HB1942:
“The Oklahoma Veteran Recovery Plan”
Restoring Lives, Reducing Entitlement Costs,
Restoring Readiness by Healing Brains in Real Time
Representative John Bennett & Senator Mark Allen

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

Paul G. Harch, M.D., President, IHMF
K. Paul Stoller, M.D., President, IHMA
William A. Duncan, Ph.D., VP of Gov’t Affairs, IHMA

4 May 2013
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?
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**
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; 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
  - OSUCHS and OUHSC and OU-Norman are all IHMF partners and have participated in research or co-published with IHMF authors.
## Israeli HBOT 1.5 Randomized-Controlled Trial (Just Published)

### 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

<table>
<thead>
<tr>
<th></th>
<th>Treatment (n=32)</th>
<th>cross over (n=24)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Memory</td>
<td>Baseline</td>
<td>HBOT</td>
<td>P1</td>
<td>P2</td>
<td>Baseline</td>
<td>Control Pre HBOT</td>
<td>Post HBOT</td>
<td>P2</td>
<td>P3</td>
</tr>
<tr>
<td></td>
<td>82.43±25.15</td>
<td>96.54±17.18</td>
<td>0.567</td>
<td>&lt;.0005</td>
<td>85.90±17.80</td>
<td>88.36±17.34</td>
<td>95.61±15.54</td>
<td>0.233</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>Executive function</td>
<td>88.26±14.74</td>
<td>96.96±11.69</td>
<td>0.367</td>
<td>&lt;0.0005</td>
<td>91.73±13.26</td>
<td>90.20±15.77</td>
<td>95.13±13.84</td>
<td>0.295</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Attention</td>
<td>85.13±20.28</td>
<td>95.30±12.90</td>
<td>0.854</td>
<td>&lt;0.005</td>
<td>86.10±18.42</td>
<td>87.05±20.98</td>
<td>92.02±18.95</td>
<td>0.368</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Information processing speed</td>
<td>85.12±15.88</td>
<td>95.04±13.75</td>
<td>0.324</td>
<td>&lt;0.0001</td>
<td>89.74±18.81</td>
<td>88.30±19.68</td>
<td>92.47±18.25</td>
<td>0.298</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>EQ-5D</td>
<td>7.87±1.36</td>
<td>6.48±1.07</td>
<td>0.615</td>
<td>&lt;0.0001</td>
<td>7.70±1.11</td>
<td>8.06±1.05</td>
<td>6.75±1.06</td>
<td>&lt;0.01</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>EQ- VAS</td>
<td>5.03±2.31</td>
<td>6.62±2.45</td>
<td>0.696</td>
<td>&lt;0.0001</td>
<td>5.26±1.70</td>
<td>5.21±1.66</td>
<td>6.39±1.80</td>
<td>0.373</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
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.
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.
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.
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](http://www.clinicaltrials.gov/ct2/show/NCT01105962)
This is a Multi-Center Study

Locations of Clinics participating in N-BIRR HBOT 1.5 Study
Sponsor: International Hyperbaric Medical Foundation
See: [http://www.clinicaltrials.gov/ct2/show/NCT01105962](http://www.clinicaltrials.gov/ct2/show/NCT01105962)
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!
NCSL Can Lead the Way to Expand Effective Care NOT Managed Care!
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!
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.
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)
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!
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 thought 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.
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 2.5 million IEF/IOF war veterans are blast/concussion casualties: 98% will experience Post-Concussion Syndrome
  - Of those 1 million casualties, about 750,000 are likely to experience TBI symptoms, PTSD or depression, all known symptoms of brain injury
  - MOST 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 $10,000 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 $2 billion per year cost to Oklahoma’s economy.

