

Mapping Canadian Provincial Data Assets to Conduct Real-World Studies on Cancer Drugs

CanREValue Collaboration Data Working Group
Interim Report 2019

CanREValue Collaboration

Overview of the CanREValue Collaboration

The Canadian Real-world Evidence for Value in Cancer (CanREValue) Collaboration is a pan-Canadian, multi-stakeholder initiative established in 2017 under a Canadian Institutes of Health Research Partnerships for Health System Improvement Grant. Led by Dr. Kelvin Chan, the central project is titled “Developing a framework for the incorporation of real-world evidence (RWE) into cancer drug funding decisions in Canada”. The goal of the project is to develop and test a framework for the generation and use of RWE for cancer drugs to facilitate:

- I. Reassessment of cancer drugs by recommendation-makers; and
- II. Refinement of funding decisions, renegotiation of drug prices, or disinvestment as appropriate by decision-makers/payers across Canada.

Once developed, the framework could potentially be used to support evidence-based policy reform, pricing, and reallocation of funding from low- to high-value settings. In addition, the framework could facilitate the accountability and sustainability of the cancer system if used by the provinces and by areas of the healthcare system.

Working Groups

As part of developing the framework, five working groups (WGs) have been established to develop the framework (Figure 1). To ensure that the framework can support the needs of various stakeholders, the CanREValue Collaboration brought together a broad range of stakeholders from across different organizations and agencies (Figure 2). The WGs and their key deliverables are listed below.

- ***RWE planning and drug selection WG:*** Recommend criteria to identify and prioritize potential drug candidates for real-world evidence studies and advise on the necessary provincial infrastructure needed for the conduct of RWE.
- ***RWE Data WG:*** Recommend strategies for data access and provide advice on harmonization of data elements relevant for RWE studies across provinces.
- ***RWE Methods WG:*** Recommend methods to analyze real-world data with methodological rigor.
- ***RWE Reassessment and Uptake WG:*** Develop a process to incorporate RWE for HTA reassessment and advise on strategies to incorporate RWE results into policy-making.
- ***RWE Engagement WG:*** Establish mechanisms to ensure that key stakeholders from across all relevant jurisdictions can provide feedback and input into the developments of each WGs.

Figure 1: CanREValue Collaboration Working Group (WG) Structure

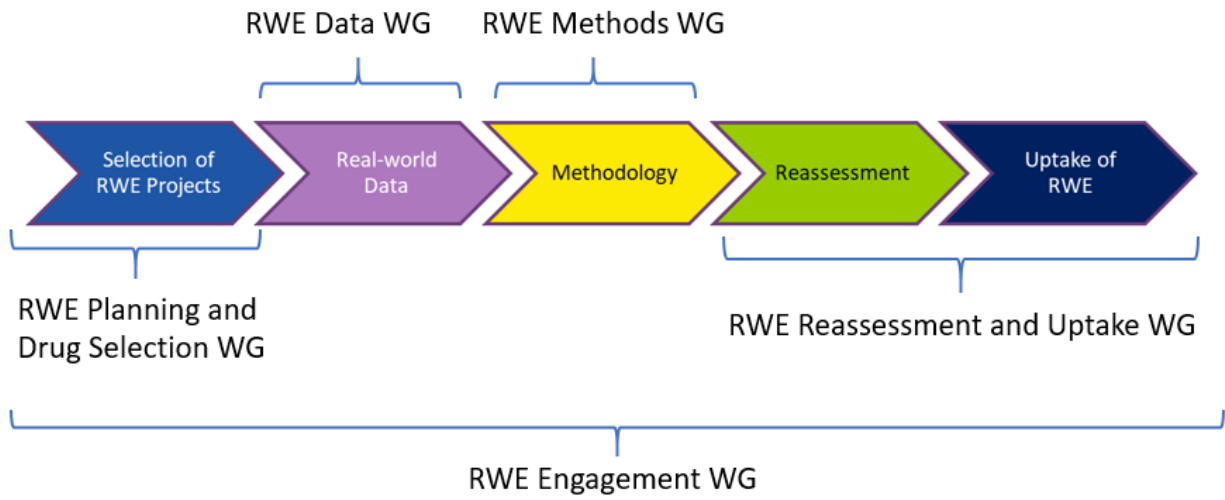
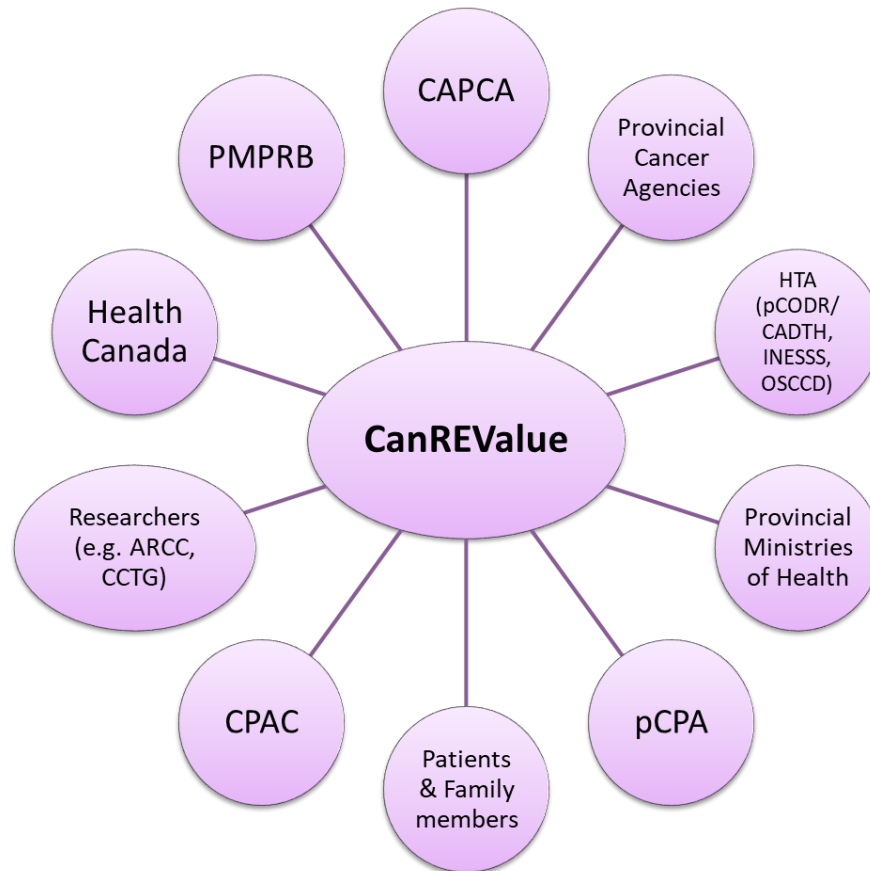


