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Brain Injury Rehabilitation Outcomes

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Brain Injury Rehabilitation Outcomes
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Brain Injury Rehabilitation Outcomes

Introduction

Brain injury is a serious public health problem in the United States with more than 3.3 million diagnosed injuries occurring per year\(^2,3\) at an annual cost to society in excess of $100 billion.\(^2,4\) Brain injury is a leading cause of death and disability in children and young adults, but people of all ages, races, genders, socioeconomic backgrounds, and educational levels are at risk for injury. An estimated 9 million Americans live with a disability due to brain injury.\(^5,6\)

Outcomes research on brain injury rehabilitation is a complex undertaking. The injury is characterized by substantial heterogeneity in etiology, severity, chronicity, and disease progression. There are vast differences in the demographics of individuals who are injured and in their access to care. There are also important distinctions in treatment settings, provider expertise, intervention types and intensities, and measurement tools. Alone or in combination, each of these variables can significantly impact the outcome of brain injury rehabilitation.\(^7\)

The Brain Injury Association of America published this position paper to provide insight into the manner by which existing outcomes research should be evaluated and to urge the utmost care be taken in the design, interpretation, and reporting of future studies of brain injury rehabilitation.

Disease Specification

An acquired brain injury is an injury occurring after birth that temporarily or permanently alters the physical integrity, metabolic process, or functional ability of brain cells. Changes to the brain’s structure and/or function might be identified using neuroradiologic techniques, such as computed tomography (CT), magnetic resonance imaging (MRI), diffusion tensor imaging (DTI) or by laboratory tests including blood or cerebral spinal fluid biomarkers. Brain injury is characterized by a change in mental status at the time of injury or in the hours, days, or weeks after injury. The change may manifest as a decreased level of consciousness for any period of time, as memory loss for events immediately before or after the injury, or in any number of neurological signs identified by clinical examination.

The above notwithstanding, “brain injury” is not a diagnosis in and of itself. Indeed, early outcomes research in brain injury rehabilitation was criticized for lacking a clear definition of the population under study and the inclusion of subjects with various brain injury etiologies within a single study.\(^8-10\) Since disease specification in the field is incomplete at this time, outcomes researchers must stratify and describe the population being studied with as much precision as possible.
Injury Mechanism

Etiology is the first such stratification. Brain injuries can be caused by trauma, vascular conditions, infections, metabolic disorders, tumors, toxic exposure, electrocution, blast exposure, and oxygen deprivation. These various injury etiologies result in different clinical presentations, treatment requirements, and recovery trajectories. All brain injury outcomes research should specify the population being studied based on the mechanism of injury and the subtype, if known.

Mechanisms of Injury

A. Traumatic Brain Injury
   - Focal
   - Multifocal
   - Penetrating
   - Diffuse
   - Specific anatomical structure

B. Infectious
   - Bacterial
   - Viral
   - Fungal
   - Prion
   - Parasitic

C. Stroke
   - Hemorrhagic
   - Ischemic
   - Aneurysmal

D. Autoimmune
   - Disease

E. Metabolic Encephalopathy
   - Septic
   - Hepatic
   - Uremic

F. Anoxia
   - Hypoxic/ischemic

G. Blast Exposure

I. Toxic Encephalopathy
   - Substance
   - Carbon Monoxide
   - Other Chemical

J. Electrocution

Injury Severity

Researchers should also report the severity of injury sustained by study subjects. The factors used to classify injury severity differ according to etiology. For example, anoxic brain injuries vary in severity by the duration and degree of oxygen deprivation, while the severity of an injury of toxic origin depends on the type of toxin and its potency.

The severity of a traumatic brain injury (TBI) – the largest subset of all brain injuries – is often characterized as mild, moderate, or severe based on a number of objective measures, including the duration of altered consciousness, duration of post-traumatic amnesia (i.e., memory loss for events immediately after injury and ability to consolidate short-term memory during PTA), and the Glasgow Coma Scale. Efforts are underway to identify better methodologies for classifying injuries.
### Factors Used to Classify Severity of Injury

