



US DEPARTMENT OF DEFENSE

# BLAST INJURY RESEARCH PROGRAM COORDINATING OFFICE

## Neurocognitive and Psychological Health Treatment Strategies

### Update on Hyperbaric Oxygen Research Project

The U.S. Army Medical Materiel Development Activity (Fort Detrick, Maryland) led the Brain Injury and Mechanisms of Action (BIMA) of Hyperbaric Oxygen for Persistent Post-Concussive Symptoms after mild traumatic brain injury (mTBI) study and parallel comparative study, known as the “Normal” study comprised a DoD, multi-center, Phase 2 trial. The BIMA and Normal study design consisted of two study arms, one at 1.5 atmospheres absolute pressurization breathing 100 percent oxygen and the other at 1.2 atmospheres pressurization breathing room air (21 percent oxygen). By study conclusion, the BIMA and Normal studies enrolled 71 and 83 subjects, respectively. Hyperbaric oxygen chamber intervention was concluded and closure of sites occurred in December 2014. Data collection for the studies was completed in January 2016.

The BIMA study baseline findings were published in a special issue of the Undersea and Hyperbaric Medicine Journal (*Weaver et al. 2016*).

The finalized clinical study report (CSR) was submitted to the U.S. Food and Drug Administration in July 2017. The findings of the CSR will be published in a primary manuscript in a peer-reviewed medical journal in FY18. Additional manuscripts are being prepared for submission to select peer-reviewed journals throughout 2018-2019. To share data across the entire traumatic brain injury research field and to facilitate collaboration between laboratories, the BIMA and Normal data will also be submitted to the Federal Interagency Traumatic Brain Injury Research informatics system by June 2018.

The findings of these studies indicate that hyperbaric oxygen treatment offers the potential for beneficial, but apparently transient, improvements in mTBI-associated post concussive and post-traumatic stress disorder symptoms.

#### REFERENCES:

Weaver, L. K., Chhoeu, A., Lindblad, A. S., Churchill, S., Deru, K., and Wilson, S. H. 2016. “Executive Summary: The Brain Injury and Mechanism of Action of Hyperbaric Oxygen for Persistent Post-Concussive Symptoms after Mild Traumatic Brain Injury (mTBI) (BIMA) Study.” *Undersea Hyperb Med* 43 (5):485-489.

