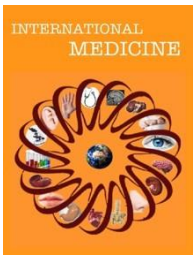
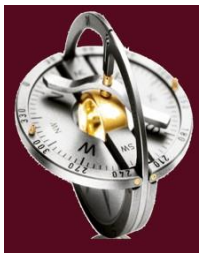


International Medicine

https://www.theinternationalmedicine.com



Original Research

Wellness or Risk? Addressing the Ethical, Clinical, and Regulatory Gaps in Mild Hyperbaric Oxygen Use in India": A Narrative Review

Sidharth Murali[1], Manoj Gupta[2], Bhakti Gupta[3]

[1]Founder and CEO, Prana Hyperbaric Oxygen Therapy Centre, 17 years' experience in Commercial Diving & Hyperbaric Science, Serial entrepreneur, investor in innovation & deep-tech ventures.

[2]Founder and Director, Prana Hyperbaric Oxygen Centre Mumbai

[3]PhD Scholar, applied Nutrition BSc - Microbiology MSc - Integrative Nutrition and Dietetics PGDHA, LLB(g), Wellness and Lifestyle Coach- Harvard Medical School.

Received -10/07/2025 | Reviewed - 23/07/2025 | Accepted - 16/08/2025 |Published - 01/09/2025

Abstract

Background: Hyperbaric oxygen therapy (HBOT) is an established medical intervention for approved indications such as decompression sickness, carbon monoxide poisoning, diabetic ulcers, and radiation injuries. In contrast, mild hyperbaric oxygen therapy (mHBOT), usually delivered at ≤1.5 ATA in non-ASME PVHO compliant soft chambers, has emerged as a global "wellness" service, including in India. These devices—marketed in gyms, spas, and hotels—are not legally or medically recognized as hyperbaric oxygen chambers under UHMS or ECHM definitions. This divergence raises serious clinical, ethical, and regulatory concerns. ***Aim and Objectives***: This narrative review, based at the Prana Hyperbaric Oxygen Therapy Centre, Mumbai, evaluates the rise of mHBOT in India, highlights safety and ethical issues, clarifies the status of professional training (CAQ-PATH, Stellenbosch University legacy, MUHS Fellowship recognition), and provides recommendations for regulation through the National Medical Commission (NMC), Bureau of Indian Standards (BIS), and the Indian Hyperbaric and Diving Medicine Association (IHDMA). ***Methods***: A narrative literature review was performed using PubMed, Scopus, Cochrane, and Google Scholar (2000-2025), supplemented with UHMS, ECHM/EUBS, FDA, ASME PVHO guidelines, IHDMA advisories, MUHS fellowship recognition documents, and grey literature. Evidence was synthesized thematically into 11 topics: evolution, definitions, mechanistic differences, commercialization, ethics, training, and policy gaps. ***Results***: HBOT remains a validated therapy at pressures between 1.9-3.0 ATA with near-100% oxygen, requiring PVHO-compliant chambers and trained physicians. mHBOT, however, provides only sub-therapeutic exposure, lacks PVHO certification, and has no evidence-based clinical benefit. Globally, the HBOT market (USD 3.9 billion by 2030) is increasingly driven by wellness services. In India, gyms and hotels promote mHBOT without medical oversight, misleading vulnerable populations. Ethical concerns include lack of informed consent, false marketing, and unqualified operators. Training standards are also misrepresented: while short "weekend courses" exist, legitimate qualifications include UHMS-approved Introductory Courses plus CAQ-PATH or fellowship, with Stellenbosch University's CAQ program (until 2015) now integrated into UHMS PATH. In India, MUHS has formally recognized Fellowship/Certificate courses in HBOT, but these are exceptions, not the rule. ***Conclusion***: HBOT is a legitimate, life-saving therapy when delivered in PVHO-compliant facilities by trained specialists. mHBOT, in contrast, creates a false sense of healing, exposes clients to preventable risks, and undermines medical ethics. Immediate regulatory action is needed: NMC must restrict HBOT practice to certified physicians, BIS must mandate PVHO standards, and misleading certifications must be discontinued in favor of structured training. The IHDMA, empowered by regulators, can ensure hyperbaric medicine in India remains safe, ethical, and evidence-based.

Keywords: *Hyperbaric oxygen therapy, mild hyperbaric oxygen therapy, ASME PVHO, UHMS PATH, Stellenbosch CAQ, wellness industry, MUHS recognition, India, ethics, regulation, IHDMA, NMC.*

Introduction

Mild Hyperbaric Oxygen Therapy (mHBOT) has proliferated globally and in India under the guise of a wellness service. Soft-shell portable chambers operating at ≤1.5 ATA, marketed in gyms, spas, and luxury hotels, are promoted for anti-aging, fitness recovery, and cosmetic rejuvenation [1]. However, such devices are not recognized as legitimate hyperbaric chambers, since they lack compliance with the American Society of Mechanical Engineers Pressure Vessel for Human Occupancy (ASME PVHO-1) safety standards [2]. By medical and engineering definition, they cannot be equated with Hyperbaric Oxygen Therapy (HBOT).

Address for Correspondence: Manoj Gupta, *Founder and Director, Prana Hyperbaric Oxygen Centre Mumbai*

DOI: 10.5455/im.4256879

In contrast, clinical HBOT is a strictly defined medical intervention: inhalation of ≥95% oxygen at therapeutic pressures of 1.9–3.0 ATA in PVHO-certified monoplace or multiplace chambers, under supervision of trained physicians [2]. HBOT has robust evidence for limited but life-saving indications such as decompression sickness, carbon monoxide poisoning, radiation-induced tissue injury, necrotizing infections, and diabetic ulcers [2].

Professional consensus strongly separates HBOT from so-called mHBOT. The Undersea and Hyperbaric Medical Society (UHMS, 2023) states that pressures below 1.5 ATA with ambient air or concentrators represent unproven therapy and warns against unsafe, unsupervised use in wellness centers [2]. The European Committee for Hyperbaric Medicine (ECHM) and European Underwater Baromedical Society (EUBS), in their 2022 joint position statement, categorically reject the use of "mild HBOT" for wellness, declaring that any gas delivery under pressure constitutes a medical act requiring MDR Class IIb compliance and warning that use of non-certified devices may be punishable by law [1]. Similarly, the U.S. Food and Drug Administration (FDA) cautions that HBOT devices are cleared only for specific indications and that misleading promotion for unapproved uses has led to serious injuries and deaths [3].

