Characteristics, patterns and outcomes of patients who present with head injuries to one tertiary emergency department: multi-method study

CONFIDENTIAL

STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)

PROTOCOL SYNOPSIS

Title	Characteristics, patterns and outcomes of head injuries presenting to one tertiary emergency department (ED).
Objectives	Primary: the incidence of patient presentations to Royal North Shore Hospital (RNSH) ED with head injury. Secondary: to follow up on patient journey at 10-14 days and four weeks from discharge. To review; the discharge process from ED, patient symptoms/progress, community management and the need for further management.
Study Design	Observational Cohort Study
Planned Sample Size	Phase 1 medical record audit: 36 months (2019/2020/2021) of electronic medical record (eMR) data ~267,000 patients. Phase 2 telephone interview: anticipate recruitment rate of 150 patients.
Selection Criteria	Phase1: what is the incidence of head injuries and does the pandemic and social isolation impact or change the rate of presentations to ED? Phase 2: patients up to 30 years of age who present to the ED with a head injury then discharged home or admitted to the ward.
Study Procedures	Identify suitable patients on presentation to ED, review eMR diagnosis/documentation, fill excel data spreadsheet, two follow up phone call interviews (at 10-14 days and four weeks from day of discharge). Qualitative study, data collection including a retrospective record review. Phase 1: retrospective 36 month eMR audit to examine the incidence, characteristics and patterns of patients that present with a head injury before and during the Covid-19 pandemic. Phase 2: telephone follow up of patients (up to 30 years of age) that present to the ED with a head injury and discharged home or admitted to the ward.
Statistical Procedures	Sample Size Calculation: phase 1 presentations for 2019 was approx. 89,000 and head injury accounts for 5%; phase 2 estimated at 350 patients. Based on an 80% response participation rate the sample size is estimated to be 280 (up to 30 years of age) participants. Analysis Plan: review data gained from pre-completed excel spreadsheet and information gained from phone call interviews
Duration of the study	November 2020 – December 2023 Retrospectively eMR audit: 1st January 2019 – 31st December 2021

1. Study Management

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1.3 Statistician (if applicable)

Mainly descriptive exploratory data will be presented and summarised using frequencies and percentages. Basic inferential statistics will be used for group comparisons to be undertaken depending on data distribution. Normally distributed data will be analysed using t test and anova. Non normally distributed data will use parametric testing Mann Whitney, Kruskall Wallis, Chi Square and Fischer exact depending on data type and coding.

1.4 Funding and resources

This is an unfunded study.

2. INTRODUCTION AND BACKGROUND

2.1 Background Information

Across Australia significant injuries result from everyday activities of adults and children. Head injuries are one of the most common injuries that result from activities such as team sports, motor vehicle accidents or falls. The Australian Institute of Health and Welfare reports that the rate of hospitalised injury cases in Australia increased over the last 10 years (2007–08 to 2016–17) by an average of 1% per year. The two main causes of hospitalised injury in 2016–17 were falls (41%) and transport crashes (12%)[1]. One of the key concerns for head injury patients is ongoing symptoms of concussion.

It is estimated the annual incidence of concussion is approximately 60-250 per 100,000 of population and of these 17% are sport related (Concussion in Sport Position Statement, 2019)[2]. This is now thought to be of greater significance particularly for school age children and that they should refrain from resuming any physical activity/sport until they are completely symptom-free[3].

Head injuries are a common presentation to emergency departments (EDs) for adults and children and symptoms of concussion can be persistent. Early and accurate diagnosis of a traumatic brain injury as well as appropriate management is critical in facilitating good outcomes[2,4,5]. To date little is known of how concussion is managed in the community by both adults and parents whose child has experienced a head injury and is symptomatic of concussion. Therefore, this study seeks to better

understand the characteristics of people that present with head injuries and symptoms of concussion to an ED and how on discharge concussion is managed in the community.

