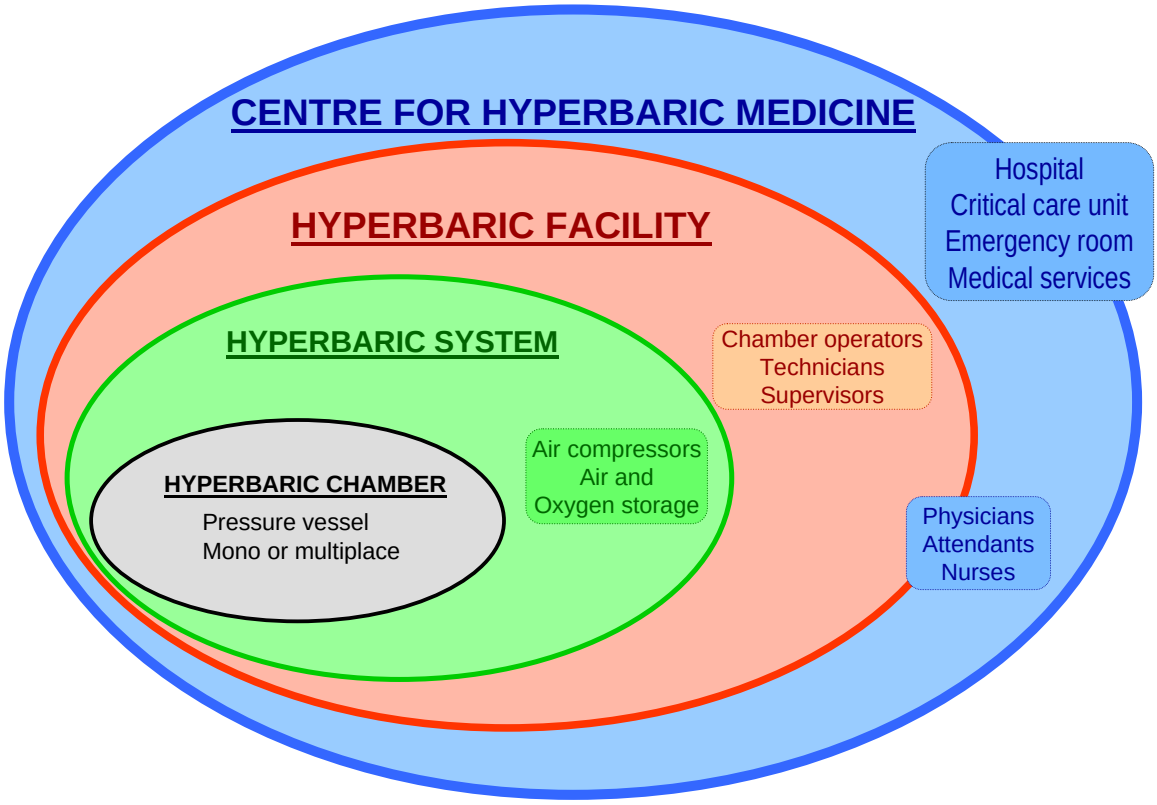
A EUROPEAN CODE OF GOOD PRACTICE FOR HYPERBARIC OXYGEN THERAPY



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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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The COST Working Group «Safety» (WGS) would like to thank the British Hyperbaric Association (BHA) for allowing the WGS to draw heavily on their document "Health and Safety for Therapeutic Hyperbaric Facilities: A Code of Practice", which was published in late 2000. This COST WGS document also draws on other European documents, directives and publications as listed in References.

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:

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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

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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.

I. The Medical examiner of divers

- Competent physician to perform the periodic "Fitness to dive assessments" of working and recreational divers and compressed air workers, except the initial assessment of novice professional divers.

IIa. The Diving medicine physician

- Competent to perform the initial and all other assessments of working and recreational divers or compressed air workers.
- Can manage diving accidents and advise diving contractors and others on diving medicine and physiology* (with the back-up of a hyperbaric expert or consultant).
- Should have knowledge in relevant aspects of occupational health. (He or she does not need to be certified specialist in occupational medicine to be in accordance with the standards).

IIb. The Hyperbaric oxygen physician

- Responsible for HBO sessions at the treatment site (with backup of a hyperbaric expert or consultant)
- Should have appropriate experience in anaesthesia and intensive care in order to manage the HBO patients (he or she does not need to be certified specialist in anaesthesia to be in accordance with the standards)
- Competent to assess and manage clinical patients for HBO treatment

III. The Hyperbaric expert or consultant (hyperbaric and diving medicine)

- Competent as chief of a hyperbaric facility (HBO centre) and/or to manage the medical and physiological aspects of complex diving activities[1].
- Competent to manage research programs.
- Competent to supervise his team (HBO doctors and personnel, health professionals and others).
- Competent to teach relevant aspects of hyperbaric medicine and physiology to all members of staff.

IV. The Associated specialists

This title is not a job qualification, but rather a function. It covers experts, consultants and specialists of other clinical specialities who can be nominated as competent to advise within their own speciality upon specific problems in the diving and hyperbaric field.

Contents of the Modules

Modules of formation and subjects	Levels of competence: a - basic b - need to know c - must be expert			
Jobs:	I	IIa	IIb	III

[1] optional additional qualification for bell diving (saturation, mostly off-shore)

1	**Physiology & pathology of diving and hyperbaric exposure:**				
1	Hyperbaric physics	**b**	**c**	**c**	**c**
2	Diving related physiology I (functional anatomy, respiration, hearing and equilibrium control, thermoregulation)	**b**	**c**	**b**	**c**
3	Hyperbaric pathophysiology (Immersion effect, blackout mechanism incl apnoea, psychology, working performance/endurance under water)	**b**	**c**	**a**	**c**
4	Hyperbaric pathophysiology (decompression theories, bubbles)	**b**	**c**	**b**	**c**
5	acute Dysbaric disorders, DCI (Barotrauma, DCS)	**b**	**c**	**b**	**c**
6	chronical Dysbaric disorders (Long term effects)	**b**	**c**	**a**	**b/c**
7	HBO-Basics (effects of hyperbaric oxygen)	**-**	**b**	**c**	**c**
8	O2 Intoxication	**a**	**c**	**c**	**c**
9	Inert gas-effects (Narcosis/HPNS)	**a**	**c**	**a**	**c**
10	medicaments under pressure	**b**	**c**	**c**	**c**
11	non-dysbaric diving pathologies (Hypothermia, near drowning, fauna&flora effects, injuries and accidents in water, the sick diver)	**a**	**c**	**-**	**c**
12	diving fatalities	**a**	**a**	**-**	**b/c**
2	**Diving technology and safety:**				
1	diving procedures (Bell diving)	**b**[1]	**b**[1]	**-**	**a /c**
2	Diving procedures (SCUBA, surface supplied, bell, TUP, SURD, 02-Deco, mixed gas diving	**b**	**c**	**a**	**a/ c**
3	Divers (Recreational SCUBA diving, technical and deep diving, Apnoea-diving, professional diving: offshore, inshore, scientific, media, recreational diving instructor, Caissonwork, astronauts)	**b**	**b**	**a**	**a/c**
4	Diving gear (SCUBA, SSUBA, mixed gas, rebreathers, monitoring equipment, working tools, suits)	**b**	**b**	**a**	**a/c**
5	Diving tables and computers (incl altitude and interval)	**b**	**b**	**b**	**a/c**
6	Regulations and standards for diving	**b**	**b**	**-**	**a/c**
7	Safety planning / management (monitoring)	**b**	**b**	**-**	**a/c**
3	**Fitness to dive**				
1	Fitness to dive criteria and contraindications (for divers, tunnel workers and HBOT patients and chamber personnel)	**c**	**c**	**c**	**c**
2	Fitness to dive assessment (diagnostics)	**c**	**c**	**c**	**c**
3	Fitness to dive standards and regulations (prof and recreational d.)	**c**	**c**	**b**	**c**
4	**Diving accidents:**				
1	Diving accidents / incidents (assessment and preclinical treatment incl. ORL, barotraumas, CPR)	**a**	**c**	**a**	**c**
2	Diving accident management clinical (Diagnostics, patient care, follow-up)	**-**	**c**	**c**	**c**

[1] as required

3	Diving accident management: Differential diagnosis	**a**	**c**	**c**	**c**
4	HBO-T for diving accidents (Tables and strategies)	**a**	**c**	**c**	**c**
5	Rehabilitation of disabled divers	**-**	**a**	**a**	**b/c**
5	**Clinical HBO:**				
1	Chamber technique (multiplace, monoplace, transport chambers, wet recompression)	**-**	**b**	**c**	**c**
2	HBO: Mandatory Indications	**-**	**a**	**c**	**c**
3	HBO: Recommended Indications	**-**	**-**	**c**	**c**
4	HBO: experimental and anecdotal Indications	**-**	**-**	**b**	**c**
5	Data collection / statistics / evaluation	**-**	**b**	**b**	**c**
6	general basic treatment (nursing)	**-**	**b**	**c**	**c**
7	Diagnostic, monitoring and therapeutical devices in Chambers	**-**	**c**	**c**	**c**
8	Risk assessment, incidents monitoring and safety plan in HBO-Chambers	**-**	**b**	**c**	**c**
9	Safety regulations	-	**c**	**c**	**c**
6	**Diverse:**				
1	Research standards	**-**	**a**	**a**	**c**
2	Paramedics teaching program	**-**	**b**	**a**	**c**
3	Management /Organisation of HBO facility	**-**	**a**	**a**	**c**
7	**Practical training:**				
1	Fitness for chamber-dive test (of the course participants)	**-**	**+**	**+**	**+**
2	CPR	**-**	**+**	**+**	**+**
3	Practice in field first aid (diving accidents)	**-**	**+**	**-**	**+**
4	Practical training FTD exam (skills)	**+**	**+**	**+**	**+**
5	Demo : professional diving	**+**	**+**	**-**	**+**
6	Demo : HBO-T	**-**	**+**	**+**	**+**
7	Introduction to (wet)-Diving	**(+)**[2]	**+**[4]	**-**	**+**
8	Practice in HBO-T (including pressure test)	**-**	**+**	**+**	**+**
9	Practice in attendants teaching	**-**	**+**[3]	**-**	**+**

