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Chapter 1: Design of a Therapeutic Hyperbaric Centre
(01) How I would design my HBO facility? [Sweden]

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Summary

Treatment with hyperbaric oxygen (HBO) requires a hyperbaric chamber with appropriate medical equipment and supervision of properly trained medical staff so that oxygen can be breathed safely at pressure by the patient. These requirements can best be fulfilled in a hospital based HBO facility. Stand-alone out-patient HBO and wound care facilities can be run professionally but HBO therapy “at home” is not acceptable. Monoplace and/or multiplace chambers can both safely be used as HBO delivery tools and should be operated and maintained according to international guidelines and regulations. Acrylic monoplace chambers pressurized with oxygen provides cost-efficient, individualized and patient friendly delivery of HBO, especially for children. The multiplace chamber is ideally suited for HBO therapy of large patient groups or in the critically ill ventilator-dependent patient with failing vital functions. The larger air compressed multiplace chamber allows appropriate ICU equipment to be used and continuous "hands-on" intensive care by an accompanying physician and/or nurse.

Multidisciplinary guidelines should be established within the hospital for the correct use of HBO as a therapeutic drug. The HBO facility should be incorporated into the hospital organization via educational efforts supported by the hospital administration. The quality of hyperbaric medicine practiced should be advanced by clinical research and development.

Introduction

The field of Hyperbaric Medicine has continued to attract attention and invite controversy in clinical medicine over the past 60 years but is becoming better acknowledged as the general understanding of the pathophysiology of many diseases as well as the pharmacological effects of HBO are better understood. Clinical evidence confirm HBO to be effective and/or very promising in a number of diseases, either as a primary mode of treatment or as an important adjunct to other treatments, such as antibiotics and surgery (Marroni et al 2004, Gesell et al 2008, Lind et al 2011).

The acceptance of HBO as a legitimate drug for certain indications has led to the expansion of therapeutic hyperbaric centers worldwide with a huge variety of designs depending on local resources and the specialty and
interest of the HBO director and local surroundings. This diversity of structure of hyperbaric centers also holds true for Europe, also within each separate European country, although there have been strong efforts to produce guidelines, regulations and standards over the past 2 decades. In Europe we follow “A European Code of Good Practice for HBO Therapy” (Kot et al 2004, www.ECHM.org) in which a HBO facility has been defined “to consist of the therapeutic hyperbaric system(s) together with associated plant, buildings, staff (both technical and medical), and a specific administrative organization. Two kinds of hyperbaric facilities exist: hospital based and standalone”. The latter can also be named “free standing HBO facility” and has been defined for this ECHM conference as a chamber which is not physically located in the main building of a hospital.

My personal view on how I would design my HBO facility is based on my special “Hyperbaric” background with active interest in sports diving, 30 years of practice as a diving doctor in the Royal Swedish Naval Reserve, 10 years of hyperbaric research in respiratory and exercise physiology at Karolinska Institutet followed by 25 years of clinical work, research and development of HBO as an Anesthesiologist and Intensivist in the academic setting of the Karolinska University hospital. I have always worked within the hospital system; I believe this to be the most proper place for a HBO center and will therefore focus on design of hospital-based HBO facilities.

Active participation in Hyperbaric Conferences since 1977 and frequent visits to other HBO centers all over the world have made me aware of the importance of staffing for a successful HBO program (rather than chambers and equipment). An energetic and motivated director and staff can do miracles which are of major importance for both patient and attendant health and safety. Each HBO centre has its own local patient population depending on available resources, opportunities, specialist clinics and referral patterns, not to mention reimbursement issues. The political and historical background of the region, country or continent has also a great influence on how the HBO facilities has been designed, or rather been developed over time. Hence, the design of a HBO facility depends primarily on what indications are to be treated and how sick the patients are; how many patients are to be treated per day and whether emergency care is required. For example, the stand-alone hyperbaric chamber on a small dive site where a “healthy” diver with decompression illness may occasionally be treated once or a few times will require a different arrangement then the wound care clinic in a general hospital with 20 to 40 or more patients being HBO treated daily.

The HBO facility with ICU capability and 24-hour emergency services in the academic university trauma hospital setting will require much more resources. Treatment of critically ill and ventilator-dependent patients under hyperbaric conditions presents a variety of additional challenges and risks due to machine-, staff- or patient-related problems. The comatose child, adult or whole family with carbon monoxide poisoning and smoke inhalation injuries rescued from a burning apartment at night present a horrific catastrophe scenario for any HBO center. The unstable septic patient with failing organ systems due to a necrotizing fasciitis being referred from another hospital to receive HBO twice a day as part of a multidisciplinary program represent a complicated patient group that call for additional HBO resources if it is not to disturb all other scheduled HBO treatments. Surgery, repeat diagnostic CT scans, dialysis etc will make it practical to have a separate ICU multiplace chamber or lock available for the special timing and treatment profiles of this ICU patient, i.e. the multiplace chamber in reality becomes a one ICU patient “monoplace” chamber. Staffing also becomes a problem when the emergency HBO patients “disturbs” regular planned HBO procedures and practice. The best quality is achieved by having the regular ICU nurse and/or doctor tend their patient during HBO as part of regular ICU care.

I advocate the use of small acrylic Monoplace or one-man chambers as the preferred HBO delivery device in most spontaneously breathing patients. They are compressed with 100% oxygen which allows the patient to
breathe comfortably without a mask or hood. They require no inside attendant, less construction work, less long-term investments and financial risk and give better hygiene, integrity and flexibility. They also give the best patient compliance, especially in children who, if need be, can be treated together with accompanying parent or personal. Monoplace chamber HBO facilities with 2-6 separate chambers are most commonly used in USA but have also been used within Europe, e.g. Stockholm, Sweden and Bergen, Norway. Many multiplace HBO facilities around the world nowadays also add the flexibility of having 1-2 monoplace chambers at their centre.

The large multiplace chamber, most commonly used in Europe, and in the large regional centers in USA, also function well and has the main advantage that more patients can be treated at the same time and that they usually have an accompanying inside attendant to help out. The comparison Bustransport (Multiplace) vs. Taxi (Monoplace) can be made as the Multiplace requires all “passengers” to be on time and follow the same route of pressurization and treatment protocol. Hence, individual treatment protocols and needs cannot always be serviced and one patient with problem to equalize the middle ear pressure will delay the procedures for all accompanying patients.

In real-life design of a new HBO center there is a multitude of alternative solutions depending on location, medical needs, rules and regulations as well as available resources (Lind & Kronlund 2008, Moon & Camporesi 2010, Weaver 2011). With this background, and avoiding political, academic and reimbursement issues, I will take on the somewhat impossible task to explain how I would design my hospital-based HBO facility focusing on the patient; to give the best care for each patient, one at a time. I will focus on the design of two separate hospital based HBO centers- both located within an existing hospital infrastructure but with different objectives.

**Design of a university hospital / regional trauma hospital/ based HBO facility**

HBO treatment centers with personnel and equipment for treating critically ill patients on a 24-hour basis should be regionalized to keep up quality and cost effectiveness. Well functioning helicopter and other emergency transportation services are necessary. Time to treatment is crucial for acute indications for HBO e.g. cerebral arterial gas embolism in a comatose diver after free ascent or the anesthetized patient not waking up after open heart surgery; the burn victim with CO and cyanide intoxication and inhalation injuries or the “toxic shock” septic patient with necrotizing fasciitis. In general, the earlier these patients with potentially life-threatening conditions are treated, the better the outcome.

HBO services for a regional hospital and trauma center require a much larger investment. My design of a HBO facility would be based on a more rigorous analysis of medical needs, resources and potential acute and elective patient volumes. The main problem will most probably be to get experienced staffing, education and support until the unit can stand on its own feet.

**Locale / Setting /Hyperbaric chamber system**

Close proximity to ICU is strongly recommended to obtain best intensive care and to minimize the risk of patient ICU bed transportation, preferably with no need for elevators, stairs or door thresholds. The chamber should enable safe HBO treatment with a minimum consumption of staff and time. HBO treatment of critically ill and ventilator-dependent patients creates a variety of additional challenges and risks due to transport-, equipment-, staff- or patient-related problems.
Since these HBO services encompass emergencies and intensive care patients around the clock the facilities should be spacious enough for a large 4-lock multiplace chamber system (see below), preferably rectangular. Ideally, if a new ICU were to be built, the chamber should be located within the ICU or better yet; ICU rooms could be built for hyperbaric use so that the patient could remain stationary between HBO treatments. The alternative solution is to have a new building constructed adjacent to the existing ICU ward to allow the HBO center to be spacious enough and to have separate entrances for ICU and non-ICU patients. The major volume of patients will be non-emergency awake spontaneously breathing patients from within the hospital (bedridden) or outpatients that need a separate entrance hall. Most of these non-acute patient groups can be treated in one or two locks of the multiplace chamber while a separate lock is being reserved for emergencies. Yet, I would still have at least two monoplace chambers in an adjoining room for increased flexibility and for treating children or doing clinical research with possibility of sham therapy.

I would advocate a rectangular 4-lock chamber system (e.g. Karolinska) with two independently operated chamber systems to provide 24-hour service. It is a flexible and cost-effective treatment option that enables HBO treatment for more than one ICU patient at a time, e.g. a family of smoke inhalation victims. It also improves safety and availability, e.g. one system is always operational also during technical service. The chamber should be lowered into the building floor to allow a ramp free and step free access for beds and trolleys throughout the chamber system. Large rectangular 1.5 m wide sliding doors allows modern ICU beds to enter smoothly also when width and length is increased due to chest drains, urinary output bags, oxygen tube with suction device, ICU ventilator and large number of infusion pumps. A modern ICU bed size is 2.2 x 1.0 m but during transport it come near to 2.5 x 1.5 m and according to Swedish Work Authority Regulations an additional 0.80 m around the bed are required for patient care. This requires large hyperbaric treatment rooms with a width exceeding 3,2 meters.

The treatment rooms should resemble conventional modern intensive-care or trauma rooms with easy to clean surfaces, washbasins and flexible air control ventilation system to provide good hygiene and infection control and a functional work environment for the staff. A suspended ceiling or channels with critical care equipment rack in the chamber roof will cover up plumbing, wiring and air circulation ducts. A regular ICU pendant can be used for additional flexibility. The design should be flexible to allow continued improvements in overall ICU care throughout the life span of the chamber system. One medical lock should be installed in each compartment of the chamber. It should be designed for easy and safe use and allow opening and closing using one hand only. It should have a flat floor and should occupy as little interior space as possible. It should be large enough to hold a regular coffee tray or to transfer an infusion pump, a defibrillator.

The computerized treatment control system should be user friendly, intuitive and logical to permit safe operation by medical staff. Flat touch screens can be used as interface between operator and pneumatics. Normally, a treatment pressure profile will be selected and run in automatic mode but e.g. pressurization can be stopped immediately if there are difficulties with e.g. equalizing the ear pressures. During treatment, a transition from one profile to another may be performed manually, e.g. if the patient needs a prolonged HBO treatment. Standard-profiles are editable (re-programmed) and expandable by local staff for continuous development and research protocols.

Members of the staff shall be able to communicate via wireless headsets either independently or all together to improve safety during HBO practice. The design of valves and ventilation should allow minimum noise. An interior surveillance system with quality cameras is also important. I would also strongly advocate a high quality
camera that can be operated via a joy stick to zoom in on e.g. medical equipment or the patient for diagnostic purposes.

Electrical power should have an Uninterrupted Power Supply battery backup with capacity to take over vital electrical power to the chamber system including ventilators, chamber working-light, communications, valve controls, system and pressure-monitors, control panel, video surveillance system and 4 ICU-monitors for at least 30 minutes.

Equipment

An Intensive Care Hyperbaric Chamber System should preferably enable HBO therapy without having to change the patient’s bed, monitoring, ventilator, infusion pumps or interrupt continuous renal replacement therapy. For this reason a close cooperation is needed between the hyperbaric and biomedical engineering departments of the hospital, the chamber producer and the notifying body. We now have a non-rechargeable, battery operated semi automatic defibrillator approved for hyperbaric use (Kronlund et al 2011). The goal is of course to have all hyperbaric ICU equipment comply with European codes and standards. At Karolinska we continue the work to get best available ICU ventilator and infusion pumps approved for hyperbaric use so that they do not have to be disconnected during transport and HBO session but can come along on battery power. It is also necessary to monitor and correct the patient's vital functions, i.e. ventilation, arterial and central venous pressure, fluid and electrolyte status, and diuresis throughout the HBO session. Monitoring of arterial blood gases and end-tidal CO2 is important as a means to prevent hypoventilation and oxygen induced seizures (Handell et al 1992). A hyperbaric critical care patient data management system can continue to provide bedside and remote clinical patient documentation and information (Kronlund & Lind 2012). Data from monitors, mechanical ventilators and syringe pumps are fed into a central clinical information management system to monitor, display trends and record data of vital parameters, ventilator settings and drugs. This will improve quality of care during HBO and facilitate research and development in hyperbaric medicine.

Special considerations, hygiene procedures and technical solutions are needed to reduce risks for spread of infection and for treatment of patients infected with multi-resistant bacteria. Wash basins should be installed in each treatment lock of a modern chamber. Due to fire risks of using alcohol disinfectant we have successfully used a new water based nontoxic, non-corrosive, acrylic- and fire safe disinfectant (Desisoft) as a broad-spectrum biocide that is effective against bacteria, spores, viruses, fungi and mould with long-lasting effects (Lind & Kronlund 2008).

Staffing

The multiplace chamber is ideally suited for HBO therapy of critically ill patients, primarily because it allows normal "hands-on" intensive care by the accompanying physician and/or nurse. Qualified staff should accompany the patient throughout the whole HBO treatment to continue regular bed-side supervision and evaluation, guide medication and do rapid medical interventions, including e.g. defibrillation. Muscle relaxation with excessive or inappropriate use of sedatives and analgesics is not an option as they carry an unacceptable risk of awareness and hypotension with increased needs for inotropic drugs etc. Septic or otherwise hemodynamically unstable patients require accurate hemodynamic monitoring, uninterrupted vasoactive drug infusion/-s and continuous blood-, fluid- and electrolyte therapy during treatment which requires well functioning syringe-or infusion pumps and attention during pressurization of the chamber.
The mechanically ventilated patient, whose trachea is intubated, often requires frequent endotracheal suctioning and risk acute tube obstruction, especially after a few days of intensive care. During pressurization of the chamber and during decompression the endotracheal cuff needs attention not to leak or harm the trachea due to overpressure, respectively. At 2,8 bar treatment pressure, the three-fold density causes a doubling of flow resistance with need for change in ventilator settings to avoid harmful high pressure, hypoventilation, carbon dioxide retention and oxygen seizure. Careful monitoring of arterial blood gases and end-tidal CO2 is therefore of great importance in caring for the HBO patient. Advanced HBO therapy of critically ill with specially designed Monoplace chambers exist, especially in USA (Weaver 2011) but I favor the multiplace chamber with accompanying staff for the above reasons.

In general a HBO facility should have a hyperbaric physician, nurse, chamber operator and technical staff employed with emergency medical assistance available in the vicinity. In my view, the doctor, nurse and technically responsible persons could all be chamber operators to improve knowledge and safety and facilitate on-call staffing. The staffing will of course differ depending on size, location and whether both multi- and monoplace chambers are used. The minimum team size for a hyperbaric session in a multiplace chamber is three; the chamber operator, the hyperbaric physician and an attendant/nurse. The medically most sound, most flexible, convenient and economical staffing 24/7 is if all the staff is working within the anesthesia intensive care clinic. Regular wound care sessions in one of the locks of the multiplace chamber can of course have other staffing than ICU personnel.

**Design of a new hospital based HBO facility without ICU capabilities**

This HBO facility is for the small-, medium to large sized hospital willing to initiate HBO services mainly for non-emergency radiation injury and wound care indications but who may consider increasing the volume if the program is successful. Spontaneously breathing patients with acute indications can be treated but no HBO intensive care capability is planned.

**Locale / Setting /Hyperbaric chamber system**

I would look for spacious facilities with easy access for outpatients as well as bed-ridden inpatients; preferably close to surgical-, endocrinology-, emergency-, and infectious disease- or ICU wards and within a surgical zone with existing infrastructure for wound care e.g. outpatient clinics. The HBO facility should permit separating infected from non-infected patients with strict hygiene and infection control to avoid spread of microorganisms. There should be a large central open area with room for at least two to three monoplace chambers with potential of expansion either to four to six monoplace chambers or maybe even a multiplace chamber if the volume increases or there is a wish to expand the program and treat intensive care patients. Large windows without direct sunlight to the chambers are essential to minimize confinement anxiety and improve patient compliance.

**Equipment**

Emergency drugs, defibrillator and equipment for tracheal intubation should be available. All HBO facilities must have the capacity to monitor and correct low blood glucose before and after each session when a diabetic patient is being treated. ECG and respiratory rate should be monitored during the first HBO session and when needed. At least four transcutaneous oxygen probes are needed in hyperbaric practice to evaluate patients with
peripheral wound healing and traumatic ischemia. Intravenous lines into the monoplace chamber with appropriate infusion pumps should be available as well as the ability to continue epidural pain relief during HBO therapy.

