

**The implementation of a program for the specific treatment  
of veterans with traumatic brain injury or posttraumatic  
stress disorder as mandated by SEA 180 (2014)**

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Indiana State Department of Health in consultation with  
the Indiana Department of Veterans' Affairs and  
the Division of Mental Health and Addiction

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## **Executive Summary**

Simply put, traumatic brain injury (TBI) is the result of a blow or jolt to the head or a penetrating head injury that disrupts the function of the brain. Post-traumatic stress disorder (PTSD) is a psychiatric disorder that can develop after direct, personal experience or witnessing of an event that poses a perceived threat of death or serious injury. Indiana’s General Assembly, concerned with the care of Hoosier service members and veterans affected by TBI and PTSD, enacted Senate Enrolled Act 180 during the 2014 Session. The impetus for SEA 180, we were told by

participants in the legislative process, came from those advocating that the State establish a program to treat veterans with TBI and/or PTSD through an intervention known as hyperbaric oxygen therapy (HBOT). The HBOT advocates maintain that, if the State would establish an HBOT program and pay the initial costs, the State could ask for funding for the program at the Federal level. However, it is not clear that the Federal government would approve reimbursement given that the FDA and Veterans Administration do not approve HBOT as a means of treatment for TBI and/or PTSD.

SEA 180 emphasizes that this report's recommendations should be "the best peer reviewed" and "evidence based" protocols and therapies. We retained an out-of-state expert to evaluate the evidence-based protocols; their report (included herein) identifies the best evidence-based protocol, largely rejects another and says there's not enough evidence to say one way or the other about the third.

Getting a handle on the numbers of veterans in Indiana with PTSD or TBI is challenging, as estimates vary widely. By our calculations, there are at least 3,500 Hoosier veterans suffering TBI symptoms (though many are mild and do not require treatment) and at least 10,000 with PTSD. Other observers place the numbers of Indiana veterans with TBI and PTSD much higher. One HBOT advocate says there are between 50,600 and 55,180 Indiana veterans "who suffer from PTSD, TBI or any of the related post-concussion syndrome symptoms." In an interview two months earlier, the same advocate said he believed there were 77,000 Hoosier veterans who suffer from TBI or PTSD. Undoubtedly, he is including many Hoosier veterans from years prior to 2002, but still, those numbers seem very high.

Regardless of where treatment for TBI or PTSD is provided, the type of treatment needed depends on the severity of the injury. Service members who sustain mild TBI (which accounts for the vast majority of injuries) may walk away from the event, seemingly unharmed; thus mild TBI may go unnoticed and untreated. Most cases of mild TBI resolve without medical attention. Treatment for patients with mild TBI focuses on symptom management and education of patient and family. A successful treatment outcome for a patient who has sustained a concussion is the return to duty/work/school or other daily activities.

The VA health care system offers a full array of treatment services for PTSD, including face-to-face mental health screening and assessment, psychotherapy (individual and group), pharmacotherapy, and adjunct services, such as employment counseling. Numerous factors influence treatment outcomes, and no single treatment, even ones that have substantial evidence bases, has been demonstrated to be effective for everyone who has PTSD. Evidence suggests that, as with TBI, identifying PTSD early and referring people to treatment can decrease symptoms and lessen the severity of functional impairment. In general, treatment for PTSD symptoms includes three broad intervention categories: psychotherapy (based on psychology techniques), pharmacotherapy (using prescription medication), and education (including coping mechanisms for the patient and family members).

Guideline recommendations reflect the lack of strong evidence supporting the use of various innovative or alternative treatments for PTSD, such as couple and family therapy and complementary and alternative medicine (CAM), which includes yoga, contemplative treatments, and acupuncture. The IoM concluded in 2012 that these treatments do not have a substantial evidence base. Many VA specialized PTSD treatment programs incorporate such complementary and alternative therapies as guided imagery, progressive muscle relaxation, and stress management-relaxation therapy, but there is considerable variability in what is offered in any particular program.

The costs associated with mental and cognitive conditions stemming from the conflicts in Afghanistan and Iraq are substantial. According to a 2008 Rand Corporation study, on a per case basis, two-year post-deployment costs associated with PTSD are approximately \$5,904 to \$10,298. Further, the Rand study found annual costs associated with TBI are even higher, ranging from \$252,251 to \$383,221 for moderate/severe cases. The Rand study adjusted these to account for 2007 prices, which are likely to be even significantly higher today. The HBOT advocates explain that PTSD and TBI can be addressed with 40-80 HBOT treatments at \$400 per treatment, for a maximum cost of \$40,000 per patient. Physician members of our committee were skeptical that hospitals would charge only \$400 per treatment, explaining that “just walking in the door of most hospitals costs \$400 or more.”

SEA 180 directed the ISDH and two other State agencies to specifically consider three main protocols or therapies: Cognitive rehabilitation, resource facilitation and hyperbaric oxygen therapy. To accomplish this task, we conducted an extensive literature search, and we contracted with Keith D. Cicerone, Ph.D., director of neuropsychology and rehabilitation psychology at the JFK-Johnson Rehabilitation Institute and the New Jersey Neuroscience Institute in Edison, New Jersey to assess the scientific evidence available regarding all three. Dr. George Parker, one of this panel’s members, summarized the Cicerone findings this way: “For a person who has suffered a mild traumatic brain injury, the available research says cognitive rehabilitation is likely to help and hyperbaric oxygen therapy will not help. Because there is little research on it, no one can say if resource facilitation will help or not.”

Interestingly, a study conducted earlier this year by the RAND Corporation found that U.S. veterans receiving mental health services from the VA were generally satisfied with that care, with room for improvement. Despite this generally rosy assessment, there are significant numbers of veterans disappointed with the care they have received. Veterans and alternative-medicine advocates are pressuring the VA to expand the range of treatments for those who cannot find relief in the standard regimen of drugs and talk therapy, and, to some extent, the VA is listening. Last year, the agency spent \$18 million (up from \$12.8 million in 2010) studying alternative treatments, for example, group yoga and bright-light therapy. But the VA is concerned about treatments whose value and safety have not been proved in large-scale scientific studies. VA officials—already under intense scrutiny over revelations that staff falsified waiting lists—do not want to be seen as carelessly experimenting on troubled veterans, the Wall Street Journal reported this summer.

If Indiana were to establish a program for the specific treatment of veterans with TBI or PTSD as suggested by SEA 180, the types of providers that would be needed would include evaluation and treatment teams made up of physicians, PhDs, RNs, masters-trained professionals, and peer counselors, plus the following specialists: Neuropsychiatrists, physiatrists, neuropsychologists, neuroradiologists, speech pathologists, occupational therapists, vision therapists, vestibular therapists and psychotherapists with specialized training/experience in working with veterans with brain injury.

An Indiana system for treating veterans with PTSD and/or TBI with cognitive rehabilitation, resource facilitation and HBOT—foregoing the VA system which provides PTSD and TBI care (albeit not including HBOT)—would cost millions of dollars. Providing HBOT care alone for roughly 14,000 Hoosier OEF/OIF/OND veterans with PTSD and/or TBI—at a maximum cost of \$40,000 per patient—would cost Indiana \$560 million. And if the HBOT advocate’s numbers of 50,000 or 70,000 Hoosier TBI/PTSD veterans is accurate, the cost would be three to five times greater. None of this accounts for the costs to administer the statewide system, which could

easily run into millions of dollars. As we'll explore more fully, Indiana cannot "send the bill to Washington" and expect the federal government to pay it.

The Indiana Veteran Recovery Plan (IVRP) includes a proposal to fund a statewide HBOT program. According to the HBOT advocates, initial implementation in 2014 would require establishing a revolving IVRP Trust for five years of about \$5 million: "This Trust would revert back to the source it was established from after the five-year period unless reaffirmed by the legislature or 60 days after the FDA approves the hyperbarics treatment as a 'standard' for care." The HBOT advocates recommend the use of "Surplus Funds" or monies from the "Rainy Day" fund. "In essence, the establishment of the IVRP Trust would be a loan from some other source to be paid back at the end of the 'loan' period (without interest). Funding for out years could come from decreases in other state accounts that these veterans are currently drawing from such as Medicaid and unemployment. If this approach is taken, the "loan" could be paid back sooner than the five years," they add. Beyond that, the HBOT advocates urge the State to "send the check to Washington."

However, the VA steadfastly insists it will not pay for HBOT for veterans, and the HBOT advocate's legal theories for how to make Washington pay for the State's HBOT program are not well-founded. Tom Mattice, medical director of the Roudebush VA center in Indianapolis, told us that "it is the policy of the VA to adhere to the use of evidence-based treatments and therapies. That is not currently the situation related to the use of HBOT for treatment of TBI or PTSD. In the future, if the use of HBOT meets that scientific level of acceptance, we will again review its use." Other funding sources that HBOT advocates cite to pay for a State HBOT program don't appear designed to work for that purpose. The HBOT advocates claim that the Federal government must pay for a State HBOT program because a 1921 federal law—the Veterans Bureau Act—requires it: "The Federal government has shifted costs from these war casualties to the states. The 1921 Veterans Bureau Act requires the VA to automatically reimburse the state for any treatment that is not provided by the VHA." But an ISDH legal opinion finds no support for these assertions:

"The (HBOT position) contains many statements that are incomplete and unsupported. It assumes that the IVRP, as written, will stand on its own and does not violate any principles of federalism. While the document discusses separation of powers on a state level as a justification for why the IVRP will guarantee reimbursement, it fails to consider the basic concept that federal law is the ultimate authority on federal matters; while state law can fill in the gaps, it cannot violate other federal regulations or force the federal government to do something that it is not already obligated to do under federal law.

"There is no guarantee that the State of Indiana could be reimbursed if it pays for HBOT for veterans for the treatment of TBI or PTSD. No state can compel the federal government to enter into a contractual agreement or to give it grant funds; furthermore, recipients of grant money are generally not in a position to dictate the terms of how the funds will be spent.

"The Veterans Bureau Act created the Veterans Bureau in 1921. Since then, there have been many other pieces of federal legislation with regards to veterans' health care and insurance that likely superseded the Act. (We) cannot find any current or past federal statute or regulation that compels the state governments to assume responsibility for the payment of health care expenses for active and retired military members; it seems to be a purely federal obligation."

HBOT advocates also claim that the Oklahoma legislature has accomplished what they're proposing in Indiana; the bill that passed includes no appropriation for the program. The International Hyperbaric Medical Foundation conducts fund-raisers to attempt to pay for it.

The State of Texas earlier this year tried to force the federal government to pay non-VA providers through Medicaid for care given to veterans: Gov. Perry announced that the state reached agreements with health facilities to provide care for veterans who cannot get timely treatment from the U.S. Department of Veterans Affairs. The federal government denied Gov. Perry's request in part because it would require major federal legislative changes authorizing expansion of the Medicaid system and changes to the medical record and IT systems to enable the VA to make required reports to Congress. These problems were judged to be insurmountable.

The HBOT advocates propose other ways to fund a statewide program for the treatment of veterans with traumatic brain injury or PTSD; unfortunately, none of these ideas appear sufficient to fund a statewide program.

There are a number of research studies underway that may result in further relief for TBI and/or PTSD patients. Some of the most exciting work is detailed herein.

The State has other options to supplement the medical care provided by the VA for Hoosier veterans. One idea that multiple states are piloting is the veterans treatment court, and the federal government has previously provided funding for such programs; Utah, Iowa, and South Dakota are in various stages of implementing such courts. Another idea being tried in Nebraska is a VA grant program that helps TBI and PTSD-afflicted veterans by awarding grants to local health departments to help veterans better connect to needed services. Tom Mattice, the medical center director for Roudebush VA Medical Center, told us the State could assist the VA in its care of veterans with PTSD and TBI by identifying other entities that could provide veterans who don't trust government facilities with their health care. In New Mexico, the Department of Veterans' Services and other groups hosted a free conference to help veterans and their families cope with post-traumatic stress disorder and, in Louisiana, Gov. Jindal signed into law this summer a bill that prohibits any person with a disability, including veterans with PTSD or TBI, from being denied admission to any public facility because of that disability. In Arizona, beginning January 1, residents who suffer from PTSD will be able to legally use marijuana to help alleviate their symptoms under a decision by the state's Department of Health Services.

Our conclusion is simple: Indiana should not entertain further the notion of establishing a statewide program for the specific treatment of veterans with TBI or PTSD. We recognize that the VA health care system is not perfect, as its many flaws have been on full display over the last year. Bad VA health care can be improved, and there are signs that it is already improving. All Hoosier veterans diagnosed or suspected of a brain injury or emotional distress should have access to specialists in these disorders; one day that may include HBOT along with other alternative treatments now being studied. Hoosier veterans—and all Hoosiers, for that matter—deserve a government that recognizes the need to initiate new treatments when they are supported by strong evidence as contemplated by SEA 180. We believe Hoosiers have such a government and we recommend the General Assembly and the Administration reject the statewide program suggested by SEA 180.

## **Introduction**

Traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) have been described as the “signature wounds” of America’s recent conflicts in Iraq and Afghanistan, but brain injuries and psychological wounds from war are not new, having been previously referred to as “soldier’s heart,” “shell shock,” “battle fatigue” and “combat neurosis.” Of course, TBI and PTSD are not solely the province of military contexts, happening every day on our streets and highways and in other occurrences of everyday life.

Simply put, TBI is the result of a blow or jolt to the head or a penetrating head injury that disrupts the function of the brain. Such an injury may range from “mild”—a brief change in mental status or consciousness—to “severe,” an extended period of unconsciousness or amnesia after the injury. The terms concussion and mild TBI are used interchangeably. PTSD is a psychiatric disorder that can develop after direct, personal experience or witnessing of an event that poses a perceived threat of death or serious injury. Symptoms that characterize PTSD arise after emotionally traumatic exposures and include re-experiencing the traumatic event through flashbacks and nightmares, avoidance of things associated with the trauma and hyperarousal (exaggerated startle and difficulty in sleeping and in concentrating). PTSD often causes substantial distress and functional impairment. The various effects and the interconnections of PTSD with other physical, mental and social outcomes can interfere with readjustment into one’s previous life. For a diagnosis of PTSD, symptoms of acute stress must persist for at least a month and cause substantial impairment in important aspects of daily life.

It is generally accepted that mild TBI, PTSD, and depression co-occur and that rates of PTSD and depression after mild TBI are much higher than rates in the general public or in non-TBI injured active duty personnel.

### **Senate Enrolled Act 180 (2014)**

Indiana’s General Assembly, concerned with the care of Hoosier service members and veterans affected by TBI and PTSD, enacted Senate Enrolled Act 180 during the 2014 Session. The full text of SEA 180 is included in the Appendix, but its most pertinent parts and what guided our report was the following:

- SECTION 2. [EFFECTIVE UPON PASSAGE] (a) As used in this SECTION, "department" refers to the state department of health.
- (b) As used in this SECTION, "veteran" refers to any individual in Indiana who has a United States military service related injury or disability, regardless of active, reserve, or retired status.
- (c) Not later than September 1, 2014, the department, in consultation with the Indiana department of veterans' affairs and the division of mental health and addiction, shall:
- (1) conduct a study; and
  - (2) report, in an electronic format under IC 5-14-6, the department's findings and recommendations to the legislative council;
- concerning the implementation of a program for the specific treatment of veterans who have traumatic brain injury or posttraumatic stress disorder.
- (d) Findings and recommendations made under subsection (c) must include the following:
- (1) After consideration by the department of treatment protocols and therapies for traumatic brain injury and posttraumatic stress disorder, including:

- (A) resource facilitation;
- (B) cognitive rehabilitation; and
- (C) hyperbaric therapy;

recommendations concerning the best peer reviewed, evidence based protocols and therapies to be used to provide the treatment described in subsection (c).

(2) Recommendations concerning the types of health care providers necessary for implementation and any certification of the program.

(3) The estimated number of veterans who have traumatic brain injury or posttraumatic stress disorder.

(4) An analysis of available federal and state funding for the program.

(5) An analysis of the costs of traumatic brain injury and posttraumatic stress disorder among veterans and the economic impact of implementation of the program.

The impetus for SEA 180, we were told by participants in the legislative process, came from those advocating that the State establish a program to treat veterans with TBI and/or PTSD through an intervention known as hyperbaric oxygen therapy (HBOT), which both the FDA and the Veterans Administration reject because it is not “evidence-based.” The HBOT advocates maintain that, if the State would establish an HBOT program and pay the initial costs, the State could “send the bill to Washington” and it would be paid. Our legal research does not bear out that contention.

### **Peer-reviewed, evidence-based protocols**

SEA 180 emphasizes that this report’s recommendations should be “the best peer reviewed” and “evidence based” protocols and therapies. This has been perhaps the most important charge the General Assembly gave us—to find the best peer-reviewed and evidence-based protocols for the treatment of TBI and PTSD. An emphasis on “peer-reviewed” and “evidence-based” is not a new exercise for the State Department of Health (ISDH), where “evidence-based best practices for public health promotion, training and health care quality” has long been one of our core values.

