



UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

APR 30 2012

The Honorable C.W. Bill Young
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report responds to Senate Report 111-201, pages 151-152, of the Ike Skelton National Defense Authorization Act for Fiscal Year 2011, requesting the Secretary of Defense submit a report on cognitive rehabilitation therapy for traumatic brain injury (TBI) to include Department of Defense-wide and Service-specific policies, procedures, and diagnostic tools for TBI. It also requests an analysis of best practices in clinical practice, staffing of facilities, evidence of clinical outcomes, and efforts to improve early detection and treatment of TBI. This issue falls under my purview and I apologize for the late submission of this report. A similar letter has been sent to the Chairmen of the other congressional defense committees.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,

A handwritten signature in black ink, appearing to read "Jo Ann Rooney".

Jo Ann Rooney
Acting

Enclosure:
As stated

cc:
The Honorable Norman D. Dicks
Ranking Member



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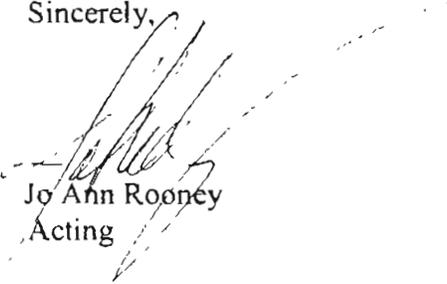
The Honorable Joe Wilson
Chairman
Subcommittee on Military Personnel
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

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The Honorable Susan A. Davis
Ranking Member



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The Honorable Daniel K. Inouye
Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510

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Vice Chairman



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APR 30 2012

The Honorable Jim Webb
Chairman
Subcommittee on Personnel
Committee on Armed Services
United States Senate
Washington, DC 20510

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Ranking Member



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The Honorable Harold Rogers
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

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The Honorable Howard P. "Buck" McKeon
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

APR 10 2012

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The Honorable Adam Smith
Ranking Member



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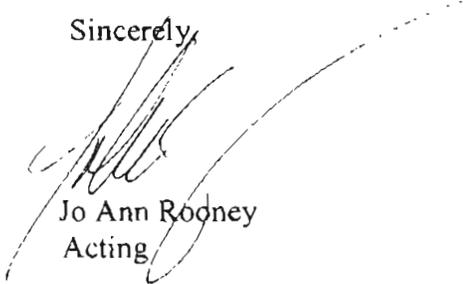
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United States Senate
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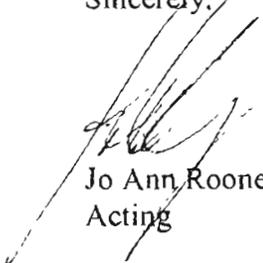
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United States Senate
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The Honorable John McCain
Ranking Member



REPORT TO CONGRESS

Cognitive Rehabilitation Therapy for Traumatic Brain Injury

Fiscal Year 2011

Preparation of this study/report cost the

Department of Defense a total of
approximately \$7,749.00

in Fiscal Year 2011.

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EXECUTIVE SUMMARY

Senate Report 111-201, of the Ike Skelton National Defense Authorization Act for Fiscal Year 2011, directed the Secretary of Defense to submit a report on cognitive rehabilitation (CR) therapy for traumatic brain injury (TBI) to include Department of Defense (DoD)-wide and Service-specific policies, procedures, and diagnostic tools for TBI. It also requested a review of best practices in clinical practice, staffing of facilities, evidence of clinical outcomes, collaborative efforts with the Department of Veterans Affairs (VA) and efforts to improve early detection and treatment of TBI. Finally, the report requested a review of coverage for CR by public and private health programs and the scientific basis for such coverage.

This review brought together various DoD-wide and Service-specific policies, procedures, and diagnostic tools for mild TBI that pertain to the three phases of the deployment cycle. Within the 12 months prior to deployment, Service members are mandated to complete a neurocognitive baseline that is available for use in conjunction with post-injury assessments to better inform in-theater return-to-duty recommendations and assist with clinical management in both the deployed and non-deployed settings. For those individuals who are exposed to a potentially concussive event in theater, DoD Directive Type Memorandum (DTM) 09-033: "Policy Guidance for Management of Concussion/Mild Traumatic Brain Injury in the Deployed Setting" helps ensure early detection, assessment and appropriate treatment. Post-deployment, Service members are required to complete the Post-Deployment Health Assessment (PDHA) and the Post-Deployment Health Reassessment (PDHRA), which include screening questions for TBI. The TBI screening questions serve as a safety net to identify those Service members with concussion exposure or lingering symptoms who need further evaluation.

Clinical practice guidelines (CPGs) are the cornerstone for providing a standardized, systems approach to further evaluate and treat TBI in the deployed and non-deployed settings. In addition to the various CPGs that guide clinical practice, several tenets of successful TBI programs have emerged from the Services in both the deployed and non-deployed settings. DoD is undertaking a multi-pronged approach in order to track the clinical outcomes of those individuals who have sustained a TBI and to better understand the natural history of recovery from TBI. This data will be used to influence CPGs and policies that will improve the care of Service members with TBI in DoD and VA.

DoD collaborates extensively with VA in the areas of TBI screening, treatment and research. The two Departments share clinical data to support the care of Service members and Veterans with TBI and work together to develop best clinical practices and policies for TBI for implementation by DoD and VA.

