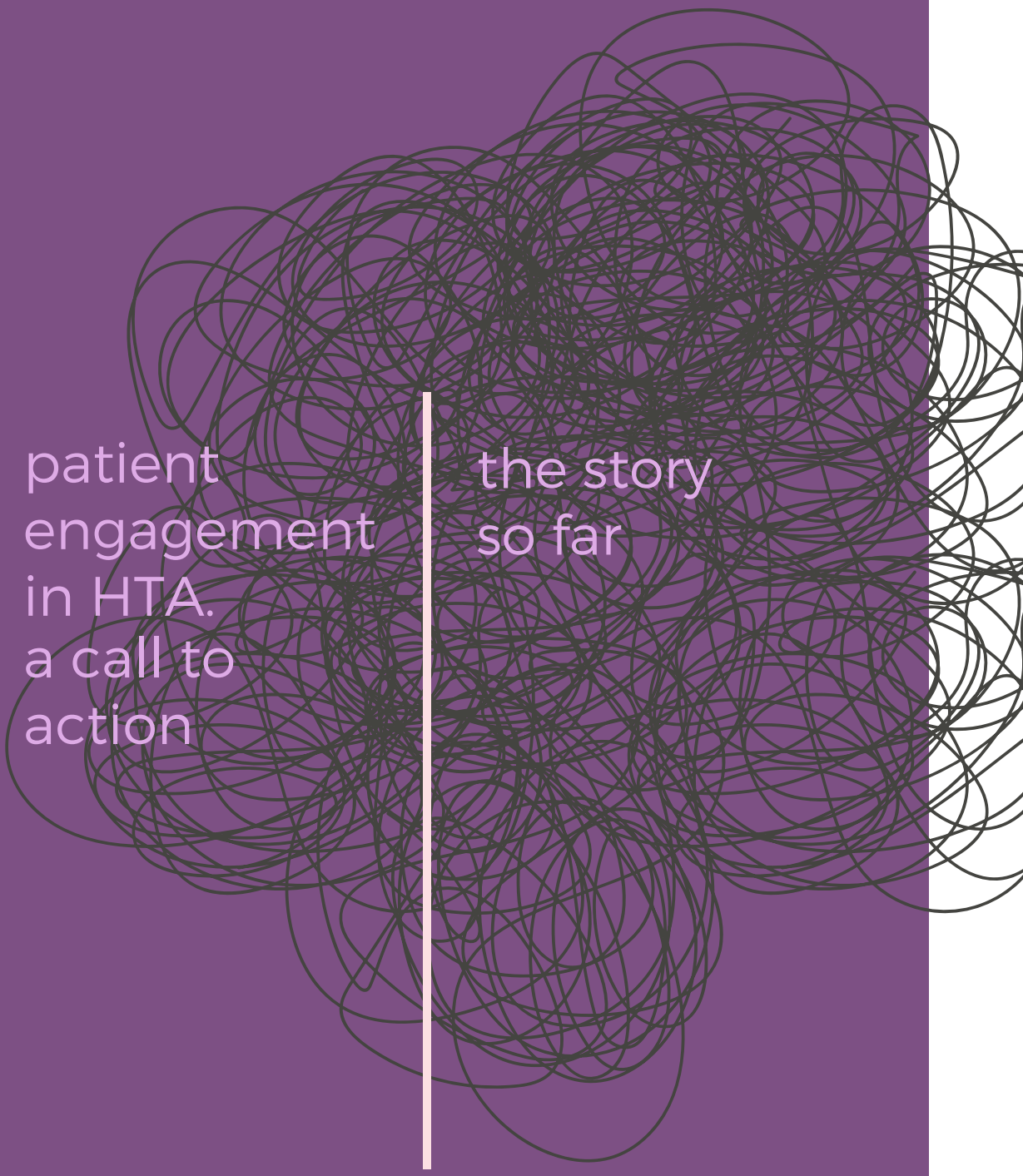
patient engagement in HTA. a call to action

the story so far



03.2025

the cancer collaborative
le collaboratoire cancer

introduction

Health Technology Assessment (HTA) plays a critical role in ensuring that healthcare systems allocate resources efficiently, balancing the need for innovation with financial sustainability. As healthcare costs rise and new therapies emerge, HTA helps determine which treatments provide the greatest value—not just in terms of clinical effectiveness, but also in their broader impact on patients, caregivers, and the healthcare system. Done well, HTA supports evidence based decision making, ensuring that limited resources are used to maximize health outcomes. However, to be truly effective, HTA must evolve alongside the changing landscape of medicine and patient needs.

