# Accelerating patient access:  addressing gaps in implementation readiness

CAPT 2025 Conference

Toronto, ON

September 22, 2025

# Housekeeping

- Presentations will be made available on the CAPT web site after the conference.

- An evaluation survey will be sent out after the conference.
  - Feedback on this session and the whole event would be greatly appreciated.

# Disclosures

- This panel session is funded with support of AstraZeneca Canada

- Dr. Glennie is a consultant to a number of pharmaceutical companies with products in the oncology space.

# Objectives

- To discuss solutions that will enable health systems to take a more proactive approach to implementation planning for complex cancer and other therapies, so that use in patients is not delayed after provincial funding decisions.

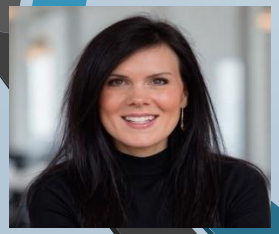
# Panel Introductions

- Dr. Judith Glennie, J.L. Glennie Consulting Inc. (moderator)

- Don Husereau, Adjunct Professor of Medicine, University of Ottawa

- Robert Bick, CanCertainty Co-Lead

- Dr. Sandeep Sehdev, Medical Oncologist - Ottawa Hospital Cancer Centre



- Jennifer Smyth, Interim Regional Vice President, Hamilton Health Sciences/Ontario Health - Cancer Care Ontario

# Agenda

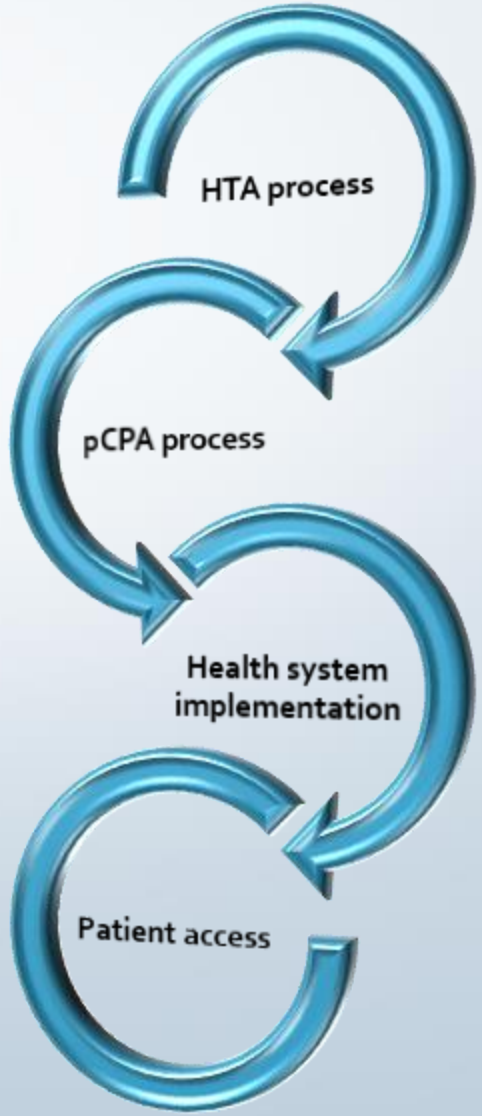
- Background/overview of recent research (Judy)
- Overview of national research on implementation readiness (Don)
- Respondent perspectives
  - Patients
  - Clinicians
  - Health system leaders
- Discussion + Q&A

# Background Information

Dr. Judith Glennie

# What do we mean by health system implementation readiness?

- Infrastructure, equipment
- Human resources
- Education and training
- New processes
- Referral systems



# Why is implementation readiness important?

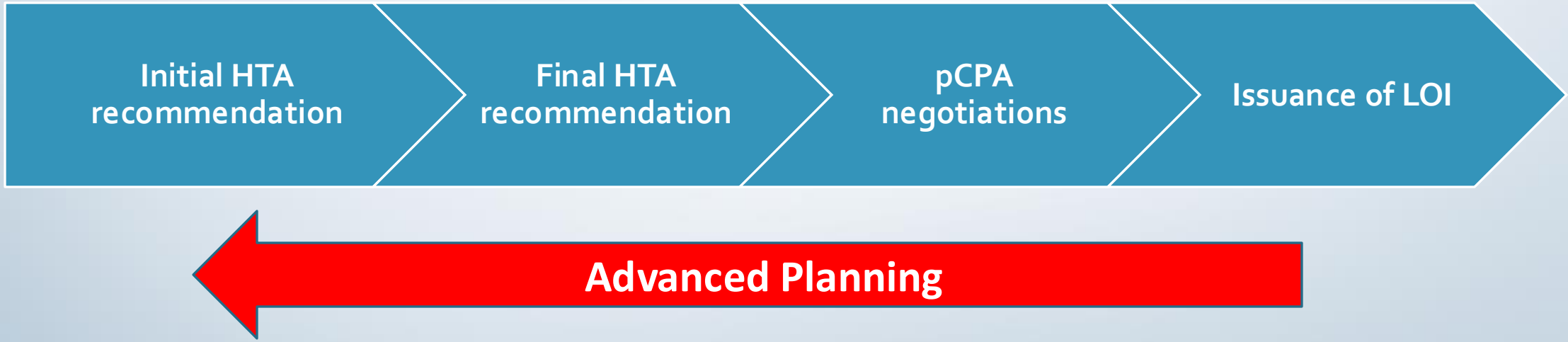
- Approval of funding for new treatments is only one step in achieving patient access.
  - These therapies can only provide benefits to patients if they are integrated into the health system and actually utilized in a timely manner.

- With complex innovative therapies (e.g., cell and gene therapies, rare disease treatments, mRNA technologies), health system implementation readiness has emerged as **an additional hurdle** in achieving timely and equitable patient access.

- A **more proactive approach is needed** to support implementation planning for complex therapies, so that actual use in patients is not delayed after the provincial funding decisions.

# Best Practices Research Project (Nov 2023)

- Multi-jurisdictional assessment to examine processes for integrating new therapies into cancer care systems.
- Timing of launch of implementation activities impacts timeliness of patient access.

