

# Substance-Related Acute Toxicity Deaths in Canada from 2016 to 2017: Protocol for a Retrospective Chart Review Study of Coroner and Medical Examiner Files

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# Substance-Related Acute Toxicity Deaths in Canada from 2016 to 2017: Protocol for a Retrospective Chart Review Study of Coroner and Medical Examiner Files

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#### Abstract

**Background:** Canada continues to experience a national overdose crisis. While studies are available at the regional and provincial/territorial (P/T) levels, detailed national data regarding the burden and context of substance-related acute toxicity deaths is limited, particularly in sub-populations. In response to the overdose crisis, the Public Health Agency of Canada (PHAC), in collaboration with P/T ministries of health and chief coroner and chief medical examiner offices, has undertaken a national chart review study.

**Objective:** This study was conducted to describe and compare the characteristics of substance-related acute toxicity deaths that occurred in Canada between January 1, 2016, and December 31, 2017, including a description of those who have died, the substances involved, and the circumstances surrounding their death. This paper describes the study methodology in detail.

Methods: This retrospective population-based cross-sectional study involved the review of coroner and medical examiner files for deaths that met the study case definition. Data were collected on demographic and socioeconomic characteristics, medical and substance use history, proximal circumstances surrounding the death, and toxicology findings using a standardized data collection tool that underwent two pilot studies. Data abstractors underwent training, and adherence to data quality standards was assessed. Data were linked to national datasets to allow for the examination of area-level geographic and socioeconomic characteristics. Descriptive analyses will examine differences across subpopulations and with the general Canadian population, where possible. Latent class, spatiotemporal, qualitative, and premature death analyses are also planned. Where possible,

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analyses will be stratified by manner of death and sex.

**Results:** The study began in the summer of 2018 and abstraction was delayed due to the COVID-19 pandemic. All activities are expected to be completed by early 2024. A total of 9,414 coroner and medical examiner files met the study case definition. In general, core study variables, including geographic variables and substances contributing to death, had very good availability. Study variables related to the person's health, history of substance use, and events surrounding the acute toxicity event were available for most records. Socioeconomic variables and those describing socially constructed identities and potentially traumatic life events were mostly unavailable.

**Conclusions:** This study provides the most detailed national information on substance-related acute toxicity deaths in Canada to date and can serve as a pre-COVID-19 pandemic baseline for assessing the evolution of the overdose crisis. Results can inform policies and programs to address the overdose crisis, the development of common approaches to medicolegal death investigations, and future research activities. Clinical Trial: Not applicable

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# **Original Manuscript**

## **Protocol**

# Substance-Related Acute Toxicity Deaths in Canada from 2016 to 2017: Protocol for a Retrospective Chart Review Study of Coroner and Medical Examiner Files

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**Disclaimer**: The views expressed in this paper are those of the authors and not an official position of our institutions.

#### **Abstract**

**Background**: Canada continues to experience a national overdose crisis. While studies are available at the regional and provincial/territorial (P/T) levels, detailed national data regarding the burden and context of substance-related acute toxicity deaths is limited, particularly in sub-populations. In response to the overdose crisis, the Public Health Agency of Canada (PHAC), in collaboration with P/T ministries of health and Chief Coroner and Chief Medical Examiner offices, has undertaken a national chart review study.

**Objectives**: This study was conducted to describe and compare the characteristics of substance-related acute toxicity deaths that occurred in Canada between January 1, 2016, and December 31, 2017, including a description of those who have died, the substances involved, and the circumstances surrounding their death. This paper describes the study methodology in detail.

**Methods**: This retrospective population-based cross-sectional study involved the review of coroner and medical examiner files for deaths that met the study case definition. Data were collected on demographic and socioeconomic characteristics, medical and substance use history, proximal circumstances surrounding the death, and toxicology findings using a standardized data collection tool that underwent two pilot studies. Data abstractors underwent training and regular intra-rater reliability exercises with a fictitious death investigation file. Data quality was assessed based on the consistency of abstractor intra-rater reliability scores and the completeness of core variables and variables for key concepts. Data were linked to national datasets to allow for the examination of area-level geographic and socioeconomic characteristics. Descriptive analyses will examine differences across subpopulations and with the general Canadian population. Latent class, spatiotemporal, qualitative, and premature death analyses are also planned. Where possible, analyses will be stratified by manner of death and sex.

**Results**: The study began in the summer of 2018 and abstraction was delayed due to the COVID-19 pandemic. All activities are expected to be completed by early 2024. A total of 9,414 coroner and medical examiner files met the study case definition. Most abstractors (96%) met the established threshold for consistency throughout abstraction without need for remedial training. In general, core study variables, including geographic variables and substances contributing to death, had very good availability. Study variables related to the person's health, history of substance use, and events surrounding the acute toxicity event were available for most records. Socioeconomic variables and those describing socially constructed identities and potentially traumatic life events were mostly unavailable.

