



Hyperbaric Oxygen Therapy (HBOT) Service Standards 2016

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Acknowledgment

Dubai Health Authority (DHA) is pleased to present the Hyperbaric Oxygen Therapy (HBOT) service standards, which represents a milestone towards fulfilling the DHA strategic objective to “Improve quality standards in healthcare facilities in the Emirate of Dubai” and promote Dubai as a “Globally recognized destination for healthcare”.

Health Regulation Department (HRD) developed this document in collaboration with Subject Matter Experts (SMEs) whose contributions have been invaluable. HRD would like to gratefully acknowledge these professionals, and thank them for their dedication to quality in healthcare and their commitment in undertaking such a complex task.

Health Regulation Department
Dubai Health Authority

I. Scope

This document applies to health facilities that opt to provide Hyperbaric Oxygen Therapy (HBOT) services, which are subjected to licensure under the Dubai Health Authority (DHA) establishment law, including semi-governmental, private and health facilities operating in free zone areas, except facilities regulated by Dubai Health Care Authority (DHCA).

DHA has the right to amend this document stipulated herein without prior notice. The latest version of this document shall be published on the DHA website

www.dha.gov.ae.

II. Purpose

This document enforces the delivery of HBOT services at the highest level of quality and safe clinical care by health facilities and healthcare professionals in the Emirate of Dubai. It also stipulates the requirements of licensure, professional, facility, patient care and fire safety.

III. Definitions

Healthcare professional shall mean healthcare personal working in healthcare facilities and required to be licensed as per the applicable laws in United Arab Emirates.

Healthcare workers shall means an individual employed by the hospital, (whether directly, by contract with another entity), provide direct or indirect patient care, this includes but not limited, healthcare professionals, medical and nursing students, administrative staff and contract employees who either work at or come to the hospital site.

Hyperbaric Oxygen Therapy (HBOT) shall be defined as a treatment in which the patient is placed in a chamber and breathes near 100% oxygen or special mixed gases at higher than local atmospheric pressure.

Hyperbaric therapeutic chamber shall mean a pressure vessel capable of accommodating one or more persons with the purpose of providing hyperbaric medical treatment.

Licensure shall be defined as a process of issuing an official permission to operate a health facility to an individual, government, corporation, partnership, Limited

Liability Company (LLC), or other form of business operation that is legally responsible for the facility's operation.

OHM shall be defined as the electric unit of resistance.

Patient shall mean any individual who receives medical attention, care or treatment by any healthcare professional or admitted in a health facility.

IV. Acronyms

ACLS	: Advanced Cardiac Life Support
ARTG	: Australian Register of Therapeutic Goods
ASME	: American Society of Mechanical Engineers
BLS	: Basic Life Support
CE	: Conformité Européenne
DCD	: Dubai Civil Defence
DHA	: Dubai Health Authority
DHCA	: Dubai Health Care Authority
DMAC	: Diving Medical Advisory Committee
FDA	: Food and Drug Administration
HRD	: Health Regulation Department
HBOT	: Hyperbaric Oxygen Therapy
IV	: Intravenous
MFDS	: Ministry of Food and Drug Safety
MITI	: Ministry of International Trade and Industry
MOH	: Ministry of Health
NEBOSH	: National Examination Board in Occupational Safety and Health
NFPA	: National Fire Protection Association
O₂	: Oxygen
OSHA	: Occupational Safety and Health Administration
Psi	: Pound per square inch
PVHO	: Pressure Vehicles for Human Occupancy
RN	: Registered Nurse
TFDA	: Taiwan Food and Drug Administration
UAE	: United Arab Emirates
UHMS	: Undersea and Hyperbaric Medical Society

1. Introduction

- 1.1. Hyperbaric Oxygen Therapy (HBOT) is a treatment in which the patient is placed in a chamber and breathes near 100% oxygen (O₂) at higher than atmospheric pressure.
- 1.2. Hyperbaric chambers are classified according to occupancy as follows:
 - 1.2.1. Class A — Human, multiple occupancy (Multiplace Chamber)
 - 1.2.2. Class B — Human, single occupancy (Monoplace Chamber)
 - 1.2.3. Class C — Animal, no human occupancy
- 1.3. HBOT is indicated for the treatment of the following conditions:
 - 1.3.1. Air or gas embolism
 - 1.3.2. Carbon monoxide poisoning
 - 1.3.3. Gas gangrene
 - 1.3.4. Crush injury
 - 1.3.5. Decompression sickness
 - 1.3.6. Arterial insufficiencies
 - 1.3.7. Severe Anemia
 - 1.3.8. Intracranial abscess
 - 1.3.9. Necrotising soft tissue infections
 - 1.3.10. Osteomyelitis
 - 1.3.11. Radiation injury
 - 1.3.12. Compromised skin grafts and flaps
 - 1.3.13. Thermal burn injury
 - 1.3.14. Idiopathic sudden sensorineural hearing loss