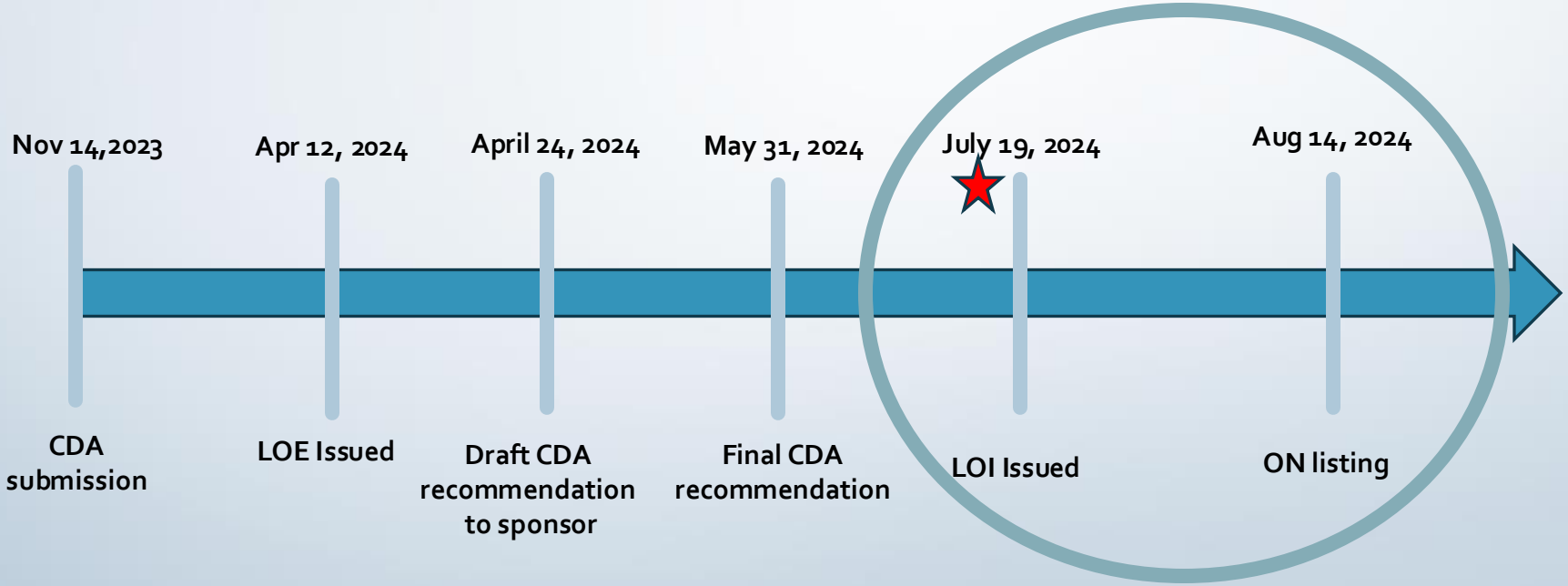





Glennie J, Gesy K, Nguyen Y (2023). Canadian public payer best practices for providing timely patient access to cancer therapies. Canadian Health Policy, Nov 2023. https://doi.org/10.54194/VIEL2883 | canadianhealthpolicy.com.

# Epcoritamab – A case study in accelerated patient access

- EPKINLY™ (epcoritamab SC) for relapsed or refractory diffuse large B-cell lymphoma
- Abbvie pursued the CDA-AMC time-limited reimbursement recommendation (TLR) pathway and the pCPA Temporary Access Process (pTAP)




**March 2024:** T-cell Engaging Antibodies Implementation WG established
**March 2025:** Organizational Readiness Recommendations for Delivering T-cell Engaging Antibodies released

# Stakeholder Consultations

- **Virtual Multi-Stakeholder meeting – October 3, 2024**
  - Objective:
    - To discuss issues and solutions to ensure timely access to cancer treatments for patients in Ontario
  - Key findings:
    - Need for early identification of the implementation needs associated with complex cancer therapies
    - Need for a system-wide planning approach
  - Report:
    - ***Collaborative Solutions to Timely Patient Access to Cancer Treatments (November 2024)***
    - https://lifesciencesontario.ca/advocacy/reports-and-publications-2/

- **On-going consultations**
  - To gain further insights into the issues faced as well as identification of potential solutions
  - Health system leaders (local, national), patient groups

# Overview of national research on implementation readiness

Don Husereau

# Accelerating patient access: Addressing gaps in Implementation Readiness

Don Husereau
(1) Adjunct Professor, School of Epidemiology and Public Health, University of Ottawa
(2) Senior Associate, Institute of Health Economics
(3) President & CEO, 9363980 Canada Inc.

# Disclosures

## I have worked for public and private sector organizations that might be interested in what I have to say.

**Public / not-for-profit**

Ontario Ministry 2019- • Ontario CED member 2015-2019 • PMPRB Advisor / Working Group member • CCRAN • CCSN • CDA (pCODR EGP 2015-present, pERC committee member 2015-2017, Strategic advisor (early scientific advice / real-world evidence), CDR)• European Commission • PAAB consultant (code changes) • Health Canada Strategic Policy Branch • Federal Innovation Council • Genome Canada • CD Howe Institute • ISPOR • IHE • HTAi • CPhA • CHEO Research Institute • ZonMW

**Private / for-profit**

AbbVie • Alexion • Amgen • Argenx • Astellas • AstraZeneca • Bei-Gene • Boehringer Ingelheim (Canada) Ltd. • Bristol Meyers Squibb • CSL Behring • Ferring Global and Canadian consultancies (Cornerstone, Evidera, IQVIA, Maple, PDCI/McKesson, Pivina etc. ) • Danish Life Sciences Council • Eli Lilly • Elvium • Esai • GSK • Hoffman-La Roche • Janssen • Leo Pharma • Lundbeck • Merck/MSD • Novo Nordisk • Otsuka • Pfizer • Purdue • Taiho • Takeda • ThermoFisher • Legal firms (as expert witness)

*Research support for readiness for complex therapies was provided by : Amgen Canada Inc, J&J Innovative Medicine Canada, Roche Canada, and Pfizer Canada ULC.*

# The story so far…


CAPT, 2024

## Transformational technology?

- *Advanced therapeutic products* are typically personalized, developed at point of care, and manufactured, distributed and used in ways that differ significantly from traditional health products[1]
- *Complex therapies* are are context dependent-- Defined by interacting components, reliance on behaviours, reliance on groups/organizational levels, and allowance for tailoring[2,3]

