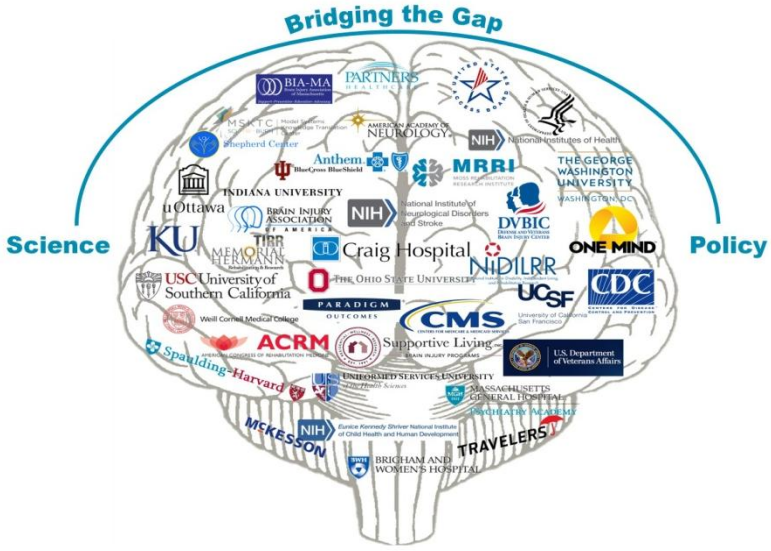
Spaulding-Harvard
Traumatic Brain Injury Model System



Rehabilitation Access and Outcome after Severe Traumatic Brain Injury

A TBI Model System-Sponsored Stakeholder Summit

United States Access Board
Washington, D.C.

May 16-17, 2016

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Preface

Traumatic brain injury (TBI) is a major public health problem in the United States. The impact of TBI is far-reaching and its disruptive effects escalate as severity increases. Persons who experience severe TBI are at the highest risk for chronic or permanent disability. In most cases, multiple systems are affected, disrupting physical, cognitive and psychosocial functions. Long-term follow-up studies are beginning to make clear that severe TBI should be viewed as a chronic condition associated with late complications, including neurodegenerative changes. Despite the enormity of this problem, access to healthcare services and other needed resources for persons with severe TBI have progressively declined. Authorization for admission to inpatient brain injury programs has become increasingly more difficult, rehabilitation lengths of stay have declined and insurance benefits for community-based services are often inadequate or unsupported. Under these circumstances, the burden of care often falls to the family, resulting in severe emotional, psychological and financial distress. These changes have also had adversely impacted TBI research efforts, in large part because fewer patients are receiving care in academic medical settings equipped to carry out complicated studies.

In view of these concerns, the Spaulding-Harvard Traumatic Brain Injury Model System, in concert with members of special interest groups sponsored by the American Congress of Rehabilitation Medicine, National Institute on Disability and Rehabilitation Research and Veterans Administration, banded together to launch a series of organized activities intended to promote public awareness and mobilize resources aimed at developing healthcare policies at the national level that will enable greater access to healthcare services for persons with severe TBI. Toward this end, we have convened a TBI Model System-Sponsored Stakeholder Summit entitled, "Rehabilitation Access and Outcome After Severe TBI," which will be held at the United States Access Board in Washington, DC on May 16-17th, 2016. The primary objectives of the summit are to identify the critical factors impeding access to healthcare services for persons with severe TBI across the lifespan, develop a strategic plan that delineates the actions required to enact evidence-informed policy guiding service authorization and establish strategic partnerships to facilitate full implementation of the aims of this initiative.

This briefing book is designed to acquaint summit participants with the clinical needs of persons with severe TBI, outline the critical gaps that exist between evidence, clinical practice and policy and offer preliminary recommendations to enable improved access to healthcare. The information contained herein was compiled by the Spaulding-Harvard TBI Model System and has not been formally approved by the summit participants. The briefing book is not intended for broader distribution as we intend to update it following completion of the summit.

We welcome input from all of the invited stakeholders and look forward to partnering on further iterations of this document.

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For further information on the Spaulding-Harvard Traumatic Brain Injury Model System, please visit: www.sh-tbi.org.

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List of Abbreviations

AHA	American Hospital Association
ARC	Acute inpatient rehabilitation center
BIAA	Brain Injury Association of America
CCM	Chronic care model
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
CORE	Center of research excellence
DBS	Deep brain stimulation
DHHS	Department of Health and Human Services
DOC	Disorders of consciousness
ED	Emergency Department
FIM	Functional independence measure
GCS	Glasgow Coma Scale
HHA	Home health agency
HMO	Health maintenance organization
ICU	Intensive Care Unit
IOM	Institute of Medicine
IRF	Inpatient rehabilitation facility
LOS	Length of stay
LTAC	Long-term acute care
MCS	Minimally conscious state
NIDILRR	National Institute on Disability, Independent Living and Rehabilitation Research
OT	Occupational therapy
PPO	Preferred provider organization
PPS	Prospective payment system
PT	Physical therapy
SLT	Speech and language therapy
SNF	Skilled nursing facility
TBI	Traumatic brain injury
TBIMS	Traumatic brain injury Model Systems Program
TBIMS-NDB	Traumatic brain injury Model Systems – National database
TRACK-TBI	Transforming Research and Clinical Knowledge in Traumatic Brain Injury
VA	Department of Veterans Affairs
VS	Vegetative state

Spaulding-Harvard
Traumatic Brain Injury Model System

Rehabilitation Access and Outcome After Severe Traumatic Brain Injury: A TBI Model System-Sponsored Stakeholder Summit

Date: May 16-17, 2016

Location: United States Access Board, 1331 F Street NW, Suite 1000, Washington, D.C

Background: Access to acute inpatient rehabilitation for persons with severe TBI has progressively declined over the last 10 years in the face of growing scientific evidence that the prospects for meaningful recovery are more favorable than previously known.

Purpose: To summarize current scientific evidence, identify more cost-effective healthcare service delivery models and develop strategies to improve outcomes in persons with severe TBI.

Participants: Pre-eminent researchers, thought leaders, service providers, funding agency program directors, insurance industry representatives, and healthcare policy experts engaged in clinical and research activities focusing on persons with severe TBI.

Objectives: 1) Identify the critical factors perceived as necessary by diverse stakeholder groups to construct evidence-informed policies aimed at shepherding access and exposure to brain injury rehabilitation services.
2) Create a strategic plan that delineates the actions required to enact policies enabling more effective authorization and delivery of inpatient rehabilitation services.

Impact: A well-defined action plan crafted by key TBI stakeholders will promote more equitable access to healthcare, reduce TBI-related disability and minimize the social and financial burden of long-term care.

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Rehabilitation Access and Outcome After Severe TBI: A TBI Model System-Sponsored Stakeholder Summit

Executive Summary

Introduction to Traumatic Brain Injury

Traumatic brain injury (TBI) is caused by an external force from direct impact to the head, rapid acceleration or deceleration, a penetrating object, or exposure to blast waves from an explosion (Marr and Coronado, 2004; Maas, et al., 2008) that disrupts the normal function of the brain (CDC, 2015). In 2010, TBI accounted for approximately 2.5 million emergency department (ED) visits, hospitalizations, and deaths (CDC, 2015). Approximately 32 to 40% of these were classified as severe TBI (Cuthbert, et al., 2015; TBIMS, 2015; Udekwu, et al., 2004). The effects of severe TBI can have devastating long-term effects for patients and their families, and for the community and the U.S. economy. In 2010, the total economic costs of TBI were estimated at $76.5 billion, with the indirect costs of disability, lost wages, and lost productivity ($64.8 billion) far outweighing the direct, medical costs ($11.5 billion) (Coronado, et al., 2012; Finkelstein, et al., 2006). Approximately 90% of the medical costs were attributed to fatal injuries or those requiring hospitalization and therefore likely to be severe (Coronado, et al., 2012; Finkelstein, et al., 2006). The CDC estimates that 3.2 million-5.3 million individuals in the US are living with TBI-related disabilities (Selassie, et al., 2008; Thurman et al. 1999; Zaloshnja et al. 200).

Clinical needs

The clinical needs of persons with severe TBI vary according to the severity of the injury and the widespread and heterogeneous effects of the injury across all body systems and symptom domains, including cognitive, neurobehavioral, psychological, physical and social (Mansour and Lajiness-O-Neill, 2015). A longstanding clinical belief is that global outcome does not improve nor deteriorate beyond two years post severe TBI, but multiple studies point to the chronic effects of severe TBI on a person's health and societal participation long after acute medical treatment and rehabilitation have ceased (Corrigan, et al., 2014; Masel and DeWitt, 2010). For most persons, a severe TBI is not a discrete event that can be treated and cured within a matter of months, but the beginning of a life-long disability with implications for the person and the person's family (CDC, 2015; Langlois, et al., 2006). An additional burden is the development of multiple medical complications (e.g. urinary tract infection, pneumonia, agitation and aggression) and comorbidities (e.g. epilepsy, Alzheimer's disease, Parkinson's disease, major depression, incontinence) that can emerge at the time of injury (Whyte, et al., 2013b) or in the years following the TBI (Institute of Medicine, 2008). These changes across multiple timelines, multiple health domains, and multiple body systems differentiates severe TBI from other diseases for which persons are more likely to receive long-term medical care, such as cancer and heart disease.

Gaps and disparities in healthcare management after severe TBI

It is now well established that severe TBI is not a discrete event, but the onset of a chronic condition (Corrigan and Hammond, 2014; Masel and DeWitt, 2010). Yet, despite this evolving knowledge of the diverse chronic care needs of individuals with severe TBI and the existence of a TBI system of care, the

current structure of the U.S. healthcare system, including its delivery mechanisms and payment policies, does not support the optimal execution and widespread implementation of a patient-need-centered TBI system of care (Cope, et al., 2005; Goka and Arakaki, 1995; Horn and Lewis, 2014). Also, it broadly assumes that the trajectory of recovery for each patient is linear, unidirectional and steady, such that each patient will assume a course of recovery from acute to post-acute to community in a predictable fashion with no need for 'upstream' services or further rehabilitation once discharged from the system (Weinrich, et al., 2005).

Access and IRF

In the current TBI system of care, access to inpatient rehabilitation is of particular importance. Inpatient rehabilitation is a core feature of the current system, offering a distinct level of specialized, multidisciplinary and intensive care that is consistent with the complex needs of persons with severe TBI, but generally does not exist in other post-acute care settings. Equally, access to inpatient rehabilitation facilitates access to community-based services (Turner-Stokes, et al., 2005; Turner-Stokes, et al., 2015), serving as a "gateway" to long-term care. However, it has been estimated that less than 15% of persons age 16 and older discharged alive from acute care with moderate to severe TBI receive any inpatient rehabilitation services (Corrigan, et al., 2013).

Access, private insurance and medical bankruptcy

The most frequently cited barrier to access to post-acute services is financial (Ottenbacher and Graham, 2007). While having insurance is necessary (Asemota, et al., 2013; Jaffe and Jimenez, 2015), it does not guarantee adequate access and coverage, particularly for those with unpredictable, long-term care needs, such as those with severe TBI. For those who are discharged to inpatient rehabilitation and/or other post-acute services, the extent to which their care is covered along the TBI system of care depends on various insurance-specific factors, such as the terms of the coverage, lifetime limits, copayments, deductibles and associated network or provider restrictions (BCBSTx, 2016). In an independent ongoing survey conducted by the Brain Injury Association of America (BIAA), almost 65% of the respondents (N=185) reported that their insurance failed to cover all of their brain-injury related services (unpublished data), the main reason for which was that the services were not covered under the respondents' health plan (64%). Consequently, medical bankruptcy is a harsh reality due to the astronomical costs of care and the high risk of unemployment after one year (Doctor, et al., 2005; Relyea-Chew, et al., 2009).

Access and Medicare

As the largest payer of post-acute rehabilitation care in the U.S. (Zorowitz, 2009), Medicare governs many of the organizational policies imposed by inpatient rehabilitation facilities (IRFs) (Granger, et al., 2009; Weinrich, et al., 2005) and inevitably influences the eligibility criteria for admission to the IRF and the reimbursement practices of private insurers, who often adopt Medicare's policies (Chan, 2007). Consequently, since the implementation of Medicare's Prospective Payment System for Inpatient Rehabilitation Facilities (PPS-IRF) in 2002, there has been a significant drop in the percentage of patients with TBI being admitted to inpatient rehabilitation across all insurance types (Hoffman, et al., 2012). Misapplication or misinterpretation of "rules of thumb", leading to increased claims denials by Medicare

fiscal intermediaries, has been suggested as a possible cause of the limited access to inpatient rehabilitation (Connelly and Thomas, 2007; UBC and AHA, 2007).

Epidemiology and surveillance

Despite the astronomical costs of TBI, an accurate estimation of the true incidence, prevalence, costs of care and long-term functional outcomes of severe TBI is lacking. The only nationally representative estimates of TBI-related disability are based on extrapolations of one-time state-level estimates of lifetime TBI-related disability (Selassie, et al., 2008; Zaoshnja, et al., 2008). While data sources are available, the absence of an effective surveillance system prohibits the determination of a true national estimate of prevalence of severe TBI and its associated disability; the examination of variation in TBI-related disability by important sub-groups (e.g. race and ethnicity, geographical location, complications, co-morbidities, service usage); the surveillance of yearly trends; and the identification of the resources being used to care for these persons (CDC, 2015).

Proposed Strategic initiatives

A first step toward improved access to healthcare across the lifespan for persons with severe TBI is the crafting of a strategic plan. We propose a focus on the following five areas of need:

Surveillance:

1. Action Needed: Develop and administer a surveillance system that tracks the incidence, prevalence, cost, and burden of severe TBI across settings from acute care through community reentry. Current efforts only count new cases of TBI, underestimating the total size of the population receiving care.

***Confirmation of Medical Necessity of Service*:**

2. Action Needed: Post-acute service authorization guidelines that require "active participation" in rehabilitation therapy services for at least 15 hours of therapy per week (i.e. "3-hour rule") to establish medical necessity for admission to an inpatient rehabilitation program (see InterQual criteria, sections 110.2.2* and 110.2.3) should not be applied to persons with severe TBI. Authorization guidelines should state that medical necessity for inpatient rehabilitation is demonstrated by the unique need for, a) specialized daily medical management and neurologic monitoring to restore physical and cognitive health and to prevent complications, b) specialized assessment procedures required for differential diagnosis, prognostication and determination of treatment needs, c) specialized behavioral and pharmacologic interventions to promote recovery of consciousness, orientation and basic self-care activities and d) caregiver education and training.

   **The patient must reasonably be expected to actively participate in, and benefit significantly from, the intensive rehabilitation therapy program that is defined in section 110.2.2 at the time of admission to the IRF. The patient can only be expected to benefit significantly from the intensive rehabilitation therapy program if the patient's condition and functional status are such that the patient can reasonably be expected to make measurable improvement (that will be of practical value to improve the patient's functional capacity or adaptation to impairments) as a result of the*

rehabilitation treatment, as defined in section 110.3, and if such improvement can be expected to be made within a prescribed period of time. The patient need not be expected to achieve complete independence in the domain of self-care nor be expected to return to his or her prior level of functioning in order to meet this standard.

3. Action Needed: For-profit entities (e.g. McKesson InterQual Criteria, Milliman Care Guidelines) that develop, disseminate and/or utilize clinical criteria for authorization of inpatient rehabilitation services should be required to release the scientific evidence upon which the current guidance is based.

***Development and Systematic Implementation of Disability Severity Metrics*:**

4. Action Needed: Standardized assessment measures that gauge severity of disability should be developed to ensure access to appropriate care for those at each juncture in the health trajectory (i.e. acute care, acute rehabilitation, sub-acute rehabilitation, post-acute rehabilitation, long-term care).

Rehabilitation Needs Assessment and Management:

5. Action Needed: Personal injury insurance policies should include a provision that requires persons with severe TBI admitted to a Level I Trauma Center, ICU or acute care hospital to undergo evaluation by a pre-designated TBI specialist for admission to an inpatient rehabilitation setting, unless contraindicated by a co-morbid medical condition or surrogate preference. Such a provision should also entitle persons not recommended for inpatient rehabilitation services at the time of discharge from the acute care setting to receive an independent medical review prior to discharge.

6. Action Needed: A case management system should be put in place for persons with persistent severe disability to ensure appropriate management of long-term needs, facilitate communication across providers, and provide an informed point-of-contact through all phases of recovery.

7. Action Needed: Persons with severe TBI should receive authorization to undergo reevaluation with a brain injury specialist upon the order of a treating physician, when there is documented evidence of a decline or improvement in functional status that may require modification of the existing level of care.

Ensuring Adequate Insurance Benefits for Catastrophic Injury:

8. Action Needed: Healthcare insurance plans should provide policy benefits that ensure adequate coverage for catastrophic injuries. Such policies should not contain fixed caps on the amount or duration of rehabilitation services, but instead should be based on individual assessment and determination of medical, rehabilitation and other healthcare needs.

Rehabilitation Access and Outcome After Severe TBI:
A TBI Model System-Sponsored Stakeholder Summit

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I. Introduction to TBI and the United States healthcare system

Traumatic brain injury

Definition and classification systems

Traumatic brain injury (TBI) is caused by an external force from direct impact to the head, rapid acceleration or deceleration, a penetrating object, or exposure to blast waves from an explosion (Maas, et al., 2008; Marr and Coronado, 2004) that disrupts the normal function of the brain (CDC, 2015). The nature, intensity, direction, and duration of these forces determine the pattern and extent of damage. Typical features of TBI include focal contusions, extracranial and intracranial bleeding, diffuse swelling, and reduced cerebral blood flow (CDC, et al., 2013; Maas, et al., 2008). The heterogeneous and unpredictable clinical outcomes described below occur as a result of the complex patterns of damage associated with TBI.