Despite its intended role as a comprehensive evaluation tool, HTA processes often struggle to fully integrate the patient perspective. While economic models and clinical trial data remain central to decision making, patient engagement is often treated as a procedural requirement rather than a meaningful contribution that shapes outcomes. This gap raises a fundamental question - ***Are patients merely an input in the HTA process, or are they genuine partners in defining value?***

Over six weeks, *the cancer collaborative* hosted three consultation sessions with patient organizations, patient thought leaders and advocates to reimagine and reshape patient engagement in the HTA process in Canada. These sessions focused on

1. co-developing a new patient submission template that captures comprehensive patient experiences, economic impacts and embeds principles of inclusion, diversity, equity and accessibility (IDEA) to provide valuable insight into the HTA deliberative process and

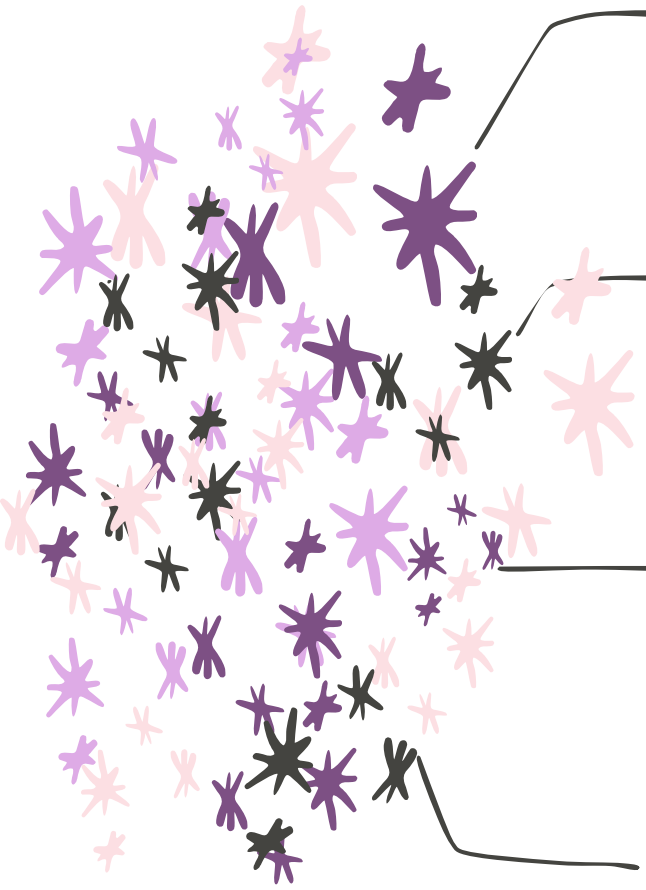
2. providing actionable recommendations to ensure meaningful patient engagement throughout the HTA process, to create a more transparent, efficient, and patient centric framework that improves healthcare outcomes while maintaining the sustainability of the healthcare system.

The discussions surfaced deep seated challenges, including the disconnect between patient inputs into HTA assessments and the realities patients face, the systemic barriers that limit meaningful participation, and the need for a more inclusive approach to how patient data is collected, assessed, and applied. At the core of these conversations was a crucial question—***how should patients be engaged in shaping HTA?*** The way HTA bodies answer this will determine whether the process remains a rigid evaluation tool or evolves into a framework that truly reflects patient priorities.

Meaningful improvement requires collective action. The recommendations in this report reflect the commitment of patient communities to actively contribute to an HTA system that is transparent, responsive, and accountable to those it serves while maintaining the sustainability of healthcare systems.

who was in the room

(included in one or more of the three consultations sessions)



Antonia Palmer. Advocacy for Canadian Childhood Oncology Research Network (Ac2orn)
Yinka Oladele. African Cancer Support Group
Bukun Adegbembo. Canadian Breast Cancer Network (CBCN)
JK Harris. Canadian Breast Cancer Network (CBCN)

Raymond Vles. CLL Canada
Durhane Wong Rieger. Canadian Organization for Rare Disorders (Cord)
Gurjot Basra. Lymphoma Canada
Nancy Zorzi. Mood Disorders Society of Canada
Homira Osman. Muscular Dystrophy Canada

Zal Press. Patient Commando
Biba Tinga. Sickle Cell Awareness Society of Canada
Alvina Nadeem. Person with lived experience
Laurie Proulx. Person with lived experience

sabrina hanna. the cancer collaborative
Facilitated by Farah Meghji. Unum Co.

This report is intended to serve as a summary of key themes and insights shared during consultation sessions with patient groups. While it reflects a range of aligned perspectives, it aims to capture the richness of the dialogue and shared priorities that emerged throughout the discussions.