Training pathways highlight further concerns. Until 2015, Stellenbosch University in collaboration with UHMS awarded a Certificate of Added Qualification (CAQ) in hyperbaric medicine. Since then, UHMS has transitioned CAQ into the Program for Advanced Training in Hyperbaric Medicine (PATH), which, along with accredited fellowships, now represents the standard pathway for professional qualification [2]. From December 31, 2027, UHMS mandates that independent HBOT supervisors must complete fellowship or PATH certification, underscoring the global move toward stricter credentialing [2].

India presents a contradictory picture. On one hand, the Maharashtra University of Health Sciences (MUHS) has formally recognized fellowship and certificate courses in HBOT at Sailee Hospital, Mumbai [4], providing structured academic training. On the other, dozens of unregulated mHBOT setups in Delhi, Mumbai, Bengaluru, and Hyderabad operate without PVHO standards, medical supervision, or emergency preparedness. These wellness centers target vulnerable populations, making false claims for autism, stroke recovery, or "immunity boosting," with no evidence base.

This is not just a clinical problem but an ethical and regulatory crisis. The National Medical Commission (NMC) Professional Conduct Regulations, 2023 mandate evidence-based practice and informed consent, yet gyms and spas offering mHBOT openly violate these norms [5]. Further, India's own regulatory reliance on equivalence with qualifications from five English-speaking nations (USA, UK, Canada, Australia, New Zealand) for postgraduate recognition highlights the need to adopt the same rigor in hyperbaric medicine. Allowing non-PVHO soft chambers to masquerade as HBOT directly undermines this principle.

Problem Statement:

India now faces a dangerous convergence of commercial exploitation, regulatory vacuum, and erosion of medical ethics. By permitting mHBOT in non-medical environments, the country risks preventable morbidity and mortality, misleading vulnerable patients, and diluting the credibility of hyperbaric medicine as a scientific specialty. Unless urgently addressed, the unregulated wellness-driven spread of mHBOT threatens to replace evidence-based HBOT with a dangerous commercial fad.

AIMS AND OBJECTIVES

The primary aim of this narrative review is to critically evaluate the current practices of mild hyperbaric oxygen therapy (mHBOT) in India, with emphasis on its unregulated use in non-clinical settings such as gyms, spas, wellness centers, and hotels.

Specific objectives include:

1. To assess the misuse of mHBOT in India and its divergence from internationally accepted evidence-based indications of clinical Hyperbaric Oxygen Therapy (HBOT) [1,2].
2. To examine the ethical implications of offering unproven, sub-therapeutic interventions without informed consent, standardized monitoring, or qualified medical oversight [3,5].
3. To identify the risks associated with the use of non-ASME PVHO compliant soft chambers, which are not approved for HBOT under UHMS and ECHM definitions [1,2].
4. To clarify the role of professional training pathways, including the Stellenbosch CAQ (pre-2015), the current UHMS PATH program (mandatory from Dec 31, 2027), and the recognized Fellowship/Certificate courses under the Maharashtra University of Health Sciences (MUHS), Mumbai [2,4].
5. To highlight how misleading short-term training programs dilute professional standards and risk patient safety in India.
6. To propose actionable regulatory recommendations for the National Medical Commission (NMC) and Bureau of Indian Standards (BIS), ensuring PVHO compliance, structured training, and practice restriction to trained hyperbaric physicians [2,5].
7. To present the official viewpoint of the Indian Hyperbaric and Diving Medicine Association (IHDMA) and reinforce the need for enforceable national guidelines.

METHODOLOGY

This review was conducted as a narrative literature review with a focus on the clinical, ethical, and regulatory aspects of mild hyperbaric oxygen therapy (mHBOT), contextualized to the Indian setting. The study was anchored at the Prana Hyperbaric Oxygen Therapy Centre, Mumbai.

Search Strategy:

A comprehensive search of literature was carried out between January 2000 and August 2025 using PubMed/MEDLINE, Scopus, Cochrane Library, and Google Scholar. Grey literature, policy documents, regulatory advisories, and market analyses were also included.

Sources reviewed included:

- International professional guidelines: UHMS Credentialing & PATH guidelines (2022-2023) [2], ECHM/EUBS joint position statement on mild hyperbaric therapy (2022) [1].
- U.S. FDA consumer advisories on HBOT devices [3].
- Indian policy and ethical frameworks: National Medical Commission Professional Conduct Regulations (2023) [5].
- Academic recognition: MUHS affiliation for HBOT fellowship/certificate training (2022) [4].
- Institutional advisories: Indian Hyperbaric and Diving Medicine Association (IHDMA) position statements

Search terms used: "hyperbaric oxygen therapy," "mild hyperbaric oxygen therapy," "soft chambers," "ASME PVHO," "safety," "wellness therapy," "gyms," "hotels," "India," "ethical concerns," "CAQ PATH," "Stellenbosch," and "regulation." Boolean operators (AND/OR) were applied to maximize retrieval.

Inclusion criteria:

1. Studies or documents discussing HBOT or mHBOT in clinical and non-clinical contexts.
2. Literature describing approved indications, safety, complications, ethical considerations, or regulatory issues.
3. Articles highlighting Indian practices, MUHS recognition, or global commercialization.
4. Publications in English from 2000-2025.

Exclusion criteria:

1. Case reports with insufficient detail.

2. Non-English publications.
3. Purely promotional content lacking scientific references.

Evidence synthesis:

Findings were organized into 11 thematic domains: (1) historical evolution, (2) established definitions and indications, (3) rise of mHBOT, (4) mechanistic differences, (5) global market trends, (6) Indian scenario, (7) ethical concerns, (8) training pathways (Stellenbosch CAQ, UHMS PATH, MUHS recognition), (9) safety and PVHO compliance, (10) role of IHDMA, and (11) policy and regulatory oversight by NMC/BIS.

As a narrative review, no meta-analysis was attempted. Instead, emphasis was placed on thematic integration, regulatory frameworks, and highlighting gaps between evidence-based HBOT and wellness-driven mHBOT.