Standards for course organisation and certification

Teaching courses

In order to comply with this EDTC/ECHM standard the person responsible for the professional contents of the course must be a hyperbaric medical expert or consultant (job type III)

[2] recommended
[4] exceptions possible, if important reasons of unfitness to dive
[3] as required

1. The course curriculum should be declared as being ”in conformity with the ECHM/EDTC standards” and the educational objective (jobs I and IIa, IIb) stated.
2. The course organisers are invited to send a copy of the curriculum to the joint medical subcommittee of ECHM/EDTC (through the national co-ordinator).
3. The final tests for individual evaluation are mandatory, and should cover all the taught subjects (see list) at the level of competence required for each subject.

The standards do not prescribe the status of the teaching institution but it is strongly recommended that courses are university based, are approved for such training courses by national health authorities, speciality training boards or are under the auspices of the national scientific society for diving medicine and/or hyperbaric medicine.

How a course is to be organised is not prescribed in these standards. Evenings, week-ends or full weeks are possible. For clinical teaching, an internship or residency may be appropriate. The acknowledgement of a high teaching standard is based on a credible final test of the candidates.

Modules and course organisation

The actual organisation and conduct of the modules will be influenced by local factors and so it is proposed that these details can be decided on a national basis and probably left to the individual course directors. The following proposal indicates the total teaching hours considered necessary to achieve appropriate competencies in the following jobs.

I	Medical examiner of divers	25 lecture hours + 3 hours practical
IIa	Diving medicine physician	The above + 30 additional lectures + 10 hours practical
IIb	Hyperbaric medicine physician	60 hours + a practical phase (5 different types of clinical cases with different indications for treatment)
III	Diving and hyperbaric medicine expert or consultant	This needs further review (see below)

The proposal serves as a guideline and is not mandatory. When one of these teaching programmes includes topics covered elsewhere a reduction in the number of lecture hours may be justifiable.

Recognition of an expert

The experience needed to become an expert cannot be learned from a course. The essentials have already been described in general terms. The candidate should already be an accredited specialist or equivalent.

Except in those countries where some equivalent or higher standards already exist, those who wish to be acknowledged as experts or consultants in the fields of diving and hyperbaric medicine should send their curriculum to their national co-ordinator (representing the Joint Medical Subcommittee or to that subcommittee itself if that nation has no co-ordinator) who may decide on the basis of the agreed standards. The Joint Medical Subcommittee will be informed by the national co-ordinator and can issue a list of experts if required. In the future the verification of achieved qualifications will be done by a national health authority or a scientific body (EU legislation). The aim is to achieve a recognition of the standards by those so that they automatically could take over the role of the national co-ordinator.

E) Continuous Medical Education (Quality Control and Competency).

The Medical Director should undertake a periodic Continuous Education programme, about the main aspects of Underwater and Hyperbaric Medicine. Participation in Courses, Workshops and Conferences organised by International Societies well-known in this field, such as the European and Baromedical Society (EUBS), the Foundation for the International Congress on Hyperbaric Medicine, the Undersea & Hyperbaric Medical Society (UHMS), or other courses approved or reviewed by the ECHM, could also be adequate.

Professional ethics and medical deontology oblige all Medical Directors to communicate their observations and improvements in the different fields of Diving and Hyperbaric Medicine to their colleagues of the international scientific community. In addition, the Medical Director must take advantage of the experiences of his international colleagues, and must take part in the wide-spread studies that might be performed.

The highest qualified Hyperbaric Centres should organise Courses, Workshops and periodical activities aiming to improve the education of specialised staff at all levels.

In most countries, the conditions for maintaining the active status of an individual are defined by some system of continuous medical education credit points (CME, as introduced in the USA some time ago). The ECHM & EDTC need to define the minimum requirement for this in a flexible way that provides enough freedom for the national bodies to establish a more detailed system. It is expected that these national requirements will be compatible with this guidance.

The following procedure is proposed:

Job I:
A minimal activity of 10 medical assessments of divers fitness per year is needed plus attendance at one refresher course (usually 2-days) in two years. Reactivation after a lapse needs participation in two 2-day refresher courses or a repeat of the full basic course.

Job IIa:
Continuing experience in the field of professional diving (e.g. advising a professional diving contractor or some equivalent activity) and participation in a course or congress previously approved by the national co-ordinator. Reactivation after a lapse should be on the basis of a specifically approved course. Where this cannot be

achieved, the candidate should submit an alternative training programme to the national co-ordinator for approval.

Job IIb:
Active employment in an HBO facility (or equivalent activity) and attendance at one national and/or international congress on hyperbaric medicine per year. Reactivation after a lapse needs a 10 working days in a HBO facility and attendance at two congresses in two years.

Job III:
Will rely on the decision of the national co-ordinator

The refresher seminars can serve to update the participants in order to confirm their active status and to reactivate those who temporarily have not maintained their required activity. They can also serve as an introduction to doctors of other specialities who may also gain CME credits in their own specialities. This not only can help the financing of a course but can be a chance for promoting HBO to those who would not attend the HBO scientific congresses.

F) Dedication.

All Hyperbaric Centres should have a permanent Medical Director, with partial or full-time dedication depending on the characteristics of each Centre, complemented by a variable number of collaborators of the same or similar background and education. Hospital centre treating patients in situation of emergency will probably need more than three medical doctors.

2 – NURSES

A) Functions.

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.

B) Background.

The Hyperbaric Nurse must have the corresponding degree of her profession. Specific education in Critical Care Nursing will be very useful. Knowledge of other specialisation like angiology, traumatology, and wound care will also be appropriate.

Special courses on Diving and Hyperbaric Medicine are essential.

The nurse may receive the necessary training in the same institution from the Medical Director.

C) Specific educational profile.

Hyperbaric Nurses should also receive a complementary education, according to their professional level, in the following matters:

1. General principles of Decompression Theory, Diving Technique, and Pneumatics.
2. Hyperbaric Technique.
3. Safety and preventive measures.
4. Operation of monoplace hyperbaric chambers.
5. Intensive critical care of patients.
6. Other aspects inherent in both Diving and Hyperbaric Medicine, concerning her profession.

D) Academic requirements and degrees.

A basic education and a nursing degree will be required.

Special courses for hyperbaric nurses are highly recommended but they will not be strictly required.

The hyperbaric nurse will be subjected to the regulations on WORK UNDER PRESSURE established by the European Community.

E) Continuous Education.

As in all fields of Health and Medicine, Hyperbaric Nurses must complete and continue their education by reading specialised texts, and attending Courses and Congresses. Their affiliation to specialised professional societies, such as the Nurses Baromedical Association or to other entities that might be created, would be of the greatest interest.

F) Dedication.

All hospital based Hyperbaric Centres should have a permanent team of Nurses, with partial or full-time dedication depending on the needs of each Centre.

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

3 – ATTENDANTS

A) Functions.

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, the majority of these activities may be adopted by doctors and/or hyperbaric specialists and nurses.

B) Background.

Attendants can come from different professions regarding Underwater and Hyperbaric Medicine, such as:

1. Sport or commercial divers.
2. Health auxiliaries, medical students, paramedics, or assistants.
3. Other professions preferably although not necessarily health/related.

Items **1** and **2** are the most adequate conditions or origins for working as an attendant. However, these degrees should not be necessarily requested.

Their education and training may be accomplished in the same hyperbaric institution.

C) Specific educational profile.

At a level according to their capacity, previous experience and kind of work, Attendants should be instructed in the following aspects:

1. General principles of Medicine and Therapeutics.
2. Medical First Aid.
3. General principles of Diving and Hyperbaric Medicine.

Their basic education may be received in the same institution from a hyperbaric specialist and/or doctors and nurses.

As a result of this non-specific education programme, the Attendants should meet the following requisites.

a) To feel comfortable in the hyperbaric environment.
b) Excellent practice with hyperbaric techniques and necessary manoeuvres for adapting patients to the pressure.
c) Sufficient knowledge of the main non invasive medical instruments generally used under pressure.
d) Capacity to interpret, but not to operate, the meaning of the control instruments placed inside the Hyperbaric Chamber. They must also be familiar with the pressure and control devices.
e) To give First Aid care in the case of an emergency.

D) Academic requirements and degrees.

There is no specific degree providing the requirements of an Attendant. Some entities organise educational courses adapted to this activity. However only a course on Medical First Aid should be strictly required.

The Attendants will be subjected to the regulations of WORK UNDER PRESSURE established by the European Community.

E) Continuous Education.

