Meeting Report

Seventh Canadian Cancer Treatment Hackathon

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Executive Summary

The Seventh Canadian Cancer Treatment Hackathon convened key stakeholders, including healthcare professionals, policymakers, patient advocates, and industry experts, to address the challenges in integrating patient experience data (PED) into Health Technology Assessments (HTAs). The Hackathon aimed to refine the tools and processes used to collect and utilize PED, to ensure that patient voices are meaningfully incorporated into drug evaluation and reimbursement decisions. By examining global best practices and identifying inefficiencies, participants worked toward solutions that enhance PED collection, improve submission processes, and align HTA frameworks with patient-centered priorities.

Preparation and Collaboration

Building on insights from previous Hackathons, the Seventh Hackathon focused on improving PED collection methods, optimizing submission templates, and aligning patient engagement with global best practices. Participants examined international models such as the U.S. FDA's patient engagement framework, NICE's structured patient input processes, and European approaches to integrating real-world data into HTAs. Through discussions and breakout sessions, stakeholders explored ways to enhance the relevance, efficiency, and impact of patient contributions to the HTA process.

Key Challenges and Context

Canada's complex drug evaluation and reimbursement framework results in significant delays in accessing new treatments, with an average of 732 days before new medicines become publicly available—one of the longest waiting periods among OECD countries. HTAs play a crucial role in determining drug reimbursement by assessing clinical efficacy, economic impact, and patient-centered outcomes.

However, several challenges exist within current PED collection and submission processes:

- **Lack of Transparency**: Patient groups receive minimal feedback on how their submissions influence HTA decisions, limiting their ability to refine future input.
- **Rigid Submission Processes**: Existing templates restrict the types of PED that can be submitted, making it difficult to capture the full spectrum of patient experiences.
- **Challenges in Patient Recruitment**: Finding patients with experience using a drug under review remains difficult, particularly for novel therapies and rare diseases.

- **Equity and Representation Gaps**: PED collection methods often fail to capture diverse patient populations, including those with limited digital access or those from underrepresented communities.
- **Limited Integration of Real-World Evidence (RWE)**: Although RWE could enhance PED submissions, HTA bodies provide little guidance on how to effectively incorporate it.
- **Short Submission Deadlines and Resource Constraints:** The 35-day submission deadline poses a significant challenge for patient groups, which often have limited resources to gather comprehensive PED.

Breakout Sessions

The Hackathon discussions explored three key thematic areas, each addressing critical aspects of PED collection and integration in HTA decision-making:

- **Improving PED Collection and Submission Processes** – Identified challenges in gathering meaningful patient data, proposed enhancements to submission templates, and explored clinician-patient collaboration to streamline input.
- **Enhancing PED Utilization in HTA Deliberations** – Examined how PED is currently weighted in decision-making, discussed the feasibility of assigning greater value to patient perspectives, and considered alternative frameworks for integrating PED into economic and clinical evaluations.
- **Global Best Practices and Innovations** – Reviewed international approaches to patient engagement, assessed the applicability of global models to Canada's HTA landscape, and identified potential reforms to improve PED collection and application.

Emerging Themes

Several key themes emerged from the discussions, shaping the Hackathon's recommendations:

- **The Need for Standardized PED Collection Practices:** Patient groups struggle with inconsistent guidance on what constitutes meaningful PED. HTA bodies need to provide clearer frameworks for data collection and submission.
- **Enhancing Transparency in HTA Deliberations:** Participants emphasized the importance of structured feedback mechanisms to clarify how PED is weighted in decision-making.
- **Expanding Data Collection Methods:** Traditional surveys and interviews remain valuable, but alternative methods such as video testimonials, caregiver interviews, and RWE can provide a more comprehensive understanding of treatment impact.

- **Ensuring Equity in PED Representation**: Underrepresentation of diverse patient populations remains a concern. More proactive engagement strategies, such as community partnerships and multilingual outreach, are needed.
- **Global Best Practices for PED Integration:** International HTA models, such as NICE's structured patient involvement and the U.S. FDA's early patient engagement framework, offer potential strategies for improving PED collection and application in Canada.

Actionable Insights and Recommendations

Hackathon participants proposed a series of actionable solutions to improve PED collection, submission, and utilization in HTA decision-making:

1. **Refine the Patient Input Template**
    - Increase flexibility in submission formats to allow for a broader range of patient experiences, including video testimonials and narrative-based data.
    - Provide real-world examples of strong patient submissions to guide patient groups.
2. **Enhance Transparency in PED Utilization**
    - HTA bodies should implement structured feedback mechanisms to communicate how PED influences decision-making.
    - Introduce a formal process for patient groups to request clarification on HTA decisions.
3. **Expand Data Collection Methods to Capture a Broader Range of Experiences**
    - Encourage the use of RWE to supplement PED submissions, particularly for rare diseases and precision medicines.
    - Support clinician-patient collaboration in data collection to improve the quality and relevance of PED.
4. **Strengthen Equity in PED Representation**
    - Establish partnerships with community organizations to engage underrepresented patient populations.
    - Develop multilingual and accessible survey tools to ensure diverse perspectives are captured.
5. **Ensure PED is Meaningfully Integrated into HTA Deliberations**
    - Consider formalizing Multi-Criteria Decision Analysis (MCDA) as a tool to systematically evaluate PED alongside clinical and economic factors.
    - Introduce structured engagement models, such as NICE's patient involvement framework, to increase patient representation in HTA decision-making.
6. **Address Submission Deadlines and Improve Flexibility**

- Provide earlier notices for PED submissions to ease the burden on patient groups, addressing the challenges associated with the 35-day submission period.
- Implement an iterative process to allow for deeper insights and continual refinement of submissions based on feedback, similar to models used by NICE, which inform patient groups earlier in the submission process and allow more time for gathering robust data.