**Conclusions**: This study provides the most detailed national information on substance-related acute toxicity deaths in Canada to date and can serve as a pre-COVID-19 pandemic baseline for assessing the evolution of the overdose crisis. Results can inform policies and programs to address the overdose crisis, the development of common approaches to medicolegal death investigations, and future research activities.

## Introduction

## **Background**

Canada continues to experience a national overdose crisis, with a large burden of harms that are inequitably distributed throughout the population. Between January 2016 and June 2023, 40,642 people died from opioid toxicity alone, with associated mortality rates increasing over time [1]. Compared to other countries where data are available, the United States and Canada have seen rapid escalations and persistently high accidental acute toxicity mortality rates [2]. Information on the characteristics and circumstances of those who have died is critical to informing and evaluating strategies aimed at preventing harms.

High quality data are particularly needed at the national level to estimate burden and explore acute toxicity deaths among subpopulations, thereby enhancing our understanding of inequities and risk factors [3-6]. Although numerous studies and reports have described substance-related acute toxicity deaths at the regional, provincial, and territorial (P/T) levels [7-24], these used a variety of methods and case definitions, making it difficult to aggregate findings at the national level and compare them across P/Ts. Vital Statistics data from medical certificates of death are standardized and routinely collated at the national level in Canada [25]. While this is a common source for acute toxicity mortality data [26-27], it lacks detailed information on the characteristics of those who died and the specific substances that contributed to their deaths [6, 28-29].

In contrast, coroners and medical examiners (C/MEs) collect demographic, socioeconomic, health, and other risk factor data during death investigations, as well as information on the circumstances of the death and toxicological findings. Although national opioid toxicity mortality surveillance uses C/ME data reported by P/Ts to the Public Health Agency of Canada (PHAC), data are submitted at an aggregate-level for some P/Ts, with stratification by a small number of variables of interest [1]. As demonstrated in similar studies, additional valuable information can be gleaned from complete C/ME files [30-32].

## **Objectives**

Our study objective was to describe and compare the characteristics of substance-related acute toxicity deaths that occurred in Canada between January 1, 2016, and December 31, 2017, including a description of those who have died, the substances involved, and the circumstances surrounding their death. This paper describes the study methodology in detail, as well as the process for developing study material and findings regarding variable completion. It may be used as a reference document and to support the development of similar studies in the future.

## **Methods**

## **Study Design**

This retrospective population-based cross-sectional study involved a review of the C/ME files of people who died from a substance-related acute in Canada between January 1, 2016, and December 31, 2017. Upon identifying C/ME files that met the study case definition, data were abstracted using a standardized data collection tool.

#### Personnel

At the study outset, the PHAC study team assembled a co-investigator team to inform the development and roll-out of the study protocol, analysis planning, the interpretation of findings, and the production of knowledge translation products. The co-investigator team consisted of 14 people

with expertise in the C/ME system, death investigations, toxicology, pharmacology, social determinants of health, surveillance, epidemiology, harm reduction, Indigenous health, qualitative research, corrections, social services, medicine, P/T health authorities, the Federal Health Portfolio, public health in Canada, and lived experience with substance use. Co-investigators were also well connected with other substance-related surveillance, research, and prevention activities occurring in Canada.

In addition to the PHAC study and co-investigator teams, numerous data abstractors and students were recruited to support data collection, preparation, and analysis activities. Additional subject matter experts were invited to participate in analysis-specific project teams. For example, people with lived experience and people with expertise in youth and older adult health, suicide, emergency medicine, substance use, pain research, race and ethnicity studies, addictions medicine, and corrections have joined specific projects focused on those topics. Finally, a team of Indigenous researchers are working with co-investigators and project team members to develop products focused on First Nations, Métis, and Inuit people who died due to acute toxicity, with a focus on protective factors.

#### Literature Review

To inform the development of the study protocol, the data collection tool, and planned analyses, a literature review was conducted to identify knowledge gaps with respect to substance-related acute toxicity deaths at the national level in Canada. Collaborating with a librarian, a search strategy with inclusion and exclusion criteria and filters were developed. The MEDLINE, EMBASE, and SCOPUS databases were searched, and two team members reviewed titles and abstracts for relevance. A grey literature search was also conducted to identify relevant reports not published in peer-reviewed journals. Finally, additional articles were identified by reviewing the reference lists of relevant articles and reports. Information was abstracted using a standardized data collection tool and synthesized based on themes.

Although the review concentrated on the Canadian context, evidence from other countries was drawn on when limited Canadian data were available. The review focused primarily on substance use, pharmaceutical prescribing, risk factors, proximal circumstances, and severe harms related to substance use, including emergency department visits, hospitalizations, and deaths. Topics of interest identified by the literature review can be found in multimedia appendix 1.

#### Consultations

In addition to the literature review and expertise of the co-investigator team, the study's design and roll-out was informed by consultations with various groups, including Chief Coroners and Chief Medical Examiners (CC/CME), CC/CME office staff, PHAC public health officers, other Government of Canada departments (including Health Canada, Indigenous Services Canada), and staff within P/T Ministries of Health. The PHAC study team also consulted with National Indigenous Organizations during the planning and analysis phases of the study, as well as a Government of Canada council of people with lived and living experience during the analysis phase.