The Attendants will be informed in the same Institution, about any news on Underwater and Hyperbaric Medicine and Technique which could affect their activity. Their attendance at activities in the field of Diving and Hyperbaric Medicine should be encouraged.

F) Dedication.

All hospital and self standing Hyperbaric Centres using multiplace hyperbaric chambers should have a permanent team of Attendants, with partial or full-time dedication depending on the needs of each Centre. One or two people will not be enough to guarantee a 24 hours/day service, as the long stays inside the Chamber that they must often endure (if a multiplace facility is used) renders them incapable of further decompressions in the following hours.

If monoplace chambers are used, the attendants may not be necessary since all their functions are done externally by nurses and doctors and/or hyperbaric specialists.

4 - CHAMBER OPERATORS

A) Functions.

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.
3. Control and application of the safety regulations concerning prevention of fire, and oxygen toxicity.
4. Calculation, application and control of compression and decompression schedules for patients, Specialists and/or Doctors, Nurses and Attendants, applying decompression stops, when necessary.
5. Sometimes, interventions inside the Chamber under pressure, in order to control or check the correct operation of determined parts of the pneumatic circuits or devices.
6. Adaptation and checking of the medical instruments carried by the patients before being introduced into the Chamber, in order to assure their correct operation, and to avoid dangerous or undesirable effects.
7. 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.
8. 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.

B) Background.

Hyperbaric Operators usually come from a commercial diving environment, where often received specialised training. This is not indispensable and Operators can come from other areas.

Despite the fact that they come from a non-health-related profession, they will need to learn elemental principles of health since they will be in contact with patients.

Some paramedical professions and health-related activities common in hospitals, may provide a good basis from which the candidate may be trained by the same institution to become a chamber Operator.

C) Specific educational profile.

Whatever their previous experience might be, the Hyperbaric Operator need good knowledge in the following subjects:

1. General Pneumatics.
2. General Mechanics and Electromechanics.
3. Decompression Theory. Decompression schedules.
4. Diving and Hyperbaric Technology.
5. Medical First Aid
6. General principles of Medicine, and Medical Therapeutics.

Courses on Diving and Hyperbaric Medicine for auxiliary staff, will provide good training in all these matters.

D) Academic requirements and degrees.

Some diving centres, off-shore facilities, and other specialised entities, result in some countries in specific degrees adapted to the activity of a chamber Operator. However, this condition should not be regarded as indispensable until the European Community establishes a specific degree for chamber Operators.

A Degree in professional diving with a specialisation in hyperbaric systems and facilities will be adequate.

A technical speciality degree in pneumatic systems, or similar titulation, would be of great benefit although it is not absolutely indispensable.

The Chamber Operators will be subjected to the regulations of WORK UNDER PRESSURE established by the European Community.

E) Continuous Education.

Hyperbaric Operators will need to receive Continuous Education according to the advances in the field of hyperbaric technology and also in decompression theory. They must be regularly updated on the main aspects of the diseases that will be treated in the chamber.

For this reason, his periodical contact with other specialised Centres is highly recommended.

F) Dedication.

Since Chamber Operators are in charge of the operation of the Multiplace Hyperbaric Chamber, their presence is absolutely essential in all hospital or self standing Multiplace Hyperbaric Centres.

A permanent Chamber Operator, with partial or full-time dedication depending on the needs of each Centre, will therefore be needed.

In monoplace facilities, their services are also appreciated, but their functions can be also attributed to other types of trained personnel.

5 – TECHNICIANS

A) Functions.

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.

B) Background.

The Hyperbaric Technician must have a high level of knowledge in high, middle and low pressure pneumatics. They should also possess a deep knowledge of diving and hyperbaric technology. Some experience in the field of medical technology would be very suitable.

Some Chamber operators can also be technicians.

C) Specific educational profile.

In some areas, real specialists in diving systems or hyperbaric facilities will probably be very difficult to find. In many cases, a high pressure Technician and some of the technical staff of a Hospital will quite easily be able to adapt his knowledge receiving some additional instruction on pneumatics and high pressure.

D) Academic requirements and degrees.

The Hyperbaric Technician must have either an official degree with speciality in Pneumatic Systems, or an official specific degree in Hyperbaric technology, in the countries where these degrees exist. This activity should not be entrusted to persons or firms which, although experienced, might not be in a legal condition to give warranties, and cover responsibilities in case of a possible disfunction, emergency, or even catastrophe.

E) Continuous Education.

The Hyperbaric Technician, being a high level Specialist, must always be aware of the latest technological advances and new changes which might occur in his sector, in order to use the most adequate systems.

F) Dedication.

Depending on the amount of work and of the technical characteristics of each Hyperbaric Centre, maintenance of the facilities might be performed by full-time Hyperbaric Technicians or by subcontracted specialised firms or enterprises. Both conditions are equally acceptable.

6 - **OTHER STAFF**

Many other professionals with different qualifications may and should be engaged with a Hyperbaric Medical Centre, depending on the special characteristics of each and the hospital or institution where it is situated. Some of them are listed below.

1. Administrative
2. Statisticians
3. Rehabilitation
4. Fire specialists
5. Engineers
6. Others

Since the activities of these professionals do not adopt special characteristics or modifications by being carried out in a hyperbaric centre, and as their duties will be similar to their usual jobs, their functions, background, requirements, and dedication will not be detailed in this document. All these conditions will be developed as in other places or jobs.

7 - **ACREDITATIONS AND CREDENTIALS**

The ECHM will create a Subcommittee for specialist assessment or accreditation, that will establish a credential document as explained in the aforementioned criteria in section **1** of this document.

The selection and guarantee process will be established by the Subcommittee in a separate document, in which the following items will be specified:

1. Educational criteria.
2. Procedure for obtaining the credential.
3. Usefulness and validity of the credential.

In the meantime, lacking specific degrees in Underwater and Hyperbaric Medicine, the aforementioned credential will be the guarantee for a Hyperbaric Specialist.

8 - MINIMAL REQUIREMENTS

The aforementioned staff may be adapted to each facility according their particular conditions. The number of persons integrating the full staff will be enough to provide in any case at least the following persons and professions for every session of hyperbaric treatment.

A) Multiplace chambers facility.
- 1 Medical Director
- 1-3 Physicians / Medical Doctors
- 1 Nurse
- 1 Chamber Operator

B) Monoplace chambers facility.
- 1 Medical Director
- 1 Nurse or attendant

The dedication and functions of each one will be developed as explained above. Other types of staff will be included optionally according to the special characteristics of each centre and their needs.

9.- THE JOINT MEDICAL SUBCOMMITTEE OF ECHM AND EDTC

This committee will operate on the basis of the tasks outlined above. The members are the two chairmen of the education and training subcommittee of the ECHM and of the medical subcommittee of the EDTC respectively. Further two to three members are nominated by the chairmen on the basis of their special competence and experience in one of the relevant topics. As the chairmen each represent a specific subcommittee, any major changes or decisions must be discussed within these subcommittees before going to the meetings of the EDTC or ECHM respectively.

Each country interested in educational courses recognised by EDTC/ECHM should be represented by a member who has been acknowledged by the national hyperbaric medicine authority (or of all such authorities if there are more than one such authority in a country). Normally this would be either the national member of ECHM or the national medical representative on the EDTC. If not the same individual, both could attend if appropriate.

The EDTC and ECHM representatives of each country should nominate a national co-ordinator of teaching programmes, who could be the joint subcommittee member himself or who could delegate for that purpose (for instance to the national health and safety authority or any representative scientific body covering all aspects of

hyperbaric medicine). The national co-ordinator will have the duty to supervise the national programs, the certification procedures and the status of the course directors.

In order to enhance credibility of certification and to help those who do not yet have the experience necessary to establish a good validation system, the Joint Medical Subcommittee will create a pool of multiple choice questions with an evaluation grid, in the main European languages. This will be available for all members. Evaluation of the answers should be done by an international group nominated by the Joint Medical Subcommittee. This Subcommittee may also certify a national teaching syllabus or educational course if desired by its organisers, thus helping the national societies or other authorities in getting accepted by their governmental health and safety department or by their speciality boards.

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Annex 2 – ECHM Recommendation for Safety in Multiplace Medical Hyperbaric Chambers 1998 (informative)

ECHM Recommendations for Safety in multiplace medical hyperbaric chambers

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E C H M RECOMMENDATIONS FOR SAFETY IN MULTIPLACE MEDICAL HYPERBARIC CHAMBERS

1-PRINCIPLES

1.1-Scope of work

The purpose of this document is NOT to produce a new set of rules, standard or regulations for the safety of H B O. These rules, standards and regulations exist and are available in various forms and countries. A list of the major international ones is given below for reference.

This document is intended to be guidelines for the manager or any responsible person in an H B O operation to help him making sure that all necessary safety precautions are taken care of properly.

1.2 Risk assessment

To make sure safety precautions are adapted to the situation, a risk assessment is necessary. This is depending on the type of hyperbaric installation, the patients and the indications, as well as the number of exposures carried out on a regular basis in the hyperbaric facility.

This document will not provide answers to all questions, it is only guidelines. An adapted response to eliminate the risks and to reduce the unavoidable ones to an acceptable level must be established under the manager control for each particular Hyperbaric Centre.