Figure 2: CanREValue Collaboration Stakeholders



CanREValue Collaboration: Data Working Group Interim Report

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Executive Summary

The generation of robust real-world evidence (RWE) depends heavily on the availability and quality of real-world data (RWD). In Canada, provinces routinely collect patient-level data during patient care. These RWD can be used to generate valuable RWE to inform clinical care and healthcare policy. This report describes the CanREValue Data Working Group's efforts to map the currently available population-based provincial data assets in Canada. The aim is to provide a high-level assessment of databases and data elements relevant to the conduct of cancer-specific RWE studies in each province.

Section I: This section identifies the key data custodians in each province that holds and maintains databases required to conduct real-world analysis. Given our focus is on publicly funded cancer drugs, descriptions of the funding model in each province are also included. The main findings include the following:

- Databases are often held by multiple data custodians, such as provincial ministries/departments of health and provincial cancer agencies. These organizations are typically the administrators of a particular healthcare treatment or service or associated funding.
- The funding model for cancer drugs often varies by provinces, especially with respect to the coverage of intravenous and oral cancer drugs.
- In some provinces, third-party organizations may also act as data custodians and can facilitate linkages between datasets.

Section II: This section focuses on the variables and data elements that would be commonly required to describe a cohort and conduct a real-world study. Data experts from each province reviewed their provincial databases to determine whether relevant data elements were available and linkable, along with any limitations in coverage and/or completeness of the data. From this asset review, we compiled two data tables:

- **The Expanded Cancer RWD table** consists of potentially relevant data elements for addressing a variety of RWE questions. The availability and linkability of the data elements varies between provinces.
- **The Essential Cancer RWD table** contains a subset of data elements from the Expanded Cancer RWD table. This data table lists variables required to identify a cohort and answer specific descriptive or comparative RWE questions. The variables included are broadly available across provinces.

Section III: This section outlines each province's assessment of their capability to conduct real-world analysis for different outcomes (e.g. effectiveness, safety). Additionally, the provinces also estimated their capacity to generate RWE based on resourcing. Our main findings are as follows:

- Canadian provinces differ in their capability to identify and evaluate different cancer treatment outcomes based on available data elements.
- Most provinces can conduct an RWE analysis on the outcomes they have data elements for within 6 – 12 months, if additional resourcing was provided.

Building upon the findings from this report, we have initiated RWE projects across Canada to assess the real-world outcomes of a funded cancer drug. We will iteratively update the data tables in this report based on the learnings from the RWE analyses. Through this iterative process, we will gain a fundamental understanding of the RWD assets that can be used to conduct RWE analysis.

Introduction

In Canada, provinces routinely collect patient-level data during patient care for administrative purposes. These real-world data (RWD) can be used to generate robust real-world evidence (RWE) that can inform clinical care and healthcare policy. In particular, RWE generated on funded cancer drugs can be used to monitor outcomes and revisit drug funding decisions. Given that the generation of robust RWE depends heavily on the availability and quality of RWD, it is critical to understand the current data assets available in Canada.

Overview of CanREValue Data Working Group

The CanREValue Data Working Group (WG) was established to explore the current state of data readiness for RWE analyses in Canada. The primary objective of the working group is to identify the availability and accessibility of RWD relevant for cancer-specific real-world studies across Canadian provinces.

Chaired by Dr. Claire de Oliveira, the working group consists of data experts/researchers from across the 10 Canadian provinces. During the first two years of the project (2017-2019), the WG held three teleconferences and met twice in-person to discuss the data elements necessary to conduct RWE studies. Through an iterative discussion, the WG members completed a data asset review in each of their provinces. The members compiled information on available databases, the status of the data elements maintained in the databases, and the capability of conducting RWE studies based on available data and resources.

Data Working Group Report:

In 2018, the Canadian Institute for Health Information (CIHI) released the pan-Canadian Oncology Drug Data Minimum Data Set report, which outlined a consistent data standard for collecting oncology drug data elements necessary to study oncology drugs.¹ The data elements listed by CIHI must be present to identify treatment exposure, patient demographic and diagnostic information. However, there may be more detailed information required to determine treatment patterns, conduct robust comparative analyses and assess a variety of outcomes, including linkage to additional databases beyond the scope of treatment data outlined by the CIHI report. Our report complements the previous work described in the CIHI report by providing additional information on data holders and data holdings, a broader list of data elements that are desired to conduct real-world studies and assessment of data availability across provinces.

This report presents the findings from the initial scoping assessment of data availability conducted by each provincial representative on the CanREValue Data WG. The first section of the report focuses on the data holdings in each province. Given the focus is on publicly funded cancer drugs, this section also outlines how cancer treatments are funded in each province to provide context and address coverage. The second section describes the data elements required to generate RWE and presents two data tables, which outlines the availability of these RWD elements by province. In the last section, we present assessments of capability and capacity to conduct real-world studies by province.

Section I: Provincial data custodians & databases

This section presents provincial data custodians and the databases they maintain or hold that are available to conduct cancer-specific RWE analyses. While the focus is on cancer-related databases, we also present non-cancer databases because they capture variables integral to conducting a robust RWE study. Given that we are interested in conducting population-based RWE studies on funded cancer drugs, we have focused on the databases that are maintained or held by public organizations.