Many protocols and therapies claim to be “evidence-based” for PTSD and TBI treatment and, to some limited extent, they are, but they are not the “best” peer-reviewed, evidence-based protocols available. “Peer review” essentially involves the evaluation of work by one or more people of similar competence to the producers of the work; in that way, it is a form of self-regulation by qualified members of a profession. Another way to put it might be that “peer review does the same thing for science that the “inspected by #7” sticker does for your t-shirt: It provides assurance that someone who knows what they are doing has double-checked for quality.

For example, many scientific journals only publish articles that have been subjected to critiques by multiple recognized scholars/experts in the field of the article to assure that published articles present the best and most authoritative information the discipline has to offer. Citations to previously published information are used to show that the new information builds on accepted knowledge in the field. Review by peers adds to the clinical assessment of research necessary for evidence based medicine.

The published information is further evaluated based upon the design of the study to assign a value to the quality of the evidence. High quality evidence is produced by studies that eliminate confounding factors/associations and/or placebo effects that may determine the outcome of



the study. High quality evidence results in strong recommendations for inclusion in Clinical Practice Guidelines (CPG). The balance of benefits and harm is weighed to determine the final strength of the recommendation. Double-blinded randomized controlled trials (RCTs) are judged to provide the highest quality evidence and result in the strongest recommendations. Low-quality evidence, commonly derived from case observations, or poorly conducted studies, result in weak recommendations or no recommendation because of insufficient evidence.

The bottom line: Do not be fooled by superficial claims of some studies that they are “evidence-based”. Digging deeper will reveal that not all “evidence-based” studies are created equal. Later in this report you will find the results from an out-of-state team of experts who evaluated a raft of “evidence-based” studies regarding PTSD and TBI treatments, recommending some and discounting others.

### **Our process to produce this report**

The ISDH began organizing this study and report immediately following the adjournment of the General Assembly in February 2014. The ISDH Division of Trauma and Injury Prevention was a logical choice as the group to lead the effort and interim Division director Katherine Gatz (since promoted to Director) and Assistant Commissioner for Health and Human Services Art Logsdon were given the specific assignment.

Our process to produce this report is more completely described in the Appendix, but essentially, these steps were critical:

- Indianapolis-area TBI/PTSD experts were interviewed to get a better understanding of the challenges.
- An organizational meeting involving the three State agencies named in SEA180—the ISDH, Department of Veterans’ Affairs and the Division of Mental Health and Addiction—was held on May 19.
- Further interviews were conducted in June with HBOT, cognitive rehabilitation and resource facilitation advocates and local Veterans Administration leaders.
- As mentioned above, we procured special assistance from an out-of-state consulting team to help us evaluate protocols for treatment of PTSD and TBI to find the best “evidence-based” protocols.

A list of panel members who helped produce this report is provided in the Appendix.

A final word about this report: Those who produced it are not PTSD or TBI experts. The report borrows heavily from both government and private sources of information, and from interviews with TBI and PTSD experts. We are indebted to the many PTSD and TBI experts—and other observers—whose published work or in-person time or phone conversations gave us the vital information we used.

## **Understanding TBI and PTSD**

**Traumatic brain injury:** There are many definitions of TBI, but perhaps the most relevant is the one employed by the Department of Defense (DoD) and the Veterans Administration (VA): A traumatically induced structural injury and/or physiological disruption of brain function as a result of an external force that is indicated by new onset or worsening of at least one of the following clinical signs, immediately following the event, such as any:

- Period of loss of or a decreased level of consciousness;
- Loss of memory for events immediately before or after the injury;
- Alteration in mental state at the time of the injury (confusion, disorientation, slowed thinking, etc.);
- Neurological deficits (weakness, loss of balance, change in vision, praxis, paresis/plegia, sensory loss, aphasia, etc.) that may or may not be transient;
- Intracranial lesion.

A TBI either temporarily or permanently disrupts the level of consciousness, memory or other neurologic (eg: vision or hearing), or neuropsychological functioning. Brain injury can be caused by an object that pierces the skull and brain tissue (penetrating injury) or when an object strikes the head without penetration but results in rapid movement and stopping of the brain within the skull causing injury (closed head injury). Blast injury is also a closed head injury and is caused by transmission of the blast wave through the brain tissue. Blast injury may be accompanied by penetrating injury and or other closed head injury depending upon the proximity of the individual to the blast. About 80% of patients with known TBIs are categorized as “mild” in nature.

Not all individuals exposed to an external force will sustain a TBI, but any person who has a history of such an event with immediate manifestation of any of the above signs and symptoms can be said to have had a TBI. The severity level immediately after the injury has prognostic value, but does not necessarily predict the patient’s ultimate level of functioning.

Problems with memory, attention, executive functions, and speed of information processing are frequent consequences of TBI. The results of research on the cognitive effects of penetrating brain injuries in military populations in previous wars clearly and consistently show a decline in cognitive functioning as a result of brain injury. TBI can have adverse effects on all aspects of social functioning, including employment, social relationships, independent living, functional status, and leisure activities.

**Post-traumatic stress disorder:** Generally, PTSD is considered a psychiatric disorder that can develop after direct, personal experience or witnessing of an event that poses a perceived threat of death or serious injury. Symptoms that characterize PTSD arise in the aftermath of such an emotionally traumatic exposure and include re-experiencing the traumatic event through flashbacks and nightmares, avoidance of things associated with the trauma, and hyperarousal.

Onset of PTSD may be acute, beginning within six months of exposure to the traumatic event, or delayed, beginning more than six months after the event. Symptoms typically begin shortly after exposure—even on the same day. If symptoms persist for two days to four weeks, the diagnosis is acute stress disorder; if the symptoms endure for more than one month, the diagnosis is PTSD. The time between exposure and development of enough symptoms to meet the diagnostic criteria is variable and may be years. It is considered to be chronic PTSD if symptoms persist for three months or longer. PTSD can be chronic and have no remission, or it can be recurrent and have periods of remission and recurrence.

PTSD can be difficult to diagnose and treat, as no objective measure can confirm a diagnosis of PTSD; diagnosis ultimately rests on a careful and comprehensive clinical evaluation performed by a qualified professional (a psychologist, social worker, psychiatrist, or psychiatric nurse practitioner) under conditions of privacy and confidentiality.

Prior to PTSD being recognized as a distinct mental health disorder by the American Psychiatric Association (APA) in 1980, characteristic symptoms of PTSD had been recognized and documented in the 19th century in civilians involved in catastrophic events, such as railway collisions, and in American soldiers fighting in the Civil War. Many Civil War soldiers had diagnoses of “nostalgia” or “melancholia,” characterized by lethargy, withdrawal, and “excessive emotionality”. Others had diagnoses of exhaustion, effort syndrome, or heart conditions variously called “irritable heart,” “soldier’s heart,” and “cardiac muscular exhaustion.” Many medical professionals and surgeons at the time believed that those conditions arose from the heavy packs that soldiers carried, insufficient time for new recruits to acclimate to the military lifestyle, homesickness, and, as one Army surgeon stated, “poorly motivated soldiers who had unrealistic expectations of war.” For much of the 20th Century, psychologic conditions and impairments in military personnel were not accorded high medical priority because of the high fatality rates from disease, infection, and injuries during war.

During World War I, shell shock and disordered action of the heart were commonly diagnosed in combat veterans. Symptoms of “shell shock” included tremors, tics, fatigue, memory loss, difficulty in sleeping, nightmares, and poor concentration—similar to many of the symptoms associated with PTSD. What is now known as delayed-onset PTSD was termed “old-sergeant syndrome” during the world wars, when after prolonged combat, experienced soldiers were no longer able to cope with the constant threats of death or serious injury. Stemming from the World War I definition of shell shock, other common diagnoses of soldiers during World War II included “exhaustion,” “battle exhaustion,” “flying syndrome,” “war neurosis,” “cardiac neurosis,” and “psychoneurosis.”

It was not until after the Vietnam War that research and methodical documentation of what was then termed “combat fatigue” began to accelerate in response to the many veterans suffering from chronic psychological problems that resulted in social and occupational dysfunction.

At this point, some readers may wonder about the veracity of claims about PTSD. Many factors drive these concerns, including media reports of rock stars who claim that fame caused them to have PTSD (“I thought the love I’d receive from fame would heal my broken parts inside,” says Alanis Morissette) or grandmothers who claim they experience bloody visions of death three times a week ever since watching the infamous 1970s horror film, “The Exorcist.”

Disability awards for PTSD have grown nearly fivefold over the last 13 years, and so have concerns that veterans are exaggerating or lying to win benefits. One caseworker cited by the Dallas Morning News in a story this summer estimated that roughly half of the veterans he evaluates for PTSD exaggerate or fabricate symptoms: “It’s an open secret that a large chunk of patients are flat-out malingering,” said Christopher Frueh, a University of Hawaii psychologist who spent 15 years treating PTSD in the VA system.

As already noted, diagnosing PTSD can be difficult in the best of circumstances. One person can suffer crippling anxiety from an experience that would not faze someone else. A 2007 study of 74 Arkansas veterans with chronic PTSD, most of them from the Vietnam War, concluded that more than half were exaggerating symptoms. Other research has found little evidence of malingering.

The VA encourages examiners to conduct comprehensive, accurate and thorough evaluations and to use their clinical judgment in deciding whether to test for malingering. In addressing the possibility that some veterans may fake or exaggerate symptoms, the VA acknowledges that there is “compelling evidence of a relationship between persistence of symptoms and

litigation/compensation seeking, but this relationship is complex, and there is no therapeutic benefit to attributing symptom expression to malingering or intentional efforts to receive compensation.” Symptom exaggeration or compensation seeking should not influence the clinical care rendered, and doing so can be counter-therapeutic and negatively impact the quality of care. Focus of the provider-patient interaction should be on the development of a therapeutic alliance, the VA says.

**Co-morbidities:** The presence of conditions that present as co-morbid with mild TBI, such as PTSD or depression, makes it difficult to separate the outcomes related to mild TBI from the outcomes related to the co-morbid conditions. There are definite distinctions between PTSD and TBI—in causation, screening, history, treatment, etc. However, the symptoms of PTSD and mild TBI are highly similar so, for many purposes of this project, PTSD and TBI are discussed interchangeably.

A 2009 Institute of Medicine (IoM) review of the literature found strong evidence of an association between TBI and depression. Regardless of the severity of the TBI (mild, moderate, or severe), the rates of major depression six months or more after injury are higher than in control groups. In addition, the odds of lifetime depression were highest in those who sustained severe TBI. The odds of depression also increased as veterans aged.

Although estimates of PTSD, mild TBI, depression, and poor health are reported to be high in Active duty personnel and veterans of Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF), the relationships among those conditions are complicated and controversial. PTSD is often co-morbid with several other mental-health disorders—such as depression, substance abuse, and suicidal behavior—and the conflicts in Iraq and Afghanistan have increased awareness of the relationship between mild TBI and PTSD, although it is confusing. Complicating the picture of PTSD that develops after a mild TBI is the issue of the overlapping symptomatology of mild TBI and PTSD. In addition, it has been noted that PTSD can impede recovery from mild TBI and make clinical management difficult.

**Incidence of TBI and PTSD:** Getting a handle on the numbers of veterans in Indiana with PTSD or TBI has been the most challenging aspect of this report, as estimates vary widely. Part of the problem comes from the fact that a clinical interview with a specialist is considered the gold standard for TBI diagnosis because of the difficulty obtaining accurate information on a veterans TBI history through brief self-report measures. Self-report measures, therefore, may overestimate the rate of TBI compared with clinical assessment just as they have been found to overestimate the rate of PTSD relative to gold standard interviews.

The range of estimates reported for PTSD also depend on when the evaluation is conducted and whether the full criteria for PTSD are met as opposed to a positive screen for PTSD. For example, before deployment, the baseline PTSD prevalence has been found to be 5%. Among infantry soldiers in a 2004 study, three months post-deployment from high intensity combat in Iraq, the prevalence of PTSD was 12.9%. Assessments of personnel in ground combat units have been conducted on a near annual basis in Iraq and Afghanistan with rates of PTSD or acute stress at 10-20%, with a strong correlation to combat frequency and intensity. Rates in support units with minimal combat exposure were similar to baseline rates (5%), with increased rates to 20% in units involved in the highest-intensity combat.

Some general information about the incidence of TBI and PTSD among U.S. veterans includes:

- 22% of all OEF and OIF combat casualties involve brain injuries. In the Vietnam War, that rate was 12%.
- Veterans with a TBI diagnosis were on average younger (32.1 versus 34.8 years old) and more likely to be male (94% versus 87%) compared with patients without a TBI diagnosis.
- Approximately 30% of VA enrollees have one or more mental-health conditions, making the VA the nation's largest provider of mental health services.

A report released earlier this year noted that there were 1,791,000 OEF, OIF and Operation New Dawn (OND) veterans eligible for VA care since 2002. Based on those national numbers—and recognizing that they do not include veterans who served prior to 2002—we performed some basic calculations to arrive at “ballpark” numbers of Hoosier veterans affected by TBI and PTSD:

- If Indiana's share of that number as one of 50 states (.02) is roughly accurate, we would expect that Indiana had 35,820 veterans from that time period eligible for VA care.
- The incidence of TBI (over a 3-year period) has been estimated to be 9.6%, leaving Indiana with approximately 3,439 veterans from those 3 conflicts with TBI.
- Further, about 80% of TBI cases are considered “mild”, which usually means they resolve on their own, leaving 20% “moderate/severe” totaling 716 veteran TBI patients in Indiana who require extensive ongoing care.
- For PTSD, the same 2014 report noted above pegs PTSD incidence among OEF, OIF and OND veterans who seek care from a Veterans Affairs Medical Center (VAMC) at about 29.3%, yielding a rough Indiana total of 10,497 veterans with PTSD.

Other observers place the numbers of Indiana veterans with TBI and PTSD much higher. One HBOT advocate says there are between 50,600 and 55,180 Indiana veterans “who suffer from PTSD, TBI or any of the related post-concussion syndrome symptoms.” In an interview two months earlier, the same advocate said he believed there were 77,000 Hoosier veterans who suffer from TBI or PTSD. Undoubtedly, he is including many Hoosier veterans from years prior to 2002, but still, those numbers seem high.

At any rate, by our calculations, there are at least 3,500 Hoosier veterans suffering TBI symptoms (though many are mild and do not require treatment) and at least 10,000 with PTSD. Co-morbidities between TBI and PTSD probably mean some of those are double-counted; on the other hand, these numbers are a calculation based only on the numbers of Hoosier veterans since 2002, which means the actual numbers might be a little higher because some Vietnam-era veterans (and those from other campaigns) still live with TBI and PTSD symptoms.

## **VA Health Care System**

The US Department of Veterans Affairs (VA) is the second-largest cabinet-level department in the federal government. Like other large government agencies, the VA administers its many programs through a number of subcabinet agencies, the relevant one for this report being the Veterans Health Administration (VHA), which administers the veterans health care system.

The VA health care system was established in the early 1900s to care for disabled and poor veterans. Expansion of the system was catalyzed first by the two million veterans returning home from World War I and second by the 12 million new veterans from World War II. The VA health care system grew rapidly after 1945. Today, it is the nation's only national direct care

delivery system. Integral to its clinical services, the VA also provides transportation, housing, vocational rehabilitation, and other social support services rarely offered by private health plans.

Since 1924, the VA has served as a national health care safety net for veterans. In federal FY 2010, the VA health care system had an operating budget of \$45.1 billion, 8.3 million enrollees, and 222,551 full-time employees, including some 14,000 staff physicians and more than 40,000 nurses. Medical treatment facilities are located in all 50 states and essentially every major metropolitan area of the country. Health care is delivered through Veterans Affairs Medical Centers (VAMCs) such as the Roudebush facility in Indianapolis, that provide acute and long-term care delivery facilities through 152 hospitals, more than 800 ambulatory Community Based Outpatient Clinics (CBOCs), 135 community living centers, 140 home-based primary care programs, 299 readjustment counseling centers, and 43 residential care facilities.

The various components of the system provide a wide spectrum of medical services, including inpatient and outpatient care, mental-health care, rehabilitation, complex specialty care, and pharmaceutical benefits and distribution. Services may be provided to veterans in non-VA facilities and fall into two broad categories: contract care and noncontract care purchased on a fee-for-service basis. The use of non-VA care is justified if there is geographic inaccessibility, a lack of clinical capacity, if medical expertise or technology is not available at the local facility, or in an emergency situation, though this may be changing as a result of this year's well-chronicled VA health care crisis.

With the enactment of the National Defense Authorization Act (PL 110-181), veterans who served in a combat theater (including National Guard and reserves) after November 11, 1998, and were discharged or released for reasons other than dishonorable on or after January 28, 2003, now have five years from their date of discharge to enroll in and obtain health care coverage from the VA.

Injuries or conditions related to combat service are treated by the VA health care system free of charge. After the designated five years, enrolled veterans are placed in the appropriate priority group on the basis of income and disability; placement determines the extent of coverage and co-payment amounts.

The VA offers acute inpatient care, intensive and regular outpatient care (e.g., psychotherapy, pharmacotherapy, and telemedicine), residential care, and supported work settings. Services include treatment for depression and anxiety, substance abuse, PTSD, severe mental illnesses (e.g., schizophrenia, schizoaffective disorder, and bipolar disorder), and special programs for veteran populations with special needs (e.g., suicide prevention services, sexual trauma, services for women veterans, homeless veterans, older veterans, and veterans within the criminal justice system).

