Developing a Framework for the Incorporation of Real World Evidence (RWE) into Cancer Drug Funding Decisions in Canada

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Disclosure

I have no actual or potential conflict of interest in relation to this topic or presentation.
Outline

- Current RWE context
- Developing RWE framework
- Next Steps
Why Do We Need RWE?

- Patient-centered
- Sustainability challenge
- Request from stakeholders
- Complementing existing evidence
Triple Aim: Patient-Centered

- Appropriateness
- Accessibility
- Affordability
The Sustainability Challenge

Cost of Approved Submitted Claims
Forecast on NDFP Growth
Forecast on Health Care Growth

NDFP projected growth based on historical increases 12% (10/11-14/15)
NDFP increase if aligned with provincial budget forecast for health sector (from 2016 budget) 1.8% (14/15-18/19)

Drug costs for claims approved under the New Drug Funding Program.
5. Real world evidence (RWE) should be used to inform and monitor the effects of funding decisions (this includes validating assumptions, evaluating the benefits of funded therapies, revisiting funding decisions, informing future funding decisions).
   
   Accountabilities: CCO, MOHLTC, CAPCA

6. A consistent process for disinvestment (or “reinvestment”) and renegotiation of prices with buy-in from the public, patients and clinicians should be explored (i.e., delisting drugs should be considered alongside the prioritization of new drugs).
   
   Accountabilities: CCO, MOHLTC, CAPCA, pCODR/CADTH
POTENTIAL NEXT STEPS FOR STAKEHOLDERS

Collecting Evidence to Reduce Uncertainty in the Clinical Benefit and Cost-Effectiveness of Bosutinib

Given the considerable uncertainty in the magnitude of clinical benefit of bosutinib in patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML), pERC concluded that any additional prospective evidence that could be collected to decrease the uncertainty in the incremental effect would be of benefit in understanding the true cost-effectiveness of bosutinib. Specific information on efficacy, safety and quality of life would be of particular value.

Pricing Arrangements to Limit Budget Impact

Given that pERC was satisfied that there is a net clinical benefit of bosutinib in patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML), jurisdictions may want to consider pricing arrangements and/or cost structures that may help reduce the uncertainty in the budget impact of bosutinib.
Evidence Package

- Clinical trial evidence
- Patient experience/input
- Feasibility
- Predictive economic evidence
- ...
- RWE
How to use RWE?

Who should be engaged?

WHAT'S NEXT?

Who will conduct the analysis?

All drugs?

How to select a drug?

How to access data?

What data do we need?

How to define RWE?

How should the existing pathway be adapted for RWE?
Next Step = Collaborations
Outline

Current RWE context

Developing RWE framework

Next Steps
Our Team

- RWE
- CAPCA
- Provincial Cancer Agencies
- HTA (pCODR/CADTH, INESSS, OSCCD)
- Provincial Ministries of Health
- pCPA (national price negotiation)
- Patients & Family members (PFAC, CCAN)
- CPAC
- Applied Researchers (e.g. ARCC, CCTN)
Our Goal

• To explore the role that Real World Evidence (RWE) should play in cancer drug funding decisions

• To develop a framework for Canadian provinces to generate and use RWE in a consistent and integrated manner
<table>
<thead>
<tr>
<th>No.</th>
<th>Objective</th>
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<tbody>
<tr>
<td>1</td>
<td>To develop a comprehensive understanding of the current state of RWE in cancer drug reimbursement in Canada</td>
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<tr>
<td>2</td>
<td>To establish formal national working groups dedicated to policy and methodological applications of RWE, and collaboratively/iteratively develop working framework for the generation and use of RWE</td>
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<tr>
<td>3</td>
<td>To validate the developed framework through the completion of multi-province RWE projects</td>
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<tr>
<td>4</td>
<td>To employ knowledge translation (KT) strategies to establish and integrate the final RWE framework into official practice of participating provinces and on a national level</td>
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Objective 1

