

CanREValue

Value-based decisions from Real World Evidence

Newsletter

Issue 6 | Summer 2019

Study Objectives:

Objective 1: (Complete & Ongoing)

- ❖ Develop comprehensive understanding of the current state of RWE nationally & internationally
- ❖ Keep current on emerging/new information related to RWE in Canada and Beyond

Objective 2: (Established & Ongoing)

- ❖ Establish formal national working groups dedicated to policy and methodological application of RWE, and collaboratively & iteratively develop a working framework

Objective 3: (piloting)

- ❖ Validate the developed framework through the completion of multi-province RWE project

Objective 4: (ongoing)

- ❖ Employ knowledge translation strategies to establish and integrate the final RWE framework

CanREValue IN-PERSON MEETING 2019

On May 29th, 2019, the CanREValue Collaboration held our second in-person meeting in Halifax, Nova Scotia, after the completion of the 2019 ARCC Conference. This all-day in-person meeting featured a mock reassessment session, study protocol development session, criteria-based analysis presentation, and other working sessions. Overall, the meeting was a great success with over 60 CanREValue members in attendance (in-person and dial in).

OBJECTIVE 3 CANDIDATE DRUG




We are excited to announce the candidate drug we have chosen to evaluate for Objective 3 of the study. Using the draft selection criteria developed by the RWE Planning and Drug Selection Working Group we had identified 3 potential candidates. For each of the candidates, the RWE Data Working Group members assessed the feasibility of conducting an RWE study in each province. Based on their inputs, we have decided to conduct an RWE study on pertuzumab, trastuzumab, and taxane for metastatic breast cancer.

This edition of our newsletter will provide an update on our in-person meeting at the 2019 ARCC Conference, as well as give you some more information about our new research team member, Mina Tadrous. As usual, we will also provide updates about current work. Should you have any questions, comments, or feedback, please let us know by emailing WeiFang.Dai@cancercare.on.ca.





CANREVALUE AT CADTH 2019



In-person meeting summary:

Morning Session: Opening Presentation	
<p>Proceedings:</p> 	<ul style="list-style-type: none"> Welcome & Introductions by Dr. Kelvin Chan Opening Remarks from Dr. Michael Sherar, Principle Knowledge User Case study presentation by Dr. Kelvin Chan: <i>Real-world study of bevacizumab for metastatic colorectal cancer in BC, SK, and ON</i>
<p>Key messages:</p>	<ul style="list-style-type: none"> The overall purpose of CanREValue Collaboration is to generate and use RWE for cancer drug funding decisions. Previous completed real-world study (funded by CPAC) will be used to guide the refinement and assessment of the framework.
Morning Session: Policy Working Group & Grant Members	
<p>Proceedings:</p> 	<ul style="list-style-type: none"> Alex Chambers (Chair, RWE Reassessment & Uptake WG), led the mock reassessment exercise to help assess the draft reassessment process. Evidence from the case study (presented during opening presentation) were presented by: <ul style="list-style-type: none"> Dr. Marianne Taylor - clinical evidence Marc Geirnaert - PAG inputs Dr. Bryson Brown - patient inputs Dr. Craig Earle - economic evidence Attendees were assigned into one of four breakout groups to deliberate upon the evidence. Alex Chambers led the debriefing session after attendees reconvened.
<p>Key learnings</p>	<ul style="list-style-type: none"> Clinical evidence: <ul style="list-style-type: none"> Real-world survival is modest and similar to trial; No overall safety concerns; Additional evidence such as ECOG, dose intensity, detailed outcome data are needed for deliberation; Critical appraisal of RWD is highly valued; Patient input: <ul style="list-style-type: none"> Bevacizumab aligns with patient values Additional evidence on quality of life, performance status, and caregiver inputs are required. More in-depth inputs from patients are also required. Economic evidence: <ul style="list-style-type: none"> Greater budget than expect; Drug is not considered cost effective. Additional evidence on quality adjusted life year is need. PAG input: <ul style="list-style-type: none"> Expenditure is different from forecast; biosimilars will affect reassessment; The evidence used for reassessment depends on the drug being assessed; need to account for the changing landscape and agreed upon a priori standards for RWE; Recommendation: groups were split between the following two recommendations: <ul style="list-style-type: none"> Status quo OR Revisit negotiation/funding criteria.
<p>Next steps:</p>	<ul style="list-style-type: none"> Refine the criteria for reassessment in each of the reassessment quadrants (clinical evidence, patient input, economic evidence, and PAG input). Refine the wording of the recommendation categories.
Morning Session: Policy Working Group & Grant Members	
<p>Proceedings:</p> 	<ul style="list-style-type: none"> Claire de Oliveira (Chair, Data WG) and Rinku Sutradhar (on behalf of the Methods WG) led a study protocol development session; aim to develop protocol for Objective 3 Members worked through the following sections of the study protocol: <ul style="list-style-type: none"> Data to identify study cohort Approaches to assign exposure status Baseline clinical and demographic variables available and required for study Outcome variables to be studied. Methods to address bias and balance cohorts
<p>Key deliverable</p>	<ul style="list-style-type: none"> Study protocol with inputs from each province.
<p>Next step</p>	<ul style="list-style-type: none"> Refine study protocol specific for each province.

