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Abbreviations and Definitions of Terms

AE	Adverse event
CHOP	The Children's Hospital of Philadelphia
TBI	Traumatic brain injury
mTBI	Mild traumatic brain injury
PeRC	Pediatric Research Consortium
PBRN	Practice-Based Research Network
ED	Emergency Department

ABSTRACT

Context:

In the United States, approximately 700,000 children sustain traumatic brain injuries (TBIs) each year. Although nearly 90% of these injuries are considered "mild" and are mostly treated on an outpatient basis, they can still lead to poor neurological outcomes that adversely affect the child's quality of life. Therefore, it is import that institutions and care networks have standardized, evidenced-based management of mild TBIs and concussions. Understanding current practice can help guide development of a comprehensive clinical care model for diagnosis, treatment, and follow-up management of children with concussion.

Objectives:

The primary objective is to assess the current state of pediatric concussion management within the CHOP Care Network. Secondary objectives include 1) identifying patient and provider factors associated with provision of particular concussion management strategies and 2) examining the agreement between emergency department (ED) concussion diagnoses as indicated by ICD-9 codes and pre-determined symptom criteria for concussion as documented in the abstracted medical record, for children with mTBI.

Study Design/Setting/Participants:

This is a retrospective review of electronic and written medical records for children 5-18 years of age who were diagnosed with a concussion or exhibited symptoms indicative of a concussion and treated for initial or ongoing care in the Children's Hospital of Philadelphia (CHOP) ED, Pediatric and Adolescent Care Network, the Center for Sports Medicine and Performance, or the Trauma Surgery Clinic from 1/01/2008 through 12/31/2010.

Study Interventions and Measures:

Patient demographics will be recorded. Outcome measures will be abstracted from the medical record and include: details of the head injury; medical and neuropsychological evaluation if present; treatment; and follow-up recommendations.

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Each year in the United States (US), an estimated 700,000 children < 18 years sustain traumatic brain injuries (TBIs).[1] Although nearly 90% of pediatric TBIs are considered "mild" and do not require hospital admission, they can still lead to poor neurological outcomes and functional disability that adversely affect the child's quality of life including: second impact syndrome, post concussion syndrome, memory problems, and emotional or behavioral changes.[2, 3] Recent data suggest that children are more vulnerable to the long-term effects of concussion and recover more slowly than do adults. Therefore, it is critical that health care-providers conduct standardized and evidence-based evaluation and management of mild TBIs and concussions, in order to determine who needs ongoing neurocognitive interventions.

1.2 Relevant Literature and Data

With the recent increased academic and public attention towards mTBI, concussion research has become a priority.[4] Two recurring themes include confusion about the diagnosis of concussion and inadequate treatment (i.e., cognitive rest); both of which can prolong symptoms and worsen outcomes. Unfortunately, misconceptions about concussion management are present in both the medical community and the lay public. Two recent studies demonstrated that ED and primary care providers do not consistently recognize symptoms or make diagnoses consistent with concussion in adults.[5, 6] One survey of ED nurses found inadequate assessment and documentation of concussive symptoms, which could affect accurate diagnosis and provision of anticipatory guidance.[7] Furthermore, pediatric primary care providers who routinely provide follow-up of concussion many lack adequate training and resources for proper neurocognitive evaluation and treatment recommendations.[8, 9] Athletic trainers often recognize concussive symptoms, but they may prematurely return concussed athletes to play, despite lower than baseline neurocognitive testing and against recommended guidelines.[10, 11] Even patients have a poor understanding of concussion; one survey of adults with mTBI found that the majority with concussion did not recognize the diagnosis and many did not seek any medical attention.[12]

Contributing factors to the confusion surrounding concussion diagnosis and management in children may include: various definitions and interpretations of mTBI and concussion terminology;[13, 14] heterogeneity and inadequate scientific assessment of concussion scales and checklists;[15, 16] and a relatively small (although growing) body of literature on long-term outcomes of pediatric concussion.[17] Standardization of concussion management may be achieved by comprehensive clinical management models that are activated from the time of initial injury and continue through recovery.[18] In order to implement such models, a baseline assessment of concussion management must be completed.

Understanding current practice can help guide development of a comprehensive and standardized clinical care model for diagnosis, treatment, and follow-up management of children with concussions.

This study will evaluate the medical record documentation surrounding assessment, treatment, anticipatory guidance, and follow-up for pediatric concussion by health care providers in the CHOP network.

1.3 Compliance Statement

This study will be conducted in full accordance with all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46, and the HIPAA Privacy Rule. Any episode of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent (unless a waiver is granted), and will report unexpected problems in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

2.1 Primary Objective

The primary objective is to characterize the current state of pediatric concussion management within the CHOP Care Network from January 2008-December 2010.

2.2 Secondary Objectives

The secondary objectives are to:

1. Identify patient and provider factors associated with provision of particular concussion management strategies.
2. Describe the level of agreement between ED concussion diagnoses based on symptom criteria documented in the abstracted medical record as compared to ICD-9 codes for concussion, in children with mTBI.