Transparency is essential in building trust in the HTA process. For the purpose of our consultations, transparency means being open, honest, and clear about the assessment process, including how decisions are made, what evidence is used, and who is involved. It allows all stakeholders—especially patients and patient groups—to understand, trust, and hold the system accountable by ensuring information is accessible, timely, and communicated with integrity.

disrupting the status quo.
a patient powered vision for HTA

At the outset of the consultative process, each participant was asked to share their hopes for what a reimagined HTA process in Canada could look like. Beyond the themes and recommendations outlined in this report, what emerged was a powerful, patient driven mandate for change. Patients and patient community representatives are calling for an evaluation framework that is inclusive, collaborative, and representative—one where patients are a driving force in shaping how new innovations are assessed and adopted.

a reimagined HTA process in Canada

- Transparency in how patient input is valued and integrated into the HTA process, as well as the specific patient experience data deemed essential for decision making
- A cohesive, coordinated and integrated framework that leverages best practice examples
- Improved coordination between regions, resulting in geographical consistency in decision making and timely access to new therapies for all Canadians
- Inclusive of patients and patient experiences end to end and not at a single point in time
- Systemic involvement and representation of patients at all stages and levels of the process
- Rationale on how economic assessments and thresholds are determined
- An iterative framework where patients and patient groups are part of the process not just an input into the process
- Enhanced trust between decision makers and patient communities
- Tailored for unique disease experiences that acknowledges that the value, impact and evidence of needs of health can vary widely between patients and populations.

framing the issues
and actionable recommendations

TRANSPARENCY & FEEDBACK

Challenges

- Patient groups lack clear guidelines on how submissions are reviewed, valued, and used, making it difficult to tailor input effectively
- Without transparency in how patient input is utilized in deliberations, patient groups are left uncertain about how and why certain recommendations are made
- Despite the time and effort invested, patient groups receive little to no feedback, making it difficult to refine future submissions or assess their impact
- Lack of transparency undermines efforts to build trust and co-create more inclusive and relevant evaluations of new technologies

Actionable Solutions

- Establish a formal mechanism for tracking and measuring the impact of patient input
- Develop clear, standardized guidelines on how patient submissions are reviewed and integrated into decision making
- Facilitate engagement opportunities with patient groups at all stages of the HTA review, similar to the engagement CDA-AMC has with industry prior to HTA submissions (scientific advice)
- Conduct an environmental scan of global best practices to enhance engagement, transparency, and improve feedback mechanisms
- Publish timely and accessible documentation outlining how patient evidence is weighed in recommendations

INCLUSION. DIVERSITY. EQUITY. ACCESSIBILITY (IDEA)

Challenges

- HTA often relies on small, unrepresentative patient samples, limiting the diversity of perspectives included in decision making
- The process does not adequately capture cultural, socioeconomic, and geographic differences, making it difficult to reflect the full spectrum of patient experiences. HTA processes

Actionable Solutions

- Engage directly with equity deserving communities that are most impacted by treatment decisions
- Provide patient groups with information on systemic barriers that affect treatment access, particularly for marginalized and underserved populations

need to move beyond a one size fits all approach and recognize that different communities experience disease and treatment access differently
- A lack of competency on how patient engagement is conducted in HTA limits the participation of marginalized and underrepresented communities

- Clearly communicate to patients and patient groups how qualitative data is valued alongside quantitative data, with clear methodology for its integration into HTA decision-making
- Establish an IDEA committee or working group to ensure the inclusion of Indigenous, racialized, and marginalized communities in HTA processes
- Evaluate whether new treatments address disparities in access by analyzing their impact across different demographic groups, with a specific focus on capturing and examining race-based and ethnicity data. This is essential to identify and address inequities in outcomes, ensure treatments work effectively across diverse populations, and support more inclusive, evidence-based decision-making in HTA

MEANINGFUL PATIENT ENGAGEMENT

Challenges

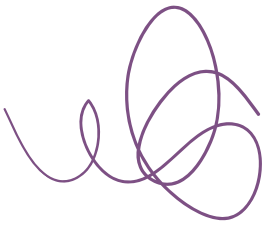
- Patient engagement in HTA is often treated as a procedural requirement rather than a meaningful collaboration
- Belief that patients and patient groups are engaged too late in the process, limiting their ability to influence decision making
- Engagement appears to be primarily restricted to the submission stage rather than integrated throughout the process
- Lack of clear guidance and accessible information makes it difficult for patient groups to participate effectively

Actionable Solutions

- Shift patient engagement from a checkbox exercise to a meaningful collaboration, ensuring patient voices are integrated throughout the HTA process
- Engage patients earlier in the HTA process so their input shapes key decision points
- Develop structured engagement opportunities beyond submission stages, including deliberative discussions
- Improve clarity and accessibility of information by developing patient friendly resources and direct communication channels with HTA agencies