In 2004, when the VA adopted a new approach to mental-health care designed to focus on recovery, it integrated mental-health care into overall health care for veteran patients. The VA also developed a five-year action plan that includes more than 200 initiatives, including initiatives aimed at raising awareness of the importance of mental health, eliminating disparities in the availability and quality of mental-health services for veterans, and providing comprehensive mental-health care services to veterans with mental illness.

In 2008, the VA published a handbook specifying which mental-health and substance-use treatment services VA hospitals and clinics are required to offer veterans and their families; in 2011 a simplified version to help beneficiaries navigate services was published.

All enrolled veterans are provided treatment and medications for service-connected illness or injury by the VA free of charge. Those who are in the higher-priority groups usually do not pay a copayment for services unrelated to their military service, while those veterans in the lower-priority groups usually pay \$15 for a primary care visit and \$50 for a specialist care visit.

Thus, veteran's health care is provided at no cost to veterans in high-priority groups and at low cost to veterans in other priority categories.

## **TBI: Screening and Treatment**

Detecting mild TBI close to the time of injury is best for preventing symptoms, optimizing care, and improving outcomes; however, mild TBI can be difficult to identify. The rigor of combat operations and lack of observable head trauma may delay assessment. In addition, identifying a head injury often relies on self-reported symptoms, but service members may be reluctant to report symptoms because they do not want to be separated from their unit and wish to avoid any stigma associated with psychological or psychiatric services. Moreover, the frequent presence of co-morbid conditions, such as PTSD, complicates recognition of mild TBI based on symptoms alone. DoD and the VA have system-wide screening and assessment procedures in place at multiple points of care to identify mild TBI in service members. A positive screen indicates the need for further evaluation to diagnose a TBI, but diagnosis cannot be made on the basis of a positive screening test alone.

In addition to screening, DoD requires all service members to undergo a baseline neuro-cognitive assessment before deployment. In 2008, DoD started routine screening of OEF and OIF service members for TBI immediately on their return from the combat theater and again 3–6 months after return. Routine screening was not implemented until 2008, so many service members have never been screened for mild TBI.

In April 2007, VA started screening all OEF and OIF veterans who were receiving medical care in the VHA for TBI; those who screen positive are offered further evaluation and treatment by clinicians who have expertise in TBI.

The DoD published its recommendations for the acute management of mild TBI in military settings in 2006 and updated them in 2008. The guidelines make recommendations in four aspects of care for mild TBI: symptom management, rest or return to duty, educational initiatives, and supportive therapies. The guidelines recognize that there is not strong evidence supporting the use of pharmacologic treatment of patients for mild TBI; however, it provides some guidance on which medications to use for common complaints (such as headache) of clients with mild TBI.

The overall treatment strategy relies on obtaining an initial symptom inventory first. Physical examination, later testing, and treatment options are then dictated by the particular symptoms endorsed by the service member. The guidelines recommend that treatment for mild TBI be managed with the guidance of an interdisciplinary team and that referrals for physical therapy, occupational therapy, speech and language therapy, pharmacy, audiology and vestibular care, and optometry be made when appropriate. They also recommend that coping strategies, stress management, and avoidance of excessive alcohol and drugs be communicated via patient education.

Memory loss, difficulty in concentrating, and difficulty in making decisions are cognitive deficits that are highly prevalent after mild TBI. Recommendations for cognition assessment and treatment are highly variable. The need for cognition assessment is articulated in all the guidelines, but there is no uniformity in which questionnaires or other measurement instruments should be used to assess the nature and degree of abnormalities. Treatment recommendations are also variable.

Regardless of where treatment is provided, the type of treatment needed depends on the severity of the injury. Service members who sustain mild TBI (which accounts for the vast majority of injuries) may walk away from the event, seemingly unharmed; thus mild TBI may go unnoticed and untreated. Most cases of mild TBI resolve without medical attention; however, an additional mild TBI in close proximity to the initial injury increases the probability of persistent symptoms or complications. Education about mild TBI can effectively normalize symptoms and provide expectation of rapid recovery.

Treatment for patients with mild TBI focuses on symptom management and education of patient and family. Education should emphasize recovery, gradual resumption of work and social responsibilities, and teaching compensatory strategies and environmental modifications. Most patients with symptoms following a single mild TBI of recent onset can be successfully managed in the primary care setting without the need for specialty intervention. Patients should be encouraged to implement changes in lifestyle including exercise, diet, sleep, hygiene, stress reduction, relaxation training, and scheduling leisure activities to improve treatment outcomes.

A successful treatment outcome for a patient who has sustained a mild TBI is the return to duty/work/school or other daily activities. Part of the early intervention for mild TBI involves protecting the patient from a secondary insult or further injury by limiting or eliminating their duty status or job requirements until proper recovery is obtained. Return to activity assessment is based on an inventory of symptoms and their severity and the patient's job-specific tasks. With the exception of those activities and duties that are characterized as high-risk for repeat concussions, all individuals with mild TBI should be encouraged to expediently return to activity at their maximum capacity.

## **PTSD: Screening and Treatment**

The VA health care system offers a full array of treatment services for PTSD, including face-to-face mental health screening and assessment, psychotherapy (individual and group), pharmacotherapy, and adjunct services, such as employment counseling. VA uses its *Uniform Mental Health Services in VA Medical Centers and Clinics* handbook to specify the minimum clinical services that must be provided at each VA medical center and community-based outpatient clinic. VA requires annual screening for PTSD for the first five years of care. It also requires that two evidence-based PTSD treatments—prolonged exposure therapy and cognitive processing therapy—be available to all veterans who need them. Other evidence-based and complementary therapies, as adjunctive treatments, are also offered in many medical centers.

Numerous factors influence treatment outcomes, and no single treatment, even ones that have substantial evidence bases, has been demonstrated to be effective for everyone who has PTSD. It has been suggested that about 33% of people in the general population who have PTSD are resistant to treatment; the non-response rates for cognitive behavioral therapy may be as high as 50% and for selective serotonin reuptake inhibitors about 20-40%. The proportion of service members and veterans who have PTSD and recover without intervention is unknown.



DoD and VA developed its Clinical Practice Guideline for Management of Post-Traumatic Stress in 2004 and updated it in 2010. This joint guideline, which has been endorsed by the Institute of Medicine (IoM), reflects the extensive evidence base for first-line and other psychotherapies and pharmacotherapies for PTSD, including complementary and alternative therapies, and delivery formats (group vs. individual sessions).

Frequent and routine monitoring of patients for possible adverse effects of pharmacotherapy or psychotherapy is imperative to ensure safety. Interdisciplinary team-based care and cross-checks—such as checklists, chart reminders and record reviews—can substantially enhance patient safety. Monitoring needs to occur at key stages of treatment—for example, at treatment initiation, shortly after initiation, periodically thereafter and when treatments are changed—or when a patient is in crisis. One safety issue that may be overlooked is the use of purchased care providers to treat service members or vets who have PTSD because those providers don't have access to a service members' or veteran's electronic health records; thus, they may not be aware of all medications (prescribed, over-the-counter and supplements) that patients are taking. This increases the potential for drug interactions or adverse effects if additional medications are prescribed.

Evidence suggests that, as with TBI, identifying PTSD early and referring people to treatment can decrease symptoms and lessen the severity of functional impairment. PTSD screening instruments help to identify people who have PTSD symptoms and inform decisions about who should receive a full diagnostic assessment by a health professional.

In general, treatment for PTSD symptoms includes three broad intervention categories: psychotherapy (based on psychology techniques), pharmacotherapy (using prescription medication), and education (including coping mechanisms for the patient and family members).

1. **Psychotherapy:** First-line psychotherapy treatments recommended by the VA/DoD guideline are trauma-focused psychotherapies that include components of exposure or cognitive restructuring or stress inoculation training (SIT). Specifically, the approach may include an exposure-based therapy, such as prolonged exposure (PE); a cognitive-based therapy, such as cognitive processing therapy (CPT); stress management therapy (such as SIT); or eye-movement desensitization and reprocessing (EMDR). In addition, the guideline identifies other approaches as having possible benefit in treating for PTSD, including relaxation techniques, imagery-reversal therapy, brief psychodynamic therapy, hypnosis, and group therapy. The treatment approach selected should reflect symptom severity, clinician expertise, and patient preference. In the VA system, CPT and PE must be available to all who need and want it.

With respect to the use of technology for the delivery of treatment, the VA/DoD guideline does not recommend Internet-based interventions for treatment for PTSD; however, it supports the use of telephone delivery and videoconferencing, particularly to overcome geographic distance or other barriers to care. Although controlled trials of technology-based delivery of PTSD treatments are underway, there are no definitive conclusions about its effectiveness.

2. **Pharmacotherapy:** For symptoms of co-morbid depression and anxiety, the first-line agents recommended by the VA/DoD guideline are mainly the antidepressants selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs). When the symptoms are unresponsive to first-line

agents, the guideline suggests that the use of second-line agents, such as mirtazapine, nefazodone, tricyclic antidepressants (TCAs), and monoamine oxidase inhibitors (MAOIs) be considered.

PTSD treatment guidelines, including the 2010 VA/DoD guideline, all recommend the use of antidepressants, specifically, an SSRI or an SNRI, in treatment for chronic PTSD.

3. **Education:** Education of the trauma survivor is a core component of all PTSD treatment. Survivors need to better understand what they are experiencing, how to cope with reactions or symptoms, and what happens in treatment. It is also helpful to provide this information to family members or to the patients' significant others so that they can more effectively support the patients' recovery.

Education may be helpful in encouraging patients to self-refer to treatment or for family members encouraging a patient to attend treatment. Chaplains, particularly in the active duty military population, can be highly effective educational liaisons. Military culture does not attach any stigma to speaking with a chaplain although some military members may be reluctant to seek mental health assistance. Education from military chaplains may reduce barriers to care.

PTSD education involves teaching the survivor to label, recognize, and understand PTSD symptoms (and other trauma-related problems) that he or she is experiencing. Education should include discussion of the adaptive nature of many of the symptoms, which have to do with survival and the body's normal responses to threat.

Guideline recommendations reflect the lack of strong evidence supporting the use of various innovative or alternative treatments for PTSD, such as couple and family therapy and complementary and alternative medicine (CAM), which includes yoga, contemplative treatments, and acupuncture. The IoM concluded in 2012 that these treatments do not have a substantial evidence base; evidence of the effectiveness of these therapies for PTSD is based on small RCTs, case studies, or anecdotal reports.

Many VA specialized PTSD treatment programs incorporate such complementary and alternative therapies as guided imagery, progressive muscle relaxation, and stress management-relaxation therapy, but there is considerable variability in what is offered in any particular program.

An example of the continuum of PTSD services available in VA facilities include those provided at the Indianapolis Roudebush VA Medical Center:

- **IOP:** An intensive outpatient program (IOP) designed to help stabilize seriously psychiatrically-impaired individuals with PTSD on an outpatient basis, to enable them to participate in treatments in less restrictive or intensive settings.
- **Inpatient psychiatry:** Acute stabilization and readiness programming for the most psychiatrically-impaired individuals.
- **Tele-mental health:** All of the services of the outpatient mental health clinic, OEF/OIF/OND clinic and a Traumatic Recovery Program (TRP) are available at any other VA facility in Indiana, plus eight community-based mental health clinics affiliated with the ASPIN program, via tele-mental health technology. This program has been identified as a "best practice" by the White House.

- **Vet-to-vet peer support groups:** Self-help groups embedded in the community, currently 17 locations throughout Indiana. Although this is now a separate entity from the VA, the VA continues to provide support and training for the group's facilitators.
- **Primary care mental health integration:** Psychologists embedded in the primary care clinics, providing screening, triage, short-term supportive PTSD programming individually and in groups. Many of their interventions are designed to help veterans engage in general and specialty mental health services.
- **Outpatient mental health clinic:** General individual, group, family and medication management services to treat many of the symptoms of PTSD. Psychological testing provided to help with differential diagnosis and treatment recommendations. These services are also provided at the VA's three community-based outpatient clinics in Bloomington, Martinsville and Terre Haute.
- **OEF/OIF/OND clinic:** Providing general individual, group, family and medication management services, as well as specialized evidence-based psychotherapies for PTSD specifically to the OEF/OIF/OND veterans. These services are also provided at the three community-based outpatient clinics mentioned above.
- **Polytrauma:** Individual, group and family psychotherapy for veterans diagnosed with PTSD who also have head trauma (TBI).
- **PTSD Clinic Team (PCT)/TRP:** The trauma recovery program (TRP) is an intensive outpatient program providing state-of-the-art diagnostic and evidence-based treatment services for individuals with PTSD. This program is designed to have rapid access. Consultation to other sections of psychiatry, including medication e-consults, is provided.

A 2014 IoM study leveled some criticism of the VA's PTSD treatment programs. For example, the IoM found fault with PTSD management strategies, saying that "PTSD management in DoD appears to be local, ad hoc, incremental and crisis-driven with little planning devoted to the development of a long-range, population-based approach for the disorder." However, the same study said that "VA has a more unified organizational structure than DoD and, therefore, is able to ensure a more consistent approach to the management of PTSD in its medical facilities." The study said that DoD and VA should develop an integrated, coordinated, and comprehensive PTSD management strategy that plans for the growing burden of PTSD for service members, veterans, and their families, including female veterans and minority group members."

## **Costs of caring for TBI/PTSD patients**

The costs associated with mental and cognitive conditions stemming from the conflicts in Afghanistan and Iraq are substantial. According to a 2008 Rand Corporation study, on a per-case basis, two-year post-deployment costs associated with PTSD are approximately \$5,904 to \$10,298. Further, the Rand study found annual costs associated with TBI are even higher, ranging from \$252,251 to \$383,221 for moderate/severe cases. The Rand study adjusted these to account for 2007 prices, which are likely to be even significantly higher today.

Dr. Jim Malec of the Indiana University School of Medicine also provided some cost estimates for the treatment of TBI and/or PTSD patients; his estimates are for the treatment of mild to moderate TBI (not the more costly moderate/severe cases included in the Rand study). He based these estimates on discussion with health care administrators about "ballpark figures" and agrees on the difficulty of estimating costs, pointing out they will differ from provider to provider and facility to facility:

At the low end in relatively straightforward cases, treatment might include an

evaluation by a single MD or PhD (\$500-600) and short-term psychotherapy (10 sessions) by a masters level therapist and/or medication management by the treating MD (\$3,000-4,000).

At the high end in complex cases, evaluation might be by multiple brain injury specialists including, for example, a physiatrist, neuro-psychiatrist, neuropsychologist (the combination of specialty evaluations might run (\$1,500-1,800) as well as neuro-imaging (probably MRI: \$1,000-1,500 including technician and neuroradiologist reading) and neuropsychological testing (\$2,000-2,500).

In addition, evaluation could include separate evaluations by a speech pathologist, occupational therapist, vestibular and/or vision therapist (probably a physical therapist). Each of these evaluations could run \$300-\$400. Treatment would include medication management and intermittent evaluation by an M.D. (this could run \$2,000-\$3,000 over the course of a prolonged treatment period, 40-50 sessions of psychotherapy (at \$300-400/hour), and 40-50 sessions of cognitive rehabilitation delivered by an occupational therapist or speech and language therapist, vision, and/or vestibular therapy (at \$300-400/hour).

So a straightforward case could cost somewhere between \$3500 and \$4600 for evaluation and treatment, Dr. Malec estimates. Evaluation and treatment for a more complex case would be anywhere from \$30,000 to \$50,000 per patient, he suggested (but this does not account for total societal economic losses).

Based on program descriptions collected by the Brain Injury Association (BIA), the estimated annual cost of resource facilitation was \$1,200 per person in 1999.

The HBOT advocates explain that PTSD and TBI can be addressed with 40-80 HBOT treatments (“depending on the doctor’s prescription”) at \$400 per treatment, for a maximum cost of \$40,000 per patient. Each treatment takes one hour, and HBOT advocates say a patient could have two treatments in a day with a five-hour break between treatments. Physician members of our committee were skeptical that hospitals would charge only \$400 per treatment, explaining that “just walking in the door of most hospitals costs \$400 or more.”

## **SEA 180: Evaluate three therapy protocols**

SEA 180 directed the ISDH and two other State agencies to specifically consider three main protocols or therapies: Cognitive rehabilitation, resource facilitation and hyperbaric oxygen therapy. To accomplish this task, we conducted an extensive literature search, and we contracted with Keith D. Cicerone, Ph.D., director of neuropsychology and rehabilitation psychology at the JFK-Johnson Rehabilitation Institute and the New Jersey Neuroscience Institute in Edison, New Jersey to assess the scientific evidence available regarding all three. A complete copy of Dr. Cicerone’s report appears in the Appendix.

**Cognitive rehabilitation:** Cognitive rehabilitation is a set of therapeutic techniques designed to improve cognitive abilities and functions such as attention, memory and problem-solving, either by retraining these skills or by teaching ways to compensate for, or work around, cognitive disabilities. “There are a number of different cognitive rehabilitation interventions and the effectiveness of each varies depending on the targeted population, time since injury/event, and

other factors. So to some degree, talking about "cognitive rehabilitation" as if it were a single intervention is mixing apples and oranges. However, overall the evidence supports most forms of cognitive rehabilitation," Dr. Malec explained.

