Organization, operation and safety: the European Code of Good Practice
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Introduction

For a long time, pressurized chambers were used to treat divers and compressed-air workers suffering from decompression illness. Such treatment was applied on-site in chambers routinely used only for decompression lacking any support for medical procedures. Increasing usage of Hyperbaric Oxygen Therapy (HBO) and expanding of indications also to critically ill patients have been a challenge for modern hyperbaric centres. In this chapter the general design of hyperbaric centres is presented including hyperbaric chambers with supporting equipment, staff team, operating and emergency procedures, codes of good practice and quality assurance. The main interest will be placed on the functional organization of the hyperbaric centres, and only recent documents on the European level will be referenced. All readers interested in standards, regulations and other documents on the national level from different countries should review some classic literature (1,2,3). To avoid any misunderstanding of terms used to describe different hyperbaric structures and functional items the definitions presented in a European Code of Good Practice for Hyperbaric Oxygen Therapy (May 2004, updated 2016) will be used (4). The general structure of different levels of hyperbaric centres and its relation with other medical services (intensive care unit, emergency department, etc) is summarized on the Fig. 1.

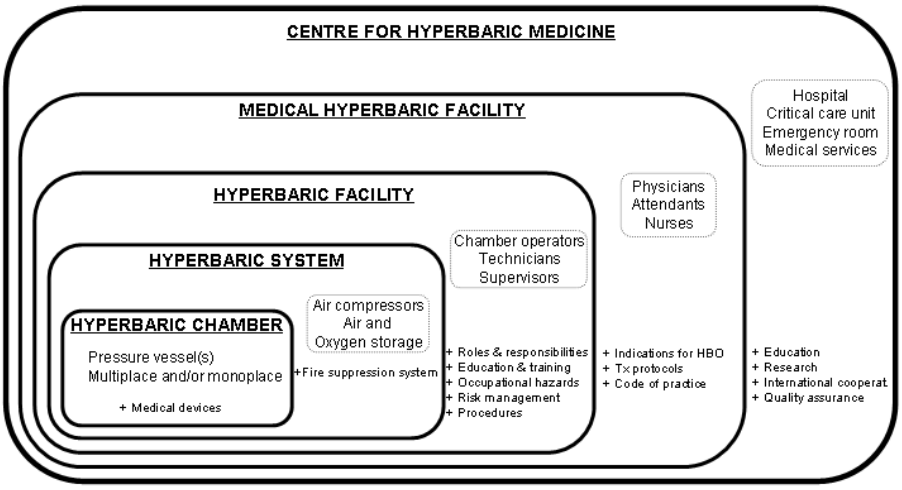

Figure 1. General structure of the centre for hyperbaric medicine (based on figure from the European Code of Good Practice for Hyperbaric Oxygen Therapy [4], modified).

Hyperbaric chambers

The very basic device used in any hyperbaric facility is the hyperbaric chamber. Since 1998 according to the European Council Directive 93/42 concerning medical devices (14 June 1993), the hyperbaric chamber has to be treated as medical device with all consequences (5). There are numbers of different chambers used nowadays and their structure and installed equipment define the capability of the centre to treat a particular patient. The most important feature is the possibility of attending the patient under pressure, therefore the type of the chamber used in the centre (monoplace or multiplace) defines its overall capability. It is important to remember that the main aspects on education of the staff, safety procedures, and required medical controls, must be equally applied to hyperbaric facilities using either monoplace or multiplace chambers, since medical conditions, therapeutical principles, and essential safety requirements are the same. Only some technical aspects on design, maintenance, and operation practice can vary when using a monoplace or a multiplace hyperbaric chamber. Until now in Europe there is no harmonized regulation for manufacturing of monoplace chambers. On the other site, there is the European Norm EN14931 “Pressure vessels for human occupancy (PVHO) – Multi-

place pressure chambers for hyperbaric therapy – Performance, safety requirements and testing" (6), which normalizes the production of multiplace chambers on the European level.

The design of hyperbaric chamber should include also individual breathing systems, for example free flow systems, demand valves and mechanical ventilators, as well as monitoring devices being permanently fixed inside the chamber. Other medical devices which are introduced into the chamber with the patient (pumps, syringes, pacemakers, transportable monitors, etc) are not treated as a part of the hyperbaric installation. Nevertheless, they should be certified by its manufacturer for hyperbaric conditions. If there is a necessity for pressurisation of a device not certified for hyperbaric environment, it is the responsibility of the user to perform checking of its compatibility with such conditions (7-12).

