

“The National Brain Injury Rescue & Rehabilitation Project (NBIRR): A Care Pathway for Brain Insults from All Sources & The Texas Veteran Recovery Plan”
Restoring Lives, Reducing Entitlement Costs, Restoring Readiness by Healing Brains in Real Time

A Partnership between the State of Texas, and the IHMF: Translating Science into Medical Practice and Public Policy to Create Healthcare Solutions for the 21st Century



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National Brain Injury Rescue & Rehabilitation Project
 A Project of the International Hyperbaric Medical Foundation



Many Partners Have Made NBIRR Possible



Semper Fi Funds



LOUISIANA STATE UNIVERSITY

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 Med 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 80,000** are in Texas (15.2% of All Gulf War Era Veterans) **Up to 25%** of all Texas Unemployed Population (200,000)
 - **MOST VETS DO NOT RECOGNIZE THEY HAVE A BIOLOGICAL INJURY!**
 - This is not because they were not "STRONG" enough to take it!
 - PTSD is not a moral weakness!
- **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 \$14,000 minimum Annual Revenue Source
 - to Federal, State and Local governments
 - Has a Reduced Need for Services
 - 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 Veteran Crisis: Shattered Lives Drive Entitlement & Other Budget Costs Among Those Who Answered the Nation's Call

Incarceration, Divorce, Substance Abuse, Remedial Education, Homelessness, Unemployment, Suicide

Left Untreated, Federal & State Economic Costs Estimated Per Veteran are approximately \$60,000 per year or over \$ 3.1 billion per year cost to Texas' economy.

Texas State Share is approximately \$40,000 per year each Without Action, Texas' Economic Cost will be \$190 billion over the Next 40 Years



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% Fed Mental Illness** (w/ Underlying untreated brain insult)
 - National Prison System Cost: 2.3 mil in Jail; 5.1 mil 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 \$30 billion**
- **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 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: We have been treating brain injury, an injury caused by a lack of oxygen, with oxygen at drug level doses, for 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.](#)
 - Delayed treatment still creates improvement, but requires more treatment.
- **Most HBOT Breakthroughs Were Created in Texas at Brook City Air Force Base! All of the Wound Care, Burn Care, for the 13 Indications, were Driven by Texas!**

In HB1942, Oklahoma Demonstrates a Path to Correct National Health Care Policy and Restore Veteran's Lives
Representative John Bennett

40%+ of Active Army and National Guard are Mission Compromised. **Restore Readiness!**



Correctly Re-Align Active Duty Military Medicine and VA Medical with Their Original Missions:

1921 -Veterans Bureau: Federal Responsibility to Pay for Veteran Care and To Reimburse the State when a State pays.



Create Correction in the Managed Care Model to Encourage Positive Patient Outcomes



John Bennett
1947-2011



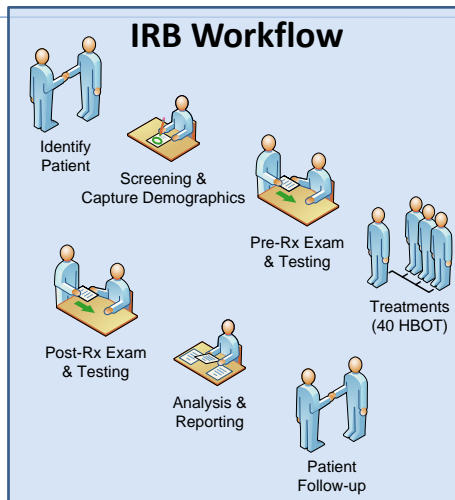


John Eisenberg Treatment Registry (JETR) Provides Structure for the NBIRR-01 HBOT 1.5 TBI/PTSD Study &

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



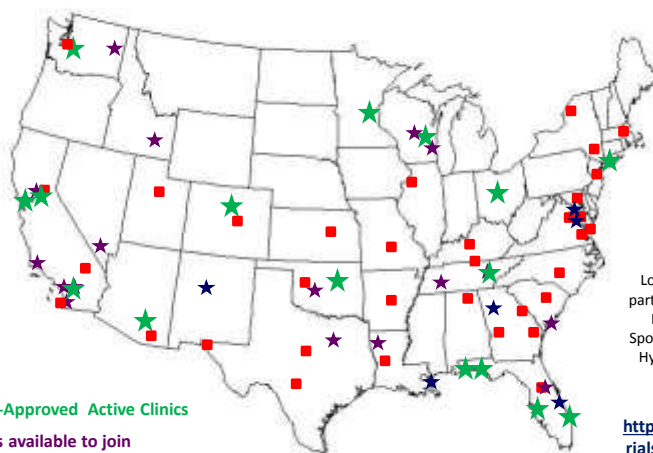
JETR is a Tool Permitting Practitioners to Proof Off-Label Uses for FDA-approved or cleared Drugs & Devices & Build Treatment Protocols



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>





Rebuild Brains in Real Time



- The IHMF's National Brain Injury Rescue & Rehabilitation Project has demonstrated it is possible to repair a damaged brain in 150 days.
 - 100% of all who completed 40 treatments had permanent clinically significant improvement. 80% of those who receive 80 treatments return to work, duty or school.
 - LSU Study: All subjects received 1/2 the clinically recommended protocol being used in NBIRR-01 ([NCT01105962](#)) *J Neurotrauma*, 2011 Oct 25. A Phase I Study of Low Pressure Hyperbaric Oxygen Therapy for Blast-Induced Post Concussion Syndrome and Post Traumatic Stress Disorder [PMID: 22026588](#) Funded by the Marine Semper FI Funds w/ many paid by Tricare
 - **Nearly 15 point IQ Increase (average)**
 - (Difference between a high school dropout & a college graduate)(14.8 P<.001)
 - **39% Reduction Post-Concussion Syndrome (PCS) symptoms (p=0.0002)**
 - 87% substantial headache reduction
 - **30% Improvement in PTSD (Largest Reduction in PTSD of any treatment EVER published)**
 - (20 points of a 85 point scale; VA considers 10% as clinically significant) (AF Study San Antonio: Both Groups Treated 17% and 16.8% improvement with the WRONG protocol HBAT1.3 (30% more O2) HBOT 2.4 (3x the correct O2 dose [toxic]) Type II Error
 - **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**
 - OSUCHS and OUHSC and OU-Norman are all IHMF partners and have participated in research or co-published with IHMF authors.



Solution: It's Just Oxygen!

HBOT: Oxygen is being 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 Request 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: 30%* 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!