Dr. Cicerone's group reported the following after reviewing data on cognitive rehabilitation:

We conducted a re-analysis of three prior systematic reviews of cognitive rehabilitation after TBI<sup>1-3</sup> and applied additional methodological criteria<sup>4</sup> to each study to assess the quality of each study (high, moderate, and low). The review of methodological quality for each study was applied to the AAN classification of evidence schemes<sup>5</sup> in order to make recommendations, based on the highest level of available evidence (see Appendix)

We identified high-quality RCTs that support the effectiveness of specific interventions for attention,<sup>15, 28, 39</sup> social and pragmatic communication skills,<sup>9, 12</sup> memory<sup>35</sup> and executive functioning<sup>19</sup> after TBI. We also identified several high-quality RCTs that support the effectiveness of comprehensive-holistic rehabilitation after TBI,<sup>11, 34, 42</sup> as well as several high quality observational studies that demonstrate improvements on participation outcomes.<sup>47, 53, 60, 61</sup>

Interventions for attention (direct attention and meta-cognitive strategy training) for patients with moderate to severe TBI during the post-acute period of rehabilitation, compared with non-specific treatments, are *likely to be effective* for improving attention impairments (based on two Class II studies<sup>15,28</sup>). Interventions for attention are *possibly effective* for improving divided attention after mild TBI (based on one Class II study<sup>39</sup>).

Compensatory memory strategy training after moderate to severe TBI is *possibly effective* for improving functional memory performance (based on one Class II study<sup>7</sup>, one Class III study<sup>13</sup> and multiple Class IV studies<sup>21,35,38</sup>).

Interventions for executive functioning are *likely to be effective* for improving planning and problem solving deficits after moderate to severe TBI (based on two Class II studies<sup>19,24</sup>). Interventions for social and pragmatic communication skills after moderate to severe TBI are *likely to be effective* for emotion perception deficits and *possibly effective* for social-communication deficits (based on one Class I study<sup>9</sup> and two Class III studies<sup>12, 18</sup>).

Comprehensive-holistic neuropsychological rehabilitation is *likely to be effective* after moderate to severe TBI, compared with standard treatment, for improving short-term participation outcomes (e.g., return to work) and subjective well-being, and *possibly effective* in reducing the severity of cognitive deficits immediately after treatment for patients with severe TBI (based on one Class I study<sup>11</sup>, one Class II study<sup>42</sup> and one Class III study<sup>34</sup>). Comprehensive-holistic neuropsychological rehabilitation is *possibly effective* in reducing emotional symptoms after mild TBI (based on one Class II study<sup>39</sup>). There is *insufficient evidence* to support or refute the evidence regarding the effectiveness of comprehensive-holistic rehabilitation in improving participation after mild TBI or for improving long-term participation outcomes (> 6 months post treatment) after moderate to severe TBI.

**Resource facilitation:** Resource facilitation assists individuals with a brain injury to return to home, community and work; several states have implemented various forms of resource facilitation ranging from "telephonic services only" to case management. As one might expect during and following TBI treatment, patients report difficulty finding behavioral supports, support groups, assistive technology, brain injury residential programs and recreational opportunities;

they also have significant difficulty transitioning from inpatient, hospital-based care to home and work, and they don't know how to navigate various governmental programs and often feel "dumped" once they no longer meet criteria for receiving services. Resource facilitation, quite simply, helps TBI patients find and use these resources.

There are few health care or clinical providers that specialize in brain injury. These professionals are often spread across multiple disciplines, including neuropsychologists, rehabilitation therapists, physiatrists or vocational specialists. People with brain injury and their families may not know what kind of professional to access for different problems, and not all professionals within a given profession may be experts in acquired brain injury. Further, there are multiple gaps between the health care system and other social supports, such as vocational services. Many patients are unfortunately discharged from acute care or acute rehabilitation hospitals without a long-term plan or without specialized brain injury follow-up. Additionally, the reimbursement for these services is obtained through different systems. Patients may have access to—but be unaware of—multiple payment systems, including private health insurance, public health insurance, or waivers.

These gaps leave the person with a brain injury and their stressed families to navigate an "ocean" with no compass, exacerbating the effects of the emotional and psychosocial consequences of their injury. This can detrimentally impact their recovery gains while setting the stage for further deterioration through the development of co-morbidities such as depression, substance abuse, family breakdown, and all too often incarceration.

Resource facilitation provides a specialized proactive navigator for the person with brain injury and their family. The results of one large study demonstrated that 64% of the participants who received resource facilitation services were able to successfully return to work or school.

Dr. Malec says: "I should point out that resource facilitation is one of those complex, common sense, and highly individualized interventions that probably does not lend itself well to evaluation with a randomized controlled trial (RCT). Although there are some general principles for resource facilitation, every participant basically gets a different intervention, and important components of treatment are the nonspecific effects (for example, keeping participants focused on goals, therapeutic alliance, other "motivational" factors) and environmental interventions to reduce barriers that we usually try to control in a RCT."

Both the VA and DoD guidelines point out that patients presenting with symptoms should be considered both initially and on an ongoing basis for referral to case management. Whether the patient has recently returned from deployment or combat, or is a veteran who has sustained non-combat related head trauma, the need for a collaborative and coordinated approach to comprehensive care is necessary.

Dr. Cicerone's examination of the evidence supporting resource facilitation revealed the following:

There is *insufficient evidence to support or refute* the effectiveness of Resource Facilitation for improving community participation after TBI. <sup>1,2</sup> Trexler et al. <sup>2</sup> conducted an RCT of resource facilitation with 22 participants with acquired brain injury of varied etiology (TBI, intracranial hemorrhage, stroke and other)(Class IV). The group who received Resource Facilitation with a focus on return to work showed improved participation. Participation was assessed with the employment item of the Mayo-Portland Adaptability Inventory by the same people who provided the Resource Facilitation. Participants in the control group were

further post injury and had lower levels of participation prior to treatment. The case series by Malec et al.<sup>1</sup> demonstrated that less time since injury and less overall disability are associated with better vocational outcomes after TBI.

**Hyperbaric oxygen therapy (HBOT):** Hyperbaric oxygen therapy (HBOT) involves breathing oxygen in a pressurized chamber in which the atmospheric pressure is raised up to three times higher than normal. Under these conditions, lungs can gather up to three times more oxygen than would be possible breathing oxygen at normal air pressure, according to HBOT advocates. "Hyperbaric oxygen therapy increases the amount of oxygen dissolved in your blood," say advocates. An increase in blood oxygen may improve oxygen delivery for vital tissue function to help fight infection or minimize injury, they add.

One of the most vocal Hoosier advocates of HBOT says: "The current FDA and VA approved treatments for TBI-PTSD is no treatment! Psychiatrist counseling and prescribing 'mind altering' drugs does not repair the injury, they make 'vegetables' out of their victims! It's so much easier to push pills out the door. Counseling is not very effective," he asserts.

Hyperbaric chambers are medical devices that require FDA clearance. FDA clearance of a device for a specific use means FDA has reviewed valid scientific evidence supporting that use and determined that the device is at least as safe and effective as another legally U.S.-marketed device. Thirteen uses of a hyperbaric chamber have been cleared by FDA. They include treatment of air or gas embolism (dangerous "bubbles" in the bloodstream that obstruct circulation), carbon monoxide poisoning, decompression sickness (often known by divers as "the bends"), and thermal burns (caused by heat or fire). However, the FDA has not approved HBOT for use with TBI or PTSD patients. FDA is concerned that some claims made by treatment centers using HBOT may give consumers a wrong impression that could ultimately endanger their health. "Patients may incorrectly believe that these devices have been proven safe and effective for uses not cleared by FDA, which may cause them to delay or forgo proven medical therapies," says Nayan Patel, a biomedical engineer in FDA's Anesthesiology Devices Branch. "In doing so, they may experience a lack of improvement and/or worsening of their existing condition(s)." FDA received more than two dozen complaints from consumers and health care professionals over the past three years about treatment centers promoting the hyperbaric chamber for uses not cleared by the agency.

Advocates for HBOT have also claimed its benefits in treating autism, but experts say HBOT may cause seizures or pulmonary complications if used improperly and "there was no evidence of any positive effect as a treatment for autism", they said.

Further, the FDA says patients receiving HBOT are at risk of suffering an injury that can be mild (such as sinus pain, ear pressure, painful joints) or serious (such as paralysis, air embolism). Since hyperbaric chambers are oxygen rich environments, there is also a risk of fire. "If you're considering using HBOT, it's essential that you first discuss all possible options with your health care professional," the FDA says on its website. "Whatever treatment you're getting, you need to understand its benefits and risks. Your health care professional can help you determine which treatment is your best option."

However, those who advocate for the use of HBOT to treat TBI and PTSD patients say the protocol is completely safe, explaining: "HBOT supersaturates red blood cells—it heals dormant blood cells; it awakens them."

"The treatment calls for 1.5 atmospheres pressure which is a very low amount of pressure applied to the human body. I'm told it's like diving about 17 feet down in the water," says one

HBOT advocate. “It increases growth factors, reduces edema and swelling, promotes neural pathway growth, activates senescent neurons, increases neuronal energy, reduces inflammation, and reduces reperfusion injury (not enough oxygen),” he adds.

Despite its claimed benefits, HBOT for PTSD/TBI is not approved by the FDA and the VA does not endorse it or pay for its use with veterans. HBOT advocates claim a variety of reasons keep HBOT from being accepted as an evidence-based approach to treating PTSD and TBI:

- Politics are keeping HBOT off the approved treatment list for PTSD/TBI.
- Doctors are the problem because they are not exposed to HBOT in their general training and after graduation, a doctor needs to maximize the number of patients and billable procedures he or she can accomplish.
- Hyperbaric medicine is a very small specialty compared to any of the other specialties. It mostly focuses on wound treatment, skin burns and difficult to treat infections. Those who have the medical society membership (and money) have bigger bullhorns and access to funding institutions. Hyperbaric medicine is tiny and underfunded.
- HBOT has been called “the Cinderella of modern medicine”, but with no large pharmaceutical interest to nurture and protect it, hyperbaric medicine languished. There are no pharmaceutical representatives to offer “free” continuing medical education on the gas laws. Apparently, the inability to accept new information—that brain cells can recover from trauma or hypoxia—prevents consideration of evidence that contradicts firmly held preconceptions.”
- Another HBOT advocate we talked to says the VA and FDA do not understand what really happens with TBI/PTSD:
  - They don’t know how badly a blast ruins the brain. They don’t sense the urgency of the suicide ‘epidemic’. We just haven’t overcome inertia and lethargy at the VA.
  - Medicine takes an awfully long time to catch up with the facts; the rule of thumb in medicine is that the culture doesn’t change without a worldwide pandemic.
- Groups like the Centers for Disease Control and Army Medicine would rather spend time on the research end than on the treatment end, one HBOT advocate told us.

Dr. Brent Masel is the President and Medical Director of the Transitional Learning Center, a brain injury treatment facility in Galveston, TX. He is also the National Medical Director for the Brain Injury Association of America. Masel has been researching hyperbarics as a possible treatment for brain injuries for the last 15 years. He says that current studies have not shown that HBOT has had much of an impact on traumatic brain injuries, though he has seen cases where it has. He says we simply do not know enough about it yet.

“I think that we are in the same place that Alexander Fleming was in in 1928, when he said, ‘I’ve got this stuff, and I’m gonna’ call it penicillin, and I think it helps with infections, but I don’t know what infections it helps, I don’t know how long to give penicillin, nor do I have any idea how much penicillin to give.’ And, that’s where we are with hyperbarics,” Masel said in a report aired earlier this year on WTIU-TV in Bloomington, IN.

Masel added that the only way to find out what the true benefits of HBOT are for brain injuries is more research, and because of cost, the money is going to have to come from the federal government. Dr. Masel is correct, as our legal research shows medical treatment for veterans is a federal issue, not one for the state.



These were the findings of the Cicerone report regarding the HBOT studies they reviewed:

Hyperbaric Oxygen Treatment (HBOT) is *highly likely to be ineffective* in reducing postconcussive symptoms, PTSD symptoms or improving cognitive functioning in patients with blast-related mild TBI.<sup>2,3,7,8</sup> Two independent Class I methodological studies (including 3 month follow-up) show no effect of hyperbaric oxygen treatment on postconcussive symptoms or cognitive functioning in mild traumatic brain injury (mTBI) military samples. There is *insufficient evidence to support or refute* the effects of HBOT on cerebral metabolic activity (SPECT) in patients with chronic post-concussion syndrome after mTBI.<sup>1, 4</sup> Combined hyperbaric and normobaric hyperoxia is *possibly effective* in improving markers of oxidative metabolism acutely after severe TBI.<sup>6</sup> Specifically, one Class II study shows that combined hyperbaric and normobaric hyperoxia led to an improvement in cerebral metabolism in noninjured and pericontusional tissue and reductions in intracranial hypertension and oxygen toxicity in a severe TBI sample enrolled 24 hours post injury.

1. Boussi-Gross R1, Golan H, Fishlev G, Bechor Y, Volkov O, Bergan J, Friedman M, Hoofien D, Shlamkovitch N, Ben-Jacob E, Efrati S. Hyperbaric oxygen therapy can improve post concussion syndrome years after mild traumatic brain injury - randomized prospective trial. *PLoS One*. 2013 Nov 15;8(11).
2. Cifu DX, Hart BB, West SL, Walker W, Carne W. The effect of hyperbaric oxygen on persistent postconcussion symptoms. *J Head Trauma Rehabil* 2014; 29:11-29.
3. Cifu DX, Walker WC, West SL, Hart BB, Franke LM, Sima A, Graham CW, Carne W. Hyperbaric oxygen for blast-related postconcussion syndrome: three-month outcomes. *Ann Neurol*. 2014; 75(2):277-86
4. Harch PG, Andrews SR, Fogarty EF, Amen D, Pezzullo JC, Lucarini J et al. A phase I study of low-pressure hyperbaric oxygen therapy for blast-induced post-concussion syndrome and post-traumatic stress disorder. *J Neurotrauma*, 2012; 29:168-185
5. Harch PG, Fogarty EF, Staab PK, Van Meter K. Low pressure hyperbaric oxygen therapy and SPECT brain imaging in the treatment of blast-induced chronic traumatic brain injury (post-concussion syndrome) and post traumatic stress disorder: a case report. *Cases J*. 2009; 2:6538
6. Rockswold SB, Rockswold GL, Zaun DA, Liu J.. A prospective, randomized Phase II clinical trial to evaluate the effect of combined hyperbaric and normobaric hyperoxia on cerebral metabolism, intracranial pressure, oxygen toxicity, and clinical outcome in severe traumatic brain injury. *J Neurosurg*. 2013;118(6):1317-28
7. Walker WC, Franke LM, Cifu DX, Hart BB.. Randomized, Sham-Controlled, Feasibility Trial of Hyperbaric Oxygen for Service Members With Postconcussion Syndrome: Cognitive and Psychomotor Outcomes 1 Week Postintervention. *Neurorehabil Neural Repair*. 2013; 28(5):420-432.
8. Wolf G, Cifu D, Baugh L, Carne W, Profenna L. The effect of hyperbaric oxygen on symptoms after mild traumatic brain injury. *J Neurotrauma*. 2012; 29(17):2606-12

Indiana observers also weighed in on HBOT:

- Dr. Malec: “Results of research on hyperbaric oxygen treatment are not consistently favorable. It looks like HBOT may be a reasonable option for treating some individuals but doesn’t have the research support to be the centerpiece or first line treatment.”
- Steven Herman, Ph.D., director Mental Health Clinic, Richard L. Roudebush VAMC: “If you want the really short version: There is absolutely no conclusive evidence that hyperbaric oxygen therapy is effective for PTSD. I think that the evidence is just not there yet.”
- The Indiana Department of Veteran Affairs is not unsympathetic to the efforts of the HBOT advocates: “We await the approval by the Federal Drug Administration, Department of Defense and US Department of Veterans Affairs. That approval brings about treatment protocols, USDVA reimbursement and clears states of any liability. Until that time, due to the lack of formal approvals and due to liability issues, we recommend that the Indiana State Legislature not consider further bills concerning HBOT,” said Russell Eaglin, deputy director of the Indiana Department of Veterans Affairs.
- Dr. George Parker, one of this panel’s members, points out that the best evidence-based studies are better than the HBOT studies: “The studies put forward by the HBOT advocates to support the efficacy of HBOT were not randomized, were not double-blind, were not placebo-controlled, and did not use a sham procedure. In other words, the researchers knew who received treatment, the patients knew they were receiving a treatment, and no one received a ‘pretend’ treatment. As a result, all of these studies (cited by HBOT advocates) were at high risk for a strong placebo finding.” He sees the Cicerone findings this way: “For a person who has suffered a mild traumatic brain injury, the available research says cognitive rehabilitation is likely to help and hyperbaric oxygen therapy will not help. Because there is little research on it, no one can say if resource facilitation will help or not.”

