




HANDOUT #3



“The Arkansas Veteran Recovery Plan”
 Part of the *National Brain Injury Rescue & Rehabilitation Project*:
 A Care Pathway for Acute & Chronic Brain Insults from All Sources
**Restoring Lives, Reducing Entitlement Costs, Restoring
 Readiness by Healing Brains in Real Time**

Based upon SB1604: The Oklahoma Veteran Traumatic Brain Injury Treatment and Recovery Act,
 signed into law June 19, 2014 by Gov. Mary Fallin

**Rebuilding America’s Safety Net, Criminal
 Justice, Rehabilitation & Future Productivity**
 July 20, 2016

**Translating Science into Medical Practice and Public Policy to Create Healthcare Solutions for the
 21st Century**

Edward Fogarty, M.D., President, IHMF
 William A. Duncan, Ph.D., President, IHMA, Patriot Clinics, Inc.

Please Be the Sovereign State of Arkansas!

- Today’s War Veteran is Up Against the Sovereign Power of the Federal Government.
 - It Prevents him/her from getting effective care
 - It refuses to acknowledge the injury (just like Agent Orange)
 - It injures your National Guard & Citizens and Does not fix them when a remedy is available.
- The State is Sovereign Also, and Designed to Protect the Citizen against the excessive power of the Federal Government
 - Power as Commander-in-Chief
 - Power under Police Powers: Health, Welfare, Morals
- I URGE YOU TO EXERCISE YOUR SOVEREIGN POWER
- Power not exercised is lost

If You Do Not Know Where You Are Going, How Will You Know When You Get There?

- **Government is involved with health care to create a healthy work force.**
- **Free market economics works when everyone protects its own interest.**
 - Therefore the state, as a payer of last resort, must protect its long term interests over the short term interest of other primary payers.
- **Managed care model based upon short term insurance company quarterly profit.**
 - Deny \$300 care today, 2 years from now you are with a different carrier and need a \$25,000 procedure. That is acceptable.
 - Works for Short Term Insurance Company Profits.
 - Completely fails when applied to any long term payer such as VA, Medicaid, Medicare, Tribal Health Care.
 - Treatment that Provides a 15 IQ Point Increase is deemed “not Medically Necessary.” Why? The Insurance Company does not have to pay for any long term consequences of loss of job, substance abuse, family disintegration, incarceration, suicide, etc.
- **Effective care model delivers care today to improve long term outcomes.**
 - Each 15 point IQ increase translates to about \$20,000 in income. Thus a smarter, more educated and healthier workforce creates a more robust and productive economy.
 - A tribe, a state and a nation all have to worry about the long term productivity of individuals, not short term quarterly profits.
 - Effective care focuses on treating the underlying cause of symptoms and erasing the cause, creating a healthy and productive work force. Effective care focuses on treatments that actually work!



Untreated Brain Insults Drive Entitlement Costs

- **Untreated brain injury is so endemic in America, its effects are not even recognized!**
 - An estimated 30-40 million working age Americans are living with an untreated brain injury. CDC reports 1.7 million new injuries per year and only 50,000 die.
 - Many more suffer from brain insults from other causes!
- **Lost tax revenue productivity: Persons who suffer from a single mTBI**
 - Have a future lifetime income loss of 50%
 - (Matched to themselves and their non-injured counterparts, matched for education, intelligence, etc. Gamboa, Chicago School of Economics)
 - 45% will be unemployed 2 years post injury.
 - 33% will have “Anger” issues rising 56.7% with co-morbid depression.
- **Incarceration: 61% County/ 56% State/ 45% Federal Mental Illness**
(w/underlying untreated brain insult)
 - National prison system cost: 2.3 million in jail; 5.1 million under supervision
 - \$51.7 billion on corrections @ \$29,000 each
 - \$10.2 billion for supervision @ \$ 2,000 each

Cut cost in half over 10 years: National savings is \$30 billion



Untreated Brain Insults Drive Entitlement Costs (cont'd)

- **Veterans:** (33%+ of all deployed) (All with PTSD)
 - Cost? Current ineffective treatments \$8,000-\$32,000/yr savings w/ effective treatment? \$Billions
- **Education (IDEA Children & Remedial Education):** 50%+ have untreated brain injury.
 - **If just 20% were brought to normal, savings would be \$18 billion per year.**
- **Welfare:** Almost all women on Welfare (Avg IQ = 85)
- **Homelessness:** 100% Vets, 72-80% all others (14 month return on HBOT treatment investment!)
- **Disability (Worker's Comp & Social Security):** 61,000 TBI plus most mentally retarded
- **Nursing Home Residents:** Dementia, Strokes, Falls
- **Mental Illness:** Most traceable to a brain insult
- **Trafficked & Battered Women & Children:** Traumatic Brain Injury
- **Substance Abuse:** Tracked to self-medication to deal with brain insult. It is even clear why some choose stimulants and others choose depressants as their drug of choice!

Cost to biologically repair and regenerate brain insults:

Acute: \$250 - \$2,500 (59% reduction in mortality for severe, Prevention of 50% future lifetime income loss/family disintegration!) or

Chronic one time cost: \$24,000 (80% return to duty, work or school)
(CMS Reimbursement Rate)



EFFECTIVE TREATMENT TODAY



Member Clinics

- **"The Improbable can be done immediately. The Impossible takes a little planning."**
Robert T. Frederick (MG, USA, Ret) (Commander, First Special Service Force & 45th Infantry)
- **11,000 treatments in Oklahoma City, 2 person multiplace plus 3 monoplace chambers (December 1, 2015)**
 - More hyperbaric treatment in one location in 2 years than any other location in the history of the United States! All patients treated for free to ensure they receive the full number of treatments needed.
 - \$500,000 worth of hyperbaric equipment assembled to enable treatment!
 - Over 600 patients, most are veterans, plus veteran family members, police officers, firefighters, victims of crime and 11 tornado victims
 - Delivered \$3.5 million HBOT, \$25,000 Physician, \$102,000 Chiropractic, \$40,000 acupuncture (\$3.67 m) for charity donations & revenue of \$230,000 over 2 years!
 - Expands to 4,800 treatments per month with the opening of Lawton, Oklahoma.
- OSU, participating in NBIRR-01 with the IHMF, did about 2,600 treatments for 50-60 people from 2010 to 2014 in the State's 14 person multiplace.
 - Tulsa veterans community saw the results in the approximately 80 veterans treated and the result was support for SB1604.
- **The goal is to treat 5,000 Oklahoma veterans with hyperbaric oxygen therapy within the next year.**
 - If EVERY hyperbaric chamber in the state is used on a 16 hour day, there are only enough to treat 1,000 per year! Full deployment of effective treatment is necessary to rescue Oklahoma veterans
- Non-profit Patriot Clinics can be set up quickly and any government, for profit or not-for profit organization in the nation. **This includes every hospital-based hyperbaric center, exactly as provided in SB1604!**
- Our focus is on effective treatment, treatment that addresses the cause of a patient's challenges, not the symptoms. All synergistic treatments are designed to help restore people to work and functional life!
- **The goal is to have hyperbaric treatment within 30 miles of every Oklahoman.**
- Patriot Clinic OKC—Reopen June 2016 Phone: (405) 999-0965
- Patriot Clinic Lawton— Lawton OK - 8 person multiplace being set up (open July 2016)
- Patriot Clinic Tulsa— 2865 E Skelly Drive Tulsa (to be opened September 2016)
- Donations can be made online to www.hyperbaricmedicalfoundation.org/donate Choose the OKVRP (Oklahoma Veteran Recovery Plan) option or sent to IHMF at 6901 NW 63rd, OKC OK 73132.