A patient roof lift should be available for transfer of bedridden patients over to the special monoplace gurney. The gurney should allow the patient to be semi recumbent to reduce the blood volume load to the heart and reduce the risk of heart failure when laying down breathing oxygen.

TV and video entertainment system is an important tool to increase patient compliance. For fire safety no electronic equipment may be used inside the monoplace chamber and special cotton bed linen and gown shall be used by all monoplace-chamber patients. The bed clothes should be washed between treatments in patients with open wounds and infections, otherwise stored in patient specific lockers.

Documentation of wounds and injuries with repeat quality photography is essential. Appropriate equipment, facilities and staffing for regular wound care is also mandatory unless available close to the HBO unit.

**Staffing**

An experienced medical director should be employed to train the HBO staff. Staffing can also be recruited externally but preferably it should also engage personnel from the hospitals own surgical, anesthesia and intensive care, emergency and infectious disease specialties.

A monoplace chamber session requires minimum two persons, a physician and a chamber operator. However, two or more chambers can easily be operated by a slightly larger crew who can also do medical or computer work whilst the patients are being treated and enjoy a good movie. Similarly, wound care, medical assessment, consultancy etc. can be done in the surrounding area.

**Research and Development**

Education, research and development of Hyperbaric Medicine should be supported by the hospital director also in a smaller HBO facility. A multidisciplinary group of specialists should be appointed to monitor and help improve medical results by developing hospital specific guidelines for the correct and cost effective use of HBO as a therapeutic drug. I believe that there is a particular great potential for the future use of HBO therapy in treating refractory wounds, postoperative complications and hospital acquired infections. Improved outcome and reduced hospital stay is of importance not only for the hospital director.

**References**


(02) How I would design my HBO facility? [Denmark]

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Analysis of need

Existing institutions

Oxynet (1) provides a good oversight over hyperbaric units in Europe. In a rough estimate one may assume that at least one million inhabitants are necessary to provide a reasonable background for a hyperbaric unit.

The patients

In the analysis of need is the prevalence of patients with diseases to be treated with hyperbaric medicine.

The main groups of patients are:
- The diabetic patients and other wound patients
- The late radiation injuries
- The patients with osteomyelitis, fractures and trauma
- The serious soft tissue infections
- The diving accidents and gas embolisms.

In the analysis it is necessary to look into the prevalence and incidence of each group. The information on the prevalence and incidence of each group is typically to find in health statistics in the region and for some of the more rare indications a national register has to be examined.

Not only has the present need to be examined. Also the future development of the patient groups and treatment has to be taken in account. As an example of an altered need for hyperbaric treatment is the use of image
modulated radiation therapy (IMRT) in the treatment of oral cancer. This modality seems to produce less osteoradionecrosis of the jaw. Similarly will the cohort of previously conventionally irradiated patients decrease either due to performed hyperbaric treatment or decrease due to increased age and mortality in the irradiated group of patients.

The professional context

Hyperbaric medicine is usually considered a highly specialized function and may be have special relations to a group of hospitals, clinics or geographical areas. It is of great influence on the solution if the HBO unit is located within a large university hospital containing all or many medical specialties or a standalone unit.

The feasibility study

When designing the HBO facility it is necessary to look into the needs and wishes of the community and the ability to provide material and installations, financial resources and intellectual capacity for the facility. This feasibility has many variables. The feasibility study will need several reiterations to decide the best solution.

Establishment of leadership and a professional network.

The leader of the hyperbaric unit needs to have the relevant medical background. The medical background may reflect the actual need of the facility. In case of many carbon monoxide or diving accidents a background in working medicine may be relevant. In areas with many radiation injury patients a background in oncology may be relevant and in units with a considerable load of patients needing intensive care the anesthesiologist may be the key person. Of course the leader should have the formal background; an EDTC certified training or similar education combined with a more traditional training of the relevant specialty. In the design of the hyperbaric centre a board of cooperating specialists is of importance. The board is advisory to the leader of the hyperbaric unit. The formation of a board provides a continuous interaction between the specialties referring patients to the hyperbaric unit. If you cannot establish a board, then form another professional forum, which provide criticism and inspiration in the daily work.

Location of the HBO unit

Where to place the HBO unit depends on the professional context. If used in one only specialty the unit should be located as near as possible to the specialty. If the unit is serving many specialties and emergency services is should be located near the intensive care unit, the trauma centre, the ambulance bay and the helipad. However if the transport organization and the devices are designed for the purpose a distance of 100 -200 meters is no problem for even very ill patients, -the problem is not different from the transport of patients to and from operation theatres.
The hyperbaric device

The monoplace chamber requires knowledge of hyperbaric medicine. However these installations require no physical challenges to the staff. The staff can have full working hours around one or several chambers and take care of the patients. The advantage of monoplace chambers is that you may increase the pressure in accordance with the ability of the patient to adapt to increased pressure and the patient can be treated as long as intended. The treatment efficiency is thereby high, as decompressions stops are not necessary. In a recent study the efficiency of the monoplace chamber is documented as having 90% of the treatment time on the intended pressure (2). As the gas in the monoplace chamber usually is oxygen the patient is breathing freely and without resistance. Some monochambers are equipped with masks for air breathing during air breaks. The evident problem of the monoplace chamber is the need to decompress the chamber in order to get access to the patient. The other problem is the risk of fire due to the pure oxygen atmosphere in the chamber. The multiplace chamber will permit, that the staff can enter the chamber when needed. When increasing the pressure all patients have to be able to equalize the pressure in the middle ear. This may means a slight prolongation of the compression time as you have to wait until all patients have equalized. However 5 minutes for compression to approximately 2.5 ATA is usually sufficient. In the study (2) is described that the efficiency of the multiplace chamber is reduced to about 50% if the staff inside is breathing air and to about 80% if the staff is breathing 60.6% oxygen. This is later discussed in section safety for the staff. For scientific purposes the monoplace chamber is ideal, as it is easy the disguise whether the patient is having air at 1.1 ATA or oxygen at 2.5 ATA. In the multichamber you may have to mix patients having air at 2.5 ATA with patients having oxygen at 2.5 ATA. The air patients are all to near a risk of decompression injury if the breathe air for 1½ hour.

Hoods or masks

The oxygen delivery system may be masks, hoods, or various tracheal tubings. The masks may be connected to a second stage regulator positioned in a panel. This system requires some inspiratory force by the patient. In an unpublished series of tests using a ScubaPro regulator it was not possible to adjust the regulator to less than 5 cm water column inspiratory negative pressure. This adjustment was made to be sure, that free flow was not the risk. The use of masks with a second stage in the mask offers virtually no resistance; you may even have a slight free flow. A mask with second stage may be a.o. the Diving UltraLite. Masks may be difficult to fit. Therefore a system for continuous monitoring the oxygen percentage in the mask is of great importance. Intake of chamber
air mixed with the oxygen may reduce the oxygen content below 90 %. The HBO treatment is therefore not the intended dosage. The use of mask is a considerable problem for patients with abnormal faces. This is often the case for the patient with osteoradionecrosis of the jaw. To overcome this problem the hood is the solution. The hood is combining the advantages of the monochamber and the multichamber as the oxygen is inspired freely and a scavenging system is removing the excess gas. However the hood is difficult to position by the patient and a helper is needed when treatment pressure is reached. Patients with tracheostoma may be intubated through the tracheostomy, but this may be quite a strain on the patient. An alternative may be to fit a colostomy bag with a ventilation hose on the tracheostoma. The adhesive of the bag is constructed not to hurt radiated skin.

The intubated patient is most often connected to a ventilator. The cuff of the tube has to be filled with water during the hyperbaric treatment. At the end of the HBO session the water has to be replaced by air. Continuous registration of the expired carbon dioxide is essential to ensure proper ventilation. The main stream reading of end tidal carbon dioxide is higher than the true value due to spectral broadening of the gas.

**Which multichamber to chose?**

Very large chambers are typically designed from the viewpoint of an intensive care unit or a large saturation system. These chambers are expensive and require special constructions of the housing. The advantage is a lot of space around the critically ill patient. Most often it is possible to keep the patient in the intensive care bed. The medico technical devices have to be cleared for use in the hyperbaric environment. The problem is the size of the chamber. It takes quite a time to compress and decompress large volumes and the staff has to stay inside the chamber during the treatment. Smaller chambers are cheaper and lighter and thereby easier to implement. The disadvantage is that the intensive care patient has to be moved to a designated trolley and the space around the patient is limited.
The advantage of a smaller chamber is that the volumes are less; thereby the compression and decompression can be performed more rapidly when needed. The smaller distances permit, that some of the medico technical devices a.o. monitors can be kept outside the chamber and some devices a.o. infusion pumps may be directed from outside. Smaller distances also provide the possibility to let the staff breathe NitrOx when inside the chamber. A smaller unit also provides the possibility to leave and enter the man chamber within a short time. The entry lock in the Copenhagen chamber has a volume of about 4 cubic meters and can be pressurized in 23 seconds. This has the consequence that the physician can be with the patient within this short time, which is quite similar to the situation in the intensive care unit. Another consequence is the possibility to decompress the main chamber within a short time. In our setting with a 14 cubic meter man chamber the chamber can reach the “surface” pressure within 2½ minutes. Thereby there is no need to have DC fibrillator inside the chamber or in the unit as this is brought by the cardiac arrest team.

The staffing

The daily staff should be clinical experts. To become an expert you need the formal training and a lot of clinical experience. In hyperbaric medicine this expert role is more difficult to obtain in comparison with many other expert areas. The scientific literature is fairly weak and the belief or non-belief in hyperbaric medicine is more diverse, than in many other fields of medicine. The medical staff therefore needs to be familiar with the current literature. Internal education and training is therefore essential. The choice of staffing is in part a result of the chosen hyperbaric device and the patients treated. The monoplace chambers do require little special health qualifications of the staff. The operations does not limit the working hours of the personnel as they are not exposed to pressure. The multiplace chambers require the health qualifications of at least equivalent to the demand of a recreational diver. The operations may limit the working hours of the personnel as they are exposed to pressure. If the persons in the chamber are breathing oxygen rich air (NitrOx) the time in the chamber may be extended and the need of decompression stops reduced or not necessary at all. The nurses will take care of the physical and psychological nursing of the often quite chronic and exhausted patients. The technicians should be qualified in the handling and maintenance of the equipment as well as maintaining the safety culture. Professional divers will have the qualified knowledge and the respect for the effect of pressure and gases.

The safety for the patients

The patients should always be dressed in clothes which cannot generate sparks. The clothes should easily be soaked by the water from the fire extinguisher. Clean clothes are provided at any session and thereby no flammable material can be brought into the chamber. Among the flammable substances is titanium material which may burn if broken.

Safety for the staff

The staff is dressed in the same way as the patients.

When inside the chamber the staff should breathe NitrOx. A NitrOx 50 is a safe mixture when working at pressure up to 2.8 ATA. The oxygen equivalent concentration FiO2 is 0.9 at 2.4 ATA and 1.2 at 2.8 ATA. The equivalent “depth” on the diving tables is 9 meters at 2.4 ATA and 12 meters at 2.8 ATA. The time to
decompression stop is therefore more than 450 minutes at 2.4 ATA and 135 minutes at 2.8 ATA (3). The ability to work is also increased as the nitrogen pressure is decreased – that may be of considerable importance when the physician has to make decisions inside the chamber. If one accepts a nitrogen loading letter G only half of the permitted time for non-deco is used, and thereby is obtained a high degree of safety for the personnel. If air is breathed more than 2 minutes the entire time in the chamber is considered an “air dive”-and still G is the maximal loading letter (4).

The staff working in the chamber should have an annual health check – as recreational divers and an annual recertification in the use of the chamber. Especially important are exercise in firefighting and procedures related to cardiac arrest.

Very little is written about the risk of decompression injury among the staff, but many rumors are around. In a questionnaire (2) to a staff breathing air was found that 31 members of staff had a total of number of 51 complaints compatible with decompression injury symptoms.

**General safety and maintenance**

The entire system is best maintained by written guidelines. Any start of the chamber unit should be controlled by use of check lists. When special devices are used – ventilators or infusion pumps – the devices should also be controlled and checked according to a list.

The general maintenance should also be checked according to the advice of the manufacturer and the controlling authority. More complex units may be maintained and controlled in accordance with the guidelines of International Maritime Contractors Association (IMCA), however being a member is more costly than useful.
A weekly safety meeting and reporting to the entire staff keeps everyone informed. The safety organization is instrumental in having the unit operational at any time. In case of major repair an arrangement with the neighboring hyperbaric unit is essential if the unit has a 24/7 service.

**Care of the patients**

Often the patient is referred to the HBO unit as a consequence of a long and difficult disease. The patients are often able to support each other and share experience on how to cope with the handicaps. By mingling the new patients with the more experienced HBO patients the mutual support is facilitated. Of course the medical staff is also supporting the patients, but the different approaches improve the result.

A telephone call to the patients a month after end of the HBO treatment provides much information from the patient to the unit and for the patient a feeling of not being forgotten.

**The contact with the referring units**

When the patient are referred to HBO treatment a plan is made, the referring units are informed about their plan and they can implement their actions in a total plan of treatment. Most HBO treatments are just one element in a larger plan.
Written information and brochures

The written information is a good support to the verbal information. Often the patients have to sign the information containing effects and side effects as an acceptance of treatment. Short brochures are also valuable as information for family and guests.

The internet home page

The patients are still better informed about their treatment. The information is obtained from many sites on HBO. The individual HBO units may have different approaches and indications. Therefore a good start in the information of the patient is a well functioning home page – it may be the patient’s first impression of the unit.

The press

The HBO unit is one of the more “action like” places in the health system. The chambers provide good pictures and background for interviews concerning unusual medical treatments and naval accidents. To be open for the press also provides possibilities to inform the public about the dangers of carbon monoxide intoxications, necrotizing fasciitis and other diseases not widely known. Within minutes you may reach a million citizens in prime time.
Scientific work

The scientific work is of utmost importance to a hyperbaric unit as well as other parts of health system. Hyperbaric medicine is in great need of deeper insight in mechanism, effects and side effects. As HBO seem to have effects not obtainable by other medications even smaller studies are of interest.

Medical students have to make smaller studies within their curriculum. Often we wish to have information about the long term results of HBO treat, -but the normal staff does not have the time for these retrospective studies. The students will obtain a personal network within science and the information may be the background for prospective cohort studies.

HBO nursing is little explored, but ample possibilities have been identified in the patients’ mutual support in an open care ward.

Physicians may have minor or major methodological and therapeutic questions to solve. The PhD. studies offers typically 3 years of concentrated study within a well defined subject.

A study of HBO treatment of cyanide intoxicated rats.

Other PhD. or post doc. studies might focus on HBO treatment of diabetic foot ulcers. A Swedish randomized controlled study showed the healing effect (5).Such studies are interesting as the disease cost the Danish society (5½ mill. inhabitants) about 100 mill. Euro annually (6).

As most of the therapeutic questions are universal it is highly interesting to promote international efforts. The Nordic Study Group on Serious soft Tissue Infections is an example and the INFECT study within the 7th EU scientific program is another example. The latter includes 14 different laboratories and institutions with an interest in necrotizing soft tissue infections.

Only few studies have been performed as randomized controlled trials. Considerable effort should be allocated to that type of studies, as these are the only ones who are widely accepted as valid information.

The problem: HBO is a drug – without the resources of the drug industry.

Financing of clinical work and science

In the previous is described the need to have tight connection to other parts of the clinical world and the public in general. In this dialogue it may be clear for the involved, that HBO has something special to offer. HBO is a
unique drug and certainly has great opportunities to offer the health sector. The dialogue has to identify the opportunities and the move into the phase of getting insight in the problem and find the solution to the problem. The dialogue is necessary for a wider group to find the resources to find the scientific solution and get into the phase of implementing the scientific results. This solution may be economical beneficial and politically attractive, -as indicated by the big resources used on Danish diabetic foot ulcers.

The approach of the fiery soul

One may chose to design a HBO-facility in an informal academic approach. However often you just get caught into fascination of hyperbaric medicine – and then you construct the facility according to your capability and vision – a fascinating approach – but may be a lonely fight and may be end with the initiator. The risk is, when the fiery soul has burned his or her energy -only an empty chamber is left.

How I would design my HBO facility?

