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A EUROPEAN CODE OF GOOD PRACTICE FOR HYPERBARIC OXYGEN THERAPY

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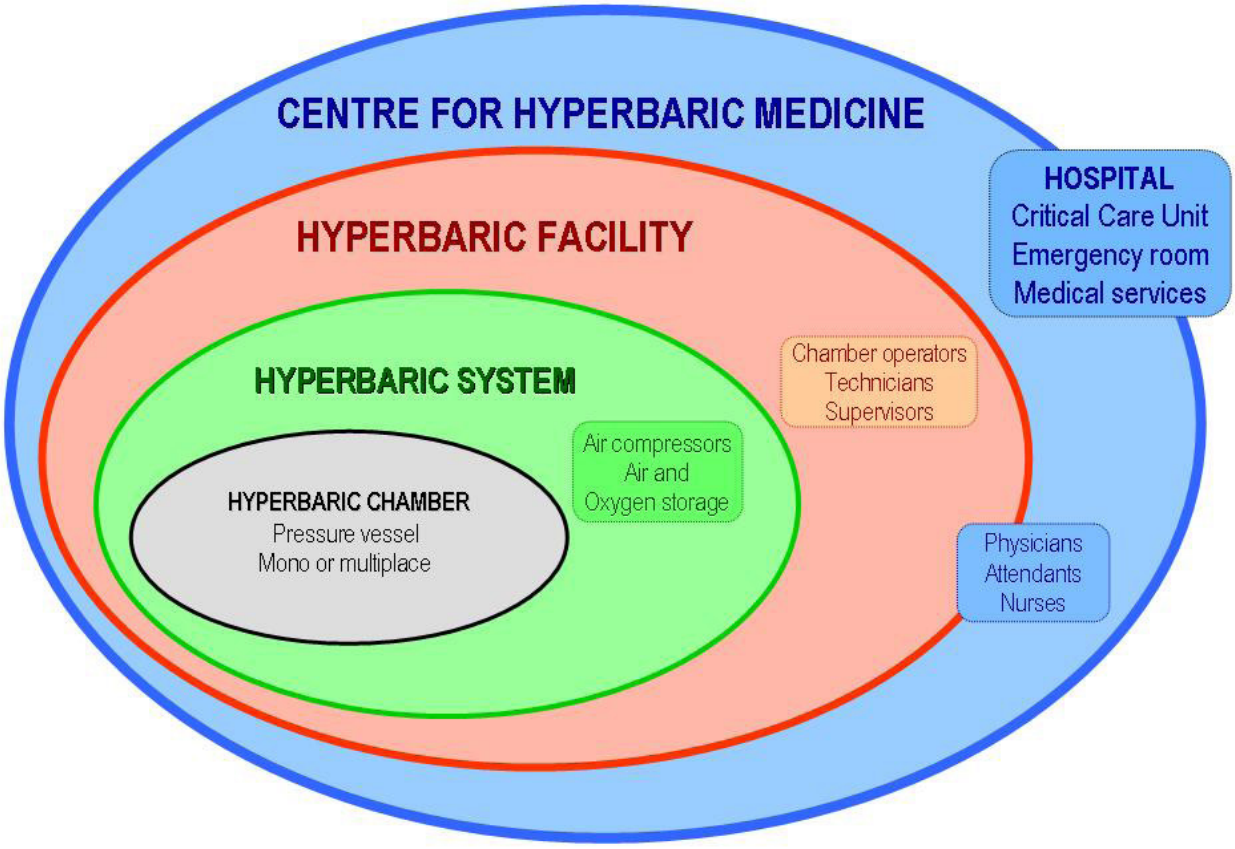

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of the COST Action B14 «HYPERBARIC OXYGEN THERAPY»
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LIST OF AUTHORS

Jacek Kot, Secretary (Poland), Jordi Desola (Spain), Folke Lind (Sweden), Peter Mueller (Switzerland), Erik Jansen (Denmark), Francois Burman (South Africa)

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The ECHM would like to thank all physicians from European hyperbaric facilities for their constructive comments to the old version of the Code, international experts for their excellent input and all parties for their assistance in the production of this document and refer you to the References for the complete list of documents that were considered when drawing up this publication.

This version of the Code is an update of the first edition of the document (published May 2004). The original 2004 edition was prepared by the Working Group "*SAFETY*" of the COST Action B14 "*HYPERBARIC OXYGEN THERAPY*" by Jacek Kot, Secretary (Polland), Jordi Desola (Spain), Antonio Gata Simao (Portugal), Roly Gough- Allen (United Kingdom), Robert Houman (Belguim), Jean-Louis Meliet / Francois Galland (France), Christian Mortensen (Denmark), Peter Mueller (Denmark), Seppo Sipinen (Finland) and approved by the ECHM Board of Representatives. The current review was approved by the ECHM Board of Representatives and endorsed by the EUBS.

The following major modifications have been introduced in the current version:

» The new job of the Safety Manager has been added to the list of hyperbaric facility staff.
» Functions for hyperbaric facility staff have been described in the main text. The specific requirements for their background as well as for initial and continuous education has been left in external, referenced documents.
» The system for classification of hyperbaric chambers, hyperbaric systems and hyperbaric facilities has been introduced.
» The number of chambers, which can be operated simultaneously by one chamber operator, and the number of patients, which can attend inside the hyperbaric multiplace chamber, depending on the patients' clinical status, have been added.
» Description of clinical indications and contraindications have been added to the main text.
» Three Annexes (1 - ECHM Educational and Training Standards for the Staff of Hyperbaric Medical Centres dated 1997; 2 – ECHM Recommendations for Safety in Multiplace Medical Hyperbaric Chambers dated 1998; 3 – on COST-B14 Working Group <Technical Aspects> Final Report dated 2001) have been removed from the main text (but referenced externally), with all their major conclusions being kept in the Code.
» The Risk Assessment for installation of the monoplace chamber has been added as an Annex 5. This Annex has been prepared by Francois Burman within his extensive and long-lasting cooperation with ECHM.

