Medtech Canada

White Paper

January 2025

Health Technology Assessment (HTA) for Medical Technologies in Canada:

The Medical Technology Industry Perspective

This white paper has been developed to convey Medtech Canada's recommendations and perspectives to help optimize Health Technology Assessment (HTA) processes in Canada.

Executive Summary: 5 Themes, 13 Recommendations

A. Industry, Patient and Clinician Stakeholder Engagement

1) HTA agencies should collaborate with Industry throughout the HTA process to enable a robust assessment, including seeking Industry feedback on any draft assessment.

2) HTA assessments should incorporate patient and clinician feedback and consider societal perspectives to bridge the gap between research and policy. .

B. Adoption of HTA recommendations

3) Positive HTA recommendations should be published within 6 months of completing the assessment.

4) A positive HTA recommendation should trigger a consultation and review by the Ministry of Health within a defined timeframe to ensure the timely adoption of valuable medical technologies.

5) HTA agencies can support the adoption of medical devices early in their lifecycle by identifying technologies that are suitable candidates for interim coverage with evidence development (CED) programs or other access pathways used by their respective Provincial Ministry of Health.

6) In situations where there is interim coverage contingent on the development of evidence, hospitals, government agencies and clinicians must be given sufficient time to generate the required evidence to satisfy the requirements of any evidence generation program.

C. Evidence Standards & Inclusion of Real-World Evidence (RWE)

7) Given the complexity of assessing the clinical effectiveness of medical devices, HTAs should include high-quality real-world evidence and consider the totality of the evidence to support informed decision making.

D. Support for Local Decision-making

8) Expand pan-Canadian collaboration to conduct and share high-quality clinical evidence reviews of medical device technologies to reduce duplication of effort and build system capacity.

9) Given the regional differences in healthcare, local decision-making is best served by provincial/local HTA agencies rather than the consolidation of medical device HTAs into a single national agency.

10) Budget holders and hospitals should retain the autonomy to adapt aspects of an HTA to their local needs, including implementation considerations, economic evaluation, pricing and reimbursement.

E. HTA Methodology

11) HTA bodies should be transparent, consistent, and accountable in the assessment of medical devices by publishing their policies related to the prioritization of topics, evaluation methodologies and timelines.

12) HTAs of medical devices cannot be rigid. HTAs must adapt to the heterogeneous and iterative nature of medical devices to keep pace with the evolution of technology; and to produce timely guidance for learning health systems.

13) The availability of new and compelling evidence should trigger a reassessment of a technology.

A
Industry, Patient and Clinician Stakeholder Engagement

Recommendation #1:

HTA agencies should collaborate with industry throughout the HTA process to enable a robust assessment, including seeking industry feedback on any draft assessment.

Additional Supporting Information:

- Canadian HTA bodies should follow global best practices and accept (but not require) value dossiers from industry, which can improve the timeliness of assessments and capacity of the agency. UK, Nordics, France, Italy, Germany, China, South Korea, and Australia invite submission dossiers and economic models from industry.
- Early engagement with industry will ensure the HTA agency understands the nuances of the technology, evidence, and utilization in clinical practice before undertaking any clinical evaluation.
- Accommodating manufacturers' request for early scientific advice increases alignment on evidence plans.
- Industry can facilitate introductions to local, national, and global clinical experts to understand the clinical value from the perspective of clinicians that have significant experience using the technology.
- HTA agencies should engage industry throughout the HTA process, including at key milestones such as the review of the draft HTA report, to improve the overall quality of the assessment.

Recommendation #2:

HTA assessments should incorporate patient and clinician feedback and consider societal perspectives to bridge the gap between research and policy.

B
Adoption of HTA recommendations

Recommendation #3:
Positive HTA recommendations should be published within 6 months of completing the assessment.

Additional Supporting Information:
- Unlike drug assessments, the HTA of medical devices are not consistently published on a public site; and some member companies report that it consistently takes more than 6 months for any HTA report to be published.

Recommendation #4:
A positive HTA recommendation should trigger a consultation and review by the Ministry of Health within a defined timeframe to ensure the timely adoption of valuable medical technologies.

