Functional Changes in Activity Limitations Across the First Year of Recovery Following Traumatic Brain Injury: A Traumatic Brain Injury Model Systems Study

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JFK Johnson Traumatic Brain Injury Model System Center: 2017-2022
The Traumatic Brain Injury Model System Centers (TBIMS Centers) program was created by National Institute on Disability Independent Living and Rehabilitation Research (previously National Institute on Disability and Rehabilitation Research) in 1987 to demonstrate the benefits of a coordinated system of neurotrauma and rehabilitation care and to conduct innovative research on all aspects of care for those who sustain TBI.

The mission of the TBIMS Centers is to improve the lives of persons who experience TBI, and of their families and communities, by creating and disseminating new knowledge about the natural course of TBI and about rehabilitation treatment and outcomes following TBI.

The influence of the TBIMS program continues to be expanded through collaborations with the US Departments of Veterans Affairs and Defense, the National Institute of Neurological Disorders and Stroke, and the Centers for Disease Control and Prevention.
TBIMS Centers

- NIDILRR funds 16 TBIMS Centers throughout the US.
- Centers **MUST** provide comprehensive systems of brain injury care to individuals who sustain TBI.
- Centers **MUST** conduct: 1) *site-specific research* and 2) *multi-site research* in collaboration with other TBIMS Centers.
- Centers **MUST** contribute/participate in the largest longitudinal TBI research effort to date - the TBIMS National Database (NDB).
  - Since 1989, the TBIMS Centers have collected and contributed information on common data elements for a centralized TBIMS NDB
  - As of December, 2016, TBIMS Centers have enrolled
    - 15,413 participants in the TBIMS NDB, with follow-up data available to date for
    - 14,728 participants at 1-year post injury;
    - 13,163 at 2 years post injury; 10,144 at 5 years post injury;
    - 5,884 at 10 years post injury;
    - 640 at 20 years post injury.
JFK Johnson TBIMS Site-Specific Research Study
TBIs vary greatly in cause, severity, and recovery resulting in variability in functional abilities of patients who sustained TBI.

Functional recovery after TBI can occur over the course of days, months, or even years after injury.

Different functions may recover at different rates, and some functions may remain compromised or even worsen, requiring specialized treatments.

Functional capacity/participation and treatment effects are meaningfully assessed at the level of everyday activity performance.

Improvements in the ability to perform functional tasks and activities of daily living represents a proximal, yet relevant and meaningful, goal of TBI rehabilitation.

Given the diversity of limitations and recovery after TBI, it is essential to develop tools capable of tracking functional recovery trajectories over time and across treatment settings – a critical feature that is missing from the currently available functional measures.
Funding agencies want to be able to monitor quality of care and outcomes across the rehabilitation continuum.

Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) – currently applies only to Medicare beneficiaries.

Rehabilitation facilities must “utilize and report cross-setting, longitudinal assessment measures that are “standardized and interoperable so as to allow for the exchange of such data among such post-acute care providers and other providers and the use by such providers of such data that has been so exchanges, including by using common standards and definitions in order to provide access to longitudinal information for such providers to facilitate coordinated care and improved Medicare beneficiary outcomes.”

No later than October 1, 2018, rehabilitation facilities must provide specific and standardized data on admission and discharge functional assessment and care plan that addresses function.

While currently this applies only to Medicare beneficiaries, other funding agencies are highly likely to follow suit.
Activity Measure for Post-Acute Care (AM-PAC)

- Functional outcomes system that can be used across post-acute care settings
- Developed by researchers at Boston University
- Developed using the World Health Organization’s International Classification of Functioning, Disability and Health (ICD) and measures the functional status of adults with various diagnoses across all post-acute settings.
- Developed with consideration of the multifaceted nature of activity functioning
  - measures activity limitation in three distinct functional domains: Basic Mobility, Daily Activities, and Applied Cognition
  - yields the assessment of multiple aspects of a person’s ability to perform specific daily activities: difficulty, need for assistance, and limitations
- Allows for tracking of patients’ functional status as they move across the continuum of care (acute care, acute inpatient rehabilitation, sub-acute rehabilitation, home care therapy, outpatient rehabilitation, discharge)
AM-PAC: forms and items

- 269 functional activities organized into three functional areas:
  - Basic Mobility (131 items)
  - Daily Activity (88 items)
  - Applied Cognitive (50 items).

- Computer- and pen-and-paper-based versions are available.

- The computer-adaptive testing (CAT) version was developed using item reduction theory where each subsequent item is selected from the item bank based on a previous response thus eliminating items that are too easy or difficult.
  - This reduces the length of overall administration, overutilization of resources, and patient/proxy burden.

