Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury and

Defense and Veterans Brain Injury Center

Consensus Conference on

Cognitive Rehabilitation for Mild Traumatic Brain Injury

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Working Groups:

1. **Assessments**
2. **Interventions**
3. **Outcome Measures**
4. **Programs**

Introduction

Mild traumatic brain injury (mTBI), also known as concussion, is one of the invisible injuries of the current conflicts in Afghanistan and Iraq. The true incidence of military mTBI is unknown. This is similar to the civilian sector as some individuals with mTBI do not seek medical care or are not properly diagnosed. However, of the combat exposed U.S. military personnel who have served in Afghanistan and Iraq since 2001, there is a 15%-22% mTBI incidence rate by self report (Hoge et al., 2008, Terrio et al., 2009).

In the mTBI literature, it is reported that a substantial majority of civilian patients with mTBI (75-90%) have symptoms that are transient and self-limiting, with apparent full recovery occurring within minutes to several weeks following injury (Levin et al., 1997). However, approximately 5%-15% of persons with mTBI do not show the expected rapid and uneventful recovery and have persistent symptoms and/or functional limitations (Iverson et al., 2006; Ruff et al., 1996). Given the incidence of mTBI in the military, and the suspected high frequency of repeated mTBI, this percentage may represent a substantial number of warriors.

Differences exist between military and civilian populations regarding mTBI. There is no evidence to determine if the recovery trajectory for mTBI sustained in combat replicates that of the civilian cohort. Additionally, the high incidence of blast-related mTBI as well as the psychologically traumatic component of the source of the wartime injuries further complicates comparisons to civilians. Thus, it is possible that the number of patients with persistent symptoms is greater than 5% of all those sustaining mTBI in the military population.

There is strong consensus in the literature that persistent mTBI symptoms include cognitive and emotional sequelae that can result in significant functional impairment and disability. Cognitive rehabilitation is a well-accepted and common component of comprehensive rehabilitation for persons with moderate and severe TBI (Cicerone et al, 2005). A parallel situation does not exist in the area of mTBI. Clinical management for patients with mTBI symptoms typically has focused on prevention of "excess disability" through education to promote expectations of rapid and complete recovery; providing a "timeout" period to permit recuperation; avoidance of dangerous activities that could lead to secondary injury; and, using aggressive medical treatment to ameliorate symptoms (e.g., headache, sleep disturbance, dizziness, etc.) that can interfere with optimal recovery (Comper et al., 2005; DVBIC/BIAA educational references). However, clinicians currently face an increasingly large population of Wounded Warriors who have sustained mTBI and go on to develop chronic symptoms and functional limitations, including cognitive impairment.

To address this need, the Defense Centers of Excellence (DCoE) for Psychological Health and Traumatic Brain Injury and the Defense and Veterans Brain Injury Center (DVBIC) established a steering committee including members with expertise in TBI nursing, neurology, family practice, neuropsychology, occupational therapy, speech-language pathology, research, and psychiatry. Military representatives were selected by their respective Surgeons' General offices. This steering committee concluded that a two-day consensus conference was needed in order to develop a guidance document for the Services that addressed the issues of assessment, intervention, programs, and outcomes/efficacy as they relate to cognitive rehabilitation. DCoE and DVBIC co-

convened a two-day Cognitive Rehabilitation Consensus Conference on 27-28 April 2009 in Crystal City, Virginia and included 50 subject matter experts, from the Department of Defense, the Department of Veterans Affairs, civilian rehabilitation centers and academia. Civilian subject matter experts were selected by the steering committee. Representatives from each of the Services as well as the National Guard, Reserves, Special Operations, and Line also participated. The results of that consensus conference are contained in this document.

Cognitive rehabilitation will be used synonymously with terms such as neurorehabilitation, neuropsychological rehabilitation, cognitive remediation and cognitive retraining.

Central Tenets

Given the breadth of the field of cognitive rehabilitation, certain core tenets were required to define the approach by which these working groups accomplished the mission: 1) This guidance will address the needs of the Service Member who is 3 months or more post-concussion with persistent cognitive symptoms, and 2) While many of these patients may have co-morbidities (e.g. psychological and emotional issues, somatic symptoms, personality factors, etc.) that need to be considered, the focus of the working groups will center on where and how in the spectrum of care should cognitive rehabilitation be applied.

Methodology

Conference participants agreed that knowledge gaps exist and that ongoing and future research will further illuminate understanding and importance of cognitive rehabilitation for persons with mTBI. Despite these limitations, conference participants strongly agreed regarding the need for clinical guidance to providers.

The working groups focused on four areas: 1) Assessment, 2) Interventions, 3) Outcome measures, and 4) Program implementation. Participants considered the published literature and the Service-specific requirements and needs as well as resource limitations. The overall mission was to produce clinical guidance on cognitive rehabilitation regarding assessments, interventions and outcomes for Wounded Warriors experiencing chronic symptoms of mTBI.

The four discussion groups were formulated by specialty of background to include neuropsychologists, speech pathologists, occupational therapists, physical therapists, physiatrists, neurologists, psychiatrists, general practitioners, clinical psychologists, audiologists, and nurses reflecting a multidisciplinary approach to the consensus process. In addition, Special Operations Forces and Reserve Affairs participated.