- Identify the need
- Find the leader
- Form the board of clinically interested colleagues
- Identify the best possible location for the unit
- Identify all regulations, “Good Clinical Practice ”, CEN-rules etc.
- Make the feasibility study
- Make a production analysis for the patients flow through your unit – from internet – to information – to the referring colleagues
- Employ as little clinical staff as possible – and they will become experts
- If you buy a multiplace chamber:-buy a small one – for 8 persons or so. Only staff inside if you can write why – and always breathing Nitrox.
- Direct as many medico technical devices from the outside. Adopt the ROV (Remotely Operated Vehicle) approach to actions in the chamber
- Let as many patients as possible enter a prospective cohort study
- Buy a monochamber –for your RCTs
- Keep your prices low – you do not need a large clinical staff – and your technicians will nurse the unit and have it working at all times.
- Have an updated database on all your patients and all your actions, -necessary if you send bills and necessary to inform the administrative units in your organization
- Keep some kind of contact with your patients – they will tell you about the long term value of the effort
- Publish your results and be open to the press
- Remember to thank the foundations who gave you all the money to your scientific work.
References

1. www.oxynet.org


(03) How I would design my HBO facility? [UK]

Philip Sayers  
Managing Director  
London Hyperbaric and Wound Healing Centres Ltd, UK

Introduction

When faced with the task of designing a HBOT facility for a specific customer, many factors must be considered, which will affect the design, cost and the running of the centre in order to generate profits for the investor.

Potential users, partners or buyers may have visited impressively large, flashy, state-owned and state-funded Hyperbaric Centres in different parts of the world and would naturally wish for the biggest and the best for an ambitious new project in their own hospital. On the other hand, private ‘Start-up’ companies will need to consider the large financial and commercial risks involved in establishing a new business, and may have very different demands on the design and in particular the pricing of the chamber, machinery and the necessary peripheral equipment.

For my perfect HBO facility I would definitely require:

- The biggest and best chamber for the least amount of money.
- A large local population of patients suffering from all of the ailments that I am able to treat in the centre.
- A high-cost / low volume caseload, with automatic funding for emergency and elective referrals.
- A cost-effective, low maintenance facility that allows me to generate the maximum return for my investment in the shortest period of time.
- A warm and sunny location for my purpose-built facility, preferably in a brand new hospital somewhere near the coast.

So how did I end up with an old second-hand chamber and a couple of containers in Whipps Cross Hospital – a hospital that was opened by King Edward VII in 1903, is located over 100 miles from the not-so-tropical beaches of England’s south coast, and is situated in one of the most depressed regions of East London?

The answer is not immediately obvious, but I hope that the following presentation will give an insight into how our team managed to make a success of the project despite the cards being stacked against us.

Initial considerations from the perspective of a private provider

The design of the facility will be influenced by the following considerations:
What type of venture is being proposed?

What sort of a hospital will the centre be located in?

What is the hospital or commissioning agency’s Service Specification?

How positive is the local funding environment?

What is the acceptance of HBOT by local clinicians? Are they likely to refer patients to us?

What access is there to support services and facilities?

What is the availability of experienced local staff?

What model and size of chamber and machinery will be MOST suitable?

How much commercial and financial risk do I want to take on?

WHAT TYPE OF VENTURE IS THE PREFERRED OPTION?

Options:

- A privately-funded, owned and operated ‘stand-alone’ facility.
- We provide the technical resources for the host hospital, leaving the clinical work to the hospital team.
- We only design, supply and install the chamber and leave everything else to the hospital.
- A public-private partnership (PPP) with a state hospital.

WHAT SORT OF A HOSPITAL WILL THE CENTRE BE LOCATED IN?

Preferences:

- A large acute district hospital in a large city with good travel links.
- The host hospital should preferably lie within a high-population density area, which can theoretically be anywhere in the country providing that local competition is not present.
- A private or state hospital with a good reputation and track record will instil confidence in patients and staff and referring clinicians.
- Access to ICU beds and critical care services when needed.
- Cooperative atmosphere and good lines of communication between departments.
- Access to ENT, paediatric, X-ray and other hospital facilities and services.
- Willingness of hospital staff to cooperate and work closely with the Hyperbaric Centre.

WHAT IS THE IDEAL SERVICE SPECIFICATION?

The prospective provider may be asked to write a specification him/herself, as the hospital or commissioning agency may not actually know what it needs or even what the options are. It may be left to the providers to put
forward proposals and designs and, in some instances, even design and build the annex or extension to the hospital building to accommodate the chamber.

Considerations:

- What type of service does the hospital or commissioners actually want to purchase or commission?
- In which region is the service needed and where geographically do commissioners actually require a facility?
- What population will the service be provided for? Local / Regional / National?
- Who will pay for the capital equipment and its installation?
- Will there be opportunities or a requirement to carry out research?
- How long will the contract be for?
- What are commissioners prepared to pay for the service?
- How will the provider receive payment?

HOW POSITIVE IS THE LOCAL FUNDING ENVIRONMENT?

This is probably the most important consideration that comes before all others, and each country will probably have its own commissioning policy. A good understanding of how local funding arrangements work is essential in determining the optimal location for the new venture.

What are the funding options?

- Private funding through insurance companies and self-payment.
- Funding applied for on a case-by-case basis for elective indications, or according to some pre-approval funding mechanism as found outside the UK.
- Case-by-case funding according to an Individual Funding Request (IFR) procedure.
- Automatic state-funding of ‘approved’ emergency indications.
- Baseline funding to cover all operational and treatment costs for an agreed list of indications, functioning as a hospital department.

Unfortunately the latest proposal in the UK is to scrap all funding for all elective conditions and only to fund HBOT for decompression illness and gas embolism.

WHAT IS THE ACCEPTANCE OF HBOT BY LOCAL CLINICIANS?

Acceptance is absolutely vital for the success of any hyperbaric facility and will depend on a number of contributing factors:

- The history of funding HBOT by commissioners and a record of quick responses in processing funding applications.
- Good clinical outcomes and an efficient organisation.
- Local access to a good hyperbaric facility.
• Trust in commissioners recognising the clinical benefit of HBOT and putting the patients’ interests first – before financial considerations.

• Clinicians’ trust in the Individual Funding Request pathway for exceptional cases.

• Unnecessary ‘red-tape’ and form-filling may discourage consultant referrals.

WHAT ACCESS IS THERE TO SUPPORTING SERVICES AND FACILITIES?

What is the best location for the facility within the hospital?

Preferences:

• Adjacent or close to ICU and/or high dependency services.

• Usually ground floor level for ease of installation and access.

• Easy access to emergency clinical services.

• Easy access for ambulances and taxis.

• Access to a helicopter landing pad.

• Availability of canteen, laundry, sterilization, Admin services, etc.

WHAT IS THE AVAILABILITY OF EXPERIENCED LOCAL STAFF?

The availability of enthusiastic, dedicated and well-trained staff is vital to the success of the facility. The mix and availability of staff will depend on the type of operation being planned and whether or not an emergency on-call service is required.

Ideally, good relationships should be developed with the host hospital and free training provided by the Hyperbaric Unit to enable local hospital physicians and nurses to join the team.

Ideally, the Medical Director, leading physicians and nurses will share their time between their main duties in their speciality and the work they are required to carry out in the Hyperbaric Unit. This arrangement promotes links and cooperation between the hospital and the Hyperbaric Unit, which can only be encouraged.

Ideally, if the centre is to provide a 24/7 emergency call-out service, a large pool of part-time staff including physicians, nurses and technicians will be a necessity.

WHAT MODEL AND SIZE TYPE AND SIZE OF CHAMBER WOULD BE MOST SUITABLE?

Considerations:

• How will the chamber be installed?

• What treatments do I hope to carry out?

• Do I need ICU capability or mixed gas capabilities?
What methods of oxygen delivery are needed? Masks, Trachys, Hoods?

How much space is available in the hospital for the chamber?

Can I provide for easy trolley access in and out of the chamber?

What can I actually afford to pay for a chamber?

Obviously the ideal chamber will be designed and equipped to cover all eventualities, but taking into account financial, logistical and operational considerations, compromises will certainly have to be made.

**Summary**

Chambers and equipment can be designed and purchased to meet virtually all conceivable requirements, providing that the customers have the money to pay for their wishes. Buying a chamber is the fun-part of establishing a new Hyperbaric facility, especially if you’re spending someone else’s money. However, in planning the ideal Hyperbaric facility I would expect to have to consider many or all of the above-mentioned factors to ensure that the centre has good prospects for a long and successful future.
Chapter 2: Hyperbaric centre in the health care system
(04) Hospital based Hyperbaric Centre

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Introduction

In the first Consensus Conference held in Lille in 1994 the educational profile of the staff working in the hyperbaric centre was defined leading to the development of standardized education programmes.

In the frame of the COST Action B14 the Working Group Safety elaborated the European Code of Good Practice for Hyperbaric Oxygen Therapy based on numerous documents of various diving and hyperbaric medical communities listed in the references. Summarizing all aspects of hyperbaric facility management, the European Code of Good Practice was published in 2004 and should serve as a reference document for establishing regulations, standards and guidelines in hyperbaric medicine in Europe (I).

According to this document, 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 categorized according to their capability to treat patients that require critical care.

The installation of a hyperbaric chamber used for therapeutic or diagnostic reasons is subject to the Medical Products Law. It regulates the responsibilities of national authorities with regard to control, accreditation, notification and safety-classification of a medical product.

Important novel features of the Medical Products Law are, on one hand, that it introduced an obligation to document undesired side-effects within the European Union, and, on the other hand, that gaseous oxygen became the status of a drug.

Since 2006 EN14931 has been applied to pressure vessels for human occupancy (PVWHO) defining the requirements for medically used multiplace chambers. A CE-marking is obligatory for each new chamber before its startup.

The organizational work can be divided into organization of staffing and education, equipment, safety management, procedures, and quality assurance (II, 2-5)

I Staffing

The responsibilities of the various professionals have to be clearly defined and designated in writing for the hyperbaric physician, hyperbaric nurse, chamber operator, and attendant. Their education should follow the ECHM/EDTC recommendations.
Minimum team requirement for a session in a multiplace chamber are 1 hyperbaric physician, 1 attendant, and 1 operator. Minimum team requirement for a session in a monoplace chamber are 1 hyperbaric physician and 1 operator.

Each person working under pressure has to pass an annual medical fitness check which in our centre consists of physical examination, ECG, chest X-ray, simple lung function testing (FeV1/ VC) and audiometry.

II Equipment

EN 14931 is applied to the equipment taken into the chamber.

III Safety management

The manager of the hyperbaric centre is obliged to organize safety and to define responsibilities, i.e., who is in charge of:

- equipment
- running the session
- patient information and check of objects eventually carried into the chamber.

A safety manual with information of “musts” to know for safety reasons has to be spread to all persons involved in hyperbaric patient care as hardware or electronically via intranet.

Safety policy also includes documentation of data concerning the hyperbaric chamber itself containing technical data, plans, and modifications as well as certificates and reports of the manufacturer. The maintenance register lists all inspections, certifications and reports on failures. The compression and decompression procedure manual describes the pressure profiles used in different clinical conditions and the compression and decompression procedures also in emergency situations. A register of pressure exposures lists names, number of sessions and pressure profiles of staff and patients.

Furthermore, the manager of a hyperbaric unit has to be concerned about fire hazard prevention, air quality control and cleaning procedures against microbial contamination.

A list of prohibited materials and a pre-compression check-list are very useful in the clinical routine.

IV Procedures

The standard operating procedures (SOPs) list the indications and the hyperbaric protocol to apply. In our hospital they are displayed via intranet.

V Quality assurance

Quality may be assured by controlling and by perpetual evaluation of patient and staff satisfaction, and by continuous education and teaching.

A lot of work has been done to establish rules for the maintenance of a hyperbaric unit; the task for the years to come may be to continue improving the procedures in detail and to consolidate hyperbaric medicine in the context with other disciplines in the hospital entity.
Considering the theory of management a medical facility is part of a complex and dynamic environment with mutual interaction. It is imbedded within a micro-environment that is defined by the type of medical aid offered and the interaction with subsequent target groups (stakeholder universe, inner circle, Fig. 1), and a macro-environment which represents the basic condition and framework with regard to ethical, medical, technical, legal, social, and economic aspects of each country (outer circle, Fig. 1). The several influencing factors have to be analyzed and understood to guarantee a good performance and to identify potential risks (II,6).

![Diagram](image)

Figure 1. Interaction of a hyperbaric centre (Modified from Seelos (II,6).

Kaizen is a Japanese expression and means to strive for continuous never-ending improvement, an attitude of mind that is introduced in private and working life. Kaizen was implemented in Japanese enterprises and spread after the 2nd World War to the western countries. It was extended from production systems (e.g., automobile production) to health care providing institutions and aims at standardizing processes and to recognize and normalize failures in a production chain. The strategy of Kaizen means in keywords: Plan-Do-Check-Act.

The continuous improvement process (CIP) philosophy should be adopted by all members of a medical hyperbaric facility aiming at increasing patient satisfaction and, furthermore, aiming at increasing safety for all subjects staying within or near a pressure vessel. However, all responsible persons should remain aware of dealing with living subjects obeying more complex laws than a machine.

With CIP being the motivation for this and all Consensus Conferences, the present paper will show some problems that may arise in hospital-based hyperbaric centres due to their structure and practical work and
propose solutions to them; however, asking no claim to be complete as running a hyperbaric unit is a perpetual challenge.

The hospital-based hyperbaric centre may be:

- an independent department
- associated to the ICU or ED
- associated to other units (burn unit, radiotherapy centre, wound care centre)
- categorized according to its capability to provide critical care or not

A questionnaire was developed and distributed aiming at updating the current problems hyperbaric facilities deal with. Furthermore, some impressions of the authors are presented as a kind of personal communication, not from top-down but from bottom-up, some long-lasting experiences of a basic worker in the hyperbaric environment.

**Assessment of chamber operations - Questionnaire for hospital-based hyperbaric hyperbaric centres**

Two questionnaires were forwarded in a “joint venture”, one concerning stand-alone chambers (Dr. Jörg Schmutz, Basel) and the other concerning hospital-based hyperbaric centres. I am indebted to Dr. Schmutz for rendering the questionnaire suitable for use in the web and for establishing contact to the UHMS.

UHMS administration was extremely helpful and supportive in data collection. I also want to thank all the participants to this questionnaire for the time they took for their answers. I apologize for not listing each centre for several reasons: not all agreed with being named and the answers were collected and transmitted collectively via the UHMS administration without indicating the origin of the answers in any case.

We received 82 answers, three of them being facilities with satellite location next to the hospital which will be addressed separately. They originated from Europe (30, including 3 satellites), U.S.A (43), Canada (1), Mexico (1), Russia (3), China (1), and Australia (3). Not all but most participants meet the hard-core criteria defining a hyperbaric centre, being rather a facility than a centre, however, their answers were considered important and included addressing general issues of interest to each category.

Nevertheless the number of answers remained low in relation to the number of forwarded questionnaires. One main obstacle was the acquisition of addresses because many of those in the OXYNET homepage are not operational any more and the manufacturers are by law prohibited to pass over addresses, and this possibly also applies to DAN directors.

**Questions and answers:**

1. Do you agree with naming your facility as a participant to the questionnaire during the conference and in the conference book? (Yes/ No)

   All answers are estimated absolutely confidential and pooled and not assigned to the single centers. A few centers refused to be listed.

2. Is your facility located directly in the hospital, is it integrated into an ICU, or located next to the hospital?
Three facilities out of 82 were located next to the hospital and are indicated as satellites in the following tables.

3. To which hospital department does your facility belong?

Table 1. Allocation of the hyperbaric center to following departments

<table>
<thead>
<tr>
<th>Allocation no.</th>
<th>Allocation no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperbaric Medicine (independent/ comprehensive); satellites: 2</td>
<td>25</td>
</tr>
<tr>
<td>General Surgery</td>
<td>3</td>
</tr>
<tr>
<td>Vascular Surgery</td>
<td>2</td>
</tr>
<tr>
<td>Plastic Surgery</td>
<td>2</td>
</tr>
<tr>
<td>Thoracic Surgery</td>
<td>1</td>
</tr>
<tr>
<td>Wound Care Center</td>
<td>10</td>
</tr>
<tr>
<td>Burn center</td>
<td>3</td>
</tr>
<tr>
<td>Outpatient Services</td>
<td>5</td>
</tr>
<tr>
<td>Flight safety (satellite)</td>
<td></td>
</tr>
</tbody>
</table>

4. Is it located in the immediate vicinity of an emergency department or an ICU?

Table 2. Location in the immediate vicinity of an emergency dept or an ICU

<table>
<thead>
<tr>
<th>No satellites: 3</th>
<th>29</th>
<th>Yes</th>
<th>40</th>
</tr>
</thead>
<tbody>
<tr>
<td>No answer</td>
<td>2</td>
<td>Another floor, good access</td>
<td>11</td>
</tr>
</tbody>
</table>

5. Does the hyperbaric center have a specific hospitalization (complete or incomplete) unit? If not where are the patients in the need of HBOT hospitalized?

The question aimed at obtaining information whether the hyperbaric unit disposes of beds of its own or whether pts. are housed in other departments/divisions of the hospital.

Table 3. Specific hospitalization

<table>
<thead>
<tr>
<th>Yes satellite: 1</th>
<th>21</th>
<th>Outpatient treatment only</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>No satellite: 2</td>
<td>47</td>
<td>Question not understood</td>
<td>10</td>
</tr>
</tbody>
</table>
6. What is the initial specialization of the medical director/physicians working presently in the HBO centre?

