Ethical Hyperbaric Oxygen Therapy

Definition of Hyperbaric Oxygen Therapy
The discipline of hyperbaric oxygen has been recogniszed as a scientific discipline by Mainstream Medicine worldwide and continuous research strengthens the evidence for various conditions.

The description of this discipline should begin with the basic scientific definition of the essential elements of hyperbaric oxygen (HBOT) treatment. However, to understand the complexities of its appropriate practice and to recognize and condemn the unfortunate proliferation of unsafe centers and unproven practices, it is necessary to go beyond the simple scientific definition. The definition is not meant to stand on its own without these additional refinements.

Scientific Definition of Hyperbaric Oxygen (HBO2) Therapy
Hyperbaric oxygen therapy (HBOT is the treatment of a disease or medical condition by the inhalation of near-100% medical grade oxygen* at pressures greater than 1.5 atmosphere absolute (ATA in a pressure vessel constructed for that purpose.

However, occasionally in cases of severe Decompression illness, treatment pressure above 3.0 ATA is utilized. Oxygen levels need to be reduced below 100% to reduce oxygen toxicity for these cases, by using a mixture of O2 and Helium, to deal with severe complications related to bubbles in tissue and circulation.

Safe Delivery and Proven Hyperbaric Oxygen Applications
Treatment chambers should be designed, constructed, operated and certified to the standards established by the NFPA (National Fire Protection Association) and ASME PVHO-1 (American Society of Mechanical Engineers-Safety Standard for Pressure Vessels for Human Occupancy) or other internationally equivalent regulatory agencies.

The Undersea and Hyperbaric Medical Society (UHMS) and the BHA has established criteria for accreditation of hyperbaric treatment facilities designed to ensure safe and clinically appropriate treatments.

*Medical grade oxygen should meet USP (US Pharmacopeia) or national equivalent standard for purity.

Most disorders require a series of treatments delivered daily for several weeks. These treatments should be prescribed and supervised by suitably qualified physicians with appropriate training to ensure daily assessment and follow-up afterwards. Quality Control of delivery of oxygen is important and continuous monitoring of the oxygen in the chamber environment is essential to decrease the risk of a fire. This includes the need for tight fitting masks or hoods to prevent leakage of o2 (and to ensure adequate dosing). With these measures, combined with regular expert inspections by the BHA, the UK has avoided any chamber fires. Sadly, fires in the hyperbaric chamber, have killed unfortunate patients on all continents. Most of these were due to inadequate maintenance and lack of expert inspection.

Conditions proven by peer-reviewed research and listed on the FDA website:

- **air and gas bubbles in blood vessels (i.e., gas embolism)**
- **anaemia (severe anaemia when blood transfusions cannot be used)**
- **burns (severe and large burns treated at a specialized burn center)**
- **carbon monoxide poisoning**
- **crush injury**
- **decompression sickness (diving risk)**
- **gas gangrene**
- **hearing loss (complete hearing loss that occurs suddenly and without any known cause)**
- **infection of the skin and bone (severe)**
- **radiation injury**
- **skin graft flap at risk of tissue death**
- **vision loss (when sudden and painless in one eye due to blockage of blood flow)**
- **wounds (non-healing, diabetic foot ulcers**

These are also endorsed by BHA, EUBS and UHMS (*https://policysearch.ama-assn.org/policyfinder/detail/D-270.986?uri=%2FAMADoc%2Fdirectives.xml-D-270.986.xml&fbclid=IwAR0RjTvmYqkr2ulJM1EKPQDqFrVzu8pnvfnQl93LFwID-fkgm39eU_wsbUXI*)

"Our AMA: (1) opposes the operation of "mild hyperbaric facilities" unless and until effective treatments can be delivered safely in facilities with appropriately trained staff including physician supervision and prescription and only when the

intervention has scientific support or rationale; and (2) will work with the U.S. Food and Drug Administration and other regulatory bodies to close facilities offering "mild hyperbaric therapy" until and unless they adopt and adhere to all established safety regulations, adhere to the established principles of the practice of hyperbaric oxygen under the prescription and oversight of a licensed and trained physician, and ensure that staff are appropriately trained and adherent to applicable safety regulations".

The US Food and Drug Administration (FDA) also expressed a strong view on the need for proper inspection and scrutiny of HBOT. The use for unproven indications is also strongly criticized. (*https://www.fda.gov/consumers/consumer-updates/hyperbaric-oxygen-therapy-get-facts?utm_medium=email&utm_source=govdelivery*)

"*If you are considering the use of a HBOT device for yourself or a loved one, be aware that some claims of what it can do are unproven. For example, HBOT devices are not proven to cure cancer, Lyme disease, autism or Alzheimer's disease. The U.S. Food and Drug Administration recommends you check with your health care provider before using a HBOT device to make sure you are pursuing the most appropriate care. If your health care provider recommends HBOT, the FDA advises that you go to a hospital or facility that has been inspected and is properly accredited."*

Unproven 'Hyperbaric Treatment' (Often Termed "Mild Hyperbaric Oxygen")
Hyperbaric treatment at minimally elevated chamber pressures (mild hyperbaric oxygen) is unproven. Mild hyperbaric oxygen therapy is currently considered to be exposures delivered at pressures lower than 1.5 ATA. Most patients (?clients) in "mild hyperbaric chambers" receive breathing gas mixes well less than 95% O2, often delivered through breathing devices such as masks that do not provide a tight seal and by the nature of their construction allow mixing of gases with the ambient chamber air, further reducing the oxygen concentration. Inadequate levels of pressure and oxygen lead to poor outcome, but the risk of oxygen fueled fire is still significant. Unfortunately, these treatments have become widely available in so-called "wellness centers". In many instances these treatments are not physician-prescribed or supervised.

The recent interest in and commercial growth of these treatments has led to the use of unsafe and unapproved chamber vessels outside medical facilities. These

are often in locations without the infrastructure to care for patients who may be unwell or may develop complications needing expert medical care. These facilities often operate without the appropriate adherence to fire safety and chamber construction standards, putting patients, staff and even the public nearby at risk for serious injury and even death.

These facilities typically deliver sessions with inadequate dosing of O2 in these low-pressure vessels for a spectrum of medical disorders or complaints, including those for which standard hyperbaric medicine has been found to be effective, but also including disorders for which there is no scientific proof. Unfortunately, in the past unscrupulous providers have profited from vulnerable people and virtually any ailment has been treated for desperate patients. There seem to be a trend in that direction at the moment, including claims at staving off the ageing process. Medical practitioners should be cautious where they refer their patients and patients should be asking for evidence, particularly if they are paying for treatment.

Hyperbaric Medicine is a discipline of mainstream medicine that is fairly young and still developing with active research in many conditions. Patients participating in such research should be commended and encouraged and should always be assured of the safety of chambers where research is being done under supervision of experienced NHS researchers.