SPECIAL COMMUNICATION

Common Data Elements in Radiologic Imaging of Traumatic Brain Injury

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ABSTRACT. Duhaime AC, Gean AD, Haacke EM, Hicks R, Wintermark M, Mukherjee P, Brody D, Latour L, Riedy G, Common Data Elements Neuroimaging Working Group Members, Pediatric Working Group Members. Common data elements in radiologic imaging of traumatic brain injury. Arch Phys Med Rehabil 2010;91:1661-6.

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.

Key Words: Clinical research; Clinical trials; Database; Head injury; Magnetic resonance imaging; Radiology; Rehabilitation; Traumatic brain injury.

RADIOLOGIC BRAIN IMAGING offers the best opportunity to visualize and categorize the location, nature, and degree of damage to the CNS in patients with TBI, both acutely and over time. In addition to its utility in triaging patients for acute interventions and determining prognosis, injury classification and characterization by means of imaging is crucial for designing natural history studies, predictive tools for long-term outcome, and effective clinical trials targeting neurobiologic mechanisms. To date, there have been more than 20 large, prospective, blinded, multicenter clinical trials in human head injury that have largely failed to identify effective acute neuroprotective interventions.[1] This failure has been thought to be caused in part by the use of inclusion criteria based primarily on acute clinical severity indexes, such as the Glasgow Coma Scale, rather than specific pathoanatomic injury type or other factors that might group patients by common pathophysiologic processes.[2] Because most neuroprotective interventions have been tested in specific pathoanatomic injury types during the preclinical phase, radiologic brain imaging is critical in selecting patients most likely to benefit from a specific intervention for that particular injury. Thus, the structure of a CDE set for neuroimaging has implications for how patients entering clinical trials will be classified, stratified, and treated and must be designed to incorporate lessons learned from prior clinical trial failures.

List of Abbreviations

CDE	common data element
CNS	central nervous system
CT	computed tomography
DAI	diffusion axonal injury
DTI	diffusion tensor imaging
DWI	diffusion weighted imaging
fMRI	functional magnetic resonance imaging
GRE	gradient-recalled echo
MR	magnetic resonance
MRI	magnetic resonance imaging
NCT	noncontrast computed tomography
PET	positron emission tomography
T2*	T2 star (T2-weighted gradient-recalled echo)
T2 FLAIR	T2-weighted fluid attenuated inversion recovery
TAI	traumatic axonal injury
TBI	traumatic brain injury

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BACKGROUND

Neuroimaging has played an important role in TBI research since its inception. Early studies focused on acute, severe injuries, clinical and radiologic predictors of outcome, and the pathophysiologic characterization of basic processes that could be visualized readily by using early technologies, such as mass lesions, brain swelling, and cerebral blood flow. Animal models and biomechanical studies helped refine the understanding of various pathoanatomic entities and their responsible mechanisms of injury. Neuropsychological and behavioral studies began to focus on long-term outcome and delayed consequences of injury. More recently, injuries in the clinically "milder" end of the acute severity spectrum, including those associated with repeated impacts or blast exposure, have garnered growing attention.

In making recommendations for a common element database for neuroimaging, the working group assessed present and future needs in clinical research. Several imaging classification and prognostication schemes have been used widely in TBI research, including tools such as the Marshall and Rotterdam scores, which incorporate acute CT findings to predict broad categories of outcome.[3,4] Although practical and useful, these prognostic CT models focus on severely injured patients, do not include specific deficits related to regional damage, and do not encompass other imaging modalities that are more reflective of physiologic changes. Currently, MRI is increasingly important in head injury diagnosis and follow-up. For the future, this and other developing imaging technologies are likely to have a major impact on the choice of acute treatments for patients with TBI and on monitoring their effects. From a clinical trials design perspective, better stratification of the patient population and entry criteria by pathoanatomic injury type and use of imaging as a surrogate endpoint for response to interventions may expedite and improve the clinical trial process. For example, treating only patients who have contusions with a drug shown to improve contusional brain swelling in animals may be a better strategy than treating all patients who present with unconsciousness with the same drug, irrespective of whether they have contusions, subdural hematomas, or diffuse axonal injury. From the rehabilitation perspective, using techniques with improved predictive value for more specific cognitive, behavioral, or neurologic outcomes may help the rehabilitation professional administer more appropriate and tailored treatments to individual patients, with the caveat that similar functional deficits may provide targets for treatment in the chronic phase after injury despite differing pathoanatomic substrates.