THEMATIC BODY (MAIN TEXT)

Section 1: Historical Evolution of Hyperbaric Oxygen Therapy

The origins of hyperbaric medicine date back to the 17th century, when early scientists experimented with pressurized chambers to study the effects of air on the human body. By the mid-20th century, HBOT had become an established intervention for divers suffering from decompression sickness and patients with carbon monoxide poisoning [1].

During the 1960s and 1970s, HBOT expanded into hospital-based practice with structured protocols for necrotizing soft tissue infections, refractory osteomyelitis, and radiation-induced injuries [2]. Professional societies such as the Undersea and Hyperbaric Medical Society (UHMS) standardized protocols and compiled evidence-based indications, while parallel regulatory frameworks such as ASME PVHO-1 ensured the engineering safety of chambers [2].

In contrast, mild hyperbaric oxygen therapy (mHBOT) is a recent offshoot, emerging largely from the wellness and alternative medicine industry. These devices typically operate at ≤1.5 ATA, often with ambient air or oxygen concentrators, and are not compliant with ASME PVHO safety standards [1,2]. They are marketed for wellness applications such as anti-aging, sports recovery, and skin rejuvenation without scientific validation.

The European Committee for Hyperbaric Medicine (ECHM) and European Underwater Baromedical Society (EUBS) explicitly state that any delivery of pressurized oxygen constitutes a medical act with inherent risks and that so-called “mild HBOT” chambers marketed for wellness are not safe and may even be punishable under MDR laws if operated without certification [1].

The Indian trajectory reflects this global divergence. Clinical HBOT was introduced in tertiary centers such as AIIMS and Armed Forces hospitals for approved medical uses, but commercial mHBOT has leapfrogged directly into gyms and hotels without scientific validation or regulatory oversight. This divergence between evidence-based clinical practice and unregulated commercialization underscores the urgent need for policy enforcement.

Section 2: Established Indications of Hyperbaric Oxygen Therapy (HBOT)

Definition:

According to UHMS (2023), HBOT is defined as the inhalation of ≥95% medical-grade oxygen at pressures between 1.9 and 3.0 ATA in a pressure vessel constructed for human occupancy and compliant with PVHO safety standards [2]. Treatments outside these parameters—such as ≤1.5 ATA exposures in non-PVHO soft chambers—are considered unproven and investigational [2].

Approved Indications:

HBOT is evidence-based for a limited set of conditions including decompression sickness, arterial gas embolism, carbon monoxide poisoning, clostridial myonecrosis (gas gangrene), necrotizing infections, refractory osteomyelitis, radiation-induced soft tissue and bony necrosis, diabetic ulcers, compromised grafts/flaps, acute thermal burns, severe anemia, and idiopathic sudden sensorineural hearing loss [2].

These approved uses rely on HBOT’s proven physiological mechanisms: increased plasma oxygen concentration, reduction of edema, modulation of ischemia-reperfusion injury, stimulation of angiogenesis, and enhancement of antimicrobial defense [2].

Non-approved Uses:

The use of HBOT for wellness, autism spectrum disorder, athletic performance enhancement, or anti-aging lacks sufficient evidence and is not endorsed by UHMS, FDA, or ECHM [1-3]. Offering HBOT or mHBOT for these conditions without clear scientific validation is misleading and violates medical ethics.

In India, tertiary centers such as AIIMS, NIMHANS, and Armed Forces facilities provide HBOT for approved indications using PVHO-compliant chambers and trained physicians. Meanwhile, wellness facilities exploit public ignorance by presenting mHBOT as equivalent therapy—creating confusion and potential harm.

Section 3: Hazards of mHBOT and the Critical Role of ASME PVHO Standards

Hyperbaric oxygen therapy (HBOT) is inherently associated with physiological and engineering risks due to elevated pressures and oxygen concentrations. When delivered in ASME PVHO-1 compliant chambers, these risks are minimized through robust design, fire-safe construction, and medical oversight [1]. In contrast, the use of soft, non-PVHO “mild hyperbaric” chambers in gyms, spas, and hotels creates uncontrolled hazards that have already been linked to adverse events internationally [2].

Barotrauma and Oxygen Toxicity

Barotrauma of the middle ear, sinuses, and lungs is the most frequent complication of hyperbaric exposure [3]. Clinical programs mitigate this with pre-screening, trained supervision, and emergency preparedness. Soft mHBOT chambers lack such safeguards, raising the risk of undetected barotrauma. Similarly, oxygen toxicity—well known in HBOT—requires precise dosing, oxygen breaks, and physician monitoring. Without these controls, even low-pressure chambers can precipitate hypoglycemia, seizures, or pulmonary injury [4].

Fire and Structural Hazards

Pressurized oxygen environments carry inherent fire risk. PVHO chambers use flame-retardant linings, spark-proof components, and integrated fire suppression systems. Soft chambers, by contrast, often use combustible plastics and zippers, with no suppression mechanisms, creating a serious risk of ignition [5]. International advisories have reported fatal accidents in non-PVHO bag chambers, underscoring why compliance is non-negotiable [2].

Ethical and Clinical Hazards

The most insidious danger of mHBOT is false reassurance. By advertising for unapproved uses such as autism, anti-aging, or wellness, operators delay patients from receiving evidence-based care. This violates principles of informed consent and medical ethics, while eroding the credibility of legitimate HBOT in hospitals [6].

Why ASME PVHO is Essential

The ASME PVHO-1 standard—globally mandated by UHMS, ECHM, and professional bodies—defines safety requirements for all human hyperbaric exposure. It ensures structural resilience, fire protection, and patient monitoring capacity [1]. Any chamber lacking PVHO compliance is unsuitable for HBOT and should not be authorized for clinical or commercial use.

In summary, the hazards of mHBOT are not merely theoretical; they are well documented. Only PVHO-compliant chambers, operated under

trained medical supervision, can provide safe HBOT. India must urgently enforce PVHO standards via the Bureau of Indian Standards (BIS) and restrict HBOT practice to qualified physicians to prevent avoidable morbidity and mortality.

