PATRIOT CLINICS

"The Oklahoma 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

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

A proposed working partnership between the State of Oklahoma, Oklahoma State University, Oklahoma University, Cognitive Systems Inc., Patriot Clinics & the IHMA and IHMF

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

Paul G. Harch, M.D., President, IHMF
William A. Duncan, Ph.D., President, IHMA
John N. Hatfield, Ph.D., Cognitive Systems, Inc.

National Brain Injury Rescue & Rehabilitation Project

A Project of the International Hyperbaric Medical Foundation

Airgas

Roberts Oxygen

Translational Medicine Group

CareVector

REIMERS SYSTEMS, INC.

ANDI

Many Partners Have Made NBIRR Possible

Oklahoma State University,
Center for Health Sciences
Center for Aerospace & Hyperbaric Medicine

Participated as one of IHMF's NBIRR study sites under NCT01105962 and coauthor on a manuscript submitted for publication.

We appreciate OSU's past cooperation in helping the IHMF rescue veterans and civilians in crisis.

Marine Semper Fi Funds

SOS hyperlite

Oklahoma University - Norman's C-SHOP, developer of ANAM,

The neurocognitive assessment adopted by DoD for pre-post deployment screening.

Members are co-authors with IHMF on treatment results using their diagnostic to measure pre-post HBOT treatment results.

We appreciate OU's past cooperation in helping IHMF rescue veterans and civilians in crisis

LSU LOUISIANA STATE UNIVERSITY

Table of Contents

Glossary of Terms

- OK HB1942 (2013): **Oklahoma Veteran Recovery Plan**: The IHMA/IHMF comprehensive plan to integrate the services available to veterans in order to achieve maximum recovery and reintegration.

- OK SB1604: **Oklahoma Veteran Traumatic Brain Injury Treatment and Recovery Act** (OKVTBITRA) (official name. . . .) passed June 2014; condensed version of HB1942

- **National Brain Injury Rescue & Rehabilitation Project (NBIRR):** National series of organized studies designed to perfect protocols to maximize recovery from brain insults from all causes, and institutionalize their adoption and routine usage, availability and payment.

- **TBI Treatment Act: HR396** (TBI Treatment Act) 112th Congress (2011) outlined the criteria for a pay-for-performance program to permit effective treatment for veterans and DoD personnel with biologically effective treatments for TBI or PTSD. The TBI Treatment Act is the basis for our work with workers compensation and insurance companies and third party payers. Unless a patient improves, no payment for treatment is expected. Thus the payer has no risk in permitting treatment, since the gain to the carrier is the reduced payout for injury, which is a far greater savings than the cost of treatment. The regional Medicare Facility Reimbursement rate is used for comparison for cost of treatment, which is the government's cost of a treatment, $321 per 1 hour treatment including physician supervision, in Oklahoma. Most regional costs cluster around that number.

- **Brain Insults:** A broader term than brain injury. Generally, brain injury, such as traumatic brain injury, involves trauma or some other acute cause. Brain insults encompass the larger causes of brain dysfunction, including trauma injury like explosive blast, falls and motor vehicle accidents (a 9 mph collision is sufficient to cause brain injury) or being hit in the head (baseball, soccer, boxing, child abuse, or assault); but also things such as disease processes like stroke or diabetes dementia; heavy metal poisoning (mercury, arsenic, lead); chemical poisoning like carbon monoxide poisoning, nerve agent poisoning, hydrogen sulfide poisoning; mechanical processes like decompression sickness, hypoxic events such as near drowning or suffocation, or brain insults like chemo brain (chemical poisoning) or pump head (reperfusion injury). In all of these cases a residual injury degrades the persons performance over time and bio-accumulates injury, leading to mountain sickness, early onset dementia, degradation in work performance, interpersonal relationships, anger, substance abuse, incarceration and suicide.

- **Hyperbaric Oxygen Therapy (HBOT):** is the use of greater than atmospheric pressure to saturate tissues with greater concentration of the gas, oxygen, and using known laws of physics (just like soda soft drinks are made.) At HBOT 1.5, 7x the amount of oxygen is dissolved in tissues, and at HBOT 2.4, 12 times the amount of oxygen is dissolved in tissue. However, since 1977 it has been known that the higher dose of oxygen is toxic to the brain and does not cause healing. HBOT 1.5 maximizes oxygen concentration and glucose metabolism in the brain. Further known mechanisms of action include activation of 8,101 genes in the DNA, which create growth repair and reduce swelling, and activation of adult stem cells in a patient 8x normal, which causes repair throughout the body.

- **No Wound will Heal Without Oxygen:** This biological fact is the chief mechanism of action for all of the FDA-approved hyperbaric oxygen indications, and is the basis for a physician prescription for any disease process (non-healing wounds) or bodily insult (crush injury, burns, radiation necrosis) or brain insult (decompression sickness, carbon monoxide poisoning or intracranial abscess, radiation necrosis). Hyperbaric oxygen therapy is the ONLY therapy currently approved by the FDA for treating four different kinds of non-healing wounds in the brain from four different kinds of insults. **Hyperbaric oxygen therapy is the only non-hormonal treatment approved for repair and regeneration of human tissue.**

- **Managed Care:** A health payment system focused on minimizing short term cost while ignoring the long term future health costs of the patient. When applied in the long term it causes a long term decrease in overall population health.

- **Effective Care:** A health payment system focused on long term health of the population. The reason government is engaged in health care is to maintain a healthy work force. This system focuses on treatments that are cost effective for long term health. This is the basis for the vaccination program. When policies focus on effective treatment, long term entitlement and health care costs are reduced in a population, especially when there is effective treatment for brain insults.

- **Computerized Cognitive Rehabilitation** Program from Cognitive System's Inc.: Cognitive Rehabilitation program that uses a computer instead of a therapist. Hyperbaric oxygen repairs injury by awaking cells, which in turn treats symptoms like sleep disorder and depression, and restores lost IQ. Cognitive rehabilitation creates new capacity that did not previously exist, which results in increased memory and IQ, but does not repair the metabolic process in damaged tissue.

-

PATRIOT CLINICS — Effective Treatment Today

- **"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)
- **7,200+ treatments in a two person multiplace since January 15, 2014. (January 31, 2015)**
  - **215 patients, of them 70 veterans, 58 veteran family members, 6 police officers, 3 firefighters, victims of crime and 4 tornado victims3**
  - **Expands to 3,600 treatments per month with the addition of 8 new monoplace chambers.**
- **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.
  - Full deployment of effective treatment is necessary to rescue the Oklahoma veteran community
- **The goal is to treat 5,000 Oklahoma veterans with hyperbaric oxygen therapy and 15,000 with cognitive rehabilitation 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!**
- 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 tat addresses the cause of a patient's challenges, not the symptoms. Thus we restore people to work!
- **The goal is to have hyperbaric treatment within 30 miles of every Oklahoman and cognitive rehabilitation available to every Oklahoman with access to a computer.**
- **Patriot Clinic OKC—Phone: (405) 603-1933 6901 NW 63rd St, Oklahoma City, OK 73132**
- **Patriot Clinic Lawton— 813 SE 4th St Lawton OK - 8 person multiplace delivered** (open 3/31/15)
- **Patriot Clinic Tulsa– Location to be Determined**
- **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.**
- **Or send donations to HUGS at 720 W Wilshire, OKC OK 73110**

150201

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)

In the OKVRP, Oklahoma Demonstrates a Path to Correct National Health Care Policy and Restore Veteran's Lives

~ OK Representative *John Bennett*

40%+ of Active Army and National Guard are mission compromised.

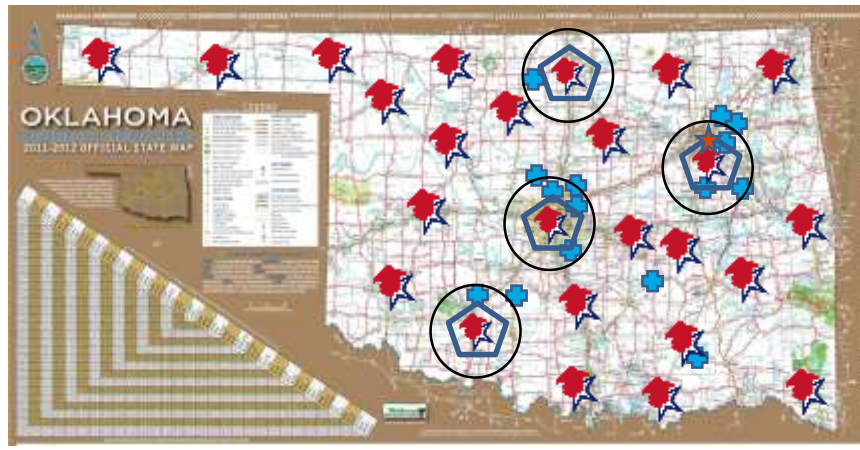
Restore Readiness!

~~~

Correctly realign active duty military medicine and VA medical with their original missions: 1921 Veterans Bureau Act: Federal responsibility to pay for veteran care and to reimburse the state when the state pays.

~~~

Switch from a Managed Care Model, which leaves persons progressively less healthy, to an Effective Care Model that focuses on maximizing life-time productivity & Health with positive patient outcomes.

Oklahoma HBOT Deployment Map

No current hospitals will sign onto the project until payment pathway and state mandate is clear
Patriot Clinics are NOT Constrained. Goal: No more than 30 miles between chamber availability



Current Hospital/Clinic Facility: 1,000/yr; Goal: 5,000/yr

OSUCHS CAHM

Patriot Clinic Mobile Units

Number Veterans Injured: 43,000 injured
Cameron College (Lawton): 1,500 Vets with PTSD

Patriot Clinic Core Clinic
(30 Treatments per Day, 1200 persons/year)

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

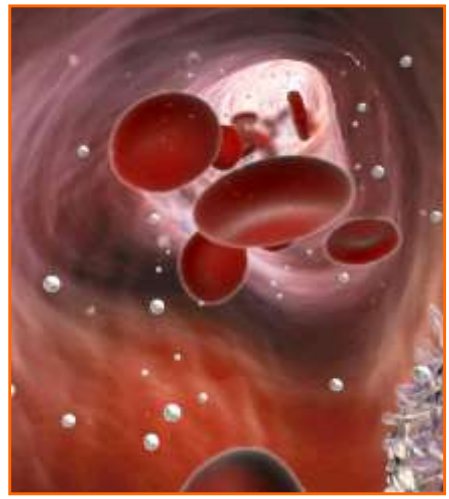
HBAT is Compressed Air & HBAT 1.3 is the FDA approved treatment for mountain sickness

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

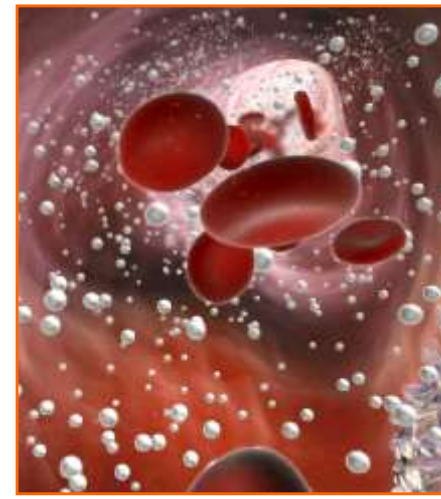
***25% more O2 in tissues is so clinically significant that DoD medicine has spent millions in research trying to achieve it. It is already available on the battlefield with mountain sickness chambers using air!**

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

FDA Accepted HBOT Indications

HBOT as used by the team is currently in use for 13 FDA-accepted indications (which means the manufacturer or practitioner can advertize those indications) by hundreds of physicians at nearly 1,000 locations across the nation, delivering approximately 10,000 treatments per day.

