Decision Determinants Guidance Document

The Ontario Health Technology Advisory Committee (OHTAC) Decision-Making Process for the Development of Evidence-Based Recommendations

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Medical Advisory Secretariat
Ministry of Health and Long-Term Care

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Introduction

The purpose of this document is to describe the components and process of decision-making used by the Ontario Health Technology Advisory Committee (OHTAC) to develop recommendations for the Ontario health care system and the Ontario Ministry of Health and Long-Term Care concerning the best course of action for the uptake of new health technologies and services in Ontario

This document has been developed because OHTAC values transparency in decision-making and strives to be accountable to all its stakeholders who include the people of Ontario, health care policy and decision-makers, and Ontario health care providers, amongst others. Through a transparent decision-making process these and other stakeholders will have a better understanding of how OHTAC arrives at making its recommendations concerning specific technologies.

In October 2006 OHTAC requested an evaluation of its decision-making processes used to develop Ontario specific recommendations for the uptake and diffusion of health technologies. At that time, OHTAC made decisions after considering criteria relevant to each health technology and determining the trade-offs between the benefits, risk and burdens as outlined in the GRADE grading strength of recommendations framework. (1) OHTAC, however, felt that to meet the obligations of transparency and accountability, a pragmatic decision determinants framework that considers explicit criteria from the initial vignette phase to final recommendations was needed. The Decision Determinants Sub-Committee (DDSC) was thus convened to provide guidance to OHTAC for developing a comprehensive and transparent decision-making framework.

In developing its guidance, the DDSC drew on information from a variety of sources including a review of other decision-making methodologies from national and international Health Technology Agencies, discussions with decision experts from the disciplines of evidence based medicine, health economics, decision analysis, bioethics, and health policy. Fundamentally, the DDSC believed that the decision-making process should strive to be and be perceived as a fair process. To this end, the committee found the framework of Accountability for Reasonableness (2) offered a compelling conceptual definition of such a process and has incorporated its concepts into the guiding principles set out in this document.

However, while the Accountability for Reasonableness offered a conceptual definition of a fair decision-making process, it did not provide guidance on the explicit relevant and reasonable decision-making criteria used in the process. In developing such criteria itself, the DDSC believed that the foremost consideration should be given to those criteria relating to scientific evidence or context-free evidence relating to a health technology. This tenet is rooted in the concept of evidence-based medicine, which is defined as "… the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." (3) The committee also recognized the value of other forms of evidence including that relating to social and ethical values, cost, and context sensitive evidence. Expert opinion, experiential evidence, and colloquial evidence should also be considered to help contextualize the scientific evidence. The importance of integrating the scientific, context-specific, and colloquial types of evidence is supported by the concept of the practice of evidence-based medicine defined as "…the integration of individual clinical expertise (proficiency and judgment acquired through clinical experience and practice) with the best available external clinical evidence from systematic research." (3)

Finally, the DDSC found that a deliberative process was the best way of integrating the various types of evidence as the overall functions of the deliberative process is to combine context-free with context-sensitive scientific evidence, to elicit colloquial evidence, and to supplement the scientific with colloquial evidence.(4) A deliberative process is defined as (4)the following:

“A tool for producing guidance based on heterogeneous evidence. It is a participatory process that includes representation from experts and stakeholders, face-to-face interaction, criteria for the sources of scientific evidence and their weight, and a mechanism for eliciting colloquial evidence while making it subsidiary to the science.

Guiding Principles of Decision Making

OHTAC decision-making is supported by a framework of seven guiding tenets outlined below.

1. Decisions should be consistent with the principles for fairness and transparency (2).

2. The decision making process ought to be consistent.

3. OHTAC decisions ought to be made after considering evidence pertaining to the following explicit criteria:
   - Overall Clinical Benefit,
   - Consistency with expected societal and ethical values,
   - Value for money, and
   - Feasibility of adoption into the health system.

   Importantly, there must first be evidence of overall clinical benefit of the health technology in question before the other criteria are evaluated.

4. Decision making involves integrating context free, context sensitive and colloquial forms of evidence to develop recommendations concerning a technology.[1] Scientific studies whenever possible will be considered first and/or colloquial evidentiary sources (i.e. experiences of stakeholders) if scientific evidence is lacking, ambiguous and/or non-generalizable to Ontario decision-making. Colloquial forms of evidence will be considered subsidiary to scientific evidence.