One limitation to the use of imaging to classify injury types and characterize pathophysiologic sequelae of TBI is that different imaging modalities are used for different applications. In addition, newer methods are applied with a variety of different technical parameters from site to site that can make intersite comparisons impracticable, and different centers use varying definitions for specific neuroimaging findings. The working group attempted to address these issues by structuring an imaging database from which imaging terminologies and results could be compared reliably among centers and across published articles. One key to creating CDEs is converting the traditional qualitative narrative radiologic evaluation to a standardized format that can be entered easily into a database. This can be achieved by using standard definitions of the pathophysiologic entities identified with the major neuroimaging techniques most commonly used to evaluate TBI. A simple checkbox method for the presence of a given lesion type or types and standardized reporting of important qualitative (eg, location) and basic quantitative (eg, hemorrhage maximum length, width, thickness) features would facilitate entry into a neuroimaging database. *By standardizing the definitions and interpretation scheme, one can create CDEs across multiple neuroimaging studies that employ different imaging techniques.* Development of a database software package that could be widely distributed (through Internet access), used at multiple centers, and updated regularly would greatly facilitate the collection of these data in a standardized fashion and would contribute to a usable infrastructure for future multicenter studies.

PURPOSE/AIM OF THE WORKING GROUP

To accomplish these goals, it was agreed that researchers working with patients with TBI would need more detailed working descriptions of specific pathoanatomic entities found in TBI. Each injury would have to be precisely defined, characterized, and quantified among patients and over time. Data elements would need to accommodate the mixture of injury entities found in individual patients, and be able to follow up the evolution of injuries as seen radiologically over time. Of equal importance, optimization and standardization of specific imaging techniques is essential to TBI research, and successful use of CDEs is dependent on such standardization and recording of the technical details associated with patient imaging. It was acknowledged that identifying and defining CDEs used in studying TBI would present challenges because of a lack of consensus in the field for certain clinical definitions, descriptors, or terms related to TBI, and lack of large comprehensive studies evaluating the capabilities of the various neuroimaging modalities in detecting or monitoring TBI. With these caveats in mind, neuroimaging panel members performed a broad background analysis of available and emerging modalities and defined some basic data elements that will provide a more standardized evaluation of TBI neuroimaging data across various research studies and among centers. In doing so, although not all terms and conditions encountered in TBI have been defined, we have tried to include many basic elements that should be considered when discussing and classifying different types of TBI with neuroimaging. The audience for this document includes practitioners and researchers who want a more detailed understanding of TBI protocols and their utility, those who seek common definitions of pathoanatomic terms relevant to radiologic diagnosis, and those who want a practical recommendation for what to include in their research protocols to answer specific clinical questions.

RECOMMENDATIONS FOR CDEs, INCLUDING GENERAL PRINCIPLES OF DATABASE STRUCTURE, STANDARDIZED IMAGING PROTOCOLS, AND PATHOANATOMIC TERMINOLOGY

The CDEs recommended by the neuroimaging group include two broad categories: (1) specific terms with standardized definitions of different types of pathoanatomic lesions resulting from trauma to the skull, blood vessels, and CNS structures; and (2) a description of specific neuroimaging protocols and techniques, with recommendations for how to perform the imaging study and what techniques to consider for specific research questions. These two element clusters necessarily are linked because terms typically are defined within the modality used to image them. The details of both of these initial element clusters appear in Appendix I[5] (Pathoanatomic Terms and Definitions) and Appendix II[5] (Suggested Imaging Protocols), which can be found at http://www.commondataelements.ninds.nih.gov/.

