<u>UHMS Position Statement – Draft version 9-25-20</u>	
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Title: Increasing participation of hyperbaric medicine centers in hyperbaric medicine registries

# **INTRODUCTION**

As the scope of hyperbaric practice, treatment standards, and reimbursement become stringently based on a high level of evidence it is incumbent upon all hyperbaric medicine practitioners to participate in data collection for outcome analysis. Because resources and funding are limited, the most expedient means for the majority of these practitioners to contribute to this knowledge base is through participation in a formal registry for data collection. Patient registries are an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes [1]. The Undersea and Hyperbaric Medical Society (UHMS) recommends all departments practicing hyperbaric oxygen (HBO<sub>2</sub>) therapy register with an interorganizational, local, national, or international registry to capture data on all patients undergoing HBO<sub>2</sub> for emergency, outpatient, experimental, and off-label treatment.

# ABSTRACT

- 1) More studies on the efficacy and effectiveness of HBO<sub>2</sub> for currently approved and non-approved indications are necessary.
- 2) Many patients are treated in departments lacking infrastructure and funding for clinical trials.
- 3) Financial support for clinical trials from federal and non-federal sources is very limited.
- 4) The UHMS recommends all departments treating patients with HBO<sub>2</sub> join a registry to gather all clinical data prior to and after treatment into databases that allow retrospective statistical analysis on demand.
- 5) Further studies performed with pooled data may be useful for determining patient outcomes, benchmarking treatment protocols, and identification of demographic patterns to assist in prescribing treatment, preventing complications and possibly identifying of additional health risks from treatment.

# RATIONALE

• Research infrastructure and funding in the field of hyperbaric medicine are lacking compared to other fields of medicine. Furthering research and improving clinical information are critical to validate and understand the therapeutic impact of HBO<sub>2</sub> on patients.

- Most patients who receive hyperbaric oxygen therapy receive their treatment in community based, nonacademic centers. Often a lack of research infrastructure makes performance of appropriately designed clinical research studies difficult.
- One solution involves collecting de-identified patient data from multiple hyperbaric medicine centers into a shared registry database.
- Hyperbaric medicine registries could offer insight into the natural history of diseases, determine clinical outcomes, assess cost-effectiveness of HBO<sub>2</sub>, and help improve quality of care.
- Actionable collected information will be used to improve treatment protocols, patient selection, and systems of hyperbaric medicine care delivery. The data could lead to new safety measures to assess and reduce possible harm or risk to patients.

A consortium of participating hyperbaric programs can provide an important platform for the development of more complex prospective studies including randomized, controlled trials. HBO<sub>2</sub> registries provide data that providers, patients, and insurers need to make decisions about hyperbaric oxygen therapy.

The UHMS goal is for every accredited hyperbaric center to collect consistent, standardized data for treatment and outcomes on all patients evaluated for HBO<sub>2</sub> treatment in a de-identified, centralized database.

# CONCLUSIONS/RECOMMENDATIONS

The UHMS recommends all departments treating patients with HBO<sub>2</sub> join an inter-organizational, local, national, or international registry to include every patient treated with HBO<sub>2</sub>.

# REFERENCE

1. Gliklich R, Dreyer N, Leavy M, eds. Registries for Evaluating Patient Outcomes: A User's Guide. Third edition. Two volumes. (Prepared by the Outcome DEcIDE Center [Outcome Sciences, Inc., a Quintiles company] under Contract No. 290 2005 00351 TO7.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014. http://www.effectivehealthcare.ahrq.gov/registries-guide-3.cfm.