5. The decision making process ought to take place within a deliberative process defined as one that involves the face-to-face interaction of OHTAC members.

6. OHTAC's recommendation for a health technology will only indicate the use of an intervention for a specific demographic characteristic (e.g., age, gender, and ethnicity) if there is clear evidence of differences based on such characteristics.

7. OHTAC's recommendations may include adoption (with or without conditions or limitations), rejection, or further evaluation (e.g. field study) of the health technology.

[1] Context free and context sensitive evidence are defined as evidence gathered through systematic and replicable methods (e.g., a randomized controlled trial is an example of context free evidence and an economic analysis is an example of context sensitive evidence.) Colloquial evidence includes evidence gathered through consultative processes (e.g., expert opinion, public engagement).

Components of Decision Making

When making draft recommendations regarding a health technology OHTAC considers evidence on four explicit criteria which comprise the decision determinants (see Table 1):

i) Overall clinical benefit

ii) Consistency with expected societal and ethical values

iii) Value for money

iv) Feasibility of adoption into the health system

Overall clinical benefit and consistency with values must be demonstrated before implementation feasibility will be considered.

Sources of Evidence

Overall clinical benefit and value for money from context free and context sensitive evidence, respectively, are demonstrated before feasibility of adoption into the health system is considered. Systematic methods to obtain scientific sources of evidence will be used to inform the overall clinical benefit and value for money criteria. Context sensitive (e.g. budget impact) and colloquial evidence (e.g. experience of experts) will be used to inform the feasibility of adoption. Currently, only colloquial forms of evidence (e.g., OHTAC deliberations undertaken at scheduled OHTAC meetings and pertaining to specific technologies) are being used to inform societal and ethical values (unless otherwise stated in OHTAC recommendations). Systematic methods to obtain evidence on societal and ethical values are currently being developed at OHTAC.

Table 1: Components of Decision-making

Main Criteria	Definition	Evaluation of Criterion	*Sub-Criteria
Overall clinical benefit	A measure of the net health benefit of a technology to diagnose or manage a disease, condition (i.e. heart failure) or health care related issue (e.g. infection control).	▪ The overall clinical benefit of the technology should be determined after evaluating its effectiveness and safety, as well as the burden of the target illness for which the technology is used. ▪ The need for the technology should also be assessed in comparison to effective alternatives.	▪ Effectiveness ▪ Safety ▪ Burden of illness ▪ Need
Consistency with expected societal and ethical values	May include measured preferences or ethical principles relevant to the use of the technology.	▪ Consistency is a balanced judgment made after considering all reasonable sources of high-quality information about the societal and ethical values associated with aspects of the use of the technology (for whom and for what it will be used).	▪ Expected societal values ▪ Expected ethical values
Value for Money	A measure of the net cost or efficiency of the health technology compared to available alternatives.	▪ Value for money is determined after completing one or more appropriate economic evaluations, for example: the incremental cost-effectiveness utility ratio (ICEUR) in terms of quality of life years gained (QALY) or life years gained (LYG), cost effectiveness acceptability curves, or cost consequence analysis. ▪ OHTAC does not use a value for money threshold.	▪ Incremental cost-effectiveness utility ratio ▪ Cost effectiveness acceptability curves ▪ Cost-consequence analysis ▪ Other appropriate economic analysis determined by OHTAC

Main Criteria	Definition	Evaluation of Criterion	*Sub-Criteria
Feasibility of adoption	A measure of the ease with which a health technology can be adopted into the Ontario health care system through the identification of specific issues likely to arise from implementation.	▪ Feasibility will be evaluated by assessing the economic and organizational feasibility of adopting the technology. ▪ Economic feasibility evaluates the net budget impact of adopting the technology. ▪ Organizational feasibility evaluates the impact of the technology on existing infrastructure (operational, capital and human resources) of the health care environment. This includes assessing the health system enablers that will encourage adoption of the technology, as well as any barriers.	▪ Economic feasibility ▪ Organizational feasibility

*Definitions are provided in Table C2.