TBI severity is typically classified as mild, moderate, or severe according to a person's neurological signs and symptoms. The most widely used classification system is the Glasgow Coma Scale (GCS) (Malec, et al., 2007; Teasdale and Jennett, 1974). The GCS is composed of three subscales (visual, verbal, motor) that are combined to give a total score that reflects level of consciousness. Additional measures, such as the duration of altered consciousness and post traumatic amnesia (i.e. loss of memory for events immediately after the TBI) are also used in clinical practice and research (Table 1). However, classifying TBI severity as mild, moderate, or severe using these blunt classification systems does not permit mechanistic targeting for treatment or clinical trials. A specific aim of the Transforming Research and Clinical Knowledge in TBI (TRACK-TBI) initiative is to combine neuroimaging, proteomic biomarkers, genetic markers, and clinical parameters to construct a comprehensive, multidimensional classification system across a wide spectrum of TBI severity and pathologic mechanisms (TRACK-TBI, 2016).

Table 1. Criteria used to classify TBI severity (Adapted from Brasure, et al., 2012; CDC, 2015)

Criteria	Mild TBI	Moderate TBI	Severe TBI
Glasgow Coma Scale score (3-15) [best score in 24 hours]	13-15	9-12	3-8
Duration of altered consciousness	<30 minutes	30 minutes – 24 hours	>24 hours
Duration of post traumatic amnesia	0-1 day	1-7 days	>7 days

Glasgow Coma Scale Score – mild TBI (13-15), moderate TBI (9-12), severe TBI (3-8).

Epidemiology

The Centers for Disease Control and Prevention (CDC) is the primary source of TBI epidemiological data for the U.S. population. The CDC funds 20 U.S. states to collect TBI data, and provides a yearly update on the estimated national incidence of TBI using information from health care administrative claims (Leibson, et al., 2011) that describe the number of TBI-related hospitalizations, emergency department (ED) visits, and deaths. Ongoing surveillance of TBI-related disability does not currently exist and so there is limited prevalence data available. The only nationally representative estimates of TBI-related disability are based on extrapolations of one-time state-level estimates of lifetime TBI-related disability (Selassie, et al., 2008; Zaoshnja, et al., 2008). Although data sources are available, there is no organized method of surveillance to document and track incidence, prevalence, treatment efficacy, cost of care or long-term functional outcomes.

The Traumatic Brain Injury Model Systems (TBIMS) program, funded by the National Institute on Disability, Independent Living and Rehabilitation Research (NIDILRR), is responsible for the TBIMS National Database (TBIMS-NDB). This large database contains prospective, longitudinal data on >13,000 persons with moderate or severe TBI that have been admitted to inpatient rehabilitation within a TBIMS-funded center since 1988 and is critical to study the course of recovery and outcomes following TBI. The TBIMS-NDB provides population estimates for characteristics from pre-injury through discharge from inpatient rehabilitation and is representative of persons who have experienced TBI in the broader U.S. population (Corrigan, et al., 2012).

Each year, approximately 30 million injury-related ED visits, hospitalizations, and deaths occur as a result of trauma in the U.S. In 2010, the CDC estimated that TBI accounted for approximately 2.5 million ED visits, hospitalizations, and deaths, either as an isolated injury or in combination with other injuries (Table 2) (CDC, 2015). It is important to note, however, that this figure does not include persons who did not receive medical care, who received outpatient or office-based care (e.g. from a primary care physician), or who were treated at a federal or military facility (Faul, et al., 2010).

Unfortunately, limited data are available on the incidence of TBI stratified by injury severity. Further, the available data are influenced by the method used to assess TBI severity (e.g. GCS, duration of altered consciousness) and the point of care at which persons are assessed (e.g. admission to ED vs. hospitalization). When injury severity is classified using the GCS the majority of persons are diagnosed with a mild TBI (54-61%), followed by those with a severe (32-40%) or moderate (7-15%) TBI (Table 2) (Cuthbert, et al., 2015; TBIMS, 2015; Udekwu, et al., 2004). In higher income countries, the incidence of TBI caused by falls is increasing as the population ages, leading to a rise in the median age of TBI populations (Table 3) (Maas, et al., 2008). Interestingly, a recent analysis of the TBIMS-NDB found that TBI severity decreased with increasing age for all TBI severity indicators (i.e. GCS, duration of unconsciousness, duration of post-traumatic amnesia), which suggests that younger persons had more severe TBIs (Cuthbert, et al., 2015).

The incidence of survival following TBI has increased dramatically due to major advances in acute medical and surgical management (Mansour and Lajiness-O'Neill, 2015). The CDC estimates that 3.2-5.3

million persons in the U.S. (approximately 2% of the U.S. population) are living with TBI-related disabilities (Selassie, et al., 2008; Thurman, et al., 1999; Zaloshnja, et al., 2008).

Although some data are available for ED visits, hospitalizations, and deaths following TBI, there is a paucity of epidemiological data for other facilities (e.g. acute inpatient rehabilitation and long-term care facilities) that treat these patients.

Table 2. Traumatic brain injury incidence data (CDC, 2015; Cuthbert, et al., 2015; TBIMS, 2015; Udekwu, et al., 2004).

Incidence of TBI – Total

2.5 million emergency department visits, hospitalizations, and deaths (CDC, 2015)

- Emergency Department visits 87% (n=2,175,000)
- Hospitalizations 11% (n=275,000)
- Deaths 1% (n=25,000)

Incidence of TBI – Segmented by injury severity

Classification system: Glasgow Coma Scale

	Mild TBI	Moderate TBI	Severe TBI
• Udekwu, et al. (2004)	60.2%	7.1%	32.7%
• TBIMS (2015)	40.0%	15.0%	45.0%
• Cuthbert, et al. (2015)	54.1%	10.3%	35.6%

Classification system: Duration of altered consciousness

	Mild-moderate TBI	Severe TBI
• Cuthbert, et al. (2015)	46.4%	53.6%

Classification system: Duration of post traumatic amnesia

	Mild-moderate TBI	Severe TBI
• Cuthbert, et al. (2015)	32.2%	67.8%

Glasgow Coma Scale Score – mild TBI (13-15), moderate TBI (9-12), severe TBI (3-8);
Duration of altered consciousness – mild-moderate TBI (<24 hours), severe TBI (>24 hours);
Duration of post traumatic amnesia – mild-moderate TBI (<7 days), severe TBI (>7 days).

Table 3. International TBI databases and studies [1980s – present] (Courtesy of A. Maas).

Study	Years of study	Number of patients	Median age (years)	Patients >50 years (%)
Traumatic Coma Data Bank (U.S.)	1984 – 1987	746	25	15
UK 4 Centre Study	1986 – 1988	988	29	27
EBIC Core Data Survey (EU)	1995	847	38	33
POCON Study (The Netherlands)	2008 – 2009	339	45	43
Austrian Severe TBI Survey	1999 – 2004	415	48	45
Italian ICU Cohort	1997 – 2007	1478	45	44
CENTER-TBI Core Data Study	2014 –	1911	50	49
CENTER-TBI Registry	2014 –	8038	52	52

CENTER-TBI – Collaborative European NeuroTrauma Effectiveness Research in TBI;
EBIC – European Brain Injury Consortium; ICU – Intensive Care Unit;
POCON – Prospective Observational Cohort Neurotrauma; UK – United Kingdom; U.S. – United States.

Costs

The effects of TBI can have devastating, long-term effects for patients and their families, but there are also consequences for the community and the U.S. economy. In the short-term, the average cost per patient has been reported to be $162,194 for acute care hospitalization, and $59,862 for acute inpatient rehabilitation (Richards and Kirk, 2010). The lifetime cost per person has been estimated to be between $600,000 and $1,875,000 (NIH, 1999). In 2010, the total economic costs of TBI were estimated at $76.5 billion with the indirect costs of disability, lost wages, and lost productivity ($64.8 billion) far outweighing the direct, medical costs ($11.5 billion) (Coronado, et al., 2012; Finkelstein, et al., 2006). Although estimates of cost for severe TBI are not available, fatal injuries or those requiring hospitalization (and are therefore presumably severe) account for approximately 90% of the total medical costs of all TBIs. For comparison, the direct medical costs of cancer care and indirect costs (valued with the human capital approach) were estimated to be $158 billion (Mariotto, et al., 2011) and $147.6 billion (Bradley, et al., 2008), respectively, based on a projection of 18.1 million cancer survivors in the US in 2020 (Bradley, et al., 2008; Mariotto, et al., 2011).

Impact

Persons with TBI, their families, and society are faced with long-term disability and medical challenges, with potentially drastic socioeconomic consequences (Humphreys, et al., 2013). The burden and cost of

care engenders unexpected changes in family routines and roles often leading to divorce, significant financial hardships, disintegration of the family unit, and less attention to patient care.

Persons who sustain a severe TBI typically have worse clinical issues and prognosis than mild or moderate TBI, but the clinical trajectory is typically unpredictable and can be vastly different across patients. For instance, some patients might regain consciousness within a matter of hours and be discharged home with minimal medical issues, whereas other patients may remain unconscious for weeks and be discharged from acute care with sustained cognitive and physical impairments, medical complications, and comorbidities directly related to the TBI. *For the remainder of this report, unless otherwise stated, severe TBI will be used in relation to persons who were diagnosed as having experienced a severe TBI (e.g. using the GCS) and who have persistent disability that interferes with vocational, academic or social functioning following discharge from the acute care setting.*

Clinical needs

Acute phase

Persons who have sustained a severe TBI require immediate medical treatment, which begins in the ED and transitions to the intensive care unit (ICU) where life-saving medical interventions are instituted. Patients with severe TBI may arrive in the ED with altered consciousness, skull fracture, significant loss of blood, respiratory distress, and major extra-cranial injuries (e.g. fractured pelvis, lacerated abdominal organs) (American College of Surgeons, 2015). In addition to altered consciousness several clinical signs and symptoms might reflect altered brain function, including post traumatic amnesia, or neurological deficits (e.g. muscle weakness, loss of balance and coordination, disruption of vision, change in speech and language, or sensory loss) (Menon, et al., 2010). In this acute phase the immediate priorities are diagnostic assessment and medical stabilization of the patient according to US Advanced Trauma Life Support standards (Maas, et al., 2008).

The focus of treatment in the ICU is on maintaining medical stability. Such activities include performing systematic neurobehavioral examinations to accurately characterize level of consciousness and instituting management protocols to prevent neuromuscular complications. Some patients who survive severe TBI experience prolonged disorders of consciousness (DOC) following emergence from coma, including the vegetative state (VS) (The Multi-Society Task Force on PVS, 1994) and minimally conscious state (MCS) (Giacino, et al., 2002). VS is characterized by the complete absence of behavioral signs of self and environmental awareness and is distinguished from coma by the reemergence of eye-opening, signaling the return of wakefulness (Jennett and Plum, 1972). During VS, clinical management focuses on promoting arousal (e.g. neurostimulant medication trials), stabilizing acute medical problems (e.g. treatment of dysautonomia) and preventing secondary complications (e.g. joint range of motion exercises) that develop rapidly in the absence of appropriate care. Systematic monitoring of level of consciousness to guide diagnostic assessment, outcome prediction, selection of treatment interventions and disposition planning is an equally critical component of care during this phase of recovery. Persons in MCS demonstrate at least one clear-cut behavioral sign of conscious awareness, most often

manifesting as visual pursuit, object manipulation, simple command-following, intelligible speech or yes-no responses (Giacino, et al., 2002). Treatment of MCS centers on improving behavioral response consistency and fostering restoration of reliable communication through therapeutic interventions and use of augmentative devices. Emergence from MCS occurs when there is clear evidence of functional yes-no communication or recovery of the ability to use objects in a functional manner (Giacino, et al., 2002). Because persons remain confused and disoriented at this stage of recovery, environmental control strategies and supervised exposure to familiar activities are required to ensure safety and facilitate restoration of autonomy in self-care.

Subsequent to medical stabilization, persons with severe TBI may be referred to an acute inpatient brain injury rehabilitation center to promote further recovery of physical and cognitive functions, and to prevent injury-related complications.

Chronic phase

Sequelae

For most patients, a severe TBI is not a discrete event that can be treated and cured within a matter of months, but the beginning of a life-long disability with implications for themselves and their family (CDC, 2015; Langlois, et al., 2006). The clinical needs of those who have sustained a severe TBI are diverse due to the widespread and heterogeneous effects of the injury across all body systems and symptom domains (Table 4). For instance, patients commonly experience profound cognitive impairments in attention, processing speed, working memory, executive function, visuo-spatial skills, memory, and the ability to encode and learn new information (Mansour and Lajiness-O-Neill, 2015).

Table 4. Impairments following severe TBI organized by functional domain (Adapted from Lorenz and Katz, 2015).

Functional domain	Impairments
Cognitive	Memory, attention, executive function, processing speed, language, visuospatial, intelligence
Neurobehavioral	Judgment, impulse, anger, disinhibition, social behavior, apathy, insight
Psychological health	Mood, anxiety, post traumatic stress disorder, psychosis, personality, resilience
Life participation	Social, vocational, recreational, sexual function, financial, transport, living situation
Physical function	Motor, sensory, perceptual, mobility, pain, sleep, endurance

A persistent misconception about severe TBI is that the brain lacks potential for clinically meaningful improvement (Fins, 2013). A longstanding clinical belief is that global outcome neither improves nor deteriorates beginning 2 years after severe TBI. However, recent studies show that impairments and global outcomes can fluctuate or are not stagnant over several years post injury (IOM, 2008).

A recent report on patients with DOC admitted to the NIDILRR-funded TBIMS Program without evidence of command-following on admission to rehabilitation, found that 20% regained functional independence in the home environment between 1 and 5 years post-injury (Nakase-Richardson, et al., 2011). Further,

Schiff, et al. (2007) found that bilateral deep brain stimulation (DBS) modulated behavioral responsiveness in a patient who had remained in the MCS state for 6 years due to severe TBI before the intervention. These data challenge the existing practice of early treatment discontinuation for patients with DOC and provide evidence that rehabilitation (Nakase-Richardson, et al., 2011) and DBS (Schiff, et al., 2007) can promote significant late functional recovery following severe TBI.

Conversely, the global outcome of 39% of persons who received 6 weeks of acute inpatient rehabilitation following moderate-severe TBI deteriorated from 1- or 2-years post-injury to follow-up at 5-years post-injury (Corrigan, et al., 2014) and approximately 33% deteriorated from a previously achieved outcome after 10 years (Wilson, et al., 1998). Further, among adolescents and adults who received rehabilitation for moderate-severe TBI, 20% will have died at 5 years post-injury, and nearly 40% will have declined in function from the level of recovery attained 1–2 years after their injury (Corrigan, et al., 2014).

These data suggest recovery from severe TBI is often unpredictable and might be bi-directional, with unique combinations of acute, persisting, and delayed-onset impairments (Corrigan and Hammond 2013; Corrigan, et al., 2014). Unfortunately, the predictors of improvement and decline are largely unknown.

Medical complications and comorbidities

The long-term impact of severe TBI is not limited to the impairments and outcomes contained within the five health domains listed above (Table 4). An additional burden is the development of multiple medical complications and comorbidities that can emerge at the time of injury (Whyte, et al., 2013a), or in the years following TBI (Table 5) (IOM, 2008). For instance, Whyte, et al. (2013a) found that >80% of patients who were admitted to acute inpatient rehabilitation between 1 and 3 months post-injury experienced at least one medical complication (e.g. urinary tract infection, pneumonia, gastrointestinal problems) over 6 weeks. Importantly, results indicated that the decrease in the number of complications observed during inpatient rehabilitation was attributable to active medical management in that setting, not simply passage of time (Whyte, et al., 2013a), underscoring the importance of intensive inpatient rehabilitation management in the first few months following severe TBI.

A large systematic review conducted by the Institute of Medicine (IOM, 2008) found that severe TBI is associated with multiple neurological and non-neurological comorbidities such as epilepsy, Alzheimer's disease, Parkinson's disease, major depression, pneumonia, and urinary/bowel incontinence (Table 5). Persons with moderate-severe TBI are at greatest risk of death from seizures, sepsis, aspiration pneumonia, and respiratory, mental/behavioral, or nervous system conditions (Harrison-Felix, et al., 2015). Additionally, persons affected by moderate or severe TBI who were discharged from rehabilitation facilities were more than twice as likely to die 3.5 years after injury compared to persons in the general population of similar age, sex, and race, with a reduced average life expectancy of 6-9 years (Greenwald, et al., 2015; Harrison-Felix, et al., 2012; Harrison-Felix, et al., 2015). These unique constellations of complications can assume different trajectories of onset, expression and resolution depending on various patient-related pre- and post-injury factors associated with the patient.

Table 5. Comorbidities and medical complications following severe traumatic brain injury (Adapted from Masel and DeWitt, 2010).

Neurological disorders	Non-neurological disorders
Neurological disorders • Seizure • Parkinsonism • Spasticity/Paralysis • Sensory loss *Neurodegenerative disorders* • Alzheimer's disease • Parkinson's disease • Chronic traumatic encephalopathy *Neuroendocrine disorders* • Post-traumatic hypopituitarism • Growth hormone insufficiency *Psychiatric disease* • Agitation/aggression • Obsessive compulsive disorder • Psychotic disorders • Major depression • Post-traumatic stress disorder • Substance abuse • Suicide • Psychosis *Cognitive disorders* • Memory • Attention • Visuoperceptual • Executive function • Language	*Metabolic dysfunction* • Diabetes *Genito-urinary* • Incontinence (bladder and bowel) • Urinary tract infections • Sexual dysfunction *Motor/musculoskeletal* • Hypertonia/spasticity • Impaired mobility • Motor restlessness/hyperkinesia *Gastrointestinal* • Digestive disorders • Vomiting • GI bleeding • Bowel obstruction • Peritonitis • Diarrhea *Respiratory* • Pneumonia • Upper respiratory tract infection *Cardiac/circulatory* • Tachycardia *Other* • Insomnia/sleep disturbance • Ulcers due to immobility

Summary of clinical needs

It is now clear that severe TBI is not a discrete event with unchanging long-term impairments and static global outcomes, but a lifelong condition with potentially permanent impairments and comorbidities that affect the brain and other body systems. These changes across multiple timelines, multiple health domains, and multiple body systems differentiate severe TBI from other diseases for which patients are more likely to receive long-term medical care, such as cancer and heart disease.

