

Advancing Integrated Research in Psychological Health and Traumatic Brain Injury: Common Data Elements

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In civilian, military, and veteran populations, there is increased recognition of the interrelationship between traumatic brain injury (TBI) and some psychological health (PH) disorders and the need to better understand the relationships by integrating research for these topics. The use of different measures to assess similar study variables and/or assess outcomes may limit important advances in PH and TBI research. Without a set of common data elements (CDEs; to include variable definitions and recommended measures for the purpose of this discussion), comparison of findings across studies is challenging. The federal agencies involved in PH and TBI research, the National Institute of Neurological Disorders and Stroke, Department of Veterans Affairs, National Institute on Disability and Rehabilitation Research, Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury, and Defense and Veterans Brain Injury Center, therefore cosponsored a scientific initiative to develop CDEs for PH and TBI research. Scientific experts were invited to participate in 1 of 8 working groups to develop recommendations for specific topic-driven CDEs. Draft recommendations were presented and discussed in the workshop "Advancing Integrated Research in Psychological Health and Traumatic Brain Injury: Common Data Elements (CDE)" held on March 23–24, 2009, in Silver Spring, MD. The overall process leading to the workshop and subsequent recommendations by the working groups are presented in this article. Topic-driven recommendations for CDEs are presented in individual reports in this edition.

Key Words: Analysis, demographics; Biomarkers; Brain injuries, traumatic; Outcome measures; Rehabilitation; Stress disorders, posttraumatic.

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THE COSTS AND CONSEQUENCES of psychological health disorders and TBI are of major importance to civilian, military, and veteran populations. The CDC reported that each year 1.6 million Americans die, are hospitalized, or are seen in an emergency department with a TBI.¹ However, this number is underestimated because it does not include people treated in physicians' offices or military care facilities. Recent reports of the prevalence of PH disorders, such as PTSD and depression, and TBI associated with military service in Iraq and Afghanistan have focused much attention on the importance of diagnosing and treating these conditions.²⁻⁴ In civilian, military, and veteran populations, there is increased recognition of the interrelationship between TBI and some psychological disorders and the need to better understand the relationships by integrating research for these topics.

The use of different measures to assess similar PH and TBI study variables and/or assess outcomes may limit important advances in PH and TBI research. Without a set of CDEs that includes at minimum variable definitions and recommended measures, comparison of findings across studies is challenging. The use of CDEs in PH and TBI studies would facilitate such comparisons by researchers, clinicians, and consumers and ultimately lead to a stronger evidence base for treatment advances.

The federal agencies involved in PH and TBI research, the NINDS, VA, NIDRR, DCoE, and DVBIC, cosponsored a scientific initiative to develop CDEs for PH and TBI research. Scientific experts were invited to participate in 1 of 8 working groups to develop recommendations for specific topic-driven CDEs. Draft recommendations were presented and discussed in

List of Abbreviations

CDC	Centers for Disease Control and Prevention
CDE	common data element
DCoE	Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury
DoD	Department of Defense
DVBIC	Defense and Veterans Brain Injury Center
NIDRR	National Institute on Disability and Rehabilitation Research
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
OEF	Operation Enduring Freedom
OIF	Operation Iraqi Freedom
PH	psychological health
PTSD	posttraumatic stress disorder
TBI	traumatic brain injury
TBIMS	Traumatic Brain Injury Model Systems
VA	Department of Veterans Affairs

From the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury, Silver Spring, MD (Thurmond, Szuflita); National Institute of Neurological Disorders and Stroke, Bethesda, MD (Hicks); Department of Veterans Affairs, Washington, DC (Gleason, Orman); National Institute on Disability and Rehabilitation Research, U.S. Department of Education, Washington, DC (Miller); and Defense and Veterans Brain Injury Center, Walter Reed Army Medical Center, Washington, DC (Schwab).

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the workshop “Advancing Integrated Research in Psychological Health and Traumatic Brain Injury: Common Data Elements” held on March 23–24, 2009, in Silver Spring, MD. The process leading to the workshop and the subsequent recommendations by the working groups are presented in this article. Recommendations by topic are presented in 6 separate reports in this edition.

