“Individuals who sustain traumatic brain injuries rarely have access to rehabilitation of sufficient timing, scope, duration, and intensity that would allow them to recover to the maximum extent possible. When a person’s care is delayed, discontinued, or denied altogether, the result is often increased re-hospitalization rates and greater levels of disability. This creates a cycle of joblessness, homelessness, and dependence on public programs.”

Susan Connors,
President and CEO of Brain Injury Association of America

Project Overview
In June of 2014, the Brain Injury Association of America (BIAA) and the Brain Injury Research Center at the Icahn School of Medicine at Mount Sinai announced to the public they were working collectively on a project to develop clinical practice guidelines for individuals with moderate to severe traumatic brain injury (TBI). At that time they were looking for clinicians and researchers who were experienced working in the field of post-acute rehabilitation to assist with this endeavor. Over 50 professionals from around the country were selected to participate in this historic project. The project is headed by a who’s who of brain injury professionals, including the project leaders and panel chairs listed on the right. A large component of a project of this nature is a transient process with public input. Visit www.biausa.org/tbiguidelines/tbi-rehabilitation-guidelines for an overview and updates.

"Guidelines for the Rehabilitation and Chronic Disease Management of Adults with Moderate to Severe TBI"

The TBI GUIDELINES PROJECT
What is it and why is it needed?

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The project itself is a three-year grant awarded by the BIAA to the Brain Injury Research Center at the Icahn School of Medicine at Mount Sinai. The principal focus is to develop guidelines for the ‘Rehabilitation and Disease Management of Adults with Moderate to Severe Traumatic Brain Injury.’ The objectives for the project are to: 1. Identify and fully describe the continuum of care available following TBI, including U.S., international and military model descriptions and analyses; 2. Develop evidence-based guidelines describing what diagnostic, treatment, preventative and other services should be provided to adults with moderate to severe TBI, in what setting(s) and/or phases after injury onset. These guidelines will be based on a review of the scientific literature and (where the literature is missing or significantly lacking in quality) on the consensus opinion of experts. 3. Disseminate these guidelines to stakeholders, including persons with TBI and their families, providers of medical, social, psychological and vocational services, payers, and policymakers.

Before providing the project details and processes, it is important to clearly understand the need for having guidelines for the treatment of moderate to severe TBI. By way of note, this is one of three articles related to the concept of clinical practice guidelines. The article entitled Evidence-Based Medicine: A Revolution in Healthcare outlines the movement away from the use of tradition and clinical acumen alone in the decision making process of patient care, toward the inclusion of evidence of efficacy in that process. The second companion article, titled Evidence-Based Guidelines: The Development and Dissemination Process, provides an overview of the rigorous methodology to be used in the guideline development process. Those articles set the groundwork for understanding the need for evidence and how guidelines are developed. Both articles are available as Continuing Education Units on our website, rainbowrehab.com. This article focuses on why guidelines for TBI rehabilitation are vital.

The Need for Guidelines: TBI is a serious problem
Annually, 2.5 million people incur a traumatic brain injury in the United States. This equates to more than 6,800 individuals daily. The annual incidence rate of TBI from 2007 to 2010 was 823 per every 100,000 individuals (Figure 1, above). The annual incidence of all cancers combined from 2007 to 2011 was 465 per 100,000. If you extrapolate the rate per 100,000 for all cancers combined, 3,786 individuals are diagnosed on a daily basis.

TBI clearly represents a national issue worthy of the thought, effort and funding that cancer so rightly is afforded. In addition, as shown in Figure 2, the rates of TBI are increasing. In 2001, the overall incidence rate was 521/100,000, and by 2010 that rate increased to 823/100,000. As the number at the bottom of Figure 2 shows in orange, the incidence rates for hospitalizations has increased, but not nearly to the degree that emergency department visits have in the last 10 years. In fact, death rates have remained largely the same leaving emergency department visits as the reason for the sharp rise.
TBI has substantial financial implications
In the year 2000, over 1.3 million people incurred a TBI. The total estimated cost associated with those 1.3 million injuries was $206 billion (in 2006 dollars). Fatal injuries comprised $135 billion of those costs. Non-fatal injuries accounted for $71 billion in medical costs and lost productivity. Of those non-fatal injuries $54 billion was for those who required hospitalizations, and $17 billion was for those who did not. This accounted for 15 percent of all injury costs in the US that year, as well as one percent of all medical spending.