TBI health service delivery in the United States

As described above, persons with severe TBI are more likely to experience a unique combination of acute, persisting, progressive and delayed-onset impairments as a result of their injury (Corrigan and Hammond 2013; Corrigan, et al., 2014; Selassie, et al., 2008), presenting a level of complexity in the management of TBI that is unmatched by any other condition. It has long been recognized that the only way to effectively and efficiently manage these unique constellations of medical, physical, cognitive, behavioral, psychosocial and vocational needs is to employ a comprehensive, patient-centered multidisciplinary system of care from the acute setting to the community (Brasure, et al., 2012; CDC, 2015; Cope, et al., 2005; Goka and Arakaki, 1991; Horn and Lewis, 2014). Depending on the setting of care and the needs of the person, this multidisciplinary system may involve a combination of specialties that includes emergency/acute medicine, physiatry, neuropsychology, physical therapy (PT), occupational therapy (OT), speech and language therapy (SLT), neurobehavioral therapy, specialized nursing care and case management (CDC, 2015).

Acute phase: System of care

Consequently, the current system of TBI care in the U.S. (Figure 1) begins in the ED, where life-sustaining medical interventions are performed, and then transitions to either the ICU or acute hospital setting. The focus in this acute phase is on medical stabilization through the active management of the primary and secondary complications of the injury. Triage guidelines stipulate that all TBI patients be transferred to the highest level trauma center that has the expertise, personnel and facilities to provide the appropriate care (CDC, 2012). There, the goal of treatment is to achieve and maintain homeostasis in terms of oxygenation, arterial blood gases/pH, blood pressure, temperature and electrolyte balance. Careful neurological and radiographic examination and intracranial pressure monitoring and management are also critical (ACS TQIP, 2015; BTF, 2007). Depending on the severity and nature of the injury, persons may need to undergo neurosurgical management. Nutritional support and secondary procedures for orthopedic or other injuries are also coordinated at this acute phase. The typical length of stay (LOS) is currently seven to 14 days (Horn and Lewis, 2014).

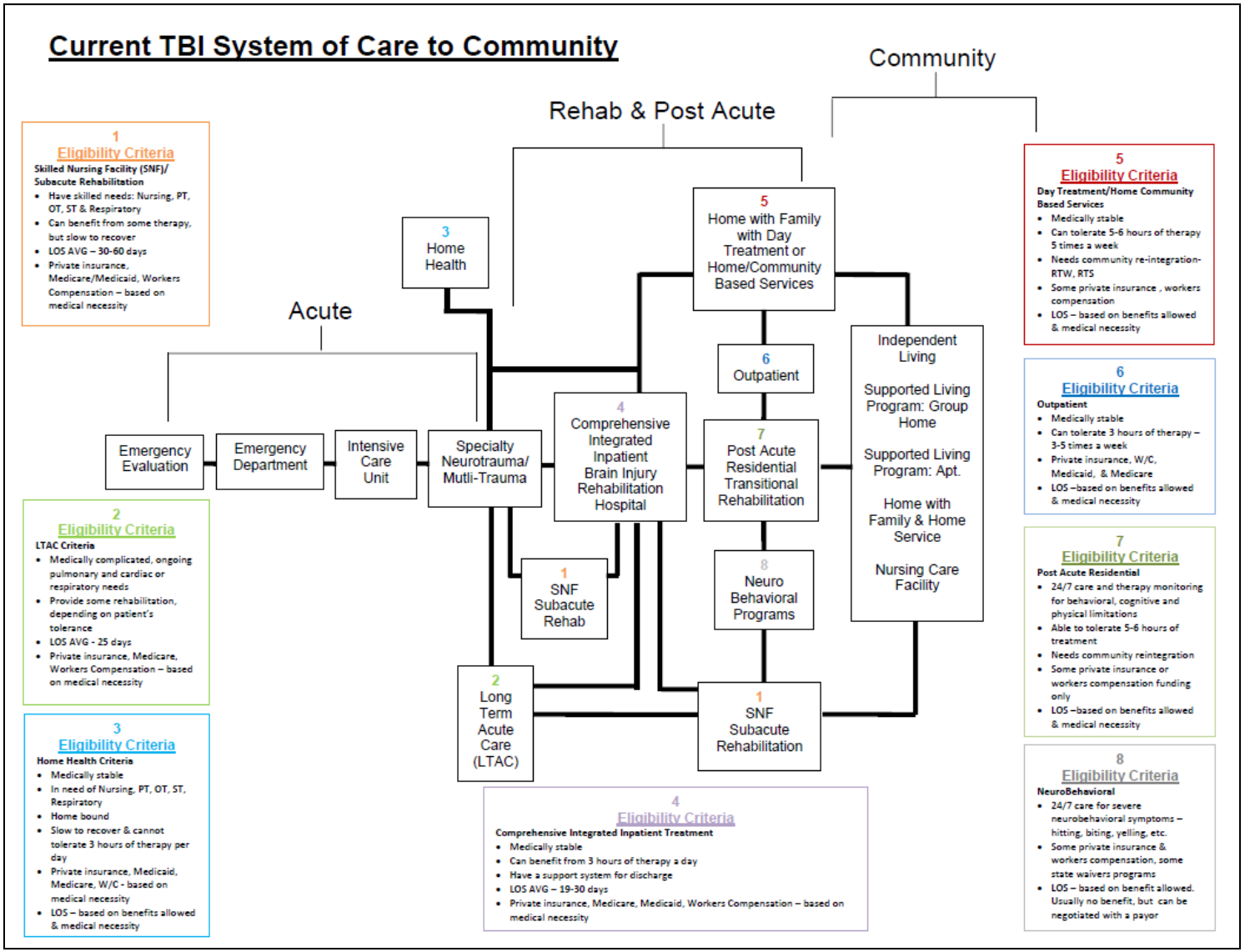
Acute phase: Evidence

Care at this acute stage has dramatically improved over the years, resulting in a 50% decrease in mortality since the 1800s (Harrison-Felix, et al., 2009; Stein, et al., 2010). Key factors contributing to this success have been an increased understanding of the acute pathophysiology, assessment and care of TBI, major advances in medical technology and neurosurgery and the corresponding development and gradual implementation of evidence-based guidelines on triage and acute management of severe TBI (Hesdorffer and Ghajar, 2007; Mansour and Lajiness-O'Neill, 2015). However, since 1990, the rate of mortality has reached a plateau at 35% (Stein, et al., 2010), suggesting that reconsideration of the management of TBI at this stage is warranted, including a better understanding of the extent of adherence to the published evidence-based guidelines (Hesdorffer and Ghajar, 2007). It has been estimated that widespread adoption of these guidelines would result in a further 50% reduction in deaths and savings of $288 million in medical and rehabilitation costs (Faul, et al., 2007).

Rehabilitation and post-acute phase: System of care

Following medical stabilization, the focus shifts to rehabilitation, functional recovery, and preparation for reintegration into the community, with ongoing medical monitoring and care to manage and prevent medical complications (Horn and Lewis, 2014; Kane, 2007; Whyte, et al., 2013a). Currently, no evidence-based guidelines have been established for the optimal management of the post-acute and rehabilitation stage of persons with severe TBI (Horn and Lewis, 2014). As a consequence, in this "Rehab & Post-Acute" setting (Figure 1), the path of care for each person diverges, depending on the person's medical, clinical and psychosocial needs as well as other factors (Cuthbert, et al., 2011). Persons with severe TBI may be discharged to a comprehensive inpatient rehabilitation facility (IRF), skilled nursing facility (SNF), or long-term acute care (LTAC) facility. Alternatively, persons may be discharged directly home with services by a home health agency (HHA) or to an outpatient facility, if substantial recovery has occurred, or with no services at all. The intensity and type of care provided at each of these settings varies substantially (Buntin, 2007). IRFs offer the most comprehensive and intensive services. Lead by a supervising physician, who monitors the person's progress on a daily basis, the person's care and rehabilitation curriculum involve at least 3 hours of multidisciplinary therapy (PT, OT, and/or SLT) a day (15 hours per week), social or psychological services and 24-hour monitoring by rehabilitation nurses. All staff must be licensed and trained according to specific personnel qualification requirements stipulated in the Federal Code of Regulations of the Centers for Medicare and Medicaid Services (CMS) and Department of Health and Human Services (DHHS) (Section 42 C.F.R. §485.70) (Buntin, 2007). SNFs, on the other hand, exhibit a greater diversity in patterns of practice with less intensive rehabilitation therapy (~5 hours per week) and staff licensing and training requirements (Buntin, 2007; Melvin, 2006). Physicians must develop a plan of care and follow up every 30 days (average LOS 30-60 days). Furthermore, on-staff nursing coverage is only required for eight hours a day with 24 hours of on-call coverage (Buntin, 2007) (Table 6). LTACs vary considerably in their services based on the diversity of patients and corresponding medical complications that they are equipped to manage. Limited rehabilitation services are generally provided, and the average length of stay is 25 days. Outpatient services may be provided by therapists, working independently or as part of a hospital outpatient facility (Buntin, 2007). The services vary according to availability of expertise and training at a particular clinic. The general program consists of three to five 1-hour sessions per week. Finally, HHAs provide therapy, nursing care and general assistance with activities of daily living from home health aides, in accordance with the physician's orders and current needs of the person. Notably, for those who are discharged directly home at this stage, particularly without services, the responsibility of care coordination and provision for the patient falls into the hands of the family member/caregiver, which may be exceedingly challenging after severe TBI.

Figure 1. Current TBI System of Care.



Boxes indicate general eligibility criteria, service provision requirements and typical length of stay (LOS) for specified setting.

Table 6. Medicare standards for inpatient rehabilitation facilities versus other post-acute facilities.

REQUIRED BY MEDICARE	IRF	SNF/LTAC/ OTHER PAC
Close medical supervision by a physician with specialized training in rehabilitation medicine	YES	NO
24-hour rehabilitation nursing	YES	NO
Persons MUST require hospital-level care	YES	NO
Physician approval of pre-admission screen and admission	YES	NO
Medical care and therapy provided by a physician-led multidisciplinary medical team including specialty-trained registered nurses	YES	NO
Persons must generally require an intensive rehabilitation therapy program; current industry standards suggest 3 hours per day, 5 days per week	YES	NO

IRF – inpatient rehabilitation facility; SNF – skilled nursing facility; LTAC – long-term acute care (Adapted from AHA, 2012; CMS, 2014; Melvin, 2006)

Rehabilitation and post-acute phase: Evidence

While the evidence for the most appropriate path at this stage is not as definitive as that for the acute, life-saving management of persons who have sustained a severe TBI, it is mounting in favor of intensive multidisciplinary inpatient rehabilitation over other settings. In particular, progression to inpatient rehabilitation earlier, either directly from acute services (Andelic, et al., 2012) or within one year of the injury (Griesbach, et al., 2015) leads to greater functional improvements with a reduced length of stay and a decrease in overall healthcare costs (Kunik, et al., 2006). Also, studies show that programs providing more intensive rehabilitation confer earlier functional gains once persons are able to tolerate the therapy schedule (Turner-Stokes, et al., 2015; Zhu, et al., 2007) and that persons who are treated in inpatient rehabilitation facilities are discharged with less complications and impairments and thus live longer than those treated in other post-acute facilities, such as SNFs (AHA, 2012; DaVanzo, et al., 2014). Furthermore, admission to inpatient rehabilitation increases patient access to the appropriate post-hospital, outpatient and/or community-based interventions (Turner-Stokes, et al., 2005; Turner-Stokes, et al., 2015).

Community phase: System of care

Depending on the demonstrated progress and residual needs of the person following the aforementioned "Rehab & Post Acute" phase, the person may be discharged to post-hospital, community-based services, such as supported living programs, independent living programs, club houses, or home with or without home-based nursing and rehabilitation services (Figure 1). The different programs are organized to support the various needs of the person at this stage in the person's recovery. They range from providing 24-hour therapeutic behavioral and cognitive support and severe neurobehavioral symptoms (e.g. biting, hitting, yelling) care, as in post-acute residential and neurobehavioral services, respectively, to providing an environment in which the members function as part of a community, as in the clubhouse setting (CDC, 2015). Finally, for those who have progressed to a stage of considering returning to work, vocational services exist to support career planning, training and goal achievement (CDC, 2015). Access to these "Community" programs is contingent upon both clinical (e.g. patient impairments, disabilities) and non-clinical (e.g. availability of service, finances) factors (Horn and Lewis, 2014; Ottenbacher and Graham, 2007). A substantial portion of persons with severe TBI have residual disabilities that preclude participation in outpatient and community-based rehabilitation programs.

Community phase: Evidence

The evidence-base for the necessity and effectiveness of post-hospital, community-based programs is also building, supporting the case for meaningful recovery well beyond the first year of injury (CDC, 2015; Horn and Lewis, 2014; Turner-Stokes, et al., 2015). Cicerone, et al. (2008) showed that group-based, intensive, milieu-based therapeutic neuropsychological rehabilitation improved community integration, productivity, and life satisfaction following severe brain injury over standard outpatient treatment. Lewis and Horn (2015) examined the effectiveness of four levels of post-hospital care, ranging from intensive neurorehabilitation for persons with impairments in behavioral control to supportive living programs for persons who need assistance in maintaining their health and activities of daily living. They noted significant reductions in impairment across the range of post-hospital, community-based services, even when participants' length of time from onset of injury was seven years (Lewis and Horn, 2015). Conversely, a clear picture is emerging as to the need for continuous, life-long "environmental enrichment" in the form of therapy, training and/or structured participation in order to maintain those acute and post-acute functional gains and prevent cognitive, behavioral, physical and social decline that persons with severe brain injury are at risk of experiencing (Corrigan, et al., 2014; Frasca, et al., 2013).

The U.S. healthcare system and TBI

Arguably, the U.S. healthcare system is comparable in complexity to TBI with its "pastiche" of delivery and funding sources and associated eligibility criteria, and reimbursement policies (Figure 1) (Cheng, 2014). Table 7 provides examples of the different combinations of payer and provider systems that operate within the U.S. and are relevant to the TBI system of care. At one end, the Veterans Administration (VA) health system approximates the socialized medicine model, whereby the federal government finances, owns and operates the healthcare facilities and services. Accordingly, the VA has established its own Polytrauma/TBI system of care and associated guidelines and policies (VA, 2016),

which it reserves for its military veterans (i.e. approximately 4.5% of U.S. population (Smith and Medalia, 2015)). At the other end are those individuals without insurance, who pay "out-of-pocket" or revert to other financing sources (e.g. "safety nets") for the health care services that they render (Zaloshnja, 2012) (Table 7). The most recent census estimated that 33 million Americans (~10% of the populations) were uninsured (Smith and Medalia, 2015). Most people in the U.S. (~66%) have some form of private health insurance, most of which is employment based (55%) (Smith and Medalia, 2015). The remaining are covered by government-based funding, such as Medicare (16%) or Medicaid (20%) (Smith and Medalia, 2015).

Adding to the complexity of the U.S. healthcare system payer-provider taxonomy is the heterogeneity in coverage among the public and private payer/funding sources and the healthcare providers; different providers accept different insurance plans, while different insurance plans or funding sources offer different types and levels of coverage. Accordingly, healthcare providers have established or adopted admissions eligibility criteria to ensure timely and adequate reimbursement from the associated payer (e.g. McKesson InterQual Criteria). Options for third-party payer coverage decrease and typically terminate once care is sought in the post-hospital, community setting (Horn and Lewis, 2014).

Table 7. Payer-provider taxonomy of the U.S. healthcare system

<table>
<tr><th colspan="8">INSURANCE/FUNDING SOURCES</th></tr>
<tr><th>PROVIDER</th><th colspan="3">Social Insurance (Ability-to-pay financing)</th><th colspan="2">Private Insurance (Actuarially fair financing)</th><th>No Health Insurance</th><th>Safety Nets</th></tr>
<tr><td></td><td>Single Payer</td><td>Multiple Payers</td><td>Non-Profit</td><td>For-Profit</td><td></td><td>Out-of-pocket</td><td>Government</td></tr>
<tr><td>State/Local Government</td><td>e.g. VA; Federal Employees Compensation; Medicare; Medicaid</td><td rowspan="2">e.g. Maryland's Healthcare system; Medicare Advantage System; Medicaid Managed Care</td><td rowspan="2">e.g. Kaiser Permanente and some BCBS plans</td><td rowspan="2">e.g. Aetna and some BCBS plans; workman's comp</td><td rowspan="2">ACA</td><td rowspan="2">Out-of-pocket</td><td rowspan="2">e.g. Medicaid; TBI Waivers; State-traffic fines; State Funding/Trusts; SSI; SSDI</td></tr>
<tr><td>Private, not-for-profit

Private, for-profit/commercial</td><td>Federal Employees Compensation; Medicare; Medicaid</td></tr>
<tr><td></td><td colspan="5">ACA</td><td></td><td></td></tr>
</table>

ACA, Marketplace insurance available as part of the Affordable Care Act. Includes combinations of private and public financing, depending on the income level of the insured. (Adapted from Cheng, 2014)

Medicare, the Prospective Payment System and the "Rules of Rehabilitation"

One of the strongest drivers in the current TBI system of care is the Medicare Program. It is the largest payer of rehabilitation care in the U.S. (Zorowitz, 2009), covering the costs of approximately 70% of all admitted patients (Chan, 2007). In a recent survey of adults receiving acute inpatient rehabilitation for a primary diagnosis of TBI between 2001 and 2010, Medicare was the largest payment source, covering

46.3% of the patients, followed by private insurance at 33.6% (Cuthbert, et al., 2015). As a result of its financial authority, Medicare governs many of the organizational policies imposed by IRFs (Granger, et al., 2009; Weinrich, et al., 2005) and inevitably influences the eligibility criteria for admission to the IRF and the reimbursement practices of private insurers, who often adopt Medicare's policies (Chan, 2007).

Most notable and relevant to the TBI system of care is Medicare's 2002 shift to a Prospective Payment System (PPS) for IRFs (MLN, 2015), which was made in an attempt to limit unnecessary testing and procedures associated with the previous "fee-for-service" payment schedule (Chan, 2007). Now, IRFs prospectively receive a pre-determined amount based on the patient's admitting condition and level of severity (MLN, 2015). Accordingly, three related "rules" came to the forefront as a result of Medicare's shift: (1) the requirement of "medical necessity"; (2) the "60% rule"; and (3) the "3-hour rule" (Granger, et al., 2009; MLN, 2015; Weinrich, et al., 2005).