Hyperbaric system

The term "hyperbaric system" covers not only hyperbaric chambers, but also air and oxygen storage, air compressors, pipelines, control consoles, communication systems, electrical systems with emergency power supplies and fire suppression system dedicated for hyperbaric conditions. The requirements presented in the EN14931 cover the whole system, but only in minimum options for using air and oxygen for treatment. If hyperbaric centre needs to expand its capability to use breathing mixtures other that air and oxygen, ~~the~~ reference to diving standards and regulations is necessary. All supporting systems for the hyperbaric chambers should be designed with the capacity allowing for backups. This is important mainly for gas storages and electrical power supplies. Design of hyperbaric systems also covers ~~also~~ the operating manual with maintenance program included.

Fire suppression systems and fire prevention

The special attention in design of the hyperbaric facility is dedicated also for fire prevention and protection, as fire is recognised as the~~a~~ single most hazardous factor leading to fatal disaster during hyperbaric sessions (13,14). The basic requirements for fire suppression systems as a part of a hyperbaric system are defined in the EN14931 (6). Those general requirements have been expanded in the norm EN16081 "Hyperbaric chambers. Specific requirements for fire extinguishing systems. Performance, installation and testing" (15). Regardless of the fire fighting system for hyperbaric chambers, the equally important problem is protection against and prevention of fire outside the chamber, in its proximity. Such event is a potential serious hazard for chamber~~'s~~ occupants, as there is a possibility that the chamber operator will be unable to safely finish the session due to direct danger to his health, or the evacuation of the chamber occupants through the zone of fire and smoke outside the chamber presents the risk of burning or carbon monoxide intoxication. Therefore, design of the hyperbaric systems should also cover ~~also~~ fire fighting systems inside and outside the hyperbaric chamber as well as maintenance program, frequent checking of the system and regular training of the personnel in its usage.

Hyperbaric facility

To operate the hyperbaric system and to convert it to a fully operational hyperbaric facility there is a need to have qualified technical personnel, including chamber operators, technicians and supervisors. Furthermore, treatment of patients needs medical personnel (physicians, nurses, attendants) and only the~~a~~n can one ~~can~~ have a medical hyperbaric facility. Details on education and responsibility are presented elsewhere in this document and here only the minimum team size needed for conducting an HBO session is discussed.

Personnel

~~As d~~Depending on types of hyperbaric chambers used, type of patients treated in the facility and system of work (continuous system versus system with predefined working hours and on-call stand-by) different functions are involved and therefore a different number of personnel is needed to keep the facility working.

During the session in the monoplace chamber the minimum team of staff consists only of hyperbaric physician to supervise the treatment and for emergency assistance (if needed) and

hyperbaric operator to control the session (4). It means that the hyperbaric session can be effectively conducted by only two persons. On the other hand, due to relatively small dimensions of such chambers there is a possibility to install more thant one chamber in the room. The open question is whether a small team consisted of only two persons can operate safely more than one monoplace chamber at the same time. In centres where there are monoplace chambers installed, one operator can sometimes serve for several chambers. Such practice depends on the status of patients and the needed level of supervision needed. In every case the decision should be left for to the medical supervisor with overall responsibility, however the logical restriction is that the maximum ratio should not be higher that than 3 chambers per one operator and that all chambers controlled by one operator need to be located in the same room (Table 1) (16).

During the session in the multiplace chamber the minimum team size consists of hyperbaric physician for supervision of the treatment, a medical attendant for taking care of patients inside the chamber (under the pressure) and an operator to control the session from outside (4). Because the size of multiplace chambers differs from 2 to even 30 patients, the actual number of medical attendants inside the chamber can be higher that one. Generally, one attendant can take care preferable of not more than 6 patients, and at last of 12 chronic patients which are familiar with the hyperbaric environment. There is a need for increasing the number of attendants if there are more patients for the first time under pressure or there are patients who need special attention (child, handicapped, mentally retarded) or the hyperbaric system consists of several chambers with some restriction of smooth movement of the internal personnel (Table 1) (16).

Table 1. Required number of personnel (chamber operators, internal medical attendants and hyperbaric physicians) for hyperbaric sessions (16).

Type of chamber	Staff requirement	Patient condition		
		Stable	Demanding	Critically ill
Monoplace	Chamber operators per chambers	1:3	1:2	1:1
	Hyperbaric physician per facility	1	1	1
Multiplace	Chamber operators per chambers	1:1	1:1	1:1
	Internal attendants per patients	1:12	1:5	1:1 or 2:1
	Hyperbaric physician per facility	1	1	1 or 2

The open question is whether the medical attendant should stay under pressure for the whole session (16). In most of European centres with multiplace chambers there is an obligation for the medical attendant to stay under pressure for the whole session. However, in some countries it is possible that in some circumstances the medical attendant can leave patients under pressure alone. For example, if a chronic patient who can take care on himself is familiar with the procedures (it is not his first time inside the chamber), he can be left during the plateau phase with the medical attendant staying outside the chamber ready for immediate access to inside if needed. The exact location of the individual members of the minimum team is the responsibility of either the duty physician or duty supervisor, however the whole nominated team should remain in the facility and immediately available including the possibility of the need to give immediate assistance under pressure (4).

