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A surveillance study to determine the accuracy of mild traumatic brain injury diagnosis in an emergency department: protocol for a retrospective cohort study.

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ABSTRACT

Introduction: Published literature confirms that a mild traumatic brain injury (mTBI) may result in long-term emotional impacts and in vulnerable subgroups, cognitive deficits. The accurate diagnosis of mTBI and its written documentation is an important first step towards providing appropriate and timely clinical care. It is recommended that surveillance studies involving emergency department (ED) and hospital-based data be prioritized as these provide incident mTBI estimates. This project will advance existing research by quantifying the presence and accuracy of mTBI diagnoses through a comprehensive audit of ED records. The study aims to provide age-specific and sex-specific incidence rates of hospital presentations involving mTBI; and identify factors that are independently associated with documenting a positive mTBI diagnosis in ED.

Methods and analysis: Retrospective chart reviews (between June 2015 and June 2016) of electronic and subsequently clinical medical records from an ED in Sydney (New South Wales, Australia) will be conducted. The study population will include persons aged 18-65 years who presented to the ED with any diagnosis indicative of mTBI. The operational criteria for the clinical identification of mTBI cases is the presence of one or more of the following: a Glasgow Coma Scale (GCS) of ≤15 assessed at the scene; a GCS of 13-15 on presentation to hospital; duration of post-traumatic amnesia (PTA) for less than 24 hours; confusion or disorientation; a witnessed loss of consciousness for ≤30 minutes; and/or positive CT brain scan. We estimate a sample size of 500 cases will be identified during this 1-year period and that this will be large enough to provide acceptable accuracy around estimates of incidence and correlates associated with a positive mTBI diagnosis.

Ethics and dissemination: The study was approved by the Northern Sydney Local Health District ethics committee. Study findings will be disseminated via presentations at national/international conferences, and peer-reviewed journals.

Strengths and limitations of this study

- Will provide previously unavailable epidemiological data on the number of patients who received an mTBI clinical diagnosis in the ED of a major metropolitan Australian hospital.
- Will provide a better understanding of the scope of mTBI by reporting accurate incidence rates and identifying limitations in the current diagnosis and/or documentation of mTBI in ED.
- Study findings may educate ED staff and/or improve clinical practice.
- The generalizability of the study's findings may be limited as mTBI cases treated by primary healthcare providers (e.g. general practitioners) or where medical attention was not sought will not be captured. This may contribute to an underestimation of mTBI incidence rates.

INTRODUCTION

A World Health Organization (WHO) review of hospital treated mild traumatic brain injury (mTBI) reported an annual incidence in the range of 100–300/100 000.[1] Because most mTBI is not treated in hospital, the true population incidence of mTBI has been estimated to range between 600/100 000 and 749/100,000 per year.[1, 2] Current literature reaffirms that mTBI may result in long-term emotional disorders,[3-5] and in vulnerable subgroups, cognitive deficits.[6] Mild TBI is now being recognized as a major health concern.[7] Common post-concussive symptoms associated with but not specific to mTBI are classified as physical (e.g. headache, blurring of vision), behavioral (e.g. irritability, anxiety) and cognitive (e.g. difficulty with memory).[3] Although post-concussive symptoms usually resolve within days or weeks, research literature indicates subjective reporting of physical, cognitive and emotional symptoms for several months or years post-injury.[8-12] Consequences for these individuals may include reduced functional ability, heightened emotional distress, and delayed return to work or school.[13,5, 14] However, early identification and subsequently early intervention such as through education and support for the guided resumption of activities, significantly reduces social morbidity and the severity of post-concussive symptoms.[15] The major limitation of research on mTBI – it is under-diagnosed and thus under-reported. Not knowing the true incidence and prevalence of mTBI renders it challenging to allocate resources and inform evidence-based health-care planning.[3]

Emergency department (ED) assessment is an important primary point of medical contact for early diagnosis; a key element in the management of mTBI for a significant number of patients.[16-18] However, the accurate clinical identification of patients with mTBI in ED is complicated by variations in the criteria used for diagnosis[19-21] and in diagnostic terminology.[19, 22-24] A prospective cohort study of all patients presenting to an urban academic ED in the US over 6 months,[24] showed that the identification of mTBI patients

using retrospectively assigned ICD-9 codes appeared to be inaccurate. These codes were associated with a significant number of false-positive and false-negative code assignments. Powell et al.[22] found that despite patients reporting findings that were consistent with an mTBI diagnosis when interviewed by study personnel, the diagnosis of mTBI was frequently absent from ED medical records. Instead, it appears that the ED staff focused on ruling out a more severe brain injury for patients with a likely mechanism for TBI. This approach perhaps reflected the primary mission of the ED to stabilize and treat serious injuries, as well as time constraints inherent in ED practice. However, it means that those persons with no clear clinical signs of mTBI on arrival at ED are more likely not to be diagnosed.[22]

Moreover, Cassidy et al. reported that 24% of people injured in a motor vehicle crash have a diagnosable mTBI,[7] and the authors concluded that mTBI is a major health concern in the long-term.[7] Falls and motor vehicle crashes are the leading causes of TBI, however, the true distribution of injury mechanisms for mTBI is not known. Given the lack of good-quality published studies on mTBI following motor vehicle crashes, there is an obvious gap in knowledge in this respect.[3] Unlike most fall-related mTBI, traffic injuries are complicated by insurance issues, and the WHO Collaborating Centre Task Force on Mild Traumatic Brain Injury has called for more studies in this setting.

Currently there is limited empirical evidence as to whether persons with mTBI are accurately identified and diagnosed in Australia ED records (including in the largest state of New South Wales, NSW). The urgent need to establish a reliable surveillance system to monitor and inform evidence-based health-care planning and effective treatment, prevention, and rehabilitation strategies for mTBI have been repeatedly emphasized.[2] Hence, this surveillance study will aim to move the research forward in this area. It will involve an electronic and subsequently clinical record search using WHO diagnostic terms[25] and secondary search terms (as previously used by Meares et al.[26]) to identify the number of

patients with possible mTBI who were seen at an ED of a major Sydney metropolitan hospital. The specific study objectives are: 1) To establish the rates of identified mTBI (meeting WHO diagnostic and secondary search terms) and documented diagnosis in ED; and provide age-specific and sex-specific incidence rates of hospital presentations involving mTBI; 2) To determine the specific mTBI incidence rates by the mechanism of injury (i.e. falls or motor vehicle crash); and 3) To identify the factors (e.g. age, sex, ethnicity, hospital admission status) independently associated with documenting a positive mTBI diagnosis in ED. The proposed study will bring us closer to understanding the scope of mTBI by reporting accurate incidence rates and identifying limitations in current ED diagnosis/ documentation and management (e.g. assessment, discharge instructions) of mTBI. Therefore, findings from this study have the potential to improve long-term patient outcomes, inform the use of health resources and promote management consistency for the mTBI patient population.