NBIRR-01: 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 IRB-approved study)**

**State Legislature Only Pays for Treatment at Medicare
Rates. The Evaluation System Operates from User Fees.**



National Brain Injury Rescue & Rehabilitation Project

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)
 - Insults Include:
 - Trauma
 - Chemical Poisoning (Alcohol & Drugs)
 - Hypoxia
 - Heavy Metal Poisoning
- **NBIRR 1.1: 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 Revolving Fund

Dedicated to Paying for Effective Treatment & Achieving Reimbursement for All Effective Treatments

(Follows Plan outlined for HB1942: Oklahoma Veteran Recovery Plan)

- Charity Donations Fund
 - Direct Treatment
 - Medicare Rate
 - Physician Supervision (Per FDA Mandate)
 - Rules of TBI Treatment Act are Followed
 - Treatment Must Be Effective (Work)
 - All Data Collected Under IRB-approved TM Study
 - Payment Sought After Recovery Demonstrated
- Oklahoma University Independently Verifies Recovery (ANAM Developer)
- Payment for Veterans from Tricare/VA (Enforced by Congress & State Gov't)
- Payment for Civilians
 - with Cooperation of State Department of Insurance under Rules outlined in HB1942: Oklahoma Veterans Recovery Plan
 - Cooperative Meetings with Insurance Carriers (like State Farm)

NBIRR 1.1-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
- Chemical Detoxification
- Infection Examination and Control
- Synergistic Treatments for PTSD (Immersion Therapy, etc.)

The Oklahoma Veterans Crisis

"If you don't like change, you're going to like irrelevance even less."
 General Eric Shinseki, as Chief of Staff, U. S. Army; presently Secretary, Veterans Administration.

Gulf War Era Veterans

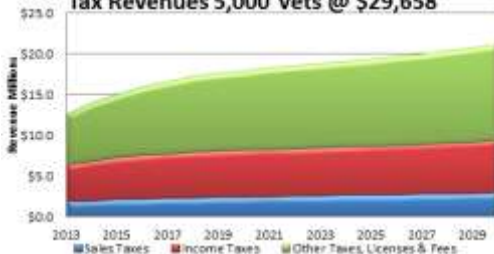
- OK Population - 94,500
 - GWEV (not Guard)
 - Number Injured 8,740
-  OK Nat'l Guard 27,500 (75%)
- **Est Ttl Number Injured 43,910**
- **Economic Cost Per Veteran Untreated \$60,000**
- Of that, State cost is approx \$40,000
- **Ttl Fed & State Cost Per Year \$2.1 billion**
- **Ttl State Cost Per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

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)

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

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

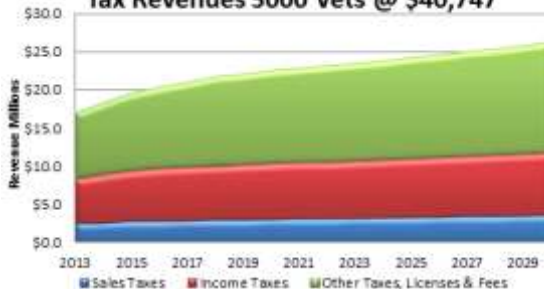


Fiscally the average revenue increase to the state from adding these veterans will be \$16.7M annually from 2013 to 2023

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.

Tax Revenues 5000 Vets @ \$40,747



Source: OK State Department of Commerce, 2013

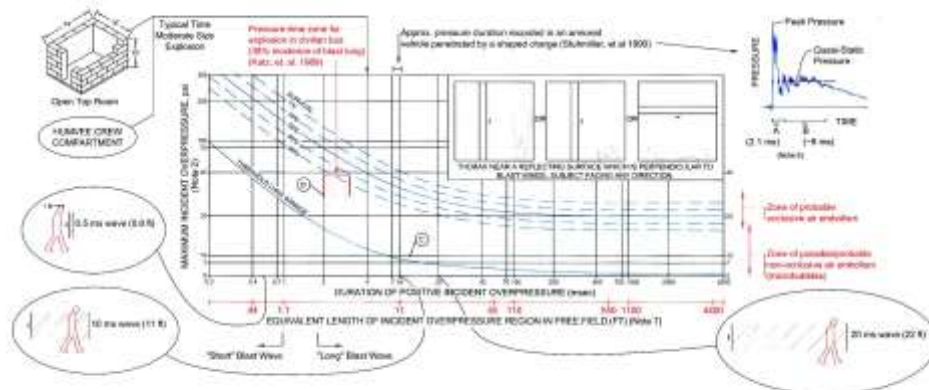
Veteran Career Employment Center OSU Department of Occupational Education

- 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
- Step 2: Refer to Partners for Effective Treatment
- Step 3: Employment & Career Intervention & Training
- Step 4: Readiness for Employment Determination (Flight Physical type medical certification)
- Step 5: Referral to participating employers who wish to Employ Veterans without the current challenges and Drama
- Long Term Tracking of successes and failures, with Intervention where needed

Tornados Can Cause DCS-II



Nature of Battle Casualty Injuries from IEDs: Blast Injury Equivalent to Decompression Sickness (The Bends) Tornado Exposure Can Cause Similar Injury



Stephen Reimers, P.E., Copyright Retained, 2012

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.
- Unless the lung damage is severe, the lesions (usually small) seal quickly (15 minutes to 3 hours) and the bubble production stops.

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

- 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

Do You Like Your Current Results?

- The Current Medical Treatment System Non-Biological Repair Treatments for Brain Injury has brought us the current endemic epidemic of untreated injuries.
- The Economic Consequences of these Choices Drive Mandatory Spending in All Governmental Budgets!
- Those who say "nothing can be done to repair brain injury" are following a "belief," a myth, from a century ago.
- They are condemning policy makers to the current failed system.
- **What is risked by trying to repair injured people, as exhibited by their symptoms and history and just paying for the ones that improve?**



Current Medical Practices are Ineffective at Restoring Lives

Medical Politics, Not Science, drives Policy Outcome

Hiring More Mental Health Professionals who do not Restore Function Does Not Answer the Challenge!

Managed Care Model Denies Care, Costing the State for a Progressively More Injured Population.

In Managed Care, restoring 15 IQ points is “not medically necessary” yet it determines whether or not a person continues to be a productive taxpayer.



Example of Managed Care Philosophy At Work

Hearing Loss From Blast Injury

- **\$10 million Federal Research on Mucomist or N-Acetyl-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-Cysteine within 4 hours of a blast prevents tinnitus & the loss of the hearing sensors inside the ears.
 - Oral Dose Costs \$3
- **Veterans Administration Spends \$2 billion per year on hearing aids**
- **Hearing Loss is a major barrier to continued military service**

Hearing Loss A Major Cause of Loss of National Guard Personnel

Decision Maker:

ADM Robinson, Navy SG

He stated:

“The \$3 is in my budget, the \$2 billion is not.”

Therefore he ruled:

“Further Research Needed”

AND PROVIDED NO FURTHER RESEARCH FUNDING!