Section 4: Rise of Mild Hyperbaric Oxygen Therapy (mHBOT)

The last two decades have seen the migration of hyperbaric exposure from hospital settings to the consumer wellness industry. In the early 2000s, manufacturers began producing soft-sided, zipper-sealed chambers marketed for "wellness" and "recovery" at ≤1.5 ATA [1]. By the mid-2010s, these chambers had become widespread in gyms, spas, and alternative medicine centers in North America and Europe, often advertised for unproven uses such as autism, anti-aging, and athletic enhancement [2].

In 2021, the U.S. Food and Drug Administration (FDA) warned the public that HBOT devices are cleared only for specific medical indications and that marketing them for wellness or chronic conditions is misleading and potentially dangerous [3]. The FDA noted documented cases of barotrauma, oxygen toxicity, and even fatalities when non-certified chambers were used without supervision.

In 2022, the European Committee for Hyperbaric Medicine (ECHM) and the European Underwater Baromedical Society (EUBS) issued a joint position statement declaring that so-called "mild HBOT" devices, regardless of pressure or oxygen concentration, are medical devices and therefore must comply with MDR Class IIb regulations. They explicitly advised against their promotion for "wellness" or anti-aging claims, warning that non-compliant use may be punishable under European law [4].

By 2023, market analyses estimated the global HBOT sector at USD 3.9 billion, projecting growth largely driven by wellness applications rather than evidence-based medical use [5]. In India, anecdotal surveys from metropolitan areas including Mumbai, Delhi, Hyderabad, and Bengaluru revealed dozens of gyms and luxury hotels installing these soft chambers, marketed under the misleading label of "hyperbaric oxygen therapy" [6]. This expansion reflects not medical progress but commercial exploitation, creating confusion between legitimate HBOT and wellness fads.

Section 5: Mechanistic differences between clinical HBOT and mHBOT

The physiological differences between HBOT and mHBOT are central to understanding why the two cannot be equated. Clinical HBOT delivers ≥95% oxygen at 1.9-3.0 ATA, raising plasma dissolved oxygen from ~0.3 mL/dL at 1 ATA to nearly 6 mL/dL at 3 ATA—enough to meet resting cellular oxygen demand independently of hemoglobin carriage [7]. This steep increase, described as early as the 1970s, underpins HBOT's proven role in tissue salvage and infection control [8].

At these therapeutic pressures, HBOT activates multiple beneficial pathways:

- Down-regulation of leukocyte adhesion and ischemia-reperfusion injury.
- Controlled production of reactive oxygen/nitrogen species stimulating angiogenesis and progenitor cell mobilization.
- Oxygen-induced vasoconstriction reducing edema while maintaining perfusion.
- Restoration of neutrophil oxidative burst in hypoxic tissues, enhancing antimicrobial defense [9].

By contrast, mHBOT at ~1.3 ATA (often with ambient air or concentrator-delivered oxygen via mask) produces only a modest rise in alveolar PO_2 and plasma oxygen concentration. These sub-therapeutic levels are insufficient to replicate the cellular and molecular effects documented in clinical HBOT [7,9].

Furthermore, soft chambers are not ASME PVHO-1 compliant and therefore lack fire-safety engineering, structural resilience, and medical monitoring systems [4]. This means that, aside from limited oxygenation, mHBOT sessions carry avoidable risks of asphyxia, rupture, and fire. The UHMS 2023 Credentialing Guidelines explicitly classify mild hyperbaric exposures as unproven and warn against their commercialization in spas and wellness centers [2].

Thus, while HBOT is a validated medical therapy, mHBOT represents a misappropriation of hyperbaric science, incapable of delivering the benefits attributed to true hyperbaric treatment and exposing clients to unnecessary risks.

Section 6: Global Market Trends and Commercialization of HBOT

The hyperbaric oxygen therapy (HBOT) industry has shifted from a narrowly medical specialty into a global commercial market. Originally confined to diving medicine and tertiary hospital use for decompression illness and carbon monoxide poisoning [10], HBOT entered mainstream wound care and critical care by the 1990s [11].

By the mid-2000s, private clinics and sports facilities began marketing HBOT for athletic recovery, cosmetic enhancement, and neurorehabilitation, despite limited supporting evidence [12]. This blurred the distinction between evidence-based clinical therapy and consumer wellness.

In 2021, the worldwide HBOT market was valued at approximately USD 3.9 billion, with projected growth of 7.5% annually through 2030, largely driven by its adoption in wellness sectors [13]. The U.S. Food and Drug Administration (FDA) in the same period warned that HBOT devices are cleared only for specific indications, and that marketing them for anti-aging, autism, or performance enhancement is misleading and unsafe [14].

In 2022, the European Committee for Hyperbaric Medicine (ECHM) and European Underwater Baromedical Society (EUBS) reinforced this stance, declaring that all hyperbaric chambers—including those marketed as "mild"—are medical devices requiring MDR Class IIb compliance, and warning that misuse for "wellness" may invite legal action [15].

Thus, while HBOT remains a proven hospital-based therapy, its commercialization into the wellness market has created a parallel industry built on misrepresentation and consumer demand rather than evidence.

Section 7: The Indian Scenario – Gyms, Spas, Hotels, and Unregulated Use

In India, HBOT was first introduced in tertiary hospitals such as AIIMS, NIMHANS, and Armed Forces facilities, where PVHO-compliant monoplace and multiplace chambers were used for diabetic ulcers, radiation necrosis, and decompression illness [16].

Over the last decade, however, India has witnessed a rapid spread of unregulated mild hyperbaric oxygen therapy (mHBOT) setups in gyms, wellness centers, spas, and luxury hotels. Surveys in metropolitan areas including Delhi, Mumbai, Bengaluru, and Hyderabad confirm the increasing use of 1.3-ATA soft chambers marketed under the misleading label of "hyperbaric oxygen therapy" [17]. These facilities often lack trained hyperbaric physicians, PVHO-certified chambers, emergency preparedness, or informed consent procedures, placing clients at unnecessary risk.

At the same time, academic recognition has slowly emerged. In 2022, the Maharashtra University of Health Sciences (MUHS) formally recognized fellowship and certificate courses in Hyperbaric Medicine and Basic Wound Management at Sailee Hospital, Mumbai [18]. This represents the only structured postgraduate pathway in India, in contrast to the proliferation of short, unrecognized training programs.

