suggest, the Single Technology Appraisal process is only used when comparing two technologies. The Multiple Technology Appraisal process, which produces a full systematic review, is used for questions that involve the assessment of more than two technologies for the same condition or one technology for more than one condition.<sup>17,50</sup>

The MSAC, which is responsible for the management of Australia’s national HTA program, only considers full systematic reviews when evaluating healthcare technologies and procedures for national coverage under the Medicare Benefits Scheme.<sup>36</sup>

### *Canadian Provincial Agencies*

In September 2009, the MAS of Ontario’s MOHLTC began publishing Rapid Updates. These are rapid reviews of technologies that were previously assessed by the MAS but did not meet the criteria for a full update. However, it is unclear what criteria are used to make these distinctions.<sup>51</sup>

## **Objective 2b – Inventory of criteria for setting priorities in HTA research**

Many HTA agencies use a two-stage system to filter questions in the priority setting process. The first stage involves using criteria to select only those questions that fall within the mandate of the organization. At the second stage, another set of criteria are applied to the final list of eligible questions to determine the order in which they will be addressed. This section of the report is concerned only with the criteria used at the second stage of this filtering process.

### **Description of included studies**

Limited resources and an insatiable demand for HTA products and services mean that all HTA agencies must, at some point, prioritize their research projects, but there is currently no consensus on how best to do this. Noorani et al. (2007)<sup>52</sup> reviewed approaches for priority setting among HTA agencies by searching literature databases from January 1996 to June 2006. The websites of member agencies of the INAHTA were also searched in February 2005. The intent was to update a previous review by Henshall et al. (1997)<sup>9</sup> on the same topic that covered literature published from 1984 to 1996. The updated review examined priority setting with respect to the methods used to identify HTA topics, the criteria used for setting topic priorities, and the rating and scoring methods used. Twelve systems from the following 11 agencies were included in the review.<sup>52</sup>

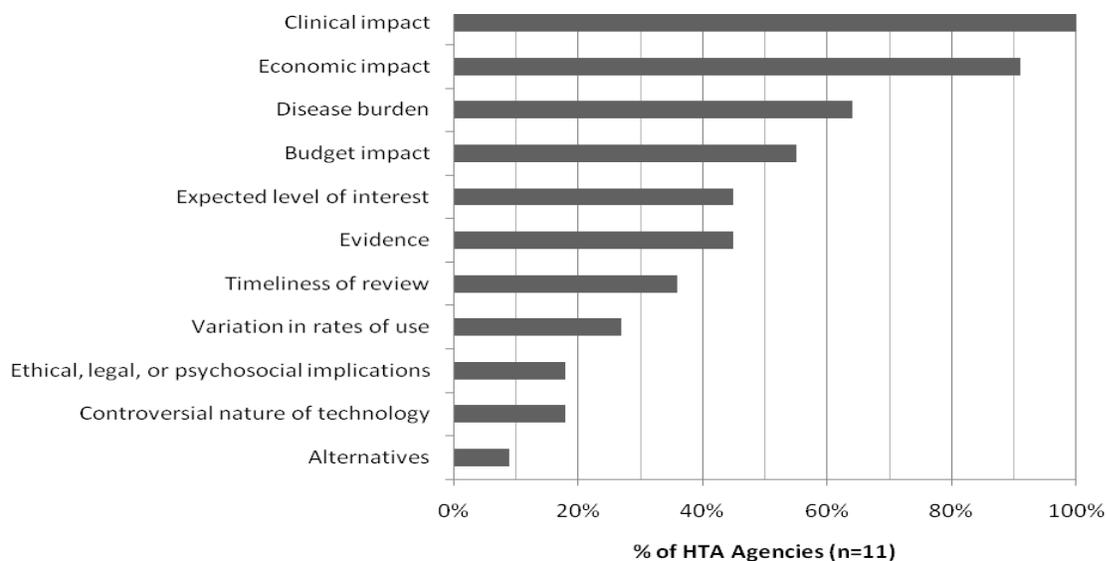
- AETMIS - the Agence d’évaluation des technologies et des modes d’intervention en santé (Quebec, Canada)
- The Alberta Heritage Foundation for Medical Research HTA Unit (Alberta, Canada) (moved to the IHE in June 2006)
- AHRQ - the Agency for Healthcare Research and Quality (United States)
- HunHTA – the Health Economics and Technology Assessment Research Centre (Hungary)
- ICTAHC - the Israeli Center for Technology Assessment in Health Care (Israel)
- MAS (Ontario, Canada)
- NCCHTA - the National Coordinating Centre for Health Technology Assessment (United Kingdom) (manages the HTA programme of the National Institute for Health Research)
- NHS QIS - the National Health Service Quality Improvement Scotland (Scotland)
- OSTEBA- the Basque Office for Health Technology Assessment (Spain)
- SBU - the Swedish Council on Technology Assessment in Health Care (Sweden)
- ZonMW - the Netherlands Organisation for Health Research and Development (The Netherlands)

The authors pointed out that, at the time of the study, the results represented only one quarter of the membership of the INAHTA.<sup>52</sup> It is unclear whether this is an artefact of the study’s reliance on published accounts of priority setting in lieu of formally surveying all of the members of the INAHTA. However, as the authors noted, it is likely that only those HTA organizations with well-developed priority setting systems would have made such information widely available.<sup>52</sup> As Noorani et al. (2007)<sup>52</sup> did not specifically distinguish between criteria used at the first and second stage of the question filtering process, it is possible that not all of the criteria listed in the study were exclusive to the second stage of the filtering process.

### Inventory of priority setting criteria for HTA

Fifty-nine unique priority setting criteria were identified across the 11 agencies. The median number of criteria used by the agencies was 5 (range 3 to 10).<sup>52</sup> These were grouped under 11 categories (Figure 1). The most common categories were clinical impact and need, economic impact, and budget impact. Of the 12 priority setting frameworks identified, only two had an explicit process for evaluating the cost benefit of conducting an assessment on one topic versus another.<sup>52</sup>

**Figure 1: Priority setting criteria used by HTA agencies<sup>52</sup>**



### Criteria used by major publicly funded HTA agencies

AHRQ and the NIHR were included in the Noorani et al. (2007)<sup>52</sup> review. CADTH was not included because it did not have explicit prioritization criteria when the study was undertaken. A comparison of the priority setting criteria used by the various publicly funded HTA agencies examined is summarized in Table 3 according to the criteria used by Noorani et al. (2007)<sup>52</sup> in Figure 1. However, an additional three criteria were added in cases where the categories were not adequately covered by those used in Noorani et al. (2007)<sup>52</sup>.

#### *CADTH*

CADTH receives topic suggestions from the Horizon Scanning Program and a variety of stakeholders including policy makers, managers, healthcare providers, industry, healthcare professional associations, and the public. These topics are prioritized by the Advisory Committee on

Pharmaceuticals and the Devices and Systems Advisory Committee, with the aim of selecting topics of national interest that will likely support health policy, purchasing, management, and clinical practice decisions.<sup>53</sup> The members of these committees consider the following six criteria to be the most important in creating priorities for HTA research: disease burden, potential clinical impact, available alternatives, potential budget impact, potential economic impact, and available evidence.<sup>54</sup>

### ***AHRQ***

The Technology Assessment Program at AHRQ provides assessments for the CMS to inform their national coverage decisions. The CMS Coverage and Analysis Group requests technology assessments from the Technology Assessment Program, which then assigns the work to an Evidence-based Practice Center. The following factors are considered in selecting topics for referral to the Evidence-based Practice Centers.<sup>55</sup>

- Burden of disease
- Controversy or uncertainty about the topic
- Availability of evidence
- Clinical impact
- Economic and budget impact
- Relevance to Medicare, Medicaid, and other Federal healthcare programs
- Likelihood that the results will be used in decision making

### ***CMS***

The CMS receives topics for National Coverage Determinations from various external stakeholders as well as via internally generated requests. The Technology Assessments conducted as part of the Coverage Determination process are produced either internally by CMS staff or externally by AHRQ.<sup>56</sup> There is little mention of the criteria used to prioritize which topics are assessed first, except that they are handled based on the magnitude of impact they are likely to have on the Medicare program and its beneficiaries.<sup>57</sup>

### ***NICE and the NIHR HTA Programme***

The Department of Health in the United Kingdom commissions NICE to develop clinical guidelines and guidance on topics sourced from health professionals, patients, the public, the Department of Health, and the National Horizon Scanning Centre, as well as NICE itself.<sup>60</sup> A Topic Selection Team works in concert with the relevant Topic Selection Consideration Panel (one for each of the following areas: cancers; children, adolescents, and maternity; vascular conditions; chronic conditions; mental health; public health; general and acute conditions) to prioritize topics for guidance in the clinical practice, public health, and health technologies domains according to the following criteria.<sup>20,60,61</sup>