Conclusion

The Seventh Canadian Cancer Treatment Hackathon underscored the critical role of PED in shaping patient-centered healthcare policies and ensuring equitable access to innovative cancer treatments. While progress has been made in integrating patient perspectives into HTA processes, significant gaps remain in transparency, data collection methods, and equitable representation.

By refining PED submission frameworks, enhancing transparency in HTA deliberations, expanding data collection methods, and leveraging international best practices, Canada has an opportunity to strengthen its HTA processes and improve patient access to life-saving therapies. Implementing the recommendations from Hackathon 7 will not only ensure a more patient-centered approach but also create a more efficient and equitable healthcare system that truly reflects the needs and experiences of Canadian cancer patients.

1.0 Introduction

1.1 Background

Access to new cancer therapies in Canada remains a significant challenge due to the complex and lengthy processes involved in drug evaluation, price negotiation, and provincial reimbursement. Patients often face delays in accessing innovative treatments due to the multi-tiered system, which includes regulatory approvals from Health Canada, health technology assessments (HTA) conducted by Canada's Drug Agency (CDA) and the Institut national d'excellence en santé et en services sociaux (INESSS), followed by price negotiations led by the pan-Canadian Pharmaceutical Alliance (pCPA). These delays impact patient outcomes, particularly as Canada continues to lag behind other developed nations in making new medicines available.

Patient Experience Data (PED) plays a crucial role in HTA processes, providing insights into the lived experiences of patients, caregivers, and clinicians that clinical trial data alone cannot capture. PED helps ensure that HTAs account for treatment burden, quality of life, and accessibility challenges. However, despite the importance of PED, current HTA processes lack transparency regarding how this data is evaluated and weighted in the decision-making process. The Seventh Canadian Cancer Treatment Hackathon aimed to address these gaps by exploring ways to enhance the collection, submission, and use of PED in HTA deliberations.

Building on the findings of previous hackathons, Hackathon 7 focused on three key themes:

1. **The Use of PED in HTA Deliberative Processes** – Examining how PED is currently integrated into HTA decisions and identifying opportunities to increase its influence.
2. **Alternative Methods for Collecting PED** – Exploring innovative approaches for collecting meaningful and diverse patient input, beyond traditional surveys and interviews.
3. **Learning from Global Best Practices** – Evaluating international HTA models to identify effective strategies that could be adapted for Canada.

The hackathon brought together patient group representatives, clinicians, industry leaders, and HTA stakeholders to discuss challenges in PED collection and integration. The event included a pre-recorded panel discussion featuring patient advocates sharing their experiences with PED submissions, followed by three breakout sessions focused on the key themes. Participants

identified barriers to PED collection, proposed improvements to patient input tools, and discussed strategies to ensure PED is valued in HTA decision-making.

Through collaboration and knowledge-sharing, Hackathon 7 aimed to develop actionable recommendations that will enhance the role of PED in HTA processes, ultimately improving access to life-saving cancer treatments for Canadian patients.

1.2 Pre-recorded Panel

Collecting PED for HTA Submissions

Introduction

The panel discussion, held as part of the Seventh Canadian Cancer Treatment Hackathon, focused on understanding how PED is collected for HTA submissions from the perspective of patient group representatives in Canada. The panel featured three experienced patient advocates:

- **J.K. Harris**, Health Policy & Advocacy Lead, Canadian Breast Cancer Network
- **Iris Karry**, Patient Education & Research Manager, Colorectal Cancer Canada
- **Jessy Ranger**, Director, Patient Programs, Health Policy & Advocacy, Myeloma Canada

Moderated by Patil Mksyartinian, Senior Program Manager at Colorectal Cancer Canada, the panel explored patient group involvement in PED collection, challenges faced, and strategies for improvement. The discussion provided valuable insights into the role of PED in HTA deliberations and highlighted opportunities to refine patient input tools to ensure HTAs better capture diverse patient needs.

Involvement in the Patient Submission Process

Panelists described their experiences in preparing patient input submissions for HTA evaluations. Jessy Ranger highlighted that Myeloma Canada has been involved in HTA submissions from the beginning, noting that for patients with relapsed or refractory myeloma, new treatments are essential for survival. PED allows patient groups to advocate for the importance of new therapies, share patient and caregiver expectations, and highlight real-world treatment experiences. J.K. Harris explained that Canadian Breast Cancer Network engages in multiple HTA submission processes, including patient input submissions, provisional funding algorithm feedback, and relevant consultations. This involvement allows Canadian Breast Cancer Network to ensure that

the patient voice is included in decision-making processes. Iris Karry emphasized that Colorectal Cancer Canada has been active in PED submissions, especially as new treatments emerge. She explained that PED provides critical insights into access challenges, treatment affordability, and quality of life impacts, helping to bridge the gap between clinical trial data and real-world patient experiences.

Importance of Including PED in HTA Submissions

Panelists agreed that PED is essential for capturing real-world treatment experiences that clinical and economic data alone cannot convey.

- PED provides insight into treatment impact on quality of life, including side effects, daily functioning, and mental health.
- It highlights challenges related to accessing treatment, such as geographic and financial barriers.
- It sheds light on caregiver burden and the impact on families, particularly for intensive or hospital-based therapies.

Despite its importance, panelists noted that PED is often condensed into a short summary in HTA reports, making it difficult to assess how it was used in decision-making. Jessy Ranger explained that while patient groups know their input is considered, they do not receive feedback on how it influenced the final decision. J.K. Harris added that greater transparency is needed to clarify how PED contributes to HTA recommendations.

