



## Common Data Elements for Research in Psychological Health and Traumatic Brain Injury

### Background

**Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (DCoE)** co-sponsored a psychological health and traumatic brain injury (TBI) workshop in March 2009 to develop common data elements for psychological health and TBI research. Nearly 50 organizations participated in the workshop, which was also cosponsored by the **National Institute of Neurological Disorders and Stroke, Department of Veterans Affairs (VA)** and **National Institute on Disability and Rehabilitation Research**.

This workshop evolved from several significant earlier events beginning with a conference on TBI classification in 2007 held by the National Institute of Neurological Disorders and Stroke. In 2008, DCoE held monthly meetings with several federal agencies to develop common standards in psychological health and TBI research. This resulted in the development of a definition of psychological health and a posttraumatic stress disorder (PTSD) case definition for patient monitoring that is now being used by several government agencies.

In late 2008, a planning committee began a more focused interagency approach. The committee estab-

lished working groups with specific focus areas in psychological health and TBI to standardize research variables in the following areas:

- **Psychological health working groups**
  - PTSD
  - Depression
  - Substance abuse/misuse
  - Operational stress
- **TBI working groups**
  - Demographics and clinical assessment
  - Neuroimaging
  - Biospecimens/biomarkers
  - Outcome measures

Prior to the workshop, the working groups submitted preliminary white papers and recommendations to the planning committee and key stakeholders. The goal of the workshop was to develop common data elements for psychological health and TBI research, including recommendations for definitions, metrics, outcomes and instrumentation, to allow for comparisons across studies in the future.



## Results

Nearly 140 national and international psychological health and TBI experts participated in the workshop, representing 21 U.S. and international universities, 19 Defense Department entities, nine affiliates from the National Institutes of Health, 16 grantee institutions from the National Institute on Disability and Rehabilitation Research, Centers for Disease Control and Prevention and other key stakeholders, including representatives of both the VA's central office and local VA medical centers.

For the broad category of psychological health, the workshop focused on a subset of topics that were relevant to civilian, military and veteran populations: PTSD, depression, substance abuse/misuse and operational stress. Operational stress was of particular interest to DCoE and broadly defined to encompass all challenges related to military service for both service members and families, whether in training or while deployed.

During the workshop, subject matter experts identified the development of common data elements as a high priority. Without a common set of data elements that includes at minimum variable definitions and recommended measures, comparison of findings across studies is challenging. As the use of different measures to assess psychological health, TBI variables and outcomes may limit research advances, implementing common data elements will facilitate comparisons by researchers and clinicians, ultimately leading to treatment advances.

In September 2010, a steering committee consisting of subject matter experts and representatives from the Defense Department, National Institute on Disability and Rehabilitation Research, National Institutes of Health and the VA met to discuss oversight of the common data elements, including refinement and validation, gaps, related activities and plans for a federated database.

## The Future

More than two million service members have completed more than three million deployments to Iraq and Afghanistan. DCoE recognizes the relationship between TBI and some psychological health conditions

and the need to better understand the connection by integrating research in this area. By doing so, DCoE seeks to develop effective psychological health assessments and TBI treatments for our service members now and in the future.

## Publications

- Nine manuscripts describing the rationale and recommendations for common data elements for TBI clinical research and psychological health were published in *The Archives of Physical Medicine and Rehabilitation*, November 2010 (Vol. 91, No. 11).
- The recommended TBI common data elements, protocols for data collection and a data dictionary are posted [online](#) and will be continuously updated as research and advancements are made.
- National Institute of Neurological Disorders and Stroke awarded a two-year grant to test the common data element recommendations for feasibility and utility. Recommended TBI common data elements were collected on 2,000 subjects who made three visits to emergency rooms or out-patient rehabilitation centers. The enrollment was completed Sept. 2011.
- Several manuscripts from a March 2010 workshop discussing pediatric considerations and necessary modifications to the recommendations are in progress and were published in the *Journal of Neurotrauma* in the winter of 2011.

## Resources

- [National Institute of Neurological Disorders and Stroke Common Data Elements Project](#)
- [Department of Veterans Affairs TBI State-of-the-Art 2008 Conference](#)
- [International Neurotrauma Society letter discussing the need for TBI common data elements](#)
- [Joint letter from American Association of Neurological Surgeons and Congress of Neurological Surgeons in support of TBI common data elements](#)