- Lack of clear guidance and accessible information creates repetitive data collection for multiple submissions for patient groups in the hopes of capturing and sharing the best information possible for HTA assessments. This increases the burden on patient groups, as much information remains unchanged
- Patient groups typically engage with HTA intermediaries who are familiar with the process but do not have direct involvement in deliberative decision making. While this helps avoid conflicts of interest, it can limit meaningful dialogue; more transparent communication with individuals who understand the intent of patient input and the deliberative process, to ensure that contributions are appropriately integrated
- No structured communication pathways exist between patient organizations and HTA decision makers
- The complexity of HTA language and processes makes meaningful participation difficult
- No formalized process for pre submission discussions between patients and patient groups and HTA intermediaries or decision makers. Such discussions can be beneficial for patient groups to align input with decision makers' needs
- Poor transparency is a barrier to optimal patient engagement
-

- Create an iterative engagement model where patient groups and HTA bodies continuously refine processes
- Establish structured feedback mechanisms for patient groups, including post-submission debriefs
- Create pathways for patient groups to proactively bring forward solutions and work collaboratively with HTA bodies to address challenges
- Adopt a patient partner model that includes early and continuous engagement, co-development of materials, and capacity-building support (e.g., BioCanRx) to ensure patient involvement in HTA is meaningful, informed, and embedded throughout the process
- Streamline submission processes by reducing redundancy and ensure patient groups know how to integrate previous data so it can be effectively reused
- Develop capacity building to support patient groups in providing high quality submissions
- Provide explicit guidance on how patient input is considered and valued in the HTA process



CHALLENGES WITH THE CURRENT FRAMEWORK

Challenges

- Cost effectiveness analysis that does not embed real world patient experiences into the process risks overlooking the full picture of a treatment's value, particularly for rare diseases and underserved populations. As well, HTA decisions rely heavily on clinical trial data, overlooking long term patient experiences, treatment burden, and quality of life (QoL) considerations
- Limited transparency on incremental cost effectiveness ratios (ICERs), quality adjusted life years (QALYs), and the economic assessment thresholds used in decision-making
- Frameworks lack alignment with patient preferences and do not fully account for the economic impact on patients and caregivers
- HTA evaluates treatments in isolation rather than considering the full disease trajectory, including diagnostic delays, access barriers, and long term outcomes
- Misalignment between CDA, INESSS, and provincial HTA bodies leads to duplicative submissions, contributing to patient group fatigue and inefficiencies
- Limited collaboration between HTA bodies and insufficient lead time for patient input restrict meaningful participation
- HTA recommendations fail to account for delays to access, which can significantly reduce the overall value of therapies and

Actionable Solutions

- Implement patient journey mapping to track the full disease trajectory, quantifying diagnostic and treatment access delays, economic burden, and system inefficiencies to ensure they are reflected in cost effectiveness evaluations
- Develop HTA evaluation guidelines that prioritize patient centered outcomes, ensuring assessments incorporate QoL, real world treatment effectiveness, and long term patient impact
- Expand the use of real world data (RWD), patient reported outcomes (PROs), and insights from patient support programs (PSPs) to improve evidence based decision making
- Standardize and streamline patient submission processes by aligning templates across INESSS and CDA and developing a centralized submission portal for provincial HTA bodies
- Improve coordination between HTA bodies and the pan Canadian Pharmaceutical Alliance (pCPA) to accelerate access and minimize administrative delays
- Establish transparent, two way communication channels between HTA and patient groups to enhance collaboration and ensure meaningful participation
- Prioritize early diagnosis and treatment approvals for conditions with narrow treatment windows to prevent delays in accessing critical interventions to ensure that the value of a therapy can be fully realized.

and disproportionately impact rare disease patients with limited treatment windows - undermining the very value HTA seeks to assess. HTA must ensure the benefits of innovative therapies are not lost before they can reach the patients who need them most
- System inefficiencies in regulatory and reimbursement processes create unnecessary access barriers, increasing financial strain on patients and caregivers

When evaluations are not aligned with the urgency of clinical need, delays in access can render treatments ineffective or irrelevant, particularly for patients with rapidly progressing or rare conditions
- Develop reimbursement models that factor in the cost effectiveness of early intervention, reducing long term financial and health burdens on patients and caregivers
- Create a system wide approach to tracking and resolving delays, using patient experience data (PEx) to identify bottlenecks and inefficiencies

DATA (REAL WORLD, PATIENT EXPERIENCE AND POST MARKET)

Challenges

- Misalignment on the collection and incorporation of real world evidence (RWE)
- Pharmaceutical companies lack the incentive to collect RWE, PROs and patient experience data (PEx) into HTA submissions
- Disconnect between the types of data patient groups collect (real world, anecdotal, and qualitative evidence)—and the structured evidence typically emphasized in HTA decision making. This gap highlights ongoing challenges in how diverse forms of patient generated insights are understood, valued, and integrated within existing evidence frameworks.
- Lack of integration of patient data in the pCPA negotiation process
- Unclear guidance on integrating real world evidence (RWE) into HTA evaluations