Table 2: Evidence Definitions

Main Criteria	Sub-Criteria	Definitions and considerations
Overall clinical benefit	Effectiveness	▪ The potential health impact of the technology compared to the available alternatives. ▪ Should be measured in terms of relevant patient outcomes including mortality, morbidity, and quality of life of persons using the technology. ▪ The magnitude and direction (increase/decrease) of the technology's effect should be considered when evaluating its potential health impact.
	Safety	▪ The frequency and severity of adverse effects specific to the new technology compared to the available alternatives.
	Burden of illness	▪ The burden of illness on society of the target condition to which the technology is applied as evidenced by the incidence, prevalence, or other measure of disease burden on the population.
	Need	▪ The need for the technology compared to the availability of an effective alternative technology to manage the target condition. ▪ Need may be great if no other alternatives are available for the target condition.
Consistency with expected societal and ethical values	Expected societal values	▪ Broadly shared values in society that bear on the appropriate use and impact of the technology.
	Expected ethical values	▪ The potential ethical issues inherent in using or not using the technology. ▪ Relevant ethical issues should be listed.
Value for money	Economic evaluations	▪ A measure of the net cost or efficiency of the health technology compared to available alternatives. ▪ OHTAC does not use a value for money threshold. ▪ Can be assessed by the appropriate economic evaluation including incremental cost effectiveness analysis, incremental cost–utility analysis, net monetary/health benefit, acceptability curves, cost-consequence analysis
Feasibility of adoption	Economic feasibility	▪ The net budget impact of the new health technology derived by determining all relevant costs and savings to the health care system. ▪ The default perspective for the budget impact analyses will be that of the funder of the health system. OHTAC may request alternative perspectives if they would better inform the decision-making process.
	Organizational feasibility	▪ The ease with which the health technology can be adopted will be evaluated by looking at the health system enablers and barriers to diffusion within the health system infrastructure (operational, capital, human resources, legislative and regulatory).

* ICEUR: Incremental Cost-Effectiveness Utility Ratio (ICEUR); QALY: Quality of Life Years gained (QALY); LYG: Life Years Gained.

Evaluation Criteria

The evaluation of the four explicit main criteria (overall clinical benefit, consistency with expected societal & ethical values, value for money, and feasibility of adoption into health system) will be reported in terms of 1 of 4 symbols (see Table 3).

Table 4 illustrates the interpretation of the legend meanings with respect to the main criteria and sub criteria.

Table 3: Quality of Evidence of Included Studies

Symbol	Meaning
	High/Large
	Moderate/Medium
	Low/Small
	Uncertainty in the evidence as reflected by quality of evidence or assessment of quality of evidence
	Unknown

Table 4: Interpretation

Decision Criteria	Overall Evaluation	Sub-Criteria	Magnitude of Evidence / Degree of Certainty*	Quality of Evidence/Data Source†
Overall clinical benefit	How likely is the technology to result in high, moderate or low overall clinical benefit?	**Effectiveness**	▪ How effective is the technology likely to be taking into account any variability? ▪ High, moderate, or low level of effectiveness?	▪ Does the effectiveness data come from high, moderate or low quality evidence (e.g. clinical trials vs. observational studies) and what is the quality of the studies)? ▪ Quality of evidence to be determined using GRADE methodology (5) where appropriate.
	How uncertain is the projected overall clinical benefit?		▪ Uncertainty of the technology's effectiveness	▪ Uncertainty regarding the quality of effectiveness data.
		Safety	▪ How safe is the technology likely to be: very, moderately or hardly safe?	▪ Does the safety data come from high, moderate or low quality evidence and what is the quality of the studies? ▪ Quality of evidence to be determined using GRADEmethodology (5) where appropriate
			▪ How uncertain are we about the safety estimates?	▪ Uncertainty regarding the quality of safety data.
		Burden of illness	▪ What is the likely size of the burden of illness pertaining to this technology? ▪ High, moderate, or low (e.g., prevalence, incidence).	▪ Does the burden of illness data come from high, moderate or low quality studies ▪ Quality of evidence to be determined using GRADE methodology (5) where appropriate.
			▪ Uncertainty regarding the size of the burden of illness (e.g., how prevalent disease is)?	▪ Uncertainty regarding the quality of the burden of illness data (e.g., incidence, prevalence).
		Need	▪ How large is the need for this technology? High, moderate, or low?	▪ Are data on the need for the technology of high, moderate or low quality?
			▪ Uncertain of whether there is high, moderate or little need for technology.	▪ Uncertain of the quality of the data pertaining to need.
Consistency with expected societal and ethical values	How likely is adoption to be congruent with expected societal/ethical values? Highly likely, moderately likely, or not so likely.	**Expected societal values**	▪ How likely is adoption of the technology to be congruent with the expected societal values? Highly likely, moderately likely, or unlikely?	▪ Is the data that provided information on expected societal values of high, moderate or low quality (e.g., utility studies or colloquial evidence?
	How certain is it that the technology is consistent with the societal and ethical values.	**Expected ethical values**	▪ Uncertainty of how likely the technology is to be congruent with expected ethical values.	▪ Uncertainty of the quality of the data pertaining to the expected societal values.