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National Emergency: A War Casualty Crisis

- Service members in **the All-Volunteer Force** are some of the best and brightest in the nation; risk-takers, leaders!
- If left untreated, a veteran's brain injury destroys their life. They are a **Casualty of War** as much as if they had been left on the battlefield
 - Divorce, unemployment, disability, substance abuse, incarceration, homelessness, suicide
 - Cascade steep for the first 2 years and continues downhill thereafter - 45% will be unemployable
- **Virtually ALL homeless veterans have a brain injury**
 - 72%-80% of all homeless persons have untreated brain insults
- **It costs society more per war casualty not to treat them**
- Current deployments have brought us within 62% of the number the Army deployed in combat operations in WWII.
 - End of **World War II**: by 1949 1/3 of all persons in prison were combat veterans
- **Vietnam**: 66% of prisoners today in jail for violent crimes "harmed" someone they knew."



We Do Not Need to Repeat the Tragedies of Previous Wars!



Veteran Casualty Crisis: Source of Performance Challenges in Veteran Programs

- Military medicine is confused: PTSD shares symptoms with Mild-TBI!
 - Sleep cycle disruption, irritability and difficulty concentrating
 - Cannot get a PTSD diagnosis from VA without 2 of 3 mTBI symptoms
- 40% of all 2.6 million IEF/IOF war veterans are blast/concussion casualties:
 - 98% will experience Post-Concussion Syndrome
 - **Of those 1 million casualties, about 858,000 are likely to experience TBI symptoms, PTSD or depression; all known symptoms of brain injury**
 - Minimum 43,910 are in Oklahoma (15.2% of All Gulf War Era Veterans + 75% of National Guard who have served (27,500) + 16,410 Vietnam War Era population.
 - This yields over 25% of all OK unemployed population (27,200) with another 10,800 discouraged workers and 29,500 marginally attached to the work force.

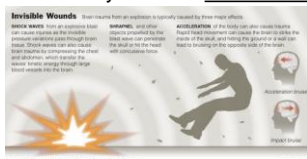
VETS SHOULD BE TOLD THEY HAVE A BIOLOGICAL INJURY!

PTSD is not because they were not "STRONG" enough to take the rigors of war!
PTSD is not a moral weakness!



Veteran Casualty Crisis: Source of Performance Challenges in Veteran Programs (cont'd)

- Each untreated casualty costs the economy \$60,000 per year
 - In safety net, substance abuse & incarceration costs & lost tax revenue
- Each casualty that returns to work
 - Is a **\$20,800 minimum annual revenue source**
 - \$ to Federal \$16,800 State and Local governments \$4,000
 - Has a reduced need for services (TANF, Medicaid, VA medical, incarceration, substance abuse, family services, food stamps, remedial education, psychological counseling, motor vehicle accidents, workers compensation, etc.)
 - Each biologically repaired person who goes to work pays for treatment through taxes and economic productivity - **\$1 million in lifetime tax revenue**
 - Each active duty rescued - **minimum \$2.6 million per veteran over lifetime**



The Oklahoma Veterans Crisis

Gulf War Era Veterans

- OK Population - 94,500
 - GWEV (not Guard) Number Injured 8,740
 - OK Nat'l Guard 27,500 (75%)
 - Est Ttl Number Injured 43,910**
 - Economic Cost Per Untreated Vet: \$60,000**
 - Of that, State's cost is approx: **\$40,000**
 - **Ttl Fed & State Cost Per Year \$2.1B**
 - **Ttl State Cost Per Year \$1.45B**
 - **Ttl Cost per 40 years \$87.6B**

Vietnam Era Veterans

- OK Population – 107,959
 - **Number Injured – 16,410**
 - Cost Per Veteran Untreated \$60,000
 - Cost Per Year – \$984.5 mil
 - Cost per 40 years - \$39.4 billion
- | | |
|--|---------|
| Unemployment Numbers Confirm Impact | |
| Unemployed | 108,800 |
| Discouraged Workers | 10,800 |
| Marginally Attached to the Workforce | 29,500 |

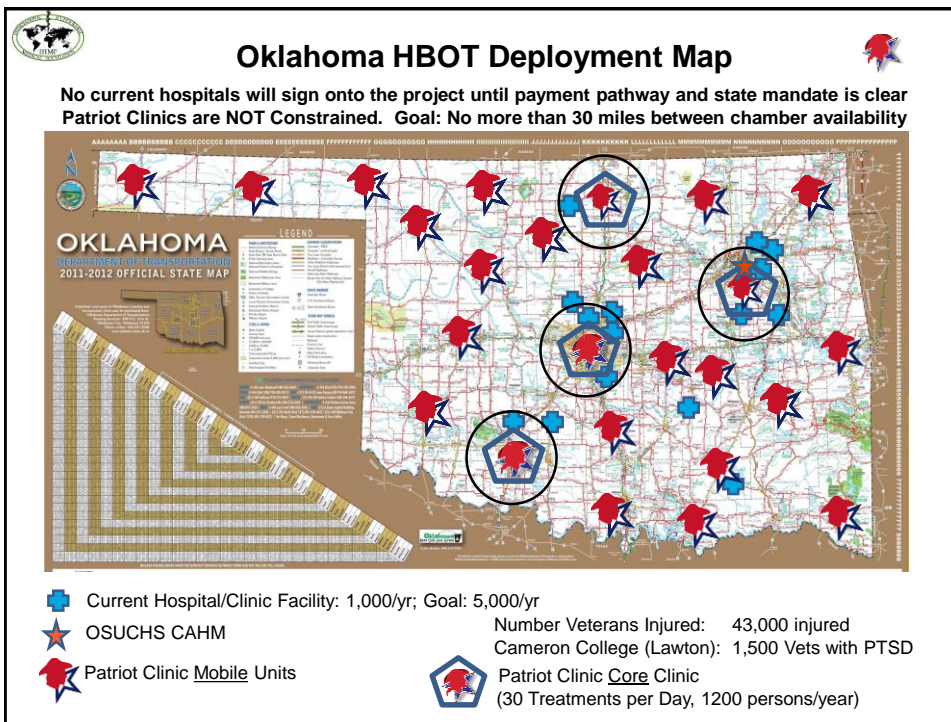
**1 in 4 OK unemployed are veterans!
(27,200 men & women)**




The Great Myth: There is No Treatment for Brain Injury

As John Maynard Keynes observed, "The difficulty lies not in the new ideas, but in escaping the old ones."

- **Fact 1: Hyperbaric oxygen treatment is already FDA-approved for brain injuries and non-healing wounds including those in the brain!**
- **Fact 2: HBOT is the ONLY non-hormonal treatment FDA-approved for repair and regeneration of human tissue.**
- **Fact 3: We have been treating brain injury, an injury caused by a lack of oxygen, with oxygen at drug level doses, for more than 77 years.**
 - It is the experience of all of the Navies and Air Forces of the world that if they get a neurological decompression sickness patient, DCS-II, [into a hyperbaric chamber within 1 hour they have a 90% single treatment cure rate. This started in 1937!](#)
 - Delayed treatment still creates improvement...but requires more treatments.
 - Those receiving the 40 treatment protocol experienced a 15 pt IQ increase, 39% reduction in Post-Concussion Syndrome, 30% reduction in PTSD, 51% Reduction in Depression, 96% improvement in Emotional Control and greatly reduced pain levels reducing the need for pain medication including narcotics! The 80 treatment NBIRR protocol improves those results by about 1/3rd. Protocol has been used since 1977 for chronic brain injury!
 - Most HBOT breakthroughs were created in Texas at Brook City Air Force Base! All of the wound and burn Care, for the 13 Indications, were driven by the Air Force Free-standing clinic (not in a hospital)!





Solution: It's Just Oxygen!


HBOT: For 77 years, Oxygen has been used to repair an injury caused by a lack of oxygen!