1.3 List of reference documents

European Directives :

CEN Medical devices:	93/42/CE	dated 14 June 1993
CEN Pressure vessels:	97/23/CE	dated 29 May 1997
CEN Noise at work :	86/188/CE	dated 12 May 1986
CEN Chemical agents:	98/24/CE	dated 07 April 1998
CEN Electric devices / explosive atmospheres	94/9/CE	dated 23 March 1994
CEN Electric devices / electrocution	73/23/CE	dated 19 February 1993

Standards : Air quality standard (medical air, breathable air...)
ASME PVHO 1998
NFPA 1998
UHMS (Monoplace 1991 and Multiplace 1994 - HBO Chamber Safety)
ECHM (Training standard) 1997

Other documents : Many independent control organisms have produced rules or certification policies for hyperbaric and diving systems which may be used for conformity assessment of pressure vessels for human occupancy of HBO chambers (Bureau Véritas, Germanishe Lloyd, Lloyds, DNV,...)

1.4 Major points to be considered

Establishing and controlling a safety policy, at work for the attendants as well as in medical practice for the patients, is one of the duties of the manager of the Hyperbaric Facility. Sub-delegation of responsibilities should be clearly set and made known to the personnel.

The equipment used for HBO treatment is susceptible to generate risks both to the personnel and to the patients, therefore some construction and maintenance standards should be referred to for the equipment control and for the monitoring of the maintenance and in case of any modification carried out on that equipment. This topic includes fire protection and fire extinguishing systems.

Operational procedures need to be specified, posted and logged.

2 - MANAGEMENT AND ORGANIZATION

2.1 Responsible persons

It is the duty of manager of the Hyperbaric Centre to organize safety in the facility and he should designate in writing who is in charge of:

- Equipment, its maintenance and control (from compressed gases supplies to the chambers, the controls panel, and the exhaust of gases and fire fighting equipment outside and inside the chambers),
- Running the sessions and monitoring the operation,
- Informing the patients, controlling their personal items and objects eventually carried inside the chamber.

2.2 - Supporting documentation

*** Safety manual**

The safety manual is prepared and signed by the manager of the facility; it should include all information necessary to carry out the hyperbaric sessions safely, including the description of duties of the personnel involved. The content of this Safety Manual should be known by all and specific information should be given to new comers to make sure they are perfectly aware of its content.

*** Hyperbaric Equipment Construction Data Book (As built)**

A technical document should contain all information concerning the plant, as built drawings, all certificates with a list and dates of validity for easy check, basic operational procedures, maintenance program recommended by the manufacturer, and logging of all modifications carried out on the equipment.

*** Maintenance register**

Based on the manufacturer recommendations, a register of maintenance should be opened to log all actions of the maintenance team, in particular formal inspections, re-certifications, and spare parts changes. Near missed or break down should also be entered for further actions.

*** Compression and decompression procedure manual**

All pressure profiles used in the treatment should be categorized and identified with proper description. This includes decompression procedures applicable to the exposed personnel on the occasion of the attendance of the patients.

Any emergency compression (access), decompression (evacuation) or recompression (in case of DCI symptoms) procedures to be used for the attendants should also be in that document.

*** Day to day logging of personnel pressure exposures**

A register of exposure should receive information about individual staff exposures, and the same data should be logged in a personal log-book supplied by the employer to each person qualified to be exposed to pressure.

2.3 - Personnel training / medical fitness

Any person exposed to pressure should be fit to do so. This is based on occupation medical fitness to undergo pressurization. A specific assessment is needed on a yearly basis. A certificate of fitness should be issued, and eventually entered in the personal log-books.

The content of medical examination may be under national rules. If not, it should be defined and agreed with the concerned occupational doctor.

2.4 - Relationship with external emergency services

A joint visit of the plant with the Fire Brigade in charge of the place is highly recommended and the conclusion should be a jointly defined contingency plan for fire outside the chamber and help in case of fire inside.

2.5 - Safety posters on site

Through out the plant, where specific safety information is needed, proper posters should remember to the patients and to the personnel the applicable safety rules (Non smoking area, items not to be taken in the chamber, maximum value for oxygen monitoring and action in case of high alarm signal...)

At the lock attendant position, information on panel operation should be clearly displayed (valve function, positions, piping diagrams, emergency items...)

3 - EQUIPMENT

3.1 - Construction of Hyperbaric Chamber

*** Pressure vessel**

Specific construction and inspection rules apply to pressure vessels according to various national rules. After 2002, European pressure vessels regulation will have been harmonized under the Directive : CEN Pressure vessels, 97/23CE, dated 29 May 1997.

*** Architecture**

Basically the number of chambers in an installation should be such that, in case of emergency it should be possible to enter the treatment chamber and provide assistance inside. The minimum is a 2-compartment installation, one chamber being kept at atmospheric pressure to give access. It is generally considered acceptable to carry out decompression of personnel in that access chamber provided a procedure is prepared to free that chamber quickly to face the need to enter the main chamber.

Patient access to the treatment chamber is of primary importance for the personnel and all effort should be made to provide mechanical help for handling beds and stretchers when the entrance doors are not with easy and wide access. Many chambers derived from diving chambers engineering are very poorly designed in this respect. In addition this is a serious hazard in case of emergency evacuation.

*** Electric devices**

Electricity may cause two types of hazards : Electrocution and Fire.

Electrocution prevention

Any electrical medical device in contact with the patients should be protected against the hazards of electrocution for the patients in accordance with medical rules applicable to such medical devices.

Any electrical device used in the chamber as tools or equipment should be protected against electrocution as a tool or equipment used in a conductive environment (CEN Electric devices, electrocution, 73/23/CE, dated 19 February 1993).

Fire precautions

Fire may be triggered in the chamber either by conductors overheating (short circuit) or by sparks. Due to the high partial pressure of oxygen always present in compressed air, fire will develop extremely fast if material burning in compressed air is present at the place of fire trigger

Therefore :

All power wires should be selected in the category : M2
All equipment should be built in such a way that no spark may start a fire.
Any equipment not specifically designed for use in compressed air should be validated by a competent person who will assess the risk of bursting a fire during normal use and in case of breakdown (fail safe).
A simple means to prevent dangerous, sparks is to select electrical equipment with CE marks showing it is acceptable for use in flammable or explosive atmosphere (CEN Electric devices, explosive atmospheres, 94/9/CE, dated 23 March 1994,

*** Plumbing**

Regular piping should be in agreement with pressure vessels systems rules.

Oxygen and gases with high oxygen concentration ($FO_2 > 0.25$) circuits, require special precautions (reduce pressure as much as practicable in all distribution lines, all equipment must be oxygen compatible and internally cleaned by a competent person on installation). No ball valve should be used to operate oxygen circuits. All gas storage area should be properly ventilated or equipped with a leakage alarm (high oxygen content).

Connecting oxygen cylinders to the circuit should be made only by qualified personnel.

*** Measurements, analysis, recorders ...**

Calibration of meters is part of the maintenance program. It should be done at regular intervals and logged into the maintenance register.

Pressure profiles and oxygen content of the atmosphere should be recorded

*** Fire fighting systems**

Internal fire fighting system includes : A manual extinguishing system operable by the attendant, a sprinkler type water deluge triggered independently from inside or outside. Override valves (inside and outside) should be available to prevent flooding when fire is eventually under control.

It is part of fire prevention to be able to decompress quickly the chamber for evacuation and at the same to cool efficiently the burning material and reduce immediately the partial pressure of oxygen closer to 0.2 bar. A fast decompression valve operable from outside at the attendant position, eventually sealed with a safety breakable thread, is a strong recommendation.

*** Breathing masks**

In case of fire it is extremely important that any extra oxygen input in the atmosphere should be stopped, and that breathing masks be available for all. Shifting HBO masks to air will cover the need for the patients; extra masks should be available, one for each attendant eventually present in the chamber.

Very little can be done to protect hoses delivering gases to the masks, they should be built in heat and fire resistant material, the deluge system is intended to protect them until evacuation can be carried out.

*** Lock attendant station**

A special care should be given by the manufacturer of the system to make the control of the chambers easy and fool proof. Proper markings are needed showing gas circuits and functions of valves as well as their position. When video screen are used, their location and brightness should be controlled. Communication system should have a back-up arrangement, and the quality of microphones and speakers in the chambers should be of good quality, a permanent listening capability for the lock attendant is needed. A telephone line in connection with the telephone control panel of the building should be available at the position of the lock attendant

Noise level due to decompression of gases should be removed from the place by proper piping and silencers.

3.2 - Construction of buildings

*** Patients access**

In addition to the access to the chamber some care should be given in the room available for patient preparation, inspection and handling around the installation in particular when intensive care patients are concerned.

*** Connection with hospital**

Many of the indications of HBO are for intensive care patients, who require special equipment and transport from the hospital, a close connection with the hospital is a must for Hyperbaric Centres accepting intensive care indications. This includes laboratories and medical analysis capabilities.

*** Fire precautions**

The hazard of fire in the Ilyperbaric, facility are related to gas storage, oxygen circuits, pressure vessels and the fact that for some indications decompression of patients for evacuation may be fatal to the patient (arterial embolism, DCI, some CO poisoning cases ...). And it also may be dangerous for the attendant involved in such cases.

A contingency plan should be prepared with the fire brigade to take into account those specific hazards and organize fire fighting procedure accordingly.