Consequently:

Hearing Loss from Blast Continues Unabated!

How the Texas Veteran Recovery Plan Works

- **Authorization from Governor's Executive Order**
 - Authority as Commander In Chief of National Guard
 - Authority of State Police Powers (Health, Welfare & Morals) over state Residents
 - 1921 Veterans Bureau Mechanism: State Reimbursed for State Expenditures by Federal Government
 - Uses Rules of TBI Treatment Act (Sessions bill)
 - State Legislature Leadership Signs off
- **Revolving Fund Administered by the State Department of Insurance (Money does not deplete) (Source: Charity Funding, State Funding, etc.)**
 - Texas Practitioner Treats Veteran Under Protections of NBIRR-01 IRB-approved study (NCT01105962)
 - Bills the State Administered Fund
 - Oklahoma University Verifies Improvement in Neuropsychological Scores and other criteria as outlined in TBI Treatment Act
 - Practitioner is Paid at State Medicare Rate, Less the Administrative Fees
 - State bills the appropriate Federal Authority for payment
- **Veteran Outcomes Tracked & Reported (IRB-approved Study)**
 - Follow-up 5 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



War Veteran Payment Solution:

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, Gait & 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



HR396: TBI Treatment Act (Con't)

- 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!

Restore Balance

Between Federal & State Authority



- Creating your {State} Veteran Recovery Plan in Your State will restore your state’s authority over health care delivery and foster innovation.
 - Get Veterans and Civilians Effective Treatment
 - Save Hundreds of Millions 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 veterans.

Health Care Revolution Created

- Create a system that prevents managed care from denying effective care for patients which then costs the state more in healthcare, entitlement, education and incarceration costs and loss of productivity and tax revenue.
- Create a system managed by the State's Insurance Department that restores physicians, not bureaucrats, to determining proper patient care, and drives scientific discoveries into active medical practice, thus correcting the flaws of the managed care model through proper applications of evidence-based medicine, translational medicine, Bayesian Analysis and Agent Based Modeling.

**Remember! The Reason for Government Involvement
In Healthcare is to create a Healthier and More
Productive Workforce!**



HBOT 1.5 Provided the Largest Published Reduction in PTSD

- LSU Pilot Study: 30% Reduction
- Cognitive Processing Therapy [TAU]: 14%↓ or 4.8%↓
-Chard, 2011 & Alvarez 2011
- Trauma Focused Group Treatment [TAU]: 2.2%↓
- Prolonged Exposure Therapy [PE]: 28%↓ -Wolf, 2012
- Transcendental Meditation [TM]: 21%↓ -Rosenthal, 2011
- Virtual Reality Exposure Therapy [VRET]: 23%↓
- Rizzo, 2011

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 x10¹⁵, a quadrillion)”

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

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



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 or 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.**

States Can Lead the Way!
**Deploy the Effective Solution for Brain
Injury & PTSD**

Infrastructure

Education & Training

Routine Payment for Effective Treatment

Improving Economic Productivity & Revenue



**Texas Can Help Lead
the Way to Expand
Effective Care NOT
Managed Care!**

Mabel Bassett Correctional Center



Cognitive Emergence Program at MBCC

- C.S.I. was introduced to MBCC in March 2006
 - 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

10/22/20112

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CSI/MBCC-Drug Abuse/ TBI

- 99% of students have had head/Spinal Injuries
- 85%-90% of students are Drug Offenders
- Approx. 91%, drug of choice is Meth
- Nationally only 3% - 5% of Meth users stay off Meth
- At CSI only 3.6% of students have returned to prison after having been addicted to Meth!
- They think differently and don't need to get high.
- They are now in control of the way they think.

10/22/20112

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Recidivism Rate for Females

- 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**
 - **Only 3.6% of CSI offenders (8) have returned**
 - **Of 221 CSI students released, many of them were repeat offenders due to their drug addiction**
- **The savings in tax \$5.35 million! (2008-12)**

10/22/20112

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Neurogenesis 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.

10/22/20112

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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.
- And, the Cognitive Reserve Lasts a Lifetime...at any age!

10/22/20112

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RBANS Percentage Gained Over All



43

Neuron



10/22/20112

44

Substance Abuse, Incarceration & Family Preservation Savings of the 3,100 OKNG Veterans who have returned

- 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
- 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

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.

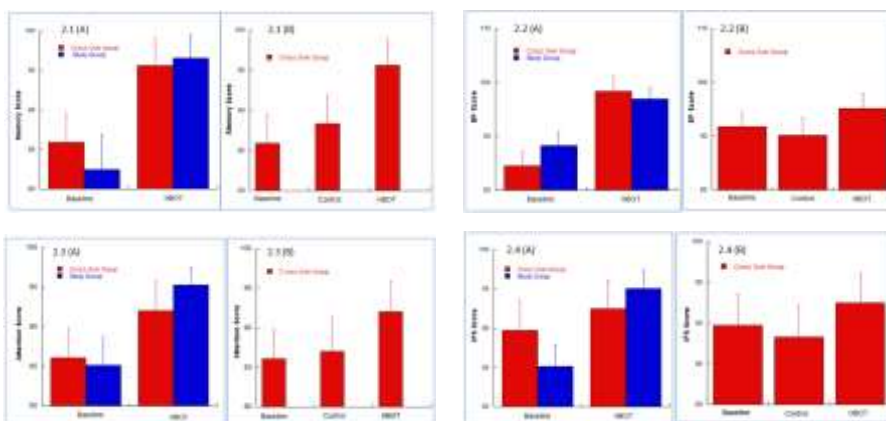
*Source: Pat Fagan, Family Research Counsel