Since we focus on conducting RWE on publicly funded cancer drugs, we also present the cancer drug funding model in each province. In general, eligible patients can access funded cancer drugs listed on the public formularies through the provincial drug reimbursement programs. Some provinces have one provincial funding program for cancer drugs, while other provinces have multiple provincial funding programs. In provinces with multiple provincial funding programs, they may differ based on route of administration or distribution setting and criteria for eligibility.

This section of the report is divided into two parts. The first part is a summary of the main findings. The second part describes the funding model and the main data custodians for each province. For details on each of the databases, please see Appendix Section 1.

Part 1: Summary of Main Findings

The CanREValue Data WG identified ninety-six databases across Canada. Provinces held on average 9 (range: 8 – 12) distinct databases containing data elements relevant for cancer-specific RWE analysis. In most provinces, databases are held by multiple data custodians, which include Ministries/Departments of Health (MoH/DoH) and provincial cancer agencies. In most provinces, cancer treatment is organized through provincial cancer agencies, which also maintain population-based cancer-related databases, such as the provincial cancer registry. In other provinces, the MoH/DoH maintains databases on all healthcare treatments (cancer and non-cancer) and services administered through provincial health insurance plans.

In most provinces, the MoH/DoH works with CIHI to capture data on hospitalizations through the Discharge Abstract Databases (DAD), and data on emergency department visits through the National Ambulatory Care Reporting Systems (NACRS). The level of reporting to CIHI varies by province and over time. All provinces, with the exception of Québec, fully report to the DAD; however, only Ontario and Alberta fully report to NACRS.

In some provinces, there are also third-party organizations (e.g. ICES in Ontario) designated as data custodians. These organization have been granted privacy authority to access and link provincial demographic and health-related databases for research and evaluation.

Part 2: Provincial Data Holdings and Cancer Funding Models

British Columbia (BC):

BC Cancer is the provincial cancer agency that administers funding for systemic therapies for cancer treatment through the Provincial Systemic Therapy Program (PSTP)^{2,3}. PSTP maintains a Benefit Drug List of all funded drugs and approved treatment protocols⁴, and includes all approved cancer therapies, regardless of route of administration or treating facility, including intravenous drugs delivered in hospital or ambulatory clinics, and outpatient oral/take-home drugs³. Supportive care medications are not covered through the PSTP². All patients with a registered cancer diagnosis enrolled in the BC Ministry of Health's Medical Services Plan (MSP) are eligible for the program². For many newly-funded drugs or indications, coverage is also contingent on the approval of a Compassionate Access Program application to verify the patient's clinical eligibility³. The full cost of benefit drugs is borne by BC Cancer². The cost of drugs for patients treated at Community Oncology Network sites, outside BC Cancer's regional cancer centres, is submitted for reimbursement by the treating facility³.

The main data custodians are BC Cancer, the BC Ministry of Health, and BC Vital Statistics Agency. BC Cancer holds the BC Cancer Registry, BC PSTP database, BC Cancer Radiotherapy database, BC Cancer Surgery database, and BC Cancer CAIS Scheduling database. The BC Ministry of Health holds the MSP registration database, MSP payment information file, PharmaNet database, Home and Community Care database, Discharge Abstract database, and National Ambulatory Care Reporting System database. The BC Vital Statistics Agency holds the Vital Statistics Death file which can be accessed via Population Data BC. The BC Cancer data holdings can be accessed internally within BC Cancer, or linked to BC Ministry of Health data and de-identified for research purposes via Population Data BC⁵.

Alberta (AB):

Cancer care in Alberta is largely managed and governed under the auspices of CancerControl Alberta, which represents a distinct branch of Alberta Health Services, (AHS), the province's sole health authority⁶. Decisions regarding the public funding of cancer drugs, for both intravenous and oral agents, are mainly based on recommendations from the Cancer Drugs Evaluation committee⁶. The delivery of these drugs is operationalized in 17 cancer centres across the province⁶. Currently, there are two tertiary, four regional, and eleven community cancer sites in Alberta. Cancer drugs covered by AHS are provided to eligible individuals in Alberta through the Outpatient Cancer Drug Benefit Program (OCDBP)⁷. Individuals are eligible to receive treatment with either intravenous or oral cancer drugs if they are Alberta residents, have a valid Alberta health card, and meet the therapeutic eligibility guidelines set out by the appropriate provincial tumour teams⁷.

The main custodians are AHS and Service Alberta. Alberta Health Services holds both cancer-related and non-cancer related databases including the Alberta Cancer Registry, Oncology-Specific Clinical Information System, Pharmaceutical Information Network, Alberta Blue Cross Claims, Population Registry, Practitioner Claims, Discharge Abstract Database, National Ambulatory Care Reporting System database, and Alberta Continuing Care Information System. Service Alberta holds the vital statistics files that can be accessed for birth and death dates. When conducting RWE studies in Alberta, these databases can be accessed via AHS⁸.

Saskatchewan (SK):

The Saskatchewan Cancer Agency (SCA) administers cancer treatments for patients through funding from the government of Saskatchewan⁹. The SCA drug formulary provides a list of anti-cancer drugs and some supportive drugs provided free of charge for eligible patients with a valid Saskatchewan health card and that are registered with SCA^{9, 10}. This list includes both oral and intravenously administered drugs. All formulary cancer drugs provided on an outpatient basis are dispensed by Cancer Center pharmacies located in the Allan Blair Cancer Centre (Regina) or the Saskatoon Cancer Centre. This includes cancer drugs administered at the two tertiary cancer centers and by the Community Oncology Program of Saskatchewan centres¹⁰. All formulary cancer drugs, injectable or oral cancer treatments are dispensed by Cancer Agency Pharmacies to the hospital for administration. Supportive care therapies, with a few exceptions (e.g., filgrastim, G-CSF), are generally provided by the hospital and not funded by the SCA¹⁰.

The main data custodians are the SCA and the Saskatchewan Ministry of Health. SCA database holdings include SK Cancer Registry, Pharmacy oncology database, Medical Oncology database and Radiation Oncology database. The Saskatchewan Ministry of Health holds Physician Claims database, Discharge Abstract database, National Ambulatory Care Reporting System database, and Continuing Care Reporting System. The SCA data holdings can be accessed internally. Data holdings from Saskatchewan Ministry of Health can also be accessed for research purposes through the SCA.

