

## New scientific definitions: hyperbaric therapy and hyperbaric oxygen therapy

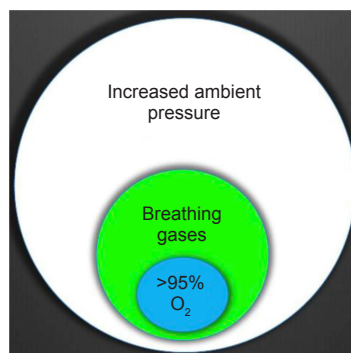
Dear Editor,

For nearly the entire 60-year modern era of clinical hyperbaric medicine, hyperbaric oxygen (HBO<sub>2</sub>) therapy has been defined as treatment with 100% oxygen at greater than one atmosphere absolute (ATA; clinically,  $\geq 1.4$  ATA), for a narrow list of diseases. These diseases have been identified by a combination of basic science, clinical studies, and expert opinion (Delphi Criteria).<sup>1</sup> Essentially, HBO<sub>2</sub> was defined within narrow parameters as a disease-specific therapy. It served the purpose in 1976 of establishing the foundation of a fledgling specialty in the USA by anchoring the therapy to the opinion of experts in hyperbaric medicine who then secured its reimbursement in the hospital setting. However, the clinical evidence for the list was scant for many of the 13 diagnoses at that time: no randomized controlled trials for 12 of the original 13 diagnoses and two of the last three recent additions (intracranial abscess and central retinal artery occlusion). The definition was also subject to change when one ventured outside the USA. For example, the therapy was disease-specific for 13 diseases in the USA, but disease-specific by the same and additional basic science, clinical science, and Delphi Criteria for 23 diseases in Russia, 48 in China, and 20 in Japan.<sup>2</sup> The USA list also appeared arbitrary to non-hyperbaric medicine physicians, i.e., the bulk of the medical profession, with no apparent connection or common thread to the disparate 13 diagnoses (physicians could not see a similarity between thermal burn, air embolism, chronic refractory bone infections or the other 10 diagnoses). The common thread, however, was the treatment of disease pathophysiology that was common to the 13 diagnoses and many more.

Another critical flaw in the definition was the absence of evidence for exclusively 100% oxygen or at least 1.4 ATA of 100% oxygen.<sup>1</sup> This historical feature is in the process of modification. In May 2022 at the Undersea and Hyperbaric Medical Society Annual Meeting, a new definition of HBO<sub>2</sub> was proposed that is based on the use of “near 100% oxygen (at least 95% oxygen)” with an exception for deep diving recompression treatment where the fractional inspired oxygen concentration is less than at least 95% to prevent oxygen toxicity. The new proposed definition further includes USA regulatory components, proscription of mild hyperbaric therapy/unproven applications, and exclusion of applications outside the proposed definition, none of which are pertinent to a scientific definition. Lastly, the modern-era definition has ignored both the 300-year history of hyperbaric medicine<sup>3</sup> and the contribution of increased barometric pressure as a distinct entity.<sup>4</sup> That history was characterized by widespread purported benefits of pressurized air, including its long-forgotten 1918 inaugural use in the USA to salvage Spanish Flu victims dying from adult respiratory distress syndrome.<sup>3</sup> The inadequacy of the modern definition has become even more apparent with the inability to reconcile the seemingly conflicting conclusions and confusion in the multiple U.S. Department of Defense mild traumatic brain injury/persistent postconcussion syndrome studies.<sup>5</sup>

Given the aforementioned flaws, the cumulative knowledge of the bioactivity of increased barometric or hydrostatic pressure,<sup>4,5</sup> the inescapable acknowledgment that HBO<sub>2</sub> includes increased pressure in addition to increased pressure of oxygen,<sup>5</sup> and the U.S. Food and Drug Administration’s identification of this dual component nature of HBO<sub>2</sub>,<sup>5</sup> it is incumbent upon the hyperbaric medicine field to change the definition of HBO<sub>2</sub> to embrace and account for the science underpinning it. Therefore, this is a proposal that HBO<sub>2</sub> should be redefined as a type of hyperbaric therapy. Hyperbaric therapy would be defined as a medical treatment that uses increased barometric pressure and increased partial pressures of breathing gases by fully enclosing a patient in a pressure vessel to treat disease pathophysiology and their diseases. Hyperbaric therapy would include any breathing gas or mixture of breathing gases with bioactivity, including argon, nitrogen, or others. HBO<sub>2</sub> would be a subset of hyperbaric therapy where the breathing gas is near-100% oxygen (at least 95% oxygen). HBO<sub>2</sub> would be defined as a medical treatment that uses increased barometric pressure and increased partial pressure of near 100% (at least 95%) medical grade oxygen by fully enclosing a patient in a pressure vessel to treat disease pathophysiology and their diseases. These definitions are displayed as a Venn diagram in **Figure 1**.

Figure 1 is a Venn diagram illustrating the definitions of hyperbaric therapy and hyperbaric oxygen therapy. It consists of three overlapping circles: a large white circle representing increased ambient pressure, a medium green circle representing breathing gases, and a small blue circle representing >95% O<sub>2</sub>. The white circle is the largest and contains the other two. The green circle is nested within the white circle, and the blue circle is nested within the green circle. The text labels each circle: "Increased ambient pressure" for the white circle, "Breathing gases" for the green circle, and ">95% O<sub>2</sub>" for the blue circle.



**Figure 1: Hyperbaric therapy and hyperbaric oxygen therapy definitions.**

Note: The white circle represents the bioactivity of increased hydrostatic or barometric pressure (for tissue culture or similar experiments without a gas interface). Green circle represents hyperbaric therapy and blue circle represents hyperbaric oxygen therapy.

With these definitions the body of knowledge on HBO<sub>2</sub> with near 100% oxygen remains intact, while the entire history of bioactivity of lesser fractional inspired oxygen concentrations, barometric pressure, or both, and barometric pressure itself, are included. The conflicting data and confusion over shams, controls, and pseudo-shams in the U.S. Department of Defense mild traumatic brain injury studies, cerebral palsy HBO<sub>2</sub> studies, and dozens of other studies using less than 100% oxygen and the traditional doses of 2.0–3.0 ATA become explicable and reconciled. The new definitions would account for the entire range of science on the bioactivity of pressure, increased pressure of breathing gases, and hyperoxia and their clinical applications. They would unify the basic science field of pressure biology and clinical hyperbaric medicine and enable the subspecialty of undersea and hyperbaric medicine to encompass the entire field of medical treatment with compressed breathing gases.



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