<table>
<thead>
<tr>
<th>Table 4. Initial specialization of the medical director/physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperbaric Medicine satellite: 1</td>
</tr>
<tr>
<td>Surgery</td>
</tr>
<tr>
<td>Internal Medicine satellite: 1</td>
</tr>
<tr>
<td>Infectious disease</td>
</tr>
<tr>
<td>Pulmonary Intensive Care</td>
</tr>
<tr>
<td>Physiatrist</td>
</tr>
</tbody>
</table>

7. Do you treat patients in the hours after regular working time? If so, which indications?

<table>
<thead>
<tr>
<th>Table 5. Treating patients in the hours after regular working time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes satellite: 1</td>
</tr>
</tbody>
</table>

Most centers stick to the ECHM/UHMS- approved indications. Necrotizing soft tissue infections, gas gangrene, DCI, AGE, and CO poisoning are on top of the emergency indications. Many centers additionally listed failing flap and compartment syndrome. Further indications for acute treatment off regular working time with no. of treating centers in parentheses:

central retinal artery occlusion (6 ), crush syndrome (6), infection or trauma of the spine (1), acute blood loss anemia (1), sudden deafness (2), postanoxic encephalopathy (2), acute myocardial or cerebral infarction (1), traumatic brain injury (1).

8. Which kind of diseases are mostly treated in your facility?

About 47% of the centres are specialized in treatment of radiation injury or diabetic wounds, in general about 75% deal with wound care (problem wounds, compromised flap, burn injury). Six centers preferentially treat anaerobic and aerobic soft tissue infections, five centers crush injury, three postanoxic encephalopathy, two centers sudden deafness, two centers CO poisoning, two cerebral or myocardial ischemia, one ophthalmic indications, one congestive heart failure (preoperative treatment before open heart surgery), spinal cord trauma, and another one traumatic brain injury.
9. Which are the main problems you face in the clinical routine in your facility?

Listed according to frequency of answers (numbers within parentheses):

- Lack of staff: nurses/physicians not available after working hours (17)
- No problems told (10)
- Financial issues (10):
  - Insurance-related problems: inadequate or no reimbursement, no reimbursement for emergent treatments,
  - Cost for HBOT taken from referring department leading to less referrals,
  - Preauthorization and funding
  - Lack of money for adequate equipment
- Difficult relationship with other specialists (7):
  - Acceptance by other specialists (6): lack of community awareness
  - Getting referrals (5): keeping HBOT in the minds of the colleagues, compliance of referring physicians
  - Patient compliance/adherence to safety issues (4)
  - Time and staff-consuming contact with other specialists (3): scheduling
  - Marketing for patient recruitment (2)
  - Absence of uniform guidelines, documents, and standards for staff (1)
  - Patient transport in and out of the chamber, noise pollution (1)

10. What, in your opinion, should be improved in the future?

We received no answers from 13 centres, others made the following proposals (no. of centres in parentheses):

- Science-related (11):
  - Better research and more prospective studies should be done
  - Increase opportunities for participation in multicenter studies
- Education-related (13):
  - Appropriate referrals treated to appropriate protocols
  - More education for physicians, health care personnel and the medical community in general
  - Incorporation of HBO in the Faculty of Medicine
  - Inclusion of hyperbaric medicine pathophysiology and ECHM indications in the last year of medical students practice
- Incorporation of HBOT in the teaching of radiotherapy
- Making dentists known late radiation wounds in the mouth and increase awareness of HBOT as a valuable treatment tool
- More contact between specialists of different countries and networking
- Inclusion of HBO in treatment protocols for various diseases
- Publishing the committee report electronically to clinicians and insurance carriers for free

Equipment-related (9):
- More providers of certified pt. care devices like motor syringes, ECG monitors, etc.
- Improvement of chamber design, e.g., chamber for bedside use
- Development of standards for technical devices to enable manufacturers to test their devices for use under hyperbaric conditions

Reimbursement issues (8):
- Better preauthorization process
- Referring department still pays for the HBO session of its patient
- Reimbursement for 24/7 facilities and emergent sessions more and more restricted
- Expanded indications should be accepted
- All HBO units should be able to accept emergent indications for treatment

Improvement of centre interaction with other health care professionals (7):
- Increased physician coverage, more staff required
- Improved acceptance by other services of the hospitals
- Better team work

Position of the HBO centre/physician in the in-and-out of hospital area (6):
- Integration of HBO physicians in diabetic foot clinics in multidisciplinary teams
- Autonomy of hospital-based hyperbaric centres
- A hyperbaric centre should be run by EM doctors
- A hyperbaric centre should belong to cardiopulmonary services rather than to nursing management
- Better interaction with other specialties
- Acquisition of a steady referral base
- Continuous marketing and advertising is important

Patient-related (3):
Myringotomy for intubated pts. should become a standard procedure (still refused by some ENT specialists)

No street clothes shall be allowed in the hyperbaric chamber

Monoplace chambers available for ICU pts.

Location-related (2)

Adding surgical and rehabilitation capabilities to the center

Larger exam rooms

11. Is it difficult to convince colleagues of other disciplines about the usefulness of HBOT?

No answers were given by three representatives of the centres

Yes: 34

No: 16

Sometimes: 29

Additional comments:

Most “nonbelievers” are among the surgeons, urologists or orthopaedists.

Some colleagues think that only haemoglobin “carries” oxygen into the plasma and deny the biologic effect of the higher amount of dissolved gas under pressure.

An appropriate selection and good results are convincing.

12. Who decides about fitness for HBOT in the intubated ICU pt.? The ICU tender or the hyperbaric physician? If it is the ICU doctor, is she/he familiar with hyperbaric medicine?

22 centres do not offer treatment in ICU pts., and there was no reply in 3 cases. Fitness for HBOT is decided by

the hyperbaric physician (40)

the ICU tender (7) the majority of them not being familiar with hyperbaric medicine

by both (10)

13. Are pts. refused HBOT due to the necessity of transporting them?

The majority of pts is not refused HBOT, 17 participants found difficulties with transportation of the patient to the chamber due to reimbursement problems to the referring department (i.e., the referring dept. has to pay!) or due to the risk of transportation of the critically ill.

One centre offers guest rooms for patients who have got a long way for daily treatment, another one hospitalizes the patient when the travelling time exceeds 45 min.
14. Who accompanies the intubated/non-intubated patient during the hyperbaric session?

There seems to be a difference in attitude: most European centres send an anaesthesiologist/intensivist into the chamber with the intubated stable and unstable patient whereas one third of the replying U.S. centres have hyperbaric ICU-/critical care-trained (ICU-RN, CC-RN) HBO nurses accompanying the stable patient with the back-up of a HBO physician, anaesthesiologist, intensivist, or respiratory therapist ready to go with the unstable critically ill.

66% of all centres primarily have a physician (mostly HBO physician, anaesthesiologist, intensivist) within the chamber.

One centre has the physician decompressed in the isopression phase when the patient is in a stable condition.

18 centres don’t treat intubated intensive care patients. Non-intubated subjects are attended by a hyperbaric nurse, less often by chamber technicians/attendants and, in rare cases, go alone after an initial training.

15. Do you have hyperbaric nurses in your staff?

16 out of 82 units work without a hyperbaric nurse, one of them has got non-certified RNs, another one “borrows” the nurses from general surgical wards.

All other units have certified HBO nurses in their staff, most of them also ICU-trained.

16. Does reimbursement by insurances pose a problem?

There is no problem of reimbursement to be found in 56% of the units, as long as preauthorization processes are correctly done (sticking to ECHM or UHMS-approved indications), sometimes a problem in 17% and clearly a problem in 27%. They commented on it as follows:

- Lack of unification, different programmes in different regions of one country
- More data are needed to prove the benefit over the costs of treatment
- Getting initial authorization is the biggest issue

Some centers start HBOT prior to approval due to acute indications that are not recognized by the insurances (e.g., jeopardized limbs) or in case of emergency leaving no time to wait. However, fortunately, in a few countries, HBOT is part of the public health system.
The Graz model – a unique version (personal communication)

The hyperbaric centre of the University Medical School of Graz is historically allocated to the Division of Thoracic and Hyperbaric Surgery as Professor G. B. Friehs installed the chamber in the late sixties of the last century. In those days heart surgery was performed in one part of the double-room walk-in chamber in the pre-ECMO (extracorporeal membrane oxygenation) era. The OR part of the chamber was still used for normobaric thoracic surgery until 2 years ago.

As the hyperbaric facility belongs to the thoracic surgeons not trained in intensive care the staff has to be drawn from the anesthesia department for sessions with hemodynamically unstable intensive care patients. This has been causing serious problems after regular working time for many years. Moreover, there are no hyperbaric nurses available in Austria until now.

Therefore the Board of Directors recently decided that at least one anesthesiologist or intensivist trained in hyperbaric medicine has to be on call every day in the near future. The colleagues willing to be trained will even be reimbursed. Secondly, a list of urgent indications was made to which the colleagues on call have to stick (DCI, carbon monoxide poisoning, gas embolism, gas gangrene). Another promising and supposedly the best solution might be that the Division of Thoracic and Hyperbaric Surgery integrates an intensivist or anesthesiologist of its own as a member to its team. As to my experience, the involvement of the HBO physician in decision-making whether a critically ill patient is fit for HBOT or not is crucial! In the case of splitting the decision, the patient might be denied a beneficial treatment.

Discussion and recommendations

The survey reveals that there is still a lack of understanding of HBOT in the medical community. Valuable proposals were made with the goal to integrate hyperbaric medicine in the medical curriculum.

Insurances have to be convinced by studies proving the benefit of HBOT to reverse their restrictive policy. An alarming article was published a couple of months ago announcing that divers were going to lose access to emergency care (www.alertdiver.com), because an increasing number of centres is not able to treat urgent cases any more.

In many states nurses trained in hyperbaric medicine are accompanying stable intubated patients during the hyperbaric session – a personnel-saving strategy which could be considered on contrary to literature (II,7).

Networking and spreading of information would be easier if addresses were available, e.g., a list of addresses of congress participants published on the ECHM/ EUBS websites after having obtained agreement (already organized during registration to the congress).
References

References concerning the European Code of Good Practice for Hyperbaric Medicine (J.Kot, et al. www.ECHM.org)

6. prEN14931. Pressure vessels for human occupancy (PVHO) – Multiplacepressure chamber systems for hyperbaric therapy – Performance, safety requirements and testing, 2004
7. European Norm 12021, Respiratory protective devices – Compressed air for breathing apparatus, 1999
9. European Pharmacopoeia

Relevant legislation, standards, guidelines:

Further references

1. First European Consensus Conference on Hyperbaric Medicine – The applications of Hyperbaric Oxygen; standards for education and training, future directions of research; technical requirements. Lille University Medical Center, Lille, France. Wattel F, ed., 1994


Acknowledgement

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(05) Hyperbaric Centre as stand-alone facility

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Introduction

A free standing or stand-alone clinic is defined as a clinic administering health services to individuals who do not require hospitalization or institutionalization. Free standing clinics are offering increasingly services that were previously offered in hospitals. More and more of these services are offered as outpatient services and are migrating outside of the hospital to free standing clinics, I.E. cataract operation, knee arthroscopy, colonoscopy, increase up to 140% in 2 years (1). Hyperbaric oxygenation (HBO) is typically a service that can be offered on an outpatient basis. Hyperbaric oxygen is actually considered by our community as a drug, with its dosage, side effects, contra indication and safety issues. As such it is subject to the same constraint as any medical treatment using hardware. Hyperbaric centers are actually disseminated in the whole world. Every country has its own regulation regarding safety, operations and management and third party regulations. However, as medicine is understood and practiced differently in a hospital or in an outpatient setting, differences exist between hyperbaric centers located inside a hospital, being part or not of an intensive care unit, and those located in a rehabilitation center or the doctor’s office. The aim of this report is to try to bring a picture on standalone hyperbaric centers. According to the European Code of Good Practice, a hyperbaric facility consists of a hyperbaric chamber with all the necessary staff to run it safely (2).

Methods

In order to improve the answer rate, we created an easy to fill in questionnaire (Figure 1) asking about items we thought to be pertinent from the point of view of a stand-alone hyperbaric chamber manager. The Email was sent according to the list of hyperbaric oxygen providers. The addresses were taken out of the data bank of OXYNET), DAN Europe (courtesy Prof. A. Marroni), Databank VDD (courtesy Dr. C. Heiden) as well as UHMS (courtesy, Dr. P. Bennett).

Figure 1. Questionnaire for Free/stand-alone hyperbaric facilities

<table>
<thead>
<tr>
<th>1. Does your facility offer 24 hours service for emergency?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐</td>
</tr>
<tr>
<td>No ☐</td>
</tr>
</tbody>
</table>
2. If yes, do you treat ICU patients?
   Yes ☐
   No ☐

3. Which kind chamber do you operate?
   Monoplace ☐
   Multiplace ☐
   Both ☐

4. What kind of disease do you treat?
   Only UHMS approved ☐
   Only Off label ☐
   Both ☐

5. Is your facility owned by?
   Yourself ☐
   Group of Physicians ☐
   Financial institution ☐
   Hospital ☐
   Foundation ☐

6. Staff in your facility:

<table>
<thead>
<tr>
<th>How many Doctors</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>How many Chamber operators</td>
<td></td>
</tr>
<tr>
<td>How many Chamber attendants</td>
<td></td>
</tr>
<tr>
<td>How many Safety Manager</td>
<td></td>
</tr>
</tbody>
</table>

   Total Staff |

7. Have you always a chamber attendant present in the chamber for routine treatment?
   Yes ☐
   No ☐

8. If yes
   What is his/her education?

9. Is your Hyperbaric Centre regularly accredited?
   Yes ☐
   No ☐
### 10. Do all your patients have to sign an Informed Consent Form prior to treatment?
- Yes ☐
- No ☐

### 11. Regular patient satisfaction assessment
- Yes ☐
- No ☐

### 12. Patient recruitment
- Referred by a colleague ☐
- Referred by a hospital ☐
- Coming of their own ☐

### 13. How do you advertise HBOT with potential referrers?
- Conferences ☐
- Email ☐
- Webpage ☐
- Other: what?

### 14. If the patients are sent by referrers or institution, do you have a financial agreement with them?
- Yes ☐
- No ☐

### 15. If yes, do they own a share of the hyperbaric center?
- Yes ☐
- No ☐

### 16. Do you have difficulties with third party payment of UHMS approved indications?
- Yes ☐
- No ☐

### 17. If yes:
| What kind? | See questions 17 |

**Results**

From the database DAN Europe (n: 139), 6 answered, 105 did not answer and 27 were sent back as invalid Email address.; from the OXYNET databank (n: 225), 11 answered, 167 did not answer and 47 were sent back
as invalid Emails address; from the UHMS databank (n: 2’295) 28 stand-alone and 92 hospital based questionnaire answered and there were no invalid Emails address.

The results are found in Table 1.

