610 Adding Affiliate Hospitals to a TBI Model System

<table>
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<tr>
<th>Review Committee: Planning</th>
<th>Start Date: 12/1/2016</th>
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<tr>
<td>Addendum: None</td>
<td>Last Revised Date: 12/1/2016</td>
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<tr>
<td>Forms: None</td>
<td>Last Reviewed Date: 12/1/2016</td>
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Introduction:
In order for a patient to be eligible for enrollment in the TBIMS National Database (NDB), he/she must receive both acute care and comprehensive rehabilitation in facilities that are a part of the system of care of a TBIMS Center. Historically, the facilities associated with a Center’s system of care are named in the grant application of the funded Center.

For an acute care hospital (trauma center) to be eligible for inclusion in a Center’s system of care, the following criteria must be met:

- All required Form 1 data elements must be available for abstraction from the rehabilitation medical record or participant information access must be sufficient so that these data elements can be collected by appropriately trained research assistants.

- This access may be provided due to the acute care hospital being part of the same system of care, a formal contract, a letter of agreement, inclusion of acute care physician(s) as co-investigator(s), or some other durable agreement that will ensure uninterrupted, timely access to all needed data elements.

For a rehabilitation facility to be eligible for inclusion in a Center’s system of care, the following criteria (defined in SOP101a “Identification of Subjects for the TBIMS National Database”) must be met:

- The facility (hospital, rehabilitation unit/hospital, hospital-based nursing facility, skilled nursing facility, or a long term acute care hospital) must provide comprehensive rehabilitation.

- Medical and rehabilitation care must be supervised by a TBIMS-affiliated physician and must have 24-hour nursing care. Affiliated physicians may or may not be co-investigators for the TBIMS project; thus, the physician’s role may be clinical only or may include active participation in research.
These rehabilitation therapies (PT, OT, Speech, Rehabilitation Psychology/Neuropsychology, and/or family support/education) must be provided to patients.

The rehabilitation program must operate in a manner consistent with (a) CARF standards for brain injury inpatient rehabilitation and/or (b) Medicare requirements for inpatient rehabilitation.

All required Form 1 data elements must be available for abstraction from the rehabilitation medical record or participant access must be sufficient so that these data elements can be collected by appropriately trained research assistants.

There has been an increasing desire for TBIMS Centers to add affiliate hospitals or facilities (AF) to their system of care after the start of the performance period of the grant. One reason to add an AF is to assist the TBIMS in meeting the minimum number of enrollees in the NDB. There is a need to develop guidelines for adding facilities to an existing Center’s system of care.

An AF is defined as a facility that is added to an existing TBIMS Center’s system of care and that meets the requirements listed in the Introduction above. An AF can be any type of inpatient facility where individuals with TBI are cared for along the continuum of care from time of injury through discharge from inpatient rehabilitation (e.g., acute care hospital/unit, long term acute hospital/unit, rehabilitation hospital/unit, nursing home, etc.).

**Purpose:**
To provide guidelines for adding AF to a TBIMS during a grant funding period, while maintaining data quality.

**Scope:**
All TBIMS Centers.

**Responsibilities:**
All TBIMS Centers are responsible for adhering to this policy and its procedures.

**Procedural steps:**
1) The TBIMS Center that wishes to add an AF to their existing system of care must send a request to their NIDILRR Project Officer. The request must:
   - Briefly describe the facility, the facility’s capacity to provide services for individuals with TBI (trauma center level, approximate number of persons with moderate/severe TBI seen per year, and any other pertinent information), and the reason for adding this facility to the system of care.
• Specify the arrangements that will be in place ensuring access to data and to ensure the maintenance of high data quality from the new AF (i.e., arrangements that ensure that all data quality targets can be achieved and data quality guidelines can be adhered to).

• Discuss the impact of adding the AF on the Center’s participation in the NDB (e.g., number of additional eligible NDB participants, additional data points).

2) If the NIDILRR Project Officer approves the addition of the AF, the Center must continue to pay close attention to all data quality targets to assure no reduction in data quality as a result of adding the new AF. The Center must continue to abide by SOP 606 “Performance Target Monitoring”, which states that if any “in year” performance target is not met for two consecutive quarters, the TBIMS Project Director in consultation with TBIMS Center staff must provide an action plan to their NIDILRR Project Officer.

Training requirements:
None

Compliance:
All TBIMS Centers are responsible for complying with this policy and its procedures.

References:
None

History:

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<td>12/1/2016</td>
<td>SOP Created and Approved by Project Directors</td>
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Review schedule: At least every 5 years.