Decision Criteria	Overall Evaluation	Sub-Criteria	Magnitude of Evidence / Degree of Certainty*	Quality of Evidence/Data Source†
Value for money	How efficient is the technology likely to be: highly efficient, moderately efficient, or displaying low efficiency?	**Economic evaluations**	▪ How efficient is the technology likely to be: highly efficient, moderately efficient, or displaying low efficiency?	▪ Is the data that provided information on value for money (efficiency) of the technology of high, moderate, or low quality?
	Uncertain of how efficient the technology is likely to be.		▪ Uncertain of how efficient the technology is likely to be.	▪ Uncertainty regarding the quality of the value for money data.
Feasibility of adoption	How feasible is adoption of the technology into Ontario's health system: highly feasible, moderately feasible, or little feasibility?	**Economic feasibility**	▪ How economically feasible is the technology: highly feasible, moderately feasible, or little economic feasibility?	▪ Is the data that provided information on economic feasibility of high, moderate or low quality?
	Uncertain of the ease with which the technology would be adopted into the Ontario health system.		▪ Uncertain of the technology's economic feasibility.	▪ Uncertainty regarding the quality of the economic feasibility data.
		Organizational feasibility	▪ How organizationally feasible is it to implement the technology (e.g., with respect to system enablers): highly feasible, moderately feasible, or little organizational feasibility?	▪ Is the data that provided information on organizational feasibility of high, moderate, or low quality? ▪
			▪ Uncertain of the technology's organizational feasibility.	▪ Uncertainty regarding the quality of the organizational feasibility data.

*Magnitude refers to the size of the effect measured for the evidence parameters (e.g., the magnitude of effectiveness may be reflected in the Odds Ratio.; the magnitude of the burden of illness is reflected in the prevalence or incidence rates)

*Degree of certainty refers to the variability around the evidence effect estimates. (e.g., wide confidence intervals will indicate a low degree of certainty in the point estimate.)

†Quality of Evidence refers to the likelihood that further research or evidence will change the magnitude and or the degree of certainty of the evidence effect estimates (5). (e.g., high quality evidence indicates further research is unlikely to change confidence in the evidence effect estimates; moderate indicates further research is likely to change confidence in evidence effect estimates, low indicates that further research is very likely to change confidence in the evidence effect estimates, and very low indicates the evidence effect estimates are very uncertain(5))

†Data Source refers to the source of the evidence. (e.g., published RCTs, Ministry of Health Database, Expert Opinion)

Decision Process and Recommendation Development

The OHTAC's decision-making takes place within a deliberative process that involves discussions about the quality of evidence and the evaluation of these criteria as they pertain to the development of recommendations concerning a health technology (see Figure 1). The relevance of a particular criterion may change on a case by case basis and, because of this a deliberative decision–making process is conducive to the individualized appraisal necessary for each health technology. Figure 1 illustrates the decision process.