## **Study Population**

The target population for this study included all people who died in Canada in 2016 and 2017 due to an acute toxicity. The accessible population included such deaths for which i) a C/ME investigation was conducted, ii) the C/ME report was accessible and available for data abstraction, and iii) the death was identified as meeting the case definition. Given the resource intensity of conducting a nation-wide chart review study, only two years' worth of data were collected; 2016 and 2017 were

selected as these were the latest two years for which data were likely available when work on the study began in 2018.

#### **Case Definition**

The study case definition was any individual who died in Canada between January 1, 2016 and December 31, 2017 after an acute intoxication or toxicity resulting from the direct effects of the administration of exogenous substances where one or more the substances was a drug or alcohol. The study case definition was based on the national C/ME case definition for an apparent opioid-related death (as of March 1, 2017) [1]. "Acute" refers to adverse health effects that occur within a short time period (measured in minutes, hours, or days) following dosage [33]. Substances included alcohol; controlled, illegal, and prescription drugs; new psychoactive substances [34]; over-the-counter pharmaceutical products; and chemicals not intended for human use (such as non-pharmaceutical inhalants, industrial or household chemicals, or veterinary drugs). Inclusion and exclusion criteria are described in Table 1.

Table 1. Inclusion and exclusion criteria for our national chart review study of substance-related acute toxicity deaths.

#### **Inclusion criteria**

## Exclusion criteria

- The death occurred in the reporting P/T.
- The death occurred in the year 2016 or 2017.
- The investigation is either ongoing (open, preliminary, or active) or closed (certified or completed).
- The manner of death was deemed either an accident (unintentional), suicide (intentional), or undetermined.
- According to either the i) death certificate, ii) autopsy summary, or iii) C/ME report, an acute toxicity resulting from the direct effects of the administration of exogenous substances where one or more of the substances was a drug or alcohol was identified as having caused or contributed to the death.

The death was solely due to any of the following:

- chronic substance use (while people who died only due to the effects of chronic substance use would be excluded from this study, people who experienced chronic substance use but died due to acute toxicity would be included)
- medical assistance in dying
- palliative or comfort care
- homicide
- occupational exposure
- trauma where an intoxicant contributed to the circumstances of the injury (for example, a death due to a motor vehicle collision involving a driver impaired by an intoxicant)
- other adverse drug effects (for example, anaphylactic shock)
- acute toxicity due to products of combustion (for example, carbon monoxide, carbon dioxide, sulfur dioxide, and nitrogen oxides)

#### **Data Sources**

Legislation exists in all Canadian P/Ts requiring that deaths believed to be the result of violence, accident, suicide, negligence, misconduct, or malpractice be reported to a C/ME. These acts also require that a C/ME investigates these deaths to establish the identity of the deceased; the date, time, and place of death; the circumstances under which the death occurred; the cause of death; and the manner of death. Case files generally include the C/ME's medical certificate of death, the C/ME's

summary report, toxicology testing results, an autopsy or external examination report (if performed), and continuation notes (file communication records). In addition, they may include a police report, an emergency medical service record, the decedent's recent medical history (the period differs across C/MEs and P/Ts), scene notes and photographs, and correspondence with individuals relevant to the case (for example, family doctors, other professionals who knew the person who died, etc.). Although there are similarities in how C/ME investigations are conducted across Canada, the information collected varies over time by P/T, the investigating C/ME, and the circumstances of the death [35].

The primary source of data for this study were physical and electronic C/ME files. While every effort was made to obtain complete information for every case, physical files were not always accessible, and the COVID-19 pandemic resulted in additional challenges to the review of case files. For all British Columbia cases and some Ontario cases, data were only obtained from electronic coroner databases and mapped to corresponding variables in the study data collection tool where variables were equivalent. Additional population size and area-level data were obtained from Statistics Canada's 2016 Census [36], Statistics Canada's Postal Code Conversion File Plus [37], Statistics Canada's Index of Remoteness [38], Statistic Canada's Canadian Index of Multiple Deprivation [39], and Environment and Climate Change Canada [40] to support specific analyses.

#### **Data Collection Tool**

Potential variables of interest were identified from i) the study's literature review (see multimedia appendix 1), ii) C/ME investigative tools already in use by P/Ts, and iii) consultations with key stakeholders. The usefulness, relevance to research questions, comparability with other studies, and privacy concerns of potential variables were considered prior to a variable's inclusion in the data collection tool. As one of the study goals was to report on data availability within C/ME files, variables of interest with low expected availability were not excluded. Data were collected on demographic, socioeconomic, and risk factors; drug, medical, and substance use history; proximal circumstances surrounding the death; and toxicology findings for each person who died (see multimedia appendix 2 for the variable list). Identifying variables, such as the name and address of the person who died, were only collected if requested by the CC/CME office for internal use and were not sent to the PHAC study team.