### *Examples*

- Fecal microbiota transplantation (FMT)
- Autologous / allogeneic stem cell therapy
- Gene therapy / editing
- Closed loop diabetes therapy
- Gene-modified cell therapy (e.g., CAR-T)
- Minimally invasive oesophagectomy
- Integrated care models
- Bispecific T-cell engagers (BiTEs)

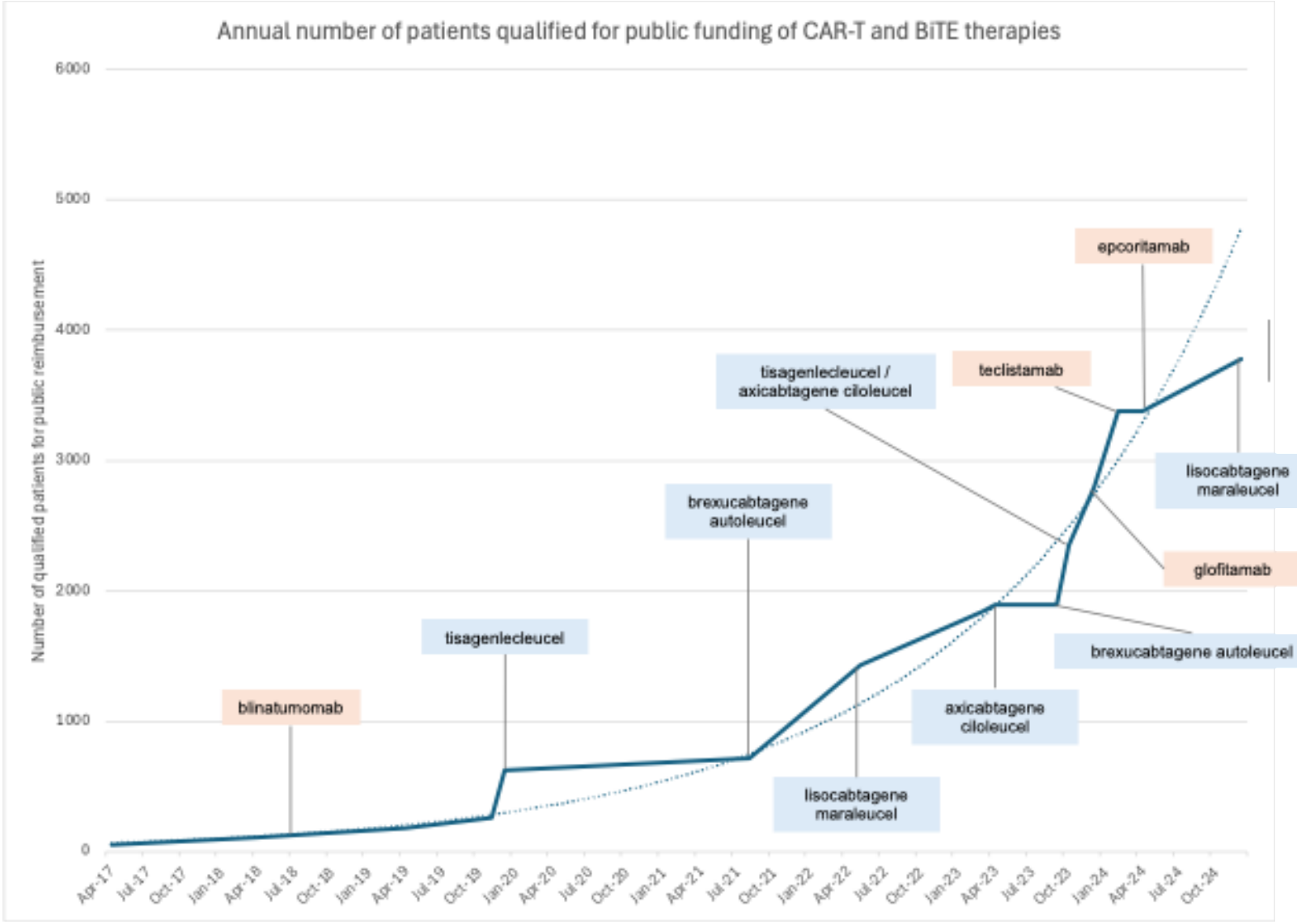

1. https://laws-lois.justice.gc.ca/eng/acts/f-27/page-3.html#h-1174034
2. Craig, Peter, Paul Dieppe, Sally Macintyre, Susan Michie, Irwin Nazareth, and Mark Petticrew. 2008. "Developing and Evaluating Complex Interventions: The New Medical Research Council Guidance." BMJ 337 (September): a1655. https://doi.org/10.1136/bmj.a1655.
3. Skivington, Kathryn, Lynsay Matthews, Sharon Anne Simpson, Peter Craig, Janis Baird, Jane M. Blazeby,