Medical necessity is not a new concept for Medicare; since the establishment of Medicare, this concept has framed the criteria under which a particular claim is eligible for coverage by Medicare (Granger, et al., 2009). Specifically for IRFs, Medicare has established the following criteria for claims to be deemed "reasonable and necessary" (MLN, 2015):

(1) Specify on pre-admission assessment that a rehabilitation physician reviewed and approved prior to IRF admission;
(2) Require a post-admission physician evaluation to verify that the patient's pre-admission assessment information remains unchanged or to document any changes;
(3) Specify requirements for an individualized overall plan of care for each patient;
(4) Emphasize the interdisciplinary approach to care provided in an IRF and require interdisciplinary team meetings at least once per week throughout the IRF stay; and
(5) Clarify the requirements for admission to an IRF by specifying that a patient must:
    a. Require the active and ongoing therapeutic intervention of multiple therapy disciplines;
    b. Generally require intensive rehabilitation program uniquely provided in IRFs;
    c. Be sufficiently medically stable to benefit from IRF services;
    d. Require close medical supervision by a physician for managing medical conditions to support participation in an intensive rehabilitation therapy program; and
    e. Require an intensive and coordinated interdisciplinary approach to care.

(MLN, 2015)

Thus, medical necessity serves to establish the level of severity and specialized care needs of the patient that warrant the specialized services offered by IRFs (Granger, et al., 2009).

The "60% rule", in turn, stipulates the types of conditions deemed most appropriate for IRF services and reimbursement by Medicare's PPS (MLN, 2015). Known as the "compliance threshold", the "60% rule" states that a minimum of 60% of the facility's inpatient population must require treatment for one of 13 pre-selected medical conditions, one of which is brain injury, in order to qualify to receive payment by Medicare as an IRF (MLN, 2015).

Finally, **the "3-hour rule"** was originally established as a benchmark for distinguishing the type and intensity of care provided at an inpatient rehabilitation facility from that provided at an acute hospital setting or skilled nursing facility (Weinrich, et al., 2005). It refers to the minimum number of hours of rehabilitation services required by and provided to patients in an inpatient rehabilitation facility – specifically, 3 hours a day for 5 days a week (or 15 hours per week), including at least therapies, one of which must be PT or OT (Weinrich, et al., 2005). The "3-hour rule" currently serves as an "industry standard" (CMS, 2014), which IRFs and private insurance providers have adopted when considering patients for admission and when reviewing PPS claims, respectively. It has been indoctrinated in McKesson's InterQual criteria, which hospital admissions departments and Medicare contractors use to assess the "medical necessity" of each patient.

Thus, when considering patients for admission, IRFs must take each of these rules into account in order to ensure that the claim is covered under Medicare's PPS for IRFs.

In conclusion, the structure of the U.S. healthcare system and its associated eligibility criteria and reimbursement policies invariably affect a patient's access to and progression through the TBI system of care, particularly beyond the acute hospital phase. As a result, it has forged a number of critical gaps between the needs of persons with severe TBI and healthcare retrieval, as discussed in Section 2.

II. Gaps and disparities in healthcare management after severe TBI

Clinical needs vs healthcare service access, policy and finance

Severe TBI is not an event, but a chronic condition

It is now well established that severe TBI is not a discrete event, but the onset of a chronic condition (Corrigan and Hammond, 2014; Masel and DeWitt, 2010). The injury itself triggers widespread, heterogeneous effects across all body systems and domains of function, such that each person experiences a unique array of acute and persisting medical complications and physical, cognitive, behavioral, psychological, and/or social impairments (Mansour and Lajiness-O'Neill, 2015; Whyte, et al., 2013a). TBI is also "disease-causing" and "disease-accelerating" (Masel, 2009) due to the increased risk of neurogenerative comorbidities, such Alzheimer's disease, Parkinson's disease and Chronic Traumatic Encephalopathy later in life. Adding to the complexity, these unique constellations of complications can assume variable and unpredictable trajectories of onset, expression, progression and/or resolution, depending on the nature and severity of the injury and the pre- and post-morbid characteristics of the individual (e.g. gender, genetics, comorbidities, socioeconomic status and health care availability and access) (DeKosky, et al., 2010; Langlois, et al., 2006; Mansour and Lajiness-O'Neill, 2015). For example, persons with severe TBI may be hospitalized again due to acute medical complications months or years after being discharged from inpatient rehabilitation or they may discharged home from inpatient rehabilitation able to function independently (Saverino, et al., 2016; Whyte, et al., 2013b). However, despite this evolving knowledge of the diverse chronic care needs of persons with severe TBI and the

existence of a TBI system of care (Figure 1), the current structure of the U.S. healthcare system, including its delivery mechanisms and payment policies, does not support the optimal execution and widespread implementation of a patient-need-centered TBI system of care (Cope, et al., 2005; Goka and Arakaki, 1995; Horn and Lewis, 2014). Also, it broadly assumes that the trajectory of recovery for each person is linear, unidirectional and steady, such that each person will assume a course of recovery from acute to post-acute to post-hospital and community in a predictable fashion with no need for 'upstream' services or further rehabilitation once discharged from the system (Weinrich, et al., 2005).

Integral to this discussion of the gaps and disparities associated with the current management of severe TBI is 'access'. In the context of healthcare, it refers to being able to receive the *appropriate care* at the *appropriate time* in the *appropriate setting* (Chan, 2007). While it is straightforward to see the clinical and health economic benefits of appropriate and timely access across all health conditions (Miller, 2010), it begets a sense of urgency for persons with severe TBI (Langlois, et al., 2006). While the U.S. is well known for its deep investment in acute, life-saving efforts (Shi and Singh, 2017), advances in the acute management of severe TBI over the past years have come to represent a "double-edge sword" for some persons, their families and public health. More and more people are surviving the initial insult of TBI, unleashing unique medical challenges and socioeconomic consequences of a growing population of persons with a complex array of disabilities (Goka and Arakaki, 1995; Harrison-Felix, et al., 2009). At an estimated 5.3 million persons living with a TBI-related disability (CDC, 2015; Langlois, et al., 2006), these numbers are non-negligible, making access to healthcare "at the right time in the right place" (Chan, 2007) critical from an individual and public health perspective in this population.

Access and inpatient rehabilitation

In the current TBI system of care, inpatient rehabilitation is a core feature, offering a distinct level of specialized, multidisciplinary and intensive care that generally does not exist in other post-acute care settings (e.g. SNFs and LTACs; Table 6). As described in section 1, there is growing evidence that those who receive inpatient rehabilitation display greater functional improvement than those discharged from SNFs or other less-intensive facilities. Persons are more likely to be discharged home and less likely to be hospitalized (AHA, 2012). Equally, access to inpatient rehabilitation facilitates access to post-hospital and community-based services (Turner-Stokes, et al., 2005; Turner-Stokes, et al., 2015), serving as a "gateway" to long-term care. However, recent studies relying on large-scale databases that include persons age 16 and older discharged alive from acute care with moderate to severe TBI conclude that, a) less than 15% receive any inpatient rehabilitation services (Corrigan, et al., 2013) and b) for every one person admitted to inpatient rehabilitation, three go directly home (Cuthbert, et al., 2011). Results from these studies suggest that as many as 116,000 Americans age 16 and older go directly home from the acute hospital after incurring a moderate to severe TBI. Among these persons, estimates suggest that nearly 50% have ongoing disability (i.e. require assistance in activities of daily living) at one year post injury (Whiteneck, et al., 2001). The key take-away is that those who go directly home following moderate to severe TBI and do not receive comprehensive rehabilitation represent a previously unrecognized public health burden.

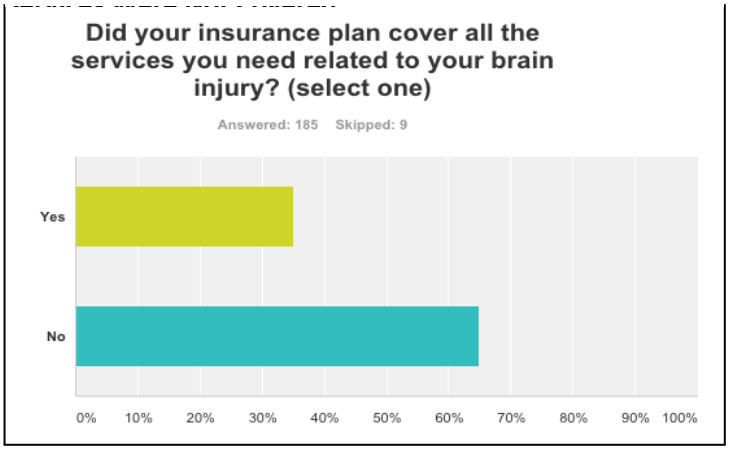
Access and private insurance

While many factors have been identified as barriers to access to post-acute services, the one most frequently cited is financial (Ottenbacher and Graham, 2007). As introduced in Section 1, access to healthcare is largely controlled by third-party payers, such as Medicare and private insurance companies (Shi and Singh, 2017). They are the major drivers of rehabilitation care in the U.S. (Goka and Arakaki, 1991; Zorowitz, 2009). The influence of insurance is so strong that merely having coverage has been shown to confer a protective advantage in the acute phase (Alban, et al., 2010). Critically, having insurance also increases a person's likelihood of subsequently being transferred to an acute inpatient rehabilitation or less-intensive post-acute (e.g. SNF or LTAC) facility for ongoing monitoring and care (Asemota, et al., 2013; Jaffe and Jimenez, 2015; Kane, et al., 2014). Those without insurance are more likely to be discharged home after their acute hospital stay (Cuthbert, et al., 2011).

While having insurance is necessary, it is not always sufficient for adequate access and coverage, particularly for those with unpredictable, long-term care needs, such as those with severe TBI. For those who are discharged to inpatient rehabilitation and/or other post-acute services, the extent to which their care is covered along the TBI system of care (Figure 1) depends on various insurance-specific factors, including the type of plan (e.g. HMO versus PPO), the terms of the coverage, lifetime limits, copayments, deductibles and associated network or provider restrictions (BCBSTx, 2016). Each insurance plan allocates distinct allowances for the different services they cover: acute inpatient (e.g. 7-14 days); inpatient rehabilitation (e.g. 2-6 weeks) or outpatient services (e.g. 20-30 visits per year for one or all rehabilitation services, PT/OT/SLT). Thus, services are considered and reimbursed as independent entities, with no allowance for overlap or 'roll-over' should a person require more of one type of care over another. Some plans have 'statutes of limitations' on the extent of time that can pass before coverage is denied, despite the evidence for the effectiveness of rehabilitation years after the injury (Lewis and Horn, 2015). For example, Health Net, Inc. specify that they will only consider cognitive rehabilitation medically necessary if it is offered as part of an inpatient, multidisciplinary rehabilitation program when the person meets various criteria associated with medical necessity, including that "the injury has occurred no more than 6 months from date of request" (Health Net, Inc., 2016). Cognitive and vocational rehabilitation services are typically not covered by insurance plans, despite evidence of their effectiveness (CDC, 2015; Cicerone, et al., 2011). Also, the further 'downstream' in the TBI system of care that an individual with TBI seeks services, the less likely resources will exist to pay for those services (Horn and Lewis, 2014), both in terms of plan coverage and out-of-pocket contributions (Relyea-Chew, et al., 2009). For those with severe TBI who are transferred directly from the acute care setting to a low-intensity SNF, the available insurance benefits may expire before the person has improved sufficiently to be considered for a more intensive rehabilitation program.

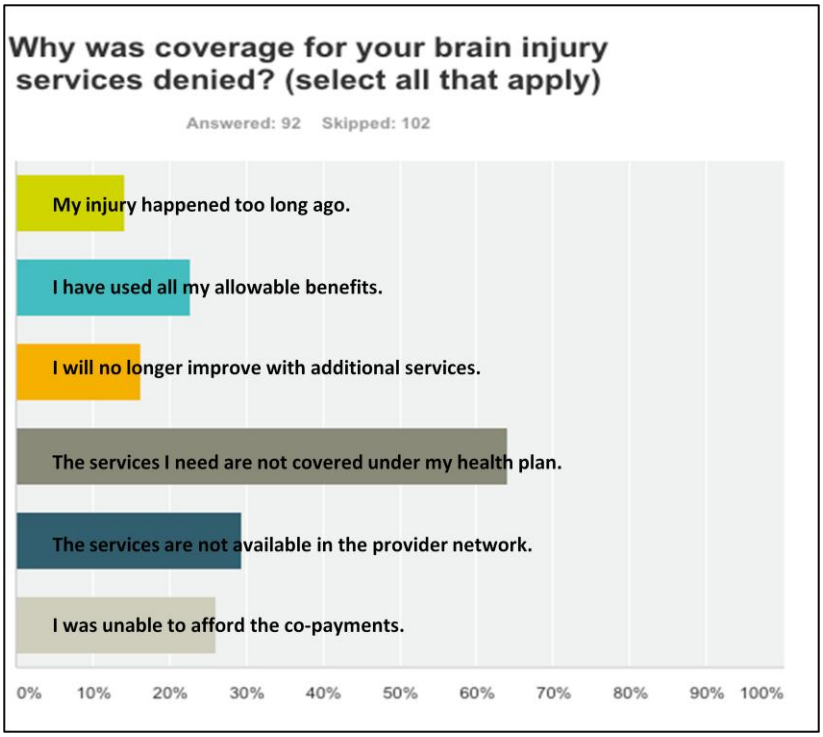
In an independent, ongoing survey conducted by the Brain Injury Association of America (BIAA) on insurance coverage for persons with TBI, almost 65% of the respondents (N=185) reported that their insurance failed to cover all of their brain-injury related services (unpublished data) (Figure 2). Cognitive therapy (53%), neuropsychological services (47%) and outpatient physical therapy (42%) were the top three services reported to be not covered by the respondents' insurers (not shown). The primary reason for the lack of coverage was because those services were not covered under the respondents' health plan (64%; Figure 3). The complete and most up-to-date results of this live survey can be found at: https://www.surveymonkey.com/results/SM-2783L9WQ/ (Courtesy of BIAA).

Figure 2. Percentage of BIAA respondents for whom services were not covered (Courtesy of BIAA).



Adding to the complexity associated with the multiple payer-provider taxonomy (Table 7) and the siloing of service provision along the TBI system of care, insurance policies also vary by state. These factors contribute to the fragmentation of the healthcare system and the lack of coordination of and continuity in care that is critical to those with severe TBI (Khan, et al., 2003).

Figure 3. Percentage of BIAA responses related to why coverage was denied (Courtesy of BIAA).

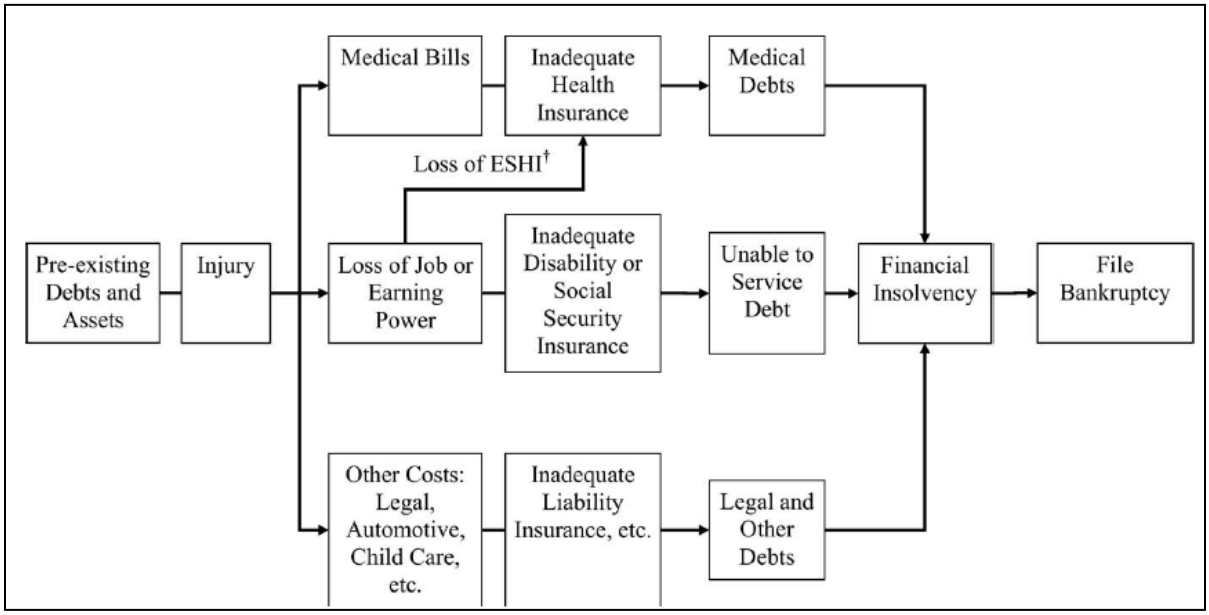


Financial insolvency and medical bankruptcy

Given the high personal cost burden of severe TBI (estimates of more than $5 million per lifetime (Bilmes and Stiglitz, 2006)), medical debt and bankruptcy are a harsh reality for patients and their families. Due to the debilitating, chronic impairments suffered by those with severe TBI, the relative risk of unemployment has been estimated at almost six times that of the general population, with approximately 60% unemployed after one year (Doctor, et al., 2005). For those who are covered

under employment-based insurance plans (as were 43% of the BIAA survey respondents), unemployment can compromise their health coverage. As a result of the rising medical bills and other costs, including pre-injury debt and costs of living, the loss of earning power and the inadequate or lost insurance coverage often place persons with TBI on the road to financial insolvency and medical bankruptcy (Relyea-Chew, et al., 2009) (Figure 4).

Figure 4. Possible road to financial insolvency and medical bankruptcy for those with TBI (Relyea-Chew, et al., 2009, Reprinted with permission).



ESHI, Employer-Sponsored Health Insurance.