- Burden of disease
- Clinical impact
- Resource impact
- Policy importance

- Presence of inappropriate variation in practice
- Factors affecting the timeliness or urgency of guidance
- Benefit of providing guidance

The NIHR HTA Programme, which contracts review groups to undertake the HTA reports used to inform NICE guidance, is one of the largest public funders of research in the United Kingdom.<sup>63,64</sup>

Topics for assessment are obtained from a variety of sources including key stakeholders, research recommendations from systematic reviews, the National Horizon Scanning Centre, researchers, and the public. The topics are prioritized by six advisory panels that cover particular fields of research: the Diagnostic Technologies and Screening Panel, the Disease Prevention Panel, the External Devices and Physical Therapies Panel, the Interventional Procedures Panel, the Pharmaceuticals Panel, and the Psychological and Community Therapies Panel. Panel members consider the following criteria during the prioritization process.<sup>62</sup>

- Likely benefit of doing the review
- Timeframe for benefits to be realized
- Value for money of the assessment
- Importance of an early assessment
- Other factors, including policy considerations, prevalence of the condition, and social or ethical concerns

### *MSAC*

The MSAC receives formal applications for the funding of new technologies under the Medicare Benefits Scheme from various stakeholders. The applications are prioritized according to the following criteria.<sup>59</sup>

- Burden of disease
- Incidence and prevalence of the condition
- Availability of a satisfactory alternative treatment
- Likely utilization
- Likelihood that the technology offers a significant advance in the management of the condition
- Cost of the technology
- Likely benefit to arise from an HTA
- Other factors, such as access and equity

**Table 3: Comparison of priority setting criteria used by major publicly funded HTA organizations in Canada and worldwide**

Criteria	Canada			United States		Australia	United Kingdom	
	CADTH <sup>54</sup>	AETMIS <sup>58</sup>	OHTAC	AHRQ <sup>55</sup>	CMS	MSAC <sup>59</sup>	NICE <sup>60,61</sup>	NIHR <sup>62</sup>
Clinical impact	✓	✓	-	✓	-	✓	✓	
Economic impact	✓	✓	-	✓	-	✓	✓	
Disease burden	✓		-	✓	-	✓	✓	✓
Budget impact	✓	✓	-	✓	-	✓	✓	
Expected level of interest			-	✓	-	✓	✓	✓
Available evidence	✓		-	✓	-			
Timeliness of review			-		-		✓	✓
Variation in rates of use		✓	-		-		✓	
Ethical, legal, or psychosocial implications			-		-	✓		✓
Controversial nature of technology			-	✓	-			
Available alternatives	✓		-		-	✓		
Doubt on underuse or overuse		✓	-		-			
High probability results will influence decision-making		✓	-	✓	-		✓	✓
Benefit of doing assessment		✓	-		-	✓	✓	✓

AETMIS - Agence d'évaluation des technologies et des modes d'intervention en santé; AHRQ - Agency for Healthcare Research and Quality; CADTH - Canadian Agency for Drugs and Technologies in Health; CMS - Centers for Medicare & Medicaid Services; MSAC - Medical Services Advisory Committee; NICE - National Institute for Health and Clinical Excellence; NIHR - National Institute for Health Research; OHTAC - Ontario Health Technology Advisory Committee

### *Canadian Provincial Agencies*

The Ontario Health Technology Advisory Committee (OHTAC) is an independent committee that makes recommendations to the Ontario MOHLTC regarding health technologies. It only accepts applications for topics if they are sponsored by a potential Ontario purchaser or provider of insured health services. The MAS of the MOHLTC produces evidence-based analyses that are used by the OHTAC to make recommendations to the MOHLTC. While OHTAC provides general guidance on the minimum criteria that each topic must meet to be considered for an assessment (i.e. the first stage of the question filtering process), there is no mention of the criteria used to prioritize the order in which the submissions are addressed.<sup>65</sup>

AETMIS is an independent organization that reports to Québec's Minister of Health and Social Services. Most requests for assessment originate within the Ministry of Health and Social Services, with the remainder coming from hospitals and healthcare organizations and associations. A Board of Members selects the topics to be evaluated according to the following criteria.<sup>58</sup>

- Clinical impact
- Presence of significant variation in the frequency of use
- Reasonable doubt as to whether the technology is being underused or overused
- Benefit of the assessment
- Relevance of the assessment
- Cost impact

### **Objective 3 – Proposed framework for fitting the HTA product to the policy question**

While a number of HTA agencies have systems for prioritizing which technologies should be assessed first, there are no documented frameworks for determining which HTA product would best answer a particular policy question. Such a framework could be useful for achieving maximum efficiency from the limited capacity available for assessment.<sup>16,66</sup> For a given policy question, decision makers must determine which HTA product will provide the optimum balance between utility, in terms of minimizing the risk of a wrong decision regarding a technology's use within the healthcare system, and efficiency with respect to production costs.<sup>9,16,67</sup> This requires active management to ensure that resources are not wasted on assessments that are unfeasible, methodologically weak, or irrelevant.<sup>9</sup>

The questions routinely asked by decision makers about a technology can be translated into medical, ethical, legal, economic, and social questions that can be addressed by HTA.<sup>15</sup> However, technologies are often moving targets that may require different types of assessment depending on their type and stage of diffusion, which in turn affects the kind of questions being raised.<sup>2,68,69</sup> The products listed in the IHE HTA product line represent a menu of information products that policy makers can use to satisfy their knowledge needs. While some of the products deviate from the gold standard of a full HTA report, by virtue of their timelines, they nonetheless have a role to play in facilitating the use of evidence in the decision-making process.<sup>49</sup>

It is not always clear when a more comprehensive review is required. Some questions regarding a technology cannot be sufficiently answered within the short timeframe of a rapid review, and it is important to know which questions these are to determine whether they are important to the topic at hand. From the preceding results, it is clear that broad topic areas requiring an in-depth investigation of fundamental issues, such as ethics, safety, or economic implications, cannot be adequately evaluated in the timeframe of a rapid review. In addition, if interdisciplinary or external input is important, a rapid review may not be appropriate.<sup>36,45,49</sup>

The draft decision matrix outlined in Table 4 was designed to facilitate discussion between decision makers and assessors on the type of HTA product that should be commissioned to answer a particular policy question. This matrix is based on a government perspective and, thus, would require modification before it could be used by other stakeholders (e.g. patients or clinicians). The elements were derived from the results obtained in objectives 1 and 2 of this report. The IHE HTA product line was used as the basis for the HTA product listing because the range of report types was found to be as comprehensive as those offered by other HTA agencies. The “evidence needs” and “technology details” categories were derived from the results in objectives 2a and 2b and were worded according to guidance from Lavis et al. (2009).<sup>69</sup> The information relating to the lifecycle stages of a technology was obtained from Joshi et al. (2009).<sup>2</sup> The analysis details section at the bottom of the matrix was derived from the information provided in the IHE HTA product line (Appendix 1.A) and Grant and Booth (2009)<sup>19</sup> (Appendix 1.B).

The study types outlined by Grant and Booth (2009)<sup>19</sup> that were encompassed by the IHE product line were scoping reviews, rapid reviews, and systematic reviews. Meta-analysis, qualitative evidence synthesis, and umbrella reviews were not discussed separately as they are types or methods of review that fall under the HTA category of the IHE product line. Likewise, although comparative effectiveness reports are listed separately in the IHE HTA product line, they were not listed as a separate product in the decision matrix. Comparative effectiveness reports are considered by some to be essentially a type of systematic review,<sup>22-24</sup> but the definition for what constitutes a comparative effectiveness report from the point of view of the Provincial HTA Program and AH has yet to be elucidated. Thus, it was not considered appropriate to list this product in the decision matrix until it is more clearly defined from the provincial perspective.

It is important to note that in designing the decision matrix, it was necessary to make some broad generalizations about the characteristics of the HTA products, which may not always apply. For example, while TechNotes generally do not include evidence from case series studies, this level of evidence may be incorporated when there is a dearth of comparative studies. In addition, the negotiation about which product type to use must include careful consideration of the timelines, particularly for rapid review products. It may be that safety is a far more important consideration than cost for a particular technology. This would necessitate a more in-depth analysis of safety aspects than is characteristic for a rapid report, making it necessary to forego information on other factors to accommodate the shortened timeline.

