

## 14 Reasons HBOT should be in use to treat and help heal TBI/PTSD/PCS/Concussion

**1. Independent peer-reviewed clinical trials demonstrate that HBOT is safe and effective for TBI/PTSD/PCS.** "There is sufficient evidence for the safety and preliminary efficacy data from clinical studies to support the use of HBOT in mild traumatic brain injury/ persistent post concussive syndrome (mTBI/PPCS). The reported positive outcomes and the durability of those outcomes has been demonstrated at 6 months post HBOT treatment. Given the current policy by Tricare and the VA to allow physicians to prescribe drugs or therapies in an off-label manner for mTBI/PPCS management and reimburse for the treatment, it is past time that HBOT be given the same opportunity. This is now an issue of policy modification and reimbursement, not an issue of scientific proof or preliminary clinical efficacy."

**2. DOD/VA/Army studies have produced data that show HBOT is safe and effective for TBI/PTSD/PCS.** Army medicine has run trials investigating the use of Hyperbaric Oxygen to treat and help heal Traumatic Brain Injury. They have shown that HBOT is both safe and effective: "*Randomization to the chamber . . . offered statistical and in some measures clinically significant improvement over local routine TBI care.*" Also: "*.... total scores for [both] groups revealed significant improvement over the course of the study for both the sham-control group .... and the HBO2 group.....*" Expert outside consultants to DOD declared that "*[HBOT] is a healing environment.*"

**3. The so-called "sham" used in the DOD/VA/Army studies has been debunked by worldwide experts. the studies have been shown to be "dosing studies" that indicate all patients got better.** DOD/VA/Army researchers state that they "believe it is biologically implausible that air at 1.2 ATA (equivalent to 2m of seawater pressure) has a beneficial effect..." Their belief is plausible if there was no scientific evidence to the contrary. However, there is substantial scientific evidence. Decades of scientific studies have proven that pressure alone is bioactive in the pressure range of the 1.2 ATA air group. This evidence is reaffirmed by clinical studies. This is science, not belief.

**4. Thousands of evidence-based success stories worldwide point to the safety and efficacy of HBOT for TBI/PTSD/PCS.** "Hyperbaric oxygen is a safe, easily used treatment that, in many cases, has resulted in a dramatic improvement in the symptoms of patients with [TBI]. Every day we are.... gathering more data validating its efficacy.... I feel , as do many of my colleagues, that there is sufficient clinical and research evidence to justify the use of [HBOT] as a standard-of-care treatment for [TBI] that should be reimbursed by CMS and Tricare.... I have no doubt that, over the next several years, [HBOT] will be proven beyond a reasonable doubt to be one of the most effective treatments for [TBI].... There is a preponderance of evidence now to justify the use and funding for the treatment...."

**5. Nothing currently in use by DOD/VA/Army medicine has produced better evidence than the use of HBOT to help reduce symptoms of TBI/PTSD/Army medical interventions.** Despite a decade of effort and the large sums of dollars expended, senior DOD/VA/Army analysts wrote: "*....no new treatments for persistent blast or impact-related postconcussion symptoms have been identified, despite the extensive investment to date. The evidence remains weak and*

inconsistent for both pharmacological . . . and nonpharmacological. . . interventions . . . concerns have been raised that current screening approaches, combined with a specialty-driven structure of concussion care in the [VHA and DOD] may inadvertently promote negative, rather than positive, recovery expectations."

**6. Virtually all interventions used in military medicine for brain injury are used off-label and are controversial, without evidence of their effectiveness, and some have been shown to hurt patients.** Interventions by DOD/VA/Army medicine do not treat the physical wound to the brain. Not one of the 80+ processes/procedures/devices, countless computer applications, and 114+ prescribed drugs has been approved by the FDA for TBI, nor do they "treat" wounds. All are used off-label for TBI. All are controversial at some level. Many of them are brand-new and haven't even been explored in the literature. No risk analysis has been performed, and no tracking is done. And over a dozen of the prescribed drugs are "black box" labeled, warning of the risk of suicidal ideation.