A standardized data collection tool was built using Microsoft Access (see multimedia appendix 3 for screenshots of the tool), and an accompanying detailed user manual and data dictionary were created to enhance data quality and consistency. The collection tool and accompanying material were pilot tested twice in six provinces and further refined prior to the official start of the study.

#### **Data Collection**

To facilitate data access and sharing between CC/CME office staff and the PHAC study team, 13 data sharing or research agreements were developed between PHAC and each P/T CC/CME office, as well as several P/T Ministries of Health.

Data collection was conducted by individuals approved by collaborators within each P/T's CC/CME office, including public health officers, CC/CME office staff, nurses, epidemiologists, health information analysts, and health sciences and epidemiology students. All abstractors completed a privacy course, received extensive standardized training on how to collect data from C/ME investigation files, and were given time to review the data collection tool, user manual, and data dictionary. Abstractors were also required to demonstrate their ability to abstract data using a fictitious test case file before data collection began.

Case identification was done using available information systems. Initial broad searches were conducted by CC/CME offices or data abstractors to identify anyone who could possibly meet the study case definition. Data abstractors then determined if each case met the case definition while reviewing the C/ME files. In offices where it was possible to identify potential cases based on an International Classification of Disease, 10<sup>th</sup> Revision (ICD-10) underlying cause of death code, relevant categories included X40 to X45, X47, and X49 (accidental poisoning); X60 to X65, X67, and X69 (intentional self-poisoning); and Y10-Y15, Y17, and Y19 (poisoning with undetermined intent) [41].

As part of the data collection process, abstractors were instructed to regularly run built-in queries to check data completion. This supported quality assurance activities and decreased the need to return to CC/CME offices for further data collection.

## Data Protection, Privacy, and Ethical Approval

Study data management activities were developed to ensure data confidentiality. All data collected for the study existed electronically in password protected datasets that were transferred to the PHAC study team via a secure data transfer method. Received data were stored in a restricted PHAC network folder accessible only to study staff responsible for data management or analysis. All study co-investigators and data abstractors were asked to sign confidentiality agreements.

To ensure confidentiality in knowledge translation products, random rounding to base three has been applied to the raw counts of all tables displaying results, counts less than 10 will be suppressed, and variable categories will be collapsed where appropriate. In random rounding to base three, values that are multiples of three do not change, and those that are not multiples of three have a two thirds chance of rounding to the nearest multiple of three and a one third chance of rounding to the second nearest multiple of three [42]. This will perturb the count to within two units of the true value. As individual counts, subtotals, and totals are independently rounded, they may not add up when summed. Percentages, which are calculated using the rounded values, also may not add up to 100%. All study products will be audited to ensure that the same cell value is rounded in the same direction across tables.

As the study was part of a time-limited, exploratory research activity, research ethics board review and approval was sought. The study protocol was reviewed and approved by the Health Canada/PHAC Research Ethics Board, the University of Manitoba Health Research Ethics Board, and the Newfoundland and Labrador Health Research Ethics Board. It also underwent privacy assessments by PHAC; the Manitoba Health, Seniors, and Active Living Health Information Privacy Committee; and the British Columbia Office of the Chief Information Officer.

## **Data Preparation**

Collected data underwent multiple stages of data preparation, including case confirmation, comment review, redundancy checks, and variable cleaning. In situations where abstractors were unsure if a case met the study case definition, they were asked to provide a non-identifying description of the situation which was shared with a subset of the co-investigator team for decision. Similarly, when abstractors were unsure of how to record information from a case file, they were instructed to leave detailed comments in the database explaining the issue. These comments were later reviewed by the PHAC study team and corresponding variables were adjusted as required.

Because the data collection tool had to allow abstractors to abstract data in a variety of formats, the

database contained redundant variables that captured the same concept in slightly different ways. The study team reviewed the logic of redundant variables to ensure that variables with missing information were completed with information from redundant variables where possible. For example, if a person was documented to have been enrolled in an opioid agonist treatment program, their medical history was updated to include a history of substance use disorder.

Finally, the dataset underwent extensive data cleaning activities, particularly for values reported in free text fields. These were reviewed by the study team to correct spelling and match with existing variable values missed by abstractors. For more complex variables, the entered values were categorized according to a framework to simplify future analyses (for example, specific medical conditions were categorized according to types of medical conditions relevant to acute toxicity). Finally, some free text variables were left 'as is' for future thematic analysis.

## **Data Quality Indicators**

## **Consistency of Data Collection**

To ensure that data were collected in a consistent manner across data abstractors and throughout the data collection period, abstractors were required to complete an intra-rater reliability (IaRR) exercise. After completing training activities and before beginning data collection, each abstractor was asked to abstract data from a fictitious death investigation file, and the abstracted data was compared to a gold standard. This was done again at the midpoint and at the end of data collection, allowing for the IaRR to be assessed at these points. Additional IaRR assessments were also conducted between any breaks in data collection, if required.