**Table 4: Draft decision matrix for matching evidence needs to an IHE HTA product**

Elements	IHE HTA Report Types						
	QwikNote	TechNote	STE Report	CompNote	HTA		
<b>Evidence Needs</b>	Benefits	○	●	●	●	●	
	Potential harms	○	●	●	●	●	
	Costs and cost-effectiveness	○	●	●	●	●	
	Ethical/legal/social issues	○	○	●	●	●	
	Process evaluation (how/why it works)	○	○	○	●	●	
	Expert opinion (EO) and peer review (PR)	○	● EO only	● EO + PR*	● EO + PR	● EO + PR	
<b>Technology details</b>	Narrow focus	✓	✓	✓	X	X	
	Broad focus (>1 comparator or >1 condition considered)	X	X	X	✓	✓	
	Large-scale implementation	X	X	✓	✓	✓	
	Stage of lifecycle	Experimental/introduction	✓	✓	X	X	X
		Adoption	X <sup>†</sup>	✓	X	X	X
		Stable use	X <sup>†</sup>	X	✓	✓	✓
		Reduced use/decommissioning	X <sup>†</sup>	X	✓	✓	✓
<b>Analysis details</b>	Timeline	1 to 2 weeks	3 months	90 days	3 to 6 months	6 to 12 months	
	Resource commitment (personnel, time, cost)	Low	Moderate	High <sup>‡</sup>	Moderate	High	
	Level of contextualization	None	Low	High	Moderate	High	
	Level of uncertainty/bias	High	Moderate	Low	Low	Low	
	Limited rigour and duration Narrow focus Limited search and evidence base No evidence synthesis No quality assessment List of abstracts only	Limited rigour and duration of process Narrow focus Limited evidence base Limited data extraction No evidence synthesis No quality assessment	Limited duration with possible limitations in depth of analysis No formal quality assessment for social and system demographics (S) and economic evaluation (E) sections <sup>§</sup>	Limited duration with possible limitations in depth of analysis No formal quality assessment <sup>§</sup>	Comprehensive assessment		

\*Peer review limited to Expert Advisory Committee only.

<sup>†</sup>QwikNotes are a list of study abstracts only, but they may be useful as a scoping mechanism for technologies at this stage of the lifecycle to help determine whether further assessment is required and what type.

<sup>‡</sup>Resource commitment for most STE reports is high because at least three full-time reviewers are required to complete them. In contrast, an HTA report, although time intensive, only requires two reviewers for the study selection, data extraction, and quality appraisal phases; one full-time reviewer completes the remainder of the work.

§Aspects of study design that may have introduced bias are discussed narratively, but formal quality appraisal by two independent reviewers using a checklist or tool is not conducted.

**Key for evidence needs subsection:** Reported: ●; Partially reported: ◐; Not reported: ○; Comprises a list of study abstracts only, with no evidence synthesis: ◑

**Key for details of technology subsection:** More appropriate = ✓; Less appropriate = X

**Key for analysis details subsection:** The categories of low, moderate, and high represent a subjective comparison relative to an HTA report, which was considered the gold standard in terms of comprehensiveness and was the benchmark against which all other reports were compared.

HTA - health technology assessment; IHE - Institute of Health Economics; STE - Social and system demographics (S), technology effects and effectiveness (T), economic evaluation (E)

## DISCUSSION

The effect of methodology on the conclusions of HTA reports is currently unclear. Some studies have found little difference in the conclusions of rapid reviews when they are compared with those of full HTAs or systematic reviews.<sup>34,36,70</sup> However, these studies also note the narrower scope, limited depth, and less detailed recommendations provided by rapid review products, which might make rapid reviews less suitable for evaluating some technologies. It is, as yet, unclear to what degree the individual components of a report influence its conclusions, what the minimum essential report elements are that may guarantee an accurate and reliable result,<sup>71</sup> and whether such elements would vary according to the topic being addressed and the quality and quantity of its evidence base.

Dialogue between assessors and decision makers is essential for ensuring that policy makers can match the time constraint for a particular decision to the kind of evidence support they need.<sup>12,30,72</sup> HTA reports are likely only needed for the complex, more invasive, ethically problematic, and costly technologies that require a more precautionary policy approach.<sup>27</sup> The use of horizon scanning, scoping reviews, and proactive planning can assist in ensuring that the existing limited assessment capacity is used efficiently to support evidence-informed policy making.<sup>72-74</sup>

The decision matrix proposed in this report is a starting point for facilitating dialogue between requestors and assessors. It provides an explicit and systematic means of summarizing the key aspects of the policy question that are addressed by the various review types alongside the strengths and limitations of each product. The matrix can be used by government decision makers and HTA researchers as a translation tool when negotiating information needs. However, use of the tool presupposes that the information gleaned from an evidence-based report will actually be used in the decision-making process. Many other factors influence decisions, so the use of such a decision matrix may be superfluous in situations where the evidence is likely to contribute little to the deliberative process regarding the implementation of a particular technology.

## Limitations

Although the decision matrix was based on information gathered from a systematic search of the literature, the short timeframe for this report meant that it relied heavily on existing evidence syntheses and reviews, some of which require updating. The list of rapid review products produced by HTA agencies was compiled by ASERNIP-S<sup>34</sup> in March 2007. Given the developments that have occurred in this area of HTA over the last decade, the inventory of rapid review products should be updated to ensure that any recent product innovations are captured, and to gather more specific details about the composition and methodology of such products. Ideally, HTA agencies worldwide would be canvassed regarding how they or their users navigate the challenge of deciding which HTA product to use for a particular policy question. Such a survey might be more meaningful if it is targeted at agencies with a varied portfolio of products. In addition, the search end date of the review by Noorani et al. (2007)<sup>52</sup> was June 2006 and reports of priority setting criteria<sup>75,76</sup> have been published since then.

Any discussion about HTA products is inevitably circumscribed by the lack of a consistent definition for a rapid review, and even for what constitutes a full HTA. As the field of HTA has expanded, the scope of HTAs has broadened to incorporate other forms of evidence such as qualitative research. The realization that there are different types of evidence that may need to be incorporated into an HTA makes standardized definitions elusive, if not impossible, as the scope

and depth of an HTA is determined by the question and the needs of the decision makers who are asking it. In addition, factors such as the lifecycle stage of a technology are affected by context and may be defined differently depending on the healthcare system. Thus, various aspects of the decision matrix need to be carefully defined to reflect the environment in which it will be used and the perspective of the decision makers using it.

The studies included in this report largely contained information that was based on a national or provincial perspective. However, priorities and information needs often differ between the macro, meso, and micro levels of decision making within the healthcare system, and this has implications for the kind of HTA product that might be required.<sup>27,33,54</sup> Thus, the decision matrix may need refinement before it can be applied to all local contexts.

## NEXT STEPS

The complexity and evanescence of decision processes make them difficult to adequately quantify and document. It is likely that much can be learned from more qualitative analysis of the often ad hoc decisions made regarding which HTA product is chosen to address a particular policy question. Documenting the dearth of literature in this area provides the impetus for moving forward in a direction that is both new and specifically informed by local needs.

The draft decision matrix presented herein is a work in progress. It will likely require modification after consultation with all key participants in the process of negotiating work plans for the AHTDP. Opinion groups (e.g. focus groups and discussion panels) and consensus methods could be used to refine the decision criteria listed in the matrix and to ensure that important elements are not missed. The criteria could then be weighted according to how important they are to the requestors, although this may not be practical as it is likely that the relative weighting will be topic dependent.

Once the definitive criteria have been established, the next stage of development might be to reformat the matrix into an algorithm. However, while visually appealing, this may not be practical given that many factors contribute to the choice of a particular HTA product. Algorithms tend to force a yes/no answer at each node, which may not be helpful in situations where multiple factors have to be considered simultaneously. A questionnaire format may be feasible, although this may not be as user friendly.

Communication between the reviewer and the decision maker is an essential component of any HTA process<sup>30</sup> and, consequently, an important determinant of its impact. Ultimately the choice of HTA product, and indeed the kind of product available, should be driven by the information needs of the decision maker. However, the HTA producer can benefit from an understanding of how HTA questions are prioritized and reimbursement decisions are made, particularly with respect to how information is collected and used in these processes. In Alberta, the source of questions for assessment is not well defined, and there are currently no formalized criteria for determining which questions move forward into the AHTDP.<sup>77</sup> Questions will inevitably differ in key aspects depending on the domain from which they are derived (i.e. policy, clinical, or public), the technology being considered, and the extant pressures within the decision process. From the decision maker's perspective, these factors can affect the perceived value of, and tolerance of uncertainty in, the information provided by an HTA product. These considerations will, in turn, affect how the decision matrix is constructed.

