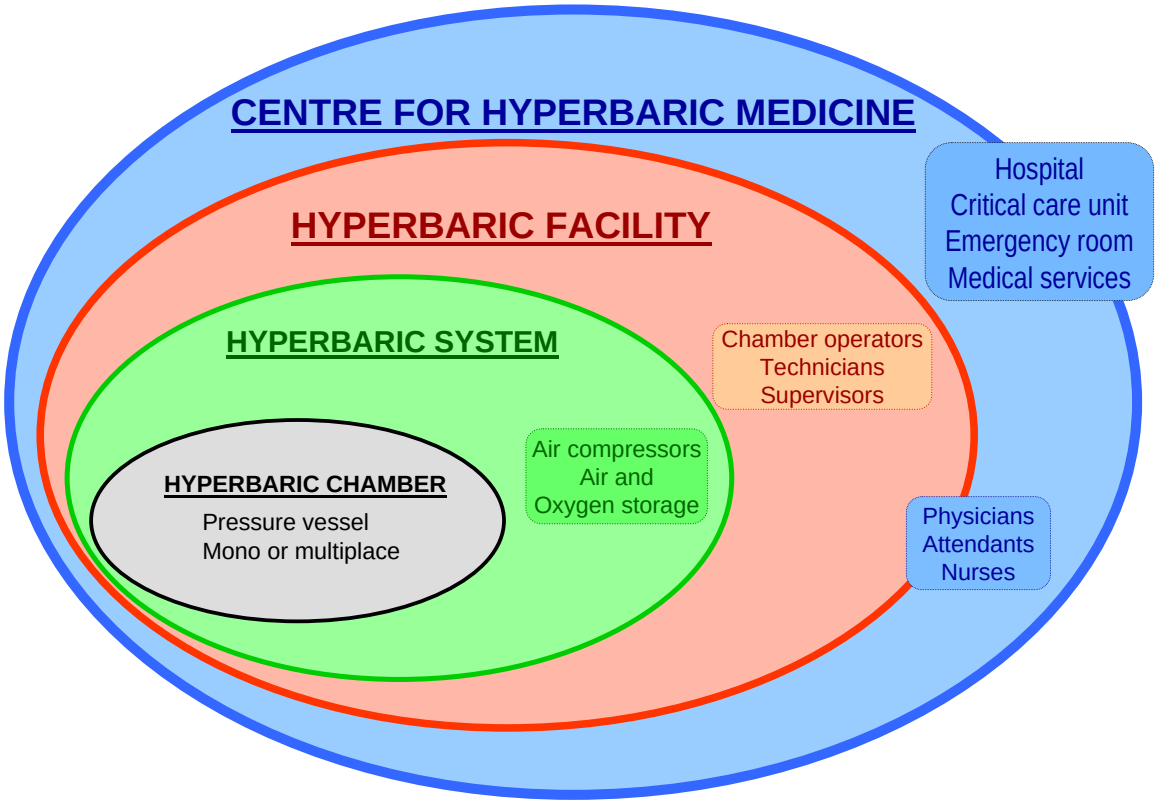
A EUROPEAN CODE OF GOOD PRACTICE FOR HYPERBARIC OXYGEN THERAPY



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of the COST Action B14 «HYPERBARIC OXYGEN THERAPY»
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A EUROPEAN CODE OF GOOD PRACTICE FOR HYPERBARIC OXYGEN THERAPY

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A special mention must also be made to the two documents of the European Committee for Hyperbaric Medicine (ECHM) listed below which were also instrumental in the production of this European Code of Good Practice for HBO Therapy.

- ECHM Educational and Training Standards for the Staff of Hyperbaric Medical Centres (Annex 1)
- ECHM Recommendations for Safety in Multiplace Medical Hyperbaric Chambers (Annex 2)

Also the contribution made by the COST Working Group «Technical Aspects» (WGT) is greatly appreciated for their previous work and report (Annex 3) and for identifying the need for this publication which is intended to compliment the forthcoming prEN14931 document once it is published.

The Draft prEN14931 document, the French diving regulations and Italian guidelines from ISPESL were also reviewed when producing this Code of Good Practice.

COST B14 WGS would like to thank 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.

1. Introduction

The main goal of this document is to present a European Code of Good Practice for HBO Therapy based on existing experience from experts of hyperbaric centres, committees, professional and scientific associations.

This document is intended to be a reference document for European countries for Guidelines, Regulations, and Standards in hyperbaric medicine.

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

This document was written by members of Working Group «Safety» of the COST Action B14 «Hyperbaric Oxygen Therapy» and approved by the Management Committee.

This document applies to all facilities for Hyperbaric Medicine that provide hyperbaric treatments to patients. Codes for ensuring the safety of patients and staff should also apply to medical research exposing human subjects to a hyperbaric environment.