Access and Medicare

An even stronger driver in the current TBI system of care, particularly inpatient rehabilitation, for those with severe TBI is Medicare. As the largest payer of rehabilitation care in the U.S. (Zorwitz, 2009), it sets the precedent for care provision and reimbursement across healthcare facilities and insurance providers (Chan, 2007). Since the implementation of Medicare's Prospective Payment System for Inpatient Rehabilitation Facilities (PPS-IRF) in 2002, there has been a significant drop in the percentage of persons with TBI being admitted to inpatient rehabilitation across all insurance types (Hoffman, et al., 2012). Many factors are likely to have played a role in this trend.

First, it has been suggested that the fiscal intermediaries contracted by CMS to review claims are often inappropriately denying payment for 'necessary and reasonable' care (AHA, 2007). In 2007 alone, 80% of Medicare PPS-IRF claims were initially denied, withholding over $25 million in Medicare payment. Upon appeal, 63% of those denials were overturned on the grounds that the claims had been wrongly denied, resulting in the return of millions of dollars back to these services. However, for those appeals that have not been successful, the financial consequences have been grave, putting the inpatient rehabilitation industry under extreme stress and resulting in the closure of 100s of facilities (Granger, et al., 2009).

Consequently, the high rate of initial denials and withheld funding and the costs and time associated with appealing each of them, as well as the financial consequences associated with losing the appeal, has resulted in a general restriction in access to inpatient rehabilitation services (AHA, 2007; Hoffman, et al., 2012).

The claims denials and associated restrictions in admission have been attributed primarily to the misapplication or misinterpretation of three "rules of thumb" (Connelly and Thomas, 2007), namely the 60% rule, medical necessity and the 3-hour rule. These rules were initially developed by Medicare to distinguish the specialized level of care and potential rehabilitation intensity uniquely provided by inpatient rehabilitation facilities from other post-acute facilities, such as SNFs, and to qualify the level of complexity and need in care required by the persons admitted to these services. The aims were to provide incentives for offering evidence-based care and limit the excess spending on unnecessary service provision that was common under the previous 'pay-for-service' system (Weinrich, et al., 2005). The 60% rule, or compliance threshold, is relatively innocuous to claims associated with the treatment of individuals with TBI since TBI is one of the 13 conditions that are required to meet this compliance threshold (MLN, 2015). It may pose a stress to the facility if they are forced to make decisions with respect to admitting persons with conditions that may not clearly fit under Medicare's threshold rules (Granger, et al., 2009; MLN, 2015).

The relevance and application of "medical necessity" and the associated "3-hour rule" to persons with severe TBI are much more contentious, leading to contested claim denials and restricted access to patients who would benefit from the unique, specialized and multidisciplinary care available only at inpatient rehabilitation facilities (Connelley and Thomas, 2007). Private insurance companies and commercial entities that develop and disseminate criteria for authorization of inpatient rehabilitation services (e.g. McKesson InterQual Criteria) subsequently adopted and adapted these Medicare "rules" to determine whether a particular claim warranted coverage or reimbursement (Granger, et al., 2009; Weinrich, et al., 2005). McKesson InterQual Criteria and the insurance companies (e.g. Health Medicine, Inc., 2016) who have implemented these criteria in their plan policies have added specifications for the level of cognitive function (Ranchos Los Amigos Level III+) that persons must exhibit on admission in order to ensure that they will be able to "actively participate" in the required 15 hours of rehabilitation per week. Strict interpretation of this rule, which is not evidence-based, would effectively prevent persons who sustain the most severe injuries (including those with disturbance in consciousness) to qualify for inpatient rehabilitation services.

In response to criticisms about the 3-hour rule, Medicare went back and qualified its expectation of the application of the rule, stating the determinations of whether inpatient rehabilitation services are "reasonable and necessary" must be based upon assessment of each patient's needs and that denials of services should *not* be based on "rules of thumb", such as the "3-hour rule" (Connelley and Thomas, 2007; Weinrich, et al., 2005). Accordingly, in Section 110.2 of the Medicare Benefit Policy Manual for Inpatient Rehabilitation (2014), it states that a "patient must *generally* require an intensive rehabilitation therapy program…", further explaining that "under current industry standards", this "generally" translates to 15 hours of rehabilitation therapy per week. Thus, under Medicare, the "3-hour rule" seems to serves more as an indicator of the level of intensity that should be required rather than

an explicit criterion and law, as with the McKesson InterQual Criteria and the insurance providers who use it (e.g. Health Net, Inc., 2016). Thus, for Medicare beneficiaries who meet the other eligibility criteria for medical necessity and would benefit from the regular neurological assessment, 24-hour multidisciplinary care and intensive rehabilitation therapy unique to inpatient rehabilitation facilities, the inability to participate in the 15 hour per week "standard" should not qualify for exclusion or denial. It is unclear, however, whether the Medicare fiscal intermediaries or contractors are unfamiliar with this distinction and applying the 3-hour rule indiscriminately (UBC and AHA, 2007).

Finally, for those who do gain access to inpatient rehabilitation, the restricted, generally insufficient budget per person has led to tight management of the length of stay and the overall service provision (Paddock, et al., 2007), often discharging the persons with severe TBI to other less intensive facilities or home before completion of the recommended rehabilitation program (Hoffman, et al., 2012).

Impact of TBI, epidemiology and surveillance

As discussed above, the CDC provides a yearly update on the estimated national incidence of TBI (CDC, 2013). However, there are several limitations of these data. First, the national incidence of TBI is likely underestimated because data are typically based on administrative claims rather than clinical records (CDC, 2015; Faul, et al., 2010). Second, the CDC estimates are not necessarily representative of the whole U.S. population because only 20 of the 50 U.S. states have been funded to collect TBI incidence data. Third, the small sample size of the dataset limits the potential to perform sub-group analyses to investigate differences related to injury severity (i.e. mild, moderate, severe), patient demographics (e.g. age, race and ethnicity, geographical location) and mechanism of injury (e.g. motor vehicle accident, fall) (CDC, 2015). Data on injury severity is particularly important as persons with severe TBI are most likely to need costly long-term care and monitoring due to sequelae and medical complications/comorbidities (Corrigan, et al., 2014; Nakase-Richardson, et al., 2011; Whyte, et al., 2013a).

Another problem is that there is no surveillance system in place to track prevalence, TBI-related disability, long-term functional outcomes, treatment efficacy, or cost of care following acute hospitalization (CDC, 2015). This problem is a result of the fragmented and siloed structure of the healthcare system in which a variety of unrelated post-acute care facilities (e.g. IRFs, LTACs, SNFs) provide care for persons with TBI. As such, there is no mechanism for long-term data collection for individual patients that is linked across the different types of facilities within the system. This problem is exacerbated by the complex sequelae and unpredictable course associated with severe TBI. In many cases, persons become "lost to follow-up" following discharge from the acute care setting, and have limited or no option to re-connect with upstream providers. A notable exception is the TBIMS Program. The TBIMS Program, which is under the auspices of NIDILRR, collects follow-up data on persons who received care in a TBIMS hospital on a fixed schedule across their lifespan.

Due to the lack of an effective surveillance system, we do not have a true national estimate of the prevalence of TBI and its associated disability, cannot examine variation in TBI-related disability by important sub-groups (e.g. race and ethnicity, geographical location, injury severity, complications, co-morbidities, service usage), cannot monitor yearly trends, and cannot identify where, how, and at what

cost these persons are being cared for (CDC, 2015). While evidence is clearly necessary to inform clinical practice, it is unclear which data, specifically, are used to develop coverage guidelines. Further, complete and valid estimates of TBI are essential for targeting prevention, predicting outcomes, monitoring clinical changes over time, addressing future care needs, identifying best practices, and implementing cost-effective treatments (Barker-Collo and Feigin, 2009; Thurman, et al., 1999).

Ethical considerations in severe TBI

There is a common misperception among acute care providers that severe brain injury with persistent loss of consciousness indicates a poor prognosis and is likely irreversible (Fins, 2009). The view that, "there is no hope for meaningful recovery," after severe TBI is often expressed to families in the intensive care setting. This practice adversely influences the care of persons with severe TBI and undermines proper diagnosis and access to treatments (Fins, 2013). For instance, physicians may urge surrogates to agree to a do-not-resuscitate order or to a decision to withdraw life-sustaining therapy. There may also be premature and over-zealous attempts to convince family members to consider organ donation, during the period in which survival is uncertain (Fins, 2013). A balance needs to be struck between preserving the right to die and affirming the right to care for those who need and desire it (Fins, 2004; Fins, 2006). The process of obtaining informed consent, of which resuscitation is one component, should acknowledge the prognostic uncertainties that exist in the first few weeks following severe TBI so that families and surrogate decision-makers have the benefit of full disclosure before making a determination. The discussion should include the broad range of outcomes possible and the time course for recovery following severe TBI.

Once it is clear that the person will survive the initial injury, family members and surrogates, may encounter placement and discharge pressures after the person is perceived to be medically stable, or the acute healthcare coverage has expired. Discharge decisions often occur with little warning, leaving surrogates scrambling to make a choice about where their loved ones will be placed. This notification often occurs without sufficient opportunity to thoroughly evaluate placement options, causing considerable anxiety as families lose the shelter of hospital, even as persons are still medically unstable. Among persons with severe TBI who are granted admission to an acute brain injury rehabilitation center, length of stay is limited and governed by 'medical necessity', which requires evidence of ongoing improvement to warrant additional treatment. Persons who fail to improve in line with payer guidelines are transferred to nursing homes that are often ill-equipped to meet the needs of the person and expectations of their families. In some cases, persons are transferred directly from the acute hospital to nursing homes that are unable to manage complex neurological and medical issues due to limitations of their insurance coverage.

The reality is that an unknown proportion of persons are relegated to custodial care early in their recovery and may go years without careful neurological reevaluation or repeat imaging studies to ensure that complications such as normal pressure hydrocephalus have not developed. Similar to displaced persons who have lost their nationality, such patients are no longer on the radar and disconnected from mainstream rehabilitation services (Fins, 2013). This is a critical gap in the existing

healthcare system as meaningful late recovery occurs in approximately 1 in 5 persons with prolonged disturbance in consciousness caused by severe TBI (Katz, et al., 2009; Nakase-Richardson, 2011).

Some have suggested that healthcare is seen as a commodity in the U.S., like food, shelter, clothing and other private consumption goods. As long as access is contingent upon affordability, some persons will always be marginalized. To achieve a more equitable distribution of services as has been accomplished in other countries, healthcare must adhere to the *principle of social solidarity*, in which it is viewed as a social good (Cheng, 2014).

III. Proposed strategic initiatives

A first step toward improved access to healthcare across the lifespan for persons with severe TBI is the crafting of a strategic plan. We propose a focus on the following five areas of need:

Surveillance:

9. Action Needed: Develop and administer a surveillance system that tracks the incidence, prevalence, cost, and burden of severe TBI across settings from acute care through community reentry. Current efforts only count new cases of TBI, underestimating the total size of the population receiving care.

   Responsibility: CDC

This large-scale surveillance system would provide more granular data within several segmentation patterns (e.g. demographic subgroups, injury severity) to improve patient care, predict functional outcome, and estimate costs.

A better understanding of how the incidence of TBI varies over time within population subgroups (e.g. age, race, ethnicity, mechanism of injury) is needed to estimate future costs associated with patient care. Data sources currently used to examine TBI-related hospitalizations and ED visits have not had sufficient sample sizes to produce single-year estimates within demographic subgroups or injury severity. As a result, cost projections cannot be reasonably estimated (CDC, 2015).

Improved individual patient characterization (e.g. mechanism of injury, co-morbidities, acute complications) *within* severity subgroups (i.e. severe, moderate, mild) is needed to more precisely target care needs, predict outcome, and project costs (CDC, 2015).

Information concerning the type, duration, and frequency of healthcare services received (e.g. SLT, PT, OT, cognitive rehabilitation, psychology) is needed to better understand the degree to which outcome is influenced by rehabilitative treatment. Current CDC estimates are limited as the data is typically based on healthcare claims rather than clinical information (CDC, 2013).

Indicators of TBI-related *disability* should be added to large, existing national health surveys (e.g. the National Health Interview Survey), and administrative datasets to produce population-level estimates of disability. Disability measures should be multi-dimensional so they can capture changes in physical, cognitive, psychosocial and psychological/emotional function over time. Currently, no true national or state-level estimates of TBI-related disability, change in nature and degree of disability over time or frequency with which different levels of functional outcome are achieved. Consequently, it is not possible to predict which services will be required at which points in the recovery trajectory (CDC, 2015).

***Confirmation of Medical Necessity of Service*:**

10. Action Needed: Post-acute service authorization guidelines that require "active participation" in rehabilitation therapy services for at least 15 hours of therapy per week (i.e. "3-hour rule") to establish medical necessity for admission to an inpatient rehabilitation program (see InterQual criteria, sections 110.2.2* and 110.2.3) should not be applied to persons with severe TBI. Authorization guidelines should state that medical necessity for inpatient rehabilitation is demonstrated by the unique need for, a) specialized daily medical management and neurologic monitoring to restore physical and cognitive health and to prevent complications, b) specialized assessment procedures required for differential diagnosis, prognostication and determination of treatment needs, c) specialized behavioral and pharmacologic interventions to promote recovery of consciousness, orientation and basic self-care activities and d) caregiver education and training.

    **The patient must reasonably be expected to actively participate in, and benefit significantly from, the intensive rehabilitation therapy program that is defined in section 110.2.2 at the time of admission to the IRF. The patient can only be expected to benefit significantly from the intensive rehabilitation therapy program if the patient's condition and functional status are such that the patient can reasonably be expected to make measurable improvement (that will be of practical value to improve the patient's functional capacity or adaptation to impairments) as a result of the rehabilitation treatment, as defined in section 110.3, and if such improvement can be expected to be made within a prescribed period of time. The patient need not be expected to achieve complete independence in the domain of self-care nor be expected to return to his or her prior level of functioning in order to meet this standard.*

    Responsibility: TBD

The primary healthcare needs during early recovery from severe TBI are: daily medical management and neurologic monitoring to prevent complications and restore physical health; specialized assessment procedures to establish differential diagnosis, accurate prognosis, and case-specific treatment needs; specialized behavioral and pharmacologic interventions to promote recovery of consciousness, orientation, and independent self-care; and caregiver education and training (Giacino, 2015).

Contrary to the InterQual criteria, there is no empirical evidence to recommend a minimum number of hours of therapy to be administered per day or week (Giacino, et al., in preparation). The InterQual

criteria prevent patients from being properly assessed to determine whether, and at what level, they can engage in the rehabilitation process. Patients who are not authorized for comprehensive inpatient rehabilitation services are typically transferred directly from the acute care hospital to a low-intensity setting (e.g. nursing home or other custodial care facility). These low-intensity settings cannot meet the primary healthcare needs of persons following severe TBI. For instance, they are poorly-equipped to prevent, detect, and manage complex medical complications (e.g. central hyperthermia, pneumonia) that often occur after severe TBI. In these facilities, patients will not receive intensive rehabilitation, and might develop complications of immobility, including bedsores and decreased range of motion (Giacino, et al., 2014).

An alternative model would allow all medically-stable persons to receive a minimum period of acute rehabilitation to enable comprehensive assessment by specialized brain injury personnel to identify those who are most likely to benefit. Upon completion of this assessment period, persons expected to benefit from specialized interventions would continue in acute rehabilitation, while those who are deemed unlikely to benefit would be sent to sub-acute or chronic care venues (Whyte & Nakase-Richardson, 2013) with the option to return to acute rehabilitation if subsequent re-assessment identified the patient would benefit from specialized interventions.

Recent studies demonstrate a high burden of medical complications and comorbidities (Ganesh, et al., 2013; Whyte, et al., 2013a) and high rates of rehospitalization in persons with severe TBI and persistent alterations of consciousness (Nakase-Richardson, et al., 2013). There is evidence that these complications are associated with reduced functional recovery, and that their rate can be reduced by active medical management by clinicians with expertise in severe brain injury (Whyte, et al., 2013a). Although understudied, one presumes that these complications increase the lifetime cost of care.

Among the most severely injured patients, including those in VS (i.e. unconsciousness), most will recover consciousness. However, this recovery may go unnoticed without the use of specialized assessment procedures performed by well-trained, experienced clinicians. Alarmingly, studies consistently show that 38-43% of persons believed to be unconscious retain at least some conscious awareness (Andrews, et al., 1996; Childs, et al., 1993; Schnakers, et al., 2009).

A growing body of converging evidence involving persons with severe TBI and disturbance in consciousness on admission to acute inpatient rehabilitation centers indicates that the average rate of recovery is relatively rapid during the sub-acute phase, and a surprisingly high proportion of patients recover substantial function at long-term follow up (Katz, et al., 2009; Nakase-Richardson, et al., 2011; Whyte, et al., 2013b). In a recent report on 396 patients with DOC admitted to the TBIMS Program without evidence of command-following on admission to rehabilitation, 66% regained this ability by rehabilitation discharge, 68% were discharged home to live in the community, and 20% regained functional independence in the home environment between 1 and 5 years post-injury (Nakase-Richardson, et al., 2011). There is also evidence that suggests deferring comprehensive inpatient rehabilitation services increases the risk of medical complications requiring re-hospitalization, increasing the probability of prolonged disability and unfavorable functional outcome (Whyte, et al., 2013b).

11. Action Needed: For-profit entities (e.g. McKesson InterQual Criteria, Milliman Care Guidelines) that develop, disseminate and/or utilize clinical criteria for authorization of inpatient rehabilitation services should be required to release the scientific evidence upon which the current guidance is based.

    Responsibility: TBD

Minimizing bias and conflict of interest are critical to ensuring the acceptability, credibility, and scientific rigor of healthcare and insurance policies that guide decisions regarding authorization of rehabilitation services. The Institute of Medicine defines conflict of interest as, "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest" (IOM, 2011).

Disclosure of financial, business, and professional interests is the most effective method of mitigating conflict of interest. To minimize bias, entities that develop, disseminate, and/or utilize authorization guidelines should be required to publicly disclose potential professional, financial, or intellectual biases that could diminish the credibility of the guidelines in the eyes of users and consumers. Individuals (e.g. patients, families, proxies) and entities (e.g. IRFs, SNFs) impacted and governed by healthcare guidelines should have the opportunity to evaluate the training background, skill level, and potential competing interests of the guideline developers as well as the strength of the evidence used to support the guidelines.

