Common data elements

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NIH encourages the use of common data elements (CDEs) in clinical research, patient registries, and other human subject research in order to improve data quality and opportunities for comparison and combination of data from multiple studies and with electronic health records.

With the advent of "big data" approaches to understanding complex systems, there is the potential to greatly accelerate knowledge about mechanisms of injury and how to detect and modify them to improve patient outcomes. High quality, well-defined data are critical to the success of bioinformatics platforms, and a data dictionary of "common data elements" (CDEs) [1)]

The management of Chiari I malformation (CMI) is controversial because treatment methods vary and treatment decisions rest on incomplete understanding of its complex symptom patterns, etiologies, and natural history. Validity of studies that attempt to compare treatment of CMI has been limited because of variable terminology and methods used to describe study subjects. The goal of this project was to standardize terminology and methods by developing a comprehensive set of Common Data Elements (CDEs), data definitions, case report forms (CRFs), and outcome measure recommendations for use in CMI clinical research, as part of the CDE project at the National Institute of Neurological Disorders and Stroke (NINDS) of the US National Institutes of Health. A working group, comprising over 30 experts, developed and identified CDEs, template CRFs, data dictionaries, and guidelines to aid investigators starting and conducting CMI clinical research studies. The recommendations were compiled, internally reviewed, and posted online for external public comment. In October 2016, version 1.0 of the CMI CDE recommendations became available on the NINDS CDE website. The recommendations span these domains: Core Demographics/Epidemiology; Presentation/Symptoms; Co-Morbidities/Genetics; Imaging; Treatment; and Outcome. Widespread use of CDEs could facilitate CMI clinical research trial design, data sharing, retrospective analyses, and consistent data sharing between CMI investigators around the world. Updating of CDEs will be necessary to keep them relevant and applicable to evolving research goals for understanding CMI and its treatment [2)].

A critical component for accelerating the clinical uptake of research data in the area of pediatric concussion or mild traumatic brain injury (MTBI) pertains to the establishment and utilization of common databases. The objective of the first phase of our CanPedCDE initiative was to agree upon pediatric common data elements (CDEs) that could best characterize children with MTBI over their recovery period. The selection of CDEs for our framework aimed to balance factors such as the comprehensiveness of outcomes collected, their applicability to diverse settings, as well as the costs associated with their use. Selection began by identifying relevant domains of functioning (e.g., post-concussion symptoms, attention, and balance). Two sources were used to make this process more efficient: 1) the World Health Organization International Classification of Functioning (ICF) Traumatic Brain Injury Core Set, and the U.S. National Institute of Neurological Disorders and Stroke Traumatic Brain Injury Common Data Elements, both of which had already suggested relevant domains to include in TBI research. The process was completed in two phases: 1) using an online survey of experts and 2) through an in-person consensus meeting. Measurement tools were also proposed that were best felt to capture these domains. Forty experts in MTBI in children from multiple health-related

perspectives (e.g., emergency medicine, pediatrics, neurosurgery, nursing, physiotherapy, and neuroscience), as well as knowledge users, participated in the selection process. The final list of CDEs included 77 distinct areas of functioning, covering all categories of the ICF model. Outcome measures were attached to each element, when applicable. The CanPedCDE initiative addresses a significant limitation in MTBI research to date and may help both researchers and clinicians to organize and standardize their assessment of children and youth post-MTBI in order to move the field in promising directions [3].

The Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) Pilot Study was a prospective observational study that utilized the NIH TBI CDEs, Version 1.0. We examined variables associated with SCC, performance on objective cognitive tests (Wechsler Adult Intelligence Scale, California Verbal Learning Test, and Trail Making Tests A and B), and agreement on self-report of SCCs as assessed by the acute concussion evaluation (ACE) versus the Rivermead Post Concussion Symptoms Questionnaire (RPQ).

In total, 68% of 227 participants endorsed SCCs at 6 months. Factors associated with SCC included less education, psychiatric history, and being assaulted. Compared to participants without SCC, those with SCC defined by RPQ performed significantly worse on all cognitive tests. There was moderate agreement between the two measures of SCCs (kappa = 0.567 to 0.680).

We show that the symptom questionnaires ACE and RPQ show good, but not excellent, agreement for SCCs in an mTBI study population. Our results support the retention of RPQ as a basic CDE for mTBI research [4].

Standardized data collection for traumatic brain injury (TBI) (including concussion) using common data elements (CDEs) has strengthened clinical care and research capacity in the United States and Europe. Currently, Ontario healthcare providers do not collect uniform data on adult patients diagnosed with concussion.