Strategies for Engaging Patients in PED Collection

Panelists described their approaches to collecting PED, including:

- Surveys: CBCN conducts comprehensive, large-scale surveys that inform multiple HTA submissions. Colorectal Cancer Canada previously created separate surveys for each submission but is now shifting towards a continuous survey model to collect ongoing patient insights.
- Interviews: All three organizations agreed that interviews provide the richest insights, allowing patient groups to ask follow-up questions and capture detailed narratives.
- Focus Groups and Support Networks: Patient support groups serve as valuable sources of PED, particularly for reaching individuals who may not respond to surveys.

Most Effective Approaches for Collecting Meaningful PED

Panelists agreed that interviews yield the most valuable insights, but finding patients who have used the drug under review remains a significant challenge. To address this, they have partnered with clinicians to help identify eligible patients for interviews. J.K. Harris noted that Canadian Breast Cancer Network's survey design allows them to collect robust data on patient priorities, while Jessy Ranger highlighted the importance of contextualizing survey questions to make responses more relevant to real-world treatment experiences.

Ensuring Equity in PED Collection

Panelists discussed efforts to reach underrepresented groups in PED collection.

- Canadian Breast Cancer Network analyzes survey demographics to identify gaps and actively seeks ways to include more diverse perspectives.
- Colorectal Cancer Canada and Myeloma Canada noted that online surveys may exclude patients without digital access, underscoring the need for alternative engagement methods such as phone interviews and clinician referrals.
- Patient support groups help connect organizations with individuals who might not typically participate in PED collection.

Summarization and Use of PED in HTA Deliberations

Panelists shared concerns that PED is often condensed into a brief summary in HTA recommendation reports, limiting its perceived influence.

- Jessy Ranger emphasized the need for clearer acknowledgment of how PED factors into final decisions.
- J.K. Harris suggested that HTA bodies provide feedback to patient groups on what aspects of their submissions were most impactful.
- Iris Karry highlighted that greater transparency would help patient groups tailor their submissions more effectively to HTA needs.

Panelists proposed that HTA bodies could develop a framework for measuring the weight of PED in decision-making, ensuring that patient input is integrated meaningfully alongside clinical and economic criteria.

Role of HTA Bodies in Supporting PED Collection

Panelists identified ways in which HTA bodies such as CDA and INESSS could improve guidance for patient groups:

- Providing training on best practices for PED collection, particularly for smaller patient organizations with limited resources.
- Offering clearer guidance on what types of patient input are most valuable, ensuring that submissions align with HTA decision-making needs.
- Facilitating knowledge-sharing among patient groups, allowing organizations to learn from each other's experiences and refine their approaches.

Panelists suggested that HTA bodies could also provide real-world examples of strong patient submissions, giving organizations a clearer understanding of best practices.

Challenges in Collecting PED for HTA Submissions

Panelists discussed the major challenges they face in collecting PED, including:

- Difficulties in finding patients with experience using a drug under review, particularly for new treatments.
- Time constraints, as HTA bodies often provide limited submission windows (e.g., 35 days for CDA submissions).
- Limited resources among patient groups, especially for smaller organizations that lack dedicated research teams.

To address these challenges, panelists recommended providing earlier notice of PED submission deadlines to give patient groups more time to gather robust data. They also suggested allocating HTA funding to patient groups to enhance PED collection, particularly for conducting interviews and surveys.

Improving the Patient Submission Process

Panelists suggested several improvements to the CDA's patient input template:

- Increasing flexibility by allowing patient groups to submit general PED separately, rather than requiring them to recollect the same information for each submission.
- Providing clearer guidance on how patient input is used, helping organizations tailor their submissions to HTA priorities.
- Offering real-world examples of high-quality patient submissions, helping organizations understand best practices.

Success Stories: PED Impacting HTA Decisions

Panelists shared examples of how PED has influenced HTA recommendations:

- A patient testimony at an FMEC (Formulary Management Expert Committee) meeting directly influenced a drug recommendation, demonstrating the power of firsthand patient accounts.
- Myeloma Canada highlighted HTA flexibility in adapting to new treatment landscapes, indicating that PED can help drive policy adjustments.
- Colorectal Cancer Canada successfully secured a positive recommendation for a new therapy by leveraging international PED when Canadian patient data was unavailable.

Key Takeaways for HTA Bodies

Panelists concluded with recommendations for how HTA bodies can enhance the collection and use of PED:

1. Increase transparency on how PED influences HTA decisions.
2. Improve the patient input template to increase flexibility and reduce redundancy.
3. Provide training and guidance to help patient groups collect robust data.
4. Foster collaboration between patient groups, clinicians, and HTA bodies.
5. Expand engagement strategies to ensure diverse patient perspectives are captured.

By implementing these changes, HTA bodies can ensure that PED is effectively integrated into decision-making, leading to more patient-centered healthcare policies and timely access to innovative cancer therapies.

2.0 Key Discussions from the Three Groups

Group 1 Discussion: The Use of PED in HTA Deliberative Processes

Breakout Session 1 of the Seventh Canadian Cancer Treatment Hackathon focused on the role of PED in HTAs and how PED can be effectively integrated into decision-making processes for cancer therapies. The session examined the balance between patient values and other HTA criteria, such as clinical benefit, cost-effectiveness, and feasibility of adoption, while identifying opportunities to improve the collection, submission, and use of PED in HTAs. Participants explored ways to refine the current patient input process, address inefficiencies in data collection, and enhance transparency in HTA deliberations.

