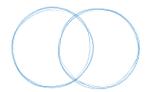


**car t-cell therapy.
accelerating adoption through collaboration**

[co]lab brief



chimeric antigen receptor [car] t-cell therapy

is revolutionizing oncology, by not only unleashing the therapeutic potential of this therapy but also the way systems approve and implement novel therapies

“

a better understanding of disruptive technologies and how they can be used to enhance services and the ways they are changing policy, processes and approaches

“

connecting very sick patients with a potentially life saving treatment takes the involvement of the highest levels of leadership

“

you can't build a new technology into an old framework

car t-cell therapy is highlighting the necessity for a more flexible and nimble process to introduce innovation into our health and cancer systems, and the urgent need for stakeholders to work collaboratively to accelerate introduction, while creating an approach that makes access available for all Canadians, equitably. innovation brings with it an enormous amount of complexity to our systems and proactive planning is needed to meaningfully integrate and help us move toward more flexible pathways for innovative therapies to be introduced in Canada. decision makers, payors and patients have been anticipating the arrival of car t-cell therapy and the impact and implications of what this means for paediatric and adult leukaemia and lymphoma.

the primary objective of this meeting was to initiate an open-discussion with the key stakeholders to address implementation and adoption barriers for maximizing patient access to car t-cell therapy that would also support broad access without limiting scientific innovation. how can stakeholders prioritize solutions that can enhance patient access to currently upcoming gene therapies through a multidisciplinary approach that can be adaptable as novel therapies and breakthroughs continue to be introduced.

enhancing patient access will require flexible thinking about how we introduce, pay for, implement and deliver car t-cell therapy across Canada. what role do we want Canada to play in car t-cell therapy delivery and what is each stakeholder's responsibility in achieving that, and recommendations | position that eliminate barriers to access.

objectives

1. consensus on recommendations | position for ethical and appropriate implementation
2. collaboration to enhance patient access | what will that look like
3. consensus on the role we want Canada to play in the delivery of car t-cell therapy and each stakeholder's role to make this happen
4. recommendations | policy to eliminate barriers to access

this meeting was organized by the cancer collaborative and supported by funding received from Novartis, Celgene and Biocanrx

accelerating
adoption through
collaboration

car t-cell therapy is a remarkable technical advancement in scientific progress on how we treat cancer, especially in that it addresses a very unmet need in a specific population. this approach is just the cusp of how we can use the immune system to treat cancer and can be expanded to cure more patients in more indications earlier in the treatment paradigm, but only if we are able to maximize the potential of this exciting advancement now. throughout our discussion, several overarching themes were repeatedly brought up.

value of car t-cell therapy

- ▶ car-t has no value if it can't get to the patients.
- ▶ **value proposition for car-t.** medical, innovation, science, economic. we need a solid position on value.
- ▶ the **evidence** that car t-cell therapy works **is very strong.** everyone believes that car t-cells are going to be used earlier in a patient's treatment path and the optimism is that they'll be used to cure more people. we must embrace this is technology through every level of approval and reimbursement.

equitable access

- ▶ ethical access for all patients is crucial to actualizing the enormous potential value of these therapies however hurdles must be overcome as we introduce this treatment approach in the canadian landscape. **approval processes does not mean access.** are provinces ready, considering the complexity of providing access?

system readiness

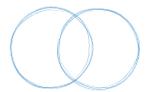
- ▶ canada needs to **enable medical research,** clinical trials infrastructure, investment or both.
- ▶ currently, clinical trials are the only way to access new drugs.

implementation | capacity

- ▶ system capacity and infrastructure will be a larger issue as we introduce car t-cell therapy in canada. need a coordinated approach to site implementation. **qualified centres**
- ▶ canada needs **a national referral centre.** commitment to the idea that children and adults deserve good healthcare closer to home.
- ▶ **improved manufacturing.** manufacturing and delivery of car-t has to be improved to eliminate limitations from our current experience

economics

- ▶ approval does not equal funding.
- ▶ we need a dynamic process in place that will be able to respond to an evolving landscape.
- ▶ "car-t pharmacare" effort to unify access for patients.