- **Simple: Lack of oxygen is bad**
- **O2 used in 5,769+ cellular processes**
- **HBOT activates 8,101 Genes!**
 - Down regulates inflammation processes
 - Up regulates growth & repair processes
 - Normobaric O2 does not!
- **We know how HBOT works!**
 - Acutely stops swelling/reperfusion injury
 - Restarts stunned cellular metabolism
 - Restarts stunned mitochondria
 - Mitochondria then requests oxygen (blood supply)
 - Body re-grows blood vessels
 - Activates stem cells 8x normal
 - to repair neural pathways
- **No wound can heal without oxygen**
 - HBOT heals wounds that have not healed
 - HBOT heals wounds 50% faster with less scar tissue
 - HBOT heals broken bones 30% faster & 30% stronger
- **Placebos have to have the potential of being inert.** Saturating injured tissue with any dose of oxygen has never been shown to have a placebo effect!

Pressure causes oxygen to saturate tissues higher than normal breathing:

HBAT 1.3: 50%* more O2
 HBOT 1.5: 700% or 7x
 HBOT 2.4: 1200% or 12x

HBAT is Compressed Air & HBAT 1.3 is the FDA approved treatment for mountain sickness

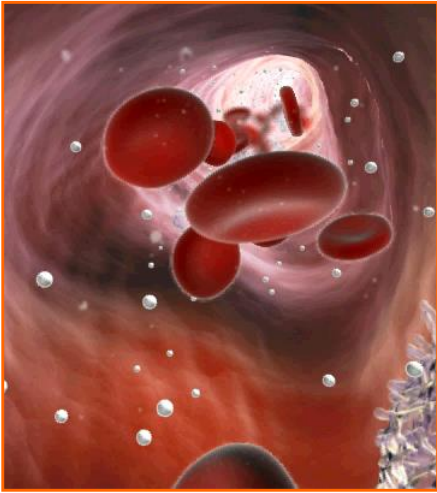


HBOT is FDA-approved & available & on-label for neurological conditions & non-healing wounds!

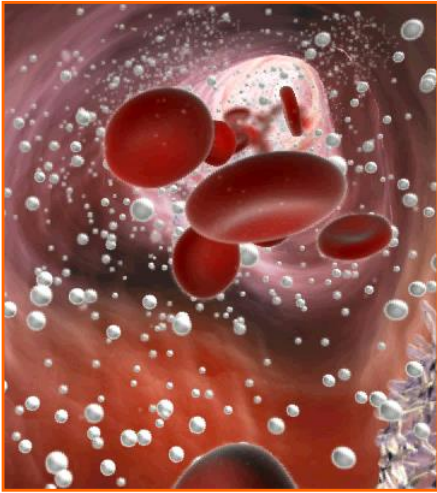
*25% more O2 in tissues is so clinically significant that DoD medicine has spent millions in research trying to achieve it. It is already available on the battlefield with mountain sickness chambers using air!

HBOT: It's About Oxygen Saturation

The body's liquids are saturated with more oxygen, helping areas with compromised circulation.





Before HBOT



After HBOT

Images courtesy of Dr. K. Paul Stoller



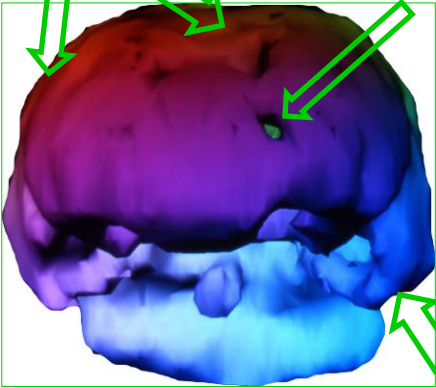
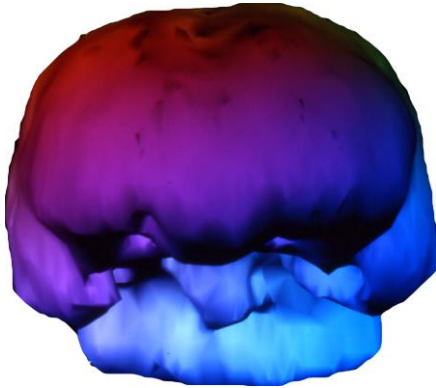


Myth: 90% Recover from Brain Injury

Traumatic Brain Injury from Child Abuse - 48 y. male

Blow from Iron Pipe
age 3


Reindeer Fawn at Santa's Village Petting
Zoo kicked in head when 8

Pre-HBOT 1.5

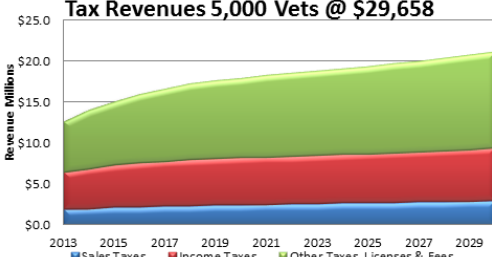
Post-HBOT 1.5

Other damage from repeated violence from alcoholic stepfather



OK State Fiscal Impact of Rescuing 22,000 of 27,500 Unemployed OKNG Injured Veterans: \$79 million/year

Tax Revenues 5,000 Vets @ \$29,658



Revenue Millions

2013 2015 2017 2019 2021 2023 2025 2027 2029

■ Sales Taxes ■ Income Taxes ■ Other Taxes, Licenses & Fees

Fiscally the average revenue increase to the state from adding these veterans will be **\$16.7M** annually from 2013 to 2023

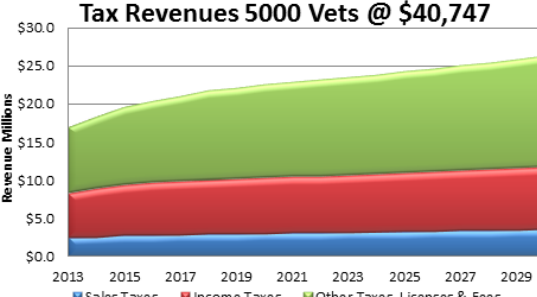
IQ differential between 1st income group & second income group? About 15 IQ points

Fiscally the average revenue increase to the state from adding these veterans will be **\$21.1M** annually from 2013 to 2023

OK Dept of Commerce uses 70% for the first group and 30% for the 2nd group.

Untreated Brain Injury Yields 50% future lifetime income loss!!! (Gamboa)

Tax Revenues 5000 Vets @ \$40,747



Revenue Millions

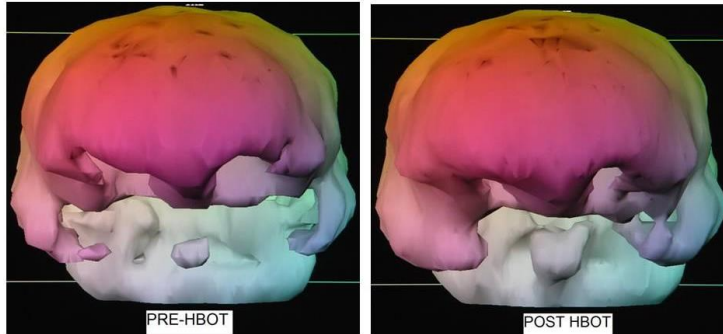
2013 2015 2017 2019 2021 2023 2025 2027 2029

■ Sales Taxes ■ Income Taxes ■ Other Taxes, Licenses & Fees

Source: OK State Department of Commerce, 2013

Solution to Brain Injury: Biologically Repair the Brain Non-Healing Wound in the Brain

Case Report: Navy SG Meeting - Aug. 2008
25 year old Humvee Machine Gunner
40 HBOT 1.5 treatments (1/2 of the Protocol)



© Retained 2008: Paul G. Harch, M.D., processed by Philip J. Tranchina.

Treated in 2008. PTSD disappeared. From living in a dark room since returning from Iraq, he became gainfully employed, turned down 1/2 of his VA disability, worked and made \$39,000 per year, and has returned to college after 2nd 40 treatments.

Finished Master in Public Administration.

