3SIXTY PUBLIC AFFAIRS

CHSPR WORKSHOP OUTCOMES REPORT

What will it take to prepare Canada for the new generation of pharmaceuticals, medical technologies, and other innovations within our health systems?

Explore ways to shift from containing costs in the short-term to investing in long-term value for patients.

Date of Workshop: 10 March 2023
Location of Workshop: Pinnacle Hotel Harbourfront, Vancouver, British Columbia

Lead Sponsor:

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1. Introduction

1.1 Background

CHSPR's 35th Annual Health Policy Conference took place in Vancouver, BC, at the Pinnacle Hotel Harbourfront, on March 9-10. As part of the conference, 3Sixty Public Affairs helped to organize a post-conference workshop on March 10 to explore challenges and opportunities within Canada to adopting new, promising medical innovation and technology into our health system. Approximately 20 participants from across Canada participated in the workshop. Participants had affiliations with Unity Health Toronto, Janssen Inc., Boehringer Ingelheim, Medtronic Canada, Western University, University of Calgary, University of British Columbia, University of Prince Edward Island, Public Health Canada's Value Based Healthcare Team, Providence Healthcare, Longwoods Publishing, Pfizer Canada, TRU Open Learning Faculty, and Quebec Cancer Coalition.

1.2 Mandate and Objectives

The aim of the workshop was to provide an opportunity for participants to learn and dialogue about how value-based tools could be applied to Canada's health technology review and reimbursement process to ensure that Canadian patients can ultimately benefit from new, promising therapies in a timely manner.

This was done through a series of presentations followed by a breakout session discussion, where participants had the opportunity to dialogue and present their ideas back to the plenary. The objectives of the breakout session were to generate ideas on value-based initiatives that could be prioritized and acted on immediately to improve patient access to new, innovative medical technology and to identify areas for collaboration.

2. Workshop Format and Presentation Summaries

2.1 Format

The workshop was organized by Kerry Allerton, Senior Associate, 3Sixty Public Affairs, and hosted and moderated by Fred Horne, former Alberta Health Minister and Senior Advisor, 3Sixty Public Affairs. Workshop participants were pre-assigned into 5 different groups, representing the federal government, provincial and territorial governments, patients / patient organizations, healthcare providers, and industry. Background materials discussing value-based healthcare (VBHC) concepts, implementation and application to managed access initiatives were circulated in advance.[1,2,3] Participants heard presentations from three individuals prior to the breakout session. There were approximately four participants per pre-assigned group. Each group was responsible for assuming the perspective of the group that they were assigned to and addressing the following two questions:

1. What value-based initiative are you prepared to undertake **now** to ensure early access to new pharmaceuticals, medical technologies, and innovation for Canadians?

2. What is the **first** step you will take to implement this initiative and how will you collaborate with other stakeholders to ensure success?

Following the breakout session, a discussion was moderated by Fred where each group had the opportunity to present their ideas.

2.2 Presentation Summaries

Fred introduced the workshop and provided an overview of the objectives and key concepts of VBHC.

Eva Villalba, Executive Director, Quebec Cancer Coalition, discussed the importance of VBHC to patients to facilitate early access to new and emerging therapies. She also discussed the work of the Quebec Cancer Coalition in supporting VBHC demonstration projects in oncology at the Montreal Jewish General Hospital.

Annette Lam, Senior Director, Global Market Access (Myeloma), Janssen / Johnson & Johnson presented a global perspective on the future of medical innovation, specifically highlighting the efficacy of promising new cell and gene therapies and the barriers to patient access created through existing health technology assessment (HTA) and reimbursement models.

Tara Cowling, President and Managing Principal, Medlior Health Outcomes Research Ltd., provided a pre-recorded presentation comparing and contrasting approaches to regulation, HTA

[1] Whittal A, Jommi C, De Pouvourville G, Taylor D, Annemans L, Schoonaert L, Vermeersch S, Hutchings A, Patris J (2022). Facilitating More Efficient. Negotiations for Innovative Therapies: A Value-Based Negotiation Framework. International Journal of Technology Assessment in Health Care, 38(1), e23, 1–8 https://doi.org/10.1017/S0266462322000095

[2] Teisberg E, Wallace S, O'Hara S (2022). Defining and Implementing Value-Based Health Care: A Strategic Framework. Academic Medicine, Vol. 95, No. 5

[3] Villalba E (2022). Value-Based Healthcare in Canada: How the shifting paradigm will impact specialty medicine. The 20Sense Report, Issue 22.

and reimbursement in multiple jurisdictions. Canada's unique position as the only country without defined mechanisms to facilitate early access to new therapies was noted.

The presentations for Annette and Tara can be found in the Appendix.