It is impossible to predict the many factors that may influence the results of a report prior to its completion. However, the decision matrix can assist decision makers in identifying the information gaps or areas of uncertainty implicit in the different types of HTA reports, thereby making it easier to ensure that the requested product provides the required information at the critical decision point. Though measuring the value of information in its broad sense is not possible, a number of authors have described methods<sup>9,20,78,79</sup> for quantifying the value of making a decision based on current evidence by estimating the cost of collecting more information to reduce the degree of uncertainty to a tolerable level. For example, in cases that require a more cautionary policy approach or where there is a positive, but highly uncertain, net benefit regarding the technology, it may be useful for the decision maker to know the economic value of adopting or rejecting the technology when the decision is based on existing information, delayed pending a request for more research, or made within a coverage with evidence development framework.<sup>80</sup>

There are obvious ethical implications for a poorly structured priority setting process that does not take into account the variability in the questions and which, inadvertently, but routinely, rejects questions from particular stakeholder domains. Thus, different matrices may be needed for questions sourced from different domains within the healthcare system. To design a streamlined and integrated priority setting system within the STEEPLE model (social and system demographics, technology, environment, economics, politics, legislation, and ethics)<sup>81</sup> of information needs, on which the AHTDP is based, it is necessary to concurrently delineate how questions are sourced and from whom, how the eligibility of questions is determined, which questions are answered first, and how best to answer these questions.

The decision matrix is ultimately limited by the fact that it relies on gross generalizations regarding the HTA products listed. The scope and depth of these HTA products are affected not only by the time provided for their completion, but also by the questions asked and the quantity and quality of the evidence base. Context-specific definitions are also needed for some aspects of the matrix, such as the lifecycle stages of a technology, which may differ between healthcare systems. Thus, the matrix should be viewed more as a negotiation or decision support tool for facilitating dialogue between policy makers and HTA producers rather than as a de facto means of ordering information from a set HTA menu.

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## APPENDIX 1.A: IHE HTA PRODUCT LINE TABLE

Product	Timeline	Methodology	Review Process	Audience	Available on Website
<b>Information Requests</b>					
Information Requests Levels A B C	Actual work time: Up to ½ day Up to 1 day Up to 3 days	Not applicable	Not applicable	Originator of request	Not available
<b>Rapid Assessment</b>					
Level 1 - QwikNote	1 to 2 weeks	<u>Search</u> : 5 years, English only <u>Approach</u> : List of abstracts	Information Specialist in consultation with Researcher	Originator of request	Listed on website and available on request
Level 2 - TechNote  Completed request form	Up to 3 months	<u>Search</u> : Best available evidence, minimum 5 years <u>Databases</u> : MEDLINE/EMBASE and relevant databases and grey literature <u>Approach</u> : Summary of evidence base; includes guidelines, ongoing clinical trials, and expert opinion	One researcher <u>Internal</u> review (Director)	General distribution list for Alberta	Entire document
Level 3 – CompNote  Completed request form and usually project scope	3 to 6 months	<u>Search</u> : Best available evidence, minimum 5 years <u>Databases</u> : MEDLINE/EMBASE and relevant databases and grey literature <u>Approach</u> : Limited analyses and contextualization; includes guidelines and ongoing clinical trials	One researcher <u>Internal</u> review (Director) <u>External</u> review (4 to 6 weeks)	General distribution list for Alberta and selected stakeholders	Entire document
<b>HTA Report</b>					
HTA Report  Completed request form and project scope	6 to 12 months	<u>Search</u> : Not limited by publication date unless appropriate <u>Databases</u> : Comprehensive search of appropriate databases and grey literature <u>Data Sources</u> : Survey, administrative data analyses, statistical analyses <u>Approach</u> : Systematic review including formal assessment of methodological quality, meta-analysis (if applicable), and contextualization	Two researchers Two researchers independently appraise quality; one researcher for data extraction (checked by a second researcher) <u>Internal</u> review (Director) <u>External</u> review (6 weeks)	General distribution plus selected experts/stakeholders	Entire document

Methodology/Research					
Information Paper	Varies according to topic	<u>Approach</u> : Focus on policy or administration (human resource) issues/concerns or methodology	Varies <u>Internal</u> review (Director) <u>External</u> review – optional	Varies	Entire document
STE Reports					
STE Report  Alberta Health Technologies Decision Process (AHTDP)	90 days	<u>Search</u> : Search limits are topic dependent and determined in consultation with the Expert Advisory Committee <u>Databases</u> : Comprehensive search of appropriate databases and grey literature <u>Data Sources</u> : Survey, administrative data analyses, statistical analyses <u>Approach</u> : Summary of social and system demographics (S); systematic review of technology effects and effectiveness (T) including formal assessment of methodological quality and meta-analysis (if applicable); and economic evaluation (E). Contextualization of results to the Alberta healthcare system.	Three researchers – one lead researcher for each section (S, T, and E) S section – one researcher T section – two researchers independently appraise quality; one researcher for data extraction (checked by a second researcher) E section – one researcher analyses economic literature; another researcher conducts the economic analysis <u>Internal</u> review (Director) <u>External</u> review (Alberta Health and Expert Advisory Committee)	Alberta Health Expert Advisory Committee	Entire document
Comparative Effectiveness Reports					
Comparative Effectiveness Report	Varies according to topic	<u>Search</u> : Not limited by publication date unless appropriate <u>Databases</u> : Comprehensive search of appropriate databases and grey literature <u>Data Sources</u> : Survey, administrative data analyses, statistical analyses <u>Approach</u> : Examines all interventions across the spectrum of a disease (e.g. from prevalence through to treatment) or a process of care (e.g. from primary care through to tertiary care), with a general focus on “real world” use. Methodological approach varies depending on topic.	Varies <u>Internal</u> review (Director) <u>External</u> review – optional	Varies	Entire document

## APPENDIX 1.B: SUMMARY OF REVIEW TYPES AND CHARACTERISTICS LISTED BY GRANT AND BOOTH (2009)<sup>19</sup>

Review Type	Aim	Method				Details		
		Literature Search	Critical Appraisal	Synthesis	Analysis	Alternative Names	Pros	Cons
<b>Scoping review</b>	Provides a preliminary assessment of the potential size and scope of available research literature	Comprehensiveness determined by time/scope constraints	No	Tables with some narrative commentary	Describes quantity of literature by study design and other key features Attempts to specify a viable review		Useful for informing policy makers on whether a full systematic review is required  Attempts to be systematic, transparent, and replicable	Results potentially biased by limited rigour and duration of process  Quality of included studies not assessed, which can result in conclusions based on the existence of studies rather than their intrinsic quality  Findings cannot be used to recommend policy/practice
<b>Rapid review</b>	Assessment of what is already known about a policy or practice issue based on existing research	Comprehensiveness determined by time constraints	Time-limited formal assessment	Narrative with tables	Quantity of literature and summary of quality and direction of effect	Accelerated review Rapid assessment	Rigorous and explicit methods Shortened timeline	Breadth or depth limited by shortcuts taken in the review process  Results potentially biased by limited rigour and duration of process
<b>Literature review</b>	Generic term for examination of recent or current published literature on a topic	May or may not be comprehensive	May or may not be included	Narrative	May be chronological, conceptual, thematic, etc.	Narrative review Quasi-systematic review	Consolidates previous research and helps identify gaps or omissions in research and to avoid duplication	Lacks explicit intent to maximize scope or analyze data  Results potentially biased by limited rigour

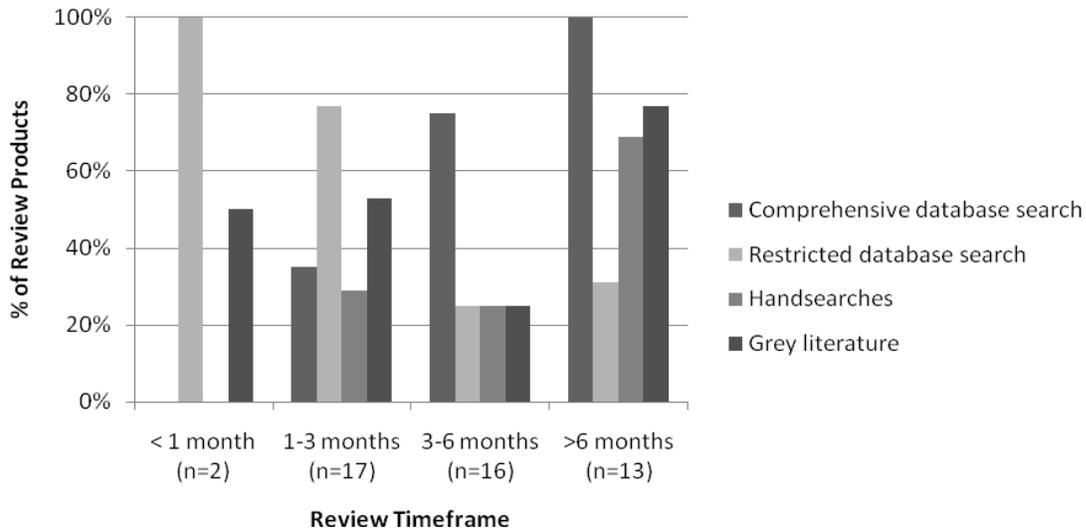
<b>Systematic search and review</b>	Addresses broad questions to produce a best-evidence synthesis	Comprehensive	May or may not be included	Tables; minimal narrative	What is known; recommendations for practice; limitations	Best-evidence synthesis	Often incorporates multiple study types rather than focusing on a single preferred study design	Critical review often prone to some of the limitations of the traditional narrative review Results may be biased by the lack of explicit inclusion and exclusion criteria and a clearly defined synthesis process
<b>Systematic review</b>	Seeks to systematically search for, appraise, and synthesize all known research evidence on a topic	Comprehensive	Yes	Narrative with tables	What is known; recommendations for practice; what remains unknown; uncertainty around findings; recommendations for future research	Qualitative systematic review – a review that does not include a meta-analysis component Quantitative systematic review – a review that includes a statistical analysis or meta-analysis component	Systematic, transparent, and replicable	Application can be limited if only studies of a single study design (e.g. randomized controlled trials) are included
<p><b>Meta-analysis</b> is a technique used in systematic reviews to statistically combine the results of the individual quantitative studies into overall measures of effect.  <i>Pros:</i> Allows individual studies, which are not in themselves sufficient to affect practice, to be aggregated into a combined evidence base.  <i>Cons:</i> Limited by the quality of the data in the individual studies; inappropriate combination of studies can produce erroneous results.</p>								