Note: An official letter shall be submitted to Health Regulation Department (HRD) with justified evidence in case hyperbaric treatment is to be given to patients with other conditions, with evidence of approval from a recognised international body such as Food and Drug Administration (FDA).
- 1.4. Hyperbaric treatment is contraindicated in certain conditions that are mentioned in Appendix 1.
- 1.5. The HBOT service could be delivered in
 - 1.5.1. Hospitals
 - 1.5.2. Day surgical centers

1.5.3. Outpatient facilities that includes at least one (1) of the following specialities:

- 1.5.3.1. Undersea and Hyperbaric Oxygen Medicine
- 1.5.3.2. Family Medicine
- 1.5.3.3. General Surgery
- 1.5.3.4. Internal Medicine
- 1.5.3.5. Occupational Medicine
- 1.5.3.6. Plastic Surgery
- 1.5.3.7. Pulmonology

2. Licensure requirements

2.1. To obtain the initial approval the applicant shall

2.1.1. Submit an application to the Health Regulation Department (HRD) through *SHERYAN*; the online licensing system which can be accessed from the DHA website www.dha.gov.ae .

2.1.2. Upon receipt of a completed electronic application, HRD will perform the following:

2.1.2.1. Verify accuracy and completeness of the information provided.

2.1.2.2. Review the design to ensure compliance with the DHA requirements.

2.1.2.3. Conduct on-site inspections.

2.1.3. HRD shall issue an initial approval letter for the HBOT service with defined services/ restrictions particular to the applicant's request.

2.1.4. In case of rejection of the application a detailed list of issues will be provided for corrective action and the applicant is required to re-submit the application.

Note: For further details regarding the application form, ownership, licensure procedures, application fee and re-submission fee please visit DHA website www.dha.gov.ae.

2.2. Final inspection and issuing the license

2.2.1. To obtain the DHA license, the applicant shall meet the following:

2.2.1.1. Employ a licensed physician in one of the specialities mention above who is licensed or certified in Undersea and Hyperbaric Oxygen Medicine, to be in-charge of the HBOT services.

- 2.2.1.2. Employ a sufficient number of certified and experienced DHA licensed healthcare professionals to provide hyperbaric services as per DHA requirements to satisfy the functional program of the facility and to meet patient needs.
- 2.2.1.3. Install and operate the equipment for provision of HBOT service in accordance with manufacturer specifications and DHA requirements.
- 2.2.1.4. The equipment used shall be approved by at least two (2) of the following international authorities:
 - 2.2.1.4.1. Food and Drug Administration (FDA)
 - 2.2.1.4.2. Health Canada
 - 2.2.1.4.3. Conformité Européenne (CE)
 - 2.2.1.4.4. Australian Register of Therapeutic Goods (ARTG)
 - 2.2.1.4.5. Ministry of Food and Drug Safety (MFDS) Korea
 - 2.2.1.4.6. Taiwan Food and Drug Administration (TFDA)
 - 2.2.1.4.7. Japans Ministry of International Trade and Industry (MITI)
- 2.2.1.5. The equipment shall be registered with the Ministry of Health (MOH) in the United Arab Emirates (UAE).
- 2.2.1.6. Provide documented policies and procedures, but not limited to the following:
 - 2.2.1.6.1. Informed Consent policy
 - 2.2.1.6.2. Patient health record/ Medical Record
 - 2.2.1.6.3. Infection control policy
 - 2.2.1.6.4. Fire safety and evacuation
 - 2.2.1.6.5. Patient safety manual
 - 2.2.1.6.6. Patient selection criteria
 - 2.2.1.6.7. Response to emergencies
 - 2.2.1.6.8. Treatment complications and treatment termination
 - 2.2.1.6.9. Staff documentation
 - 2.2.1.6.10. Incident Reporting
 - 2.2.1.6.11. Contraband Policy

- 2.2.1.7. These documents shall be read and signed off by all staff at the facility.
- 2.2.1.8. The facility shall maintain contracts with, but not limited to:
 - 2.2.1.8.1. Nearby hospital to accept patients in case of any complication or emergency
 - 2.2.1.8.2. Ambulance service
 - 2.2.1.8.3. Annual preventive maintenance of the HBOT chambers with the manufacturing company or an authorized dealer
- 2.2.1.9. In case of application rejection, a detailed list of issues shall be provided via the electronic system for corrective action.
- 2.2.1.10. Relocation of HBOT chamber to provide services shall be possible only with DHA approval.
- 2.2.1.11. The facility shall notify DHA if they plan to discontinue the HBOT service.
- 2.2.1.12. If the services provided by the facility pose an imminent risk to the safety of patients, community or healthcare professionals working in the facility, DHA may issue an order of suspension of the facility's services.