3. Discussion Summary

The main ideas discussed and presented by the pre-assigned breakout groups are illustrated in *Table 1*. Please note that these ideas are for the purpose of the workshop discussion to identify future research and discussion questions and do not reflect the ideas of the organizations / groups to which participants were assigned.

Table 1. Discussion Summary

Group Assignment	Discussion Guide: What value-based initiative are you prepared to undertake now to ensure early access to new pharmaceuticals, medical technologies, and innovation for Canadians? What is the first step you will take to implement this initiative and how will you collaborate with other stakeholders to ensure success?
Federal Government	• Coordinate activities that are already underway to share learnings from industry and other stakeholders and develop follow-up recommendations • Invest in health information and technology to develop a more coordinated approach to patient registries and the collection of health outcomes data • Develop and implement a pan-Canadian drug program for rare diseases. The new program would coordinate regulatory, HTA and reimbursement for drugs and technologies for rare diseases, implement new reimbursement models such as managed access, and directly reimburse Canadians in lieu of existing provincial drug programs • Canadian Institute of Health Research (CIHR) could define research initiatives and have a pocket of investments for research and patient groups • The federal government is best positioned to take on the economic development and innovation agenda • Limitations exist in value assessment frameworks used for HTA, leaving room to improve methods as a good first step
Industry	• Jurisdictional scanning to see what is happening and what works in leading international jurisdictions • Ensure patient advocacy groups have a voice in defining value

	• Develop trust and ensure transparency between industry, governments and other stakeholders
Provincial and Territorial Governments	• Use bilateral agreements between the federal government and the provinces/territories to develop a broad inventory of patient identified outcomes • Elevate the patient identified outcomes to the federal level and include as an accountability metric within the bilateral agreements
Healthcare Providers	• Work together to define value by listening to patients • Providers should collaborate to treat people with similar conditions, and assume some of the risk with respect to delivery of new innovative treatments (as opposed to governments and HTA agencies setting parameters for managed access) • Collaborate more closely with patients and patient organizations because the more patient voices, and voices in general, the closer we will come to achieving better outcomes that matter to patients
Patients / Patient Organizations	• Look to other countries that provide access to early-stage therapies to estimate potential outcomes. Where possible, use global data as a proxy to support HTA • There is a huge role for patients to play in these earlier stages to take on the risk of pulling away the treatment should they find it not effective • Patients should be involved in reassessment and disinvestments of therapies that are found to not provide their intended value • Essentially, patients should be involved in the 'start and stop' rules

4. Conclusion

The cost of healthcare in Canada is rising and continues to represent a greater portion of total government spending. At the same time, Canada is falling behind on key health metrics such as access to care, long wait times for diagnostics and procedures, and access to treatments. Thus, a shift away from making decisions solely on cost is necessary in order for Canada's healthcare system to do what it is intended: improve health outcomes. VBHC offers a promising way forward to provide better care for patients, better access to care, and ensure our healthcare system is robust, resilient and improves health outcomes. Implementing VBHC will require change management across all governments and stakeholder groups. Through presentations and moderated discussion, this workshop aimed to explore how VBHC tools and principles can be applied to assessing and reimbursing new medical technology in Canada in order to improve

patient access to promising new therapies. Seven key themes and ideas that emerged throughout the workshop were:

1. The need to involve patients and patient organizations in defining value and assessing risk.
2. The importance of sharing learnings across leading jurisdictions with defined mechanisms to facilitate early access to new therapies to better understand outcomes and identify elements that could be applied in the Canadian context.
3. The opportunity to define value and hold provincial / territorial governments accountable within federal and provincial / territorial bilateral agreements.
4. The importance of investing in better data infrastructure to ensure a more coordinated approach to patient registries and health outcomes data across the country.
5. The need for HTA agencies to broaden their perspectives on value and limitations of cost per QALY value frameworks.
6. The role of the federal government in funding and coordinating activities for high-risk therapies and orphan drugs.
7. Better collaboration, trust and transparency between stakeholders to identify solutions that work for all parties.

It is hoped that the workshop discussion and outcomes identified in this report will support future research and a continued dialogue involving multiple stakeholder groups in order to advance VBHC in Canada so that ultimately, patients will be able to access new, highly promising medical technologies, like cell and gene therapies, if and when they need it.

