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Two Brain-Injured Airmen Recover

Because of HBOT 1.5™ Treatment by Air Force Physician

In January 2010, a peer reviewed journal published a case series report regarding two brain-injured airmen who were casualties of an IED in Iraq. Both were going to be medically boarded out of the service. Their military physician prescribed Hyperbaric Oxygen Therapy (HBOT 1.5™). Both of them recovered and they were both retained on active duty. The article is attached as Appendix A.

The protocol that was used for the two airmen is the exact protocol the International Hyperbaric Medical Association began sharing with DoD in 2001 and testified to Congress about in 2002 and twice in 2004. This effort is called the National Brain Injury Rescue & Rehabilitation Project (NBIRR). NBIRR will directly impact the greatest public health crisis of our age, untreated brain insults including traumatic brain injury. Federal, state and local budgets are paying for the consequences of modern medicine failing to treat brain insults with protocols that biologically repair brain damage. Lost performance and aberrant behavior of injured individuals costs billions and billions each and every year in entitlement, prison, education, and safety net programs, not to mention the challenges faced by current and past combat veterans.

The case series report is authored by Colonel James Wright, M.D., at Hurlburt Field in Florida (720th Special Tactics Group); plus Eddie Zant, M.D., treating physician; and Robert E. Schlegel, PhD, PE, the developer of the DoD's ANAM neuropsychological testing battery. Colonel Wright had previously directed all Air Force Aerospace and Hyperbaric Medicine Research at Brooks City Base in Texas, and trained physicians in the use of hyperbaric medicine so they could become board certified.

Hyperbaric Oxygen Therapy (HBOT) is FDA-approved for many kinds of non-healing wounds and is the only FDA-approved non-hormonal treatment for the repair and regeneration of human tissue. It causes a biological repair to tissue damaged by a lack of oxygen or compromised circulation and signals DNA to begin the healing process. Tricare and VA reimburse for many hyperbaric indications, including non-healing wounds, and diabetic foot wounds, but do not routinely pay for treatment for persons who recover or make significant improvement from their brain injuries or non-healing wounds in their brain after they have been treated with HBOT.

The Airmen were treated with the Harch HBOT 1.5™ treatment protocol in September of 2008, one month after Dr. Harch presented the first five combat casualties results to the Surgeon General of the Navy on August, 14, 2008. While the SG was "studying HBOT 1.5™," Colonel Wright looked at the presentation from the August 14th meeting and applied it to these two airmen with dramatic results, as outlined in the article. He had seen the story of the two airmen in his local paper.

Both of these Airmen had their careers saved and were able to continue duty. Their recovery is noted in the article. Prior to treatment, both were going to be discharged from the service for their brain injury symptoms. The treatment costs were $24,000 for the pair of them. Their recovery was a significant savings to the Federal government as qualified non-commissioned officers were able to continue to serve. The irony here is that despite the dramatic recoveries the two airmen experienced, Tricare declined to pay Dr. Zant for their HBOT treatments.

The article describing the recovery of the two airmen is the second peer-reviewed publication of brain-injured battle casualties making a major recovery after having been treated with HBOT 1.5™. In June, 2009, the *Cases Journal,* a peer-reviewed open-access journal, published a detailed report on the second combat casualty treated with HBOT 1.5™, a Marine machine gunner who had experienced 6 IED's and an RPG hit in two tours of Iraq. That case report is attached herewith as Appendix B and can be found on the internet at http://casesjournal.com/casesjournal/article/downloadFile/6538/.

This Marine at the time of his treatment had already been discharged from the service, and after treatment was one of the three of five treated war veterans who testified before the Navy Surgeon General and the Deputy Commandant of the Marine Corps on August 14, 2008. He had gone from living in a dark room to employed. He had also elected to take only 1/2 of the offered VA disability pension in exchange for being allowed to work. His chief remaining complaint is the extensive hearing loss he suffered, for which he deserves a continued disability payment. That hearing loss may also have been prevented or reduced had it addressed quickly (see discussion of Mucomist below). Had this Marine been treated with HBOT earlier, he has stated that he would have remained on active duty and continued his successful career as a Marine.

Doctors Harch and Wright have continued to treat additional active duty and discharged veterans. Dr. Harch will be presenting the findings from about 20 war veterans on March 12th at the International Brain Injury Annual Meeting in Washington, D.C. To date 80% of those treated with this protocol have been able to return to duty, work, or school. On average they have experienced a 15 point IQ increase, a 37% decrease in post-concussion syndrome symptoms, and a 28% reduction in PTSD, after the first 40 of 80 treatments. These results are dramatic and greater than those produced by any other therapy or combination of therapies currently available to physicians today. HBOT is safer and more effective than drugs black-labeled by the FDA as causing "suicidality" in persons under 25, routinely given to military personnel and veterans seeking help for PTSD at the VA.