Actionable Solutions

- Create incentives for pharmaceutical companies to collect RWE, PROs and PEx
- Create incentives for pharmaceutical companies to bring drugs and medical interventions to the Canadian marketplace
- Increase transparency on how RWE is evaluated and used in decision making
- Work with pCPA to integrate patient data into pCPA negotiations, ensuring negotiations reflect challenges and impact
- Use PROs and RWE to quantify the impact of access barriers, ensuring that delays are factored into cost effectiveness and value assessments

illustrating the point

Early diagnosis and intervention are essential not only for improving patient outcomes but also for reducing the long term burden on healthcare systems. Timely access to drugs can reduce the need for healthcare utilization (emergency room visits, etc), it also can potentially limit disease progression, reducing the need for subsequent interventions.

Example. Spinal Muscular Atrophy (SMA), is a severe neuromuscular disorder caused by a missing or defective SMN1 gene. Early diagnosis through newborn screening is critical, as administering treatment within the first weeks of life can significantly improve motor function, prevent irreversible damage, and dramatically alter the disease trajectory.

From an economic perspective, failing to diagnose and treat SMA early leads to significantly higher long term costs due to the need for intensive medical care, respiratory support, and lifelong disability management.(1) Beyond financial implications, delayed diagnosis results in avoidable suffering and diminished QoL. This underscores the broader principle that early access to innovative therapies should be a cornerstone of value based healthcare—where value is defined not only by clinical outcomes, but also by quality of life, long term cost savings, and the lived experiences of patients and families.

The psychosocial and economic burden on parents must also be noted. The need for around the clock care often forces one or both parents to reduce work hours or leave their jobs entirely, leading to significant loss of income, job insecurity, and financial strain. Additionally, out of pocket expenses for medical equipment, home modifications, and travel for specialized care further compound the financial burden. Social isolation, mental health challenges, and caregiver burnout are common as families struggle to balance their child's intensive medical needs with daily life. (2.3)

The natural history of the disease is is lacking from the HTA assessment, focusing instead on the disease at one point in time and a certain outcome.(4) HTA needs to look at the healthcare resource utilization and what are the expected resources that the individual(s) is using with life limiting conditions or disease in the long term. A clear understanding of how an intervention can help to mitigate these challenges is essential.

Example. Some of the interventions in rare or chronic diseases can be high, but the cost of being hospitalized in ICU for three weeks is also costly and these trade offs for the healthcare system need to be considered.(5.6)

Societal vs Individual impact.Does a certain intervention allow you to be a better parent? The economic impact of the disease extends beyond the measurable costs like hospital costs and absenteeism - it also includes harder to quantify factors, such as a person's ability to be a functioning parent, support their children with school work, or maintain employment. Certain direct costs can be tracked, but there is no standardized societal framework to capture the broader implications of lost function and well being. This makes it difficult to fully assess the true economic and social burden of illness.

Lack of available data. Many conditions do not have an assigned diagnostic code, preventing proper tracking of healthcare utilization, such as emergency room visits or hospitalizations. As a result, patient advocates must rely on anecdotal evidence and cost-of-illness studies to highlight hidden costs, including out of pocket expenses, home and vehicle modifications, and lost productivity. However, these costs are often absent from patient registries and public health administrative datasets, making it challenging to present a compelling case for policy and reimbursement decisions without dedicated, rigorous research. Who is responsible for this work?

Social determinants of health (SDoH), quality of life (QoL) and surrogate endpoints

HTA relies on measurable clinical outcomes to evaluate treatments, yet this approach falls short in areas where traditional biomarkers are lacking.

Example. Mental health lacks established biomarkers to objectively diagnose conditions or predict treatment response. Mental health assessment relies on clinical observations, patient reported symptoms and qualitative measures, making diagnosis and treatment inherently complex. This absence creates a significant challenge for traditional HTA because it does not offer the same level of quantifiable certainty as endpoints such as progression free survival (PFS) or overall survival (OS) in other conditions.(7)

This underscores the critical role of social determinants of health (SDoH) - factors such as socioeconomic status, education, housing, and accessibility to care based on location - significantly influence outcomes for people living with mental health conditions. Without biomarkers, SDoH provides essential context for understanding disease burden, treatment effectiveness, and patient needs. It also highlights that health outcomes can not be assessed through a one size fits all lens. Tailored approaches that consider the impact of social and structural factors on symptom progression, treatment effectiveness, and how success is defined are essential to truly capture the value of a drug or intervention.

As a result of the lack of quantifiable endpoints, the impact of treatments in mental health is often undervalued in decision making. Yet for individuals with mental illness, improvements in quality of life (QoL) - such as being able to get out of bed, take a shower, or engage in social interactions - represent meaningful progress. For individuals with mental illness, improvements in daily functioning and emotional well being often represent the most meaningful outcomes of care. Without appropriate measures to capture these improvements, the full benefit of mental health interventions may go unrecognized.