Appendix

1. Tara Cowling's pre-recorded presentation found HERE using passcode: **o&&dw4vu**
2. Annette Lam's Presentation

Regulators have approved 6 CAR-T therapies based on single-arm phase 2 data studies

KYMRIAH (tisagenlecleucel)	YESCARTA (axicabtagene ciloleucel)	TECARTUS (brexucabtagene autoleucel)	Breyanzi (lisocabtagene maraleucel)	Abecma (idecabtagene vicleucel)	CARVYKTI (ciltacabtagene autoleucel)
RR B-cell precursor ALL*, RR LBCL, & RR FL	RR LBCL & RR FL	RR MCL & RR B-cell precursor ALL	RR LBCL	RR MM	RR MM
FDA	FDA	FDA	FDA	FDA	FDA
EUROPEAN MEDICINES AGENCY	EUROPEAN MEDICINES AGENCY	EUROPEAN MEDICINES AGENCY	EUROPEAN MEDICINES AGENCY	EUROPEAN MEDICINES AGENCY	EUROPEAN MEDICINES AGENCY
Health Canada Santé Canada	Health Canada Santé Canada	Health Canada Santé Canada	Health Canada Santé Canada	Health Canada Santé Canada	Health Canada Santé Canada

ALL –acute lymphoblastic leukemia; FL – follicular lymphoma; LBCL – large B-cell lymphoma; MCL – mantle cell lymphoma; MM – multiple myeloma; RR – relapsed or refractory
*Indicated for patients ≤25 years
Table above highlights FDA, EMA, and Health Canada approvals and does not reflect all countries where these products may be approved.
Please refer to approved labelling for information on exact indication(s).

HTA Bodies & Payer Perspective:

- Lack of **mature survival/long-term outcomes**
- **No comparative data** in studies

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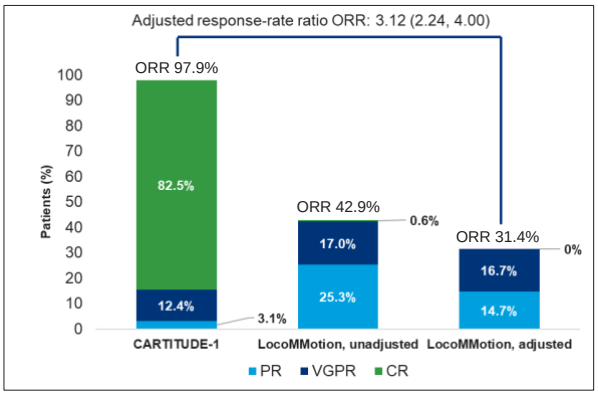
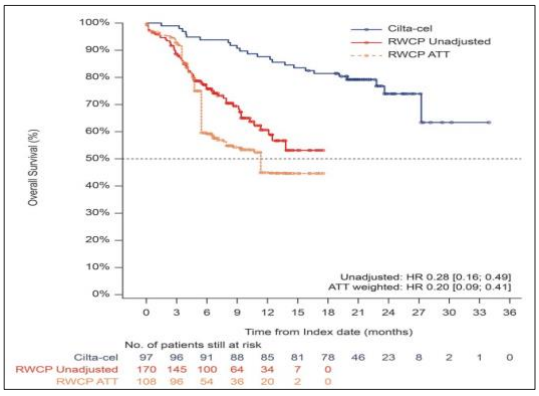
CARVYKTI (Cilta-cel) demonstrated improved efficacy in heavily pre-treated relapsed/refractory multiple myeloma (RRMM) based on indirect comparison vs. prospective real-world standard of care (SOC) data





Almost all patients treated with CARVYKTI responded, 3x more than patients treated with real-world SOC

CARVYKTI significantly **reduced the risk of death by 80%** vs. real-world SOC

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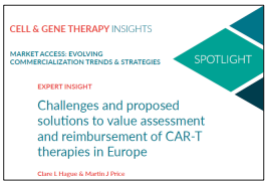
Reference: Mateos et al. Haematologica. 2022 Dec 22. doi: 10.3324/haematol.2022.280482.
Please refer to approved labeling for safety information.

Examples of Innovative Payment Models to Enable Access to Cell Therapies

1



2

3

Countries							
Coverage with Evidence (CED)	✓	3 ✓		1 ✓	1 ✓	2 ✓	
Outcomes-based Agreements	✓		1 ✓	1 ✓			1 ✓
Staged Payments			✓		✓		✓
Combination of Above	2 ✓ CED + outcomes based		2 ✓ Outcomes based + stage payments	3 ✓ CED + outcomes based	2 ✓ Outcomes based + stage payments		2 ✓ Outcomes based + stage payments

References: 1. Jorgensen & Kefalas. Regenerative Medicine 2021; 16 (4): 331-422.; **2.** Hague & Price. Cell & Gene Therapy Insights 2020; 6(7): 1013-1028; **3.** Dietrich et al. Cell & Gene Therapy Insights 2021; 7(7): 725-744.

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In summary, partnerships with all stakeholders are key to exploring and adopting new approaches

Early and continuous dialogue between innovators, HTA agencies and payers is needed prior to, during and post-launch

- Engage early and explore different options together
- Shift towards long-term sustainable win-win relationships

Explore and adopt innovative payment models to enable faster patient access through addressing uncertainties from an HTA perspective and payer perspective

Broaden perspective of value by HTA agencies and recognize limitations of cost-per-QALY value frameworks

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