Manitoba (MB):

In Manitoba, intravenous and oral cancer drugs are administered by different programs. The provincial cancer agency, CancerCare Manitoba, administers intravenous cancer drug funding through the Provincial Oncology Drug Program (PODP)¹¹, which was created by The Ministry of Health, Seniors and Active Living in 2006¹¹. The program directly covers the full drug costs of all the approved intravenous cancer drugs and necessary support drugs administered in hospitals and outpatient cancer facilities across Manitoba¹¹. Oral cancer drugs are covered under the provincial Home Cancer Drug (HCD) Program¹². Created in 2012, the Home Care Drug Program is a publicly funded program of the Ministry of Health, Seniors and Active Living¹². The program directly covers the full costs of all approved oral cancer and supportive care drugs in Manitoba¹². Individuals qualify for both programs if they are residents of Manitoba and have a valid Manitoba health card¹². Cancer drug approval in Manitoba mirrors the national process of cancer drug approval, through the pan-Canadian Oncology Drug Review, and other national bodies, with input from the local Medication Management and Safety Committee.

The main data custodians are CancerCare Manitoba and the Ministry of Health, Seniors and Active Living. CancerCare Manitoba holds the PODP database, HCD database, Manitoba Cancer Registry database, and Radiation Oncology database. The Ministry of Health, Seniors and Active Living holds the Manitoba Health Insurance Plan database, Drug Program Information Network database, Medical Claims database, Discharge Abstract database, and National Ambulatory Care Reporting System database. The databases can be assessed internally through CancerCare Manitoba.

Ontario (ON):

In Ontario, funding for intravenous and oral cancer drugs are administered by different programs under the Ontario Public Drug Programs (OPDP) at the Ministry of Health (MOH). Intravenous cancer drug funding is administered by Cancer Care Ontario (CCO), the provincial cancer agency, on behalf of the MOH through the New Drug Funding Program (NDFP)¹³. The program directly covers the full drug cost of intravenous cancer drugs on its formulary that are administered at outpatient ambulatory clinics in hospitals and cancer centres in Ontario¹³. Individuals qualify for the NDFP if they are a resident of Ontario, have a valid Ontario health card, and meet clinical eligibility criteria for the specific funded intravenous cancer drugs and indications requested¹³. The Ontario Drug Benefit Program (ODB) at the MOH covers for eligible beneficiaries most of the cost of drugs dispensed in outpatient cancer or community pharmacies for take home use, such as orally administered cancer drugs¹⁴. People are eligible for the ODB program if they are Ontario residents with a valid health card, under the age of 25 (without health insurance coverage) or over the age of 65 years, on social assistance, residing in homes for special care and long-term care homes, receiving professional home care services, or registrants in the Trillium Drug program (subject to income criteria)¹⁴. Costs for take-home cancer drugs not listed on the ODB formulary may be covered, on a case-by-case basis, through the Exceptional Access Program (EAP)¹⁵. Finally, older systemic intravenous treatments administered in a hospital setting may also be paid for through hospital budgets or through CCO's Systemic Treatment – Quality Based Procedures (ST-QBP).

In Ontario, the main data custodians are CCO and the MOH. CCO maintains the NDFP database, along with the Activity Level Reporting database (capturing cancer-related activities from hospitals, including systemic treatment and ST-QBP data, radiation and surgery), the Ontario Cancer Registry, and Symptom Management database. The MOH maintains the Registered Persons Database insured persons population registry, Ontario Health Insurance Plan physician billings database, ODB claims database, and Home Care Database. These databases as well as the Discharge Abstract Database and National Ambulatory Care Reporting System database are housed and can be linked for research purposes at CCO and at ICES.

Québec (QB):

In Québec, the Public Prescription Drug Insurance Plan, administered by the Régie de l'assurance maladie du Québec (RAMQ) provides basic drug coverage for all Québécois¹⁶. Individuals are eligible if they do not have a private prescription drug insurance plan, are over the age 65, or require financial assistance¹⁶. Prescription drugs covered by RAMQ are listed on the List of Medications¹⁷. Many drugs used to treat cancer are approved for coverage only under certain conditions, as exceptional medications. These exceptional medications and their recognized indications for payment are included in the List of Medications under a separate appendix¹⁷.

The main data holders are RAMQ, the Ministère de la Santé et des Services sociaux du Québec, and Institut de la statistique du Québec. RAMQ database holdings include Fichier d'inscription des personnes assurées, Services rémunérés à l'acte, Fichier d'admissibilité au régime général d'assurance médicaments, and Services pharmaceutiques. In addition, RAMQ also hold certain Ministère de la Santé et des Services sociaux du Québec databases including Maintenance et exploitation des données pour l'étude de la clientèle hospitalière, Banque

de données communes des urgences, and Système d'information sur la clientèle et les services des CSSS - mission CLSC. Ministère de la Santé et des Services sociaux du Québec database holdings include Performance hospitalière, Fichier des tumeurs, and Registre québécois du cancer. Institut de la statistique du Québec holds the Fichier des décès which can be used as the vital statistics file. Data availability indicated here reflects access via the Institut national d'excellence en santé et services sociaux.

New Brunswick (NB):

In New Brunswick, injectable and oral cancer drugs are funded through different mechanisms. Injectable oncology drugs administered in hospitals and outpatient cancer treatment facilities are funded by the Regional Health Authorities (RHAs) for all residents who have a valid New Brunswick Medicare card and meet clinical eligibility criteria. The New Brunswick Department of Health provides funding to the RHAs for new injectable oncology drugs. Oral cancer drugs and supportive care medications are covered by the New Brunswick public drug plans for eligible beneficiaries that include seniors, clients of the Department of Social Development, nursing home residents and individuals who do not have public or private drug insurance. The New Brunswick Drug Plans Formulary lists the specific drugs, and any clinical eligibility criteria, that are covered for eligible beneficiaries.

The main data custodian is the New Brunswick Department of Health. Databases held there include the NB Cancer Treatment Access Repository, Citizen Database, NB Cancer Registry, NB Physician Billing database, NB Drug Plans Claims database, Drug Information System Database, NB Long-term care database, and Discharge Abstract Database.