To develop the gold standard, study co-investigators and PHAC study team members created a fictitious C/ME test file. Next, several PHAC study team members not involved in data collection independently used the data collection tool to collect data from the C/ME test file. The data collected were reviewed by members of the co-investigator and PHAC study teams to identify inconsistencies in what was collected and to come to consensus regarding what should have been captured in the data collection tool's fields. Since the data collection tool includes hundreds of fields, it was not optimal to base IaRR measurements on all data variables. Instead, the IaRR measurements were based on a subset of variables that were deemed of critical importance, as well as variables for which data collection was inconsistent during the pilot phase.

As variables were mostly categorical, IaRR was measured using Cohen's kappa ( $\kappa$ ) which accounts for the extent of agreement possible, having controlled for consensus by chance [43]. In instances where variables were not categorical (for example, dates), the kappa was based on whether the abstracted fields were consistent with the gold standard. The abstracted field was considered consistent only if blank variables in the gold standard were also blank in the data abstracted during the IaRR exercise, or if the IaRR exercise data captured the same information in the same variable field as the gold standard. All other scenarios would deem the field to be discordant with the gold standard. This approach dichotomized non-nominal data, so that they could contribute to the kappa coefficient calculations.

The baseline measurement for each data abstractor was taken prior to starting data collection for the study. No specific feedback on their performance was provided as they were asked to abstract the same file again over the course of data collection for the IaRR assessments. Generally, a minimum value of 0.60 was expected for kappas calculated against the gold standard, as per the approach recommended by Landis and Koch [44]; values below this threshold resulted in remedial abstraction training (Table 2). IaRR kappa values calculated against previous timepoint measurements were

considered alongside the IaRR kappa values calculated against the gold standard to determine the need for remedial training at each timepoint. This was to ensure that any decreases to the kappa value were appropriately interpreted in cases where discordances between timepoints resulted from incorrect responses being changed to correct responses.

Table 2. How data abstractor intra-rater reliability kappa values were interpreted for our national chart review study of substance-related acute toxicity deaths.

Kappa value		
Test versus gold standard	Test between time points	Actions
Low (<0.60)	High (≥0.60)	Abstractor is consistent across time points, but accuracy is problematic. Remedial action is required.
High (≥0.60)	Low (<0.60)	Abstractor is exhibiting improved accuracy. Provided that that gold standard kappa is greater than 0.60, no remedial action is required.
Low (<0.60)	Low (<0.60)	Abstractor is not exhibiting acceptable accuracy. Further investigation to determine why IaRR kappa remains low and remedial action is required.
High (≥0.60)	High (≥0.60)	Abstractor exhibits consistent, high-quality abstraction. No remedial action is required.

## Data Completeness

The availability of information for core variables and a set of variables capturing key concepts in the data collection tool was used as an indicator of data completeness. For each data source, this was measured as the proportion of records missing information for each core variable and key concept.

## **Data Analysis**

The variables selected for analysis were based on hypothesized relationships with substance use, acute toxicity, and acute toxicity mortality, or as theoretical intervention points to prevent acute toxicity deaths (for example, contacts with the health care system). Descriptive statistics were used to compare subgroups among people who died of acute toxicity (within the dataset), as well as to compare people who died of acute toxicity with the general Canadian population. Data obtained through linkage to Statistics Canada's Postal Code Conversion File Plus [37] and the Canadian Index of Multiple Deprivation [39] based on the postal code or municipality of residence, acute toxicity event, and death will allow for the assessment of area-level geographic and socioeconomic characteristics.

Many of the study's variables have missing data since only information that was available in C/ME files was used for data abstraction. As cases with missing data will not be removed from analyses unless they were systematically not available for a P/T, most of the descriptive analyses will present minimum proportions or rates; that is, the minimum number of people who died of acute toxicity with a given characteristic. This is an important consideration for comparisons with the general population as proportions or rates from the study population that are lower than those observed in the general population may be due to missing data. The true value could be lower, equal to, or higher than the national statistic. However, if the study population's proportion or rate is higher than that of the general population, we expect that it is at least that high and may be higher. In situations where it is known that a variable was only available for select P/Ts, subnational analyses may be performed.

More complex analyses of the study dataset are also planned. These include using latent class analysis to identify subpopulations among those who died of acute toxicity, spatiotemporal analysis to determine if geographic and temporal clustering exists in the distribution of acute toxicity deaths, and a case-crossover analysis of weather patterns and acute toxicity deaths. Several free text variables will also be used for thematic qualitative analyses. Finally, data from the study will be compared with that of other sources of Canadian mortality data (national surveillance data on apparent opioid-related deaths and Vital Statistics data) [1, 25] to measure case ascertainment and premature mortality.

Where possible, analyses of the study dataset have been stratified by manner of death and used a sexand gender-based analysis plus approach to understand how intersectional identities, histories, and the distribution of resources contribute to acute toxicity deaths [45].

