

Attacking the Suicide Epidemic/TBI/PTSD/PCS/Concussion using Hyperbaric Oxygen Therapy: The essential elements of the argument

EXECUTIVE SUMMARY

DOD/VA/Military Services are experiencing epidemics of suicide; traumatic brain injuries; incidents of post-traumatic stress disorder; and deaths through substance overdose. Peer-reviewed evidence of Hyperbaric Oxygen Therapy's (HBOT) safety and effectiveness urge adoption for immediate use to reverse the trends. Neither the DOD nor the VA nor the military services have been effective in healing the wounds of brain-injured active duty and veteran service members, despite billions of dollars of research and drug-dependency. None are prepared to immediately intervene using rules for addressing epidemics; those rules have been invoked many times in the last decade for pandemics like Ebola and Zika. Based on positive evidence already collected in a tiny VA Pilot Demonstration, the VA knows that the private sector has the infrastructure to begin immediately and can produce evidence of success within sixty days of beginning treatment of thousands of brain-wounded patients. Unused appropriated funds are available in the Suicide Prevention Program. Additional available funds exist via budget-neutral movement of funds from the VA drug budget since patients who successfully complete HBOT treatment are known to quit using most of the prescribed drugs that do not heal the wound to the brain and in most cases lead to suicidal ideation. The end goal of the TreatNOW Coalition is to have HBOT for TBI/PTSD/Concussion as an insured standard of care across medicine.

The Challenge: Reverse the impacts of the brain wounds and suicide epidemics ASAP, using well-known rules for intervening to stop epidemics safely and quickly.

The Short History:

- 1.** Since at least 2008, pressure has intensified on the DOD/VA/Army to do something about brain injuries. Suicides, now at epidemic levels in the military, are closely linked in veterans to brain injuries.
- 2.** Hundreds of millions of dollars were subsequently spent by DOD/VA/Army on studies and research related to drugs, devices, processes and interventions to deal with brain injuries and suicide prevention. [see attached "Interventions"]
- 3.** One of the interventions investigated by DOD/VA/Army was Hyperbaric Oxygen Therapy (HBOT). At least five studies were conducted at the cost of over \$180 Million. The data in all the studies demonstrate that HBOT is safe and effective; subjects in the studies got better. Positive findings in Army Studies include: "***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."*** The premier researcher for the Army says on the Veterans Affairs web site: ***"People did get better and we can't ignore those results."*** Yet they do ignore the impact of not treating with HBOT which their own data show leads to improvements.

4. As the controversy continues, DOD/VA/Military Services are experiencing self-admitted epidemics of suicide; drug abuse, over-prescription and overdose deaths; traumatic brain injuries; and incidents of post-traumatic stress disorder:

- U.S. Special Operations suicides tripled in 2018.
- The Air Force's top brass is concerned that 2019 could be the deadliest yet when it comes to suicides. "We lose more airmen to suicide than any other single enemy, even more than combat," according to Kaleth Wright, chief master sergeant of the Air Force. . . .If we don't do something, we could lose up to 150, 160 airmen in 2019."
- Marine suicides reached the highest level in a decade despite the end of Large-Scale Combat Operations.
- More than 50,000 Iraq and Afghanistan Army veterans who developed mental health conditions during their military service received other-than-honorable discharges, making them ineligible for health benefits.
- The Veterans Administration is reported to have spent less than 10% of the monies allocated for Suicide Prevention marketing campaigns.
- VA doctors with responsibility for brain injuries have quietly started prescribing HBOT for TBI and PTSD. There are over a dozen instances of VA facilities paying for those treatments. DOD physicians are similarly prescribing HBOT for TBI and several DOD facilities are already successfully treating TBI and PTSD using HBOT.
- The VA has started a Pilot Demonstration to observe the use of HBOT for treating and helping heal brain wounds. The program is expanding, based on near total success with those patients already treated.

The Science arguing for use of HBOT

5. Simultaneously, over the last the last ten years, numerous other studies were conducted in the US and worldwide to test HBOT for helping heal brain wounds [see attached "HBOT Research and Science"]. The overwhelming evidence and data from those studies suggest that HBOT is both safe and helpful in reversing the effects of TBI/PTSD. Evidence-based and clinical medicine over that same ten year period has resulted in successful use of HBOT for TBI/PTSD in over 6,100 cases recorded in the 90+ participating TreatNOW Coalition clinics all over the US. In addition to the nearly 1,500 veterans successfully treated, subjects included first responders, police, fire, athletes, citizens old and young, and dozens of active duty Special Operations warriors.