<b>Qualitative evidence synthesis</b>	Integrates or compares findings from qualitative studies to broaden the understanding of a particular phenomenon	May employ selective or purposive sampling	Yes – typically used to mediate messages	Narrative	Thematic analysis; may include conceptual models	Qualitative systematic review Qualitative meta-synthesis Meta-ethnography	Complements other research evidence by providing information on user and patient considerations	Methods are still under development Lack of consensus regarding the most appropriate method for undertaking such reviews
<b>Umbrella review</b>	Compiles evidence from multiple reviews to provide evidence on a broad condition or problem for which there are competing interventions	Identification of component reviews only	Yes - of studies within component reviews and/or the reviews themselves	Narrative with graphs and tables	What is known; recommendations for practice; what remains unknown; recommendations for future research	Overview of overviews Overview of reviews Review of reviews Summary of systematic reviews Synthesis of reviews	Provides an overview and exhaustive list of reviews relevant to the topic	Relies on the existence of the narrower focus component reviews Methods are still under development Limited by the quality of the data in the individual reviews Inappropriately combining reviews can produce erroneous results

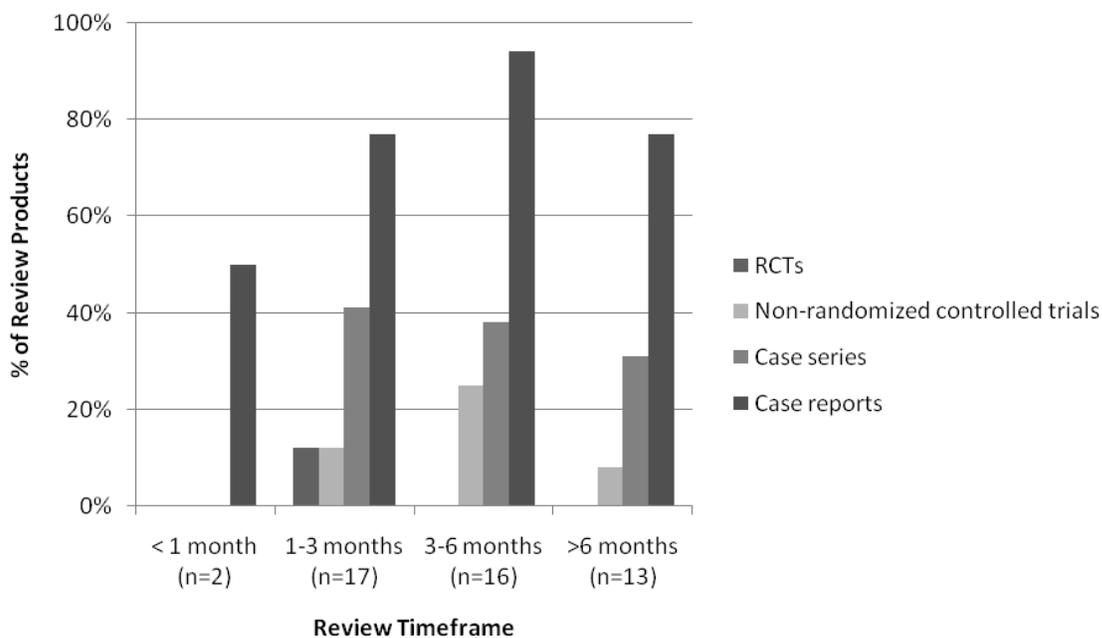
## APPENDIX 1.C: GRAPHICAL SUMMARY OF RESULTS FROM CAMERON ET AL. (2007)<sup>34</sup>

Note: IHE HTA product line documents were included in the survey results

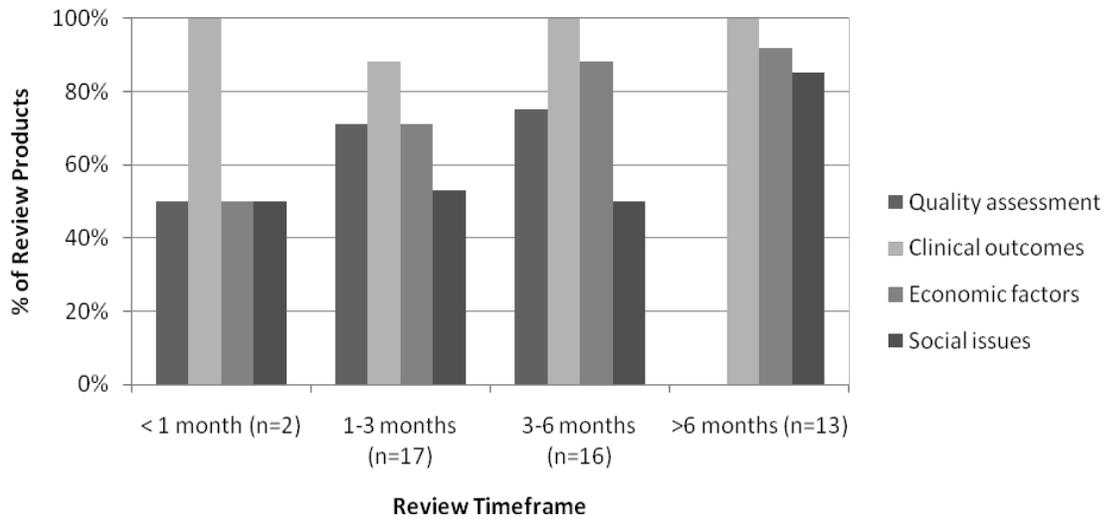
### Search Strategy



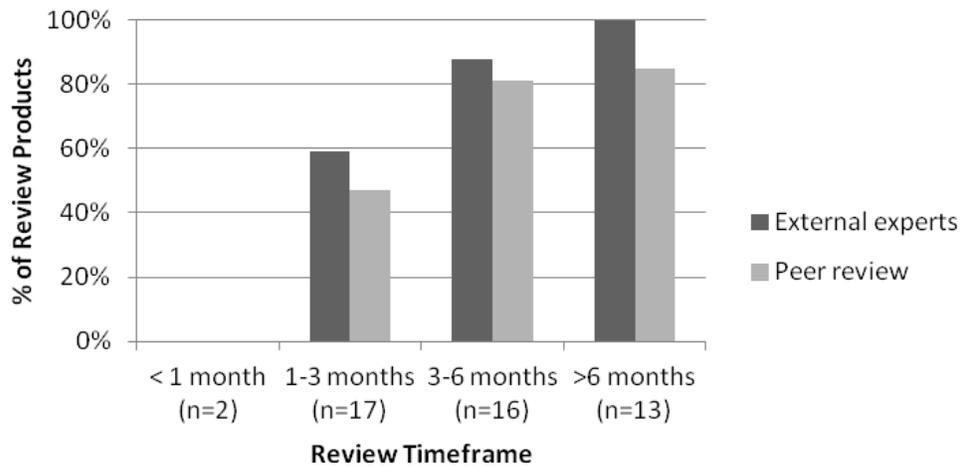
### Study Exclusions



### Composition



### External Input

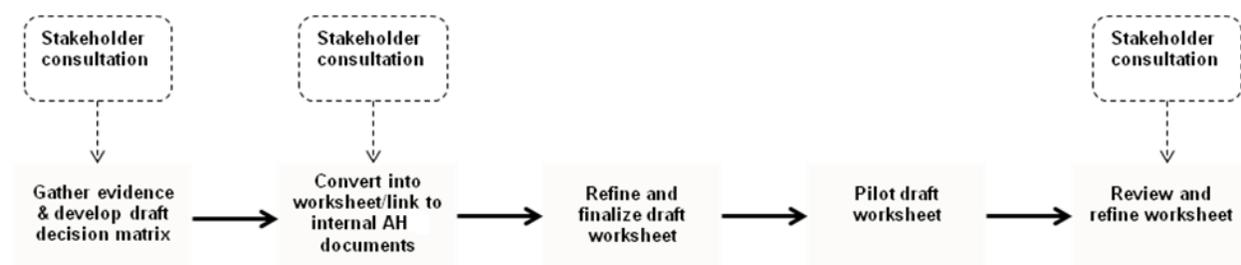


## SECTION 2: OVERVIEW

### Consultation and revision process

Section 1 of this document was delivered to AH on March 4, 2010. At the request of AH, a plan for moving the decision matrix from prototype to implementation stage was proposed (Figure 2). Accordingly, feedback on the report and the draft decision matrix document was sought through a series of meetings with stakeholders in the Alberta HTA production process. The review process was cyclical in that each revision of the documents was presented to the stakeholders for comment until no further changes were requested.