<table>
<thead>
<tr>
<th>Factor</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structural Neuroimaging</td>
<td>Normal</td>
<td>Normal or abnormal</td>
<td>Normal or abnormal</td>
</tr>
<tr>
<td>Loss of Consciousness</td>
<td>0 – 30 min</td>
<td>30 min – 24 hrs</td>
<td>&gt; 24 hrs</td>
</tr>
<tr>
<td>Alteration of Consciousness</td>
<td>A moment – 24 hrs</td>
<td>&gt; 24 hrs</td>
<td>&gt; 24 hrs</td>
</tr>
<tr>
<td>Post-Traumatic Amnesia</td>
<td>0 – 1 day</td>
<td>1 – 7 days</td>
<td>&gt; 7 days</td>
</tr>
<tr>
<td>Glasgow Coma Score</td>
<td>13 – 15</td>
<td>9 – 12</td>
<td>3 – 8</td>
</tr>
</tbody>
</table>

Department of Defense & Department of Veterans Affairs Traumatic Brain Injury Task Force (Table A1, p. 17).(12)

Injury severity can influence recovery and, therefore, rehabilitation outcomes, although not in a linear fashion. That is, a severe injury does not necessarily predict a poor rehabilitation outcome nor does a mild injury always predict a favorable outcome.(13) TBI outcome model path analysis suggests injury severity influences outcome one year post injury indirectly by influencing cognitive status and functional status.(14)

### Injury Location

The location of injury within the brain influences the type and amount of treatment required. For example, an individual who sustains a hemorrhagic stroke in the cerebellum may require physical rehabilitation to overcome difficulties with balance or coordination. Similarly, an individual who sustains a diffuse frontal lobe injury may require extensive cognitive rehabilitation and may experience considerable residual disability after treatment. Recent advances in technology have also revealed injury due to shearing of the brain’s long connecting nerve fibers (often referred to as diffuse axonal injury (DAI)). To the extent possible, outcomes researchers should report the composition of samples as precisely as possible in the study findings.
Disease Causation & Acceleration

The neurologic damage associated with brain injury is not static. Any injury, regardless of etiology, severity, or location, can negatively impact musculoskeletal, genitourinary, gastrointestinal, circulatory, pulmonary, cardiac, endocrine, immune, and sensory functions. For a significant subset of persons with brain injury, the brain injury is often disease causative and disease accelerative.(15) In fact, evidence exists for progressive neurodegeneration after brain injury.(16-18) Processes associated with aging and progression of other-system diseases further complicate neurodegenerative progression. For many individuals, brain injury becomes a chronic condition.(19)

Heterogeneity of Population

Individuals with brain injuries are an extremely heterogeneous group and, consequently, a broad range of rehabilitation outcomes are possible. As discussed more fully below, the variables known to influence outcomes include: age, gender, genome,(20, 21) intelligence, impairment profile, time since injury (chronicity), injury characteristics, medical co-morbidities, psychiatric history, substance abuse history, socioeconomic status, vocational status, and family support.

Predictive relationships have been demonstrated between demographic variables (e.g., age, gender, level of education/intelligence, and employment history) and certain injury characteristics (e.g., injury severity, injury etiology, location of injury, and secondary complications from injury, such as increased intracranial pressure), with regard to outcome.(22-29) Psychosocial factors, such as marital status, social support, and family involvement, have all been shown to impact outcome and employment following brain injury.(30)

Substance use and misuse (i.e., alcohol, drugs, and prescription medications) are risk factors for sustaining a brain injury and influence recovery. Individuals who sustain a brain injury while under the influence of alcohol and/or drugs tend to have more severe injuries and more medical complications during acute medical management (e.g., infections, respiratory problems), leading to poorer outcomes. A substantial percentage of individuals with alcohol abuse/dependence tend to return to pre-injury drinking patterns within 1-2 years after injury, which negatively impacts rehabilitation outcomes.(31)

Socioeconomic status (SES) can impact outcome from brain injury. Individuals from a lower SES tend to have less access to healthcare, shorter lengths of stay in acute rehabilitation, are discharged home more often following acute care, and have less access to post-acute rehabilitation.(32, 33) Insufficient access to care and shorter lengths of stay have been associated with less than favorable outcomes following brain injury.(34) These
factors affect the course of treatment and must be clearly defined and controlled when conducting research and characterizing treatment outcomes.(35)

Treatment Settings

Brain injury causes neuroanatomical and neurophysiological changes that often require differing levels of medical management and rehabilitation treatment. A specialized continuum of care began to emerge in the 1970s to meet the unique and complex treatment demands associated with brain injury. This continuum evolved to include acute services, post-acute rehabilitation, and community-based services.