## Results

## **Study Timeline**

Work on the study began in the summer of 2018 and all activities are expected to be completed by 2024 (Table 3). The extended lag between the start of the study and the dissemination of findings is related to several factors. This ambitious project was the first research collaboration between the PHAC and all CC/CME offices across the country. As these were new partnerships, time was invested in developing data sharing agreements and seeking approvals from research ethics boards, privacy committees, and P/T officials. The nature of the study itself, a chart review, required significant personnel and time resources to review files, abstract, and prepare data, with each case file taking approximately 60 minutes (range: 30 to 100 minutes) to review. Finally, study progress was also impacted by the COVID-19 pandemic, which diverted resources and significantly interrupted data collection, particularly where abstractors were working with physical files in office locations.

Table 3. Study timeline for our national chart review study of substance-related acute toxicity deaths.

Phase	Timing		
Consultations, planning, data tool and	August 2018 to October 2019		
documentation development and piloting, and			
research approvals, including departmental,			
scientific, security, research ethics board, and			
privacy reviews			
Development of data sharing agreements with	February 2019 to March 2022		
CC/CME offices			
Abstractor training and data collection	March 2019 to October 2022		
Data preparation	October 2019 to November 2022		
Data analysis and knowledge translation			
Release of preliminary results [46,47]	June 2022 to September 2022		
National summary report [48]	December 2022		
Peer-reviewed publications [49-52]	January 2023 to December 2024		
Evaluation	May 2023 to March 2024		

#### **Available Files**

A total of 9,414 C/ME files met the case definition and were accessible for the study (Table 4). The records available from British Columbia included only deaths due to "street drugs" or diverted prescriptions that were accidental or had an undetermined manner of death. As such, data for people who experienced acute toxicity deaths by suicide or due solely to prescribed substances or alcohol

were not available. Based on a report released by the British Columbia Coroners Service, there were approximately 199 poisoning deaths due to suicide in 2016 and 2017 that may have met this study's case definition [53].

Due to COVID-19-related public health measures, the ability to abstract physical case files was limited, resulting in data being collected from electronic files or databases in two provinces. Altogether, 681 Ontario cases from 2017 (23% of all Ontario cases) were mapped from an electronic database, and 426 Quebec cases from 2017 (40% of all Quebec cases) were abstracted from electronic coroner reports rather than physical files.

Table 4. Study population size <sup>a</sup> and data sources by jurisdiction and year for our national chart review study of substance-related acute toxicity deaths.

Province or	2016	2017	Total	Data source(s)	
territory	deaths	deaths	deaths		
British Columbia	993	1,494	2,487	Electronic database	
b					
Alberta	807	951	1,758	Physical files	
Saskatchewan	123	123	246	Physical and electronic files	
Manitoba	180	198	378	Physical files (46 files were partially abstracted)	
Ontario	1,311	1,710	3,021	Physical files and electronic database (data for	
				681 cases from 2017 came from the electronic	
				database only)	
Quebec	534	537	1,068	Physical files for most, electronic coroner	
				reports for 426 2017 cases	
Newfoundland	30	42	75	Physical files	
and Labrador					
New Brunswick	66	63	126	Physical files	
Nova Scotia	84	99	183	Physical and electronic files	
Prince Edward	15	15	30	Physical files	
Island					
Yukon	sup	sup	21	Physical files	
Northwest	sup	sup	sup	Physical files	
Territories					
Nunavut	sup	sup	sup	Physical files	
Total	4,164	5,247	9,414		

<sup>&</sup>lt;sup>a</sup> To protect privacy, counts have been randomly rounded to base three and numbers less than 10 have been suppressed (sup). As counts have been randomly rounded to base 3, they may not add up when summed.

## **Data Quality Indicators**

## Consistency of Data Collection

Baseline measurements for the fictitious C/ME test file were within the established threshold for 96% of all abstractors, and IaRR measurements taken thereafter over the course of abstraction remained within that threshold for 96% of all abstractors. Abstractors that did not meet this threshold

<sup>&</sup>lt;sup>b</sup> Data from British Columbia were only available for people who experienced accidental or undetermined acute toxicity deaths involving "street drugs" or pharmaceutical substances not prescribed to them. As such, data for people who experienced acute toxicity deaths by suicide or due solely to prescribed substances or alcohol were not available.

received remedial training and were reassessed. All obtained satisfactory kappa values through this process, allowing them to start or resume abstraction.

## Availability of Data on Key Concepts

Information collected by our study from C/ME files was available when: i) it was systematically collected during death investigations, ii) it was collected during death investigations but not systematically, or iii) it was not specifically sought by the C/ME during death investigations but was serendipitously captured in the case file. As investigation protocols, forms, and records available to C/MEs varied by jurisdiction, the availability of information also varied. Where the data source was an electronic file or database, less information was often available, except for electronic files from Saskatchewan, which included scans of all paper documents included in the case file.