Additional Supporting Information:
- Often when an HTA agency issues a favourable recommendation, there is no corresponding pathway or mechanism to facilitate the adoption and implementation of a positive HTA.
- Provincial Ministries of Health should develop a pathway to support the adoption and implementation of medical devices that receive a positive HTA recommendation. This improves certainty in timelines for industry and supports decisions to invest and bring medical device innovation to Canada.
- Positive HTA recommendations should be accompanied by an action plan to implement the recommendations.
- A positive HTA recommendation validates a technology's incremental clinical value and should be communicated to regional and hospital HTA groups.
- Given the cost and resources required to produce HTAs, HTA agencies should track and report on the adoption of medical devices that receive a positive HTA recommendation.

Recommendation #5:
HTA agencies can support the adoption of medical devices early in their lifecycle by identifying technologies that are suitable candidates for interim coverage with evidence development (CED) programs or other access pathways used by their respective Provincial Ministry of Health.

Additional Supporting Information:
- Rather than issue an unfavourable HTA recommendation due to lack of evidence base for medical technologies that are in the early stages of their lifecycle, evidence uncertainty associated with medical devices early in their lifecycle can potentially be managed through innovative models such as Coverage with Evidence Development programs*, pilot programs or other access pathways. HTA agencies should provide guidance regarding the specific evidence gaps that need to be addressed.
- Innovative funding and access models should accept non-randomized control trial data, such as but not limited to Real World Evidence (RWE), field studies, and feasibility studies.

* Coverage with Evidence Development (CED) funding model is a mechanism to provide interim access to a promising medical technology contingent on the development of data to confirm the value of the technology. This CED model has been adopted in Ontario, the USA, UK, Australia, Germany, Netherlands, France, Belgium, Switzerland and Spain. [1] [2]

Recommendation #6:
In situations where there is interim coverage contingent on the development of evidence, hospitals, government agencies and clinicians must be given sufficient time to generate the required evidence to satisfy the requirements of any evidence generation program.

Additional Supporting Information:
- Timelines for generation of evidence must consider the timelines and delays in accessing data from provincial and national data registries.
- Industry does not have direct access to the relevant datasets for CED and the burden of evidence generation may fall to clinicians, hospitals or government agencies.

For example:
- Industry has limited access to Canadian Institute for Health Information and Institute (CIHI) for Clinical Evaluative Sciences (ICES) datasets.
- Industry cannot access British Columbia, Alberta or Quebec datasets.
- Industry cannot access the datasets or algorithms through the Health Data Research Network (HDRN).

C

Evidence Standards & Inclusion of Real-World Evidence (RWE)

Recommendation #7:

Given the complexity of assessing the clinical effectiveness of medical devices, HTAs should include high-quality RWE and consider the totality of the evidence to support informed decision-making.

Additional Supporting Information:

- HTAs continue to prioritize randomized controlled trials (RCTs) over other types of evidence and choose to discount or exclude RWE in an assessment.
- This can lead to the conclusion that there is insufficient evidence, despite the availability of high-quality RWE.
- HTAs should not prioritize randomized controlled trials over high-quality RWE when assessing medical devices. Some HTA bodies consider RWE to be insufficient to inform decision-making and this can lead to RWE being deprioritized or excluded by HTAs.
- If there is limited RCT evidence, the inclusion of RWE in a HTA can extend the evidence base for the medical device. This is especially true in situations where the medical device has been well adopted in other regions and Canada is a late adopter of the medical device.
- Common barriers to performing RCTs on medical device including randomization, blinding, timing of the assessment considering device modifications and impact of the learning curve. The impact of some factors such as training and organizational factors may be better suited to RWE studies than RCTs.
- HTA should communicate standards for RWE studies.
- Increased focus on the lifecycle evaluation of medical technology requires RWE, especially in situations where the technology has been well adopted or later in the technology lifecycle.

D
Support for Local Decision-making

Recommendation #8:

Expand pan-Canadian collaboration to conduct and share high-quality clinical evidence reviews of medical device technologies to reduce duplication of effort and build system capacity.

Additional Supporting Information:

- It is common for the same technology to undergo multiple assessments by HTA agencies at the provincial, regional or hospital level.
- Existing provincial HTA agencies have the infrastructure and expertise but may struggle with resource constraints and capacity.
- Inter-provincial collaboration on the clinical evidence review phase of a HTA can create efficiencies without compromising local decision-making. A provincial HTA agency can use a clinical evidence review completed by a provincial HTA peer and adapt it to their local context, which may potentially reduce duplication, grow capacity, reduce timelines and lead to more consistent coverage and medical management for all Canadians regardless of where they live.
- Leveraging the clinical evidence review of provincial HTA peers promotes collaboration, sharing of expertise, and supports the adoption of a fit-for-purpose approach to HTAs of medical devices.
- Positive HTA recommendations should be shared with other provinces to reduce duplication of effort, improve timelines to access innovative medical device technology, and facilitate the timely initiation of the non-clinical aspects of HTA that are critical to adopting HTA recommendations.

