



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

August 8, 2017

The Honorable Joe Donnelly
United States Senate
Washington, DC 20510

Dear Senator Donnelly:

Thank you for your July 19, 2017, letter to the Department of Veterans Affairs (VA) requesting information on VA's review of Hyperbaric Oxygen Therapy (HBOT) as a treatment option for Veterans with traumatic brain injury (TBI), persistent post-concussion syndrome (PPCS), posttraumatic stress disorder (PTSD), and substance use disorder (SUD).

VA provides state of the art, evidence-based health care for Veterans with TBI (to include PPCS), PTSD, and SUD. As Under Secretary for Health, I stood up the Center for Compassionate Innovation (CCI) as an entry point to explore emerging therapies that are safe and ethical to enhance Veteran physical and mental well-being when other treatments have not been successful. My intention is to offer help and hope to the small segment of Veterans who have not responded to evidence-based therapy.

Regarding your question on reviews of the evidence on HBOT, a recently-published literature review¹ from the Samueli Institute analyzed all HBOT clinical trials for TBI, including Department of Defense (DoD) clinical trials in which VA collaborated. The authors found that both HBOT and a sham intervention provided similar outcomes for the persistent effects of mild TBI/concussion; however there was evidence that HBOT may be beneficial in acute moderate-to-severe TBI, which is not a typical patient population seen in VA facilities. The new VA/DoD Practice Guideline for PTSD, released in June 2017, rated the evidence as insufficient to make any recommendations for or against using HBOT to treat PTSD. There have been no adequately-controlled trials of HBOT for the treatment of PTSD. Finally, there is currently no compelling evidence on the safety or effectiveness to support HBOT for treatment of SUDs. In fact, there are no published, controlled clinical trials of HBOT for the treatment of SUDs and no registered clinical trials of HBOT for the treatment of SUDs in the United States. There is also a safety concern that those who are undergoing narcotic withdrawals or have alcohol dependence may be more at-risk for seizures when receiving standard HBOT.

We have received several congressional and constituent inquiries related to VA support of HBOT for Veterans with TBI and PTSD. Currently, CCI is collaborating with subject matter experts on a potential way forward within the scope of CCI's mission. In addition to exploring options for HBOT for Veterans within their community, CCI is evaluating other promising innovations that may have compelling evidence and are

¹ Crawford C, et al. (2017) Is Hyperbaric Oxygen Therapy Effective for Traumatic Brain Injury? A Rapid Evidence Assessment of the Literature and Recommendations for the Field. *Head Trauma Rehabilitation*, 32(3), E27-E37.

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approved by the Food and Drug Administration for Veterans with treatment-resistant PTSD and TBI.

VA recognizes the need for further researching evidence for potentially using HBOT in treating various disorders, particularly among the Veteran or military population. To that end, VA researchers are collaborating with DoD on an upcoming research collaboration to investigate the effectiveness of HBOT for PTSD. The 3-year randomized, control trial is expected to enroll 150 active duty Servicemembers in HBOT at three DoD sites. Participants will have pre-treatment, post-treatment, and long-term outcome evaluations utilizing the VA/DoD Chronic Effects of Neurotrauma Consortium Longitudinal Study assessment battery.

Thank you for your interest in VA's review of HBOT as a treatment option for Veterans with TBI (including PPCS), PTSD, and SUD.

Thank you for your continued support of our mission.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Shulkin", with a long horizontal line extending to the right.

David J. Shulkin, M.D.