BACKGROUND

Each of the federal agencies that cosponsored the CDE Workshop support and advance a wide range of research efforts related to PH and TBI. Selected agency activities relevant to the CDE include the following items:

National Institute of Neurological Disorders and Stroke

The goal of promoting data standardization and cross-study comparability fits well within the mission of the NINDS, which is to decrease the burden of neurologic disease, a burden borne by every age group, every segment of society, and people all over the world. The project builds on a workshop on TBI Classification sponsored by the NINDS in October 2007,⁵ when scientists recommended that a pathoanatomic-based classification system be developed for TBI. However, a major obstacle to developing a new pathoanatomic classification system was a lack of standardization of terminology and CDEs.

Another NINDS-supported activity that provides a foundation for this CDE effort is the NINDS CDE Project, which aims to decrease study start-up time for clinical studies and accelerate data sharing in neurology. To this end, the NINDS has developed core data elements that commonly are collected in all clinical studies regardless of type of study or therapeutic area, such as demographic information. Core data elements are available on the NINDS CDE Web site (www.nindscommondataelements.org).

Department of Veterans Affairs

Standardization of data elements for PH and TBI will help advance the VA's research in these important areas affecting veterans' health and well-being. VA research supports an extensive network of scientists working in a nationwide health care system dedicated to providing the best care for U.S. veterans, including for PH and TBI. VA scientists are conducting cutting-edge research aimed at improving the understanding and treatment of diseases or injuries in the veteran population, with a rich history of discoveries related to PH and, more recently, TBI, as well as advances in research methods. For example, the VA cosponsored with the NIH and DoD offices an expert working group to develop recommendations for PTSD clinical trials (<http://www.research.va.gov/programs/csrd/default.cfm>).

To ensure that the TBI research program supports innovative and timely research that complements civilian and military research programs, the VA invited national and international experts to participate in a State of the Art Conference in June 2008 to inform development of its TBI research agenda (www.hsrd.research.va.gov/meetings/sota/TBI/introduction.pdf). A publication summarizing the State of the Art recommendations can be found in the November 2009 issue of the VA's *Journal of Rehabilitation Research and Development*.⁶

National Institute on Disability and Rehabilitation Research

The NIDRR of the U.S. Department of Education has a long-standing investment in promoting standardization of data elements for rehabilitation research. These investments support the NIDRR's mission of generating new knowledge and pro-

moting its effective use to improve the lives of people with disabilities. The NIDRR's TBIMS Centers Program funds centers of excellence throughout the country to provide comprehensive systems of brain injury care, conduct clinical research, and contribute to a centralized prospective longitudinal database. The database includes CDEs for diagnostic and functional information about persons with TBI from inpatient admission through 20 years postinjury and is a rich resource for research. In 2008, the NIDRR and its grantee, the TBIMS National Data and Statistical Center at Craig Hospital, Englewood, Colorado, partnered with the VA and DVBIC to fulfill a congressional mandate for the creation and maintenance of a VA TBI Veterans Health Registry, which includes information about who served as members of the Armed Forces in OIF/OEF. OIF/OEF members must show symptoms associated with TBI and apply for services or file a disability claim. This collaboration also has resulted in the creation of a VA Polytrauma Rehabilitation Centers longitudinal database, populated by the subset of those in the registry who experienced moderate or severe TBI. This database includes the same (common) data elements already being collected with civilians for the TBIMS National Database.

To improve measurement of rehabilitation outcomes and make tools available for adoption as CDEs, the NIDRR has invested heavily in measurement development, including TBI-specific tools (see <http://www.tbims.org/combi/> and <http://www.neuroqol.org/default.aspx>). The NIDRR also was a partner in early efforts to create CDEs for spinal cord injury research,⁷ an initiative that conceptually parallels that of the current CDE effort for TBI.

Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury

DCoE contributed to the initial efforts toward developing CDEs for PH and TBI. In the 2007 National Defense Authorization Act, Congress established the DCoE. The center was to be a focal point for PH and TBI issues and currently serves as the DoD's “open front door” in areas of PH and TBI.

Recognizing the need to have CDEs and standardization in PH and TBI research, the DCoE began meeting with representatives from federal and nonfederal agencies that fund research in PH and TBI, including the NINDS and VA. Other participating agencies included the CDC, Force Health Protection and Readiness in Health Affairs, Armed Forces Health Surveillance Center, U.S. Army Center for Health Promotion and Preventive Medicine, National Naval Medical Center, Walter Reed Army Medical Center, National Guard Bureau, and the uniformed services. It was during these meetings that subject matter experts from these agencies identified the development of CDEs as a high priority and indicated that standardization of data elements was needed to permit robust comparisons across studies.