The costs associated with TBI care are clearly problematic, and are part of the larger problem of rising healthcare costs in the U.S. By 2017, it is estimated that the overall health care costs will reach 19.5% of the total GDP. With nearly two-fold the injuries in 2010 as compared to 2001, the financial aspect of TBI is becoming increasingly more significant.

TBI has substantial social impacts
While the financial impacts are sizable, those may well be eclipsed by the individual social impacts TBI brings. Though the data is fairly limited, it is estimated that 3.2 million people are living with a disability as the result of a TBI. TBI can leave an individual with impairments in neuropsychological, psychological, cognitive, physical, behavioral and social domains. The latter two categories alone highlight the social impact of TBI, both on the individual living with the brain injury as well as their family/support network. Brain injury has often been characterized as isolating. For the individual living with a brain injury, there may be many losses as a result: loss of who they were prior to their injury, loss of social opportunities, loss of independence; loss of roles and the list goes on. For families, the list may be nearly duplicative, especially if they have become the primary caregivers for the injured person. Collectively, these losses, coupled with impairments in a variety of life domains, can result in decreased self-efficacy, fewer social contacts, and reduced life satisfaction to name a few.

To summarize thus far, rates of TBI are rising, the financial costs of TBI are significant and growing, and the social costs are even more consequential. What hasn’t been addressed yet, the elephant in the room of sorts, is the ubiquitous lack of access desperately needed for care and treatment after brain injury, particularly for those with the moderate to severe variety. Lack of access often means lack of funding. Lack of funding is seen in two different arenas—at the federal level in terms of the amount of money dedicated to research diagnosis, prevention and treatment. The other area where funding is lacking is at the level of the patient, where the rubber meets the road so to speak.

Lack of access to appropriate care
At the individual patient level, there are significant barriers in the way to successful access of care and treatment.
Putting this discussion in the context of the existing continuum of care will help to point out the deficiencies in care access. The top of Figure 3 outlines the continuum of care in brain injury. The left side of the continuum encompasses the acute (or hospital-based) side, while the right represents the post-acute (or non-hospital) side of the continuum. Not all individuals will need to access the entire continuum, nor does the continuum necessarily represent a linear path. But what the continuum does represent is the chance for people, after their lives changed in an instant, to reclaim themselves and to put the pieces back together to the greatest degree that they can.

For those who need the continuum to start the rebuilding process after injury, the barriers to actually accessing it are substantial and pervasive. Two of these barriers include the high cost of the specialized services needed at both the acute and post-acute ends of the spectrum, as well as the lack of available, adequate coverage to pay for those costs.

On the lower half of Figure 3, the bird’s eye view of brain injury coverage is shown and highlights the financial barriers to accessing the full continuum. The red area of the bars indicates, on the whole, inadequate coverage for those services in the continuum. The purple indicates a level of coverage that exceeds the “red” coverage. However, even within the purple areas, the level of coverage can be widely varied. An auto policy in one state may have a $50,000 limit on medical benefits, while another policy in another state may not have an arbitrary set limit. What this clearly highlights is insufficient access overall, and dismal levels of access to the post-acute side of the continuum.

Coverage itself is just one aspect of the access equation. Coverage does not necessarily equate to appropriate access. In the acute, medical management phase of treatment, the average length of stay (LOS) over time has steadily...
decreased from 27 days in 1990 to 15.8 days in 1996 as shown in Figure 4 (blue line). Likewise, data for acute inpatient rehabilitation (orange line) shows a large decline from 47.7 days in 1990 to 29.5 days in 1996, followed by a steady, though less pronounced decline from 2000-2008. When comparing the inpatient rehabilitation LOS (orange line) and FIM® Total Change data (green line) from 2000-2008, it is apparent that reduction in LOS did not correspond with concomitant gains in FIM® change scores. In fact, as LOS decreased, so too did FIM® change scores, indicating patients had fewer days in rehabilitation and left with less function, on average.

In another study which measured LOS in acute rehabilitation settings (from Oct. 2001-Dec. 2007), 67.5 percent of patients were discharged within 19 days of admittance (Figure 5, the red bars). This study set out to examine long-term outcomes post injury and found that 20.6 percent of the 13,700 patients had died within five years of their injury. For the patients who remained alive at five years post injury, 12 percent were re-hospitalized at least once, 57 percent were moderately or severely disabled, and 39 percent lost gains made in the first two years after their injury. The takeaway from this data is that patients are discharged "quicker and sicker," and mortality and morbidity declined at five years post injury, indicating poorer outcomes over time.