- All AM-PAC forms and versions yield the same metrics allowing comparison across and between forms, patients, and settings.
AM-PAC: Populations

- The AM-PAC has been validated in individuals with stroke, complex medication conditions, and orthopedic injuries.

- It has not been studied in individuals with TBI.
Scoring: T-score conversions

- Mean = 50
- SD = 10
- Range
  - Basic Mobility: 4.2-95.8
  - Daily Activity: 7.7-100
  - Applied Cognitive: 0-65.2
Functional Stages

- Provides a context for interpretation that may be more meaningful.
- Scores for each domain are divided into ranges that represent functional stages.
- Functional stage: profile of the types of activities a patient might be able to accomplish at different scale score levels
  - Hierarchical
  - Each consecutive stage represents increasingly more difficult activities
Basic Mobility Functional Stages

- **84 – 100 Strenuous Recreation/Sports:**
  - Your score suggests a high level of independence in moving about both at home and in the community. You may be able to participate in most physical activities without much difficulty.

- **66 – 83 Moving Around Outdoors:**
  - Your score suggests that you are able to walk inside your home and other buildings without any difficulty. You may be able to move about outdoors without any limitations. You should be able to bend over and pick up things without much difficulty. Activities that might be difficult to manage without assistance include climbing a full flight of stairs, bending, kneeling or stooping. Vigorous activities such as playing sports or walking several miles may be very difficult to complete.

- **52 – 65 Moving Around Indoors:**
  - Your score suggests that you may be able to move about on the ground floor of your home where you are familiar with the environment. Activities that might be difficult to manage without assistance include sitting and standing from a low chair, climbing stairs, bending, kneeling or stooping. You may have some difficulty moving about outdoors and in the community.

- **34 – 51 Limited Mobility Indoors:**
  - Your score suggests significant difficulty in moving about independently and the need for assistance. You may be able to move about in a small area of your home that has been adapted to eliminate safety hazards. You may have difficulty moving from a sitting to standing position, climbing stairs and you may have a great deal of difficulty moving about outdoors and in the community.

- **0 – 33 Limited Movement:**
  - Your score suggests you may have a lot of difficulty or are unable to get out of your bed, to stand for several minutes and/or to walk short distances. You might have some difficulty completing the most basic mobility tasks including repositioning yourself in bed.
Daily Activity Functional Stages

- **84 – 100 On Your Own:**
  - Your score suggests that you may not be having any difficulty completing the daily tasks of bathing, dressing, grooming and eating independently.

- **62 – 83 Getting Things Done:**
  - Your score suggests that you may require some assistance with housekeeping and laundry, but otherwise you may be able to complete daily tasks of bathing, dressing, grooming and eating independently without much difficulty.

- **53 – 61 Difficult Activities:**
  - Your score suggests some difficulty in the ability to perform daily tasks. You may be struggling with things such as bathing and dressing. Housekeeping tasks may be too difficult for you to perform. They may experience some difficulties with your fine motor skills such as buttoning clothes, using utensils and combing your hair.

- **41 – 52 Daily Tasks are a Struggle:**
  - Your score suggests that you may experience significant struggles with performing most daily tasks. You may have significant difficulties in getting dressed and bathed. Tasks that require fine motor skills such as buttoning a shirt or tying your shoes may be too difficult to complete.

- **0 – 40 No Independent Tasks:**
  - Your score suggests daily tasks that require fine motor skills may cause considerable difficulty to the extent that you may be unable to complete them. Bathing and dressing may be so difficult that you may be unable to complete these tasks without assistance. You may be able to feed and groom yourself but with difficulty. You may be unable to tie your shoes or button your shirt.
Applied Cognitive Functional Stages

- **Applied Cognitive 56 – 65 On Your Own:**
  - The score suggests that you may be able to complete complex tasks such as reading a newspaper, counting money, using a phone and having a conversation with another person without difficulty. You might be able to complete multi-step activities such as following a recipe or completing an insurance form without difficulty.

- **42 – 55 On the Move:**
  - The score suggests that you may be able to complete complex tasks such as reading a newspaper, counting money, using a phone and having a conversation with another person without difficulty. You might have some difficulty in completing multi-step activities such as following a recipe or completing an insurance form.

- **34 – 41 Minor Difficulties:**
  - The score suggests that you may have some difficulties that are noticed by people who know you well. Difficulties may arise in communicating with others, e.g. carrying on a conversation in a crowded restaurant. Reading and carrying out complicated tasks such as preparing a meal, looking up numbers or names in an address book, or managing a checkbook may also be a challenge.

