

**Protocol for population-based, sex-stratified cohort studies to understand the impact of concurrent traumatic brain injury and mental health and/or addictions on health system level outcomes**

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## Abstract

**Introduction.** Mental health disorders and/or addictions (MHA) are prevalent among survivors of traumatic brain injury (TBI). This protocol describes population-based, sex-stratified studies to determine the sex-specific impact of concurrent TBI and MHA diagnoses on the following problematic system level outcomes: (1) delayed discharge from acute care, (2) re-hospitalization, (3) repeat non-urgent emergency department (ED) visits, and (4) direct medical cost of publicly-funded health service use. **Methods and Analysis.** Patients with a TBI or MHA-related ED or acute care visit between April 1, 2012 and March 31, 2017 in Ontario, Canada, will be identified using codes from the International Classification of Diseases Version 10 in population-based health administrative data. Sex-specific descriptive analyses will be conducted to describe the sample of patients with only TBI, only MHA, and concurrent TBI and MHA at the time of healthcare encounter. Overall and sex-specific regression analyses will be conducted to (a) determine the impact of concurrent TBI and MHA on the health system level outcomes and (b) identify the predictors of these health system level outcomes among individuals with a concurrent TBI and MHA. **Ethics and Dissemination.** Research ethics approval will be obtained from Ontario Tech University and the University of Toronto. Fact sheets, reports, infographics, and peer-reviewed manuscripts will be generated; presentations will also be made at academic conferences and at ministerial departments, healthcare settings, and relevant consumer-led associations to reach a broad audience. Findings will provide policy-relevant data to direct resources and provide the right care in order to meet health service needs at the health system level. This protocol also provides the foundation for future research using and linking across multiple large population-based datasets to generate comprehensive and longitudinal sex-specific data on individuals with concurrent TBI and MHA.

Keywords: Brain Injuries; Mental Health; International Classification of Diseases; Population Health; Public Health; Substance-Related Disorders

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## Introduction

Traumatic brain injury (TBI), which includes concussions, has been defined as “an alteration in brain function, or other evidence of pathology, caused by an external force” (Menon et al., 2010, p. 1637). It is a global public health concern that has been estimated to affect 50 million individuals each year worldwide (James et al., 2019). Even a mild TBI can have a significant negative impact on functioning that may increase the risk for adverse mental

health outcomes (Whiteneck et al., 2016; Whiteneck et al., 2016). Research using population-based health administrative data found that patients with TBI were 182% more likely to have a mental health disorder and 313% more likely to experience substance abuse five-years prior to the TBI event, compared to individuals without TBI, matched by age, sex, income level, and rurality of residence (Mollayeva et al., 2019). At the population level, compared to individuals without TBI, those who reported

experiencing a TBI in their lifetime were at least 52% more likely to have elevated psychological distress, 100% more likely to use cannabis, 93% more likely to experience suicidal ideation, and 239% more likely to have attempted suicide (Ilie, Adlaf, et al., 2014; Ilie, Adlaf, et al., 2015; Ilie, Mann, et al., 2014; Ilie et al., 2016; Ilie, Mann, et al., 2015). More common types of mental health disorders experienced by survivors of TBI include depression, anxiety, post-traumatic stress disorder, and changes in personality (Koponen et al., 2011; Malec et al., 2019; Ouellet et al., 2018; Schwarzbald et al., 2008; Zaninotto et al., 2016; Zgaljardic et al., 2015).

Despite these alarming statistics on the co-occurrence of mental health disorders or addictions (MHA) and TBI, there is currently limited population-based data to understand the impact of concurrent TBI and MHA on health system level outcomes, such as delayed discharge from acute care, re-hospitalizations, and repeat non-urgent emergency department (ED) visits. These represent significant policy concerns because they are resource-intensive, associated with increased healthcare costs and reduced quality of healthcare, and negatively affect patients' outcomes (Baker et al., 2004; Everall et al., 2019; Little & Hirdes, 2015; Schwendimann et al., 2018). Current research on patients with TBI have found that those with a comorbid MHA are significantly more likely to experience re-hospitalization and delayed discharge (Chen et al., 2012; Saverino et al., 2016). However, these studies did not consider patients with MHA who have a comorbid TBI. Further, there is currently limited sex-stratified population-based data on the predictors of these problematic health system level outcomes among individuals with concurrent TBI and MHA. These findings are crucial to support appropriate and cost-effective healthcare planning.

This is a protocol for population-based cohort studies that will address the gaps identified above. Specifically, all patients with a TBI or MHA diagnosis code between April 1, 2012 and March 31, 2017 will be identified from population-based health administrative data in the province of Ontario in Canada, home to 39% of Canadians (Statistics Canada, 2018). The primary research objective will be to determine the sex-specific impact of concurrent TBI and MHA diagnoses on: (1) delayed discharge from acute care, (2) 30-day re-hospitalization, (3) repeat non-urgent emergency department (ED) visits, and (4) cost of publicly-funded health service use. A secondary research objective will be to identify the sex-specific determinants of these system level outcomes among individuals with concurrent TBI and MHA. Findings will provide comprehensive and policy-relevant data for decision-makers and healthcare administrators to direct resources to

provide the right care and meet health service needs at the health system level.