The use of surrogate endpoints provides essential insights into real world patient insights, but remains underutilized in HTA assessments. HTA must better integrate surrogate endpoints into decision making which requires expanding the criteria for effectiveness beyond conventional clinical outcomes measures. Without this shift, critical therapies may be overlooked, not because they lack effectiveness, but because current HTA frameworks rely on traditional endpoints that fail to capture their full impact of a therapy on patients' lives, particularly in areas where measurable, long term outcomes are delayed, difficult to quantify, or not feasible within the typical assessment timelines. This risks undervaluing therapies that meaningfully improve patient quality of life, slow disease progression, or provide earlier clinical benefits.

Diagnostic testing

From both an economic and clinical perspective, decision makers seek greater certainty regarding the effectiveness of treatment options. Diagnostic testing provides this certainty by identifying patients most likely to benefit, ensuring that funding is allocated efficiently. However, without a robust diagnostic infrastructure, healthcare systems risk higher costs by administering treatments indiscriminately, potentially providing ineffective therapies to patients who may not benefit. Standardized and accessible testing is essential to optimizing treatment allocation, improving patient outcomes, and reducing unnecessary healthcare expenditures.(8)

Conversely, the absence of accessible diagnostic testing means that some patients will go untested, preventing them from receiving the most appropriate therapies. As a result, they may be subjected to suboptimal treatment, leading to increased healthcare resource utilization, higher long-term costs, and a greater burden of disease. This not only diminishes quality of life but also exacerbates avoidable suffering, highlighting the critical need for equitable access to diagnostic testing.

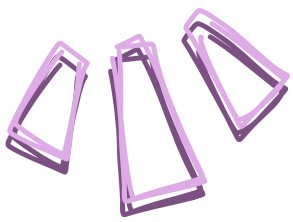
Example. Myotonic dystrophy, a neuromuscular disease, currently has four ongoing clinical trials, with the potential of receiving regulatory approval if they continue to show effectiveness. Access to these disease altering interventions will require a molecular diagnosis through genetic testing. The challenge - most patients will only receive a clinical diagnosis based on symptoms and family history, as the country lacks sufficient lab infrastructure and funding for genetic testing. Without changes to testing accessibility, patients could face a critical barrier - having disease modifying treatment without the ability to access them.

Example. In cancer, diagnostic testing will play an increasing role in treatment decision making and treatment response yet access to testing is not uniform across the country. Molecular profiling also has the potential to go beyond treatment decision making, to provide prognostic, predictive and disease monitoring value. However diagnostic testing must be accessible, standardized and reliably integrated into healthcare systems across the country. Understanding the impact of companion diagnostics and barriers to access will be critical. The approval of a treatment is meaningless if the necessary diagnostic test is not available, as patients cannot access the therapy regardless of reimbursement status.

Value of a Drug. Beyond Cost

HTA must adopt a holistic approach to value assessment, recognizing that the true value of a drug extends beyond its price and clinical efficacy, encompassing quality of life improvements, healthcare system efficiencies, caregiver burden reduction, and long term societal benefits. Treatments that enable patients to maintain employment, reduce hospitalizations, and enhance overall well being create economic and social value that must be integrated into decision making. Additionally, patient preferences, access barriers, and real world treatment challenges should be systematically captured to ensure that HTA recommendations reflect the realities of those directly impacted. A more comprehensive value assessment framework will lead to better informed healthcare decisions, improved patient outcomes, and a more equitable system that prioritizes meaningful innovation.

The meaningful involvement of people with lived experience in the planning, design, delivery, and evaluation of health systems delivers the greatest value when their experiential knowledge is genuinely respected, prioritized, and integrated as a core component of the process.(9)



summary of *recommendations*

1. Update the patient submission template to incorporate the recommendations outlined in the report with guidance on what questions HTA is trying to answer with these patient input submissions
2. Develop a single, unified patient submission template across national HTA agencies and provincial offices, in French and English
3. Establish a formalized iterative framework for patient engagement - collectively working with patients and patient groups to define what this framework looks like
4. Strengthen communications and build trust with patients and patient groups
5. Work with patient groups to develop educational materials and capacity building resources
6. Work with patient groups across disease areas to implement the recommendations throughout the report
7. Appropriately support patients and patient groups for the expertise and skills they bring to improving the process
8. Incentivize pharmaceutical companies to bring drugs and technologies to the Canadian market, working with partners to develop this so that these incentives are market/condition appropriate
9. Work with the pCPA to integrate patient data into the negotiation process