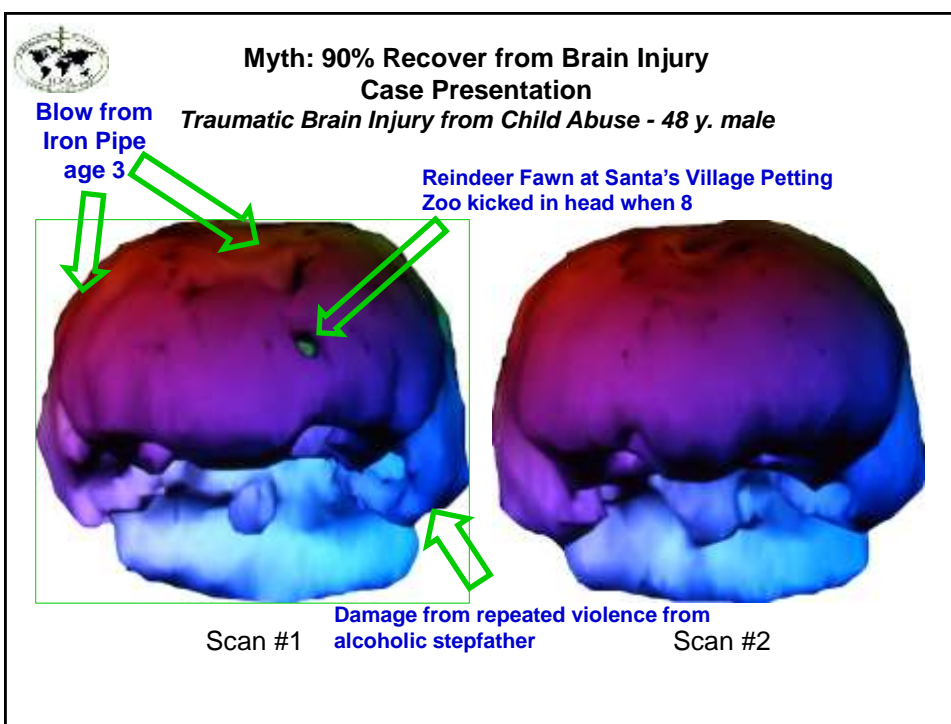
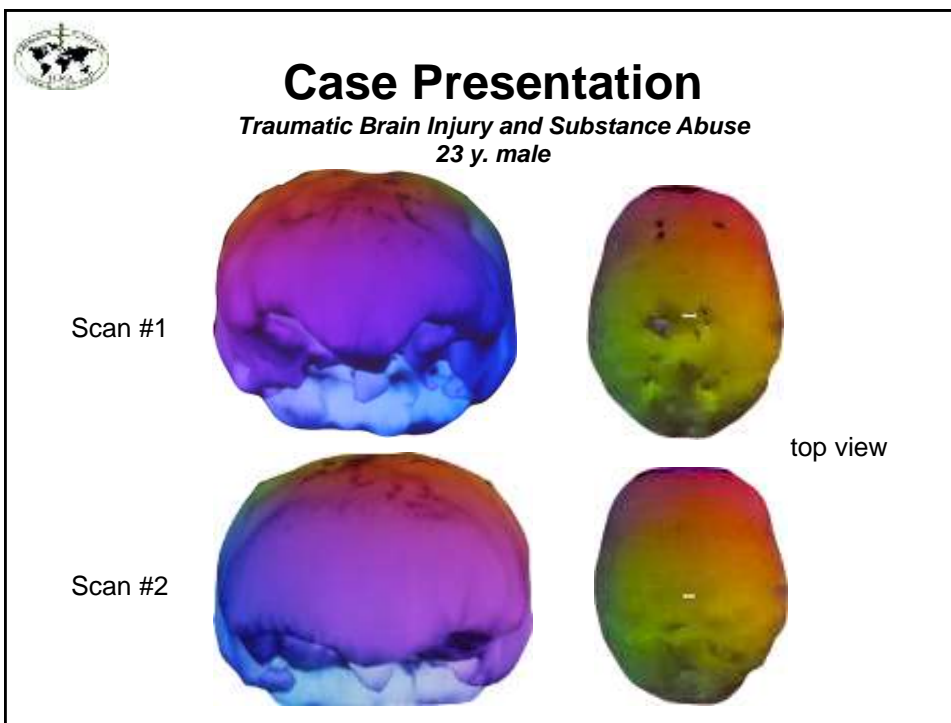
Israeli HBOT 1.5 Randomized-Controlled Trial (Just Published)


	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	<0.005	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	<0.001	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	<0.001	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	<0.001	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.

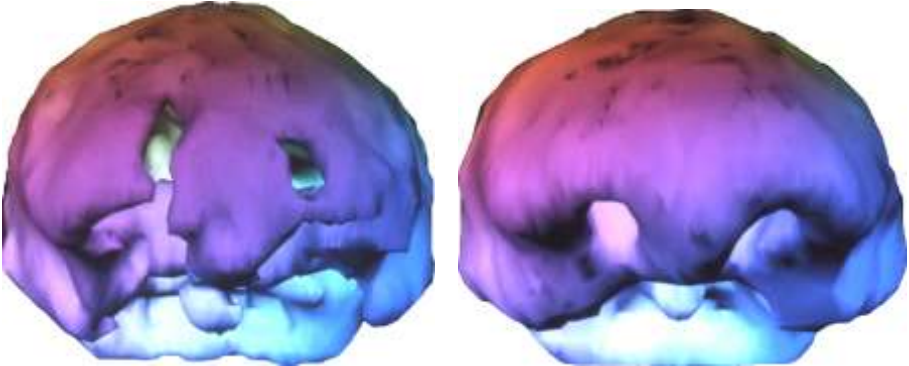






Non-Healing Wound of the Brain


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



Pre-HBOT 1.5 Post-HBOT 1.5

No wound will heal without oxygen!

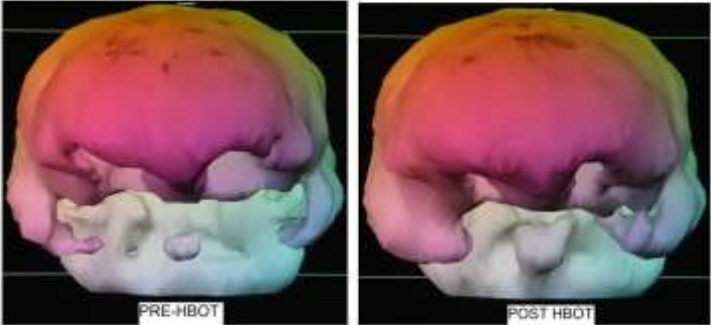
What is the difference between the diabetic non-healing foot wound and the non-healing brain injury? Essentially nothing. FDA has already approved HBOT for 3 kinds of non-healing wounds and 3 neurological injuries!



Solution to Brain Injury: Biologically Repair the Brain

Non-Healing Wound in the Brain

Case Report: Harry S. Hatching - Aug. 2008
25 year old Murvaoe Machine Operator
42 HBOT 1.5 treatments (1/2 of the Protocol)



PRE-HBOT POST HBOT

©Retained 2008 Paul G. Harch, M.D., processed by Philip J. Tran China

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

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



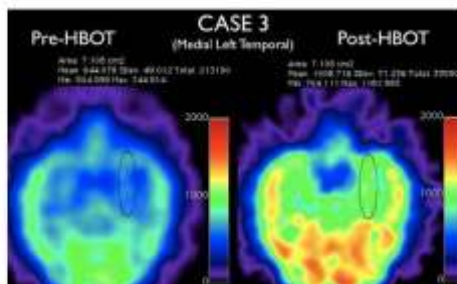
Brain Insults often Result in a 50% Decrease In Brain Metabolism HBOT Restores Brain Metabolism

HBOT 1.5 Restores Brain Blood Flow & Metabolism

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

Pre and post HBOT sets of images are exactly on the same scale. Below is a quantitative assessment that shows the actually percent increase in up take to an area of the brain quite vulnerable to TBI. Note the mean uptake in this area went from 644 to 1000. Similar changes are evident everywhere else.