All markings in relation with fire fighting and evacuation must be displayed

*** Gas storage, compressors room, distribution plumbing...**

It is of primary importance that, in all situations, pressure could be maintained in the chamber and that ventilation should not be interrupted for more than a few minutes. The gas supply system should be so arranged that in case of failure (compressor, electricity, cooling water, piping breaks ...) a back up system become operational at once to match the gas requirements for the treatment and the possible required decompression of personnel. This can be achieved via gas storage, emergency compressors, emergency electric supply... A document should demonstrate the risk assessment, which leads to the choice of an adapted solution. The corresponding emergency procedure should be in writing and should be part of the training of the personnel in charge.

*** Equipment authorized for use under pressure**

The equipment permanently used in the chamber and designated for use under pressure should be devoted to that activity and be clearly identified. It should have been evaluated for suitability of the purpose either by the initial manufacturer of the chamber or jointly by the user and the manufacturer of the equipment.

A list of those equipments should be part of the safety manual. Example: hospital wheel chairs should be greased with non burning grease, private wheel chairs have to be left outside, ...

Any new item to be entered into the chamber should be controlled by a competent person who will sign an authorization to use under pressure, eventually in association with special recommendations or safety rules when applicable and after questioning the manufacturer.

3.3 - Maintenance Program

*** Schedule for maintenance operations**

In the instruction manual provided by the manufacturer of the installation, there should be proper guidelines for the maintenance schedule. The manager of the installation will formalize the maintenance program in the safety manual.

In particular only products and spare parts recommended by the manufacturer should be used (oxygen compatible lubricants for example).

*** Air quality controls.**

The frequency of air quality controls is depending of the type of compressors used, the type of filtering units and the activity of the centre. This should be defined in agreement with the guidelines given by the manufacturer(s) of the gas production plant and incorporated into in the safety manual.

*** Maintenance logging**

All maintenance operations carried out by technicians should be logged in the maintenance register and signed by the technician in charge.

Entries should be left open for the personnel to report on day-to-day breakdowns and remedial actions taken.

*** Emergency drills**

The manager of the installation should recommend safety drills, mostly oriented towards fire prevention and fire fighting, all personnel should participate to those safety drills, which should also be logged in the operation log-book.

4 -OPERATIONS

4.1 - Staffing

*** Number and role of persons**

During any treatment 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

Depending on the type of centre, the number of simultaneous use of pressure chamber the minimum team stalling is variable. There should be a minimum of 3 qualified persons outside (Supervision, lock attendant and emergency help).

Any staff member accepted for compression should be medically fit to undergo pressurization.

*** Under pressure patients attending policy**

It is presently a common practice in several hyperbaric units not to attend walk-in patients for the whole session, the attendant being locked out after compression or even not being compressed at all when patients have experience of the exposure

The policy on patient attending under pressure should also be clearly defined in the safety manual. Instructions to un-attended patients should be sufficient for them to face minor problems under pressure and to control properly oxygen mask leakage (both ways).

4.2 - Patient preparation / control

*** Information to the patients**

The content and the procedure of information to the patients should be clearly established, eventually with a specific leaflet or document to be given to the patients, on the occasion of exposures. Who is in charge of this information and copies of the documents are to be included in the safety manual.

*** Medical preparation**

Before entering the chamber, all patients should be controlled to assess their medical situation, in particular when they are connected to medical devices or when they were dressings on wounds ...

*** Practical preparation**

Policy concerning patients clothing, bedding equipment, inspection of personal items is needed, A recommendation should be that patients keep a minimum of personal clothes and receive at least a blouse covering the remaining clothes. That blouse being made out of low flammability material (cotton). Consequently a personal items storage look should be made available for each patient.

5-CONCLUSION

Basically there are few construction problems left when the manufacturer of the HBO facility is safety conscious and the buyer ready to invest in a safe system. Most of the safety problems in HBO are related to the procedures used and the precautions enforced during the day-to-day work.

These precautions are directly under the control of the personnel. The personnel should be well aware of the centre safety policy; he (she) should have received the initial training, a copy of the safety manual and be given a clear definition of his (her) responsibilities during the sessions.

The management, after establishing that policy in a safety manual, should also make sure it is properly applied. This needs personal involvement and frequent controls.

Annex 3 – COST B14 Working Group «Technical Aspects» Final Report 2001 (informative)

WG Technical Aspects: Presentation of the results

In order to push forward the development of a European norm for therapeutic hyperbaric facilities, the COST B14 Working Group «Technical Aspects» conducted a risk analysis, following the format of the European Norm "Medical Devices – Risk Analysis" (EN 1441).

The main aim was to demonstrate the need for a norm, by identifying all the risks linked to the use of any hyperbaric installation. For this Annex C of the EN 1441 was used.

Five different types of risk have been summarised:

- **Energy Hazards** (Electricity, heat, mechanical force, pressure)
- **Biological hazards** (bio contamination, toxicity, pyrogenicity)
- **Environmental hazards** (inadequate supply of power or coolant, incompatibility with other devices)
- **Hazards related to the use of the device** (inadequate operating instructions, inadequate specification of accessories, use by unskilled/ untrained personnel)
- **Hazards arising from functional failure, maintenance and ageing** (inadequacy of performance characteristics for the intended use, inadequate maintenance)

As a complement to this identification of the risks and with a view to make a more comprehensive document, method statement EN 1441 outlining the functional analysis was also documented.

The results, which you can find in the annex, are a list of all risks linked to the use of the HBO Facility. Each type of risk is identified with its consequences for the patient (P), the accompanying personnel (A) and the operators (O).

Each identified risk may have additional implications or introduce another type of risk and therefore these are listed in the cross reference column.

The work presented is intended to be a non-exhaustive list of risks. It is the first step, which should bring us closer to a normalisation process. These results may therefore be integrated into the ongoing normalisation process, as well as highlighting the need for the future work of the Working Group «Safety Aspects».

This study was the first step of a process needed to be carried out and was the achievement of the Working Group «Technical Aspects».

On behalf of the members of WGT.

Robert HOUMAN
Secretary

C2: Assesment form for hazards occurring during hyperbaric oxygen

Items	Hazard/ type of error	Consequences	P	A	O	Cross Ref.
ENVIRONMENT	Earthquake zone	Walls crash-collaps	X	X	X	
	High risk of flooding	Flooding of the chamber locals	X	X	X	
	High risk of pollution	Bad quality of compressed air	X	X		3, 4
PREMISES	Room do not fit to receive the chamber	Patient's way is full of difficulties	X	X	X	4, 6
	Not enough space for ancillary rooms	Bad organization	X	X	X	4
	Not good foundation	Collapse of the frame	X	X	X	
MECHANICAL	Bad construction as cracks on: - steel plates; - forged pieces; - diaphragms; - elliptic ends; - portholes; - medical lock.	Collapse of the frame - crash - explosion when in pressure	X	X	X	4, 6
ELECTRICAL SERVICE	Short circuit of: - lighting system; - electric devices; - comunication system.	Fire - explosion	X	X	X	2, 4
	Electric spark	Fire - explosion	X	X	X	4
	Electrostatic spark	Fire - explosion	X	X	X	4
	Spark from mechanical friction	Fire - explosion	X	X	X	4
FIRE PROTECTION	Bad working of fire fighting system	No fire extinguishing	X	X	X	4, 5, 6

COMPRESSED AIR SYSTEM	Bad working	Uncorrected compression or decompression protocole	**X**	**X**		3, 5, 6
OXYGEN SYSTEM	Dirt inside circuit	Explosion	**X**	**X**	**X**	
	High pressure	Explosion	**X**	**X**	**X**	
	Rust inside piping	Explosion	**X**	**X**	**X**	
	Build up inside chamber	Explosion	**X**	**X**	**X**	
	High temperature inside circuit	Explosion	**X**	**X**	**X**	
	Bad lubrication	Explosion	**X**	**X**	**X**	
	Wrong gasket	Explosion	**X**	**X**	**X**	

C3 : BIOLOGICAL HAZARDS

Items	Hazard / type of error	Consequences	P	A	O	Cross Ref.
1 – Risks linked to hardware : chambers and pressure part design and manufacturing						
	Over pressurisation above the rated working pressure	Damage to structures	X	X	X	2, 5, 6
	Pressurisation over the stop pressure	Decompression illness	X	X		5, 6
	Pressurisation rate too fast	Rise in ambient temperature	X	X		2, 5, 6
	Depressurisation rate too fast	Decompression illness Pulmonary barotrauma	X	X		2, 5, 6
Chamber paint	Incorrect type	Contamination of chamber atmosphere	X	X		4
Adequate Chamber ventilation	Contamination of chamber atmosphere	Inability to complete therapy	X	X		4, 6
Reducers	Failure open / free-flow	Damage to pressure vessels / explosion / rupture	X	X	X	4
Exhausts	Inadequate size / not protected / not well placed to avoid pocketing of 0_2	Noise / unnecessary ventilation / suction injury / blockage				4, 6
Noise	Health hazard	Hearing loss	X	X	X	
2 – Risks linked to hardware : Respiratory gases						
Medical Gases	Correct label/type/purity	Poisoning/Hypoxia	X	X		4, 5, 6
Purity of gases	Contamination	Poisoning of inside personnel/ hypoxia. Fire	X	X		4
Purity of Air	Contamination	Poisoning of inside personnel/ hypoxia. Fire	X	X		4
Compressor air intakes	Incorrect position height etc.	Contamination of atmosphere	X	X		2
Compressor high pressure	Faulty contaminated air	Poisoning of chamber personnel	X	X		2
Compressor Low pressure	Faulty contaminated air	Poisoning of chamber personnel	X	X		2
Purity of oxygen	Contamination	Poisoning of inside personnel/ hypoxia. Fire	X	X		4
Liquid Oxygen	Position / safe distances Cleanliness	Injury / off-gassing / Fire			X	
Purity of helium	Contamination	Poisoning of inside personnel/ hypoxia. Fire	X	X		