Newfoundland and Labrador (NL):

In NL, the Newfoundland and Labrador Hospital Insurance Plan is a publically funded program that covers insured inpatient and outpatient services administered at hospital-based settings¹⁸. Eligibility for coverage under the Hospital Insurance Plan (HIP) is linked with eligibility for coverage under the Newfoundland and Labrador MCP¹⁹. All beneficiaries of the MCP are automatically entitled to coverage under the HIP¹⁹. Funding for cancer drugs in NL varies depending on whether the drug is intravenous and oral drugs are funded by two different programs. Intravenous cancer drugs are administered by the NL Cancer Care Program at regional centres and hospitals across the province. Each funded drug and indication has a set of specific eligibility criteria. Intravenous cancer drugs are fully funded for residents with valid Medical Care Plan (MCP) coverage who meet the clinical eligibility criteria for the requested drug. Individual requests for non-funded intravenous cancer drugs may be considered by the NL Cancer Care Program on a case-by-case basis. Oral cancer drugs are funded for residents through the Newfoundland and Labrador Prescription Drug Program (NLPDP) which provides financial assistance for the purchase of eligible prescription medications²⁰. People are automatically eligible for drug coverage NLPDP if they are residents of NL with a valid health card, and who are in receipt of income support benefits, Guaranteed Income Supplement payment or Old Age Security benefits, and for those diagnosed with Cystic Fibrosis or Growth Hormone Deficiency and meets medical criteria²¹. People may also be eligible dependent on their income or if they have high drug costs in relation to income²¹.

In NL, the main data holders include NL Cancer Care Program, NL Centre for Health Information, and the regional Health centers including Eastern Health, Central Health, Western Health, and Labrador Grenfell Health. The NL Cancer Care Program holds Medical Oncology database, Radiation Oncology database, Cancer Registry, Provincial Systemic Therapy database, and OPIS database. NL Center for Health Information holds databases including Pharmacy Network, NLPDP database, and Medical Care Plan Billing database. The health centres maintain their data in Meditech. These databases can also be accessed through Eastern Health.

Nova Scotia (NS):

Intravenous and oral cancer drugs are administered by the NS Health Authority's Cancer Care Program²². Nova Scotia Pharmacare provides residents of Nova Scotia assistance with the costs of drugs, including cancer drugs, listed in the Nova Scotia Formulary²³. The various assistance programs under the Nova Scotia Pharmacare entail different eligibility criteria²³. In February 14, 2018, Nova Scotia Health Authority's Cancer Care Program established the Take Home Care Drug Fund to provide assistance to patients requiring oral cancer treatment²⁴.

The main data custodian is NS Health Authority. Databases held by the NS Health Authority include NS Cancer Registry, OPIS, hospital pharmacy, and imaging systems. Additional databases, such as the NS Physicians Billings database, Discharge Abstracts Database, Seniors Pharmacare Program, and the Drug Information System, can be accessed through Health Data Nova Scotia at Dalhousie University.

Prince Edward Island (PEI):

In PEI, cancer drugs listed in the provincial formulary can be accessed from Health PEI through two channels²⁵. The first channel is through Pharmacare, which includes medications covered under one or more PEI Pharmacare programs which are routinely dispensed from community pharmacies. Eligible patients must be enrolled in the applicable Pharmacare drug program for which coverage is required. Specific medications may be covered under different Pharmacare drug programs. The formulary code for the corresponding program is listed within the Funding Status field. Coverage of listed medications only applies if the patient meets the funded eligibility criteria provided. Second, the Cancer Treatment Centre Formulary includes covered medications that are dispensed and administered at PEI oncology sites (Queen Elizabeth Hospital or Prince County Hospital) or other approved hospital sites. All patients with a valid PEI Health Card are automatically eligible to receive medications listed under this program at no cost to the patient. Coverage of listed medications only applies if the patient meets the funded eligibility criteria provided.

The main data holder in PEI is Health PEI. Health PEI holds databases including PEI Cancer Registry, Drug Information System, PEI Cancer Treatment Centre, Physician's billing System, Provincial Pharmacy, and Clinical Information System.

Section II: Data elements for conducting real-world studies

This section of the report describes the data elements required for the conduct of a real-world study. As a guide to the types of data required, we introduce the three main components of a real-world study: cohort creation, identifying baseline demographic and clinical characteristics for comparability and covariate adjustments, and outcomes to be studied. For each component, we list common and relevant variables that are used.

Building from the real-world study components from a previous RWE study conducted in Ontario, Saskatchewan, and British Columbia (funded by the Canadian Partnership Against Cancer), the CanREValue core team compiled a list of data elements required for RWE analysis. The data experts from each province were asked to identify the database that contains the variable, an assessment of whether the data element is available and linkable, and any limitations in coverage and/or completeness. The compiled data table from all provinces is the Expanded Cancer RWD Table (Table 1). At the 2019 in-person meeting, the CanREValue Data Working Group identified a list of variables that are essential to generate RWE and are available in all provinces. The purpose was to create a list of variables that are minimally necessary in order to conduct a real-world study. This compiled data table is the Essential Cancer RWD Table (Table 2).

This section of the report is divided into two parts. The first part is a summary of the components of a real-world study and the variables relevant for each component. The second part consists of details about the two data tables. For details on each data element, please see Appendix Section 2.

Part 1: Real-world Study Components:

To conduct a real-world study, researchers need to build an appropriate study cohort, identify potential demographic and clinical characteristics to describe the cohort and use as covariates to adjust for differences between groups, and identify the appropriate outcomes of interest.

Cohort Creation:

- Variables to identify the disease of interest: morphology, topography, behaviour, stage, date of diagnosis;
- Variables to identify treatments of interest: treatment received (drug, regimen/protocol), indication/line of therapy, intent of treatment, date of treatment, route of administration.

Demographic and Clinical Characteristics:

- Baseline demographic and clinical variables: age, sex, neighbourhood income level, rurality, comorbidity, performance status, prior treatments;
- Subsequent treatments: chemotherapy, radiation, cancer-directed surgery.

