



Published in final edited form as:

J Head Trauma Rehabil. 2024 ; 39(2): 115–120. doi:10.1097/HTR.0000000000000900.

Rationale for the Development of a Traumatic Brain Injury Case Definition for the Pilot National Concussion Surveillance System

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Abstract

Background: Current methods of traumatic brain injury (TBI) morbidity surveillance in the United States have primarily relied on hospital-based data sets. However, these methods undercount TBIs as they do not include TBIs seen in outpatient settings and those that are untreated and undiagnosed. A 2014 National Academy of Science Engineering and Medicine report recommended that the Centers for Disease Control and Prevention (CDC) establish and manage a national surveillance system to better describe the burden of sports- and recreation-related TBI, including concussion, among youth. Given the limitations of TBI surveillance in general, CDC took this recommendation as a call to action to formulate and implement a robust pilot National Concussion Surveillance System that could estimate the public health burden of concussion and TBI among Americans from all causes of brain injury. Because of the constraints of identifying TBI in clinical settings, an alternative surveillance approach is to collect TBI data via a self-report survey. Before such a survey was piloted, it was necessary for CDC to develop a case definition for self-reported TBI.

Objective: This article outlines the rationale and process the CDC used to develop a tiered case definition for self-reported TBI to be used for surveillance purposes.

Conclusion: A tiered TBI case definition is proposed with tiers based on the type of sign/symptom(s) reported, the number of symptoms reported, and the timing of symptom onset.

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For the remaining authors, no conflicts of interest were declared.
The authors declare no conflicts of interest.

Keywords

concussion; public health; surveillance; survey research; traumatic brain injury

A 2014 NATIONAL ACADEMY OF SCIENCE ENGINEERING AND MEDICINE (NASEM) report, “Sports-Related Concussions in Youth: Improving the Science, Changing the Culture,” recommended that the Centers for Disease Control and Prevention (CDC) “establish and oversee a national surveillance system to accurately determine the incidence of sports-related concussions, including those in youth ages 5 to 21.”¹ This recommendation sought to address previously identified gaps outlined in that publication in current sports-related concussion surveillance; in particular, underidentification that results in underestimates of the true public health burden of concussion. Since the publication of the NASEM report, “CDC has considered the surveillance recommendation as a call to action, not only to provide incidence estimates for youth sports concussion but to improve [traumatic brain injury] TBI surveillance more broadly.”^{2(p253)} To begin addressing this NASEM recommendation, CDC conducted a pilot administration of a National Concussion Surveillance System (NCSS) to capture all causes of TBI in children (ie, not only sports- and recreation-related TBIs) and adults. The primary goals of this pilot were to test (a) the methodology (ie, random-digit dial telephone survey) as a means to capture comprehensive estimates of TBI incidence and prevalence and (b) a novel TBI case definition for use in classifying TBIs based on self-report data. This manuscript will describe the rationale behind the development of a preliminary case definition and the process by which this case definition was developed. A separate manuscript will describe the analytic process and results of evaluating and modifying the proposed case definition (cite manuscript in this issue).

GAPS IN TBI SURVEILLANCE ESTIMATES

TBIs are a significant public health concern in the United States. In recent years, TBIs have contributed more than 223 000 hospitalizations and 64 000 deaths on an annual basis.³ These national estimates, however, are an underestimate of the true burden of TBIs in the United States because they are based on healthcare administrative and vital statistics data that only capture information on the number of hospitalizations and deaths identified as TBI-related.^{4,5} A 2016 study in a pediatric healthcare system found that nearly 80% of treated concussions, often referred to as mild TBIs (mTBIs), were initially treated outside of the emergency department (ED), suggesting that hospital-based surveillance systems may capture less than 20% of all pediatric concussions.⁶ Current estimates do not account for TBIs treated by physicians during office visits or in other outpatient settings (eg, urgent care),⁴ or TBIs that are identified solely by athletic trainers,⁷ or untreated and undiagnosed TBIs.^{7–9} The majority of TBIs are mild and for many may not involve seeking care from a healthcare provider.¹⁰ A recent survey of more than 6000 adults showed that only about half of people who indicated they had sustained a concussion reported that they were evaluated by a doctor or nurse after their injury,¹¹ making an accurate estimate of undiagnosed TBIs critical for the purpose of providing truly comprehensive estimates of TBI and the associated public health burden. While the most common reason that people report not seeking care

after a suspected TBI is because they did not think the injury was serious, upwards of 10% did not seek care because of difficulty paying, not being able to take time off of work, or not having transportation to the doctor.¹¹ This could mean that a certain fraction of persons with TBI, particularly the most socially disadvantaged, has never been captured in past estimates of TBI incidence or prevalence. This is particularly problematic because people at the lower end of the socioeconomic scale might be a higher risk for TBI given some of their life circumstances (eg, more dangerous occupations).¹²