Table 1. Survey on free/standalone hyperbaric chambers (US: United States of America, E: Europe)

<table>
<thead>
<tr>
<th>Total centers that answered the survey</th>
<th>28</th>
<th>17</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>US</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>E</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>1. Does your facility offer 24 hours service for emergency?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☐</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>No ☐</td>
<td>19</td>
<td>6</td>
</tr>
<tr>
<td><strong>2. If yes, do you treat ICU patients?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ☐</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td><strong>3. Which kind chamber do you operate?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monoplace ☐</td>
<td>25</td>
<td>10</td>
</tr>
<tr>
<td>Multiplace ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>4. What kind of disease do you treat?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only UHMS approved ☐</td>
<td>6</td>
<td>16</td>
</tr>
<tr>
<td>Only Off label ☐</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Both ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>5. Is your facility owned by?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yourself ☐</td>
<td>17</td>
<td>9</td>
</tr>
<tr>
<td>Group of Physicians ☐</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Financial institution ☐</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Hospital ☐</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Foundation ☐</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td><strong>Staff in your facility:</strong> Mono</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How many Doctors</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>How many Chamber operators</td>
<td>2.4</td>
<td></td>
</tr>
<tr>
<td>How many Chamber attendants</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-----</td>
<td>----</td>
</tr>
<tr>
<td>7. Have you always a chamber attendant present in the chamber for routine treatment? (only multiplace)</td>
<td>2.6</td>
<td>3.6</td>
</tr>
<tr>
<td>8. If yes: education? RN, CHT, CHRN, paramedics, md as needed</td>
<td>7.2</td>
<td>14.2</td>
</tr>
<tr>
<td>9. Is your Hyperbaric Centre regularly accredited?</td>
<td>(8)</td>
<td>(17)</td>
</tr>
<tr>
<td>10. Do all your patients have to sign an Informed Consent Form prior to treatment?</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>11. Regular patient satisfaction assessment</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td>12. Patient recruitment (multiple responses)</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>13. How do you advertise HBOT with potential referrers? (multiple responses)</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Conferences</td>
<td>21</td>
<td>10</td>
</tr>
<tr>
<td>Email</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Webpage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td>23</td>
<td>14</td>
</tr>
<tr>
<td>USA:</td>
<td>19</td>
<td>14</td>
</tr>
<tr>
<td>Related magazines, direct marketing, office visits, brochures,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>marketing team, mailers, visits, faxes, no, routine hospital public</td>
<td></td>
<td></td>
</tr>
<tr>
<td>relation, kiosk in community centers, lunch and learns, newspaper</td>
<td>9 11</td>
<td></td>
</tr>
<tr>
<td>TV advertisement, TV segments, luncheons, speakers bureau,</td>
<td>5 8</td>
<td></td>
</tr>
<tr>
<td>Traveling marketing, brochure, marketing at MD offices, CME</td>
<td>18 1</td>
<td></td>
</tr>
<tr>
<td>Conferences, medical director does a lot of marketing, talks to</td>
<td>10 3</td>
<td></td>
</tr>
<tr>
<td>Colleagues, newsletter mailed to members of medical community and local homes, mass mailing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Europe:

- Talks at dive centers, short conferences in hospitals, listed in fire and rescue department, articles in newspapers, own medical journal, scientific TV’s, lectures, no advertising at all

14. If the patients are sent by referrers or institution, do you have a financial agreement with them?
   - Yes ☐
   - No ☐

15. If yes, do they own a share of the hyperbaric center?
   - Yes ☐
   - No ☐

16. Do you have difficulties with third party payment of UHMS approved indications?
   - Yes ☐
   - No ☐

17. If yes: what USA:
   - No coverage from public insurances, any kind, sometimes, depending of the indication, we have to hire insurance consultants, denials to pay, getting them to honor the authorizations they give us, agreement with contract hospital, Medicare declines payment even for Medicare approved indications
   - 5 7
   - Germany: Emergency treatment are not paid if not treated in-hospital, not paid by German insurances
   - 0 0
Switzerland: no problems in accepted indications
Finland: no coverage
Italy: Delay

Discussion

Due to the high number of incorrect Email addresses and to the fact that the exact number of hyperbaric in USA is not known to UHMS, the same being true for Europe where there is no real governing body, the response rate to the survey cannot be calculated. Though there are clearly fewer answers from standalone hyperbaric centers than from hospital based hyperbaric centers (35 versus 92), several remarks can be done. Except for the database of UHMS, the European data bases are incomplete and inaccurate. The response rate is very low compared with the 80% response rate of the study by Saththasivam et al. (3).

Question 1

25/45 (44%) of all standalone hyperbaric centers never treat emergencies. European centers treat double as much emergencies than the US ones (7/17 (64%) versus 19/28 (32%)). This means that stand alone chambers treat mainly outpatients and that they are probably less equipped with costly medical equipment and highly trained staff. This opens the question of the necessary size of the staff and of its educational requirements in hyperbaric centers not treating emergencies, the most important challenges being probably the safety issues, fire, and technical problems.

According to the available data, in an outpatient setting and patients treated at 2.4 ATA, epileptic attacks can occur in 1/6000-40'000 compressions (0.015-0.002%) (4). Barotrauma of the lung is reported in a few single cases in the whole history of hyperbaric medicine (<0.01%). The other side effects are from the non-dangerous type: myopia is fully reversible and cataract appears only after a high dosage that is no more in use. Finally the rate of barotrauma of the ear can be reduced with adequate compression rate (5) or with transitory interruption of the treatment.

According to the Standard Swiss Drug Register (6), side effects are categorized to their frequency and dangerousness:

Very common (> 1/10, 10%), common (> 1/100, <1/10 1-10%), occasional (> 1/1000, <1/100, 0.1-1%), rare (1/10, 000, <1/1000, 0.01-0.1%), very rare (<1/10 000, less than 0-01%) including isolated reports.

If we consider HBO as a drug and compare it with the rate of side effects of other medicine we are surprised by its relative harmlessness.

Aspirin: it is a medicine often sold “over the counter” without any medical prescription. Looking at its side effects as they are presented by the manufacturer, we find following information: micro hemorrhage: very
common >70%, dyspepsia, nausea, vomiting, diarrhea: 0.01-0.1%, asthma: 0.01-0.1%, stomach ulcer: 0.001-0.01%.

If we look at a well-tolerated and widely used antibiotic:

Ciprofloxacin: we find following side effects in the official prospectus: infection with fungi: 0.1-1%, eosinophilia: 0.1-1%, skin rash 0.1-1%, anorexia: 0.1-1%, psychomotor hyperactivity, 0.1-1%, headache, confusion, insomnia 0.1-1%, nausea, diarrhea, loss of appetite, stomach ache: 1-10%, increase liver enzymes, bilirubin: 0.1-1%, arthralgia 0.1-1%.

Though, it can be said that HBO is very safe and that its side effects compare very favorably with the rate of side effects of most drugs.

**Question 2**

For those standalone hyperbaric centers who offer 24 hours service, the European ones are much more involved in the treatment of ICU patients with 7 centers out of 17 (41%) compared with 3/28 (10%) for the US centers. These centers fall rather in a category treating difficult conditions and should be looked at separately regarding the qualification of their staff.

The data confirm that standalone chambers mainly treat, outpatients, mostly suffering from chronic wounds, diabetic foot injury, radionecrosis. Most hospital based centers are located in wound clinics and offer mostly pharmacological and wound care besides of HBO (7, 3).

**Question 3**

Multiplace (24/45, 53%) and monoplace (23/45, 51%) hyperbaric chambers are equally represented in the total of all centers that answered the survey. Considering the geographical repartition, the picture is different, we find 22/28, (71%) monoplace chambers in USA and 16/17 (94%) multiplace chambers in Europe. The advantage of monoplace chamber is that they demand less personal and less investment. The consequence is that they are more numerous than multiplace chambers and can easily treat patients in the periphery, reducing by this way the travelling distance of patients. This is a very important point for elderly patients (8). Such patients represent the majority of patients who receive HBO for diabetic foot ulcer (9). From the marketing point of view, it allows a better dissemination of hyperbaric oxygen to the physicians and to the consumer in the periphery.

**Question 4**

17/28 (61%) of our hyperbaric centers in the US and 9/17 (53%) in Europe treat only UHMS approved indications, the rest treat as well UHMS as off label indications. The reason for that is difficult to find out exactly. One possible reason for it would be that standalone hyperbaric centers may be more dependent of income related to HBO for their survival and are more willing to treat “off label” diseases. Another possible explanation is that some indications, I.E. sudden deafness are still not paid by third party providers, though the positive effect of HBO seems to be better documented than other treatment forms.
Question 5

Surprisingly, 15/28 (54%) of the standalone chambers in USA compared to only 3/17 (18%) in Europe are property of a hospital. In Europe, doctors are more often owner of the standalone chambers 7/17 (41%) compared to 1/28 (1%) in USA. It may be of concern that in USA private persons can run standalone hyperbaric chambers without being a doctor, (7/28 (21%) in USA versus 0% in Europe). Financial companies are owner of the standalone hyperbaric centers more often in Europe than in USA (4/28 (4%) for USA versus 6/17 (35%) for Europe). There is also a very special situation in USA with large companies like Heallogics, Oxyheal owning many hyperbaric centers. Heallogics (10), is the largest provider of wound care and related disease management in the country running actually over 450 hyperbaric centers, all located in medical office buildings (11).

The fact that doctors or companies hiring a medical staff can own a hyperbaric chamber involved mainly in the treatment of chronic conditions is not conflicting. If we take the situation of cardiologists doing stress echo or treadmill echo’s or EKG, the risk of serious complications is much higher for them than for the hyperbaric physician. If one compares with the number of events susceptible to occur in a cardiologist’s office during a routine treadmill EKG, it is clear that HBO is a rater safe procedure (8.86 severe complications per 1’000 treadmills testing (0.09%) (12). If one considers now stress echo, the complication rate climbs to 1/300 exams (0.3% for dobutamine and 0.1% for dipydamole) (12).

Question 6

There is no very big difference between the amount and education of staff between USA and Europe. According to the European Code of Good Practice (2), the minimal team requirement for multiplace hyperbaric chambers is one doctor, one inside attendant and one chamber operator completed by a safety director and the one for monoplace hyperbaric centers is one doctor and one chamber operator. The data found in our survey show numbers which are over this requirement. This can be explained by partial time jobs and reserve for holidays and unexpected absence of staff members, either for personal reasons or because they have to fulfill other tasks in the hospital or center, i.e.: other nursing task, administrative or hardware maintenance duties, etc. If we however consider the risk inherent to treadmill exercise is higher than the risk of HBO, one must admit that the constraints set to HBO are much higher than the ones set to a cardiologist. Furthermore, there are no requisite for the education of the cardiologist’s assistant, except maybe of CPR. Differential guidelines for staff education in hyperbaric centers treating only problem wounds should be established in order to meet the specificities of all types of hyperbaric centers.

Question 7

25% (2/6) of hyperbaric standalone centers running multiplace chambers in USA and 41% (7/17) in Europe have no inside tender during the treatment. These data suggest that the staff dimension set by the European Code of Good Practice could be overestimated, especially for hyperbaric centers treating only problem wounds. Another concern regarding inside tenders in multiplace chambers treating chronic wounds with HBO is that these staff members are uselessly exposed to the risk of iatrogenic DCS even if this risk, 1/1’000 compression can be considered as low (13).
Question 8

Hyperbaric centers that have an inside tender during the whole treatment have mostly staff with medical background. This medical background is however very different from center to center, ranging from a physician if requested by the clinical situation to a paramedic. If we consider again the risk category attributed to standalone hyperbaric centers providing care to patients suffering from chronic wounds, paramedics or even divers with a basic education in primary resuscitation would be competent enough to cope with an acute problem provided a physician is readily available. In Europe specific education for hyperbaric staff can only be provided by courses offered by medical societies. In USA, an increasing number of private societies are offering this service (14, 15). This may be necessary for doctors but not necessarily for the other personal. This constraint is a barrier in personal flexibility and could interfere with the growth of standalone hyperbaric centers.

Question 9

Only 11/28 (40%) of the standalone hyperbaric centers in USA who answered this survey are accredited compared with 100% in Europe. These data are however to be taken with precaution because the accreditation process is different in every country and because our data is scarce. Googling with the key word “accreditation of hyperbaric centers in USA”, we can find a center claiming that they are only 60 accredited hyperbaric centers among 800 that are in use in USA (16). Another US center reports an accreditation rate of 10% in USA (17). There are actually no European accreditation procedures for hyperbaric centers. In USA this service is offered by the UHMS (18). In Europe, if such a process is to be set, it should be chosen carefully among the several types of accreditation processes currently used (EFQM, TQM) and fulfilled with the European guidelines (19).

Question 10

All centers in USA ask their patients to sign an informed consent form before they are allowed to enter the hyperbaric chamber for treatment. The rate (75%, 12/16 centers) is lower in Europe. This can be considered as a weakness in the European centers. Informed consent is a part of standard care in any hospital and as such should be adopted by all hyperbaric centers. According to Chan et al, public oriented and centralized information on HBO could help the correct dissemination of HBO (20).

Question 11

Over 70% of the centers who were surveyed use patient satisfaction assessment tools. Assessment of patient satisfaction is a tool which is more and more used in any type of service, ranging from hospitality to airline services. An increasing number of hospitals are using this tool. It reflects the consumer’s perspective and is important for the measurement of quality of care. It is also a good marketing tool for the health provider (21). In clinical practice and possibly improve the dissemination of the discipline.

Question 12

Patients are coming to standalone hyperbaric center by different ways. All possible ways of recruitment are equally used: Over 80% are sent directly by colleagues or hospitals. However a larger percentage 67% in USA and 81% of the centers who responded to the survey treat patients who came from their own, which represents the usual way for patients to have access to specialized medical services. The health system is confusing and
difficult to navigate; primary care physicians are unaware of services that are available and are uncertain how to access these services (22). It is important for Standalone hyperbaric centers to directly inform the primary care physician as well as the end user about the possibility of hyperbaric oxygen treatment. Doctors in charge of standalone hyperbaric centers should discuss the information patients have gathered from health website and guide them to the correct treatment facility if appropriate. According to Mc Mullan (23), patients search the internet for their specific disease before and after they were offered a treatment for their disease. This affects their choice of treatment. Many hospital use also telemedicine to better inform their patients (24).

**Question 13**

Except one center in USA and one in Europe who deny doing any type of advertisement all other center are using this mode of information spreading to recruit patients for their facility. There seems to be a kind of cultural difference in patient acquisition between USA and Europe. 64% of US centers have a web page compared with 6% in Europe. On the contrary Europeans seem to like more sending Emails.

In fact every center has its own way of advertising as can be seen from the variety of answers obtained. On has to be cautious with advertising in the field of hyperbaric medicine (25). Direct To Consumer Advertising is allowed only in the USA and in New Zealand, they are not allowed in other countries.

**Question 14**

Five out of 28 (18%) centers in the USA have financial agreements with their patient providers compared with 7/17 in Europe (41%). Collaboration between public health and medical providers is an attractive way to pool costs and skills in order to improve the general health status of the population. In a survey by Halverson et al. (26) it was found that more than half of the hospitals had collaborative relationship with medical providers. Only 40% were formalized with contracts. 66% of these contracts were dealing with agreements on patient referral.

**Question 15**

None of the centers either in USA or Europe had sold share of their center to the providers.

**Question 16 and 17**

Hyperbaric centers have less often reimbursement difficulties in USA (10/28 (36%) than in Europe (9/17 (52%). Mostly Germany had problems with third party reimbursement for so called UHMS approved indications. There are different reasons for that. In USA, for UHMS approved indications, reimbursement problems often occur because of wrong coding. In Europe, reimbursement is done on a national basis, after hearings done by special committees; there is no recommendation on a European level.

**Recommendations to the jury**

**Recommendation 1:**

Improve the existing OXYNET.org website; it would be of great value to find a part time secretary with special consideration to: regularly updated databank of Emails, of a register of active hyperbaric centers.
Recommendation 2:

Proof and possibly adapt the staffing guidelines of hyperbaric centers according to their activity.

Recommendation 3:

Allow medical directors or head of technical staff to teach their own personal according to the guidelines of ECHM.

Recommendation 4:

Start an action for a practical and reality based accreditation process in Europe.

Recommendation 5:

Produce a European harmonized informed consent form for HBO.

Recommendation 6:

Enlarge the OXYNET Website with regularly updated evidence based information on hyperbaric, containing the same evidence based information on treatment competitors (I.E. summary of Cochrane reviews).

Recommendation 7:

Start a lobbying action with industrials interested in the promotion of HBO to expand the visibility of the field.

Recommendation 8:

Start an action to harmonize reimbursement for HBO in Europe.

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(06) Diving Oriented Hyperbaric Centre (DOHC)

Adel Taher (Egypt)

Note from the Author:

Going through the scant available literature addressing the topic of DOHCs, the author soon realized that the efforts made by the British Hyperbaric Association (BHA) and the ECHM and task groups of the COST B14 which yielded the “European Code of Good Practice for Hyperbaric Oxygen Therapy” and the amendments made cover most aspects in a detailed manner. Thus, the concentration on aspects relating mainly to personal experiences that are not mentioned in the previous reports. The distinguished colleagues presenting other expert reports will be covering detailed topics that fall within their fields of experience and so, there was no need for repeating information that will be presented by them.

The author planned, designed, built, trained staff and personnel and managed two “Diving Oriented Hyperbaric Centres” (DOHC) in two highly frequented diving destinations: Sharm el-Sheikh & Dahab, in the Sinai, Egypt. Over the years since 1993 many experiences were gathered and the opinions expressed in this report relate to them. The impact of a DOHC on the local community and the destination as a whole, issues to be confirmed and recommendations and issues to study are mentioned.

Introduction

The estimated number of human beings breathing compressed gas under the water and on land is very hard to estimate accurately. Diving organizations, commercial diving bodies, naval forces and compressed air workers companies and associations and syndicates do not allow free access to their data base and there is no global hub or authority that could gather all the information and issue near accurate numbers.

The estimation/guesstimation is that 15 to 16 million human beings have been trained, through recognized training bodies (and some through friends), to breathe some sort of compressed gas on this planet currently. About 9 million represent the sport, recreational and technical divers. For accuracy, one needs to subdivide this group into “active” and “non-active” divers, though this task seems to be quite difficult for lack of data.

The rest are the commercial/industrial, navy, military and law enforcement, research, fishing and aqua-harvesting and underwater archeological divers. In addition we have the various Caisson and tunnel compressed air workers.

All categories join in one common denominator: they all dive and breathe gas under hyperbaric conditions… and this activity could result in a diving accident.

