SPECIAL COMMUNICATION

Common Data Elements for Traumatic Brain Injury: Recommendations From the Interagency Working Group on Demographics and Clinical Assessment

Andrew I. Maas, MD, Cynthia L. Harrison-Felix, PhD, David Menon, MD, P. David Adelson, MD, Tom Balkin, PhD, Ross Bullock, MD, Doortje C. Engel, MD, PhD, Wayne Gordon, PhD, Jean Langlois Orman, ScD, Henry L. Lew, MD, PhD, Claudia Robertson, MD, Nancy Temkin, PhD, Alex Valadka, MD, Mieke Verfaellie, PhD, Mark Wainwright, MD, David W. Wright, MD, Karen Schwab, PhD

ABSTRACT. Maas AI, Harrison-Felix CL, Menon D, Adelson PD, Balkin T, Bullock R, Engel DC, Gordon W, Langlois Orman J, Lew HL, Robertson C, Temkin N, Valadka A, Verfaellie M, Wainwright M, Wright DW, Schwab K. Common data elements for traumatic brain injury: recommendations from the Interagency Working Group on Demographics and Clinical Assessment. Arch Phys Med Rehabil 2010;91:1641-9.

Comparing results across studies in traumatic brain injury (TBI) has been difficult because of the variability in data coding, definitions, and collection procedures. The global aim of the Working Group on Demographics and Clinical Assessment was to develop recommendations on the coding of clinical and demographic variables for TBI studies applicable across the broad spectrum of TBI, and to classify these as core, supplemental, or emerging. The process was consensus driven, with input from experts over a broad range of disciplines. Special consideration was given to military and pediatric TBI. Categorizing clinical elements as core versus supplemental proved difficult, given the great variation in types of studies and their interests. The data elements are contained in modules, which are grouped together in categories. Three levels of detail for coding data elements were developed: basic, intermediate, and advanced, with the greatest level of detail in the advanced version. In every case, the more detailed coding can be collapsed into the basic version. Templates were produced to summarize coding formats, motivation of choices, and recommendations for procedures. Work is ongoing to include more international participation and to provide an electronic data entry format with pull-down menus and automated data checks. This proposed standardization will facilitate comparison of research findings across studies and encourage high-quality meta-analysis of individual patient data.

Key Words: Clinical protocols; Clinical studies; Data collection; Forms and records control; Rehabilitation; Standardization; Traumatic brain injury.

VARIABILITY IN DATA collection and coding procedures in studies on TBI complicates comparisons between studies and makes a meta-analysis of individual patient data a formidable undertaking. For example, in the IMPACT studies, within which individual patient data from 8 randomized controlled trials and 3 observational studies were included, it took more than 10 person-years of work to merge the data in preparation of analysis.[1,2] These studies, however, confirmed the potential benefits of analyzing data across studies, especially in a field in which populations are heterogeneous, uncertainty exists regarding many aspects of care, trials can never be performed in all areas, and moreover, are extremely costly. Efforts to standardize procedures for data collection and to obtain a general consensus on choice and coding of variables

List of Abbreviations

AIS	Abbreviated Injury Scale
CDE	common data element
GCS	Glasgow Coma Scale
ICP	intracranial pressure
IMPACT	International Mission on Prognosis and Clinical Trial Design in TBI
ISS	Injury Severity Score
LOC	loss of consciousness
OMB	Office of Management and Budget
PTA	posttraumatic amnesia
TBI	traumatic brain injury

From the University Hospital Antwerp, Edegem, Belgium (Maas); Craig Hospital, Englewood, CO (Harrison-Felix); University of Cambridge, Cambridge, United Kingdom (Menon); Phoenix Children's Neuroscience Institute, Phoenix, AZ (Adelson); Walter Reed Army Institute of Research, Washington, DC (Balkin); University of Miami Miller School of Medicine, Miami, FL (Bullock); University Hospital Heidelberg, Heidelberg, Germany (Engel); Mount Sinai School of Medicine, New York, NY (Gordon); Department of Veterans Affairs, Rehabilitation Research and Development Service, Washington, DC (Langlois Orman); Defense and Veterans Brain Injury Center and Department of Physical Medicine and Rehabilitation, Virginia Commonwealth University School of Medicine, Richmond, VA (Lew); Baylor College of Medicine, Houston, TX (Robertson); University of Washington, Seattle, WA (Temkin); Seton Brain and Spine Institute, Austin, TX (Valadka); Boston VA Health Care System and Boston University School of Medicine, Boston, MA (Verfaellie); Northwestern University, Chicago, IL (Wainwright); Emory University School of Medicine, Atlanta GA (Wright); and Defense and Veterans Brain Injury Center, Washington, DC (Schwab).

Support for the meetings and activities of the Working Group on Demographics and Clinical Assessment was funded in the context of the interagency initiative toward "an integrated approach to Research in Psychological Health and Traumatic Brain Injury" (National Institutes of Health-National Institute of Neurological Disorders and Stroke [NIH-NINDS]; the National Institute on Disability and Rehabilitation Research; the Department of Veterans Affairs; the Defense and Veterans Brain Injury Center and the Defense Centers of Excellence). The development of CDEs was further supported by a supplemental grant from NIH-NINDS (grant no. NS 042691).

Views expressed are those of the authors and do not necessarily reflect those of the agencies or institutions with which they are affiliated, including the U.S. Department of Veterans Affairs, the U.S. Department of Defense, the U.S. Department of Health and Human Services, the National Institutes of Health, the National Institute of Mental Health, or the Uniformed Services University of the Health Sciences. This work is not an official document, guidance, or policy of the U.S. Government, nor should any official endorsement be inferred.

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated.

Correspondence to Andrew I. Maas, MD, Dept of Neurosurgery, University Hospital Antwerp, Wilrijkstraat 10, 2650 Edegem, Belgium, e-mail: andrew.maas@uza.be. Reprints are not available from the author.

0003-9993/10/9111-00286$36.00/0
doi:10.1016/j.apmr.2010.07.232

are not only highly desirable from a scientific point of view, but will also reduce costs to funding institutions because the requirement for repeated development of case report forms for new studies will be reduced.