Furthermore, even within existing healthcare administrative-based surveillance, there is evidence that many TBIs may go undiagnosed in the ED,^{13,14} particularly in multitrauma cases,¹⁵ and there are documented ICD-10-CM coding challenges that significantly impact TBI surveillance estimates.¹⁶ Finally, another limitation of healthcare administrative databases and vital statistic systems are that they contain limited data elements and do not allow for the assessment of contextual factors of injuries (eg, the mechanism of injury [MOI]) and outcomes of TBI (including time to symptom resolution and impact on daily functioning).

Given the limitations of identifying TBI in clinical settings, especially mTBIs, one potential way to approach surveillance of TBI in the United States is through self-report surveys. Furthermore, a recent 2022 NASEM report recommended that the CDC enhance TBI surveillance efforts by adding standardized TBI questions to weighted population-based surveys.¹⁷ Despite the potential challenges of collecting TBI data via self-report data (eg, recall bias, telescoping), thus far it has been the only method identified that is able to capture TBIs that are treated outside of the hospital setting or goes untreated.

CHALLENGES IN ESTABLISHING A TBI CASE DEFINITION

A critical aspect of public health surveillance is the identification of a case definition for the specific disease or condition for which surveillance is conducted. The case definition establishes the criteria by which a person is classified as a case (counted as someone with a particular disease or condition), or a noncase (counted as someone who has not experienced a particular disease or condition). However, assessing TBI in any context is challenging, owing largely to the heterogeneity of the condition. Those who sustain a TBI can experience a broad range of signs and symptoms.^{18,19} Any two people who sustain a TBI may have no overlap in the signs and symptoms they experience. Adding to the complexity is that there is still a lack of consensus among experts as to how to distinguish between a mTBI and no TBI. A comprehensive assessment of TBI on a survey typically requires asking a series of questions about a range of signs and symptoms that are attributed by the respondent to the head injury they experienced.

This context is different from the assessment of many other health conditions (eg, diabetes, asthma, HIV) that are frequently assessed in health surveys. Many health conditions can be assessed by simply asking a respondent whether they have been diagnosed with a particular disorder. Assessing the condition in this way is relatively straightforward because for many health conditions people consistently seek care and there are comparatively clear diagnostic criteria or objective clinical tests. It can also be assumed that most clinicians are well-trained

to recognize those conditions and will communicate the diagnosis clearly to a patient. In contrast, making a TBI diagnosis is frequently more complex, as is communication of that diagnosis to patients, for a variety of reasons. First, in the absence of objective criteria, as there are for many other health conditions, TBI diagnosis relies largely on self-report of symptoms to a clinician. An exception to this is the use of imaging, but imaging is not recommended as a means to diagnose TBI,²⁰ particularly for TBIs at the milder end of the severity spectrum. Second, medical students and residents may not receive adequate training on mTBI diagnosis and management.^{21,22} Third, TBI is often considered a “hidden injury”; because the physical damage is internal and unseen, it may not be assessed in places, such as the ED, if it is not the presenting concern or in instances of polytrauma. Fourth, TBIs are often referred to by multiple names (ie, TBI, mTBI, concussion, head injury) and patients may not understand the similarities among the terms. It is unclear what term or terms may be used and how a TBI diagnosis is communicated to a patient, or the parent of a child with a suspected TBI. Finally, some people purposefully avoid talking about their TBI or are reluctant to disclose their symptoms (eg, some athletes may fear not being able to play after sustaining a TBI).²³ In these cases where disclosing injury is purposefully avoided, prompts such as “has a doctor or healthcare provider ever told you ... ” to elicit self-report are likely to underidentify TBIs.