In-person meeting summary:

Afternoon Session: Policy Working Group & Grant Members	
<p>Proceedings:</p> 	<ul style="list-style-type: none"> • Scott Gavura (Chair, RWE Planning and Drug Selection), led a session on the selection and prioritization of RWE projects. • Scott presented the latest version of draft selection framework, as well as the results from the most recent survey. • Guest Speaker, Dr. Francois Dionne, presented the background and application of multi-criteria decision analysis (MCDA). • After the presentation, Scott facilitated a discussion on the benefits and challenges of using MCDA for prioritization of RWE projects.
Key messages:	<ul style="list-style-type: none"> • Prioritization of the identified RWE projects needs both a deliberative approach and an analytical approach. • MCDA is a potential analytical approach to facilitate the prioritization of RWE projects.
Next step:	<ul style="list-style-type: none"> • Refine the prioritization process of RWE projects.
Afternoon Session: Data Working Group	
<p>Proceedings:</p> 	<ul style="list-style-type: none"> • Claire de Oliveira (Chair, Data WG), with facilitation from Jaclyn Beca, worked with members from each province to discuss how to initiate objective 3. • The discussion included: <ul style="list-style-type: none"> ○ Refining the study protocol specific to each province ○ REB applications ○ Data access process ○ Resourcing needs for conducting analysis
Next step:	<ul style="list-style-type: none"> • Initiate Objective 3 in the participating provinces: refine study protocol, applying for ethics approval, submitting paper work for access data, and hiring analysts.
Afternoon Session: Method Working Group	
<p>Proceedings:</p> 	<ul style="list-style-type: none"> • Rinku Sutradhar (on behalf of the Methods WG), with facilitation from Wanrudee Isaranuwatthai and Mina Tadrous, worked with methods experts to plan around the upcoming two manuscripts: <ul style="list-style-type: none"> ○ Paper 1: Outline different methods for conducting survival analysis and how they can be used for real-world analysis. ○ Paper 2: Develop a practical document for methods explored in paper 1 (which will include simulated dataset, codes, results, and interpretation) for a wider community who are interested in doing the analysis.
Next steps	<ul style="list-style-type: none"> • Add proposed methods for Objective 3 (propensity score matching, inverse probability weight, and disease risk score (and to be explored IV)). • Complete the manuscript draft for paper 1. • Develop the outline for paper 2 .
Closing presentation	
<p>Proceedings:</p> 	<ul style="list-style-type: none"> • The chair of each working group presented a brief summary on <ul style="list-style-type: none"> ○ Progress to date ○ Accomplishments of the day ○ Next steps for their working group