Defense and Veterans Brain Injury Center

Congress created the DVBIC in 1992 during the Persian Gulf War to integrate specialized TBI care, research, and education across the military and veterans' medical health care systems. A fourth mission, force management, was added in 2008, with the DVBIC designated as an office of responsibility or executive agent for at least 6 DoD initiatives, to include a TBI registry and surveillance for all services and predeployment cognitive testing. The DVBIC consists of 19 TBI specialty military, VA, and civilian centers and is the primary operational TBI component of the DCoE.

From its inception, the DVBIC's congressionally mandated missions have required collaboration between the DoD, VA,

and civilian sites. Recent collaborative initiatives between the DVBIC, CDC, VA, NIDRR, and NIH have included large multicenter longitudinal studies, interagency research TBI registries, and critical database initiatives. Sets of CDEs including standardized data collection procedures have been required and developed for these multicenter trials and initiatives. As a result, the DVBIC has endorsed and promoted the development of CDEs to facilitate these projects and ensure that research findings can be compared across various TBI populations. Recently, TBI in members of the Armed Forces who served in OEF/OIF has increased national awareness of the problems and difficulties associated with these injuries in the military, veteran, and civilian populations. The development of CDEs has become an urgent requirement as funding has been provided to develop evidence for the long-term consequences of TBI, the impact of blast-related TBI, the impact of cognitive problems on quality of life, and the ability of injured service members to lead productive lives.

METHODS

A CDE Interagency Steering Committee composed of representatives and stakeholders from the cosponsoring agencies identified (1) 4 PH and 4 TBI topic areas and (2) working group chairs and scientific experts for each topic area; PH and TBI topics were selected based on the priority needs for clinical research in PH and TBI common to all cosponsors. Stakeholders were identified and invited to provide feedback to the CDE working groups and workshops. Stakeholders include those providing clinical care and assessment and those caring for patients with PH disorders and/or TBI. The stakeholders were expected to provide perspectives from the clinical and patient communities useful to the development of research priorities and tools. For the broad category of PH, the Interagency Steering Committee focused on a subset of topics relevant to civilian, military, and veteran populations and also potentially co-occurring with TBI: PTSD, depression, substance abuse/misuse, and operational stress. Operational stress was of particular interest to the DCoE and generally was defined broadly to encompass all challenges related to military service for both service members and their families, whether in training or while deployed. Overall, the 4 areas in PH were among the more pressing topics that may benefit from establishing CDEs.

For TBI, the 4 working group topics were selected based on perceived need for further delineation of CDEs as follows: demographics and clinical assessment, neuroimaging, biospecimens/biomarkers, and outcome measures. The goal was to generate recommendations for CDEs that would be relevant to a broad spectrum of clinical studies, including research with both men and women in civilian, military, and veteran populations and with persons of all ages, levels of injury severity, types of injury (impact, acceleration-deceleration, blast, penetration, combination), and times postinjury (from acute to long term).

In all groups, CDE recommendations were formulated using the 3 general descriptive levels of core, supplemental, and emerging. Data elements described as core are intended to encompass the minimal set of measures to characterize a broad spectrum of subjects on the domain. A supplemental element is intended for greater depth/breadth of exploration and/or more specialized subpopulations. Data elements described as emerging may require further validation, but may fill gaps in currently validated measures and/or substitute for recommended measures when validation is complete. These levels were intended to provide further description to the recommendations and use of data elements. The editorial process (described next)

addressed the consistency of these descriptive levels across topic-specific manuscripts.

The working group chairs, the Interagency Steering Committee, and stakeholders communicated extensively before the workshop. The working groups, with input from the Interagency Steering Committee and stakeholders, prepared preliminary white papers and recommendations in advance of the workshop and presented and further refined recommendations during the workshop. After the workshop, the working groups finalized recommendations in a set of manuscripts. John Whyte, MD, PhD, Geoff Manley, MD, PhD and Jennifer Vasterling, PhD edited the manuscripts before submission to the journal. An editorial process was instituted to ensure consistency and reduce redundancies or overlap across the manuscript series. Two editors reviewed each manuscript to (1) provide editorial comments, (2) determine whether there were conflicts in recommendations, and (3) assess parallel treatment of the 3 data element levels. After editorial review, working groups were asked to revise their manuscripts before submission to the *Archives of Physical Medicine and Rehabilitation* for independent review. Leighton Chan, MD, MPH served as the liaison between the journal and these editors to facilitate publication. A list of participants for the working groups can be found in the respective publications within this special section of the issue.