## **Policy discussion**

Thus far, we’ve seen that the VA has developed guidelines for its health care system to screen and treat veterans with TBI and/or PTSD; these guidelines include cognitive rehabilitation techniques and to a lesser extent resource facilitation (more commonly referred to as case management). However, neither the VA nor the FDA yet approves the use of HBOT to treat TBI or PTSD. The experts we retained to examine the literature to find the best evidence-based protocols for such treatment concludes that these studies commend cognitive rehabilitation, but the science isn’t yet sure about resource facilitation. And, neither the VA nor the federal government will pay Indiana’s bill for a statewide system to replace VA care for veterans with TBI and PTSD, no matter the HBOT advocates assertions to the contrary, as we’ll examine momentarily.

To improve implementation of treatment regimens, the VA has undertaken a national effort to disseminate evidence-based psychotherapies for PTSD and other mental-health conditions throughout the VA health care system. Since 2007, VA has been working to disseminate CPT and PE therapy for PTSD. Competence-based training of VA mental-health care providers in the delivery of those therapies is a component of the initiative.

**Veterans generally like their health care system:** Interestingly, a study conducted earlier this year by the RAND Corporation found that U.S. veterans receiving mental health services

from the VA were generally satisfied with that care, yet with room for improvement. The RAND study was published in the journal *Psychiatric Services*, and is based on a survey of more than 5,000 veterans who had received services from the Veterans Health Administration for mental health or substance use problems.

"We found that veterans who received services from the VA for mental health or substance use problems reported satisfaction with their care that was similar to or slightly lower than people who receive similar care in other public or private health care systems," said the study's lead author and a senior behavioral scientist at RAND, a nonprofit research organization.

Researchers used VA records to survey patients who had been treated over the prior year for bipolar disorder, major depression, PTSD, schizophrenia or substance use disorder. Participants were asked about their need for housing and employment services, timeliness and recovery orientation of their care, satisfaction with care and perceptions of symptom improvement. About 74% of patients reported being helped by their treatment, yet just 32% said that their symptoms had improved.

**Still, some veterans want alternative treatments:** Despite this generally rosy assessment of VA treatment, there are significant numbers of veterans disappointed with the care they have received. These veterans want something else.

The Wall Street Journal reported extensively in mid-September the lengths to which veterans are willing to go in experimenting with new ways to heal wounds left by their war experiences—and many are demanding the U.S. government do the same. "Some are trying hikes on the Appalachian Trail, scuba diving and horseback riding. Their pursuit of alternative treatments has spawned a cottage industry of dance, drama, companion dogs, tai chi, fish-oil supplements and high-pressure oxygen treatments to treat brain injuries or post-traumatic stress disorder."

The therapies may sound far-fetched. But veterans and alternative-medicine advocates are pressuring the VA to expand the range of treatments for those who cannot find relief in the standard regimen of drugs and talk therapy.

And, to some extent, the VA is listening. Last year, the agency spent \$18 million (up from \$12.8 million in 2010) studying alternative treatments, for example, group yoga and bright-light therapy. But the Journal said that the VA is concerned about treatments whose value and safety have not been proved in large-scale scientific studies. VA officials—already under intense scrutiny over revelations that staff falsified waiting lists—do not want to be seen as carelessly experimenting on troubled veterans, the Journal reported.

The VA has embraced some new ideas, approving acupuncture to treat sleeplessness, and Botox to treat combat-related headaches. For many other alternative therapies, though, "the research isn't there yet," said Paula Schnurr, acting director of the VA's National Center for PTSD. The VA and military are jointly researching whether concentrated blueberry extract reduces brain inflammation, a grave risk after head injuries. A study on bright-light therapy—exposing patients to hours of intense light—failed to show improvement, VA doctors said. And a VA study in Boston found female veterans with PTSD had no greater benefit from practicing yoga together than they did from meeting to talk.

"We're fairly open to establishing the evidence base for anything that would help the conditions that veterans are affected by," said Theresa Gleason, head of the VA's clinical research-and-development service for alternative medicine.

So, many urge quicker action by the VA, while others urge caution. The Wounded Warrior Project, a nonprofit service organization for Iraq and Afghanistan veterans, endorses only treatments with the VA seal of approval. "Don't bring me a bunch of anecdotes," the Journal quoted the group's head of government affairs, who called for data instead.

But alternative-medicine advocates are lobbying the VA, the U.S. military and Congress to do more and do it faster. It's the HBOT advocates who got the attention of the Indiana General Assembly during the 2014 Session, prompting the passage of SEA 180.

As many as half of veterans report trying alternative medicine to cope with the residual effects of war, according to the VA's National Center for PTSD.

The Journal article noted that "some people are urging the military to treat combat brain injuries with the same HBOT used to treat deep-sea divers with the bends. It has been tried at some military facilities, including the Marine Corps' Camp Lejeune. But a physician with the VA Medical Center in Richmond, Virginia said there has not been enough research to validate its use for brain injuries. "Unfortunately in hyperbaric oxygen," he said, "nobody is replicating another person's study."

Even further afield is a program called BattleTap, founded in 2011 by an Iraq veteran. Clients are taught to tap or apply karate chops at nine points on the head and chest, while thinking about difficult memories and emotions and reciting slogans about accepting their feelings so that one day they will feel peace. There have been no studies specifically demonstrating BattleTap's effectiveness, though aspects of the treatment have been shown to work.

A practitioner in New Mexico is urging the State to appropriate \$90,000 for a study on the efficacy of naprapathic medicine in treatment veterans suffering from PTSD. What is naprapathy? It is a form of physical therapy that works on the soft connective tissue that holds the skeletal frame together. Currently, the VA does not sanction naprapathy for treatment of PTSD. A spokesman said in an email, "Naprapathy therapy for PTSD is not considered the standard of care within state VA or nationally. This therapy is not used at our clinics."

The Washington Post has also recently reported on veterans' disaffection with the care they receive in the VA health care system, and highlighted an alternative therapy program at the same Richmond, Virginia VA hospital cited above that marks a dramatic departure from the health care offered by the VA elsewhere in the country: "Among the options: Equine therapy. Alpha stimulation. Qigong. Guided imagery. Life coaching. Yoga and Pilates. Hypnosis. Aqua therapy. Botox."

The Post reported that the Richmond hospital and three other pilot programs offering these therapies are part of an effort by the VA to reduce the dependence of tens of thousands on opiate painkillers. While doctors say the highly addictive drugs can help in the short term, they also can be harmful and often require another round of prescription medicines to counteract side effects that can include insomnia, constipation, bone pain, anxiety and depression. However, the Post reported, "The scientific basis for these alternative therapies is mixed, and much of the research is preliminary."

In November, the National Institutes of Health and the VA announced the launch of a five-year, \$21.7 million initiative to study the effectiveness of alternative treatments. The undertaking includes 13 separate research projects. Some of the alternative treatments are proving

effective. The FDA, for instance, in 2010 approved Botox to prevent headaches and treat neck pain in adults. Insurance companies are increasingly covering acupuncture for treating four chronic pain conditions: back and neck pain, osteoarthritis, chronic headache and shoulder pain.

**Use of Complementary and Alternative Medicine by the VA:** The VA's National Center for PTSD's website acknowledges that the use of Complementary and Alternative Medicine (CAM), which is "VA speak" for treatment protocols that don't yet have good evidence to support them, "is widespread for the management of mental health problems, including PTSD." There is only limited evidence about the effectiveness of CAM as a treatment for PTSD; however, the evidence suggests that some CAM approaches have modest beneficial effects as a treatment for PTSD," says the VA website.

Broadly conceptualized, "complementary and alternative medicine" (CAM) refers to treatments not considered to be standard in the current practice of Western medicine: "Complementary" refers to the use of these techniques in combination with conventional approaches, and "alternative" refers to their use in lieu of conventional practices.

Many treatments and techniques that are considered CAM within the U.S. are part of conventional medicinal practices in other parts of the world. As Western practitioners and consumers increasingly adopt these approaches, the boundaries between conventional medicine and CAM continue to shift, the VA says on its website. HBOT is not considered CAM.

In general, reported rates of CAM use are similar in veteran and civilian samples, ranging from approximately one-quarter to one-half of respondents, depending on the type of CAM and health conditions assessed. Active military personnel are not captured in nationally representative or veteran samples, but research suggests rates of CAM use in the military are similar if not higher than rates of CAM use among veterans and civilians.

Despite the widespread use of CAM among individuals with PTSD, evidence to support the efficacy of CAM for treating PTSD is limited. Some CAM examples include acupuncture, meditation, relaxation, yoga and other mind-body practices such as energy therapy.

Overall, the VA concludes that "the current evidence base does not support the use of CAM interventions as an alternative to current empirically-established approaches for PTSD, or as first-line interventions recommended within evidence-based clinical guidelines. CAM may be best applied as an adjunct to other PTSD treatments or as a gateway to additional services for patients who initially refuse other approaches," the VA website notes.

The VA says it is "committed to providing patient-centered care that includes evidence-based treatments for veterans with mental health and behavioral health conditions. Recognizing the interest among many Veterans in being able to access CAM approaches, VA facilities may choose to provide supportive services in addition to established evidence-based therapies and medications. VA does not have specific policies or guidance related to the provision of CAM therapies for PTSD. However, VA is implementing mechanisms to track the use and effectiveness of CAM among VA patients, which will inform future clinical guidance, policies, and best practices for use of CAM modalities."

A 2011 survey of all 141 VA facilities (which includes health care systems) by VA's Healthcare Information and Analysis Group (HAIG) found:

- 89% of VA facilities offered CAM and 1% were in the process of developing CAM programs.
- The top five uses of CAM were for, in order: stress management, anxiety disorders, PTSD, depression, and back pain.
- CAM is used as an adjunctive therapy 72% of the time, but this was not reported as specific to PTSD or other disorders.
- 65% of facilities reported offering one of more types of CAM for PTSD.
- Another recent survey of all 170 VA specialized PTSD treatment programs found:
  - 96% of the 125 programs that responded reported offering CAM.
  - 88% reported using types of CAM in addition to guided imagery, progressive muscle relaxation, and stress management/relaxation, treatments that are considered to be CAM but are used in conventional mental health care.
- The types of treatments used most often in specialized PTSD programs were: mindfulness, stress management/relaxation, progressive muscle relaxation, and guided imagery, all of which were offered in more than 50% of treatment programs.

**Other Indiana PTSD/TBI services of note:** The mission of the Indiana Department of Veterans Affairs is to assist Hoosier veterans, service personnel, their dependents and/or survivors in obtaining every benefit and advantage due them under the laws of the State of Indiana and the United States. The Department works with a network of certified County Veteran Service Officers who assist with information and the preparation of paperwork at no cost.

Other Indiana state services specially provided either to, or on behalf of, veterans:

- The **Indiana Spinal Cord and Brain Injury Research Fund** was created by the 2007 Indiana General Assembly under IC 16-41-42.2-4; a Board appointed by the Governor reviews applications for spinal cord and brain injury grant funds and recommends funding amounts to the State Department of Health, which oversees the Fund's activities. Board members include representatives of the Southern Indiana Traumatic Brain Injury Foundation, the technical life sciences industry, the National Spinal Cord Association, Rehabilitation Hospital of Indiana and the Brain Injury Association of Indiana. State appropriations for 2013-2014 totaled \$1.55 million; grant funds of more than \$1 million were awarded, with remaining monies being used to pay ISDH staff and to maintain the State's trauma registry which is operated by the ISDH. Grant recipients in 2013-2014 included Indiana and Purdue university researchers.
- The General Assembly last year adopted House Enrolled Act 1358, which requires the ISDH to adopt rules to establish a license and provide regulations for **a facility that provides specialized treatment and services for traumatic brain injuries**. Indiana has long had to send Hoosiers afflicted with TBI to out-of-state facilities for treatment and care—at sometimes exorbitant prices—a practice that can now end soon.
- The **Military Family Research Institute** at Purdue University operates a program called the Star Behavioral Health Providers (SBHP), which is a system for improving the quality of and access to behavioral health services for service members, veterans and the family and loved ones who care for them. They enable civilian behavioral health providers and other related professionals through training, which raises their awareness and sensitivity of the unique challenges faced by the military population, and they enable the military population to more easily locate the behavioral health resources they need

by establishing and maintaining a registry of behavioral health providers which have received SBHP training.

The Star program serves as “resource facilitators”, not case managers, as they’re not clinical, but they “help make the health care system work for veterans,” says Shelley MacDermid Wadsworth, director of the Military Family Research Institute and a professor of human development and family studies at Purdue University. The Star program now operates in 4 states (Michigan, Indiana, Georgia and California), but is looking to move into more. “We’re a ‘value add’ and ‘force multiplier’,” Wadsworth says. More information is available about them at their website: [www.starproviders.org](http://www.starproviders.org).

- **The Indiana Brain Injury Leadership Board** has been created as a result of a Health Resources and Services Administration (HRSA) grant—the Traumatic Brain Injury State Implementation Partnership Grant Program—which has been applied for and received by one of the state’s pre-eminent TBI authorities, Dr. Lance Trexler of Indianapolis. The purpose of the grant is to support state governments as they address barriers to needed services encountered by children, youth and adults with, and at high risk, for TBI. Indiana’s grant will focus on Indiana Department of Correction (DOC) inmates and establish Resource Facilitation as a best practice model for improving rates of return to work or school and improved functionality for patients with TBI. The target population is offenders who are either engaged with parole or community corrections in Marion or Allen counties. The project will use the resource facilitation model and apply it to the offender population, so that when entering parole or community corrections, offenders will be screened for the presence of a TBI by correctional staff. The project will also provide education and training to correctional staff and primary health care providers with the goal of increasing their knowledge and awareness on the issue and effective ways to communicate and treat people impacted by TBI. The grant is for up to \$250,000 per year for a maximum of four years.
- **The Office of Vocational Rehabilitation** is also able to assist veterans who: 1) Have a physical or mental impairment that substantially interferes with the ability to prepare for, enter, engage, or retain employment; and, 2) If Vocational Rehabilitation services are required for the individual to become employable. A determination of eligibility should be made within 60 days from the date of application. Medical documentation or other eligibility qualification (i.e., Social Security Disability Insurance, or SSDI) is typically what is used to make determinations.

Services provided if determined appropriate can include, but are not limited to:

- Diagnostic testing and assessment to determine eligibility for Vocational Rehabilitation services and also to determine needs.
- Vocational counseling and guidance.
- Job related services including job search and placement assistance.
- Vocational, on the job, and other training education services.
- Treatment for physical, mental, and emotional impairments which are considered a substantial impediment to employment.
- Transition services for students to help make the transition from school to work.
- Rehabilitation technology including telecommunications, sensory, and other assistive devices and aids.
- Placement assistance and follow-up.
- Supported employment.

- Limited post-employment services may be provided. This is determined on a case by case basis.

Most of the veteran clientele at Vocational Rehabilitation have non-service related disabilities (since the federal VA Vocational Rehabilitation and Evaluation, VR&E, organization provides Vocational Rehabilitation service to them). However, they do have a memorandum of understanding with VR&E that allows the State of Indiana to work in conjunction with the VA VR&E counselors and “share” clients when federal policy prohibits certain services to be paid for by them, but Indiana state policy allows for the paid service. This is often the case for transportation and/or other educational services.

**What kind of providers would be needed for an Indiana system?:** If Indiana were to establish a program for the specific treatment of veterans with TBI or PTSD as suggested by SEA 180, the types of providers that would be needed, according to Dr. Malec, would include evaluation and treatment teams made up of physicians, PhDs, RNs, master’s-trained professionals, and peer counselors, all needed to ensure that providers function efficiently and perform at the upper level of their credentials and privileges, but also the following specialists:

- Neuropsychiatrists
- Psychiatrists
- Neuropsychologists
- Neuroradiologists
- SLPs (speech pathologists)
- OTs (occupational therapists)
- Vision therapists
- Vestibular therapists (probably physical therapists) and
- Psychotherapists with specialized training/experience in working with veterans with brain injury.

An Indiana system of care for vets with TBI and/or PTSD, that essentially displaced the VA health care system, would need to address excessive wait time for veteran’s health care, which is a complaint often expressed by both active-duty and veteran service members. Long wait times can compromise health because of delayed use and decreased patient satisfaction. In addition, adverse long-term outcomes, such as death and preventable hospitalizations, are more common for veterans who seek care at facilities that have longer wait times than for veterans at facilities that have shorter wait times. Poor availability and misdistribution of mental-health specialists in many parts of the United States, especially in rural areas, present substantial barriers to OEF and OIF veterans’ access to mental health care.

Andy Brown, the Supervisory Rehabilitation Coordinator/Polytrauma Program Coordinator at the Roudebush VA Medical Center, Indianapolis, says that programs for treatment of TBI incorporate an interdisciplinary approach utilizing rehabilitation, mental health, and primary care providers with TBI expertise.

**What would an Indiana system cost?:** SEA 180 directs us to analyze the costs of TBI and PTSD among veterans and the economic impact of implementing the suggested program. The economic impact includes both costs of implementing the program (and foregoing the VA system which pays for nearly all veterans’ TBI and PTSD care today) and the economic benefit of rescuing more veterans’ lives (and those of their loved ones) from factors like unemployment and suicide. We have already discussed the costs of providing care to PTSD and TBI patients,



including the more traditional cognitive rehabilitation and resource facilitation, as well as HBOT. We have also already seen that the VA and FDA reject HBOT because it is not “evidence-based” treatment; there has been some testimony in this report that HBOT may have helped a select few veterans, but overall, its impact is highly suspect. Thus, we fail to see how HBOT offers significant economic benefit from being included in the statewide system proposed by SEA 180.