4

| Type of therapy | | Patient population |
|---|---|---|
| ***Health Canada-approved therapies*** | | |
| **CAR-T therapies** | | |
| | Kymriah (tisagenlecleucel) | Pediatric/young adult B-cell ALL; adult DLBCL; FL |
| | Yescarta (axicabtagene ciloleucel) | Relapsed/refractory FL / DLBCL |
| | Tecartus (brexucabtagene autoleucel) | Mantle cell lymphoma / ALL |
| | Breyanzi (lisocabtagene maraleucel) | DLBCL |
| | Carvykti (ciltacabtagene autoleucel) | Multiple myeloma* |
| | Abecma (idecabtagene vicleucel) | Multiple myeloma* |
| | Canadian-led Immunotherapies in Cancer (non-commercial CAR-T) | CD19+ ALL, CLL and NHL* |
| **Bispecific T-cell engager (BiTE) therapies** | | |
| | Blincyto (blinatumomab) | ALL |
| | Columvi (glofitamab) | DLBCL |
| | Tecvayli (teclistimab) | Multiple myeloma |
| | Elrexfio (elranatamab) | Multiple myeloma* |
| | Epkinly (epcoritamab) | DLBCL |
| | Imdelltra (tarlatamab) | ES-SCLC* |
| | Talvey (talquetamab) | Multiple myeloma* |
| | Lunsumio (mosunetuzumab) | Refractory FL* |
| ***Investigational therapies**** | | |
| **Allogeneic CAR-T Therapies** | | |
| | BCMA-ALLO1 | |
| | CD19CD20-ALLO1 | |
| **Tumor-infiltrating lymphocytes (TIL) therapy** | | |
| | Amtagvi (lifileucel) | Melanoma |
| | Canadian-led | Melanoma, Ovarian cancer, Mesothelioma |
| | US-led | Gastrointestinal cancers |
| **T cell receptor (TCR) therapy** | | |
| | Tecelra (afami-cel) | Synovial sarcoma |
| | IMA203 | Melanoma/sarcoma |
| | T-plex | Melanoma, head/neck, lung, ovarian, others |
| | ANOC-001 (Anocca) | Pancreatic cancer |
| | TAC01-CLDN18.2 (Triumvira) | GI, lung, ovarian, pancreatic, others |
| **Trispecific T-cell engager (TriTE) therapies** | | |
| | 53L10 Tribody | Lung, breast |
| | JNJ-79635322 | Multiple myeloma |
| **Bispecific T-cell engager (BiTE) therapies** | | |
| | Cevostamab | Multiple myeloma |
| **T-cell costimulatory agents** | | |
| | Englumafusp alfa | B-cell Non-Hodgkin Lymphoma |

# T-cell redirecting therapies as an example of a complex intervention

- *Highly specialized care* - Require more personnel for workup and toxicity management
- Require *collaboration* across health service delivery programs


Annual number of patients qualified for public funding of CAR-T and BiTE therapies
Number of qualified patients for public reimbursement
6000
5000
4000
3000
2000
1000
0
Apr-17
Jul-17
Oct-17
Jan-18
Apr-18
Jul-18
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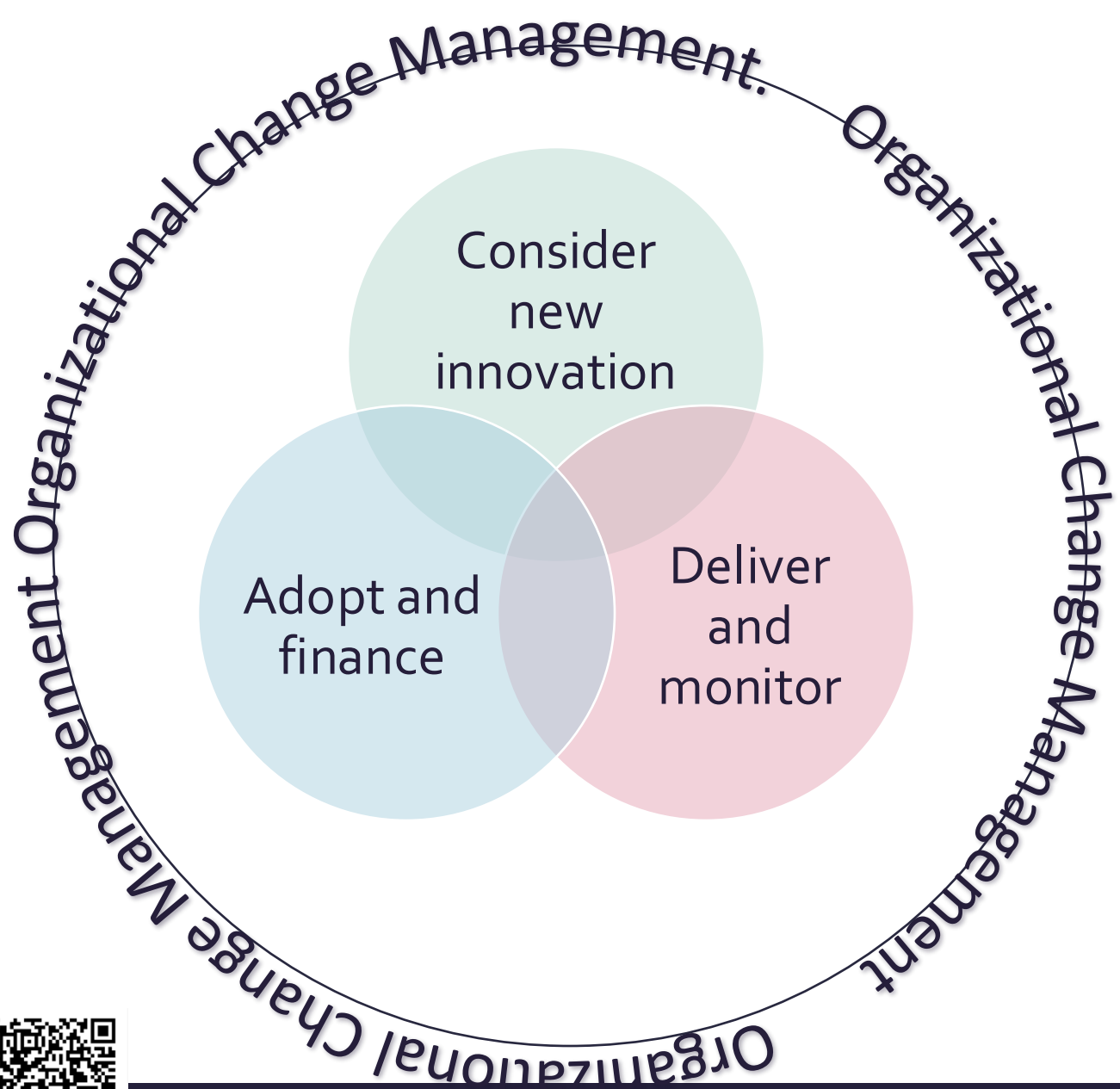
blinatumomab
tisagenlecleucel
brexucabtagene autoleucel
tisagenlecleucel / axicabtagene ciloleucel
lisocabtagene maraleucel
axicabtagene ciloleucel
teclistamab
epcoritamab
glofitamab
brexucabtagene autoleucel
lisocabtagene maraleucel
Date of provincial funding decision

# What happens if we are not ready?

Table 7: Potential impact of 6-month delay in access to new treatments for DLBCL and R/R multiple myeloma