State Share is approximately $40,000 per year each

Without Action, Oklahoma’s Economic Cost will be $65.4 billion over the Next 40 Years
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

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
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
Case Presentation

Traumatic Brain Injury and Substance Abuse

23 y. male

Scan #1

Scan #2

top view
Myth: 90% Recover from Brain Injury
Case Presentation

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
- Damage from repeated violence from alcoholic stepfather
Non-Healing Wound of the Brain

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

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

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 Restores Brain Metabolism

HBOT 1.5 Restores Brain Blood Flow & Metabolism

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

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

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

Analysis of blast injured veteran in LSU IRB Study # 7051: Edward Fogarty, MD, Neuro-radiologist, Chair, University of North Dakota School of Medicine, (701) 751-9579 40 Treatments: 3% of NBIRR 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
ANAM Scores - pre-injury, post-injury, after HBOT

Budget Savings from Restoring 4 Military Personnel to Duty: $11.2 million
Long Term Additional Savings: $8 million ($19.2 million) Cost? $96,000
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.
Executive Function is a Measure of the Person’s Ability to Function, and Manage Their Daily Affairs
Physical Symptoms Questionnaire

Personal Health Q-15 Results (N = 16)

Eliminated or Reduced Need For Pain or Sleep Medication:
Government Cost Savings as well as Quality of Life Improvement:
55% no drugs in Harch Pilot study. 45% reduced need for drugs!
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.

<table>
<thead>
<tr>
<th>Neurology: Alzheimer's</th>
<th>Psychiatry Anti-anxiety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ebixa</td>
<td>Lectopam</td>
</tr>
<tr>
<td>Klonopin</td>
<td>Tranxene</td>
</tr>
<tr>
<td>Neurontin</td>
<td>Valium</td>
</tr>
<tr>
<td>Lyrica</td>
<td></td>
</tr>
<tr>
<td>Topamax</td>
<td></td>
</tr>
<tr>
<td>Dalmame</td>
<td></td>
</tr>
<tr>
<td>Symmetrel</td>
<td></td>
</tr>
</tbody>
</table>

- Psychiatry (Con't)
- Antidepressents (All Black Label Warning Suicide)
- Celexa
- Lexapro
- Prozac
- Luvox
- *Paxil
- *Zoloft
- Cymbalta
- Effexor
- Wellbutrin
- Remeron
- Desyrel

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

The Veteran Suicide Rate is 120 per week! (CDC Numbers)

All in Red Fail to beat Placebo yet 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
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 ischémias
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.)

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!
Non-Healing Wound of the Foot

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

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)

Copyright retained: Kenneth Stoller, M.D., 2010 & IHMA
DFU Amputation Prevention with HBO Based on Wagner Score

<table>
<thead>
<tr>
<th>Wagner Score</th>
<th>Sample Size 'n&quot;</th>
<th>Helped by HBO%</th>
<th>Expected # of Treatments</th>
<th>Expected Cost/ prsn (Southern CA) Medicare</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>3</td>
<td>100</td>
<td>10</td>
<td>$4,474</td>
</tr>
<tr>
<td>II</td>
<td>130</td>
<td>83.1</td>
<td>20</td>
<td>$8,947</td>
</tr>
<tr>
<td>III</td>
<td>465</td>
<td>77.2</td>
<td>40</td>
<td>$17,894</td>
</tr>
<tr>
<td>IV</td>
<td>138</td>
<td>64.5</td>
<td>40+</td>
<td>$17,894</td>
</tr>
<tr>
<td>V</td>
<td>37</td>
<td>29.7</td>
<td>40+</td>
<td>$17,894</td>
</tr>
</tbody>
</table>

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.
Returning Athletes to Competition

- 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

These Kinds of Injuries are Identical to those suffered by Workers covered under State Workers Compensation.
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. 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

• NBIIRR-01 Begins Enrolling Patients March 2010. Preliminary Results from multi-site study support Harch’s Findings.

  – 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 NBIIRR-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
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 x 10^{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 x 10^{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_
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
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.

Copyright retained: Paul G. Harch, M.D., 2010 & IHMA
**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.
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, 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
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!
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

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

Current Hospital/Clinic Facility
OSUCHS CAHM
Planned OK Dept of Vet Affairs
Planned OKVRP Site
Types of Hyperbaric Chambers

Monoplace and Multi-Place Hyperbaric Chambers

Sechrist

SOS Hyperlite

Perry

ETC Bara-med XD

Reimers Q-Ball

Hyperbaric Stretcher & Treatment System

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

- Battlefield injuries in the combat zone
- Pressure related injuries (diving & high altitude)
- Submarine escape & rescue
- Aeromedical evacuation
- Hazmat/carbon monoxide & smoke inhalation

Visit us at www.hyperlite.co.uk

SOS Hyperlite Ltd. Millennium House, Victoria Road, Douglas, Isle of Man.
Tel: 44(0) 942 263 8155 • Fax: 44(0) 942 263 8154 • info@hyperlite.co.uk
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
3 MONPLACE CHAMBER TREATMENT POD CONFIGURATION FOR QUICK INSTALLATION ON A TEMPORARY BASIS.