2.2 Research Question

Phase 1: Primary question: What are the characteristics, patterns and outcomes of people (up to 30 years of age) that present with signs and symptoms of head injuries to one major tertiary referral hospital ED and does the COVID-19 pandemic and social isolation impact on or change the presentation rate for patients with head injuries?

Phase 2: To follow up on a patient's health trajectory journey at 10-14 days and then four weeks post discharge. Follow up will involve exploring the discharge processes, patient symptoms/progress, community management and follow up with a community practitioner.

2.3 Rationale for Current Study

We have very little understanding of the nature, rate, characteristics and outcomes of and for patients who present to a major tertiary referral hospital ED after sustaining a head injury. Head injuries, including concussion, are a serious condition with potential long term health consequences. Currently there is an increased awareness of potential long term outcomes of repeated concussions and the possible association with chronic traumatic encephalopathy[4]. Therefore, early identification and diagnosis of head injuries and such conditions as concussion is important to ensure appropriate care, management and discharge education needs to optimise referral, appropriate community management and follow up care. So that evidence based timely care is provided to patients who present to the ED with a head injury, examination of management and discharge processes need to be explored to optimise patient safety.

It is unclear what constitutes standardised or routine head injury management whilst in the ED. Further, ED head injury discharge processes, management and communication to patients, families and carers remains poorly elucidated. Importantly, the discharge plan and appropriate follow up for this patient cohort remains inconsistent and ad hoc.

Inconsistent management of head injury both within the hospital environment and transition to home in the community may not optimise best patient outcomes. Further, how clinicians communicate the discharge plan and manage activities such as return to work/study and or resuming sporting activities needs to be explored further. In addition, patient compliance and adherence with discharge instructions is also critical for optimising the recovery trajectory, health outcomes and avoidable representations and yet little is known about patient compliance and adherence for this group.

3. STUDY OBJECTIVES

3.1 Primary Objective

Phase 1 To explore the characteristics, patterns and outcomes of patients (up to 30 years of age) that present with signs and symptoms of head injuries to one major tertiary referral hospital ED over a 36 months. To establish the number of patients (up to 30 years of age) who are discharged from ED or admitted to the ward with the diagnosis of head injury.

Phase 2 To follow up on the patient's journey at 10-14 days and four weeks from discharge.

Secondary Objectives

1) To determine current ED management and discharge processes for patients with a head injury and discharged home or admitted to the ward.
2) How are head injury patients managed in the community and the need for further management.

4. STUDY DESIGN

4.1 Type of Study

Observational Study

4.2 Study Design

This is an observational Cohort Study of people that present to a major tertiary hospital with a head injury. The study comprises of two phases;

Phase 1 medical record audit: To explore the characteristics, patterns and outcomes of people (up to 30 years of age) that present with signs and symptoms of head injuries to one major tertiary referral hospital ED comparing pre and during the COVID-19 pandemic.

Phase 2 telephone interviews: Stratified prospective sample of patients (up to 30 years of age) who present to ED and diagnosed with head injury, given written and verbal discharge education / information / instructions and followed up appropriately in the community using telephone interview.

4.3 Number of Participants

Phase 1: N=267,000. All patients (up to 30 years of age) presenting to the RNSH ED will be reviewed for evidence of signs and or symptoms of head injuries over a 36 month period to compare pre and during the COVID-19 pandemic. The annual presentation is approx. 89,000 it is anticipated that 5% may have experienced head injury and/or displaying signs/symptoms of head injury. So the anticipated sample size would be approx. 4,450 patients.

Phase 2: N=280. All patients presenting to the RNSH ED and discharged home or admitted to the ward will be invited to participate in a telephone interview. Stratified prospective sample of patients (up to 30 years of age) who present to ED are diagnosed with head injury and discharged home or admitted to the ward. Recruitment will begin from the in 1st January 2021 – 31st December 2021.

4.4 Study sites

Royal North Shore Hospital Emergency Department

4.5 Expected Duration of Study

November 2020 – December 2023

6 weeks from the last patient included in the study.