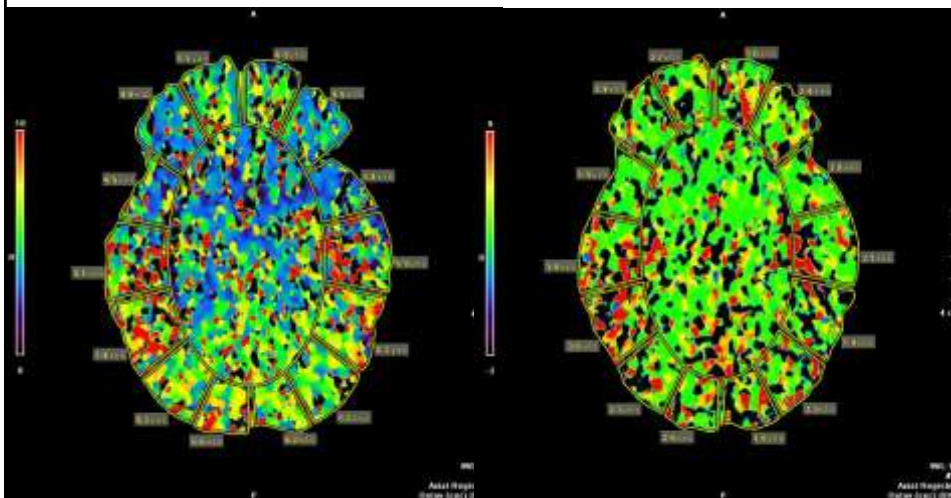
In ballpark numbers a change from green to red is a doubling of metabolism.



Analysis of Medial temporal return to USO 708 Study #7055; Edward Fogarty, MD; Neuro-radiologist, Chief, University of North Carolina School of Medicine, (701)751-9578. **42 Treatments; As of 10/28/09 Protocol.**

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

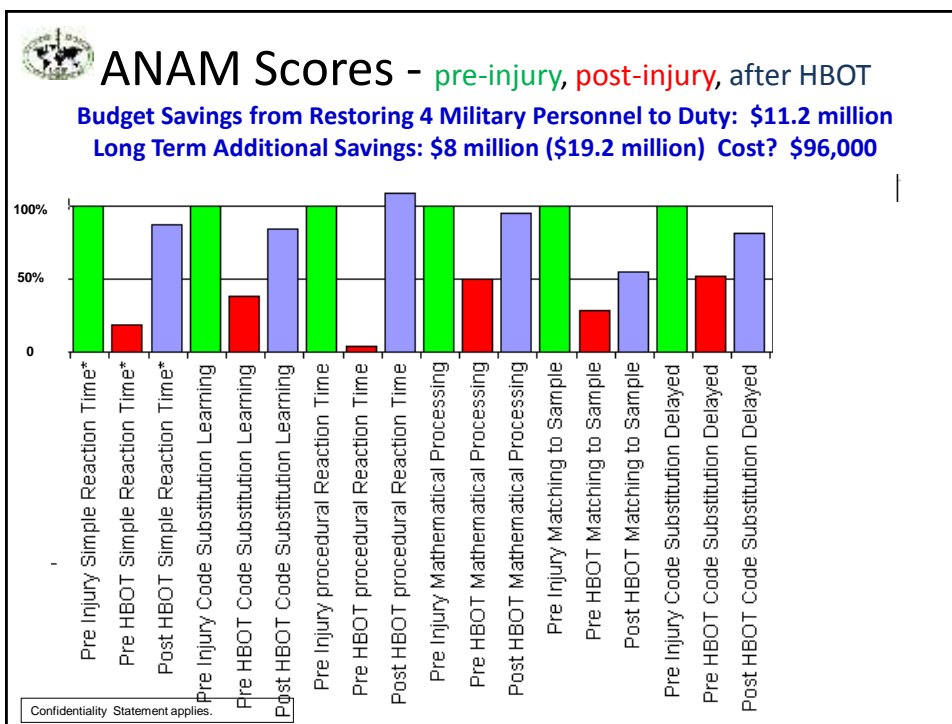
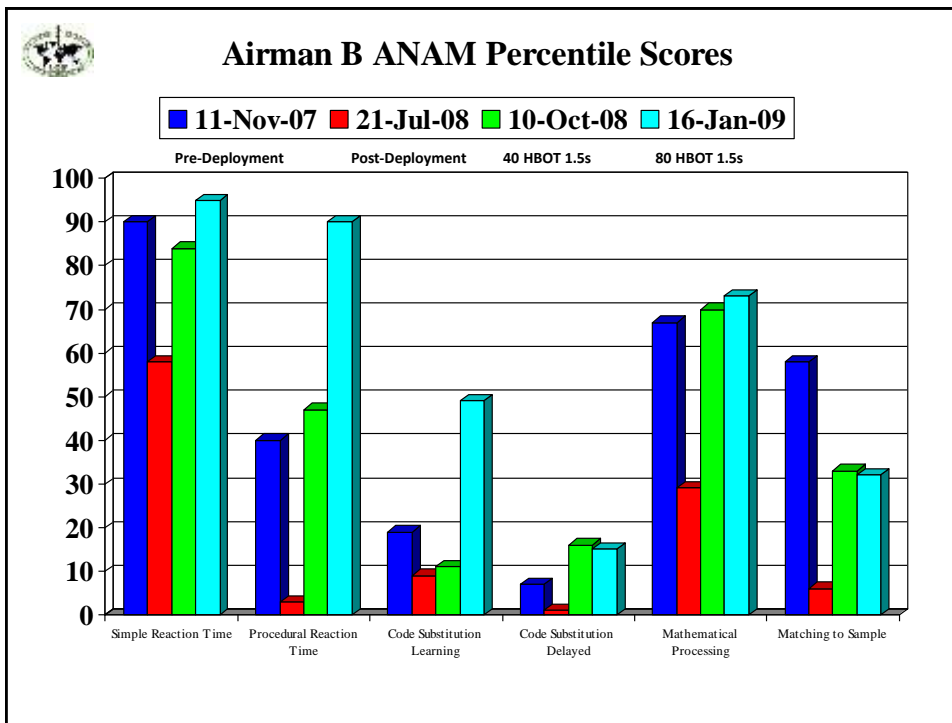
Severe TBI Patient: Whole Brain CT Perfusion Pre & Post HBOT