The 13 accepted indications for HBOT treatment include:

1. Air or gas embolism.
2. **CO poisoning, CO poisoning complicated by cyanide poisoning *(Neurological)***
3. Clostridial myositis and myonecrosis (gas gangrene)
4. Crush injury, compartment syndrome and other acute traumatic ischemias
5. **Decompression sickness *(Neurological)***
6. **Arterial Insufficiency: *(non-healing wound)***
   - **Enhancement of healing in selected problem wounds** (includes uses like diabetic foot wounds, hypoxic wounds and other non-healing wounds, etc.)
7. Exceptional blood loss anemia
8. **Intracranial abscess *(Neurological)***
9. **Necrotizing soft tissue infections**
10. Osteomyelitis (refractory)
11. **Radiation tissue damage (soft tissue and bony necrosis) *(non-healing wound)***
12. **Skin grafts and flaps (compromised) *(non-healing wound)***
13. Thermal burns[1]
14. *(Acute hearing loss has just been added by the UHMS Scientific Committee but it is not yet FDA accepted.)*

[1] Hyperbaric Oxygen Therapy: 1999 Committee Report. Editor, N.B. Hampson. Undersea and Hyperbaric Medical Society, Kensington, MD. See also: Harch PG. Application of HBOT to acute neurological conditions. Hyperbaric Medicine 1999, The 7th Annual Advanced Symposium. The Adams Mark Hotel, Columbia, South Carolina, April 9-10, 1999; and Mitton C, Hailey D. Health technology assessment and policy decisions on hyperbaric oxygen treatment. Int J of Tech Assess in Health Care, 1999;15(4):661-70.

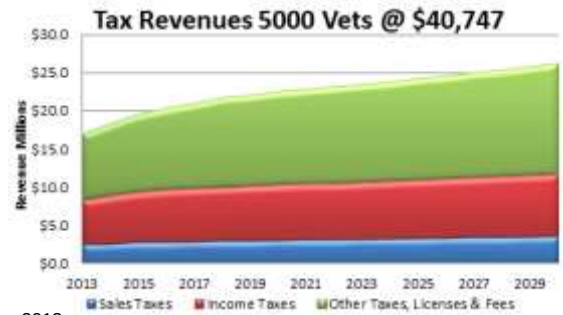
OK State Fiscal Impact of Rescuing 22,000 of 27,500 Unemployed OKNG Injured Veterans: *$79 million/year*

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.

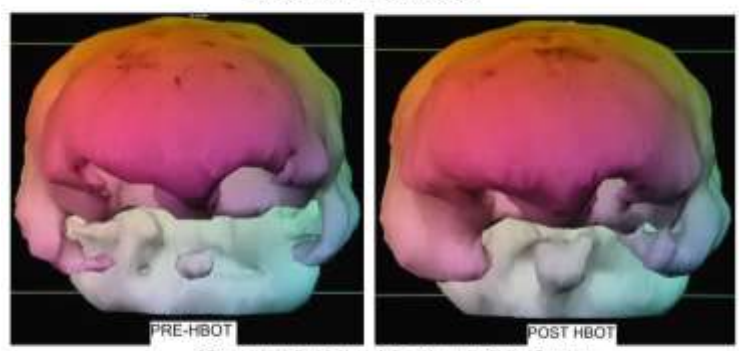


Source: OK State Department of Commerce, 2013

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, MD., processed by Philip J. Tranchina

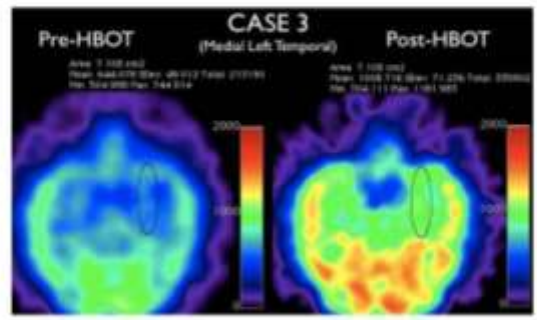
Treated in 2008. PTSD disappeared. From living in a dark room since returning from Iraq, he became gainfully employed, turned down ½ of his VA disability, worked and made $39,000 per year, and has returned to college after 2nd 40 treatments.

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

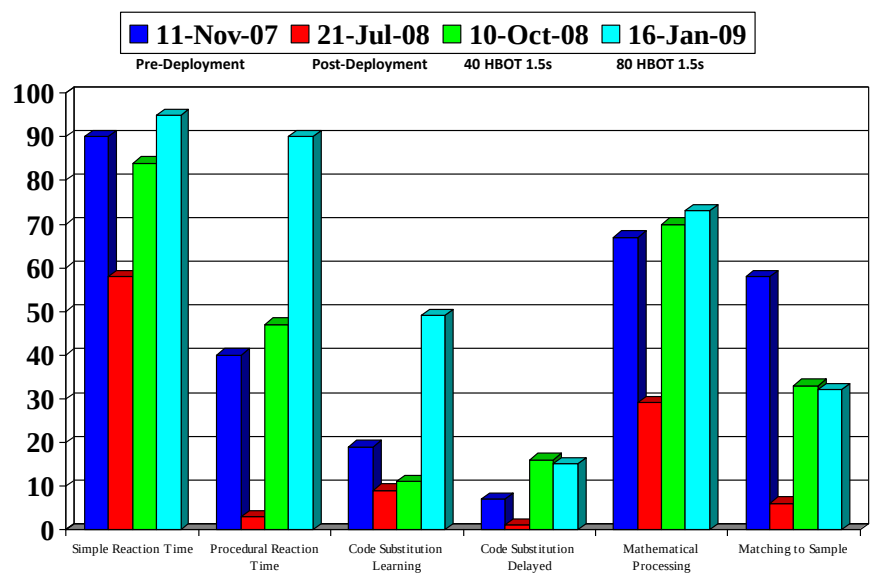
HBOT 1.5 Restores Brain Blood Flow & Metabolism

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



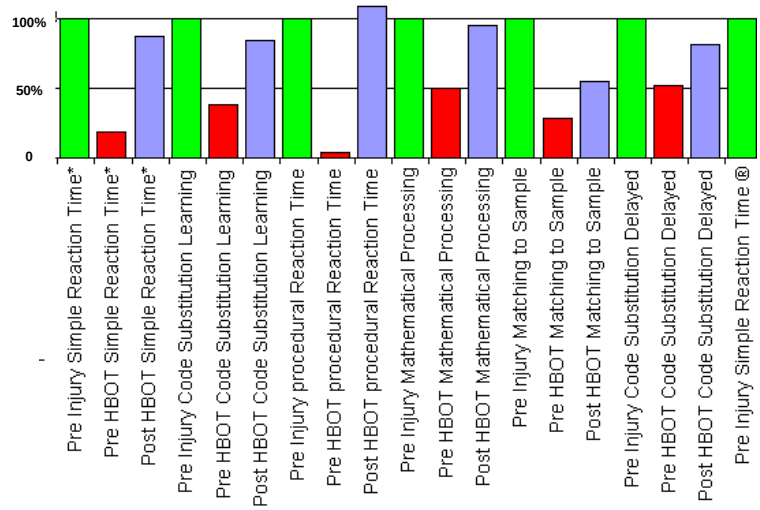
Case Published in: Cases Report June 2009 http://casesjournal.com/casesjournal/rt/suppFiles/6538/31370

Airman B ANAM Percentile Scores



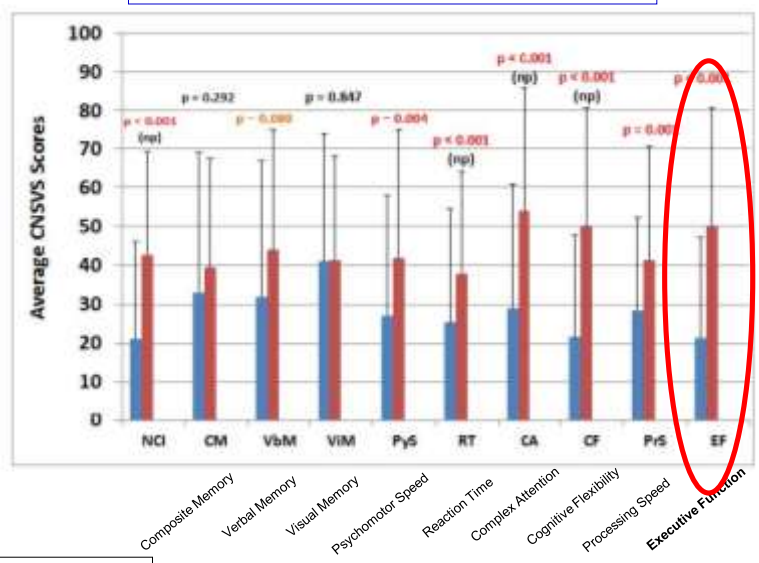
ANAM Scores - Pre-injury, Post-injury & after HBOT

Budget savings from restoring 4 military personnel to duty: **$11.2 million** (1st year)
Long term additional savings: $8 million (+$11.2 = **$19.2 million**) **Treatment Cost? $96,000**

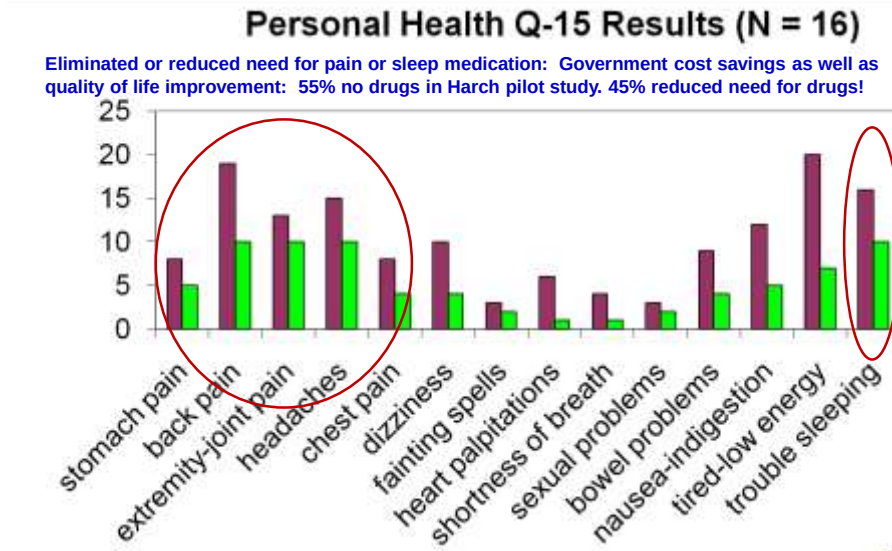


CNSVS Neurocognitive Scores

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



Physical Symptoms Questionnaire



Confidentiality Statement applies.