Corresponding author: *Prof. Jacek Kot, MD, PhD, ECHM President, National Centre for Hyperbaric Medicine, Institute of Maritime and Tropical Medicine in Gdynia, Medical University of Gdansk, Powstania Styczniowego 9B, 81-519 Gdynia, Poland*
Telephone: *+48 58 6225163*
Fax: *+48 58 6222789*
Email: *jacek.kot@gumed.edu.pl*

1. Introduction

The main goal of this document is to present a European Code describing the minimum of requirements for operation of any medical centre serving hyperbaric therapies. This code has been compiled based on the existing experiences of experts from hyperbaric centres, committees, professional and scientific associations.

This code does not replace any national regulations, but it is intended to be a reference document for European countries to provide Guidelines, Regulations, and Standards **in all fields** of hyperbaric medicine.

It relates to hyperbaric treatment as a procedure affecting patients, staff and any third parties involved in the therapeutic process but not to the medical treatment protocols unless they could affect the level of safety.

This document was written by members of the ECHM Editorial Task Force and was reviewed and approved by the ECHM Management Committee.

This European Code of Good Practice applies to all medical facilities using hyperbaric chambers, either for a single person (monoplace) or for several patients simultaneously (multiplace), for therapeutic and/or research purposes, as well as other accepted medical procedures.

It does not relate to manufacturing aspects and design requirements for hyperbaric systems and other medical devices used in hyperbaric treatments as they are, or will be, covered by dedicated European Norms of their own.

The main aspects on education of the staff, safety procedures, and required medical controls, must be applied equally to hyperbaric facilities using either monoplace or multiplace chambers, since medical conditions, therapeutic 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. While there are many documents and standards referring to the risk assessment of multiplace chamber facilities, including previous version of this code (see also references), until now there is no European regulation for monoplace chambers. Therefore, the specific requirements for monoplace chambers have been described and detailed in the Annex 5.

2. Definitions and classification

The following terms and definitions are used in this code:

Hyperbaric Therapies are methods used to treat diseases or injuries using pressure higher than local atmospheric pressure inside a hyperbaric chamber.

Within hyperbaric therapies:

Hyperbaric Oxygenation (HBO) is a form of therapy directed to significantly increase the partial pressure of oxygen in the blood and in the tissues of the patients to the levels significantly exceeding those achieved in normobaric conditions.

Hyperbaric Oxygen Therapy (HBOT) consists of breathing oxygen at a pressure higher than local atmospheric pressure for the treatment or prevention of specific diseases. There is a general consensus that the term HBOT can only be applied when the partial pressure of oxygen in breathing mixture exceeds 1.5 absolute atmosphere (ATA) for a minimum period of 60 minutes (excluding compression and decompression.

The actual exposure pressure, the oxygen partial pressure, and the duration of each treatment session should be according to the state-of-art.

HBOT is thus defined by all three essential elements:

- breathing oxygen
- increased ambient pressure
- a hyperbaric chamber, either mono or multiplace

A **Hyperbaric Therapeutic Chamber** (**HTC**) is a pressure vessel capable of accommodating one or more persons with the purpose of providing medical treatment. Two kinds of therapeutic chambers exist:

- ***Multiplace*** chambers have two or more compartments and allow access of staff/patients and equipment while maintaining pressure in the main compartment. They are intended to hold two or more persons including the attendant.
- ***Monoplace*** chambers are single compartment vessels primarily designed for only one patient. They do not allow direct access to the patient during the treatment.

A **Hyperbaric Chamber System** (**HCS**) consists of the Hyperbaric Therapeutic Chamber(s) plus the support equipment (gas and energy supplies, air compressors, gas storage devices, valves, instrumentation and monitors, and fire deluge systems amongst other equipment). A HCS is currently defined as a medical device under the European directive 93-42-EEC.

A **Hyperbaric Facility** (**HF**) consists of the Hyperbaric Chamber System(s) together with associated facility plant, buildings, staff (both technical and medical), and the specific administrative organisation. Two kinds of Hyperbaric Facilities exist, viz. ***hospital based*** and ***standalone facilities***. However, in each hyperbaric facility there should be an area adequately equipped to receive and to take care of any relevant medical emergencies.

A **Centre for Hyperbaric Medicine** (**CHM**) is a medical Hyperbaric Facility that provides HBO and additional treatments for patients, including surveillance and attention to their medical conditions. The CHM must be physically located in or functionally linked to a hospital. Centres should be categorised according to their capability to treat patients that require critical care.

A **Hyperbaric Session** (**HS**) is a period of increased pressure within a HTC, for therapeutic purposes. It includes applications breathing oxygen, air, or other breathable mixtures.

A **Hyperbaric Treatment** (**HT**) consists of the total number (one or more) of hyperbaric sessions as prescribed.

A **patient** is any person suffering from a medical condition, who may occupy an HTC for the purposes of a HT with the intended purpose of altering the natural course of their illness. This definition also applies to persons who receive prophylactic hyperbaric oxygen, or to those who act as control subjects in trials for hyperbaric therapies.

A **third party** means every other person in the vicinity of the facility not necessarily involved in the hyperbaric treatment (e.g., patient's family, transport staff, or others.).

A **breathable gas** means any single gas or gas mixture administered to the occupants of the hyperbaric chamber at a specific pressure.

A **standard operating procedure** describes the previously detailed working practice for all normal activities within the HTF.

An **emergency operating procedure** describes the behaviour of the staff in response to unusual but necessary operational conditions or during any foreseeable unplanned or unexpected situations.

A **medical device** is any item or equipment required for the treatment of patients but not for the operation of the chamber, which is itself a medical device.

Internal equipment is a part or element of the hyperbaric chamber system.

2a. [NEW] Classification

Hyperbaric chamber can be classified according to the number of occupants as:

- monoplace
- and multiplace

Hyperbaric system can be classified according to its working capabilities as:

- oxygen/air only vs breathing mixtures (nitrox, heliox, trimix)
- and low pressure (up to 2.5 bar) vs medium pressure (2.5 to 5 bar) vs high pressure (above 5 bar)

A hyperbaric facility can be classified according to its treatment capabilities as:

- only monoplace chamber(s) vs only multiplace chamber(s) vs both mono- and multiplace chambers
- and non-intensive care inside the hyperbaric chamber vs intensive care

3. Staffing

All hyperbaric facilities need various staff with specific and different functions and skills as 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). The minimum staff for any hyperbaric facility is the Medical Director plus minimum team for any hyperbaric session defined below. Each staff member should be familiar with their allocated functions and delegated responsibilities.