The author tried to investigate the number of “Diving Oriented Hyperbaric Centres” in the world and realized that this was not an easy, nor straightforward task. The reasons for that are multiple: The non-existence of a central/global registry covering all hyperbaric facilities and updating their information, the lack of reliable sources, no updates on the condition of the facilities mentioned and whether they still exist and function as such
or not, the state of readiness of such centres, and of course, the fact that many hyperbaric facilities treat diving accidents only occasionally and are thus not considered “Diving Oriented”, and when they do it is usually as part of a continuation of treatment or follow up, but not as a primary provider. The following figure is taken from the DAN Chamber Database and is still not very accurate. The updating of the status of DOHCs is not always carried out by the national directors and not all available chambers in the country are registered or used by DAN. DAN-Europe supplied the most accurate information regarding the cases treated, but then again, these are only the cases that were paid by the insurer, other unpaid claims are not included. The figures supplied are also missing a large number of cases which were never reported to DAN or other insurers as the NHS or Social Security/social Health System covered them to their own nationals within the country. An Englishman having an accident in Britain will be most probably treated through the NHS, a Frenchman having an accident in France will be treated through the French governmental health service…etc. All these cases do not show on any tangible and accessible database. So what do we have?

We have 975 Recompression Chambers registered through the DAN database, 403 are in the USA and about 200 in Europe. We do not know, how many are stand-alone DOHCs and how many are hospital based and offer treatment to diving accidents among other HBOT indications. DAN-Europe provided the number of accidents treated and covered from Jan 2009 till Dec 2011: 894 cases in total, 229 females and 665 males.

The creation of an international body, a “registry”, to hold all the information and update it on a regular basis as well as provide links connecting the working DOHCs together can only be strongly emphasized. It would also allow an agreement on international-rather than national or regional-standards, encounter forms, easier auditing and recertification. Having a common pool for all the information provided by the respective data bases, would definitely boost the research and maybe yield a different epidemiological picture than the one we embrace to date.

**Hyperbaric Centres in Europe**

Using “Oxynet” and the database of DAN-Europe, it was possible to establish that Europe has about 200 operational hyperbaric facilities. Assuming that all hyperbaric facilities should be capable of treating diving accidents, we would be entitled to label them all “potentially” diving oriented hyperbaric centres. This is not the case though. The design codes of pressure vessels and the different shapes they take allow for the production of “low pressure” (e.g.: the Quadra and some transport chambers) and “high pressure” chambers. Only the “high pressure chambers” can provide adequate treatment to diving accidents. Another important aspect is the geographic location of most of them, which places them away from areas of diving activities. They could, though, be involved in the treatment of “dry diving” accidents, as in compressed air works or even in wet diving accidents if they serve as referral hyperbaric centres for follow up treatments after the initial treatment(s) have been given somewhere else.

The definitions agreed upon in the European Code of Good Practice for Hyperbaric Oxygen Therapy are largely used in this report and we will include three levels in this report:

- Hyperbaric Chamber
- Hyperbaric System
Hyperbaric Facility: being the actual functional unit that could be considered a “Diving oriented Hyperbaric Centre”.

Most “Diving oriented Hyperbaric Centres” in the world are the ones in close proximity to diving destinations or ones easily accessible by land-, sea-, or air transport from diving destinations. In addition we should mention here, the mobile units that are present in many locations attached to Caissons and tunneling sites, the deck decompression chambers on oil rigs and the mobile units used by the naval forces aboard vessels or on land. Most of these DOHCs are free standing and not attached to a supporting hospital system.

The first question regards the “need” for establishing such centres and the answer shows that it exceeds the obvious therapeutic value to encompass economical, developmental and marketing issues. Furthermore, there is a definite impact and ramifications on the whole local society and the area the DOHC operates within.

Answering the question:

The safety of the divers in an area that does not have a recompression facility, nor is one reachable within an acceptable distance and time of transport. Another reason is to develop and promote a diving industry in an area with a promising potential for tourism. Especially in areas that do not possess an infra-structure of a hospital where a hyperbaric facility could be housed. It is noteworthy, that in many remote diving areas, the Diving oriented Hyperbaric Centre represents the only available medical facility and doubles as a GP and trauma clinic.

In other areas, the need is for a facility for a specific task, as in offshore oil exploration on rigs and production platforms and in some military and naval operations. These are usually, “Deck Decompression Chambers” (DDC) and mobile containerized recompression chambers. Some naval and marine biological vessels as well as under water archeological research vessels have hyperbaric facilities onboard together with the adequately trained staff and personnel.

Several attempts have been made to categorize hyperbaric facilities. These attempts where mainly addressing centres that offer treatments to clinical indications (HBOT) as well as diving accidents. The NFPA 99, addresses three categories: classes A,B and C representing a chamber used for multiple human occupancy (Class A, multiplace), and one used for single human occupancy (Class B, monoplace) and a chamber used for animal experiments and research on diving equipment (Class C). The author believes that DOHCs should have a different categorization based mainly on the current situation and function (transport under pressure, hyperbaric therapy, both):

- One man transport chamber (monoplace)
- Two man transport and treatment chamber (duo chamber)
- Deck Decompression chamber (DDC)
- Multiplace, multilock chamber

A further sub-categorization would include, whether the unit is equipped to receive and treat ventilated divers or not (should contain approved mechanical ventilator and other medical devices according to European Norm ISO14971, Medical devices and European Directive CEN Medical devices: 93/42 CE)

The British Hyperbaric Association (BHA) categorized hyperbaric facilities in a similar fashion. Four categories are recognized, the first three are multiplace chambers, where the first is equipped to deal with critically ill patients in need of hyperbaric intensive care, the second deals with elective cases and referrals for patients needing to receive HBOT for a variety of different indications, provided they are not critically ill or ventilated or...
in need of hyperbaric intensive care and the third is mainly for treating diving and compressed air work accidents. The fourth category represents the monoplace chambers and usually these operate at a lower pressure and lack the air-lock facility. Cases treated in these monoplace chambers are considered stable enough by the supervising physician to warrant a treatment session without an expected need to gain access to the patient during the treatment.

The European Code of Good Practice for HBO Therapy differentiates between two categories of hyperbaric facilities: the hospital based and the free standing or standalone facility. It states though, correctly, that the latter should be in proximity of hospital services and that the system for communication and transportation should be pre-defined.

In view of the multitude of categorizations, we strongly believe that a single, globally agreed upon classification is needed and would suffice and help reach a more efficient and unified plan for the organization, risk assessment and staffing requirements. The author suggests two subdivisions in that categorization, one for clinical HBOT and one for diving oriented hyperbaric facilities.

**Creating a DOHC**

At the beginning there is the “Planning Stage”, in which the justification for such a project is laid down and discussed, the targeted beneficiaries identified and a preliminary feasibility study prepared. Once the initial acceptance and approval are granted, the feasibility study is then upgraded to a detailed one. We recognize two types of operations, either a “private sector” or a “community service”, which is usually a government owned operation. The major single component that may determine the feasibility, is the availability of the needed infrastructure such as power supply (electricity), potable water, roads, communications, helipad or runway) which are needed to facilitate the functionality and sustainability of the DOHC.

Social and logistical considerations need to be considered and carefully weighed in. The characteristics of the general population, their traditions and beliefs and how they would respond to having a DOHC in their area and how it should be presented to them. Logistically, it is of great importance to realistically gauge the level and extent of technical support available or attainable in the area of operation of the DOHC. Spare parts, medical grade gases, communications and IT and simple materials are very difficult to get in some places. The availability of local personnel and facilities to train them are other aspects to consider.

The presence of a reachable (easy/difficult/with great difficulty) medical support in the form of a hospital or specialized medical centre to supply the diagnostic and investigative radiological and laboratory examinations needed, an intensive care unit (ICU) and emergency department are crucial for the management and contingency planning later on.

We also strongly recommend that medical support and consultations be rendered via an international network of consultants through telemedical facilities. Telemedicine is now almost as easily attainable as having internet and it should be one of the pre-requisites to operate a modern DOHC. Other means of international communications (telephone land line, mobiles and satellite telephones) are also acceptable.

The scope of work and the efficiency of managing and handling diving accidents relies to a great extent on a whole team, outside and inside the DOHC, but very closely related. On the outside, an efficient Search & Rescue (SAR) team is a great asset and should be encouraged and supported by the DOHC. The SAR operation depends
on the area of operation, the local laws and regulations, the hardware (RHIs, Speed boats, jet skies, helicopters), training of personnel, communication and the community’s support and if possible sponsorship.

The DOHC should have in place operational plans to transport cases that need to be transported to a higher level of medical care (triage).

Good contacts and working relations with international alarm centers, diving insurances and assistance companies as well as tour operators are essential to cover the administrative part of the management. They could also be a valuable source of needed information in an emergency and have a staff dedicated to working out logistical solutions.

An aspect that is very often neglected and the author believes should be addressed as part of the standards, is that the DOHC and the staff and personnel should all be properly insured.

Financially speaking, the DOHC, in most cases, is either owned by a private sector investor or company, or government owned. The private sector facility will be run in a profit minded way. The feasibility study will include suggestions and work schemes to create and maximize the revenue. Often these schemes include offering a short term insurance or membership plan to ensure covering at least their running costs (break even point). Often these insurance plans/memberships are deemed illegal according to the country’s laws as they overshadow the legal status and work of insurance companies. Financial audits and checks should also be carried out as the last few years have revealed an increase in cases of insurance fraud.

The government owned DOHC is usually part of a “community service” provided and states that they are non-profit. This is not entirely correct, as there is a profit and it is sometimes immense, but indirect and reflects itself clearly in the form of an increase in the national income from diving tourism. Sustainability is usually the challenge and the local and diving communities help in supporting the DOHC. Voluntary contributions collected through dive centers help in supporting internal programs of continuing medical education (CME) and technical training of the personnel.

DOHC represent a medical service provider that raises the ceiling of safety in diving in the area of operation. Any provision of service is coupled with expectations on the part of the receiver/beneficiary and the regulatory bodies controlling the service. In practical terms, a DOHC should provide the following minima in terms of (a) autonomy in treatment, (b) provision of medical measures and (c) logistics of operation.

(a) autonomy in treatment:

1. It should be able to provide the longest Oxygen US Navy treatment table (USN TT) with all extensions according to the US Navy Diving Manual. 2. Should have enough gas volume and pressure storage to conduct such a treatment and enough reserve to deal with a second emergency (USN Diving Manual, Volume 1, D-7). 3. Sufficient storage of Oxygen and other mixed treatment gases (if applicable and in the scope of treatments offered) to carry out the treatment mentioned. 4. Independent power supply to assure the proper uninterrupted function of all life support systems within the DOHC for the duration of the treatment. 5. Solid system for emergency communication with emergency back-up (tel. land lines, mobile phones, VHF-radio, satellite tel.).

(b) provision of medical measures:

Basic medical skills and the provision of medical measures, also under hyperbaric conditions, should be safely assumed, such as: 1. Inserting and caring for an intra venous (I.V.) line, outside the chamber and
under hyperbaric conditions. 2. Administration of parenteral medication. 3. Catheterization. 4. Intubation and mechanical ventilation (using Ambu bag, or connected to BIBS line inside the chamber, or mechanical ventilator approved for work inside the chamber under hyperbaric conditions). 5. Suction. 6. Defibrillation outside the chamber (Defibrillator with an external pace maker is preferred to an AED) and resuscitative measures. 7. Sterilization of equipment, tools, masks and the chamber.

(c) logistics of operation:

24/7 readiness for diving emergencies. Staff and personnel should be on call and work in shifts if possible. An international telephone line and if available, internet and telemedicine capabilities, are preferred.

A local hotline is essential and should always be manned and carried by an experienced physician that can give immediate advice, instructions and help with first aid measures on-site and facilitate the logistics of transport to the DOHC.

The service receivers should also assume that the medical staff and technical personnel are specialized and updated on a regular basis.

Triage capabilities should be secured and the transportation needed for that available or could be made available in an acceptable time.

**Points to study in the near future**

1. The role of the DOHC needs to be fostered, not only as therapeutic center, but also as the trusted diving medical center that can perform the diving eligibility examinations to divers. Many accidents occurred as a direct effect of the ignorance of the examining physician! Clear directives should be issued to all health and safety governmental bodies stating that Diving Medical Eligibility Examinations may only be carried out by a Diving Medical Examiner or Diving Specialist. This will not only help prevent disastrous diving accidents from happening, but will also increase the flow to the physicians working in the DOHC and support the facility as well as add to the experience of the medical staff working there.

2. Adding to the standard equipment of a DOHC breathing gas analyzers, especially in areas where technical diving is practiced. Grave mistakes in identifying the right mixes have resulted in several fatalities and many accidents. Gas analyzers will help demystify the cause of accidents.

3. Providing DOHCs with modems and software to download various dive computers could help in identifying the aetiology of some diving accidents.

4. Standardizing the encounter forms dealing with the accidents is necessary as it will allow us to study the epidemiology of diving accidents and make accurate statistics. (DAN had introduced in 2008 the DAN Medical Services Call Center [DAN-MSCC] form). No “accurate” single statistic exists that covers epidemiological data on diving accidents in the sport and recreational sector worldwide. This is due to lack of sharing and cooperation between DOHCs as well as not having a standardized form to enter the data and facilitate research.

5. In areas where internet is available, telemedicine capabilities would be recommendable to any DOHC.
6. Handicapped divers are increasing all over the world and they are subject to dive accidents. Although the topic of providing slides and hoists and other mechanisms to help enter and egress the chamber easily is mentioned in the Code of Good Practice of HBOT (6.3 Specific Hazards, M), we believe it deserves to be defined clearly and become one of the standards.

7. The experiences gathered in some of the DOHCs (including Sharm el-Sheikh, Dahab & Murnau) demonstrated clearly the effectiveness and benefits of starting the physiotherapy at a very early stage of treatment under hyperbaric conditions. This was observed in cases involving spinal decompression and had a direct positive effect on the prognosis. We suggest a multicentre study be started to evaluate the efficacy of the practice.

8. In the recent years, we noticed an increase in the numbers of diving accidents, where alcohol and recreational drugs abuse were either a direct cause or a collaborating factor. Most diving destinations changed character due to obvious economical reasons and became “resort destinations”. Alcohol and recreational drugs are unfortunately among the “commodities offered” at competitive prices! As this trend represents a true hazard, we suggest testing diving accidents victims routinely for alcohol levels and drugs to establish statistical data that could be the base for further recommendations.

9. The European Standard, prEN 14931 titled: Pressure Vessels for Human Occupancy (PVHO) – Multi-place Pressure Chamber Systems for Hyperbaric Therapy – Performance, Safety Requirements and Testing), needs an update to address the newly arisen need for using treatment gas mixes other than air and Oxygen, mainly HELIOX. An increasing number of DOHCs use Heliox to treat cases of neurological DCI. This shift towards Heliox is closely linked to the increasing number of technical divers and the accidents that occur involving Trimix as a breathing gas and is based on a strong, clinically unfounded believe, that the COMEX CX30 treatment table utilizing Heliox 50/50% is a better choice to treat neurological DCI resulting from mixed gas diving accidents…which leads us to the next point…

10. An evidence based medical study needs to be initiated comparing globally the results of treatments with USN TT6 and COMEX CX 30 in the sector: “sport, recreational and technical diving”. The studies presented so far were not conclusive and did not cover a large number of treatments.

11. Oxygen dosing is another issue of uncertainty and there is no unified consensus regulating the dose of Oxygen needed to treat specific cases. The Gesellschaft fuer Tauch- und Ueberdruckmedizin (GTUEM) did excellent work in producing and updating the “Guidelines for Diving Accidents”, but many DOHCs treat with a lower dose of Oxygen than the ones prescribed and get equally good results. Are we overdosing on Oxygen and could we achieve the same results with less? A retrospective study examining cases treated with “less” Oxygen and their outcome would shed a light on the Oxygen dosing issue. A study on the quantitative values of Oxygen needed to achieve therapeutic aims will be needed.

12. As “recreational technical diving” is becoming a main branch of sport and recreational diving and represents in areas like the Egyptian Red Sea and Sinai 7 to 8% of all diving activity, we suggest that the syllabus approved by the EDTC and DEMAC for teaching Diving Medicine, should include a chapter on “recreational technical diving” in addition to some practical training. The diving medical examiners and specialists working in DOHCs need the information to appreciate the problems concerned and deal in a more professional way with the technical diving accidents. And, as they are performing “Diving Eligibility Examinations” to prospective technical divers, they need to understand and appreciate the physical-,
physiological- and psychological stresses and overloads involved in this type of diving and the fitness level needed to perform it in a safe manner.

13. A free electronic journal with all updates and ongoing research in the fields of diving medicine and chamber operation needs to be created and offered at no cost to all DOHC staff and personnel. Most of them are not members in prestigious societies like the UHMS, EUBS and SPUMS or others and often cannot afford travelling to international conferences. The sponsoring for such a project could come from the major diving organizations as well as the insurance companies. Disseminating the knowledge should be our concern and it would reflect favorably on the safety of the divers and the outcome of the treatments.

DOHCs create direct and indirect effects in their area of operation, in the community surrounding them and very often in the whole country they are located in.

In Sharm el-Sheikh for example the whole city experienced a major boom in development which started six months after the DOHC arrived. Currently, the diving related tourism is generating 25 to 30% of the national income of Egypt from the tourism sector. The city was voted the fastest growing city in the world in 1998 and this was directly linked to the DOHC.