When examining LOS from a global perspective, shorter lengths of stay do not appear to benefit the patient. While some of the shorter LOS is attributable to advancements in medical care related to TBI, the FIM® data clearly points to some level of deleterious effect. If shorter stays were beneficial, we should expect equal or greater gains on average over time. Likewise, if shorter acute phase LOS was followed by intensive treatment at a post-acute level, acute LOS may well be a moot point. But what does the data tell us?
Discharge Disposition
In a recent study with a sample of 2,130 patients who received treatment in specialized brain injury inpatient rehabilitation settings (average LOS = 26.5 days), 84 percent discharged to a private home, 2 percent went to an acute care hospital, and 14 percent went to other post-acute settings (Figure 6). Using acute care LOS data from 1996 as a conservative example, these samples of moderate to severe TBI patients spent, on average, 42.3 days in acute settings (26.5 days from above + 15.8 days from Figure 4).

Discharge to home may mean outpatient or day treatment services, community-based services, or, quite likely, no or inadequate services secondary to funding limitations. By way of example, Medicare does not cover long-term care, state Medicaid Waivers typically cover short-term stays, health insurance policies typically have limited numbers of treatment sessions, (and not all cover cognitive rehabilitation), and the majority of property and liability coverages have limitations.

Why is this important?
In the past 40 years or so, a variety of improvements have led to a significant decrease in the mortality rate (the proportion of deaths to population) due to TBI. As Figure 7 shows, the greatest reductions in mortality (percentage by decade) occurred from 1970-1990 (reduction of 9 percent per decade), followed by a relatively stable death rate around 17 percent. Starting in the 1970s, greater numbers of individuals survived their injuries, with resultant, significant morbidity (the incidence of disease). This morbidity is now recognized for what it is—a chronic disease process.

Shedding the “injury” moniker in favor of “chronic disease” paints a clearer picture of TBI, particularly that of moderate and severe. Because many young people are seriously affected by TBI, more and more people will experience decades-long living with the effects.

Because the brain is the control center for our volitional as well as autonomic functions, when it is severely injured, the impact to the rest of our function and our health can also be severely impacted.

Research has shown, time and again, that TBI impacts our health directly and indirectly in myriad ways. A number of years ago, Brent Masel authored a BIAA white paper titled Conceptualizing Brain Injury as a Chronic Disease. He outlined the available research which showed that people with TBI had differential rates of co-morbid conditions than those of the general population. In doing so, the terms “disease-causative” and “disease-accelerative” became part of the brain injury vernacular. What these terms point to is that, if not for a brain injury, these patients would otherwise not have incurred certain health conditions, or, given a propensity for a health condition, the brain injury may have accelerated that condition.

Overall, TBI appears to clearly impact both mortality and morbidity. In terms of mortality, TBI reduces life expectancy by four years, and increases the likelihood of death by 1.5 times as compared to similar cohorts (same age, sex and race). Figure 8 reports causes of higher mortality and their increased likelihood for TBI patients one year post injury versus the general population. For example, after one year post-injury an individual is 49 times more likely to die of aspiration pneumonia than a similar individual from the general population.

TBI also impacts morbidity. There are a variety of conditions brought about by TBI, which in the absence of brain injury would otherwise be relatively unlikely to occur (Figure 9). Neurological (epilepsy),
musculoskeletal (spasticity), and psychiatric conditions (depression) are just a few areas affected post TBI.\textsuperscript{14} By chronicling TBI across the lifespan, and understanding the increased morbidity and mortality that comes with TBI, it is clear that significant care across the lifetime is needed. This care comes at significant cost and it would not be a leap of faith to suggest that by reducing some of the sequelae that contribute to these chronic comorbidities that costs, too, could be reduced. By showing that early rehabilitation on the post-acute side can reduce long-term costs of care, it is expected that the barriers to accessing care may then be addressed.

Early rehabilitation = Long-term cost reductions

Lynn Turner-Stokes evaluated two systematic reviews that looked at the efficacy of rehabilitation as well as cost effectiveness of rehabilitation following acquired brain injury.\textsuperscript{15} There were three findings of interest. First, the review found grade A (high level) evidence to support that rehabilitation can reduce ongoing care needs. Most significantly, the savings from these reduced care needs exceeded the original rehabilitation costs. Second, there was grade A evidence that for those returning to paid employment, the benefits of return to paid employment (i.e., salary) reduced costs to taxpayers and exceeded the cost of the intervention to return to work. Third, there was grade B evidence (moderate) that early, coordinated rehabilitation can result in cost savings to health service providers via reducing length of stay (without co-occurring reductions in function).