METHODS

Sample selection

The proposed study will employ a retrospective surveillance system to determine if an mTBI diagnosis was documented. The data source for this study will be all electronic and clinical medical records that encompassed an ED stay at Royal North Shore Hospital (RNSH) in metropolitan Sydney (NSW, Australia) over a 1-year period (between June 2015 and June 2016).

Inclusion and exclusion criteria

The inclusion criteria is persons aged 18-65 years who presented to the ED within 24 hours post- injury with any diagnosis indicative of mTBI[27] (using search terms based on the WHO criteria for mTBI[22, 25]): 1) a Glasgow Coma Scale (GCS) of 15 or below at the scene; 2) a

GCS of 13-15 on presentation to hospital; 3) a duration of post-traumatic amnesia (PTA) of less than 24 hours; 4) confusion or disorientation; 5) a witnessed loss of consciousness for 30 minutes or less; and/or 6) positive CT brain scan, indicating intracranial injuries not requiring neurosurgery.[2, 25, 28] The exclusion criteria includes: penetrating brain injury; moderate/ severe TBI, spinal cord injury, and pre-existing cognitive impairment.[22, 26] Any person with head trauma, who does not meet the WHO criteria, but who: 1) is assessed for PTA and obtains optimal scores on the Abbreviated Westmead Post-traumatic Amnesia Scale (A-WPTAS);[18] or 2) presents to the ED for post-concussive symptoms,[29] transient neurological deficits or queried loss of consciousness will be classified as indeterminate mTBI. Although the literature[27] suggests that a diagnosis of mTBI should not be based only on post-injury symptoms, these cases may nevertheless reflect the difficulty in obtaining accurate diagnostic information (i.e. WHO criteria) from ED records, or the mildest injuries, where manifestations of mTBI resolve prior to the arrival of the medical personnel or presentation to hospital.[26] Indeed, these cases are the most difficult to identify.

Patient screening and data collection

A mTBI case identification protocol (with input from all investigators) was developed and the chart auditors (IP and KVV) were trained with the aim of maximizing consistency in the identification of mTBI cases, for which inter-rater reliability will be assessed. Patient information will be extracted by the research team from the information management system, FirstNet, a module of the Health Electronic Medical Record that is used in NSW (Figure 1). A limitation of FirstNet is that only a principal diagnosis can be recorded and guidelines are not explicit on whether symptoms or a diagnosis is to be entered.[30] If mTBI is the diagnosis of interest, and the patient is not categorized accordingly they will not be identified through FirstNet. To increase the accuracy of identifying possible mTBI patients, ED presentations

will be reviewed by a two-step process (Figure 1). Individuals with possible head trauma, will be first identified by the research team, based on discharge diagnosis and triage presenting information available electronically, indicating the following: 1) a diagnosis of head trauma, head injury or brain injury; 2) a mechanism of injury consistent with a possible mTBI (transport-related accident, assault, or fall); 3) an injury description that includes head lacerations, bruising, swelling, facial fractures, or other musculoskeletal injuries; and 4) mTBI-related symptoms, such as pain, neurological or behavioral symptoms. Cases will be excluded if the mechanism of injury is not consistent with mTBI or if the trauma does not involve an impact to the head.

Second, clinical records will be examined to confirm if individuals meet the diagnostic criteria and to document alcohol and illicit drug usage at the time of injury.[18, 22, 26] The audit of ED records will help obtain information (if available) regarding GCS scores, with mTBI defined as a GCS score of 13-15 on hospital admission. Information from the A-WPTAS, a valid measure of PTA, will be collected. This scale includes the eye opening and motor components, and the 5 verbal orientation items from the GCS and 3 picture cards to measure amnesia.[18] Other measures of mTBI, which will be collected to determine whether an accurate mTBI diagnosis was made in the ED, include: documented GCS of <15 at the scene; signs of confusion or disorientation; a witnessed loss of consciousness of 30 minutes or less; a diagnosis of head trauma, head injury or brain injury; and investigation reports from brain CT scan, facial or skull X-Ray.

When the criteria of any of the above are unclear for the chart auditors, all clinical evidence will be referred to and reviewed by the study investigators (BG, SM) on a weekly basis. The data will be collected using data collection sheets, and will be subsequently entered into a secure online platform, called Research Electronic Data Capture (REDCap).

The proposed retrospective surveillance system will also allow us to obtain socio-demographic data from the electronic records of confirmed mTBI cases, and these variables will include: postcode, age, sex, and ethnicity. An audit of all medical records that encompass patient's ED stay will allow us to obtain information on the date of injury and the mechanisms of injury (e.g. motor vehicle crash, falls, sports-related).

Further, for the purpose of this study, mTBI-related diagnoses (i.e. brain injury, concussion, post-concussion syndrome) listed in the ED medical records and the assigned diagnostic codes will be collected through retrospective review to determine whether an mTBI clinical diagnosis is documented or not.

Sample size

A 1-year audit of clinical and electronic ED records from RNSH will achieve reasonable numbers. We base this assumption on a previous study by Meares (data not published), which showed that annual patient presentations to another major NSW ED in 2010 were 54473 and increased in 2011 to 56903. An audit of electronic and clinical medical records indicated that between April and September 2010, there were 19,084 attendances of individuals aged between 18 to 65 years of age, and between April and September, 2011 there were 20,024 attendances. The proportion identified with mTBI was 1.1% (n = 228) between April and September 2010, and between April and September 2011 were 1.3% (n = 252). Hence, in this study, we estimate that around 500 mTBI positive cases will be documented in ED medical records over a 1-year period. We expect that this sample size will be large enough to provide accuracy around estimates of incidence and correlates associated with a positive mTBI diagnosis.

Outcomes

The primary outcome is the rate of positive mTBI diagnosis or the annual mTBI incidence determined from ED records. Secondary outcomes are: 1) specific mTBI incidence rates among people who have had a motor vehicle crash versus those injured in a fall or sports-related incident; and 2) specific factors (e.g. age, sex, ethnicity, hospital admission status) independently associated with documenting a positive mTBI diagnosis in the ED.

Data analysis plan

Demographic and clinical data will be summarized using means and standard deviations for continuous variables and frequencies or percentages for categorical variables. While FirstNet allows possible mTBI cases to be identified in the first instance, an audit of hospital records will allow for an identification of mTBI based on meeting ≥1 of WHO criteria, and/or secondary criteria; this is considered a gold standard approach. We will compare those cases identified as an mTBI through retrospective audit with the accuracy of an ED working diagnosis, which is entered by clinicians in Systematized Nomenclature of Medicine - Clinical Terms or SNOMED CT (used within hospital electronic medical records). Further, the ICD diagnoses for in-patient admissions of mTBI will also be compared in separate analyses. The statistical comparison between these different sources to calculate agreement or amount of misclassification will be achieved using kappa statistics.