education

- ▶ misconception in canada that once health canada approval has been received that patients will have access. coupled with the fact that the drug has been approved in the US for awhile now. car-t, currently is for a very specific patient population and it's not the gold standard, although it may come to that.
- ▶ need for **medical information sharing**. what the learnings have been across the country and globally. clinicians have platforms to get informed, conferences etc., platforms to inform and educate payors.
- ▶ why bringing car-t to canada is important.

policy

- ▶ we need to have a more **PROACTIVE approach** as we introduce more disruptive technologies into our system to better anticipate and prepare for these therapies. and create a process that is consistent throughout the provinces.
- ▶ health technology assessment and prioritization of innovative treatments need to reduce reimbursement hurdles and access delays.
- ▶ long-term outlook.

leadership

- ▶ we are just at the beginning. we need to prepare for what's coming down the pipeline.
- ▶ we have an opportunity to position canada as a leader in the implementation and delivery of car-t, will we step up to the plate.

collaboration

- ▶ **stakeholder engagement**. iSAID, private sector | industry, academic, ministers of health | innovation, patient advocacy, cancer agencies, biotech, hospitals, CADTH | INESSS, DGC, etc. collaboration for responsible implementation, access, and site prioritization.
- ▶ creating system readiness. we all have a part to play in it to create a supportive ecosystem.

science

infrastructure- constrained, already lacking in capacity major challenge now more than funding

continued **investment in academic work** through clinical trials to identify patients who can benefit from car t-cell therapy

a lot of possibility | great option

manufacturing slots

manufacturing at point of care may be an approach to tackle timely and equitable access

showcasing car- t within the **IO** armamentarium | value of car-t cell therapy

supportive ecosystem

[canadian labs need to do a better job at protecting their IP]

policy

we need to have a more **PROACTIVE approach** as we introduce more disruptive technologies into our system - better anticipate and prepare for these therapies.

playing catch up even though everyone knew it was coming

regulatory | reimbursement only just recognizing the uniqueness of car-t

a lack of a **clear pathway** and experience dealing with car-t

adequate reimbursement models and **value-based agreements**

car-t as an investment | need for government investment to build capacity

RWE important part in policy for implementation - how are we tracking health outcomes from a health economics perspective

government **transparency**. a lot of unknowns, publicly

work to do in order to make canada a competitor

patient **prioritization**

funding policy for 2nd infusion

equitable access

who's property? who do the cells belong to

advocacy

access is not equitable and this is not the canadian way. determined by where a patient lives. infrastructure and resources are not in place currently to achieve equitable access. this is a major concern

myeloma | paediatric models for collaboration

all stakeholders want to see car t-cell therapy implemented in canada. need for groups to collaborate earlier in the process to ensure appropriate **implementation and accelerated adoption** [working together will make a difference]

UK | sickkids can be **models for best practice**

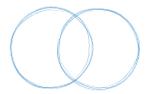
québec can be a model. if we can better understand what is happening there

education of regulators | payors

sickkids has a commitment to treat any patient able to get to their hospital

HEP C- case study

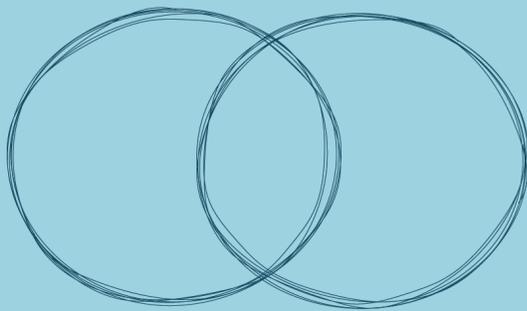
barriers to access and sustainability



recommendations | position

FINAL OBJECTIVES

1. consensus on recommendations | position for equitable and appropriate implementation
2. collaboration [myeloma and paediatric models of collaboration | networks]
3. canada to play a leadership role in the delivery of car t-cell therapy , best practices, scalable model for implementation and delivery, stakeholder engagement, collaboration, innovative payment | reimbursement models
4. need for education for different audiences [communication, management of expectations, adverse events, etc.]
5. broader, proactive engagement of stakeholders in delivery of car t-cell therapy [including responsible implementation, patient access, site development]
6. one shared repository of information
7. solid position on the value of car t-cell therapy that also creates excitement, desire and willingness
8. information sharing, knowledge translation | exchange
9. need for a catalyst



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