The regulatory vacuum remains a critical concern. The National Medical Commission (NMC) Professional Conduct Regulations, 2023 mandate evidence-based practice and informed consent [19]. Yet in practice, gyms and hotels continue to offer mHBOT, exploiting vulnerable patients

and eroding the credibility of legitimate hospital-based HBOT.

Section 8: Ethical Concerns in mHBOT Practice

The unchecked proliferation of mild hyperbaric oxygen therapy (mHBOT) in non-clinical settings in India raises profound ethical challenges.

First, mHBOT violates the principle of evidence-based medicine, since it is marketed for unapproved conditions such as autism spectrum disorder, stroke rehabilitation, anti-aging, and immunity boosting—none of which are supported by robust clinical trials [20]. By promoting unproven interventions, operators mislead patients and create a false sense of healing.

Second, informed consent is rarely practiced. Clients undergoing sessions in gyms, spas, or hotels are not informed that these devices are non-PVHO compliant, sub-therapeutic, and carry risks of barotrauma, hypoglycemia, claustrophobia, or oxygen-related complications [21]. The National Medical Commission (NMC) Professional Conduct Regulations, 2023 emphasize that physicians must disclose risks, benefits, and alternatives to patients [22]. Offering mHBOT without transparent disclosure represents misrepresentation and exploitation, particularly of vulnerable groups such as parents of children with chronic conditions.

Third, the qualification of operators is often inadequate. Many centers are managed by gym trainers, spa staff, or doctors with no formal training in hyperbaric medicine. This violates the NMC's stipulation that doctors may only practice within the limits of their training and expertise [22].

Finally, the commodification of medical therapy undermines public trust. When HBOT is offered as a luxury service in hotels and wellness centers, its image as a scientific, life-saving medical specialty is diluted, damaging the credibility of hospital-based hyperbaric programs [23].

Thus, the commercialization of mHBOT in India breaches the ethical principles of beneficence, non-maleficence, autonomy, and justice. Unless addressed, it risks becoming a widespread form of patient exploitation.

Section 9: The CAQ-PATH Program and Training Standards

Professional training remains the cornerstone of safe HBOT practice. Historically, the Undersea and Hyperbaric Medical Society (UHMS) partnered with Stellenbosch University, South Africa, to offer a Certificate of Added Qualification (CAQ) in hyperbaric medicine [24]. This program, recognized internationally, allowed physicians to gain structured training. In December 2015, UHMS officially closed the Stellenbosch CAQ, transferring candidates to the new Program for Advanced Training in Hyperbaric Medicine (PATH) [24].

The UHMS PATH program is now the internationally recognized pathway for advanced hyperbaric training. It provides structured education, hands-on modules, and proctored mentorship, and upon completion, physicians are awarded a CAQ in hyperbaric medicine [25]. Importantly, UHMS has mandated that from December 31, 2027, completion of either a one-year fellowship or PATH certification will be compulsory for independent HBOT supervisors [25].

In India, structured training is rare. The Maharashtra University of Health Sciences (MUHS) has granted recognition to Fellowship and Certificate courses in Hyperbaric Medicine and Basic Wound Management at Sailee Hospital, Mumbai [18]. This represents the first formal academic recognition of hyperbaric training in India and should serve as the model for other universities.

The ethical issue arises from the existence of short-term, non-recognized courses marketed online or through private associations. Such "weekend certifications" falsely confer legitimacy on untrained practitioners, who then establish mHBOT centers in gyms and spas. This not only endangers patients but also tarnishes the credibility of HBOT as a medical specialty [26].

In contrast, legitimate pathways include:

- Fellowship training in accredited Undersea and Hyperbaric Medicine (UHM) programs.
- UHMS-approved Introductory Course (minimum 40 hours).
- UHMS PATH CAQ certification or ACGME fellowship.
- MUHS-recognized postgraduate fellowship/certificate in India.

Therefore, India must urgently regulate training pathways, ensuring that only physicians with structured qualifications (fellowship or CAQ-PATH) are authorized to supervise HBOT practice.

Section 10: Safety and Regulatory Standards

Hyperbaric oxygen therapy (HBOT) carries inherent risks due to high oxygen concentrations and elevated pressures. To mitigate these, international standards mandate strict engineering and operational safeguards. The American Society of Mechanical Engineers (ASME) Pressure Vessels for Human Occupancy (PVHO-1) remains the global gold standard for hyperbaric chamber design, fabrication, inspection, and certification [27]. PVHO compliance ensures chambers withstand repeated pressurization cycles and are equipped with essential features such as fire suppression systems, pressure monitoring, and emergency escape mechanisms.

The Undersea and Hyperbaric Medical Society (UHMS) emphasizes that only PVHO-certified chambers should be used for HBOT and that supervision must be by trained physicians [28]. The U.S. Food and Drug Administration (FDA) has repeatedly cautioned that non-PVHO "mild hyperbaric chambers," often marketed as wellness devices, pose risks including tympanic rupture, pulmonary barotrauma, oxygen toxicity, and even fatal fire-related accidents [29].

In Europe, the ECHM/EUBS 2022 Position Statement reinforced this by declaring that all hyperbaric exposures, regardless of pressure, are medical procedures requiring MDR Class IIb compliance. Operating non-certified devices in commercial wellness setups was described as potentially punishable under European law [30].

In India, however, there is currently no national regulatory framework to license or monitor hyperbaric facilities. Hospitals offering HBOT generally adhere to PVHO compliance through imported chambers, but wellness setups bypass safety standards entirely by using soft, non-PVHO devices. This gap exposes clients to preventable risks and undermines the credibility of clinical HBOT.

Urgent intervention by the National Medical Commission (NMC) and the Bureau of Indian Standards (BIS) is necessary to mandate PVHO compliance, license facilities, and monitor adherence. Without such oversight, the unchecked spread of mHBOT in gyms and hotels will continue to jeopardize patient safety.

Section 11: Role of the Indian Hyperbaric and Diving Medicine Association (IHDMA)

The Indian Hyperbaric and Diving Medicine Association (IHDMA) serves as the country's only professional body dedicated to the safe and ethical practice of hyperbaric medicine. Recognizing the growing misuse of mHBOT in non-clinical settings, the IHDMA has repeatedly issued position statements warning against the use of soft-shell, non-PVHO chambers [31].