In addition to DoD's ongoing operational TBI policy outlined in the DTM, DoD has made a substantial investment in basic and clinical research to improve early detection and treatment of mild TBI. These efforts encompass the areas of objective diagnostics, complementary and alternative medicine, and pharmacological and non-pharmacological treatments such as CR.

There are a variety of public and private health programs that provide coverage for CR. The literature suggests that CR is effective in helping patients learn and apply compensations for residual cognitive limitations but provides more limited evidence regarding improvements at the level of functional activities. Further research is still needed to identify the patient and treatment factors that contribute to successful outcomes.

I. DOD-WIDE AND SERVICE-SPECIFIC POLICIES, PROCEDURES, AND DIAGNOSTIC TOOLS CONCERNING TRAUMATIC BRAIN INJURY BEFORE, DURING, AND AFTER DEPLOYMENT

Before Deployment

In response to the National Defense Authorization Act (NDAA) for Fiscal Year 2008, baseline pre-deployment neurocognitive testing was mandated per direction of the Assistant Secretary of Defense for Health Affairs. The objective of the program is to obtain neurocognitive baseline assessments on deploying Service members during the 12 months prior to deployment. This information is then available for use in conjunction with post-injury assessments to better inform in-theater return-to-duty recommendations and assist with clinical management in both the in-theater and non-theater settings.

The Defense Department chose the Automated Neuropsychological Assessment Metrics (ANAM) battery as its computerized Neurocognitive Assessment Tool (NCAT) with which to implement this program pending further evaluation of computerized neurocognitive assessment tools. As a result, the Army was funded to develop a pre-deployment testing program across all Services. The long-term goal is that each Service will establish its own office to implement pre-deployment testing. To date, more than one million Service members have undergone pre-deployment baseline ANAM testing.

During Deployment

Since identification of moderate, severe, and penetrating TBI is usually prompt due to the obvious nature of the injury, DoD's current efforts are largely focused on screening for and identifying mild TBI, also known as concussion. Early detection that leads to assessment and appropriate treatment is the cornerstone of successful recovery following concussion. It is common, however, for symptoms following mild TBI to go unrecognized and therefore, untreated. As a result, the Deputy Secretary of Defense issued DoD DTM 09-033 in June 2010. This policy made significant changes to in-theater screening, treatment, and return-to-duty decisions related to concussion.

The DTM changed DoD's approach to in-theater concussion screening from symptom-based screening to incident-based screening. If a Service member is involved in one of four potentially concussive events, he/she automatically receives a medical evaluation and rest period, regardless of the presence of symptoms. This policy represents a significant cultural change in DoD in that it identifies responsibilities for both medical personnel and line commanders. The DTM mandates that commanders, or their

representatives, ensure that those Service members who are involved in any one of four inciting events receive the above-mentioned medical evaluation.

In support of the DTM, U.S. Central Command (CENTCOM) issued Fragmentary Order (FRAGO) 09-1656 on July 13, 2010. The FRAGO details how to implement the DTM in the CENTCOM area of responsibility, mandating new operational, medical, and reporting requirements and responsibilities following one of the defined potentially concussive events. The reporting requirements mandate complete medical documentation within the electronic medical record and identify those data elements that must be tracked, documented, and reported by the line commanders through CENTCOM to the Joint Trauma Analysis and Prevention of Injury in Combat Program (JTAPIC).

Embedded within the DTM are four clinical algorithms that provide clinical guidance for varying levels of medical providers regarding assessment and treatment. One of the main tools mentioned throughout the algorithms is the Military Acute Concussion Evaluation (MACE). The MACE was developed for in-theater medics and corpsmen to help them quickly identify those Service members who may have sustained a concussion. In April 2010, the Defense and Veterans Brain Injury Center (DVBIC) made two revisions to enhance the MACE. First, they changed the score to a three-part score representing the three components of the MACE: cognitive screening, brief neurological screening, and presence of symptoms. This revised scoring improves the utility of the MACE as a clinical tool. Second, they added an additional history question regarding the number of concussions sustained by the Service member in the previous 12 months to ensure that Service members who sustain multiple concussions receive appropriate comprehensive evaluations and care.

In terms of Service specific efforts, the Army piloted the first Concussion Care Center (CCC) in 2009 at Forward Operating Base Shank and currently operates eight in-theater CCCs in Afghanistan. Physicians oversee these centers and seven of the eight CCCs are staffed by occupational therapists. The Navy and Marine Corps opened their first in-theater, multidisciplinary Concussion Care Restoration Center in Afghanistan in 2010. This facility is staffed by primary care physicians, a psychiatrist (a physician who is a rehabilitation medicine specialist), physical therapists, occupational therapists, and a psychiatrist. Additionally, an in-theatre neurologist consultant is available at Kandahar Air Field and Bagram Air Field for concussion evaluation. The in-theater neurology consultant also is instrumental in efforts to educate deployed providers and line leaders on the evaluation and management of TBI. These centers allow the injured Service member to remain in treatment and in-theater as long as he/she continues to improve. The availability of this in-theater capability has reduced the need for medical evacuations and increased the likelihood that a Service member will return to his/her unit, thereby reducing unit disruption.