Note: For further details regarding the application form, ownership, licensure procedures, application fee and design re-submission fee please visit the DHA website www.dha.gov.ae.

3. Facility requirements

- 3.1. The HBOT facility shall not be located in a mall or an industrial area.
- 3.2. Class A (multiplace chambers) shall be used only in hospitals and research centres and shall be located on the ground floor.
- 3.3. Class B (Monoplace chambers) shall be used in approved health facilities as mentioned above.
- 3.4. Class C chambers shall not be used in health facilities.
- 3.5. A HBOT facility shall have an emergency exit with visible signs directing patients in case of an emergency.

- 3.6. There shall be patient education material provided to patients and their families at the reception in the form of print or videos, to educate them about the safety aspects of the treatment.
- 3.7. For general facility requirements the health facility providing HBOT shall abide with the Outpatient Facilities Regulation that can be found on www.dha.gov.ae.
- 3.8. The HBOT service area shall include but not limited to:
 - 3.8.1. Reception and waiting area
 - 3.8.2. Consultation/ Examination room
 - 3.8.3. Holding area for inpatients
 - 3.8.4. Patient changing facility
 - 3.8.5. HBOT treatment room
 - 3.8.6. Gas storage room
 - 3.8.7. Compressor room
 - 3.8.8. Gurney/ stretcher storage
 - 3.8.9. Clinical and non-clinical storage
 - 3.8.10. Clean and dirty utility
 - 3.8.11. Administrative activities area
- 3.9. HBOT treatment room shall:
 - 3.9.1. Conform to National Fire Protection Association (NFPA) 99, Chapter 14 and Dubai Civil Defence (DCD) requirements.
 - 3.9.2. Have an antistatic, impervious and washable flooring.
 - 3.9.3. Not have carpets or wooden flooring.
 - 3.9.4. Have fire proof, monolithic and joint free floor covering.
 - 3.9.5. Have an outside wall with window(s).
 - 3.9.6. Be adequately ventilated with a smoke evacuator.
 - 3.9.7. Have easy access for wheelchairs and washrooms.
 - 3.9.8. Be provided by approved sprinkler heads equipped with fusible and temperature elements that have ratings as low as possible.
 - 3.9.9. Have “No smoking” signs visibly displayed.
 - 3.9.10. Preferably provide a metal detector at the entrance of the HBOT treatment room to ensure that the patient do not carry any form of metal into the chamber.
- 3.10. Class A (Multiplace) treatment room requirements:

- 3.10.1. The facility housing a Class A chamber shall be designed not to obstruct egress of patients and staff.
 - 3.10.2. The rapid or emergency removal of a patients or healthcare professional from one chamber/compartment shall not restrict the orderly, rapid, and simultaneous removal of patients or healthcare professional from other chambers/compartment.
 - 3.10.3. Doorways of egress shall have a minimum opening of 86.36 centimeters.
 - 3.10.4. The direction of door swing shall be designed not to inhibit the removal of patients or healthcare professional from any chamber/compartment.
 - 3.10.5. A minimum of two (2) exits shall be provided for the treatment room unless a single exit opens directly to a primary evacuation route.
 - 3.10.6. The Class A chamber room should have a minimum clearance of 2.5 meters in front of a chamber entry door that is intended for gurney/stretchers access.
 - 3.10.7. Entries designed for wheelchairs or wheeled gurneys should have access ramps. A ramp should be a minimum width of 1.14 meters, a maximum of height of 0.75 meters, have a maximum slope of 1 in 12, and have handrails on both sides.
 - 3.10.8. These ramp specifications are not necessary if the slope of the ramp is no steeper than 1 in 20.
 - 3.10.9. There shall be a minimum of 0.9 meter clearance around any part of the chamber system that defines an exit pathway.
 - 3.10.10. If the chamber control console is immediately adjacent to the chamber, there should be a minimum clearance of 0.9 meter between the control console and any obstruction.
 - 3.10.11. There should be a minimum clearance of 0.6 meters in a pathway that allows access to valves used in chamber operation.
 - 3.10.12. There should be a minimum clearance of 0.6 meters in a pathway that allows access to areas of the chamber that require cleaning or maintenance.
 - 3.10.13. All material inside the chamber shall be fire resistant and HBOT environment compatible.
- 3.11. Class B (Monoplace) treatment room requirements:

- 3.11.1. The space required to house Class B chambers and supporting equipment shall not be less than eighteen (18) square meters to host one (1) monoplace hyperbaric chamber and patient-transfer gurney.
- 3.11.2. The facility housing a Class B chamber shall be designed not to obstruct egress of patients and staff.
- 3.11.3. In the case of multiple Class B chambers installed in a single setting, the rapid or emergency removal of a patient from one chamber shall not restrict in any way the rapid and simultaneous removal of patients from any other chambers.
- 3.11.4. Exit doorways of egress shall have a minimum opening of 86.4 centimeters.
- 3.11.5. There shall be a minimum clearance of 0.9 meters around any part of the chamber system that defines an exit pathway.
- 3.11.6. If the chamber control console is integrated into or immediately adjacent to the chamber, there shall be a minimum clearance of 0.9 meters between the control console and any obstruction.
- 3.11.7. There shall be a minimum clearance of 0.6 meters in a pathway that allows access to valves or controls used in chamber operation. If the chamber has a patient loading device, this clearance shall be maintained when the patient loading device is extended out of the chamber.
- 3.11.8. Any part of the chamber that must be accessed shall be at least 0.3 meters away from any obstruction, unless the chamber is fitted with casters.
- 3.11.9. There shall be an O₂ shut-off valve for each chamber that is accessible to the chamber operator.
- 3.11.10. Any electrical service outlets located within 3 (three) meters of the Class B chamber entrance shall be located no less than 0.9 meters above floor level.
- 3.11.11. Lighting over the Class B chamber shall be incandescent, preferably with dimmer control.
- 3.11.12. Fluorescent lighting installed in rooms housing Class B chambers shall not be located directly over the chambers.
- 3.11.13. If the room housing Class B chambers has windows, the chambers should be protected from direct exposure to sunlight.

- 3.11.14. There shall be screens between chambers to ensure patient privacy.
- 3.11.15. There shall be a 0.3 meters clearance at the foot of the chamber for unobstructed gas connection at the foot of the chamber.
- 3.12. Class B (Monoplace Chambers)
- 3.12.1. The chambers shall
- 3.12.1.1. Not be located in direct sunlight or close to a heat source.
- 3.12.1.2. Be easily accessible to the patient and staff.
- 3.12.1.3. Be free of cracks internally or externally.
- 3.12.1.4. Be free of corrosion, damage, dents, gouges or other damage internally and externally.
- 3.12.1.5. Have an atmosphere free of toxic or flammable gases.
- 3.12.1.6. Have alarms for low pressure gas monitoring panel which are tested and maintained routinely.
- 3.12.1.7. Be equipped with audible and visual alarms.
- 3.12.1.8. Have a warning sign displaying prohibited material inside the hyperbaric chamber, which can be posted at the chamber entrance *Appendix 2*.
- 3.12.1.9. Some chambers have masks available to provide an alternate breathing gas (such as air).
- 3.12.1.10. Acrylic windows shall carry certification such as a “U”/ a partial “U2” ASME stamp, with PVHO-1 or an equivalent certification.
- 3.12.1.11. Have a manual access for the operating controls for pressurization, depressurization, parameter condition monitoring and safety interlocking.
- 3.12.1.12. Have external exhaust termination with the pipe elbow facing down.
- 3.12.1.13. Have a dedicated vent line to release the O₂ after treatment.
- 3.12.1.14. Have earth grounding system with a regular documented maintenance.
- 3.12.1.15. Be grounded to a common building (pipe/steel) or true earth ground.

- 3.12.1.16. Recommended to have the resistance between the grounded chamber hull and electrical ground not exceeding one (1) Ohm (DO NOT use the building electrical panel or wall outlet ground to ground the chamber).
- 3.12.1.17. Have a quick release access door.
- 3.12.1.18. Have viewing ports if not completely transparent.
- 3.12.2. All openings leading from the chamber to external fittings or controls shall be free from obstruction.
- 3.13. Gas cylinder storage room shall
 - 3.13.1. Be large enough able to store enough (H) cylinders and manifolds for the reserve breathing gases required for chamber operations.
 - 3.13.2. Have a minimum of six (6) medical O₂ tanks for facilities with multiplace or monoplace chambers.
 - 3.13.3. Have a minimum of one (1) 400 liter liquid t O₂ tank with vaporizer.
 - 3.13.4. Be designed to comply with DCD and NFPA 99 requirements.
 - 3.13.5. Have explosion proof electrical fittings.
 - 3.13.6. Have an external exhaust ventilation provided outside the building area.
 - 3.13.7. Have an automatic gas manifold monitored by alarm.
 - 3.13.8. Maintain an alarm that monitors the high and low gas pressure. There shall be proper documentation of staff training in emergency procedures in the event of gas pressure release incident.
 - 3.13.9. Have a concrete or tiled flooring.
 - 3.13.10. Have a visibly displayed “No smoking” sign in this room.
 - 3.13.11. Provide a door to the room with door vents for O₂ to pass in case of leakage from cylinders.
 - 3.13.12. Provide access for a truck to refill the O₂ in case the facility uses liquid O₂ for the treatment.
- 3.14. The facility shall maintain the following medical equipment and supplies:
 - 3.14.1. Apparatus to measure blood pressure.
 - 3.14.2. Electrocardiographic monitoring equipment.
 - 3.14.3. Crush trolley equipped with resuscitation equipment and apparatus, medical O₂ and medications.
 - 3.14.4. Intravenous (IV) supplies such as syringes, needles, tape, etc.