WORKSHOP PROCEEDINGS

National and international PH and TBI experts (N=137) participated, representing 21 U.S. and international universities, 19 DoD entities, 9 NIH-affiliated institutes, 16 NIDRR grantee institutions, the CDC, and other key stakeholders, including representatives of both the VA Central Office and local VA medical centers. The workshop was composed of 4 sessions as follows: (I) Building the Core Data Set for PH and TBI, (II) Integrating PH and TBI Research, (III) Refining CDE, and (IV) Final Recommendations for CDEs.

Session I: Building the Core Data Set for PH and TBI

During this session, the chairperson of each of the 8 working groups presented their draft recommendations. A brief question-and-answer session followed each presentation, which helped contribute to the working group's refinement of their recommendations later during the day. Session I helped workshop participants understand the efforts of each working group and highlighted areas of overlap.

Session II: Integrating PH and TBI Research

In addition to being tasked with the development of CDEs for a particular area of assessment within PH or TBI (as seen in Session I), workshop participants were asked to identify areas of overlap between PH and TBI. Participants also were asked to discuss the potential for CDEs that might foster the study of patients with and without co-occurring diagnoses of PH disorders and TBI. This breakout session brought together participants from PH and TBI working groups, as well as key stakeholders.

Session II discussion focused on priority areas for research on the potential overlap between patients with PH problems and TBI: demographic variable(s), tool(s), screening measure(s), definition(s), metric(s), and so on, recommendations to best capture and characterize this overlap; identification of ways to organize relevant concepts to facilitate prudent integration of PH and TBI research; and recommendations for future workshops and/or work group focus areas to help advance our understanding of PH, TBI, and areas of overlap in patient populations.

The Interagency Steering Committee purposefully ensured that each group in Session II included a mix of scientists and subject matter experts in the areas of PH and TBI. The intent was to encourage dialogue regarding overlaps and set the stage for future discussions of the implications of these overlaps.

Session III: Refining the CDEs

A primary goal of the workshop was to prepare recommendations for CDEs for PH and TBI research. A secondary goal was to recommend steps toward integrating data for PH and TBI research. In Session III, each working group met with assigned members of other working groups and stakeholders to further refine their recommendations with the benefit of feedback from members of the other working groups and the stakeholders' committee. The working groups in Session III focused on finalizing recommendations for the data elements to include the descriptions of core, supplemental, and emerging levels; identify research gaps and/or the next steps toward creating a large human PH and TBI database for such purposes as phenotyping and genotyping, pathoanatomic classification, and tracking; explore the next steps for integrating PH and TBI research; and finalize plans for writing the CDE manuscript.

Session IV: Final Recommendations for CDEs

During this session, the working group chairs presented their final recommendations to the larger group. Session IV provided an opportunity for participants to share their revised recommendations and discuss the next steps to continuing this CDE effort.

CONCLUSIONS

Scientists began the CDE initiative to meet an important need in the areas of PH and TBI research, which included the need for a common battery of measures and methods that will promote multisite research and better enable comparison of research results across studies.

The work groups met throughout the process and also met with the CDE Interagency Steering Committee. Work group members participated in extensive discussions and reviewed evidence for measures, as well as areas that make use of CDEs and areas that need further research. During manuscript development, each group continued discussions until agreement was reached for the recommendations. Although no formal voting process was used, recommendations are based on agreement among participants.

This initiative has resulted in the following accomplishments:

- Recommendations for CDEs for TBI research for the following categories of variables: demographics, acute clinical assessment, neuroimaging, biomarkers/biospecimens, and outcome measures
- Identification of some shared data elements for PH and TBI research
- Definitions for some PH variables and for related terminology for PTSD and operational stress

- Increased communication between PH and TBI clinical researchers as a foundation for future coordination and collaboration

Most of the progress to date has resulted in the accompanying set of 6 topic-specific articles. Two topics, depression and substance use/abuse, are not presented here and may follow in future publications.

The federal agencies that cosponsored this initiative plan to make the CDE recommendations for PH and TBI available electronically and to link them across agency Web sites. The agencies envision the CDEs as a dynamic, rather than static, effort. To this end, the CDEs described here are also being evaluated for their relevance to pediatric populations. This work is in progress, but it is anticipated that modifications and/or additions may be needed to ensure relevance across the life span. Scientists involved in this initiative understand that it will also continue to evolve based on pending validation studies for recently completed instruments and those nearing completion and on more distant advances in tools and knowledge. Establishment of an ongoing review committee will be essential for evaluating and facilitating updates and revisions to the present recommendations.

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