**Figure 2: Worksheet/questionnaire implementation plan**



As a result of the extensive consultation process, several important changes were made to key documents from the original report (Section 1), and additional supporting documents were created, as follows.

- The IHE product line table (Section 1, Appendix 1.A) was expanded to include a listing of STE report types (Appendix 2.A)
- The original draft decision matrix (Section 1, Table 4) was converted into a question/answer worksheet with an accompanying glossary (Section 2, Appendix 2.B)
- A questionnaire was developed (Section 2, Appendix 2.C) to serve as an interface between the evidence needs of the policy maker and the research-oriented listing of HTA products represented by the STE product line table, decision matrix, and worksheet.

In addition, the electronic literature search and handsearch were updated to March 2011. However, none of the identified studies met our inclusion criteria and no additional data were extracted.

### Next steps

The questionnaire in Appendix 2.C was designed to assist policy makers in choosing the most appropriate STE report for addressing a particular policy question, with the aim of increasing the efficiency of the AHTDP. The questionnaire, STE product line (Appendix 2.A), and draft decision worksheet (Appendix 2.B) require further evaluation and refinement to accurately capture the array of STE report types currently being produced within the AHTDP, including hybrid reports that straddle more than one report category. Future modifications must also reflect the topic-dependent variations in the complexity and depth of analysis of the S, T, and E sections that occur between reports. Thus, the questionnaire must be piloted within the AHTDP to determine whether it can be formally adopted by Alberta Health, the HTA Partners, and other end users.

## APPENDIX 2.A: IHE STE PRODUCT LINE TABLE

Detail	AHTDP STE Reports			
	Scoping Report	Level 1	Level 2	Level 3
General description	Based on abstracts only Narrow focus Limited search and evidence base Limited summary of evidence trends No quality assessment	A brief summary of available studies on S, T, or E components Narrow focus Limited rigour Limited evidence base and data extraction No evidence synthesis No quality assessment	May focus on one or two of the three S, T, or E components Narrow focus Moderate rigour with possible limitations in study selection, quality assessment, and depth of analysis	Comprehensive assessment including all three S, T, and E components
<b>Data collection</b>				
Search strategy				
Electronic databases	PubMed/ Cochrane/CRD	EMBASE/Cochrane MEDLINE/CRD	Level 1 + other relevant databases	Level 1 + other relevant databases
Grey literature	Limited	Limited	Full	Full
Pearling	No	No	Yes	Yes
Limited by language	Yes	Yes	Yes	Topic dependent
Limited by date	Yes	Yes	Topic dependent	Topic dependent
Additional data sources				
AHS administrative databases	No	No	If applicable	Yes
AH administrative databases	No	No	If applicable	Yes
National/provincial registry data	No	No	No	Topic dependent
Stakeholder input (e.g. patients, providers, manufacturers)	No	No	No	Topic/time dependent
Guidelines, ongoing trials, and regulatory information	No	Yes	Yes	Yes
Clinical expert opinion	No	Yes	Yes	Yes
<b>Methodology</b>				
No. of researchers selecting studies from full-text articles (for each section)	Full-text articles are retrieved only to verify study design	1	1	2
No. of researchers extracting data (for T & E sections only)	NA	1	1	2*
No. of researchers conducting quality appraisal (for T section only)	NA	NA	1	2 (checklist or tool)
Data analysis				
Qualitative synthesis	NA	No	Yes	Yes
Quantitative synthesis		No	No	If applicable

Detail	AHTDP STE Reports			
	Scoping Report	Level 1	Level 2	Level 3
<b>Methodology (cont'd)</b>				
Economic analysis	NA			
Literature review		Yes	Yes	Yes
Economic burden of disease		No	Yes	Yes
Model-based evaluation		No	No	Yes
Budget impact <sup>†</sup>		No	If applicable <sup>‡</sup>	If applicable
Value of perfect information <sup>§</sup>		No	No	If applicable
Cost attribution <sup>§</sup>	No	No	If applicable	
Desktop analytic package	NA	No	No	If applicable
<b>Peer review</b>				
Internal review	NA	Yes	Yes	Yes
External review		No	EAC members only	EAC members only
<b>Risk of bias<sup>  </sup></b>				
Source bias	High	High	Moderate	Low
Scope bias	High	Low to moderate (topic dependent)	Low to moderate (topic dependent)	Low
Selection bias	High	High	Moderate to high	Low
Coding bias	NA	Moderate <sup>¶</sup>	Moderate	Low
<b>Dissemination</b>				
Originator of request	Yes	Yes	Yes	Yes
AH and EAC	Yes	Yes	Yes	Yes
Alberta general distribution list	No	No	Yes	Yes
Selected stakeholders/experts	No	No	Yes	Yes
Available on website	No	No	Yes	Yes
<b>Resource commitment</b>				
Timeline <sup>#</sup>	3 to 6 weeks	2 to 3 months	3 to 6 months	6 to 12 months
Personnel (no. of individuals)				
Administrative	1	1	1	1
Information services	1	1	1	1
Research (reviewers and health economists)	1	1	1 to 2	≥3

\*Data extracted by one researcher and accuracy checked by a second researcher.

<sup>†</sup>Should only be conducted on technologies that are cost-effective after an economic evaluation has been undertaken to identify which alternatives provide the best value for money.

<sup>‡</sup>The budget impact analysis can be conducted for a Level 2 analysis, but only if the cost-effective technology has already been established.

<sup>§</sup>Cannot be undertaken without the development of a model-based economic evaluation.

<sup>||</sup>Source bias encompasses database, publication, and source selection bias; Scope bias includes geographic, temporal, and language bias; Selection bias refers to bias introduced in the study selection process; Coding bias refers to bias introduced in the data extraction process.

<sup>¶</sup>Only limited extraction of individual study data is undertaken.

<sup>#</sup>As measured from the Charter sign-off.

CRD - Centre for Reviews and Dissemination; EAC - Expert Advisory Committee; NA - not applicable; STE - Social and system demographics (S), technology effects and effectiveness (T), economic evaluation (E)

## APPENDIX 2.B: DRAFT DECISION WORKSHEET FOR MATCHING EVIDENCE NEEDS TO AN STE REPORT

### Overview of the Depth of Analysis and Degree Risk of the STE Report Types\*

	Scoping Report	STE Level 1	STE Level 2	STE Level 3
Depth of analysis	Very limited	Limited	Moderate	Comprehensive
Risk of bias in the evidence synthesis	High	Moderate to high	Moderate	Low

\*Refer to STE product line table for further information (Appendix 2.A)

### Question Details (circle the appropriate response)

	Scoping Report	STE Level 1	STE Level 2	STE Level 3
Is the population heterogeneous?	Comprises a list of study abstracts with a brief summary of evidence trends only	No	No	Yes
Is the focus broad? (>1 technology or >1 condition considered)		No		Yes
Will the technology have multi-stage application? (e.g. treatment plus prevention or diagnosis)		No		Yes
Will the technology have long-term application?		No	Yes	
Is large-scale implementation considered?		No		Yes
Are regulatory issues important?		No	Yes	
What is the lifecycle stage of the technology in Alberta?  Experimental/introduction Adoption Stable use Reduced use/ decommissioning		Yes		
		Yes		
			Yes	Yes
			Yes	Yes
Which S, T, and E sections are required?  Only one Only two All three		Yes		
			Yes	
				Yes
What is the timeline for completion?	3 to 6 weeks	2 to 3 months	3 to 6 months	6 to 12 months

STE - Social and system demographics (S), technology effects and effectiveness (T), economic evaluation (E)