Now working for a major Metropolitan Fire Department

Case Published in: Cases Report June 2009 <http://casesjournal.com/casesjournal/rt/suppFiles/6538/31370>



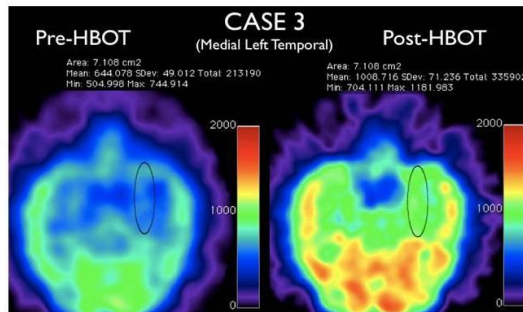
Brain insults often result in a 50% decrease in brain metabolism

HBOT 1.5 Restores Brain Blood Flow & Metabolism

Scale actually goes from 0 to 2000 so it ENDS at 2000. Those pixels that are hitting near 2000 are red and are the most active, the less metabolically active are "cooler" colors of yellow, green and blue. So if you draw a line across the middle of the scale you can see what pixels are registering at 1000 by the corresponding color.

Both pre and post HBOT sets of images are exactly on the same scale. Below is a quantitative assessment that shows the actually percent increase in uptake in an area of the brain quite vulnerable to TBI. Note the mean uptake in the area went from 644 to 1008. Similar changes are evident everywhere else.

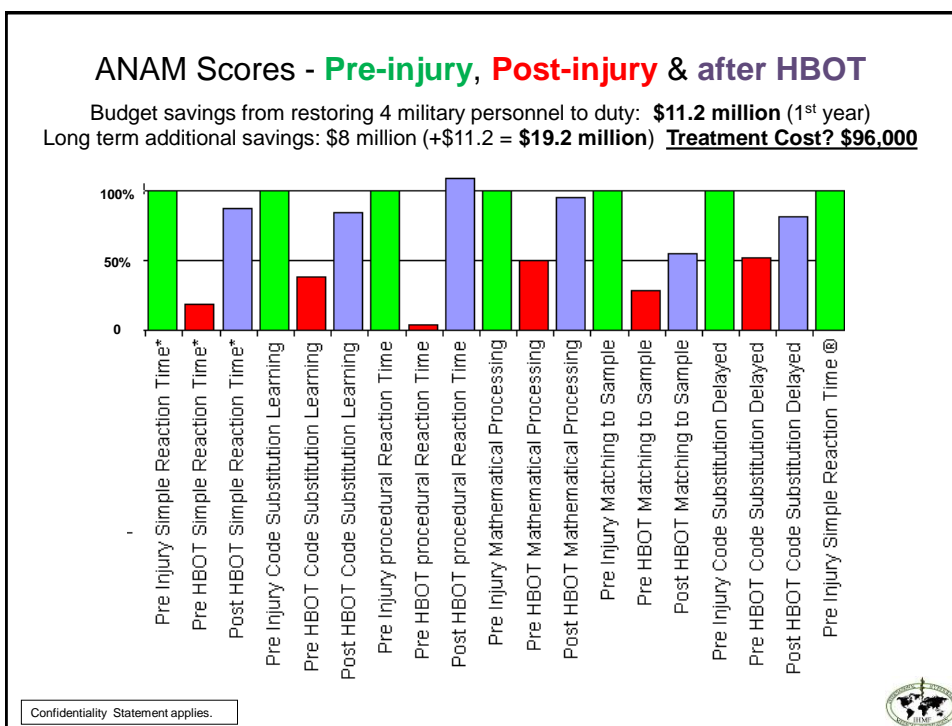
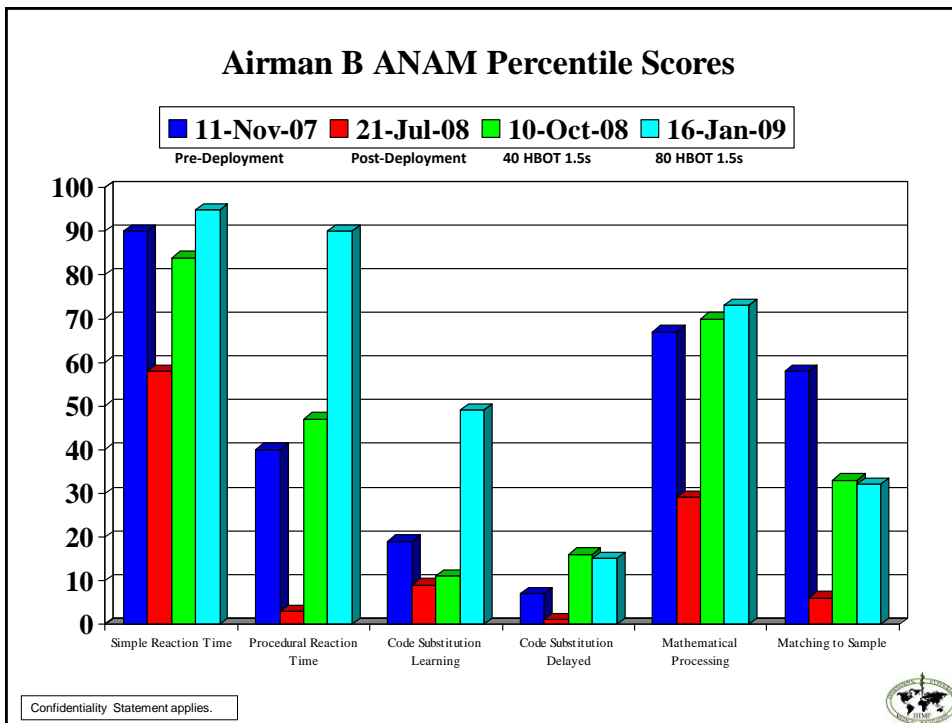
In ballpark numbers a change from green to red is a doubling of metabolism.



Analysis of blast injured veteran in LSU IRB Study # 7051: Edward Fogarty, MD, Neuro-radiologist, Chair, University of North Dakota School of Medicine, (701) 751-9579 40 Treatments: 1/2 of NBIRR Protocol

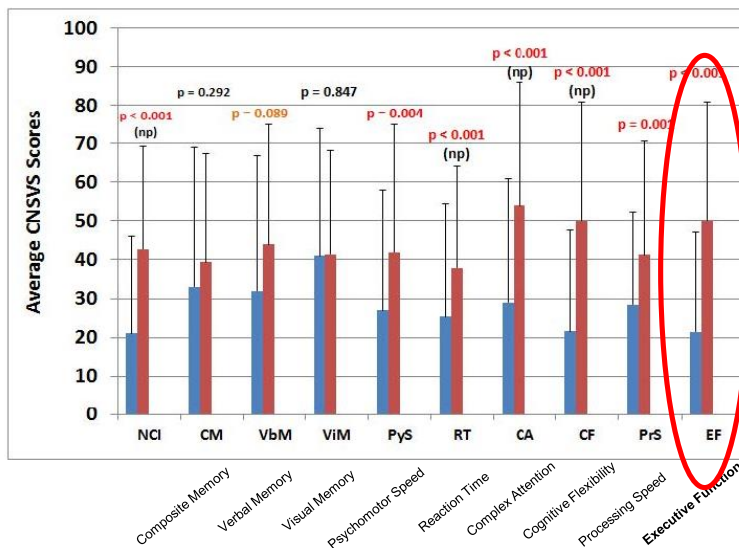
Case Published in: Cases Report June 2009 <http://casesjournal.com/casesjournal/rt/suppFiles/6538/31370>





CNSVS Neurocognitive Scores

Executive Function is a measure of a person's ability to function and manage their daily affairs



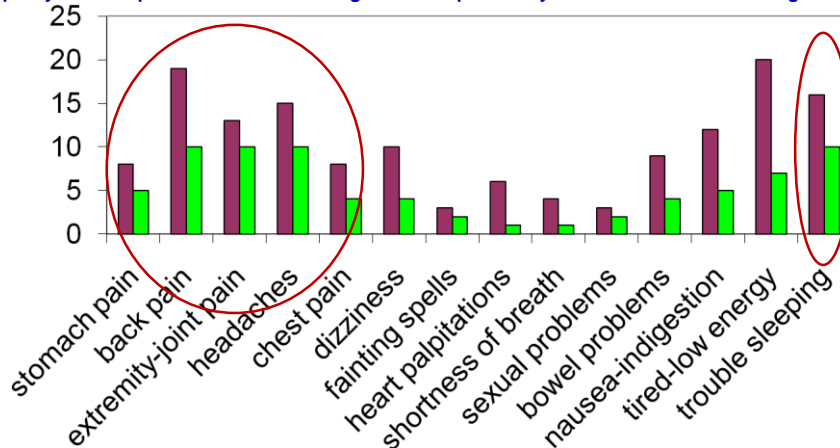
Confidentiality Statement applies.