3.1. Responsibilities

The **Medical Director** is the appointed physician responsible for all functions developed in the hyperbaric centre.

The **Hyperbaric Physician** is responsible for the clinical activity related to hyperbaric treatments.

The **Hyperbaric Nurse** is responsible for the practical implementation of patient care during a hyperbaric treatment.

The **Safety Manager** is responsible for development and maintenance of safety management system and for its appropriate dissemination.

The **Hyperbaric Supervisor** is responsible for the safety of all activities within the Hyperbaric centre as well as for the maintenance of the chamber and of the complete hyperbaric facility.

The **Attendant** is responsible for direct care of the patient inside the multiplace chamber, within the limitation of his/her qualification.

The **Chamber Operator** is responsible for the safe operation of the chamber system according to the operating procedures.

The **Technician** is responsible for maintenance and repair of equipment in accordance with laid down procedures, always according to indications of the Hyperbaric Supervisor.

Others

Many other professionals with different qualifications may be engaged within the staff of a hyperbaric centre, depending on the special characteristics of each and of the hospital or institution where it is located.

3.2 [NEW] Functions

Medical Director

The **Medical Director** is responsible for all functions developed in the Hyperbaric Centre. This includes the following aspects.

1) Supervision of the correct operation of the hyperbaric facilities.
2) Quality assurance.
3) Follow up of patients.
4) Definition of protocol procedures for treatment.
5) Organisation and participation in multicentric over all protocols and treatments.

The functions of the main Medical Director are complemented by a variable number of collaborators of the same or similar background and education, in which the Medical Director can delegate some responsibilities, but always under his control.

Hyperbaric Physician

The **Hyperbaric Physician** is responsible for:

1) Qualifying patients for hyperbaric treatment.
2) Medical care to the patients inside the Hyperbaric Facility.
3) Medical care to the patients inside the Chamber, if a multiplace facility is used and whenever it might be necessary, due to reasons of critical care depending on the severity of the case, or special controls during therapeutical procedures.
4) Follow up of patients.

One or two physicians will not be enough to guarantee a 24 hour service, as the long stays inside the Chamber (when a multiplace facility is used) that they must often endure, renders them incapable of further decompressions in the following hours. A whole hyperbaric medical staff working in shifts would therefore be necessary.

Hyperbaric Nurse

As in all fields of medicine, nurses complete medical treatment and they are responsible for the practical implementation of patient treatment.

The Hyperbaric Nurses perform the usual functions of their profession with some variations due to the characteristics of the hyperbaric activity:

1) Nursing measures belonging to the common pathologies of the Hyperbaric Therapeutics to be applied to the patients in a self-standing chamber.
2) Nursing assistance of patients inside the hyperbaric chamber, taking special care of the specific conditions of the hyperbaric environment.
3) Adaptation of conventional medical techniques and specific treatments of each illness to the hyperbaric environment, so the other treatments that the patient is habitually receiving have not to be interrupted while in the chamber.
4) In some cases, operating the external controls of a Monoplace Hyperbaric chamber according to the compression and decompression schedules established.

Safety Manager

The **Safety Manager** of the Medical Hyperbaric Facility:

1) Responsible for development and maintenance of safety management system and for its appropriate dissemination.
2) Should have knowledge in medical aspects, technical aspects, ergonomy and safety aspects of the hyperbaric treatment, and maintain his competence by continued education efforts.
3) Should be able to perform (or at least be part of team which performs) the risk assessment of a facility and should be responsible for this risk assessment including also not specifically medically related factors concerning hyperbaric system.
4) Should establish (or accept) operational and emergency procedures, internal guidelines for safety.
5) Should establish and monitor the maintenance program for hyperbaric system.
6) Should establish an incident/accident reporting system and monitoring system of operational procedures.
7) Should establish a system for regular re-evaluation of the safety management system (including internal audits, reports).
8) Should cooperate on elaborating of internal and external education programs; should be aware of the requirements for continuous education of all members of the hyperbaric team, should be responsible for ensuring continuous education and skills training of all members of the hyperbaric team under the direct supervision of the medical director.

Attendant

Patients inside a multiplace chamber need always to be under the control and supervision of trained personnel. Critical patients will always be joined by a doctor, a nurse, or both.

Other patients however do not need such kind of direct and special medical and nursing assistance, and in those cases

the participation of a type of staff, specially trained, although not necessarily highly qualified may be adequate.

These are some of the activities attributed to attendants:

1) Patient care in non-invasive, non-specialised medical activities inside and outside the chamber.
2) Accompanying patients who are receiving treatment inside the Multiplace Chamber, but who do not need special assistance by doctors and nurses, but only by way of support, control, and to give them confidence.
3) Other activities to develop inside or outside the Chamber, indicated by the Medical Director or the Nurse.

If monoplace chambers are used, most of these activities may be adopted by doctors and/or hyperbaric specialists and nurses.

Operator

A Hyperbaric Facility may achieve a high level of sophistication that will require specialised attention and care. The Hyperbaric Chamber itself, the air-compressors, other pressurised gas sources, or the gas reserves, have some special devices whose manipulation might be very complex.

Monoplace chambers are handled sometimes by nurses and doctors and/or Hyperbaric specialists.

When multiplace chambers are used, the Hyperbaric Centre must have qualified personnel to manage the hyperbaric facilities. These functions must be preferably carried out by specialised chamber Operators.