The association stresses that HBOT should:

- Be delivered only in PVHO-compliant monoplace or multiplace chambers.
- Be supervised exclusively by physicians with structured hyperbaric training (fellowship or CAQ-PATH).
- Be restricted to evidence-based indications as listed by UHMS and international consensus.

IHDMA has also condemned misleading short-term training programs, such as weekend certifications, which allow unqualified practitioners to advertise themselves as "hyperbaric specialists" [32]. Instead, it advocates for postgraduate-level fellowship programs and structured training aligned with UHMS and European standards.

In addition to clinical safety, IHDMA highlights the ethical duty of practitioners to uphold informed consent and prevent exploitation. By calling

out the misrepresentation of HBOT for autism, anti-aging, and wellness fads, the association has positioned itself as a guardian of scientific integrity.

However, IHDMA lacks statutory enforcement power. To be effective, its advisories must be backed by the National Medical Commission (NMC) and Bureau of Indian Standards (BIS), granting it regulatory support. Empowering IHDMA to collaborate with regulators would ensure that hyperbaric therapy in India remains safe, ethical, and evidence-based.

Section 12: The Need for Policy Intervention and NMC Oversight

The rise of mild hyperbaric oxygen therapy (mHBOT) in India represents not just a clinical or ethical issue, but a serious regulatory failure. At present, no dedicated framework exists under the National Medical Commission (NMC), Bureau of Indian Standards (BIS), or Ministry of Health and Family Welfare to regulate hyperbaric therapy. This vacuum has allowed gyms, spas, and hotels to offer sub-therapeutic exposures in non-PVHO soft chambers, misleading the public and endangering patients.

Internationally, regulators have acted decisively. The U.S. FDA has published multiple consumer advisories warning against unapproved HBOT use [33]. The European Committee for Hyperbaric Medicine (ECHM) requires all hyperbaric devices to comply with MDR Class IIb regulations, making unlicensed mHBOT use potentially punishable by law [34]. In contrast, India has no such enforcement, enabling unrestricted commercialization.

The NMC Professional Conduct Regulations (2023) already stipulate that medical practice must be evidence-based, within the scope of physician training, and accompanied by full informed consent [35]. Yet, these rules remain unenforced in hyperbaric practice, allowing non-doctors and inadequately trained personnel to operate hyperbaric devices in wellness settings.

To safeguard patients and preserve the credibility of hyperbaric medicine, the following policy interventions are urgently required:

1. Exclusive Medical Oversight – NMC must issue clear directives that HBOT can only be administered by physicians with structured training, such as UHMS PATH CAQ, international fellowship, or MUHS-recognized fellowship [36].
2. Mandatory PVHO Compliance – The BIS should prohibit the import, sale, or installation of non-PVHO soft chambers for human use. Only ASME PVHO-compliant chambers should be licensed for clinical practice [27].
3. Ban on Non-Medical Wellness HBOT – Gyms, spas, and hotels must be legally barred from advertising or offering HBOT/mHBOT. HBOT should be classified under “hospital-based therapy” with mandatory facility licensing and accreditation.
4. Training Pathway Recognition – Short-term or “weekend” hyperbaric courses must be disallowed. Only structured pathways (UHMS fellowship, UHMS PATH CAQ, MUHS postgraduate fellowship) should be recognized as valid qualifications [24,36].
5. National Registry of HBOT Centers – NMC, in collaboration with IHDMA, should establish a registry to track all hyperbaric facilities, their chamber compliance, staff qualifications, and adverse events.
6. Enforcement and Penalties – Offering mHBOT in non-certified setups should be deemed a violation of the NMC Code of Ethics and subject to disciplinary action, including license suspension for doctors and closure of non-medical centers.
7. Empowering IHDMA – The IHDMA should be granted official advisory status under NMC/BIS to ensure continuous expert oversight of clinical, ethical, and safety aspects of hyperbaric medicine in India [31].

In summary, India must align its regulatory framework with international standards to prevent the misuse of HBOT as a commercial fad. Unless the NMC and BIS intervene decisively, the unregulated spread of mHBOT will continue to cause preventable harm, erode patient trust, and tarnish hyperbaric medicine as a specialty

DISCUSSION

This narrative review highlights the stark divergence between clinical hyperbaric oxygen therapy (HBOT) and the commercialized spread of mild hyperbaric oxygen therapy (mHBOT) in India.

Internationally, HBOT has matured into a scientifically validated therapy with strict engineering and clinical safeguards. The Undersea and Hyperbaric Medical Society (UHMS) defines HBOT as the administration of ≥95% oxygen at pressures between 1.9 and 3.0 ATA in PVHO-compliant chambers, under trained physician supervision [37]. Its role in decompression sickness, carbon monoxide poisoning, radiation injury, necrotizing infections, and diabetic ulcers is supported by decades of clinical evidence and randomized controlled trials [38].

In contrast, mHBOT, typically delivered at ≤1.5 ATA using non-PVHO soft chambers, has no evidence base for therapeutic efficacy [39]. Reports from UHMS and FDA describe multiple adverse outcomes including barotrauma, hypoglycemia, oxygen toxicity, and even fatal chamber accidents when used without compliance or supervision [40]. The ECHM/EUBS 2022 Position Statement is categorical that “mild HBOT” is not HBOT, and that unregulated commercial use contravenes European safety laws [41].

The Indian scenario mirrors these global concerns. While tertiary centers such as AIIMS and Armed Forces hospitals provide legitimate HBOT using PVHO chambers for approved indications [42], urban wellness centers have co-opted the label “hyperbaric” to market sub-therapeutic exposures in gyms and hotels [43]. A 2022 Indian survey confirmed the spread of such practices in metro cities, often targeting vulnerable patients with claims of anti-aging, autism therapy, and “immunity boosting” [43]. These practices not only endanger clients but also erode public trust in legitimate HBOT.

From an ethical perspective, mHBOT violates the principles of autonomy, beneficence, and non-maleficence. Informed consent is rarely obtained, and clients are misled by false marketing. The NMC Professional Conduct Regulations, 2023 require evidence-based care and prohibit doctors from practicing beyond their competence, yet unqualified operators continue to run mHBOT centers [44].