Pre HBOT – 10/16/09 Post HBOT – 10/28/09

Images Courtesy of Dr. Germin, Las Vegas

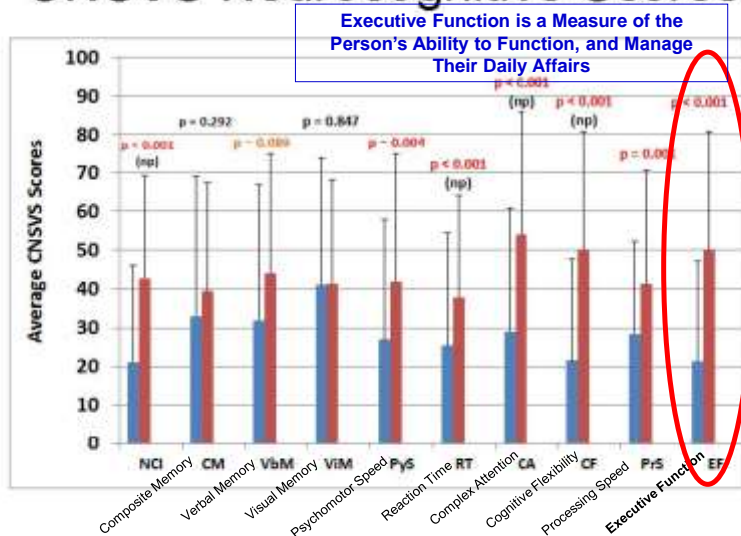


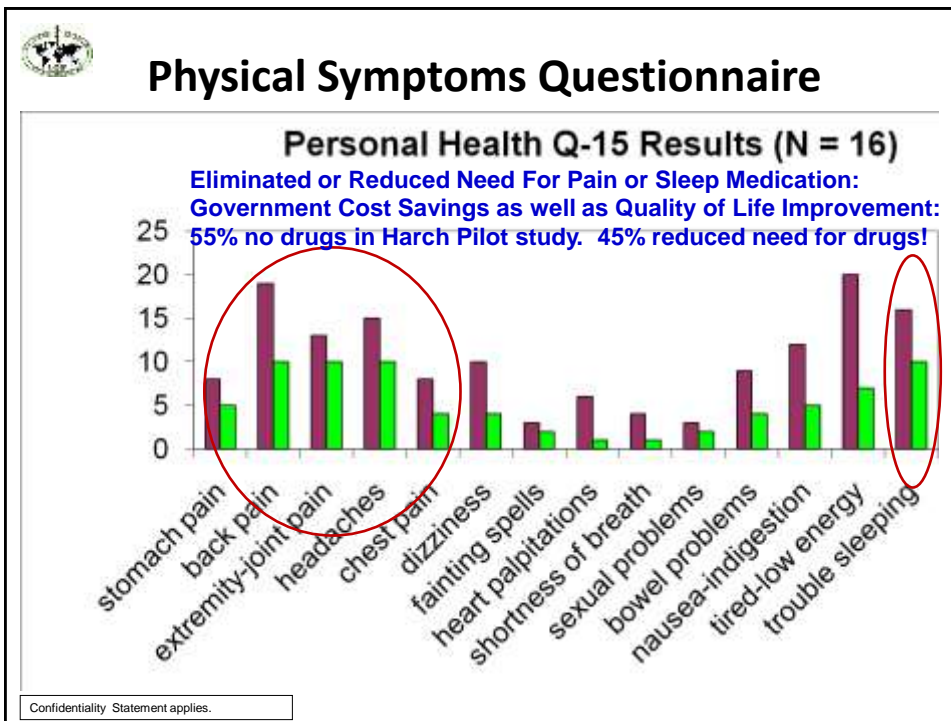


Oklahoma's ANAM Saga

- Congress Angry that DoD & VA medicine was diagnosing ARNG as “pre-existing conditions.
- Congress Orders pre-post testing.
- Automated Neuropsych Assessment Metric (ANAM) chosen from Oklahoma University
- Pretesting of OK National Guard & Reserve begins 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's General
- Surgeon's General Actions:
 - Oklahoma National Guard is forbidden by Army SG to do ANAM post-testing.
 - Immediately SGs issue a “letter” ordering ANAM Pre-Test but Post Test would be a questionnaire (PHQ-9 or PHQ-15).
 - Study started 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.
- Congress says the SG's letter countermanding its order is “okay.”
- 5 year attempt by Army & Navy to discredit ANAM. (Destroy the value of 1.2 million baselines, including that from multiple deployed individuals)
- 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 provides funding to OU-Norman to further validate, develop and implement ANAM as a workforce screening tool, in accordance with its original mission and purpose. It was originally developed for Agent Orange Dementia.

CNSVS Neurocognitive Scores





Current DoD-VA Pays for Largely Ineffective Drug Treatments: Only 2 On-Label for PTSD!

Clear Cause of Suicide Epidemic!

Suicides now exceed losses from combat casualties!

There is no drug currently approved by the FDA to treat TBI. 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
<u>Alzheimer's</u>	<u>Anti-anxiety</u>
• Ebixa	Lectopam
• Klonopin	Tranxene
• Neurontin	Valium
• Lyrica	
• Topamax	
• Dalmane	
• Symmetrel	

- **Psychiatry (Con't)**
- **Antidepressants (All Black Label Warning 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

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 Millions Spent!


(Journal of Clinical Psychiatry, Nov 29, 2011)

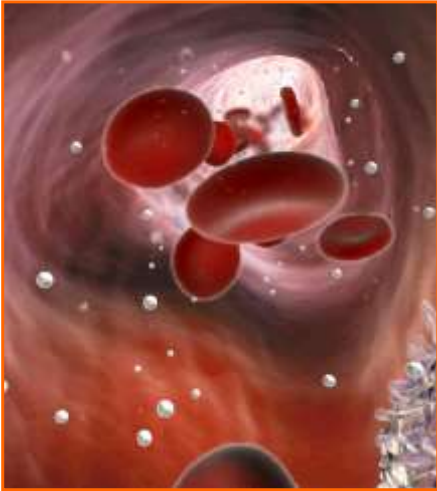
August 2, 2011: \$717 million spent by VA on Drug that does not work!!!

DoD Could have repaired 176,000 themselves w/ O2!

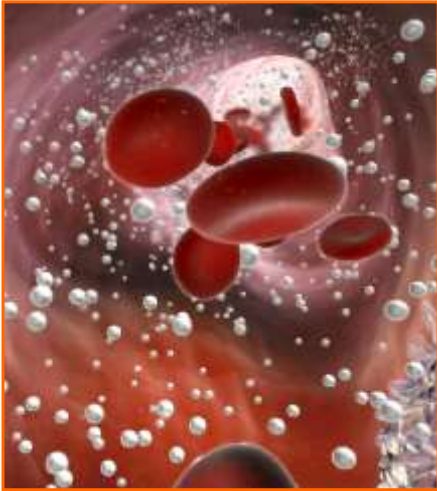
"Antipsychotic Doesn't Ease Veterans' Post-Traumatic Stress, JAMA Published Study Finds" - NYTimes.com

*FDA Approved for PTSD

 **HBOT: It's About Oxygen Saturation**
The body's liquids are saturated with more oxygen, helping areas with compromised circulation.