**Evidence Needs and Level of Analysis Required (circle the appropriate response)**

	Scoping Report	STE Level 1	STE Level 2	STE Level 3
<b>S Section (if not required, go to next section)</b>				
<i>What is the level of analysis required for each aspect?</i>				
Burden of illness	Comprises a list of study abstracts with a brief summary of evidence trends only	Limited	Moderate	Comprehensive
Patterns of care		Limited	Moderate	Comprehensive
Social issues		Limited	Moderate	Comprehensive
Ethical issues (e.g. capacity, access)		Limited	Moderate	Comprehensive
Legal issues		Limited	Moderate	Comprehensive
<b>T Section (if not required, go to next section)</b>				
<i>What is the level of analysis required for each aspect?</i>				
Effects/effectiveness	Comprises a list of study abstracts with a brief summary of evidence trends only	Limited	Moderate	Comprehensive
Potential risks/harms		Limited	Moderate	Comprehensive
Process evaluation (how/why it works)		Not required		Required
<b>E Section (if not required, go to next section)</b>				
<i>What is the level of analysis required for each aspect?</i>				
Literature review	Comprises a list of study abstracts with a brief summary of evidence trends only	Limited	Moderate	Comprehensive
Economic burden of illness		Not required	Required	
Budget impact		Not required	Required	
Model-based evaluation		Not required		Required
Value of perfect information		Not required		Required
Cost attribution		Not required		Required
Desktop analytic package		Not required		Required
<b>External input</b>				
Input from clinical experts	NA	Optional	Required	
Input from patients, providers, or manufacturers		Not required		Required
<b>Contextualization</b>				
Contextualization of evidence	NA	Not required	Optional	Required

**Key:** Limited, moderate, and comprehensive descriptors refer to the level of analysis provided in the report  
 NA - not applicable; STE - Social and system demographics (S), technology effects and effectiveness (T), economic evaluation (E)

## Glossary for Draft Decision Worksheet

### Overview of the depth of analysis and degree of risk of the STE report types

**Depth of analysis:** “Analysis” is the process of breaking down a complex topic into smaller parts to facilitate a better understanding of it. Analyzing a question related to a [health technology](#) involves looking for patterns in information to identify cause and effect or to answer specific questions, such as whether the technology works and what the risks of using it are.<sup>1</sup> “Depth of analysis” refers to the sources of data that will be used to answer questions relating to the clinical effectiveness, safety, or cost-effectiveness of a technology. As a [scoping report](#) provides neither a synthesis of results nor an appraisal of the methodological strength of the included studies, it is not considered an analysis. STE report levels 1, 2 and 3 represent a continuum of depth of analysis, ranging from a description of the highest [level of evidence](#) available in a Level 1 report through to an in-depth analysis and synthesis of all pertinent literature, regardless of evidence level, in a Level 3 report.

**Risk of bias in the evidence synthesis:** “Bias” refers to a systematic error, or deviation from the truth, in the results of an evidence synthesis. Biases can lead to underestimation or overestimation of the true intervention effect, and they can vary in magnitude: some are small (and trivial compared with the observed effect) and some are substantial (so that an apparent finding may be entirely due to bias).<sup>2</sup> Bias in an evidence synthesis may result from errors in identifying and selecting studies for inclusion and extracting the data for analysis. The “risk of bias” refers to the degree to which bias may have affected the results. A low risk of bias indicates that the methods used to produce the evidence synthesis minimized, as far as possible, the effects of potential biases; a high risk of bias indicates that the methods used to produce the evidence synthesis are unlikely to have minimized the influence of potential biases.

### Question Details

**Broad focus:** Focus refers to the number of conditions or technologies being considered. If more than one condition (or subgroup of a population) or more than one index technology is being considered, the focus of the STE report is considered broad.

**Evidence base:** Refers to the known evidence (systematic reviews or primary studies) that exists regarding the use of the technology in the population of interest. While sometimes difficult to judge a priori, an estimate of the number and types of studies available is helpful in determining the time and resources required to conduct an evidence synthesis.

**Heterogeneous population:** Heterogeneity is the differential response of two or more subgroups in a population to the [health technology](#) in question. Such subgroups may be identified by clinical (e.g. disease severity or comorbidity) or demographic (e.g. age or ethnicity) factors.

**Large-scale implementation:** The scale of implementation refers to the proportion of the health region that is likely to be affected by the [health technology](#). “Large-scale implementation” refers to a technology that is used in multiple settings (e.g. primary, secondary, and tertiary care) and/or across the whole province.

**Lifecycle stage:** The lifecycle stage refers to the maturity and marketing saturation of the technology in question. In theory, all technologies pass through similar stages of development and use, from experimental through to obsolescence and decommissioning.

**Long-term application:** The term of application refers to the time period that the [health technology](#) will be utilized over the lifetime of the patient/user. If the technology is likely to be used to treat a chronic condition that is not immediately life threatening, then the application is considered long term.

**Multi-stage application:** Stage of application refers to the point in a process of care (diagnosis, treatment, prevention) where the technology may be used. If the technology is being considered for use at more than one point in this process, it is considered “multi-stage”.

**Regulatory issues:** Refers to issues regarding formal (i.e. legislative) and informal (e.g. practice guidelines, professional associations) approval and use of the [health technology](#) both nationally (e.g. through Health Canada) and provincially.

## Evidence needs

**Contextualization:** “Context” refers to the conditions and circumstances that are relevant to the application of the technology (e.g. the setting, providers, and patient population). Within STE reports, contextualization refers to the process of gathering and summarizing information relating to the provincial healthcare context (prevalence and severity of disease, population demographics, pathways of care, available services, etc.) to better understand how to interpret and apply results from clinical and cost-effectiveness analyses to the local environment. This information is typically a focus of the S component of an STE report.

**Cost attribution:** An analysis that assesses the systematic differences in costs between alternative technologies, not only to elucidate the resource implications on disparate health sectors (such as laboratory, physician, inpatient, and outpatient services), but also to identify the factors (i.e. cost attributing) driving the cost differences. This can help identify areas within the system where resources could be shifted to facilitate the adoption of the cost-effective technology.

**Desktop analytic package:** These are self-contained Excel-based software programs that allow decision makers to conduct their own scenario analysis based on user-defined inputs. For instance, analytic packages can be developed to supplement a budget impact analysis.

**Level of analysis:** “Level of analysis” refers to the extent that types of patterns are sought in the data and to what degree the results can be used to support conclusions about a particular [health technology](#). The three STE report types differ in the level of confidence that can be assigned to their results. *Limited* analysis means that only a description and grouping of the evidence is provided. *Comprehensive* analyses examine patterns in the data to a degree that allow one to be reasonably confident that the results support conclusions about the effects of a particular technology; that is, they provide a strong basis for inference. *Moderate* analyses provide a level of analysis that is intermediate between limited and comprehensive.

**Model-based evaluation:** A full economic evaluation assessing the cost-effectiveness (i.e. value for money) of a technology through a simulation model.

**Value of perfect information:** An analysis that quantifies the extent of uncertainty surrounding existing evidence on cost-effectiveness and examines the value of conducting further research to reduce uncertainty and the likelihood of making an incorrect decision (i.e. making the decision with perfect information) about adopting a technology. This information not only informs whether additional evidence is required to support a decision, but also identifies what type of information is needed if the current evidence is insufficient.

## General terms

**Health technology:** Any intervention administered with the aim of improving the health status of patients or of populations.<sup>3</sup>

**Level of evidence:** Studies are often grouped into a hierarchy according to their validity or the degree to which they are susceptible to bias. The hierarchy indicates which studies should be given most weight in an evaluation.<sup>4</sup> Various hierarchies are used in HTA. Most commonly, for studies on therapy, prevention, etiology and harms, systematic reviews of randomized controlled trials receive the highest ranking, followed in descending order by randomized controlled trials, non-randomized comparative studies, case series, and case reports.

**Scoping report:** Provides a list of study abstracts and a brief summary of trends in the evidence base. Although relevant studies are retrieved to verify their design, an appraisal of the methodological strength of the included studies is not undertaken.

## References

1. Health Technology Assessment International (HTAi). HTAi consumer and patient glossary. Edmonton, Canada; HTAi: 2009. Available from: <http://img.eurordis.org/newsletter/pdf/nov-2010/58-1%20HTAi%20Patient%20And%20Consumer%20Glossary%20October%202009-1.pdf> (accessed October 9, 2012).
2. Higgins JPT, Altman DG (editors). Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.1 (updated September 2008). The Cochrane Collaboration, 2008. Available from: [www.cochrane-handbook.org](http://www.cochrane-handbook.org) (accessed October 9, 2012).
3. Muir Gray JA. *Evidence-based Healthcare*. New York, NY, USA: Churchill Livingstone; 1997.
4. International Network of Agencies for Health Technology Assessment (INAHTA). Health technology assessment glossary. Stockholm, Sweden; INAHTA: 2006. Available from: [http://www.inabta.org/upload/HTA\\_resources/Edu\\_INAHTA\\_glossary\\_July\\_2006\\_final.pdf](http://www.inabta.org/upload/HTA_resources/Edu_INAHTA_glossary_July_2006_final.pdf) (accessed October 9, 2012).