The only study we found discussing the potential economic impact of providing cognitive rehabilitation, resource facilitation or HBOT was the study done by the Center for Business and Economic Research at Ball State University, which simulated the economic impact solely of resource facilitation on the estimated population of Hoosier brain injury victims on an annual basis and provided estimates of the earnings losses associated with brain injury and the resultant long-term disability. The study found that resource facilitation intervention in brain injury cases results in 64% of patients being employed post-treatment, meaning that an average 1,003 Indiana residents would return to work after the intervention. The study concluded that the average economic impact of resource facilitation treatment is slightly more than \$31 million annually in avoided lost wages; if further adjusted by age, percent employed and educational attainment, it would recapture an additional \$22.5 million in additional earnings on an annual basis. The authors of the study said those numbers are probably very conservative because, for one, they don’t reflect annual losses to business tax revenue or personal tax revenue that results from work force loss.

An Indiana system for treating veterans with PTSD and/or TBI with cognitive rehabilitation, resource facilitation and HBOT—and that foregoes the VA system which provides PTSD and TBI care (albeit without including HBOT)—would cost millions, if not billions, of dollars. And what would be gained over and above those results that the VA achieves today?

Providing HBOT care alone for roughly 14,000 Hoosier OEF/OIF/OND veterans with PTSD and/or TBI—at a maximum cost of \$40,000 per patient—would cost Indiana \$560 million. And if the HBOT advocate’s numbers of 50,000 or 70,000 Hoosier TBI/PTSD veterans is accurate, the cost would be three to five times greater. And, none of this accounts for the costs to administer the statewide system, which could easily run into the millions of dollars. As we’ll explore more fully, Indiana cannot “send the bill to Washington” and expect the federal government to pay it.

If Indiana’s system were to include cognitive rehabilitation and resource facilitation for these 14,000 Hoosier veterans each year, the costs would be astronomical and reckless to take on in the face of the VA health care system that already has the responsibility to pay those costs.

**How would an Indiana system be paid for?:** The Indiana Veteran Recovery Plan (IVRP) includes a number of proposals to fund a statewide HBOT program:

Initial implementation in 2014 would require establishing a revolving IVRP Trust for five years of about \$5 million. This Trust would revert back to the source it was established from after the five-year period unless reaffirmed by the legislature or 60 days after the FDA approves the hyperbarics treatment as a “standard” for care. (We) recommend the use of “Surplus Funds” or from the “Rainy Day” fund. In essence, the establishment of the IVRP Trust would be a loan from some other source to be paid back at the end of the “loan” period (without interest). Funding for out years could come from decreases in other state accounts that these veterans are currently drawing from such as Medicaid and unemployment to name a few.

If this approach is taken the “loan” could be paid back sooner than the five years.

Beyond that, the HBOT advocates urge the State to establish a HBOT program for veterans suffering from TBI or PTSD, and “send the check to Washington.” One HBOT advocate actually told us in an interview:

I’d get the Governor to look at his own record when he was in Congress and his concern for veterans demonstrated over and over again with an Executive Order he could sign to use x number of state dollars to be treating and healing. We hope every Governor would recognize that he is obligated the way the Secretary of Defense should be but isn’t to treat and heal the wounded. Then send the bill to Washington.

Another Hoosier HBOT advocate adds: “If the state would just provide the medical treatment, the Feds will reimburse them.”

The VA steadfastly insists it will not pay for HBOT for veterans and the HBOT advocate’s legal theories for how to make Washington pay for the State’s HBOT program are not well-founded. And, other funding sources that HBOT advocates cite to pay for a State HBOT program don’t appear to be designed to work for that purpose.

The VA’s position on paying for HBOT, as expressed by Tom Mattice, director of the. Roudebush VA Medical Center in Indianapolis, is pretty clear:

“HBOT has been proposed as a possible therapeutic modality for the treatment of Traumatic Brain Injury (TBI), and especially mild TBI, as well as for Post-Traumatic Stress Disorder (PTSD). No organization has as much interest in treating these two conditions as the VA . . . . When new modalities for the possible treatment of one or both of these conditions emerge, the VA has a great interest in determining the effectiveness of those possible treatments. For that reason, the VA, in partnership with the Department of Defense (DoD), has sponsored research into the efficacy of HBOT, and reviewed other research extensively.

Most of the clinical studies completed have centered on the use of HBOT for TBI. Far less research has been done related to its use for PTSD. Some studies into the use of HBOT for TBI showed promise. (However), a follow-up study reported that [HBOT] at 2.4 ATA pressure had no effect on post-concussive symptoms after mild TBI.” That is, the study showed that there was no difference between the treated group and those who appeared to receive treatment but in fact were subjected to a placebo. Three further studies published in 2013 and 2014 confirmed the results of this study.

It is noteworthy that the U.S. Food and Drug Administration (FDA) similarly categorizes the use of HBOT for these purposes as experimental, and notes that there is “more than minimal risk” associated with its use (see above). The US Department of Health and Human Services Centers for Medicare and Medicaid Services also does not authorize HBOT as standard care for TBI nor PTSD, and it is not reimbursable.

Research into the use of HBOT for treatment of PTSD has not been nearly as comprehensive. As of 2010, only case reports and anecdotal evidence were available. Unbiased, independent and scientifically solid research is needed to determine whether

this modality of care holds promise for the treatment of PTSD. A recent communication to me from . . . .the VA-DoD Mental Health Integration Office confirmed that at this time, the evidence for the use of HBOT for PTSD is insufficient to consider it to be an evidence-based treatment for PTSD.

In conclusion, it is the policy of the VA to adhere to the use of evidence-based treatments and therapies. That is not currently the situation related to the use of HBOT for treatment of TBI or PTSD. In the future, if the use of HBOT meets that scientific level of acceptance, we will again review its use.”

Some HBOT advocates believe that FDA and VA will approve the use of HBOT to treat PTSD and TBI patients within the next five years.

The HBOT advocates claim that the Federal government must pay for a State HBOT program because a 1921 federal law—the Veterans Bureau Act—requires it. “The Federal government has shifted costs from these war casualties to the states. The 1921 Veterans Bureau Act requires the VA to automatically reimburse the state for any treatment that is not provided by the VHA. The proposed solution would include the State of Indiana Insurance Commission managing and processing documents for reimbursement. Thus the costs of treatment would be totally reimbursed. The cost to the state of Indiana would be to administer the claims received from providers and submission to the VA.”

But an ISDH legal opinion finds no support for these assertions:

“The (HBOT position) contains many statements that are incomplete and unsupported. It assumes that the IVRP, as written, will stand on its own and does not violate any principles of federalism. While the document discusses separation of powers on a state level as a justification for why the IVRP will guarantee reimbursement, it fails to consider the basic concept that federal law is the ultimate authority on federal matters; while state law can fill in the gaps, it cannot violate other federal regulations or force the federal government to do something that it is not already obligated to do under federal law.”

There is no guarantee that the State of Indiana could be reimbursed if it pays for HBOT for veterans for the treatment of TBI or PTSD. No state can compel the federal government to enter into a contractual agreement or to give it grant funds; furthermore, recipients of grant money are generally not in a position to dictate the terms of how the funds will be spent.

The Veterans Bureau Act created the Veterans Bureau in 1921. Since then, there have been many other pieces of federal legislation with regards to veterans’ health care and insurance that likely superseded the Act. (We) cannot find any current or past federal statute or regulation that compels the state governments to assume responsibility for the payment of health care expenses for active and retired military members; it seems to be a purely federal obligation.”

HBOT advocates also claim that the Oklahoma legislature has accomplished what they’re proposing in Indiana: “The legislature in Oklahoma recently passed a bill (SB 1604, the Oklahoma Veterans Traumatic Brain Injury Treatment and Recovery Act of 2014 ) stating that they were going to provide treatment for returning veterans of the National Guard using hyperbaric oxygen to treat those with TBI and PTSD.” However, the legislature committed no

money to it, making it a fairly hollow victory. The International Hyperbaric Medical Foundation conducts fund-raisers to attempt to pay for the program.

The State of Texas earlier this year tried to force the federal government to pay non-VA providers through Medicaid for care given to veterans: Gov. Rick Perry in mid-June announced that the state reached agreements with health facilities to provide care for veterans who cannot get timely treatment from the U.S. Department of Veterans Affairs. The federal government denied Gov. Perry's request in part because it would require major federal legislative changes authorizing expansion of the Medicaid system and changes to the medical record and IT systems to enable the VA to make required reports to Congress. These problems were judged to be insurmountable.

HBOT advocates propose other ways to fund a statewide program for the treatment of veterans with traumatic brain injury or PTSD; unfortunately, none of these ideas appear sufficient to fund a statewide program:

- **The Veterans Access, Choice and Accountability Act of 2014**
  - This is the \$17 billion program approved by Congress this summer to improve access to and quality of care for veterans in response to allegations that veterans received poor medical care, even after waiting months to get it.
  - Under the legislation, VA is required to offer an authorization to receive non-VA care to any veteran who has enrolled in the VA health care who has waited more than a month for a medical appointment or who lives more than 40 miles from the nearest VA medical facility, but we could find nothing in the legislation that would permit non-VA providers to give non-VA-approved care (and be paid for it).
  - The law does provide great things for veterans:
    - Improved access to outside care, as mentioned above
    - Expanding VA staff by hiring thousands of doctors, nurses and mental health counselors, though this will take months to get underway and years to complete.
    - Extends for three years a unique VA pilot program that provides assisted living and therapy to those with moderate to severe TBI. As such injuries have ballooned in recent years, Congress directed the VA to test out how assisted-living services could help veterans with rehabilitation, quality of life, and reintegration. In 2011, the department signed up 20 certified residential brain injury rehabilitation providers for services at 150 sites across the United States.
  - However, there appear no provisions in the law to pay for the kind of program contemplated in SEA 180.
- **U.S. House Resolution 1098**, which would reauthorize a CDC project to reduce the occurrence of traumatic brain injury and support the establishment of brain injury registries through FY2019. Our reading of the resolution reveals it's not intended for medical treatment of TBI patients.
- Another resolution, this one **U.S. House Resolution 4080**, would reauthorize trauma care system planning grants to boost access to trauma care. Again, these grants are intended for states to implement trauma care systems, not for direct patient medical care.

- **Substance Abuse and Mental Health Service Administration (SAMHSA) block grants** are another idea suggested by the HBOT advocates. While these hold some potential—as they provide funding for substance abuse and mental health services—funding for care of TBI and PTSD patients who are veterans would compete with a number of other segments of the population for which the state receives these grants, and thus there would be no guarantee much, if any, portion of the grant, if received, would go to care for veterans with TBI and/or PTSD. And the lack of evidence-based data to support HBOT might also doom the idea at the grant award stage. Members of this panel are not expert in block grants, but our reading reveals that grantees use the funds to plan, implement, and evaluate activities that prevent and treat substance abuse and promote public health, not for medical treatment itself. Even if all these obstacles are overcome, it is unclear that a block grant award for Indiana would include enough money to fund HBOT care for thousands of injured Hoosier vets.
- **The Indiana Spinal Cord and Brain Injury Research Fund** is administered by the Indiana State Department of Health and is used primarily to fund research projects in the field of spinal cord and brain injury. Again, this is probably not an appropriate source of funds to pay for HBOT treatments, as it would rapidly bankrupt the Fund which is intended for research purposes only.
- Perhaps the best idea the HBOT advocates propose is to pay for a State program to replace VA care for TBI/PTSD patients through **social impact bonds**, also known as a “pay for success bond” or “social benefit bond”, which amounts to a public-private sector arrangement in which a commitment is made by a public sector entity (in this case, the State of Indiana or a political subdivision) to pay for improved social outcomes (conducted by a private entity), resulting in public sector savings. The downside is that the idea is brand new, which means it would likely take time to get traction. And, as with any of these ideas where the State would replace current VA programs by employing a non-evidence-based program like HBOT, we’re talking about funding non-evidence-based science.

**Ongoing research:** There are a number of research studies underway that may result in further relief for TBI and/or PTSD patients. Some of the most exciting work is detailed here:

- New research on mice shows promise for literally getting to the root of the problem: morphing painful memories into positive ones. Researchers first shocked male mice with electricity to form a “bad memory” when the mice moved into one part of a cage. In a different part of the cage, the male mice were allowed to cavort with female mice, thereby creating a pleasurable memory associated with the cage. However, while the mice were still cavorting with the females, they were again given a small electric shock. That small movement changed their brain chemistry so that the memory of the shock became connected to neurons in the brain responsible for encoding pleasure and the cavorting connected to the neurons responsible for pain in the brain. The researchers were able to rewire the brain, they note, because memories are not like “tape recorders” where the mice simply play back a memory. Instead, remembering is a creative process. Although more research is needed before anything could be applied to humans with PTSD, the researchers are hopeful because of the human memory’s similarity with mice’s memory.

- Breathing meditation is a powerful ally for military veterans recovering from PTSD, according to Stanford research recently published in the *Journal of Traumatic Stress*. For several years, researchers at Stanford's Center for Compassion and Altruism Research and Education have been studying the effects of breathing-based meditation practices on veterans suffering from PTSD. This is the first RCT on a form of meditation or yoga for veterans with PTSD that has shown such long-term, lasting effects.

The Stanford researchers examined 21 American veterans from the wars in Iraq and Afghanistan as they participated in a breathing-based meditation practice known as Sudarshan Kriya yoga. Other studies have shown that this form of yoga, which incorporates breathing exercises with periods of discussion and stretching, to be effective in treating anxiety, addiction and depression. The participants met for three-hour sessions over seven days. Researchers measured eye-blink responses to loud noises, respiration rates and self-reported descriptions of participants' PTSD symptoms. Assessments were taken at four intervals – before, during, one month later and one year after the treatment. “Overall, the results were fruitful. It resulted in reduced PTSD symptoms, anxiety and respiration rate,” wrote researchers.

- The premise of the movie *Inception* involves implanting or extracting information from a person's mind as they sleep. Thus far, no such treatment exists. A paper recently published in the journal *Biological Psychiatry* argues that it may be possible to treat PTSD by altering patients' memories. The paper reviews a growing body of scientific literature on memory reconsolidation, a relatively new (and, in humans, still somewhat contentious) concept in which old information is called to mind, modified with the help of drugs or behavioral interventions, and then re-stored with new information incorporated—like a piece of metal that has been melted down, remolded, and left to harden into a different shape. Though different types of memories are solidified in different ways—the fear-driven memory of driving over a bomb, for example, will make its way through the brain differently than a mundane memory of yesterday's breakfast—there are general neurological processes that all memories follow.

Typically, the more often memories are recalled, the stronger they become. “If you're trying to memorize something in a book, you sit there and repeat it over and over,” explains one researcher. “That's also an example of how things get consolidated. You repeat [them] over and over.” But with reconsolidation, consciously recalling a memory is also what allows it to be manipulated. “[Memories] are not necessarily fixed but can be changed long after storage,” they write. “Seemingly stable memories may re-enter an unstable state when they are retrieved, from which they must be re-stabilized ... During reconsolidation, memories are susceptible to modification again.”

Perhaps more compelling for the treatment of PTSD, though, are the experiments that involve tampering with fear-driven memories using pharmaceuticals. In one study, published in *Nature Neuroscience*, volunteers were stimulated to generate fear memories after being subjected to loud noises and images of spiders; later on, one group was given propranolol (a beta-blocker used to slow heartbeat and sometimes used in the treatment of anxiety disorders) before being made to recall the fearful experience, while the other was given placebo pills. When the two groups were again reminded of the memory days after the experiment began, those who had taken the propranolol showed markedly less fear than those who had not.

- Can you screen for PTSD in the same way you screen for breast cancer? A new paper from researchers at the Mount Sinai School of Medicine suggests that gene expression could reveal which individuals are most likely to develop PTSD, a development that could accelerate the search for a therapy to effectively pretreat the disorder through a pill. The relationship between low cortisol, stress, and susceptibility to PTSD has been established for decades, but therapies that use cortisol to prevent or pre-treat stress are still in the experimental phase, and some of the most ambitious work is taking place outside of the United States.
- New PTSD therapies for veterans were the subject of a “60 Minutes” documentary in late May 2014 (originally broadcast Nov. 24, 2013). The story recounted the two million veterans who’ve served in Iraq and Afghanistan; one in five have returned with PTSD. The VA decided to try new treatments originally designed for rape victims, and the new PTSD therapy (called “prolonged exposure”, or “cognitive processing therapy”) has been promising. Vets in the program (the “60 Minutes” piece was filmed at the VA hospital in Little Rock, Arkansas) live there for eight weeks to break through emotions that have derailed their lives. “Prolonged exposure” forces the PTSD veteran to work at remembering every detail of what he’s tried to forget, and relive the story of what brought on his/her PTSD five times per therapy session. There’s a tape running and the veteran will listen to the memory throughout the day to break its power, reported CBS. A physician treating the vets at the Little Rock VA hospital said: “They’ve done everything they can to push these memories away. In the process, they haven’t gained a full realization of the impact and the meaning that these stories have in their lives. I like to use the term ‘we’re staring the dragon in the eye.’”