Before HBOT



After HBOT

Image Courtesy of Dr. 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 advertise those indications) by hundreds of physicians at nearly 1,000 locations across the nation, delivering approximately 10,000 treatments per day. The thirteen 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, Bailey D. Health technology assessment and policy decisions on hyperbaric oxygen treatment. Int J of Tech Assess in Health Care, 1999;15(4):661-70.



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)

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2010 & IHMA

DFU Amputation Prevention with HBO Based on Wagner Score

Wagner Score	Sample Size 'n'	Helped by HBO%	Expected # of Treatments	Expected Cost/ prsn (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 that 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: Avg Cost of 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 is 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 she where she was shopping.



Picture Courtesy of Paul Cianci, M.D.

Discussion 1

A. 23-year-old white female with facial burns from flooding gasoline and hot oil 12 hours after injury.

B. 24 hours later (24 hours after injury) after two HBOT treatments. HBOT resolution of airway.

C. 72 hours later (24 hours after injury) after six HBOT treatments.

D. Healing before discharge.



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



The Specific Science for HBOT 1.5

- 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: 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](#)
- August 14, 2008: Briefing to Surgeon General of the Navy & Deputy Commandant, US Marine Corps: 5 blast injured veterans treated. All five made improvements, some dramatic. Four of five were able to return to duty or civilian employment! First Case was Published April 2009 [PMID: 19829822](#) (PubMed)
- September 2008: 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)
- **March 12, 2010: 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. ¼ 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
- **NBIRR-01 Begins Enrolling Patients March 2010.** Preliminary Results from multi-site study support Harch's Findings.
- **LSU Pilot Published in the Journal of Neurotrauma**, [JNeurotrauma](#), 2011 Oct 25. A Phase I Study of Low Pressure Hyperbaric Oxygen Therapy for Blast-Induced Post Concussion Syndrome and Post Traumatic Stress Disorder [PMID: 22026588](#)
 - **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



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 not Black-Labeled by the FDA, as are many drugs currently being prescribed for post-traumatic stress disorder or traumatic brain injury.

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Oklahoma Veterans Recovery Plan

Governor

- Exercise Authority as Commander in Chief over National Guard Health Care
- Carries out HB1942
 - Utilizes Oklahoma Veterans Recovery Plan Revolving Fund
 - Orders Agency Compliance
 - Orders Coordination
 - Coordinates Veteran & Civilian Treatment using OKVRP under State Police Powers
 - Through State Insurance Department, coordinates State Collection of Expenses from Federal Gov't and Private Payers

State Legislature

- Exercise Authority under Police Powers over Healthcare Policy in State for All Residents
- Legislation
 - Authorizing use of Oklahoma Veterans Recovery Plan Trust Fund
 - Appropriating \$7 mil to Veterans & \$2 Civilian Medical Treatment REVOLVING FUNDS Yielding \$28 million or 1,000 veterans treated
 - Authorizing Expenditures as Outlined
 - Authorizing State Insurance Commissioner to Collect from Responsible Party

HB1942: Oklahoma Veterans Recovery Plan Act of 2013

- \$7 million in Emergency Funding for Veterans & Civilians to Immediately to Launch the OKVRP to Provide Immediate Relief and Prevent further Tragedy (\$28 million with Reimbursement to the Fund)
 - Immediate Drop in Suicide: Hope
 - Slow Family Disintegration and Despair
 - Saves Lives Immediately
 - Begins Lowering State Budget Costs in Excess of Appropriations
- **Only State Insurance Department Permitted to Draw Funds from Accounts**
- A 45th Infantry Field Grade Officer treated
 - 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 Being Promoted
 - \$750,000 Savings

Oklahoma Veteran Recovery Plan

- **In Partnership with Louisiana State University, OSUCHS Center for Aerospace & Hyperbaric Medicine Coordinates:**
 - All Medical Treatment at Each Facility
 - All Diagnostics and Research Practices in State
 - All bills for treatment sent to State Insurance Dept
 - All Training and Professional Education
- **Oklahoma Evidence-based Practice Center (OUHSC College of Public Health & OU-Norman Cognitive Science Research Center) (in cooperation with OSU) 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**



OK State Insurance Department

- Pays Sites from Revolving Fund after OUHSC CPH Verifies Positive Treatment Result under TBI Treatment Act
- Collects from Responsible 3rd Party Payer to Reimburse the Revolving Fund
 - Legislation Specifies Medical Necessity is Determined by the Oklahoma TBI Treatment Act. I.E. The patient got better on one of four measures.
 - Collect from Tricare or Veterans Administration (mandatory or from Private Carriers who Voluntarily send patients for treatment.
- Authority to Collect from other State agency funds such as Medicaid or Workers' Compensation.

OKVRP Process Flow

- **Subject Enrolls in Study and Receives Treatment at a participating facility**
 - Statewide Treatment Oversight by OSUCHS CAHM
 - Results logged in to IHMF's Web-based Database
 - Oklahoma Evidence-based Practice Center Verifies Data Entry and Results
- **Site sends the bill for treatment to State Insurance Dept**
 - OSID Verifies with OSUCHS CPH that OK TBI Treatment Act Criteria is met
 - OSID Draws from OKVRP Trust Fund
 - Site Receives Payment, Less Administrative Fees
 - Administrative Fees sent to OUHSC CPH, OSUCHS CAHM and IHMF for their respective work to keep the system functional
- **Subject data sent to State Insurance Dept for Collection from 3rd Party Payer Responsible for Study Subject**
- **Trust Fund Replenished from 3rd Party Payer Payments**

Oklahoma Immediate HBOT Deployment Map

No Current Hospitals will Sign Onto the Project until Payment Pathway and State Mandate is Clear
 Goal: No more than 30 miles between chambers in populated areas



- Current Hospital/Clinic Facility
- OSUCHS CAHM
- Planned OK Dept of Vet Affairs
- Planned OKVSRP Site

Most Recent 45th Inf Return: 3,100
 Number Injured: 1,550 to 2,325
 Cameron College (Lawton) has 1,500 Vets
 w/ PTSD Enrolled

