

NINDS CDE Project

Subgroup in Sport Concussion: Persistent/Chronic

Three subgroups of experts were formed to represent the acuity/chronicity continuum of sport-related concussion: Acute (<3 days post injury), Sub-Acute (3 days – 3 months post-injury), and Persistent/Chronic (> 3 months post injury). The interdisciplinary Persistent/Chronic sub-group began by reviewing the existing Common Data Elements (CDEs) for Traumatic Brain Injury (TBI), particularly those relevant to mild TBI and concussion, to determine applicability to individuals with sport-related concussion in later post-injury phases. Initial screening was done independently by working group members prior to scheduled conference calls, which were dedicated to discussion and achieving consensus on specific items where *a priori* consensus did not exist. The working group considered variables and measures that would be relevant across a wide spectrum of age, from young children to older adults. Consistency with other Acute and Subacute working group recommendations was considered, where applicable, to facilitate longitudinal studies or those with a focus on initial symptoms that persist beyond 3 months. However, the working group also attempted to incorporate measures specifically relevant to longer-term sequelae to accommodate studies with a developmental focus or studies which address potential long-term neurodegenerative change. With regard to testing instruments, data related to adequacy of psychometric characteristics or existing literature supporting use in this population, cost, availability in multiple languages, and ease of use were also considered by working group members.

All existing measures from the CDE recommendations for mild TBI and concussion were considered and discussed for inclusion in the sport-related concussion CDEs. However, in some cases, the Persistent/Chronic working group did not recommend retaining some measures that were considered to have limited applicability in sport-related concussion studies. The intent of the working group was not implying that such measures should not ever be used in studies of sport-related concussion, but rather reflected an attempt to streamline the recommended instruments to those with the broadest applicability and greatest utility in the field of sport-related concussion *per se*. In other instances, new domains and instruments were suggested, reviewed and recommended to capture additional areas of interest in this field, based on working group members' professional expertise and knowledge of the sport concussion literature. The working group's recommendations reflected the stance that when there is no recommended measure to address a given domain or construct, investigators would be encouraged to select additional measures that best suited the research focus of their studies.

Following the identification of all potential CDEs, the individual items were categorized into one of four categories:

Sport-Related Concussion Core: A data element that collects essential information applicable to any sport-related concussion study. The NINDS and its appointed working groups assign the disease "Core" classification based on the current clinical research best practices. In each case, the Sport-related Concussion Core CDEs are a small subset of the available CDEs, where it is anticipated that investigators will need to collect the Sport-related Concussion Core CDEs on any type of study. These are required for all sport-related Concussion studies.

Sport-related Concussion Supplemental - Highly Recommended: A data element which is essential based on certain conditions or study types in sport-related concussion clinical research studies. In most cases, these have been used and validated in sport-related concussion. These data elements are strongly recommended for most sport-related condition conditions, study types or designs

Sport-related Concussion Supplemental: A data element which is commonly collected in sport-related concussion clinical research studies (or research that can be deemed appropriate for use in sport-related concussion). Use depends upon the study design, protocol or type of research involved. These are recommended, but not required, for studies.

Sport-related Concussion Exploratory: A data element that requires further validation, but that may fill current gaps in the CDEs and/or substitute for an existing CDE once validation is complete. Such data elements show great promise, but require further validation before they are ready for use in sport-related concussion clinical research studies. This category may also include CDEs that have been used successfully in other study populations, including other forms of traumatic brain injury, but may have had more limited use in sport-related concussion *per se*. These elements are reasonable to use with the understanding that they have limited or no validation in sport-related concussion.

The Sport-related Concussion *Core* and *Supplemental – Highly Recommended* CDEs will generally have broad applicability across both different sports and post-injury intervals. However, there are anticipated to be situations where certain measures classified as “supplemental – highly recommended”, “supplemental” and “exploratory” may be classified differently by the three Working Groups as they target constructs that are more applicable at certain post-injury intervals versus others. For example, measures assessing concussion-related orientation may be deemed as more important in the acute versus chronic post-injury intervals. Additionally, there may be elements that are more or less applicable depending on the age range of the study population (younger children versus collegiate athletes versus older retired professional athletes), the study setting (e.g., brief acute sideline assessment versus clinical or laboratory assessment that allows access to specialized equipment, longer evaluation, etc.) and the research question (e.g., effects of acute assessment versus long-term effects of repetitive injury). Note that there may also be preferred instruments for situations requiring longitudinal (repeated) evaluation versus a single assessment due to the existence of alternate forms to mitigate practice effects. Finally, there may be injury-related elements that are more or less applicable in different types of sport.