Specific topics for discussion by these groups included: 1) Assessments, concentrating on who should receive cognitive rehabilitation services and how this population could be defined in a way that could promote consistent application throughout the Department of Defense (DoD); 2) Interventions, focusing on the specific cognitive rehabilitation strategies and scope of services that are to be

recommended for broad implementation; 3) Outcome measures, with emphasis on the aspects of patient and program data elements that should be captured so that future decisions on the efficacy of cognitive rehabilitation can be made with better information and, finally; 4) Programs, to investigate the recommended elements of a cognitive rehabilitation program, at the DoD and command level, which are necessary to maximize the probability of successful implementation. Each group used the provided seed questions as a basis for their discussions. Sample questions included:

- What is the threshold of a person for referral to cognitive rehabilitation? What types of clinics and what kinds of providers should be the referral source for cognitive rehabilitation?
- What impairments are being targeted? What are the treatment modalities and rehabilitation techniques that would best serve this population?
- What are the necessary program outcome measures? Similarly, what are reasonable patient outcome measures?
- Will one type of program be sufficient? Who comprises the rehabilitation team?
- How can cognitive rehabilitation be adapted to a particular setting? What are the training needs for the team members?

Cognitive Rehabilitation for Chronic Symptomatic mild TBI

The following consensus based recommendations were established using existing evidence-based reviews, with conference membership to include authors of these reviews, and expert clinical knowledge and experience from current cognitive rehabilitation programs within the DoD, DVA and in the civilian communities.

Assessment

Assessment is required to determine the clinical indication for cognitive rehabilitation and to guide the treatment plan as inappropriate enrollment could result in frustration to the patient and provider, misuse of time and resources and potential negative emotional and psychological sequelae for the patient. To best determine eligibility while ensuring open access, an initial evaluation by a TBI-experienced provider who is also familiar with other deployment-related health conditions (e.g. nurse, nurse practitioner or a physician assistant) in the primary care setting should establish that the patient is a

1) Service member (Active Component, Reserve Component, National Guard, Veteran). If Reserve Component/National Guard, determination of line of duty is required so as to establish eligibility of care within the Military Health System (MHS), and

2) Has a history of TBI (as established by standard DoD criteria) with self-reported persistent cognitive symptoms or signs of cognitive impairment.

Referral to the initial evaluation may be made by any provider. These cognitive symptoms may be observed/reported by the patient, family, community or any combination of the above. If the patient does not report cognitive symptoms but displays evidence of cognitive dysfunction on measures of objective screening or in his/her daily, social, or occupational functioning, then a referral should also be made.

The initial evaluation may occur in different settings (e.g., cognitive rehabilitation program or a primary care clinic with an embedded TBI-knowledgeable professional). The assessment should occur less than 30 days after the referral. The cognitive rehabilitation evaluation should be incorporated into a more comprehensive TBI referral and assessment process if one exists at an individual command.

The purpose of this initial evaluation is to answer the following questions: Has the person being referred sustained a TBI? If so, does the individual complain or present with cognitive symptoms? Does the individual present with other comorbidities that affect cognitive function?

This initial process should include a thorough intake history to include a description of the injury event and the duration of loss of consciousness or altered mental status, confirmation of TBI diagnosis, evaluation of ongoing symptoms [including completion of the Neurobehavioral Symptom Inventory (NSI), Posttraumatic Stress Disorder Checklist – Military or Civilian Version (PCL-M, PCL-C)] (Weathers et al., 1993; Blanchard et al., 1996), a mental health evaluation and an evaluation for chronic pain, sleep disorders and substance abuse. The following potential scenarios may result (see Figure 1):

1) Provider determines no cognitive symptoms are present with or without TBI. Education and reassurance to both referring provider and patient should occur.

2) Provider determines that there are no indications of TBI but cognitive symptoms are present. The provider should refer the patient back to the primary care provider for further evaluation of either a medical or a mental health condition.

3) Provider determines that other co-morbidities or other symptoms (i.e., chronic pain or substance abuse) are too severe for the patient to undergo cognitive assessment. An appropriate specialty clinic referral should be placed and a case manager assigned.

a) If a patient is referred to a specialty clinic, the patient should be re-evaluated for cognitive rehabilitation in 4 weeks in addition to receiving case management follow-up. This will ensure that these patients may still receive a cognitive assessment and that they are not lost to follow-up.