***Development and Systematic Implementation of Disability Severity Metrics*:**

12. Action Needed: Standardized assessment measures that gauge severity of disability should be developed to ensure access to appropriate care for those at each juncture in the health trajectory (i.e. acute care, acute rehabilitation, sub-acute rehabilitation, post-acute rehabilitation, long-term care).

    Responsibility: CMS

Persons who sustain severe TBI demonstrate highly variable degrees and rates of recovery over time. Two individuals assigned the same GCS score in the ED may achieve markedly different outcomes by 6 or 12-months post-injury. Thus, standardized metrics are required to accurately gauge current areas of disability and assess the type of program and services that are most likely to improve person-centered outcomes. While measures of disability have been developed, all have significant floor and ceiling effects. For example, persons who sustain very severe TBI typically perform at the floor on the Functional Independence Measure (FIM), arguably the most widely-used disability outcome measure in the U.S. Consequently, the FIM cannot discriminate levels of disability within this cohort, may be insensitive to change until a higher level of function is attained and cannot distinguish different care needs within this range of function (Granger, et al., 1990).

The IMPACT Act of 2014 (H.R. 4994, 2014) called for the development of standardized quality measures to monitor medical, functional, cognitive and social needs across post-acute care settings. The intent of the Act is to enable information exchange and access to longitudinal information for providers to promote coordinated care, improved outcomes, and overall quality comparisons. To this end, CMS has developed the Comprehensive Assessment Reporting Evaluation (CARE) tool, however, this measure has not yet been tested in practice. The availability of a disability measure that provides a common frame of reference for assessing care needs among persons with severe TBI would facilitate determination of appropriate treatment intensity at each phase of recovery (i.e. acute, subacute, chronic). Such an instrument would also provide a means for reliably detecting change in the burden of disability over time, assessing the influence of treatment interventions on outcome and determining phase-specific costs of care.

Rehabilitation Needs Assessment and Management:

13. Action Needed: Personal injury insurance policies should include a provision that requires persons with severe TBI admitted to a Level I Trauma Center, ICU or acute care hospital to undergo evaluation by a pre-designated TBI specialist for admission to an inpatient rehabilitation setting, unless contraindicated by a co-morbid medical condition or surrogate preference. Such a provision should also entitle persons not recommended for inpatient rehabilitation services at the time of discharge from the acute care setting to receive an independent medical review prior to discharge.

    Responsibility: TBD

The spectrum of impairment associated with severe TBI ranges from coma to loss of independence in self-care and activities of daily living. As severe TBI results in damage to multiple brain networks, patients experience deficits across a variety of physical (e.g. sensory loss, motor impairment) and cognitive (e.g. attention, memory, executive control) domains that can fluctuate within and between days. Proper evaluation requires serial administration of empirically-calibrated measures by appropriately-trained TBI specialists. Acute care settings rarely have the time or expertise (Andrews, et al., 1996; Childs, et al., 1993; Schnakers, et al., 2009) to perform such assessments, jeopardizing appropriate decision-making regarding intensity of treatment (including the decision to withdraw care) and the need for acute inpatient rehabilitation (Whyte and Nakase-Richardson, 2013).

14. Action Needed: A case management system should be put in place for persons with persistent severe disability to ensure appropriate management of long-term needs, facilitate communication across providers, and provide an informed point-of-contact through all phases of recovery.

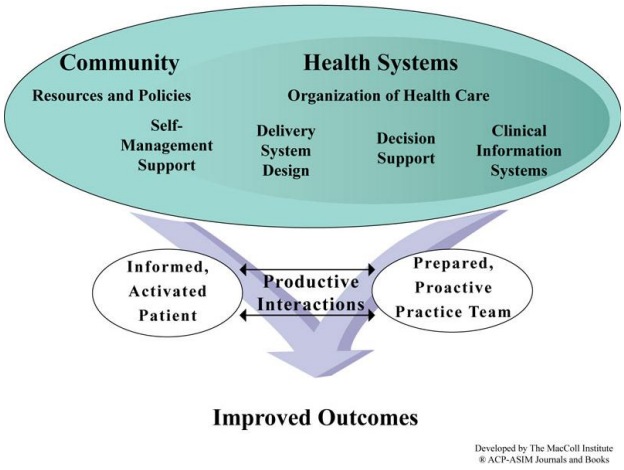
    Responsibility: CMS/TBD

15. Action Needed: Persons with severe TBI should receive authorization to undergo reevaluation with a brain injury specialist upon the order of a treating physician, when there is documented evidence of a decline or improvement in functional status that may require modification of the existing level of care.

    Responsibility: TBD

It is now well established that sustaining a TBI is not a discrete event, but an event that predisposes to co-morbidities, which may worsen over time and evolve into a chronic condition accompanied by permanent disability (Corrigan, et al., 2014; Wilson, et al., 1998). An added complexity is that the clinical trajectory of persons who sustain severe TBI is difficult to predict and often variable, particularly during the first 12 months post-injury. In view of these disease characteristics, there is a need to transition to a TBI-specific chronic disease management approach that is capable of addressing evolving issues both proactively and reactively to maintain health and promote functional recovery (Corrigan and Hammond, 2013). The Chronic Care Model (CCM) (Wagner, et al., 1996), which aims to transform the daily care of patients with chronic illnesses from a case-specific, reactive approach to one that is proactive, planned, and population-based (Coleman, et al., 2009), provides a useful framework for considering a more effective approach to TBI care.

Figure 5. The Chronic Care Model (ICIC, 2016).



Introduction to the Chronic Care Model

The CCM has been used extensively in the management of patients with chronic illnesses (e.g. diabetes (Chin, et al., 2007) and chronic heart failure (Asch, et al., 2005)) that, like severe TBI, require active management by the patient and/or their caregivers in association with ongoing interactions with multiple actors within the healthcare system (e.g. medical staff, care managers, payers) (ICIC, 2016). The CCM is designed (Figure 5) to optimize the patient's health and personal satisfaction through planned interactions with the healthcare team, access to community resources, integrated decision support, and clinical information systems (e.g. patient registries) that capture and use relevant clinical information (Coleman, et al., 2009). These elements facilitate productive interactions between active and informed patients, and healthcare providers that can offer resources and expertise. Such an approach has led to healthier patients, more satisfied providers, and cost savings in the management of other chronic diseases (Coleman, et al., 2009). Although the CCM is applicable to the long-term care of persons with severe TBI, we currently lack the knowledge-base and infrastructure required to effectively implement such a system of care.

Knowledge-base required to guide a TBI-specific (chronic) disease management approach
Over the last decade, there has been rapid expansion of knowledge concerning the long-term impairments, co-morbidities, and complications associated with severe TBI. However, several key questions must be answered to fully inform a TBI-specific (chronic) disease management approach.

1. *What pre-morbid co-morbidities (e.g. heart disease, diabetes) increase risk of developing post-injury medical complications?*
2. *Who has sufficient risk to be followed prospectively?*
3. *What co-morbidities develop post-injury that we should be on the lookout for, which could identify patients likely to benefit from preventive or early intervention?*
4. *What management strategies focusing on what complications would be most effective?*
5. *How does self-management have to be adapted for persons with executive dysfunction?*

These knowledge gaps can be addressed through a deeper investment in surveillance and funded research that supports population-based studies and demonstration projects that inform the development of infrastructure designed to enable long-term monitoring and coordinated care of patients across the lifespan.

Infrastructure required to implement a TBI-specific (chronic) disease management approach
The basic components required for a TBI-specific disease management approach are already contained within the existing healthcare system (see Figure 1). Key elements include well-equipped Level I trauma centers, LTACs, IRFs, sub-acute rehabilitation facilities, SNFs, comprehensive outpatient rehabilitation centers and community support programs. A major gap in the existing system is that the critical elements have not been integrated into a true "continuum of care" in which needs assessment and service delivery are centrally-managed. Communication across providers and facilities is poor leading to inconsistent goal-setting, fragmented care, increased risk of complications, and unfavorable outcomes. This situation is exacerbated further by the absence of a single-payor reimbursement system that accounts for evolving healthcare and disability needs across all phases of recovery.

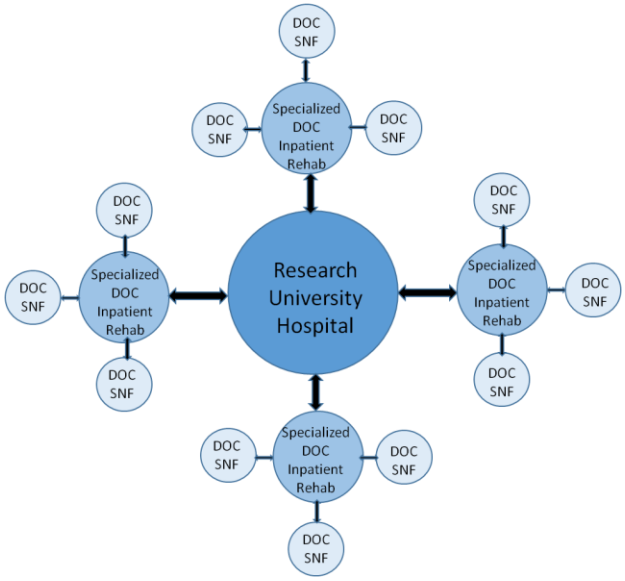
In keeping with the basic tenets of the CCM, a re-configured system of care tailored to the needs of persons with severe TBI was detailed in 2006 in The Mohonk Report to Congress (Berube, et al., 2006). The backbone of the recommendations centered on the creation of organized networks of institutions equipped to provide gradations of specialized TBI care. Each network would include three types of participating institutions (Figure 6):

1. Academic medical centers with Centers of Research Excellence (COREs) charged with acute medical management and expertise in cutting edge research involving persons with severe TBI.
2. Acute inpatient Rehabilitation Centers (ARCs) with specialized expertise in rehabilitative management of persons with severe TBI. These facilities would carry out daily medical management and neurologic monitoring protocols to restore physical and cognitive health and prevent complications, perform specialized assessment procedures required for differential diagnosis, prognostication and determination of treatment needs, implement specialized

behavioral and pharmacologic interventions to promote recovery of consciousness, orientation and basic self-care activities and conduct caregiver education and training.

3. Skilled nursing facilities (SNFs) with specialized programs for long-term management of persons with severe TBI who are unable to reside in community settings. These programs would receive payment incentives in exchange for commitment to participate in referral and data systems.

Figure 6. The "Mohonk Model" (Courtesy of John Whyte).



Each CORE would be linked to one or more ARCs and a larger number of SNFs, such that each system would be responsible for approximately 50 persons with severe TBI. This nationwide network of care would consist of three to five COREs, 10-15 ARCs, and their linked SNFs and other community resources. The SNFs would be the locus of long-term care within discrete geographical boundaries. Each SNF would have clinical and administrative management arms that would work collaboratively with the patient and their family and/or caregivers. Networks would have centralized case management to promote sharing of expertise, enhance communication across providers and allow freedom of movement within the network as clinical needs arise and wane. The case manager would also serve as the liaison between the provider network and the patient's primary caregiver or decision-maker.

Research Infrastructure

In contrast to the limited extent of infrastructure currently in place to support a chronic healthcare model, significant strides have been made in establishing large-scale, well-coordinated TBI research infrastructure. The National Institute on Disability, Independent Living and Rehabilitation Research ("TBI Model Systems"), National Institute on Neurological Disorders and Stroke ("Translating Research and Clinical Knowledge in TBI"), U.S. Department of Defense ("TBI Endpoint Development Project") and Veterans Administration ("VA Polytrauma Network") have all invested in substantial funding initiatives aimed at building collaboration and consensus regarding the most pressing research questions, optimal approaches to investigating TBI, the most effective measurement tools and best practices for translating research into practice and policy.

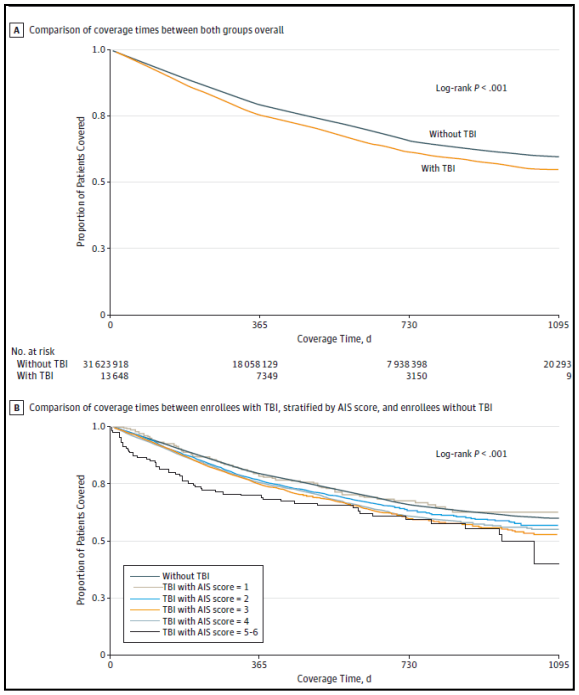
Ensuring Adequate Insurance Benefits for Catastrophic Injury:

16. Action Needed: Healthcare insurance plans should provide policy benefits that ensure adequate coverage for catastrophic injuries. Such policies should not contain fixed caps on the amount or duration of rehabilitation services, but instead should be based on individual assessment and determination of medical, rehabilitation and other healthcare needs.

    Responsibility: TBD

The chronic nature of many of the health issues that arise following severe TBI highlights the importance of ensuring access to rehabilitation services and maintaining adequate insurance coverage throughout the later phases of recovery. Yet, despite the unpredictability and chronicity of care needs attendant to this population, recent evidence suggests that TBI accelerates change in insurance coverage, especially among the most severely injured (Lin, et al., 2014). In a retrospective analysis of a large claims database of privately-insured Americans, Lin and colleagues reported that persons with severe TBI demonstrated the shortest median time to coverage change when compared to those without TBI (145 vs 258 days) (Lin, et al., 2014). Among patients with TBI (n = 13 558), there was a clear relationship between injury severity and time to change in coverage (see Figure 7). For example, persons with the most severe injuries experienced 44% shorter coverage relative to those without TBI.

Figure 7. Changes in coverage: enrollees with TBI vs. enrollees without TBI (Courtesy of Lin, et al., 2016).



The burden of co-morbid disease was also associated with accelerated change in coverage. Loss of employment coupled with disruption of employment-based health insurance can dramatically impact access to care and may have devastating effects on the financial stability of the nuclear family.

Beyond the obvious problems that can emerge as the result of even transient disruptions in health insurance, many persons in the U.S. are substantially under-insured for catastrophic injury. The benefits allocated through most healthcare plans do not provide sufficient coverage to fully implement the inpatient, outpatient and home-based rehabilitative interventions that have been developed to achieve optimal outcomes. Consequently, for many families, the only option is to liquidate their assets so they qualify for publically-funded healthcare benefits such as Medicaid. In 2012, Craig Hospital in Englewood Colorado, commissioned Milliman, an independent actuarial and consulting firm, to model the cost of various coverage limits for rehabilitation benefits for three catastrophic injury types (TBI, spinal cord

injury, and multiple traumas). Their analysis found that the cost of increasing the inpatient rehabilitation benefit limit from 30 to 60 days was $2.68, and from 60 to 90 days, $3.47. Similarly, the cost of increasing the outpatient visit limit from 30 to 45 visits was $2.42, and from 45 to 60 visits, $0.86 (Milliman Rehabilitation Limits Study commissioned by Craig Hospital, 2014). Based on these results, Craig Hospital recommended that individuals and employers purchase a minimum of 60-90 days of inpatient rehabilitation, durable medical equipment and outpatient therapy visits as medically necessary benefits. While healthcare costs following personal catastrophic injury are high, the incidence of severe TBI is low relative to the overall population. Bolstering healthcare coverage for catastrophic injury such as severe TBI is expected to have a significant favorable impact on all stakeholders.