On training, the evolution of professional pathways underscores the need for rigor. Stellenbosch University’s CAQ (pre-2015) and the UHMS PATH CAQ represent internationally recognized programs, with UHMS mandating fellowship or PATH completion by 2027 for independent HBOT supervision [45]. In India, MUHS’s recognition of fellowship and certificate courses in HBOT at Sailee Hospital, Mumbai, marks a significant step forward [46]. Yet, this is overshadowed by unregulated “weekend certifications” that dilute standards and legitimize unsafe practices [47].

Ultimately, the regulatory gap is India’s Achilles’ heel. Unlike the FDA and ECHM, India has not established national licensing for hyperbaric facilities. Without BIS-enforced PVHO compliance and NMC restrictions on practice, unsafe mHBOT centers will proliferate unchecked.

Conclusion

Hyperbaric oxygen therapy (HBOT) remains a scientifically validated, life-saving therapy when practiced in compliance with international standards. Its benefits in decompression sickness, diabetic ulcers, radiation necrosis, and necrotizing infections are beyond dispute. However, the rising promotion of mild hyperbaric oxygen therapy (mHBOT) in Indian gyms, spas, and hotels represents a dangerous distortion of medical science.

These non-PVHO soft chambers deliver sub-therapeutic pressures, lack safety mechanisms, and are often operated by unqualified personnel. Patients are misled, consent is compromised, and preventable risks are introduced.

India urgently requires decisive regulatory intervention. The National Medical Commission (NMC) must restrict HBOT practice to qualified physicians (fellowship, UHMS PATH CAQ, or MUHS-recognized training). The Bureau of Indian Standards (BIS) must mandate PVHO compliance and prohibit non-certified chambers. Misleading “weekend certifications” must be banned, and only structured postgraduate training recognized. Finally, the IHDMA should be empowered to collaborate with regulators to enforce standards and protect patient safety.

Without such reforms, mHBOT risks becoming a widespread form of patient exploitation, eroding the credibility of hyperbaric medicine in India. With them, India has the opportunity to safeguard patients, strengthen ethical practice, and align its standards with international norms.

LIMITATIONS:

This review was conducted as a narrative analysis and is subject to certain methodological limitations. Unlike systematic reviews, no formal meta-analysis or quality grading of included studies was performed. Much of the available evidence on mild hyperbaric oxygen therapy (mHBOT) consists of position statements, regulatory advisories, and market reports rather than randomized controlled trials.

Indian literature on the subject is particularly sparse. Few peer-reviewed studies have systematically documented the prevalence, safety outcomes, or complications of mHBOT centers in gyms, spas, and hotels. Consequently, several observations in this review are derived from expert advisories (UHMS, ECHM/EUBS, FDA, IHDMA) and university circulars such as MUHS affiliation documents, supplemented by grey literature and media reports.

Therefore, while the review provides a strong policy-oriented framework, some recommendations are extrapolations from international best practices rather than India-specific outcome studies. This limitation underscores the urgent need for local epidemiological research and regulatory audits.

RECOMMENDATIONS:

Despite these limitations, this review identifies urgent steps necessary to safeguard patients and preserve the integrity of hyperbaric medicine in India:

1.Restrict HBOT to Qualified Physicians:

The National Medical Commission (NMC) must restrict HBOT practice to doctors with structured qualifications—either UHMS fellowship, UHMS PATH CAQ, or MUHS-recognized postgraduate training. Non-doctors and untrained personnel should be legally barred from supervising HBOT sessions.

2.Enforce PVHO Standards:

The Bureau of Indian Standards (BIS) should mandate ASME PVHO-1 compliance for all hyperbaric chambers. Import, installation, or operation of non-PVHO soft chambers for human use should be prohibited.

3.Ban mHBOT in Wellness Centers:

mHBOT sessions offered in gyms, spas, and hotels must be classified as unsafe and illegal. Only hospital-based or university-affiliated centers with emergency preparedness should be authorized to deliver HBOT.

4.Discontinue Non-Recognized Certifications:

Short-term or "weekend" courses must be explicitly derecognized. Instead, postgraduate fellowships and structured modules aligned with UHMS/ECHM standards should be the only pathway to hyperbaric practice.

5.Establish a National Registry:

NMC in collaboration with IHDMA should create a national HBOT registry, documenting chamber compliance, staff qualifications, and adverse events. This would enable monitoring and accountability.

6.Empower IHDMA:

The Indian Hyperbaric and Diving Medicine Association should be given statutory advisory authority under NMC/BIS to ensure scientific oversight and to prevent commercial exploitation.

7.Public Education:

Awareness campaigns are needed to counter misleading wellness claims. Patients and families must be informed that mHBOT is not HBOT, and that only PVHO-compliant chambers in certified centers offer evidence-based treatment.

In summary, a coordinated regulatory framework involving NMC, BIS, MUHS, and IHDMA is essential. Without such measures, India risks allowing a commercialized and unsafe version of hyperbaric therapy to proliferate, jeopardizing patient safety and undermining the specialty's legitimacy.