The functions of the Chamber Operator of a Multiplace facility will be:

1) Operation of the internal and external devices of the Chamber.
2) Control and operation of the mechanisms for compression and decompression, and for delivering gas mixtures and oxygen.
4) Control and application of the safety regulations concerning prevention of fire, and oxygen toxicity.
5) Calculation, application and control of compression and decompression schedules for patients, Specialists and/or Doctors, Nurses, and Attendants, applying decompression stops, when necessary.
6) Sometimes make interventions inside the Chamber under pressure, in order to control or check the correct operation of determined parts of the pneumatic circuits or devices.
7) Adaptation and checking of the medical instruments carried by the patients before being introduced into the Chamber, to assure their correct operation, and to avoid dangerous or undesirable effects.
8) Control and checking of the operation of auxiliary facilities of the Chamber: air-compressors, sources of compressed air or medical gases, air reserves, pneumatic circuits, control systems.
9) Maintenance of the facility. Small repair jobs or technical interventions due to problems which occasionally might occur, and which do not require the intervention of highly specialised technical staff.

Technician

The Hyperbaric Centre needs employ to specialised technical staff, whose functions will be the checking and control of the chamber, pneumatic circuits, gas or compressed air reserves, air-compressors, and the rest of the technical parts of the facility.

3.3. Competencies and education

Competencies and education of hyperbaric personnel should follow the standards presented in the ECHM/EDTC document (see References). This document needs to be updated regularly so the aspects not covered currently may require the use of national standards in the meantime.

The main aspects on education of the staff must be applied equally to hyperbaric facilities using either monoplace or multiplace chambers, since medical conditions, therapeutic principles, and essential safety requirements are the same.

All staff should maintain their skills by training and continuous education which should be documented.

According to European Directive No. 89/391/EEC the employer must ensure that all staff are also adequately trained in the occupational hazards.

3.4. Minimum team during a hyperbaric session for multiplace chambers

During any session the functions involved are:

- Supervision of the treatment (medical aspect and safety of operations);
- Operation of the chambers;
- Attendance of patients under pressure;
- Emergency assistance under pressure if needed.

Thus, the minimum team size is three people:

- One hyperbaric physician;
- One attendant;
- One operator.

Actual team sizes will depend on risk assessments and shall consider the multi-role abilities of the available staff. Special consideration should be made for the possibility of the need to give immediate assistance.

A supervisor must be appointed.

The 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.

[NEW] For each hyperbaric session in a multiplace chamber, one chamber operator can operate only one hyperbaric system, which can consist of several chambers physically connected and operated from one operating desk.

[NEW] During each session in multiplace chamber, one internal attendant can take care of maximum of 12–15 stable patients. In case of unstable patients, the ratio of patients:attendant cannot exceed 5:1 or 6:1. For intensive care patients, the ratio of patients:attendant cannot exceed 1:1 or 2:1.

3.5. Minimum team during a hyperbaric session for monoplace chambers

During any treatment the functions involved are:

- Supervision of the treatment (medical aspect and safety of operations);
- Operation of the chambers;
- Emergency assistance if needed.

Thus, the minimum team size is two people:

- One hyperbaric physician;
- One operator.

The 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.

[NEW] One chamber operator can operate more than one monoplace chamber assuming that all of them are located in one room, and can be simultaneously supervised without any restrictions. The ratio of chambers:operator cannot exceed 3:1 for stable patients. In the case of demanding patients this ratio cannot exceed 2:1 and for intensive are patient 1:1.

3.6. Fitness and health surveillance

Exposure to the pressurised environment may result in occupational hazards. To prevent the risks:

- People working even occasionally under pressure must undergo an appropriate initial and periodical medical examination to be recognised fit for hyperbaric exposures according to national regulations for work under pressure. Consideration should also be given to daily fitness, and the possibility of pregnancy or illness.

Any illness related to working under pressure must be reported according to national regulations. The employee must be declared fit for hyperbaric exposures before returning to work under pressure.

Facilities must adopt a set of published decompression procedures to reduce to a minimum the risks associated with single and repeated exposures. They may include additional safety considerations to the standard procedures (for example, breathing nitrox during session or oxygen during decompression). 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 (see section 6.3.5.). Obligation for decompression stops should be kept to the minimum, enabling decompression to atmospheric pressure within a reasonable time. In any event, procedures for immediate recompression of attendants should be in place.

4. Equipment

4.1. Multiplace hyperbaric chambers

Multiplace hyperbaric chambers and internal equipment must comply with the EN14931.

4.2. [NEW] Monoplace hyperbaric chamber

Until there is no European regulation for monoplace chambers, the Medical Director is responsible for Risk Assessment of each installation. The main aspects on safety procedures must be equally applied to hyperbaric facilities using either monoplace or multiplace chambers, since medical conditions, therapeutic 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 mutiplace hyperbaric chamber. It is recommended that the minimum requirement defined in the Annex 5 must be met.

4.3. Medical devices

Medical devices should comply with the recommendations of the Annex B of the EN14931.

4.4. Other equipment

Equipment that does not belong to the internal equipment of the chamber and which is not a medical device, should be of an appropriate design and fit for use in the hyperbaric environment up to the maximum working pressure of the chamber it is used within. General safety recommendations given in the Annex B of the EN14931 may be applicable.

4.5. Maintenance

All the facility's equipment should be maintained according to the manufacturer's instructions.

4.6. [NEW] Cleaning and disinfecting

Appropriate solutions using broad-spectrum agents against pathogens and compatible with the chamber materials should be used to clean and disinfect the hyperbaric chamber between sessions. In case of seasonal or pandemic airborne transmitted diseases (e.g., influenza, COVID-19) the chamber atmosphere should be appropriately cleaned with closed UV systems avoiding direct exposure on PVC windows.

5. Gas supply

5.1. Quality

Breathable gases administered to the patients must comply with the European Pharmacopoeia, with consideration given for impurities and their additional toxic effects due to the increased ambient pressure. Gases not listed in the European Pharmacopoeia (i.e., helium) should comply at least with appropriate standards covering breathing gases for divers at work.

Air to pressurise the chamber(s) must comply at least with EN 12021. In the absence of available standards, any other gas must be breathable at least with the same level of safety as for divers at work.

5.2. Quantity

The volume of all gases must comply with the EN14931.

6. Risk management

6.1. Process

Risk management is a systematic application of management policies, procedures, and practices to the tasks of analysing, evaluating, and controlling risks.

