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Original Articles

National Institute of Neurological Disorders and Stroke and Department of Defense Sport-Related Concussion Common Data Elements Version 1.0 Recommendations

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Abstract

Through a partnership with the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health, and Department of Defense, the development of Sport-Related Concussion (SRC) Common Data Elements (CDEs) was initiated. The aim of this collaboration was to increase the efficiency and effectiveness of clinical research studies and clinical treatment outcomes, increase data quality, facilitate data sharing across studies, reduce study start-up time, more effectively aggregate information into metadata results, and educate new clinical investigators. The SRC CDE Working Group consisted of 32 worldwide experts in concussion from varied fields of related expertise divided into three Subgroups: Acute (<72 h post-concussion), Subacute (3 days-3 months post-concussion) and Persistent/Chronic (>3 months post-concussion). To develop CDEs, the Subgroups reviewed various domains, then selected from, refined, and added to existing CDEs, case report forms and field-tested data elements from national registries and funded research studies. Recommendations were posted to the NINDS CDE Website for Public Review from February 2017 to April 2017. Following an internal Working Group review of recommendations, along with consideration of comments received from the Public Review period, the first iteration (Version 1.0) of the NINDS SRC CDEs was completed in June 2017. The

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recommendations include Core and Supplemental–Highly Recommended CDEs for cognitive data elements and symptom checklists, as well as other outcomes and end-points (e.g., vestibular, oculomotor, balance, anxiety, depression), and sample case report forms (e.g., injury reporting, demographics, concussion history) for domains typically included in clinical research studies. The NINDS SRC CDEs and supporting documents are publicly available on the NINDS CDE website www.commondataelements.ninds.nih.gov. Widespread use of CDEs by researchers and clinicians will facilitate consistent SRC clinical research and trial design, data sharing, and metadata retrospective analysis.

Keywords: assessment tools; clinical outcomes; clinical research; common data elements; data sets; traumatic brain injury

Introduction

In 2006, the National Institute of Neurological Disorders and Stroke (NINDS) initiated the development of Common Data Elements (CDEs) to assist NINDS-funded investigators studying various neurological diseases in collecting clinical and research data in a standard and consistent format. The overall goals of the NINDS CDE Project are to: 1) disseminate standards for the collection of data from participants enrolled in studies of neurological diseases; 2) create easily accessible tools for investigators to collect study data; 3) encourage focused and simplified data collection to reduce burden on investigators and practice-based clinicians to facilitate their participation in clinical research; and 4) improve data quality while controlling cost by providing uniform data descriptions and tools across NINDS-funded clinical studies.[1] The traumatic brain injury (TBI) CDE initiative began in 2008 with support from the NINDS in cooperation with representatives from other federal agencies funding TBI-related research (i.e., Department of Veterans Affairs [VA], the National Institute of Disability, Independent Living, and Rehabilitation Research of the Department of Education, the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury of the Department of Defense [DoD], and the Defense and Veterans Brain Injury Center of the DoD). Expert panel members addressed four types of data collection: 1) acute injury and demographic data; 2) biospecimens; 3) neuroimaging; and 4) outcome measurements. The original (Version 1.0) recommendations for each of these areas in TBI and psychological health were published in November 2010 in a special issue devoted to the TBI CDEs,[2–10] and additional recommendations for pediatric populations were published in 2012.[11–14]

In response to user experience and acknowledging the limitations of the initial version of the TBI CDEs, the TBI CDE workgroups were restructured to better address more circumscribed ranges of acuity and severity and additional research foci. New workgroups were established to tailor the original recommendations for 1) epidemiological studies, 2) acute hospitalization studies, 3) rehabilitation studies, and 4) mild TBI/concussion. Recommendations from these efforts were published in Version 2.0 of the TBI CDEs in 2013[15] and are publicly available.[16] Although many TBI CDE outcome data elements and variables from Version 1.0 were retained in Version 2.0, additional measures were added to specifically address common research questions specific to mild TBI and concussion. Additionally, a preliminary effort was made to incorporate a limited set of elements relevant to studies of sport-related concussion (SRC) and mild TBI within military populations. However, despite these adjustments, the detailed and systematic consideration of CDEs for SRC *per se* was a recognized weakness, particularly considering the large number of funding proposals, published manuscripts, and active projects in this particular area of TBI research.