Improving PED Collection

Participants identified several challenges in the current PED collection process and explored potential solutions to improve data quality and efficiency:

- **Comparative PED vs. Cross-Sectional Data**: Participants emphasized that PED comparing previous treatments to current treatments provides more valuable insights than cross-sectional experiences. By focusing on changes in patient outcomes over time, HTAs can better assess the real-world impact of new therapies.
- **Combining Clinician and Patient Input**: There was discussion on whether clinician and patient submissions should be integrated to streamline the process. While a combined submission could provide a more holistic view of treatment impact, feasibility concerns remain, particularly regarding the additional workload for clinicians and logistical challenges in aligning patient and clinician perspectives.
- **Challenges in Identifying Patients for Input**: Patient groups often struggle to find individuals who are actively using the drug under review, particularly for smaller patient populations or newly approved therapies. Partnerships between patient groups and clinicians may help improve recruitment and data collection.
- **Clinician Participation Barriers:** Many clinicians face capacity issues, which can limit their ability to provide meaningful submissions. Some clinicians may not perceive their submissions as impactful due to time constraints or uncertainty about the value of their input in HTA decisions. To improve efficiency, HTA bodies could clarify the key questions they need answered, ensuring that submissions are more targeted and useful.
- **Refining Submission Questions**: HTA committees, such as the pan-Canadian Oncology Drug Review Expert Review Committee (pERC), could provide clearer guidance on the

specific types of PED they value most. This would help patient groups focus their submissions on quality-of-life data, treatment impact, and other key areas, improving the relevance of the data provided.

- **Early Notification for PED Submissions:** The current 35-business-day window for submitting patient input under CDA's process can be challenging. Earlier notifications could give patient groups more time to collect robust data, aligning with international models like NICE, where earlier engagement allows for stronger submissions.

HTA Deliberations and the Role of PED

- **Assigning Weight to PED in Decision-Making:** Currently, patient values do not have a defined weight in HTA deliberations. PED is often used to support decisions based on clinical and economic evidence rather than being considered as an independent criterion. Participants discussed whether PED should be assigned equal weight to clinical and economic factors in pERC's deliberative framework. While greater emphasis on PED could strengthen patient-centered decision-making, trade-offs related to budget constraints and finite healthcare resources must also be considered.
- **Enhancing Patient Advocacy in Deliberations**: The inclusion of a patient advocate in HTA deliberations could improve how patient values are considered. This approach could help ensure that PED is not just a supporting factor but a key element in the review process.
- **Challenges in Post-HTA Decision-Making:** Even when PED is collected and incorporated into HTA deliberations, challenges remain in ensuring that patient values continue to influence post-HTA decisions, such as reimbursement and policy implementation. The session discussed ways to improve transparency in how PED is used after the initial HTA review.

Transparency and Reporting of PED in HTAs

- **Need for Greater Clarity on How PED is Used in Decision-Making**: The CDA provides examples of how patient and clinician input influences reviews, but consistency varies across diseases and treatments. More structured feedback loops from HTA bodies to patient groups could help refine future submissions and improve the overall quality of PED.
- **Exploring International Best Practices:** Collaboration with international HTA organizations, such as Health Technology Assessment International (HTAi), could help improve how PED is collected, reported, and integrated into decision-making frameworks.

By learning from global models, Canadian HTA bodies could enhance patient involvement and ensure PED is effectively utilized.

Recommendations

1. Improve the PED Submission Process
    - Provide earlier notification to patient groups to allow for more comprehensive data collection.
    - Clearly define the types of PED that HTA committees value most, ensuring submissions focus on relevant information.
    - Explore iterative submission processes where PED can be refined and expanded over time.
2. Enhance Collaboration Between Clinicians and Patient Groups
    - Encourage partnerships between patient groups and clinicians to improve recruitment for PED collection.
    - Consider structured ways for clinicians to contribute PED, such as case studies or specific sections in HTA submissions, without adding to their workload.
3. Strengthen the Role of PED in HTA Deliberations
    - Assess whether PED should be given equal weight alongside clinical and economic evidence in pERC's deliberative framework.
    - Increase patient advocacy in deliberations to ensure patient perspectives are consistently represented.
4. Improve Transparency and Communication on PED Use
    - Provide structured feedback to patient groups on how their input influenced HTA decisions.
    - Align Canadian HTA processes with global best practices to enhance the consistency and impact of PED in decision-making.

Conclusion

Breakout Session 1 highlighted key challenges in collecting, submitting, and utilizing PED in HTA deliberations. While improvements in submission timelines, clinician participation, and transparency are needed, participants also emphasized the importance of ensuring PED is assigned appropriate value in decision-making frameworks. By refining data collection tools, strengthening clinician-patient collaboration, and learning from international best practices,

Canada can enhance the role of PED in HTAs, ultimately ensuring that patient perspectives are meaningfully integrated into cancer drug evaluations and reimbursement decisions.

Group 2 Discussion: Exploring Alternative Methods for Collecting PED

Breakout Session 2 of the Seventh Canadian Cancer Treatment Hackathon focused on alternative methods for collecting PED and ensuring that HTA bodies—CDA and INESSS can better guide patient groups on what types of data they consider valuable. The session explored current challenges in defining meaningful PED, improving feedback mechanisms from HTA bodies, and expanding data collection methods beyond structured questionnaires. Additionally, discussions highlighted biases in data collection, barriers in clinical trial participation, and the importance of integrating RWE into PED submissions.

How Can HTA Bodies Determine What Kind of PED is Meaningful in the Assessment of Cancer Therapies?