After Deployment

Identifying Service members with persisting symptoms due to concussion after deployment is challenging especially due to the time that has elapsed post injury, which

may hinder the Service member's ability to recall details of the injury event. Post-deployment, Service members are required to complete the PDHA and the PDHRA, which include screening questions for TBI. The TBI screening questions serve as a safety net to identify those Service members with concussion exposure or persisting symptoms who need further evaluation. The Armed Forces Health Surveillance Center (AFHSC) maintains data on the number of Service members who are evaluated using these assessments.

According to AFHSC, during fiscal years 2009 and 2010, two percent of Service members screened positive for potential TBI with enduring symptoms on the PDHA and four percent of Service members screened positive for potential TBI with enduring symptoms on the PDHRA. It should be noted that these screening rates are likely underreported due to stigma. For example, a recent study (Warner et al., 2011) noted, in contrast to reporting on the PDHA, a two- to four-fold increase in reporting of depression and posttraumatic stress symptoms, which co-occur with mild TBI, could be obtained if the reporting process were anonymous. It is also important to note that a positive screen does not indicate a TBI diagnosis. The diagnosis of TBI is confirmed through a clinical interview.

Additionally, Landstuhl Regional Medical Center (LRMC) performs TBI screening on all Service members who are medically evacuated or are otherwise redeployed from theater. This screening helps to identify those Service members with a prior history of TBI, concussion exposure, newly symptomatic or those with polytrauma whose injuries may have precluded an earlier evaluation for mild TBI.

After the LRMC screening, the DVBIC Care Coordination Program receives notification of stateside destination of all Service members who screen positive and triages those Service members to the appropriate DVBIC regional care coordinator for assessment of ongoing needs and connection to Services. Service members with moderate to severe TBI or mild with other complex/qualifying needs may be referred to the Federal Recovery Care Coordination program for lifetime care coordination and follow up as well as support in finding TBI-specific resources and services as close as possible to the Service member's geographic location. Service members also are screened for eligibility for referral to their branch-specific Wounded Warrior Care Coordination Program and the DoD Recovery Care Coordination Program. Facility-based case management is available through the Military Treatment Facilities (MTFs) or VA Poly-Trauma Hospitals for coordination of medical and rehabilitative treatments and provision of resources to patients and their families. Mild TBI patients who are symptomatic are tracked through the DVBIC Regional Care Coordination Program and provided education, support and assessment of needed medical or rehabilitative care.

II. BEST PRACTICES IN CLINICAL PRACTICE AND STAFFING OF MILITARY TREATMENT FACILITIES AND CLINICS FOR PROVIDING TREATMENT FOR TRAUMATIC BRAIN INJURIES

Clinical practice guidelines (CPGs) and clinical recommendations are the cornerstone for providing a standardized, systems approach to TBI treatment by incorporating state-of-the-art science, technology, and knowledge-based outcomes. The most recent examples of this type of clinical guidance are the four clinical algorithms embedded within the DTM, as previously mentioned, that address the treatment for acute and recurrent concussion in theater. The management of patients with subacute or chronic mild TBI symptoms in the non-deployed setting is guided by the VA/DoD Evidence-based Practice Working Group's Management of Concussion/Mild Traumatic Brain Injury CPG. The intent of this in-garrison guideline is for Service members and Veterans with mild TBI to receive care in the primary care setting while remaining at their home duty stations. In addition, there are guidelines regarding the treatment of the more severe categories of TBI. Some of these guidelines include the Guidelines for Management of Severe TBI, the Guidelines for Field Management of Combat Related Head Trauma and Guidelines for the Management of Penetrating Brain Injury.

In addition to the various CPGs that guide clinical practice, the Services have contributed several tenets of success for mild TBI programs. These tenets of success include a collaborative, multidisciplinary treatment centered approach to the primary care of the patient, as well as standardization of the evaluation, education and treatment processes for affected Service members and their families. In addition, regular communication and coordination with the warrior transition unit (or Service-specific equivalent) ensures the unit is fully informed and engaged in the care provided to the Service member.

The in-theater Concussion Care Restoration Centers and CCCs, as previously discussed, are facilities in which the Military Health System incorporates the various CPGs and tenets of success. Stateside, the National Intrepid Center of Excellence (NICoE), which opened in June 2010, serves as DoD's premier TBI facility, dedicated to advancing the diagnosis, clinical care and research of complex combat-related TBI and psychological health conditions affecting Service members who seek restoration to full duty and deployment. This state-of-the-art 72,000-square-foot outpatient facility is located on the campus of the Walter Reed National Military Medical Center. NICoE provides an interdisciplinary team assessment in a holistic, patient- and family-centered environment combined with high-tech diagnostic capability, treatment planning, and long-term follow up to foster physical, psychological, and spiritual healing.