## APPENDIX 2.C: INTERFACE QUESTIONNAIRE FOR MATCHING EVIDENCE NEEDS TO AN STE REPORT

### Which Evidence Report Do I Need?

This questionnaire aims to serve as an interface between the evidence needs of policy makers and the menu of products available from HTA producers. It has been designed to facilitate discussion between policy makers and reviewers on what type of HTA product should be commissioned to answer policy questions that have been identified by the AHTDP prioritization process as requiring an HTA analysis.

#### Section 1: What is the policy question?

Please answer the following questions.

- |    |  |                                     |                                      |  |
|----|--|-------------------------------------|--------------------------------------|--|
| 1  | What is the main focus of the question? (More than one option can be checked.)*  | <input type="checkbox"/> S          | <input type="checkbox"/> T           | <input type="checkbox"/> E   |
| 2  | How would you describe the lifecycle stage of the technology† in Alberta?  | <input type="checkbox"/> Stable Use | <input type="checkbox"/> Reduced Use | <input type="checkbox"/> Does not have fee-for-service code              |
| 3  | Does the target population comprise subgroups that require separate analyses (e.g. according to disease severity, comorbidity, age, or ethnicity)? | <input type="checkbox"/> Yes        | <input type="checkbox"/> No          | <input type="checkbox"/> Uncertain                                       |
| 4  | Is there more than one technology requiring analysis?  | <input type="checkbox"/> Yes        | <input type="checkbox"/> No          | <input type="checkbox"/> Uncertain                                       |
| 5  | Is there more than one condition being considered?   | <input type="checkbox"/> Yes        | <input type="checkbox"/> No          | <input type="checkbox"/> Uncertain                                       |
| 6  | Will the technology be applied at more than one point in the process of care (prevention, diagnosis, treatment)?                                   | <input type="checkbox"/> Yes        | <input type="checkbox"/> No          | <input type="checkbox"/> Uncertain                                       |
| 7  | Will the technology be used for a chronic condition, i.e. long-term application?   | <input type="checkbox"/> Yes        | <input type="checkbox"/> No          | <input type="checkbox"/> Uncertain                                       |
| 8  | Will the technology be used in multiple settings (e.g. primary, secondary, and tertiary care) and/or across the whole province?                    | <input type="checkbox"/> Yes        | <input type="checkbox"/> No          | <input type="checkbox"/> Uncertain                                       |
| 9  | Are regulatory issues important?   | <input type="checkbox"/> Yes        | <input type="checkbox"/> No          | <input type="checkbox"/> Uncertain                                       |
| 10 | Are you aware of any relevant Alberta data regarding this technology?  | <input type="checkbox"/> Yes        | <input type="checkbox"/> No          | <input type="checkbox"/> Uncertain                                       |
|    | If yes, are these data available?  | <input type="checkbox"/> Yes        | <input type="checkbox"/> No          | <input type="checkbox"/> Uncertain                                       |
| 11 | Is the technology controversial or politically sensitive?  | <input type="checkbox"/> Yes        | <input type="checkbox"/> No          | <input type="checkbox"/> Uncertain                                       |
| 12 | Would you like input from clinical experts?  | <input type="checkbox"/> Yes        | <input type="checkbox"/> No          | <input type="checkbox"/> Uncertain                                       |
| 13 | Would you like input from patients, providers, or manufacturers?   | <input type="checkbox"/> Yes        | <input type="checkbox"/> No          | <input type="checkbox"/> Uncertain                                       |
| 14 | When do you need this report?  | <input type="checkbox"/> 3-6 weeks  | <input type="checkbox"/> 2-3 months  | <input type="checkbox"/> 3-6 months <input type="checkbox"/> 6-12 months |

\*S - social and system demographics; T - technology effects and effectiveness; E - economic evaluation

†A health technology is defined as any intervention administered with the aim of improving the health status of patients or of populations

**Section 2: What level of analysis do you need?**

Please answer the following questions for each of the sections required.

**S Section**

Please indicate the type and level of analyses required for the S section

- |                       |                                  |                                   |   |                                       |
|-----------------------|----------------------------------|-----------------------------------|---|---------------------------------------|
| S.1 Burden of illness | <input type="checkbox"/> Limited | <input type="checkbox"/> Moderate | <input checked="" type="checkbox"/> Comprehensive | <input type="checkbox"/> Not Required |
| S.2 Patterns of care  | <input type="checkbox"/> Limited | <input type="checkbox"/> Moderate | <input checked="" type="checkbox"/> Comprehensive | <input type="checkbox"/> Not Required |
| S.3 Social issues     | <input type="checkbox"/> Limited | <input type="checkbox"/> Moderate | <input checked="" type="checkbox"/> Comprehensive | <input type="checkbox"/> Not Required |
| S.4 Ethical issues    | <input type="checkbox"/> Limited | <input type="checkbox"/> Moderate | <input checked="" type="checkbox"/> Comprehensive | <input type="checkbox"/> Not Required |
| S.5 Legal issues      | <input type="checkbox"/> Limited | <input type="checkbox"/> Moderate | <input checked="" type="checkbox"/> Comprehensive | <input type="checkbox"/> Not Required |

**T Section**

Please indicate the type and level of analyses required for the T section

- |   |   |                                       |   |                                       |
|---|---|---------------------------------------|---|---------------------------------------|
| T.1 Effects/effectiveness                 | <input type="checkbox"/> Limited            | <input type="checkbox"/> Moderate     | <input checked="" type="checkbox"/> Comprehensive | <input type="checkbox"/> Not Required |
| T.2 Potential risks/harms                 | <input checked="" type="checkbox"/> Limited | <input type="checkbox"/> Moderate     | <input checked="" type="checkbox"/> Comprehensive | <input type="checkbox"/> Not Required |
| T.3 Process evaluation (how/why it works) | <input type="checkbox"/> Required           | <input type="checkbox"/> Not Required |   |                                       |

**E Section**

Please indicate the type and level of analyses required for the E section

- |                                  |                                       |  |   |                                       |
|----------------------------------|---------------------------------------|--|---|---------------------------------------|
| E.1 Literature review            | <input type="checkbox"/> Limited      | <input type="checkbox"/> Moderate            | <input checked="" type="checkbox"/> Comprehensive | <input type="checkbox"/> Not Required |
| E.2 Economic burden of illness   | <input type="checkbox"/> Not Required | <input checked="" type="checkbox"/> Required |   |                                       |
| E.3 Budget impact                | <input type="checkbox"/> Not Required | <input checked="" type="checkbox"/> Required |   |                                       |
| E.4 Model-based evaluation       | <input type="checkbox"/> Not Required | <input checked="" type="checkbox"/> Required |   |                                       |
| E.5 Value of perfect information | <input type="checkbox"/> Not Required | <input checked="" type="checkbox"/> Required |   |                                       |
| E.6 Cost attribution             | <input type="checkbox"/> Not Required | <input checked="" type="checkbox"/> Required |   |                                       |
| E.7 Desktop analytic package     | <input type="checkbox"/> Not Required | <input checked="" type="checkbox"/> Required |   |                                       |

**Recommendation Key**

**Section 1:**

If you answered mostly 'yes' to questions 3-14, a level 2 or 3 STE report is required.

If you answered mostly 'no' to questions 3-14, a level 1 or 2 STE report is required.

**Section 2:**

If you answered mostly 'comprehensive' to questions S.1-S.5 and T.1-T.2, a level 3 STE report is required.

If you answered mostly 'required' to questions E.2-E.7, a level 3 STE report is required; otherwise a level 1 or 2 report is required.

If you answered mostly 'limited' to questions S.1-S.5 and T.1-T.2, a level 1 STE report is required.

If you answered mostly 'moderate' to questions S.1-S.5 and T.1-T.2, a level 2 STE report is required.

## **Author Contribution Statements**

*Ann Scott* contributed to study conception and design, data analysis and interpretation, and approved the final version for publication.

*Christa Harstall* contributed to study conception and design, revision of manuscript for critical content, and approved the final version for publication.

This project is concerned with describing a comprehensive set of HTA products, not the methods used to produce them. The report describes various products produced by HTA agencies and provides a summary of the basic elements of these products, but an in-depth analysis of, or comparison between, the various products in terms of their methodology is beyond its scope.



**INSTITUTE OF  
HEALTH ECONOMICS**  
ALBERTA CANADA

Institute of Health Economics  
1200 – 10405 Jasper Avenue  
Edmonton AB Canada T5J 3N4  
Tel. 780.448.4881 Fax. 780.448.0018  
info@ihe.ca

[www.ihe.ca](http://www.ihe.ca)

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