CDA-AMC versus INESSS
strengths and areas for improvement

Aspect	CDA Strengths	INESSS Strengths	Areas for Improvement
Stakeholder Engagement	Hosts a conference to engage and communicate with partners (provides limited travel scholarships for patient groups)	Organizes clinician and patient focus groups for deeper discussions	INESSS has limited engagement with non Québec stakeholders. Public outreach could be broader Partners would like to see INESSS host a conference
Transparency	Communicates changes in HTA processes and engages in public consultations	Increasing openness to patient engagement	Both lack clear guidance on how patient input is used in final decisions Rationale for ICERs/QALYs thresholds
Flexibility in Evidence Consideration	Collaboration with international networks	More open to incorporating RWE	CDA is more rigid in evaluating RWE
Accessibility	Easier to access information on website, email communications	Recognizes unique provincial healthcare challenges	INESSS website is not user friendly- information difficult to find
Alignment with Patient Needs	Currently undergoing modernization efforts	More tailored assessments for Québec's system	Both agencies lack a formalized approach to integrating patient perspectives throughout the process

key considerations
for patient input in the HTA deliberative process

A well structured patient submission should provide decision makers with a comprehensive, real world perspective on the impact of a condition and the value of a new treatment. The following key areas were identified as essential to strengthening patient input in HTA deliberations

1. Inclusion, Diversity, Equity and Accessibility (IDEA)
2. Access Barriers. Landscape and Implementation considerations
3. Social Determinants of Health (SDoH) including Economic Considerations & Financial Burden
4. Improved Outcomes. Benefit vs Risk considerations. Trade offs. Quality of Life (QoL) - and what matters most to patients
5. Role of Diagnostics
6. Other Considerations (ethical, policy, real world application & feasibility, patient preferences & values, treatment decision dynamics)
7. Allow for additional submission formats (patient interviews, testimonials, social listening, etc)

The patient experience must be evaluated holistically rather than in isolation. When considered as separate, disconnected elements, its full impact and relevance may be overlooked. However, when examined comprehensively, it provides a clearer, more meaningful picture of the challenges, needs, and outcomes that shape healthcare decisions.

* see below for the template designed with input from these discussions

in conclusion.
redefining HTA

We can no longer afford to rely on rigid frameworks that fail to capture the full spectrum of value in healthcare decision making. Instead, we must work together—patients, HTA bodies, policymakers, industry, and healthcare providers—to build a system that balances constrained resources with meaningful patient centric assessments.

Patients and patient groups have demonstrated a strong willingness to collaborate with HTA bodies in refining and implementing the recommendations outlined in this report. A fundamental question remains - ***are patients merely an input into the HTA process, or are we an integral part of it?*** If patients are only an input, then HTA must be transparent about that reality. If patients are truly part of the process, then meaningful engagement must go beyond consultations and fragmented input that disappears into the system. True engagement requires an iterative, transparent, and structured dialogue—one that evolves in tandem with scientific advancements, economic constraints, and emerging healthcare challenges.

Breaking down silos is no longer optional. Addressing systemic barriers to access, equity, and value, requires cross sector collaboration. HTA frameworks must move beyond clinical trial endpoints and economic models that fail to account for the lived experiences of patients. Much like the integration of real world evidence (RWE) alongside traditional trial data, we must learn to incorporate patient experiences, social determinants of health, and other complementary qualitative insights into value assessments. Without these perspectives, we risk reinforcing a system that prioritizes cost effectiveness over patient well being, limiting access to therapies that could significantly improve quality of life.

The patient community is ready to engage—not as passive contributors, but as active partners committed to shaping an HTA process that reflects the realities of those it is meant to serve. Without this shift, HTA will continue to miss critical insights, reinforcing a system that assesses cost effectiveness without fully accounting for impact on those it is meant to serve.

patient input submission template

The specifics described in each category are meant to be illustrative of the significant potential value patient submissions could bring to the deliberative process (beyond anecdotes and testimonials,) but not an exact example of what the template should look like. The integration of patient perspectives across the drug review and reimbursement system can be strengthened by aligning the patient input template with the requirements of PMPRB, pCPA, and provincial HTA bodies.

1. Submission overview

Patient organization name
Contact person
Date of submission
Health technology under assessment
Condition/disease area

2. Impact of the condition on patients, current standard of care & unmet needs - summarize patient experiences, how the condition affects their daily lives, feedback on existing treatments and gaps in care

- Description of the disease burden (Based on patient insights, describe how the disease impacts physical, mental, social, and economic well being)
- Current challenges in managing the condition (List barriers to treatment access, gaps in care, and quality of life challenges faced by patients)
- Impact on caregivers and families (Describe caregiver burden and family impact, if applicable)
- Challenges with current treatments (Side effects, accessibility, financial burden, lack of effectiveness)
- Unmet needs identified by patients (What do patients feel is missing in current treatment options)

* while this is an important consideration, HTA should be in a position to summarize the current landscape given their holistic view

3. Current patient perspectives on the new health technology - summarize patient expectations, hopes, and concerns about the new health technology under review

- Expected benefits (What improvements do patients hope to see in symptoms, QoL, accessibility, etc?)
- Concerns & risks identified by patients (Any worries about side effects, safety, affordability, or access?)
- Preferences (Do patients see this as a better alternative? Why or why not?)