- A key challenge is the lack of transparency regarding the types of PED considered valuable by HTA bodies.
- Patient groups frequently submit detailed data, yet HTA bodies typically summarize it briefly, leaving patient advocates uncertain regarding which aspects of their input were most influential.
- Without detailed feedback from HTA committees, patient groups cannot effectively refine future submissions or focus on prioritized data.
- Real-time feedback from the pERC following deliberations would help clarify which specific elements of PED have the greatest impact.
- Although the CDA has published summaries showing how patient and clinician input influences reviews, these summaries lack the necessary detail for meaningful guidance.
- Participants noted a gap between HTA-defined priorities and those identified by patient groups, as HTA bodies rely on structured rating scales for clinical and economic evidence but do not have an equivalent standardized framework for PED.
- Clearly outlining the most valuable types of PED would allow patient groups to tailor submissions, resulting in more impactful and relevant patient data for HTA decision-making.

Challenges in Collecting Quality-of-Life Data in PED Submissions

- A significant issue is the frequent lack of quality-of-life (QoL) data collected during clinical trials.

- This was exemplified by Taiho's submission for Lonsurf (trifluridine/tipiracil), where CDA did not accept indirect measures of QoL due to the absence of direct clinical trial data.
- Precision medicine and rare disease therapies often face challenges collecting QoL data due to limited patient populations and difficulties conducting large-scale trials.
- HTA bodies set high expectations for clinical evidence, making it challenging for innovative treatments to fulfill assessment criteria.
- Strict evidence requirements by HTA bodies often restrict the incorporation of meaningful patient-reported outcomes when clinical trial data is incomplete or missing.

How Can HTA Bodies (CDA and INESSS) Guide Patient Groups on the Types of Data They Find Most Valuable?

- Current HTA guidance from CDA and INESSS lacks specificity regarding which types of PED are most valuable, leading patient groups to submit broad narratives that might lack clinical or policy relevance.
- Participants recommended adopting practices similar to NICE in the UK, which shares key drug information from manufacturers with patient groups prior to submission deadlines, ensuring submissions align with relevant clinical data.
- Integration of HTAi's patient engagement framework, which provides detailed methodologies and guidance on patient-centered approaches, could improve the quality and impact of PED submissions in Canada.

What Other Forms of Data Should Be Considered in the HTA Deliberative Process?

- Current PED submissions typically rely on structured questionnaires, interviews, and focus groups, potentially missing deeper insights into the patient experience.
- Alternative data sources proposed include:
  - Video testimonials
  - Caregiver interviews
  - RWE
- RWE could bridge gaps in clinical trial data collection, particularly for rare diseases and precision medicine.
- Kidney Cancer Canada's successful use of global patient registries demonstrates the potential value of international RWE collaboration in enhancing PED submissions.

How Can Patient Engagement Influence the Collection of Robust PED?

- Insufficient financial support for patient organizations significantly limits robust data collection, as many operate under resource constraints.
- Participants suggested manufacturers could provide dedicated funding to patient groups specifically for comprehensive PED collection activities.
- Recruitment of patients within the limited 35-business-day submission window is challenging, especially given declining clinical trial enrollment.
- Adopting NICE's model of employing patient engagement specialists could enhance patient recruitment and facilitate timely and robust PED submissions in Canada.

How Can the Quality and Consistency of PED Submissions Be Improved?

- Clearer guidance from HTA bodies is essential to improve PED submission quality, including:
  - Standardized frameworks defining meaningful PED.
  - Expanded use of real-world evidence and narrative-based data collection methods.
  - Increased financial resources for patient groups.
- Economic and societal impacts, such as return-to-work rates and long-term societal contributions by cancer survivors, are frequently overlooked in PED submissions and could significantly demonstrate broader therapeutic value.
- Participants highlighted HIV treatment cost analyses as examples where long-term investments in innovative treatments resulted in reduced healthcare expenditures, suggesting similar models could strengthen cancer PED submissions and their influence on HTA decision-making.

Recommendations

1. **Enhance Transparency and Guidance on PED Collection**
   - Provide real-time, detailed feedback from the pERC immediately after deliberations to clarify the most impactful aspects of PED.
   - Clearly define and communicate specific types of PED that CDA and INESSS value most, enabling patient groups to submit more targeted and relevant data.
   - Adopt structured frameworks similar to those used by NICE and HTAi, outlining explicit criteria for meaningful PED.
2. **Improve Collection of Quality-of-Life Data**
   - Encourage and potentially mandate inclusion of quality-of-life measures in clinical trials to ensure direct, patient-centered evidence is available for HTA evaluations.

- Develop flexible approaches for accepting patient-reported outcomes (PROs) or indirect quality-of-life data, particularly in the context of precision medicine and rare diseases where traditional trials are challenging.

3. **Expand and Diversify Data Collection Methods**
    - Integrate alternative data collection approaches into PED submissions, including video testimonials, caregiver interviews, and RWE.
    - Foster international collaboration to utilize global patient registries, enhancing the robustness and relevance of Canadian PED submissions.
4. **Strengthen Support for Patient Engagement and PED Submission**
    - Allocate dedicated financial resources from manufacturers or HTA bodies to patient groups for comprehensive PED data collection.
    - Implement patient engagement specialist roles, modeled after NICE's approach, to assist patient groups in recruiting patients efficiently within submission timelines.
5. **Include Broader Economic and Societal Impacts in PED Submissions**
    - Encourage submissions to include data on economic impacts such as return-to-work rates and long-term societal contributions of patients undergoing treatment.
    - Utilize long-term cost-benefit analysis models, such as those demonstrated in HIV treatment, to illustrate the broader societal and economic benefits of innovative cancer therapies.

By adopting these recommendations, Canadian HTA bodies can significantly enhance the effectiveness, consistency, and patient-centered nature of PED submissions, leading to better-informed and more transparent decision-making processes.