The neuroimaging group had 5 major components to their general recommendations for conceptualizing and organizing CDEs with respect to radiologic characterization of injury, as listed below.

1. As mentioned, the first recommendation is the stipulation of *strictly defining lesions* for operational purposes, including creating an appendix with specific "instructions" for what is meant by each pathoanatomic term as it is used in the database. Many traumatic lesions are seen best by using MRI as opposed to CT. Therefore, the group defined most lesions operationally by means of both CT and MRI characteristics. The panel recommended that imaging data elements be chosen that can be *defined objectively* to maximize interrater reliability, a particularly important feature for a database that may be used by a large number of centers. Thus, an attempt was made to define lesions by *exactly what can be seen on imaging*, trying to avoid pathophysiologic assumptions or clinically defined labels. The group recognized that many terms used commonly in TBI are defined differently by different disciplines and in different contexts (eg, consider the various uses of terms such as "diffuse axonal injury" or "ischemia"), and these semantic differences can lead to confusion in the TBI literature. To maximize the chance that different people using a large widely available database will be entering data that can be compared with data of others, we have tried to be precise about the exact definitions of the pathoanatomic terms as used in this data set, recognizing that not all users will agree with every aspect of these operational definitions.
2. To promote uniformity among centers, we believe the data set should include *an appendix with recommended or suggested specific radiologic protocols*. An initial set of such recommendations is included in Appendix 2[5] (available at http://www.commondataelements.ninds.nih.gov/). In addition to standard structural CT and MRI, the data set must be able to expand into areas such as CT and MR perfusion, DTI, PET, fMRI, and other techniques that not all centers use at present, with the thought that such a database must be flexible enough to adapt as techniques evolve. Along these lines, we recommend that *the "protocols index" and, indeed, the dataset itself be maintained and updated on a regular and ongoing basis by a revolving expert committee* to take into account new terminology, conceptual changes regarding pathophysiologic entities, and upgrades in imaging technology and software.
3. To track the evolution of injuries over time and include operational descriptors of pathophysiologic processes, as well as to accommodate rapid changes in technology, the proposed database is designed with various levels of detail ("core," "supplementary," and "emerging" elements). Thus, for some research studies, the simple *presence or absence* of a given lesion type is all that may be needed; these are "core" data and would be included in all studies using the database. For other research studies, *quantification* of lesions or their sequelae over time will be necessary and may require additional data entry, as well as additional imaging or image processing capabilities. For example, treatment trials may need to track responses to intervention by quantification of such entities as brain edema, measures of structural integrity, or volumetric changes on serial images. Such data, or data involving other details of the anatomic findings, would be considered to reside in the "supplemental" tier. Data elements in the "emerging" tier would be those in which the collected data reflect techniques that may not be standard or widely available, have not yet been fully validated or correlated with outcome measures, or in which consensus has not been reached about exactly which elements of the data may be relevant or optimal for the clinical question at hand. An example of an "emerging" element would be quantification of lesion load (total lesion volume) as a marker of injury severity, which might be measured by using quantification software available at only a few research centers. Another example of the "emerging" category would be collection of data about the trajectory of a missile injury, which might be of interest to specific researchers for prognostic modeling, but might not be collected by all centers entering data.
   Within the CDE data set will be a mechanism to enter whether neuroimaging was or was not performed (or if this is unknown) for a given patient; such basic data likely would be contained in an "administrative core data set" that will include basic general information for each patient. In this way, patients with different levels of entry into a TBI system could be accommodated by the overall data set, from those with acute severe injuries to those entering in a chronic or mild severity setting and for whom imaging might not have been performed at any time. It is assumed that all users of the database entering patients who underwent neuroimaging would enter patient neuroimaging data at least at the core level, and this includes all types of information currently shown in numerous studies to provide prognostic value for acute injuries, including the presence or absence of various mass lesions, subarachnoid or intraventricular hemorrhage, brain shift, cisternal compression, and brain edema or swelling.[3,4]
4. One critical characteristic of the database structure includes moving away from static, serial hard-copy data forms to be filled out, toward a *flexible electronic database format that uses interactive drop-down menus*. This construct is essential to move beyond one of the major hurdles in TBI data collection in the past, namely, balancing having forms with too much detail and too many choices that are too long and cumbersome and difficult to collect and analyze, and having enough choices so that characterization of an individual patient's injuries is as specific as possible. Moving toward more interactive databases opens the possibility of having more choices and details without producing enormously lengthy or cumbersome forms. Each patient in essence will have a customized form for his/her specific injuries. The degree of detail about each patient's images can be customized to the needs of the study at hand, but as mentioned, it is expected that all patients in any research design will have at least a basic-level data set entered (ie, the core level within the CDEs, as described). Because of technologic improvements in data processing schema, this kind of analysis of more complex and variable data sets has become increasingly feasible, and will provide the critical details necessary to understand both natural history, prognosis, and treatment effects of specific injury types in different populations of patients.
5. We recommend that the data set be flexible enough that *researchers interested in studying specific populations* can find what they need in an interactive database that is able to describe all elements that might apply to that specific injury scenario, both acutely and during evolution of the injury. Neurotrauma radiology data sets typically used in the past have been biased toward comatose adult patients with a moderately wide variety of acute injury types, mostly imaged by means of acute CT. Our hope is to move toward a database that can focus on a wider variety of host, injury, temporal, and imaging modality specifics.