Outcomes

- (I) ***Clinical Effectiveness:*** When stakeholders are interested in assessing real-world effectiveness, survival analyses can be performed.
 - Overall survival: first date of treatment, date of death, study end date/date of last contact with the healthcare system

- Other time-to-event endpoints (if available): first date of treatment, date of event of interest (e.g., treatment discontinuation, progression etc.), study end date, date of last contact with the healthcare system
- (II) **Safety & Toxicity:** Real-world safety of a drug can be assessed by determining the occurrence of hospitalisations or emergency department visits during or following the treatment period.
 - Hospitalisations and/or emergency department visits: date of visit, reason for visit
- (III) **Cost-Effectiveness:** The real-world cost-effectiveness of a treatment can be determined using estimates from an effectiveness analysis combined with a costing analysis. Data required for effectiveness analyses are listed above. In order to conduct costing analyses, comprehensive data on the cost accrued by the patient are required.
 - Sources of cost data: systemic therapy drugs, radiotherapy, surgical treatment, hospitalizations, same-day surgeries, physician services, prescription drugs, home care, palliative care, continuing and long-term care (where available), ambulatory care (where available)
- (IV) **Budget Impact:** To undertake a budget impact from the payer's perspective, population treatment patterns and spending are required
 - Cost of drug, number of patients per year, height, weight, dose per patient, dose per cycle, cycles per patient, treatment duration, market size (number of patients eligible for treatment), and market share (% of patients receiving drug of interest)
- (V) **Patient Reported Outcomes:** When information from patients is collected in a setting that assesses their symptoms or quality of life, this information can complement the analysis above. For example, patient-reported quality of life utilities can be used to calculate quality adjusted life years (QALYs).
 - Patient-reported assessments of quality of life or symptoms

Part 2: Real-world Data elements:

Expanded Cancer RWD Table:

The Expanded Cancer RWD Table, presented in Table 1, is a data asset inventory on a generic list of variables relevant for the conduct of real-world studies. While some of the variables listed in Table 1 can be captured by one data element (e.g. gender), other variables are derived from multiple data elements (e.g. age at first treatment, which requires date of birth and treatment date). Details for each variable are listed in the description column.

This list of variables is developed from a previous population-based real-world evidence study conducted in British Columbia, Saskatchewan, and Ontario. There may be additional variables that are relevant for a specific drug or disease that are not listed (e.g. disease- or drug-specific biomarkers). These variables will need to be assessed on a case-by-case basis when undertaking a specific evaluation. Additionally, variables that are not

routinely collected or reported to population-based databases stored by public organizations are also currently not included from this list, but may be considered for future iterations.

While most provinces have data on patient demographics (e.g. age, sex) and cancer diagnosis related variables (e.g. morphology, topography), the availability and linkability of data on cancer treatment, clinical characteristics, and drug costs varies among provinces. Additional details regarding data elements can be found in Appendix Section 2.

Essential Cancer RWD Table:

The Essential Cancer RWD Table (Table 2) includes the minimally necessary data elements needed for real-world studies. The data elements listed in this table are available in all ten provinces. Additionally, when conducting an RWE analysis, these data elements are required for both descriptive and comparative analysis.

Table 1: Expanded Cancer RWD Table

Category	Variables	Description	BC	AB	SK	MB	ON	QB	NB	NS	NL	PEI
Cohort Creation: Identify disease of interests	Topography	ICD-O-3 Code from International Classification of Diseases to identify the part of the body affected by disease or the site of origin of the neoplasm						?				
	Morphology	ICD-O-3 Code from the morphology section of the International Classification of Diseases to identify the microscopic structure of cells, tissues, and organs						?				
	Behaviour	Reportable histological behaviour – the 5 th digit of reported histology, based on reported site						?				
	Date of diagnosis	Diagnosis date – the date of first diagnosis of the primary site of cancer										
Cohort Creation: Identify treatment of interest	Drug Identifier – IV	Identifies IV drug received by patient				✓			?	?		
	Drug Identifier – Oral	Identifies oral drug received by patient					✓			?		
	Treatment Indication	Identifies specific indication for use			?	✓	✓	?	?	?	✓	
	Intent of treatment	Adjuvant, curative, or palliative	✓	✓	✓	✓	✓		?	?	✓	✓
	Line of therapy	Line of therapy such as first-line setting	✓	✓	?	✓	✓		?	?	✓	✓
	Date of treatment administration	Date of treatment for particular drug – IV medication					✓		?	?		?
	Dispensing date	Dispensing date for particular drug - oral medication					✓	✓		?		
Demographic and Clinical Characteristics	Provincial Patient Identifier	Unique patient identifier										
	Sex	Patient Sex										
	Date of Birth	Date of birth										
	Age at first treatment	Age at first treatment is derived from date of birth and date of treatment										
	Rural/Urban residence	Use postal code to identify urban or rural residence										
	Neighbourhood Income Quintiles	Determined using the PFFC macro and postal code										
	Regional Health Authority	Health authority regions (if applicable)										N/A
	Charlson's Score	Co-morbidity measure derived from hospitalizations dates and reasons for admission						?	✓		?	?
	Adjusted Clinical Groups(ACG)	Co-morbidity measure using the John Hopkin's ACG system and derived from hospitalization dates, reasons for admission, physician visits, and ED visits	?						✓			