6. DOD/VA/Army studies have been challenged worldwide for a fundamental flaw in their procedures that permit a mischaracterization of their results. Their claim of a

"sham" control has been debunked by scientists and HBOT researchers as flawed. Their studies are, in fact and in science, "dosing studies." Hyperbaric medicine was administered in all cases and all patients showed improvement. Even the Army admits to that. The USAF did a reanalysis of the data in the original DOD/VA/Army study. Dr. George Wolf, a principle co-author of that first Army study, effectively admitted the errors. [E.G. Wolf, L.M. Baugh, C.M.S. Kabban, et al. ***Cognitive function in a traumatic brain injury hyperbaric oxygen randomized trial***. UHM 2015, Vol. 42, No. 4, 2015. <https://bit.ly/2faBldN>] The study concludes: "This 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.] <http://bit.ly/2faBldN>

Failure of Current Approaches

- 7.** DOD/VA/Army continue to ignore a treatment that works. Some large portion of over 800,000 wounded (post-9/11) and an equal number of Vietnam veterans and their families languish on disability and welfare, with degraded lives while BILLIONS of \$\$\$ are expended on drugs and fruitless psychological and other unproven interventions. Research dollars are being spent on experiments with pot, LSD and psychotropics.
- 8.** DOD/VA/Army will not use HBOT to treat brain wounds; their position reduces to flawed conclusions about cost, danger, size of problem, closed minds, and entrenched interests, especially default to drug interventions. They even go so far as to warn patients they could lose benefits or cause themselves harm.
- 9.** Cost to the wounded: interminable wait times, mis-diagnoses, drugs and semi-permanent welfare status, families in crises, wives with secondary TBI/PTSD, degraded quality of life.
- 10.** The cost to the nation: 20+ suicides a day, major impact on Special Operations forces, \$60,000 cost/per year for each untreated brain injury, and corrosive effects of wounded who are told: "There is no treatment to help heal your brain wound." The default position continues to be psychopharmacology, group and one-on-one discussion, and cognitive psychotherapy.

CONGRESSIONAL Intervention to use HBOT: Ten Years of Safety, Efficacy and Success

11. The Treatment does exist: Hyperbaric Oxygen Therapy when used by the TreatNOW Coalition and multiple clinics across the US and world have positive scientific and clinical evidence in over 6,100 cases that HBOT helps heal wounded brains and returns patients to a life denied them by DOD/VA/Army that will not use or pay for HBOT treatment for TBI/PTSD/PCS/Concussion.

12. The solution is hiding in plain sight: allow brain-wounded to go on civilian/private market to obtain pre-approved treatment. The value in immediate use of the private clinics to confront the epidemics:

1. No need for new hearing or legislation: CHOICE/MISSION already exists and is funded
2. Provides immediate help to veterans with brain injury and relief to an overloaded VA system
3. Starts a process of providing needed services unavailable in VA or DOD
4. Short-circuits establishment's efforts to continue researching a problem that it cannot and will not solve on its own
5. Delivers on the Administration's promise to act quickly to cut through Establishment bureaucracy
6. Saves money and lives
7. Results from science and clinical practice can be available in 60 days. Expected results: >85% success rate based on 6,100+ patients to date..... many done pro bono.

13. The Authority for Congress to intervene exists in at several pieces of legislation related to epidemics and gaps in care. It is hard to find any stakeholder that does not recognize the need to address the simultaneous epidemics: the US Food and Drug Administration (FDA), payers such as health plans and large employers, pharmaceutical manufacturers, state policymakers, as well as provider and patient groups.

** On December 2016, the President signed The 21st Century Cures Act. A major component of the law is an effort to expedite approval of breakthrough medical technologies for patients with life-threatening illnesses and limited treatment options. Without specifically focusing on the suicide epidemic, opioid crisis or brain injuries in general, the Cures Act spelled out conditions for breakthrough interventions like HBOT: available immediately, with a record of safe and effective use, a strong propensity to treat causes of the disease of addiction, with broadly-distributed access.

** Congress passed and the President signed the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law No. 113-5, March 2013. Epidemics were at the heart of the call for speed, safety, innovation, and red-tape-cutting.

** Congress passed the VA Mission Act in June, 2018. This legislation's formal name is the VA Maintaining Systems and Strengthening Integrated Outside Networks Act. It is

designed to allow veterans to go outside the VA system to procure therapies that are not available in VA facilities; HBOT is not available within DOD or the VA for TBI. Multiple chambers exist within the DOD inventory but they are restricted use.