## Methods

### Sample

All individuals in Ontario, Canada, who used publicly funded ED or acute care services, who required same-day surgery, or who occupied a psychiatric bed between April 1, 2012 and March 31, 2017 will be identified from population-based health administrative data.

Patients with TBI will be identified using the following International Classification of Diseases Version 10 (ICD-10) codes: S02.0, S02.1, S02.3, S02.7, S02.9, S06, S04.0, and S07.1. Literature reviews have identified an association between these codes and TBI, and have been used extensively in Ontario to identify TBI from health administrative data (Chan et al., 2016; Chan et al., 2015; Ng et al., 2015). Patients with MHA will be identified using the following ICD-10 codes: F00-F99; these codes have also been used extensively to study MHA using health administrative data (Institute for Clinical Evaluative Sciences & Centre for Addiction and Mental Health, 2013; Lin et al., 2014). Given the publicly-funded nature of Ontario's health system, this study will include all patients with TBI or MHA diagnosis codes during the study period.

Patients will be further categorized into three groups based on their diagnosis codes at the time of the outcome event of interest (described below in *Variables*): (a) TBI only, defined as patients with TBI ICD-10 diagnosis code(s) at the time of outcome; (b) MHA only, defined as patients with MHA ICD-10 diagnosis code(s) at the time of outcome; and (c) TBI and MHA, defined as patients with both TBI and MHA ICD-10 diagnosis codes at the time of outcome.

### Data Sources

The following population-based health administrative data from Ontario will be used to develop the sample: (a) National Ambulatory Care Reporting System (NACRS) to identify patients who received ED or ambulatory care; (b) Discharge Abstract Database (DAD) to identify patients from all publicly-funded hospital records; (c) Same-Day Surgery (SDS) to identify patients who visited a hospital for a same day procedure; and (d) Ontario Mental Health Reporting System (OMHRS) to identify all patients with MHA from designated inpatient mental health beds.

Unique de-identified patient IDs will be used to identify patients with a TBI or MHA diagnosis code who used publicly-funded ED or acute care services, who required same-day surgery, or who occupied a psychiatric bed in the following population-based datasets: (a) Registered

Persons Database (RPDB) for sociodemographic information on the sample; (b) Ontario Health Insurance Plan (OHIP) to identify a history of TBI and MHA diagnosed at the physician's office; (c) National Rehabilitation Reporting System (NRS) to identify patients who used inpatient rehabilitation services; (d) Complex Care Reporting System (CCRS) to identify patients who used long term care homes or continuing care services in hospitals; and (e) Home Care Database (HCD) to identify patients who used homecare services. These datasets undergo routine data quality assessments (Canadian Institutes of Health Information, 2019, 2019, 2019, 2019, 2019; ICES, 2020) through the Canadian Institute for Health Information or ICES (formally Institute for Clinical Evaluative Sciences).

### **Variables**

Outcomes of interest are (a) ALC days, defined as days in which a patient is occupying an acute care bed but no longer requiring the intensity of acute care service (Black et al., 2011); (b) re-hospitalization, defined as re-admission to the hospital setting within 30-days of initial acute care discharge; (c) repeat non-urgent ED visits, defined as re-admission to the ED with a Canadian Triage and Acuity Score (CTAS) of 4 (less urgent) or 5 (non-urgent) (Ministry of Health and Long-Term Care, Emergency Health Services Branch n.d.); and (d) direct medical costs, defined as the total cost of publicly-funded health service within one-year of discharge from ED, acute care, inpatient mental health facility, or same-day surgery.

Covariates will be grouped using the taxonomy described by the Andersen Behavioural Model of Health Service Utilization, which has been widely used to assess determinants of health service use, and includes predisposing, need, and enabling factors (Babitsch et al., 2012).

Predisposing factors are those that existed prior to the TBI or MHA event that increase the likelihood of health service use, and will include: (a) sex, (b) age, and (c) patient group at the time of outcome (TBI only, MHA only, concurrent TBI and MHA).

Need factors are those that create a need for health service use, and will include: (a) prior TBI – yes vs. no, defined as the TBI diagnosis code in the physician's office, ED, or acute care settings prior to the outcome; (b) prior MHA – yes vs. no, defined as at least two visits within one year to a medical specialist for a MHA or MHA diagnosis codes in the ED, acute care, or inpatient mental health settings prior to the outcome; (c) TBI severity – mild, moderate, severe, and unknown (i.e., the ICD-10 code was not specific enough to determine injury severity), defined using the Abbreviated Injury Score (Brown & Herman,

2015); (d) cause of TBI – falls, motor vehicle collision, struck by/against an object, multiple causes, and other (Chang et al., 2014; Sutton et al., 2018); (e) resource utilization bands – non-user, healthy user, low morbidity, moderate morbidity, high morbidity, and very high morbidity, defined using the Johns Hopkins Adjusted Clinical Groups to measure the expected use of healthcare resources using data two years prior to the outcome (University of Manitoba, 2015); (f) length of stay (LOS), defined as the number of hours in the ED or number of days in the acute care setting; (g) special care days – yes vs. no, defined as days spent in the intensive care units; (h) number of visits to a general practitioner/family practitioner in the year prior to the outcome; and (i) number of visits to a psychiatrist in the year prior to the outcome.