The scope of this document covers the safety of patients, staff, third parties and the infrastructure which includes the organisation of the facility, staff education, standard and emergency procedures.

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

2. Definitions

In this Code the following terms and definitions are used:

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 Oxygen Therapy** (HBO) consists of breathing oxygen at a pressure higher than local atmospheric pressure. Pressure of session, oxygen partial pressure and duration of session should be according to the state-of-art.

Thus, HBO is defined by all three essential elements:

- breathing oxygen
- increased ambient pressure
- a hyperbaric chamber.

Therefore, this document applies to all hyperbaric therapies, and the term HBO is used to describe them all.

A **hyperbaric therapeutic chamber** 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 designed for a single patient. They do not allow direct access to the patient during the treatment.

A **hyperbaric chamber system** consists of the hyperbaric chamber(s) including the support equipment (gas and energy supplies, etc).

A **hyperbaric facility** consists of the therapeutic hyperbaric system(s) together with associated plant, buildings, staff (both technical and medical), and a specific administrative organisation. Two kinds of hyperbaric facilities exist: hospital based and standalone. However, in each and every hyperbaric facility there should be an area adequately equipped to receive and care for medical emergencies.

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 centre for hyperbaric medicine 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** is a period of increased pressure above ambient atmospheric pressure, within a therapeutic hyperbaric chamber, for the purposes of treatment of a patient. It includes treatment when breathing oxygen, air, or breathable mixtures.

A **hyperbaric treatment** consists of the total (one or more) hyperbaric sessions as prescribed.

A **patient** is any person suffering from a medical condition, who may occupy a hyperbaric chamber during a hyperbaric treatment with the purpose of altering the natural course of their illness. This definition of a patient includes persons who receive prophylactic hyperbaric oxygen, and those who are control subjects in therapeutic trials of hyperbaric therapy.

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

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

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

An **emergency operating procedure** describes the behaviour of the staff in abnormal operational conditions or during any foreseeable unplanned or adverse situations.

A **medical device** is defined as any item of equipment required for the treatment of the patient and not for the operation of the chamber (which is itself a medical device).

Internal equipment is a part of the hyperbaric chamber system.

3. Staffing

Each staff member should be familiar with their functions and responsibilities.

3.1. Responsibilities

All hyperbaric facilities need various staff with different skills and these staff are referred to by the skill they bring to the team. These skills are defined below.

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 hyperbaric treatment.

The **Supervisor** is responsible for all safety during the hyperbaric session.

The **Attendant** is responsible for direct care of the patient inside the multiplace chamber, within the limitation of their 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.

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

3.2. Competencies and education

Competencies and education of hyperbaric personnel should follow the standards presented in the ECHM/EDTC document (see Annex 1). This document needs to be regularly updated so the aspects not currently covered may require the use of national standards in the meantime.

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

According to European Directive N° 89/391/EEC the employer must ensure that all staff are also adequately trained in the occupational hazards.

3.3. 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 recommended 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.

3.4. 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 recommended 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.

3.5. Fitness and health surveillance

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

3.5.1. 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.

3.5.2. 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.

3.5.3. 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 (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. Hyperbaric chambers and internal equipment must comply with the prEN14931.

4.2. Medical devices should comply with the recommendations of the Annex B of the prEN14931.

4.3. 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 prEN14931 may be applicable.

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

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 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 prEN14931.

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.

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

The first step in **risk management** is a **risk assessment** which is a careful examination of what, in the work place, could cause harm to people, so that one can weigh up whether enough precautions have been taken or more should be done to prevent harm. The aim is to take all reasonable steps to make sure that no one gets hurt or becomes ill. The important things to be decided are whether a hazard is significant, and whether it is covered by satisfactory precautions so that the risk is small.

Taking into account the **intended use** of the hyperbaric chambers (types of sessions, breathing mixtures, numbers of persons inside, treatment protocol) it is necessary to look for the hazards (**hazard identification**), where a hazard is something with the

potential to cause harm (this may include, by its very nature, the hyperbaric environment, plant, equipment, and human factors).

For each identified hazard there is a **risk estimation**, where a risk is the possibility that harm will occur and its nature and severity.

All risk assessments should be documented and all the staff should be informed about outcomes of the assessment. Records from risk assessment should be kept for future reference.

After the evaluation of risk, the decision is taken whether the existing precautions and practices are adequate or whether more could be done (**risk acceptability decisions**). If there is a possibility to take some precautions to avoid a hazard or to minimise the risk (**risk control**), the analysis of possible solutions is performed (**option analysis**) and modifications to the system are implemented.

After each modification the whole process of risk assessment is repeated. Even after all precautions have been taken, some risk usually remains (**residual risk**). For each significant hazard the decision should be made if it is acceptable (**overall risk acceptance**).