2.3 General Schema of Study Design

This study is a retrospective review of electronic and written medical records for children 5-18 years of age who were diagnosed with an mTBI and treated for initial or ongoing care within the CHOP Network.

2.4 Study Duration, Enrollment and Number of Sites

2.4.1 Date Range of Study

Cases will be included if the initial treatment of mTBI occurred between 1/1/2008 through 12/31/2010.

2.4.2 Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted at CHOP and will include patients from the ED, Pediatric and Adolescent Care Network, the Center for Sports Medicine and Performance, and the Trauma Surgery Clinic. All patients meeting the inclusion criteria below will be identified. Up to 200 randomly selected cases from among eligible patients will be abstracted.

2.5 Study Population

2.5.1 Inclusion Criteria

1) Patient presenting between 1/1/2008 and 12/31/2010.

2) Males or females 5 to 18 years old.

3) Any presentation of mTBI based on the following ICD-9 codes: skull fracture (800.0, 800.5, 801.0, 801.5, 803.0, 803.5, 804.0, 804.5), concussion (850.0, 850.1, 850.5, 850.9), intracranial injury, unspecified, (854.0), and head injury, unspecified (959.01).[19]

2.5.2 Exclusion Criteria

1) Visits in which the patient expired.

2) Patients with more than 30 minutes of loss of consciousness.

3) Patients with more than 24 hours of post-traumatic amnesia.

4) Glasgow Coma Scale score of <14.

5) Patients with radiographic evidence of a brain hemorrhage (including subdural hemorrhage, epidural hemorrhage, intraparenchymal hemorrhage, and cerebral or cerebellar contusion).

6) Patients requiring surgical intervention.

7) Admission to an intensive care unit.

8) Post-injury hospitalization for >48 hours.

3 STUDY PROCEDURES

3.1 Data Sources

3.1.1 Case ascertainment

Potential cases will be identified through two sources: 1) the PBRN PeRC database for all patients seen in CHOP-based primary care clinics, trauma clinic, and sports clinics, and 2) an extant electronic administrative database for patients seen in the ED. Cases meeting our age criteria will be identified through specific ICD-9 codes for mTBIs. Customized abstraction from this data set will be based on the inclusion criteria, and chosen via a random sample of the patients from the database. A

purposeful sampling of at least 40% females overall (up to 80 total), and at least 40% children ages 5-11 (up to 80 total) will be completed to ensure that these groups are adequately represented in the sample.

3.1.2 Data sources

Once the cases are identified, three electronic medical records will be used for further data abstraction: EpicCare (Epic, Verona, WI) [for all primary care, trauma, and sports medicine patients], ChartMaxx, v3.4 (MedPlus, Mason, OH) [for all ED patients], and Sunrise Clinical Manager, v5.7 (Eclipsys Corporation, Atlanta, GA) [for ED patients]. The electronic and digitized medical records will be reviewed and the abstractor will confirm eligibility through the inclusion and exclusion criteria. If the case meets eligibility, the abstractor will proceed. If the patient is not eligible, the abstractor will choose an alternate patient until the 200 patient sample is reached.

3.2 Data Elements to be Abstracted

3.2.1 Electronic extraction by CHOP IT (PeRC for outpatient and extant ED database for ED)

- Medical record number
- Date of birth
- Sex
- Zip code
- Race
- Ethnicity
- Date of visit
- Weight
- Height
- ICD-9 diagnosis codes
- E-Codes for injury mechanism
- Disposition (for ED patients only)
- Arrival, triage, and discharge times (for ED patients only)

3.2.2 Manual abstraction by study team (EpicCare (for outpatient) and ChartMaxx/Sunrise Clinical Manager (for ED patients))

- Transfer from another hospital

- Symptoms associated with concussion[20]
    - 1) Symptoms: somatic (eg, headache), cognitive (eg, feeling like in a fog) and/or emotional symptoms (eg, lability)
    - 2) Physical signs (eg, loss of consciousness, amnesia)
    - 3) Behavioral changes (eg, irritability)
    - 4) Cognitive impairment (eg, slowed reaction times)
    - 5) Sleep disturbance (eg, drowsiness)
- Radiographic imaging reports (including x-rays, computed tomography)
- Major procedures and interventions (including wound care, venous catheter placement, endotracheal intubation)
- Documented trauma surgery consultation
- Treatment plan (recommendation of cognitive rest, categories of restrictions (exercise/sports, school, other), duration of restrictions)
- After visit instructions or discharge instructions (instructions from a template, free-typed instructions, both, or neither)
- Follow-up recommendation and compliance with follow-up (provider type-primary care provider, trauma clinic, sports medicine clinic, neurologist, or other; duration until follow-up)
- Disposition

4 STATISTICAL CONSIDERATIONS

4.1 Primary and Secondary Endpoints

The primary endpoint is to assess the current state of pediatric concussion management with the CHOP Care Network. The secondary endpoints are to 1) identify patient and provider factors associated with provision of particular concussion management, and 2) describe the level of agreement between ED concussion diagnoses based on symptom criteria documented in the abstracted medical record as compared to ICD-9 codes for concussion, in children with an mTBI. To describe the level of agreement, we will capture all children with mTBI per the inclusion criteria; some of who will have a concussion diagnosis by ICD9 codes, some with a concussion diagnosis by symptom criteria, and others with both.