Quality calibration gases	Incorrect specification	Inaccurate analysers	X	X		
Mixing of gases	High oxygen level	Cerebral/pulmonary oxygen toxicity	X			4, 5, 6
Mixing of gases	High Nitrogen partial pressure	Nitrogen narcosis	X	X		4, 5, 6
3 - Risks linked to hardware : gas breathing devices and associated pipes						
Reducers	Failure open / free-flow	Damage to BIBSs / explosion / rupture of pipes / damage to the patient	X	X	X	4, 5
BIBS	Contaminated/poor fitting/leaking. Breathing resistance	Raised ppO_2 in chamber Fire risk Patient not receiving 100% O_2	X	X	X	4, 5
BIBS tracking regulator	Malfunction	Vacuum injury/pressure loss	X			2, 4, 6
	Allergenic substances	Allergic reaction	X			
	Transmission of infectious diseases	Infectious cutaneous, broncho-pulmonar or general diseases	X			4, 5
4 - Risks linked to hardware : accessories / others						
Plastic	Non chamber compatible	Burning/off gassing Contamination	X	X		4, 6
Inappropriate Materials/ furnishings	Static electrical discharge. Off gasing if burning	Fire	X	X	X	4, 6
Chamber Lights	Too Hot / Not bright enough	Fire/ heat source Medical procedures difficult	X	X	X	2, 4, 5
Speakers	Electrical short	Sparks / Fire	X	X	X	2, 4, 6
Heat Source	Over heating	Fire / Burn risk	X	X	X	4
Fire extinguishers	Incorrect type	Not function at depth/contaminated atmosphere	X	X	X	5
Equipment charging areas	Fumes/off gassing Electrical faults Heat	Electrical shock/ Fire	X	X	X	4
Loose Cables/Wires	Trapped/ Chaffing/Arching/Fire	Electrical Shock	X	X	X	4
5 - Risks linked to chamber operations						
Control panel alarms	Lack of function/ settings to high	Contamination/ Fire risk Hypoxia / Poisoning	X	X	X	5, 6
Humidity control	Incorrect safe level	Sparks /Fire/ Uncomfortable	X	X	X	6
Compression rates	Injury to personnel inside chamber	Barotrauma / Heat	X	X		5, 6
Decompression rates	Injury to personnel inside chamber	DCI	X	X		5, 6
Incorrect / Dirty Clothing	Contamination	Fire	X	X	X	4

Dirt/ Dust / Contamination	Poor house keeping	Contamination / Fire / Explosion /	X	X	X	4, 6
Banned Substances	Contamination	Fire / Off gassing	X	X		4, 6
Banned equipment / Substances inside Chamber	Biggest single causes of accidents / Fire	Injury / Fire	X	X	X	4
Inappropriate cleaning chemicals	Contamination	Contamination of atmosphere. Scratching of view ports	X	X		4
Water supply	Insufficient Volume/ clean/	Unable to fight O_2 rich fire Contamination / diseases	X	X		6

6 - Risks linked to medical devices

Equipment touch key pads	All come on together with compression / faulty	Patient vital equipment inoperable	X			
Laryngoscopes /Battery equipment	Incorrect batteries / sparking switch	Fire risk	X	X	X	4
Patient Ventilator	Affected by pressure / density of ambient pressure	Patient inadequately ventilated	X			4, 5
Artificial ventilation	Resistance of patient	Pulmonary barotrauma	X			5
Infusion Pumps	Affected by pressure / density of ambient pressure	Patient inadequately supplied with drug doses prescribed	X			4, 5
Intravenous infusions	Lack of sealing Ingress of bubbles	Gaseous embolisations	X			5
Bed/trolley type	Rams/Oil/ pneumatic	Contamination, loss of height of bed	X	X		4, 6
Diabetic monitors	Affected by pressure	Inaccurate	X			4, 6
Patient Monitoring	Affected by pressure / density of ambient pressure	Inaccurate / can not change settings / failure	X			4, 6

7 - Risks linked to managing the patient

Patient Changing areas	Lack off	Contamination of chamber environment/ Fire risk	X	X	X	4, 6
Infection Control	Poor standards/ inadequate	Cross infection of patients / Staff	X	X		4, 6
Shoes/Overshoes	Lack off / dirt / Oil in Chamber	Contamination / Fire	X	X	X	4
Patient Lockers	Lack off/ not lockable	Will mean patient will take banned substances into chamber/ Fire / Contamination	X	X	X	4, 6

C4 Environmental Hazards

Items	Hazards/type of error	Consequences	P	A	O	Cross Ref.
ENTRANCE TO CHAMBER						
Entrance into the chamber	Inadequate construction, improper use,	Personnel injury, damage of material	X	X	X	4, 6
Incorrect/ Dirty Clothing	Contamination, electrostatic spark	Cross infection, Fire	X	X	X	3, 4
Shoes/Overshoes	Lack off / dirt / Oil in Chamber	Infection, Fire	X	X	X	3, 4, 5
Prohibited items	Contamination, Spark, malfunction	Cross infection, injury, fire	X	X	X	3, 4
BUILDING & CHAMBER						
Building/ housing	Combustible/ insufficient fire protection	Inability to escape. Burns, lack of protection	X	X	X	2, 4
Building Architecture	Design	Injury / lack of safety / Lifting / Fire protection	X	X	X	2, 4, 6
Chamber ergonomics	Inadaptable device	Personnel Injury, damage of material	X	X	X	4
Medical lock size	Unable to quickly lock in/ out essential equipment	Poor quality care to patients/ dangerous due to delays with essential drugs More items inside than strictly necessary	X			4
Chamber paint	Non compatible	Poisoning	X	X		3, 4
Plastic	Non compatible	Burning/off gassing, Contamination	X	X	X	2, 3, 4
Inappropriate cleaning chemicals	Contamination	Poisoning, damage of equipment	X	X	X	3, 4, 6
Environmental control unit/ Regenerator of air	Failure/ lack of regular maintenance	Infection, intoxication, Hypo and hyperthermia, sparks, fire	X	X	X	4, 6
Communication systems/External assistance	Inadequate, malfunctions, Can not call for assistance	Early termination of treatment, Poor quality care to patients Inability to call for urgent or any assistance	X	X	X	2, 4, 6
BIBS exhaust	Free flow/ Malfunction	Vacuum injury, leak into chamber atmosphere	X	X		2, 4, 6
Mains electrical systems	Break down/ power cuts.	Inability to complete exposition safely	X	X		2, 4, 6

Battery electrical systems	Hydrogen gas/ insufficient power / time	Explosion, Fire, Inability to complete exposition safely	X	X	X	2, 4, 6
UPS electrical systems	Not working when required, Sufficient time/power for emergency requirements	Inability to complete exposition safely	X	X		2, 4, 6
Emergency generator electrical systems	Not working when required, Sufficient time/power for emergency requirements	Inability to complete exposition safely	X	X		2, 4, 6
Chamber ventilation	Inadequate ventilation, failure	Intoxication,	X	X		3, 4, 5, 6
Infection Control	Poor standards/ inadequate	Cross infection	X	X	X	3, 4, 5, 6
Door seals/ "O" rings	Damage	No Compression / loss of pressure	X	X		2, 4, 5, 6
Door weight/handles	Lack of door stops / doors not hung correctly	Physical Injury	X	X	X	2, 4, 6
Silencers	Dirty/ Blocked / corroded	Explosion, physical Injury	X	X	X	2, 4, 6
Pipework	Inadequate	Injury/ damage/ explosion	X	X	X	2, 4, 6
Pressure relief valves	Not large enough / incorrectly set / Faulty	Explosion, Damage to pressure hull, Injury	X	X	X	2, 4, 6
Reducers	Failure open / free-flow	Unintentional Increase of pressure	X	X		2, 3, 4, 5,6
Equipment charging areas	Fumes/off gassing Electrical faults Heat	Intoxication, electrical shock, fire	X	X	X	2, 3, 4, 6
Exhausts	Inadequate construction, malfunction	Noise, O2 pockets, suction injury, DCS	X	X		2, 3, 4, 6
Chamber Lights	Malfunction, short-circuit	Poor quality care to patients, fire	X	X	X	2, 3, 4, 5, 6
Heat Source	Over, lack of heat	Fire / Burn risk / Hypothermia	X	X	X	2, 3, 4, 5, 6
Loose Cables/Wires	Trapped/ Chaffing/Sparks	Electrical Shock, fire	X	X	X	2, 3, 4, 5, 6
Compressor high pressure	Faulty, contaminated air	Infection, intoxication	X	X		2, 3, 4, 5, 6