- 3.15. HBOT equipment shall be regularly maintained and all necessary parts shall be changed as per equipment manufacturers' recommendation.
- 3.16. The facility shall maintain a record of HBOT chamber:
 - 3.16.1. Installation checklist
 - 3.16.2. Assessment checklist
 - 3.16.3. Operational checklist
 - 3.16.4. Cleaning checklist
 - 3.16.5. Maintenance log
 - 3.16.6. Log of use of the chamber

4. Service requirements

- 4.1. The physician in-charge of the HBOT services shall be a DHA licensed consultant/ specialist in Undersea and Hyperbaric Oxygen Medicine or one of the specialties mentioned above with a successful completion of HBOT training and a minimum of six (6) months experience.
- 4.2. The training shall comprise of two (2) months (not less than 240 hours) of practical clinical training, including assessment and management of clinical cases, supervision of routine hyperbaric treatment sessions and a requirement for consultation on complicated cases and must include a minimum of twenty (20) cases recorded and documented.
- 4.3. The physician in-charge of the HBOT services shall:
 - 4.3.1. Supervise the operations of the HBOT service.
 - 4.3.2. Be responsible for the overall medical care of the patient receiving the service.
 - 4.3.3. Be responsible for the quality assurance of the HBOT service.
 - 4.3.4. Be responsible for patients follow up after the hyperbaric treatment.
 - 4.3.5. Define the protocol, procedures for the treatment.
 - 4.3.6. Ensure healthcare workers in the facility are qualified to perform their duties and knowledgeable of the risks and hazards.
 - 4.3.7. Ensure policy and procedure manuals for the administration of the facility, the operation of equipment, and the management of patients are prepared, maintained and readily accessible to staff.

- 4.4. All healthcare professionals shall be trained in HBOT and have Basic Life support (BLS) and Advanced Cardiac Life Support (ACLS).
- 4.5. Valid certificate of Pediatric Advanced Life Support (PALS) when applicable.
- 4.6. All staff shall maintain their skills by training and continuous education, which shall be documented.
- 4.7. Staff working under pressure in the chambers must undergo an appropriate initial and periodic medical examination to be recognised as fit for hyperbaric exposures.
- 4.8. The HBOT treating physicians shall be responsible to:
 - 4.8.1. Assess the suitability and the fitness of the patient for HBOT
 - 4.8.2. Determine the risk benefit profile
 - 4.8.3. Interpret any related diagnostic testing
 - 4.8.4. Generate a therapeutic dosing profile
 - 4.8.5. Evaluate subsequent clinical course
 - 4.8.6. Manage any related side effects and complications (refer to *Appendix 3*)
 - 4.8.7. Be present at the premises and immediately available at all times that the chamber is occupied.
 - 4.8.8. Ensure the safe and ethical care of patients.
- 4.9. Chamber operating person
 - 4.9.1. Registered Nurses (RNs) with recognised training and adequate experience could be appointed as chamber operators.
 - 4.9.2. Since chamber operators are in charge of the operation of the multiplace or monoplace hyperbaric chamber(s), their presence is absolutely essential in all health facilities or self-standing centres providing HBOT services.
 - 4.9.3. The chamber shall be operated by a healthcare professional with minimum forty (40) hours recognised training to operate the HBOT chambers and an experience for at least six (6) months as hyperbaric technicians.
 - 4.9.4. There shall be one (1) chamber operator for every two (2) monoplace chambers during all working hours of the facility.
 - 4.9.5. There shall be two (2) chamber operators for every multiplace chamber during all working hours of the facility.

- 4.9.6. The chamber operating person shall be trained to safely implement prescribed therapy.
- 4.9.7. The chamber operating person shall be responsible to:
 - 4.9.7.1. Conduct a general check-up of the patient, including vital signs and the initial assessment and file this in the medical records.
 - 4.9.7.2. Maintain visual and audio contact with patient during their treatment.
 - 4.9.7.3. Notify the physician immediately in case a patient complains or shows signs suggesting an unanticipated change in status.
 - 4.9.7.4. Not carry out hyperbaric treatment without patient-specific hyperbaric physician signed medical orders.
- 4.9.8. The chamber operating person of a multiplace chamber must be qualified and trained to carry out the specialized chamber operations.
- 4.9.9. The multiplace chamber operator shall be responsible to:
 - 4.9.9.1. Operate the internal and external devices of the chamber in-between sessions.
 - 4.9.9.2. Control and operate the mechanisms for compression and decompression, and deliver gas mixtures and O₂.
 - 4.9.9.3. Control and application of the safety regulations concerning prevention of fire and O₂ toxicity.
 - 4.9.9.4. The Undersea and Hyperbaric physician shall calculate the decompression time and the chamber operator shall apply and control compression and decompression schedules for the patients. Specialists and/ or physicians, nurses and attendants, apply decompression stops, when necessary.
 - 4.9.9.5. Intervene inside the chamber under pressure, in order to control or check the correct operation of the pneumatic circuits or devices.
 - 4.9.9.6. Adapt, adjust and check the medical instruments carried by the patients before being introduced into the chamber, in order to assure their correct operation, and to avoid dangerous or undesirable effects.