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.
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 effect 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 list of specific hazards is included in the COST B14 Working Group «Technical Aspects» Final Report – see Annex 3.

A hyperbaric treatment requires a number of 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 there 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 7);
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 breathe 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 or intracerebral pathology.

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 prEN14931. The installation of additional electrical equipment (eg. 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 7.

6.3.4. Fire safety

The risk 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 fire fighting systems are detailed in the prEN14931; 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 a barotrauma 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. Therapeutic hyperbaric facility staff should receive training 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 particular 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 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 prEN14931.

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, taking into account the training and knowledge of the users.

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

In consequence, each therapeutic hyperbaric facility should develop its own operating manual which 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 4.

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 immediately available for any operating staff.

7.1. Standard Operating Procedures

The Standard Operating Procedures 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 4.

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. particular 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 potentially affected by such hazards should be made aware of this information which

should be an intrinsic part of the facility's Standard Operating Procedures 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 5.

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.

A guide of matters that can be developed for the phases of patient management and associated issues is summarised in Annex 6 and 7.

REFERENCES, RELEVANT LEGISLATION, STANDARD, GUIDELINES AND LITERATURE

References:

1. Health and Safety for Therapeutic Hyperbaric Facilities: A Code of Practice, British Hyperbaric Association, 2000
2. Council Directive 93/42 of June 1993 concerning medical devices (12.7.93 N°L 169/1 – 169/43, 1993
3. Council Directive 89/391/EEC of 12 June 1989 - Introduction of measures to encourage improvements in the safety and health of workers at work, 1989.
4. French Diving Regulations (decree 90-277 of 28 March 1990 and applying orders – Brochure N° 1636 "Works in Hyperbaric Environment", French Republic Official Journal), 1990.
5. ISPESL – Guidelines – Safety Supervision of multiplace hyperbaric chambers in a clinic environment – Rev Oct 1999.
6. prEN14931. Pressure vessels for human occupancy (PVHO) – Multiplace pressure chamber systems for hyperbaric therapy – Performance, safety requirements and testing, 2004
7. European Norm 12021, Respiratory protective devices – Compressed air for breathing apparatus, 1999
8. European Norm ISO 14971, Medical devices – Application of risk management to medical devices – Amendment 1: Rationale for requirements (ISO 14971:2000/AM1:2003).
9. European Pharmacopoeia
10. 6th ECHM Consensus Conference on Prevention of dysbaric injuries in diving and hyperbaric work, Geneva, 2003

Relevant legislation, standards, guidelines:

1. DIN 13256 , Part 2: Pressure vessels for human occupancy: accessible pressure vessels for hyperbaric therapy; safety requirements and testing. Beuth Verlag GmbH, Berlin, 2000
2. DIN 13256. Part-3: Pressure vessels for human occupancy: fire extinguishing systems in pressure vessels: safety requirements and testing, Beuth Verlag GmbH, Berlin, 2001
3. Guide to Fire Safety Standards for Hyperbaric Treatment Centres, British Hyperbaric Association, 1996
4. Guide to Electrical Safety Standards for Hyperbaric Treatment Centres, British Hyperbaric Association, 1996
5. National Fire Protection Association (NFPA 99) Chapter 20 Hyperbaric Facilities, 2002

Relevant literature:

1. First European Consensus Conference on Hyperbaric Medicine – The applications of Hyperbaric Oxygen; standards for education and training,

future directions of research; technical requirements. Lille University Medical Center, Lille, France. Wattel F, ed., 1994
2. Handbook of hyperbaric medicine. Oriani-G; Marroni-A; Wattel-F (Ed.), Berlin, Springer: 737-740, 1996
3. Multiplace chamber safety guidelines, UHMS,1994, UNITED-STATES
4. Hyperbaric Facility Safety: A Practical Guide. Workman-T (Ed.), Best Publishing USA, 1999
5. Hyperbaric Medicine Practice - Second Edition, Edited by Eric P. Kindwall, Harry T. Whelan, 2000
6. Textbook of Hyperbaric Medicine. Jain-KK (Ed.), Hogrefe & Hubner Publishers, USA, 1999
7. The Training and Education of Hyperbaric Unit Personnel, British Hyperbaric Association, 1999

8. Annexes

Annex 1 – ECHM Educational and Training Standards for the Staff of Hyperbaric Medical Centres 1997 (informative)

EDUCATIONAL AND TRAINING STANDARDS FOR THE STAFF OF HYPERBARIC MEDICAL CENTRES

Written by
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FOREWORD

These educational and training standards are the result of some years of international discussion which began prior the 1st European Consensus Conference on Hyperbaric Medicine, Lille, in September 1994 where one session was devoted to "Personnel education and training policies". A comprehensive paper and the subsequent debate defined the 5 different personnel categories ideally involved in the staff of a Centre of Hyperbaric Medicine.