AIM

The global aim of the Working Group on Demographics and Clinical Assessment of the larger multiagency effort described by Thurmond et al[3] was to develop recommendations on coding of demographics and clinical assessments for studies across the broad spectrum of TBI. We strived to make the elements applicable both to milder and more severe injuries, to acute and long-term studies, to studies including patients early after injury, to those enrolling patients at later periods, and to studies in the civilian, military, or pediatric settings. We explored the feasibility of categorizing elements as core, supplemental, and emerging. Core elements are intended to encompass the minimal set of measures to characterize the broad spectrum of subjects on the domain. A supplemental element is one intended for greater depth/breadth of exploration, for more specialized subpopulations, or both. Emerging elements are those that may require further validation, but may fill gaps in currently validated measures or substitute for recommended measures, or both, once validation is complete.

APPROACH

These aims posed a formidable challenge to the working group. The wide range of expertise, affiliation to many agencies and organizations, and the tremendous commitment of all working group members, however, provided optimal conditions to meet these challenges. Collectively, the working group had access to a wide range of data collection forms as examples. These included the codings developed by the IMPACT study group, the data collection forms of the National Institute on Disability and Rehabilitation Research–funded TBI Model Systems, the Acute Concussion Evaluation distributed by the U.S. Centers for Disease Control and Prevention, and the Clinical Tracking Forms developed by the Defense and Veterans Brain Injury Center.

A decentralized approach was adopted, with focus groups addressing specific topics. These included definition of TBI,[4] subject characteristics, socioeconomic status, injury details and emergency care, assessments and evaluations, and rehabilitation or postacute care. Specific considerations were given to pediatric and military TBI.

The progress and recommendations of the focus groups were discussed during weekly teleconferences, held from February 3 until late July 2009. In-depth discussions were conducted during face-to-face meetings in March, June, and October. Preliminary recommendations were presented to stakeholders and other working groups during the interagency workshop on Standardization of Data Collection in TBI and Psychological Health (March 2009, Washington, DC). The feedback obtained led to substantial refinements and initiated the development of templates, providing details on coding formats, procedures, and motivation of choices. The final recommendations of the focus groups were incorporated into a "beta version" of the TBI CDEs, reviewed by all working group members and structured to ensure compatibility with the National Institute of Neurological Disorders and Stroke–broad CDEs project.

THE PRODUCT: COMMON DATA ELEMENTS FOR TRAUMATIC BRAIN INJURY DEMOGRAPHICS AND CLINICAL ASSESSMENTS

We successfully managed to develop general consensus on the coding of data elements for use across the broad spectrum of TBI. The data elements are contained in modules, which are grouped together in categories. For example, the data elements "age, gender, and race" are contained in the module "demographics," under the category "subject characteristics." The main categories relevant to this article are as follows:

- Participant/Subject Characteristics
- Participant/Subject and Family History
- Injury/Disease-Related Events
- Assessments and Examinations

The main intent was to present the data elements in a transparent format. Various elements and modules can be used as "plug-in" elements and used multiple times in clinical data collections. For example, the module on "GCS and pupils" may be recorded only on admission, or also prehospital, as well as daily during the acute care phase. We were less successful in our attempts to categorize elements as core, supplemental, or emerging as proposed by the planning committee.[3] What may be considered a core element for an acute-phase study may, for example, be totally irrelevant for an epidemiologic- or rehabilitation-oriented study. The broad range of settings and types of studies within TBI therefore precludes a large number of core clinical data elements that would be truly appropriate to all studies. Exploratory discussions further showed considerable variation among both working group members and international experts as to which clinical variables might be categorized as core, supplemental, or emerging. Consensus did exist that as a minimum, the most relevant predictors of outcome should be collected in studies on severe and moderate TBI in the acute setting. As such, these predictors should be considered core elements for clinical studies of moderate and severe TBI. Rather than—in the absence of evidence or consensus—arbitrarily categorizing other elements as core, supplemental, or emerging, the working group considered it more relevant to propose a format for consistent and compatible coding of variables across the diversity of settings in TBI.

The working group recognized that the level of detail required can vary greatly with the design and aim of a specific study. Observational studies or large pragmatic clinical trials require less detail than highly focused phase II or phase III trials. We therefore chose to develop up to 3 versions for each data element: basic, intermediate, and advanced, with the greatest level of detail in the advanced version. The coding of these versions is such that in every case the advanced version can be collapsed to the intermediate or basic versions, thus facilitating comparison and meta-analysis of individual patient data between studies.

A complete overview of the modules and data elements, including the core data elements, together with the templates, may be found online (http://www.tbi-impact.org) and will be posted subsequently on the National Institute of Neurological Disorders and Stroke website (http://www.commondataelements.ninds.nih.gov). It should be recognized that the intent was to keep the relevance for the CDEs as broad as necessary for the different types of investigations likely to use them (ie, epidemiologic/observational studies, acute/rehabilitation clinical trials). Different formats for data collection may, however, be appropriate in different circumstances. As an example, we propose different data elements for early details of injury, and referral details for patients presenting early versus those presenting late. For

patients who present early, referral policy and time of arrival, as well as mode of transport and emergency services provision, are relevant. For patients presenting late, the main reason for presentation and more general information on delivery of initial care and the specifics of such care are more appropriate. Capturing information on the reason for presentation is important also for later characterization of the population captured. Because mild TBI may be overreported by subjects with possible financial gain, but underreported by subjects highly motivated to return to team play, to work, or to support military operations. Studies of mild TBI may want to capture variables such as insurance coverage and motivation for return to work or duty.

The selection of elements to be used in a particular study will strongly depend on the type and aim of that study. To this purpose, it is recommended that investigators select and mix basic, intermediate, and advanced versions of different data elements, always including core elements, according to the requirements of their study.

As an example, figures 1 and 2 present formats for combining elements for an acute-phase study in severe TBI (see fig 1) and for a late presentation study of mild TBI (see fig 2) including therapy, adverse effects, and other clinical study-related items.

We emphasize that the current recommendations of the working group represent a beta version; we are still in the process of incorporating feedback from a more international forum with the intent to make this a global initiative.[5] The recommendations should be subjected to field testing before general acceptance. This field testing may also serve to provide evidence for categorizing elements as core, supplemental, or emerging. Below we highlight some of the main recommendations and motivation thereof, differentiated per category.