IV. References

1. Alban RF, Berry C, Ley E, Mirocha J, Margulies DR, Tillou A, Salim A (2010) Does health care insurance affect outcomes after traumatic brain injury? Analysis of the National Trauma Databank. *Am Surg*, 76(10):1108-1111.
2. American College of Surgeons (2015) Best practices in the management of traumatic brain injury. Trauma Quality Improvement Program.
3. American Heart Association (AHA) (2012) Inpatient Rehabilitation Facilities Factsheet [online]. *AHA*. Available at: http://www.aha.org/content/12/12factsheet-irf.pdf [Accessed May 9, 2016].
4. Andelic N, Bautz-Holter E, Ronning P, Olafsen K, Sigurdardottir S, Schanke AK, Sveen U, Tornas S, Sandhaug M, Roe C (2012) Does an early onset and continuous chain of rehabilitation improve the long-term functional outcome of patients with severe traumatic brain injury? *J Neurotrauma* 29(1):66-74.
5. Andrews K, Murphy L, Munday R, Littlewood C (1996) Misdiagnosis of the vegetative state: Retrospective study in a rehabilitation unit. *BMJ* 313:13-16.
6. Asch SM, Baker DW, Keesey JW, Broder M, Schonlau M, Rosen M, Wallace PL, Keeler EB (2005) Does the collaborative model improve care for chronic heart failure? *Med Care*, 43(7):667-675.
7. Asemota AO, George BP, Cumpsty-Fowler CJ, Haider AH, Schneider EB (2010) Race and insurance disparities in discharge to rehabilitation for patients with traumatic brain injury. *J Neurotrauma*, 30(24):2057-2065.
8. Barker-Collo SL and Feigin VL (2009) Capturing the spectrum: suggested standards for conducting population-based traumatic brain injury incidence studies. *Neuroepidemiology*, 32:1-3.
9. Berube J, Fins J, Giacino J, et al. (2006) The Mohonk report: a report to Congress improving outcomes for individuals with disorders of consciousness. Charlottesville: National Brain Injury Research, Treatment & Training Foundation.
10. Bilmes L and Stiglitz J (2006) *The Economic Costs of the Iraq War: An Appraisal Three Years After the Beginning of the Conflict*. National Bureau of Economic Research: NBER Working Paper No. 12054.
11. BlueCross BlueShield of Texas (BCBSTx) (2016) Glossary of health terms. Available at: http://www.bcbstx.com/insurance-basics/understanding-health-insurance/glossary [Accessed 9th May, 2016].
12. Bradley CJ, Yabroff KR, Dahman B, Feuer EJ, Mariotto A, Brown ML (2008) Productivity costs of cancer mortality in the United States: 2000-2020. *J Natl Cancer Inst*, 100(24):1763-1770.
13. Brain Trauma Foundation (BTF) (2007) Guidelines for the Management of Severe Traumatic Brain Injury, 3rd Edition. *Journal of Trauma,* 24(Supplement 1):S1-S106
14. Brasure M, Lamberty GJ, Sayer NA, Nelson NW, MacDonald R, Ouellette J, Tacklind J, Grove M, Rutks IR, Butler ME, Kane RL, Wilt TJ (2012) Multidisciplinary Postacute Rehabilitation for Moderate to Severe Traumatic Brain Injury in Adults. (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2007-10064-I.) AHRQ Publication No. 12-EHC101-

EF. Rockville, MD: Agency for Healthcare Research and Quality; June 2012, Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

15. Brown ML, Yabroff KR (2006) Economic impact of cancer in the United States. In: Schottenfeld David, Joseph F Faumeni J., editors. Cancer Epidemiology and Prevention. New York, NY: Oxford University Press; pp. 202–214.
16. Buntin MB (2007) Access to postacute rehabilitation. *Arch Phys Med Rehabil*, 88:1488-1493.
17. Centers for Disease Control and Prevention (CDC) (2012) Guidelines for field triage of injured patients: Recommendations of the National Expert Panel on Field Triage, 2011, *MMWR* 61(1):1-20.
18. Centers for Disease Control and Prevention (CDC) (2015) Report to Congress on Traumatic Brain Injury in the United States: Epidemiology and Rehabilitation. *National Center for Injury Prevention and Control; Division of Unintentional Injury Prevention.* Atlanta, GA.
19. Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), Department of Defense (DoD), and Department of Veterans Affairs (VA) Leadership Panel (2013) Report to Congress on Traumatic Brain Injury in the United States: Understanding the Public Health Problem among Current and Former Military Personnel. *CDC, NIH, DoD, and VA.*
20. Centers for Medicare and Medicaid Services (CMS) (2014) Chapter 1: Inpatient Hospital Services Covered Under Part A Medicare Benefits Policy Manual Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-Ioms-Items/Cms012673.html [Accessed 9th, May 2016].
21. Chan L (2007) The state-of-the-science: challenges in designing postacute care payment policy. *Arch Phys Med* Rehabil, 88(11):1522-1525.
22. Cheng T-M (2014) Statement before the U.S. Senate Committee on Health, Labor, Education & Pensions Subcommittee on Primary Health and Aging hearing on “Access and Cost: What the US health care system can Learn from other countries”, March 11, 2014, Washington DC.
23. Childs NL, Mercer WN, Childs HW (1993) Accuracy of diagnosis of persistent vegetative state. *Neurology.* 43(8):1465-1467.
24. Chin MH, Drum ML, Guillen M, Rimington A, Levie JR, Kirchhoff AC, Quinn MT, Schaefer CT (2007) Improving and sustaining diabetes care in community health centers with the health disparities collaboratives. *Med Care*, 45(12):1135-1143.
25. Cicerone KD, Langenbahn DM, Braden C, Malec JF, Kalmar K, Fraas M, Felicetti T, Laatsch L, Harley JP, Bergquist T, Azulay J, Cantor J, Ashman T (2011) Evidence-based cognitive rehabilitation: updated review of the literature from 2003 through 2008. *Arch Phys Med Rehabil*, 92:519-530.
26. Cope DN, Mayer NH, Cervelli L (2005) Development of systems of care for persons with traumatic brain injury *J Head Trauma Rehabili,* 20(2):128-142.
27. Coleman K, Brian T. Austin, Cindy Brach and Edward H. Wagner (2009) Evidence On The Chronic Care Model In The New Millennium, *Health Affairs* 28(1):75-85.
28. Connelley RS and Thomas PW (2007) Solving the riddle of inpatient rehabilitation coverage *Healthcare Fiscal Management.* March, 2007.

29. National Institutes of Health Consensus Development Panel (1999) NIH Consensus Development Panel on Rehabilitation of Persons with Traumatic Brain Injury. *Journal of the American Medical Association*, 282:874-983.
30. Coronado VG, McGuire LC, Faul MF, Sugerman DE, Pearson WS (2012) Traumatic brain injury epidemiology and public health issues. In: Zasler ND, Katz DI, Zafonte RD, eds. Brain injury medicine: principles and practice. 2nd ed. New York, NY: Demos Medical Publishing.
31. Corrigan JD, Cuthbert JP, Whiteneck GG, Dijkers MP, Coronado V, Heinemann AW, Harrison-Felix C, Graham JE (2012) Representativeness of the Traumatic Brain Injury Model Systems National Database. *J Head Trauma Rehabil* 27(6): 391–403.
32. Corrigan JD and Hammond FM (2013) Traumatic Brain Injury as a Chronic Health Condition. *Archives of Physical Medicine and Rehabilitation* 94(6):1199-1201.
33. Corrigan JD, Cuthbert JP, Harrison-Felix C, Whiteneck GG, Bell JM, Miller AC, Coronado VG, Pretz CR (2014) US Population Estimates of Health and Social Outcomes 5 Years After Rehabilitation for Traumatic Brain Injury. *J Head Trauma Rehabi* 29(6):E1–E9.
34. Craig Hospital (2014) Employers urged to provide adequate catastrophic injury insurance (White paper). Mike Fordyce, President and CEO Hospital, Craig Hospital. Available at: https://craighospital.org/uploads/WHITEPAPERAUGUST2014.pdf [Accessed 7th May, 2016].
35. Cuthbert JP, Corrigan JD, Harrison-Felix C, Coronado V, Dijkers MP, Heinemann AW, Whiteneck GG (2011) Factors that predict acute hospitalization discharge disposition for adults with moderate to severe traumatic brain injury. *Archives of Physical Medicine and Rehabilitation* 92(5):721-730.
36. Cuthbert JP, Harrison-Felix C, Corrigan JD, Kreider S, Bell JM, Coronado VG, Whiteneck GG (2015) Epidemiology of Adults Receiving Acute Inpatient Rehabilitation for a Primary Diagnosis of Traumatic Brain Injury in the United States. *J Head Trauma Rehabil* 30(2):122–135.
37. DaVanzo JE, El-Gamil A, Li JW, Shimer M, Manolov N, Dobson A (2014) Assessment of Patient Outcomes of Rehabilitative Care Provided in Inpatient Rehabilitation Facilities (IRFs) and After Discharge. Final Report 13-127 Submitted to ARA Research Institute.
38. DeKosky ST, Ikonomovic MD, Gandy S (2010) Traumatic brain injury--football, warfare, and long-term effects. *N Engl J Med*, 363(14):1293-6.
39. Doctor JN, Castro J, Temkin NR, Fraser RT, Machamer JE, Dikmen SS (2005) Workers' risk of unemployment after traumatic brain injury: a normed comparison. *J Int Neuropsychol Soc*, 11(6):747-752.
40. Faul M, Wald MM, Rutland-Brown W, Sullivent EE, Sattin RW (2007) Using a cost-benefit analysis to estimate outcomes of a clinical treatment guideline: testing the Brain Trauma Foundation guidelines for the treatment of severe traumatic brain injury. *J Traum* 63(6):1271-1278.
41. Faul M, Xu L, Wald MM, Coronado VG (2010) *Traumatic brain injury in the United States: Emergency department visits, hospitalizations, and deaths 2002–2006.* Atlanta, GA: Centers for Disease Control and Prevention, National Center for Injury Prevention and Control.
42. Finkelstein ES, Corso PS, Miller TR (2006) The incidence and economic burden of injuries in the United States. New York, NY: Oxford University Press.
43. Fins JJ (2003) Constructing an ethical stereotaxy for severe brain injury: balancing risks, benefits and access. *Nat Rev Neurosci* 4:323-327.

44. Fins JJ (2006) Affirming the right to care, preserving the right to die: disorders of consciousness and neuroethics after Schiavo. *Palliat Support Care* 4:169-178.
45. Fins JJ (2009) Lessons from the injured brain: a bioethicist in the vineyards of neuroscience. *Camb Q Healthc Ethics* 18:7-13.
46. Fins JJ (2013) Disorders of Consciousness and Disordered Care: Families, Caregivers, and Narratives of Necessity, *Archives of Physical Medicine and Rehabilitation* 94:1934-1939.
47. Fins JJ, Plum F (2004) Neurological diagnosis is more than a state of mind: diagnostic clarity and impaired consciousness. *Arch Neurol* 61:1354-1355.
48. Frasca D, Tomaszczyk J, McFadyen BJ, Green RE (2013) Traumatic brain injury and post-acute decline: what role does environmental enrichment play? A scoping review. *Front Hum Neurosci*, 7:31.
49. Giacino JT, Ashwal SA, Childs N, Crawford R, Jennett B, Katz DI, Kelly JP, Rosenberg JH, Whyte J, Zafonte RD, Zasler ND (2002) The minimally conscious state: definition and diagnostic criteria. *Neurology* 58(3):349-353.
50. Giacino JT (2015) Building Capacity: Formal Introduction and Implementation of Recommendations for the Management of Persons with Disorders of Consciousness. *Full-day pre-conference instructional course presented at the 92nd Annual Meeting of the American Congress of Rehabilitation Medicine.* Dallas, TX
51. Goka RS and Arakaki AH (1991). Centers of excellence: choosing the appropriate rehabilitation center. *J Insur Med* 23(1):66-69.
52. Goka RS and Arakaki AH (1994-95) Brain injury rehabilitation; A continuum of care. *Journal of Insurance Medicine*, 26(4): 420-426.
53. Granger CV, Cotter AS, Hamilton BB, Fiedler RC, Hens MM (1990) Functional assessment scales: a study of persons with multiple sclerosis. *Arch Phys Med Rehabil*, 71:870-875.
54. Granger CV, Carlin M, Diaz P, Dorval J, Forer S, Kessler C, Melvin JL, Miller LS, Riggs RV, Roberts P (2009) Medical necessity: is current documentation practice and payment denial limiting access to inpatient rehabilitation? *Am J Phys Med Rehabil*, 88:755-765.
55. Griesbach GS, Kreber LA, Harrington D, Ashley MJ (2015) Post-acute traumatic brain injury rehabilitation: effects on outcome measures and life care costs. *J Neurotrauma*, 32(10):704-711.
56. Harrison-Felix DL, Whiteneck GG, Jha A, DeVivo MJ, Hammond FM, Hart DM (2009) Mortality over four decades after traumatic brain injury rehabilitation: a retrospective cohort study. *Arch Phys Med Rehabil*, 90(9):1506-13.
57. Health Net, Inc. (2016) National Medical Policy: Cognitive Rehabilitation Post Traumatic Brain injury (TBI) Available at: https://www.healthnet.com/static/general/unprotected/pdfs/national/policies/CognitiveRehabiCognitiveRehabi.pdf [Accessed 9th May, 2016]
58. Hesdorffer DC and Ghajar J (2007) Marked improvement in adherence to traumatic brain injury guidelines in United States trauma centers. *J Trauma*, 63(4):841-848.
59. Hirsch et al. (2001) fMRI reveals intact cognitive systems in minimally conscious patients. *Soc Neurosci Abst*, 27:529.14
60. Hoffman JM, Donoso Brown E, Chan L, Dikmen S, Temkin N, Bell KR (2012) Change in inpatient rehabilitation admissions for individuals with traumatic brain injury after implementation of the

Medicare inpatient rehabilitation facility prospective payment system. *Arch Phys Med Rehabil,* 93(8):1305-12.

61. Horn GJ and Lewis FD (2014) A model of care for neurological rehabilitation. *Journal of Nurse Life Care Planning*, 14(3):681-692.
62. H.R. 4994 (2014) IMPACT Act of 2014. To amend title XVIII of the Social Security Act to provide for standardized post-acute care assessment data for quality, payment, and discharge planning, and for other purposes. *113th Congress*, Available at: https://www.govtrack.us/congress/bills/113/hr4994 [Accessed May 9, 2016].
63. Humphreys I, Wood RL, Phillips CJ, Macey S (2013) The costs of traumatic brain injury: a literature review. *Clinicoecon Outcomes Res*, 5:281-287.
64. Improving Chronic Illness Care. The Chronic Care Model. Available at: http://www.improvingchroniccare.org/ [Accessed May 2, 2016].
65. Institute of Medicine (IOM) (2009) *Gulf War and Health, Volume 7: Long-term Consequences of Traumatic Brain Injury*. Washington, DC: The National Academies Press.
66. Institute of Medicine (IOM) (2011) *Finding What Works in Health Care: Standards for Systematic Reviews.* Washington, DC: The National Academies Press.
67. Jaffe KM and Jimenez N (2015) Disparity in rehabilitation: Another inconvenient truth. *Arch Phys Med Rehabil*, 96:1371-1374.
68. Jennett B, Plum F (1972) Persistent vegetative state after brain damage. A syndrome in search of a name. *Lancet* 1(7753):734-737.
69. Kane RL (2007) Assessing the effectiveness of postacute care rehabilitation. *Arch Phys Med Rehabil*, 88:1500-1504.
70. Kane WG, Wright DA, Fu R, Carlson KF (2014) Racial/ethnic and insurance status disparities in discharge to posthospitalization care for patients with traumatic brain injury. *J Head Trauma Rehabil*, 29(6): E10-17.
71. Khan F, Baguley IJ, Cameron ID (2003) Rehabilitation after traumatic brain injury. *Med J Aust*, 178(6):290-5.
72. Kunik CL, Flowers L, Kazanjian T (2006) Time to rehabilitation admission and associated outcomes for patients with traumatic brain injury. *Arch Phys Med Rehabil*, 87(12):1590-1596.
73. Langlois JA, Rutland-Brown W, Wald MM (2006) The Epidemiology and Impact of Traumatic Brain Injury: A Brief Overview, *Head Trauma Rehabil* 21(5)375-378.
74. Leibson CL, Brown AW, Ransom JE, Diehl NN, Perkins PK, Mandrekar J, Malec JF (2011) Incidence of traumatic brain injury across the full disease spectrum: A population-based medical record review study. *Epidemiology*, 22(6):836-844.
75. Lewis FD and Horn GJ (2015) Neurologic continuum of care: Evidence-based model of a post-hospital system of care *NeuroRehabilitation* 36:243-251.
76. Lin JA, Canner JK, Schneider EB (2016) Continuity of private health insurance coverage after traumatic brain injury. *JAMA Surg*, DOI: 10.1001/jamasurg.2016.0040 [Epub ahead of print].
77. Lorenz L and Katz G (2015) Severe brain injury in Massachusetts: Assessing the continuum of care. *Issue Brief: The Massachusetts Health Policy Forum (No. 45).*
78. Maas AIR, Stocchetti N, Bullock R (2008) Moderate and severe traumatic brain injury in adults *Lancet Neurol* 7:728-741.

79. Maas AIR (2016) The changing landscape of TBI care, its research and the role of neurosurgery. *11th World Congress on Brain Injury of the International Brain Injury Association*, The Hague, The Netherlands: March 2-5 2016.
80. Mariotto AB, Yabroff KR, Yongwu S, Feuer EJ, Brown ML (2011) Projections of the cost of cancer care in the United States: 2010-2020. *J Natl Cancer Inst*, 103(2):117-128.
81. Marr AL and Coronado VG (Eds.) (2004). *Central nervous system injury surveillance data submission standards—2002.* Atlanta, GA: Centers for Disease Control and Prevention, National Center for Injury Prevention and Control.
82. Masel BE (2009) *Conceptualizing Brain Injury as a Chronic Disease*. Vienna, VA: Brain Injury Association of America.
83. Masel BE and DeWitt DS (2010) Traumatic brain injury: A disease process, not an event. *J Neurotrauma*, 27:1529-1540.
84. Malec JF, Brown AW, Leibson CL, Flaada JT, Mandrekar JN, Diehl NN, Perkins PK (2007) The Mayo classification system for traumatic brain injury severity. *Journal of Neurotrauma*, 24(9): 1417-1424.
85. Mansour A and Lajiness-O'Neill R (2015) Call for an Integrative and Multi-Disciplinary Approach to Traumatic Brain Injury (TBI). *Psychology* 6:323-374.
86. Mazmanian PE, Kreutzer JS, Devany CW, Martin KO (1993) A survey of accredited and other rehabilitation facilities: education, training and cognitive rehabilitation in brain-injury programmes. *Brain Inj*, 7(4):319-331.
87. Medicare Learning Network (MLN) (2015) *Inpatient Rehabilitation Facility Prospective Payment System* Department of Health and Human Services Centers for Medicare and Medicaid Services (2015) Available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/InpatRehabPaymtfctsht09-508.pdf [Accessed 9th May, 2016]
88. Melvin JL and Medical Inpatient Rehabilitation Criteria Task Force (2006) *Standards for assessing medical appropriateness: Criteria for admitting patients to rehabilitation hospitals and units.* American Academy of Physical Medicine and Rehabilitation.
89. Menon DK, Schwab K, Wright DW, Maas AI, on behalf of The Demographics and Clinical Assessment Working Group of the International and Interagency Initiative toward Common Data Elements for Research on Traumatic Brain Injury and Psychological Health (2010) Position statement: definition of traumatic brain injury. *Arch Phys Med Rehabil* 91:1637-1640.
90. Miller HD (2010) Value-based payments, outcomes and costs. In Institute of Medicine (US) Roundtable on Evidence-Based Medicine; Yong PL, Saunders RS, Olsen LA, editors. Washington (DC): National Academies Press (US).
91. Ottenbacher KJ and Graham JE (2007) The state-of-the science: access to postacute care rehabilitation services. A review. *Arch Phys Med Rehabil*, 88:1513-1521.
92. Paddock SM, Escarce JJ, Hayden O, Buntin MB (2007) Did the Medicare inpatient rehabilitation facility prospective payment system result in changes in relative patient severity and relative resource use? *Med Care*, 45(2):123-30.