HOW THE TBI CDE IMAGING DATABASE WOULD WORK

With these principles in mind, the neuroimaging group designed elements for a database that would work as follows.

1. Every patient entered into the database would have the potential of having each imaging study performed on that patient entered into the database; which studies would be entered would be determined by the specific requirements of that research study or trial.
2. For each imaging study entered into the database, a set of terms with specific definitions, each of which can be characterized by specific details on a sequential drop-down menu of increasing detail, is used to characterize findings on the images (see Appendix 1[5] at http://www.commondataelements.ninds.nih.gov/).
3. Each individual lesion encountered on a given patient's imaging study would be entered. If a patient has, for example, two separate contusions, each would be entered and characterized further as an individual lesion by using a drop-down menu. It would be expected that many, if not most, patients would have more than one lesion type listed.
4. Depending on the specific research protocol, a core tier of data entry would include simply the presence or absence of the lesion; a more supplemental tier would include more details, such as specific location and size; and an emerging tier might include even more detail, such as specific radiologic findings or those requiring special image processing capabilities.
5. For each *separate* scan obtained for the patient, the specific lesions seen on that scan obtained on that date would be analyzed and entered, depending on the specific research protocol. In this way, the evolution of lesions over time could be captured.
6. Some lesions are pathophysiologic processes, and these may be seen particularly well on specific imaging modalities or may vary with the techniques used. Therefore, for each imaging examination, details of the scan technique also would be entered, again using a drop-down menu.

The working group recognized that for some studies, only a limited number of data elements would be needed. For others, more complex data would be preferred. This is why it is the recommendation of the imaging work group that the data set be constructed with flexibility and adaptability to accommodate different research questions.