A working group being formed to define the requirements for medical doctors in the fields of diving and hyperbaric medicine. An important feature of this project was the collaboration between the European Committee for Hyperbaric Medicine (ECHM), which is primarily a medical committee, and the European Diving Technology Committee (EDTC) which is a 15-nation committee with not only government, industry and trades union representatives but also with a doctor nominated from each member country. This joint subcommission was formed by J. Desola (Spain), D.Elliott (United Kingdom), P. Longobardi/ P. Pelaia (Italy), F. Wattel (France), and J. Wendling (Switzerland). It was chaired by J.Desola on behalf of the ECHM and J.Wendling by the EDTC.

The Goal-setting Principles for Harmonised diving Standards in Europe was published by the EDTC in 1997 and includes a section on the "Qualifications, education and training of medical doctors"(appendix 2).

The work presented here has been done by the Joint Medical Subcommittee of these two main committees and, from time to time, reports by this Subcommittee have been submitted to and approved by each of the two parent bodies.

It is the purpose of this paper to summarise what has been accomplished and to look at the future tasks of a Joint Medical Subcommittee of the ECHM & EDTC.

INTRODUCTION

A Hyperbaric Centre must guarantee the best use of its equipment, and services.

Depending on the kind of facility and of the final aim of its services, the Hyperbaric Centre can function on a continuous (24 hours a day) basis or intermittently, during periods of time scheduled in advance.
Depending on its technical availability's, the location, and the available medical services, the Hyperbaric Centre can be a hospital facility, or an open self standing Centre.
A hospital Hyperbaric Centre must guarantee its assistance 24 hours a day, and must be able to offer adequate treatment for all kinds of diseases, including those requiring critical care inside the Chamber.
A self standing Hyperbaric Centre might have a certain work schedule, and must limit its services to those patients not in emergency situation. It must be in functional relation or contact with a general hospital.
In cases that a transportable hyperbaric chamber is used, the schedules, profiles, staff and regulations will be the same of a self standing centre.
Staff requirements affecting these types of facilities should agree with the aforementioned conditions of availability and system of work.
This work aims to review the kind of staff needed by the Hyperbaric Centre, to define their behaviour and giving some general rules to be applied in each situation, depending on the conditions of each Centre. In the final items, the minimal personal requirements of a Hyperbaric Centre will be mentioned.
In order to develop its functions correctly, a hyperbaric Centre needs different professional qualifications. These could be summarised as follows:

1) The Medical Director and Physicians/Medical Doctors
2) Nurses
3) Attendants
4) Chamber Operators
5) Technicians
6) Others

Characteristics, functions and background which should be followed by the whole staff will be reviewed. In each category the following items will be detailed:

A) Definition of functions
B) Background
C) Specific educational profile
D) Academic requirements and degrees
E) Continuous Education
F) Dedication

1 – THE MEDICAL DIRECTOR THE PHYSICIANS / MEDICAL DOCTORS

A) Functions.
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. 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.
3. Quality assurance.
4. Follow up of patients.
5. Definition of protocol procedures for treatment.
6. 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.
One or two people will not be enough to guarantee a 24 hours a day 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.

B) Background.
The Medical Director is a Medical Doctor with a wide multidisciplinary education. Internal Medicine, Critical Care and/or Intensive Medicine, Reanimation and Anaesthesiology, can provide the best background.
Other specialisation might also be adequate, if the candidate has documented experience and he has received the necessary education and training in Hyperbaric Medicine.
Sport or commercial diving can give to the Medical Director a great deal of additional knowledge. This also provides awareness of the whole problem concerning this specialisation and it can add some complementary knowledge on diving and hyperbaric technology and practice. However this actual diving experience will not be required for the recognition of the Medical Director.

C) Educational profile.
The Medical Director should have followed a full Medical Educational Multidisciplinary Programme, in different fields of Medicine. A Medical Doctorate in Medicine is the basis. The medical education must be completed with Postgraduate courses in both Diving and Hyperbaric Medicine, preferably followed in University Departments.

D) Academic requirements and degrees.
The Medical Director, like all the medical staff in a Hyperbaric Centre, will be subjected to all regulations of WORK UNDER PRESSURE established by the European Community.
Even if Medical Directors have received a good self-trained education, they need a specific titulation degree, in order to avoid legal problems concerning the possible responsibilities deriving from the practice.

Definition of jobs
The training objectives of each job need to be defined in relation to the competencies that are expected from the incumbent. A number of the jobs in diving and hyperbaric medicine have tasks and objectives in common and so it is possible to optimise the efficiency of the educational program and avoid too much overlap by adopting a modular structure.