SUBJECT CHARACTERISTICS

Demographics

Age. Recording age in TBI studies is of great importance. Causes of injury differ per age group and lead to different types of injury. Age is one of the strongest predictors of outcome in TBI, with older patients faring more poorly than younger patients.[6,7]

The choice for recording age or date of birth was discussed extensively. Although date of birth is commonly recorded in TBI studies and provides the most detailed and source-verifiable information, it was thought that date of birth might be considered a patient identifier and thus subject to institutional board oversight and necessitating appropriate adherence to Health Insurance Portability and Accountability Act regulations in the United States. Nevertheless, recording date of birth is recommended for the intermediate and advanced versions. In other studies, however, simply recording age may be prefer-

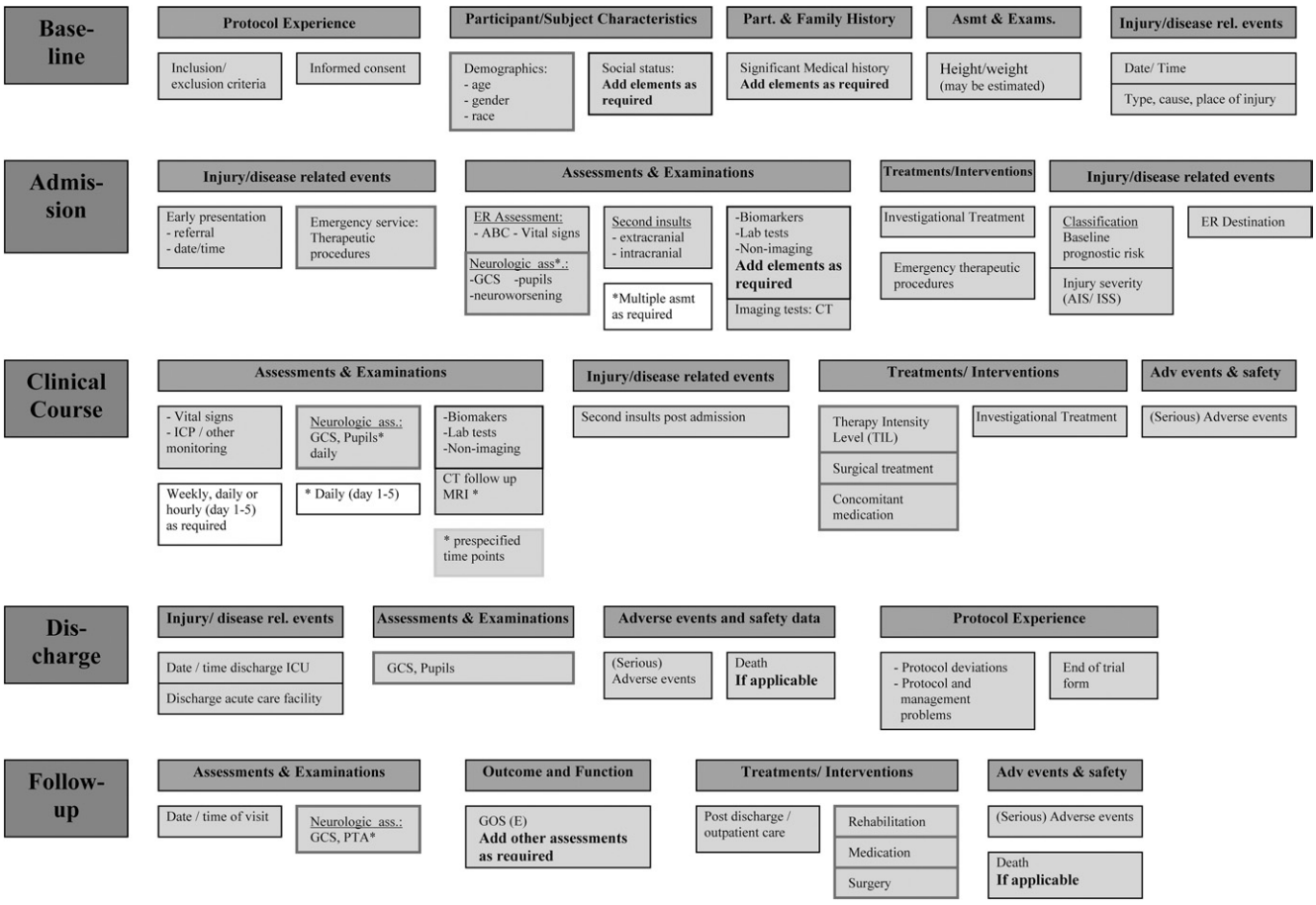

Fig 1. Example elements for an acute-phase study in severe TBI. Abbreviations: ABC, airway, breathing, and circulation; CT, computed tomography; ER, emergency department; GOS(E), Extended Glasgow Outcome Scale; ICU, intensive care unit; MRI, magnetic resonance imaging.