DoD is adopting a version of the TBI categorization used by the Army since 2007 in which each MTF's TBI service is based on the level of care provided by each facility. This DoD categorization will establish standards of care to ensure that services, physical facilities, equipment, and staffing levels are sufficient and consistent enterprise wide. The DoD TBI Program category descriptions are as follows:

- Category 1- Inpatient and outpatient care for the full spectrum of TBI severity, which provides neurological intensive care unit care, comprehensive inpatient rehabilitation, outpatient rehabilitation services, an outpatient mild TBI program, and case management. Staffing may include clinical neurosurgery, neurology, psychology, neuropsychology, neuropsychiatry, social work, nursing, physiatry, physical therapy, occupational therapy, speech-language pathology, recreation therapy, chaplaincy, and assistive technology.
- Category 2- Inpatient and outpatient care for mild and moderate TBI, which provides inpatient and outpatient care for mild and moderate TBI. The programs are short-stay (approximately 7 days) inpatient units and provide comprehensive outpatient rehabilitation services.
- Category 3- Outpatient medical and rehabilitative care for those with mild-moderate TBI, which provides outpatient medical and rehabilitative care for patients with mild and mild-moderate TBI.
- Category 4- Outpatient medical care for mild TBI, which provides referrals for additional services as, needed. Provide outpatient medical care for patients with mild TBI. These programs are staffed by a physician and case manager with other specialists available by referral on a consultation basis.
- Category 5 - Provides limited outpatient medical care for mild TBI.

III. EVIDENCE OF CLINICAL OUTCOMES

DoD is undertaking two major efforts to assess clinical outcomes following TBI. First, DVBIC is conducting a 15-year longitudinal study of the natural history of TBI within a military cohort. Through this study, DVBIC will develop a data repository containing neurobehavioral, neurocognitive, neuroimaging, blood specimen, and sensory/motor data. Once these data are analyzed and better understood, the findings will be used to influence CPGs and policies, which will improve the care of Service members with TBI and their families.

Second, DoD proactively documents Active Duty Service members' exposure to potentially concussive events in deployed settings in the Combined Mild Traumatic Brain Injury Registry. Theater operational data regarding exposure to potentially concussive events is compiled in the Combined Information Data Information Exchange (CIDNE) via the Blast Exposure and Concussion Incident Report (BECIR). Subsequent documentation of screening, diagnosis and care for these Service Members is confirmed from the electronic medical record. The system enables commanders (and their representatives) and medical personnel to ensure completion of the DoD-required screening, evaluation, tracking and reporting of potentially concussive events in accordance with DTM 09-033. Ultimately, this system will allow DoD to ensure proper identification and care for all Service Members at risk for mild TBI and to continually advance the clinical standards of care for mild TBI in deployed settings.

IV. COLLABORATION WITH THE DEPARTMENT OF VETERANS AFFAIRS IN SCREENING, TREATMENT, AND RESEARCH

Screening

A major feature of the DoD/VA collaboration effort in TBI screening is the use of screening questions used by both Departments. These four questions ask about exposure to an event that placed the Service member/Veteran at risk for TBI, the nature of the alteration of consciousness, the presence of symptoms following the event, and the presence of current symptoms related to that event. These questions are part of the VA/DoD mild TBI CPG (2009) for the care of mild TBI and are part of each Department's efforts to ensure that symptoms related to TBI are assessed and treated as soon as possible. In DoD, they are embedded within the PDHA. In VA, these questions appear as a mandatory TBI Clinical Reminder in the electronic health record to be completed by VA clinicians. Responses to the questions, if positive, trigger further comprehensive TBI evaluations in both DoD and VA health care systems. After a Service member has transitioned to Veteran status, the Periodic Health Assessment (PHA) and PDHA are transmitted to the Veteran's electronic health record and are viewable by VA clinical providers through the Bidirectional Health Information Exchange. The ANAM neurocognitive baseline data also are currently available to VA healthcare providers.

To ensure appropriate classification of injury and compatibility of coding systems across the two systems of care, DoD and VA cooperated on revisions to the ICD-9-Clinical Modification (CM) diagnostic codes for TBI, resulting in improvements in identification, classification, tracking, and reporting of TBI. These modifications will continue to be represented in the upcoming release of the ICD-10-CM.

Treatment

The Department of Defense and VA have worked diligently to develop systems of care that provide the injured Service member with continuity of care from the battlefield through the MTF, VA facility, and community. One of the goals is to provide a seamless transition of care, which refers to the careful and well-coordinated transfer of active duty and recently discharged Service members from a MTF to a VA facility. This seamless transition of care includes the establishment of VA points of contact within DoD treatment facilities, and DoD points of contact within VA and requires bidirectionality of information between VA and MTF before, during, and after treatment (Leskin et al.2007).

The VA has a robust system established to provide transition and care management for wounded, ill and injured (WII) Service members and Veterans. Key VA components include VA Liaisons for Healthcare, social workers, or nurses placed at MTFs with large concentrations of recovering Service members returning from Afghanistan and Iraq. The VA currently has 33 VA Liaisons for Healthcare stationed at 18 MTFs to transition WII Service members from the DoD to VA system of care. Likewise, DoD staff members

have been integrated in VA Lead TBI Centers to augment clinical care, participate in educational opportunities and conduct research for patients with TBI.

The Federal Recovery Coordination (FRC) Program is a joint program of the DoD and VA, with the VA serving as the administrative home, and ensures that severely injured Service members and Veterans receive access to the benefits and care they need in order to recover. Since 2008, the FRC Program has helped coordinate and provide access to federal, state and local programs, benefits and services for WWII Service members, Veterans, and their families through recovery, rehabilitation, and reintegration into the community. In addition, military liaisons, Marine Corps recovery care coordinators, and Army Wounded Warrior program advocates are located at VA Polytrauma System of Care facilities to support active duty patients by coordinating interdepartmental issues for patients and their families.