Not all patients require treatment in each component of the continuum, but the varied nature of the injury and individual response to treatment require a broad range of treatment options. Progression across the continuum is not linear. In fact, some patients may move from a lower acuity setting back to a higher acuity setting depending on medical complications.

Access to the various components of the continuum is influenced by several factors, including individual needs, medical professional and family awareness of the setting of care, referral patterns and biases, bed availability, geographic proximity, family or patient treatment choice, and sufficient insurance or financial resources. Any one of these factors can delay the delivery of care or preclude the delivery of services altogether, thereby negatively impacting the trajectory and extent of recovery and, ultimately, the long-term outcome from brain injury.
Although an effective array of treatment settings has emerged, practice at each level of care has yet to be standardized. Indeed, another criticism of early outcomes research was the variability in treatment plans and programming at each level in the continuum of care. Recognizing that rehabilitation plans are, of necessity, highly individualized, a description of settings and plans is useful in replicating efficacious interventions in clinical practice and future research.

Rehabilitation Plans/Programs

The Brain Injury Association of America (BIAA), the nation's largest non-profit organization dedicated to the brain, asserts rehabilitation is the single most effective treatment to mitigate disease progress while maximizing health and functional outcome and increasing independence and community participation after brain injury. The National Association of Insurance Commissioners defines rehabilitation as:

“Health care services that help a person keep, get back, or improve skills and functioning for daily living that have been lost or impaired because a person was sick, hurt or disabled. These services include physical and occupational therapy, speech-language pathology and psychiatric rehabilitation services in a variety of inpatient and/or outpatient settings.” (37)

Unlike cardiac or orthopedic rehabilitation, the nature of brain injury is such that psychological, cognitive and communicative, physical, and neurobehavioral deficits must be addressed simultaneously and sequentially, creating the need for dynamic treatment plans that allow for the coordination and participation of multiple medical and allied health disciplines. The complexity of treatment plans in combination with the heterogeneity of the patient population and the injury result in a broad range of rehabilitation outcomes.

**Timing**

Brain injury outcomes are better if individuals have access to rehabilitation in acute care or within the first year of injury. (38) Similarly, individuals who are admitted to post-acute rehabilitation less than one year after injury demonstrate more significant improvements than those admitted one year or more after injury, and they experience greater lifetime cost savings. (39-41) Individuals who access post-acute rehabilitation within the first six
months after injury have an increased rate of recovery, reduced supervision needs, and reduced costs compared to those who enter post-acute rehabilitation more than six months after injury.\(39, 41, 42\)

Although earlier access to post-acute rehabilitation is associated with greater gains and overall cost reduction, later rehabilitation also results in significant functional treatment gains and reduced costs, even many years after injury\(39, 42-50\) or for those patients who have an overlay of psychiatric or behavioral issues.\(43, 46, 51\)

A determination of effectiveness of treatment must consider confounding factors such as time since injury (chronicity) and potential contribution to rate of recovery by spontaneous recovery. Evidence is found for faster recovery rates in those closer to the date of injury.\(41\) However, individuals further from injury (6-18 months and greater than 18 months) also show statistically significant improvement though requiring more time and money per unit of improvement.\(52-54\) Thus, characterization of timing as a confounding variable in outcome assessment is required.

**Intensity**

Treatment intensity is continuously re-evaluated based on individual characteristics, time since injury, response to treatment, stage of adjustment, and targeted goals. Consequently, characterization of varying treatment intensity as a confounding variable to outcome assessment is also required.

Higher treatment intensity in the acute rehabilitation phase leads to a reduction in hospital length of stay\(55-59\) but may not necessarily positively influence treatment outcome, which may be more influenced by the provision of the correct therapy at the right time.\(60\) Higher treatment intensity in the post-acute rehabilitation phase is also considered beneficial, although evidence is limited by the variability in post-acute settings, program types, time since injury (several weeks to several years), and, among other factors, constraints placed on service providers by funding sources.

