Building a Reassessment Process for Cancer Drugs: Lessons Learned From the CanREValue Collaboration Mock Reassessment Exercise

2020 CADTH Symposium
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Disclosure

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

CanREValue Collaboration is funded by the Canadian Institutes of Health Research: Partnerships for Health System Improvement for Cancer Control grant

CanREValue Collaboration also receives additional support from the Canadian Centre for Applied Research in Cancer Control (ARCC). ARCC receives core funding from the Canadian Cancer Society (Grant #2015-703549).

The views expressed in this presentation do not represent the views of the organizations that I am affiliated with:

• University of Toronto
• Canadian Centre for Applied Research in Cancer Control
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Background: New definition of HTA

Movement towards broadening current HTA definition by INAHTA and HTAi to encompass the full *lifecycle health technology assessment*¹

❖ Managing a health product throughout its lifecycle from pre-market to post-market/post-funding, with the potential for disinvestment.

Central to lifecycle HTA is the process of *reassessment*

❖ Re-evaluate funded drugs and/or technology as new evidence emerges

Abbreviations: INAHTA = International Network of Agencies for Health Technology Assessment; HTAi = Health Technology Assessment International

Background: Why is reassessment important?

1. Optimize quality of clinical care with emerging new evidence
2. Inform optimal allocation of healthcare resources
3. Ensure sustainability within the healthcare system
CanREValue Collaboration: Overall Objective

**Purpose:** To develop a framework for Canadian provinces to generate and use RWE for cancer drug funding decisions in a consistent and integrated manner

**Potential System Impact**
- Reassessment of cancer drugs by recommendation-makers
- Refinement of funding decisions or renegotiations/disinvestment by decision-makers/payers across Canada
CanREValue Collaboration: Preliminary Framework

**Topic Identification Process**
- **Step 1**
- **Step 2** Screening Process (Filters Potential Questions)

**Prioritization of Potential Questions for RWE Analysis**
- **Step 3**

**Initiate RWE Project**
- **Step 4**

**Conduct RWE Project**
- **Step 5**

**Step 6** Reassessment Submission
- **Step 7** Reassessment of the RWE
- **Step 8** Uptake of RWE & Reassessment Rec
CanREValue Collaboration: Working Groups

- RWE Data WG
  Chair: Claire de Oliveira
- RWE Methods WG
  Chair: Jeff Hoch
- Reassessment & Uptake of RWE
  - RWE Reassessment and Uptake WG
    Chair: Erica Craig & Brent Fraser

- Selection & Prioritization of RWE questions
- Real-world Data
- Methodology

- RWE Planning and Drug Selection WG
  Chair: Scott Gavura
- RWE Engagement WG
  Chair: Bill Evans
Development of Reassessment Process

CanREValue Collaboration’s RWE Reassessment & Uptake WG members

- Perspectives: Health Canada, CADTH, INESSS, PMPRB, pCPA, Payers, Clinicians, and Patient representatives

Approach: Modified Delphi method

1st Teleconference & Post meeting survey

Feb 2018

2nd Teleconference & Post Meeting Survey

May 2018

3rd Teleconference & Post Meeting Survey

Sept 2018

In-person Meeting

May 2019
Preliminary Reassessment Process

**Transparency**

**Patient and Clinician Engagement**

- Province initiated
- Industry initiated

**CADTH* review**
- Review data to address uncertainty
- Type/source of data may be different than initial review

**Committee Recommendation**
- Similar deliberative framework as pERC, with differences in adoption/feasibility.

**Status quo**
- No change

**Revisit negotiation**
- pCPA

**Disinvestment**
- Committee rec categories

**Funding decision**

Timeline ~6 months
Mock Reassessment Exercise: Objectives

Objectives:
1. Evaluate the feasibility of the reassessment process
2. Identify relevant real-world evidence required for issuing an reassessment recommendation
Mock Reassessment: mock reassessment exercise

• Half-day mock reassessment exercise on May 29th, 2019
  • Format: modeled after the initial drug review conducted by CADTH-pCODR Expert Review Committee (pERC)

• Two sections:

1. Presentation of Case Study
   • **Clinical evidence**: presented by a clinician
   • **Economic evidence**: presented by a former pERC member
   • **Patient value evidence**: presented by a patient representative
   • **Implementation & Sustainability**: presented by payer decision-maker

2. Breakout group discussion
   • 8 – 9 attendees in each group
   • Two main topics:
     • Topic 1: review evidence from the case to make a reassessment recommendation
     • Topic 2: feedback on the reassessment process
Mock Reassessment: mock reassessment attendees

32 attendees from CanREValue Collaboration

- Health Canada
- PMPRB
- pCPA
- CADTH/INESSS
- Payers
- Patients
- Researchers
- Clinicians
Mock Reassessment: Case Study Evidence

Clinical Evidence
Evidence from the real-world study conducted in 3 Canadian Provinces compared to RCT
- Overall survival
- Safety outcomes

Economic Evidence
Evidence from real-world study conducted in 3 Canadian Provinces
- Average cost per patient
- Incremental cost effectiveness ratio

Patient Value
Evidence from published literature
- Patient reported quality of life
- Patient reported adverse events

Implementation & Sustainability
Evidence from real-world study in 3 Canadian Provinces
- Real-world treatment utilization and spending compared to budget impact analysis
### Case Study: insights from deliberation

#### Clinical Evidence
- Modest survival benefit
- Similar to the initial RCT evidence

#### Economic Evidence
- Not cost-effective
- Similar to the initial suggestion by HTA Committee

#### Patient Value Evidence
- Limited evidence to conclude alignment with patient values*
  - Not representative of Canadian population
  - Small sample size

#### Implementation & Sustainability
- Expenditure greatly exceeded initial budget forecast
- Treatment landscape changed with recent price changes of alternatives

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*Note: The patient value evidence provided for mock exercise was obtained from published literature*
Case Study: Reassessment Recommendations

**Status Quo**
- RWE evidence aligns with initial trial evidence
- Lack of relevant evidence on patient value (due to evidence provided for reassessment)
- Recent prices changes that will improve cost-effectiveness and budget impact going forward

**Revisiting Price**
- Not cost-effective;
- High budget impact; drug impacts large patient population; large volume
- Entrance of cheaper alternative options allows for potential renegotiation
Considerations for generating evidence for reassessment

1. **Source of real-world data**
   - Trust in the RWE is dependent on the source and method of data collection
   - Generalizability of real-world evidence is perceived as a major strength

2. **Collecting relevant evidence for reassessment**
   - Some evidence that were noted as important and relevant includes:
     - Quality adjusted life years
     - Patient experiences and expectations
     - Dose delays, dose intensity
Considerations for process improvements

1. **Patient engagement**
   - Engage patients throughout the process of reassessment
     - Solicit patient input when conducting reassessment
     - Transparency is key

2. **Accounting for context and changing landscape**
   - Treatment landscapes are complex and ever evolving
   - Timing of when reassessment review is conducted is critical and should address the needs of appropriate stakeholders

3. **A priori study plan**
   - Develop standards for conducting RWE analysis
   - Standards must be agreed upon by all the stakeholders affected by and involved within the reassessment process
Current Work

• Continuing to refine the reassessment process based on the lessons learned from the mock reassessment exercise
• Developing a process for the uptake of the reassessment recommendations
• Ongoing engagement with relevant stakeholders regarding the framework
Thank you!

We would like to connect with you!

Please visit us at: https://cc-arcc.ca/canrevalue/

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