4.6 Primary and Secondary Outcome Measures

Primary outcome:

- To explore the characteristics, patterns and outcomes of patients that present with head injuries to one major tertiary referral hospital ED.
- How are head injury patients managed in the community and the need for further management.

Secondary outcomes:

- To compare data both pre and during the COVID-19 pandemic
- Identification of evidence based concussion assessment and management in the ED
- How were head injury patients managed in the ED
- Identification of the type and appropriateness of discharge information, education and instructions
- What discharge instructions were provided for commencing post head injury activities such as return to school, work and sporting activities
- What were the patterns of community referrals

5. PARTICIPANT ENROLLMENT AND RANDOMISATION

5.1 Recruitment

Patients up to the 30 years of age have been included in the study as this patient cohort are more likely to be involved in team contact sports and less likely to have co-morbidities. Posters will be positioned in all areas of the ED (with the exception of the resuscitation bays).

Phase 1: A 36 month (1st January 2019 - 31st December 2021) eMR audit of all patients (up to 30 years of age) presenting to ED will be reviewed for evidence of head injuries. Limitation of snowmed diagnostic codes will require review of all emergency presentations eMR to determine patients that have presented or been discharged with signs/symptoms of head injury or concussion. Review of eMR will be undertaken by the lead researcher to identify participants meeting inclusion criteria for phase 1. Due to the large number of patient records being accessed data for 2021 will only be accessed in early 2022 and as such, will be retrospective in nature.

Phase 2: A 12 month (1st January – December 31st 2021) prospective study of patients (up to 30 years of age) who present to ED with a head injury will be included in the study. The aim of the telephone interview is to collect data after the patient has been discharged from the ED. To obtain information from the patient such as; feedback on the discharge process, ongoing symptoms, return to sport, school, study or work or the need for further medical review.

For phase 2 potential participants will identified then recruited by clinicians or the emergency research volunteers, who will seek written consent whilst they are in the ED to participant in two telephone interviews.

All patients will have the opportunity to opt out of the study without any impact on care practices. Randomisation will occur 1:1 ratio for patients < 16 years of age and patients > 16 years of age to identify 20 participants per week, who will be contacted 10-14 days post injury and then four weeks post discharge. Telephone interviews will be conducted by either ED research volunteers, the lead researcher or associate researchers from the RNSH ED Office. Prior to the commencement of the telephone interview each patient/parent/carer on contact will be again given the opportunity to opt out and verbal consent will be obtained. Each participant will be invited to select an interview schedule time suitable for them. Potential participants will only be contacted three times and if unable to be contacted will be considered as declining to participate in the study. Potential participants will only be contacted between the hours of 0800am until 0600pm (Monday – Friday).

All emergency clinicians will be briefed about the study via email, posters and short in-services.

5.2 Eligibility Criteria

5.2.1 Inclusion Criteria

Phase 1 medical record audit: All patients (up to 30 years of age) presenting to ED at RNSH from 1st January 2019 - 31st December 2021 (36 months) will be reviewed for evidence of head injuries.

Phase 2 telephone interview: Patients (up to 30 years of age) who present to ED with a head injury will be included in the study and who are discharged home or admitted to the ward.

5.2.2 Exclusion Criteria

Phase 2: Patients older than 31 years, patients given a triage category 1, and patients allocated to the resuscitation area, children identified as a child at risk at time of treatment or children transferred to a tertiary paediatric hospital.

6. Informed Consent Process

Phase 1 medical record audit: For the collection of retrospective data we would request a waiver of consent given the difficulties of obtaining consent for this patient cohort. There would be no phone calls to this group of patients.