- 4.9.9.7. Control and check the operation of auxiliary facilities of the chamber: air compressors, sources of compressed air or medical gases, air reserves, pneumatic circuits, control systems.
- 4.9.9.8. Maintain the facility by doing small repair jobs or technical interventions in case of problems which may occasionally occur, and which do not require the intervention of highly specialized technical staff.
- 4.10. Registered Nurse
- 4.10.1. The ratio of the RN to the physician shall be 1:1
- 4.10.2. The RN shall conduct the general check-up of the patient, such as vital signs, initial assessment etc. and document it in the health records.
- 4.10.3. The RN shall be trained and responsible for going through a checklist before placing the patient inside the chamber.
- 4.10.4. In case of a multiplace chamber the RN shall be present inside the multiplace chamber during treatment to monitor patients.
- 4.10.5. The nurse shall be exposed to a maximum of ninety (90) minutes of treatment time per day. In case of more time necessary inside the chamber, the RN must breathe oxygen according to the preplanned decompression table.
- 4.10.6. The time gap between two sessions shall be at least 12 hours.
- 4.10.7. The RN shall be responsible to manage any medical emergencies that may arise when the patient is in the facility.
- 4.11. Safety officer
- 4.11.1. Any healthcare worker employed in the HBOT facility could be nominated as the safety officer.
- 4.11.2. The safety officer shall undergo formal and comprehensive training in the safety aspects of hyperbaric medicine and related technology from National Examination Board in Occupational Safety and Health (NEBOSH) or Occupational Safety and Health Administration (OSHA).
- 4.11.3. The safety officer shall develop, maintain and manage a safety program based upon compliance with recognized standards, which shall

demonstrate effective elements of hazard mitigation, while employing recognized risk management concepts.

4.11.4. The safety officer shall be responsible for maintaining a daily, weekly and annual checklist of the HBOT chambers.

4.12. Fire Marshal

4.12.1. Any healthcare worker employed in the HBOT facility could be nominated as the fire marshal.

4.12.2. The facility shall ensure that these fire marshals are formally trained and at least one (1) fire marshal shall be present on the premises during working hours.

4.12.3. The fire marshal shall orient and train the staff on fire safety measures and response to fire events in the facility.

4.12.4. The training shall be documented and included in staff files.

4.12.5. Conduct and document fire evacuation drills at least 2-3 times a year.

5. Patient Care

5.1. The treating physician shall see first-time patients for a complete clinical and physical examination, and determine the treatment plan according to his/ her scope of practice.

5.2. In case treating critically ill or unstable patients, HBOT shall be carried out only in hospital setting and always with a hyperbaric physician inside the chamber.

5.3. Patient's health records shall be created and maintained in the facility according to the DHA Health Records guideline.

5.4. The consent form must be in English and Arabic, and can also be translated to the other languages that patient understands or familiar with.

5.5. Informed Consent form shall be obtained from the patient for the HBOT service. If the age of the patient is below eighteen (18) years, the parents or legal guardian shall fill and sign the consent form. The Informed Consent obtained shall be in accordance to the DHA Informed Consent Policy.

5.6. All patients, guardians of children or incapacitated patients must sign a consent form before the treatment.

5.7. The consent form shall contain the following but not limited to:

5.7.1. Organization name

5.7.2. Client name, age and gender

- 5.7.3. Treating therapist and supervisor name
- 5.7.4. Precautions (for details refer to *Appendix 4*)
- 5.7.5. Pre and post treatment management
- 5.7.6. Possible complications
- 5.7.7. Care regulation.
- 5.8. If a patient approaches a HBOT facility more than once for different medical conditions then a new informed consent shall be requested due to the change in medical condition and hence change in treatment plan.
Note: For further information regarding the consent form refer to the DHA Informed Consent Policy and Appendix 5.
- 5.9. Prior of HBOT treatment all patients shall:
 - 5.9.1. Avoid carbonated drinks or alcohol four (4) hours prior to the treatment.
 - 5.9.2. Have a shower to ensure that the patient is free of any makeup or other flammable lotions or balms.
 - 5.9.3. Wear cotton scrubs without pockets that are provided by the facility.
 - 5.9.4. Wear a grounding device.
- 5.10. After HBOT treatment all patients shall:
 - 5.10.1. Avoid flying
 - 5.10.2. Avoid climbing high altitudes more than 300 meters (note that the Burj Khalifa height is higher than the safety limit)
- 5.11. Inflatable chambers shall not be used in any health facility as they are NOT recognised medical devices for hyperbaric oxygen treatment by the FDA and no supporting clinical studies validate their effectiveness.