We will calculate age- and sex-specific incidence rates of mTBI over the 1-year period. 95% confidence intervals using Fisher's exact test will be calculated for the incidence rate. The odds of receiving an mTBI diagnosis in the ED will be determined using multivariable logistic regression analyses. Potential confounders to be assessed will include: age, sex, ethnicity, date of injury, and mechanism of injury. A level of $p < 0{\cdot}05$ will be considered statistically significant. We will use SPSS and/or SAS programs for data analyses.

ETHICS AND DISSEMINATION

The study was approved by the Northern Sydney Local Health District Human Research Ethics Committee. The committee deemed this study as low risk in terms of ethical issues. The written papers from this study will be submitted for publication in quality peer-reviewed medical and health journals. Study findings will also be disseminated via presentations at local, national and international conferences.

Contributors: The authors' responsibilities were as follows—BG, IP, IDC, SM, AC, MG, and AK: study concept and design; IP, KVV, and AL: acquisition of data; BG, IP: drafting of the manuscript; IP, BG, IDC, SM, AC, and KVV: critical revision of the manuscript. All authors have given final approval of the version to be published.

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Competing interests: None declared.

Ethics and dissemination: The Northern Sydney Local Health District Human Research Ethics Committee approved the study (reference: RESP/16/259). Findings will be disseminated through research conferences and peer-reviewed journals.

Data sharing statement: Study data will be available on request to BG once the research team has completed the pre-planned analyses.

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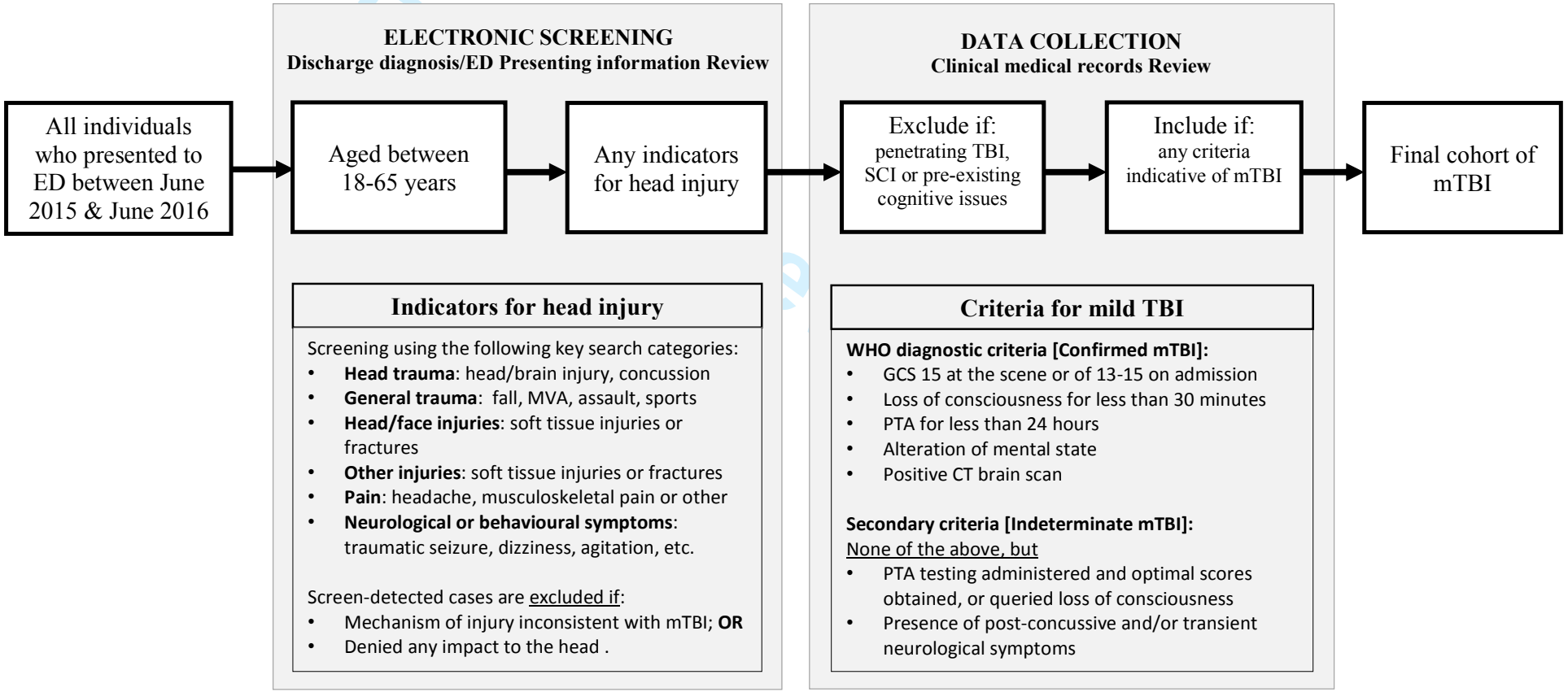
FIGURE 1. Screening and data collection flow chart. Grey boxes indicate study selection process for identification of mTBI.

ED: Emergency Department; TBI: Traumatic Brain Injury; SCI: Spinal Cord Injury; MVA: Motor Vehicle Accident; GCS: Glasgow Coma Score; PTA: Post-Traumatic Amnesia.



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ABSTRACT

Introduction: Existing literature confirms that a mild traumatic brain injury (mTBI) may result in long-term emotional impacts and, in vulnerable subgroups, cognitive deficits. The accurate diagnosis of mTBI and its written documentation is an important first step towards providing appropriate and timely clinical care. Surveillance studies involving emergency department (ED) and hospital-based data need to be prioritized as these provide incident mTBI estimates. This project will advance existing research by estimating the occurrence of mTBI in an ED and quantifying the accuracy of mTBI diagnoses recorded by ED staff through a comprehensive audit of ED records. The study aims to provide age-specific and sex-specific incidence rates of mTBI in an ED, and describe the characteristics of individuals with a confirmed mTBI diagnosis.

Methods and analysis: Retrospective chart reviews (between June 2015 and June 2016) of electronic clinical records from an ED in Sydney (New South Wales, Australia) will be conducted. The study population will include persons aged 18-65 years who attended the ED with any clinical features potentially indicative of mTBI. The WHO operational criteria for the clinical identification of mTBI cases is the presence of: (i) a GCS of 13-15 after 30 minutes post-injury or on presentation to hospital; (ii) one or more of the following: post-traumatic amnesia (PTA) of less than 24 hours' duration, confusion or disorientation, a witnessed loss of consciousness for ≤30 minutes, and/or positive CT brain scan. We estimate that 30,000 ED attendances will be screened and that a sample size of 500 mTBI cases will be identified during this 1-year period, which will provide high precision of estimation for mTBI incidence in the ED setting .

Ethics and dissemination: The study was approved by the Northern Sydney Local Health District ethics committee. Study findings will be disseminated via presentations at national/international conferences, and peer-reviewed journals.