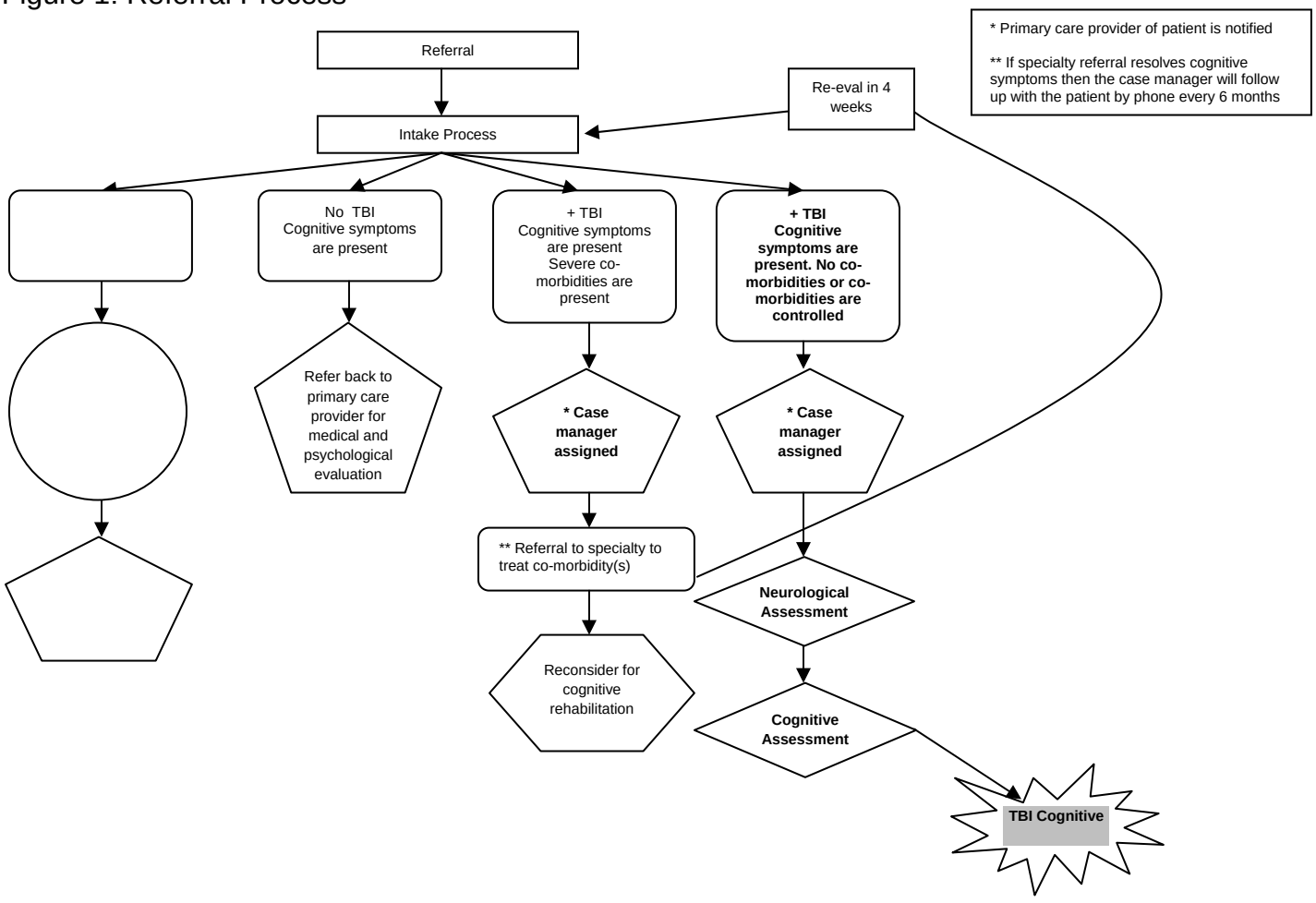
b) If the patient is referred to a specialty clinic and all the cognitive symptoms resolve, the patient should be followed monthly by telephone consultation by the case manager to ensure that the symptoms remain resolved for 6 months. If possible, “face-to-face” interviews are recommended if there is any uncertainty concerning how the patient reports changes in symptoms.

4) Provider determines that the patient has symptomatic mTBI and further cognitive assessment is indicated.

Any suspicion of a TBI with cognitive symptoms is reason for referral for further cognitive evaluation. Once a patient has undergone this initial process, a note should be sent to the patient's primary care provider and the referral source (if different) to ensure continuity of effective communication and treatment coordination.

Prior to cognitive assessment for cognitive rehabilitation, the patient must undergo a comprehensive neurological examination. During this time, any other medical conditions that may result in cognitive impairment should be evaluated and treated. This examination should also include a thorough review of the medical records to look for prior cognitive disorders. This comprehensive neurological examination does not need to be completed by a neurologist, but rather, by a physician with sufficient expertise and knowledge in the examination as well as in the medical work-up of cognitive symptoms. If no confounding findings are noted, the patient should next receive a comprehensive cognitive assessment.

Figure 1: Referral Process



The cognitive assessment should consist of a thorough neurobehavioral and cognitive evaluation using standardized performance and self-report measures, including measures of effort. This

assessment may be undertaken by an interdisciplinary group that includes a neuropsychologist, occupational therapist and speech-language pathologist, or a smaller group based on limited resources. This evaluation quantifies the current level of cognitive function and assists in the development of rehabilitation goals. An interdisciplinary process cannot occur at all military treatment facilities (MTF's) due to resource limitations. It may be that only one or two disciplines are available for the assessment/intervention or it may be that the assessment provider is different from the intervention provider. Both the assessment and intervention providers must be competent in evaluating persons with known or suspected TBI, and be capable of making appropriate differential diagnoses in complicated cases. In all situations, regardless of the necessary program structure, appointment of a team leader with close group communication and coordination are paramount to providing effective and efficient cognitive rehabilitation.

There are a variety of neurobehavioral assessment tools and approaches that are available. No one tool or approach is recommended over another. If a neuropsychologist is involved in the evaluation, American Academy of Clinical Neuropsychology (AACN) guidelines should be followed in the evaluation (AACN Practice Guidelines for Neuropsychological Assessment and Consultation, 2007). Key domains that should be evaluated prior to proceeding with cognitive rehabilitation are listed in Table 1. The process should consider an approach similar to the World Health Organization's (WHO) approach towards the purpose of assessments: to identify and describe strengths, deficits and effects of the deficits on capacity and function in every day activities; to identifying barriers to successful participation in rehabilitation (Carroll et al., 2004).