Category	Variables	Description	BC	AB	SK	MB	ON	QB	NB	NS	NL	PEI
	ECOG-Performance Status	Performance Status			✓	✓	✓			✓	✓	
	Palliative Performance Status	Performance Status			✓		✓			✓	✓	
	Radiation Use	Identifies patients who received radiation										
	Radiation – Dose/minutes per fraction	The dose of radiation delivered		?								
	Radiation – Intent	The intent of radiation treatment as determined by the radiation oncologist at the time of booking the planning/treatment visit. (e.g. adjuvant, curative)		?					✓		?	
	Radiation – visit date	Patient's visit date for radiation treatment		?								
	Surgical resection code	The CIHI CCP/CCI procedure code describing the procedure administered to the patient										
	Surgical resection date	Date of surgical intervention associated with CCP/CCI codes										
Clinical Effectiveness	Date of Death	Date of death										
	Date of last contact	Variable derived from dates of healthcare service utilization (e.g. discharge date, date of last treatment)										
Safety & Toxicity ¹	ED Visit - Date of registration	Date of registration to emergency department	?		✓	✓		?	?	?	?	
	ED Visit - Main Problem	Type of separation from the ambulatory care service	?		✓	✓		?	?	?		✓
	ED Visit - Visit disposition code	Most clinically significant diagnosis, condition, problem or circumstance	?		✓	✓		?		?		✓
	Hospital Visit - Date of admission	Date of admission to inpatient										
	Hospital Visit - Diagnosis codes or procedure codes	Status of the patient upon leaving the hospital										
	Hospital Visit - Discharge disposition	ICD diagnosis code and type (most-responsible diagnosis)										
Cost-effectiveness	Drug (IV) – total cost	Cost of dose administered to patient (unless calculated from total amount administered and unit cost)		?						?		
	Drug – reimbursed cost	Total cost of drug to a drug program, if different from total cost (i.e., if patient pays co-pay)		?					✓	?		?
	Drug (oral) – total cost	Total cost of dispensed drug (unless calculated from total amount dispensed and unit cost)		?						?		
	Drug – Dispensing fees	Total cost of drug dispensing fee to a drug program		?		✓				?		

¹ Definitions for ED and Hospital visits in the report and appendix are taken from Canadian Institute for Health Information.^{26,27}

Category	Variables	Description	BC	AB	SK	MB	ON	QB	NB	NS	NL	PEI
	Drug – Compounding fee	Total cost of drug compounding fee to a drug program		?					?	?		
	Physician fee – Billing code	Billing codes for physician service	✓	?						?		
	Physician fee – Amount paid	Amount paid for physician service	✓	?						?		
	Outpatient laboratory and imaging services – Billing code	Billing codes for service	✓	?						?	?	
	Outpatient laboratory and imaging services – Amount paid	Amount paid for service	✓	?						?	?	
	ED cost/resource intensity weight	Resource intensity weight (RIW) for Comprehensive Ambulatory Classification System case mix grouping of the visit. Cost of visit calculated by multiplying the patient visit's RIW by the cost per weighted case for the jurisdiction and year	✓	?						?	?	?
	Hospitalization cost/resource intensity weight	RIW (see above) for hospital admission case mix group grouping for the visit to calculate cost of hospitalization		?						?		
	Home Care	Cost associated with home care		?						?		
	Complex continuing care	Cost of complex continuing care		?	✓					?		?
Budget Impact	Doses dispensed – Days supplied	Estimated number of days supplied or amounts dispensed – oral medication					✓	✓	✓	?		
	Treatment dose given	Dose given to patient for IV medication		✓	✓	✓	✓		?	?	✓	
	Body Surface area	Patient's body surface area at treatment		✓	✓	✓	✓			?	✓	
	Height	Patient's height at treatment		✓	✓	✓	✓			?	✓	✓
	Weight	Patient's weight at treatment		✓	✓	✓	✓			?	✓	✓
Patient reported outcomes	Edmonton Symptom Assessment Score	Patient Reported Outcomes		✓	✓	✓				?	✓	

Note: While some of the variables listed in Table 1 can be captured by one data element (e.g. gender), other variables are derived from multiple data elements (e.g. age at first treatment). Details for each variable are listed in the description column.

Legend: ICD-O-3 = International Classification of Disease for Oncology third version; IV = Intravenous; ACG = Adjusted clinical group; ED = emergency department; ECOG = Eastern Cooperative Oncology Group; CIHI = Canadian Institute for Health Information; CCI = Canadian Classification of Health Interventions; CCP = Canadian Classification of diagnostic, therapeutic, and surgical procedure (CCP);

	Data available and linkable	?	Data availability and linkability to be determined after conducting RWE analysis
✓	Data available and linkable with caveats		Data not available or linkable

Table 2: Essential Cancer RWD Table

Data element	Description	Database	Purpose		
			Cohort	Covariate	Outcome
Provincial Patient ID	Unique patient identifier	All databases used	Y	Y	Y - linkage
Diagnosis Topography code	ICD-O-3 Code from International Classification of Diseases to identify the part of the body affected by disease or the site of origin of the neoplasm	Cancer Registry	Y		
Diagnosis Morphology code	ICD-O-3 Code from the morphology section of the International Classification of Diseases to identify the microscopic structure of cells, tissues, and organs	Cancer Registry	Y		
Date of diagnosis	Diagnosis date – the date of first diagnosis of the primary site of cancer	Cancer Registry	Y	Y	
Drug Identifier – Drug name/code/regimen/DIN	Drug name, regimen, or DIN (Health Canada identifier) to identify study drugs, prior and subsequent treatments	Treatment/claims	Y	Y	
Treatment date	Date of treatment for particular drug – IV medication	Treatment/claims	Y	Y	Y - Survival
Treatment dose given	Dose given to patient for IV medication	Treatment/claims			Y – Budget Impact
Drug (IV) - total cost	Cost of dose administered to patient (unless calculated from total amount administered and unit cost)	Treatment/claims			Y - Costs
Dispensing date	Dispensing date for particular drug - oral medication	Treatment/claims (outpatient prescriptions)	Y	Y	
Doses dispensed – Days supplied	Estimated number of days supplied or amounts dispensed – oral medication	Treatment/claims (outpatient prescriptions)			Y – Budget Impact
Drug (oral) – total cost	Total cost of dispensed drug (unless calculated from total amount dispensed and unit cost)	Treatment/claims (outpatient prescriptions)			Y - Costs
Sex/Gender	Patient sex	Population Registry	Y	Y	
Date of birth	Date of birth	Population Registry	Y	Y	
Postal code	To determine categories of neighbourhood income quintile, rurality	Population Registry, Census data (2016)		Y	
Date of death	Date of death	Population Registry, Vital Statistics	Y		Y - Survival
Surgical Intervention code CCP/CCI Code	The CIHI CCP/CCI procedure code describing the procedure administered to the patient	CIHI-DAD		Y	Y - Costs
Surgical resection date	Date of surgical intervention associated with CCP/CCI codes	CIHI-DAD	Y	Y	Y - Costs
Discharge date of hospitalisation	Discharge date	CIHI-DAD		Y	Y - Safety