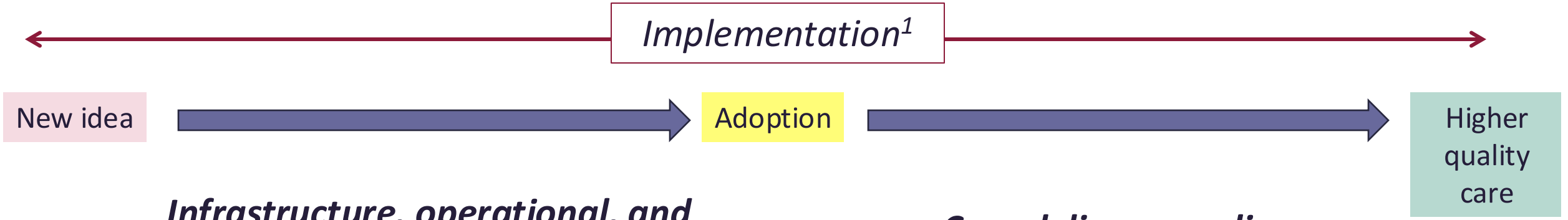
| Therapy / patient population / | Expected change | Patient numbers in Canada | Impact of 6 month delays | Potential life-years lost |
|---|---|---|---|---|
| **BiTEs** | | | | |
| DLBCL | Change from 3L+ to 2L+ | Change from 437 to 1054 | An additional 10% of patients alive at 6 months | 30.85 LYs |
| **CAR-Ts** | | | | |
| R/R Multiple myeloma | Change from 4L+ to 2L+ | Change from 441 to 2077 | An additional 20% of patients alive without disease at 6 months | 207.7 LYs |
| | | **Life-years lost, total** | | **239 LYs** |

*"This equates with 1.3 years of life-lost for every day delay in access to these therapies"*




- *Complex* or disruptive technologies may require fundamental changes to any of these health system functions.
- Effective change requires *effective change management*
- For T-cell redirecting therapies these changes include:
  - *Specialized* personnel for workup and toxicity management
  - *Collaboration* across health service delivery programs for delivery
  - Unique *financial* arrangements

# Being *ready for implementation* means addressing a number of questions…




***Infrastructure, operational, and environmental readiness***

- Planning
- Engaging
- (Evaluating)

***Care delivery readiness***

- Executing
- Reflecting

1. Damschroder, L. J. *et al.* Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* **4**, 50 (2009).

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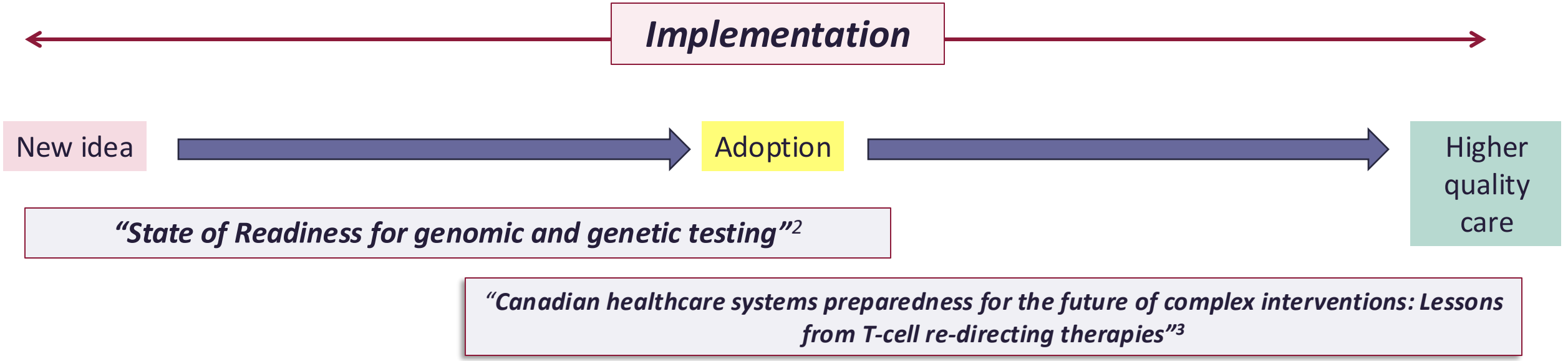
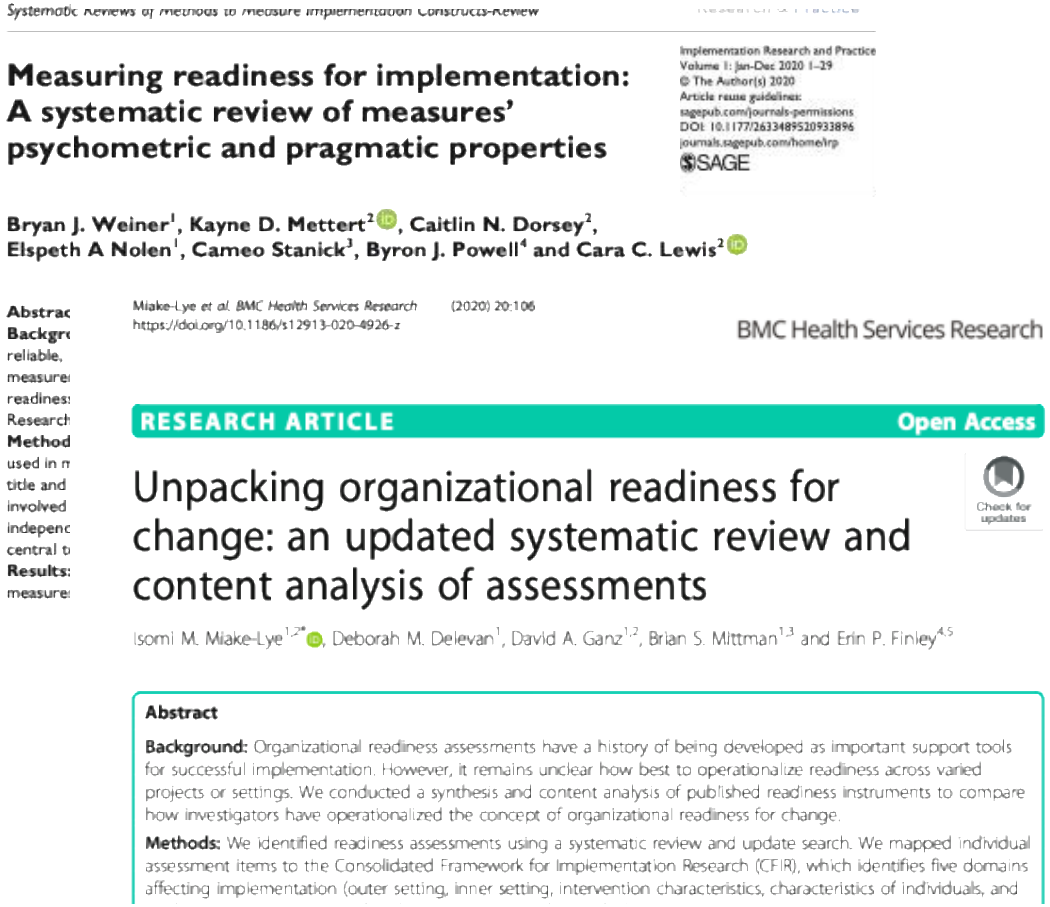