Colonel Wright, part of the Special Operations Command medical system, has treated a number of SOCOM personnel and others as outlined in Appendix C.

Impact on the the NBIRR Team has had on the DoD, VA and Federal Budget

Value of Helping a Service Member Return to Duty

According to DA PAM 385-40 (6 March 2009) "Army Accident Investigations and Reporting," saving the careers of the experienced NCOs treated by Dr. Wright was a $500,000 savings each, and their lost time prior to being treated (7 months@$375 per day) was worth $78,750 each. At a minimum, it would have cost $155,000 each to replace them with E-1's from basic training. Therefore their loss to the service and replacing them with E-1s, was $500,000+$78,750+$155,000=**$733,750 each** or $1.467 million for both of them.

VA Disability Costs

The savings figure above does not count the follow-on VA disability payments the two airmen would have received for the rest of their lives from the Treasury. Those payments are estimated to be $1,283,000 each based on published figures for an unmarried veteran for the forty years from age 25 to age 65 without cost of living adjustments. This adds $2.566 million in costs to the $1.467 million computed above.

Lost Tax Revenue due to Mild-Moderate Traumatic Brain Injury/PTSD

Neither does it count lost tax revenue. At 100% disability, the airmen would not work. For these two airmen, the loss to the public treasury resulting from them not working is an additional $548,911 each in lost tax revenue over their lifetime (counting them as high school graduates). Adding the costs up, there is a $733,750 cost for the loss to the service and replacement with an E-1, plus a $1.283 million cost for 100% lifetime disability and a lifetime loss in tax revenue of $548,911. This comes to a grand total of $2.6 million each or a cost of about $5.2 million for the pair. All that was saved for a cost of $24,000 in hyperbaric oxygen therapy.

The U.S. Marine Dr. Harch treated had been discharged from the service already, so the savings that could have been realized, such as his months in the Wounded Warrior Brigade, the decreased blast injuries if he had been treated acutely in theater using the "HBOT at the Forward Edge of Battle" (FEB-HBOT) emergency medicine treatment protocols, etc. were not attainable. However, he had sufficient recovery to accept only 1/2 of the Veteran Disability payment offered him, because he wanted to continue to work. His recovery has been sufficient to work for a year, earning sufficient money to pay about $10,000 in taxes and FICA, and has now returned to school to earn his Bachelor's degree. His hearing loss from blast injury was sufficient to merit his disability payment. His savings to the taxpayer, for $16,000 worth of HBOT 1.5™, (again unreimbursed by DoD's Tricare or VA), was $0.64 million in reduced lifetime VA benefits plus $0.4 million in additional lifetime tax revenues for a total benefit to the government of about $1.04 million (approximately $26,000 per year over 40 years).

Unfortunately, much like FEB-HBOT combat protocols delivered acutely for TBI and PTSD, he never received the acute treatment that could have prevented his hearing loss. That treatment is "Mucomist" which CAPT Balough in San Diego, (using $10 million Navy research dollars), discovered when given within the first 4 hours of a blast injury prevents much of the blast-induced hearing loss combat veterans suffer. (See Appendix D) It is one of those treatments that would greatly enhance the readiness of the active duty force, as a Marine who cannot hear is obviously at a disadvantage in a combat environment. For some inexplicable reason, DoD medicine has not widely adopted this treatment, even though the VA spends $2 billion per year

in hearing aids, and we have an all volunteer service, so we do not have huge numbers of draftees as in prior wars where hearing loss did not matter as much to readiness.

Mild TBI Results in a Loss of Lifetime Income and Loss of Tax Revenue

If these airmen had received no VA disability, and struggled to work, the government still loses a significant amount of revenue and the economy takes a real hit. Dr. Gamboa, a vocational economic analyst (Vocational Economics, Inc.) has calculated that a high school graduate who experiences a mild TBI will lose $1,081,000 (Present Value) in life-time earnings which translates to $270,250 in lost tax revenue (FICA + 10% income tax) or $6,756 in lost tax revenue per injured enlisted member per year.

For those that have a Bachelor's degree or could have gotten a Bachelor's degree before injury, the loss of earnings from a mild TBI is $1,873,00.0 over their life time. This results in an associated lifetime loss in tax revenues of about $468,000 or about $11,700 per year.

