What we know about NBIRR data and the Observational Study.

1) The National Brain Injury Rescue and Rehabilitation (NBIRR) Consortium began an Observational Study in April 2010 to determine if Hyperbaric Oxygen Therapy sessions at 1.5 atmospheres (HBOT 1.5) help, worsen, or have no effect on subjects with chronic TBI/PCS (Traumatic Brain Injury/Post-Concussion Syndrome) and/or PTSD (Post-Traumatic Stress Disorder). [http://www.clinicaltrials.gov/ct2/show/NCT01105962?term=NCT01105962&rank=1
2) This is a Multicenter Observational Study of Hyperbaric Oxygen Therapy (HBOT) in Chronic Traumatic Brain Injury (TBI)/Post-Concussion Syndrome (PCS) and/or TBI/Post-Traumatic Stress Disorder (PTSD).
3) The study is sponsored by the International Hyperbaric Medical Foundation (IHMF) and under the review of the Western Institutional Review Board.
4) There are currently 13 clinics registered in the Study from 11 states.
5) All subjects in the Study receive treatment with HBOT 1.5. Almost all the treatments are done pro bono or at minimal costs.
6) **As of June 1, 2013, 89 subjects screened for the protocol; 32 finished the protocol. Preliminary analysis of data on those 32 subjects shows positive results. [Update: nealry 250 subjects are now in the NBIRR database. All of those who have finished over 40 HBOT treatments confirm the outcomes in the data from the first 32 who have been analyzed.]**
7) Outcome measures included repeated self-assessment measures, and automated neurocognitive tests.
8) All subjects demonstrated improvement in most measures after HBO2 and significant improvement in 21 of 25 neurocognitive test measures was observed.
9) The objective neurocognitive test components showed significant improvement in 13 of 17 measures.
10) HBO2 administration was accompanied by significant reductions in symptoms and improvement in neurocognitive screening test scores even several years after sustaining mTBI.
11) Of note: ideation of suicide was reduced or eliminated in almost all cases where it had been reported by subjects prior to treatment with HBOT.
12) Earlier administration of HBO2 post injury, younger age at time of injury and HBO2 administration, military status, and increased number of HBO2 administrations were characteristics associated with improved outcomes.
13) NBIRR subjects had failed to improve, sometimes after decades, and only improved after HBO2 administration.
14) The safety of the HBO2 protocol at 1.5 ATA was established and there were no adverse events.
15) We are aware of no other known treatment demonstrating the degree of improvement for chronic stable or deteriorating mTBI as seen in the NBIRR study.
16) Importantly, N-BIRR has replicated the previous reported experience of HBOT 1.5 ATA in an animal model (Brain Research, 2007), 3 case reports (2009 and 2010), and a prospective series of 16 Veterans (Journal of Neurotrauma, 2012), demonstrating that HBOT at this dose/protocol is effective in the hands of other practitioners throughout the United States.

These studies and now the N-BIRR results have been further confirmed at 1.5 ATA in a study of 56 subjects published by Israeli researchers in 2013.

17) The NBIRR Consortium started down the road of the Observational Study for several reasons:

a) Evidence with HBOT 1.5 used off-label suggested that it would help treat and heal brain-injured veterans, thus possibly helping arrest the suicide epidemic afflicting the military. At the time, no significant work was being done by the military to break out of the cycle of palliating symptoms as opposed to treating and healing the brain injury.

b) We knew that the cardinal rule of "epidemics" was and is: Early Detection, Early Response. The nation needed to act quickly, despite a general sense in military medicine that the problem was not as bad as outsiders were claiming.

c) It was widely established that HBOT was safe; we needed to establish efficacy.

d) We had no money or sponsorship and could not afford an RCT, but we could arrange to treat several subjects for free and collect, store and analyze the data.

e) We assumed that DoD and the VA would not have the infrastructure to handle the hundreds of thousands of brain injured, and believed that we could build a network of civilian clinics that could immediately be put into service.