- "How can I avoid care interruptions, wait times, or inequitable care?"
- "How can I avoid access challenges?"
- "How can I avoid technology creep *and* inappropriate or inefficient / low value care?"
- "How can I support innovation policy and a better understanding of population health?
- "How can I provide effective care and prepare for the future?"

2. Husereau, D. et al. Progress toward Health System Readiness for Genome-Based Testing in Canada. Curr Oncol 30, 5379–5394 (2023).
3. Husereau, D, et al. Canadian healthcare systems preparedness for the future of complex interventions: Lessons from T-cell re-directing therapies

# … but evaluating readiness for implementation is not straightforward



Systematic Reviews of Methods to Measure Implementation Constructs-Review

**Measuring readiness for implementation: A systematic review of measures' psychometric and pragmatic properties**

Implementation Research and Practice
Volume 1: Jan-Dec 2020 1–29

DOI: 10.1177/2633489520933896
journals.sagepub.com/home/irp
SAGE

Bryan J. Weiner[1], Kayne D. Mettert[2], Caitlin N. Dorsey[2], Elspeth A Nolen[1], Cameo Stanick[3], Byron J. Powell[4] and Cara C. Lewis[2]

Abstrac
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Results:
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Miake-Lye et al. BMC Health Services Research (2020) 20:106
https://doi.org/10.1186/s12913-020-4926-z

BMC Health Services Research

RESEARCH ARTICLE Open Access

Unpacking organizational readiness for change: an updated systematic review and content analysis of assessments

Isomi M. Miake-Lye[1,2*], Deborah M. Delevan[1], David A. Ganz[1,2], Brian S. Mittman[1,3] and Erin P. Finley[4,5]

**Abstract**

**Background:** Organizational readiness assessments have a history of being developed as important support tools for successful implementation. However, it remains unclear how best to operationalize readiness across varied projects or settings. We conducted a synthesis and content analysis of published readiness instruments to compare how investigators have operationalized the concept of organizational readiness for change.

**Methods:** We identified readiness assessments using a systematic review and update search. We mapped individual assessment items to the Consolidated Framework for Implementation Research (CFIR), which identifies five domains affecting implementation (outer setting, inner setting, intervention characteristics, characteristics of individuals, and

*"The findings of this review indicate that measurement of organizational readiness for change in mental and behavioral health care, much like measurement in implementation science generally, is poor."*

*"organizational readiness for change" has been defined and measured in different ways. Some definitions and measures focus on the characteristics of individuals within an organization…others focus on macro-level factors, such as collective commitment or collective efficacy."*

4. Weiner, B. J. et al. Measuring readiness for implementation: A systematic review of measures' psychometric and pragmatic properties. Implementation Research and Practice 1, (2020).
5. Miake-Lye, I. M., Delevan, D. M., Ganz, D. A., Mittman, B. S. & Finley, E. P. Unpacking organizational readiness for change: an updated systematic review and content analysis of assessments. BMC Health Serv Res 20, 106 (2020).

# What does good look like? (1/2)

- Often best done through programs focused on the scale, spread, and sustainability (3S) of these new interventions.[6]
- The effectiveness and ability to implement these programs relies on factors related to leadership, governance and accountability.
- In general, these conditions relate to the adaptability and tolerance of the healthcare system to change and new knowledge and the ability for leaders to act and govern necessary changes.
- Healthcare systems that lack the ability or necessary conditions to learn and change will not be well suited to the adoption of these interventions.[7]

| Support conditions | Enabling | Limiting |
|---|---|---|
| Substance (innovativeness) | Adaptable | Static |
| Leadership | Distributed | Hierarchical |
| Accountability | Reciprocal | Unilateral |
| Context (capacity for new knowledge) | Absorptive | Tense |
| Timing and pace of change | Iterative | Linear |
| Management Support | Empowering | Symbolic |
| Governance | Decentralized | Centralized |

6. Côté-Boileau, É., et al. The unpredictable journeys of spreading, sustaining and scaling healthcare innovations: a scoping review. Health Res. Policy Syst. 17, (2019).
7. Greenhalgh, T., et al.. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. Milbank Q. 82, 581–629 (2004).

# What does good look like? (2/2)

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| Phases | Desired | Usual |
|---|---|---|
| Setting Goals | Tight | Loose |
| How to achieve | Loose | Tight |
| Success/failure regime | Tight | Loose |

**Stolen from John Sproule:**
**The "Tight-Loose-Tight" framework**

6. Côté-Boileau, É., et al. The unpredictable journeys of spreading, sustaining and scaling healthcare innovations: a scoping review. Health Res. Policy Syst. 17, (2019).
7. Greenhalgh, T., et al.. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. Milbank Q. 82, 581–629 (2004).

# Some examples of good in practice…

- ***For genetic and genomic testing***
  - *Alberta* established a single service organization (APL) that provides oversight and resource planning coupled with an integrated laboratory information across province
  - APL hosts a single-entry point for new testing. An intake form can be filled out by anyone (physicians, patients, innovators or the public)
  - Alberta also hosts the Alberta Diagnostic Ecosystem Platform for Translation (ADEPT)[8] hosted at the University of Alberta, to allow innovators access to clinical samples and related data to test, validate and scale their technologies.