Therefore, the estimated 600,000 war veterans that RAND corporation estimates have an untreated TBI (as reflected by symptoms of mTBI/PTSD/Depression), is estimated at $4.35 billion in lost tax revenue per year. This assumes all of them are gainfully employed at something.

Unfortunately, we know that many of this population are not only not employed, but also wards of the government in one manner or another. Many of them have already entered the criminal justice system (reports are up to 10% of county jail inmates are recently returned veterans), 154,000 of them are homeless, and recent reports list as many as 184,000 unemployed.

An examination of the homeless veteran population gives us an idea of the magnitude of the problem, and how HBOT, by biologically repairing these persons, could help the Treasury. **Current programmatic costs for this community from the current stimulus package are approximately $3 billion on an annualized basis. The stimulus money plus $2.4 billion in lost tax revenue is $5.4 billion PER YEAR in revenue drain.** If this group were treated with HBOT for a one-time cost of $2.4 billion, and 80% of them were able to return to work or school, the savings would be $4.3 billion per year in programmatic costs and increased tax revenue. Remember that most of these veterans are under 25.

Many of those who are unemployed have experienced blast-related injuries, as outlined in the RAND report. Many of them, due to suffering a mild-TBI, are under-employed and would enjoy income gains if properly treated with a biological repair treatment like HBOT. This lost revenue and these programmatic costs are certainly a drain on the U.S. economy and the Treasury.

Cost of HBOT 1.5™ Treatments

The cost of the HBOT 1.5 treatment for both of the airmen reported by Dr. Wright was approximately $16,000 for the one who received 80 treatments, and $8,000 for the one who received 40 treatments, or $24,000 for both. On average, 80 HBOT 1.5 treatments (the recommended NBIRR Harch HBOT 1.5™ protocol) at the CMS-set outpatient reimbursement rate is about $16,000.

Eddie Zant, M.D., the Florida physician who delivered the treatments to the two airman, had a Tricare referral from Dr. Wright. Nonetheless, Tricare declined to pay Dr. Zant for the treatments, despite the fact that Tricare pays for HBOT treatment for the 13 FDA-approved indications. Somehow, the fact that the treatment worked and both of these airmen recovered and returned to duty, thus saving the government $1.4 million for $24,000 in treatment costs, failed to impress Tricare. As a result Congressman Cannon and Congresswoman Napolitano introduced HR 7299 in the last hours of the 110th Congress.

Congressman Sessions has recently reintroduced the legislation, "The TBI Treatment Act," H. R. 4568, with Congressman Pascrell and Platts, co-chairs of the Brain Injury Caucus. The legislation is straight forward. If a treatment improves a patient suffering from TBI symptoms, on any of four independent measures, it is to be paid for by DoD or Tricare. The patient must be enrolled in an IRB-approved study, under the same kind of rules as the CMS's "Coverage with Evidence" program. The International Hyperbaric Medical Association is urging all members of the House to cosponsor H. R. 4568 and hopes to have a Senate companion bill soon.

Payment for this biological repair treatment for brain injury is the single largest obstacle to having it available in the medical system. One thousand HBOT centers are doing 10,000 treatments every workday across the nation, and there is considerable additional capacity available. Most treatments are delivered for the purpose of healing non-healing wounds (like diabetic foot wounds or radiation necrosis).

Note that there is more evidence for HBOT 1.5™ than there was for angioplasty or tPA for acute stroke treatment, when both of these therapies were first reimbursed by Medicare. The scientific studies that showed these two therapies were clinically effective were conducted later. It was deemed too great a risk to patients to withhold these "promising" treatments. That is the case with HBOT as well. The mild traumatic brain injured that is produced as a result of exposure to blast is a very stable injury. Once the injury is six months or more old, it changes very, very little over time. Veterans leaving the service with mTBI's now (and there are thousands of them every month), in two year's time have a high probability of having lost their families, become incarcerated, homeless, unemployed, on disability, or any combination thereof. Those are much more difficult concurrent problems to address than simply biologically repairing their brain injury. The suicide rate in this community is also well above that for the general population, now calculated at over 17 per day by CBS news investigative reporters.