Research

In 2008, a DoD/VA/NIH consensus conference determined the relevant research questions that would generate the knowledge needed to advance the understanding and treatment of TBI, including the diagnosis of TBI, the short- and long-term TBI effects, and develop new treatment approaches. There have been a number of collaborative and coordinated research-based initiatives that have streamlined the research portfolios of both the DoD and VA and increased visibility of research efforts in TBI. There is an annual inventory conducted by DoD/VA Deployment Health Working Group of deployment health research projects. In addition, VA's Office of Research Development (ORD) has representation on the DoD Joint Program Committees that develop, review, and coordinate technical content and priorities of Defense Health Program research and development programs, DoD Peer Review Panels. The DoD has commensurate representation on VA's Scientific Review Panels.

DoD and VA actively collaborate on research, not only at the strategic level but also at the level of individual protocols. There is an active study to determine the efficacy of hyperbaric oxygen (HBO₂) for chronic symptomatic mild to moderate TBI, which is led by DoD and includes VA sites. In addition, at individual VA sites, DoD and VA personnel collaborate on interagency research protocols that receive support from DoD, VA ORD, or an outside funding source. The U.S. Army Medical Research and Materiel Command (MRMC) and the VA collaborate in research across the TBI portfolio, including studies on CR. The VA investigators who are funded present at MRMC In-Progress Reviews, which also are attended by representatives from ORD and Patient Care Services.

V. EFFORTS TO IMPROVE EARLY DETECTION AND TREATMENT OF MILD TBI

Early detection, as close to the point of injury as possible, that leads to assessment and appropriate treatment, is the cornerstone of successful recovery following a concussion.

To that end, DTM 09-033 has improved the early detection and identification of individuals exposed to potentially concussive events, as previously discussed.

Significant education and training efforts have complemented this policy, providing TBI teaching and resources to line leaders, healthcare professionals, and Service members. Ensuring DTM awareness, understanding, and utilization increases the likelihood of early detection and access to appropriate treatment.

Furthermore, DoD continues to collaborate with numerous agencies, including the VA as mentioned above, on a number of innovative practices and research projects in order to improve early detection and treatment of mild TBI. Increased funding in response to the significant increase in TBI since the onset of Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) has enabled the expansion and expedition of research efforts. The following list is a brief review of current endeavors for improving early detection and treatment of mild TBI:

- Objective Early Detection – Multiple studies are ongoing to explore the need for a validated objective tool for diagnosing concussion. Potential areas include quantitative encephalography, eye movement tracking, vestibular balance plates, and evoked response potentials.
- TBI Multidisciplinary Research Consortium – Members of the Mission Connect Mild TBI Translational Research Consortium include experienced TBI investigators from four academic institutions and the major trauma facilities in the Houston-Galveston, Texas area and collaborate on basic and clinical research to improve diagnosis and treatment of concussion and reduce disabilities caused by concussion.
- CR Studies – DoD has undertaken a three-pronged approach to studying CR and includes the following: a review of current literature to determine if there exists sufficient evidence for effective treatment using CR for TBI; a randomized, controlled, treatment trial evaluating the efficacy of CR for Service members who served in OEF and OIF and have TBI with persistent post-concussive symptoms; and a portfolio of studies sponsored by the Congressionally Directed Medical Research Program (CDMRP).
- Hyperbaric Oxygen – DoD is sponsoring three studies to evaluate the safety and efficacy of hyperbaric oxygen in the treatment of chronic symptomatic mild to moderate TBI.
- Pharmacological Treatments – As of 2011, no pharmacologic agent has been approved by the Food and Drug Administration for use as a treatment for TBI. In consultation with the National Institute of Neurological Disorders and Stroke (NINDS) and other nationally and internationally recognized experts in clinical trials, DoD is working to assess the factors that underlie the failure of so many promising clinical trials. To accomplish this, researchers are undertaking an exhaustive series of comparative-effectiveness trials of current TBI management. The data from these comparative effectiveness trials, gathered according to the NINDS Common Data Elements criteria and collected in a unified TBI patient data repository, will be

analyzed to identify patient characteristics and interventions that lead to improved outcomes. This information will then be used to refine clinical trial design and animal models of pharmacology.

In addition, DoD currently manages a neurotherapeutics portfolio of more than 70 projects investigating more than 25 drugs and drug combinations, nutraceuticals, neuroprotectants, cell and gene therapies, neuroprostheses and neuromodulators, and rehabilitation methods and devices.

- Complementary and Alternative Medicine – DoD currently funds studies utilizing acupuncture for the treatment of symptoms associated with TBI, including headache, pain, insomnia, mood alterations, and impaired cognition. One of these studies primarily seeks to treat symptoms of posttraumatic stress disorder but also includes impact on symptoms of TBI.