Table 1: Assessment Domains

- Attention
- Memory
- Processing Speed
- Executive Functioning
  - reasoning and problem solving
  - organizing, planning and self-monitoring
  - emotional regulation
- Post-Traumatic Stress Disorder (PTSD) Screen
- Post-Concussive Syndrome (PCS) Symptom Rating
- Pain Screen
- Symptom Validity Test
- Substance Abuse Screen
- Depression Screen

It is critical for the team to determine the primary factor contributing to symptoms (i.e., is mTBI the primary cause of the symptoms or is a co-morbidity such as major depression considered the primary contributor?) and to document this determination. The assessment tests should include a measure of motivation and engagement although a suboptimal result on any of these tests should result in further evaluation and not an automatic disqualification for consideration for cognitive rehabilitation as there are many potential reasons for poor engagement.

Upon completion of the cognitive assessment, the team should be able to determine the following:

1) What are the cognitive deficits associated with the diagnosis of TBI?

2) Is cognitive rehabilitation needed? Warranted?

3) What kind of rehabilitation? This should be patient specific and target return to function.

4) What are the short- and long-term goals (both functional and measurable)?

The cognitive assessment process may determine that a patient does not require a full cognitive rehabilitation program but rather a more limited program that assists with goal-setting and provides education on developing mental and emotional skills to improve day-to-day functioning (modeled after the Army Center for Enhanced Performance) or a short return-to-duty refresher training to increase confidence in one's ability to return to full duty. Malec and Basford (Malec & Basford, 1996) describe a range of postacute brain injury rehabilitation programs available in the civilian sector. Most cases resulting from mTBI in the military will be similar to "community re-entry" or "community services only" programs, the latter describing a structured, supervised, and supported return to community. Regardless, a patient should not be discharged from the cognitive assessment process without a planned intervention.

Finally, due to the increased risk of mood, anxiety and substance use disorders associated with TBI, cognitive assessment and rehabilitation should occur in conjunction with full mental health assessment, and mental health treatment as indicated.

Interventions

Despite the difference in combat related and non-combat related mTBI, there is presently no evidence to suggest that the resulting cognitive deficits are different between the military and civilian traumatic brain injured (Belanger et al., 2009). The following are interventions with demonstrated efficacy and utility for cognitive rehabilitation: direct attention training; selection and training of external memory/organizational aids; training in internal memory strategies; metacognitive strategy training; social pragmatics training (targeting self-perception, self-awareness, and social skills); environmental modification (more organized and less distracting environments); brain injury education for patients, family, and employers; and aggressive support but gradual reentry into community and vocational/educational activities. Comprehensive holistic rehabilitation provides integrated treatment of cognitive, emotional, interpersonal, and practical skills to improve community functioning and quality of life after TBI. In addition to remediating discrete cognitive impairments, this approach focuses on metacognition (e.g., awareness and self-appraisal) and emphasizes self-regulation of cognitive and emotional processes to improve quality of life despite persisting limitations (Cicerone et al., 2008).

Interventions for persistent postconcussion cognitive symptoms uniformly emphasize improvement in attention abilities (Gordon et al., 2006). Attention in all its various components (e.g., alertness, sustained attention, divided attention and alternating attention) is the prerequisite for basic as well as complex behaviors involving memory, judgment, social perception, and executive skills. Impairments

in attention will have direct effects on specific attention tasks, and substantial indirect effects on all aspects of a patient's behavior. Moreover, attention deficits often can masquerade as deficits in other cognitive functions. For example,”memory impairment" may be the downstream result of poor attention, with concomitant impairments for registration of information, thus degrading memory performance even in the absence of a true memory deficit.

Attention training was one of the earliest approaches to cognitive rehabilitation (Sohlberg & Mateer, 1989). It has been the subject of a number of well-designed studies and remains one of the cornerstones of cognitive rehabilitation interventions (Cicerone et al., 2000; Cicerone et al., 2005; Sohlberg et al., 2002; Sohlberg et al., 2003). Attention training has been a core element of diverse programs, ranging from single-service/single-provider programs to multidisciplinary "holistic" programs (Gordon, 2006) and numerous studies have confirmed its benefit (Sohlberg & Mateer, 2001; Cicerone, 2002). Moreover, attention training has been successful for remediating TBI-related cognitive disorders apparently far removed from attention dysfunction, as illustrated by a recent study showing the effectiveness of attention training for reading difficulties secondary to mild aphasia: "The positive gains noted for this individual's reading skills were felt to be the result of improvement in allocation of attentional resources rather than improvement in linguistic skills (Sinotte & Coelho, 2007).”

Attention process training is designed to improve attention skills through a set of standardized auditory and visual procedures made challenging by systematically increasing level of distractions. This intervention organizes attention and concentration tasks into subcomponents of sustained attention, selective attention, alternating attention, and divided attention. Training procedures place gradually increasing demands upon attentional capacity by using visual distractors, and noise and other audio distractors (standardized by using varying levels of noise and auditory distraction on audio CDs, printed cards of visual distractors, etc.), and combining single tasks into dual task procedures where the patient must alternate attention or divide attention across simultaneously presented procedures. Interventions for remediation of attention should incorporate a combination of direct attention training and metacognitive strategy training.