6. Fire Safety

The risk of fire is a major concern in the hyperbaric environment. The potential for accidental ignition of flammable materials is increased in the hyperbaric environment and their burning rate is markedly enhanced by a raised percentage or raised partial pressure of O₂.

- 6.1. The facility shall exclude flammable material or other sources of ignition from the treatment room by a rigorously enforced “Contraband Policy”.
- 6.2. Only 100% cotton or other hyperbaric compatible materials should be worn by patients when undergoing HBOT treatment.
- 6.3. All the linen used inside the hyperbaric chamber shall be 100% cotton.

- 6.4. The facility should comply DCD and NFPA 99 (chapter for HBOT) regarding fire safety standards.
- 6.5. There should be evacuation maps posted in the facility to indicate current locations marked with "You are here" to provide information regarding escape routes, fire exits and fire extinguishers.
- 6.6. All fire exit doors shall be unobstructed and in proper working condition with exit points marked correctly.
- 6.7. There shall be "No Smoking" signs visibly displayed all around the facility.
- 6.8. The facility shall establish a fire safety plan for early detection, confining, extinguishment, rescue, evacuation and alerting the DCD.
- 6.9. The facility shall maintain fire extinguishers, smoke alarms, sprinkler system and other fire protection equipment and devices as per the DCD requirements.
- 6.10. Fire extinguishers shall be properly and accessibly located. They must be fixed securely on the wall with safety pins fitted, seals intact, charged and current service record available.
- 6.11. The facility shall have trained staff as fire marshals and at least one (1) fire marshal shall be present on the premises during working hours.
- 6.12. Staff shall have fire and safety training to respond to fire events in the building. Orientation on the fire safety measures must be included in new staff induction program.
- 6.13. All staff shall be aware of the following:
 - 6.13.1. Location and use of fire hose reel/ cabinets/ blankets
 - 6.13.2. Assembly points
 - 6.13.3. Fire alarms/ call points break glass/ pull station
- 6.14. Fire evacuation drill should be conducted and documented at least two (2) times a year.
- 6.15. Fire in the facility buildings and evacuation procedures including removing patients from the chamber should be documented.
- 6.16. The installation of additional electrical equipment should be limited only for devices which comply with hyperbaric conditions.

Appendix (1) - Contraindications of HBOT – Absolute and Relative

Absolute Contraindications

Untreated pneumothorax - Surgical relief of the pneumothorax before the HBOT treatment, if possible, removes the obstacle to treatment.

Relative Contraindications-- “Conditions in which caution must sometimes be observed but which are not necessarily a contraindication to HBOT.” (Kindwall, 1995)

1. History of spontaneous pneumothorax
2. Severe sinus infection
3. Upper respiratory infection
4. Asymptomatic pulmonary lesions on chest x-ray
5. Uncontrollable high fever (greater than 39C)
6. History of chest or ear surgery
7. Congenital spherocytosis
8. Any anemia or blood disorder (Although HBOT treats different types of anemia.)
9. Any convulsive disorder (Although many patients have seizure disorder and are treated successfully with HBOT.)
10. History of optic neuritis or sudden blindness
11. Middle ear infection
12. Diabetes mellitus (insulin therapy) (Patients with diabetic wounds are treated successfully with HBOT.)
13. Pregnancy
14. Nicotine use/addiction
15. Acute Hypoglycemia (Many patients are treated successfully with HBOT.)
16. Emphysema with CO2 retention

Appendix (2) - Prohibited Materials in Hyperbaric Environment

The following items comprise a reasonably comprehensive listing of items and materials that should be either prohibited or severely limited inside the chamber. The letter(s) for each item indicates the general reason for prohibiting it, the coding is shown below.