f) It was not clear if an independent group of citizens could start and Observational Study and derive scientifically-significant findings to add to the body of evidence-based-medicine with respect to TBI and PTSD.

g) We knew that our work would have to be open, transparent, secure, web-enabled, and accessible to doctors, subjects, care givers and adjudicators.

h) We wanted to build a data repository that would allow all clinics in the network, and all members of the Consortium, to have access to summary reporting at all times, and to be able to export all data to independent, outside statisticians and adjudicators for their analysis and reporting.

i) all the information technology and science would need to be flexible, in effect treating the Observational Study as a permanent rapid prototype that could be altered to adjust to individual clinic needs, new science, additional information and results of learning along the way. In a phrase, we had to build a Knowledge Base that could be adjusted on the basis of accumulated information and learning.

16) In all significant areas listed, we have succeeded. It has not been without hiccups: not all clinics could rise to the rigorous attention to detail demanded of a clinical trial; not all clinics had doctors; minimal data collection requirements could not be met in all cases, nor could clinics working pro bono take the time to input all the data, not was data input as clean as it should have been. Nevertheless, the majority of clinics and their volunteer efforts resulted in data collection and analysis that has improved for over three years.

17) More importantly we have treated and helped heal significant numbers of wounded warriors while collecting and analyzing scientific evidence that shows overwhelmingly -- and this is true around the world -- that HBOT1.5 is being used off-label safely and effectively, along with other treatments (as appropriate), to address the whole person.

18) In the course of those successes, we have established relationships with over 80 clinics which are now in NBIRR or will be willing to join NBIRR when they can be paid for their work.

19) With current capacity, the NBIRR Consortium could sustain treating nearly 500 subjects every day. That clinic capacity could be ready to treat those subjects within one month.
20) We believe we are closer to an end goal: insured coverage for use of HBOT for TBI, PTSD, PPCS and related mental health problems.

NOTE: Science is not without struggle. HBOT is no different from other non-conventional treatments brought into the field. The suicide epidemic in the military demands action. Medicine has made positive, history-altering decisions about intervention numerous times in the past: penicillin is but one example. The brain injury crisis among our military demands such consideration. Rather than a decades-long, costly series of research efforts overseen by the DoD and the VA, we can view the off-label efforts with HBOT around the world in the context of the new form of clinical trial, the Bayesian trial. Neubauer made an observation in the mid 1970s about his foot osteomyelitis patients with multiple sclerosis whose MS improved while he was treating their osteo. He subsequently applied his findings to other neurological conditions (primarily stroke and a few global ischemia patients) and adjusted dose along the way with the feedback of each patients. Harch made the same observation in divers afflicted by the bends, lowering the pressure to the dose Neubauer had used and applied this to now 80 neurological conditions, adjusting based on the response. While there was no formal "a priori" data set, the entire experience became a running a priori data set, the latest group of which are the Veterans.

With respect to ongoing efforts to test the use of HBOT brain injury, the work in NBIRR and the Army's on-going research are also part of a worldwide Bayesian trial. Science has sprung up around the world and numerous researchers are gathering evidence with HBOT. The Israeli's recent RCTs on both TBI and stroke; the Russian and the Scottish experiments with addiction; independent clinics treating and healing veterans with TBI. The Army keeps coming up with "not proven". The rest of the world keeps coming up with "look at this!" results. In a Bayesian trial, the PI would begin to adjust resources and attention toward the "Look at this!" results and away from the "not proven." [Leslie Groves did exactly this with the nearly dozen efforts to build an A-bomb, and 3 survived at the end of the war.] Thus, after a time, increased resources are moved toward positive results and away from negative results. Ergo, following the principles of the "new science", positive results are encouraged and rewarded with funding. If we can get Congress to move resources to THAT WHICH APPEARS TO WORK, we can continue to show positive results. Evidence will mount. Lives will be saved. TREAT NOW.