Recommendation #9:

Given the regional differences in healthcare, local decision-making is best served by provincial/local HTA agencies rather than the consolidation of medical device HTAs into a single national agency.

Additional Supporting Information:

- Reviews of the clinical evidence by a single agency can reduce duplication of effort; whereas the other aspects of a HTA are most relevant if conducted locally.
- Any decisions or recommendations regarding a medical device must consider the local context and is best served by provincial/local HTA agencies given the regional differences in health care.
- If there is a shift to HTA for medical devices by a single national agency, this may lead to guidance that does not reflect the local patient pathway. Any HTA intended for national use should identify the factors that need to be addressed locally..

Recommendation #10:

Budget holders and hospitals should retain the autonomy to adapt aspects of an HTA to their local needs, including implementation considerations, economic evaluation, pricing, and reimbursement.

Additional Supporting Information:

- Budget holders, hospitals or local HTA groups must retain the flexibility to consider the clinical assessment in the context of the patient populations and providers they serve.
- Budget holders, hospitals or local HTA groups must maintain the autonomy to adapt any implementation guidance to address the needs of their local health system, patient population, and clinicians/providers.
- Budget holders must retain the flexibility to determine the type of economic analysis based on their local needs and objectives, as well as the stage of decision-making.
- This approach acknowledges the vast geography of Canada and supports hospitals' and health systems' efforts to provide equitable access to care and to deliver care closer to home.

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E
HTA Methodology

Recommendation #11:

HTA bodies should be transparent, consistent, and accountable in the assessment of medical devices by publishing their policies related to the prioritization of topics, evaluation methodologies and timelines.

Additional Supporting Information:

- HTA agencies should continue to prioritize assessments of medical devices considering those that offer the most potential value for patients, clinicians, and the health system.

Recommendation #12:

HTAs of medical devices cannot be rigid. HTAs must adapt to the heterogeneous and iterative nature of medical devices to keep pace with the evolution of technology; and to produce timely guidance for learning health systems.

Additional Supporting Information:

- Evidence standards for drugs cannot be directly applied to medical technologies. For example, outcomes demonstrated in an RCT of two medical technologies may reflect user experience/skills rather than the efficacy of the technology itself.
- Medical devices undergo frequent iterative changes that may lead to improvements in efficacy, efficiency, patient-reported outcomes, and drive health system benefits. HTAs must keep pace with the iterative nature of medical device technologies to provide timely recommendations and avoid issuing a recommendation for a device that is already outdated or may be approaching the end of its lifecycle.
- HTA bodies should select the most appropriate analysis to address disparate medical device technologies such as digital devices, interventional procedures, surgical devices, implantables, diagnostics, consumer devices, software, and large capital equipment, which can have different value propositions based on the care setting and will have differing ability to generate traditional data.

* An Adaptive HTA is a full HTA where scope and timing has been adapted considering the: nature of the technology, the urgency of the unmet medical need, data availability and potential impact on the health system.

Recommendation #13:

The availability of new and compelling evidence should trigger a reassessment of a technology.

Additional Supporting Information:

- HTAs should take a lifecycle approach to the evaluation of medical devices and prioritize recent evidence in the review and any re-evaluations of a medical technology.
- Devices frequently undergo product modifications, which may impact efficacy and efficiency. Evaluations should prioritize evidence associated with the current generation of technology in market.

1 Reckers-Droog V. et al. Challenges with coverage with evidence development schemes for medical devices: A systematic review, Health Policy and Technology, Volume 9, Issue 2, 2020, Pages 146-156, ISSN 2211-8837, https://doi.org/10.1016/j.hlpt.2020.02.006.

2 Federici C. et al. Coverage with evidence development schemes for medical devices in Europe: characteristics and challenges. Eur J Health Econ. 2021 Nov;22(8):1253-1273. doi: 10.1007/s10198-021-01334-9. Epub 2021 Jun 12.

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ABOUT MEDTECH CANADA

Medtech Canada is the national association representing Canada's medical technology companies. Our association advocates for achieving patient access to leading edge, innovative technology solutions that provide valuable outcomes. Our members are committed to providing safe and innovative medical technologies that enhance the quality of patient care, improve patient access to health care, and help enable the sustainability of our health care systems.