The medical services offered to the local communities ranged from very poor to non-existent before the DOHC arrived and they improved markedly by adding three more physicians, a GP clinic and trauma centre to serve the community. Right now the DOHC is starting a program to use one of the two available chambers to offer HBOT for non diving related clinical indications.

**Recommendations**

- We strongly recommend that any DOHC should set up a system of support and sponsorship to back its activities involving the local diving community.

- Technical and preventative maintenance schedules should be adhered to stringently and audits and technical risk evaluation should be welcomed and invited.

- The regular training of the medical (CME credits) and technical staff should be a high priority and budget allocations should be made specifically to assure the continuity of the practice.

- DOHC should nurture a healthy relation to the official governmental bodies and the regulators of the diving industry in the country they are in and strive to have an advisory function in the fields of diving safety and regulations, tourism and environmental protection.

- A healthy and strong relationship with the dive center managers and owners is essential to facilitate the cooperation and assure that the safety recommendations issued by the DOHC are respected and followed in the area of operation.

- Other facilities working in the field of diving accident management and treatment should be contacted and protocols of scientific and technical cooperation and exchanging experiences should be agreed upon and encouraged. If possible at all, the DOHC should get involved in ongoing research projects, both locally and internationally. DOHCs are perfect sources for data collection.

- We also recommend transferring the “know how” regarding the use of Heliox in treatments to DOHCs in areas where technical diving is practiced.
The “extra” roles of a DOHC…

Marketing

A properly functioning DOHC is unequivocal the best marketing tool to promote a remote, new diving destination.

Example: Sharm el-Sheikh, March 1993 (The Hyperbaric Medical Centre arrived on 08.03. and was operational on 10.03.1993)

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Tour operators, dive centers and insurances use the DOHC to sell their product and market their activity.

Education

A DOHC has an educational role to fulfill towards the local diving community, the native community, diving medical research and technical training. It also has an advisory role towards the private sector and investors as well as governmental agencies through supplying them with statistics reflecting the reality of the diving tourism. The fields of diving medicine, general safety, first aid courses, awareness and Oxygen Provider courses are just an example of the educational role towards the community. The DOHC might be the only place where a reference library in these and associated fields may be found. Research with universities and research centres could involve a major portion of the local diving community. Ideally, a DOHC should have a lecture room or hall, a program for invited speakers, training and hands-on experience programs for physicians specializing in the field as well as interested medical students (elective placement program) and offer hyperbaric tender courses to dive professionals in the area and from abroad on a regular basis.

Prevention

The success of a DOHC should not be measured only by the number of accidents it treats every year, but rather with the accidents it managed to prevent from happening. A steady decrease in the percentage of accidents in relation to the number of inflowing divers should be a good indication to the efforts exerted in the prevention.
This is achieved through utilizing the data retrieved from accident analysis, raising the level of dive safety awareness, better screening through diving eligibility medical examinations, suggesting different and better adapted dive techniques and gas mixes when appropriate...(e.g.: diving with Nitrox on the Thistlegorm and sending two Divemasters).

**Treatments**

A variety of treatment tables are commonly used and some differ from the conventional Oxygen/air tables and involve using other gas mixes like Nitrox and Heliox. Most DOHCs in remote areas do not offer the COMEX CX 30 because they do not have the “know how”, the gas mix or a chamber equipped to provide any treatment gases other than Oxygen and air. Areas where technical diving has a foot hold, have gas mixing and filling stations that could supply the gas mixes needed. Modern DOHCs have their own gas mixing capability.

The choice of the treatment table depends mainly on the clinical presentation of the case and studying the dive profiles and other factors. The “Guidelines for Diving Accidents” are a perfect advisor if the treating physician is in doubt. With increased experience, the choices might differ from those suggested in the “Guidelines”. Alterations to established treatment tables should be avoided, unless dire circumstances dictate them and we advice discussing the case with experienced diving medical consultants prior to doing so. It is noteworthy, that although the USN TT6A is not a recommended treatment table on the guidelines, it is being used extensively without modification in DOHCs directed by ex-military and ex-navy physicians and DOHCs belonging to the navy but treating sport and recreational divers.

**Literature Search**

The author experienced great difficulty in finding suitable articles addressing the topic „Diving Oriented Hyperbaric Centre“ and cannot recommend any single source that covered the subject methodically.

- The ECHM conferences, consensus conferences and meetings covered many of the aspects of the topic being discussed.
- The works provided by Francois Burman in the framework of the Recompression Chamber Assistance Program (RCAP) was also a valuable guide.
- DAN-Europe and International DAN provided highly appreciated assistance through their database and statistical annual reports and listings of affiliated recompression chambers
- Search for the topic yielded many articles and sources that do not directly address the subject but merely state the existence of „Diving Oriented Hyperbaric Centres“ in their text bulk.

**Literature Review**

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## Attachment

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Chapter 3: Staff of the Hyperbaric Centre
(07) Initial training of physicians in the Hyperbaric Centre

Dr Ramiro Cali-Corleo MD MSc MMCFD (Malta, ECB)

Introduction

Up till the 70’s most chambers were operated by the navies and air forces and aimed only at treating decompression sickness. Now DCI only represents around 3% of a typical hyperbaric unit caseload. Increasing credibility of HBO as a science has interested universities in offering diploma and even degree courses in Baromedicine. However some countries are much more advanced than others in this.

Besides training, there is felt the need for a properly structured orientation program, primarily to ascertain the true competency of an individual entering into the field of Baromedicine to perform the job requirements and secondly, to facilitate a smooth transition into the new work environment.

As yet, not all EU countries have recognised the value of Baromedicine as a ‘stand alone’ specialisation. In fact in quite a number, the ‘Hyperbaric Doctor’ and the ‘Diving Doctor’ is a medical practitioner who, having developed an interest in the subject, either underwent one or more of the one week crash courses in diving medicine and fitness to dive or having become attached to a functioning Hyperbaric Unit, underwent a sort of hands-on apprenticeship with the already experienced doctor/s already working at that Unit.

At the 1st European Consensus Conference of the ECHM in 1994, it was recommended that, in order to function correctly with a guarantee of the best use of its equipment and services, the doctors and in particular the medical director of a Hyperbaric Unit should have formally trained in and acquired knowledge and skills in a number of medical fields which must include as a minimum respiratory physiology, pressure related physics and gas laws, critical care, Angiology, Traumatology, Neurology, ENT, Ophthalmology, Epidemiology, Diving medicine, Hyperbaric medicine, diving technology, hyperbaric technology, general principles of Pneumatics, and safety in the hyperbaric environment. It was also recommended that even if the doctors working in the Baromedicine field had a good self-training form of education, in order to comfortably carry out all the possible responsibilities deriving from the practice and in particular to avoid legal problems, it was necessary that a formal specific qualification in both Diving and Hyperbaric medicine is obtained.

In 2004, as part of the COST Action B14 of the EU, the Working Group on Education and Training in Hyperbaric Medicine met on May 5th (Turku, Finland), September 15th (Ajaccio, France) and December 1st (Lille, France) and following these physical meetings, as well as numerous virtual meetings and e-mails, issued their final report as approved by the Management Committee on the 2nd of December, 2004.

The Working Group, in their Report, made an inventory of the various educational courses and diplomas already existing in Europe and, basing itself on the ECHM/EDTC Standards on Education, defined the levels of education and training required in order to reach the target level of competencies as well as creating a modular syllabus for the preparation of educational courses for Level I and Level II competency in Diving and in Hyperbaric medicine. A system of credit allocation for each course module made possible the mutual recognition of diplomas throughout Europe as well as the possibility for students to receive multi-site education and training is so desired or required.
Another important need identified by the Working Group was the need for a European textbook on hyperbaric oxygen therapy. Up till then, only textbooks reflecting the US perspective existed. Due to the existing differences between the US and European viewpoint, particularly with regard to Hyperbaric medicine indications and practice, the WG proposed the publication of a multidisciplinary textbook on hyperbaric oxygen therapy, co-authored by the COST B14 members and reflecting the current European point of view as well as describing the advances in the field resulting from the COST B14 action itself. The Management Committee approved this suggestion and the first edition of the EU sponsored textbook was published in 2006. The guidelines for medical training in diving and hyperbaric medicine which were jointly prepared by the medical sub-committees of the ECHM and the EDTC were also published in 2005 as part of Volume 2 of the ECHM Collection.

The application of the above principles and guidelines when carrying out a number of level II courses over the last 8 years and discussions with other educators in the medical field has permitted the author to put together what he believes is the next step in defining a possible template for effective and efficient training of diving medicine doctors.

Following a historical review of diving and hyperbaric training to date, the paper will discuss in turn 4 of the 5 elements the author believes are critical for the proper training of Baromedicine physicians, namely, the course content, the trainer/educator, the materials and the venues. The 5th element, Continuing Medical Education, will be the subject of another paper.

**Historical review**

In general, the original interest and training in pressure related medicine was practically only military based and diving related. As exploration for oil and gas grew, oil companies hired former armed services personnel to provide medical, paramedical (most attendants were ex military divers) and technical support at the dive sites.

It was only after many decades that isolated clinical institutions and academic bodies started offering training in hyperbaric medicine, especially following the growth of number of civilian treatment facilities, particularly in the last 2 decades, that had created the need for more trained doctors and specialists than can be generated from the ‘retired naval doctors’ pool.

Manufacturers of chambers, besides providing the equipment and technical support, sometimes also provided/organised some medical training however, most medical personnel were trained ‘on the job’ following a kind of apprenticeship, the duration and quality of which varied considerably. Every unit had its own idea, based on its mission and client base, on what type of personnel it needed and what experience and training was required, especially since there was (and still is in many countries) no regulatory pressure from the Health Authorities to ensure that diving and hyperbaric medical personnel are brought in line with the requirements expected of other medical specialities.

Below is an outline of the progress in Baromedicine training and accreditation in a number of key areas in the world.
Australia and New Zealand

Specialist diving and hyperbaric medical knowledge is regarded as an essential postgraduate training and has been established through SPUMS. Courses are offered by several facilities, mostly of the Level I (fit to dive) type lasting one week and a couple of institutions offer an advanced course, also of around one week, which covers treatment of divers and HBOT. These courses do not usually include patient contact or clinical attachments but following a 6 month full time apprenticeship at a hyperbaric facility (or part-time equivalent) and the successful completion of an approved peer-reviewed research project, the doctor can earn a certificate of completion from SPUMS. This system has been under review for some time.

USA

Up to the 1970s most hyperbaric chambers were operated by the military and most of the medical training was oriented towards managing Decompression Illness. However with the growth of oil and gas exploration and the growth in the practice of clinical hyperbaric medicine the need for better trained personnel became obvious. At first the clinicians were chosen from the already existing pool of the surrounding hospitals but training content and quality varied greatly and so, in the late 1980’s, the UHMS determined that a standardised training and certification program was sorely needed and the National Board of Diving and Hyperbaric Technology was formed in 1991. This body introduced a certification program for all staff working in the Baromedical field, including medical researchers and clinical physicians involved in undersea, hyperbaric and aviation medicine. Entry level requirements to courses included experience in critical care or a strong background in medical/surgical patient care but type and years of experience required were not well defined.

The certification required not only successfully completing an approved course (at least 40 hours of classroom teaching) and passing the required examination but also a minimum 480 hours of clinical internship in diving, hyperbaric or aviation medicine. Re-certification is on a biennial basis on completion and verification of the required CME.

Southeast Asia

Many of the mostly multiplace chambers are military based and the doctors manning the chambers are mainly trained by the military, primarily in diving medicine, and follow military type protocols. Although there are hospital based chambers where HBOT is practiced, the doctors are often trained in-house or have followed short one week crash courses provided by western institutions.

South Africa

HBO started in the early 1960s mainly to treat divers and as radio-enhancers but later started being used for the other traditional indications for HBOT. In 1992 the Southern African Undersea and Hyperbaric Medical Association was formed by the physicians working or interested in the field. Training at the time was still based on the attendance of intensive short courses abroad but in the late 1990’s the first clinical hyperbaric training program was set up based on the American model. Much more recently, Stellenbosch University started offering a BScMedScHons (Hyperbaric Medicine) degree programme which can be read either as a distance learning course or on site and the programme is presented over a 2-year period for part-time students and over a 1-year
period for full-time students. Successful completion of the degree programme enables graduates to register hyperbaric medicine as an additional qualification with the Health Professions Council of South Africa.

**Latin America**

Most training, except for that provided by national navies, has been and continues to be of the ‘hands-on’ type, often with a minimum of actual apprenticeship with an experienced diving/hyperbaric physician or the attendance of one of the available ‘crash courses’ available internationally. There have been efforts by the Latin American Chapter of the UHMS to standardise the medical development in the field but as this region consists of 39 different countries with a great diversity of cultures and languages the task has not proved straightforward. However Cuba and Argentina both have formal training and certification in hyperbaric medicine as do Brazil and Mexico where Hyperbaric Medicine is a recognised sub-speciality. However these courses vary widely in duration and curriculum and a great need is felt for standardisation and regulated certification of such courses.

**Japan**

The Japanese Society for Hyperbaric Medicine has been responsible for all forms of training and qualifications concerning hyperbaric medicine for many years. The main requirements for a doctor wishing to enter into the Baromedicine field are that the applicant has to be a member of the society for at least two years, have acquired some years experience in clinical hyperbaric medicine at an approved facility and having followed and successfully completed the JSHM training course for hyperbaric physicians. Japan is one of the few countries that require continuous membership in the society to retain the qualification as well as having satisfied further academic requirements at the time of renewal of qualification after 10 years.

**Europe**

In Europe, Medical Specialisation is regulated by Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications. Section 5.1.2. of this Directive lists the evidence of formal qualifications of specialisation doctors must have to be able to call themselves specialists and practice the profession legitimately in the EU. The total period of training/internship leading to the issue of the formal qualifications listed below must not be less than 4/5 years depending on the country.

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<tr>
<td>België/Belgique/ Belgien</td>
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<td>Fachärztliche Anerkennung [1976]</td>
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France

1. Certificat d'études spéciales de médecine [1976]
2. Attestation de médecin spécialiste qualifié
3. Certificat d'études spéciales de médecine
4. Diplôme d'études spécialisées ou spécialisation complémentaire qualifiante de médecine

Ireland

Certificate of Specialist doctor [1976]

Italia

Diploma di medico specialista [1976]

Κύπρος

Πιστοποιητικό Αναγνώρισης Ειδικότητας [2004]

Latvija

"Sertifikāts"—kompetentu iestāžu izsniegs dokuments, kas apliecinā, ka persona ir nokārtojusi sertifikācijas eksāmenu specialitātē [2004]

Lietuva

Rezidentūros pažymėjimas, nurodantis suteiktą gydymo specialisto profesinę kvalifikaciją [2004]

Luxembourg

Certificat de médecin spécialiste [1976]

Magyarország

Szakorvosi bizonyítvány [2004]

Malta

Čertifikat tu Specjalista Mediku [2004]

Nederland

Bewijs van inschrijving in een Specialistenregister [1976]

Österreich

Facharztdiplom [1994]

Polska

Dyplom uzyskania tytułu specjalisty [2004]

Portugal

1. Grau de assistente [1986]
2. Titulo de especialista

Slovenija

Potrdilo o opravljenem specialističnem izpitu [2004]

Slovensko

Diplom o špecializácii [2004]

Suomi/ Finland

Erikoislääkärin tutkinto/Specialläkarexamen [1994]

Sverige

Bevis om specialkompetens som läkare, utfärdat av Socialstyrelsen [1994]

United Kingdom

Certificate of Completion of specialist training [1976]

However, despite all the efforts in the EU to harmonise education and qualification standards in medicine, such as the Professional Qualifications Directive 2005/36/EC with the aim of facilitating the application of Directive 2006/123/EC on Freedom of Services in the Internal Market in order to facilitate freedom of establishment for providers in other Member States and the freedom of provision of services between Member States, there is still a rather unsatisfactory situation where educational standards and qualifications in Baromedicine are concerned. While some EU countries such as France, Italy and Malta recognise Hyperbaric medicine as a specialty or a sub-specialty, the authorities of others such as Germany and the UK have not accepted to set up a specialty board.
even though there are well established diving and hyperbaric medical societies that have offered structured post
graduate training and accreditation in the field for many years.

Since its first Consensus Conference on Hyperbaric Medicine held in Lille, France in 1994, The European
Committee for Hyperbaric Medicine has lead the discussion on the pan-European standardisation of training,
accreditation and qualification in Baromedicine and following the process described above, issued its guidelines
on training standards in diving and hyperbaric medicine in 2004 and in 2005 published this as a document
prepared by the Joint subcommittee of the ECHM and the EDTC.

This document recognised four levels of postgraduate training and qualification in Baromedicine:

Level I - The Medical Examiner of Divers, who after following the required course will be competent 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. This course is not sufficient training for physicians at a
hyperbaric facility.