Waiver of consent;

a) *The benefits from the research justify any risks of harm associated with not seeking consent:* There are significant potential benefits of the research in providing information on which to enhance the current approaches to treatment of people presenting to mental health inpatient units. The outcomes of this research have the potential for significant impact on inpatient mental health services.

b) *It is impracticable to obtain consent:* We estimate that there will be up to 267,000 medical records reviewed. These are retrospective audits from a time period of up to 36 months ago. Therefore it would not be feasible to contact that number of potential participants for consent within the resources of this study.

c) *There is no known or likely reason for thinking that participants would not have consented if they had been asked:* There is no known reason for participants in the program to not consent for de-identified data to be analysed in the way proposed.

d) *There is sufficient protection of their privacy:* Audit data will be de-identified at the point of data collection. No quotations or other textual data will be retained from the audit and data will be aggregated for reporting.

e) *There is an adequate plan to protect the confidentiality of data:* Data analysed and stored for the study will be stored securely, will contain no identifying information, and will be reported only in aggregated and summarised form.

f) *In case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them:* Stored data will not contain identifying information and will be aggregated for reporting. Data are retrospective. Findings will inform emergency management of patients presenting with head injury and may therefore benefit future consumers.

g) *The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled:* There is no foreseeable commercial application for the findings of this study.

h) *The waiver is not prohibited by State, federal, or international law:* Audit data will be de-identified on collection. Data that are de-identified are not subject to the statutory guidelines on research in New South Wales under the Health Records and Information Privacy Act 2002 (Information and Privacy Commission New South Wales, 2004). Use of administrative data for a secondary purpose is addressed in the Privacy Act 1988 (Cth), sections 16B and 95A.

Phase 2 telephone interview: potential participants will be identified by clinicians or the emergency research volunteers, who will seek their permission to participant in telephone interviews whilst the patient is in the ED using the participant information sheet and consent form. Verbal consent will be obtained prior to commencement of the telephone interview and documented.

Within all ED clinical areas there will be available study information sheets that align with the posters if any potential participants request further information about the study. At the start of the telephone interview the study information will again be provided as part of the telephone script and verbal consent obtained, documented and dated. If a potential participant declines while in the ED the treating clinician will complete the withdrawal form for the study. No impact on care practices will occur because of withdrawal. Clinicians will be mindful and respectful of patients/parents/carers decline or choose to withdraw from the study.

6.1 Participant Withdrawal

All patients/parents/carers will have the opportunity to withdraw/opt out at any stage of the study. Including those who may choose to decline during their initial presentation to ED. In this instance the patient/parent/carer will complete a form withdrawing consent from the study this will be deposited into a sealed collection box (in paediatric area or fast track area) and will be collected by the lead researcher.

7. ADVERSE EVENT REPORTING

This is a low risk project for patients/parents/carers. We do not anticipate the procedures used in this study will cause concern or harm for participants. However, we will implement measures to mitigate any potential distress. If the patient (or their person responsible) becomes distressed during the telephone interview, he or she will be referred to the ED social worker or other appropriate helpline agency/ services. If patients reported ongoing symptoms or concerns they would be encouraged to seek further medical attention through their general practitioner or present to their local ED.

8. STATISTICAL METHODS

The retrospective eMR audit does not require a power calculation as we are not testing an intervention but seeking to explore and characterise service data. Phase 1 data to be collected includes: patient demographic information (age, gender, etc.) and clinical information (for example date/time of arrival, triage category, reason for ED presentation, assessment and diagnostic code, discharge summary, nursing documentation, community referrals, length of stay, disposition, ED clinical space) to determine patients that have presented or discharged with signs/symptoms of head injury or concussion pre COVID 19 and during the pandemic.

For the descriptive exploratory study quantitative data will be presented using descriptive statistics and summarised using frequencies and percentages. Examining for central tendency means, standard deviation (normally distributed data), or median and interquartile range (non-normally distributed data) will be analysed. For continuous data comparison will be conducted using T test and Chi square will be used for categorical data. If the data allows (there are sufficient observations and the distribution of data is appropriate) we will conduct multivariate analyses to explore the determinants of patient compliance with ED discharge information. Quantitative data analysis will be performed using SPSS v.21 and Excel for data cleaning, mining and summaries of data sets. All data will be de-identified.