Actual team size which is needed to keep the medical hyperbaric facility working depends on several factors:

– System of work: 24 hours / 7 days a week vs predefined working hours with or without on-calls
– Type of patients treated: emergency patients / intensive care patients / chronic patients / injured divers

– Type of chambers used: monoplace / multiplace, number of seats
– Type of sessions conducted: recompression / non-recompression schedules, time / pressure / breathing mixtures
– Multi-role abilities of the available staff
– System maintenance: self-conducted vs contracted ~~by~~ to third parties.

The organisation of the hyperbaric facility should include clear definitions of all skills involved in the treatment process (physicians, nurses, supervisors, attendants, chamber operators, technicians and others) and clearly defined functions and responsibilities are mandatory. For all members of staff there is a need for ensuring the initial background, education and training in the field of hyperbaric medicine, as well as planning of refreshment courses and continuous education. Those aspects are described in detail~~s~~ elsewhere in the document.

Occupational hazards

The pressuri~~s~~ze~~d~~ environment by itself, as well as medical devices, including hyperbaric chambers, used in the hyperbaric treatment introduces additional risks for patient, personnel and third parties present in the facility. It is especially important when there is an exposure to the pressurised environment by medical attendants resulting in occupational hazard similar to professional diving. This implies that the hyperbaric facility should develop for its personnel the a system of appropriate medical examination, prevention of decompression illness, and reporting of any work related negative consequences (17). In order to cooperate in prevention and reporting of pressure related health problems, all personnel need to be adequately trained in recognisionn~~g~~ of signs and symptoms of decompression illness. Also procedures for recompression of an ill person need to be prepared in advance ~~al~~together with adequate gas volume to conduct the recompression schedule. Facilities must adopt a set of published decompression procedures in order to reduce to a minimum the risks associated with single and repeated exposures. They may include additional safety considerations to the standard procedures. Procedures should consider the limits of repeated exposures (pressure, duration and surface interval) per person within a 24-hour period and the number of daily exposures without a break. To further decrease the incidence~~t~~ rate of decompression illness of hyperbaric staff either using nitrox for exposure (18) or an oxygen decompression (17) is recommended. Some centres further decrease the risk of decompression illness by avoiding decompression obligation of medical attendants using the system of exchange of the inside attendants according to no-decompression limits (19).

Risk management process

To minimize all risks that can affect patients, staff or the third parties, the risk management process is necessary and it should cover any activity within the hyperbaric facility. The risk management process should be documented and should include risk analysis, risk evaluation and risk control (20). Parts of the risk management process are generic for all medical facilities allowing partial usage of solutions from other facilities. On the other ~~site~~hand, some hazards are specific for hyperbaric medicine and strongly depend on its specialized equipment. Therefore, those parts should be prepared for each individual hyperbaric facility ~~by themselves~~. As a basis, the basic reference should be used (21). One of the results of such process is a collection of operating procedures – standard and emergency – which describe in detail~~s~~ the working practices for all anticipated activities within the facility. Those procedures should be included in the operating manual of the facility at the design time; they should be reviewed periodically and updated as appropriate (4).

Clinical indications and contraindications for HBO

Every HBO centre should prepare the list of clinical indications being treated there. There are some good examples of such lists based on Evidence Based Medicine, prepared by world-wide known organisations, including ECHM (22) or UHMS (23). For different reasons, the accepted list of clinical indications treated in the centre can be adapted with some modifications. In every such situation a careful evaluation of a risk/benefit ratio should be performed and it is strongly advised that for such

indications the good quality research protocols are put in place to assure and reinforce the credibility of hyperbaric oxygen therapy (24). The list of absolute (if any) and relative contraindications for using HBOT in a specific centre, for example due to technical restrictions or staff limits, should be prepared.

Treatment protocols

Like other medical services, the hyperbaric facilities shall operate according to ethical principles using the best knowledge and accepted or well documented medical protocols.

Medical protocols for HBO therapy should include:

– Type of sessions: pressure, time, breathing mixtures (if different from 100% oxygen), air breaks
– Intervals between sessions and total number of sessions
– Concomitant treatment (antibiotics, dressing changesing, surgical procedures, others if appropriate).

The optimal conditions for a standard HBO session have not yet been defined, but it is generally accepted that in order to be clinically effective the HBO treatment should be done under pressure of at least 2 ATA and it should last at least 60 minutes (25).