According to EN ISO 14971 it is the responsibility of the manufacturer to perform the risk management of the medical device.

Any activity within the hyperbaric facility needs to be covered by the risk management process performed by each individual facility. Parts of the risk management process are generic and/or specific for each facility. Other facilities may have some similar process, but it is a facility's duty to analyse and reduce the risks to an acceptable level. It is not acceptable to copy or use other risk assessments without first applying them to each individual hyperbaric facility.

The risk management process shall be documented and shall include the following elements:

- Risk analysis
    - Intended use / intended purpose identification
    - Hazard identification
    - Risk estimation
- Risk evaluation
    - Risk acceptability decisions
- Risk control
    - Option analysis
    - Implementation
    - Residual risk evaluation
    - Overall risk acceptance

In a centre for hyperbaric medicine, risks may arise from medical, technical, mechanical, administrative, environmental, or human factors related to the functioning of the facility. Where the risk cannot be eliminated completely, substitution of the existing arrangement by an alternative, safer, procedure or method should be considered. Where elimination of a hazard is not possible, the control measures and procedures to minimise the risk should be defined and documented in the Standard Operating Procedures.

This process is annually reviewed or whenever introducing new equipment, machinery or when other local events may affect the working environment.

6.2. Generic hazards

Hazards may be divided into subcategories as suggested in Annex D of the ISO EN 14971:

a) Energy hazards and contributory factors.
b) Biological hazards and contributory factors.
c) Environmental hazards and contributory factors.
d) Hazards resulting from incorrect output of energy and substances.
e) Hazards related to the use of the medical device and contributory factors.
f) Inappropriate, inadequate or over-complicated user interface.
g) Hazards arising from function failure, maintenance, ageing and contributory factors.

6.3. Specific hazards

A hyperbaric treatment requires several phases, which must be in the correct sequence. Some of these phases may be complex and involve technical as well as medical procedures, which on their own do not present a hazard but in combination may. It is essential to take account of this potential problem when conducting the risk assessments. Before the facility can accept any patient, it is vital to check if it has the competence (including technical, medical, and staffing) to treat a patient with their specific condition. All system checks and evaluation of the patient should be completed before any session starts. Many factors need to be considered and it is not possible to provide an exhaustive list of hazards and risks in this code, but some examples of

hazards found in therapeutic hyperbaric facilities are listed below:

a) Pressures (risk of explosion, loss of pressure vessel integrity);
b) Adequacy and integrity of pressurised gas supplies;
c) Pressure differentials (catheter / cannula cuffs, seals, vascular lines, drainage);
d) Oxygen (risk of ignition, cerebral and pulmonary toxicity);
e) Quality and quantity of breathing gas supplies;
f) Electricity (electrical safety within the pressure vessel);
g) Prohibited materials within the chamber (see Annex 4);
h) Fire (procedures for prevention, suppression, and evacuation);
i) Suitability of medical devices used inside the chamber;
j) Staff health and safety, including medical surveillance and precautions against dysbaric injuries in staff;
k) Hygiene and infection control (disinfection of masks, hoods, ventilators and associated equipment, alert pathogens policy, chamber disinfection);
l) Management of body fluids, waste, sharps and infected materials;
m) Manual handling of patients on entry, exit from chamber and during treatment (use of slides, hoists and other patient handling aids);
n) Noise hazards and control measures (both for internal occupants of chambers and external staff);
o) Thermal stress;
p) Any other hazards (display screen equipment, slip, trip, bump and fall hazards etc).

6.3.1. Oxygen toxicity

Cerebral oxygen toxicity is an inherent risk to both patients and attendants who breath greatly increased partial pressures of oxygen during, or while decompressing from hyperbaric treatments. The risk of convulsions due to cerebral oxygen toxicity may be considerably greater in cases such as pyrexia, hypoglycaemia, elevated inspired carbon dioxide levels, increased cardiorespiratory workloads, intracerebral pathology, or consumption of immunosuppressive drugs including steroids.

The possibility of unpredictable oxygen convulsions, both in patients and attendants, should be anticipated and individual therapeutic facilities should develop and document procedures for responding to such events and their foreseeable sequelae.

Pulmonary oxygen toxicity in staff is unlikely outside the context of saturation recompression of a diving casualty. It may become a problem in patients given extended or frequent repeated treatments, or acutely ill patients receiving high levels of inspired oxygen between treatments. This possibility should be kept in mind by medical staff when deciding the risks and benefits of alternative treatment regimens for individual patients. Calculation of Units of Pulmonary Toxicity Dose (UPTD) may help in some cases, but each case must be judged on its merits.

6.3.2. Electrical safety

Electrical safety and the risk of fire in the hyperbaric environment are closely linked. Guidance on electrical safety issues is detailed in the Annex B of the EN14931. The installation of additional electrical equipment (e.g., for research) should be limited only for devices which comply with hyperbaric conditions.

6.3.3. Prohibited materials

The single greatest risk to accidents comes from introducing prohibited materials inside the pressure vessels. Therefore, it is essential that all patients and staff ensure that checks are in place to avoid this risk. For the list of prohibited materials refer to Annex 4.

6.3.4. Fire safety

The risk of fire is very low if recommended safety procedures are correctly applied. However due to its potentially catastrophic consequences, prevention of fire is a major and very real 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 oxygen. Care must be taken to exclude various flammable substances and equipment that could be sources of ignition as many different types of equipment may not be appropriate for the hyperbaric environment. For multiplace chambers, fire prevention and firefighting systems are detailed in the EN14931; however, an individual risk assessment should be made in all cases. Chambers should have a written emergency policy detailing procedures for in-chamber fire prevention, and general actions in the event of fire in the chamber and/or the facility buildings. Fire in the facility buildings and evacuation procedures including removing patients from the chamber should be specifically considered and documented.

6.3.5. Dysbaric injuries during / after hyperbaric treatment

Patients who have breathed oxygen during the majority of their hyperbaric treatment may develop barotraumas, as any person occupying the chamber, but are unlikely to develop decompression illness/sickness.