93. Relyea-Chew A, Hollingworth W, Chan L, Comstock BA, Overstreet KA, Jarvik JG (2009) Personal bankruptcy after traumatic brain or spinal cord injury: the role of medical debt. *Arch Phys Med Rehabil,* 90(3):413-9.
94. Richards PM and Kirk JW (2010) Traumatic Brain Injury Across the Lifespan: A Neuropsychological Tutorial for Attorneys. *Psychol Inj and Law*, 3:3-24.
95. Rodriguez SR, Mallonee S, Archer P, Gofton J (2006) Evaluation of death certificate-based surveillance for traumatic brain injury – Oklahoma 2002. *Public Health Rep*, 121(3):282-289.
96. Schnakers C, Vanhaudenhuyse A, Giacino J, Ventura M, Boly M, Majerus S, Moonen G, Laureys S. (2009) Diagnostic accuracy of the vegetative and minimally conscious state: Clinical consensus versus standardized neurobehavioral assessment. *BMC Neurol* 9(35):9-35.
97. Saverino C, Swaine B, Jaglal S, Lewko J, Vernich L, Voth J, Calzavara A, Colantonio A (2016) Rehospitalization After Traumatic Brain Injury: A Population-Based Study. *Arch Phys Med Rehabil*, 97(2 Suppl):S19-25.
98. Selassie AW, Zaloshnja E, Langolis JA, Miller T, Jones P, Steiner C (2008) Incidence of long-term disability following traumatic brain injury hospitalization, United States, 2003. *Journal of Head Trauma Rehabilitation,* 23(2):123-131.
99. Shi L and Singh DA (2017) Chapter 1 Major Characteristics of US Health Care Delivery In: Essentials of the U.S. Health Care System, Fourth Edition Jones & Bartlett Learning, LLC Burlington, MA (http://samples.jbpub.com/9781284100556/FrontMatter.pdf).
100. Smith JC and Carla Medalia (2015) U.S. Census Bureau, Current Population Reports, P60-253, *Health Insurance Coverage in the United States: 2014*, U.S. Government Printing Office, Washington, DC.
101. Stein SC, Georgoff P, Meghan S, Mizra K, Sonnad SS (2010) 150 Years of treating severe traumatic brain injury: a systematic review of progress in mortality. *J Neurotrauma* 27(7):1343-1353.
102. Teasdale G and Jennett B (1974) Assessment of coma and impaired consciousness. A practical scale. *Lancet* 13(2):81-84.
103. The Multi-Society Task Force on PVS (1994) Medical aspects of the persistent vegetative state. *N Engl J Med*, 330(21):1499-1508.
104. Thurman DJ, Alverson C, Dunn KA, Guerrero J, Sniezek JE (1999) Traumatic brain injury in the United States: A public health perspective. *Journal of Head Trauma Rehabilitation,* 14(6): 602-615.
105. TRACK-TBI (2016) Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) Clinical Protocol (Version 12), March 3 2016, Available at: http://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/Final%20TRACKTBI%20U01%20Clinical%20Protocol%20V12-March%203%202016%20Current.pdf [Accessed May 9, 2016].
106. TBIMS (2015) Traumatic Brain Injury Model System Presentation. *National Data and Statistical Center*, Available at: https://www.tbindsc.org/StaticFiles/Documents/2015%20TBIMS%20Slide%20Presentation.pdf [Accessed May 2, 2016].
107. Turner-Stokes L, Disler PB, Nair A, Wade DT (2005) Multi-disciplinary rehabilitation for acquired brain injury in adults of working age. *Cochrane Database Syst Rev*. 20(3):CD004170.

108. Turner-Stokes L, Pick A, Nair A, Disler PB, Wade DT (2015) Multi-disciplinary rehabilitation for acquired brain injury in adults of working age. *Cochrane Database Syst Rev*. 22(12):CD004170.
109. United BioSource Corporation (UBC) and American Heart Association (AHA) (2007) *Limiting access to inpatient medical rehabilitation: a look at payment denials for Medicare patients treated in inpatient rehabilitation facilities* [online]. Available at: http://www.aha.org/content/00-10/071003rehablcd.pdf [Accessed 8th May, 2016].
110. Veterans Affairs (VA) (2016) "Polytrauma/TBI System of Care". Available at: http://www.polytrauma.va.gov/system-of-care/index.asp [Accessed 9th May, 2016].
111. Wagner EH, Austin BT, Von Korff M (1996) Organizing Care for Patients with Chronic Illness. *Milbank Q,* 74(4):511-544.
112. Weinrich M, Stuart M, Hoyer T (2005) Rules for rehabilitation: an agenda for research. *Neurorehabil Neural Repair*, 19(2):72-83.
113. Whiteneck G, Melick D, Brooks C, Harrison-Felix C, Nobel K, Sendroy TM, editors. (2001) *Colorado Traumatic Brain Injury and Follow-up System*. Craig Hospital; Englewood, CO.
114. Whyte J and Nakase-Richardson R (2013) Disorders of consciousness: outcomes, comorbidities, and care needs. *Arch Phys Med Rehabil*, 94(10): 1851-1854.
115. Whyte J, Nordenbo AM, Kalmar K, Merges B, Bagiella E, Chang H, Yablon S, Cho S, Hammond F, Khademi A, Giacino J (2013a) Medical complications during inpatient rehabilitation among patients with traumatic disorders of consciousness. *Arch Phys Med Rehabil*, 94(10):1877-1883.
116. Whyte J, Nakase-Richardson R, Hammond FM, McNamee S, Giacino JT, Kalmar K, Greenwald BD, Yablon SA, Horn LJ (2013b) Functional Outcomes in Traumatic Disorders of Consciousness: 5-Year Outcomes From the National Institute on Disability and Rehabilitation Research Traumatic Brain Injury Model Systems. *Arch Phys Med Rehabil*, 94:1855-1860
117. Yabroff KR, Bradley CJ, Mariotto AB, Brown ML, Feuer EJ (2008) Estimates and projections of value of life lost from cancer deaths in the United States. *J Natl Cancer Inst*, 100:1755-1762.
118. Zaloshnja E, Miller T, Langlois JA, Selassie AW (2008) Prevalence of long-term disability from traumatic brain injury in the civilian population of the United States, 2005. *The Journal of Head Trauma Rehabilitation*, 23(6): 394–400.
119. Zaloshnja E, Miller TR, Coben J, Steiner C (2012) How often do catastrophic injury victims become Medicaid recipients? *Med Care*, 50(6):513-519.
120. Zhu XL, Poon WS, Chan CH, Chan SH (2007) Does intensive rehabilitation improve the functional outcome of patients with traumatic brain injury (TBI)? A randomized controlled trial. *Brain Injury*, 21(7):681-690.
121. Zorowitz RD (2009) Inpatient rehabilitation facilities under the prospective payment system: lessons learned. *Eur J Phys Rehabil Med*, 45:259-263.

Agenda

Rehabilitation Access and Outcome After Severe TBI:
A TBI Model System-Sponsored Stakeholder Summit

Purpose: Survivors of severe traumatic brain injury (TBI) and their families face enormous medical, personal, financial and familial challenges associated with this condition. Longitudinal studies indicate that persons with severe TBI are at increased risk of premature mortality, persistent cognitive impairment, and social isolation. Severe TBI typically evolves into a lifelong health condition, which may deteriorate further across the life span. Ongoing surveillance and proactive management are essential to health maintenance, independent function and participation in society. Despite these pressing needs, access to acute inpatient rehabilitation, the gateway to post-acute care, has progressively declined over the last 10 years. This invitational meeting will assemble a broad range of stakeholders to review recent scientific evidence regarding recovery from severe TBI, assess prevailing healthcare models and consider novel approaches intended to improve functional outcome while maintaining cost effectiveness.

Objectives: The summit is designed to generate two outputs: 1) compilation of the critical factors influencing regulatory policies concerning access to rehabilitation services across the lifespan of persons with severe TBI, and 2) a strategic plan that delineates the actions required to enact evidence-informed policy guiding authorization of post-acute rehabilitation services.

Date: May 16-17, 2016

Location: United States Access Board, 1331 F Street NW, Suite 1000, Washington, D.C

Organizer:
Joseph T. Giacino, PhD
Project Director, Spaulding-Harvard TBI Model System
Director of Rehabilitation Neuropsychology
Director, SRN Disorders of Consciousness Program
Spaulding Rehabilitation Hospital
300 First Avenue, Charlestown, MA 02129

Facilitators:

Ian D. Graham, PhD, FCAHS
Professor
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University of Ottawa, Ontario Canada
Senior Scientist, Centre for Practice-Changing Research
Ottawa Hospital Research Institute
Ottawa, Ontario Canada

Martha Hodgesmith, JD
Associate Director
Research and Training Center on Independent Living
University of Kansas
1000 Sunnyside Avenue
Lawrence, Kansas

Invited Stakeholders 1) TBI Research Centers: Spaulding-Harvard TBI Model System, Rocky Mountain TBI Model System, Moss TBI Model System, TIRR Memorial Herman TBI Model System, Indiana University TBI Model System, Shepherd Center, Ohio State University TBI Model System, NIDILRR Center on KT for Disability and Rehabilitation Research, TBI Model System Knowledge Translation Center, University of Kansas Research and Training Center on Independent Living, James A. Haley Veteran's Hospital, 2) Federal/Funding Agencies: Centers for Medicare and Medicaid Services, Centers for Disease Control and Prevention, National Institute of Neurological Disorders and Stroke, National Institute on Disability, Independent Living, and Rehabilitation Research, National Center for Medical Rehabilitation Research, Washington DC VA Medical Center, One Mind for Research, 3) Professional Organizations: American Congress of Rehabilitation Medicine, American Academy of Neurology, 4) Payors: Centers for Medicare and Medicaid Services, Paradigm Outcomes Corp., Travelers Insurance Co., Anthem Blue Cross, McKesson Health Solutions, 5) Consumer Advocacy Groups: Brain Injury Association of America, Brain Injury Association of Massachusetts, Supportive Living, Inc., 6) Health Policy Centers: University of Southern California Leonard D. Schaeffer Center for Health Policy and Economics, Ottawa Hospital Research Institute Centre for Practice-Changing Research, Brigham and Women's Hospital Center for Surgery and Public Health 7) Legislative Personnel

Deliverables: 1. Strategic plan to promote evidence-informed policies for appropriate access to rehab care for persons with severe TBI
2. White paper on the need for evidence-informed policy to support healthcare needs of persons with severe brain injury across the lifespan
3. Creation of Task Force on Severe TBI and Evidence-Informed Healthcare Policy

Rehabilitation Access and Outcome After Severe TBI:
A TBI Model System-Sponsored Stakeholder Summit

Agenda

SUNDAY, MAY 15, 2016

7:00 – 9:00 PM **Welcome Reception with Buffet Dinner**
Westin Washington, DC City Center Hotel, Monticello Ballroom

MONDAY, MAY 16, 2016

7:30 – 8:00 AM **Breakfast**

8:00 – 8:30 AM **Welcome, Introductions, Delineation of Charges**
Joseph T. Giacino, PhD
Spaulding Rehabilitation Hospital/Harvard Medical School
David Capozzi
U.S. Access Board
John Tschida, MPP
National Institute on Disability, Independent Living and Rehabilitation Research
Ross Zafonte, DO
Spaulding Rehabilitation Hospital/Harvard Medical School
Ian Graham, MA, PhD, FCAHS
Ottawa Hospital Research Institute

Severe TBI Landscape Analysis (Rapid-Fire Presentations)

Purpose: To increase understanding of existing gaps between clinical care, research, health service delivery and healthcare policy relative to persons with severe TBI

8:30 – 8:40 AM **So where do we start?**
Martha Hodgesmith, JD (University of Kansas)
Focus: Identification of the critical gaps between existing knowledge, care needs, access to healthcare and current healthcare policy relative to persons with severe TBI and their families

8:40 – 9:00 AM **Through the Looking Glass Part I: A Neurosurgeon's View of TBI Care**
Geoffrey Manley, MD, PhD (University of California San Francisco)
Focus: A clinician-scientist's perspective on the current status of health service delivery after severe TBI
Gap: Clinical needs v. availability of downstream health services

MONDAY, MAY 16, 2016 (cont.)

9:00 – 9:20 AM **Through the Looking Glass Part II: A Patient's View of TBI Care**
Scott Hamilton (San Francisco, CA)
Focus: A patient's personal perspective on negotiating the existing healthcare system
Gap: Personal needs v. availability of health and community support services

9:20 – 9:40 AM **Severe TBI in the U.S.: What are the Numbers?**
Juliet Haarbauer-Krupa, PhD (Centers for Disease Control and Prevention)
Focus: Summary of current knowledge concerning epidemiology of TBI focusing on limitations of existing epidemiologic data regarding severe TBI and implications
Gap: High burden and cost of care v. limited knowledge of epidemiology of severe TBI

9:40 – 9:55 AM **Coffee Break**

9:55 – 10:15 AM **Outcome Following Severe TBI: Bridging the Gap Between Evidence Practice and Policy**
J. Giacino
Focus: Review of recent evidence on long-term outcome after TBI highlighting the gaps between evidence and policy, guidelines, practice and research support (include some focus on importance of monitoring for medical complications as lead in to next talk).
Gap: Empirical evidence v. existing guidelines for clinical practice and reimbursement policy

10:15 – 10:35 AM **TBI as a Chronic Disease: Time for a Paradigm Shift**
John Corrigan, PhD (Ohio State University)
Focus: Review of recent evidence indicating that TBI requires a chronic disease management model
Gap: Need for a TBI-specific chronic disease management approach v. knowledge-base and infrastructure to guide and implement TBI-specific disease management

10:35 – 10:55 AM **Systems of Care: The Good, the Bad and the Ugly**
John Whyte, MD, PhD (Moss Rehabilitation Research Institute)
Focus: Comparative review (pros and cons) of models of rehabilitation health service delivery (e.g., front v. back-loaded) with discussion of an alternative vision of care
Gap: Clinical needs v. adequacy of existing model of health service delivery

MONDAY, MAY 16, 2016 (cont.)

10:55 – 11:15 AM **Where the Rubber Hits the Road: The Intersection of Clinical Care and Payment Models**

Seth Seabury, PhD (University of Southern California)
Barbara Gage, PhD, MPA (George Washington University)

Seabury Focus: Short-term cost savings may lead to higher later costs and worse outcomes.
Gage Focus: How existing payment systems influence access to appropriate care and how level of care impacts outcomes
Gap: Chronic care needs v. payment systems based on acute episodes of care

11:15 – 11:35 AM **The Struggle to Retain Personhood After Severe TBI: Ethical Issues, Rules and Rights**

Joseph J. Fins, MD (Weill-Cornell Medical College)

Focus: Impact of the existing system of care on the civil rights of persons with severe TBI
Gap: The civil rights argument for better care v. constraints of the current healthcare finance system

11:35 – 11:45 AM **Commentary on the State of TBI in the U.S.**

General Peter Chiarelli, U.S. Army General (Ret.) (One Mind)

11:45 – 12:00 PM **Q and A**

12:00 – 1:00 PM **Lunch**

Stakeholder Roundtable Sessions

Purpose: To identify barriers and promote solutions moving toward evidence-informed rehab policy from the perspective of diverse stakeholder groups

1:00 – 1:15 **Strategic Priorities and Workgroup Assignments**

J. Giacino

1. Surveillance
2. Medical necessity
3. Measurement of disability
4. Rehabilitation needs assessment and management
5. Ensuring adequate benefits

MONDAY, MAY 16, 2016 *(cont.)*

1:15 – 2:15 PM	**Roundtable Session I: The impact of existing policies and identification of barriers to enacting Strategic Priorities List items** *Moderators: I. Graham, M. Hodgesmith*
2:15 - 2:45 PM	**Session I Roundtable Group Reports** *Roundtable Leaders*
2:45 – 3:00 PM	**Session I Formulation and Analysis** *I. Graham, M. Hodgesmith*
3:00 - 3:15 PM	**Break**
3:15 – 4:15 PM	**Roundtable Session II: The impact of existing policies and identification of barriers to enacting Strategic Priorities List items** *Moderators: I. Graham, M. Hodgesmith*
4:15 - 4:45 PM	**Session II Roundtable Group Reports** *Roundtable Leaders*
4:45 – 5:00 PM	**Session II Formulation and Analysis** *I. Graham, M. Hodgesmith*
5:00 - 5:15 PM	**Closing Remarks/Plan for Day 2** *J. Giacino*
5:15 PM	**Adjourn**

TUESDAY, MAY 17, 2016*

7:30 – 8:00 AM	**Breakfast**
8:00 – 8:30 AM	**Summary and Discussion of Day 1** *J. Giacino* Review of points of consensus on barriers and solutions for each strategic priority
8:30 – 10:00 AM	**Development of Strategic Initiative Action Steps** *Moderators: I. Graham, M. Hodgesmith* For each strategic priority, determine: 1. What actions need to be taken? 2. What is the timeline for completion of each step? 3. What strategic partnerships are needed/available? 4. Which people/organizations will take responsibility for each step? 5. What additional resources are needed to implement the plan?

TUESDAY, MAY 17, 2016 (cont.)

10:00 – 10:15 AM	**Coffee Break**
10:15 – 12:15 PM	**Development of Strategic Initiative Action Steps *(cont.)*** *Moderators: I. Graham, M. Hodgesmith*
12:15 – 1:15 PM	**Lunch**
1:15 – 2:00 PM	**Discussion of Operational Plan** *Moderators: J. Giacino, I. Graham, M. Hodgesmith* 1. Steering committee? 2. Task Forces/Volunteers? 3. Communication plan (teleconferences)? 4. Funding?
2:00 – 2:45 PM	**Discussion of Dissemination Plan** *J. Giacino* 1. White paper/Proceedings? 2. Journal Commentary or Brief Communication? 3. Editorial? 4. Professional symposia?
2:45 – 3:15 PM	**Summary and Closing Remarks** *I. Graham, M. Hodgesmith, J. Giacino, R. Zafonte*

*Observers will participate in Day 1 only in view of potential COI issues

Copies of the briefing book, presenters' biographies and presentations are available at www.mghcme.org/spauldingtbi.

Notes