**Duration**

Duration of treatment in the post-acute rehabilitation setting is also highly variable and depends on a variety of factors, including program type, injury characteristics, individual response to treatment, family variables, financial resources, and geographic considerations. Lengths of stay in acute and post-acute rehabilitation have steadily decreased over the past 20 years without regard to level of disability at discharge.\(61, 62\) Recent research cast doubt on the relationship between treatment duration and outcome within the acute rehabilitation level of care.\(60\) However, funder requirements and uncertainty about the precise relationship between treatment and outcome at various points along the rehabilitation journey make treatment duration a particularly important variable to consider when conducting or evaluating brain injury rehabilitation outcomes research.
**Treatment Expertise**

Variability across rehabilitation programs with regard to level of expertise of service providers, team composition and orientation, clinical model, use of evidence-based interventions, and inclusion of adjunctive interventions has been demonstrated. Consensus from clinical observation is that treatment delivered by providers with a high level of brain injury expertise is likely to produce more efficient and superior outcomes than programs delivered by non-experts. This consensus is reflected in the post-acute outcomes literature for individuals who are treated in a specialty unit versus those in a general medical or nursing home setting.(63-67) Credentials such as Brain injury Medicine (BIM) certification through the American Board of Physical Medicine and Rehabilitation (ABPMR) and Certified Brain Injury Specialist (CBIS) through the Brain Injury Association of America (BIAA) help distinguish expertise in the field.

**Treatment Approach**

Treatment approaches differ with regard to the inclusion of interventions to address comorbidities as well as social and environmental factors that are relevant to community reintegration goals. Adjunctive therapies, such as family interventions,(68) alcohol and substance abuse treatment,(69) and vocational services/resource facilitation,(70-73) have been found to improve community integration outcomes in the post-acute setting. Single discipline intervention has been shown to be less effective than multidisciplinary approaches,(74, 75) and transdisciplinary approaches may be more effective than single discipline or multidisciplinary approach.(76-79) Researchers should define and describe interventions and factors that interfere with intervention application to facilitate replication and refinement of efficacious interventions in clinical practice and future research.

**Measurement Tools**

In acute brain injury, survival and proper functioning of organs or organ systems are the primary outcome measures. As patients recover, functioning in multiple domains is assessed and aggregated into general functional status assessments using tools such as the Functional Independence Measure (FIM)(80) and the Mayo-Portland Adaptability Inventory.(81) These outcomes measures are necessarily broad and may be less sensitive to change and, thus, more applicable to assessing progress over longer treatment intervals (weeks to months). Other scales provide enhanced specificity within particular domains. In the physical domain, for example, outcome assessments are available for gait, balance, strength, range of motion and other physical factors. Such outcomes measures have a higher probability of documenting change given their increased specificity and may be more applicable to assessing changes occurring over shorter treatment intervals (days to
weeks). Readers interested in a comprehensive assessment of outcome measures are encouraged to read Wilde et al. (2010) Recommendations for the use of common outcome measures in traumatic brain injury research. (82)

Measurement of treatment outcomes in post-acute brain injury rehabilitation is particularly challenging due to the variety and severity of impairments remaining after hospitalization and the post-acute focus on overall functioning of the individual in activities of daily living in real world settings. (83) Such outcomes can be defined in many domains, including independent living, psychosocial adjustment, employment, and behavioral stability.

In the 1998 NIH Consensus Development Conference on the Rehabilitation of Persons with Traumatic Brain Injury, functional outcome measurement was seen as useful in gauging the effectiveness of post-acute rehabilitation, and a number of measures demonstrating good reliability and validity were identified, including the Functional Independence Measure, Mayo-Portland Adaptability Inventory, Supervision Rating Scale, and Neurobehavioral Functioning Inventory. These and other tools are available from the Center for Outcome Measurement in Brain Injury (COMBI), a collaborative project of the Traumatic Brain Injury Model Systems of Care, which is funded by the National Institute on Disability, Independent Living, and Rehabilitation Research. (See http://www.tbims.org/combi).

Accurate measurement of all constructs associated with rehabilitation outcomes may not be possible with a single measure; therefore, to fully appreciate the range of possible outcomes, a multifaceted approach is indicated. The Interagency Traumatic Brain Injury (TBI) Outcomes workgroup recommended the use of multiple measures in TBI outcomes research. A similar argument can be made for the use of a multifaceted approach to assess outcomes during and after post-hospital rehabilitation. To this end, the Interagency TBI Outcomes workgroup has recommended the use of outcome measures with sound psychometric properties that demonstrate utility with the brain injury population. (82) At a minimum, measures selected should assess global level of function, neuropsychological impairment, psychological status, activity limitations and participation restrictions, and perceived health-related quality of life. Most rehabilitation programs employ multiple measures to assess function in several domains as part of a comprehensive outcomes or program evaluation system.