For Phase 2 involves qualitative interview data obtained from semi-structured telephone interviews. Data to be collected includes: patient demographic information (age, gender, etc.), history including mechanism of injury, signs/ symptoms of concussion, management in ED and follow up plan. All responses provided by patients or their persons responsible will be analysed and organised thematically and stored and managed using NVivo™ v12. Thematic analysis will be guided by Gibbs's (2007) framework which includes: 1) transcription and familiarisation; 2) code building; 3) dis/confirmatory theme development; and 4) data consolidation and interpretation. This framework provides a systematic approach for interpretation (Lichtman, 2010, Brodie and Irving, 2007). The investigators will discuss and review emerging coding and themes.

8.1 Sample Size Estimation

This is an observational study not requiring a powered sample.

Phase 1 medical record audit: 36 months of ED data characterising approximately 267,000 patients. All data is routinely collected and will be obtained through eMR

Phase 2 telephone interview: anticipate recruitment rate 280 patients or until data saturation is reached.

8.2 Statistical Analysis Plan

We will conduct measures of frequency and central tendency to analyse the collected data set. Incomplete data sets will not be used in our statistical analysis. We will report the number of incomplete data sets collected.

9. DATA MANAGEMENT

Phase 1 and Phase 2: All electronic data will be de-identified and stored using REDCap (on the NSLHD server) accessible by the lead researcher and other associate investigators. All paper data will be stored in a locked filing cabinet within the RNSH ED Office only accessible by the lead researcher. Phase 1: Data will be accessed as an eMR audit and will only contain de-identified records to enable the exploration for all potential ED head injury presentations.

Phase 2 data an electronic (Excel) master copy of codes for patient data will be stored using REDCap (on the NSLHD server) and will only be accessible by the lead researcher. All data will be de-identified so that there is no personal data collected (e.g. medical record number and name will not be collected) for the interviews. Instead patient participants will be allocated a unique identifier (study number) to ensure confidentiality, privacy and beneficence and ensure accuracy during data analysis. Phase 2: All interview paper forms / data will be kept in a locked filing cabinet within the RNSH ED Office only accessible by the lead researcher. Any paper notes taken by the investigators will be shredded using an industrial grade shredder located at the conclusion of the study. Data will be aggregated for analysis and publications will not contain any information that may identify an individual participant.

9.1 Data Storage

Phase 1: all electronic data will be coded to protect patient privacy on password protected excel sheet stored using REDCap (on the NSLHD server). Only the lead investigator will have access to the data source and database and will keep the password safeguarded.

Phase 2: all paper forms and data will be kept in locked filing cabinet within the RNSH ED Office only accessible by the lead investigator. All electronic data will be re-coded to protect patient privacy. Only the lead investigator will have access to the patient data and the telephone database and will be kept stored using REDCap (on the NSLHD server) only accessible to the lead investigator.

9.2 Data confidentiality

Phase 1 medical record audit: On extraction of first data patients will only be temporarily identified to establish representation rate then all patients will be coded and de-identified.

Phase 2 telephone interview: There is low risk for participants completing the telephone survey. No identifying personal data will be documented on the survey which will therefore remain anonymous to ensure confidentiality, privacy and beneficence. It will be communicated to the participants that they can exit from the interview at any time.

9.3 Study Record Retention

All records will be retained for a minimum of 5 years post study completion or last publication.

10. ADMINISTRATIVE ASPECTS

10.1 Independent HREC approval

The study has only been submitted to the Northern Sydney Local Health District HREC, reference number:

10.2 Amendments to the protocol

Any amendments will be submitted to the NSLHD HREC for review prior to implementation as per HREC guidelines.

10.3 Participant reimbursement

There are no reimbursements as this is an unfunded study.

10.4 Financial disclosure and conflicts of interest

The research team have no financial conflict of interest to disclose.

11. USE OF DATA AND PUBLICATIONS POLICY

The results of the study would lead to peer reviewed journal publications and conference presentations. We anticipate the findings of this study will lead to policy change for discharge and care practices. In addition the findings will contribute to the education programs for clinicians in the ED. Other changes anticipated would be the identification of gaps or issues pertaining to community care.

12. REFERENCES

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