VI. COVERAGE FOR COGNITIVE REHABILITATION THERAPY BY PUBLIC AND PRIVATE HEALTH PROGRAMS, AND THE SCIENTIFIC BASIS FOR SUCH COVERAGE

Cognitive and behavioral sequelae of TBI can be the most enduring and disabling of all symptoms following moderate and severe TBI, disrupting a Service member's ability to resume independent living and vocational functioning. Functional gains in cognition can lead to improvement in other areas indirectly (improvement in memory may facilitate medication compliance) (Tsaousides & Gordon, 2009). Improving the injured person's ability to perform tasks that require cognitive abilities including their capacities for emotional and behavioral self-regulation is the goal of CR. CR is not a single therapy, but a collection of individual treatment strategies that are designed to improve problems with memory, attention, perception, learning, planning and judgment brought about by a TBI. CR is a well-accepted and common component of comprehensive rehabilitation for persons with moderate and severe TBI (Cicerone et al, 2005) and is provided by 95 percent of all brain injury rehabilitation programs in the United States (Mazmanian et al., 1993).

A parallel situation does not exist in the area of mild TBI. CR has not yet been shown in randomized clinical trials as an effective treatment for mild TBI. Various members of the medical community, however, including public and private health programs as well as TRICARE, have embraced CR, or components of it, as a covered therapy for mild TBI as the science continues to emerge.

Public Health Programs

The Centers for Medicare and Medicaid Services administers Medicare, a federal health care program for the elderly and disabled, and covers the lives of 40 million Americans. Outpatient visits to neuropsychology, speech language pathology, and occupational therapy, the specialties most often providing services, are covered under Medicare Part B medical insurance, when such medical services are deemed medically necessary. In the early 1990's, a code for CR was included in the American Medical Association's Current

Procedural Terminology (CPT) manual, which was the basis for health care payment determination by Medicare and all other health insurance carriers. In 2005, Medicare announced that CPT 97770, CR, was a covered service (Foxhall, 2001). CPT code 97770 was defined as the “development of cognitive skills to improve attention, memory and problem solving, includes compensatory training and/or sensory integrative activities, direct (one-on-one) patient by the provider.” The CPT code has since changed to 97532, but the definition is the same.

Medicare does not have a national coverage policy for CR; therefore, local carriers can establish their own local coverage determinations (LCDs). Section 522 of the Benefits Improvement and Protection Act defines a LCD as “a decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act.” For example, Highmark Medicare Services, a local carrier for the Washington, DC, metropolitan area, Pennsylvania, Delaware, New Jersey, and Maryland, states that CR may be medically necessary for patients with acquired cognitive impairments from head trauma, acute neurological events, or other neurological disease. Furthermore, services are covered when there is an expectation that the patient’s level of function can be restored or significantly improved in a reasonable period of time.

States provide medical assistance to individuals with low incomes through Medicaid. Waivers for services not covered in Medicaid can be provided to maintain an individual in the community and avoid placement in a medical institution. Medicaid home and community-based waivers allow states to select services that best meet the needs of a targeted population. Approximately half of the states have brain injury-specific Medicaid waivers that fund services needed by individuals with brain injury, such as case management, home health care, and respite care (King & Vaughn, 2005). In 56 percent of these states, CR is included among those services available for funding (Katz et al., 2006).

Private Health Programs

The private sector varies in its coverage of CR by insurer. Many third-party payers restrict scope, duration, timing, and intensity of CR services (Katz et al., 2006). The largest insurance company with respect to covered lives is Blue Cross Blue Shield (BCBS), a collection of 39 companies that provides healthcare coverage to nearly 100 million people, or one in three Americans. WellPoint, which provides coverage for 34 million members, and United Healthcare (UHC), which provides coverage for 70 million members, are also large private health insurance companies. Together these three companies provide health insurance coverage for more than half of the U.S. population (2008).

The BCBS Medical Advisory Panel’s initial coverage decision for CR was based on a report about CR studies by its own Technology Evaluation Center (TEC) in 2002. TEC was founded in 1985 by BCBS to produce evidence-based technology assessments and evaluations of the clinical effectiveness and appropriateness of medical procedures, devices, and drugs. The staff consists of research scientists and professionals in relevant

disciplines. The initial BCBS TEC assessment of CR for TBI in 2002 found only two studies that met the BCBS definition for CR, which resulted in the conclusion that CR did not improve the health outcomes of patients with cognitive deficit due to TBI. Based on this review, most member plans of BCBS opted not to provide coverage for CR (Katz et al., 2006).

In 2008, TEC conducted another review of CR in which it examined 11 randomized controlled trials of CR for specific cognitive support, which resulted in the conclusion that there was “inconsistent support” for CR. Furthermore, they concluded that CR does not meet the TEC criteria for permitting conclusions concerning the effect of the technology on health outcomes.

WellPoint is made up of a 2004 merger of WellPoint Health Networks, Inc., and Anthem, Inc. and is an independent licensee of the Blue Cross and Blue Shield Association (BCBSA). In 2008, Anthem issued a medical policy regarding CR in which it determined that CR is medically necessary but investigational for patients with significantly impaired cognitive function and not medically necessary for other etiologies of impaired cognitive function. Anthem reviewed this policy in 2010 and again determined that CR is medically necessary for individuals with TBI. One of two studies cited in their rationale is a randomized controlled trial by Salazar and colleagues (2000) of military personnel who sustained TBI with loss of consciousness for more than one hour.