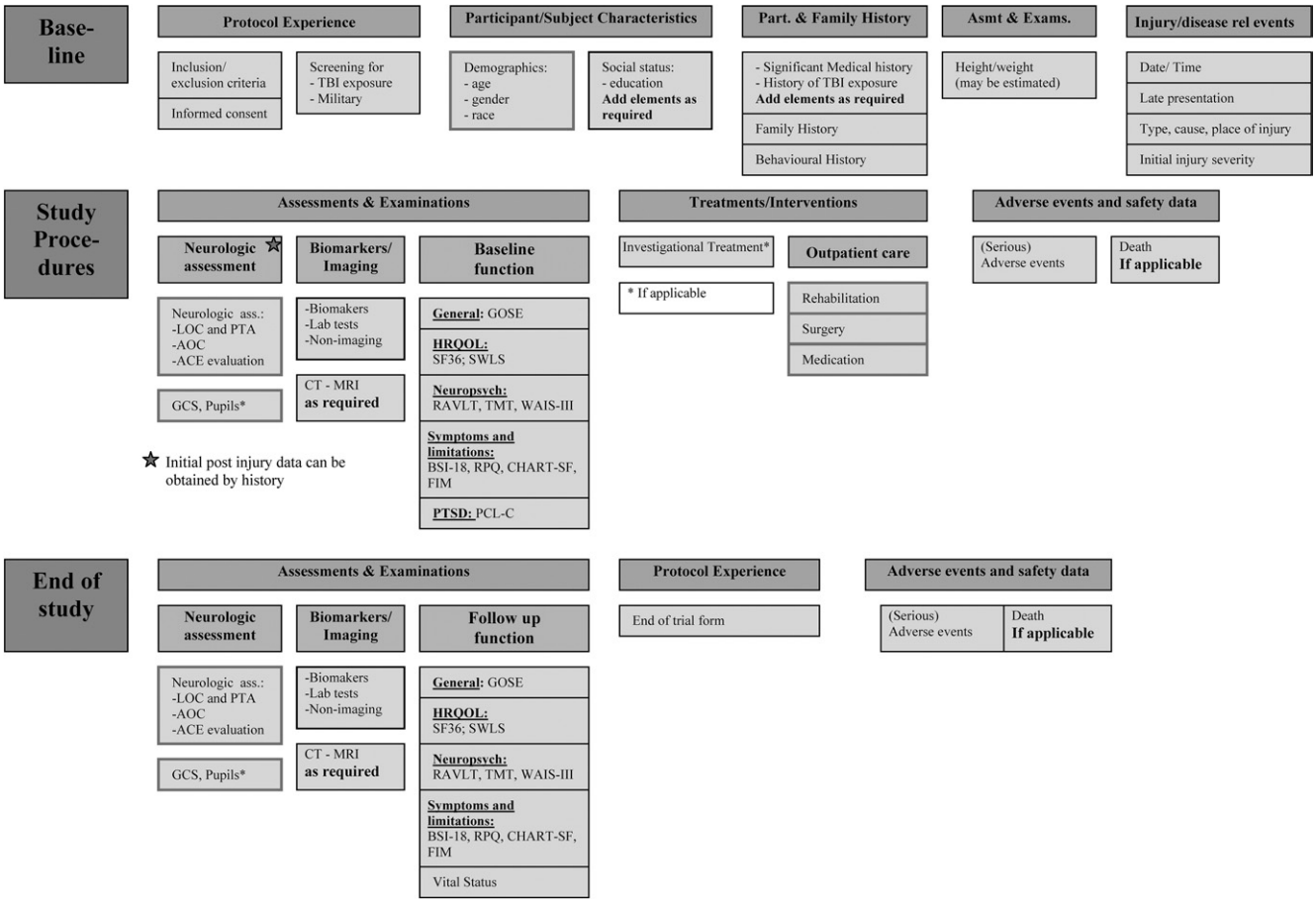

Fig 2. Example elements for TBI studies focused on late presentation of mild TBI. Abbreviations: ACE, Acute Concussion Evaluation; AOC, alteration of consciousness; BSI-18, Brief Symptom Inventory 18; CHART-SF, Craig Handicap Assessment and Reporting Technique Short Form; CT, computed tomography; GOSE, Extended Glasgow Outcome Scale; HRQOL, health-related quality of life; MRI, magnetic resonance imaging; PCL-C, Posttraumatic Stress Disorder Checklist–Civilian Version; PTSD, posttraumatic stress disorder; RAVLT, Rey Auditory Verbal Learning Test; RPQ, Rivermead Post-Concussion Symptoms Questionnaire; SF36, Medical Outcomes Study 36-Item Short Form Health Survey; SWLS, Satisfaction With Life Scale; TMT, Trail-Making Test; WAIS-III, Wechsler Adult Intelligence Scale–Third Edition.

able. When reporting the relationship between age and outcome, a continuous analysis is preferred over the use of threshold values.

Race and ethnicity. Race and ethnicity are separate and overlapping concepts. International standards do not exist for the classification of race or ethnicity, resulting in uncertainty, ambiguity, and inconsistency in recording these variables between and even within different nations.[8,9] There is little agreement among journals regarding the appropriateness of providing race and ethnicity data in publications, or where such data reporting is recommended, or the way in which it should be collected.[10] Indeed, there is little uniformity in reporting such data between articles within the most prestigious of medical journals.[11]

Notwithstanding this, several countries have adopted one or more systems of classification that are based on race, ethnicity, or both, and used these in clinical research. For example, detailed recommendations for reporting race were mandated by the OMB of the U.S. Government in October 1997 (http://www.whitehouse.gov/omb/fedreg/ombdir15.html). The OMB document mandates a minimum of 5 categories for data on race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. Two categories for data on ethnicity are required: "Hispanic or Latino" and "Not Hispanic or Latino." However, there is substantial variation in these definitions between sources and over time. For instance, subjects from the Indian subcontinent are now categorized as Asian, although until recently they were considered "white" in the U.S. Census.[12] The United Kingdom has, on the other hand, no officially mandated system of classification. However, 2 systems are commonly used in research studies.[10] One is based on the classification used by the national census, while the other is that used by the United Kingdom National Health Service. As with the United States, both schemes depend on self-reported ethnicity. Self-identification is also the basis for the Brazilian census (http://www.ibge.gov.br/home/estatistica/populacao/censo2000/), which defines 6 categories.

Classification of race is not always anthropologically or scientifically based and is heavily influenced by geographic patterns and ethnic identity. There is an increasing recognition that race is a social and cultural construct, and that using race as a shorthand for genetic variation is likely to be incorrect, because only approximately 10% of genetic variation occurs between races.[13] Consequently, genetic association studies of disease increasingly use DNA-based estimates of "ancestry" as

a basis for stratification of background genetic differences.[14] At a more detailed level, there is at least the hope that full genetic characterization of subjects will result in the holy grail of "personalized medicine."[15]

Despite the existing ambiguities and lack of scientific basis for classification, it is important to record race and ethnicity,[16] and specifically in TBI trials, for the following reasons:

- An association between race and outcome has been demonstrated in TBI, which cannot be explained by differences in cause of injury or in injury severity.[7]
- Differences may reflect disparities in preinjury health, access to health care, or both, in the acute phase and during rehabilitation after TBI. These data can therefore inform policy aimed to ensure equitable access to health care.
- Comparison of populations can help researchers interpret changes in disease trends and assess whether the health of minority groups deviates from expectations.
- Racial variations in drug pharmacokinetics or pharmacodynamics may exist. Although racial and ethnic descriptors provide an inexact approximation of pharmacogenomic effects, it has to be conceded that, at least for the present, this may be the only means of providing some traction in such analyses of large studies.
- The adoption of uniform reporting measures may allow researchers to check whether their study populations are representative of the wider community.