Strengths and limitations of this study

- Will provide previously unavailable epidemiological data on the number and proportion of patients attending the ED of a major metropolitan Australian hospital with mTBI, and the number and proportion with clear documentation of mTBI in their ED and medical record.
- Study findings may educate ED staff and/or improve clinical practice.
- The current study will determine the incidence of mTBI from an ED in NSW, Australia, and the findings may not generalize to other setting mTBI cases admitted to other EDs, treated by primary healthcare providers (e.g. general practitioners) or where medical attention was not sought will not be captured. This may contribute to an underestimation of population-based mTBI incidence.
- As this is not a prospective study, the availability and accuracy of relevant documented clinical information in ED and medical records is essential to mTBI identification and diagnosis in this study, and inadequacies in this information may limit conclusions about mTBI in some cases.

INTRODUCTION

A World Health Organization (WHO) review of hospital treated mild traumatic brain injury (mTBI) reported an annual incidence in the range of 100–300/100 000.[1] Because most mTBI is not treated in hospital, the true population incidence of mTBI has been estimated to range between 600/100 000 and 749/100,000 per year.[1, 2] Current literature reaffirms that mTBI may result in long-term emotional disorders,[3-5] and, in vulnerable subgroups, cognitive deficits.[6] mTBI is now being recognized as a major health concern.[7] Common post-concussive symptoms associated with but not specific to mTBI are classified as physical (e.g. headache, blurring of vision), behavioral (e.g. irritability, anxiety) and cognitive (e.g. difficulty with memory).[3] Although post-concussive symptoms usually resolve within days or weeks, research literature indicates subjective reporting of physical, cognitive and emotional symptoms for several months or years post-injury.[8-12] Consequences for these individuals may include reduced functional ability, heightened emotional distress, and delayed return to work or school.[13,5, 14] However, early identification and subsequent early intervention such as through education and support for the guided resumption of activities, significantly reduces social morbidity and the severity of post-concussive symptoms.[15] The major limitation of research on mTBI is that it is under-diagnosed and thus under-reported. Not knowing the true incidence and prevalence of mTBI renders it challenging to allocate resources and inform evidence-based health-care planning.[3]

Emergency department (ED) assessment is an important primary point of medical contact for early diagnosis; a key element in the management of mTBI for a significant number of patients.[16-18] However, the accurate clinical identification of patients with mTBI in ED is complicated by variations in the criteria used for diagnosis[19-21]. Furthermore, variations in diagnostic terminology and diagnostic coding make it difficult for mTBI to be identified through an administrative database.[19, 22-24] A prospective cohort study of all patients

presenting to an urban academic ED in the US over 6 months,[24] showed that the identification of mTBI patients using ICD-9 codes assigned on discharge appeared to be inaccurate. These codes were associated with a significant number of false-positive and false-negative code assignments. Powell et al.[22] found that despite patients reporting findings that were consistent with an mTBI diagnosis when interviewed by study personnel, the diagnosis of mTBI was frequently absent from ED medical records. Instead, it appears that the ED staff focused on ruling out a more severe brain injury for patients with a likely mechanism for TBI. This approach perhaps reflected the primary mission of the ED to stabilize and treat serious injuries, as well as time constraints inherent in ED practice. However, it means that those persons with no clear clinical signs of mTBI on arrival at ED are more likely not to be diagnosed.[22]

Moreover, Cassidy et al. reported that 24% of people injured in a motor vehicle crash have a diagnosable mTBI,[7] and the authors concluded that mTBI is a major health concern in the long-term.[7] Falls and motor vehicle crashes are the leading causes of TBI, however, the true distribution of injury mechanisms for mTBI is not known. Given the lack of good-quality published studies on mTBI following motor vehicle crashes, there is an obvious gap in knowledge in this respect.[3] Currently there is limited empirical evidence as to whether persons with mTBI are accurately identified and diagnosed in Australian ED records (including in the largest state of New South Wales, NSW). The urgent need to establish a reliable surveillance system to monitor and inform evidence-based health-care planning and effective treatment, prevention, and rehabilitation strategies for mTBI have been repeatedly emphasized.[2] Hence, this surveillance study will aim to move the research forward in this area. It will involve an electronic clinical record review employing WHO diagnostic criteria[25] and secondary criteria previously used by Meares et al.[26] to identify the number of patients with evidence of mTBI who were seen at an ED of a major Sydney metropolitan hospital.

The specific study objectives are: 1) To estimate overall, age-specific and sex-specific mTBI incidence rates in an ED setting, based on confirmed WHO diagnostic criteria, and based on suggestive but insufficient or indeterminate evidence using secondary criteria; 2) To assess the extent to which MTBI cases identified above via chart review are explicitly identified and documented by ED staff using recorded medical diagnoses and diagnostic codes, and to characterize the terminology and codes currently being used in these cases; 3) To assess the proportion of mTBI cases that occurred due to falls, motor vehicle crashes, or other mechanisms of injury; and 4) To describe sociodemographic, injury-related and admission-related characteristics of individuals who attended ED with mTBI based on confirmed WHO diagnostic criteria, and of individuals with suggestive but insufficient or indeterminate evidence based on secondary criteria. The proposed study will bring us closer to understanding the scope of mTBI by reporting accurate estimates of its incidence in an ED setting and identifying limitations in current ED diagnosis, documentation and management (e.g. assessment, discharge instructions) of mTBI. Therefore, findings from this study have the potential to improve long-term patient outcomes, inform the use of health resources and promote management consistency for the mTBI patient population.

METHODS

Sample selection

The proposed study will employ a retrospective surveillance system to determine if an mTBI occurred and a diagnosis was documented by the ED staff. The data source for this study will be all electronic clinical records that related to ED attendances with or without an associated hospital admission at Royal North Shore Hospital (RNSH) in metropolitan Sydney (NSW, Australia) over a 1-year period (between June 2015 and June 2016).

Inclusion and exclusion criteria

The inclusion criteria (see Figure 1) arepersons aged 18-65 years who presented to the ED within 24 hours post- injury with any clinical features indicative of mTBI[27] based on the WHO criteria for mTBI[22, 25]: (i) GCS of 13-15 after 30 minutes post-injury or on presentation to hospital;(ii) at least one of the following: post-traumatic amnesia (PTA) of less than 24 hours ' duration, confusion or disorientation, a witnessed loss of consciousness for 30 minutes or less, and/or positive CT brain scan, indicating intracranial injuries not requiring neurosurgery.[2, 25, 28] The exclusion criteria include: penetrating brain injury; moderate/severe TBI, spinal cord injury, and pre-existing cognitive impairment.[22, 26] Persons who attended ED with head trauma but did not meet the WHO criteria will be classified as indeterminate mTBI if they meet one of the following secondary criteria : 1) is assessed for PTA and obtains optimal scores (i.e. 18 out of 18) on the Abbreviated Westmead Post-traumatic Amnesia Scale (A-WPTAS);[18] or 2) presents to the ED for post-concussive symptoms,[29] transient neurological deficits or queried loss of consciousness. Although the literature[27] suggests that a diagnosis of mTBI should not be based only on post-injury symptoms, these cases may nevertheless reflect the difficulty in obtaining accurate diagnostic information (i.e. WHO criteria) from ED records, or the mildest injuries, where manifestations of mTBI resolve prior to the arrival of the medical personnel or presentation to hospital.[26] Indeed, these cases are the most difficult to identify.