Attendant staff may breathe compressed air during much of a hyperbaric treatment, and they are potentially at risk of any kind of dysbaric injuries. Furthermore, attendants may need to make repetitive entries inside the chamber. Therapeutic hyperbaric hospital-based facilities staff should be trained in the recognition and prevention of decompression illness/sickness in themselves and attendants, and procedures should be in place to ensure the timely assessment and

recompression treatment of any staff members if required. Restrictions on travel and physical exercise may need to be considered.

Hyperbaric facility staff should be aware of the limitations on diving, flying, or travel in mountainous regions for a specified time after attending a hyperbaric treatment, depending on the pressure and length of exposure.

6.3.6. Manual handling

Hyperbaric chambers treating unconscious, ventilated patients, and patients who are less than fully ambulant, particularly in multiplace chambers with no walk-in door, may recognise an appreciable risk of musculoskeletal injury to staff involved in the transfer of patients in and out of the chamber. Mechanical hoists, slide systems, and other patient handling aids should be used to control, and reduce the risks to all the staff. The specific methods employed should be dictated by risk assessments in the context of each individual therapeutic facility. Written procedures for reasonably predictable scenarios should be developed.

6.3.7. Thermal stress

For the comfort and safety of attendants and patients, the Standard Operating Procedures (SOP) for the therapeutic hyperbaric facility should specify ways in which the chamber environment can be maintained in thermal balance to avoid detrimental effects of excessive heat or cold to the chamber occupants. Upper and lower limits should be set and adhered to. Guidance on thermal parameters is detailed in the EN14931.

7. Procedures

Council Directive 93/42 states that it is the responsibility of the manufacturer to supply the information needed to use all the medical devices, considering the training and knowledge of the users.

Council Directive 89/391 states that the employer must identify safety measures to prevent hazards linked to their activity becoming a problem.

In consequence, each therapeutic hyperbaric facility should develop its own operating manual that details the working practices for all anticipated activities within the facility.

The operating manual should contain all such information and instructions, including standard and emergency procedures, and contingency plans to give advice, to guide, or to regulate the behaviour of those taking part in the function of the facility, either in a medical or technical capacity. Emergency procedures must be developed to cover unplanned events. The manufacturer's operating manual must become an integral part of the facilities operating manual.

A proposed framework for operating manual for hyperbaric facility is given in Annex 1.

The operating manual should be reviewed periodically and updated as appropriate. All staff should be familiar with the guidance contained therein, relevant to their position. A copy must be available available immediately for any operating staff.

7.1. Standard Operating Procedures (SOP)

The SOP shall cover the general procedures for therapeutic hyperbaric chamber operation as well as hyperbaric treatment protocols. They shall also provide contingency procedures for any reasonably foreseeable emergency (see below).

A clinical assessment of the risks and benefits of hyperbaric exposure specific to individual patients in the context of the disease processes or injuries from which they are suffering are the responsibility of the Medical Director. Areas that may warrant attention are listed in Annex 3.

7.2. Emergency Operating Procedures

All hyperbaric facilities will either adopt their hospital general emergency procedures, or develop their own.

During hyperbaric treatments, medical and system events that require technical action as well as medical input for their prompt and appropriate management are inherent and predictable occurrences. The technical constraints of the hyperbaric environment complicate the management of medical emergencies. Hyperbaric facilities may approach such emergencies in different ways, depending on their specific circumstances (type of hyperbaric facilities and chambers, availability of specialised personnel, condition of patients, medical devices used in treatment). Each hyperbaric facility should develop and document procedures to guide the actions of its staff in the event of specific emergencies and these must be integrated with the general emergency procedures.

Emergency Procedures must be clearly defined, understood, and exercised on a regular basis to ensure that the whole team is adequately trained. Areas that may warrant attention are listed in Annex 4.

7.3. Maintenance

Each hyperbaric facility shall ensure that the hyperbaric system is serviceable and maintained in a safe working condition.
Based on the manufacturer's instructions, a register of maintenance should:

- Describe all maintenance procedures and the frequency that each task needs to be carried out;

- Record all actions (i.e., formal inspections, re-certifications, spare parts changes) and technical incidents or breakdowns.

7.4. Record keeping

Therapeutic hyperbaric facilities should record and maintain data relating to the Health and Safety, technical, and clinical aspects of their operation. All staff affected potentially by such hazards should be made aware of this information which should be an intrinsic part of the facility's SOP documentation. Record keeping should be kept on three levels: facility, system, and patient. The minimum set of information recorded in the logs is presented in the Annex 2.

7.5. Patient safety

Standard Operating Procedures for therapeutic hyperbaric facilities should document guidelines or facility policy for the reception, treatment, and discharge of patients in the facility.

Reception of a patient should involve medical staff taking a clinical history or hand over of the patient's clinical details as his/her clinical condition indicates or allows. This should be accompanied by an appropriate pre-treatment assessment by the hyperbaric physician.

[NEW] Special attention must be taken for the following situations:

- Small children who must be accompanied inside the chamber by the parent or any other family member or authorised guardian. In such cases the medical assessment of the accompanying person must be conducted prior the treatment and the informed consent must be received.
- Intensive care patients, which need transportation to and from the hyperbaric facility and the chamber, its accommodation within the chamber, stabilisation period before commencing the HBOT, proper monitoring and continuation of required intensive therapy during hyperbaric session, observation toward adverse effects, the possibility of conducting basic medical procedures (e.g., thoracocentesis) inside the chamber.

A guide of matters that can be developed for the phases of patient management and associated issues is summarised in Annex 3 and 4.

[NEW] Every situation exceeding SOPs, including adverse effects, complications, aborting of HBOT session or whole treatment must be registered and subjected for the following analysis, as a part of the quality control.

7.6. [NEW] List of indications

Every Hyperbaric Facility should adopt the list of clinical indications approved for standard hyperbaric treatment. This should be done in accordance with local regulations (if any), nationally accepted standards of health care and approved by the Hospital authorities.

The internationally recognised list of indications established using Evidence Based Medicine and Consensus agreement of internationally recognised experts is regularly published by the ECHM (see References).