A few comments are in order about the currently proposed pathoanatomic data elements. As noted, exact operational definitions for the terms, along with additional details about how such a database would work, can be found in Appendix 1,[5] at http://www.commondataelements.ninds.nih.gov/. It should be noted that this is at present an initial proposal for such a database, and much work will be needed to create a robust working database over time. As a starting point, the specific entities presently include the following pathoanatomic terms listed essentially centripetally, from the skull inward: skull fracture, epidural hematoma, extra-axial hematoma, acute subdural hematoma, chronic/subacute subdural hematoma, mixed subdural collection, subarachnoid hemorrhage, arterial dissection, traumatic aneurysm, venous sinus injury, venous sinus thrombosis, midline shift, cisternal compression, fourth ventricle shift/effacement, contusion, intracerebral hemorrhage, intraventricular hemorrhage, diffuse axonal injury, traumatic axonal injury, penetrating injury, cervicomedullary junction/brainstem injury, edema, brain swelling, ischemia/infarction/hypoxic-ischemic injury, pneumocephalus, hydrocephalus, vasospasm, and brain atrophy.

OVERVIEW OF IMAGING METHODS

We briefly introduce some of the more commonly used neuroimaging techniques for evaluation of TBI. Additional details may be found in a companion article[6] published in the *Journal of Magnetic Resonance Imaging*, available on the CDE website at http://www.commondataelements.ninds.nih.gov/. We begin with the conventional frontline imaging modalities of CT and MRI, then branch out into more advanced MR methods, followed by the use of other imaging modalities.

Structural imaging in the form of routine CT and MRI are the core neuroimaging examinations that serve as the basis for the initial evaluation of TBI.[7,8] These techniques probe changes in brain architecture. The presence of blood, edema, and mass effect are common indicators of TBI and enable accurate diagnosis of the patient's evolving condition. It is probable that many research questions require imaging at the acute stage to predict short-term outcome and treatment and additional imaging at the subacute and chronic stages to best predict the patient's long-term outcome. Thus, as noted, radiologic data elements must be organized and accessed in a flexible manner to maximize utility for various users and have the capability to capture data from multiple imaging studies of the same patient over time.

Computed Tomography

NCT has a pivotal role in the rapid initial assessment of patients with head trauma and in follow-up. NCT classically is used to determine whether early surgical management is indicated and to prognosticate clinical outcome. NCT examinations of patients suspected of head trauma are evaluated for a standard set of structural anomalies that includes skull fracture, epidural or subdural hematoma, subarachnoid hemorrhage, brain parenchymal hematoma/contusion, brain swelling and edema, and mass effect, manifested as midline shift, subfalcine herniation, or effacement of the basilar cisterns. These features have been grouped in different scoring systems, such as the Marshall CT classification[3] or the more recent Rotterdam CT classification.[4] These classification schemes focus on patients with more severe injuries. Although patients with these findings are of great interest and may be the focus of intensive research, most patients with TBI have clinically mild injuries, and most of these have normal results from CT of the head. Thus, other imaging modalities are needed for many aspects of TBI research.

Magnetic Resonance Imaging

The findings in standard MRI studies of TBI are similar to CT, but MRI is more sensitive than CT for small lesions, such as those seen with DAI, also termed TAI when the lesions are more regional than diffuse (see Appendix 2[5] for specific definitions of these and other terms). Most conventional MR methods, including T1-weighted imaging, T2-weighted imaging, and T2 FLAIR, show structural changes in the form of mass lesions and mass effect, midline shift, cisternal compression, internal loculations or septations for subdural hematomas, blood in the contours of sulci and cisterns for subarachnoid hemorrhage, and volume changes for long-term postinjury analysis, such as hippocampal atrophy when this occurs. Thin-slice 2-dimensional or volumetric 3-dimensional and T1- and T2-weighted MRI offer high-resolution structural information for diagnosis, potential neurosurgical intervention, and volume quantification. A potentially useful quantitative marker of tissue damage is lesion load or total lesion volume. Measuring lesion load can be accomplished by using semiautomated software and is a means to quantify both hemorrhagic