Restore Balance

Between Federal & State Authority

- Creating <u>your</u> {State} Veteran Recovery Plan in <u>your</u> state will restore <u>your</u> state's authority over health care delivery and foster innovation.
  - Get veterans and civilians effective treatment
  - <u>Save hundreds of millions</u> in health care, entitlement, workers compensation, incarceration and education costs while increasing the state's productivity and tax base and restoring lives.
  - Strengthen the power of the states to resist cost-shifting from the federal budget to the states
  - Break the ability of federal bureaucracies to shift pass health care costs to states without consequence to those bureaucracies **by forcing the federal government to pay for proper treatment for war casualties.**
- (Note: For DoD Medicine to pay for 80 HBOT treatments, the cost is $480 and VA cost is $4,800, **NO**T $25,000 at the civilian Medicare rate. If treatment had been given acutely, right after injury, only 10 treatments, not 80 would have been required!)

The Veterans Administration Cannot Fix Their Problems

- The current crisis at the Veterans Administration has decades of bureaucratic decisions based on **the managed care model**.
  - Nothing Congress or the President can do will change the problem. Hiring more mental health professionals does NOTHING to solve the actual problem. 22 suicides per day is a leading indicator of the failure of the current health care model.
- The Institute of Medicine just announced VA has spent $9 billion on ineffective treatment for PTSD, almost all of it "off-label" treatments not approved by the FDA. DoD Announced in New Orleans, May 2014, the only treatments for TBI are: "Yoga, horse therapy and art therapy."
  - Yet HBOT is already FDA approved for treating 3 kinds of acute brain injury, 1 chronic brain injury and 3 kinds of chronic non-healing wounds.
- Because VA has chosen to treat symptoms and not the causes of a veterans injury, **the VA have never has had and will never have the necessary resources to properly care for nor compensate the veteran population.**
  - Their perceived solution? "Delay, Deny, Hope you Die!" per the USC School of Social Work Bulletin.
- It is highly unlikely the VA will be able to change their medical paradigm internally.

The Veterans Administration Cannot Fix Their Problems

(cont'd)

- In our constitutional system based on Federalism, states are the check on the federal system failure and historically are the source of innovations that fix problems.
- Therefore states provide the pathway to an effective care system since Managed Care, designed for short term insurance company quarterly profits, has failed when applied long term.
- As states show how effective care can be achieved, the Veterans Administration can then adopt treatments that work.
- **VA and DoD Healthcare assume HBOT is a $500,000 cost per veteran and there is no treatment for brain injury.**
  - **Those two errors drive the entire resistance to effective treatment, including doing DoD and Cifu studies where the correct protocol was never used and no actual placebo sham was used!**

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!

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 threat 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:	Psychiatry:
Alzheimer's	Anti-anxiety
• Ebixa	Lectopam
• Klonopin	Tranxene
• Neurontin	Valium
• Lyrica	
• Topamax	
• Dalmane	
• Symmetrel	

Psychiatry (Con't)

Anti-depressents (All Black Label warning for Suicide)
- Celexa
- Lexapro
- Prozac
- Luvox
- *Paxil
- *Zoloft
- Cymbalta
- Effexor
- Wellbutrin
- Remeron
- Desyrel

Antimanic
- Tegretol
- Lamictal
- Eskalith
- Topamax
- Depakote

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

*FDA Approved for PTSD

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)

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

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

Cost to biologically repair and regenerate brain insults:

Acute: $250 - $2,500 (59% reduction in mortality for severe) or
Chronic one time cost: $24,000 (80% return to duty, work or school)
(CMS Reimbursement Rate)

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 75 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 95% 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.
  - 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)!

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."
(cont'd)

- **Fact 4: We have known about cognitive rehabilitation creating neurogenesis for 30 years!**
  - Developed by Israel for Yom Kippur War battle casualties. Came to USA (OKC) in 1980! Available with computer as therapist for over 10 years!
  - Hyperbaric medicine repairs injury to some extent, but it does not take someone beyond a pre-injury level to give them capability they never had. 80 treatment yield about 20-25 IQ points.
  - Cognitive rehabilitation does take non-injured people beyond their current capability, 7-15 IQ Points, and uses different repair mechanisms than HBOT to create new neurons, build new neural pathways, and increase capability and capacity creating an enhanced cognitive reserve.

Using both recovery systems synergistically, HBOT and Cognitive Rehabilitation, will maximize recovery!

The Science of Rebuilding Brains Historical Timeline

- 1937: CAPT Behnke publishes the U.S. Navy Oxygen Diving tables and study in Navy Medicine. Officially adopted by the Navy in 1968.
  - **Neurological decompression sickness is the first indication for HBOT and in 75 years no substitute was found for oxygen. Note that the 1924 tables, used until 1968, used compressed air as the treatment.**
- 1977 Study: Holbach & Wasserman PMID: 75249 : HBOT 1.5 puts the most oxygen into the brain because more triggers an autonomic response to keep extra O2 out! Chronic stroke patients treated at numerous locations.
- 1990: Dr. Paul Harch treats first demented diver for delayed decompression sickness. Numerous small studies published. (See Memorandum)
- 2002: US Army verifies HBOT 1.5 repairs white matter damage in children. ISSN1524-0436
- 2007: Rat HBOT 1.5 study for chronic TBI published in Brain Research. Human protocol in animals. First improvement of chronic brain injury in animals in the history of science. PMID: 17869230
- 2008, August 14: Briefing to Surgeon General of the Navy & Deputy Commandant, US Marine Corps: Five blast injured veterans treated. All five made improvements, some dramatic. Four of the five were able to return to duty or civilian employment! First case was published April 2009 PMID: 19829822 [PubMed]
- 2008, September: US Air Force Hyperbaric Researcher & Special Forces Command physician treats two airmen. Results verified by ANAM neuropsych test. Both are restored to duty saving the Federal government an estimated $2.6 million each in lifetime costs. They continue their careers. More active duty personnel are treated. Published in January, 2010 in peer reviewed journal (PMID: 20112530) (See Research www.HyperbaricMedicalFoundation.org)
- 2010, March 12: Report on 15 blast injured veterans under LSU IRB-approved study. Report is clinically and statistically significant and sufficient proof because of dramatic improvement in patients. ½ of protocol given (WBIC0653)
  - 15 point IQ jump in 30 days p<0.001, 40% improvement in post-concussion symptoms p=0.002 (np), (10% is considered clinically significant enough to warrant approval and payment for HBOT according to DoD researchers in December 2008.)
  - 30% reduction in PTSD symptoms p<0.001, 51% Reduction in Depression Indices p<0.001

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

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 x10^{15}, a quadrillion)"

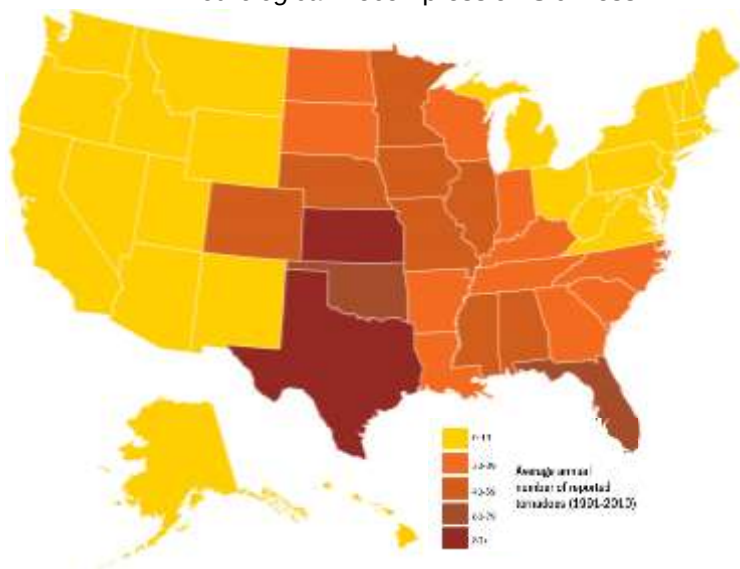
"**Furthermore, even though there is about a 66% chance that random fluctuations alone (in the absence of any true HBOT efficacy) could cause at least one of the 21 variables to have p<0.05, there is only about one chance in 1,000,000,000,000,000 (1 x10^{15}, a quadrillion) that random fluctuations alone 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-Pezzullo Letter to the Editor J-Neurotrauma, 2012

Tornados & Hurricanes Can Cause DCS-II

(Decompression Sickness)

= *Neurological* Decompression Sickness



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

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!