As mentioned above, poor memory often is an artifact of poor attention, and some memory deficits respond quite well to remediation of attentional problems. Moreover, memory training has had a controversial past. As noted in several recent comprehensive reviews, approaches based on repetitive drills, "memory as a muscle," have shown little evidence of efficacy (Rees, 2007; Schutz 2007). However, other approaches to memory training, generally those based firmly in cognitive neuroscience, have shown efficacy. For example, success has been shown with various mnemonic techniques and other memory-enhancing strategies that permit patients to develop techniques to enhance registration and encoding of information, as well as develop methods for searching their memory in order to improve memory retrieval (e.g. Kaschel et al., 2002). Of interest, Kaschel et al., (2002) report that memory strategy training is most effective for persons with mTBI and mild memory impairment, with decreasing effectiveness as injury severity and memory impairment increase.

External aids have been used to address both memory and executive function impairments. The majority of more recent memory training studies have focused upon the use of "memory notebooks"

and electronic equivalents, essentially serving as "memory prosthetics." A number of these studies have compared different memory notebook formats and training procedures to identify the most effective. For example, Ownsworth and McFarland (1999) compared two memory training procedures, one a Diary Only condition in which patients were taught the mechanics of using a diary, while in the other condition they received the diary training within a more comprehensive approach focusing on how the diary could be used to solve problems in daily activities, particularly when used proactively. Thickpenny-Davis and Barker-Collo (2007) combined strategy training with memory notebook training, using the added efficiency of a group format for an eight-session program, and found improvement in both the use of memory strategies as well as the use of memory prosthetics, with these improvements extending into patients' everyday memory functioning. For a review of the evidence examining efficacy of use of external aids for managing memory impairments, see Sohlberg et al., 2007.

Disorders of social pragmatics are common sequelae of more severe TBI. These disorders include symptoms such as reduced social sensitivity, difficulties with emotional and impulse control, and difficulty comprehending "nonverbal" social cues. Social skills training (typically within a group format) has shown effectiveness in improving these problems. For example, Dahlberg et al., (2007) describe the following program as effective, citing four key components: "The first was the use of co-group leaders from different clinical backgrounds (i.e. social work, speech-language pathology). This allowed for two clinical perspectives, two role models, and two clinicians collaborating and sharing their expertise. The second component was an emphasis on self-awareness and self-assessment, leading to individual goal setting. A third component was the use of the group process to foster interaction, feedback, problem solving, a social support system, and awareness that one is not alone. The final component was a focus on generalization of skills, addressed through the involvement of family and friends, and weekly assignments completed in the home or community…. Generally, sessions followed a consistent format: (1) review of homework, (2) brief introduction of the topic, (3) guided discussion, (4) small group practice, (5) group problem solving and feedback, and (6) homework (p. 1564-1565)." A major portion of this program utilized the Goal Attainment Scaling procedure developed by Malec (1999), which also has been used in numerous other programs to positive effect. Moreover, while Dahlberg describes this program as “training of social communication skills,” the above brief description clearly indicates that the program is more comprehensive and has many psychological and psychosocial components.

Disorders of executive functioning, including difficulties with behavioral and emotional regulation, are also common after more severe TBI. Interventions that incorporate training in problem solving orientation and emotional regulation, problem solving skills, self-monitoring and self-regulation have broad application in the treatment of attention, memory, communication, and executive function deficits (Rath et al., 2003; Cicerone et al., 2008).

A robust literature supports the use of metacognitive strategy training as an intervention for executive function impairments due to TBI. At least five randomized control trials have evaluated executive function outcomes from training use of multiple step strategies, strategic thinking and/or multitasking. In an early study, positive outcomes were reported from problem solving therapy where patients were taught to identify problems and solutions, weigh the pros and cons of solutions and monitor

performance (vonCaramon et al., 1991). Subsequently, a goal attainment scaling technique was shown to have specific positive results on goal setting (Webb & Gluecauf, 1994). Fasotti and colleagues (2000) showed improved problem solving and solution generation with a step by step time pressure management approach. Similarly, a step by step task completion strategy, Goal Management Training, was shown to improve proofreading skills (Levine et al., 2000) in a group of participants with brain injury. Finally Rath et al., (2003) showed positive effects of group therapy aimed at improving emotional self regulation by the use of a problem-solution orientation.

A similar "holistic" focus is seen in Tiersky et al., (2005), who focused on cognitive rehabilitation of mTBI. These authors compared a manualized program of cognitive rehabilitation in conjunction with cognitive behavioral therapy, comparing it to a program that consisted of cognitive rehabilitation only. The 11-week, three times per week, cognitive rehabilitation program focused primarily on attention, information processing, and memory, although the authors note that organizational and problem-solving skills were addressed throughout the cognitive retraining program "because these abilities are a corollary of memory and attentional skills (p. 1568)." The cognitive behavioral therapy (CBT) arm was a relatively traditional application of CBT and focused on increasing the use of adaptive coping, reducing levels of distress, training in methods of preventing relapse, and improving acceptance of sadness and loss related to cognitive and physical impairments.

Clinical experience with Wounded Warriors suggest that a comprehensive holistic approach, which provides individual and group therapies within an integrated therapeutic environment, addresses the functional impairment and disability resulting from cognitive and emotional sequelae of chronic symptomatic mTBI. Involvement of family members and the Service Member's Command is highly encouraged to optimize rehabilitation outcomes. Group therapy in addition to individual therapy provides a supportive context for rehabilitation and reinforces the concept of unit cohesion in military culture. The above studies are but a sample of those leading the Intervention Group to its primary conclusions regarding cognitive rehabilitation interventions. The following table succinctly describes some of the empirically supported inventions including specific examples targeting cognitive domains affected by TBI.