Goal
• Better understanding and information to guide the formation of our work
• Definition of RWE
• Current state of RWE (e.g., data availability/accessibility/usage across jurisdictions)
• Potential (need) for RWE (national, provincial)

Objective
• To develop a comprehensive understanding of the current state of RWE in cancer drug reimbursement in Canada

Approach
• Environmental Scan
• Qualitative interviews
Objective 1: Current landscape of RWE

• Environmental Scan
  – Scoping review on RWE
  – Current national and international landscape of RWE
  – Draft report available in summer 2018

• Qualitative Interviews
  – Conducting interviews with relevant stakeholders and subject matter experts
  – Current perspectives of RWE from key Canadian stakeholders
  – Predicted completion in fall 2018
Objective 2

Goal: A working framework for the generation and use of RWE

Objective: To establish formal national working groups dedicated to (i) policy and (ii) methodological applications of RWE, and collaboratively/iteratively develop working framework for the generation and use of RWE

Approach:
- Assembly of committees
- Development of framework
Drug selection
Collection of Data
Reassessment
Funding Decision

RWE Planning and Drug Selection WG
RWE Uptake and Reassessment WG

RWE Methods WG
RWE Data WG
To develop criteria to identify potential drug candidates for real world evaluation and establish provincial infrastructure for RWE.

Responsibilities include, but not limited to:
- One in-person meeting and three teleconferences per year
- During the development and refinement of framework, there will be additional meetings
Topics and Questions to Explore:

Examples

What are triggers for RWE?

Who will use RWE? How?

How should drugs be selected?
National Working Groups (WG)

RWE Methods WG

RWE Data WG

Drug selection

Collection of Data

Reassessment

Funding Decision

RWE Planning and Drug Selection WG

RWE Uptake and Reassessment WG
• To recommend methods to analyze real world evidence feasibility with methodological rigor (minimal bias)

<table>
<thead>
<tr>
<th>Task</th>
<th>Status</th>
<th>Timeline</th>
<th>Responsible Person</th>
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<tbody>
<tr>
<td>Identify Chair</td>
<td>Completed</td>
<td></td>
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<tr>
<td>Recruit/Confirm membership</td>
<td></td>
<td>Mar/Apr 2018</td>
<td>Chair</td>
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<td>First Meeting</td>
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<td>Apr 2018</td>
<td>All members</td>
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<td>First Milestone: Draft Framework</td>
<td></td>
<td>Jul 2018</td>
<td>All members</td>
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What outcomes should we consider (e.g., safety, effectiveness, cost-effectiveness)?

What methods should be used for different outcomes?

How to characterize the uncertainty?

How to pool results across provinces?
Topics and Questions to Explore: Examples

What databases are available?

What data elements are available?

How to access data?

How long would it take?
Reassessment WG Mandate

• To develop strategies for implementing real-world evidence and results for HTA reassessment and policy making decisions
Topics and Questions to Explore:

Examples

1. How to initiate the reassessment?
2. Who should conduct the reassessment?
3. What are the enablers and barriers to (e.g., conducting reassessment and revisiting funding decision)?
4. How might it be different than what evidence is reviewed for initial drugs?
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Timeline

Year 1: 2017-18
- Environmental scan
- Qualitative interviews
- Framework planning

Year 2: 2018-19
- Framework development
- RWE evaluation 1

Year 3: 2019-2020
- Qualitative interviews
- Framework revision
- RWE evaluation 2

Year 4: 2020-2021
- Qualitative interviews
- Framework revision
- Knowledge translation
Acknowledgement – Grant Members

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- Daniel Sperber
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- Elena Lungu
- Nevzeta Bosnic
- Basanti Ghosh
- Melissa Hunt
- France Hall
- Rhonda Kropp
To get through the hardest journey, we need take only one step at a time. But we must keep on stepping.

-Chinese Proverb
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