SRC represents a subset of mild TBI, which occurs during athletic competition or practice.[17] These injuries are often observed and evaluated at the point of injury by sports medicine professionals (e.g., athletic trainers, physiotherapists, and physicians), but may not be evaluated until later post-injury time-points by primary care, neurological, neuropsychological, neurosurgical, pediatric, emergency department or specialty clinic healthcare professionals. SRCs may be complicated by a number of modifying factors or risk factors, including prior concussion, as reflected by its high incidence among athletes relative to the general population.[17] Research involving SRC includes initial identification of acute injury, injury biomechanics, assessment of involved domains across all phases of injury (i.e., acute, subacute, chronic), recovery monitoring, and clinical trials of the effectiveness of interventions to reduce morbidity and recovery time. Research participants in SRC studies typically range in age from childhood through at least middle adulthood, but the residual effects of SRC in children and older individuals are also of interest. With expanding research activity in each of these areas of SRC and populations, NINDS recognized the need to develop appropriate CDEs to harmonize data collection across studies, with a particular emphasis on federally-funded projects, to enable comparison of results across studies from this burgeoning area of investigation. This paper describes the process wherein NINDS recruited worldwide experts representing diverse research and clinical backgrounds in SRC to serve on committees that evaluated and recommended candidate CDEs for specific post-injury time-points.

Methods

The multi-disciplinary panel used to identify SRC CDEs was created using current and former SRC grantees from domestic and international governmental funding agencies, participant lists from international SRC guideline development, and lead personnel in SRC related organizations. A principal consideration was to include a diverse knowledge across academic backgrounds, sport, participant age, clinical expertise, and research methodology. During the planning of this project, two working groups were proposed with a recommended minimum of eight persons per working group. We assumed an approximate 50% acceptance rate to participate and developed an initial list of 35 invitees, including experts in both adult and pediatric SRC, from diverse training and expertise backgrounds that included athletic training, kinesiology, neurosurgery, neurology, neuroradiology, neuropsychology, physical therapy, physical medicine and rehabilitation, psychiatry, and general pediatrics.

To establish the SRC CDEs, the injury spectrum was ultimately divided into three Subgroups based on injury chronicity: 1) Acute, 2) Subacute, and 3) Persistent/Chronic. Acute SRC CDEs were identified based on typical clinical or research evaluations that would occur from the time of injury until 72 h post-injury. This time frame was implemented to include delayed reporting and at least one clinic examination in most instances. Subacute SRC CDEs were identified as assessments that would occur between 72 h and 3 months post-injury. This time period was used to focus more on clinical and laboratory measures typically used following an initial

acute or on-field evaluation. Persistent/Chronic CDEs focused on common injury-related variables and data elements of interest that would occur during a post-injury interval of 3 or more months. This time frame specifically incorporated CDEs to address longer-term sequelae and accommodate studies with a developmental focus or studies that addressed potential long-term SRC-related neurodegenerative change.

The NINDS Program Directors selected chairpersons for each Working Group to lead discussions and coordinate specific tasks. The Working Group included members with expertise in both adult and pediatric populations. Members of each Working Group began by evaluating existing NINDS mild TBI/concussion CDEs. The initial screening was done independently by the group members prior to organized conference calls, with call time dedicated to achieving consensus on specific items where *a priori* consensus did not exist. Following the review of the previously available CDEs, each member of the Working Group was asked for suggestions related to other tools/instruments based on his or her knowledge of the SRC literature and professional experience. Deliberations of each panel led to inclusion/exclusion and subsequent ranking of the candidate data elements for a specific context of use (e.g., to assess cognition during the first 72 h post-concussion in adolescents) based on the evidence for the measure's utility in SRC populations, accessibility, psychometric characteristics (e.g., validity, reliability), ease of administration, and burden on the injured athlete. The following sections report the recommendations of the three Working Groups.

Following the identification of all potential CDEs, the individual data elements were categorized into one of four categories of priority based on their evidenced-based support in the SRC literature and psychometric properties, a stratification consistent with the convention of other CDEs: Core, Supplemental–Highly Recommended, Supplemental, or Exploratory.[18] A description of each category is provided in Table 1.

Working Group members attempted to streamline the recommended data elements to those with the broadest applicability and greatest utility in the SRC field *per se*. In other instances, new domains and data elements 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 SRC literature. The Working Groups' recommendations reflected the position that when there was no recommended measure to address a given domain or construct, investigators would be encouraged to select additional data elements that best suited the research focus of their studies.