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 iIntervention 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 Preparing for Life
  - 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

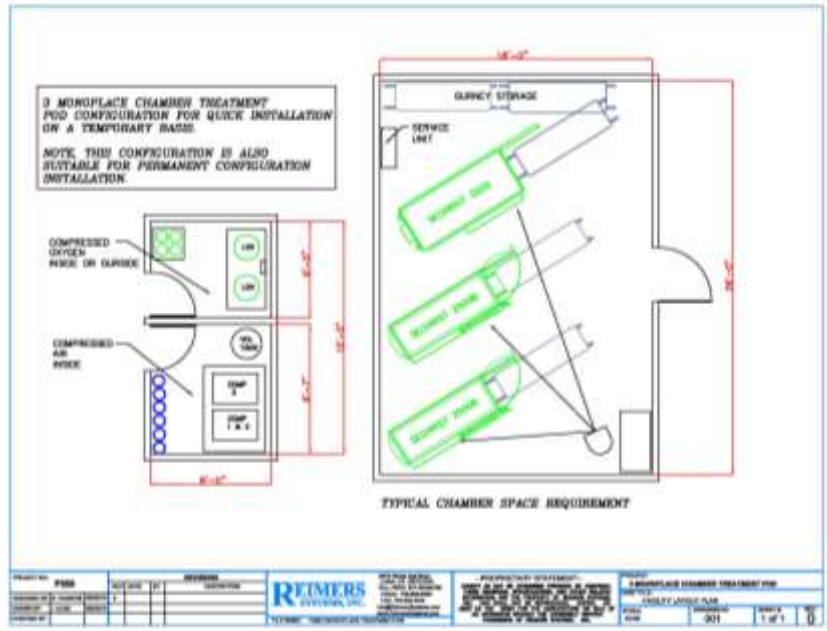
- Use of all current HBOT facilities in the State
  - 46 treatment berths @ 40/year for each 16 hour day treatment berth equivalent:
    - **1,140 Casualties/year**
  - Chambers from the Used Chamber Market
    - **148 Berths Available at 40/year - 5,920 Casualties/year**
  - Build chambers in Oklahoma 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.

Rapidly Deployed HBOT POD Configuration



Principals Underlying Payment (HR 396-TBI Treatment Act)

- Subject must have TBI or PTSD and be a veteran under 66
- Voluntarily treated by civilian physician
- **ANY FDA-approved or cleared treatment (any purpose)**
- ***Patient must improve for practitioner to be paid***
  - Neuropsych testing (IQ, ANAM, CNS Vital Signs, etc.)
  - Standardized instruments (PCS, PTSD, Depression scales)
  - Neurological imaging (functional MRI, SPECT, QEEG)
  - Clinical examination (coma state, gate & balance)
- **Must be enrolled in IRB-approved study**
- No discrimination against practitioner for any reason
- Paid 30 days after presentation of valid bill to MM or VA
- Other necessary protections for the treated veteran

Principals Underlying Payment (HR 396-TBI Treatment Act) (cont'd)

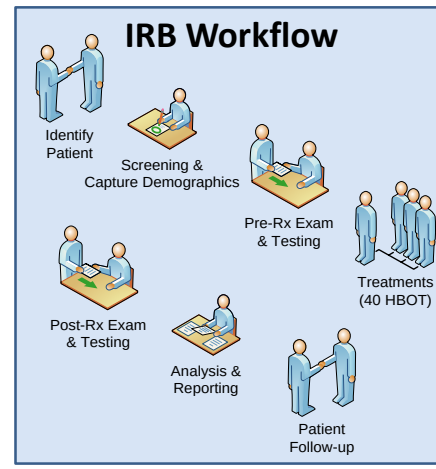
- Changes focus from "bureaucratic decision" on health care coverage to:
  - "What Actually Worked for the Patient?"
  - ALL TREATMENT MODALITIES INCLUDED
- Outlines a "rational" way of determining what works and what doesn't.
- HC provider is ONLY paid if the treatment works (true pay for performance).
- All data is collected under OHRP rules for patient protection.
- Provides valid evidence-based medicine data very inexpensively! (10% of the cost of standard NIH-funded study!)
- As a principle of federal law, the Bill radically alters the ability of patients to get effective treatment!

Multi-State Coordination for Effective Treatments

The John Eisenberg Treatment Registry (JETR)

Provides Structure for the NBIRR-01 HBOT 1.5 TBI/PTSD Study and is a Clinical Research Platform for Translational Medicine Powered by CareVector®

- **Platform Follows FDA-Devices Methodology for Medical Evidence**
  - Supports **multi-site world-wide** studies
  - Online data entry forms
  - Security roles protect patient privacy
- **Site Records all DoD ANAM Test Scores & All Other Diagnostics**
- **Web-based Reporting & Analysis**
  - 3rd party payer/policy auditing as requested
  - Analysis tools available to auditors
  - Permits CMS "Coverage with Evidence" rules
- **All Patients get Real Treatment - No Placebo!**
- **NO BARRIER To 3rd Party Reimbursement**
  - Normally "study" treatments are not reimbursable because of placebo (no) treatment provided. This study design permits 3rd party payers to pay for treatment and have it tracked for analysis and rapid proofing.
  - Willing to only be paid when the treatment works under the rules of HR 396, TBI Treatment Act
- **Evidence-based Medicine Rules & Bayesian Analysis Permits**
  - Rapid publication & potential FDA marketing approval
  - Rapid 3rd party payment for new indications



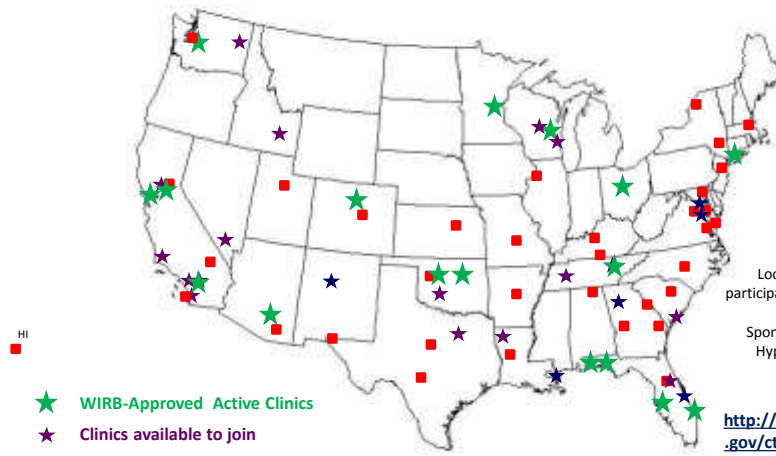
JETR is a Tool Permitting Practitioners to Proof Off-Label Uses for FDA-approved or Cleared Drugs & Devices & Build Treatment Protocols

Nationwide Location of Clinics participating in N-BIRR HBOT 1.5 Study

Sponsor: International Hyperbaric Medical Foundation

See: http://www.clinicaltrials.gov/ct2/show/NCT01105962

This is a Multi-Center Study



- WIRB-Approved Active Clinics
- Clinics available to join
- WIRB-Approved Clinics on standby
- Warrior Transition Units in US

Locations of Clinics participating in N-BIRR HBOT 1.5 Study
Sponsor: International Hyperbaric Medical Foundation
See: http://www.clinicaltrials.gov/ct2/show/NCT01105962

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**

The CSI Cognitive Emergence Program™ (CEP)

CSI's teletherapy creates neurogenesis thus rebuilding the brain and restoring productive lives

Neurogenisis in the Brain

- Hippocampus generates "baby" neurons
- Each new neuron makes 30,000 connections
- Damaged or underdeveloped neuronal pathways are permanently developed or re-connected.
- With usage, new connections form a 'Cognitive Reserve', allowing the damaged brain to more quickly restore its functioning.

Cognitive Reserve

- With use, the cognitive reserve becomes so robust, it's like having a second hard drive in a computer, backing up the operating system.
- Or, like having a second gas tank in a truck, extending the mileage/functioning.

Plus, the Cognitive Reserve lasts a lifetime…at any age!

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

- **The Executive Skills:**
  - Attentional Skills: Receive & utilize Information
  - Information processing: Perception & techniques of analysis
- **Foundations I:**
  - Integrates visual & auditory skills to improve discrimination, initiation, inhibition and differential responding.
- **Foundations II:**
  - Multiple attention, greater concentration, longer periods of sustained attention.
  - Training in switching from world-view to detailed information.
- **Visuospatial I:** Visuospatial analysis & Visuomotor integration.
- **Visuospatial II:** Mental imagery skills
- **Memory I and Memory II:** Build up the attention and executive skills utilized in storing and retaining information and stimulates rewiring of neuro-pathways in the brain; resulting in higher levels of cognition.
- **Problem Solving I:** Enhanced problem solving skills
- **Problem Solving II:** Integration and utilization of all of the attention and executive skills for enhanced logical thinking and deductive reasoning skills.

Cognitive Rehab: Developed in Israel, deployed in Oklahoma

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

13 yrs .in Marine Corps – returned to active duty 10/5/04, 1 yr. after TBI

Car accident 10/2003

Cost: Paid by Tricare for 3 months of CSI Teletherapy: $1,500

Patient spent 5 to 8 hours per day 5 days per week over 2 months on the system: Over 200 hours of therapy

Normal is 72 hours minimum, 3x per week, over a 6 month period: $4,080 ($630/mo)

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

Oklahoma

Recidivism Rate for Females

The state's savings in tax revenue:
$5.35 million! (2008-12)

- Recidivism: High return rate for drug offenders (statewide & nationally)
- Oklahoma Department of Corrections
  - Based on the past 6 years, 14% of all incarcerated females will return to prison
  - Of 221 CSI students released, many of them repeat offenders due to their drug addiction, only 8 have re-offended and returned to prison
    - ✓That's is a 3.6% recidivism rate instead of the standard 80%
- A charity donation ran the program ($5,000/year) ($25,000)

NBIRR-01, -03 & -04: Phase IV Post-Market Approval HBOT Study to Validate whether the Treatment Works When Deployed Under Controlled Conditions

Biological Repair of Brain Injury

Examination of the Societal Impacts
of Deploying Effective Treatment
(must be conducted under an IRB-approved study)

- The state legislature only pays for treatment at Medicare rates.
- The evaluation system & reemployment program operates from user fees.

National Brain Injury Rescue & Rehabilitation Project
- NBIRR -

Care Pathways Include Integrating All Effective Treatments Modalities to Maximize Biological Repair and Patient Recovery

- **NBIRR-3: Acute Treatment for Brain Insults from All Causes**
  - Emergency Rescue (Van Meter)
  - Emergency Medicine (Rockswold)
  - Acute Treatment (up to 14 days Post-Injury) (Povlashok & Harch)
  - Insults Include:
    - Trauma (Rockswold)
    - Chemical Poisoning (Alcohol & Drugs) (USC, 1986)
    - Hypoxia (Van Meter)
    - Heavy Metal Poisoning

- **NBIRR 4: Sub-Acute & Chronic Treatment for Brain Insults from All Causes** (Holbach/Wasserman & Neubauer/Harch
  - Sub-acute Starts 14 days Post Injury
  - No Time Limit on Starting Treatment After Injury
    - (Oldest) Age 91, Landed on the Beach at Normandy Under Fire
    - Significant Recovery

NBIRR 4-Synergistic Treatments

- **Hyperbaric Oxygen Therapy**
  - 15 point IQ increase (1st 40 of 80 treatments)
  - 30% reduction in PTSD
  - 39% reduction in Post-Concussion Syndrome
  - 51% decrease in depression
  - Over 50% return to work duty or school at 40 treatments, with 80% by 80 treatments
  - Improved executive function & decrease in pain
- **Cognitive Rehabilitation**
  - 7-15% IQ increase
  - Improved executive function
  - Improved return to duty, work or school
  - Reduced return-to-prison for inmates (80% to 3.6%)
- **Chemical Detoxification**
- **Infection Examination and Control**
- **Synergistic Treatments for PTSD** (Immersion Therapy, etc.)