Physical Symptoms Questionnaire

Personal Health Q-15 Results (N = 16)

Eliminated or reduced need for pain or sleep medication: Government cost savings as well as quality of life improvement: 55% no drugs in Harch pilot study. 45% reduced need for drugs!



Confidentiality Statement applies.

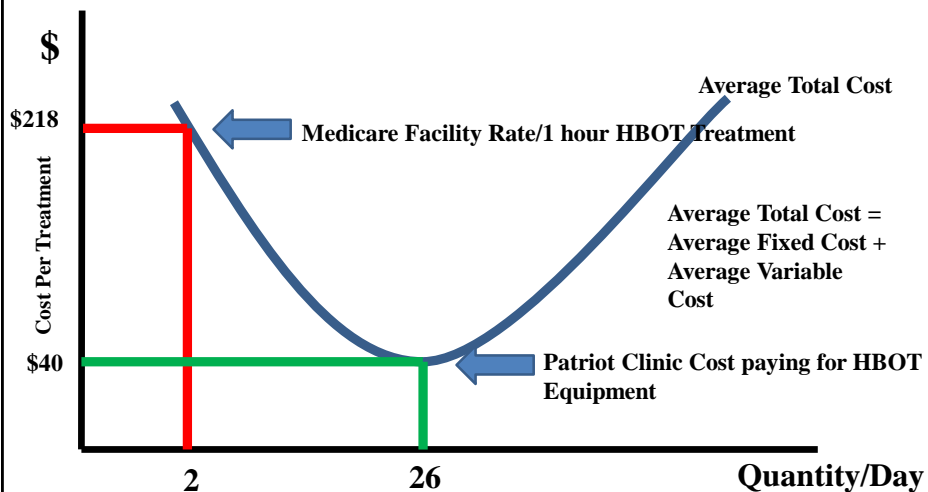


Patriot Clinics & Public Health Policy Makers: Shared Goals

- Saving Brains, Lives and Increasing Productivity
- Saving the Health Care System
 - Better patient outcomes for lower costs
 - Increased profits for hospitals
 - Increased clinic profits
- Fixing Workers Compensation
- Reducing Mandatory Gov't Spending
- Reducing the Impact and Scourge of Diabetes
- Reduced Long Term Disability Payments
- Creating Greater Insurance Company Profits

Hyperbaric Oxygen Therapy as a Public Good

Like Public Education or An Aircraft Carrier





Currently DoD-VA Only Pays for Symptom Control

They are using off-label drug treatments and none are approved for TBI;
and only 2 are on-label for PTSD! Clear Cause of Suicide Epidemic!

Suicides now exceed losses from combat casualties!

Treatments are largely ineffective!

There is no drug currently approved by the FDA to treat TBI and only HBOT (oxygen) is approved to treat 3 kinds of neurological injuries.

The only drugs approved for PTSD are Zoloft and Paxil. All other treatment with drugs for these conditions is off-label and intended to treat symptoms.

In fact, a significant percentage of psychiatric medications are prescribed off-label. Further, the use of antipsychotics in these patients is often as a chemical restraint.

The following list of drugs are FDA approved for psychiatric and neurologic disorders. The great majority of these drugs have been and are currently prescribed by DoD Medicine off-label for TBI/PTSD in the service members Dr. Harch has treated with HBOT 1.5 in New Orleans.

Neurology:

- Alzheimer's
- Ebixa
- Klonopin
- Neurontin
- Lyrica
- Topamax
- Dalmane
- Symmetrel

Psychiatry:

- Anti-anxiety
- LECTOPAM
- Tranxene
- Valium

- Psychiatry (Con't)
- Anti-depressants (All Black Label warning for Suicide)

- Celebra
- Lexapro
- Prozac
- Luvox
- *Paxil
- *Zoloft
- Cymbalta
- Effexor
- Wellbutrin
- Remeron
- Desyrel

All in red carry a **black label** warning for suicidality in those under age 25!

The veteran suicide rate is **120 per week!** (CDC Numbers)

All in red fail to beat placebo yet million\$ spent!

(Journal of Clinical Psychiatry, Nov 29, 2011)

- Antimanic
- Tegrretol
- Lamictal
- Eskalith
- Topamax
- Depakote

Antipsychotics

- Clozaril
- Zyprexa
- Seroquel
- Risperdal
- Geodon
- Abilify

August 2, 2011: \$717 million spent by VA on Drug that does not work!
DoD could have ,themselves, repaired 176,000 veterans, w/ O2!

"Antipsychotic Doesn't Ease Veterans' Post-Traumatic Stress, JAMA Published Study Finds" - NYTimes.com

*FDA Approved for PTSD

The Science of Rebuilding Brains Historical Timeline (cont'd)

- 2010, March - NBIRR-01 Begins Enrolling Patients. Preliminary results from multi-site study supports Harch's findings.
- 2011, October 25 - LSU Pilot published in the Journal of Neurotrauma, [J Neurotrauma](#). A Phase I Study of Low Pressure Hyperbaric Oxygen Therapy for Blast-Induced Post Concussion Syndrome and Post Traumatic Stress Disorder [PMID: 22026588](#) Imaging for every patient!
 - Subjects as a group showed significant improvements on most measures of intelligence, function and quality of life
 - All subjects received 1/2 the clinically recommended protocol being used in NBIRR-01 ([NCT01105962](#))
 - Nearly 15 point IQ increase (average) (difference between a high school dropout & a college graduate)(14.8 P<.001)
 - Post-Concussion Syndrome (PCS): 39% Reduction in PCS symptoms (p=0.0002); 87% substantial headache reduction
 - 30% Improvement in PTSD (20 points of a 85 point scale; 10% is considered clinically significant)
 - 51% Reduction in depression indices with large reduction in suicide ideation(p=0.0002)
 - 64% had a reduced need for psychoactive or narcotic prescription medications
 - 100% showed sustained improvement on neuropsychological tests 6 months post treatment
 - Functional improvements: Cognitive 39% (p=0.002); Physical 45% (p<0.001); Emotional 96% (p<0.001)
 - Significant reduction in anger issues!
 - Placebo effect ruled out! Results too great to be placebo effect and neurological imaging is inconsistent with a placebo effect
- 2014, November - Israeli Study: Randomized-Controlled trial plus imaging for every patient.
 - Uses actual HBOT 1.5 protocol: Hyperbaric Oxygen Therapy Can Improve Post Concussion Syndrome Years after Mild Traumatic Brain Injury - Randomized Prospective Trial
 - <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0079995>



HBOT 1.5 Provided the Largest Published Reduction in PTSD

• **LSU HBOT Pilot Study: 30% Reduction ↓**

- Prolonged Exposure Therapy [PE]: 28% ↓ - Wolf, 2012
- Virtual Reality Exposure Therapy [VRET]: 23% ↓ - Rizzo, 2011
- Transcendental Meditation [TM]: 21% ↓ - Rosenthal, 2011
- Cognitive Processing Therapy [TAU]: 14% ↓ & 4.8% ↓
Chard, 2011 & Alvarez, 2011
- Trauma Focused Group Treatment [TAU]: 2.2% ↓