Despite these listed applications of race and ethnicity data, the geographic variations in reporting such data mean that comparisons between countries may not be viable. Even within-country comparisons need to be carefully assessed to determine whether descriptors for classifications are consistent. Even with consistent definitions, self-reporting makes it possible for subjects with similar (or even identical) ethnicities to choose to classify themselves completely differently. There are both opportunities and pitfalls of undertaking pharmacogenomic analyses in admixed populations.[17] However, although authoritative expert groups provide detailed analyses of the problems in this area,[14] they provide little practical guidance to the individual researcher searching for robust definitions on which classification can be based.

Although in general, self-reporting may be considered preferable, this is not possible in the more severe cases of TBI, and this may confound comparisons with reports on patients with milder injuries in whom self-reporting of race and ethnicity was followed.

Given these considerations, the working group took a pragmatic approach to recording race and ethnicity and chose to further subdivide the broad categories prescribed by the OMB at several levels. The more detailed categories were designed to map backwards, so that they can be aggregated into broader groupings. Given the regulatory mandate in the United States to collect ethnicity data in a specific way, and the difficulty in reconciling ethnic and racial classifications, we chose to separate them, but realize that recording ethnicity as Hispanic or Latino versus Not Hispanic or Latino will make little sense in such places as Latin America or Spain. Regardless of the classification scheme adopted, we believe that as a minimum, any study must include clear definitions of terminology used for describing race and ethnicity, thus facilitating (as much as possible) post hoc reconciliation of different studies. The template on race as contained in our recommendations (www.tbi-impact.org) provides some guidance here.

Social Status

Educational level. For adults, educational level is a basic descriptor and an important component of socioeconomic status. Educational attainment is a strong correlate of income level and, presumably, cognitive ability. An association exists between educational level and outcome after TBI.[7] Documenting at least some basic information on education is therefore considered relevant to TBI studies. Various approaches exist toward documenting educational level. Achievement of years or level of education is probably more relevant than partial years of attendance as a descriptor or predictor of outcome. We recommend that both the number of years of education completed and the highest level of education are recorded.

Productive activity. Employment is considered a basic population descriptor, and return to work a relevant outcome parameter for patients in the paid workforce before injury. Employment, as relevant to TBI studies, differentiates "paid competitive employment (earning at least minimum wage)" from "special employment (sheltered workshop, supportive employment, job coach, less than minimum wage)." Other social role activities, such as student, homemaker, or volunteer work, are equally relevant, and it is therefore recommended to collect data on these role activities separately.

Marital status and living situation. TBI can cause relational stress and family disruption. The speed and degree of recovery may be influenced by factors related to marital status and living situation. Although studies commonly report the "primary person the patient with TBI is living with," we thought that it would be more appropriate to allow entries in multiple categories and to document the number of persons the patient is living with, because this would capture a better picture of the support and care that a patient might expect when returning to the home situation.

SUBJECT AND FAMILY HISTORY

Details on medical history and use of medication are collected in nearly every TBI clinical study. However, medical history data are typically the least reliable data collected and are almost universally collected in a free text format, thus prohibiting any meaningful analysis. Nevertheless, preexisting conditions may influence the disease course and chances of recovery, and information on medical history is essential for interpretation of adverse events occurring during clinical trials. It is therefore highly relevant to accurately record medical history and medication. To facilitate better use of such data, we recommend prespecified categories.

INJURY- OR DISEASE-RELATED EVENTS

Type and Cause of Injury

Recording details on the type, place, nature, and mechanism of injury is highly relevant, both from an epidemiologic perspective (with implications for prevention programs) and because different pathophysiologic mechanisms occur in different types of injury. After much debate, we recommend a broad classification of type of injuryinto 4 categories: closed, penetrating, blast, and crush. Blast injuries are defined by any form of TBI occurring in association with a blast explosion. Worldwide, armed conflicts and terrorist activities are causing more brain injuries from improvised explosive devices, and blast injuries are now recognized as a specific entity.[18,19] Crush injuries are defined as any form of TBI resulting from a slow mechanical force applied to the skull. Generally, such a type of injury causes substantial damage to the skull, while the brain injury may be limited. We recommend that coding of injury

type permit multiple codes for injury type (eg, blast and closed) where relevant. In many previous studies, variables capturing injury details mix elements of cause, setting, and mechanism. We recommend a clearer separation: the place of injury is intended to capture information on the location (eg, street, home/domestic, work/school, or sports/recreation); the element cause of injury is more directed toward the causative factor (eg, road or traffic incident or fall). Indirectly, these imply a certain element of mechanism, but more detailed information on the mechanism of injury can be recorded separately.

Classification

Traditionally, TBI has been classified by mechanism (closed vs penetrating), by clinical severity (GCS, length of LOC, and/or length of PTA), or by assessment of structural damage (neuroimaging). A substantial limitation of all these approaches is that they categorize patients artificially. For example, in classifying patients by clinical severity, patients are somewhat arbitrarily grouped into 3 distinct categories: severe (GCS, 3–8), moderate (GCS, 9–12), or mild (GCS, 13–15). This approach insufficiently recognizes that the severity of TBI lies along a continuum, and that the GCS may fluctuate. Furthermore, classification of TBI by clinical severity is increasingly limited in the acute setting by confounders, such as medical sedation, neuromuscular blockade, or intoxication. The advances in modern neuroimaging techniques and the emerging technology of biomarkers offer new opportunities toward development of a multidimensional classification for TBI. We see a great need for further research in this field.