The program reports that 77% of vets in the program graduate with a drop in their PTSD symptoms; “60 Minutes” reported that 145 veterans have been through the program and hundreds more have signed up.

- Regions Hospital in Minnesota is one of a handful of hospitals around the country participating in a study to see if a medication can help prevent long-term damages from traumatic brain injury. Participants are hoping to determine if Tranexamic Acid, also called TXA, will stop brain bleeding in patients with brain injuries. TXA is FDA-approved to stop bleeding and has already been used for combat injuries; some doctors believe the medication may be able to stop bleeding in the brain too.
- In an accelerated project announced in early July 2014 by the research arm of the Pentagon—known as DARPA (Defense Advanced Research Projects Agency)—University of Pennsylvania scientists will lead a complex national effort to treat memory impairment by delivering very small doses of electricity to the brain. DARPA is funding the \$22.5 million, four-year effort to seek treatments for the thousands of returning veterans with TBIs. A similar \$15 million project is being led by the University of California, Los Angeles. Researchers will measure brain activity as the patients engage in memory games and other tasks, to determine what electrical patterns are associated with memory when it is operating at peak performance. The resulting data will be used to guide delivery of mild electric stimulation to nudge the brain into that optimal learning state as needed.
- DARPA is also working to develop wireless, implantable brain prostheses for service members and veterans who suffer memory loss from TBI. Called “neuroprostheses,” the

implant would help declarative memory, which consciously recalls basic knowledge such as events, times and places, DARPA officials said. To overcome such memory deficits, "these neuroprosthetics will be designed to bridge the gaps in the injured brain to help restore that memory function," said Dr. Justin Sanchez, DARPA's "Restoring Active Memory Program manager.

- One of the biggest challenges for caregivers is convincing the returning veteran with PTSD to seek treatment. The University of Southern California's Institute for Creative Technologies (ICT) has been working closely with the military to develop innovative strategies for treating PTSD using video game technology. The therapy also may help anyone dealing with trauma. A research scientist at the institute explains that "the goal here is to help the patient experience some moderate level of anxiety that their memories bring up, but to do it in a safe environment." It is less the visual surroundings that make the experience realistic as it is sound and smell. "We have bad smells, gun powder, rotting garbage, body odor," ICT explains. "We know theoretically smell is intimate for emotion and memory."
- The National Brain Injury Rescue and Rehabilitation Project (NBIRR) is a research project designed to treat 1,000 patients with mild TBI and/or PTSD using a standard HBOT protocol. Sponsored by the International Hyperbaric Medical Foundation, analytic methods were to be designed to minimize the effects of having no placebo control group. However, this study has recently suspended recruitment, pending clarification of regulatory status.

**Other options to help TBI/PTSD victims:** One idea that multiple states are piloting is the veterans treatment court, and the federal government has previously provided funding for such programs.

The Department of Justice's Bureau of Justice Assistance (BJA) supported four drug courts designed to meet veterans' needs under the Adult Discretionary Drug Court Program. Veteran treatment courts help veterans within the criminal justice system manage their substance abusing habits so that they can safely return to their communities. A total of more than \$1 million dollars was provided to the Judicial Council of California; Hennepin County, Minnesota.; the 13th Judicial District Court in Yellowstone County, Montana, and Spokane County, Washington. There are more than 150 veteran courts in the U.S., and more than 100 in the planning stage, according to Justice for Vets, a division of the National Association of Drug Court Professionals.

"Eighty-one percent of all justice-involved veterans have a substance abuse problem prior to incarceration, and 25% of these veterans have a mental illness," said one assistant attorney general. "It is our hope that these veteran drug courts can provide the services and treatment that these soldiers need in order to help them rejoin our communities safely as the heroes we know them to be."

Veteran treatment courts integrate substance abuse treatment, mandatory drug testing, sanctions and incentives, and transitional services in a supervised court setting. In addition, with programmatic support from the Department of Veterans Affairs, participants are connected with Veterans Justice Outreach specialists for help with obtaining veterans' benefits and services to address their treatment and other recovery support needs.



"By identifying justice-involved veterans early and connecting them with mental health and substance abuse services at home, veteran treatment courts can stabilize veterans and ensure that they are able to return to honor and live productive lives," said BJA Director Denise E. O'Donnell. "At BJA, we are proud to support these drug and mental health court programs that serve the men and women who fought so bravely to protect our nation." Several other states are also experimenting with treatment courts for veterans:

- **Utah:** The Utah State Courts are working to implement courts that will be similar to other "problem-solving courts" already in place, such as mental health and drug courts, that aim to go beyond punishment by providing treatment and long-term solutions for those facing criminal charges while struggling with such issues. Citing the fact that veterans bring with them different problems than those in drug court and mental health court, these courts will build in a mentor system to pair veterans who land in court with other veterans who can connect to them and help navigate treatment and the court processes. Utah's state court administrator cited research showing there are benefits to treating veterans separately from other mental health or drug court participants. Some districts within the Utah court system have chosen not to create a separate court but a separate court calendar to solely address veterans' legal issues.
- **Iowa:** At least one Iowa district court judge, who knows that military veterans, many having served multiple tours of duty in recent wars, are entering his court in trouble; he is leading an effort to establish a veterans treatment court in Woodbury County. It is a program that would get veterans of any age who commit crimes there needed help and, he hopes, keep them out of jail. It would be the first such court in Iowa. The judge acknowledges there are different models for veterans courts, and says he envisions one that would match offenders with a mentor, a fellow veteran with similar military experiences. Mentors aren't meant to be counselors, but rather someone the offender can go to for advice.
- **South Dakota:** A veterans court was scheduled to begin operating in Watertown this summer.

Another idea that is being tried in Nebraska is a VA grant program that tries to help TBI and PTSD-afflicted veterans by awarding grants to local health departments to help veterans better connect to needed services. Three Rivers Health Department, along with 13 other Nebraska health departments, will share in a grant to help with this outreach. The VA awarded the \$2 million grant to the Nebraska Association of Local Health Directors for a two-year project. The grant will be divided among health departments covering 71 of Nebraska's 93 counties. The funds will provide resources to health departments to provide veterans returning to their homes in rural Nebraska access the support they need to reintegrate into the community. The Nebraska Association of Local Health Directors' project is one of five pilot programs nationally to be funded by the VA. The grant will enable local health departments to increase their focus on meeting the unique needs of veterans, while providing veteran-specific training and support for rural health and service providers.

Tom Mattice, the medical center director for Roubidoux VA Medical Center, told us the State could assist the VA in its care of veterans with PTSD and TBI by identifying other entities that could provide veterans who don't trust government facilities with their health care. He said that outside entities would have to get separate authorization and would have to follow VA guidelines. He said cost to the state would be "nothing" because VA already has treatments for cognitive behavior or resource facilitation (but not for HBOT because it is not evidence-based).

In New Mexico, the Department of Veterans' Services and other groups hosted a free conference to help veterans and their families cope with post-traumatic stress disorder. Part of the conference focused on services and programs available for veterans with PTSD. A clinical psychologist discussed therapies used by the Veterans Affairs health care system.

In Louisiana, Gov. Jindal signed into law this summer a bill that prohibits any person with a disability, including veterans with PTSD or TBI, from being denied admission to any public facility because of that disability. It also prohibits individuals with disabilities from being denied the use of a cane, service dogs, wheelchair, crutches or other device of assistance.

In Arizona, beginning January 1, residents who suffer from PTSD will be able to legally use marijuana to help alleviate their symptoms under a decision by the state's Department of Health Services. The decision is a big win for medical marijuana advocates, many whom have long said cannabis is effective in treating PTSD. The state cited a recent study published in the *Journal of Psychoactive Drugs* that provides evidence that marijuana may be helpful in the palliative care of PTSD in some patients. Certifying physicians will be required to attest that they have reviewed evidence documenting that the patient is currently undergoing conventional treatment for PTSD before signing the medical marijuana certification. Arizona joins nine states that allow medical marijuana for PTSD, including Connecticut, Delaware, Maine, New Mexico, Oregon, Michigan and Nevada, says Karen O'Keefe, director of state policies at the Marijuana Policy Project in Washington, D.C.

State lawmakers in Kentucky considered the medical marijuana issue for those with PTSD, but at last word, had chosen not to proceed. Testimony to the Joint Committee on Veterans, Military Affairs and Public Protection in mid-July was the latest in a series of legislative hearings this year on allowing cannabis for health conditions such as pain and cancer symptoms. Clinical and psychiatric experts from the Louisville Veterans Affairs Medical Center cautioned lawmakers over a lack of controlled drug trials and clinical evidence for treating PTSD patients with marijuana. They testified that there are no statistics showing whether veterans who have been treated with the drug in other states are doing better than those receiving conventional medicine. Two bills to permit medical marijuana in Kentucky did not pass in committee during the 2014 General Assembly session.

## **Conclusion**

Our conclusion is simple: Indiana should not entertain further the notion of establishing a statewide program for the specific treatment of veterans with TBI or PTSD. We recognize that the VA health care system is not perfect, as its many flaws have been on full display over the last year. Bad VA health care can be improved, and there are signs that it is already being improved. But as this report showed, veterans are largely satisfied with their VA health care system.

But no matter the VA health care system's issues, it would be reckless and irresponsible for Indiana to establish its own system of providing health care for Hoosier veterans, especially if that system included HBOT, which both the VA and the FDA (and this report) identify as non-evidence based medicine. The federal government will not reimburse Indiana for this effort, no matter the "guarantees" that the HBOT advocates issue that it will happen. The main reason to reject the HBOT proposal is that it is not evidence-based medicine; the reason that runs a close second is the cost of implementing an Indiana system, especially one including HBOT.

This study revealed a number of things that Indiana can do to supplement the VA health care system and its treatment of PTSD and TBI, everything from veterans' treatment courts to taking advantage of VA grants to local health departments to help veterans better connect to needed services. Tom Mattice, the medical center director for the Roudebush VA Medical Center in Indianapolis, suggested that the State could assist the VA by identifying other entities that could provide veterans who don't trust government facilities with their health care; the VA's director of intergovernmental affairs told us essentially the same thing.

This discussion has never been about what is the single best treatment for TBI or PTSD—cognitive rehabilitation, resource facilitation or HBOT. As it stands now, the VA is beginning to consider more and more alternative treatments for TBI and PTSD; the HBOT advocates believe that their preferred therapy will be approved by the FDA in a few short years. All Hoosier veterans diagnosed or suspected of a brain injury or emotional distress should have access to specialists in these disorders; one day that may include HBOT along with other alternative treatments now being studied.

Hoosier veterans—and all Hoosiers, for that matter—deserve a government that recognizes the need to initiate new treatments when they are supported by strong evidence as contemplated by SEA 180, and when to stand pat. We believe Hoosiers have such a government and we recommend the General Assembly and the Administration reject the program suggested by SEA 180.

## **Appendix**

### **Senate Enrolled Act 180 (2014)**

AN ACT to amend the Indiana Code concerning veterans. *Be it enacted by the General Assembly of the State of Indiana:*

SECTION 1. IC 10-17-12.5 IS ADDED TO THE INDIANA CODE AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]:

Chapter 12.5. Veterans Disability Clinic Fund

Sec. 1. As used in this chapter, "commission" refers to the Indiana veterans' affairs commission established by IC 10-17-13-4.

Sec. 2. As used in this chapter, "department" refers to the Indiana department of veterans' affairs established by IC 10-17-1-2.

Sec. 3. As used in this chapter, "director" refers to the director of veterans' affairs.

Sec. 4. As used in this chapter, "fund" refers to the veterans disability clinic fund established by section 7 of this chapter.

Sec. 5. As used in this chapter, "qualified law school" means a law school:

- (1) located in Indiana; and
- (2) approved by the American Bar Association; that operates a veterans disability clinic.

Sec. 6. As used in this chapter, "veterans disability clinic" means a law school clinical program that:

- (1) offers practice opportunities to law students to counsel or represent veterans in claims for veterans disability compensation;
- (2) is part of the educational curriculum of the law school;

(3) is under the direction of a law school faculty member who is recognized by the United States Department of Veterans Affairs under 38 U.S.C. 5904; and

(4) provides legal services at no cost or nominal cost to veterans.

Sec. 7. (a) The veterans disability clinic fund is established to provide funding for grants to qualified law schools that establish or maintain a veterans disability clinic.

(b) The fund shall be administered by the commission.

(c) The fund consists of the following:

(1) Appropriations made by the general assembly.

(2) Donations to the fund.

(3) Interest.

(4) Money from any other source authorized or appropriated for the fund.

Sec. 8. A qualifying law school that wishes to receive a grant to establish or maintain a veterans disability clinic under this chapter shall consult with the department to:

(1) identify veterans in need of counsel or representation in a claim for veterans disability compensation;

(2) inform veterans about the availability of legal services through the veterans disability clinic; and

(3) develop an educational outreach program as part of the veterans disability clinic to advise veterans of their rights in the claims process for veterans disability compensation.

Sec. 9. The commission may adopt rules under IC 4-22-2 to implement this chapter.

SECTION 2. [EFFECTIVE UPON PASSAGE] (a) As used in this SECTION, "department" refers to the state department of health.

(b) As used in this SECTION, "veteran" refers to any individual in Indiana who has a United States military service related injury or disability, regardless of active, reserve, or retired status.

(c) Not later than September 1, 2014, the department, in consultation with the Indiana department of veterans' affairs and the division of mental health and addiction, shall:

(1) conduct a study; and

(2) report, in an electronic format under IC 5-14-6, the department's findings and recommendations to the legislative council;

concerning the implementation of a program for the specific treatment of veterans who have traumatic brain injury or posttraumatic stress disorder.

(d) Findings and recommendations made under subsection (c) must include the following:

(1) After consideration by the department of treatment protocols and therapies for traumatic brain injury and posttraumatic stress disorder, including:

(A) resource facilitation;

(B) cognitive rehabilitation; and

(C) hyperbaric therapy;

recommendations concerning the best peer reviewed, evidence based protocols and therapies to be used to provide the treatment described in subsection (c).

(2) Recommendations concerning the types of health care providers necessary for implementation and any certification of the program.

(3) The estimated number of veterans who have traumatic brain injury or posttraumatic stress disorder.

(4) An analysis of available federal and state funding for the program.

(5) An analysis of the costs of traumatic brain injury and posttraumatic stress disorder among veterans and the economic impact of implementation of the program.

(e) This SECTION expires January 1, 2015.

SECTION 3. [EFFECTIVE UPON PASSAGE] (a) The general assembly urges the legislative council to assign to an appropriate interim committee during the 2014 interim a study of veterans' benefits. The study must include the following:

- (1) How transforming Indiana's veterans' benefit services can increase benefits to veterans and beneficiaries in compensation, pensions, education, medical care, and other areas.
- (2) How Indiana compares to other states in each component of benefits, as reported annually by the Veterans Benefits Administration, including the following:
  - (A) Total expenditures, compensation, and pensions.
  - (B) Education.
  - (C) Medical and related care.
- (3) How Indiana's structure of assisting beneficiaries in obtaining veterans' benefits and tools may be restructured, including reviewing the following areas:
  - (A) Management, organization, staffing, and information technology.
  - (B) Education.
  - (C) Employment.
  - (D) Compensation, pensions, and other benefits.
  - (E) Health care education and delivery.

(b) This SECTION expires December 31, 2014.

SECTION 4. An emergency is declared for this act.

### **Our process to produce this report**

The Indiana State Department of Health (ISDH) began organizing the effort to study this issue and write this report mandated by SEA 180 immediately following the adjournment of the General Assembly in February 2014. The ISDH Division of Trauma and Injury Prevention was a logical choice as the group to lead the effort and interim Division director Katherine Gatz (since promoted to Director) and Assistant Commissioner for Health and Human Services Art Logsdon were given the specific assignment. By mid-April, our work was underway.

In early May, preliminary conversations about the charge of SEA 180—and specifically, its reference to the three treatment modalities of resource facilitation, cognitive rehabilitation and HBOT—were conducted with Indiana brain injury experts including Jim Malec, M.D., and Lance Trexler, M.D., and arrangements were made to meet with study partners from the state's department of veterans' affairs and division of mental health. The organizational meeting was held May 19 with ISDH, DVA and DMH all represented.

The parties decided that ISDH would take the lead in organizing meetings of the group, scheduling of interviews and writing the report. The group resolved that to gather information, we would invite TBI and PTSD experts and advocates of the three treatment modalities to make us aware of their opinions in one of three ways:

- Meet with us at in-person interviews that we'd arrange.
- Talk to us by phone.
- Submit their opinions in writing.

Following the organizational meeting, the ISDH proposed to schedule in-person and phone interviews for June 16, 24, 26 and 27. We asked those we met with to provide their thoughts in writing in advance, and we permitted them to supplement their interview after the fact. We

limited these interviews to 30 minutes each (however, we permitted Gen. James Bauerle a full hour to share his thoughts), and we permitted only one person at a time to meet with us (i.e., no group interviews). We supplemented these information-gathering opportunities with telephone interviews we conducted with others, as well as hours of research. We received suggestions for interviews from resource facilitation and cognitive rehabilitation experts, and HBOT advocates. We left the month of July open to talk to people we weren't able to squeeze into the four late-June in-person opportunities.