ECONOMIC IMPACT

Substance Abuse, Incarceration & Family Preservation

Savings of the 3,100 OKNG Veterans who have returned in 2012-2013

- Of the 3,100 who have returned from theater in the National Guard
  - 13.9%+ are projected to become substance abusers
  - Annual state cost: $9.1 million
- 90% Family disintegration costs Welfare
- Incarceration:
  - 10% projected to have negative interaction with law enforcement & become incarcerated in county jail or state prison
  - Cost $6 million per year
- It costs $6,000 to put someone in jail over the weekend. 4 trips to jail are the same cost as fixing the brain injury

ECONOMIC IMPACT

Preserving Families

(From a 90% Divorce Rate)

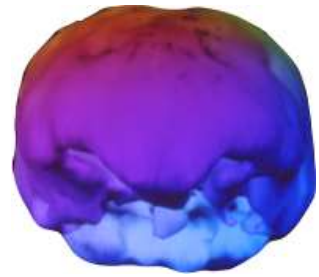
- Preserving families (90% divorce rate) prevents 29% of wives & children of war veterans being thrown onto TANF*
- Unmarried males make 30% less income*
- Highest net worth and highest income is to intact (never divorced) families
- Treating brain injury as soon as possible after return from theater will save the State of Oklahoma a lot of budget money.

*Source: Pat Fagan, Family Research Counsel

Case Presentation

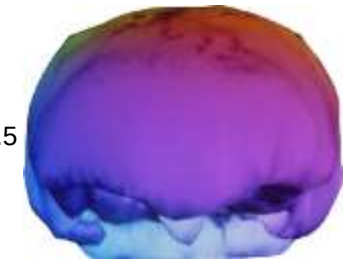
Traumatic Brain Injury and Substance Abuse
23 y. male

Pre-HBOT 1.5



top view

Post-HBOT 1.5

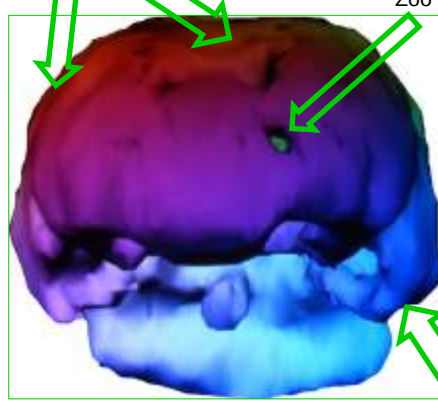


90% Recover from Brain Injury

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



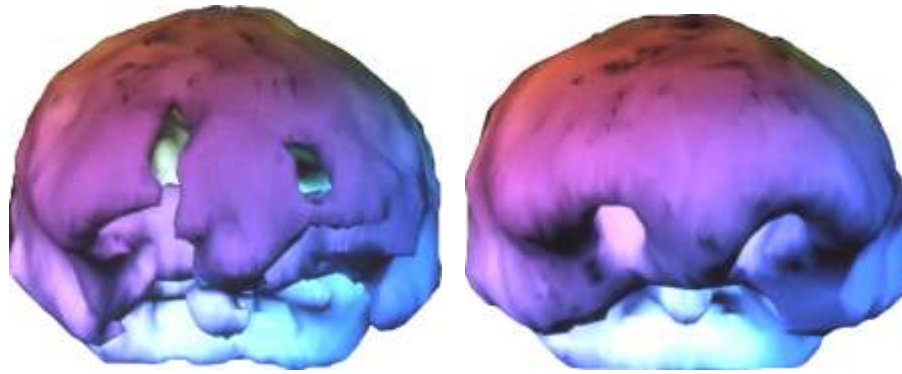
Pre-HBOT 1.5

Post-HBOT 1.5

Other damage from repeated violence from alcoholic stepfather

Non-Healing Wound of the Brain

Physical Abuse - 9 years after Injury - 21 y. female



Pre-HBOT 1.5 Post-HBOT 1.5

No wound will heal without oxygen!

What is the difference between the diabetic non-healing foot wound and the non-healing brain injury? **Essentially nothing.** FDA has already approved HBOT for 3 kinds of non-healing wounds and 3 neurological injuries!

Case Presentation

Alzheimer's Disease

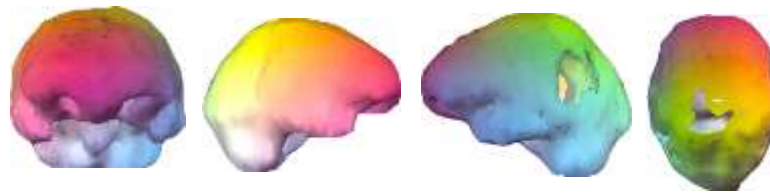
- 58 year old male.
  - Accomplished architect with decline in work & memory 8 years ago.
- Alzheimer's diagnosis 5½ years ago; started on Aricept.
  - Continued to decline over next 3 years. Started CPAP (for sleep apnea) 9/98 without effect 3 years prior to HBOT treatments.
  - Switched to Neotrophin for 9 months – limited improvement.
  - 9/2000 began Exelon; dose increased to maximum level 6 weeks before HBOT.
    - Wife notes improvement in cognition & behavior.
- 89 HBOT treatments.
  - During treatment progressive slow improvement in cognition/behavior.
  - Generalized non significant improvement in scores.
  - Some new learning ability.
  - Symptomatically patient better.
  - Patient taken off Exelon due to side effects.
  - Continuing HBOT & beginning to resume normal life activities.

Case Presentation (cont'd)

Alzheimer's Disease
58 y. male

Baseline

After 89 HBOT Treatments



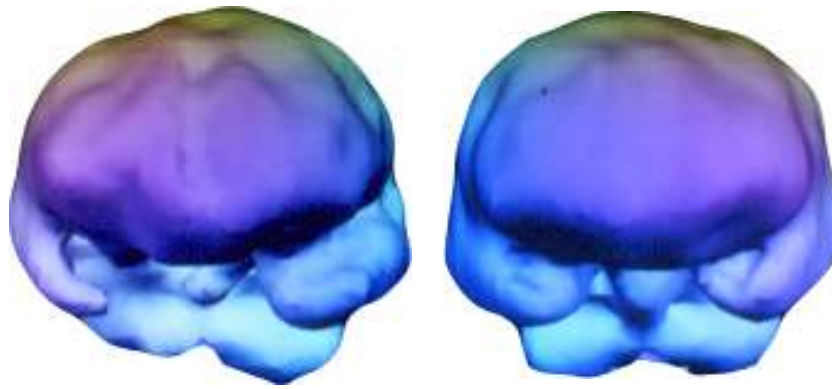
Case Presentation

Stroke

- 60 year old male. 2 years post stroke.
  - History of multiple white matter strokes.
- Complaints of body weakness, intractable dizziness, difficulty swallowing, speech problems.
  - 1st scan: Surface of brain with coarse texture & markedly decreased blood flow in right temporal lobe.
- 80 HBOT treatments.
  - 2nd scan: Improvement in coarse texture & greatly increased blood flow.
- Dizziness reduced to point that patient could:
  - Leave house.
  - Walk without cane.
  - Stopped using left knee brace.
  - Speech & swallowing improved.
  - Overall mood improved.

Case Presentation

Stroke
60 y. male



Pre-HBOT 1.5 Post-HBOT 1.5

Translational Medicine Multi-Center Studies

- NBIRR-01: Chronic TBI (approved and recruiting)
  - Moving to chronic brain insults of all kinds
- Acute brain insults (motor vehicle accidents, police officer, falls, near drown)
- HAPI (Hyperbaric Amputation Prevention Initiative including blunt-trauma and crush injury)
- Falls
- Fractures (also needed for Falls)
- Pre-Post surgery HBOT treatment
- Acute & chronic diabetes intervention improvements
- Acute & chronic stroke
- Thermal burns, frostbite
- Infection intervention including MRSA
- Necrotizing soft tissue infection

All patients receive real treatment & tracked results, compared to budget costs & revenue

Workers' Compensation & Disability & Liability Insurance Savings

- **Adding the healing tool that HBOT represents, as well as its neurological and physiological properties will save billions in lost productivity and insurance claim settlements.**
  - Over ½ of neurologically injured persons with CHRONIC injury are able to return to duty or work. Retraining success, where necessary improves. (15 IQ points goes a long way to improve success.)
  - When treated acutely, most neurological injuries can be virtually erased! Waiting to treat is more costly and requires more treatment than when treating acutely (1-10 treatments vs. 40-200).
  - Similarly, blunt trauma & crush injuries, as well as fractures, are very effectively treated
    - HBOT Treatment for blunt trauma & crush injury is already an FDA-approved and accepted indication.
- **Thus, a typical $3 million settlement for a neurological injury will be much less if $24,000 is spent giving most of a victim their brains back. Similar savings accrue for all other injuries, improving patient outcomes and reducing system costs.**
  - If an automobile carrier REQUIRED acute HBOT treatment for car accident victims, their costs of care would drop dramatically. (The US Olympic Team in San Diego routinely treats their athletes for torn tendons, fractures, concussions, etc. Motor vehicle accident victims have routinely have similar injuries.)
  - The conflict of trying to prove a person that was hit in the head with a crow bar 12 times is "malingering" and just not wanting to return to work, will largely be alleviated, to the benefit of the system, public relations, and especially those who are injured and need real assistance.

Human Resources Department

- **Create a more rational HR policy & enhance employee productivity**
  - Improve employee performance
  - Reduce workers compensation costs
  - Reduce corporate liability
  - Create rational criteria to return to work after injury
- **Step 1: Incorporate screening for injuries into hiring and evaluations after injury.**
  - **Hiring:** This is <u>NOT</u> a diagnostic to determine whether a given professional should be hired. It is a diagnostic to determine who is injured though otherwise eligible.
  - Neurocognitive screening tests like the Military's Automated Neuropsychological Assessment Metrics (ANAM) or CNS Vital Signs.
    - These tests have "normative scores" for the general population.
      - ANAM, for instance, is 80% accurate at determining if someone has been injured with no pre-test and 98% accurate at determining if someone was injured compared to a baseline test.
  - **Rational Criteria for Return to Work**
    - Post-injury, post-recovery assessment is no longer a "game" between the evaluator trying to determine if the employer is at risk allowing an employee to return to work. A neurocognitive test result makes the process much more rational.
      - This ONLY works when biological repair treatment is used to return the employee to near prior injury status.