Research Challenges

Study Design

There are more than 16,000 articles showing the benefits of brain injury rehabilitation. However, a frequent limitation cited with outcomes research in brain injury rehabilitation
is the lack of a true control group (i.e., studies did not meet the criteria of a randomized control trial). The lack of a control group does not constitute a lack of evidence. Payers have used this limitation to restrict access or deny coverage for post-acute rehabilitation, stating that interventions used are “experimental” or “educational” in nature. The same rationale had been used to deny access and funding for cognitive rehabilitation interventions. However, well controlled trials demonstrated the effectiveness of specific cognitive interventions for the remediation of visuo-spatial deficits, memory impairments, and attentional deficits, to list a few. (84-88)

Failing to treat individuals with brain injury for the purposes of satisfying experimental rigor is difficult to justify ethically. Despite this challenge, a number of well-designed studies have appeared in the literature. Many studies meet criteria as prospective, randomized controlled trials. Others are well-designed cohort studies, retrospective case control studies, or clinical series with well-designed controls that have provided a wealth of information about the effectiveness of brain injury rehabilitation.

**Evidence-Based Medicine**

There is confusion about the purpose and use of evidence-based medicine (EBM) within the field of brain injury. EBM is a mechanism to provide thoughtful review of a multitude of medical interventions in an attempt to deduce those that are most effective and most cost efficient. (89) EBM uses all levels of research to consider the efficacy of interventions. The intent is to assess the evidence on a specific treatment relative to the risks and benefits of that treatment, including no treatment. One challenge for using an EBM approach is when there is debate about what constitutes a desirable outcome, which can often be the case when trying to incorporate quality of life measures.

Ideally, EBM encourages medical practitioners to make use of the body of scientific evidence to inform their daily practice. Until such scientific evidence exists, professional consensus often constitutes the best available evidence. EBM is not intended to discount the need of the practitioner to treat conditions for which best practices have yet to be defined, either due to a lack of undertaking or a lack of evidence upon which to base such judgments. The intent of EBM is not to provide a rationale for denying access to treatment when a suitable body of evidence is not available from which to derive EBM conclusions. (89)

**Value-Based Outcome Management in Brain Injury**

Since *Redefining Health Care* was published in 2006, (90) the concept of value in healthcare – improved health outcomes for the money spent – has risen to the level of accepted norm. The approach requires consideration of what is valuable to the patient and development of a care delivery and measurement system to achieve those outcomes. The benefit of this
approach is obvious and, for some disease processes, the implementation of such systems has been a tremendous success. Efforts are underway to create a value-based model of care for brain injury. However, these models will be feasible when there is sufficient disease specification, concomitant outcome measures, and when access to brain injury rehabilitation across the continuum of care is universal.

Conclusion

Permanent disability and the commensurate need for post-hospital services due to brain injury remain poorly understood and inadequately funded. A central intent of this white paper has been to describe the current state of outcomes research in the field of brain injury and to identify the factors to consider when evaluating existing studies and embarking on future outcomes research. This paper also highlights opportunities for improving outcomes research for brain injury interventions. With respect to readiness for value-based care models and a value-based outcome measurement system,(91) the complexity and variability presented by diagnoses of brain injury necessitate great caution in consideration of utilizing such approaches.

Justifiably so, the current healthcare market expects service providers to document success in a manner that allows the purchaser of care to critically assess the value of their purchase. The nature by which the continuum of care evolved does not yet consistently allow for this critical analysis of value. Further, determination of to whom value must be provided is important. The perception of value, defined as the difference between the perceived benefit of the service or product and its cost, will be different for the person with the brain injury, their family, the financially responsible party, or a case manager. The brain injury rehabilitation field must commit to meeting these varied expectations, recognizing that doing so will result in the improvement of services for persons with brain injury.

Improved research design, an evidence-based approach to providing care, and the standardization of measurement tools across the continuum will help move brain injury rehabilitation outcome measurement in a positive direction.
References