Conclusion

Breakout Session 2 highlighted the need for more structured, transparent, and patient-centered approaches to PED collection. Participants identified key opportunities for improvement, including enhanced feedback mechanisms from HTA bodies, expanded data collection methods, improved equity in patient representation, and greater consideration of economic and societal impacts in PED submissions. By adopting best practices from international HTA organizations, supporting real-world evidence integration, and providing financial resources for patient groups, Canada can enhance the role of PED in cancer drug evaluations, ensuring that patient voices are effectively incorporated into HTA decision-making.

Group 3 Discussion: Global Best Practices and Operational Improvements for pCPA

Exploring Best Practices from International Models

Breakout Session 3 of the Seventh Canadian Cancer Treatment Hackathon focused on examining global best practices in PED collection and how international HTA organizations incorporate patient and caregiver perspectives into their deliberative processes. Participants discussed key HTA models from Scotland, the UK, Germany, and the United States and explored how HTAi resources could be adapted to improve PED collection and integration in Canada. The discussion also covered multi-criteria decision analysis (MCDA) as a tool for evaluating PED, the need for transparency in expert consultations, and the importance of structured engagement models to ensure patient perspectives meaningfully influence HTA decisions.

How Do International HTA Organizations Collect PED?

- U.S. FDA involves patients early in drug development, including protocol design, providing richer, real-time input.
- Scotland's Patient and Clinician Engagement (PACE) model formally integrates patient and clinician perspectives into decisions regarding end-of-life or severe-condition treatments, explicitly documenting treatment burden and quality of life.
- UK's NICE allows a longer PED submission window (60 days) compared to Canada's 35-business-day window, and includes patient experts in appraisal committees, ensuring continuous patient input.
- Germany's IQWiG emphasizes patient-reported outcomes (PROs), particularly symptom control (pain, side effects, functional independence), ensuring PED meaningfully influences evaluations.

How Do International HTA Organizations Use PED in Their Deliberative Process?

- NICE integrates PED meaningfully, directly influencing recommendations related to oral therapies, caregiver burden, and patient quality of life.
- IQWiG explicitly addresses patient-specific needs like symptom control in evaluations, avoiding secondary treatment of patient experiences.

- Canada's shorter PED submission timelines (35-business-day for CDA, seven-week for INESSS) hinder robust PED collection by resource-constrained patient groups.
- Participants suggested extending Canada's timelines to NICE's 60-day model to enhance PED quality.
- Participants expressed concern about bias in PED evaluation and urged adopting structured frameworks to ensure transparent and meaningful consideration rather than a superficial "checkbox" approach.

How Can International HTA Models and HTAi Resources Be Adapted for Canada?

- HTAi's Patient and Citizen Involvement Group (PCIG) provides valuable resources (guidance documents, plain language summaries, methodologies) that Canadian patient groups could adopt to align submissions with HTA requirements.
- CDA aligns partially with HTAi frameworks, emphasizing relevance, fairness, equity, legitimacy, and capacity building; however, INESSS does not currently adhere formally, leading to inconsistencies.
- Participants recommended INESSS formally adopt HTAi guidelines to enhance transparency and consistency across Canadian HTA bodies.
- Structured patient engagement models like NICE or Scotland's PACE model could be adapted in Canada, ensuring consistent integration of patient perspectives into deliberations.

The Role of Multi-Criteria Decision Analysis (MCDA) in PED Valuation

- Participants discussed using MCDA as a structured approach to assign weights to PED alongside clinical and economic criteria.
- MCDA could enhance transparency but risks oversimplifying patient experiences by reducing them to numerical values.
- Participants proposed balanced approaches combining structured frameworks (e.g., MCDA) and qualitative human judgment.
- A scorecard or dashboard was suggested as a transparent method to track how PED influences HTA decisions, ensuring active integration rather than passive acknowledgment.

Ensuring Transparency in PED Engagement and Expert Consultations

- Concerns were raised about limited diversity among clinician experts consulted by Canadian HTA bodies, possibly not reflecting broader clinical practice.
- Currently, patient groups have no involvement in clinician selection for HTA consultations, limiting representation of varied perspectives.
- Participants suggested patient groups should help select clinical experts consulted in HTA processes, ensuring broader and more accurate clinical input.
- Structured checkpoints at multiple stages in the HTA process, instead of only initial stages, were proposed to ensure ongoing relevance and inclusion of patient and clinician perspectives throughout evaluations.

Recommendations for Group 3

1. **Adopt International Best Practices in PED Collection**
    - Engage patients early in the drug development process, similar to the U.S. FDA model, to capture real-time patient input and ensure protocols align closely with patient needs.
    - Extend the PED submission timelines to 60 days, aligning with NICE practices, to allow patient groups sufficient time to compile comprehensive, quality submissions.
    - Formally integrate patient and clinician perspectives using structured engagement frameworks, such as Scotland's PACE model, particularly for treatments addressing end-of-life or severe conditions.
2. **Implement Transparent and Structured PED Integration Frameworks**
    - Adopt Multi-Criteria Decision Analysis (MCDA) as a structured method to transparently weight PED alongside clinical and economic evidence, ensuring patient experiences meaningfully influence HTA evaluations.
    - Establish a transparent tracking system, such as a scorecard or dashboard, to visibly demonstrate how PED has impacted HTA decisions.
3. **Enhance Consistency and Alignment with HTAi Resources**
    - Encourage INESSS to formally adopt HTAi's Patient and Citizen Involvement Group (PCIG) framework to ensure uniform standards and greater transparency across Canadian HTA bodies.

- Utilize HTAi guidance documents, plain language summaries, and structured methodologies as standard tools for Canadian patient groups to align their submissions with HTA requirements.