Core study variables had good availability overall and across data sources (Table 5). By using a combination of postal codes and municipalities, the study was able to collect the census subdivision of residence for 95% of people who died during the study period. Full toxicology report results were available for 91% of people who died but were unavailable for 434 Ontario 2017 records that were mapped from an electronic database where only partial toxicology results were available (5% of all people who died). Toxicology information was also unavailable in instances where there was decomposition of the person before they were found (<1% of cases) or a prolonged hospital stay prior to death, resulting in the unavailability of a blood sample from when they were admitted (<2% of cases).

In general, information on socioeconomic variables (including education, occupation, and industry), potentially traumatic life events, and socially constructed identities (such as gender (not shown), ethnicity, and race), were often unavailable. Conversely, variables related to the person's health, history of substance use, and events surrounding the acute toxicity event were available for most records. Some exceptions include if the person had an accessible family doctor (missing=69%), the apparent mode of substance use at the time of the acute toxicity event leading to death (missing=54%), and if Naloxone was administered (missing=55%).

Table 5. Availability of information for core variables and key concepts among 9,414 C/ME case files for our national chart review study of substance-related acute toxicity deaths.

Concept	Percent unknown or unavailable	Data sources with missing information for > 90% of records <sup>a</sup>
Core variables	3	
Age	0%	None
Sex	0%	None
Manner of death	0%	None
Date of death	0%	None
Residence census subdivision	5%	None
Residence postal code	23%	Quebec electronic files
Residence location type	11%	None
Acute toxicity event census subdivision	13%	None
Acute toxicity event postal code	19%	Quebec electronic files
Acute toxicity event location type	7%	None
Death census subdivision	1%	None
Death postal code	17%	Quebec electronic files
Death location type	1%	None

Concept	Percent unknown or unavailable	Data sources with missing information for > 90% of records <sup>a</sup>
Toxicology report available	9%	None
Specific substances contributing to death	9%	None
Classes of substances contributing to death	9%	None
Key concepts		
Race	56%	Partially abstracted Manitob cases, Quebec electronic files Nova Scotia
Ethnicity	91%	Alberta, Manitoba, Ontario electronic database, Quebec New Brunswick, Nova Scotia Prince Edward Island Newfoundland and Labrador Yukon
Who the person who died lived with	50%	British Columbia, Ontarion electronic database, Prince Edward Island
Education	96%	British Columbia, Alberta Saskatchewan, Manitoba Ontario, Quebec electroni files, New Brunswick, Princ Edward Island, Yukon
Income source	49%	British Columbia, Prince Edward Island
Occupation classification	75%	Saskatchewan, Quebe electronic files, Princ Edward Island
Industry classification	79%	Saskatchewan, Quebe electronic files, Princ Edward Island
Potentially traumatic events	58%	Prince Edward Island
Had an accessible family doctor	69%	British Columbia, Princ Edward Island
Contact with the health system in the year before death	23%	None
Medical history	29%	None
Mental health history	30%	None
Prescription history	48%	British Columbia
History of substance use	15%	None
Known substances used	39%	British Columbia
Frequency of substance use (excluding alcohol) in the year prior to death	44%	Partially abstracted Manitob cases, Ontario electroni database, Prince Edwar Island, Yukon
Evidence of a previous non-fatal acute	14%	None

Percent unknown or unavailable	Data sources with missing information for > 90% of records <sup>a</sup>
43%	Ontario electronic files
33%	British Columbia
54%	Partially abstracted Manitoba cases, Ontario electronic database
46%	British Columbia
45%	British Columbia
41%	None
23%	British Columbia
45%	Prince Edward Island
	unknown or unavailable 43% 33% 54% 46% 45% 41% 23%

<sup>&</sup>lt;sup>a</sup> This table excludes data from Nunavut and the Northwest Territories due to small numbers.

### **Discussion**

As Canada continues to grapple with an ongoing overdose crisis, there is an increased need for high quality data that can support clinicians, public health experts, and advocates in their efforts to refine interventions. This can be supported by relevant, comparable, and timely C/ME data.

Our study confirms that C/ME files are a rich source of information that is highly relevant to public health practitioners. Work has begun on knowledge translation products [46-52], including a summary report of findings from this study that provides insight into national trends over time and by geography, sociodemographic factors, health and substance use history, the circumstances of the acute toxicity event, and substances involved [48]. Improving the usefulness of C/ME files as data sources for acute toxicity mortality data will depend upon how Canadian P/Ts meet three broad challenges. First, C/MEs do not primarily collect data for the purpose of public health intervention, but rather to meet their investigation mandate needs. As illustrated in Table 5, the availability of variables of public health interest varies across P/Ts. Second, C/ME offices have different approaches to the collection, storage, and transfer of data. With respect to data infrastructure, some offices have electronic systems that are readily searched, and some keep mostly paper-based files. The electronic systems that do exist are not compatible with each other. Third, as C/MEs use classification systems and terminology that suit the needs of local internal and external stakeholders, systems and terms may not be comparable across P/Ts, necessitating resource-intensive studies such as the one described here to allow for comparable data.