Following the process outlined above, all identified CDEs were made available for public viewing and comment for a 3-month period between February and April 2017. The public was informed via email to investigators and listservs, as well as through national meetings where the public review period was advertised to clinical research investigators. The public review packet consisted of all the materials that were to be posted on the website, including summary tables of recommendations, template case report forms and recommended instruments for measuring various outcomes, and endpoints. Following the public review period, the SRC Working Groups reviewed a compilation of suggestions and edits received from outside reviewers, which consisted of clinical and research experts in the field, patient advocates, and other stakeholders. These revisions were addressed with responses sent to public reviewers as necessary. Further review and revision of CDEs were encouraged on the NINDS CDE website via the feedback links on each page. On June 1, 2017, Version 1.0 of the SRC CDE recommendations were posted on the NINDS CDE website.[19]

Table 1. Description of CDE Categories

CDE category	*Description*
Core	Data elements that are essential and applicable to any SRC study. The NINDS and its appointed Working Groups assign the ''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 demonstrating appropriate test psychometrics specific to SRC. Core CDEs may be required for SRC studies.
Supplemental–Highly Recommended	Data elements that are essential to specific conditions or study types in SRC clinical research studies. These elements have been used and validated in previous SRC research or specified SRC conditions, study types, or designs. Supplemental–Highly Recommended CDEs are strongly recommended for SRC studies.
Supplemental	Data elements that are commonly collected in SRC clinical research studies, but with limited validation in previous SRC research. Use depends upon the study design, protocol or type of research involved. Supplemental CDEs are recommended for SRC studies.
Exploratory	Data elements that require further validation but may fill current gaps in CDEs and/or substitute for existing CDEs as validation evolves. Such data elements show promise but require further validation before they are ready for use in SRC clinical research studies. Exploratory CDEs are reasonable for SRC studies, with the understanding that they have limited or no validation in SRC.

CDE, Common Data Element; SRC, sport-related concussion; NINDS, National Institute of Neurological Disorders and Stroke.

Results

Of the initial 35 invitees, 32 agreed to participate, providing a diverse representation of knowledge and skills across disciplines and research methodology, including both pediatrics and adults. CDEs specific to each of the three post-injury temporal periods were identified following the process outlined above. Table 2 summarizes the Core (i.e., may be required) and Supplemental–Highly Recommended (i.e., strongly recommended) symptom and clinical outcome data elements. These data elements cover domains including neuromotor functioning, neuropsychological functioning, and post-concussive/TBI-related symptoms. However, depending on the focus of the study, additional Supplemental and Exploratory outcome data elements may be selected (please refer to the comprehensive table of CDEs for SRC on the NINDS website for measures in the Supplemental and Exploratory categories). Additional information on individual data elements within each category can be located on the NINDS CDE website. Further, depending on the post-injury timepoint of interest, the data elements below also may be recommended as Supplemental or Exploratory.

Table 2. SRC Core and Supplemental–Highly Recommended CDEs across Groups

Core Common Data Elements

Domain	*Outcome measure name*	*Acute*	*Subacute*	*Persistent/ chronic*
Post-concussive/mild TBI-related symptoms*	Health and Behavior Inventory (HBI)††		✓	✓
	Post-Concussion Symptom Inventory (PCSI)†	✓	✓	✓
	Post-Concussion Symptom Scale (PCSS)**	✓	✓	✓
	The Rivermead Post Concussion Symptom Questionnaire (RPQ)	✓	✓	✓
Neuromotor function	Balance Error Scoring System (BESS)†	✓		
Cognitive assessments*	Automated Neuropsychological Assessment Metrics (ANAM)	✓	✓	✓
	Axon Sports Computerized Cognitive Assessment Tool (CCAT)	✓	✓	✓
	Computerized Neurocognitive Assessment Software (CNS) Vital Signs	✓	✓	✓
	Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT)	✓	✓	✓
	Standardized Assessment of Concussion (SAC)†	✓		

Supplemental–Highly Recommended Common Data Elements

Domain	*Outcome measure name*	*Acute*	*Subacute*	*Persistent/ chronic*
Post-concussive/mild TBI-related symptoms	Health and Behavior Inventory (HBI)††	✓		
Neuromotor function	Dynamic Gait Index			✓
	Functional Gait Assessment			✓
Cognitive assessments	Children's Orientation and Amnesia Test (COAT)	✓		
	Controlled Oral Word Association Test (COWAT)	✓	✓	✓
	Hopkins Verbal Learning Test -Revised (HVLT-R)	✓	✓	✓
	Trail Making Test (TMT)	✓	✓	✓
	Wechsler Adult Intelligence Scale (WAIS-IV)	✓	✓	✓
	Wechsler Intelligence Scale for Children (WISC-V)	✓	✓	✓
	Standardized Assessment of Concussion (SAC)†		✓	
Other symptoms	Brief Symptom Inventory-18 Item (BSI-18)	✓		
Mood/Anxiety	Center for Epidemiologic Studies Depression Scale (CES-D)	✓		
Vestibular and oculo-motor function	Dizziness Handicap Inventory (DHI)		✓	✓
	Vestibular/Ocular Motor Screening Tool (VOMS)		✓	
Quality of life/patient-reported outcomes	Pediatric Quality of Life Inventory (PEDS-QL)		✓	

*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.