This <u>cannot</u> be used as a pre-screening "hire" determination because unions will object and block this entire effort to improve the work force.

Human Resources Department (cont'd)

- **Step 2: Treat with NBIRR-01 Protocol**
  - **Treatment of these new hires is very cost effective.**
    - For example, it is $300,000 to put a new police cadet through the academy. "Resetting" the cadet's neurological baseline will reduce the drop out rate, improve cadet performance and police officer performance on the job.
    - Police officers are far more valuable than police cadets and they have long retention rates in any give system. Keeping them performing and healthy is a major priority.
    - Costs can be controlled rationally through HBOT treatment contracts.
      - Those costs are "part" of the health care plan offered by the employe, and will not significantly increase costs, though they will greatly enhance an employees performance and productivity.
      - Statistics show that a brain injured person has a 50% future life-time loss of income, which is a direct measure of the employee's productivity. Productivity and capability has been shown to return to nearly pre-injury level, and often an employee's performance exceeds that of their capabilities at their original hire date.
      - (No provider can charge less than the "Medicare" rate legally.)

Is Hyperbaric Medicine Safe? **Yes!**

Source: "HBOT for TBI" Consensus Conference, December 2008

- **Treatment involves simply breathing pure oxygen under pressure** (often while sleeping or watching TV).
- **Ten thousand plus similar treatments are given every day at 1,200+ locations nationwide for other indications.**
- The DoD White Paper stated: **"side effects are uncommon and severe or permanent complications are rare…"** *(White Paper for the HBOT in TBI Consensus Paper, 12/08)*
- The DoD After Action Report stated: **"safety of the treatment is not an issue."** *(After Action Report HBOT in TBI Consensus Conference, Defense Centers of Excellence, 16 Dec 2008)*

People who say "it cannot be done" should not interrupt those who are "doing it."

-Aaron Bennett-

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!

IHMA & DoD/VA Medicine History

- Presented Correct Protocols starting in 2001!
  - Before the War ever started
  - Made Presentations every year to 2 years from 2001 to 2008
- Admiral Walsh (VCNO Navy) and General Conway (Commandant, US Marine Corps) forced a HBOT for TBI Consensus Conference December 5 and 6 2008!
- Protocols and correct Placebo methodology presented by knowledgeable hyperbaric physicians

Response?

- After numerous Marines were successfully treated by Dr. Harch under the Commandant of the Marine Corps' view, General Conway was preparing to put HBOT chambers at all military bases and use Semper Fi Charity funds to pay for treatment of all injured DoD personnel. Admiral Robinson threatened to personally sue the Commandant if he did so if any personnel got so much as a "hang nail" from being treated. The Navy Secretary did not back the General.
- Admiral Robinson & General Schomacher tell DoD and the public that it will cost $250,000 to treat each casualty with hyperbaric medicine. (Actual DoD cost is $480 for 80 treatments, VA Cost is $4,800 for 80 treatments, and Civilian cost is $25,000 for 80 treatments.
- Therefore oppose the effort to get them treated.
- Obfuscation is organized and coordinated.

Agent Orange Tactics on Brain Injury

- Secretary of the Army (Gerald Ford), Marty Hoffmann, forced DoD to stop spraying Agent Orange in Vietnam.
- The Science was overwhelmingly clear that this was bad for the health of U.S. service members and civilians.
- Plans were made to find out how to detoxify U.S. service members
- A campaign of denial began the day after Jimmy Carter was elected President

Brain Injury

- Basic Tactic: "There is no brain injury, it is all PTSD, and we have treatments for that." (Note they did not say effective treatments.)
- ANAM, developed by OU-Norman, is chosen as the mandated test. It demonstrates a 98% effectiveness on pre-post testing of an individual in detecting changes in performance
- ANAM is given
- Post-testing is prevented & ANAM is attacked
- All service member pre-tests are "classified" and not available to an individual for determination of VA brain injury disability, in direct contravention of Congressional intent.
- Research is sponsored that there is no brain injury, and PTSD is not at all related to blast or concussion. (Hoge articles)

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. Meaninglesss 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.

CSI

Cognitive System's, Inc.

Cognitive Emergence Program™ (CEP)

(*computerized cognitive rehabilitation software*)

The CSI Cognitive Emergence Program™ (CEP)

Effects and Medical Conditions Helped

- **Neurogenesis**
  - Damaged or underdeveloped neuronal pathways are permanently developed or re-connected.

- **Mirror Neurons**
  - Move information to long term memory
- **Synapses**
  - Increases strength, quickness & accuracy of response
- **I.Q.**
  - Rises between 7% and 15% as cognitive processing speed increases

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

Effects and Medical Conditions Helped

- Cognitive Deficits that overcomes problems of motor, auditory, visual and abstract thinking secondary to:

Traumatic brain injury (TBI)	Cerebral palsy
Post-Traumatic Stress Disorder (PTSD)	Downs Syndrome
Strokes or brain attacks	Mental retardation
Heart attacks with anoxia	Executive dysfunction disorder
Hypoxia or anoxia (lack of oxygen)	Chemo-brain
Developmental delays	Attachment Disorder
Learning disabilities	Dementia
ADD/ADHD in children and adults	Dyslexia
Fetal Alcohol Syndrome	
Personality disorders or social dysfunctions	
Long and short term memory loss	

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

- Executive Skills are enhanced:
  - Attention Skills
  - Information Processing
  - Memory
  - Problem Solving
- Psycho-Social Improvements:
  - Impulse Control
  - Decreased Substance Abuse
  - Dramatically Lower Recidivism in Incarcerated Individuals

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

- **The Executive Skills:**
  - Attentional Skills: Receive & utilize Information
  - Information processing: Perception & techniques of analysis
- **Foundations I:**
  - Integrates visual & auditory skills to improve discrimination, initiation, inhibition and differential responding.
- **Foundations II:**
  - Multiple attention, greater concentration, longer periods of sustained attention.
  - Training in switching from world-view to detailed information.
- **Visuospatial I:** Visuospatial analysis & Visuomotor integration.
- **Visuospatial II:** Mental imagery skills
- **Memory I and Memory II:** Build up the attention and executive skills utilized in storing and retaining information and stimulates rewiring of neuro-pathways in the brain; resulting in higher levels of cognition.
- **Problem Solving I:** Enhanced problem solving skills
- **Problem Solving II:** Integration and utilization of all of the attention and executive skills for enhanced logical thinking and deductive reasoning skills.

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

- The system is synergistic will all other treatment modalities.
- CSI has saved the federal and state governments millions by improving productivity in individuals and restoring lives.
- The program has greatly benefited government by reducing recidivism in previously incarcerated individuals.
  - Clients cumulatively, save millions in retraining, recruiting & disability costs, as well as improved productivity.
- CSI has helped thousands, from students to others police officers, blast injured war veterans, NFL players & athletes, crime & accident victims and incarcerated individuals to improve their quality of life.
- Many have been able to continue their careers or return to productive lives.

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

Mabel Bassett Correctional Center (MBCC) (N=524)

- Normal inmate recidivism ranges 80% in the Meth incarcerated population to 14% in the regular population.
- 91% of MBCC program participants were former Meth users and 99% had documentable head/spinal injuries.
- **The recidivism rate in MBCC participants who have completed the program was 3.6%.**
- **Former inmates** report they now **think differently** more quickly and can think things out **before making decisions** that could be harmful to others.
- 100 hours is sufficient to cause significant clinical improvement in the activities of daily living.
- 200 hours is sufficient to cause improvement in executive function and productivity**.**

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

Using Artificial Intelligence to Enhance Human Intelligence

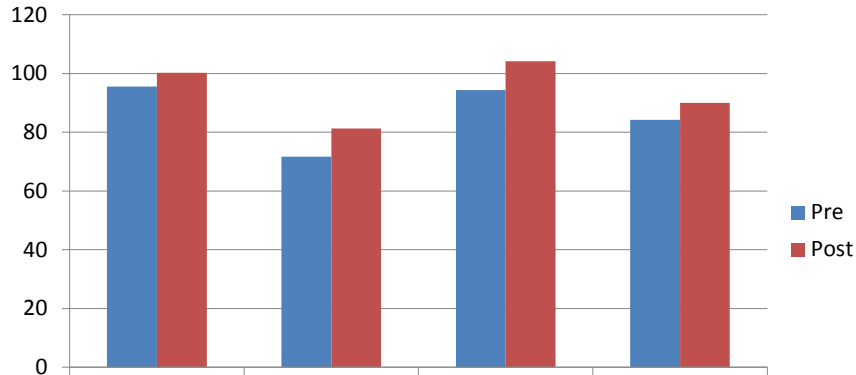
- CEP is based on the cognitive rehabilitation exercises derived from Psychological Software Services PSS CogRehab Version 95©.
- CSI has a proven track record of using cognitive rehabilitation therapy, delivered over the Internet or through a closed computer network, using a series of modules, that permit persons, to create neurogenesis after brain insult.
- This includes those institutionalized or in remote locations. **This system has been shown to have significant clinical, quality of life, productivity and a more positive future for clients.** Information Technology lowers the costs of treatment to maximize patient recovery for minimum cost.
- Because of the use of artificial intelligence instead of intensive human on human interaction, CSI's product has been very cost effective for health care practitioners, institutions and individuals seeking to improve outcomes for those they serve who have suffered brain insults.