4.2 Measures to Avoid Bias

We will assess a random sample of the population of all patients with a broad definition of minor head injury (as described in the inclusion criteria) in order to maximize the sensitivity of the query and ensure that all patients with a concussion, within the larger group of all mTBI, are captured.

4.3 Statistical Methods

Data spreadsheets will be imported into Stata (StataCorp, College Station, TX). Standard descriptive summaries (e.g. means and standard deviations for continuous variables such as age and percentage for categorical variables such as gender) will be used to summarize demographic variables. Comparisons of categorical variables between subgroups will be made using the Chi-square test or the Fisher's exact test, depending on the size of the sample. Comparisons of continuous variables will be completed using independent t-tests or nonparametric tests depending on normality of distribution. Other associations will be explored using univariate and multivariate analyses.

4.4 Sample Size and Power

This descriptive study will include all visits that meet the ICD-9 based and age-based inclusion criteria that occurred at CHOP and will include patients from the ED, Pediatric and Adolescent Care Network, the Center for Sports Medicine and Performance, or the Trauma Surgery Clinic. There are approximately 2000 patients per year with mTBI seen in the CHOP ED alone. This will provide for an adequate sample size of up to 200 patients with concussion (with up to 80 total female patients and up to 80 patients aged 5-11 years), during the three year study period.

5 STUDY ADMINISTRATION

5.1 Data Collection and Management

Visits will be assigned a unique study identification number (UID). Data will be abstracted electronically in a comma separated variable format for a statistical software package. The databases will be maintained on CHOP secured server within the CHOP password protected computer system. Only members of this research study team will have access to the data.

During data abstraction, the medical record numbers will be converted to unique study numbers. Birth date will only be used to calculate an exact age in years and months. Upon completion of data collection, the age will replace the birth date. A master data sheet will include the relevant PHI for the study with the matching study numbers. A separate data sheet used for statistical analyses will have only the study numbers with deidentified information. The electronic data will be deleted within seven years following publishing.

5.2 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy. The investigator and other study team members will not use such data and records for any purpose other than conducting this study. Safeguards for confidentiality are described under Data Collection and Management, Section 5.1.

5.3 Regulatory and Ethical Considerations

5.3.1 Risk Assessment

This study is a minimal risk study. The primary risks are breach of privacy and confidentiality. This study involves abstraction of data from records of previous medical visits during which data were collected as part of routine clinical evaluation and management. Data will be stored in password-protected spreadsheets on a password-protected computer. The patient identifiers of medical record number, birth date, and discharging health care provider name will be converted to a unique study number, age in years, and provider category.

5.3.2 Potential Benefits of Study Participation

There are no direct benefits to patients who have already been treated for concussion. However, there are potential benefits to future children with mTBI and concussion.

5.3.3 Risk-Benefit Assessment

As a minimal risk study, the potential benefits to society and future patients of improved education and guidance outweigh the risk of potential breach of privacy.

5.4 Informed Consent/Assent and HIPAA Authorization

5.4.1 Waiver of Consent

We are requesting a waiver of consent based on the following qualifications: the research is limited to existing data; the data involves no more than minimal risk to the subject; waiver of consent will not adversely affect the rights and welfare of subjects, and the research could not be practicably be carried out without the waiver.

5.4.2 Waiver of Assent

We are requesting a waiver of assent since the research could not practicably be completed without the waiver.

5.4.3 Waiver of HIPAA Authorization

We are requesting a waiver of HIPAA authorization based on the following qualifications: the use or disclosure of PHI involves no more than minimal risk, the

research could not practicably be conducted without the waiver or alteration, and the research could not practicably be conducted without access to and use of PHI.

The following procedures are in place to protect the identifiers from improper use and disclosure and destroy the identifiers at the earliest opportunity consistent with conduct of the research.

During data abstraction, the medical record numbers will be converted to unique study numbers. Birth date will only be used to calculate an exact age in years and months. Upon completion of data collection, the age will replace the birth date. A master data sheet will include the relevant PHI for the study with the matching study numbers. A separate data sheet used for statistical analyses will have only the study numbers with deidentified information. The electronic data will be deleted within seven years following publishing.

The protected health information will not be reused or disclosed to any other person or entity, except as required by law or for authorized oversight of the research project.

6 SAFETY MANAGEMENT

6.1 Clinical Adverse Events

Unanticipated problems involving risks to subjects and others will be monitored throughout the study.

6.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk and are limited to existing data and specimens, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study these will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. Unanticipated problems that don't involve risks to subjects or others but that are will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

7 PUBLICATION

The principal investigator intends to present the results at national conferences and publish in peer-reviewed medical journals.

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