Table 2: Interventions

Area of Cognitive			
Memory	Various mnemonic techniques	Story method Acronyms Sentences/ acrostics Method of loci Chunking Repetition	Ryan & Ruff, 1988 Berg et al., 1991 Thickpenny-Davis & Barker-Collow, 2007
	Visual imagery mnemonics	Imagery based training	Kaschel et al., 2002 Westerberg et al., 2007 Glisky & Glisky, 2002
Executive functioning **Social pragmatics**	Social communication skills training groups	Group cognitive therapy	Dahlberg et al., 2007 Levin et. al., 1997

Attention **Memory** **Executive functioning** **Social pragmatics**	Integrated use of individual and group cognitive, psychological and functional interventions	Cicerone et al., 2008 Rattock et al., 1992 Sarajuri et al., 2005 Goranson et al., 2003 Carney et al., 1999 Cicerone et al., 2000 Cicerone et al., 2005 Comper et al., 2005 Gordon et al., 2006 Griesbach et al., 2009 Hoge et. al., 2008 Kim et. al., 2009 NIH Consensus Panel, 1999 Prigatano, 1999 Salazar et al., 2000 Serino et al. 2007 Terrio et al. 2009 Tsaousides & Gordon, 2009 Vanderploeg et al. 2008

Outcome Measures

Evidenced-based medicine has become the cornerstone to informing quality care and identifying advances in therapies. While adequate literature exists to support creating clinical programs, the limited available research for cognitive rehabilitation in this particular population (Service Members with persistent symptoms of mTBI) indicates a need for clinical trials to evaluate efficacy. Any such study should ideally involve long-term follow-up data. In the meantime, it is important for individual programs to present and publish their clinical experiences as well their individual outcome data to inform clinical services while awaiting results of such randomized controlled trials. To that end, it is critical to have identified outcome measures, both program-based and patient-based.

It is crucial to understand the complexity of the particular patient population being discussed. Many of the service members with persistent symptoms of mTBI have comorbid psychological diagnoses (such as depression or PTSD) that may be resulting in greater cognitive deficit than the mTBI alone. These patients may report cognitive symptoms and functional limitations but have essentially normal neuropsychological findings. While these patients should absolutely be evaluated for cognitive rehabilitation, it will be essential to have a distinct data element that captures the degree to which the rehabilitation team believes that a comorbidity is contributing to the cognitive deficit.

The working group identified several categories of required data elements (Table 3): administrative performance metrics (e.g. number of patients seen); pre-post- assessment differences; pre-post-functional differences; moderating variables that may affect outcome; discharge environment and patient status at time of discharge; consumer satisfaction (including the patient but can extend to family, employer/Command, and referral source; and, aggregate program outcome data to permit evaluation of the program rather than just the individual patient. Specific data points within the above categories sometimes overlap even though the purpose of collecting these data elements is different.

The administrative data elements identified include metrics such as: number of patients seen; number of patients referred for medical appointments; length of stay in the program, both in terms of treatment duration and daily intensity; length of time the patient is on profile or limited duty; and, return to duty/return to work rates.

Pre-and post-assessment differences are considered the cornerstone of outcome data. It is recommended that this assessment not be limited to formal neurocognitive evaluation, but include and emphasize assessment of symptom status and functional status as well. While formal neurocognitive assessments should be made pre- and post-rehabilitation, monthly re-assessments with these tests are not recommended. Areas of objective testing and symptom reports that are included in pre- and post-rehabilitation measuring should be consistent with those areas initially evaluated during the Assessment phase (see Table 1). Formal neurocognitive assessments should be administered at appropriate intervals to protect the integrity of these tests or repeatable versions should be used.

A functional goal characteristically refers to changes in the ability of an individual to function within important areas of daily life, as opposed to neurocognitive assessment goals that refer to performance on cognitive tests. Among the functional areas determined as important for assessment as outcome measures are: job performance, need for redesignation/duty restrictions or limitations; ongoing comparisons between pre-injury fitness reports/evaluations and current functional abilities as they improve within the program; performance on simulators (rifle, flight, etc.); quality of life assessment; community participation assessment; and social-skills pragmatics assessment.

Results from scheduled monthly re-assessments of symptoms and functional status using tools such as Goal Attainment Scaling (GAS), (Malec, 1999) can assist with clinical decision-making about goal setting. The GAS procedure prescribes that the goals should be objective, measurable, and time-based; that they should be generated by the treatment team with active involvement from the patient; and that they should be functional, based on the patient's lifestyle and needs.

Cognitive rehabilitation programs must describe their outcomes in ways that advance the published science of cognitive rehabilitation. In order to do so, it is important to carefully describe the patients receiving cognitive rehabilitation, since some patients may respond much better than others to specific interventions. For the same reason, it is felt that careful identification of moderating variables, confounds, and comorbidities is essential. These include pain; comorbid physical injuries; type of injury; age, rank, job duties and gender of patient; psychological health and substance abuse; number of deployments; date(s) of injury(s); trauma history to include life events prior to entering the military; family and broader psychosocial support system; aptitude/education; duty status; prior neurologic illnesses or injuries; motivation for retention; expectations of recovery; years of service; and, possible sources of secondary gain. Patient characteristics of those who do not favorably respond to cognitive rehabilitation should be thoroughly studied. Understanding which patients respond to cognitive rehabilitation interventions and which patients do not is the key to advancing this field in medicine.