Compressor Low pressure	Faulty, contaminated air	Infection, intoxication	X	X		2, 3, 4, 5, 6
Oxygen supply	Malfunction, purity, amount	Hypoxia, DCI, fire	X	X	X	2, 3, 4, 6
Computers outside	Failure	Inability to complete treatment safely	X	X		2, 4, 5, 6
Manifolds	Wrong position / inappropriate material / rating / erroneous labeling	Asphyxia, hypoxia, intoxication, DCI	X	X		2, 4, 5, 6
INTERNAL EQUIPMENT						
Internal fixed equipment	Not ergonomic	Personnel injury	X	X	X	4
Internal equipment	Un-allowed air pockets, malfunction	Damage, health hazard	X	X		4, 5, 6
Internal battery equipment	Malfunction, sparks	Fire, health hazard	X	X	X	2, 3, 4, 6
Patient Ventilator	Malfunction, affected by pressure & density of gas	Hypo- hyperventilation, lung overpressure	X			3, 4, 5, 6
Infusion Pumps	Malfunction, affected by pressure / density of ambient pressure	Patient inadequately supplied with drug doses prescribed	X			3, 4, 5, 6
Patient Monitoring	Malfunction, affected by pressure / density of ambient pressure	Poor quality care to patients	X			3, 4, 5, 6
Diabetic monitors	Affected by pressure	Inaccurate	X			3, 4, 5, 6

C5 Hazards related to the use of a medical device

Chambers for Hyperbaric Oxygen Therapy

a) Inadequate labelling

Items	Hazard/Type of error	Harm/Consequences	P	A	O	*Cross Ref.*
Chamber	Main chamber with patient lock	No compression	X			6
	Confusion inlet valve with outlet valve	No compression	X			
Fire suppression	Confusion main chamber and personnel lock	Inability to stop a fire, accidental deluge	X	X		6
Electrical power	Main chamber light	Darkness, panic, inability to observe patients	X	X		6
	Alarms, warnings	Inability to detect technical problem: Overpressure, high PPO_2 of the chamber atmosphere etc	X	X	X	6
	Loss of different functions i.e. $TcPO_2$, communication devices, TV, panel illumination etc.	Inability to perform the corresponding functions	X	X		6
Breathing place number	If different gases are simultaneously used	Treatment failure, incorrect patient statistic, treatment evaluation etc	X	X		3
Gases	Confusion O_2 with air	DCI for personnel	X	X		3, 6
	Confusion air with O_2	Fire risk, Oxygen toxicity	X	X	X	3, 6
	Confusion Helium with O_2	Asphyxia for personnel	X	X		3, 6
	O_2 with Mix	Therapeutic failure in patients, risk of DCI for personnel	X	X		3, 6
	Mix with O_2	Oxygen toxicity	X	X		3, 6

b) Inadequate operating instructions

Items	Hazard/Type of error	Harm/Consequences	P	A	O	Cross Ref.
Chamber	Fast compression Fast decompression Overpressurization	Barotrauma Oxygen toxicity	X	X		3, 6

Gas: Air	Starting a treatment without enough supply	Aborted treatment	X	X		3, 6
Gas: Oxygen	Starting a treatment without enough supply	Fire if use of lubricants, Aborted treatment	X	X	X	3, 6
Gas: Helium	Starting a treatment without enough supply	Inability to perform a saturation or deep treatment	X			3, 6
Gas: Gasmix	Starting a treatment without enough supply	Inability to perform a saturation or deep treatment	X			3, 6
Electricity	Unplugged device	No function, malfunction of device before or during treatment	X	X	X	6
Patients	Patient instructions	Barotrauma Oxygen toxicity Risk of fire if patients carry banned substances	X	X	X	6

c) Inadequate specification of accessories

Items	**Hazard/Type of error**	**Harm/Consequences**	**P**	**A**	**O**	***Cross Ref.***
Fire suppression	Malfunction	Inability to stop a fire, accidental deluge	X	X	X	2, 6
Electrical power	Main chamber light	Darkness, panic, inability to observe patients	X	X	X	6
	Alarms, warnings	Inability to detect technical problem: Overpressure, high PPO_2 of the chamber atmosphere etc	X	X	X	6
	Loss of different functions i.e. $TcPO_2$, communication devices, TV, panel illumination etc.	Inability to perform the corresponding functions	X	X	X	6
BIBS	If different gas are simultaneously used	Treatment failure, incorrect patient statistic, treatment evaluation etc	X	X		3
Hoods	Reuse of old hoods	Rupture of the hood, risk of fire, interruption of treatment	X	X	X	6
Vacuum bottles	Not suitable for high pressure, Rupture of Glass/plastic	Lack of suction	X			6
Respirator	Not suitable for high pressure	Inefficient patient ventilation	X			3, 6
Infusion pumps	Not suitable for high pressure	False volume delivery	X			3, 4, 6

Infusions	Unsuitable for overpressure	Rupture, air insufflations in the patient's vein	X			3, 4, 6
$TcPO_2$	No or false readings under hyperoxia	False wound evaluation of $TcPO_2$	X			4, 6
EKG	No or false readings under pressure	Misinterpretation of results	X			4, 6
Blood pressure	No or false readings under pressure	Misinterpretation of results	X			4, 6

g) Use by unskilled/untrained personnel

Items	Hazard/Type of error	Harm/Consequences	P	A	O	Cross Ref.
Chamber	Overpressure, prolonged exposure	Oxygen toxicity DCI	X	X		3, 6
Compression rate	Fast compression or decompression	Barotrauma	X	X		3, 6
IV lines	Introduction of air bubbles in the iv line	Air embolism	X			3, 4, 6

h) Reasonably foreseeable misuse

Items	Hazard/Type of error	Harm/Consequences	P	A	O	Cross Ref.
Oxygen	Sparks in chamber	Fire, explosion, oxygen toxicity	X	X	X	2, 6
Pressure	Overpressurization	Damage to chamber	X	X	X	2, 3, 6

i) Insufficient warning of side effects

Items	Hazard/Type of error	Harm/Consequences	P	A	O	Cross Ref.
Patients	Missing selection of high risk patients	Increase of side effect (Oxygen toxicity, Claustrophobia, Barotrauma)	X	X		6

j) Inadequate warning of hazards likely with the reuse of a single use device

Items	Hazard/Type of error	Harm/Consequences	P	A	O	Cross Ref.
Filters	Reuse of mask filters	Contamination	X			3, 4, 6

k) Incorrect measurement and other methodological aspects

Items	Hazard/Type of error	Harm/Consequences	P	A	O	Cross Ref.

Chamber pressure gauge	Pressure lower than real	Insufficient treatment	X			6
	Pressure higher than real	Risk of DCI in tenders Oxygen toxicity in patients	X	X		6
Air supply gauge	Pressure lower than real	Premature interruption of treatment	X			6
	Pressure higher than real	None				6
O_2 supply gauge	Pressure higher than real	None				6
	Pressure lower than real	Premature interruption of treatment	X			6

l) Incorrect diagnosis

Items	Hazard/Type of error	Harm/Consequences	P	A	O	Cross Ref.
Patients	Insufficient response to complications	Oxygen toxicity, Barotrauma	X	X		6
	Choice of treatment protocol	Ineffective treatment, risk of complication	X	X		6

m) Erroneous data transfer

Items	Hazard/Type of error	Harm/Consequences	P	A	O	Cross Ref.
Treatment number	False reporting (under/over)	Unjustified Treatment failure, false billing	X			6
Pressure	False reporting (under/over)	Medico legal implications in case of permanent disability in patient	X	X	X	6
Treatment duration	False reporting (under/over)	Medico legal implications in case of permanent disability in patient	X	X	X	6

o) Incompatibility with consumables/accessories/other devices

Items	Hazard/Type of error	Harm/Consequences	P	A	O	Cross Ref.
Ventilator	Insufficient ventilation	Insufficient treatment	X			3, 4, 6
Infusion pumps	False volume delivery	Insufficient treatment	X			3, 5, 6
Infusions	Unsuitable for overpressure	Rupture, gas embolism	X			3, 5, 6
Vacuum bottles	Unsuitable for overpressure	Rupture, gas embolism / gas emphysemas	X			3, 6

IV lines	Air entrapment	Gas embolism	X			3, 6
Pomades, creams, oil pads	Flammable topical creams	Risk of fire	X	X	X	4, 6
Various	Flammability	Fire	X	X	X	4, 6

C6 Hazards arising from functional failure, maintenance and ageing

1. Inadequacy of performance characteristics for the intended use

ITEMS	Hazards/ type of error	Harm/ Consequences	P	A	O	CROSS REF.
Air compression	Failure on compression system: too fast, too slow, not enough, no compression	Overpressure, Unable to complete therapies, injury, Barotrauma / Heat	X	X		2, 3, 5
Cylinder gas storage HP	Lack of volume / size	Unable to complete therapies if power cut	X	X		
Cylinder gas storage LP	Lack of volume / size	Unable to complete therapies if power cut	X	X		
Pipework for all gases	Inadequate / size / pressure rating / material	Unable to carry on treatment / injury damage/ explosion	X	X	X	4
Reducers	Failure open / free-flow	Damage to pressure vessels / explosion / rupture	X	X	X	4
Air decompression	Failure on decompression, Too slow, too fast, no decompression	DCI,	X	X		5
Air ventilation	Not adequate, failure, Inadequate size / not protected / not well placed to avoid pocketing of 0_2	FO_2 increase, Fire danger, Hyperoxia, Noise / unnecessary ventilation / suction injury / blockage	X	X	X	5
Heating /Cooling	Insufficient / poor	Inability to complete treatments safely	X	X		4
Humidification	Incorrect levels	Static/Sparks/ Fire /Shocks/Comfort	X	X	X	
Distribution of therapeutic gas	Not adequate, failure, leak O_2 inside chamber	Fire danger, Hyperoxia	X	X	X	3
Self contained Breathing Apparatus (SCBA)	Not available/malfunction/ Staff not trained in its use.	Operators unable to stay to assist in the emergency evacuation of chamber personnel	X	X	X	
BIBS tracking regulator	Malfunction	Vacuum injury/pressure loss	X	X		4