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

Elementary School Students

Special Ed-Oklahoma: Horace Mann (Jim Thorpe)

2002-2003: 6 Month program



	WISC-III Performance IQ	WRAML_Verbal Memory	WRAML_Learning Index	WRAML_General Memory
Pre	95.59	71.65	94.35	84.18
Post	100.29	81.24	104.12	90

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

Elementary School Students

- The teletherapy system offers much promise for the academic environment."
- "[I]ncreases in general intellectual functioning were not expected, as this domain is relatively constant over the lifespan." Ruwe p.14
- "[E]ven children who are the greatest risk for academic failure benefit from treatment with therapeutic neurocognitive exercises." Ruwe p. 18.
- Improvement in domains that are vital to academic success:
  - Learning and memory
  - Fluid or non-crystallized intelligence
  - Increased speed of information processing

Cognitive System's, Inc. Organizational Licenses

- **OK State Dept of Rehabilitation Contract (Individual)**
  - $380/month for use of software
  - $300 per month for therapist oversight
    - 6 months (72 hours) yields permanent improvement
    - No limit on individual hours of use. More therapy = more improvement
- **CSI Contracts with an Organization (or per prison)**
  - $5,000 plus training or unlimited training at 7,500 per year ($5,000 annual renewal)
  - Unlimited use of cognitive rehabilitation tools
  - Unlimited clinical & technical assistance
- **In partnership with IHMF, additional health practitioners (neurologists, psychiatrists, psychologists, pediatricians, emergency and family practice specialists.)**
- **Organization Provides**
  - Personnel capable of overseeing 50 participants per supervisor
  - Telemedicine & internet & computers needed (a prison is a closed system)

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

Mabel Bassett Correctional Center

The savings in state tax revenue $5.35M (2008-12)

- CSI was introduced to MBCC in March 2006
  - Program cost: $7,500/year unlimited training
  - Currently paid by charitable donation to the prison
  - ➢ 159 students have completed CSI from beginning to end.
  - ➢ 221 of the enrolled students have discharged from MBCC
    - ➢ Of the 221 students only 8 have re-offended and returned to prison
    - ➢ After CEP training by CSI only 3.6% of students have returned to prison after having been addicted to Meth!
  - ➢ **3.6% recidivism rate instead of the standard 80%**

- 99% of students have had head/spinal Injuries
- 85%-90% of students are drug offenders
- Approx. 91%'s drug of choice is Meth
- Nationally only 3% - 5% of Meth users stay off Meth
- They said they now think differently and don't need to get high.
- They said they are now in control of the way they think and choices they make.

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

Oklahoma State Trooper

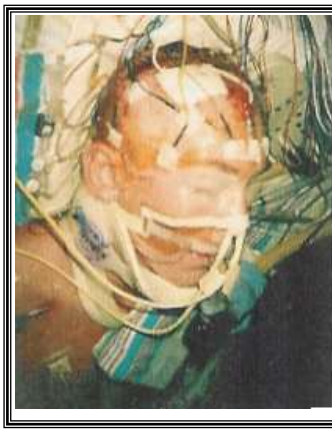
- Severe TBI – Jan 2000
- Intensive rehabilitation through June 2000
- *State previously spent* an estimate: **$250,000**
  - Unfit for duty & unable to return to work
- *Cost of CSI paid by state workers compensation for 24 months*:

  $15,120
- Now driving
  - Completed 4,000 mile trip
  - Firing on range
- Working & building custom cars

The CSI Cognitive Emergence Program™ (CEP) (cont'd)

Kyle - Before and After:

Sitting on the sidelines during high school football can be hazardous when your entire team as well as the other team run over you during a play.

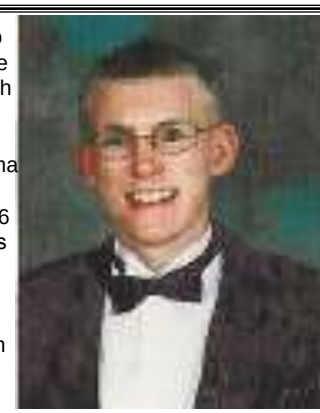


Freshman, two concussions the first week of high school

23 days in a coma

Recovers after 6 months of CSI's Teletherapy program

Graduates from high school & college



The CSI Cognitive Emergence Program™ (CEP) (cont'd)

Kyle was a freshman in high school

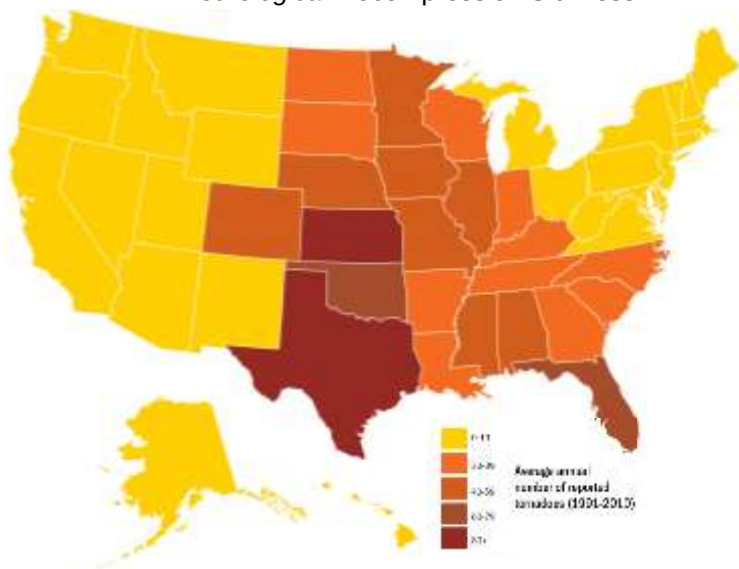
- A concussion during play put him on the sidelines
- He was not wearing his helmet, since he was benched.
- A play ran over him.
- 2nd Concussion in a short time.
- 20th day in ICU, the doctors recommended pulling the plug.
- On the 23rd day, Kyle opened his eyes and said, "Mom, I love you."
- Survived but could not function during his sophomore year.
- After 6 months of CSI's teletherapy, Kyle completed high school in the top of his class and went on to college.
- Kyle now has an Associates Degree & working
- Cost: Paid by school insurance: $5,670
  - (9 months)

Key Cause of Battlefield Injuries

Tornados & Hurricanes Can Cause DCS-II

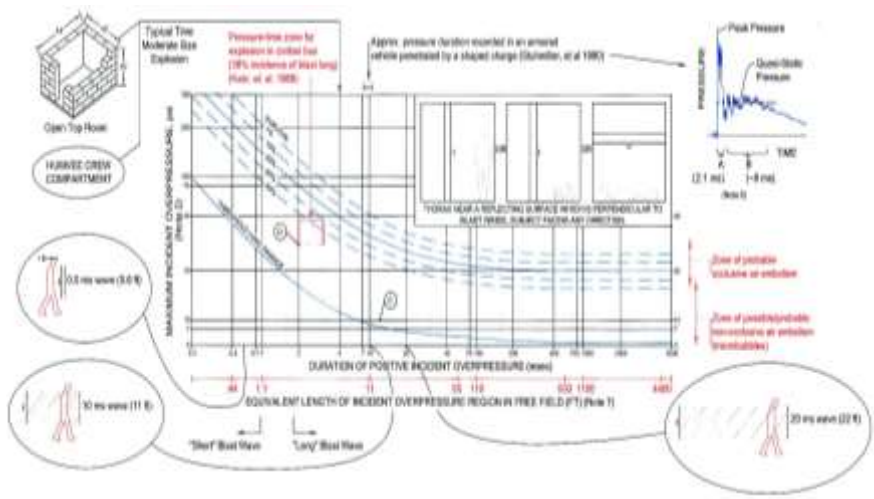
(Decompression Sickness)

= *Neurological* Decompression Sickness



Nature of Battle Casualty Injuries from IEDs:
Blast Injury Equivalent to Decompression Sickness (The Bends)

~ Tornado & Hurricane Exposure Can Cause Similar Injury



Micro Air Embolism Contribution to Blast-Induced MTBI (Reimers, et. al, UHMS ASM, 2011)

- Think of a blast wave not as a "shock wave" but rather as a fast-moving region of high pressure air with real length.
- If the length of the pressure wave is short relative to thorax dimensions(e.g. like from small munitions in open areas) the effect is like being hit by a flying wrestling mat.
- However, if the pressure wave is long relative to the thorax (e.g. from large IEDs, blasts occurring inside enclosed spaces, big blasts at long range, etc.) the wrestling mat is followed by rapid & extreme chest compression & rebound
- The chest compression event produces disruptions of the aveoli/capillary boundaries, often microscopic, that result in microbubbles being released into the blood stream.

Micro Air Embolism Contribution to Blast-Induced MTBI (Reimers, et. al, UHMS ASM, 2011) (con't)

- Unless the lung damage is severe, the lesions (usually small) seal quickly (15 minutes to 3 hours) and the bubble production stops.
- The lungs filter out 95+% of bubbles in returning venous blood.
- Therefore, once the bubble production stops, circulating bubbles are eliminated within a few minutes.
- However, bubbles are a 'foreign substance' to the body, and the damage they do while present remains; endothelial irritation in the brain, etc.
  - The cascade of events initiated by the bubbles, even though they may be present for only a short time**, is a major contributor to what shows up a few days later as mTBI and possibly also joint pain similar to that from DCS**

Israeli HBOT 1.5 Randomized - Controlled Trial Published (2014)

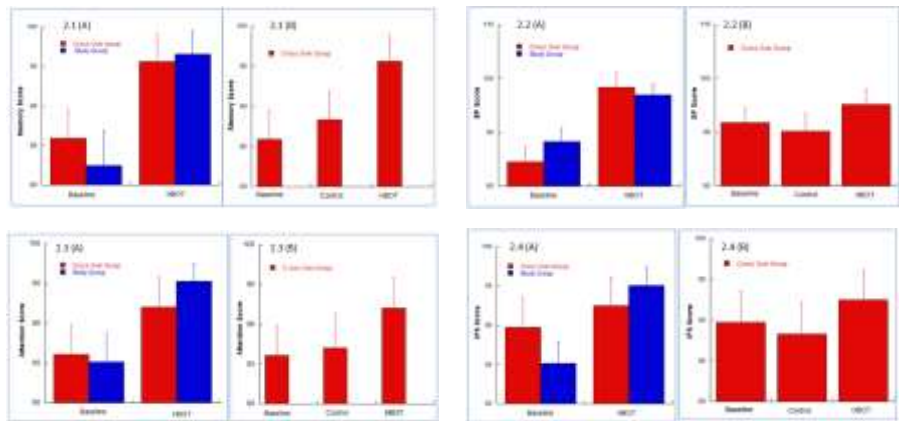
HYPERBARIC OXYGEN THERAPY FOR CHRONIC COGNITIVE IMPAIRMENTS DUE TO TRAUMATIC BRAIN INJURY- RANDOMIZED PROSPECTIVE TRIAL

Rahav Boussi-Gross1, Haim Golan3. Gregori Fishlev1, Yair Bechor1, Olga Volkov3, Jacob Bergan1, Mony Friedman1, Eshel Ben-Jacob2,4,5, Shai Efrati 1,2, 1The Institute of Hyperbaric Medicine, 2Research and Development Unit

