

National Institute of Neurological Disorders and Stroke (NINDS) CDE Project

Subgroup in Sport Concussion: Acute

The process of developing the Sport-Related Concussion (SRC) Common Data Elements (CDEs) began by first dividing the larger Working Group into three Subgroups: Acute, Sub-Acute, and Chronic. Acute was defined as the time from the initial injury until 72hrs post-injury to include delayed reporting and at least one clinic exam in most instances. Using this as a framework, the interdisciplinary Acute Subgroup began by reviewing the existing Traumatic Brain Injury (TBI) CDEs for applicability to acute concussion. Initial screening was performed independently by the group members prior to organize conference calls, with call time dedicated to achieving a consensus on specific items where *a priori* consensus did not exist. CDEs were identified as applicable within the 72 hour window or for use if combined with an assessment at the other post-injury intervals (i.e. sub-acute and chronic). Following the review of the previously available CDEs, each member of the committee was asked for suggestions of other tools/instruments based on their knowledge of the SRC literature and personal experience that may also have applicability. These suggestions were reviewed using the same process as above.

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

Core is a data element that collects essential information applicable to any SRC study. The NINDS and its appointed working groups assign the injury “Core” classification based on the current clinical research best practices. In each case, the SRC Core CDEs are a small subset of the available CDEs, where it is anticipated that investigators will need to collect the SRC Core CDEs on any type of study. These are required for all SRC studies.

Supplemental - Highly Recommended is a data element which is essential based on certain conditions or study types in SRC clinical research studies. These elements have been used and validated in previous SRC research. These data elements are strongly recommended for specified SRC conditions, study types or designs.

Supplemental includes data elements which are commonly collected in SRC clinical research studies (or research that can be deemed appropriate for use in SRC). Use depends upon the study design, protocol or type of research involved. These are recommended, but not required, for SRC studies.

Exploratory is a data element that requires further validation, but 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 ‘prime-time’ use in SRC clinical research studies. They are reasonable to use with the understanding that they have limited or no validation in SRC.

Many of the CDEs listed for Acute SRC overlap with those identified for mild TBI. However, the identified Acute SRC CDEs are also unique from mild TBI with inclusion of sport specific measures or removal of items that are not relevant to sport concussion. Two specific unique issues arose while developing the SRC CDEs. First, the acceptance/rejection of CDEs specific to the Acute concussion time frame. This was a challenge as some items are not appropriate for application within 72 hours of injury when no other timepoints are collected. These same items would have research application if also collected at later time points (i.e. sub-acute and chronic). Second, the CDE categorization into the Core, Supplemental –

Highly recommended, Supplemental, and Exploratory categories. This was difficult based on the definitions provided, specifically the application of “validated in Sport Concussion” under SRC *Supplemental - Highly Recommended*. The difficulty arose from the working definition of validation and that many items from the TBI literature and CDE list have been used effectively for Sport Concussion, but do not have psychometric research specific to concussion. Lastly, CDEs surrounding head impact biomechanics, fluid biomarkers, and imaging are in need of further research and development.

Below are some summary tables depicting the *Core* and *Supplemental- Highly Recommended* CDEs recommended specifically for the Acute 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	Acute (time of injury until 72 hours)
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*	Standardized Assessment of Concussion (SAC) †	Core
Cognitive Assessment	Children's Orientation and Amnesia Test (COAT)	Supplemental-Highly Recommended
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	Acute (time of injury until 72 hours)
Neuromotor Function	Balance Error Scoring System (BESS) [†]	Core

Table 3. Core and Supplemental-Highly Recommended Outcome Measures for the Other Symptoms Subdomain

Sport-Related Concussion Subdomain	Outcome Measure Name	Acute (time of injury until 72 hours)
Other Symptoms	Brief Symptom Inventory -- 18 Item (BSI-18)	Supplemental - Highly Recommended

Table 4. Core and Supplemental-Highly Recommended Outcome Measures for the Post-Concussive/Mild TBI-Related Symptoms Subdomain

Sport-Related Concussion Subdomain	Outcome Measure Name	Acute (time of injury until 72 hours)
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
Post-concussive/mild TBI-Related Symptoms	Health and Behavior Inventory (HBI) ^{††}	Supplemental - Highly Recommended

Table 5. Core and Supplemental-Highly Recommended Outcome Measures for the Mood/Anxiety Subdomain

Sport-Related Concussion Subdomain	Outcome Measure Name	Acute (time of injury until 72 hours)
Mood/Anxiety	Center for Epidemiologic Studies Depression Scale (CES-D)	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.