NOTE, THIS CONFIGURATION IS ALSO SUITABLE FOR PERMANENT CONFIGURATION INSTALLATION.

TYPICAL CHAMBER SPACE REQUIREMENT
Q-8601 PRE-TESTED ASSEMBLIES PASS THROUGH A STANDARD 48 INCH DOOR FOR FINAL ARRANGEMENT IN YOUR SPACE.
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.)
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)

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
Introduction

Massive air embolism (AE) from lung disruptron is the accepted principal etiology of mortality in blast injuries. White et al. (1990) reviewed lung damage due to underwater blast, and found that AE was a major cause of lung injury. Air embolism has been ignored, considered innocuous or believed to have not occurred. The high incidence of post-concussive syndrome (PCS), neurocognitive deficits, and mental health issues resulting from sub-lethal blast injuries in U.S. Iraq and Afghanistan War veterans has vestr military and medical specialists. We propose that micro air embolism is a heretofore unappreciated etiologic factor.

Materials and Methods

Materials and Methods: Using PubMed, Psyinfo, Google Scholar, Sciyo, and Pubcrawler, a systematic review of the literature was conducted identifying published papers in the following domains: biodynamics and physics of blast overpressure, primary blast injury, microbubbles in systemic circulation from diving and iatrogenic causes; neurological problems and microbubbles; domains: biodynamics and physics of blast overpressure; primary blast injury; microbubbles in systemic circulation from diving and iatrogenic causes; neurological problems and microbubbles.

Results

Blasto-duced AE

• For mammals that die promptly from either air or underwater blast, air embolism has long been recognized as the primary cause of death (Desaga, 1950; Shapack, Johnson & Phillips, 1990; Robbins & Damon, 1991). Lung disruptron is proportional to both magnitude and length of blast overpressure exposure. Lung tissue damage can occur at moderate overpressures easily within the range of pressures experienced by U.S. combat troops from improved explosive devices (IED) (Fig 1 & 3). The disruptron threshold is lowered by exposures near reflective surfaces, exposures inside structures that impede disruptron of the blast gases, and by longer exposure times. It is further lowered by exposures in less than 24 hours (Shumiller, Phillips & Richmond, 1990). Benzinger (1950) concluded that because symptoms were only present when a blast hit the thorax, air embolism must originate in the thorax. The model also found that small amounts of air in an arterial circuit could readily reproduce neurololgcal deficits. Air microbubbles injected into the pulmonary veins of a dog was sufficient to reproduce the electrocardiographic changes seen in blast-injured dogs (Phillips, 1990).

• Motorola (1971) suffocated a dog with a Doppler bubble detector on the carotid artery, exposed the dog to an LD50 air blast, and subsequently observed bursts of Doppler deflections going up the carotid correlating with respirations for approximately 30 minutes post blast. The dog's carotid was an especially tempoarly exposed, and each group of echoes, possibly indicating reduced blood flow due to temporary distal occlusions (Fig 2). The dog initially showed severe respiratory distress, but recovered from the experiment with no apparent evidence of residual lung hemorrhage, but no other damage. Most concluded that the bubbles were "clinically silent."

• A conceptual model of how AE sequels to blast exposure occurs, confirmed with rabbit model data, can be found in White (1971). Any-fast rising blast pressure wave long enough to produce significant shock compression is likely to produce some AE.

• Goh (2009) and Mayo & Kleger (2006) in separate articles regarding civilian blast casualty management advise that AE is a possible complication of exposure to air blast. However, neither author addresses the possibility of neurocognitive sequelae from AE.

• Protective vests reduced mortality & neural fiber degeneration in rats exposed to air blast (Bauman et al., 2009).