Discharge criteria include: accomplishment of the goals of treatment; plateauing of improvement and/or failure to improve (typically following 3 to 4 weeks of treatment and medical reevaluation to

rule out treatable reasons); worsening symptoms (again with need for reevaluation and possible case reformulation); and, a clear but flexible definition of the maximum duration of treatment.

Program outcome measures were felt essential for quality and process improvements for the program as a whole. Patient and family satisfaction measures are useful for identifying quality improvement possibilities within a program, but also are extremely important for identifying whether the program improves the quality of life and functional outcome for the patient and family. Variables to be evaluated for satisfaction include education, treatments and effectiveness of the interventions.

The following factors overlap with the administrative evaluation of the program, but also relate strongly to program quality: type and number of service providers; range of services readily available; consistent and well-defined admission criteria; consistent and well-defined discharge criteria; clear description of the program and interventions; sufficient documentation to permit reasonable consistency of treatment across providers; and, clear documentation to permit audit of patient care against these definitions.

Table 3: Outcome Measures

Admin-istrative Perform-ance Metrics	Pre-Post-Assessment Differences	Pre-post-Functional Differences	Moderating Variables	Discharge Criteria & Patient Status at Time of Discharge	Consumer Satisfaction	Aggregate Program Outcome Data
•# of patients seen •# of patients referred for medical appts •duration & daily intensity of prgm •length of time patient is on limited duty	•formal neuropsych evaluation •symptom status •functional status •domains tested during Cognitive Assessment	•job performance •need for redesignation/ duty restrictions •pre-injury fitness reports/evals vs. current functional abilities •performance on simulators •quality of life assessment •community participation assessment	•degree to which co-morbidity may be resulting in cognitive symptoms •pain •severity of associated physical injuries •mechanism of injury •age •rank/MOS •gender •psychological health co-morbidities •substance abuse co-morbidities •# of deployments •date(s) of injury(s) •trauma history to include life events prior to entering the military •family/broader psychosocial support systems •aptitude/education •military status •history of ADHD or LD •other prior neurologic illnesses or injuries •motivation for retention •expectations of recovery •years of service •possible sources of secondary gain	•goals attained •plateauing of improvement and/or failure to improve •worsening symptoms	•patient, family, employer/ command, and referral source •education •treatments •efficacy	•type and # of service providers •range of services •consistent/ well-defined entry criteria •consistent/ well-defined discharge criteria •clear description of the program/ interventions •clear documentation

Program Implementation

With Command support, the decision to develop a cognitive rehabilitation program at a particular site requires an analysis of the current patient population and their resource utilization, the on-site and local resources available, and the overall base population (e.g., training base versus infantry base). Special considerations will need to be given to the specific needs of the Reserve Component including the National Guard, and Special Operations, which sometimes have different needs from other Branches of Service. If a TBI program exists at the MTF, the cognitive rehabilitation program should be a sub-component of this program (see Figure 2).

The ideal cognitive rehabilitation team is holistic in nature (Schutz & Trainor, 2007). A holistic program combines intensive cognitive treatment with psychotherapy or counseling staged in a conventional clinic environment with carry over activities in the larger community. Alternatively, cognitive treatment can be offered as a discrete therapy usually assigned to speech-language pathology or occupational therapy. This model also does not have a mechanism in place to ensure consistent integration of services. In general, research findings concerning the effectiveness of cognitive rehabilitation tend to favor the holistic programs (Gordon et al., 2006; Cicerone et al., 2008).

Optimal delivery of the cognitive rehabilitation program requires an interdisciplinary team of clinicians who are competent in brain injury rehabilitation and military culture and are capable of developing a therapeutic alliance with their patients. Strong team leadership is required, both programmatically and medically, to ensure unified goals and quality care. Interdisciplinary case conferences for patient management and goal setting/review should occur regularly. Coordination of care is also required with the patient's family, other medical providers, and the unit chain of command. A program leader is required to help resolve patient care issues that may arise.

Core elements that must be considered in order to successfully execute a cognitive rehabilitation program in the Military Health System include:

1. Assessment prior to treatment : ensure that proper initial evaluation and assessment have been completed
2. Identification of Individualized Cognitive Rehabilitation goals that target:
    - Symptom reduction through restoration and compensation
    - Functional improvements/gains: activities of daily living, return to duty, vocational, avocational, interpersonal effectiveness, and social functioning
    - Therapeutic alliance: development of trust and mutually agreed upon goals of the cognitive rehabilitation program by the patient, family, and the treating clinicians
3. Development of an interdisciplinary Individualized Treatment Plan, addressing all associated conditions, as well as different demands of operational environment, pre-injury personality traits, occupational status and psychosocial stress.