Recognizing some of these challenges and opportunities, PHAC, all 13 Canadian CC/CME offices, and Statistics Canada established the CC/CME and Public Health Collaborative in 2021, with a mandate to support the development of common approaches to death investigations and data infrastructure requirements. The Collaborative has identified substance-related acute toxicity as one of its prioritized causes of death and will consider the knowledge gaps and lessons learned from this study in its development of core and minimum data elements to improve the comparability, usefulness, and accessibility of national mortality data. Increased knowledge transfer and collaboration across public health and CC/CME jurisdictions in the development and implementation of common practices in death investigations will enhance the availability of timely and comparable data for public health use.

The authors are aware of how critical timeliness is to public health practitioners and community members who work on interventions. This study took longer than anticipated, partly due to challenges encountered during the global COVID-19 pandemic as well as navigating legislative and administrative requirements aimed at ensuring good data governance across multiple departments within fourteen governments. We anticipate that future similar national studies and surveillance activities can now occur more efficiently using the pathways created for this study. While data collected by this study may no longer reflect current trends in acute toxicity deaths, they provide an important baseline early in Canada's overdose crisis that can be used to measure future progress.

#### Limitations

Though efforts were made to identify all C/ME files that met the study case definition, it is possible that some people who died of acute toxicity were not included in this study if i) their death was not reported to the C/ME office or ii) they were not identified as a potential case. Systematic differences in study data sources (Table 4), how data were abstracted, and data availability associated with differences in death investigation processes, death classification methods, and toxicology testing methods (Table 5) may result in an underestimation of burden and could bias findings. Extensive standardized training and documentation were provided to abstractors, all of whom underwent IaRR assessments throughout data collection. Nonetheless, as data from each case file was collected from a single abstractor, error and bias may have resulted from differences in how abstractors assessed if cases met eligibility requirements and abstracted data.

As most variables collected by our study had a non-trivial amount of missing data, study findings will be reported as minimum counts, proportions, and mortality rate estimates that likely underestimate the true population prevalence of reported characteristics. Results from variables with a high percentage of missing data should be interpreted with caution, particularly since the distribution of values where the information was known may not be the same as the distribution where information was unknown. The lack of information on demographic and socioeconomic variables and socially constructed identities (such as gender) will hinder our ability to apply a sexand gender-based analysis plus approach to our analyses, though efforts will be made to describe the distribution of people who died by sex as well as area-level characteristics where possible.

#### Conclusions

This study provides the most detailed national information on substance-related acute toxicity deaths in Canada to date. It is anticipated that results will allow for comparisons across P/Ts, provide evidence to inform programs and policies at all levels, inform the expansion of national surveillance activities on substance-related harms, supply evidence to inform the development of common approaches to medicolegal death investigations and routine post-mortem testing, and serve as a platform for future research activities. It also provides a baseline of acute toxicity mortality prior to the COVID-19 pandemic for assessing the evolution of the overdose crisis. Finally, the partnerships and processes initiated by this study have contributed to fruitful new collaborations between Canada's public health and C/ME communities.

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## **Data Availability**

The national chart review of coroner and medical examiner files dataset generated for the study is not publicly available due to provisions in the data sharing agreements with P/T data providers. The corresponding author can assist in directing inquiries about data access to the original data providers.

## **Author Contributions**

JR, BA, MB, SBE, JH, DH, BJ, GJ, FK, JL, RM, ER, and ES conceptualized and designed the study protocol and data collection tool. JR and AV were responsible for project administration and supervision. JR, TK, RM, ES, and AV participated in the acquisition of data. JR, TK, and AV curated and analyzed the data. JR, MB, TK, FK, DS, and AV drafted the manuscript, and all authors revised the paper. All authors have read and agreed to the published version of the manuscript.

### **Conflicts of Interest**

None declared.

#### **Abbreviations**

- C/ME: Coroner or medical examiner
- CC/CME: Chief Coroners and Chief Medical Examiners
- IaRR: Intra-rater reliability
- PHAC: Public Health Agency of Canada
- P/T: Provincial and/or territorial

## **Multimedia Appendices**

- 1. Multimedia appendix 1: Topics of interest identified during the literature review
- 2. Multimedia appendix 2: Variable list
- 3. Multimedia appendix 3: Database screenshots
- 4. Multimedia appendix 4: French version of this manuscript

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# **Supplementary Files**

## **Multimedia Appendixes**

Topics of interest identified during the literature review.

URL: http://asset.jmir.pub/assets/9e403549ba1c166bb6124b535909684a.docx

Variables collected for our national chart review study of substance-related acute toxicity deaths.

URL: http://asset.jmir.pub/assets/6ca8b9a0c9c73e83b471a1a088941cce.docx

Screenshots of the study's data collection tool.

URL: http://asset.jmir.pub/assets/c14fe678cdc21e534d5367294a6043f1.docx

French version of the protocol (version française du protocole).

URL: http://asset.jmir.pub/assets/c2dab56f5c1206136f9800de262fb775.docx