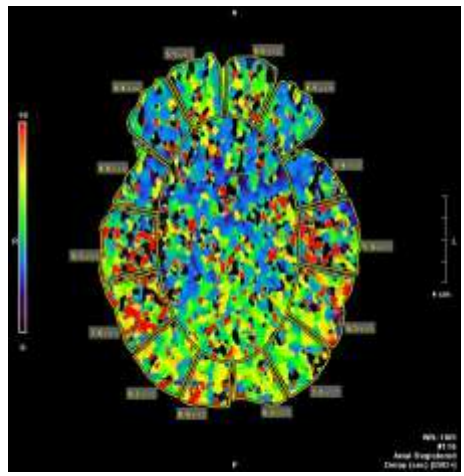
	Treatment (n=32)				cross over (n=24)					
	Baseline	HBOT	P1	P2	Baseline	Control-Pre HBOT	Post HBOT	P2	P3	P4
Memory	82.43±25.15	96.54±17.18	0.567	<.0005	85.90±17.80	88.36±17.34	95.61±15.54	0.233	<0.005	0.835
Executive function	88.26±14.74	96.96±11.69	0.367	<0.0005	91.73±13.26	90.20±15.77	95.13±13.84	0.295	<0.05	0.595
Attention	85.13±20.28	95.30±12.90	0.854	<0.005	86.10±18.42	87.05±20.98	92.02±18.95	0.368	<0.05	0.443
Information processing speed	85.12±15.88	95.04±13.75	0.324	<0.0001	89.74±18.81	88.30±19.68	92.47±18.25	0.298	<0.05	0.55
EQ-5D	7.87±1.36	6.48±1.07	0.615	<0.0001	7.70±1.11	8.06±1.05	6.75±1.06	<0.01	<0.0001	0.362
EQ- VAS	5.03±2.31	6.62±2.45	0.696	<0.0001	5.26±1.70	5.21±1.66	6.39±1.80	0.373	<0.0001	0.696

Israeli Graphs Demonstrating Consistent Improvement After HBOT 1.5 Treatment was Delivered

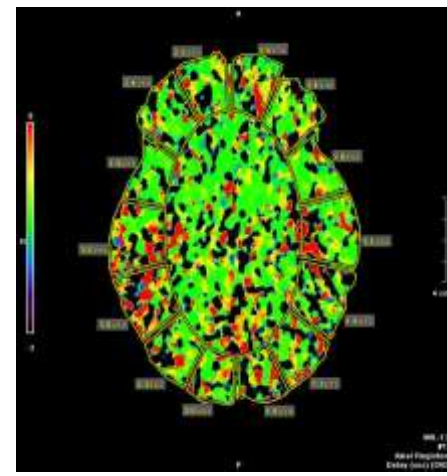
Figure 2.1-2.4. Mean scores+SE of cognitive tests (memory, executive function, attention and information processing speed, respectively) for (A) HBOT and cross group at baseline and following treatments; (B) Cross group at baseline, following waiting period, and following treatments.



Severe TBI Patient:
Whole Brain CT Perfusion Pre & Post HBOT



Pre HBOT – 10/16/09

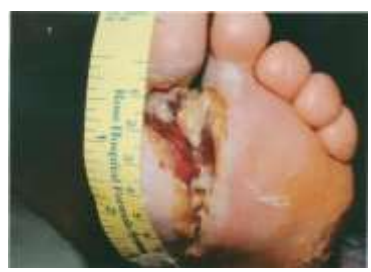


Post HBOT – 10/28/09

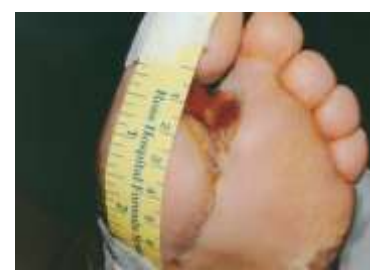
Images Courtesy of Dr. Germin, Las Vegas

Non-Healing Wound of the Foot

Diabetic Foot Ulcer: This Wagner Grade III was present for one year and unresponsive to conventional therapy.



1 Day Prior to Scheduled Amputation



26 HBOT Treatments

50 HBOT Treatments

Hyperbaric Oxygenation prevents 75% of amputations in diabetic patients. Therapy approved by CMS for Medicare upon application by IHMA to CMS for coverage, August 2002.

These photographs are the property of Kenneth P. Stoller, MD, FAAP
Permission given by Dr. Stoller to the IHMA to publish on this CD (2004)

DFU Amputation Prevention with HBO Based on Wagner Score

Wagner Score	Sample Size 'n"	Helped by HBO%	Expected # of Treatments	Expected Cost/ person (Southern CA) Medicare
I	3	100	10	$4,474
II	130	83.1	20	$8,947
III	465	77.2	40	$17,894
IV	138	64.5	40+	$17,894
V	37	29.7	40+	$17,894

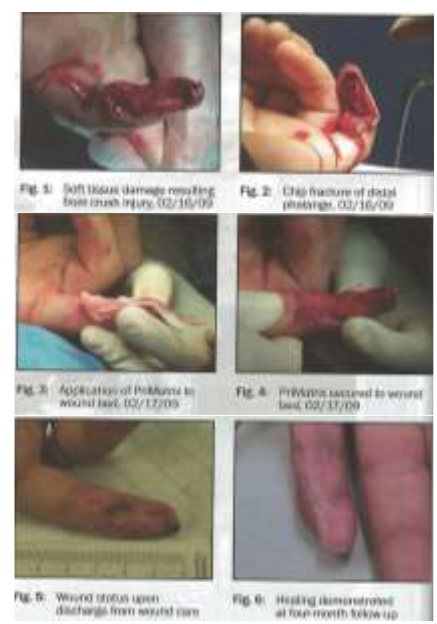
Note: The Regranex (becalpermin) clinical trials in DFU healing involved Wagner II ulcers (922 patients in 4 trials (478 patients received Regranex).

Baseline healing rates of 25%, control healing rates 29%, Regranex healing rates 43%

CDC: Average Cost of an Amputation: $38,077

Acute Amputation Prevention Blunt-Trauma, Crush, Post-Surgical Repair

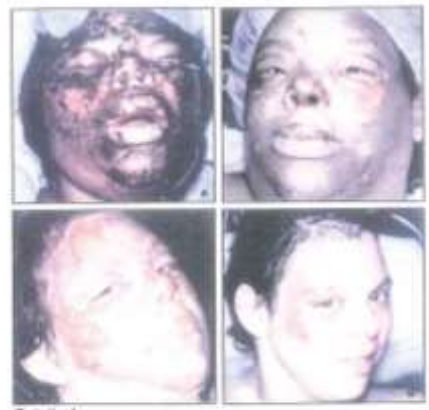
- Crush injury
- Amputation recommended by orthopedics
- PriMatrix provided
- HBOT 2x daily crush protocol
- Continued as outpatient until healed
- Follow up at 4 months



Source: WC&HM 2010: Higgs

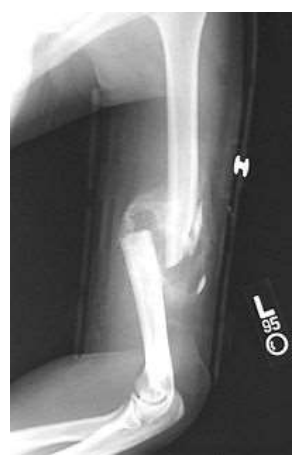
Treating Burn Patients with HBOT Saves Money, Yet Most Burn Patients NEVER Receive HBOT Treatment!

Burning aviation fuel & hot tar from a plane crashing into the roof of the mall where she was shopping.



Picture courtesy of Paul Cianci, M.D.

Fractures



- **Dr. Wright's Air Force research demonstrated that fractures heal 30% faster and 30% stronger when hyperbaric oxygen is used.**
  - Shorter back to work time
  - Stronger fusion
- Cost effective through reduced down time

The effect of hyperbaric oxygen on fracture healing in rabbits, completed 2003. J Wright

Returning Athletes to Competition

These kinds of injuries are identical to those suffered by workers covered under state workers compensation.

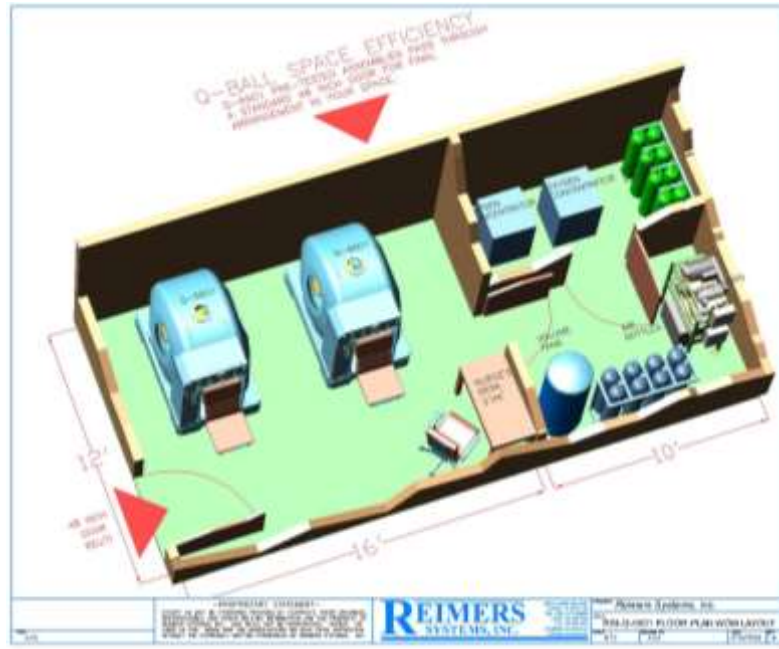
- **U.S. Olympic Team**
  - Treated at San Diego IHMF-NBIRR site
  - Sports injuries
  - Concussions
  - Summer & Winter sports
- **U.S. Navy SEALs & SOCOM Members**
  - Treated for fractures
  - Treated for knee replacement
  - Treated for TBI and PTSD

Typical Monoplace Hyperbaric Chamber

OSU Medical School's Multiplace Hyperbaric Chamber

Hyperbaric Medicine has been used for 75 years to treat brain insults!

- HBOT is approved for 13 indications and treatment is reimbursed by all major third party payers including Medicare, Tricare and the Veterans Administration.
- Hyperbaric oxygen therapy is the only non-hormonal treatment approved by the FDA for biologically repairing and regenerating human tissue.
- It is FDA-approved and effective for the treatment of 3 kinds of non-healing wounds.
- It is currently FDA-approved as the primary treatment for 3 different kinds brain injuries: Carbon monoxide poisoning, arterial gas embolism and cerebral decompression sickness.
- Hyperbaric oxygen therapy is black-labeled by the FDA, as are many drugs currently being prescribed, for post-traumatic stress disorder or traumatic brain injury.



Types of Hyperbaric Chambers

Monoplace and Multi-place Hyperbaric Chambers


Sechrist


SOS Hyperlite


Perry


ETC Bara-med XD


Reimers Q-Ball

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

-Aaron Bennett-