4. Periodic cognitive reassessment and review of goals, and updates to the clinical and re-integration plan

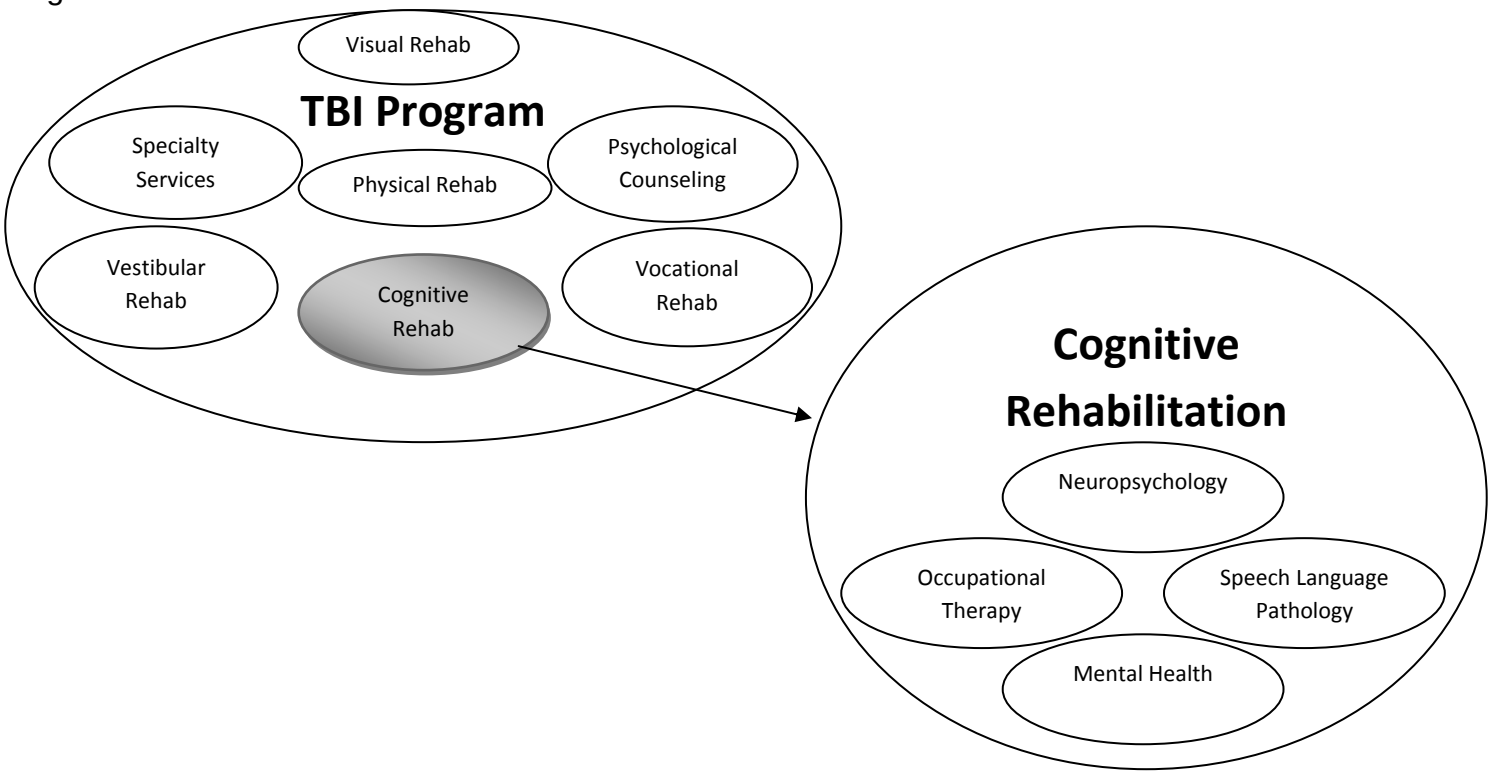
5. Development of well defined discharge plan to include specific criteria (as discussed previously), community re-integration plan, and follow-up plan

As with any program, evaluation of efficacy through the use of outcome measures will be important. The outcome measures should be both patient driven and program driven. The patient driven measures may evaluate which patients improved and which patients did not. The program driven measures should evaluate the quality and effectiveness of the program, including the expertise of the clinical staff.

It will be crucial to recruit, train and retain providers with specific TBI expertise. The discipline of providers to deliver a cognitive rehabilitation program should include, but is not limited to, neuropsychologists, speech-language pathologists, occupational therapists and mental health providers. Continued professional education in the area of the assessment and treatment of TBI and associated conditions is an on-going need. These may include the Annual Military Training Event program, other continuing education programs, telemedicine, mentoring and preceptorships.

Development of a concept of operations for a cognitive rehabilitation program should include attention to space requirements (quiet treatment spaces and group intervention spaces), equipment (to include assistive technology and virtual reality systems) as well as funds to cover transportation for community activities and social networking opportunities. A program such as this will need substantial administrative support.

Figure 2:



Recommendations:

1. Recommend immediate implementation of this clinical guidance into current DoD TBI treatment algorithms, specifically as an extension of the May 2008 mTBI Clinical Guidance for non-deployed settings. Cognitive rehabilitation clinical guidance will be updated and refined as research in this area unfolds.

2. Standardize outcome measures followed for DoD cognitive rehabilitation programs to further inform future research (with appropriate Institutional Review Board (IRB) protocol approval) and further program development.

3. Provide new opportunities for ongoing provider continuing education related to cognitive rehabilitation in the military TBI population

4. Consider further discussion regarding cognitive rehabilitation as a separate reimbursable rehabilitation technique for the traumatic brain injured with persistent cognitive deficits.

Appendix A: DoD TBI definition

Appendix B: DoD Mild TBI Clinical Guidance

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