4. **Broaden Expert Consultations and Improve Patient Involvement**
    - Involve patient groups directly in selecting clinical experts for HTA consultations, ensuring representation of diverse medical practices and real-world experiences.
    - Introduce structured check-ins at multiple points throughout the HTA evaluation process to maintain continuous and relevant patient and clinician input.

Conclusion

Participants discussed key international HTA models that could strengthen PED collection and integration in Canada, including structured engagement processes used by NICE and Scotland's PACE model, Germany's emphasis on symptom control in IQWiG evaluations, and the FDA's early patient involvement in trial design. The discussion emphasized the need for longer PED submission timelines, greater alignment with HTAi standards, and structured engagement models to ensure that patient perspectives meaningfully influence HTA deliberations. Participants also examined MCDA as a potential tool for weighting PED in HTA decisions, while recognizing the importance of balancing structured evaluation with human judgment. Concerns about bias in PED evaluation, expert selection processes, and transparency in HTA deliberations were also raised, with participants advocating for more inclusive and representative expert consultations. By adopting international best practices, improving transparency, and ensuring PED is valued in a meaningful way, Canada can enhance patient-centered decision-making in drug evaluations and improve timely access to innovative cancer therapies.

3.0 Conclusion

Hackathon 7 provided a platform for critical discussions on improving the integration of PED into HTAs. Participants examined challenges in PED collection, explored international best practices, and proposed actionable recommendations to ensure that patient voices are meaningfully incorporated into decision-making processes.

Key Takeaways from the Pre-Recorded Panel

Patient group representatives emphasized the importance of PED in highlighting real-world treatment experiences, quality-of-life considerations, and accessibility challenges. However, panelists expressed concerns over the lack of transparency in how PED is used in HTA decisions. They called for clearer feedback mechanisms from HTA bodies, more flexible patient input templates, and greater collaboration to improve data collection and submission processes.

Breakout Session 1: Improving the Use of PED in HTA Deliberations

- Participants discussed the role of PED in HTA evaluations and identified barriers preventing its meaningful integration:
- PED is often summarized into a brief section in HTA reports, making it difficult to assess its influence on final decisions.
- There is no standardized weighting for PED compared to clinical and economic evidence, limiting its impact in deliberations.
- HTA bodies lack consistent feedback mechanisms to inform patient groups on how their input was used.
- Greater transparency is needed in post-HTA decision-making to track the long-term impact of PED.

Recommendations from the session included:

- Developing a Structured Framework for PED Evaluation – Ensuring that PED is assigned clear weight alongside clinical and economic data.
- Increasing Patient Advocacy in Deliberations – Involving patient representatives in HTA discussions to strengthen the patient voice.
- Enhancing Post-HTA Transparency – Providing structured feedback on how PED influenced decisions.

Breakout Session 2: Exploring Alternative Methods for Collecting PED

- Participants explored innovative ways to improve the collection of meaningful PED and expand the diversity of patient input:
- Traditional survey-based approaches may not capture the full complexity of patient experiences.
- RWE and caregiver interviews can provide valuable supplementary data.
- Limited funding and short submission timelines hinder the ability of patient groups to collect robust data.

Proposed solutions included:

- Expanding Data Collection Methods – Encouraging the use of video testimonials, focus groups, and patient registries to enrich PED.
- Providing Financial Support for PED Collection – Ensuring patient groups have the resources to conduct comprehensive data collection.
- Extending Submission Timelines – Aligning Canada's PED submission timelines with international models, such as NICE's 60-day period.

Breakout Session 3: Learning from Global Best Practices

Participants analyzed international HTA models to identify strategies that could be adapted for Canada:

- The UK's NICE and Scotland's PACE models emphasize structured patient engagement and longer submission timelines.
- The FDA involves patients early in the clinical trial design process, allowing for dynamic input throughout drug development.
- Germany's IQWiG model prioritizes symptom control and patient-reported outcomes in evaluations.

Key recommendations from this session included:

- Aligning Canada's HTA Processes with International Standards – Implementing structured engagement models similar to NICE and PACE.
- Adopting Multi-Criteria Decision Analysis (MCDA) for PED – Exploring MCDA as a tool for transparently weighing PED in decision-making.
- Increasing Patient Involvement in Expert Consultations – Ensuring that patient groups have input in selecting clinical experts for HTA evaluations.

Next Steps: Implementing Recommendations

Hackathon 7 participants emphasized the need for continued collaboration to implement the following key recommendations:

- Improve Transparency on How PED Influences HTA Decisions – Providing structured feedback loops to patient groups.
- Improve the Patient Input Template – Increasing flexibility and reducing redundancy in PED submissions.
- Support Patient Groups in Collecting PED – Offering financial resources and training to improve data collection quality.
- Expand Data Collection Methods – Encouraging innovative approaches such as RWE and caregiver perspectives.
- Strengthen Collaboration Between Patient Groups and HTA Bodies – Establishing formalized engagement processes to ensure PED is consistently integrated into HTA deliberations.

By implementing these strategies, HTA bodies in Canada can ensure that PED is valued in a meaningful way, leading to more patient-centered drug evaluations and faster access to innovative cancer therapies. Hackathon 7 underscored the importance of refining patient input tools, expanding engagement strategies, and learning from global best practices to create a more efficient and transparent HTA system that prioritizes patient needs.

4.0 Post-Event Survey Report

The Seventh Canadian Cancer Treatment Hackathon focused on improving the integration of PED into HTA processes. The event aimed to explore innovative ways to refine input tools, ensure PED reflects diverse patient needs, and align PED collection with core HTA values for patient engagement. To assess the effectiveness of discussions and identify areas for improvement, a post-event survey was conducted. The survey gathered feedback from participants, including industry leaders, HTA representatives, patient group advocates, policymakers, and researchers. It examined the current use of PED in HTAs, explored transparency and submission challenges, and identified recommendations to enhance PED collection and utilization.