Classifying extracranial injuries. In the past, relatively little attention has been paid in TBI to assessment of the occurrence and severity of extracranial injuries. Nevertheless, extracranial injuries occur frequently in combination with TBI and may affect short- and long-term outcome. Practicality dictates that any scoring system used to quantify systemic injury must be widely disseminated and easily understood. For these reasons, the AIS is the most logical candidate. The AIS is defined as an anatomically based, consensus-driven, global severity scoring system that classifies each injury by body region according to its relative importance on a 6-point ordinal scale.[20]

For expressing the overall severity of injuries, the ISS can be calculated from the AIS.[21] The spine is not considered separately in the original ISS classification, but given the association between TBI and in particular cervical spine injuries, we consider it important to record spinal injuries separately.

Prognostic classification. A relatively novel approach for expressing severity is to calculate the baseline prognostic risk for early mortality or functional outcome. Recently, well-validated models developed on large patient samples have become available to facilitate this approach.[22,23] These models can further facilitate comparisons of outcome between different patient series and enable the setting of baselines for clinical audits. Furthermore, from the perspective of clinical trial design, these models offer opportunities for stratification at enrollment, or for covariate adjustment in the analysis phase. Establishing the baseline prognostic risk is recommended for all TBI studies. The core predictors are summarized in table 1.

Table 1: Core Predictors for Early Mortality and Functional Outcome in Moderate and Severe TBI

Category	Variable
Demographics	Age
Clinical severity	GCS motor score
	Pupil reactivity
	Major extracranial injury
Second insults	Hypoxia and hypotension
Structural abnormalities	CT classification
	Traumatic subarachnoid hemorrhage
	Epidural hematoma
Laboratory tests	Glucose
	Hemoglobin

Abbreviation: CT, computed tomography.

Second Insults

Second insults—often inappropriately termed "secondary insults"—may be systemic (extracranial) or intracranial. Second insults may aggravate processes of secondary damage in a brain already rendered vulnerable by the primary injury. The main systemic insults are hypoxia, hypotension, hypothermia, and hyperthermia. The adverse effect of the occurrence of such insults both prehospital and in hospital is well established.[24-26] Second insults are commonly defined by threshold values. Although this may be appropriate for recording second events in the prehospital setting, we do not consider the use of these threshold values appropriate for the clinical setting, where blood pressure and oxygen saturation are generally monitored continuously, certainly in the intensive care setting. It would be better to capture more detail on depth and duration of lower values, for example, by presenting the percentage of time over which predefined ranges of values occur during a given 24-hour period. This approach has been implemented as a research tool in various intensive care units, but unfortunately software for this purpose is not routinely available. We see a great need for further development and implementation of dedicated software for this purpose in existing monitoring systems. Multiple TBIs may also affect outcome, We recommend recording of previous TBIs.

ASSESSMENTS AND EVALUATIONS

Vital Signs

Documentation of blood pressure, heart rate, temperature, and oxygen saturation is recommended for all patients with TBI who are admitted to the hospital directly after injury. This is important for 2 reasons. First, therapeutic interventions in a trial may increase the incidence of abnormal physiology, and such adverse effects need to be recorded on safety grounds. Second, regardless of whether or not physiologic insults are due to trial interventions, systemic hypotension, low cerebral perfusion pressure, hypoxemia, or hyperthermia may aggravate ischemic damage to the injured brain. Conversely, a high blood pressure may lead to a protracted course of increased ICP and, where therapeutically induced, carries an increased risk of cardiopulmonary complications. As a minimum, vital signs should be recorded on admission and further, on a daily basis during the acute phase of clinical studies. For the basic version, we recommend recording the average and lowest blood pressure over a given period. In the intensive care unit environment, recording blood pressure on an hourly basis is recommended when ICP is monitored, to permit determination of cerebral perfusion pressure, calculated as mean arterial blood pressure minus ICP.

Intracranial Pressure

Monitoring of the ICP is recommended in all patients with severe TBI, with documentation of a summary measure and the

highest value on at least a daily basis. Periods of artifactually high ICP (eg, during calibration of the monitor) or short-duration ICP increases caused by coughing, straining, or both, should be excluded when determining the highest ICP. For the intermediate and advanced versions, recording hourly values is recommended. In the analysis phase, we recommend that all hourly data are referenced to the date and time of injury, because this represents the only fixed time event that is common to all patients. For valid comparisons of results between patients and across studies, a common approach toward zeroing the ICP monitor should be agreed on, for which we suggest that the ICP monitor be zeroed to the level of the foramen of Monro. The format recommended for recording ICP can also be applied for other monitoring modalities, such as brain tissue oxygen tension or jugular venous oxygen saturation. The choice to document the highest or lowest daily value is dependent on the monitoring modality.

The module on ICP monitoring includes capturing information on procedures and problems encountered. Recording the duration of ICP monitoring is essential. Documentation of the reason for stopping monitoring (eg, clinically no longer required, device failure, or for reasons of futility) is relevant when interpreting measured values and their relation to therapy intensity. Identification of possible device malfunction (eg, partial blockage of a ventricular catheter) and revisions of the monitoring device is highly relevant for an accurate interpretation of values. We should further realize that the current approaches to analysis of hourly values is often rather crude. We strongly advocate further development of software aimed at capturing the frequency distribution of measured values during continuous monitoring, and further research into the benefits of such an approach relative to calculation of mean values, or the percentage of time measured hourly values are above or below a certain threshold (eg, for ICP above or below 20 or 25mmHg).

Neurologic Assessment

Assessments of the level of consciousness should be performed by the GCS. The GCS has evolved into a universal classification system for the severity of TBI. It consists of the sum score (range, 3–15) of the 3 components (eye, motor, and verbal scales). For assessment of severity in individual patients, the 3 components should be reported separately. A standardized approach is advocated. If painful stimuli are required to elicit response, nailbed pressure and supraorbital pressure (to test for localizing) are recommended.

We further recommend documentation of the occurrence and duration of LOC and of PTA, as well as the duration of periods of other alterations of consciousness (including confusion). Predefined categories of symptom duration are preferred because accurate assessment in minutes is often impossible and, if performed, unreliable. In addition, the source of verification of such data should be documented. These parameters are particularly relevant for milder injuries, in surveys or epidemiologic studies outside clinical centers, and for patients who present late. The length of LOC, PTA, or other alteration of consciousness is a key measure in establishing the diagnosis of mild TBI and its differentiation from more severe TBI. Self-report is acceptable (Centers for Disease Control and Prevention report to Congress), but verification establishes higher levels of evidence. In patients presenting late, information will generally be obtained by history.