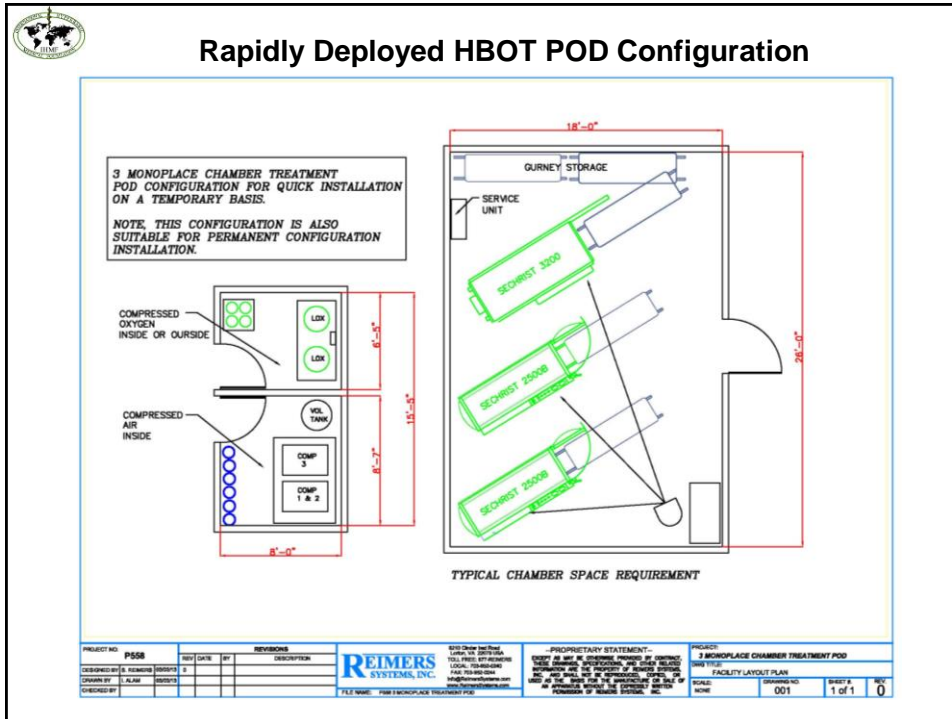
Note: All results are time adjusted for the length of treatment in the LSU study



Misleading Studies

- 2005: Army rejects Air Force study with 3 arms. 1.3 air (50% more O2), 1.75 O2, 2.4 O2 (3x brain repair dose) Hyperbaric Air also expands capillaries, increasing O2 availability.
 - Army then dictates to AF that the 1.3 Air and the 2.4 O2 study would be done. “Placebo” designated group at 50% more O2 do better than the 3x correct dose.
- Cifu (VA study) sponsored by Adm Robinson & Gen Schomacher: 2.0 ATA study (never used to repair brain injury) with oxygen mix changes to mimic room air, 1.5 O2. Claimed to have done the Harch protocol without doing it. Meaningless statistics reported to hide the actual results of the study. Cifu is later awarded \$65 million grant after completing this study and calling media all over the nation to block HBOT treatments for Veterans.
- Miller, the DoD Drug Czar, publishes data in JAMA. For the first time the 1.5 protocol is actually used. Because of criticism, 1.3 ata is replaced with 1.2 ata air (50% more oxygen reduced to 35% more O2.) While saying the HBOT treatment did not work, the 3rd comparison group was the best PTSD/TBI therapies given, and the HBOT treated group did better than any current therapies. The effect was chalked up to Placebo despite 77 years of hyperbaric oxygen research and 6 related currently approved indications for which HBOT is not a placebo.
- None of the studies used as rigorous measures at the Harch or the Israeli study did. The imaging in both of these studies uses a person as their own control, since imaging is not subject to placebo.
- When bureaucracies do this kind of research (which happens a great deal in government), it gives policy makers bad information. The policy makers have a greater budget to worry about. In fact, HBOT treatment, even at \$25,000 each, is cheaper to society than leaving them injured.





Example of Managed Care Philosophy At Work
Hearing Loss From Blast Injury

- **\$10 million Federal Research on Mucomyst or N-Acetyl-L-Cysteine (FDA - Approved for Cystic Fibrosis)**
 - Conducted by CAPT's Ben Balough and Michael Hoffer at Naval Medical Center San Diego.
 - Acute delivery of N-Acetyl-L-Cysteine within 4 hours of a blast prevents tinnitus & the loss of the hearing sensors inside the ears.
 - Oral Dose Costs \$3 per incident
- **Veterans Administration spends \$1 billion per year on hearing aids**
- **Hearing loss is a major barrier to continued military service**

Hearing loss is a major cause of loss of National Guard personnel

Decision Maker:
ADM Robinson, Navy SG

He stated:

“The \$3 is in my budget, the \$1 billion is not.”

Therefore he ruled:
“Further Research Needed”
 AND PROVIDED NO FURTHER RESEARCH FUNDING!

Consequently:
hearing loss from blast continues unabated!

Oklahoma's ANAM Saga

- Congress is concerned that DoD & VA medicine was ignoring the injuries of many guard members and war veterans. One congressional hearing focused on the fact that DoD and VA medicine were denying many veterans claims based upon “pre-existing conditions” and “personality disorders.”
 - The sheer number of injuries from the war and impacts of invisible wounds needed to be examined.
- Congress Orders pre-post testing.
- DoD Medicine chooses Automated Neuropsych Assessment Metric (ANAM) from Vista Partners, developed by Oklahoma University. (It was originally designed for Agent Orange dementia.)
- Pretesting of OK National Guard & Reserve and all of DoD deployed begins March of 2008, some OK-ARNG is done 2007.
- 101st Airborne Pre-Post Deployment test conducted.
 - Test was VERY accurate at demonstrating level of injury based upon injury history.
 - Data provided to Surgeon Generals
- Surgeon Generals actions:
 - Oklahoma National Guard is forbidden by Army SGs to do ANAM post-testing.
 - Immediately SGs issues a “letter” ordering ANAM Pre-test but ANAM Post-test not be done.
 - Questionnaires PHQ9 & PHQ-15 are used on exit from theater. Admission of injury prevents return to family and deployment to wounded warrior brigade (as reported by Congress’ first elected Gulf War veteran.)
 - DoD starts a study in theater with improper baselines. “Results stated that ANAM was accurate 80% of the time.” That is when there are no baselines and old normative data is used. 98% accurate with baseline data, which was ignored in the study.



Oklahoma's ANAM Saga (cont'd)

- Congress says the SGs letter countermanding its order is “okay.”
- Five year attempt by Army & Navy to discredit ANAM. (this destroys the value of 1.2 million baselines, including that from multiple deployed individuals that could have been used to evaluate whether a member was too injured to be redeployed!)
- Army/Navy Medicine try to “steal” OU’s intellectual property and call the test its own.
- ANAM is further validated but a ban on OU getting research funding for further development of ANAM.
- IHMF validates ANAM by demonstrating it does indeed accurately record injury, recovery and cross-correlates with all other clinical and quality of life measures.
- Army/Navy then claim that the service member’s baseline is the “property of the government” and cannot be provided to the service member to establish a level of injury or their pre-existing status.
 - This is directly contrary to the purpose of the original law.
 - Senator Inhofe fights to get the record released. He “wins” but no one can get their ANAM now except through the IHMF’s NCT IRB-approved NBIRR-01 study.
- OK Veterans Recovery Plan will provide funding to OU-Norman to further validate, develop and implement ANAM as a workforce screening tool, in accordance with its original mission and purpose.



VA & DoD Medicine Make the Largest Type II Error in the History of Medicine: Rejecting Effective Treatment for Brain Injury!



Key: Veterans Bureau Act of 1921

- **Concurrent Resolution from the Legislature of South Dakota - 1921**

The Concurrent Resolution from the Legislature of South Dakota is instructive and is reproduced for the reader here.

