

DA001 Identification of Subjects	
Review Committee: Planning	Start Date: 4/01/2007
Attachments: None	Last Revision Date: 12/19/2019
Forms: None	Last Reviewed Date: 7/16/2024

Introduction:

The TBIMS use established criteria to determine eligibility for enrollment and participation in the TBIMS National Database (NDB).

Purpose:

To institute standard inclusion / exclusion criteria for identifying and enrolling potential subjects into the NDB.

Scope:

Current TBIMS centers which are identifying and enrolling subjects into the NDB.

Responsibilities:

TBIMS staff responsible for identifying and enrolling subjects into the NDB (e.g., TBI researchers or clinicians, research assistants, study coordinators).

Procedural steps:

The Case Definition for inclusion in the NDB is:

TBI is defined as damage to brain tissue caused by an external mechanical force as evidenced by medically documented loss of consciousness or post traumatic amnesia (PTA) due to brain trauma or by objective neurological findings that can be reasonably attributed to TBI on physical examination or mental status examination. Penetrating wounds fitting definition listed above are included.

This definition of TBI excludes several conditions when criteria above are not met: Lacerations or contusions of the face, eye, or scalp, without other criteria listed above; Fractures of skull or facial bones, without criteria listed above; Primary anoxic, inflammatory, toxic, or metabolic encephalopathies which are not complications of head trauma; Brain infarction (ischemic stroke); Intracranial hemorrhage (hemorrhagic stroke) without associated trauma; Airway obstruction (e.g., near - drowning, throat swelling, choking, strangulation, or crush injuries to the chest); Seizure disorders (Grand mal, etc.); Intracranial surgery; Neoplasms.

Each potential TBIMS subject should be screened with the following inclusion/exclusion criteria.

The Inclusion Criteria for the TBIMS NDB are:

All persons:

1. fitting the above definition;
2. meeting at least one of the following criteria for moderate to severe TBI:
 - PTA > 24 hours
 - Trauma related intracranial neuroimaging abnormalities
 - Loss of consciousness exceeding 30 minutes (unless due to sedation or intoxication)
 - GCS in the emergency department of less than 13 (unless due to intubation, sedation, or intoxication);
3. who are age 16 or older at the time of injury;
4. presenting to the TBIMS's acute care hospital within 72 hours of injury;
5. must receive both acute hospital care and comprehensive rehabilitation in a designated brain injury inpatient rehabilitation program within the TBIMS. Comprehensive rehabilitation must occur in a hospital, rehabilitation unit, rehabilitation hospital, hospital-based skilled nursing facility, skilled nursing facility, or long-term acute care hospital that meets the following criteria:
 - Medical and rehabilitation care are supervised on a regular basis by a physician affiliated with the TBIMS
 - 24-hour nursing care is provided to the patient
 - PT, OT, Speech, Rehabilitation Psychology/Clinical Neuropsychology, and family support/education are provided in an integrated, team approach with the expectation of further gain.
 - Regardless the setting in which it is constituted, a comprehensive rehabilitation program operates in a manner consistent with (a) CARF standards for brain injury inpatient rehabilitation and/or (b) Medicare requirements for inpatient rehabilitation.
 - If a TBIMS's comprehensive rehabilitation program co-exists with programming that does not meet the above criteria, the TBIMS must explicitly define its methodology for establishing the dates of admission and discharge from comprehensive rehabilitation that will be reported to the TBIMS Data and Statistical Center (NDSC). These dates will represent the period of time during which CARF and/or Medicare criteria are met. This period may include interruptions during which the criteria are not met for medical reasons but after which a rehabilitation programming meeting CARF and/or Medicare criteria is resumed.
 - All data required by the National Database are accessible and transferable to the NDSC with appropriate informed consent;
6. who understand and provide informed consent to participate or, if unable, family or legally authorized representative understands and provides informed consent for the patient.

Additional Guidelines for inclusion/exclusion of cases are:

- Submit cases which expire any time after inpatient rehabilitation has begun; even if the patient was transferred back to acute care from rehabilitation prior to expiring.
- Subjects who have a preexisting central nervous system problem (anoxia, stroke, aneurysm, etc.) will be included in the database as long as all other inclusion criteria are met.
- Subjects who have concurrent events (e.g., aneurysm rupture with TBI, syncope/stroke/fall with TBI) will be included if the admitting physiatrist determines that the predominant mode of central nervous system injury is traumatic, as long as all other inclusion criteria are met.
- Subjects are included if the time of injury can be approximated within a 12-hour window. If time of injury cannot be approximately determined within 12 hours, the subject should be excluded.
- If date of injury is in question, it will be decided by the midpoint of the theoretical 12-hour (or less) window.
- If, prior to admission to comprehensive rehabilitation, a patient leaves a designated TBIMS facility for more than 72 hours, the patient should be excluded from the study. Once the patient enters comprehensive rehabilitation and meets the inclusion criteria, the subject should be retained even if she/he is subsequently transferred to a non-TBIMS facility.
- If a patient completes acute care and comprehensive rehabilitation and is then transferred outside of the TBIMS or to an alternate level of care that does not meet the criteria for comprehensive rehabilitation specified above (regardless of whether it is a designated TBIMS facility or not), this is considered the rehabilitation discharge date [RHB], and the residence at discharge [RES] should reflect this alternate level of care discharge.
- If a patient is transferred to an alternate level of care within the designated TBIMS prior to inpatient rehabilitation, the alternate level of care length of stay should be added to the TBIMS acute care stay [ACUTE] or comprehensive rehabilitation stay [RHB], whichever is most applicable.
- Do not exclude a person from the database because of early discharge from inpatient rehabilitation. There is no minimum amount of therapies that the patient must receive to be eligible.
- If patient expires prior to consenting, attempts should be made to obtain consent from family members in order to include data in the dataset (to avoid biasing the dataset).
- Patients who are in law enforcement custody at admission to the designated rehabilitation unit or who are taken into custody prior to discharge from the designated rehabilitation unit are not eligible for the TBIMS study and should not be approached for consent.

Training requirements:

Staff who are responsible for recruitment and enrollment of subjects into the TBIMS should be familiar with these criteria.

Compliance:

Only participants that meet these inclusion / exclusion criteria will be enrolled into the TBIMS NDB. These criteria should be reported in any presentations or publications related to analysis of the NDB data.

References:

Definition of TBI adopted from:

Thurman DJ, Snieszek JE, Johnson D, Greenspan A. Guidelines for Surveillance of Central Nervous System Injury, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control; 1995 (with some revisions from 2002).

History:

Date	Action
4/1/07	Version of inclusion criteria used to create this SOP
9/16/08	Transferred to SOP template and approved by SOP Review Committee
12/12/08	Revised definition with approval of Planning Committee and Project Directors
5/13/2012	Added language explaining that persons in law enforcement custody should not be enrolled in the TBIMS
1/1/2013	Updated variable numbers to variable group names
12/19/2019	Added language explaining that there is no minimum amount of therapies that the patient must receive to be eligible.
7/16/2024	SOP reviewed

Review schedule:

At least every 5 years.