Any indication from outside the list could be accepted only: in the frame of a clinical trial (with a protocol approved by an ethic committee, etc.); or in the frame of a compassionate use[1] which means that, a) there is an acceptable scientific rationale, b) patient, referral physician(s) and third party payer (if any) have been extensively informed about potential risk and questionable benefit and still agree for HBO use, and c) HBO treatment is offered at no cost for the patient.

7.7. [NEW] List of contraindications

There is virtually no absolute contraindication for the HBOT, as the reason why HBOT should be used in specific patient may overweigh the risk. In any case of conditions known as contraindication to HBOT, a benefit/risk balance for each specific patient should be made before applying HBO. This should take into consideration the experience of the hyperbaric facility medical staff and equipment that can be used.

Footnote: [1] See ref: http://www.mayoclinic.com/health/compassionate-use/AN02061. In certain situations, the Food and Drug Administration (FDA) allows companies to provide their experimental drugs for compassionate use. However, accessing pre-approval drugs through a compassionate use program can be a long and challenging process. The FDA's compassionate use program typically reserves permission for people who have no other treatment options. In order to receive experimental drugs through the compassionate use program, the FDA may require that: Your disease is fatal; You haven't been helped by the approved treatments for your disease; You have a rare disease that has no treatment; You aren't eligible for the clinical trials currently studying the experimental drug that you think might help you; Your doctor agrees that you have no other options and may benefit from an experimental treatment; The company that makes the experimental drug agrees to offer it to you.

[2] Means organisation external to the Hyperbaric Facility or internationally recognised experts from outside the Hyperbaric Facility.

7.8. [NEW] Accreditation

Every Hyperbaric Facility should seek accreditation specific for the hyperbaric operations. If not available locally this should at least include external[2] validation of the equipment and procedures.

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8. Annexes

Annex 1 – Framework for Operating Manual

FRAMEWORK FOR OPERATING MANUAL FOR HYPERBARIC FACILITY

1. DESCRIPTION AND FUNCTION OF THE HYPERBARIC SYSTEM

1.1 Pressure chamber(s)
1.2 Control panel (including computer system if fitted)
1.3 General supply panel
1.4 Gas supply:
  1.4.1 Compressors
  1.4.2 Gas storage
  1.4.3 Oxygen supply
1.5 Power supply and backup supplies
1.6 Breathing systems
1.7 Monitoring of patients
1.8 Communication (primary and secondary)
1.9 Environmental control
1.10 Fire protection and fire fighting
1.11 Maintenance

2. STANDARD OPERATING PROCEDURES

2.1 System
  2.1.1 Preparation
    2.1.1.1 Daily and session checks
    2.1.1.2 Preparation dependent on patient condition
  2.1.2 Operation
    2.1.2.1 Conducting single and successive sessions (including the monitoring of critical parameters. i.e. pressure, time, oxygen breathing, chamber oxygen percentage, gas supplies, attendant times etc.)
    2.1.2.2 Use of locks
    2.1.2.3 Recording the session (Treatment Log)
    2.1.2.4 Shut down procedure after each session
    2.1.2.5 End of day shut down procedure
  2.1.3 Management of supplies (gas, drugs, etc.)
  2.1.4 Cleaning and disinfecting procedures
  2.1.5 Use of all medical devices
2.2 Treatment protocols (standard and extended) with detailed instructions
2.3 Patient
  2.3.1 Admission (including informed consent)
  2.3.2 Preparation
  2.3.3 Handling, management and monitoring
  2.3.4 Assessment and management of adverse effects (see Emergency Procedures)
  2.3.5 Discharge
2.4 Team
  2.4.1 Contact details and call out procedures
  2.4.2 Qualification requirements
  2.4.3 Team roles and sizes
2.5 Record keeping
  2.5.1 Facility

2.5.2 System
2.5.3 Patient

3. EMERGENCY OPERATING PROCEDURES

3.1 Medical
3.1.1 cardio-respiratory complains including procedures for safe defibrillation
3.1.2 loss of consciousness
3.1.3 convulsions
3.1.4 neuropsychologic acute reactions (including panic, claustrophobia, aggression)
3.1.5 vomiting
3.1.6 dysbaric injuries to patients and staff:
3.1.6.1 any barotrauma
3.1.6.2 decompression illness / sickness
3.2 System
3.2.1 uncontrolled change of pressure
3.2.2 loss of gas supplies
3.2.3 contamination of gas supplies
3.2.4 contaminated atmosphere inside chamber
3.2.5 high oxygen levels in the chamber atmosphere
3.2.6 inability to maintain adequate temperature
3.2.7 fire in the chamber
3.2.8 fire in the facility
3.2.9 loss of communications (visual, verbal)
3.2.10 power failure
3.2.11 internal equipment malfunction
3.2.12 medical device malfunction
3.2.13 BIBS malfunction
3.2.14 any external threats to the facility

Annex 2 – Record Keeping

RECORD KEEPING

Levels of record keeping:
1. Facility
a. Personnel:
- Recording of initial and continuing education programs,
- Staff duty rotas
- Staff hyperbaric exposure recording

b. Protocols for the assessment and treatment of all conditions for which the facility offers hyperbaric therapy
2. System
a. Session record should include:
Identification of chamber (for multi chambers facility),
Name of the duty hyperbaric physician,
Name of the duty supervisor,
Name of operator(s) and attendant(s),
Patients name and location in the chamber,
Number of treatments (treatment number for each patient)
Use of specific medical devices ($TcPO_2$, ventilator, monitor, etc.)
Patients' incidents
Safety checks (prevention fire, shoes, clothing, etc.),
Protocol used
Start date/time and compression time,
Breathing mixtures for patients and attendants,
Time of delivery of therapeutic breathing mixtures,
Time and pressure of attendant's exposures,
Session end date/time
Technical actions (eg. ventilation of chamber),
Technical incidents
Any other factors likely to affect the safety or health of any person engaged in the operation
b. Before / after use
General checks and tests of facility's systems:
1. Recording of all available supplies (air, oxygen, electricity, etc.)
2. Recording the status of the alarms systems,
3. Recording the status of the emergency systems,
4. Recording of daily functional tests (pre use) following the operating instructions,
5. Recording of functional test (pre use) of specific medical devices ($TcPO_2$, ventilator, monitor, etc.)