Enabling factors are those that enable individuals to access health services, and will include: (a) fiscal year of discharge; (b) rural residence – yes vs. no, determined based on individual postal codes designated as 'rural' by the Canadian Postal Service; (c) number of beds per 1,000 residents in each local health network (responsible for planning, integrating, and funding healthcare in each local region); (d) continuity of care - <75% vs.  $\geq 75\%$ , defined as the proportion of primary care visits to the same primary care physician within two years prior to the outcome (Health Quality Ontario, 2020); (e) neighbourhood income quintile – 1 (lowest) to 5 (highest), as determined by the location of the patient's residence within dissemination areas ranked according to income; (f) marginalization index score – 1 (low level of marginalization) to 5 (high level of marginalization), derived using the Ontario Marginalization Index that measures four dimensions of marginalization (residential instability, material deprivation, dependency, and ethnic concentration) (Public Health Ontario, 2020); and (g) discharge disposition from ED or acute care – e.g., home, home with homecare, inpatient rehabilitation, complex continuing care, long-term care, death.

### **Statistical Analyses**

Sex-specific descriptive analyses will be conducted to describe the three patient groups (i.e., TBI only, MHA only, and TBI and MHA) for each outcome of interest. Overall and sex-specific multivariable regression analyses will be conducted to (a) determine the impact of concurrent TBI and MHA on system level outcomes and (b) identify the sex-specific determinants of system level outcomes among individuals with concurrent TBI and MHA. To determine the direct medical costs of publicly-funded health services, a unit cost or price per service will be applied to each encounter. Costs associated with shorter-term episodes (ED, acute care, same-day surgery, and inpatient rehabilitation) will be calculated using their resource intensity weights (i.e., how much resources were

used for each encounter) and the cost per weighted case; costs associated with longer-term episodes (i.e., complex continuing care/long-term care, mental health beds) will be calculated based on weighted days; and costs for visits/claims (i.e., physician services, homecare) will be calculated based on the cost for each visit/claim recorded directly in the dataset. This methodology has been used extensively by researchers in Ontario to determine direct medical costs (Wodchis et al., 2013).

### **Ethics and Dissemination**

Research ethics board approval will be obtained from Ontario Tech University and University of Toronto.

To maximize knowledge transfer and exchange, members of a Program Advisory Committee (PAC) from the Research Program entitled 'Integrating brain injury, mental health, and addictions', will be engaged (Chan et al., 2019). This PAC was established to promote collaboration with end-users to maximize uptake and relevance of research, and includes representatives from local and provincial brain injury and mental health organizations and individuals with lived experience. Fact sheets, reports, and infographics will be created and disseminated to members of the PAC. Peer-reviewed manuscripts will be published to encourage collaboration and sharing of research methods and outcomes with the international academic community. Presentations will be made at relevant conferences at the local, national, and international level, and in more ad hoc contexts including ministerial departments, healthcare settings, and relevant consumer-led associations, to ensure that our findings reach a broader audience.

A major strength of the cohort studies described in this protocol is the use of population-based data from a publicly-funded healthcare system where reporting of this data is mandatory. As such, these studies will be virtually free of sampling bias (i.e., all Ontarian residents, regardless of socioeconomic status, who use publicly funded health services will be captured). Second, all patients with a TBI or MHA diagnosis code during the study period will be included; by identifying patients with MHA, the cohort studies will capture patients with MHA who also have a comorbid TBI as well as patients with TBI who have a comorbid MHA. Unique de-identified patient IDs will ensure that patients are only counted once and will enable the identification of these patients in all health administrative datasets described in this protocol. Finally, overall and sex-specific analyses will be conducted to identify sex differences and similarities, and to inform healthcare planning which takes into account the patient's sex.

In summary, this protocol describes population-based cohort studies that are positioned to address issues of timely and equitable access, integration, and coordination in care delivery. The health system level outcomes examined represent significant policy concerns because they are resource-intensive, associated with potentially avoidable higher healthcare costs and reduced quality of healthcare, and negatively affect patients' outcomes. Findings from this study will provide policy-relevant data to direct resources to provide the right care and meet health service needs at the health system level. Importantly, this protocol provides the foundation for future research using and linking across multiple large population-based datasets to generate comprehensive and longitudinal sex-specific data on individuals with TBI and MHA.

### **Authors' Contributions**

VC, RB, and AC conceptualized and designed the studies. VC drafted the manuscript, and VC and DT conducted the literature review for this manuscript. All authors revised the manuscript critically for important intellectual content, approved the version to be published, and participated sufficiently in the work to take public responsibility for the content of this paper.

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### **Competing Interests**

All authors declare they have no conflicts of interest.

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