8. https://www.albertalabdiagnostics.ca/

# Some examples of bad practice…

- ***For T-cell redirecting therapy***
  - Lack of anticipatory planning
  - Inappropriate organizational governance
  - Inadequate financing
  - Lack of knowledge by care providers
  - Inadequate models of service delivery
  - Uncertainty about value for money
  - Lack of information and support for patients

8. https://www.albertalabdiagnostics.ca/

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"…people making the decisions don't have any clue about where medicine is going to be in 2030"

8. https://www.albertalabdiagnostics.ca/

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"…the Cancer Center doesn't want to actually see them because it's after hours. They want to close after business hours. And the health region really has new model, at least in our province, for how to deal with outpatient care"

8. https://www.albertalabdiagnostics.ca/

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  - Lack of information and support for patients

"…we really need to find a standardized way of describing [procedures] to patients because I was on … what was supposed to be a 10-minute discussion … [and] the patient started with 'what you're engineering my cells? Are you changing me? Are you changing the way I am?'"

8. https://www.albertalabdiagnostics.ca/

# Findings

- There is generally a lack of preparedness across Canada for a future of T-cell redirecting therapy.
  - Healthcare system leadership will need to better address the complexity of care delivery, and its associated need for personnel, and additional resources if capacity issues are to be avoided.
  - *Solid tumour* and non-oncologic applications will create challenges, as current service programs of care are *based on hematologic programs.*
  - *Financing of therapies* needs to account for additional human resources, training, toxicity management, care navigation and coordination, and associated patient travel and lodging expenses.

# Recommendations

- Creating healthcare system level oversight for future complex care to facilitate changes in governance and service delivery models. This includes creating organizational change functions and leaders focused on health system transformation, and innovation spread, scale, and sustainability.
- Creating specialized programs of care which coordinate service delivery, plan for future resource use, and oversee the development and implementation of navigational tools and educational strategies directed to providers and patients.
- Ensuring there are transparent processes to develop and evaluate technologic developments, borrowing from best practices in implementation science and health technology assessment.
- Improving data collection to measure the cost and impact of new complex interventions.
- Revisiting approaches to financing new technologies to manage risk including programs of spread and scale, discretionary spending, and risk sharing.

# Take aways

- Report appears on resilient healthcare coalition website http://www.resilienthealthcare.ca/
- I hope this report is useful for future advocacy efforts for these and other complex therapies


Those who have knowledge, don't predict.
Those who predict, don't have knowledge.

--Lao Tzu, 6th Century BC


- Don Husereau
- +16132994379
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# Respondent:  Patient Organization Perspective

Bob Bick

# Respondent:  Clinician perspective

Dr. Sandy Sehdev

ssehdev@toh.ca

# Cancer Clinician Advocacy Forum

Dr. Sandeep Sehdev, Co-Chair

Dr. Mita Manna, Co-Chair

Access to diagnostic testing

Access to molecular / genetics testing

Managed access programs

# Implementation Challenges

Application of approved treatments may be further delayed

## Funding Shortfalls

Private insurance formularies

## Biomarker Testing

Slow adoption of biomarker testing adds weeks to diagnosis timelines

## Radiology / Imaging

Fewer CT and ultrasound devices per capital than Chile or Turkey

# Infrastructure Challenges

## Human Resources

Staffing formulas outdated for today's complexity of care; longer survival and broader indications for treatments (adjuvant, later line)

## Inadequate Regional Distribution

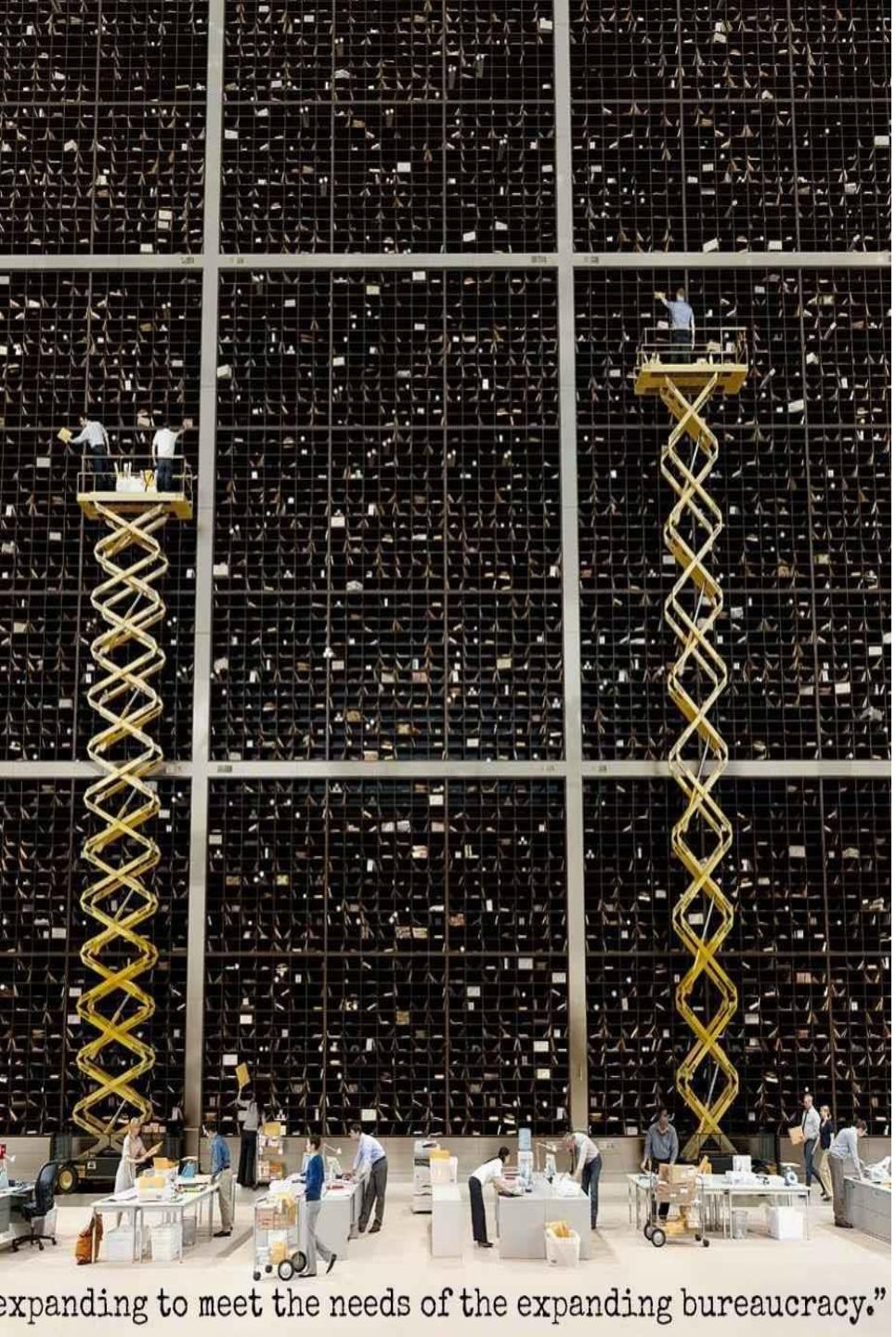
Concentration of specialized cancer facilities in urban centers creates significant access barriers for rural and remote communities.