In 2010, Wellmark, a BCBS company, followed suit and determined that CR is considered medically necessary following a stroke or TBI, given the reasonable expectation of achieving measurable improvements. A select list of references that support Wellmark’s policy include three randomized trials including the above-mentioned Salazar study. Several BCBSA state plans that changed their coverage policies in 2010 also determined that CR is medically necessary in the rehabilitation of patients with TBI. They provide coverage when patients have the potential for improvement based on their pre-injury functioning and demonstrate continued improvement in functioning once rehabilitation has begun.

In May 2009, UHC revised its medical policy on coverage for CR. The revised policy states that CR is medically necessary and proven for the treatment of TBI and brain injury due to stroke, aneurysm, anoxia, encephalitis, brain tumors, and brain toxins. CR is defined as “including specific interventions for functional communication deficits including pragmatic communication conversational skills and compensatory memory training.” Multiple sources of evidence described by UHC were used in the determination and include the year 2000 systematic review by the Brain Injury Interdisciplinary Special Interest Group of the American Congress of Rehabilitation Medicine; research studies including the 2004 nonrandomized prospective study by Cicerone et al., of a comprehensive program; Cochrane reviews; a 1999 National Institutes of Health Consensus Statement on the rehabilitation of persons with TBI; an evidence report on CR for TBI by the Agency for Healthcare Research and Quality; the

2008 BCBSA technology evaluation; and the 2002 position statement by National Academy of Neuropsychology on CR.

TRICARE

TRICARE, administered by TRICARE Management Activity (TMA), is the health insurance program for military personnel, their dependents, military retirees, their dependents, National Guard/Reserve members, and their dependents, survivors, and others entitled to DoD medical care. The process by which TRICARE has reviewed coverage for CR for Service members recovering from TBI, like all covered TRICARE services, is based on statute (Chapter 55 of Title 10, United States Code) and regulation (Title 32 Code of Federal Regulations (CFR), Part 199). Under the TRICARE Basic Program, the law requires all medical services to be medically or psychologically necessary, that is, appropriate care in keeping with generally accepted norms for medical practice in the United States. To protect Service members and their families, the Department insists and the law requires that any medical treatment, including CR, be proven safe and effective as medically or psychologically necessary and appropriate medical care.

The TMA commissioned the ECRI Institute (ECRI – the company name is not an acronym) in 2007 and again in 2009 to perform a systematic review of the scientific literature on the efficacy of CR for treating mild, moderate and severe TBI. ECRI's review included several meta-analytical studies using data from randomized controlled trials. The review compared CR to alternative interventions, including standard rehabilitation treatments. Non-randomized trials and studies of patients with brain injury other than TBI were not included and the review was restricted to studies with more than 10 subjects per treatment arm. The report concluded that adults with TBI who receive comprehensive, holistic CR (treatment structured to address multiple cognitive deficits) report improvement on measures of quality of life compared to patients who receive a less intensive form of therapy. The strength of the evidence for this conclusion was considered low. In addition, the evidence was considered insufficient to determine if comprehensive, holistic CR is more effective than less intensive care in improving patients' employment status or other patient-oriented outcomes. Finally, the evidence was deemed too weak to draw any definitive conclusions regarding the effectiveness of CR for treating cognitive impairments in attention, memory, visuospatial skills, and executive function.

There are times, however, when treatments that are under ongoing evaluation are considered so promising and important to the health and mission readiness of our Service members that DoD finds every means possible to provide that treatment. Under these circumstances, DoD has the authority to provide that treatment for Service members, as long as it is considered safe, while still considering the medical evidence that is required to make the intervention fully available to dependents under the TRICARE program. Therefore, while the research evidence about CR is inconclusive and limited, the DoD has made CR available to Service members with cognitive and behavioral deficits subsequent to TBI. The Institute of Medicine (IOM), in a recently released report on cognitive rehabilitation, supports the ongoing clinical application of CRT interventions

for individuals with cognitive and behavioral deficits due to TBI. The DoD does this while it urgently performs research of its own and intensively studies the work of others. During this interval, a bundled or inclusive payment for a CR package of services will not be available under TRICARE. However, dependents who require rehabilitation may access medically necessary physical, occupational, and speech therapy, as well as psychological and behavioral therapy (all aspects of CR) when delivered by a certified TRICARE provider and billed separately.

The DoD, through direct provision of care in MTFs, TRICARE, and Supplemental Health Care Programs, is providing aspects of CR to the vast majority of Active Duty and Guard members with TBI who are seeking treatment. Since 2009, the DoD has directly provided more than 71,000 hours of CR services for thousands of Active Duty, Guard and retired Service members with TBI. Additionally, TRICARE has reimbursed more than 54,000 hours of services in the private sector.

As evidence accumulates to support the effectiveness of the individual techniques of CR, those individual CR techniques will be specifically reimbursed by TRICARE when administered as the sole treatment during a medical visit. Within military hospitals and clinics, DoD relies on the medical judgment of its health care professionals when determining how and what types of CR to provide to wounded Service members. For care delivered in the private sector, TRICARE relies on the experienced health care specialist (e.g. speech therapist, occupational therapist, psychotherapist, neurologist, physical therapist, etc.) to incorporate into their regimen of care only those techniques of CR that have been concluded will effectively improve the condition of a patient with TBI.