Safety

A safety policy must be prepared in every hyperbaric centre (4). In most cases the medical director of the hyperbaric facility is responsible for all functions developed in the hyperbaric facility but usually he appoints a safety manager as a person directly responsible for preparation of a safety policy. The implementation of this policy aeffects the whole team taking care of the patients or operating the hyperbaric systems. The crucial role of any safety program is education, training and the compliance of personnel. A periodical retraining of in the Standard Operating Procedures and Emergency Procedures should be instituted for every member of the team. Also patients need to be informed about the safety aspects before starting a hyperbaric treatment; and informed consent for treatment should include a statement about all safety precautions.

All facilities should develop some form of documented incident and accident reporting procedure, where incident is defined as an event that occurs which does not result in loss but may have involved an unsafe condition or unsafe act and accident is a sudden, unplanned, often violent event that causes loss.

Itf would be desirable to have a European system for incident monitoring related with hyperbaric exposures, similarly to the one that is operational working in Australia since 1996 – the Hyperbaric Incident Monitoring Study (HIMS) (26), which would give a valuable tool for improving the quality of care for hyperbaric patients.

Code of practice

Codes offer best practice being prepared and agreed by international groups of experts. In 2004 a European Code of Good Practice for Hyperbaric Oxygen Therapy was published by the members of COST Action B14 (4). This document covers staffing (responsibilities, competencies and education, minimum team size during HBO sessions, fitness and health surveillance), equipment and gas supply, risk management and procedures (standard, emergency, maintenance and record keeping). The updated version of the Code is being prepared to be published in 2016.

Centre for hyperbaric medicine

A centre for hyperbaric medicine is a medical facility that provides HBO for patients and additional treatments, surveillance and attention to the medical conditions of the patient. The design of the centre for hyperbaric medicine should cover also the links to other medical services, including emergency and operational rooms, consultants in different specialities, landing places for air evacuation, etc.

Categorisation of hyperbaric chambers, facilities and centres

The categorisation of hyperbaric facilities is mainly done according to the type of hyperbaric chambers installed as well as overall capability to treat emergency and intensive care patients.

According to the NFPA 99 (27) there are three categories of hyperbaric chambers:

- Class A chamber – a chamber used for multiple human occupancy (multiplace).
- Class B chamber – a chamber used for single human occupancy (monoplace).
- Class C chamber – a chamber used for animals, not human occupancy.

The British Hyperbaric Association defines four categories of hyperbaric chambers (28), which in fact are categories of hyperbaric facilities:

- Category 1 (multiplace) chambers – comprehensive hyperbaric facilities capable of supporting the treatment of patients who are critically ill, from any cause, and who may require hyperbaric intensive care.
- Category 2 (multiplace) chamber – facilities capable of receiving elective or emergency referrals for any accepted application of hyperbaric oxygen therapy, but excluding patients who are critically ill at the time of referral or are considered likely to become so.
- Category 3 (multiplace) chamber – facilities without some of the capabilities of categories 1 or 2, which are sited specifically to support diving projects (either commercial or recreational) and work in compressed air. These facilities should also be capable of providing elective treatment of residual symptoms of decompression illness.
- Category 4 (monoplace) chambers – facilities operating at relatively low pressure and without an air-lock capability. These facilities should be capable of receiving elective and emergency referrals of patients in any diagnostic category where the responsible doctor supervising the treatment judges that a requirement to have access to the patient during hyperbaric session is unlikely.

In the European Code of Good Practice for HBO Therapy (4) there are enlisted two types of hyperbaric facilities as depending on their relation to the hospital services:

- Hospital based facility which is a facility physically located on the hospital area.
- Standalone facility which can be distant from the hospital, however still there should be functional link to hospital services, like emergency, diagnostics and general medical support and the system of communication and transportation shall be defined in advance.

Quality assurance

The level of reference and quality of services should be subjected for independent survey in order for hyperbaric patients to be assured that the highest quality medical care is available to them, regardless of the facility's affiliation. This aim can be accomplished either by certification, which is a process by which an independent party (certification body) confirms by written notification that a product, process or service meets predetermined requirements (i.e. ISO 9000, MDD 93/42/EEC) or accreditation, which is a process by which an association or agency (accreditation body) grants public recognition to facility or centre that has met certain established qualifications or standards (i.e. UHMS, European College of Baromedicine).

Summary

The design of the modern hyperbaric centre should cover all aspects of structure, organization and functioning of the hyperbaric medical facility for treatment, education and research in the international network of hyperbaric institutions and organisations. This is done on the basis of European norms and standards for hyperbaric medical chambers and systems. However, in some particular points where there is a lack of existing regulations, it relies on codes of good practice as well as clinical experience with the hyperbaric environment. In all cases, as the minimum, the European hyperbaric facility shall comply with the European Code of Good Practice and the ECHM list of clinical indications for Hyperbaric Oxygen Therapy as the basis for accreditation process and national reimbursement policy.

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