Gas distribution Panels	Poor design / Maintenance/ failure	Lack of gas inability to treat Incorrect gas/ hypoxia/ poisoning	X	X		3
Control panel	Not adequate (ergonomic), failure,	Positioning, accident	X	X	X	3, 5
Control panel alarms	Lack of function/ settings to high	Contamination/ Fire risk Hypoxia / Poisoning	X	X	X	3, 5
Watch systems and alarms (passive), Analyzers, …	Not adequate, failure, Lack of function	Contamination/ Fire risk Hypoxia / Poisoning	X	X	X	3, 5
Protective systems (active), Sprinkler	Not adequate, failure, Lack of function	Contamination/ Fire risk Hypoxia / Poisoning	X	X	X	2, 3, 5
Fire extinguishers	Incorrect type	Not function at depth/contaminated atmosphere	X	X	X	2, 3, 5
Fire suppression Outside chamber	Lack of function/ Maintenance	Inability to fight fire Injury to personnel	X	X	X	2, 3, 5
Fire explosive hazards	Lack of care in following standard operating procedures	Fire / Hazards/ Injury	X	X	X	2
Temperature control	Hyper-/ Hypothermia	May require early termination of treatment	X	X		3, 4, 5
Software	Malfunction	Therapy terminated early	X	X		3, 4, 5
Equipment touch key pads	All come on together with compression / faulty	Patient vital equipment inoperable	X		X	3, 5
Communications/ Primary	Poor quality	Confusion / Errors / Panic	X	X		3, 5
Communications/ Secondary	Not functioning	Panic / incorrect actions / injury / lack of communications	X	X		3, 5
Speakers	Electrical short	Sparks / Fire	X	X	X	2, 3, 5
Lighting primary	Inadequate	Mistakes at work	X	X		5
Lighting secondary	Lack of maintenance	Inability to complete treatments safely	X	X		5

Ergonomics in and outside the chamber	Not adequate	Injuries to personnel	X	X	X	2, 3
Patient Access	Steps / Door widths / Wheel chair access	Delays / Lifting / Injury	X	X		2, 3, 4
Door weight/handles	Lack of door stops / doors not hung correctly	Injury to personnel	X	X	X	2, 3, 4
Silencers	Dirty/ Blocked / corroded	Explode / fracture / Injury	X	X	X	4
Pressure Gauges	Inaccurate	Decompression Illness	X	X		5
Equipment tagging & numbering	Inadequate/ incorrect	Break down / failure Unable to treat patients	X	X		5
Equipment charging areas	Fumes/off gassing Electrical faults Heat	Electrical shock/ Fire	X	X	X	4
Accessories	Not adequate, failure	Explosion, Fire, Injury	X	X	X	3, 5
Medical records	Incorrect for patient / Inadequate / not complete / up to date /available	Poor quality of care	X	X		5
Mains electrical systems	Break down/ power cuts/ Not adequate	Inability to complete treatments safely	X		X	2, 5
Battery electrical systems	Hydrogen gas/ insufficient power / time	Inability to complete treatments safely	X		X	4
UPS electrical systems	Sufficient time/power for emergency requirements	Inability to complete treatments safely	X		X	4
Generator electrical systems	Not working when required	Inability to complete treatments safely	X		X	4, 5
Personal	No adequate education	Accident, safety not assured		X	X	5

2. Lack of, or inadequate specification for maintenance, including inadequate specification of post maintenance functional checks,

ITEMS	Hazards/ type of error	**Harm/ Consequences**	P	A	O	Cross ref
Safety inspection	Not adequate/ regularly	Potentially harmful conditions	X	X	X	5
User manual	Not adequate, (no identification of each element	Damage, Injury, failure	X	X	X	5
Technical Documentation	Not adequate	Damage, Injury, failure	X	X	X	5

Compressor filtration system	Failure/ lack of regular maintenance	Contamination/ Injury	X	X	X	3
Environmental control unit/ Rain	Failure/ lack of regular maintenance	Contamination/ Injury	X	X	X	4
View Ports	Damage /Scratched/ Out of date	Severe pressure loss Decompression Illness	X	X	X	
Back up machinery	Inadequate/ lack off Not serviced. maintained	Break down / failure Unable to treat patients	X		X	4
Patient monitoring	Failure/ lack of regular maintenance	Inaccurate / injury	X	X	X	3, 4, 5
O_2 Analyzers/ Primary	Failure cell expired Inaccurate / maintenance	Too high $PP0_2$ Fire risk	X	X	X	3, 4, 5
O_2 Analyzers/ Secondary	As above & Needs to agree with primary	Too high $PP0_2$ Fire risk	X	X	X	3, 4, 5
CO_2 analyzers	Failure/ inaccurate	Contamination/ inadequate flushing/ ventilation/ poisoning	X	X	X	3, 4, 5
CO_2 Scrubbers	Noise/chemical burns/ corrosion. Electrical faults.	Contamination/ inadequate flushing/ ventilation/ poisoning	X	X	X	4
Door seals/ "O" rings	Damage	No Compression / loss of pressure		X	X	2, 4, 5
Valves needle	Lack of maintenance	Lack of compression / Supply		X	X	
Fire suppression Inside chamber	Tested/function for hyperbaric environment And gas density. Electrical connection trip	Inadequate fire suppression & electrical shock	X	X	X	2, 3, 5
Power fuses Switchboards	Bad position / incorrect rating / faulty trips / resets	Lack of power for life support			X	2, 3, 5
Liquid Oxygen	Position / safe distances Cleanliness	Injury / off-gassing / Fire	X	X	X	4
Computers & VDU's	Failure inside or outside chamber. Affected by pressure. Heat	Lack of compression Inability to treat patients Inability to finish treatment Heat/ Fire			X	2, 3, 5
Unauthorized chamber equipment	Malfunction / Fire. Contamination / Electric Shock	Malfunction / Fire. Contamination / Electric Shock	X	X	X	4, 5
Humidity control	Incorrect safe level	Sparks /Fire/ Uncomfortable	X	X	X	3, 5

Banned equipment / Substances inside Chamber	Biggest single causes of accidents / Fire	Injury / Fire	X	X	X	3, 4, 5
Patient Lockers	Lack off/ not lockable	Will mean patient will take banned substances into chamber/ Fire / Contamination	X	X	X	
Patient Ventilator	Affected by pressure / density of ambient pressure	Patient inadequately ventilated	X	X		3, 4, 5
Infusion Pumps	Affected by pressure / density of ambient pressure	Patient inadequately supplied with drug doses prescribed	X	X		3, 4, 5
Patient Monitoring	Affected by pressure / density of ambient pressure	Inaccurate / can not change settings / failure	X	X		3, 4, 5
Bed/trolley type	Rams/Oil/ pneumatic	Contamination, loss of height of bed	X	X	X	3, 4
Diabetic monitors	Affected by pressure	Inaccurate	X	X		3, 4, 5
Loose Cables/Wires	Trapped/ Chaffing/Arching/Fire	Electrical Shock	X	X	X	2

3. Inadequate maintenance,

ITEMS	Hazards/ type of error	**Harm/ Consequences**	P	A	O	cross ref
User manual	No determination of each responsibility,	Lack of planned maintenance/ breakdown			X	5
Duties of staff	Personnel unclear of their duties	Injury/ damage		X	X	5
Equipment maintenance	Break down	Unable to treat patients	X	X	X	5
Equipment documentation	Lack of adequate records	Lack of planned maintenance/ breakdown			X	5

4. Lack of adequate determination of end of device life,

ITEMS	Hazards/ type of error	**Harm/ Consequences**	P	A	O	CROSS REF
User manual	Work safety of the facility	Damage, injury			X	5

5. Loss of mechanical integrity,

ITEMS	Hazards/ type of error	**Harm/ Consequences**	P	A	O	CROSS REF

Mechanical elements	Work safety of the facility	Damage, injury	X	X	X	2
Valves 1/4 turn	Lack of maintenance	Lack of compression / Supply/ Exhaust			X	
Non Return Valves	Lack of maintenance	Reduced gas flow too slow compression			X	
Pressure relief valves	Insufficient size/ faulty	Damage to pressure hull			X	4
Manifolds	Position / material / rating / labeling	Incorrect gases supplied / Injury	X	X	X	4, 5

6. Inadequate packaging (contamination and/ or deterioration of the device),

ITEMS	Hazards/ type of error	Harm/ Consequences	P	A	O	CROSS REF
BIBS	Contaminated/poor fitting/leaking. Breathing resistance	Raised PPO_2 in chamber Fire risk, Patient not receiving 100% O_2	X	X	X	

7. Improper re-use

ITEMS	Hazards/ type of error	Harm/ Consequences	P	A	O	CROSS REF
Accessories	Contamination	Cross infections	X	X		3, 4

Annex 4 – 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 5 – 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.)
    c. Disinfection records:
        - Records of changing masks, equipment and consumables,
        - Records of cleaning and disinfection of chamber, masks, hoods, tubes, etc.)
    d. 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 6 – 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 7 – Prohibited Materials

Each and every item added to the hyperbaric environment posses 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.