## Space Constraints

Limited physical capacity in existing facilities restricts patient volume, creates overcrowding, and impedes implementation of new technologies.

## IT Infrastructure Limitations

Fragmented health information systems and insufficient digital infrastructure hinder data sharing, virtual care options, and integrated cancer care delivery.




# Bureaucratic and Policy Barriers

## Rigid Frameworks

Outdated processes slow evaluation of new therapies

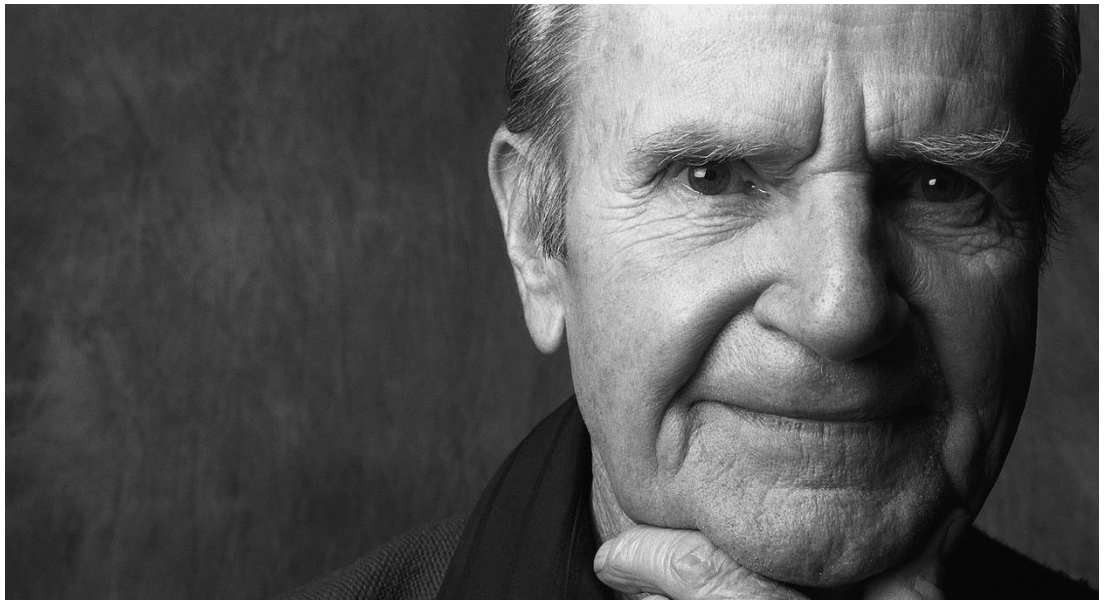
## Silos

!!

## Patchwork Policies

Inconsistent approaches and "fuzzy" strategic commitments between regions

# Impact on Patients: Delays and Outcomes



> Patients are dying while waiting for drugs already approved elsewhere.

## Real Human Cost

- Emotional anguish for patients awaiting treatment access
- Clinicians frustrated by inability to provide best care
- Disease progression during waiting periods
- Poorer prognosis due to delayed optimal therapy
- Preventable suffering and shorter survival

# Toward Faster and Fairer Access

## Streamlined Processes

Build in implementation at approval points

## Technology Adoption

Creating seamless pathways for integrating innovative therapies into care

## Expand Capacity

Now —overdue

## Faster Diagnostics

Quality metrics

# Respondent:  health system leader perspective

Jennifer Smyth

# Implementation Plan

New Cancer Therapy Adoption Framework


## Consider Evidence

- Review trial data (efficacy, safety).
- Compare with standard of care.
- Initiate impact analysis.

## Key Partner Approvals

- Gain internal approval (DST, PT&T, Exec).
- Review HC, CCO guidelines.
- Understand eligibility criteria.

## Enablers and Hurdles

- Assess infrastructure
- Develop education/ training plan for protocol and adverse event management.
- Integrate into EMR and Decision Support systems.

## Operational Planning

- Perform budget impact analysis.
- Procurement, storage, distribution.
- Align with reimbursement and coding requirements.

## Patient Engagement

- Patient navigation and support.
- Feedback and co-design.
- Assess education and methods of shared decision making.

## Outcomes and Experience

- Track/review outcomes and adverse events.
- Initiate quality improvement cycle.
- Integrate PROMs where possible.

# Q & A and Discussion

# Key Take-aways

- The number and scope of complex therapies in development is significant.
- Sectors across the health system need to work collaboratively to enable early identification of the implementation needs (and potential solutions) associated with complex therapies
  - To ensure that infrastructure, human resource, and/or other issues are addressed in parallel to funding decisions.
- Engagement of and collaboration amongst all stakeholders on these issues is a key step in ensuring timely access medications in the patients who need them.

# Housekeeping

- Presentations will be made available on the CAPT web site after the conference.
- An evaluation survey will be sent out after the conference.
  - Feedback on this session and the whole event would be greatly appreciated.

# Thank You!

- Thank you to our panel members!
- Thank you to CAPT and AZ for supporting today's session!
- Thank you to our audience!

# Thank You!