OBJECTIVE: The Ontario Concussion Care Strategy (OCCS) is a collaborative network of multidisciplinary healthcare providers, brain injury advocacy groups, patient representatives, and researchers with a shared vision to improve concussion care across the province, starting with the collection of standardized data.

METHODS: The International Framework of Functioning Disability and Health was selected as the conceptual framework to inform the selection of CDEs. The CDEs recommended by the OCCS were identified using key literature, including the National Institute of Neurological Disorders and Stroke-Zurich Consensus Statements for concussion in sport and the Ontario Neurotrauma Foundation Concussion/mTBI clinical guidelines.

RESULTS: The OCCS has recommended and piloted CDEs for Ontario that are readily available at no cost, clinically relevant, patient friendly, easy to interpret, and recognized by the international scientific community.

CONCLUSIONS: The implementation of CDEs can help to shift Ontario toward internationally recognized standard data collection, and in so doing yield a more comprehensive evidence-based approach to care while also supporting rigorous research [5].

A study collected measures recommended by the TBI Common Data Elements (CDE) Workgroup. Patients presenting to 3 emergency departments with a TBI of any severity enrolled in TRACK-TBI prospectively after injury; outcome measures were collected at 3 and six months postinjury. Analyses examined frequency of impairment and overlap between impairment status across the CDE outcome domains of Global Level of Functioning (GOSE), Neuropsychological (cognitive) Impairment, Psychological Status, TBI Symptoms, and Quality of Life. GOSE score correlated in the expected direction with other outcomes (M Spearman's rho = .21 and .49 with neurocognitive and self-report outcomes, respectively). The subsample in the Upper Good Recovery (GOSE 8) category appeared quite healthy across most other outcomes, although 19.0% had impaired executive functioning (Trail Making Test Part B). A significant minority of participants in the Lower Good Recovery subgroup (GOSE 7) met criteria for impairment across numerous other outcome measures. The findings highlight the multidimensional nature of TBI recovery and the limitations of applying only a single outcome measure [6].

Chronic subdural hematoma (CSDH) is an increasingly common subtype of head injury, especially in the elderly population. The optimization of treatment strategies has been hampered by the collection of heterogeneous outcome measures and data elements, precluding cross-study comparisons. This study aimed to quantify the heterogeneity of data elements in the pre-operative, operative, and post-operative phases of care, and build the basis for the development of a set of common data elements (CDEs) for CSDH. This systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and was registered with the PROSPERO register of systematic reviews (CRD42014007266). All full-text English studies with more than 10 patients (prospective) or more than 100 patients (retrospective) published after 1990 examining clinical outcomes in CSDH were eligible for inclusion. One hundred two eligible studies were found. Only 40 studies (39.2%) reported the main presenting symptom/feature and 24 (23.5%) reported additional symptoms/features. Admitting neurological/functional status was classified by the Glasgow Coma Scale (25 studies; 24.5%), the Markwalder Score (26 studies; 25.5%) and the modified Rankin Scale (three studies; 2.9%). Fifty-four studies (52.9%) made some mention of patient comorbidities and 58 studies (56.9%) reported the proportion or excluded patients on anticoagulant medication. Eighteen studies (17.6%) reported baseline coagulation status. Sixty-four studies (62.7%) stratified or assessed severity based on radiological findings, although the methods used varied widely. There was variable reporting of surgical technique and post-operative care; 32 studies (31.4%) made no mention of whether the operations were performed under general or local anesthetic. This study, a part of the Core Outcomes and Common Data Elements in CSDH (CODE-CSDH) project, confirms and quantifies the heterogeneity of data elements collected and reported in CSDH studies to date. It establishes the basis for the consensus-based development of a set of common data elements, facilitating robust cross-study comparisons and resulting improvements in patient outcomes [7].

Radiologic brain imaging is the most useful means of visualizing and categorizing the location, nature, and degree of damage to the central nervous system sustained by patients with traumatic brain injury (TBI). In addition to determining acute patient management and prognosis, imaging is crucial for the characterization and classification of injuries for natural history studies and clinical trials. This article is the initial result of a workshop convened by multiple national health care agencies in March 2009 to begin to make recommendations for potential data elements dealing with specific radiologic features and definitions needed to characterize injuries, as well as specific techniques and parameters needed

to optimize radiologic data acquisition. The neuroimaging work group included professionals with expertise in basic imaging research and physics, clinical neuroradiology, neurosurgery, neurology, physiatry, psychiatry, TBI research, and research database formation. This article outlines the rationale and overview of their specific recommendations. In addition, we review the contributions of various imaging modalities to the understanding of TBI and the general principles needed for database flexibility and evolution over time to accommodate technical advances [8)].

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