Postacute Assessments

Several major issues must be considered when developing CDEs for use in the postacute setting. First, there can be multiple pathways of care during the postacute period. Second, disparities in access to postacute care may influence the recovery process and confound outcome assessment. Third, the highly variable periods at which treatments may occur and assessments are recorded, confound comparability of studies and interpretation of their results. Thus it is the recommendation of this working group to capture details on duration and intensity of all postacute treatment received, and further capture postacute assessments at predetermined, fixed periods.

No single measure exists to capture the progress of a patient during recovery. We advocate further research in development of a valid, global clinical assessment tool for use in TBI rehabilitation. Relevant tools for the assessment of aspects of progress during rehabilitation are the resolution of symptoms, the FIM, and assessments of neuropsychological function. Considerable overlap between the relevant tools for the assessment of progress during the postacute period, while recovery and treatment may still be ongoing, and those that measure outcome exists. Assessments performed on initiation of rehabilitation care may be endpoints for acute care trials, and assessments that measure progress during rehabilitation may coincide with assessments of outcome. Thus we recommend use of the same measures, including the neurocognitive test battery, as proposed by the outcomes group.[27]

SPECIFIC SUBPOPULATIONS

Military TBI

A critical question is how, and the extent to which, the nature and severity of TBI sustained by military personnel may differ from TBI sustained by civilians in nonmilitary environments. Injuries in military personnel including TBI are common in peacetime, as well as during combat, because they routinely engage in risky activities.[28] Clearly though, soldiers in the combat environment are more likely to sustain such injuries through exposure to blast overpressure or to sustain penetrating injuries (eg, bullet or shrapnel wounds) than are civilians in a noncombat environment. About 10% to 20% of returning troops from Operation Enduring Freedom and Operation Iraqi Freedom screen positive for probable TBI in recent studies.[29-31] These incidence rates are much higher than civilian incidence figures for similar periods. It has been estimated that mild TBI is complicated in 40% of cases in this population by posttraumatic stress disorder.[29] Civilian TBI studies have rarely included measures of posttraumatic stress disorder, and consequently the incidence of a combined diagnosis is not known in civilian populations.

Military personnel may be distinctly sensitive to the impact of TBI (eg, as a result of sleep deprivation) or distinctly resilient to TBI. Evidence suggests that the frontal cortex is not fully developed until 22 years of age, so young soldiers may have a relatively greater capacity for neural growth and plasticity and consequently recovery. Critical to identifying the mechanisms for such differences will be the construction and adoption of survey instruments that capture all the relevant factors (epidemiologic and situational or environmental) that might reasonably be hypothesized to mediate sensitivity and resilience to TBI events in military personnel. It was considered particularly relevant to capture information on military occupational specialty and deployment history. The risk of injury and type or cause of injury are likely to vary by military occupational specialty, with the greatest risks incurred by those involved in combat. The severity of psychological problems has been shown to correlate with the number and length of combat deployments, the time between deployments, and the severity of combat experiences.

Pediatric TBI

The response to injury, diagnostic approaches, and therapeutic modalities may differ between pediatric and adult TBI populations. In pediatric patients with more severe injuries, early swelling is common. It may be difficult to detect deficits in arousal, attention, or memory in newborns, infants, and preverbal children. It was further realized that with respect to neuroimaging studies and outcome assessment, specific recommendations were required. In a later phase of the project, a proposal was accepted to institute a dedicated working group with the goal to provide integral recommendations specific to pediatric TBI. This work is still in progress. Here, we summarize recommendations pertinent to the working group on Demographics and Clinical Assessments.

With respect to age, if the child was born before term (38 weeks) and is younger than 1 year, the age should be adjusted to account for prematurity. If age is recorded rather than date of birth, this should be measured in months for children younger than 2 years and in weeks for those younger than 2 months. The employment status and educational level of each parent should be recorded separately. Consent by the parent or legal guardian is typically required. In cases of intentional trauma where one parent is identified as the perpetrator, consent would be obtained from the other parent.

Regarding the medical history and clinical assessment, the working group recommended the following. The medical history should include pediatric disorders that are likely to impinge on functional neurologic outcome after TBI in the developing brain. These include epilepsy, psychiatric disorders, and developmental problems. Other variables relevant to TBI include congenital heart disease and sickle cell disease. In the case of nonaccidental trauma, the working group agreed that additional details will be needed and remain to be determined. To record the neurologic examination, the working group recommended the pediatric GCS. To record in-hospital treatment of pediatric TBI, the working group recommended the use of the Pediatric Intensity Level of Therapy Scale.[32]

A number of gaps in knowledge are specific to pediatric TBI and may serve to focus future research in this age group. In newborns and infants, the definition of mild TBI by alteration in consciousness is not reliable. This is related to the lack of consensus as yet on the measures to assess and classify the initial level of neurologic injury in infants and children. There are limited data on normal values for, and age dependence of, key physiologic parameters including ICP and cerebral perfusion pressure.[33] Consent must be obtained from parents or the legal guardian. Long-term outcome studies are needed to assess the impact of the sequelae of TBI on school performance, self-esteem, the ability to enter the workforce, and the impact of this injury on the child's family. These studies are limited by the duration required, and the need for a consensus on the measures needed to assess long-term functional outcome.