1. C - possibility of damaging the fabric of the chamber
2. D - contamination of the environment
3. E - explosion risk
4. F - fire source (including static charges) or a combustible substance
5. L - could be broken or damaged by pressure
6. M - will possibly cause a mess
7. P - affects ability of diver

Listing of prohibited items in the HBOT chambers (in alphabetical order):

1. Adhesives (F)
2. Aerosols (D, E, F)
3. Aftershave (D, F)
4. Alcohol (D, F, P)
5. Batteries with unprotected leads (F)
6. Chemical cleaners, e.g.; trichloroethylene, 'Freon', etc. (D)
7. Cigarettes, cigars, tobacco of all kinds (F, M)
8. Cleansing powder (C, F, P)
9. Clothing, bedding included blankets, sheets, pillows, mattresses, etc. (F)
10. Drugs, non-prescribed (P)
11. Electrical equipment including tape recorders, radios, etc. (F)
12. Explosives (F)
13. Glass thermometers, including batteries containing mercury (C, D, P)
14. Ink pens (M)
15. Lighters, matches (F)
16. Newspaper (F)
17. Non-diving watches (L, M)
18. Petroleum based lubricants, grease, fluids (F)
19. Sugar and fine powders and other flammable food stuffs (E, F)
20. Thermos flasks (L, P)

More specifically items strictly excluded from the chamber include but not limited to:

1. Shoes/stockings (cotton socks permitted)
2. All flammable fabrics (wool, synthetics, bedding)
3. Street clothing, including undergarments made of wool, nylon, silk or satin
4. Bras with metal under-wiring
5. Any static-producing material (Velcro)
6. Oils and grease (make-up, lipstick, hair preparations, sunscreen, skin lotion)
7. Hairspray/gel
8. Nail polish
9. Perfume/cologne
10. Jewellery (all must be removed or covered with white tape)
11. Chewing gum
12. Dentures
13. Metallic objects (bobby pins, hair clips, car keys)
14. Batteries/battery-powered equipment (headphones, watches, hearing aids)
15. Electronics/MP3 players
16. Phones/pagers
17. Medications
18. Newspapers/magazines
19. Coins/money
20. Petroleum-based dressing (Vaseline gauze)
21. Alcohol-based applications
22. Hand warmers/transdermal heat patches
23. Cigarettes
24. Matches/lighters
25. Sharp toys
26. Unnecessary items

Appendix (3) - Side Effects of HBOT

Possible symptoms or side effects after HBOT can include fatigue and lightheadedness. More serious complications can include:

1. Damage to the lungs
2. Rupturing of the middle ear
3. Damage to the sinuses
4. Changes in vision, causing nearsightedness, or myopia
5. Oxygen toxicity, which can cause lung failure, fluid in the lungs, or seizures

Appendix (4) - HBOT Cautions

Hyperbaric oxygen therapy is not safe for everyone. In general, you shouldn't receive HBOT if you:

1. Have a pacemaker
2. Are pregnant
3. Have certain types of lung diseases, because of an increased risk for a collapsed lung
4. Take certain chemotherapy drugs
5. Have a collapsed lung
6. Take the drug disulfiram (Antabuse)
7. Use the topical cream sulfamylon
8. Have heart failure; HBOT can make symptoms worse
9. Have a cold or a fever
10. Are claustrophobic

Appendix (5) - Sample- Informed Consent Form for Hyperbaric Oxygen Therapy

I, do hereby authorize
.....and its trained staff to treat me with
hyperbaric oxygen and to render such other supportive or additional care that their
professional judgment may dictate during the course of the above treatment.
The protocols and procedures for Hyperbaric Oxygen Therapy (HBOT) and the adjunctive
treatments have been explained to me by the staff.

I have been provided with an orientation to HBOT which has included (but was not limited
to) indications, contraindications, risks and side effects, benefits, safety, equalization
techniques, patient rights, flying after treatment, use of tobacco and HBOT and a chamber
and facility overview.

I have been made aware of the possible risks and side effects of HBOT including but not
limited to:
Barotrauma in the ears sinuses or teeth, Pulmonary Barotrauma, Oxygen Toxicity, Fire risks,
Risk of near-sightedness, Maturing or ripening cataracts, Temporary improvement in far-
sightedness, Numb Fingers, Serious Otitis, Fatigue, Decompression Illness, Gas Embolism.

I have been given an opportunity to obtain further information and to ask questions about
HBOT, and I understand that I can ask questions or stop treatment at any time.

I consent to.....collecting and
keeping information about my health for the purpose of making sure that I receive
appropriate care and treatment, and for associated administrative tasks. I understand that my
health information will be securely stored and that I am entitled to request access to and
correction of my health information. I agree to provide all information about me voluntarily.

I am aware that the practice of medicine and surgery is not an exact science and that I have
been made no guarantees as to the results of hyperbaric oxygen therapy.

My signature below constitutes my acknowledgement (1) that I have read and agreed to the
foregoing, (2) that HBOT has been satisfactorily explained to me and that I have all the
information I desire, and (3) that I hereby give my authorization and consent to the use of
HBOT on myself.

Name of patient: Signature of Patient:

And/or Authorized Representative:

*I confirm that I am the authorized representative legally entitled to sign this Consent for
Hyperbaric Oxygen Treatment on behalf of..... I have read and
understood the Patient Orientation Handbook and this Consent and I confirm the matters
contained in this Consent and I consent to the treatment of*

Representative Name:

Witness signature: Date:

Witness Name: Time:

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