Wood et al, found that, on the post-acute side of the continuum, early rehabilitation resulted in reduced care needs.\textsuperscript{16} For these neurobehavioral patients, the length of time of admission to post-acute services related to the level of care reduction evidenced by three groups: those admitted within 24 months of injury, those admitted within 24-60 months post-injury, and those admitted after 60 months post-injury. The group treated within two years of injury showed higher reductions in care needs than those admitted later post-injury. While each group had some level of care need reduction, early intervention provided better outcomes. Across all three groups, the care need cost reductions were then estimated. The early intervention group corresponded to estimated lifetime cost savings of £1,098,020 (in 1998 British pounds, or roughly $1.7 million).

In 1995, the Brain Trauma Foundation developed a set of clinical guidelines for the treatment of acute hospital care for severe TBI. Despite wide dissemination of these guidelines, adoption was not universal. Interestingly, characteristics of the trauma center impacted guideline adoption rates. For example, for guidelines related to ICP monitoring, Level 1 trauma (versus Level 2 or 3) and centers with neurosurgery residency programs (versus those without) had the highest levels of compliance (68 percent and 76 percent respectively).\textsuperscript{17} Full compliance with the entire set of guidelines was only 16 percent, partial compliance was 17 percent leaving full non-compliance at 67 percent (as measured by not following at least ICP guidelines).

In 2007, Faul et al. completed a cost-benefit analysis to estimate the outcomes if the guidelines had been fully adopted.\textsuperscript{18} They estimated that with high compliance 3,607 lives would have been saved, and that even 50% compliance would have saved 1,305 individuals lives. The annual savings would have been in the neighborhood of $4.6 billion (Figure 9).

Collectively, these findings outline that rehabilitation not only provides tangible benefits to the patient, but that those efforts also result in tangible savings over the lifetime. The savings impact numerous arenas, including the taxpaying public, which then has implications for potential public policy change. For individuals with moderate and severe injury, the development of guidelines would be a wise investment towards improving lives through gaining access to appropriate and timely rehabilitation.

In the world of brain injury rehabilitation, it would surely be easier to conceptualize, let alone treat, if there were a single medical pathway to follow. But the reality of moderate and severe TBI is that care and treatment is very complex, because the brain is very complex. Whether examining...
acute care or post-acute care, complexity is abundant. In the last few years, researchers have begun to take a look at some of the factors that contribute to variability in treatment of moderate to severe TBI.

While a significant amount of research over the years has examined patient factors to explain outcomes, a newer tact has been to examine treatment center factors that impact patient outcomes. In 2013, Dahdah and colleagues looked to assess patient functional outcomes across TBI Model System inpatient rehabilitation centers.\(^\text{19}\) Overall, across 21 inpatient rehabilitation settings, they found substantial differences in patient outcomes. When analyzing the data, and controlling for patient level characteristics (e.g., demographics, injury severity, and functional deficits at admission) the differences in patient outcomes across the centers were significant. The authors postulated that the differences by center may point to structural variables such as the number of beds, budgets, equipment resources, staff experience, and the number or types of specialists available to patients.\(^\text{19}\)

A study in 2015 further elucidated this idea of institutional variation impacting patient outcomes in inpatient rehabilitation settings.\(^\text{20}\) They reported three notable findings. First, they found substantial variations in the program characteristics across the 10 participating centers (census size, referral flow, payer mix, bed numbers, specialty programs and resources), as well as substantial variations of patient characteristics (age, injury severity, functional status, date of injury to admission and LOS). Second, they found that the delivery of treatment services varied considerably across centers, particularly for OT, PT and SLP hours delivered weekly. Lastly, and the key here, they found that the \textit{center} characteristics explained substantially more variation in patient service delivery than did the \textit{patient} characteristics. Thus, it appears that institutional level processes, resources or preferences (for example, how many minutes of SLP to provide per day) rather than the patient’s overall clinical presentation (for example, the FIM\(^*\) Cognitive Score) dictate treatment practices. Perhaps an oversimplification of sorts, but the key point is that there is institution variation, and it does impact patient outcomes. What could clearly impact or reduce variability in clinical practice would be clear guidelines based on evidence of efficacy, which focuses on the patient’s clinical presentation. This is precisely the impetus for the Guidelines Project.