Patient screening and data collection

An mTBI case identification protocol was developed with input from all investigators. Patient information will be extracted by the research team from the information management system, FirstNet, a module of the Health Electronic Medical Record that is used in NSW (Figure 1). A limitation of FirstNet is that only a principal diagnosis can be recorded and guidelines are

not explicit on whether symptoms or a diagnosis is to be entered.[30] If mTBI is the diagnosis of interest, and the patient is not categorized accordingly they will not be identified through FirstNet. To increase the accuracy of identifying possible mTBI patients, all ED presentations meeting study age and interval period will be reviewed by a two-step process (Figure 1). First, individuals with any possible indicators of mTBI as their discharge diagnosis, will be identified by the research team, using the following key search categories: 1) a diagnosis of head trauma, head injury or brain injury; 2) a mechanism of injury consistent with a possible mTBI (e.g. transport-related accident, assault, or fall); 3) an injury description that includes head lacerations, bruising, swelling, facial fractures, or other musculoskeletal injuries; and 4) mTBI-related symptoms, such as pain, neurological or behavioral symptoms. Triage presenting information will then be reviewed and the individual excluded if the mechanism of injury is not consistent with mTBI.

Second, for the possible cases identified in step 1, a thorough review of all documentation available in clinical records will confirm if individuals meet the relevant WHO diagnostic criteria for mTBI and document alcohol and illicit drug usage at the time of injury.[18, 22, 26] The audit of ED records will help obtain information (if available) regarding GCS scores, with mTBI defined as a GCS score of 13-15 after 30 minutes post-injury or on hospital admission. Information from the A-WPTAS, a validated measure of PTA, will also be collected. This scale includes eye opening, motor and verbal components from the GCS and a test of ability to recall 3 picture cards to measure amnesia.[18] Other measures, which will be collected to confirm occurrence of mTBI include: signs of confusion or disorientation; a witnessed loss of consciousness of 30 minutes or less; and a positive finding from brain CT scan or skull X-Ray. Lastly, the presence of post-concussive symptoms is also recorded, whether in isolation (indeterminate mTBI) or in association with other indicators.

Two chart auditors (IP and KVV) were trained in study inclusion and exclusion criteria and case identification, and pilot testing was conducted to work through disagreements or differences of opinion until the two auditors arrived at a common understanding and were extracting the same cases at initial screening (percent agreement of 91%). The first stage of the screening procedure was then assigned to KVV and the second stage to IP, so each step will be consistently undertaken by the same chart auditor. If the chart auditors are unsure about a record, all clinical evidence will be referred to and reviewed by the study investigators (BG, SM) on a weekly basis. The data will be collected using data collection sheets, and will be subsequently entered into a secure online platform, called Research Electronic Data Capture (REDCap).

The proposed retrospective surveillance system will also allow us to obtain socio-demographic, injury-related and admission-related data for individuals identified as having confirmed mTBI based on WHO diagnostic criteria or suggestive but insufficient or indeterminate evidence based on secondary criteria. These variables will include: postcode, age, sex, ethnicity date of injury, mechanisms of injury (e.g. motor vehicle crash, falls, sports-related), and hospital admission status.

Further, for the purpose of this study, mTBI-related diagnoses (i.e. brain injury, mTBI, concussion, post-concussive symptoms or syndrome) listed in the ED medical records and the assigned diagnostic codes (SNOWMED and ICD-10 codes) will be collected through retrospective review to determine whether an mTBI diagnosis was documented or not by ED staff.

Sample size

A 1-year audit of clinical and electronic ED records from RNSH will achieve sufficient numbers. We base this assumption on a previous study by Meares (data not published), which

showed that annual patient presentations to another major NSW ED in 2010 were 54473 and increased in 2011 to 56903. An audit of electronic and clinical medical records indicated that between April and September 2010, there were 19,084 attendances of individuals aged between 18 to 65 years of age, and between April and September, 2011 there were 20,024 attendances. The proportion identified with mTBI was 1.1% (n = 228) between April and September 2010, and between April and September 2011 were 1.3% (n = 252). Hence, in this study, we estimate that approximately 30,000 ED attendances will be screened and that 500 mTBI cases will be identified from RNSH medical records over a 1-year period. This sample size provides high precision of estimation of mTBI incidence in the ED setting (95% confidence intervals of ± 0.2% for the overall point estimate, and ± 1.6% for a study stratum that includes only 1% of the total sample).

Outcomes

The primary outcome measure is mTBI incidence in an ED setting among all patients treated in RNSH ED over a one year period, based on confirmed WHO diagnostic criteria from ED records and based on suggestive but indeterminate evidence using secondary criteria. Secondary outcomes are: 1) the proportion of mTBI cases that occurred as a result of a motor vehicle crash versus those injured in a fall or sports-related incident; and 2) characterizing the sociodemographic and other characteristics (e.g. age, sex, ethnicity, hospital admission status) of individuals attending the ED with an mTBI diagnosis confirmed based on WHO diagnostic criteria and with suggestive but indeterminate evidence of mTBI based on secondary criteria 3) characterize whether and how mTBI diagnoses are explicitly noted and recorded by ED staff, and management of those injuries in the ED setting.

Data analysis plan

Demographic and clinical data will be summarized using means and standard deviations for continuous variables and frequencies or percentages for categorical variables. Overall, age-specific and sex-specific incidence rates of mTBI over the 1-year period will be calculated with 95% confidence intervals. While FirstNet allows possible mTBI cases to be identified in the first instance, an audit of hospital records will allow an identification of mTBI based on meeting ≥1 of WHO criteria, and/or secondary criteria. Among ED attendances identified as involving an mTBI through retrospective chart audit, the accuracy of the ED working diagnosis, documented by clinicians in the medical records, and the accuracy of diagnostic coding entered in Systematized Nomenclature of Medicine - Clinical Terms or SNOMED CT (used within hospital electronic medical records) will be examined. Further, the ICD diagnoses for in-patient admissions of mTBI will also be compared in separate analyses. Rates of agreement and misclassification will be quantified and the kappa statistic for agreement computed.

Sociodemographic, injury-related, and admission-related characteristics of mTBI cases will be described. Analyses will be conducted using SPSS and/or SAS statistical software.

ETHICS AND DISSEMINATION

The study was approved by the Northern Sydney Local Health District Human Research Ethics Committee. The committee deemed this study as low risk in terms of ethical issues. The written papers from this study will be submitted for publication in quality peer-reviewed medical and health journals. Study findings will also be disseminated via presentations at local, national and international conferences.