**7. The vast majority of brain-injured treated with HBOT for their brain injuries showed significant medical progress on a battery of tests, including sleep, depression, memory, executive function, anger and balance, among many others. Importantly, virtually all patients were able to quit using black-box labeled and other drugs prescribed by military doctors for their various ailments.** "This [HBOT] pilot study demonstrated no obvious harm [and] both groups showed improvement in scores and thus a benefit. Subgroup analysis of cognitive changes and PCL-M results regarding PTSD demonstrated a relative risk of improvement . . . . There is a potential gain and no potential loss. The VA/Clinical Practice Guidelines define a "B evidence rating" as "a recommendation that clinicians provide (the service) to eligible patients. **At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm.** . . . [emphasis added] Hyperbaric oxygen therapy for mild traumatic brain injury and PTSD should be considered a legitimate adjunct therapy if future studies demonstrate similar findings or show comparable improvement to standard-of-care or research-related treatment modalities." [NOTE: subsequent worldwide studies already published and those underway show comparable improvements.]

**8. Brain imaging -- conclusive, objective evidence -- shows functional and physical improvements in brains treated with HBOT. The ADOD/VA/Army studies have no such objective evidence, images that categorically disprove the "HBOT-is-placebo" thesis.** With respect to the images captured in Israel and the US before, during and after HBOT: "SPECT data as a biomarker of changes in brain metabolic activity is undeniable. . . . Nowhere in science has a 'placebo' effect caused statistical data to narrow its standard of deviation across so many points of assessment. . . . This SPECT data is a compelling additional biomarker of treatment effects that were also tabulated against many psychological parameters. In clinical medicine, radiologists use functional data such as PET exams in oncology patients to show changes over time in therapeutic interventions. Mirroring a clinical oncology imaging model we don't really need placebos to gather further evidence of effect by our interventions. . . . we have advanced the objective-measures-of- success argument all over the world, using functional outcomes. Brain-injured veterans live in a functional, not a statistical world. We can actually show why subjects are functioning better because of HBOT treatments."

**9. Recent Army research shows that BLAST injury causes significant brain injuries distinctly different from mere impact injuries. They further point to evidence that PTSD may be a secondary effect of blast injury. The clear implication is that tens of thousands of invisible wounds that have been diagnosed as "only PTSD" may in fact be mild- to moderate-TBI primary brain injuries.** This research is preliminary proof of what medicine has been saying without proof for nearly 100 years -- blasts cause physical damage, and this physical damage leads to psychological problems, i.e., PTSD. The importance of this admission cannot be overstated: this is a DOD discovery with documented evidence that blast injury [IEDs, breaching, whether in training or combat, enemy and/or friendly fire] can lead directly to physical brain damage and the accompanying psychological/emotional/mental health effects, many of which have been heretofore diagnosed as "only PTSD."

**10. The relative "cost" of HBOT is miniscule alongside initial and yearly costs associated with payments to non-treated brain injuries. Disabled TBI service members on full-disability cost the American tax payer nearly \$60,000 per year, every year. The cost of HBOT is less than a one-time cost of ~\$16,000.** Assuming a population of persons of only 200,000 brain-injured service members, the probable cost-to-society just on the basis on disability expenses and of lost tax revenues only (not including the collateral costs of homelessness, broken families, incarceration, suicide, etc.), will be \$ 288.7 Billion over 50 years to continue with the status quo, where safe and effective treatments are denied. With HBOT treatments, the cost to treat and heal those 200,000 veterans will be ~\$5 Billion [this is not factoring in economies of scale that can be realized when volume will drive the costs down enormously.] ***Simply put, for less than 1.7% of the status quo costs, treating with HBOT is the healing of hundreds of thousands of the wounded and injured with a safe therapy that thus far has enabled approximately 80% of those treated to return to work, school or duty.*** Left out of this calculation, of course, is the intangible benefit to the wounded and to their families of getting their lives back.