• Recent Combat Military Literature

• Bauman et al. (2008) provides a summary of the test conditions and initial results from the PREVENT (Preventing Violent Explosive Neurotrauma) research program being conducted by DARPA. In the tests reported (swine model), the thorax and upper abdomen were protected to minimize the possibility of brain injury by indirect pathways. Some neurological damage was observed, and its significance is still being determined. However, the test conditions are of interest as they are also ones where lung injury can readily occur. Point G in Fig 1 represents a typical Friedlander wave reported by the blast tube. Test setup is designed to simulate exposures in the crew compartment of a Humvee with a blast under its floor and above the contined space (open top room with dimensions shown in Fig 1). In both cases the overpressure durations from a moderate sized charge were reported to be about 4 ms. The overpressure data was reported in general form only without numeric values. However, in all three cases the pressures required to produce lung injury are not large. In situations where the Humvee or building were to be fully closed, both the magnitude of blast pressures can be expected to be proder.

• Buamou (2009) reports results from a computer model developed by Defence R & D Canada (CRDC) for estimating the blast damage to the lungs of ships and humans. He reports that intra-thoracic pressure range currently accepted the "threshold" for lung damage is 70 kPa (695 cmH20) to 110 kPa (1,091 cmH20), which corresponds roughly to the intra-thoracic pressures predicted by the model at exposures near the lung damage threshold line on the Bowen charts. The intra-thoracic pressures produced by even moderate size blasts can be very substantial (Fig 3). They also vary with both time and location in the target, so that opportunities for local AE may be plentiful. The model also indicates that complex (multi-peak) blast waves can produce higher lung pressures, and therefore greater risk of lung damage than a single peak, classic Friedlander waves of the same impulse value.

• Recent work by Yang et al., 1996 (sheep model) suggests the lung damage threshold pressure is as much as 0.7 kPa lower (Fig 4) than the threshold of 0.8 kPa suggested by the CRDC model. The threshold pressure is taken as the lowest pressure at which lung tissue damage is observable by light and electron microscopy.

• It is well established that microbubbles sequelae of exposure to air blast. It is also well established that microbubbles are harmful to brains, and that symptoms may be delayed for several days.

• Blast overpressure exposures typical of the current wars in Iraq and Afghanistan, particularly blast exposures in confined spaces, are sufficient to create risk of lung damage. Quickly recognized.

• It is reasonable to expect that the degree of blast-related AE is a continuum ranging from no AE to up to 100% AE.

• Blast-related AE can manifest as very massive amounts depending on the exposure.

• The blast-related intra-thoracic pressures can be very substantial (Fig 3). The range customarily accepted as the threshold for lung injury is 7 to 11 times higher than the 80–130 kPa (10.7 kPa) differential known to produce disruption of avascular capillary beds in lung tissues in slowly varying pressure environments such as diving (Neuman, 1971).

• Wang Yang, et al. (1996) suggests that lung tissue damage, and the concurrent possibility of transient microbubble release, can occur at lung damage levels insufficient to produce clinical blast lung and at overpressures substantially lower than indicated by the widely-used criteria for blast lung injury.

• The CRDC model confirms suggestions from prior efforts that complex blast waves typical of air blast exposures are more likely to be damaging to lungs than are the simpler waveforms typical of free-blasts.

• Blast related bubble production, when it does occur, has been shown to be transient, lasting only up to 15 min at most significant AE (Yang et al., 1996). The duration of AE microbubble production can be expected to be shorter still making them hard to detect. Although this is not necessarily due to "trace" damage, including a recent review article (Deamle & Noble, 2009), were silent on the possible role of microbubbles as a mechanism for blast-related brain injury.

• Widespread factors that may favor microbubble production are considered, it is difficulty to expect they do not occur.

• Undetected air microbubbles have the potential to significantly confuse research into other mechanisms of blast-related brain injury. In research studies where there is a possibility of microbubble production, monitoring for their occurrence is recommended.

The contribution of micro air embolism to blast-related brain injury may be significantly greater than has been previously believed.

Available literature suggests that transient AE from primary blast exposure is possible, perhaps probable, at sub-lethal overpressures similar to the overpressures experienced by U.S. Cold warrior. Arterial microbubbles have been shown to be neurologically harmful and may contribute to the incidence of post concussive syndrome in blast injured veterans. Current research efforts are almost exclusively focused on the direct cerebral effects of blast waves. The AE pathway deserves prompt and thorough investigation.
Tornados Can Cause DCS-II

Storm chasing
Tornado Alley Zone

Tornado Alley