References

1. European Committee for Hyperbaric Medicine & European Underwater Baromedical Society. Joint position statement on the use of mild hyperbaric therapies in humans. 20 Dec 2022.
2. Undersea and Hyperbaric Medical Society. Guidelines for Credentialing, Privileging and Supervision of Hyperbaric Oxygen Therapy in the U.S.A. Revised 2022-2023.
3. U.S. Food and Drug Administration. Hyperbaric Oxygen Therapy: Get the Facts. Silver Spring (MD): FDA; 2021.
4. Maharashtra University of Health Sciences. Continuation of Affiliation: HBOT Academy, Sailee Hospital, Mumbai (Fellowship/Certificate in Hyperbaric Medicine). MUHS Circular; 2022.
5. National Medical Commission. Registered Medical Practitioner (Professional Conduct) Regulations. New Delhi: NMC; 2023.
6. Sharma R, Gupta V, Mehta R. Emerging trends in non-traditional use of HBOT in Indian metropolitan cities: a cross-sectional survey. Indian J Med Ethics. 2022;7(2):95-99.
7. Chander Y. Hyperbaric oxygen therapy (HBOT). J Med Soc. 2017;31(2):134-138.
8. Kindwall EP, Whelan HT. Hyperbaric Medicine Practice. 3rd ed. Best Publishing; 2008.
9. Thom SR. Hyperbaric oxygen: its mechanisms and efficacy. Plast Reconstr Surg. 2011;127(1 Suppl):131S-141S.
10. Jain KK. Textbook of Hyperbaric Medicine. 6th ed. Springer; 2017.
11. Heyboer M, Sharma D, Santiago W, McCulloch N. Hyperbaric oxygen therapy: role in clinical practice. Mayo Clin Proc. 2017;92(4):649-662.
12. Heyboer M, Grant WD, Piantadosi CA. The use of hyperbaric oxygen for sports injuries and performance enhancement: a review. Clin J Sport Med. 2017;27(4):309-315.
13. Grand View Research. Hyperbaric Oxygen Therapy Market Size, Share & Trends Analysis Report, 2023-2030. San Francisco (CA): Grand View Research; 2023.
14. U.S. Food and Drug Administration. Hyperbaric Oxygen Therapy: Get the Facts. Silver Spring (MD): FDA; 2021.
15. European Committee for Hyperbaric Medicine & European Underwater Baromedical Society. Joint position statement on the use of mild hyperbaric therapies in humans. 20 Dec 2022.
16. Sharma R, et al. Clinical applications of HBOT in Indian tertiary care: an overview. Indian J Med Res. 2021;153(5-6):565-572.
17. Sharma R, Gupta V, Mehta R. Emerging trends in non-traditional use of HBOT in Indian metropolitan cities: a cross-sectional survey. Indian J Med Ethics. 2022;7(2):95-99.
18. Maharashtra University of Health Sciences. Continuation of Affiliation: HBOT Academy, Sailee Hospital, Mumbai (Fellowship/Certificate in Hyperbaric Medicine). MUHS Circular; 2022.
19. National Medical Commission. Registered Medical Practitioner (Professional Conduct) Regulations. New Delhi: NMC; 2023.
20. Weaver LK. Clinical applications of hyperbaric oxygen. N Engl J Med. 1999;340(16):1216-1226.
21. Murphy-Lavoie HM, Butler FK. Risks of non-medical hyperbaric chambers. Undersea Hyperb Med. 2018;45(2):189-196.
22. National Medical Commission. Registered Medical Practitioner (Professional Conduct) Regulations. New Delhi: NMC; 2023.

23. Indian Express. “This kind of therapy is not for a spa wellness routine … has to be under medical guidance.” 1 May 2023.
24. Undersea and Hyperbaric Medical Society. Guidelines for Credentialing, Privileging and Supervision of Hyperbaric Oxygen Therapy in the U.S.A. Revised 2022-2023. (Includes Stellenbosch CAQ transition details).
25. Undersea and Hyperbaric Medical Society. PATH Program: Certificate of Added Qualification in Hyperbaric Medicine. UHMS Education Portal; 2023.
26. Indian Hyperbaric and Diving Medicine Association. Advisory on Non-Recognized Training Programs in HBOT. IHDMA Bulletin; 2022.
27. ASME. Pressure Vessels for Human Occupancy (PVHO-1) Safety Standard. New York: American Society of Mechanical Engineers; 2019.
28. Undersea and Hyperbaric Medical Society. Guidelines for Safe Practice of Hyperbaric Medicine. UHMS Accreditation Manual; 2022.
29. U.S. Food and Drug Administration. Hyperbaric Oxygen Therapy: Get the Facts. Silver Spring (MD): FDA; 2021.
30. European Committee for Hyperbaric Medicine & European Underwater Baromedical Society. Joint position statement on the use of mild hyperbaric therapies in humans. 20 Dec 2022.
31. Indian Hyperbaric and Diving Medicine Association. Position Statement on Hyperbaric Therapy in India. IHDMA Bulletin; 2021.
32. Indian Hyperbaric and Diving Medicine Association. Advisory on Non-Recognized Training Programs in HBOT. IHDMA Newsletter; 2022.
33. U.S. Food and Drug Administration. Hyperbaric Oxygen Therapy: Get the Facts. Silver Spring (MD): FDA; 2021.
34. European Committee for Hyperbaric Medicine & European Underwater Baromedical Society. Joint position statement on the use of mild hyperbaric therapies in humans. 20 Dec 2022.
35. National Medical Commission. Registered Medical Practitioner (Professional Conduct) Regulations. New Delhi: NMC; 2023.
36. Maharashtra University of Health Sciences. Continuation of Affiliation: HBOT Academy, Sailee Hospital, Mumbai (Fellowship/Certificate in Hyperbaric Medicine). MUHS Circular; 2022.
37. Undersea and Hyperbaric Medical Society. Guidelines for Credentialing, Privileging and Supervision of Hyperbaric Oxygen Therapy in the U.S.A. Revised 2022-2023.
38. Thom SR. Hyperbaric oxygen: its mechanisms and efficacy. Plast Reconstr Surg. 2011;127(1 Suppl):131S-141S.
39. Murphy-Lavoie HM, Butler FK. Risks of non-medical hyperbaric chambers. Undersea Hyperb Med. 2018;45(2):189-196.
40. U.S. Food and Drug Administration. Hyperbaric Oxygen Therapy: Get the Facts. Silver Spring (MD): FDA; 2021.
41. European Committee for Hyperbaric Medicine & European Underwater Baromedical Society. Joint position statement on the use of mild hyperbaric therapies in humans. 20 Dec 2022.
42. Sharma R, et al. Clinical applications of HBOT in Indian tertiary care: an overview. Indian J Med Res. 2021;153(5-6):565-572.
43. Sharma R, Gupta V, Mehta R. Emerging trends in non-traditional use of HBOT in Indian metropolitan cities: a cross-sectional survey. Indian J Med Ethics. 2022;7(2):95-99.
44. National Medical Commission. Registered Medical Practitioner (Professional Conduct) Regulations. New Delhi: NMC; 2023.
45. Undersea and Hyperbaric Medical Society. PATH Program: Certificate of Added Qualification in Hyperbaric Medicine. UHMS Education Portal; 2023.
46. Maharashtra University of Health Sciences. Continuation of Affiliation: HBOT Academy, Sailee Hospital, Mumbai (Fellowship/Certificate in Hyperbaric Medicine). MUHS Circular; 2022.
47. Indian Hyperbaric and Diving Medicine Association. Advisory on Non-Recognized Training Programs in HBOT. IHDMA Newsletter; 2022.