Stakeholder Consultation Webinar

Presenters: CanREValue Collaboration
Date: November 6th, 2019
Welcome
Agenda

1. Introduction of CanREValue Collaboration
2. Introduction of preliminary framework
3. Stakeholder Consultation process
4. Questions
CanREValue Collaboration

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

- Reassessment of cancer drugs by recommendation-makers
- Refinement of funding decisions or renegotiations/disinvestment by decision-makers/payers across Canada
CanREValue Members

- PMPRB
- Health Canada
- Researchers (e.g. ARCC, CCTG)
- CAPCA
- Provincial Cancer Agencies
- HTA (pCODR/CADTH, INESSS, OSSCD)
- Provincial Ministries of Health
- CPAC
- Patients & Family members
- pCPA
CanREValue Working Groups

- RWE Data WG
- RWE Methods WG
- RWE Planning and Drug Selection WG
- RWE Reassessment and Uptake WG
- RWE Engagement WG
Framework Development

• The five Working Groups are tasked with developing the framework

• Through multiple teleconferences and two in-person meetings, the Working Group members have drafted a preliminary framework

• The findings from each Working Group are summarized in interim reports for stakeholders consultation

• Based on the inputs from the stakeholders, the Working Groups will update the preliminary framework through an iterative process
CanREValue Preliminary Framework

1. **Topic Identification Process** (Identify Potential Questions)
2. **Screening Process**
3. **Prioritization of Potential Questions for RWE Analysis**
   - **Select a Question for RWE Analysis**
   - **Initiate a RWE Project**
   - **Assess Real-world Data Capabilities**
   - **Assess appropriate Methodology**
   - **Re-evaluating Priorities**

4. **Conduct RWE Analysis**
   - **CADTH Reassessment**
   - **Reassessment Recommendations**
   - **Uptake of RWE**

5. **Reassessment Submission**
   - **Status Quo/Revisit funding criteria/Renegotiation/Reinvestment**

**CanREValue Planning & Drug Selection WG**
- RWE Planning & Drug Selection WG

**CanREValue Data WG**
- RWE Data WG

**CanREValue Method WG**
- RWE Method WG

**CanREValue Reassessment & Uptake WG**
- RWE Reassessment & Uptake WG
Planning & Drug Selection Working Group

Chair: Scott Gavura, Director, Provincial Drug Reimbursement Programs (Cancer Care Ontario)

RWE Planning and Drug Selection WG

To develop criteria to identify potential drug candidates for real world evaluation and establish provincial infrastructure for RWE
Developing the framework component

- From Jan 2018 to Oct 2019, the WG members have completed:
  - 5 teleconferences
  - 2 annual in-person meetings
  - 6 surveys

- The working group members have
  - Developed a topic identification process
    - Applied it to identify 3 potential candidate drugs for RWE evaluation
  - Consulted with experts regarding prioritization process development
    - Identified multi-criteria decision analysis (MCDA) approach to priority-setting
    - Established a plan to develop and incorporate an MCDA based tool
Triggers of potential RWE questions:

• Trigger 1: Uncertainties in the clinical benefit and/or alignment with patient values.

• Trigger 2: Uncertainties in value for money or feasibility of adoption of the drug

• Trigger 3: The uncertainties identified in triggers 1 & 2 are not expected to be resolved by evidence from future planned studies
Screening & Prioritization Process – under development

• WG members will develop a multi-criteria decision analysis based rating tool for prioritizing RWE questions

• Two sets of criteria are being considered for prioritization:
  ✓ The importance of the uncertainty identified
  ✓ The likelihood of resolving the uncertainty identified using administrative data
Data Working Group

Chair: Dr. Claire de Oliveira, Associate Professor, University of Toronto; Health Economist, Centre for Addiction and Mental Health

To identify strategies to access data across provinces and harmonize data elements relevant for RWE studies
Data holding across provinces

- Data experts from the ten provinces were iteratively consulted from March 2018 to September 2019 to complete the asset review via
  - 4 teleconferences
  - 2 in-person meetings
  - Two surveys
  - Multiple iterative exchanges via emails

- A survey was circulated to identify the main data custodians in each province and the available databases held by each jurisdiction.

Example: Survey on Data Holding

<table>
<thead>
<tr>
<th>Province</th>
<th>Data Holder</th>
<th>Databases</th>
<th>Date Range</th>
<th>Update Frequency</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Province</td>
<td>Custodian name</td>
<td>Database name</td>
<td>Year – Mar 2019</td>
<td>E.g. annual</td>
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Data elements held in databases

• Within each database, we requested information on the name of each data element and descriptions.

• Data experts were asked to assess whether the data elements were available and linkable, and any limitations in coverage and/or completeness.