Self-report through a national survey can provide a mechanism for identifying people who are not currently identified through administrative databases which typically capture ED visits, hospitalizations, or deaths. However, current self-reported data collections of TBI have limitations, in part due to constraints on the amount of space for TBI-related questions. For example, some surveys ask about TBIs using a single question that includes a list of many symptoms.²⁴ These types of questions have an implied case definition that equates to having had a head injury plus sustaining at least 1 TBI sign/symptom, and this could result in an overestimate of TBI prevalence. Other surveys have included questions that ask about a limited subset of symptoms or require the respondent to only report about TBIs for which they received a diagnosis.²⁵ This leads to underreporting if respondents did not seek care for the injury or if their symptoms were not among those assessed. Furthermore, many surveys rely on questions that ask respondents to report TBI with loss of consciousness (LOC).^{26,27} While experts in the TBI field have more confidence that a TBI was sustained when a person self-reports LOC, evidence suggest that only approximately 10% of people experience this symptom.^{28–30} Thus, surveys that only collect data on respondents that have had a TBI with LOC, by definition, underestimate TBI burden. Furthermore, current self-reported TBI data collections have limited space to capture detailed mechanism of injury information that contributed to each TBI reported per respondent. For example, a validated survey may use a single question to determine whether sports or recreation contributed to the respondent’s TBI history but provide no information on type of sport or contact level engaged which can help fill research gaps in sports-related concussion prevention.³¹

ADDRESSING THESE CHALLENGES

One potential way to address challenges in establishing a TBI case definition is through the use of a case definition that is tiered by level of certainty. Patients (or survey respondents) present with a varying amount of information supportive of a TBI diagnosis/determination.

A tiered case definition can be used to represent, to some degree, the varying level of confidence that a TBI has occurred. Specifically, there can be a continuum of evidence (and confidence) in classifying a TBI that varies based on factors such as: which signs/symptoms are reported, how many symptoms are reported, and the proximity (in time) of symptom onset to the head injury. Recently, similar approaches have been employed in clinical research to classify TBIs according to severity and certainty.^{32–35} For example, Kutcher and Giza³⁴ created a 3-level system to classify sports-related concussion diagnoses into definite, probable, or possible concussions. Their classification system is based not on specific symptoms but on the clinical presentation and the most likely cause of the symptoms (ie, traumatic insult vs overexertion). Similarly, Garcia and colleagues³³ used a data-driven approach with predictive modeling to categorize head injuries sustained by athletes into definite, probable, possible, and unlikely concussions. Their data were drawn from time of injury characteristics and postinjury clinical assessments, such as the Standard Assessment of Concussion, Sport Concussion Assessment Tool symptom survey, and the Balance Error Scoring System. In most clinical categorization schemes, specific signs and symptoms indicative of disruption of brain function (eg, LOC, altered consciousness or confusion, amnesia) suggest a higher level of certainty that a TBI occurred.^{10,36} Other symptoms may be frequently experienced after a TBI, but they may be experienced as a result of another health condition(s) and thus will confer less certainty. The case definition proposed by CDC to use in the NCSS pilot data collection utilized a signs and symptoms-based system corresponding to level of certainty that a TBI occurred.

DEVELOPMENT OF A TBI CASE DEFINITION FOR THE NCSS PILOT

As mentioned, the primary aims of the NCSS pilot were to evaluate the methodology of collecting selfreport information on nonfatal TBIs for the purpose of surveillance and to test and refine a tiered TBI case definition. Prior to NCSS data collection, the research team conducted a review of the literature and convened a group of TBI experts from multiple disciplines (eg, epidemiology, neurology, pediatrics, sports medicine, athletic training) to provide insight into survey content. In addition, CDC consulted the literature to identify previously developed case definitions and consulted the same group of experts to develop a preliminary case definition. Among the prior case definitions examined, the American Congress of Rehabilitation Medicine (ACRM) definition of mTBI included any period of LOC, any loss of memory before or after the accident, any alteration in mental state at the time of the accident, and any focal neurological deficits.³⁶ Similarly, the World Health Organization (WHO) includes 1 or more of the following as criteria for mTBI: confusion or disorientation, LOC for 30 minutes or less, posttraumatic amnesia for less than 24 hours, and other transient neurological abnormalities.³⁷ The Mayo TBI Severity Classification System incorporated a category below mTBI called “symptomatic” or possible TBI, which includes symptoms other than LOC and amnesia, including blurred vision, dizziness, and headache.³² This category allowed for the possibility, but not the certainty, of TBI.

From this review of existing case definitions and symptom inventories, we identified the TBI signs and symptoms that were most commonly assessed. The research team that included CDC team members and 2 external experts drafted the list of TBI signs and symptoms to include in our case definition. We sent the list and the proposed 3-tiered case definition to

a wider group of experts for review and feedback and modified both in response to their input. We recognize that despite this process and our selection of a robust list of signs and symptoms that commonly present after TBI, all possible signs and symptoms may not have been included.