HBOT is not new, it has simply been unrecognized

HBOT has been used for 80 years to heal neurological deficits resulting from decompression sickness and air embolism, as well as problem or non-healing wounds. Many of its mechanisms of action have not been understood until the last 20 years, due to advances in molecular biological and neurological imaging. **HBOT is the only FDA-approved non-hormonal treatment for biological repair of damaged tissue.** HBOT for brain injury apparently repairs non-healing wounds in the brain, just as it does in other parts of the body, when the correct oxygen dose is used. Many consider it "off-label" or not one of the 13 FDA-approved indications. Actually, HBOT for these neurological injuries fits under item number 6 on the FDA-approved indications list, "Arterial Insufficiency," sharing that spot with other chronic non-healing wounds like diabetic foot wounds, hypoxic wounds, bed sores, etc. From the imaging

and animal studies done to date, it is apparent that HBOT 1.5 is restoring normal blood flow and repairing non-healing wounds in the brain, just as it does diabetic foot wounds or radiation necrosis, or the other tissues in the body. The Marine's brain scans show a doubling of brain-blood flow in 35 days, as well as repair to the non-healing wounds in his brain.

It takes time to get results published. These airmen are the first two of the many service members Dr. Zant has treated. To date he has not been reimbursed by the government, despite similar recoveries among these war veterans. Scores of war veterans have now been treated by IHMA affiliated physicians, including Dr. Paul Harch, using the Harch HBOT 1.5™ protocol. An estimated 80% of service members or war veterans with mild/moderate TBI or PTSD have recovered sufficiently to have been able to return to duty, work or school, as these airmen did. However, without reimbursement, at CMS-set rates, a physician would go bankrupt if they treated every veteran in their area that needed treatment. The government has an obligation to help these men and women recover. They answered their nation's call and effective biological repair treatment is readily available.

Impact on the Federal Budget

We hope this information will help policy makers as the new Federal budget numbers for DoD and VA are pondered. Note that symptoms that had persisted in Dr. Wrights airmen for 7 months with standard DoD medicine treatments were greatly relieved after the first 10 treatment on the HBOT 1.5™ protocol. The airmen were able to resume many of their regular duties during the time they were being treated. The treatments required only 1 hour per day plus transportation time, leaving the remainder of their days available for normal duties. This was after 7 months of being unavailable for duty.

It is important to note that from a public health standpoint, the breakthrough that has been made on HBOT 1.5™, will, long and short term, create the greatest single improvement to the entitlement spending budgets of federal, state and local governments since 1923 when the first federal safety-net milk subsidy program was established. Today it is well known that 50% of all IDEA children, 70-82% of all homeless persons (and nearly 100% of all homeless veterans), 50% of everyone in prison, and a large number in drug treatment programs, on welfare, or struggling through the vocational rehabilitation programs, have an untreated brain injury or brain insult. **Please take a moment to ponder the benefits to the nation's public treasuries if even half of these populations could experience the benefits that HBOT 1.5™ is consistently showing in 80% brain-injured veterans.** (100% have shown improvement during treatment.)

Note that according to CDC, 1.2 million people per year experience a brain injury. Most TBI's happen between the ages of 1 to 4 and 15 to 19. Of the number that live (50,000 per year die as a result of their injuries), an estimated 30 million are working age in our society. The lost annual tax revenue alone from this many people, earning under their potential, is conservatively estimated at $8,900 each or $99 billion per year. If just the prison system population were able to be cut by 1/2 over the next ten years, the savings would be nearly $26 billion per year.

Off-Label Statement by DoD Medicine to the HAC-D & HASC

As noted in previous written congressional testimony regarding the true cause of suicides in the veteran population, almost all of the drugs being prescribed for these service members are "off-

label" (only 2 antidepressants are approved for PTSD, and all antidepressants are black labeled by the FDA for increasing the risk of suicidality in 17-24 year olds). There are no FDA approved drugs for TBI.

HBOT does not have any black label listing from the FDA. Note that the claim previously made by DoD Medicine, that they do not do off-label treatments is incorrect, because all but two of the drugs being given for PTSD symptoms are also off-label. It amazes us that they actually had the Secretary of Defense tell the Armed Services Committee this information, and that Ellen Embry told this to Chairman Murtha and Congressman Dicks. Eighty percent of pediatric medical practice is off-label. Consequently, if the military's "we never treat off-label" statement were true, there would be few children properly treated by military medicine.

Safety

HBOT 1.5 is noted by DoD in the official White Paper for the December 5-6, 2008 "Consensus Conference on HBOT for TBI" as follows: "Side effects from HBOT are uncommon, and severe or permanent complications are rare, especially at the doses of HBOT used "off-label" for TBI patients (approximately 1.5 atm abs for 60 minutes.), compared to HBOT for HHS covered indications (2 to 2.4 atm abs for 120 to 90 minutes.)"