and nonhemorrhagic TBI lesions.[9] Standard T2-weighted, T2 FLAIR, and GRE imaging methods often detect small lesions missed on CT. The sensitivity of these methods increases with increasing magnetic field strengths; for example, 3-Tesla T2* GRE detects twice as many tiny (several millimeter) parenchymal hemorrhages (sometimes referred to as microbleeds[10]) as at 1.5 Tesla.[11] As good as these methods are, there are more advanced MRI methods yet to be commonly practiced that offer more sensitive measures of blood products (susceptibility-weighted imaging), blood flow and perfusion (perfusion-weighted imaging), microstructural white matter tract integrity (DTI), metabolic activity (MR spectroscopy), and hemodynamic brain function (fMRI). These methods, along with the areas for which they are most sensitive and useful in clinical diagnosis, are presented in more detail in Appendix 2. Tables 1 to 4 contain the full imaging protocols for MRI, and CT protocols are shown in Tables 5–7.[5]

For even greater sensitivity, especially for clinically milder cases of TBI, one must look for secondary findings beyond obvious blood products and edema. In this regard, DWI is a method that assesses the microscopic motion of water molecules in brain tissue. DWI and, more recently, DTI have improved the identification of DAI/TAI through their superior sensitivity to microstructural changes in the movement of water molecules through tissue with various forms of axonal injury.[12,13] These highly sensitive methods may aid in understanding the correlation between site and degree of damage and specific long-term cognitive and behavioral outcomes. In addition, because these emerging techniques show promise of elucidating connectivity between brain regions and distributed networks, this may be of great interest for those interested in how disruption affects patients acutely, as well as during recovery. It should be noted that because these techniques are new, the members of the work group decided not to cover them in detail in this particular iteration of the recommendations, with the understanding that an evolving data set would need to have the flexibility to incorporate newer techniques smoothly and on an ongoing timeline.

With respect to more long-term injury, there is a correlation between brain volume–determined atrophy and cognitive outcome in adults[14,15] and children.[16] The hippocampus, thalamus, fornix, corpus callosum, frontal lobe, cingulate gyrus, cerebral peduncles, and brainstem are specific brain regions that show atrophy after some forms of TBI.[14,17,18] The long-term volume loss appears to result from cellular loss and axonal degeneration.

Other Imaging Modalities

There are a number of other key radiologic techniques that can be applied to study TBI. For example, modalities to assess cerebral blood flow and perfusion include single photon emission CT, CT, MR, and Doppler ultrasonography. Modalities to assess brain function include PET, magnetoencephalography, and fMRI. For a detailed review of these methods and their role in TBI, please refer to the companion review[6] in the *Journal of Magnetic Resonance Imaging*, posted at http://www.commondataelements.ninds.nih.gov/.

Example MRI and CT Neuroimaging Protocols

As shown in this article, imaging offers a number of different means and modalities by which to monitor TBI. Within each modality, there also can be flexibility in how the patient is imaged to determine tissue damage. In Appendix 2[5] (http://www.commondataelements.ninds.nih.gov/), we present sample MRI and CT protocols with the caveat that the exact implementation will depend on the imaging equipment manufacturer being used. We highlight the critical parameters that should be quoted when presenting data in any publication or presentation of research or clinical data. The reader should be advised that these are meant to be baseline protocols that can be modified for each type of scanner, research population, and hypothesis. These protocols are presented in a multitiered approach from basic radiologic imaging necessities to more advanced imaging protocols.

SUMMARY

The goals of this working group were to identify CDEs from neuroimaging studies that can be used in a consistent way for clinical research and treatment trials across institutions and research studies. These CDEs include a listing of the injuries that can be identified, with definitions of terms used to describe these injuries on the images, and recommended protocols and descriptors for image acquisition methods. A format for a flexible interactive database that can be tailored to multiple research questions requiring different levels of detail is outlined. Finally, recommendations are made about which imaging parameters, diagnostic readings, and other data should be recorded in a TBI imaging database. These recommendations can be applied in upcoming or imminent research programs in TBI and should help set the stage for consistency across the field.

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