Following this process, a preliminary TBI case definition (see Table 1) was identified to classify cases in the NCSS pilot data. Specifically, TBIs were classified into 1 of 3 tiers. Tier 3 (or probable TBI) was indicative of the highest level of certainty that a TBI occurred and included the cardinal symptoms most emblematic of disruption of brain function (being dazed, confused, or having trouble thinking straight; difficulty remembering; LOC). Tier 2 (or possible TBI) was indicative of a moderate level of TBI certainty and included some less specific symptoms associated with TBI (nausea or vomiting; headache; dizzy, clumsy, or balance problems; blurred or double vision; or trouble concentrating immediately or in the minutes after the injury). Finally, tier 1 (or delayed possible TBI) was indicative of the lowest level of TBI certainty and included the same symptoms as tier 2, except respondents indicated that particular symptoms appeared later on (ie, not immediately after the injury), as well as difficulty learning or remembering new things, sensitivity to light or noise, change in mood or temperament, and change in sleep or more tired than usual. The lower level of certainty in tier 1 is due to the fact that a respondent reported that they did not experience certain symptoms immediately after the head injury (eg, a respondent reporting a headache or dizziness/clumsiness that did not begin immediately or in the minutes after the injury); consequently we would have less confidence that the symptom was caused by the injury and less confidence that they had sustained a TBI.

The number of symptoms experienced by respondents was also incorporated into the preliminary tiered TBI case definition. Specifically, experiencing 3 symptoms from tier 2 would indicate a probable TBI while experiencing 3 symptoms from tier 1 would indicate a possible TBI. In addition, cases were classified as tier 1 if a respondent reported that they experienced symptoms that typically evolve over a sustained period of time (difficulty learning or remembering new things, change in mood or temperament, change in sleep or more tired than usual). Each head injury reported by respondents was classified into a tier; however, the refinement of the case definition (see companion piece) was based only on the most recent head injury reported. This was due to concerns about survey burden and the additional questions required for refinement of the TBI case definition.

CONCLUSION

Current surveillance estimates of TBI (and youth sports concussion) are significant underestimates. CDC concluded that the only feasible way to obtain comprehensive estimates of TBI is through a household survey. There remain significant challenges in classifying TBI cases and some of these challenges can be addressed by using a tiered case definition based on the level of certainty that a TBI occurred. CDC, after consulting the literature and TBI experts, developed a tiered case definition to be tested and refined through analysis of NCSS pilot data. Case definition tiers were based on the type of sign/symptom(s) reported, the number of symptoms reported, and the timing of symptom onset. The companion piece in this issue outlines the process used to refine the TBI case definition

through an analysis of NCSS pilot data. Because the proposed case definition, and the refined case definition described in the adjoining article, are based on signs and symptoms experienced by any person who has sustained a suspected TBI, it has utility in surveillance efforts for multiple and varied populations: general population adults and children, veterans, incarcerated and formerly incarcerated people, people experiencing homelessness, and various other groups. It is our intent that the TBI case definition can be utilized in diverse surveillance efforts moving forward.

Acknowledgments

The findings and conclusions in this manuscript are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Dr Corrigan's effort was supported in part by a grant from the National Institute on Disability, Independent Living, and Rehabilitation Research to The Ohio State University (grant 90DPTB0026). NIDILRR is a center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this publication do not necessarily represent the policy of NIDILRR, ACL, or HHS, and you should not assume endorsement by the Federal Government.

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Centers for Disease Control and Prevention’s National Concussion Surveillance System pilot TBI case definition

TABLE 1

The proposed case definition requires the report of a bump, blow or jolt to the head and the endorsement of at least 1 sign or symptom as a result of that head injury, with cases delineated further by the tiers described below:	
Tier 3: Probable TBI: At least one of the following signs are reported immediately or in the minutes after injury:	
<ul style="list-style-type: none">• Dazed, confused, or trouble thinking straight• Difficulty remembering• Loss of consciousness	
or	
• 3 or more of the immediately occurring symptoms from tier 2	
Tier 2: Possible TBI: At least one of the following symptoms are reported immediately or in the minutes after injury:	
<ul style="list-style-type: none">• Nausea or vomiting• Headache• Dizzy, clumsy, or balance problems• Blurred or double vision• Trouble concentrating	
or	
• 3 or more symptoms from tier 1	
Tier 1: Delayed possible TBI: At least one of the following symptoms are reported sometime after the injury:	
<ul style="list-style-type: none">• Difficulty learning or remembering new things• Sensitivity to light or noise• Change in mood or temperament• Change in sleep or more tired than usual	
or	
• Any tier 2 symptom that does not develop in the minutes after the injury is classified as a tier 1 symptom due to the possibility that it may be attributable to an event or health condition other than the head injury in question	
Noncases: Head injuries with no reported signs or symptoms	

Abbreviation: TBI, traumatic brain injury.