Survey Findings

1. **Comprehensive Use of PED in the HTA Process**

Participants emphasized the importance of integrating PED into HTAs from the outset rather than treating it as a secondary consideration. Suggestions included enabling live patient presentations at pERC meetings to provide real-time input and clarifications. They also recommended expanding PED to include RWE from international patient registries and support programs to facilitate earlier market access. Respondents highlighted that patient input should reflect daily treatment challenges, caregiver burdens, and access barriers, ensuring that evaluations capture real-life experiences.

2. **Comprehensive Use of PED in Post-HTA Decisions**

PED should extend beyond HTA deliberations to influence pricing negotiations and reimbursement decisions. Respondents suggested integrating PED into pan-Canadian Pharmaceutical Alliance (pCPA) negotiations to ensure that patient burdens and unmet medical needs are considered in funding agreements. They also proposed mechanisms for patients to provide input on draft HTA recommendations, ensuring that decision-makers fully understand patient priorities before finalizing outcomes. Direct engagement between patient representatives and policymakers in the post-HTA phase was seen as critical to maintaining patient-centered decision-making.

3. **Weighting of HTA Criteria**

While the pERC deliberative framework considers clinical benefit, patient values, cost-effectiveness, and system feasibility, there was strong support for assigning defined weights to

these criteria to ensure greater transparency and consistency. The majority of respondents believed that weighting PED would help clarify its influence in decision-making, prevent it from being treated as a procedural formality, and guide patient groups in crafting more impactful submissions. However, concerns were raised that rigid weightings could oversimplify complex cases and limit flexibility in unique situations.

4. Timeframe for Collecting PED

Most respondents found the current 35-business-day submission period inadequate, citing the difficulty in identifying patients with experience on the drug under review within such a limited window. There was strong support for extending the preparation period or providing rolling PED collection opportunities throughout a product's lifecycle. Participants also suggested earlier notification of upcoming submissions and formalizing early engagement mechanisms to help patient groups prepare more comprehensive input.

5. Transparency in PED Utilization

There was consensus that HTA bodies need to improve transparency regarding how PED influences final recommendations. Respondents recommended clearer references to PED in HTA reports, specific feedback on which aspects of patient input shaped decisions, and allowing patient representatives to participate in deliberative discussions. Some suggested opening portions of HTA deliberations to public observation to increase accountability and build trust in the process.

6. Refining the Patient Input Process

Most participants supported the idea of HTA bodies pre-identifying key questions for patient groups to focus on in their submissions. By providing clear guidance on what types of patient input are most valuable, HTA bodies could help patient organizations prioritize their data collection efforts. While some respondents believed all questions in the patient input template were equally important, the majority felt that a targeted approach would improve the relevance and quality of submissions.

7. Training and Resources for Patient Groups and Clinicians

To improve the quality and consistency of PED submissions, respondents identified several areas where additional support is needed. The most frequently cited needs included training modules on PED collection and analysis, methodology guidelines, webinars, self-assessment checklists,

and access to data analysis tools. Some participants suggested establishing a dedicated training institute in Canada, similar to EUPATI in Europe, to provide standardized education for patient groups and clinicians involved in HTA submissions.

8. Translating Hackathon Findings into Action

To ensure that insights from the Hackathon lead to tangible improvements, respondents prioritized policy briefs, public awareness campaigns, and roundtable discussions with HTA and regulatory bodies. Strengthening international partnerships, increasing capacity-building efforts, and advocating for greater patient engagement in HTAs were also identified as key actions. One respondent emphasized the importance of securing sustainable funding and resources to drive these initiatives forward.

Conclusion

The post-event survey for the Seventh Canadian Cancer Treatment Hackathon reinforced the need for greater integration, transparency, and support for PED collection and use in HTAs. Respondents emphasized that PED should be incorporated earlier in both HTA deliberations and post-HTA reimbursement decisions, with opportunities for direct patient engagement. There was strong support for assigning clear weightings to HTA criteria, extending PED submission timelines, and enhancing transparency in how patient input shapes recommendations. Additionally, participants highlighted the importance of training, capacity-building, and knowledge-sharing to improve the quality and impact of PED submissions. To translate these findings into action, respondents recommended policy development, advocacy efforts, and increased stakeholder collaboration to ensure that HTA bodies, patient groups, and policymakers work together to create a more patient-centered drug evaluation and reimbursement system in Canada.

Appendix 1: Hackathon #7 Agenda

Time	Agenda item	Lead
12.30 – 12.45pm	Opening remarks	Barry Stein
12.40 – 1.30pm	• Review agenda and highlight purpose and intended outcome. • Roundtable introductions • Review outcomes from previous Hackathons	Bill Dempster
1.30 – 1.40pm	Review format and breakout group assignments	Bill Dempster
1.40 – 1.50pm	BREAK	All
1.50 – 2.30pm	Breakout groups	All
2.30 – 3.00pm	Presentations to the plenary (10-15 mins. per group)	All
3.00 – 3.20pm	Group discussion	All
3.20 – 3.30pm	Closing remarks and next steps	Barry Stein

Appendix 2 – List of experts and representatives on the pre-recorded panel

Panel Discussion: Canadian Patient Group Perspective: Collecting Patient Experience Data for HTA Submissions

- Iris Karry- *Patient Education & Research Manager* at Colorectal Cancer Canada
- JK Harris – *Health Policy & Advocacy Lead* at the Canadian Breast Cancer Network
- Jessy Ranger – *Director, Patient Programs*, Health Policy & Advocacy at Myeloma Canada