- **29 – 33 Communication Limitations:**
  - The score suggests that difficulties may be apparent to all of those who interact with you. These difficulties may include a decline in expressive communication skills and reading. You may need assistance in carrying out the tasks that require memory and organization such as managing money, food shopping, food preparation and filling out a form.

- **0 – 28 Limited Applied Cognitive Skills:**
  - The score suggests you may have a lot of difficulty or are not able to complete tasks such as using a phone, reading printed material and having a conversation. You may not be able to communicate regarding topics that involve recent memory, attention or organized thought.
Site-Specific Research: Rationale

Accurate and Efficient Outcomes Assessment of Activity Limitations in All Persons with TBI Across All Post-Acute Settings

- There is a demonstrated clinical and research need, and a legislative mandate, to develop functional assessment tools capable of capturing the occurrence of and changes in functional limitations over time to accurately assess patient needs.

- Furthermore, gathering data on functional recovery across settings, between patients, and over time will contribute to the yet limited understanding of post-TBI functional recovery.

- AM-PAC certainly meets these standards and bridges most of the existing gaps.

- However, it has not been evaluated in individuals with TBI.
Objective
Evaluate the presence of and changes in activity limitations related to mobility, daily activities, and applied cognition over the course of rehabilitation for traumatic brain injury (TBI).
Site-Specific Research: Aims/Hypotheses

- **AIM 1.** Evaluate the sensitivity of AM-PAC to measure longitudinal changes in activity limitations in individuals with TBI receiving acute rehabilitation (ACR) and post-acute rehabilitation (PACR).

  Three distinct methods will be used to examine both mean grouped performance as well as individual variations in functional limitation change:

  1) group-based parametric measures will be used to analyze overall changes across the first year of recovery (**hypothesis 1a**) and in relation to post-acute treatment effects (**hypothesis 1b**);

  2) minimum detectable change statistic will be used in order to examine **clinically meaningful** variations in specific recovery trajectories; and

  3) functional change scores will be used to allow for description of **clinically meaningful** directional changes in functioning in a way that is **directly accessible to clinicians, patients, and other stakeholders**.

  **Hypothesis 1a (ACR sample):** AM-PAC will be sensitive to longitudinal changes in activity limitations across the three functional domains (basic mobility, daily activity, and applied cognitive) in individuals with TBI receiving acute specialized inpatient rehabilitation from admission to discharge, and at 6- and 12-months post injury.

  **Hypothesis 1b (PACR sample):** AM-PAC will be sensitive to treatment-related change in activity limitations among individuals with TBI receiving post-acute outpatient brain injury rehabilitation.
AIM 2. Examine the relationship between AM-PAC scales and traditional discipline/setting-specific measures of function (convergent and discriminant validity) in post-acute TBI settings.

- Hypothesis 2a (ACR sample): AM-PAC scale scores of patients receiving acute inpatient rehabilitation will be correlated with FIM scores at admission and discharge and with Participation Assessment with Recombined Tools-Objective (PART-O) at 1-year follow-up.

- Hypothesis 2b (PACR sample): AM-PAC scale scores of patients receiving post-acute outpatient rehabilitation will be correlated with traditional discipline-based functional measures.

- Hypothesis 2c (PACR sample): Pre-post differences in AM-PAC scale scores and traditional discipline-based functional measures of patients receiving post-acute outpatient rehabilitation will yield comparable effect sizes.
AIM 3. Evaluate agreement between patients and proxy respondents.

- **Hypothesis 3a (ACR sample):** There will be significant correlations between patient and proxy respondent AM-PAC ratings at inpatient brain injury discharge.

- **Hypothesis 3b (PACR sample):** There will be significant correlations between patients and proxy respondent AM-PAC ratings at outpatient brain injury rehabilitation admission and discharge.
Sample Population

- **The ACR sample** will be recruited from individuals with TBI receiving acute specialized in-patient rehabilitation in the JFK BTU. Our BTU admits at least 100 individuals with TBI annually, all of whom would potentially be eligible for this study. Assuming an enrollment period of 43 months for this study and an estimate of 2-3 participants enrolled each month, we expect to enroll approximately 100 participants into the ACR sample. With an overestimated 20% loss to follow-up, we expect to retain 80 participants at 1-year follow-up.