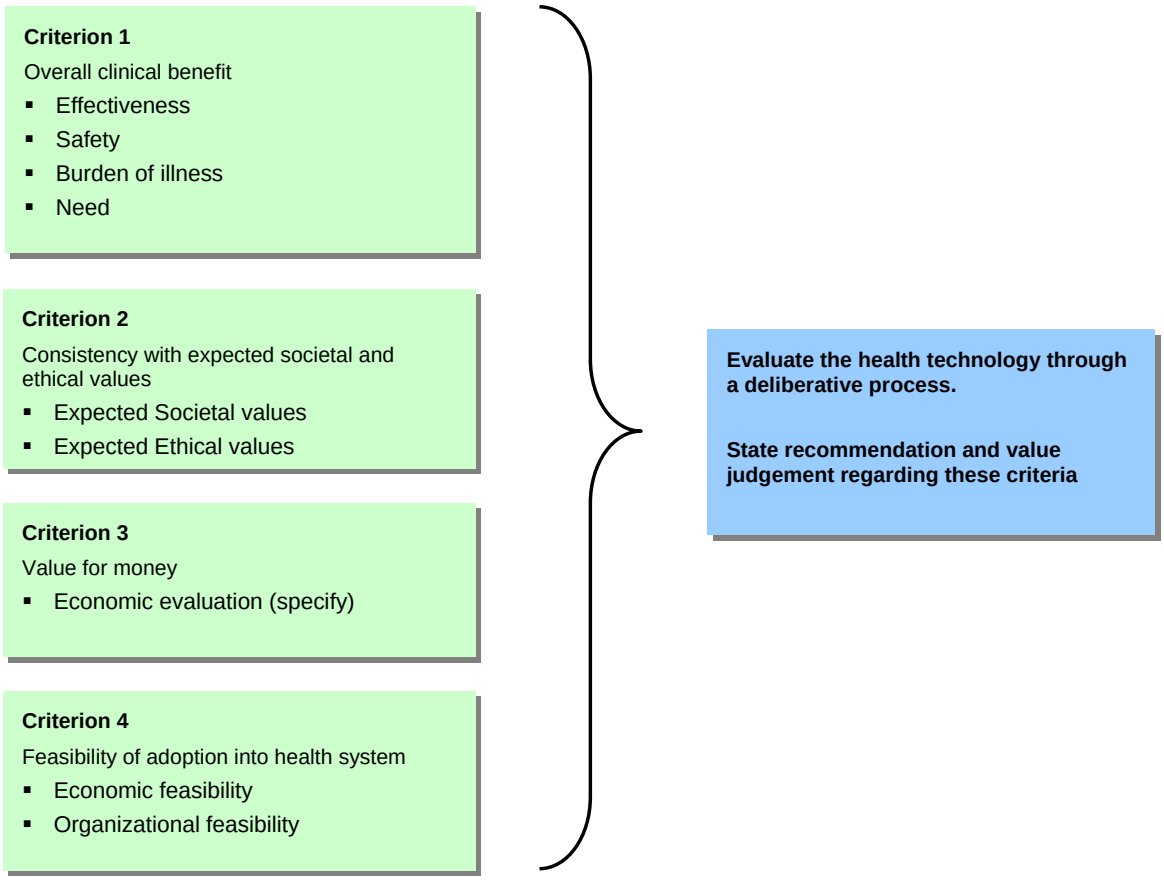

Figure 1: OHTAC decision making model

Overview of OHTAC Decision-Making

Figure 2 provides an overview of the HTA cycle and the four phases where the decision determinants criteria and associated evidence parameters may be applied (shaded boxes). These may be applied at:

- the vignette phase (Phase 1),
- the recommendation development phase (Phase 3),
- the public engagement phase (Phase 5), and
- the appeal process phase (if an OHTAC recommendation should be subject to an appeal) occurring during the post recommendation phase (Phase 6).

Phase 1: The Vignette Phase

During this phase the decision determinants criteria will be reviewed to help identify knowledge gaps and the stakeholder engagements that need to be initiated in order to fully understand the health technology under review. In addition, comments on the relevant outcomes being evaluated to determine overall clinical benefit in part will be solicited from the public at this phase (through the OHTAC website) to assist OHTAC in framing the research question for the health technology reviews.

Phase 3: The Recommendation Development Phase

During this phase, the evidence will be reviewed with respect to the decision determinants criteria in order to formulate a recommendation regarding the health technology under review.

Phase 5: The Public Engagement Phase

Comments on the Draft OHTAC recommendation are solicited from the public and this information is used for further assessment of the technology, particularly if new information, evidence, or values become evident. The public engagement comments will be reviewed with respect to their impact on the evaluation of the four main decision determinants criteria, which can be amended pending any new or significant information obtained. If needed, the OHTAC recommendation will be revised, following which it will be finalized and posted on the OHTAC/MAS website.