Data element	Description	Database	Purpose		
			Cohort	Covariate	Outcome
Date of admission of hospitalisation	Date of admission to acute care	CIHI-DAD	Y	Y	Y - Safety
Visit disposition code	Status of the patient upon leaving the hospital	CIHI-DAD	Y	Y	Y - Safety
Main problem	ICD diagnosis code and type (most-responsible diagnosis)	CIHI-DAD	Y	Y	Y - Safety
Hospitalization/SDS - RIW	Resource intensity weight (RIW) to calculate cost	CIHI-DAD/NACRS			Y - Costs
Hospitalization/SDS – Cost per Weighted Case	Cost per weighted case	CIHI-DAD			Y - Costs
Physician Billing	Physician billing code (or amount paid)	Physician billings database			Y - Costs
Physician Service date	Date of physician visit	Physician billings database			Y - Costs
Radiation Use	Identifies patients who received radiation	Radiation database		Y	Y - Costs
Radiation - Intent	The intention of radiation treatment as determined by the radiation oncologist	Radiation database			Y - Costs
Radiation - visit date	The patient's visit date	Radiation database	Y	Y	Y - Costs

Note: The first two columns list the data elements and a brief description of each data elements. The third column provides the type of database(s) that the data elements may be located in. The fourth, fifth, and sixth columns provide information on what the variable may be used for among cohort creation, demographic or clinical covariate, or outcome definition. 'Y' dictates that the variable will be used for purpose listed in the column header.

Legend: DIN = Drug Identification Number; ICD-O-3 = International Classification of Disease for Oncology third version; IV = Intravenous; ACG = Adjusted clinical group; ED = emergency department; ECOG = Eastern Cooperative Oncology Group; CIHI = Canadian Institute for Health Information; CCI = Canadian Classification of Health Interventions; CCP = Canadian Classification of diagnostic, therapeutic, and surgical procedure (CCP); DAD = Discharge Abstract Database; NACRS = National Ambulatory Care Reporting System;

Section III: Provincial capability and capacity assessment

This section outlines the capability and capacity assessment to conduct RWE studies by each province. Data experts from each province were asked to conduct the assessments. First, provinces were asked to examine the capability to conduct an RWE analysis on different types of outcomes (e.g. effectiveness) based on the available data elements. Second, we asked the provinces to assess the anticipated time required to perform certain each step of the analysis based on currently available resources and based on dedicated personnel and funding.

Capability Assessment:

Data experts were asked to evaluate the capability of conducting an RWE analysis on the different outcomes based on the currently available data elements. Given differences in funding models and data holdings in some provinces based on setting, we asked the provincial data experts to conduct this assessment for both intravenous and oral drugs. A province's capability to conduct a RWE project based on currently available data depends on the outcome of interest and the study drugs being evaluated.

Table 3: Capability assessment for conducting a comparative analysis on intravenous cancer drugs

Outcomes	BC	AB	SK	MB	ON	QB	NB	NS	NFL	PEI
Effectiveness (survival)										
Safety & Toxicity										
Budget Impact (public payer's perspective)										
Cost-Effectiveness Analysis										
Patient reported outcomes, quality of life										

Table 4: Capability assessment for conducting a comparative analysis on oral drugs:

Outcomes	BC	AB	SK	MB	ON	QB	NB	NS	NFL	PEI
Effectiveness (survival)										
Safety & Toxicity										
Budget Impact (public payer's perspective)										
Cost-Effectiveness Analysis										
Patient reported outcomes, quality of life										

	Analysis can be completed
	Analysis can be completed with caveats
	Analysis cannot be completed

Capacity Assessment:

Data experts evaluated how long it would take to complete each step of the RWE analysis based on two scenarios: i) dedicated personnel and funding, and ii) currently available resources. With the currently available resources, few provinces are able to complete the analysis within 12 months.

Table 5: How long would it take to complete these analyses *if there is dedicated personnel and funding?* (i.e., based on data access issues only)

Analysis	BC	AB	SK	MB	ON	QB	NB	NS	NFL	PEI
Cohort creation										
Effectiveness (survival)										
Safety & Toxicity										
Budget Impact (public payer's perspective)										
Cost-Effectiveness Analysis										
Patient reported outcomes, quality of life										

Table 6: How long would it take to complete these analyses *based on currently available resources?*

Analysis	BC	AB	SK	MB	ON	QB	NB	NS	NFL	PEI
Cohort creation										
Effectiveness (survival)										
Safety & Toxicity										
Budget Impact (public payer's perspective)										
Cost-Effectiveness Analysis										
Patient reported outcomes, quality of life										

	Analysis can be completed within 3 to 6 months
	Analysis can be completed within 6 to 12 months
	Analysis cannot be completed or takes more than 12 months to complete

Next steps

The CanREValue Data WG will evaluate the accessibility and availability of these data elements by conducting RWE project on an intravenous and oral cancer drugs across the provinces. Based on our findings from conducting the real-world studies and the stakeholder consultations, we will iteratively update the contents of this report accordingly. A final report of the updated data holdings and elements will be released after the completion of our multi-province real-world evaluations of cancer drugs. Through this iterative process, we will build a fundamental understanding of the data assets that can be used to conduct RWE analysis. Additionally, this work will also be used to inform future work in conducting real-world evidence studies.

Stakeholder consultation

We welcome any stakeholder input regarding the contents of the interim Data Report. In particular, we have outlined three consultation questions below for your inputs.

To provide feedback and input on the interim Data Report, please use the [feedback template](#). Please submit your completed feedback by 5:00pm EDT on Friday, December 13th, 2019 to canrevalue@cc-arcc.ca.

Note: All feedback will be collated and our subsequent responses to the feedback will be made publicly available.

Consultation questions:

- I. Are you aware of any potentially relevant data elements that are not listed in the report? (please also note the database in which they are available if known)
- II. Are you aware of **privately/academically** held databases that could be used for RWE analysis?
- III. Please provide any additional comments on the content of the report.

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