Types of Hyperbaric Chambers

Monoplace and Multi-Place Hyperbaric Chambers



Sechrist



SOS Hyperlife



Parry



ETC Bara-med XD



Reimers Q-Sol

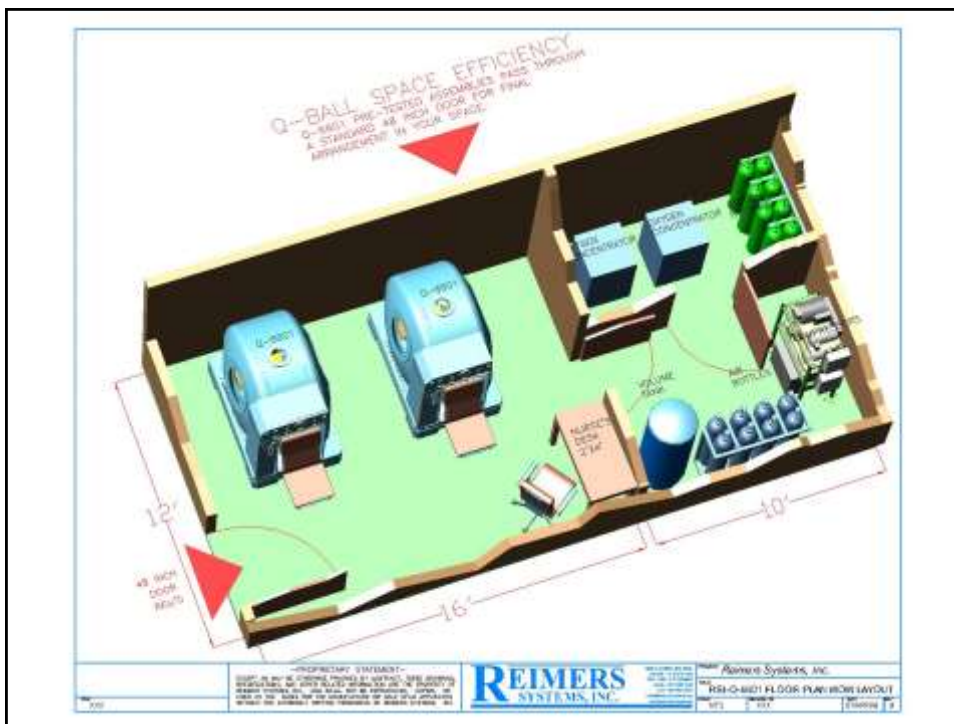
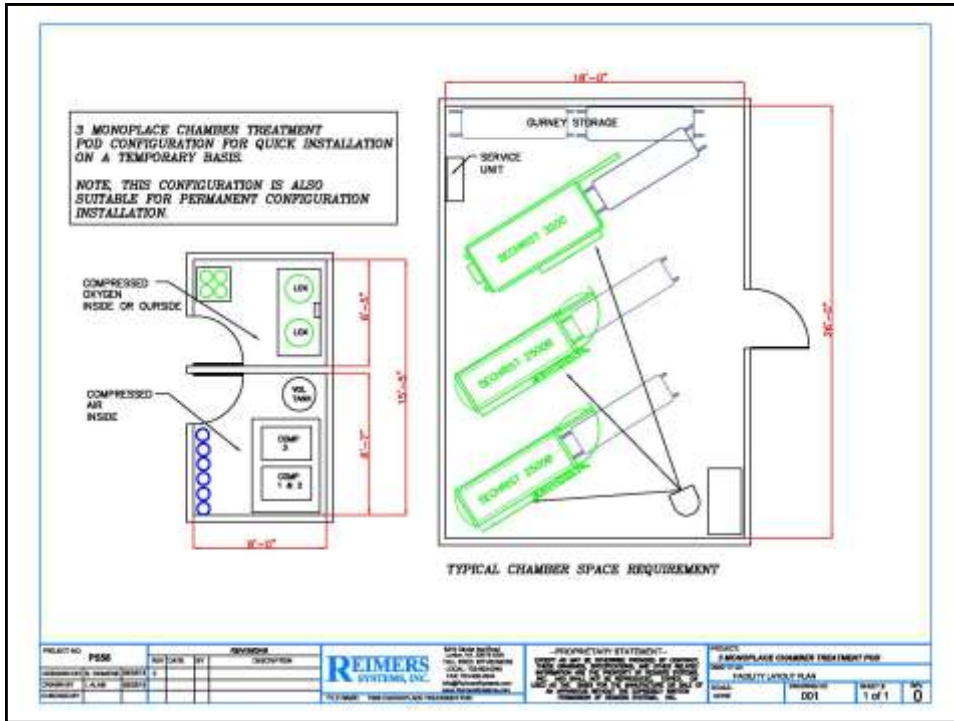


Deployment of Effective TBI/PTSD Treatment

- 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**

Education & Training

- Physicians Need Appropriate Training for Physician Supervision Requirement - 40 hrs
- EMTs & Nurses need training for Chamber Operations - 50 hrs.
- Specialists brought to the State
- State Distance Learning Permits Large Scale Training through One-Net at Multiple Sites
- Coordination with all CMEs but also with State Education System for Tuition for those currently in EMT & Nursing & Medical School



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 NOT 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 cannot be used as a pre-screening "hire" determination because unions will object and block this entire effort to improve the work force.**
- **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 employer, 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 levels, 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?

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*)



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!
- Acupuncture
- Bio-Feedback
- Counseling & Coping Skills



CSI: Maximizing Brain Performance and Recovery By Creating Neurogenesis* For Thousands of People Since 2000

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CSI is Affiliated with the National Brain Injury Rescue & Rehabilitation Program (NBIRR)

* Neurogenesis: Creation of new neurons in the hippocampus which can make 30,000 new neuronal pathways, while improving reaction time, increasing processing speed and creating improved decision making and executive function. This process also increases reserve capacity, thus reducing dementia risk and the challenges caused by future brain insults.

The CSI-Cognitive Emergence Program™ (CEP)

- CEP is based on the cognitive enhancement and rehabilitation exercises developed by clinical neuropsychologists.
- 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)

- The system is synergistic with all other treatment modalities.
- CSI has saved 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, and regain their independence.

The CSI-Cognitive Emergence Program™ (CEP)

- 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)

Mabel Bassett Correctional Center (MBCC)

- Normal Inmate Recidivism ranges 80% in the Meth incarcerated population to 14% in the regular population.
- 80% of MBCC program participants were former Meth users and 91% had documentable brain insults.
- **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 more clearly before making decisions that could be harmful to others.

The CSI-Cognitive Emergence Program™ (CEP)

Effects and Medical Conditions Helped

- Neurogenesis
- Mirror Neurons
 - Move Information to Long Term Memory
- Synapses
 - Increases Strength, Quickness & Accuracy of Response
- Brain Reserve Capacity
 - increases, enabling one to more quickly recover from future brain insults.
- I.Q.
 - Rises between 7% and 15% as cognitive processing speed increases

The CSI-Cognitive Emergence Program™ (CEP)

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	