Conclusion

The International Hyperbaric Medical Association looks forward to working with the U.S. Congress to help solve key public health problems during this next fiscal year. Helping solve untreated traumatic brain injury, brain insults, and PTSD will lead to huge improvements in the lives of millions.

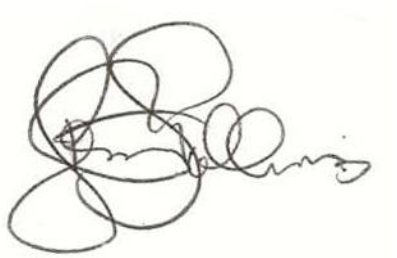
The IHMA has already prepared and presented material to CMS so that they would pay for hyperbaric oxygen treatments for diabetic foot wounds. When employed correctly, this treatment prevents 75% of all diabetic foot amputations. It is estimated that during the coming year about 13,500 amputations will be prevented, with a savings of an estimated $298 million per year in Medicare spending. Savings started in 2003. Right now only about 11% of patients who could benefit from HBOT to prevent amputations are receiving that treatment. A far smaller percentage are receiving HBOT biological repair treatment for their brain injuries.

There is no patent possible on oxygen, so none of these treatment funds go to royalty payments. IHMA is not making any income from having gotten CMS to approve diabetic foot wounds, but Medicare beneficiaries and the treasury are both benefiting. It is good public policy to reduce the costs of the current health care system, while massively improving outcomes. That is what the IHMA and her sister organization, the International Hyperbaric Medical Foundation, are dedicated to doing.

For the mild traumatic brain injury patient, clinical experience demonstrates that this treatment is far less risky to the patients than leaving them untreated. It is also far less costly to society to treat them than to lose the earnings and tax revenue, pay for social safety net costs, prison costs, etc, that accrue from not treating these patients.

We look forward to working with the United States Congress, and the Executive Branch, to make HBOT more available to prevent amputations, and to break through the barriers that exist

to adopting HBOT 1.5™ as standard-of-care for brain insults and traumatic brain injury including PTSD.



Kenneth P. Stoller, M.D., FACHM
President

Appendix A: Wright, et. al., "Case Report: Treatment of mild traumatic brain injury with hyperbaric oxygen." UHM 2009, Vol. 36, No. 6, 2009, Undersea and Hyperbaric Medical Society.

Appendix B: Harch, et. al., "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 Journal, 9 June 2009, http://casesjournal.com/content/2/1/6538

Appendix C: Chart of Additional War Veterans Treated by the IHMA Team

Appendix D: Mucomist for Acute Hearing Loss Prevention

Hearing Loss-As most of our veterans and their families are well aware, the two items that end efficiency in combat and result in medical board processing are traumatic brain injury or hearing loss. The DoD has in fact spent about $10 million according to one media report, studying the following treatment. It is our understanding from another source that this treatment has not been deployed in the combat forces because of concerns about cost.

As you are all too well aware, hearing loss after blast injury has been a major cause of retention loss in our combat forces. Hard to kick down doors for a living when you cannot hear what is going on inside the place you are entering. One news report stated this research program was $10 million. There has been discussion about deploying this treatment to our troops in the field which we do not believe has happened. The fact that the VA pays $2 billion per year for hearing aids this treatment sounds like a good idea.

The drug is N-Acetyl-Cysteine and the research was conducted by CAPT's Ben Balough and Michael Hoffer at Naval Medical Center San Diego. The N-Acetyl-Cysteine prevents tinnitus and the loss of the hearing sensors inside the ears but must be given acutely, within four hours, for best effect. The original use of this medication was for the treatment of cystic fibrosis (inhaled) and then found to be the antidote for Tylenol overdoses (intravenously), and now in a pill form (orally) for treatment and prevention of hearing loss secondary to blast/noise exposures. Its original brand name was "Mucomist." It is not available in pill form in the civilian market but the 10% solution was available at Giant by prescription for $10.99 for 4 ml. DoD's costs would be much lower than that.

Note that one of the veterans treated in the HBOT 1.5 pilot at LSU, the Marine Machine Gunner in the published case report, no longer needs his hearing aids, despite fighting the Navy for two years to get them. The HBOT 1.5 treatments improved his brain's ability to process sound. It did not improve his ability to hear the original tones. Obviously preventing hearing loss and tinnitus in combat veterans is just a good idea, especially for the reasonable cost of this medication.