Contributors: The authors' responsibilities were as follows—BG, IP, IDC, SM, AC, MG, and AK: study concept and design; IP, KVV, and AL: acquisition of data; BG, IP: drafting of

the manuscript; IP, BG, IDC, SM, AC, and KVV: critical revision of the manuscript. All authors have given final approval of the version to be published.

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Competing interests: None declared.

Ethics and dissemination: The Northern Sydney Local Health District Human Research Ethics Committee approved the study (reference: RESP/16/259). Findings will be disseminated through research conferences and peer-reviewed journals.

Data sharing statement: Study data will be available on request to BG once the research team has completed the pre-planned analyses.

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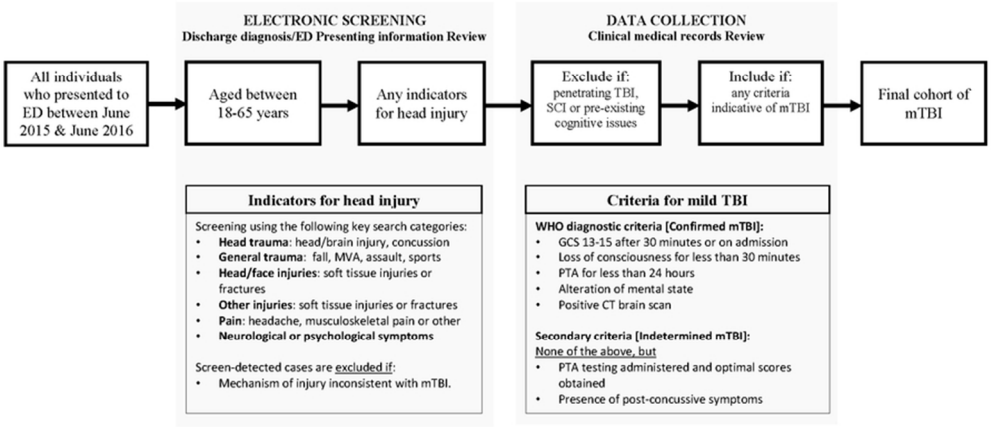
FIGURE 1. Screening and data collection flow chart. Grey boxes indicate study selection process for identification of mTBI.

ED: Emergency Department; TBI: Traumatic Brain Injury; mTBI: Mild Traumatic Brain Injury; SCI: Spinal Cord Injury; MVA: Motor Vehicle Accident; GCS: Glasgow Coma Score; PTA: Post-Traumatic Amnesia: CT: Computed Tomography.



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A surveillance study to determine the accuracy of mild traumatic brain injury diagnosis in an emergency department: protocol for a retrospective cohort study.

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ABSTRACT

Introduction: Previous literature confirms that a mild traumatic brain injury (mTBI) may result in long-term emotional impacts and, in vulnerable subgroups, cognitive deficits. The accurate diagnosis of mTBI and its written documentation is an important first step towards providing appropriate and timely clinical care. Surveillance studies involving emergency department (ED) and hospital-based data need to be prioritized as these provide incident mTBI estimates. This project will advance existing research findings by estimating the occurrence of mTBI among those attending an ED and quantifying the accuracy of mTBI diagnoses recorded by ED staff through a comprehensive audit of ED records.

Methods and analysis: Retrospective chart reviews (between June 2015 and June 2016) of electronic clinical records from an ED in Sydney (New South Wales, Australia) will be conducted. The study population will include persons aged 18-65 years who attended the ED with any clinical features potentially indicative of mTBI. The World Health Organization (WHO) operational criteria for the clinical identification of mTBI cases is the presence of: (i) a Glasgow Coma Scale (GCS) of 13-15 after 30 minutes post-injury or on presentation to hospital; (ii) one or more of the following: post-traumatic amnesia (PTA) of less than 24 hours' duration, confusion or disorientation, a witnessed loss of consciousness for ≤30 minutes, and/or a positive computed tomography (CT) brain scan. We estimate that 30,000 ED attendances will be screened and that a sample size of 500 mTBI cases will be identified during this 1-year period, which will provide reliable estimates of mTBI occurrence in the ED setting.

Ethics and dissemination: The study was approved by the Northern Sydney Local Health District Ethics Committee. Study findings will be disseminated via presentations at national/international conferences, and peer-reviewed journals.

Strengths and limitations of this study

- Will provide previously unavailable data on the number and proportion of patients attending the ED of a major metropolitan Australian hospital with mTBI, and the number and proportion with clear documentation of mTBI in their medical records.
- Study findings may educate ED staff and/or improve clinical practice.
- The current study will determine the rates of mTBI diagnosis among ED attendances only, and the findings will not be generalizable to the wider community, as it will not capture those cases treated by primary healthcare providers (e.g. general practitioners) or alternatively where medical attention was not sought, which may contribute to an underestimation of population-based mTBI incidence.
- As this is not a prospective study, the availability and accuracy of relevant documented clinical information in ED medical records is essential to mTBI identification in this study, and inadequacies in this information may limit conclusions about mTBI in some cases.

INTRODUCTION

A World Health Organization (WHO) review of hospital treated mild traumatic brain injury (mTBI) reported an annual incidence in the range of 100–300/100 000.[1] Because most mTBI is not treated in hospital, the true population incidence of mTBI has been estimated to range between 600/100 000 and 749/100,000 per year.[1, 2] Current literature reaffirms that mTBI may result in long-term emotional disorders,[3-5] and, in vulnerable subgroups, cognitive deficits.[6] mTBI is now being recognized as a major health concern.[7] Common post-concussive symptoms associated with but not specific to mTBI, are classified as physical (e.g. headache, blurring of vision), behavioral (e.g. irritability, anxiety) and cognitive (e.g. difficulty with memory).[3] Although post-concussive symptoms usually resolve within days or weeks, research literature indicates subjective reporting of physical, cognitive and emotional symptoms for several months or years post-injury in a subgroup of individuals.[8-12] Consequences for these individuals may include reduced functional ability, heightened emotional distress, and delayed return to work or school.[13,5, 14] However, early identification and subsequent early intervention, such as through education and support for the guided resumption of activities, significantly increases social participation and decreases the severity of post-concussive symptoms.[15] The major limitation of research in this area is that mTBI cases are often under-diagnosed and thus under-reported. Not knowing the true incidence and prevalence of mTBI renders it challenging to allocate resources and inform evidence-based health-care planning.[3]

Emergency department (ED) assessment is an important primary point of medical contact for early diagnosis; a key element in the management of mTBI for a significant number of patients.[16-18] However, an accurate clinical identification of patients with mTBI in ED is complicated by varied criteria used for diagnosis[19-21]. Furthermore, variations in diagnostic terminology and diagnostic coding make it difficult for mTBI to be identified

through an administrative database.[19, 22-24] A prospective cohort study of all patients presenting to an urban academic ED in the US over 6 months,[24] revealed inaccurate identification of mTBI patients using International Classification of Diseases 9th Revision criteria (ICD-9 codes) assigned on discharge, . These ICD-9 codes were associated with a significant number of false-positive and false-negative code assignments. Powell et al.[22] found that despite patients reporting symptoms consistent with an mTBI diagnosis when interviewed by study personnel, the diagnosis of mTBI was frequently absent from ED medical records. Instead, it appears the ED staff were more focused on ruling out severe brain injury for patients with a likely mechanism for TBI. This approach perhaps reflected the primary mission of the ED, that is, to stabilize and treat serious injuries, and time constraints inherent in ED practice may also have influenced findings. However, it was concluded that persons with a possible mTBI on arrival at ED were more likely not to be diagnosed.[22]