NEXT STEPS

We consider the initiative toward standardization of data collection across TBI studies of great importance. It should be realized, however, that this is an ongoing process. Despite the broad and expert input with representation from different disciplines and stakeholder organizations, the current proposals represent only a beta version, which will require further refinement and validation in clinical practice. Furthermore, we consider it essential to obtain broad support and acceptance of the final recommendations among the TBI community. We would like to see this initiative evolve as an international effort that has the potential to set global standards for data collection in TBI. To accomplish this goal, the following steps are proposed:

- Refinement of recommendations in collaboration with international partners, and ratification by stakeholders and international scientific bodies
- Translation of the modules into a web-based data entry format with pull-down menus and automated data checks
- Validation of the data elements in observational studies

References

1. Maas AI, Marmarou A, Murray GD, Teasdale SG, Steyerberg EW. Prognosis and clinical trial design in traumatic brain injury: the IMPACT study. J Neurotrauma 2007;24:232-8.
2. Marmarou A, Lu J, Butcher I, et al. IMPACT database of traumatic brain injury: design and description. J Neurotrauma 2007; 24:239-50.
3. Thurmond VA, Hicks RA, Gleason T, et al. Advancing integrated research in psychological health and traumatic brain injury: common data elements. Arch Phys Med Rehabil 2010;91:1633-6.
4. Menon DK, Schwab K, Wright DW, Maas AI. Position statement: definition of traumatic brain injury. Arch Phys Med Rehabil 2010;91:1637-40.
5. Maas A. Standardisation of data collection in traumatic brain injury: key to the future? Crit Care 2009;13:1016.
6. Bullock RM, Chesnut RM, Clifton GL, et al. Management and prognosis of severe traumatic brain injury. Guidelines for the management of severe traumatic brain injury. J Neurotrauma 2000;17:451-627.
7. Mushkudiani NA, Engel DC, Steyerberg EW, et al. Prognostic value of demographic characteristics in traumatic brain injury: results from the IMPACT study. J Neurotrauma 2007;24:259-69.
8. Bhopal R, Donaldson L. White, European, Western, Caucasian, or what? Inappropriate labelling in research on race, ethnicity, and health. Am J Public Health 1998;88:1303-7.
9. Haga SB, Venter JC. FDA faces in wrong direction. Science 2003;301:466.
10. Smart A, Tutton R, Martin P, Ellison GT, Ashcroft R. The standardization of race and ethnicity in biomedical science editorials and UK biobanks. Soc Stud Sci 2008;38:407-23.
11. Ma IW, Khan NA, Kang A, Zalunardo N, Palepu A. Systematic review identified suboptimal reporting and use of race/ethnicity in general medical journals. J Clin Epidemiol 2007;60:572-8.
12. Wright L. The New Yorker. 1994 Jul 15:46-55.
13. Jorde LB, Wooding SP. Genetic variation, classification and "race." Nat Genet 2004;36(Suppl):S28-S33.
14. Caulfield T, Fullerton SM, Ali-Khan SE, et al. Race and ancestry in biomedical research: exploring the challenges. Genome Med 2009;1:8.
15. Tutton R, Smart A, Martin PA, Ashcroft R, Ellison GT. Genotyping the future: scientists' expectations about race/ethnicity after BiDil. J Law Med Ethics 2008;36:464-70.
16. Wynia MK, Ivey SL, Hasnain-Wynia R. Collection of data on patients' race and ethnic group by physician practices. N Engl J Med 2010;362:846-50.
17. Suarez-Kurtz G. Pharmacogenomics in admixed populations. Trends Pharmacol Sci 2005;26:196-201.
18. Wolf SJ, Bebarta VS, Bonnett CJ, Pons PT, Cantrill SV. Blast injuries. Lancet 2009;374:405-15.
19. Ling G, Bandak F, Armonda R, Grant G, Ecklund J. Explosive blast neurotrauma. J Neurotrauma 2009;26:815-25.
20. Medicine AftAoA. The Abbreviated Injury Scale, 1990 Revision. Des Plaines: Association for the Advancement of Automotive Medicine; 1990. p 15-24.
21. Baker SP, O'Neill B, Haddon W, Long WB. The injury severity score: a method for describing patients with multiple injuries and evaluating emergency care. J Trauma 1974;14:187-96.

22. MRC CRASH Trial Collaborators, Perel P, Arango M, et al. Predicting outcome after traumatic brain injury: practical prognostic models based on large cohort of international patients. BMJ 2008;336:425-9.
23. Steyerberg EW, Mushkudiani N, Perel P, et al. Predicting outcome after traumatic brain injury: development and international validation of prognostic scores based on admission characteristics. PLoS Med 2008;8:e165.
24. Chesnut RM, Marshall LF, Klauber MR, et al. The role of secondary brain injury in determining outcome from severe head injury. J Trauma 1993;34:216-22.
25. McHugh GS, Engel DC, Butcher I, et al. Prognostic value of secondary insults in traumatic brain injury: results from the IMPACT study. J Neurotrauma 2007;24:287-93.
26. Signorini DF, Andrews PJ, Jones PA, Wardlaw JM, Miller JD. Adding insult to injury: the prognostic value of early secondary insults for survival after traumatic brain injury. J Neurol Neurosurg Psychiatry 1999;66:26-31.
27. Wilde EA, Whiteneck GG, Bogner J, et al. Recommendations for the use of common outcome measures in traumatic brain injury research. Arch Phys Med Rehabil 1650-60.
28. AFHSC. Armed Forces Health Surveillance Center. Traumatic brain injury among members of active components, U.S. Armed Forces, 1997-2006. Med Surveillance Mon Rep 2007;14:2-6.
29. Hoge CW, McGurk D, Thomas JL, Cox AL, Engel CC, Castro CA. Mild traumatic brain injury in U.S. soldiers returning from Iraq. N Engl J Med 2008;358:453-63.
30. Vasterling JJ, Proctor SP, Amoroso P, Kane R, Heeren T, White RF. Neuropsychological outcomes of army personnel following deployment to the Iraq war. JAMA 2006;296:519-29.
31. Schell TL, Marshall GN. Survey of individuals previously deployed for OEF/OIF. In: Tanidian T, Jaycox LH, editors. Invisible wounds of war: psychological and cognitive injuries, their consequences, and services to assist recovery. Santa Monica: Rand Corp; 2008. pp 87-115.
32. Shore PM, Hand LL, Roy L, Trivedi P, Kochanek PM, Adelson PD. Reliability and validity of the Pediatric Intensity Level of Therapy (PILOT) scale: a measure of the use of intracranial pressure-directed therapies. Crit Care Med 2006;34:1981-7.
33. Chambers IR, Stobbart L, Jones PA, et al. Age-related differences in intracranial pressure and cerebral perfusion pressure in the first 6 hours of monitoring after children's head injury: association with outcome. Childs Nerv Syst 2005;21:195-9.