A single summary table showing the CDEs, grouped by domain and listed by row with category (i.e., Acute, Sub-Acute, and Persistent/Chronic) listed by column. Each cell can indicate the CDE level (i.e., Core, Supplemental – Highly Recommended, Supplemental, Exploratory) or other relevant information. Many of the CDEs listed for Persistent/Chronic Sport-related Concussion overlap with CDEs recommended for mild traumatic brain injury/Concussion as noted in the approach section above (item 1). However, other identified Persistent/Chronic Sport-related Concussion CDEs are also unique; recommendations reflect inclusion of additional items that are specific to sport, and the removal of other items that are not relevant to sport concussion.

Specific issues that arose when developing the CDE standards included the following:

- a) As with the other working groups, some constructs or instruments may be more or less relevant to a specific post-injury interval. Signs and symptoms that are considered important in the acute post-injury interval (e.g., orientation) may be less important or difficult to measure in a chronic interval, or may require different emphasis.
- b) CDE categorization into the Core, Supplemental, and Exploratory categories was difficult at times due to the paucity of the literature specifically examining the psychometric properties of certain measures specific to sport-related concussion despite their use in TBI at other ranges of severity.
- c) Some recommended measures require specialized equipment or expertise and may not be readily implemented in certain settings
- d) Lack of a single definition of the construct of “concussion” itself to indicate the limits of the range of injury severity.

It is important to note some of the unmet needs/unanswered questions identified via the CDE process in sport-related concussion. Some of the existing CDE measures have unknown sensitivity to change in concussion. In addition, CDEs surrounding head impact biomechanics, fluid biomarkers, and imaging warrant attention. Below are some summary tables showing the Core and Supplemental- Highly Recommended CDEs recommended specific to the Persistent/Chronic Subgroup. Each cell can indicate the CDE level or other relevant information.

Table 1. Core and Supplemental-Highly Recommended Outcome Measures for the Cognitive Assessment Subdomain

Sport-Related Concussion Subdomain	Outcome Measure Name	Persistent/Chronic (3 months and greater post concussion)
Cognitive Assessment*	Automated Neuropsychological Assessment Metrics (ANAM)	Core
Cognitive Assessment*	Axon Sports Computerized Cognitive Assessment Tool (CCAT)	Core
Cognitive Assessment*	CNS Vital Signs	Core
Cognitive Assessment*	Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT)	Core
Cognitive Assessment	Controlled Oral Word Association Test (COWAT)	Supplemental-Highly Recommended
Cognitive Assessment	Hopkins Verbal Learning Test - Revised (HVLt-R)	Supplemental-Highly Recommended
Cognitive Assessment	Trail Making Test (TMT)	Supplemental-Highly Recommended

Cognitive Assessment	Wechsler Adult Intelligence Scale (WAIS-IV)	Supplemental-Highly Recommended
Cognitive Assessment	Wechsler Intelligence Scale for Children (WISC-V)	Supplemental-Highly Recommended

Table 2. Core and Supplemental-Highly Recommended Outcome Measures for the Neuromotor Function Subdomain

Sport-Related Concussion Subdomain	Outcome Measure Name	Persistent/Chronic (3 months and greater post concussion)
Neuromotor Function	Dynamic Gait Index	Supplemental-Highly Recommended
Neuromotor Function	Functional Gait Assessment	Supplemental-Highly Recommended

Table 3. Core and Supplemental-Highly Recommended Outcome Measures for the Post-Concussive/Mild TBI-Related Symptoms Subdomain

Sport-Related Concussion Subdomain	Outcome Measure Name	Persistent/Chronic (3 months and greater post concussion)
Post-concussive/mild TBI-Related Symptoms*	Health and Behavior Inventory (HBI) ††	Core
Post-concussive/mild TBI-Related Symptoms*	Post-concussion Symptom Inventory (PCSI) †	Core
Post-concussive/mild TBI-Related Symptoms*	Post Concussion Symptoms Scale (PCSS) **	Core
Post-concussive/mild TBI-Related Symptoms*	The Rivermead Postconcussive Symptom Questionnaire (RPQ)	Core

Table 4. Core and Supplemental-Highly Recommended Outcome Measures for the Vestibular Function Subdomain

Sport-Related Concussion Subdomain	Outcome Measure Name	Persistent/Chronic (3 months and greater post concussion)
Vestibular Function	Dizziness Handicap Inventory (DHI)	Supplemental - Highly Recommended

* Only one assessment is needed for each time point.

**PCSS is included in IMPACT, but may be administered separately.

†The assessment is available within the Sport Concussion Assessment Tool (SCAT-5), but may be administered separately.

†† The assessment is available within the Child Sport Concussion Assessment Tool (Child SCAT-5), but may be administered separately.