Moreover, Cassidy et al. reported that 24% of people injured in a motor vehicle crash have a diagnosable mTBI,[7] and these authors concluded mTBI to be a major health concern in the long-term.[7] Falls and motor vehicle crashes are leading causes of TBI, however, the true distribution of injury mechanisms for mTBI is not known. Given the lack of good-quality published studies on mTBI following motor vehicle crashes, there is an obvious gap in knowledge in this respect.[3] Currently there is limited empirical evidence as to whether persons with mTBI are accurately identified, diagnosed and recorded in Australian ED records (including in the largest state of New South Wales, NSW). The need to establish a reliable surveillance system to monitor and inform evidence-based health-care planning and effective treatment, prevention, and rehabilitation strategies for mTBI has been repeatedly emphasized.[2] Consequently, this mTBI surveillance study will aim to move the research forward in this area. It will involve an electronic clinical record review employing WHO diagnostic criteria[25] and secondary criteria previously used by Meares et al.[26] to identify the

number of patients with evidence of mTBI who were seen at an ED of a major Sydney metropolitan hospital. The study objectives are: 1) To estimate overall, age-specific and sex-specific occurrence rates of ED attendances with mTBI, using ; 2) To assess the extent to which mTBI cases identified via chart review are explicitly identified and documented by ED staff using recorded medical diagnoses and diagnostic codes, and to characterize the terminology and codes currently being used in these cases; 3) To assess the proportion of mTBI cases that occur due to falls, motor vehicle crashes, or other mechanisms of injury, and 4) To describe sociodemographic, injury-related and admission-related characteristics of individuals who attended ED with mTBI based on either confirmed WHO diagnostic criteria, or on suggestive but insufficient/ indeterminate evidence using secondary criteria. The proposed study will clarify the nature and scope of mTBI by reporting accurate estimates of its occurrence in an ED setting as well as identifying limitations in current ED diagnosis, documentation and management (e.g. assessment, discharge instructions) of mTBI. Therefore, findings from this study have the potential to improve long-term patient outcomes, inform the use of health resources and promote management consistency for the mTBI patient population.

METHODS

Sample selection

The proposed study will employ a retrospective surveillance system to determine if an mTBI occurred and a diagnosis was documented by ED staff. The data source for this study will be electronic clinical records related to ED attendances with or without an associated hospital admission at Royal North Shore Hospital (RNSH) over a 1-year period (between June 2015 and June 2016). RNSH is a large hospital in metropolitan Sydney, New South Wales (NSW), Australia, serving a population of 213,000 inhabitants in 2016, across four local government

areas. The overall number of RNSH ED attendances in the study year was approximately 80,000, and of these, 30,000 were aged 18-65 years old.

Inclusion and exclusion criteria

The inclusion criteria (see Figure 1) are adults aged 18-65 years who presented to the ED within 24 hours post- injury with any clinical features indicative of mTBI[27] based on the WHO criteria for mTBI[22, 25] which are: (i) Glasgow Coma Scale (GCS) of 13-15 after 30 minutes post-injury or on presentation to hospital; (ii) at least one of the following: post-traumatic amnesia (PTA) of less than 24 hours duration, confusion or disorientation, a witnessed loss of consciousness for 30 minutes or less, and/or positive computed tomography (CT) brain scan indicating intracranial injuries not requiring neurosurgery.[2, 25, 28] The exclusion criteria include: penetrating brain injury; moderate/severe TBI, spinal cord injury, and pre-existing cognitive impairment.[22, 26] Persons who attended ED with head trauma but did not meet the WHO criteria will be classified as indeterminate mTBI if they meet one of the following secondary criteria : 1) is assessed for PTA and obtains optimal scores (i.e. 18 out of 18) on the Abbreviated Westmead Post-traumatic Amnesia Scale (A-WPTAS);[18] or 2) presents to the ED for post-concussive symptoms,[29] transient neurological deficits or queried loss of consciousness. Although the literature[27] suggests that a diagnosis of mTBI should not be based only on post-injury symptoms, these cases may nevertheless reflect the difficulty in obtaining accurate diagnostic information (i.e. WHO criteria) from ED records, or the mildest injuries, where manifestations of mTBI resolve prior to the arrival of the medical personnel or presentation to hospital.[26] Indeed, these cases are the most difficult to identify.

Patient screening and data collection

mTBI case identification protocol was developed with input from all investigators. Patient information will be extracted by the research team from the information management system, FirstNet, a module of the Health Electronic Medical Record that is used in NSW (Figure 1). A limitation of FirstNet is that only a principal diagnosis can be recorded and guidelines are not explicit on whether symptoms or a diagnosis is to be entered.[30] If mTBI is the diagnosis of interest, and the patient is not categorized accordingly, they will not be identified through FirstNet. To increase the accuracy of identifying possible mTBI patients, all ED presentations meeting study age and interval period will be reviewed by a two-step process (Figure 1). First, individuals with any possible indicators of mTBI as their discharge diagnosis, will be identified by the research team, using the following key search categories: 1) a diagnosis of head trauma, head injury or brain injury; 2) a mechanism of injury consistent with a possible mTBI (e.g. transport-related accident, assault, or fall); 3) an injury description that includes head lacerations, bruising, swelling, facial fractures, or other musculoskeletal injuries; or 4) mTBI-related symptoms, such as pain, neurological or behavioral symptoms. Triage presenting information will then be reviewed and the individual excluded if there is no traumatic mechanism involved or if the mechanism of injury is not consistent with mTBI.

Second, for the possible cases identified in step 1, a thorough review of all documentation available in clinical records will confirm if individuals meet the relevant WHO diagnostic criteria for mTBI. The review will also document whether alcohol and illicit drug usage was involved in the injury.[18, 22, 26] The audit of ED records will help obtain information (if available) regarding GCS scores, with mTBI defined as a GCS score of 13-15 after 30 minutes post-injury or on hospital admission. Information from the A-WPTAS, a validated measure of PTA, will also be collected. The A-WPTAS scale includes eye opening, motor and verbal components from the GCS and a test of ability to recall three picture cards to measure amnesia.[18] Other measures, which will be collected to confirm occurrence of

mTBI, include: signs of confusion or disorientation; a witnessed loss of consciousness of 30 minutes or less; and a positive finding from brain CT scan or skull X-Ray. Lastly, the presence of post-concussive symptoms is also recorded, whether in isolation (indeterminate mTBI) or in association with other indicators.