Please note that some of the measures listed above are for both pediatric and adult populations. Please visit the SRC recommendations on the NINDS CDE website for specific details.

SRC, sport-related concussion; CDEs, Common Data Elements; TBI, traumatic brain injury.

Cognitive assessments (i.e., Automated Neuropsychological Assessment Metrics, Axon Sports Computerized Cognitive Assessment Tool, CNS Vital Signs, or Immediate Post-Concussion Assessment and Cognitive Testing [ImPACT] in Table 2) were identified as a Core CDE by all Subgroups, but researchers should be cognizant that only one cognitive assessment is needed as a Core CDE in study implementation. In addition, we note that despite the standardization and primary use of computerized tools in the acute and subacute post-injury intervals, there may be situations where the administration of these measures is also useful in the chronic post-injury interval. An example may include the use of these measures in longitudinal assessment (for direct comparison with data collected at an earlier time interval). However, we acknowledge that there also may be circumstances or research designs where these measures are not as useful in the chronic interval.

Similar to the cognitive assessments, only one Core post-concussive/mild TBI-related symptoms assessment need be implemented, some of which are bundled with the cognitive assessments but may be administered independently. For example, the Post-Concussion Symptom Scale is included with the ImPACT tool, but it also can be administered separately as a paper and pencil test.

Note that the SRC Core and Supplemental–Highly Recommended CDEs generally have broad applicability across different post-injury intervals. However, specific elements were classified differently (i.e., Supplemental–Highly recommended, Supplemental, and Exploratory) by the three Working Groups, as the target constructs were more or less applicable to particular post-injury intervals. For example, data elements assessing concussion-related disorientation were deemed more important in the acute phase as opposed to the chronic post-injury interval. Additionally, there were elements whose applicability depended upon the age range of the study population (e.g., younger children vs. collegiate athletes vs. older retired professional athletes), the study setting (e.g., brief acute sideline assessment vs. clinical or laboratory assessment that allows access to specialized equipment, longer evaluation, etc.) and the research question (e.g., effects of acute concussion vs. long-term effects of repetitive injury). The Working Group members also acknowledged there may be preferred data elements 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 data elements that are more, or less applicable in different types of sport and populations.

In addition to outcome and objective CDEs, there is a set of Core demographic variables which should be collected in all neurological disease research studies to characterize the sample from which data are collected. These data are obtained by self-report, from a parent or legal guardian when minors are enrolled, or from another reliable source. Case report forms (CRFs) are available on the website[1] for these and other Supplemental (not Core or Supplemental–Highly Recommended) SRC-specific demographic, socioeconomic status, general health history (including personal medical history, participant and family psychological history, concussion history, migraine history and substance use), injury report, return to sports, clinical examination, vital signs, medications, imaging, and treatment variables.

Lastly, the SRC injury assessment data elements include CRF templates for reporting injury (see Injury Report CRF), and medical intervention (see Treatments Interventions NCAA Concussion Treatment CRF), prior concussion history (see Concussion History CRF including loss of consciousness/duration of loss of consciousness, post-traumatic amnesia, post-concussive symptoms and mechanism of injury variables), and return to sports elements such as rehabilitation status (see Return to Play CRF). Other specific CRFs for associated conditions of interest in SRC, such as migraine history, are also available (see Migraine History and Personal Medical History CRFs), as well as CRFs to record the provision of treatments common in SRC (see Injury Report CRF; e.g., cognitive rest, physical exertion therapy, vestibular/oculomotor therapies, vision therapies, medications). In addition, data elements for imaging variables were included with assessments of cavum septum pellucidum and white matter hyperintensities in addition to other CDEs used in more severe TBI (see Imaging CRF). Although these features may be considered benign and/or incidental, recent interest in these findings prompted inclusion to more accurately determine their base rate and relation to outcome in athletes with SRC. These template CRFs can serve as the foundation for documenting participant characteristics, participant and family history, injury reports, assessments and examinations, and interventions.