Be it resolved by the Senate of the State of South Dakota (the House of Representative concurring):

Whereas proper facilities for the care and treatment of war veterans suffering from disability or wounds incurred in the service have not been provided by the Federal Government out of the money appropriated by Congress for that purpose; and Whereas many of such veterans are now being sent by the Government to local asylums, almshouses, and sanitariums operated for private gain, and which in many instances are unfit as places in which to furnish such care or treatment; and Whereas the Rogers bill, known as H.R. 14961, now before Congress for consideration, provides for a consolidation of the several Government agencies dealing with such matters, and provides for the efficient administration of the funds appropriated by Congress for such purposes..... **Congressional Record, Senate, February 25, 1921.**

- **Veterans Bureau Act Creates Mechanism to Reimburse States when they Pay for a Veteran's Treatment**

- Method currently funds all state-owned veterans homes and the State Department of Veterans Affairs
- Greater obligation than paying health care providers directly.
- No obligation to pay back non-profit organizations for care they deliver.

- **Precedence: Lincoln Nebraska Hospital.**

The Lincoln Nebraska hospital had delivered \$10 million worth of treatment to veterans over a three year period. VA was refusing to pay the legitimate hospital bills for veterans treated. Dr. Duncan was asked to help. Along with the Nebraska staff member from the Congressional delegation, they went to see Art Wu on the House Veterans Affairs Authorizing committee, in charge of oversight. They explained the situation, Art picked up the telephone, made a phone call. It went something like this, "Hey, do you owe Lincoln Nebraska \$10 million over the last three years? You do, great. Do you want to pay them or shall I come do an audit? Thank you, that's what I thought." A check for \$10 million arrived 72 hours later by FedEx and after that not another payment was missed.

Key: Veterans Bureau Act of 1921 (cont'd)

- **Tricare and VA have both paid for HBOT numerous times for brain injured veterans. Payment is not routine.**
 - General Patt Maney, at Walter Reed Hospital, when the Harch protocol was delivered at George Washington University Medical Center, 80 treatments for \$250 each.
 - They initially refused then paid for the two Airmen that demonstrated the need for the TBI Treatment Act, after it was introduced. They claimed they would not pay for any more treatments, but they have paid for numerous Special Forces (SOCOM) members, and 50% of all treated in Dr. Harch's Louisiana State University study, when case officers secured pre-approval. A number of Marines have been treated, also paid by Tricare, and a person is Tricare eligible if they have sufficient disability rating from the military, six months prior to departure and two years post-return from theater.
 - The VA has paid for this same treatment in New Mexico and elsewhere.
- Nothing prevents them from paying except their bureaucratic refusal to permit veterans to recover. Thus the TBI Treatment Act was written. It states that when a treatment causes recovery from TBI or PTSD, DoD or VA medicine have 30 days to pay.
- **Therefore, when the Sovereign State of Oklahoma sending a bill for a treatment that was effective at causing a veteran to have recovery, the Federal government IS obligated to pay that state back. Thus charity money, given to the state, will seed the revolving fund to create a cascade of recovery, first in Oklahoma, then across the nation.**

**THE COST OF INJURED VETERANS HAS BEEN SHIFTED TO THE STATES
AND THAT SHIFT CAN BE REVERSED AND LIVES RESTORED IN THE PROCESS!**



How ANY State Veteran Recovery Plan Works

- **Authorization from Legislation or Governor's Executive Order**
 - The Governor has **authority** as Commander-In-Chief of National Guard
 - The Legislature has **authority** of state police powers (health, welfare & morals) over state residents
 - Note: these State authorities were NOT eroded by the Affordable Healthcare Act.
 - In fact the Supreme Court decision specifically stated that the federal authority for the AHCA was taxation and not police powers, which preserves the States' **authority** over healthcare.
 - 1921 Veterans Bureau Act mechanism: state reimbursed by federal government for state expenditures
 - Oklahoma Veteran Traumatic Brain Injury Treatment and Recovery Act published by Oklahoma State University Medical School, Center for Aerospace and Hyperbaric Medicine (*review SB1604 (2014) and HB1942 (2013) for specific details*)
- **Revolving Fund Administered by the Oklahoma Office of Management and Enterprise Services (OMES)**
 - Money does not deplete
 - Source: charity funding, state funding, etc.)
 - State has contracts with participants to fulfill roles
 - State practitioner treats veteran under protections of NBIRR-01 IRB-approved study (NCT01105962)
 - Bills the state administered fund (run OMES)
 - Oklahoma University (ANAM developer) verifies improvement in neuropsychological scores and other criteria as outlined in TBI Treatment Act;
 - State university validates result and sends to Insurance Commissioner

Continued on page 2



How ANY State Veteran Recovery Plan Works (cont'd)

- **Revolving Fund Administered by the Oklahoma Office of Management and Enterprise Services (OMES)** (continued)
 - Practitioner is paid at State Medicare rate, less the administrative fees
 - “Glue Money” created from administration fees to coordinate efforts between State Dept of Veterans, State Dept of Rehabilitation Services, State Health Care Authority, State Dept of Education, State Dept of Labor and Universities.
 - State Veteran Career Employment Center created, run by a designated State University, to provide support services and verification of fitness to return to work
 - Employers assured of receiving a veteran who has been treated with effective treatment and is a fit employee (who will not create social problems or increased workers compensation claim and will be productive like veterans usually are when they are not war casualties!)
 - Oklahoma Department of Veterans Affairs bills the appropriate federal authority for payment
- **Veteran Outcomes Tracked & Reported (IRB-approved Study)**
 - Follow-up in five years, including occupational and employment program to reintegrate Veteran into work force
 - Tracking on all measures (unemployment, incarceration, substance abuse, suicide, domestic violence, homeless status, etc.)
 - Revenue to the state from returning veterans to work, \$4,000 per year (based on OK Dept of Commerce numbers). Estimate 80% return to work, duty or school of those completing 80 treatments who are homeless, unemployed or at-risk population



Examples: HBOT is Synergistic with Other Treatments

- **Drug Protocols**
 - Patients in the LSU study were on no medication or less medication
 - Medication was now more effective at controlling remaining symptoms
- **Nutritional Programs**
 - NBIRR Nutritional Program reduced aberrant violent behavior in felons in 30 RCT studies by 39-41%
 - Harch did not use NBIRR supplement in his study
- **Cognitive Rehabilitation**
 - Treatment cannot begin until a patient can sleep through the night
 - HBOT repairs sleep cycles and most patients can begin sleeping at 10 HBOT treatments
 - When brain tissue is recovered, it is somewhat disorganized! Cog Rehab reorganizes
 - Prison recidivism reduced from 80% to 3.6% in 7 year study
- **Acupuncture**
- **Bio-Feedback**
- **Counseling & Coping Skills**



Patriot Clinic 11 Needle Acupuncture Protocol

Scott Rigsbee Acu (originally from Vimal DeAlwis, MD Sri Lankan Olympic Team Physician)

穴位 Xué Wèi (Acupuncture point) list.