Phase 6: Post Recommendation Phase - Appeal Process

During this phase, any new evidence introduced during the appeal process will be evaluated using the decision determinants criteria.

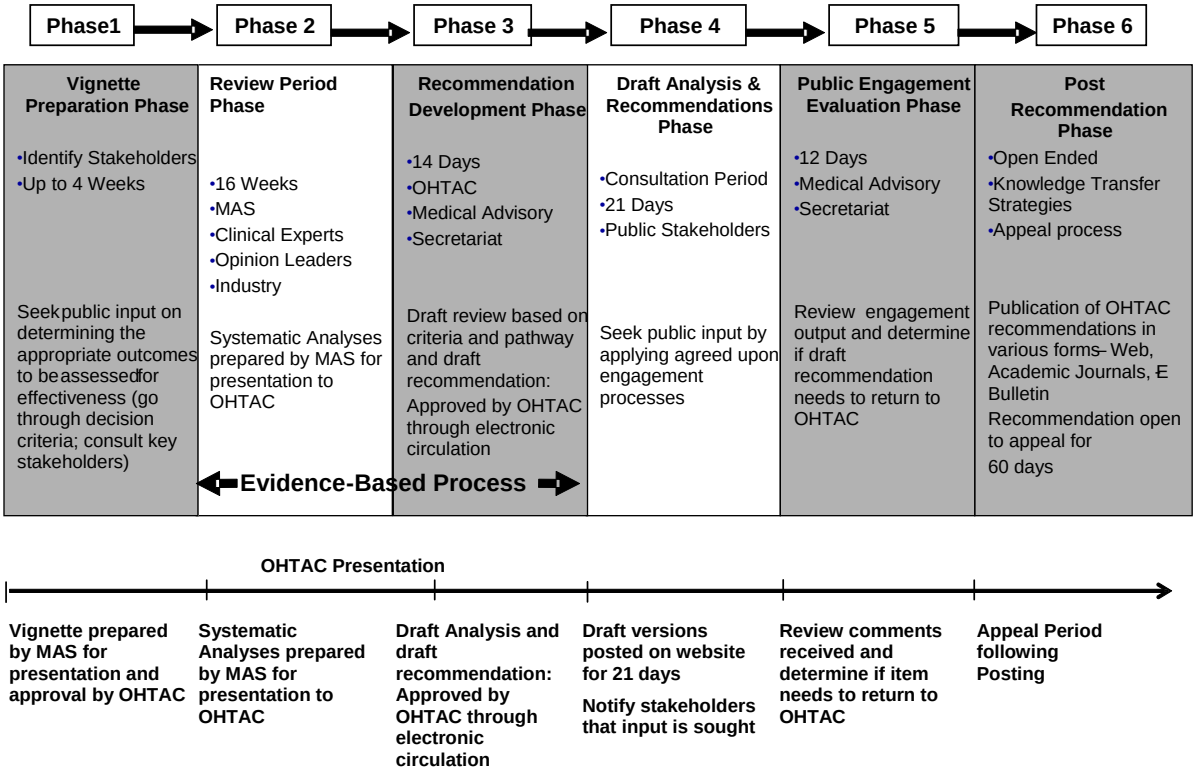

Figure 2: OHTAC decision making phases

Glossary

Health Technology Policy Assessment (HTPA)	A systematic review of the scientific evidence to determine the effectiveness, safety, and cost-effectiveness of a health technology and the quality of the evidence providing this information, as well as context-specific review of the possible social, ethical, and legal implications of using or not using the technology.
Decision-Making	Evaluation/consideration of scientific evidence, social, ethical and legal implications and value judgments concerning the net benefit of a health technology within a context-specific application.
Health Technology	Health technology includes a wide range of procedures, devices and equipment applied to the maintenance, restoration and promotion of health. Technology encompasses interventions at any stage of health care including primary prevention, early detection of disease and risk factors, diagnosis, treatment, rehabilitation and palliative care. (6)
Criterion	A standard by which the merit of a health technology will be judged.
Evidence	Information indicating that a criterion holds true or is substantiated.

References

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