Discussion

In view of the high incidence of SRC reported in the literature and the expanding research in this type of TBI, it is timely to implement CDEs into clinical research, similar to other types of TBI.[20–22] This article outlines the NINDS SRC CDEs for use in observational research and clinical trials. Specifically, this article highlights Core and Supplemental–Highly Recommended CDEs across three distinct SRC temporal categories that represent domains including cognitive function, post-concussive symptoms, neuromotor function, mood/anxiety, vestibular and oculomotor function, and quality of life. These SRC CDEs and previous CDEs developed by NINDS represent the standard by which outcome data are to be collected to ensure data quality using consistent definitions and uniform capture methodologies. CDEs are designed to facilitate comparison of results across studies by harmonizing SRC characterization, demographic characteristics, and clinical outcome data elements. While not mandatory in all instances, use of CDEs is strongly encouraged to merge data from multiple sources and many CDEs are currently being used by the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system.[23] The FITBIR platform allows data from multiple studies to be integrated and re-analyzed with greater statistical power than any single study can provide.

Investigators should be mindful of the CDEs identified herein with similarities to other injuries along the TBI spectrum. Many of the SRC CDEs were derived from existing TBI CDEs, while others were unique and specific to SRC research during specific data collection time-points (i.e., Acute, Subacute, Persistent/Chronic). At a minimum, the Core SRC variables should be collected whenever feasible, with strong consideration of the Supplemental–Highly Recommended CDEs. The Supplemental–Highly Recommended CDEs, however, in addition to those identified as Supplemental and Exploratory, should not be used in isolation of other study-specific variables (i.e., variables not currently identified as a CDE) developed by the investigative team. Indeed, study specific variables are necessary to facilitate the cutting-edge research necessary to keep the field moving forward and develop new CDEs that reflect our evolving knowledge of SRC. To that end, the CDEs listed here represent the first iteration of data elements to be used in SRC research. As studies are completed and the science evolves, it is projected that CDEs will change accordingly. Experience, increased evidence, and new data elements will inform the revision process, but the current version offers standardization across investigations, as opposed to the current colloquial nature of data collection.

Limitations and remaining gaps

Several important issues confronted the Working Groups during their review and selection of CDEs for SRC. First, categorization by the Working Group of candidate data elements into the Core, Supplemental–Highly Recommended, Supplemental, and Exploratory categories of outcome data elements was challenging due to the paucity of literature examining the psychometric properties of many of the data elements when used to specifically assess SRC. Second, members of the Working Group acknowledged that some of the CDEs may require specialized equipment or expertise and may not be feasible to implement in certain settings.[17] In addition, the temporal classifications of Acute, Subacute, and Persistent/Chronic may not reflect all age categories.[24] Third, although it was acknowledged that military personnel may sustain SRC as part of their training or during, before, or after deployment, Working Group members elected to exclude data elements that were specific to combat or blast exposure, or concussions sustained

as part of military training. We suggest that investigators studying military populations consider additional data elements appropriate for military personnel listed in the V2.0 CDEs for mild TBI/concussion. Finally, it is important to acknowledge the unmet needs/unanswered questions identified via the SRC CDE process. Some of the current CDEs have unknown psychometrics and sensitivity to change in SRC, and CDEs surrounding head impact biomechanics, fluid biomarkers, and imaging warrant further attention for application in future research on SRC. In addition, while the CDEs identified here will apply to the majority of sports, there may be instances in which they do not apply.

To address some of these concerns and the ever-evolving nature of the field, an annual Oversight Committee will be formed starting in 2018 to review all recommendations for updates. This Oversight Committee will be comprised of eight to 10 members selected from the current SRC Working Group in addition to outside members that will provide a fresh perspective on the current CDE recommendations. New members may include athletes, patient advocates, industry representatives, and additional SRC experts. The Oversight Committee recommendations may be posted for public comment before being finalized and posted to the NINDS CDE website.

Conclusions

The NINDS SRC CDE Working Group's recommendations are the initial step in an evolving process. In this first iteration, we provide CDEs for SRC that can help bridge current inconsistencies in research and facilitate data sharing, and combined dataset analyses. However, we recognize the need for further investigation of the psychometric properties of several CDEs, especially in areas in which there are limited published data such as in children and youth sports, older adult athletes, and SRC in female athletes. Long-term or longitudinal data on the late chronic effects of SRC are also presently limited, thus, future updates of the CDEs will be necessary as additional data is collected. Future CDEs may also address outcome data elements for specific interventions, which involve new technologies or novel application of existing technologies. Despite these limitations, application of the Working Group's recommendations will facilitate harmonization of methods across federal and non-federally funded studies, enable comparison of their results and secondary analysis of their data when accessed by other investigators through FITBIR.

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Author Disclosure Statement

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