Du-20 百會 Bǎi Huì (Hundred Convergences)
* 印堂 Yìn Táng (Hall of Impression)

The points listed below are done bi-lateral

LI-11 曲池 Qū Chí (Pool at the Bend)
LI-4 合谷 Hé Gǔ (Union Valley)
ST-36 足三里 Zú Sān Lǐ (Leg Three Li)
SP-6 三阴交 Sān Yīn Jiāo (Three Yin Intersection)
BL-60 昆侖 Kūn Lún (Kunlun Mountains)

* (Scott's Acupuncture point addition to the DeAlwis PTSD protocol)

Source: A Manual of Acupuncture

Types of Hyperbaric Chambers

Monoplace and Multi-place Hyperbaric Chambers

Sechrist

SOS Hyperlite

Perry

ETC Bara-med XD

Reimers Q-Ball

Hyperbaric Stretcher & Treatment System

The SOS Hyperlite is a compact, lightweight, rapidly deployable and portable hyperbaric chamber that provides a casualty with up to 20 times ambient oxygen levels for:

- Battlefield injuries in the combat zone
- Pressure related injuries (dysbaric & high altitude)
- Submarine escape & rescue
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The Likelihood that *Chance* Explains Significant Clinical Improvement in over 200 War Veterans on 15 of 21 Independent Variables

“one chance in 1,000,000,000,000,000 (1 x10¹⁵, a quadrillion)”

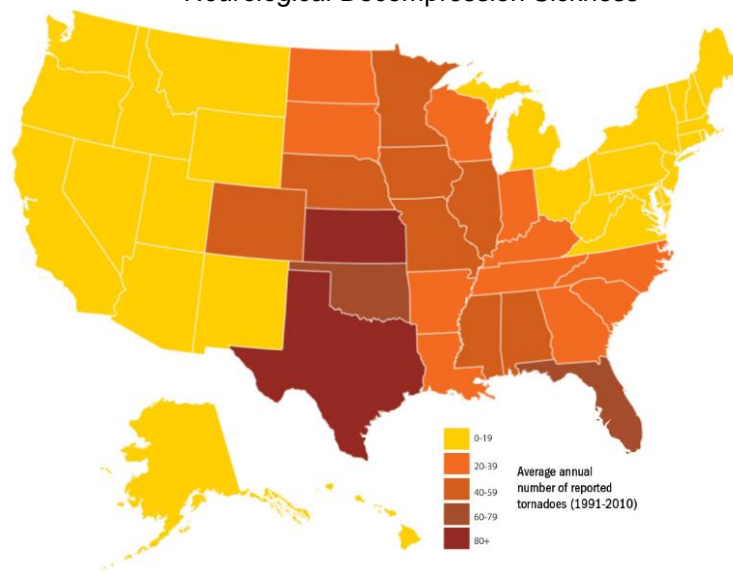
“Furthermore, even though there is about a 66% chance that random fluctuations alone (in the absence of any true HBOT efficacy) could cause at least one of the 21 variables to have $p < 0.05$, there is only about one chance in 1,000,000,000,000,000 (1 x10¹⁵, a quadrillion) that random fluctuations alone could cause 15 of the 21 variables to have $p < 0.05$. If we combined this figure with the chance of random fluctuations explaining the associated imaging findings a chance explanation for all of our findings would be many orders of magnitude smaller.”

Harch-Pezullo Letter to the Editor J-Neurotrauma, 2012



Tornados & Hurricanes Can Cause DCS-II (Decompression Sickness)

= *Neurological Decompression Sickness*



State Veteran Career Employment Center

OSU Department of Occupational Education

Follows IHMF's Plan for Veteran Career Employment Center

- All tracked under IRB-approved NBIRR-1.1 study
- Metrics for employment, homelessness, substance-abuse, incarceration, etc.
- **Step 1: Evaluate status & needs**
- **Step 2: Refer to partners for effective treatment**
- **Step 3: Employment & career intervention & training**
- **Step 4: Readiness for employment determination post treatment**
 - Flight physical type medical certification
 - Certification provided to employer
- **Step 5: Referral to participating employers who wish to employ veterans without the current challenges and drama**
- **Long term tracking of successes and failures, with intervention where needed**

“Their’ Criticism?: “This program will not work because my current veteran employment program does not work.”




Effects of OKVRP's (SB1604) Implementation

- **\$3 million in charity donations becomes \$12 million (roll over cycle about every 90 days.)**
 - \$3 million enough for 120 veterans. Roll over makes it 480 veterans/year!
 - Thus a \$25,000 donation becomes \$100,000 donation.
 - Thus a donation of \$100,000 from Marine Semper Fi Funds (for example) into the State Fund becomes a \$400,000 donation that is perpetual every year!
 - Otherwise the donation is just expended and never reimbursed.
- **Charity donations for veterans & civilians provide immediate relief and prevents further tragedy**
 - Immediate drop in suicide: Hope
 - Slows family disintegration and despair
 - Saves lives immediately
 - Begins lowering state budget costs in excess of donations
- **Oklahoma State University Treated 80 for less than \$500,000**
 - A 45th Infantry Field Grade Officer treated: \$1 million savings
 - Medical Board was cancelled and took command of his Battalion with the 45th Infantry: \$1 million savings to the OK National Guard.
 - 1LT treated, retained & now promoted to CPT: \$750,000 Savings

Everyone treated had improvement. Many returned to work.



Oklahoma Veterans Recovery Plan

- **Under IRB-approved study, with a registered IND from the FDA for TBI, in partnership with Louisiana State University, the IHMF & Patriot Clinics Coordinates with OSUCHS CAHM agrees to the protocol:**
 - All medical treatment at each facility
 - All diagnostics and research practices in the state
 - Coordinates research & professional education
 - **MetroTech, OK**  **Metro Technology Centers**
 - Coordinates and trains Hyperbaric Medical Technicians (HMT) in the first state licensure of hyperbaric providers.
 - **Under contract with the Office of Management & Enterprise Services, OUHSC College of Public Health & OU-Norman Cognitive Science Research Center coordinates:**
 - All analysis of treatment results
 - Follow up of all study subjects
 - Metrics involving collateral damage such as changes in:
 - Incarceration rates, homelessness, education performance, unemployment, workplace performance, health care costs, motor vehicle accident rate: 5 year follow up
- **Goal: Accurate Information for Decision Makers & Payers**



OK Office of Management & Enterprise Services and the OK Department of Veterans Affairs

- **State Office of Management & Enterprise Services**
 - Pays sites from revolving fund after OUHSC CPH verifies positive treatment result under TBI Treatment Act rules
- **OK Department of Veterans Affairs**
 - Collects from responsible 3rd party payer to reimburse the revolving fund
- By cooperative agreements, the fund can also coordinate with **other payers**
 - state agencies
 - Medicaid
 - Workers' Compensation
 - private payers
 - State Farm
 - Allstate
 - Progressive
 - Etc.



Oklahoma Veterans Recovery Plan *Process Flow*

- **Subject enrolls in study and receives treatment at a participating facility**
 - Statewide treatment specified by OSUCHS CAHM
 - Results logged in to IHMF's web-based database
 - OUHSC College of Public Health verifies data entry and results
 - OU-Norman CSHOP verifies patient improvement in accordance with HR396
- **Site sends the bill for treatment to State Office of Management & Enterprise Services**
 - OSDF verifies with OSUCHS CPH that OK TBI Treatment Act criteria is met
 - OSDF draws from OKVTBITRA revolving fund
 - Site receives payment, less administrative fees
 - Administrative fees sent to OSDF, OSVA, OUHSC CPH, OSUCHS CAHM and IHMF for their respective work to keep the system functional
- **Subject data sent to ODVA for collection from 3rd party payer responsible for study subject**
- **Trust fund replenished from 3rd party payer payments**



Deployment of Effective TBI/PTSD Treatment

- Use of all current HBOT facilities in the State
 - 46 treatment berths @ 40/year for each 16 hour day treatment berth equivalent:
 - **1,140 Casualties/year**
 - Chambers from the Used Chamber Market
 - **148 Berths Available at 40/year - 5,920 Casualties/year**
 - Build chambers in Oklahoma at Oklahoma PVHO approved sites
 - **100 chambers at 40/year – 4,000 casualties per year**
- **Goal: Treatment within 30 minutes travel from home**





HBOT is Rapidly Deployable

- **Note the Level of Education needed for health care professional providing treatment in the previous slide.**
 - Subjects in other therapies had a Masters, Ph.D. or physician level therapist.
- **HBOT can be delivered** by a health care provider with **EMT level 1 or better training**; with overall physician supervision.

*Thus HBOT is more readily deployable,
a lower strain on resources and
more effective than any other published therapy.*



**People who say “it cannot be done”
should not interrupt those who are “doing it.”**

-Aaron Bennett-