**11. Ethically, we owe the brain injured access to information about HBOT, a form of "informed consent."** Currently, the brain injured either never hear about HBOT, are warned about the negative effects, or are warned that they could lose their benefits if they go for HBOT on their own. More than 125,000 Iraq and Afghanistan veterans have what are known as "bad paper" discharges that preclude them from receiving care. About 6.5 percent of all Iraq and Afghanistan troops have these "Other Than Honorable" discharges. The highest rate is found in the Marine Corps, where one in 10 is now ineligible for benefits. "We separate people for misconduct that is actually a symptom of the very reason they need health care." Hundreds of wounded service members who find their way to HBOT have reported on their experiences with DOD/VA/Army medicine. Over a thousand brain-injured have died of prescription overdoses. The problems with the VA are daunting and the default position for mental health is talk therapy, drugs, cognitive psychotherapy and "individualized treatment plans." Nowhere in the system does DOD/VA/Army medicine treat the wound to the brain, and HBOT is not available in VA facilities. Sadly, we learn that the VA was improperly testing for traumatic brain injuries from 2007 through 2015; nearly 25,000 veterans may have been misdiagnosed. Couple those numbers with the 325,000 service members diagnosed with "only PTSD" that may be the

secondary outcome of TBIs caused by Blast, along with the 345,000 acknowledged TBI diagnoses, and the numbers of untreated brain injuries are staggering.

**12. Medically, we owed the brain injured an opportunity to try non-pharmacological interventions.** Traumatic Brain Injury (TBI) is now recognized as a causative factor for hormonal deficiencies associated with PTSD and personality changes. Psychological, physiological, and functional manifestations include: mood swings, bouts of anger, inability to concentrate, learning disabilities, sleep deprivation, increased risk for heart attacks, strokes, high blood pressure, diabetes, loss of libido, menstrual irregularities, pre-mature menopause, obesity, loss of lean body mass, muscular weakness, and a number of other medical conditions that can arise subsequent to head trauma. The use of drugs to palliate symptoms is already revealed to be at epidemic proportions. Put that behavior alongside clinical evidence that HBOT helps patients reduce their drug ingestion dramatically.

**13. Militarily, the use of HBOT can help with the retention and force readiness issues.** HBOT has been used with dozens of Special Operations warriors, allowing them to heal and avoid medical boarding out. Special Operations warriors commit suicide at twice the rate of their peers; women service members are twelve times more likely to commit suicide than their peers. In the past four years, more than 2,000 active and reserve military personnel have killed themselves; a general officer was recently added to the list. The stigma and career-ending potential of mental health issues -- and the penalties for admission of "weakness" -- are especially acute when the wounded are told there is no cure, only interventions to adjust to the new normal.

**14. NEWS UPDATE: Stem cell therapy appears to have TBI treatment effect.**

**A.** Results of a cellular therapy clinical trial for traumatic brain injury (TBI) using a patient's own stem cells showed that the therapy appears to dampen the body's neuroinflammatory response to trauma and preserve brain tissue, according to researchers at The University of Texas Health Science Center at Houston. \$6.8M has been awarded for a new clinical trial sponsored by the Joint Warfighter Program within the U.S. Army Medical Research Acquisition Activity, aimed at extending the research.

**B.** Over a decade ago, Thom and team showed that HBO2 mobilizes bone-marrow derived stem/progenitor cells eightfold by stimulating nitric oxide synthesis, thus bypassing the need for autologous stem-cell transplantation. Put another way: HBO2 accomplishes non-invasively and cheaply what is being done with the more costly and risky process of bone marrow harvesting, cell processing and re-infusion.

**C.** "The acute inflammatory response plays an important role in secondary brain damage after TBI. . . . Reducing inflammation is essential for the treatment of TBI. HBO2 has been shown to suppress inflammation in many studies (Vlodavsky et al., 2006; Lin et al., 2012; Zhang et al., 2014a; Meng et al., 2016a, b). ... The inhibitory effect of HBOT on inflammation is closely associated with the decreased brain edema, blood-brain barrier leakage, cell apoptosis and improved neurological disorders after TBI."

**A + B + C =** Current research on stem cells and inflammation can be accelerated at less cost and risk by the use of HBOT to demonstrate a current therapy for TBI.