Ten Guidelines for Patients and Referring Physicians

In Selecting Safe Hyperbaric Oxygen Treatments (Submitted April 2025) - Version 4-17-25

The recent accident and tragic loss of life of a young boy during a hyperbaric oxygen exposure has brought the application of hyperbaric oxygen under close scrutiny. Hyperbaric oxygen treatment is a well-established medical treatment, practiced in over 1,000 facilities across the U.S., and in medically supervised programs on every continent except Antarctica. With over 50 years of clinical use, HBO₂ has demonstrated safety and efficacy for numerous evidence-based indications when delivered in accordance with established protocols and safety standards. Additionally, its therapeutic potential is being actively explored for other emerging medical conditions.

Unfortunately, in recent years there has been a concerning rise in unregulated, non-medical HBO₂ services offered by spas, wellness centers, and storefront operations. These facilities often use terms like "mild hyperbaric oxygen" and operate at subclinical pressures. Frequently, these services are provided by individuals without formal medical training, without physician oversight, and without adherence to national safety standards. Not infrequently, treatments provided at these centers do not adhere to effective treatment protocols, even when the condition being treated would have benefited from standard hyperbaric treatment protocols. In this scenario, the patient is being misled into believing that they are getting a bona fide medical treatment, and they are not. These treatments are often marketed for conditions not proven to benefit from HBO₂ and are sometimes delivered using devices not cleared by the U.S. Food and Drug Administration (FDA).

The Undersea and Hyperbaric Medical Society (UHMS), as the leading international authority on hyperbaric and undersea medicine, offers a comprehensive Accreditation Program that rigorously evaluates hyperbaric facilities for compliance with clinical, operational, and safety standards. This program includes an on-site review and post-survey assessment by a council of hyperbaric medicine experts. The Joint Commission has recognized the UHMS Accreditation Program as complementary to its own hospital accreditation process, often accepting UHMS accreditation in lieu of further inspection.

The FDA has recommended that those seeking hyperbaric oxygen treatments search out facilities that have achieved UHMS Accreditation, signifying a demonstration of commitment to excellence and safety. The UHMS accreditation program has been active for nearly 25 years. For the patient and their physicians, this certification provides confidence that the accredited facility has been reviewed for compliance to these very important and even life-saving standards. To many, it is considered the most cost-effective risk management assessment tool that a hyperbaric facility can employ. Accreditation does not guarantee safety, but it does

enhance the likelihood of good practices, and good practices can be expected to lead to a safe treatment environment.

The central elements of a safely operated hyperbaric medical service are discussed below. Hyperbaric facilities that have achieved accreditation have demonstrated their adherence to these important safety practices through documentation and inspection. Patients and their physicians can be confident that these elements have already been carefully scrutinized. If the decision is made to seek treatment at a non-accredited facility, the patient should review each of these standards individually with the non-accredited facility staff.

1. HBO₂ is the Practice of Medicine

The American Medical Association (AMA) recognizes HBO₂ as the practice of medicine. Treatment must be based on an evaluation and prescription by a licensed physician trained in hyperbaric medicine (a minimum 40-hour UHMS-approved Introductory Course in Hyperbaric Medicine). The treatment must be supervised by a physician actively involved in the patient's care.

2. Chamber Design Must Meet National Standards

Hyperbaric chambers must comply with engineering and safety standards established by the National Fire Protection Association (NFPA), the American Society of Mechanical Engineers (ASME PVHO), and the U.S. Food and Drug Administration (FDA). Only FDA-cleared chambers (e.g., with documented 510(k) approval) should be used for medical treatment. Many unapproved chambers enter the U.S. illegally and pose serious risks, including explosion or fire.

3. Routine Chamber Inspections

Chambers must undergo daily safety inspections using validated checklists, and more comprehensive maintenance checks must follow manufacturer-recommended schedules. These measures are essential to avoid mechanical failure and injury.

4. Proper Training and Credentialing of Staff

Chamber operations must be conducted or directly (in the treatment room) overseen by personnel who have completed an Undersea and Hyperbaric Medical Society (UHMS), National Board of Diving and Medical Technology (NBDHMT), or American College of Hyperbaric Medicine (ACHM) (**face-to-face ONLY**) approved 40-hour hyperbaric medicine course and maintain ongoing education and documented competency in safety protocols. Ideally, staff should hold certification from a recognized credentialing body, and each facility must designate a trained Safety Coordinator.

5. Strict Prohibition of Flammable Materials

Products that produce flammable vapors are fire risks and must be excluded from oxygenenriched environments.

6. Availability of Safety Equipment and Regular Drills

Facilities must maintain functioning safety equipment and conduct regular, documented emergency response drills involving all operational staff.

7. Electrical and Static Hazards Must Be Eliminated

Any electrical or static-generating devices must be excluded from the chamber. A procedural "time-out" must be conducted before each treatment to confirm the patient's identity, treatment plan, and safety readiness. Extra precautions should be taken for pediatric patients or those with cognitive impairment, including physical checks when warranted. In monoplace chambers using 100% oxygen, patients should wear grounding straps to eliminate static discharge risks.

8. Continuous Monitoring

Patients must be continuously monitored visually and audibly throughout the treatment session by trained personnel.

9. Emergency Preparedness

All staff must be trained to manage rare but potentially serious emergencies. Simulated drills and response training are essential, even if events are uncommon in well-run facilities.

10. Proper Patient Clothing

Clothing must be issued by the hyperbaric facility or approved by the hyperbaric safety coordinator, be uncontaminated, and be free of prohibited articles before chamber pressurization.

100% cotton garments and cotton/polyester blends are allowed in the Multiplace (Class A) chamber. Keep silk, wool, and synthetic materials out of the chamber unless approved by the hyperbaric physician and safety coordinator.

100% cotton garments and cotton/polyester blends with no more than 50% polyester are allowed in the Monoplace (Class B) chamber. Keep silk, wool, and synthetic materials out of the chamber unless approved by the hyperbaric physician and safety coordinator.

This guidance summarizes key safety standards recommended by the Undersea and Hyperbaric Medical Society to assist patients, families, and healthcare providers in identifying credible and safe HBO₂ facilities. While UHMS sets the clinical and operational standards for hyperbaric practice, chamber construction and hardware safety are also governed by longstanding federal and industry regulatory bodies, including the National Fire Protection Association (NFPA), the American Society of Mechanical Engineers Pressure Vessels for Human Occupancy (ASME PVHO), and the FDA.

A complete list of UHMS publications, educational programs, and official safety guidelines is available at <u>www.uhms.org</u>.