Two chart auditors (IP and KVV) have been trained in study inclusion and exclusion criteria and case identification, and pilot testing conducted to work through disagreements or differences of opinion until the two auditors arrived at a common understanding and were extracting the same cases at initial screening (percent agreement of 91%). The first stage of the screening procedure was then assigned to KVV and the second stage to IP, so each step will be consistently undertaken by the same chart auditor. If the chart auditors are unsure about a record, all clinical evidence will be referred to and reviewed by the study investigators (BG, SM) on a weekly basis. The data will be collected using data collection sheets, and will be subsequently entered into a secure online platform, called Research Electronic Data Capture (REDCap).

The proposed retrospective surveillance system will also allow us to obtain socio-demographic, injury-related and admission-related data for individuals identified as having confirmed mTBI based on either WHO diagnostic criteria or suggestive but insufficient/ indeterminate evidence using secondary criteria. Variables will include: postcode, age, sex, ethnicity date of injury, mechanisms of injury (e.g. motor vehicle crash, falls, sports-related), and hospital admission status.

Further, for this study, mTBI-related diagnoses (i.e. brain injury, mTBI, concussion, post-concussive symptoms or syndrome) listed in the ED medical records and the assigned diagnostic codes (SNOWMED and ICD-10 codes) will be collected through retrospective review to determine whether an mTBI diagnosis was or was not documented by ED staff.

Sample size

A 1-year audit of clinical and electronic ED records from RNSH will achieve substantial sample numbers. We base this assumption on a previous study by Meares (data not published), which showed that annual patient presentations to another major NSW ED in 2010 were 54473, increasing in 2011 to 56903. Meares reported in an audit of electronic and clinical medical records that between April and September 2010, there were 19,084 attendances of individuals aged between 18 to 65 years of age, and between April and September 2011 there were 20,024 attendances. The proportion identified with mTBI was 1.1% (n = 228) between April and September 2010, and between April and September 2011 were 1.3% (n = 252). Therefore, for this study, we estimate that approximately 30,000 ED attendances will be screened and that 500 mTBI cases will be identified from RNSH medical records over a 1-year period. This sample size provides high precision of estimation of mTBI incidence in the ED setting (95% confidence intervals of ± 0.2% for the overall point estimate, and ± 1.6% for a study stratum that includes only 1% of the total sample).

Outcomes

The primary outcome measure is the rate of mTBI diagnosis among ED attendances (aged 18-65 years) at RNSH over a one year period, based on confirmed WHO diagnostic criteria from ED records. Secondary outcomes are: 1) the proportion of mTBI cases that occurred as a result of a motor vehicle crash versus those injured in a fall or sports-related incident; and 2) characterizing the sociodemographic and other characteristics (e.g. age, sex, ethnicity, hospital admission status) of individuals attending the ED with an mTBI diagnosis confirmed based on WHO diagnostic criteria versus suggestive but indeterminate evidence of mTBI using secondary criteria 3) characterize how mTBI diagnoses are noted and recorded by ED staff, and explore the management of those injuries in the ED setting.

Data analysis plan

Demographic and clinical data will be summarized using means and standard deviations for continuous variables and frequencies or percentages for categorical variables. Overall, age-specific and sex-specific rates of mTBI over the 1-year period will be calculated with 95% confidence intervals. While FirstNet allows possible mTBI cases to be identified in the first instance, an audit of hospital records will allow an identification of mTBI based on meeting ≥1 of WHO criteria, and/or secondary criteria. Among ED attendances identified as involving an mTBI through retrospective chart audit, the accuracy of the ED working diagnosis, documented by clinicians in the medical records, and the accuracy of diagnostic coding entered in Systematized Nomenclature of Medicine - Clinical Terms or SNOMED CT (used within hospital electronic medical records) will be examined. Further, the ICD diagnoses for in-patient admissions of mTBI will also be compared in separate analyses. Rates of agreement and misclassification will be quantified and the kappa statistic for agreement computed.

Sociodemographic, injury-related, and admission-related characteristics of mTBI cases will be described. Analyses will be conducted using SPSS and/or SAS statistical software.

ETHICS AND DISSEMINATION

The study was approved by the Northern Sydney Local Health District Human Research Ethics Committee. The committee deemed this study as low risk in terms of ethical issues. The written papers from this study will be submitted for publication in quality peer-reviewed medical and health journals. Study findings will also be disseminated via presentations at local, national and international conferences.

Contributors: The authors' responsibilities were as follows—BG, IP, IDC, SM, AC, MG, and AK: study concept and design; IP, KVV, and AL: acquisition of data; BG, IP: drafting of the manuscript; IP, BG, IDC, SM, AC, and KVV: critical revision of the manuscript. All authors have given final approval of the version to be published.

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Competing interests: None declared.

Ethics and dissemination: The Northern Sydney Local Health District Human Research Ethics Committee approved the study (reference: RESP/16/259). Findings will be disseminated through research conferences and peer-reviewed journals.

Data sharing statement: Study data will be available on request to BG once the research team has completed the pre-planned analyses.

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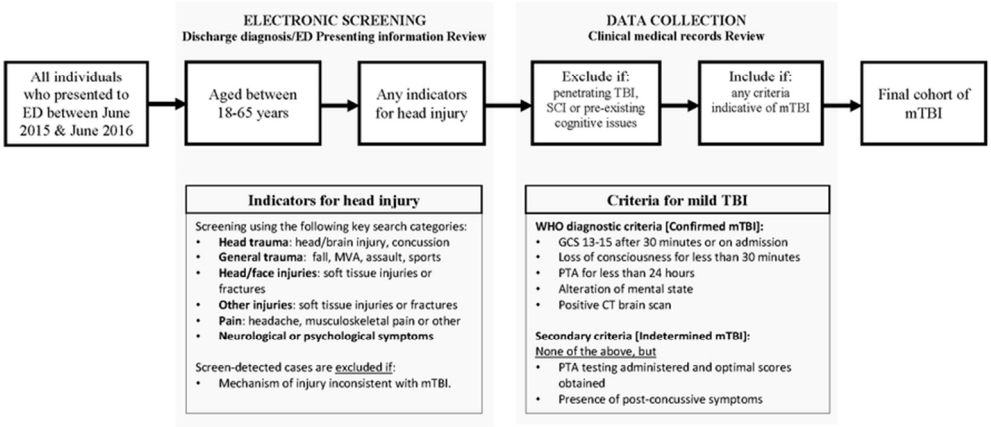

FIGURE 1. Screening and data collection flow chart. Grey boxes indicate study selection process for identification of mTBI.

ED: Emergency Department; TBI: Traumatic Brain Injury; mTBI: Mild Traumatic Brain Injury; SCI: Spinal Cord Injury; MVA: Motor Vehicle Accident; GCS: Glasgow Coma Score; PTA: Post-Traumatic Amnesia: CT: Computed Tomography.

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