- **The PACR sample** will include patients with TBI enrolled in our specialized post-acute outpatient rehabilitation program at JFK-JRI. Our program enrolls an annual average of 130 TBI treatment patients who would be eligible for this study. Assuming an enrollment period of approximately 46 months, and a very conservative estimate of 1-2 participants enrolled each month, we anticipate enrolling approximately 70 participants into the PACR sample. With an overestimated 10% loss to treatment follow-up, we expect to retain 63 participants for post-treatment assessment.
Inclusion/Exclusion Criteria

Inclusion Criteria

Medical documentation of having sustained a TBI because of mechanical impact or acceleration/deceleration injury followed by a period of loss of consciousness or post traumatic amnesia or altered consciousness and changes in neurologic or cognitive functioning

At least 18 years of age

English-speaking

ACR Sample
Referred from an acute care hospital for acute inpatient rehabilitation at JFK-JRI
Provide consent either by patient or proxy

PACR Sample
Enrolled in outpatient brain injury rehabilitation at JRI Center for Brain Injuries
Able to provide informed consent
Adequate communication skills and ability to allow completion of interviews and testing

Exclusion Criteria

Current cognitive complaints or neurological dysfunction precede the TBI
Active psychiatric illness and/or substance abuse, which will be screened for at the time of enrollment via Cornell Psychiatric Screen
Assessment Measures

- **AM-PAC** will be the primary measure in this study for both samples. It is currently being utilized at JFK-JRI in a research study evaluating the effectiveness of a novel recovery program for individuals with stroke – a population in which its application is well-validated. Thus, this assessment tool is well-integrated in the JFK-JRI infrastructure.

- **Inpatient**
  - Functional Independence Measure (FIM) is a functional ability measure that assesses the severity of disability.
  - Participation Assessment with Recombined Tools-Objective (PART-O) is an outcome scale that measures participation in the community and is part of the TBI Model Systems form II follow-up assessment.

- **Outpatient**
  - Dynamic Gait Index (DGI) is a performance-based physical therapy measure of functional mobility. DGI will serve as an established performance-based measure of Basic Mobility.
  - Texas Functional Living Scale (TFLS) is a performance-based measure of functional competence with an emphasis on higher-level instrumental activities of daily living (IADLs) that are more susceptible to cognitive decline than basic activities of daily living. TFLS will serve as an established performance-based measure of Daily Activities.
  - Neuropsychological Assessment Battery: Daily Living scales (NAB) is a performance-based measure of functional cognitive skills intended to evaluate cognitive abilities in relation to real-life tasks. Each of the 5 domain-specific modules contains a specific test that involves real-world scenarios that are generalizable, targeted, and ecologically valid to demonstrate daily living skills in everyday situations. These NAB tasks will serve as an established performance-based measure of Applied Cognition.
  - Mayo-Portland Adaptability Inventory (MPAI-4) contains a rating of impaired self-awareness, which will be extracted for the purposes of secondary analysis in the proposed study. This MPAI-4 item has been shown to be equivalent to patient-family disagreement on a more extensive Awareness Questionnaire in monitoring and predicting outcomes after TBI\(^6\).
Experimental Design

**ACR Sample**

- **BTU Admit:**
  1. proxy AM-PAC
  2. FIM

- **BTU D/C:**
  1. proxy AM-PAC
  2. patient AM-PAC
  3. FIM

- **6-Month post-TBI:**
  1. patient AM-PAC

- **1-Year post-TBI:**
  1. patient AM-PAC
  2. PART-O

**PACR Sample**

- **Outpatient Admit:**
  1. patient AM-PAC
  2. proxy AM-PAC
  3. Traditional Functional Assessment

- **Outpatient D/C:**
  1. patient AM-PAC
  2. proxy-AM-PAC
  3. Traditional Functional Assessment
Data collected January – October 2016
Pre-post data complete on 88 patients with TBI
Protocol on BTU:
- Clinicians complete the AM-PAC for all patients
  - Basic Mobility – PT
  - Daily Activities – OT
  - Cognitive - ST
- This eliminates the concerns about communication deficits and any lack of deficit awareness.
BTU Mean Pre-Post Scores

AC AM-PAC Scores

- COGNITIVE**: Pre: 22.76, Post: 31.50
- DAILY ACTIVITY**: Pre: 32.34, Post: 43.54
- MOBILITY**: Pre: 33.13, Post: 45.94
### BTU Recovery Trajectories: MDC-based

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<th>%</th>
<th>Cognitive</th>
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Procedure

- AM-PAC E-CAT administered to patients on admission and discharge from specialized outpatient TBI rehabilitation program.
- Pre-post data complete on 19 patients with TBI
- Protocol on COG:
  - Patients complete the AM-PAC via interview by trained clinician.
Results: Mean Scores

PAC e-CAT AM-PAC

- **Cognitive**
  - Pre: 42.28
  - Post: 46.50

- **Daily Activity**
  - Pre: 51.05
  - Post: 61.11

- **Mobility**
  - Pre: 59.89
  - Post: 64.94
Recovery Trajectories: MDC-Based

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# Functional Stage-Based Change

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