4. Access & equity considerations - summarize insights on barriers to access, equity challenges and social determinants of health, including economic & financial burden

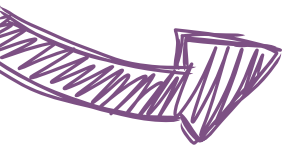
- Barriers to access (eg. geographic limitations, financial burden, cultural/language barriers, are there delays in diagnostic testing, specialist referrals or administrative requirements that create barriers)
- Equity considerations (Does this technology address or widen existing disparities ? Are certain populations disproportionately affected? Are certain racial/ethnic groups disproportionately affected by the disease or treatment access barriers, are indigenous populations facing additional challenges due to systemic healthcare inequities? Are there sex differences in how people experience the disease? Age related considerations? Are lower income patients less likely to access this treatment due to cost, transportation or work related challenges? How does socioeconomic status impact treatment decision making?)
- Role of diagnostics in access (Are additional tests required for eligibility? How does this impact access to the treatment? Are tests available and reimbursed in each province/territory, do delays in testing impact treatment eligibility and outcomes, are there disparities in access to diagnostic testing)
- Social determinants of health (SDoH) - recognizing that health outcomes are shaped by factors beyond medical care, how do SDoH influence patient access and outcomes for this condition/with this intervention under review
- Income and employment - does financial strain affect patients ability to 'afford' treatment, take time off work, or travel for care
- Housing & living conditions - do unstable housing situations impact treatment adherence? Are there barriers to at home care?
- Food security & nutrition - Does diet and access to nutritious food influence treatment effectiveness or ability to manage side effects?
- Social support & caregiving - Do patients have the necessary caregiver or community support to navigate treatment?
- Healthcare system trust & discrimination - Are certain patient groups hesitant to seek care due to past negative experiences or culturally ingrained mistrust with the healthcare system
- Transportation & mobility
- Out of pocket costs for current treatment (eg. medication supplies, travel/accommodations, parking, etc?)
- Impact on employment & productivity (How does the condition/treatment affect the patient's ability to work?)
- Potential financial impact of the new technology (Could this treatment reduce or increase the financial burden?)

5. What matters most to patients with the condition - capture key insights on the priorities and values that patients consider most important in treatment decisions, including benefit vs Risk & trade offs - summarize the benefits and risks and trade offs patients with the condition are or are not willing to accept

- Perceived benefits (eg. improved survival, better symptom management, increased QoL, reduced treatment need, reduce healthcare resource utilization, shorter treatment time, etc)
- Potential risks & concerns (side effects, long term effects/safety, accessibility challenges, financial implications)
- Patient willingness to accept risks - are patients willing to accept higher risks for better outcomes, are there specific risks they find unacceptable?
- Trade offs patients consider acceptable (Would patients accept a higher financial cost, more side effects, or a more invasive procedure for a greater benefit? eg. are patients willing to accept shorter survival for improved QoL, etc)
- Top priorities for patients (What aspects of treatment are most important—survival, quality of life, ability to work, ease of use?)
- QoL considerations (How do side effects, treatment schedules, and recovery time affect daily living and long-term well being?)
- Psychosocial & emotional needs (Are mental health, social support, and emotional well being important considerations in treatment choices?)
- Decision making factors (What influences patient treatment choices—efficacy, safety, accessibility, physician recommendations, personal experience?)

6. Broader health system impact - summarize patient input on how this technology could impact healthcare system

- Healthcare utilization (Will this/has this reduce(d) hospital visits, emergency care, or other healthcare related costs)
- Long term outcomes (Does this technology have the potential to improve survival rates, reduce disease progression or enhance patient well being over time?)



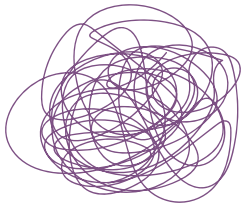
7. Summary of patient perspectives & Key takeaways - provide a high level summary from patient input

- Main takeaways from patient input (summary of key points)
- Policy & HTA considerations (What should decision makers prioritize when evaluating this intervention?)
- Final recommendations from patient groups (What actions or considerations should be taken based on patient insights?)

8. Supporting Data & Patient Testimonials

- Alternative methods used for data collection (survey, focus groups, interviews, social listening, etc)
- Patient quotes, videos, story telling, patient presentations or case studies - provide (anonymized) quotes or real world patient experiences to illustrate key points
- Input into literature reviews on patient experiences

Implementation Guidance (to be co-developed with HTA bodies and patient organizations)



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