Example: Survey on Data element

<table>
<thead>
<tr>
<th>Province</th>
<th>Data Element</th>
<th>Description</th>
<th>Database Name</th>
<th>Available &amp; Linkable</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Province</td>
<td>Age</td>
<td>Patient age</td>
<td>Cancer Registry</td>
<td>Green</td>
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<td>Province</td>
<td>Drug cost</td>
<td>Cost of drug</td>
<td>Treatment database</td>
<td>Yellow</td>
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- Green: Data available and linkable
- Yellow: Data available and linkable with caveat
- Red: Data not available or linkable
## Capability to conduct real-world analyses

- Data experts from each province was asked to assess their capability to conduct a real-world study on different outcomes of interest.
- Capability for conducting a RWE study varies by:
  - Type of outcome examined
  - Type of oncology drug (based on route of administration)
  - Province

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<th>Intravenous Cancer Drug Analysis</th>
<th>BC</th>
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<th>SK</th>
<th>MB</th>
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- Analysis can be completed
- Analysis can be completed with caveat
- Analysis cannot be completed
Method Working Group

Chair: **Dr. Jeffrey Hoch**, Professor and Chief, Division of Health Policy and Management, Department of Public Health Sciences, UC Davis; Associate Director, Center for Healthcare Policy and Research
Generating RWE from RWD

Two stages of analysis must be conducted to generate RWE from RWD
1. Adjusting for biases between exposure and controls
2. Statistical analysis to examine associations between exposure and outcome
Identifying the appropriate methods

• The WG has held 2 teleconferences and 2 in-person meetings

• The group has adopted an outcomes-focused approach
  • Papers will focused on methods to evaluate different outcomes (e.g. survival)

• We have a paper exploring different approaches for survival analysis
Adjusting for biases – checklist of methods

- Multivariable-based regression
- Propensity score related analysis
- Instrumental variable methods
- Other methods
Reassessment & Uptake Working Group

Co-Chairs:

**Erica Craig**, Provincial Pharmacy Director, New Brunswick Cancer Network

**Brent Fraser**, Vice President of Pharmaceutical Reviews, Canadian Agency for Drug and Technologies in Health

RWE Reassessment and Uptake WG

*To develop strategies for implementing RWE results for HTA reassessment and policy making decisions*
Developing the framework component

• Between Jan 2018 to October 2019, the working group members have completed:
  • 4 teleconferences
  • 2 annual in-person meetings
  • 4 surveys
  • 1 mock reassessment session

• The working group members have
  • Developed a draft reassessment process
  • Evaluated the process by conducting a mock reassessment session
    • Members were presented with real-world evidence from a funded cancer drug and were asked to
      I. Deliberate upon the evidence presented and make a recommendation
      II. Evaluate the reassessment process (e.g. what type of evidence is needed during a reassessment)
Reassessment Process

Conduct RWE Analysis

Reassessment Submission → CADTH Reassessment → Reassessment Recommendations → Uptake of RWE → Status Quo/ Revisit funding criteria/ Renegotiation/ Reinvestment
Reassessment Process

*Based on the learnings from the mock reassessment, the WG members are working revising the recommendation categories.
Uptake of RWE

Conduct RWE Analysis

Reassessment Submission → CADTH Reassessment → Reassessment Recommendations → Uptake of RWE

Status Quo/Revisit funding criteria/Renegotiation/Reinvestment
RWE Engagement Working Group

Chair: Dr. Bill Evans, Medical Oncologist, Professor Emeritus, McMaster University

To ensure appropriate input from key stakeholders cross-jurisdictionally, at all steps of the framework development
Stakeholder Consultation

• We aim to seek inputs from the public and all stakeholders on the preliminary framework process.

• A series of interim reports were drafted to outline the different components of the framework:
  - Report 1: Interim Data Report
  - Report 3: Interim Method Report
Feedback Process

• Interim Report can be accessed via:
  I. CanREValue Website
     ❖ Reports will be posted on the website: https://cc-arcc.ca/canrevalue-kt
     ❖ Under the tab labelled “CanREValue Working Group Reports”
  II. Register with CanREValue mailing list
     ❖ Sign up at: CanREValue@cc-arcc.ca or follow @CanREValue
     ❖ Reports will be send out to the mailing list

• Feedback can be provided in the feedback form
  ➢ Feedback forms will be included with the report
  ➢ Accept feedback from all stakeholders through written submission
  ➢ Feedback (maximum 5 pages) will be accepted for 1 month after release of draft report

• Updated report will be released with reply to all feedback
  ➢ All replies and comments may be made public
Timeline for report release

Interim Data Report
- Contents developed by the Data WG
  - November 11th, 2019

Interim Policy Report
- Section 1: Contents developed by Planning & Drug Selection WG
- Section 2: Contents developed by Reassessment & Uptake WG
  - Early December

Interim Method Report
- Contents developed by the Method WG
  - Mid January
Questions?

Reports can be accessed one of the following ways:

- Register for the CanREValue mailing list ([CanREValue@cc-arcc.ca](mailto:CanREValue@cc-arcc.ca))
- Visit the CanREValue website ([https://cc-arcc.ca/canrevalue-kt](https://cc-arcc.ca/canrevalue-kt))
Next steps

- Access the Interim reports
- Provide feedback to the Interim reports
- If you have any questions, please email us at CanREValue@cc-arcc.ca