The DoD has several initiatives to further its understanding of CR for TBI. In September of 2010, DoD asked the Institute of Medicine to perform a comprehensive review of the effectiveness of CR to treat the specific impairments associated with TBI. The Institute of Medicine is well respected for its independence, comprehensiveness, and for tailoring a systematic review of the literature to the complexities of research in the field. The goal of the evaluation, which was completed in October of 2011, was to identify whether specific CR interventions have a sufficient evidence base to support their widespread use within MHS, including coverage through the TRICARE benefit.

The IOM report stated that the current medical literature is insufficient to state with high confidence which CR practices would be the most effective treatment(s) for a particular patient. The insufficiency of the evidence was due to a number of identified factors including limitations in the research designs, small sample sizes, lack of operational definitions of different forms of CR, and the variety of premorbid conditions, comorbidities, and contextual factors across studies. Further, variability of when in the recovery phase CR is applied, to which populations, for what specific cognitive deficits, and by what specialty disciplines all may moderate the value of a given form of CR across patients and across the range of outcomes. The IOM, however, supports the ongoing clinical application of CR interventions for Service members with cognitive and

behavioral deficits due to TBI. Safe and well-established treatments can continue to be used.

The Assistant Secretary of Defense for Health Affairs initiated a mild TBI CR Pilot Program in April 2010 at 13 MTFs to demonstrate the feasibility of implementing a standardized approach to the provision of CR services for mild TBI according to clinical practice recommendations developed at a 2009 consensus conference. As this program matures, it may prove to be an appropriate platform to examine the clinical effectiveness of CR in mild TBI. Preliminary results from this Pilot Program are expected in February 2012.

The DVBIC began the Study of Cognitive Rehabilitation Effects (SCORE) in June 2011. This randomized controlled study compares the efficacy of four different types of treatment on patients with mild TBI: psycho-educational (control), computer-directed CR, therapist-directed CR, and integrated interdisciplinary CR combined with cognitive behavioral therapy. In addition, Congress has appropriated \$10 million for research to specifically examine the effectiveness of CR in TBI. The MRMC reviewed the submitted research proposals and selected four multi-year studies for funding.

VII. CONCLUSION

The DoD continues to pursue the development of policies, procedures, and diagnostic tools to provide optimal, state-of-the-science care for Service members with TBI. Identification and evaluation of best practices, collaboration with partner organizations, such as VA, and extensive support of cutting edge research in the diagnosis and treatment of TBI continue to evolve as information about leading practices and the results of studies and pilot projects become available. CR in mild TBI is one treatment for which the DoD has placed significant resources to advance the field in this area and gain further insights related to its efficacy. As the science emerges, clinical practice standards will appropriately evolve with the goal of enabling Service members to enjoy a quality of life they want and deserve in their jobs, with their families and in their communities. Continuation of a coordinated approach to TBI that is centered around the primary concepts of accurate and timely diagnosis and appropriate management and disposition will ultimately ensure that Service members who sustain a TBI, regardless of Service and location, receive the best care possible, now and in the future.

APPENDIX A: TEXT OF SENATE REPORT 111-201, TITLE VII, SUBTITLE C

NDAA 2011: Senate Report 111-201

Title VII HEALTH CARE PROVISIONS

Subtitle C—Reports

Pages 151-152

Items of Special Interest

CR therapy for traumatic brain injury

Section 723 of the National Defense Authorization Act for Fiscal Year 2010 (Public Law 111–84) required the Secretary of Defense to conduct a clinical trial to assess the efficacy of CR therapy for members and former members of the armed forces who have been diagnosed with a traumatic brain injury, and to recommend whether or not such therapy should be a covered benefit under the TRICARE program.

According to the Department of Defense (DOD), CR therapy is a “long-standing and a significant component of comprehensive rehabilitation for persons with moderate and severe traumatic brain injury,” and, when provided in conjunction with therapies to improve speech, language, occupational capabilities and physical therapy, cognitive rehabilitative therapy is provided both within numerous military treatment facilities and under the TRICARE program. However, scientific literature supporting the efficacy of CR therapy in patients with persistent symptoms and/or functional limitations as a result of mild traumatic brain injury—one of the most common injuries sustained on the battlefield—remains small. The committee is pleased that the Department has issued guidance to the military departments to track the outcome of CR therapy for patients with mild traumatic brain injury provided by military treatment facilities beginning in calendar year 2010. Additionally, the committee has been informed that the Department will conduct the clinical trial required by section 723 of Public Law 111–84 utilizing up to 2 military treatment facilities in conjunction with 17 clinical sites of the Defense and Veterans Brain Injury Center. These efforts demonstrate the commitment of the Department to validating the most effective therapies, based on needed scientific evidence, for mild traumatic brain injuries incurred on the battlefield. Together, these efforts can lead to better health outcomes and inform policymakers within the Department on future benefit changes within the TRICARE program.

The committee directs the Secretary to report no later than February 1, 2011, on the following:

- (1) DOD-wide and service specific policies, procedures, and diagnostic tools concerning traumatic brain injury before, during, and after deployment;
- (2) Best practices in clinical practice and staffing of military treatment facilities and clinics for providing treatment for traumatic brain injuries;
- (3) Evidence of clinical outcomes;
- (4) Collaboration with the Department of Veterans Affairs in screening, treatment, and research; and
- (5) Efforts to improve early detection and treatment of mild traumatic brain injury.

The report shall also include a review of coverage for CR therapy by public and private health programs, and the scientific basis for such coverage.