** Congress passed the Support for Patients and Communities Act in October 2018. And these stakeholders, which in the United States include regulators such as the US Food and Drug Administration (FDA), payers such as health plans and large employers, pharmaceutical manufacturers, state policymakers, as well as provider and patient groups, are all active in their own ways in an attempt to address opioid-related injuries and deaths. In 2017, more than 72,000 people in the US died of drug overdoses. hundreds of them veterans using prescribed drugs. At least two-thirds of overdoses were linked to opioids, based on preliminary data from the Centers for Disease Control and Prevention. That's the highest number of Americans who ever died of drug overdoses in a single year — and more than were ever killed by guns, car crashes, or HIV/AIDS in a single year in the US. Suicides accounted for 129 deaths per day; that's over 47,000 civilian suicides a year, added to the 7,300+ military suicides and the failed 16,000 attempts every year.

** On March 5, 2019, the President signed the Executive Order on a National Roadmap to Empower Veterans and End Suicide. The EO calls for immediate action to identify the latest research discoveries and translate them into practical applications for quick implementation. While the year-long Task Force works, HBOT can be used across the country to inform the strategy of the public-private partnerships already existing in the states. Oklahoma, Texas, Indiana, Kentucky and Arizona have all passed legislation calling for the use of HBOT for brain wounds; North Dakota and North Carolina re not far behind. Veteran Service Organizations have identified HBOT as a legislative priority. The epidemic must be met with immediate action commensurate with the crisis.

** The suicide epidemic, coupled with opioid addiction epidemic, qualify as adequate incentive for Congress to force DOD and the VA to intervene with Hyperbaric Oxygen Therapy and any other alternative therapy with a record of safety and published, scientific validity. This combination drug-device has been called one of the safest devices ever reviewed by the FDA. The published record of efficacy for the past thirty years is additional evidence of the need for immediate Congressional intervention. Previous FDA/CDC efforts can serve as guideposts to facilitate and expedite review of HBOT under rigid rules to address unmet medical need in the treatment of a serious or life-threatening conditions: Ebola; Zika virus; chikungunya virus disease; enterovirus D68; H1N1 flu; HIV; and Princeton's outbreak of serogroup B meningococcal disease in 2014. Spurred by the tens of thousands of deaths, suicide and the opioid epidemics certainly qualify as sufficiently alarming to push for FDA-approved emergency use of HBOT: fast track designation; breakthrough therapy designation; accelerated approval; priority review; and breakthrough devices program.

Problem bigger than originally thought

Refusal to recognize and treat the brain wound does not lead to healing. Symptoms may abate and the wounded may feel better, but beware the long-term effects, particularly when the insults to the head continue. There is this fact: Since the Army now recognizes that BLAST injury is a likely contributor to the sequelae diagnosed as "only PTSD" we are confronted with an additional 325,000 likely misdiagnosed TBIs in combat veterans. Another little-explored medical reality is that while "PTSD-only" without TBI is real, PTSD can cause brain injury because of the chemical and physical alterations occasioned by the body's response to psychological symptoms. Further, drug addiction and substance abuse cause brain damage. Fortunately, research shows that HBOT reduces pain and time-to-withdrawal by one-half; patients who undergo a full course of HBOT treatment typically get off almost all of their drugs.

Concussion Crisis is getting worse: HBOT is a curative

14. NOTE: An essential component of our culture is the Concussion Protocol as practiced by the DOD/VA/Army, the NFL, the NCAA, the overwhelming number of ERs and high schools around the country. It is the equivalent of negligence to not treat the wound to the brain, especially during the acute phase, i.e. within the first ten days. For example, Dr. Daphne Denham has shown in 248 out of 250 Acute Concussion cases that symptoms of the concussion are resolved, and the wounded athlete is back in school, symptom free, in under four HBOT treatments. <https://tinyurl.com/ybldktgn>

15. State Legislatures have picked up the cause that the DoD/VA/Army medicine refuse to touch: immediate treatment of veterans' brain wounds. Seven States have passed legislation calling for the use of HBOT to treat brain wounds among veterans: Oklahoma, Texas, Indiana, Kentucky, Arizona, Florida, and North Carolina.

16. These videos give more insight into successes and science:

MSGT Scott Roessler [Ranger]
Dave Rogers, Navy SEAL
GnySgt Rotenberry & wife
MAJ Ben Richards
CAPT Smotherman/Rep John Bennett
Joe Namath, football
The Honorable Patt Maney (BG, USA)
Brian Fleury - Hockey Player
Robin Read, Stroke Patient
Latest Ben Richards video
Roy Jefferson, football

<http://tinyurl.com/hf3czmw>
<https://youtu.be/kZ3TFGjbptA>
<http://tinyurl.com/gpzpxqy>
<http://tinyurl.com/jts2jv3>
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