ARCC CONFERENCE & IN-PERSON MEETING 2019



Working Group Updates and Next Steps:

Working Group	Updates & Next Steps
RWE Planning and Drug Selection	<p>Update</p> <ul style="list-style-type: none"> Members responded to survey 5 on refining identification criteria and feasibility assessment Members provided inputs to the draft progress report <p>Next Step:</p> <ul style="list-style-type: none"> Develop the prioritization process which includes deliberative and analytical components
RWE Data	<p>Update</p> <ul style="list-style-type: none"> Members assessed the data availability to conduct RWE for the candidate drugs Members provided inputs to the draft data report <p>Next Steps:</p> <ul style="list-style-type: none"> Refine the study protocol specific to each province, submit REB application, and submit paper work for data access
RWE Method	<p>Update</p> <ul style="list-style-type: none"> Members provided inputs on paper 1 <p>Next Steps:</p> <ul style="list-style-type: none"> Refine the study protocol specific to methods to be used Complete manuscript draft for overview of methods for real-world analysis of survival outcome (paper 1) Start an outline for a practical document on methods in paper 1
RWE Uptake and Reassessment	<p>Update</p> <ul style="list-style-type: none"> Members provided inputs on draft reassessment process <p>Next Step:</p> <ul style="list-style-type: none"> Refine reassessment process based on the mock reassessment learnings
Stakeholder Engagement	<p>Next Steps:</p> <ul style="list-style-type: none"> Working with stakeholders to make them aware of our work to date and get them ready for the actual engagement process Developing a larger stakeholder engagement strategy and framework (Summer) for launch in the Fall

Member Spotlight – Mina Tadrous

We want to introduce you to Mina Tadrous, who has joined the CanREValue Core Team. In addition to helping with the CanREValue Collaboration, Mina works as a scientist at Women's College. We sat down with Mina to learn a bit more about him:

Q: What is your educational background and how did it lead to an interest in RWE?

I completed my Doctor of Pharmacy (PharmD) at the Albany College of Pharmacy in 2008 and a 2-year Residency and Masters in Health Outcomes and Policy Research at the University of Tennessee and St. Jude's Childrens Research Hospital in 2010. I subsequently completed my PhD training at the University of Toronto in 2015, where I specialized in pharmacoepidemiology with a particular focus on novel methodological applications in the use of large administrative databases and network meta-analysis. My passion for working in real-world evidence began to grow with my work as a research associate with the Ontario Drug Policy Research Network (ODPRN). The ODPRN is a government funded group of researchers who respond rapidly to the needs of policymakers on a provincial and national level. During my time with the ODPRN I worked closely with other researchers and decision-makers to use real-world data to inform numerous drug policy decisions on both the provincial and national level. I saw first-hand the impact RWE can have.



Q: What aspect of the CanREValue project are you the most excited to work on? It is a tie between the methods and the engagement. My nerdy side cannot help but get really excited for the methods work. During my PhD I did some work in the area of propensity Scores and Disease Risk Scores, so I am excited to leverage those skills in the methods working group and learn from the other members of the group. I also look forward to helping the team engage key stakeholders with all the amazing work being done to ensure strong dissemination and uptake of this work.

Q: What are some of your personal hobbies? Does RWE count? – I have a real passion for sports with my two favorites being football and basketball. I hung up the football cleats long ago but I still attempt (it really does look like an attempt) to play basketball often. I also love to talk food and travel- if you ever need a food tour of Toronto let me know (back-up career if this research thing doesn't work out).

Q: How can we reach you?

You can email me at mina.tadrous@wchospital.ca or follow me on twitter @mina__T

Next Steps

- ❖ Initiate Objective 3 real-world study in different provinces
- ❖ Teleconferences and surveys in policy working groups to refine framework