\textbf{TBI Guidelines}

The focus of the project is on individuals with moderate to severe traumatic brain injury, and the overarching goal is guideline development. The project scope addresses two very important areas—rehabilitation as well as disease management. The innovators of this massive undertaking include Wayne Gordon, Marcel Dijkers, Susan Connors, Brent Masel and Mark Ashley. Embarking on this project was no small feat. It took many individuals, whose collective vision was ultimately to positively impact the lives of people living with brain injury and their families, as well as those of us in the field dedicated to helping them realize their dreams after injury.

To fulfill this vision, a clear path must be followed. That path must include transparency and rigorous methodology to ensure that when all is said and done, the guideline development process is free and clear of bias, and crystal clear on its development methods. This rigorous methodology is outlined in the companion article \textit{Evidence-Based Guidelines: The Development and Dissemination Process}.

While there are many steps in a project of this scope, the main process of guideline development is outlined in Figure 10. Because brain injury results in such a wide array of functional deficits, and impacts every domain of life, the scope of the project is quite broad. To be able to manage such a wide scope, five separate panels were created, each with a project leader, with 10 professionals from around the country to participate in the panel. These panels are Behavioral, Cognitive, Functional, Medical and Participation/Vocational.

\begin{figure}[h]
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\includegraphics[width=\textwidth]{Steps_to_Systematic_Review.png}
\caption{Steps to a Systematic Review}
\end{figure}
To a degree, the systematic review process for this project entails five ‘smaller’ systematic reviews occurring simultaneously, one for each panel. The first step of initiating the systematic review has been completed. This entailed development of the standards for the review up front, establishment of the review team (a separate team for each panel), obtainment of input from stakeholders, management (i.e., minimization) of any conflict of interest or bias from participants, development of the review topic, development of the systematic review protocol and submission of the protocol for peer review with public availability to the protocol.

The next step, to find and assess individual studies for each panel, is the step currently in process. From the dozens of research questions developed in the Initiation of the Systematic Review phase (see PICOT sidebar), a massive literature search has begun. The steps involved in this search are highlighted in Figure 11, and show which steps are complete, in process, or incomplete. To date, the PICOT questions, along with the comprehensive set of search terms have been used to search formal databases such as PubMed, the Cochrane Library and the National Guideline Clearinghouse, to name a few. These searches have resulted in thousands of abstracts. Each of the panels team members are reviewing the abstracts for appropriateness, using a guided methodology for inclusion or exclusion from the process. Each abstract is reviewed by two panel members. If both determine it is not appropriate it is excluded. If both determine it is appropriate it is included. If the first review results in a difference of opinion, the two members work together through a process to obtain a final answer.

Once the final list of abstracts for each panel is decided, a team of data analysts read the full text articles, and then extract the key data elements for inclusion in the remaining steps of the process. The key remaining steps of finding and assessing individual studies must be completed, followed by synthesizing the entire body of evidence for each panel, and then reporting on the findings of the systematic review. Once the systematic review is complete, guideline development from each of the panels must occur, followed by the guideline dissemination process.

While a lot of work has been done thus far, much of the heavy lifting is yet to come. The coming years should bring about very exciting project movement, and every step toward guideline development for the rehabilitation and chronic disease management of adults with moderate to severe traumatic brain injury brings us closer towards the supreme goal of increasing access to the right care, at the right time for every person living with a traumatic brain injury.
The Evidence-Based Search Question: PICOT

In order to complete a systematic review, it is necessary to first develop concise clinical questions that lend themselves to finding appropriate literature when conducting a literature search. The searchable question is the key to finding any and all available evidence when developing evidence-based guidelines. If the question itself is written poorly, the output of the search may yield the same poor result.

PICO is a mnemonic to assist with understanding the elements needed to develop a searchable question. While there are numerous versions of question formats, the focus here is on the PICOT structure. The original formation was PICO (Davies, 2011), but the T is sometimes used, as are a variety of other variations. These are the PICOT elements:

- **P**  Population, Patient or Problem. Who are the subjects or the main disease or healthcare problem?
- **I**  This refers to the intervention, treatment or diagnostic tool that is being reviewed.
- **C**  This refers to comparison, or the main comparative intervention. What is being compared? In some cases it can also refer to the control group used in studies.
- **O**  This represents the measurements or desired outcome.
- **T**  This represents time frame.

So, how would this question look once all the elements are in place?

Do adults with diabetes mellitus, who are treated with medical nutrition therapy versus blood glucose monitoring alone, achieve and maintain blood glucose levels in the normal or close to normal range within six months?