We invited more than 30 TBI/PTSD experts and HBOT advocates to speak to us; all told, we talked to more than a dozen experts and a half-dozen HBOT advocates, and received multiple studies advocating one approach or another. For the interviews done in-person and by phone, we allowed questions to and from the experts and advocates and the state panel that interviewed them, but we insisted that we would let "peer-reviewed, evidence-based" information be our guide, and that these interview opportunities would not devolve into debates or arguments and we were successful in achieving both goals.

Before the interviews began, Dr. Trexler suggested two things that enriched our experience: First, that we include a representative of the state's Bureau of Rehabilitation Services on our panel and secondly, he offered to help us find an out-of-state expert to assist in analyzing the mountain of studies we ultimately received. We gratefully accepted Dr. Trexler's suggestions and we believe our study and this report are better for it. Peri Rogowski from the Bureau of Rehabilitation Services joined our group in time for the in-person interviews, and in mid-June we selected Keith D. Cicerone, Ph.D., ABPP-Cn, the director of Neuropsychology and Rehabilitation Psychology at the JFK-Johnson Rehabilitation Institute and the New Jersey Neuroscience Institute, as our expert analyst for the studies we were asked to review.

### **Those serving on our committee**

**David Bozell** has been with the Indiana Division of Mental Health and Addiction since 1998. He currently serves as the Assistant Deputy Director for Adult Services in the Office of Recovery, Integration, Prevention and Policy. He has a Master's degree in Public Administration from Indiana State University.

**James M. Brown** was appointed Director of Indiana Department of Veterans' Affairs in February 2013. He began his military career in the United States Army in 1969 and served as a squad leader and acting platoon sergeant in Vietnam. He joined the Indiana National Guard in 1983 and served the next 10 years in the 38th Infantry Division as a team leader, operations sergeant and detachment First Sergeant. He is a Purple Heart recipient and, in his civilian capacity, he has 25 years of small business ownership and management of a transportation company.

**Themen S. Danielson, MD, MPH**, holds MD degree from the University of Wisconsin School of Medicine and an MPH degree from Harvard. His residency in General Psychiatry and Fellowship in Child and Adolescent Psychiatry were done at the Indiana University School of Medicine. He is retired from the community and private practice of child and adolescent psychiatry in central Indiana. He maintained a public health practice with the Marion County Public Health Department and the Indiana State Board of Health. He currently is the medical director of the Health and Human Services Commission of the Indiana State Department of Health.

**Russell L. Eaglin** is the deputy director of the Indiana Department of Veterans Affairs. He is the vice-president of the Marine Foundation of Indiana, Inc. and serves on the board of directors for Indy Veteran House, Inc. He is a highly-decorated Marine Corps veteran, having served in Vietnam from April 1968 to May 1969, and again in 1971. He is a past state commandant of the Marine Corps League (2009-2011) and was appointed by Indianapolis Mayor Ballard as Marion County's first Veteran Service Officer (2010).

**Katherine (Katie) Gatz** is the director of the ISDH Trauma and Injury Prevention Division. Prior to being promoted to that position in 2014, she served as the division's trauma registry manager. Before joining the ISDH, she was a frontline supervisor at Pepsico in Frankfort, IN. A graduate of Purdue University, she has a B.S. in industrial engineering.

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### **Acronyms used in this report**

APA	American Psychiatric Association
ASPIN	Affiliated Service Providers of Indiana
BIA	Brain Injury Association
BJA	U.S. Department of Justice's Bureau of Justice Assistance
CAM	Complimentary and Alternative Medicine
CBOC	Community Based Outpatient Clinics
CBT	Cognitive Behavioral Therapy
CDC	U.S. Centers for Disease Control and Prevention
CPG	Clinical Practice Guidelines
CPT	Cognitive Processing Therapy

DARPA	Defense Advanced Research Projects Agency
DOC	Indiana Department of Corrections
DoD	U.S. Department of Defense
EMDR	Eye Movement Desensitization and Reprocessing
GCS	Glasgow Coma Score
FDA	Food and Drug Administration
HAIG	VA's Healthcare Information and Analysis Group
HBOT	Hyperbaric Oxygen Therapy
HEA	Indiana House Enrolled Act
HRSA	Health Resources and Services Administration
ICT	Institute for Creative Technologies of the University of Southern California
IoM	Institute of Medicine
IOP	Intensive Outpatient
ISDH	Indiana State Department of Health
IVBHN	Indiana Veterans Behavior Health Network
IVRP	Indiana Veterans Recovery Plan
MAOI	Monoamine Oxidase Inhibitor
MTBI	Mild Traumatic Brain Injury (Concussion)
NBIRR	National Brain Injury Rescue and Rehabilitation Project
OEF	Operation Enduring Freedom
OIF	Operation Iraqi Freedom
OND	Operation New Dawn
PCT	PTSD Clinical Team
PE	Prolonged Exposure
PTSD	Post-Traumatic Stress Disorder
RCT	Randomized Controlled Trials
SAMHSA	Substance Abuse and Mental Health Services Administration
SBHP	Star Behavioral Health Providers
SEA	Indiana Senate Enrolled Act
SIT	Stress Inoculation Training
SNRI	Serotonin Norepinephrine Reuptake Inhibitor
SSRI	Selective Serotonin Reuptake Inhibitor
TBI	Traumatic Brain Injury
TCA	Tricyclic antidepressants
TRP	Traumatic Recovery Program
TXA	Tranexamic acid
VA	U.S. Department of Veterans Affairs
VAMC	Veterans Affairs Medical Center
VHA	Veterans Health Administration
VR&E	Vocational Rehabilitation and Evaluation

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## Cicerone full report

### Evidence-based Analysis of Studies of Cognitive Rehabilitation, Resource Facilitation, and Hyperbaric Oxygen Therapy after Traumatic Brain Injury

#### I. Cognitive Rehabilitation

We conducted a re-analysis of three prior systematic reviews of cognitive rehabilitation after TBI<sup>1-3</sup> and applied additional methodological criteria<sup>4</sup> to each study to assess the quality of each study (high, moderate, and low). The review of methodological quality for each study was applied to the AAN classification of evidence schemes<sup>5</sup> in order to make recommendations, based on the highest level of available evidence (see Appendix)

We identified high-quality RCTs that support the effectiveness of specific interventions for attention,<sup>15, 28, 39</sup> social and pragmatic communication skills,<sup>9, 12</sup> memory<sup>35</sup> and executive functioning<sup>19</sup> after TBI. We also identified several high-quality RCTs that support the effectiveness of comprehensive-holistic rehabilitation after TBI,<sup>11, 34, 42</sup> as well as several high quality observational studies that demonstrate improvements on participation outcomes.<sup>47, 53, 60, 61</sup>

Interventions for attention (direct attention and metacognitive strategy training) for patients with moderate to severe TBI during the post-acute period of rehabilitation, compared with non-specific treatments, are *likely to be effective* for improving attention impairments (based on two Class II studies<sup>15,28</sup>). Interventions for attention are *possibly effective* for improving divided attention after mild TBI (based on one Class II study<sup>39</sup>).

Compensatory memory strategy training after moderate to severe TBI is *possibly effective* for improving functional memory performance (based on one Class II study<sup>7</sup>, one Class III study<sup>13</sup> and multiple Class IV studies<sup>21,35,38</sup>).

Interventions for executive functioning are *likely to be effective* for improving planning and problem solving deficits after moderate to severe TBI (based on two Class II studies<sup>19,24</sup>).

Interventions for social and pragmatic communication skills after moderate to severe TBI are *likely to be effective* for emotion perception deficits and *possibly effective* for social-communication deficits (based on one Class I study<sup>9</sup> and two Class III studies<sup>12, 18</sup>).

Comprehensive-holistic neuropsychological rehabilitation is *likely to be effective* after moderate to severe TBI, compared with standard treatment, for improving short-term participation outcomes (e.g., return to work) and subjective well-being, and *possibly effective* in reducing the severity of cognitive deficits immediately after treatment for patients with severe TBI (based on one Class I study<sup>11</sup>, one Class II study<sup>42</sup> and one Class III study<sup>34</sup>). Comprehensive-holistic neuropsychological rehabilitation is *possibly effective* in reducing emotional symptoms after mild TBI (based on one Class II study<sup>39</sup>). There is *insufficient evidence* to support or refute the evidence regarding the effectiveness of comprehensive-holistic rehabilitation in improving participation after mild TBI or for improving long-term participation outcomes (> 6 months post treatment) after moderate to severe TBI.

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## II. Resource Facilitation

There is *insufficient evidence to support or refute* the effectiveness of Resource Facilitation for improving participation after TBI. <sup>1,2</sup> Trexler et al. <sup>2</sup> conducted an RCT of resource facilitation with 22 participants with acquired brain injury of varied etiology (TBI, intracranial hemorrhage, stroke and other)(Class IV). The group who received Resource Facilitation with a focus on return to work showed improved participation. Participation was assessed with the employment item of the Mayo-Portland Adaptability Inventory by the same people who provided the Resource Facilitation. Participants in the control group were further post injury and had lower levels of participation prior to treatment. The case series by Malec et al. <sup>1</sup> demonstrated that less time since injury and less overall disability are associated with better vocational outcomes after TBI.

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## III. Hyperbaric Oxygen Therapy

Hyperbaric Oxygen Treatment (HBOT) is *highly likely to be ineffective* in reducing postconcussive symptoms, PTSD symptoms or improving cognitive functioning in patients with blast-related mild TBI.<sup>2,3,7,8</sup> Two independent Class I methodological studies (including 3 month follow-up) show no effect of hyperbaric oxygen treatment on postconcussive symptoms or cognitive functioning in mild traumatic brain injury (mTBI) military samples. There is *insufficient evidence to support or refute* the effects of HBOT on cerebral metabolic activity (SPECT) in patients with chronic post-concussion syndrome after mTBI.<sup>1, 4</sup> Combined hyperbaric and normobaric hyperoxia is *possibly effective* in improving markers of

oxidative metabolism acutely after severe TBI.<sup>6</sup> Specifically, one Class II study shows that combined hyperbaric and normobaric hyperoxia led to an improvement in cerebral metabolism in noninjured and pericontusional tissue and reductions in intracranial hypertension and oxygen toxicity in a severe TBI sample enrolled 24 hours post injury.

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## Cicerone Appendix

### About the authors

**Keith D. Cicerone, Ph.D., ABPP., FACRM** is the primary author of three systematic evidence based reviews on cognitive rehabilitation after traumatic brain injury (TBI) and stroke (which have been cited over 1000 times in the scientific literature), and has actively addressed methodological issues in conducting and evaluating comparative effectiveness research. He is currently conducting the fourth updated review of cognitive rehabilitation through the ACRM, and also serves as a Co-Investigator and Chair of the Panel on Cognitive Issues for the Brain Injury Association of America development of Guidelines for Rehabilitation and Chronic Disease Management of Adults with Moderate to Severe TBI.

Dr. Cicerone is the Director of Neuropsychology and Rehabilitation Psychology at the JFK-Johnson Rehabilitation Institute and New Jersey Neuroscience Institute, JFK Medical Center. He has been the Clinical Director of the Cognitive Rehabilitation Department at JFK-Johnson

Rehabilitation Institute since 1985. He holds academic appointments as Clinical Professor of Physical Medicine and Rehabilitation at the University of Medicine and Dentistry of New Jersey and as Associate Professor of Neuroscience, Seton Hall University Graduate School of Medical Education. Dr. Cicerone is Board Certified in Clinical Neuropsychology by the American Board of Professional Psychology, and is a Fellow of the National Academy of Neuropsychology, American Psychological Association (Divisions of Rehabilitation Psychology and Clinical Neuropsychology), and the American Congress of Rehabilitation Medicine.

Dr. Cicerone is the author of more than 75 peer reviewed publications in the areas of traumatic brain injury and neuropsychological rehabilitation. His research has addressed the development and validation of interventions for impairments of attention and executive functioning after traumatic brain injury, and controlled trials of holistic neuropsychological rehabilitation. He is the primary author of three evidence-based reviews of cognitive rehabilitation after traumatic brain injury and stroke, conducted through the Brain Injury – Interdisciplinary Special Interest Group of ACRM. He currently serves as Chair of the Cognitive Rehabilitation Panel for the development of Guidelines for Rehabilitation and Chronic Disease Management of Adults with Moderate to Severe Traumatic Brain Injury through the Brain Injury Association of America.

Dr. Cicerone's work towards demonstrating the effectiveness of cognitive rehabilitation has complemented his work as an advocate for people with acquired cognitive and neurologic disabilities. As a recognized expert in the area of cognitive rehabilitation for people with traumatic brain injury, Dr. Cicerone has testified to the Institute of Medicine, Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury, and Congressional Brain Injury Task Force. Professional recognition of his work includes Distinguished Lectureships from the Rusk Institute of Rehabilitation Medicine (2007), Rotman-Baycrest Research Institute (2012) and John Stanley Coulter Lecture, American Congress of Rehabilitation Medicine (2011); the 2008 Gold Key award from the American Congress of Rehabilitation Medicine for "extraordinary service to the cause of rehabilitation"; 2011 Mitchel Rosenthal Award from the NIDRR TBI Model Systems Knowledge Transition Center; 2012 Stanley and Elizabeth Licht Award for Excellence in Scientific Writing; 2012 Robert L. Moody Prize for Distinguished Initiatives in Brain Injury Research and Rehabilitation; 2013 Clinical Research Award for Lifetime Achievement, North American Brain Injury Society; and the 2015 Leonard Diller Award from APA Division 22 Rehabilitation Psychology "in recognition of significant scholarly contributions and achievements in neurorehabilitation, cognitive rehabilitation and holistic neuropsychological rehabilitation.

**Yelena Goldin, Ph.D.**, is a co-investigator on both the current ACRM systematic review of cognitive rehabilitation, where she serves as a primary data analyst, and for the BIAA Guidelines for Rehabilitation and Chronic Disease Management of Adults with Moderate to Severe TBI. Since 2001, she has been adjunct assistant professor at the Ferkauf Graduate School of Psychology at Yeshiva University, as well as a neuropsychologist in the Cognitive Rehabilitation Department, Center for Head Injuries at the JFK Johnson Rehabilitation Institute and assistant clinical professor in the Department of Physical Medicine and Rehabilitation at the Robert Wood Johnson Medical School at Rutgers University. She is a graduate of Pace University, where she obtained a B.A. in psychology, Long Island University, where she earned an M.A. in psychology, and Yeshiva University, where she earned a Ph.D. in clinical psychology. She was a postdoctoral fellow at the Department of Rehabilitation Medicine, Mount Sinai Medical Center, New York, N.Y. from 2009-2011.

**Keith Ganci, Ph.D.**, is a co-investigator on both the current ACRM systematic review of cognitive rehabilitation, where he serves as a primary data analyst, and for the BIAA Guidelines for Rehabilitation and Chronic Disease Management of Adults with Moderate to Severe TBI. He

is a graduate of James Madison University (B.S., psychology) and Fairleigh Dickinson University (Ph.D., clinical psychology) and has been a neuropsychologist at the JFK Johnson Rehabilitation Institute since September 2012.

### **Classification of Evidence Schemes (Therapeutic)**

#### **Class I**

- Randomized, controlled clinical trial (RCT) in a representative population
- Masked or objective outcome assessment
- Relevant baseline characteristics are presented and substantially equivalent between treatment groups, or there is appropriate statistical adjustment for differences
- Also required:
  - a. Concealed allocation
  - b. Primary outcome(s) clearly defined
  - c. Exclusion/inclusion criteria clearly defined
  - d. Adequate accounting for dropouts (with at least 80% of enrolled subjects completing the study) and crossovers with numbers sufficiently low to have minimal potential for bias

#### **Class II**

- Cohort study meeting criteria a–d (see Class I) or an RCT that lacks one or two criteria a - d (see Class I)
- All relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences
- Masked or objective outcome assessment (*subjective patient reports are acceptable for describing subjective outcomes such as symptom severity or life satisfaction, if no other observer biases are apparent*)

#### **Class III**

- Controlled studies (including well-defined natural history controls or patients serving as their own controls)
- A description of major confounding differences between treatment groups that could affect outcome
- Outcome assessment masked, objective or performed by someone who is not a member of the treatment team.

#### **Class IV**

- Did not include patients with the disease
- Did not include patients receiving different interventions
- Undefined or unaccepted interventions or outcome measures
  - No measures of effectiveness or statistical precision presented or calculable

### **Conclusions**

The level of certainty directly relates to the *highest* class of evidence with adequate power used to develop the conclusion. Thus, conclusion language will vary on the basis of the following levels of evidence:

- Multiple Class I studies:  
Are *highly likely to be effective*...
- Multiple Class II studies or a single Class I study:  
Are *likely effective*...
- Multiple Class III studies or a single Class II study

Are *possibly* effective...

- Multiple Class IV studies or a single Class III study:

There is *insufficient evidence to support or refute* the effectiveness ...

Similar wording is used in cases where the evidence suggests a lack of effect, e.g, are *highly likely to be ineffective*, or *highly likely to not be effective*.