b. Disinfection records:
Records of changing masks, equipment and consumables,
Records of cleaning and disinfection of chamber, masks, hoods, tubes, etc.)
c. Register of maintenance,
Records of all maintenance and repairs
Records of quality control of gases
Records of incidents and accidents
3. Patient
a. Patient identification and administrative information
b. Informed consent to treatment
c. Introduction to hyperbaric procedures (including preparation, protocols, environmental factors, possible adverse effects)
d. Medical diagnosis with indication for hyperbaric treatment
e. Alert Data (allergies, contraindications, infections, etc.)
f. Medical and nursing records (consultations, clinical results, drugs, surgery, $TcPO_2$ results, etc.)
g. Protocol of treatment
h. Record of each hyperbaric session (see 2a above)

Annex 3 – Patient Management

PATIENT MANAGEMENT

1. Reception
1.1 Method(s) of patient referral
1.2 Assessment of patient suitability for type of facility

1.3 Transport of patients to the therapeutic hyperbaric facility
1.4 Pre-treatment clinical assessment of patient for suitability of medical condition for hyperbaric oxygen treatment
1.5 Pre-treatment clinical assessment for other medical conditions which might be affected by hyperbaric treatment including possible relative and absolute contraindications for hyperbaric therapy
1.6 Introduction of patient to the hyperbaric procedure, including
1.6.1 Preparation (prohibited items, patient clothing policy)
1.6.2 Protocols (methods of oxygen delivery)
1.6.3 Chamber environmental factors (pressure, temperature, humidity, noise)
1.7 Patient briefed as to possible adverse effects of HBO
1.8 Informed consent to treatment
2. Treatment
2.1 Procedures during compression for different patient conditions
2.2 In-chamber patient management including physiological and clinical monitoring
2.3 Procedures during decompression for different patient conditions
2.4 Patient clinical record keeping, including monitoring of side and adverse effects
2.5 Re-assessment of patient
3. Follow-up/discharge
3.1 Admission/transfer/referral for in-patient hospital care
3.2 Referral to other hyperbaric facilities
3.3 Patient discharge and review arrangements
3.4 Written instructions for the patient on discharge;
3.5 Arrangements for transfer of clinical responsibility to alternative speciality when hyperbaric phase of treatment is complete;
3.6 Written discharge summary;
3.7 Follow-up including possible long-term effects

Annex 4 – Prohibited Materials

Every item added to the hyperbaric environment poses a potential risk which should be assessed prior to its approval. All approved items taken inside the hyperbaric chamber should be assessed for their necessity.

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) following each item indicates the general reason for prohibiting it, the coding is shown below.

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

LISTING (in alphabetical order):

Adhesives (F)
Aerosols (D, E, F)
Aftershave (D, F)
Alcohol (D, F, P)
Batteries with unprotected leads (F)
Chemical cleaners, eg; trichlorethylene, 'Freon', etc (D)
Cigarettes, cigars, tobacco of all kinds (F, M)
Cleansing powder (C, F, P)
Clothing, bedding included blankets, sheets, pillows, mattresses, etc. (F)
Drugs, non-prescribed (P)
Electrical equipment including tape recorders, radios, etc (F)
Explosives (F)
Glass thermometers, including batteries containing mercury (C, D, P)
Ink pens (M)
Lighters, matches (F)
Newspaper (F)
Non-diving watches (L, M)
Petroleum based lubricants, grease, fluids (F)
Sugar and fine powders and other flammable food stuffs (E, F)
Thermos flasks (L, P)

IMPORTANT NOTE

It is important to be aware that the clothing of occupants entering the chamber and bedding constitute an additional hazard as it may be either synthetic, wool, contaminated or containing prohibited items. 100% cotton or other hyperbaric compatible materials should be used.

Annex 5 – Risk Assessment for the medical installation of monoplace chambers

Annex 5 is available on *Diving and Hyperbaric Medicine* journals website: https://www.dhmjournal.com/index.php/journals?id=324.

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DIVER EMERGENCY SERVICES PHONE NUMBERS

AUSTRALIA – DAN
1800-088200 (in Australia toll free)
+61-8-8212-9242 User pays
(outside Australia)

NEW ZEALAND – DAN Emergency Service
0800-4DES-111 (in New Zealand toll free)
+64-9-445-8454 (International)

ASIA, PACIFIC ISLANDS – DAN World
+618-8212-9242

EUROPE – DAN
+39-06-4211-8685 (24-hour hotline)

SOUTHERN AFRICA – DAN
+27-10-209-8112 (International call collect)

USA – DAN
+1-919-684-9111

JAPAN – DAN
+81-3-3812-4999 (Japan)

ADSF
AUSTRALASIAN DIVING SAFETY FOUNDATION

Scholarships for Diving Medical Training for Doctors

The Australasian Diving Safety Foundation is proud to offer a series of annual Diving Medical Training scholarships. We are offering these scholarships to qualified medical doctors to increase their knowledge of diving medicine by participating in an approved diving medicine training programme. These scholarships are mainly available to doctors who reside in Australia. However, exceptions may be considered for regional overseas residents, especially in places frequented by Australian divers. The awarding of such a scholarship will be at the sole discretion of the ADSF. It will be based on a variety of criteria such as the location of the applicant, their working environment, financial need and the perception of where and how the training would likely be utilised to reduce diving morbidity and mortality. Each scholarship is to the value of AUD5,000.00.

There are two categories of scholarships:

1. ADSF scholarships for any approved diving medical training program such as the annual ANZHMG course at Fiona Stanley Hospital in Perth, Western Australia.
2. The Carl Edmonds Memorial Diving Medicine Scholarship specifically for training at the Royal Australian Navy Medical Officers' Underwater Medicine Course, HMAS Penguin, Sydney, Australia.

Interested persons should first enrol in the chosen course, then complete the relevant ADSF Scholarship application form available at: https://www.adsf.org.au/r/diving-medical-training-scholarships and send it by email to John Lippmann at johnl@adsf.org.au.