The course syllabus must include sufficient teaching in hyperbaric physics, diving related physiology, hyperbaric
pathophysiology, hyperbaric pathophysiology, acute dysbaric disorders, chronic dysbaric disorders, O2
intoxication, inert gas-effects, medication under pressure, non-dysbaric diving pathologies, causes of diving
fatalities, diving systems and procedures, types of diving and other pressure exposures, diving equipment and
tools, diving tables and computers, regulations and standards for diving, safety planning and dive
management/monitoring, assessment and first aid in diving accidents, diving accident differential diagnosis.
Training must produce full knowledge and competence in fitness to dive criteria and contraindications, fitness to
dive assessment and fitness to dive standards and regulations

Level IIa - The Diving Medicine Physician, who after following the required course will be competent to
perform the initial and all other assessments of working and recreational divers or compressed air workers as
well as manage diving accidents and advise diving contractors and others on diving medicine and physiology (if
necessary supported by a Level III hyperbaric expert or consultant). This individual should be already an
accredited specialist in an appropriate field such as intensive care, anaesthesia, occupational medicine, surgery,
internal medicine, family practice etc and should have knowledge in relevant aspects of occupational health even
if he/she does not need to be certified specialist in occupational medicine to be in accordance with this standard.

The course syllabus must include sufficient teaching in the same topics of the level I course but in much higher
detail as well as in basic effects of hyperbaric oxygen, diving accident clinical management, rehabilitation of
disabled divers, treatment chamber types and techniques, mandatory indications for HBOT, methods of data
collection and evaluation, general basic hyperbaric nursing care, diagnostic, monitoring and therapeutic devices
in treatment chambers, risk assessment, incident monitoring and safety plans for treatment chambers, safety
regulations, research standards, paramedic training, management and organisation of a hyperbaric treatment
facility.

Besides the formal course training which should include some 200 hours of formal training over a period of at
least a year, in order to be eligible for specialist status in the EU, a specialist ‘in training’ must also undergo an
internship equivalent to 4 full time years (including the one year of formal training)

Level IIb - The Hyperbaric Oxygen Physician, who after following the required course will be competent to
assess and manage clinical patients requiring and undergoing HBO treatment and be responsible for HBO
sessions at the treatment facility (with the support of a Level III hyperbaric expert or consultant if required) This
individual should be already an accredited specialist in an appropriate field such as intensive care, anaesthesia, occupational medicine, surgery, internal medicine, family practice etc and should have appropriate experience in anaesthesia and intensive care in order to properly manage the HBO patients during their treatment even if he/she does not need to be certified specialist in anaesthesia to be in accordance with the standards.

The course syllabus must again include sufficient teaching in the same topics of the Level I course except for non-dysbaric diving pathologies, causes of diving fatalities, diving systems and procedures, regulations and standards for diving, safety planning and dive management/monitoring, but in much higher detail as well as in basic effects of hyperbaric oxygen, diving accident clinical management, rehabilitation of disabled divers, treatment chamber types and techniques, mandatory indications for HBOT, recommended indications for HBOT, experimental and anecdotal indications for HBOT, methods of data collection and evaluation, general basic hyperbaric nursing care, diagnostic, monitoring and therapeutic devices in treatment chambers, risk assessment, incident monitoring and safety plans for treatment chambers, safety regulations, research standards, paramedic training, management and organisation of a hyperbaric treatment facility.

Similarly to Level Ia, besides the formal course training which should include some 200 hours of formal training over a period of at least a year, in order to be eligible for specialist status in the EU, a specialist ‘in training’ must also undergo an internship equivalent to 4 full time years (including the one year of formal training)

It is also possible for an individual to qualify to level II in both Diving Medicine as well as Hyperbaric Medicine by completing all the subjects in both IIa and IIb. This doctor will be designated as a Level IIa+b and following the completion of the 4 year internship become eligible for accreditation as a specialist in Baromedicine (both Diving and Hyperbaric Medicine) Since Hyperbaric treatment facilities in Europe practically invariably treat both diving illness and patients requiring HBOT, with the exception of purely military chambers who continue to have their system of ‘in-house’ training for their chamber physicians, this qualification is, in the opinion of the author the minimum level required for the initial training of Baromedicine Physicians.

Level III - The Hyperbaric Expert or Consultant (hyperbaric and diving medicine) who after following the required course leading to a Level IIa+b, acquired Specialist status after the required internship and gained peer recognised expert knowledge and experience in all areas of the specialty, will be considered competent to act as the head of a hyperbaric facility and to manage the medical and physiological aspects of complex diving activities. He/she would also be competent to manage research programs, supervise a team of doctors, hyperbaric nurses and paramedics and teach all relevant aspects of hyperbaric medicine and physiology to all members of staff.

The Methods and Materials for Training

The teaching methods of the past were either formalised classroom training in a medical school or other teaching institution lecture room or informal tutorials at the chamber facilities themselves and the materials used were usually overheads or slides supplemented with either lecture handouts or the student’s own hand written notes. Very few textbooks were available in a universal language such as English and those that existed were from the USA. These materials were very infrequently updated because of the cost and effort involved in remaking them from scratch.
Things have much improved nowadays with the practically universal use of PowerPoint presentations with embedded video files permitting the easy updating of materials with the latest knowledge and concepts. Where textbooks are concerned, the situation has improved with the publication in 1996 by Oriani, Marroni and Wattel of their multi-author ‘Handbook on Hyperbaric Medicine’ which was revised and updated in 2006 by Mathieu, again as a multi-author textbook. The publication of the ECHM collections Volume I, II and III in published in 2005, 2005 and 2008 respectively again added significant multi-author treatises on multiple subjects of relevance to the student of Baromedicine. For the more advanced scholar of diving and hyperbaric medicine, there are the proceedings of the annual scientific congresses of the UHMS, EUBS, SPUMS and ICHM as well as the translated abstracts from national and international scientific journals found on dedicated medical web databases such as Medline.

What is still lacking in the European context, is an entry to mid level textbook similar to the ‘Lecture Notes’ medical series published by Oxford University Press which provides the doctor in training with an up to date but condensed version of the current knowledge in Baromedicine as a supplement for his/her personal lecture notes when preparing for qualifying examinations.

The venue

The traditional venue of medical training is the university and to date this is still the most accepted institution of certification of medical expertise, especially at entry level, but less frequently at specialist level where, although training will occur at a teaching hospital, the examinations and accreditation will be under the direction and control of discrete specialist accreditation institutions and colleges.

In Diving and Hyperbaric medicine, the practical part of the training and the gaining of experience through internship have always naturally occurred at a hyperbaric facility. However the theoretical training often required the candidate to travel away from their workplace to attend one or more short modules that have no continuity between them except in those few areas in Europe where a holistic complete university based course was offered such as those offered in Spain, France, Italy and Serbia.

A more recent development is the availability of on-line distance learning courses such as the one pioneered by the University of Stellenbosh who offers a BScMedScHons (Underwater Medicine) and a The BScMedScHons (Hyperbaric Medicine) degree programmes, both structured on the European Committee on Hyperbaric Medicine(ECHM)/Diving Medical Advisory Committee (DMAC)/ European Diving Technology Committee (EDTC) model that can be read over a 2-year period for part-time students and over a 1-year period for full-time students. Successful completion permits the candidate to register Diving medicine and/or Hyperbaric medicine with the Health Professions Council of South Africa (HPCSA) as an additional qualification. The course consists of different modules of theoretical on-line instruction that can be followed separately and the practical training (where applicable) at present takes place in Cape Town or Durban, depending on the availability of instructors and practical training facilities at the time but the University is in the process of reaching agreements with a number of institutions around the world which would be accredited in the coming years to carry out/supervise the practical training thus permitting the contact time, and thus the whole course, to become decentralized at a later stage.
Minimum training for Hyperbaric Physicians

Following the creation and publication of the ECHM/EDTC Educational and Training Standards, the European College of Baromedicine, the executive arm of the ECHM, has approved a number of courses, including a few of Level II standard, based on the modules described in that document. One such course format consists of 66 classroom teaching sessions with the following lecture titles:

- 00 - Introduction to Baromedicine
- 01 - Physics of Pressure Medicine I
- 02 - Physics of Pressure Medicine II
- 03 - Pressure related human physiology
- 04 - Oxygen as a Drug
- 05 - Inert Gas Narcosis & HPNS
- 06 - Hyperbaric Pathophysiology I
- 07 - Hyperbaric Pathophysiology II
- 08 - Signs and symptoms of Decompression Illness
- 09 - DCI Emergency Triage and First Aid
- 10 - DCI Clinical Triage Algorithm & Case Management
- 11 - Examination of injured diver
- 12 - Differential Diagnosis of DCI
- 13 - Diving Procedures and Practices
- 14 - Diving Gear in recreational and commercial diving
- 15 - Diving and Treatment chambers
- 16 - Chronic Dysbaric Disorders
- 17 - Ear problems in diving
- 18 - Carbon Dioxide
- 19 - DCI Treatment Tables
- 20 - Management of DCI
- 21 - Recompression treatment
- 22 - Rehabilitation of the injured/disabled diver
- 23 - Diving related Fatalities & Investigation
- 24 - Drowning & hypothermia
- 25 - DCI Treatment – European standards
- 26 - Decompression theory
- 27 - Decompression tables & Computers
- 28 - Medication under pressure
- 29 - Fitness to dive criteria
- 30 - Diving regulation and planning
- 31 - FTD assessments
- 32 - FTD investigations
- 33 - Marine life injuries
- 34 - Introduction to Hyperbaric Oxygen Therapy
- 35 – Management of a Hyperbaric Facility
- 36 - HBO Protocols
- 37 - Carbon monoxide poisoning
- 38 - Gas Gangrene and necrotising infections
- 39 - Diabetic foot
- 40 - Radiation induced lesions
- 41 - Chronic Osteomyelitis
- 42 - Crush injuries
- 43 - Flaps and Grafts
- 44 - HBO in other approved conditions
- 43 - ECHM indications
- 46 - HBO in Stroke
- 47 - Selection of patients for HBO
- 48 - Oxygen Toxicity
- 49 - HBO nursing
- 50 - Medical Devices
- 51 - Practical considerations
- 52 - Critical care in Hyperbaric conditions
- 53 - Critical care in Europe
The above course includes all the topics considered essential for level IIa+b and others that the author and his co-course director believe add knowledge and skill sets necessary for Baromedicine physicians who aspire to reach Specialist status and be responsible for a Hyperbaric facility and later even reach Expert status. It includes a variable number of hours of practical training at the host training facility as well as remote supervision of continued internship at the candidate’s workplace. The duration of this course ranges from an intensive 3 weeks to one/two university semester/s to 2 years part time depending on the scope of the course.

The Trainer/Educator of Hyperbaric Physicians

The trainer and educator in Baromedicine should be a doctor who has reached at least specialist status or preferably Consultant/Expert Level III status. This individual will not only be responsible for the formal teaching of Baromedicine but also the supervision and mentoring of trainee Baromedicine physicians during their formative journey in Baromedicine practice. The concept of Trainer/Educator of Hyperbaric Physicians is to be regarded as a direct derivative of the educational theory of apprenticeship. This theory assumes that doctors should be trained and can be trained by experienced colleagues and can themselves, once sufficiently qualified and experienced, eventually train others. This leads to the pragmatic objective of this concept – what skills and qualities should a trainer possess in order to train effectively and subsequently how to assess this teaching ability.

In order to succeed, all trainers must develop and share a special one to one relationship with their trainee in order to provide the latter with the motivation, support, guidance, teaching and discipline needed to reach the required target, that is a full formed Baromedicine physician who has developed critical thinking, decision making abilities and knowledge application as well as the integration of essential knowledge from the required disciplines and thus be able to handle any clinical and management situation required of him/her.

The many characteristics and essential qualities of a medical trainer must include a passion for teaching, be clear and organised, accessible, supportive, compassionate, able to establish a rapport, provide direction and feedback, exhibit integrity and respect for others and obviously demonstrate clinical competence. He/she should also be able to utilise planning and orienting strategies, possess a broad repertoire of teaching methods, draw on multiple forms of knowledge and target his/her teaching to the level of the trainees.

The attributes of a Baromedicine Trainer/Educator can be summarised into 3 domains:

1) The ‘wise’ person (personal attributes)
a) Knowledge: self-awareness, knowledge of human nature

b) Skills: reflection, sharp observer, self-control, stress management, time management, resourcefulness.

c) Attitudes: integrity, honesty, patience, humility, openness to feedback, respect, empathy, diligence, availability, takes care of own health, practices lifelong learning.

2) Accomplished Baromedicine practitioner (professional attributes)

a) Knowledge: extensive up to date knowledge base, clinical experience

b) Skills: expertise in diagnosing and managing all diving related pathologies and all acute and chronic conditions that can benefit from HBOT. Proficient in health promotion, disease prevention and screening, leadership, management skills, skilled use of information technology, teamwork.

c) Attitudes: enthusiasm for Baromedicine, holistic approach, interdisciplinary, professional ethics, patient-centeredness, evidence-based approach, community orientation, continuous professional development.

3) Gifted teacher (teaching attributes)

a) Knowledge: knowledge about teaching and teaching methodologies.

b) Skills: making an educational diagnosis, able to plan and tailor teaching, listening and communication, giving feedback, constructive criticism, conflict management, counselling, assessment skills.

c) Attitudes: passion for teaching, motivator, holistic educational approach, ethical teaching, trainee-centeredness, safely challenging, supportive, continuous/updating training in teaching.

Hence the Baromedicine Trainer/Educator is a wise person, an accomplished Baromedical Specialist/Expert and a gifted teacher all rolled into one and naturally, there is a fair degree of overlap between these three facets of the trainer.

References


(08) **CME of Physicians working at the Hyperbaric Centres**

Wilhelm Welslau

Past President Gesellschaft für Tauch- und Überdruckmedizin e.V. (GTÜM)

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**Information Basis**

The publications listed below are result of a hand search. All publications were found on the websites of national and international societies and working groups. Search was restricted to websites in English and German language with German texts translated into English. This search does not claim to be complete, even though it gives a good overview over different possible approaches to CME of physicians working in hyperbaric centres.

**European Union of Medical Specialists / Union Européenne des Médecins Spécialistes (UEMS)**

- Ref. 1 - Charter on Training of Medical Specialists in the European Community (1994)  
  www.uems.net/fileadmin/user_upload/uems_documents/old_website_documents_admin/906.pdf

- Ref. 2 - Criteria for international accreditation of CME (2007)  

**ECHM & COST B14 publications**

- Ref. 3 - Educational and training standards for the staff of hyperbaric medical centres – European Committee for Hyperbaric Medicine (ECHM, 1997) (www.echm.org, download 10th Jul. 2012)

- Ref. 4 - A European code of good practice for hyperbaric oxygen therapy - COST B14 working group safety, WGS-S103 V. 11, 20th Sep. 2004 (www.echm.org, download 10th Jul. 2012)


**International & national Hyperbaric Medicine Societies’ online publications**

- Ref. 7 - The training and education of hyperbaric unit personnel - report of a working party of the British Hyperbaric Association (BHA, 1999) (www.hyperbaric.org.uk, download 10th Jul. 2012)
Ref. 8 - Post graduate education regulations for diving and hyperbaric physicians’ qualifications - German Diving and Hyperbaric Medical Society [Weiterbildungsordnung der GTÜM e.V. für tauch- & hyperbarmedizinische Qualifikationen für Ärzte] (GTÜM, 1st Jan. 2011) (www.gtuem.org, download 10th Jul. 2012)


Ref. 12 - Programme of competency in diving medicine - Swiss Undersea and Hyperbaric Medical Society (SUHMS) (www.suhms.org, download 10th Jul. 2012)


**German employer's liability insurance association [Berufsgenossenschaften]**


### Relevant Content of publications listed above

At first we will have a short look to European publications to CME in general. After this we look for CME statements in ECHM publications and papers co-authored by ECHM. We go on with relevant statements on websites of different hyperbaric medical societies (BHA (UK), GTÜM (Germany), ÖGTH (Austria), SAUHMA (South Africa), SPUMS (Australia/New Zealand), SUHMS (Switzerland), and UHMS (USA). The last publication shown here is issued by German employer’s liability insurance association.

**Ref. 1 - Charter on Training of Medical Specialists in the European Community (1994)**

The Treaty of Rome provides for the free exchange of persons, services, goods, and capital within the European Community. Free exchange of persons and services within the medical sector has been achieved by mutual recognition of basic and specialist medical qualifications brought into effect by the Commission of the European Communities (EC) in 1975. The Directives have been consolidated in the Directive 93/16/EEC of 5 April 1993.

*Comment*
Established in 1958, the Union Européenne des Médecins Spécialistes / European Union of Medical Specialists (UEMS) is the representative organisation for specialist doctors from the national associations of EU/EEA countries. Its activities cover all issues associated with specialised medical practice, and are jointly carried out by doctors serving as representatives on its Management Council and on its more than thirty Specialist Sections and Boards. The UEMS recognises and values differences in the structure, funding and priorities of healthcare systems in Europe.

Ref. 2 - Criteria for international accreditation of CME (2007)

Quality of international CME: D 9908 / Rev 2007

Quality assurance of Continuing Medical Education (CME) in the European countries is the responsibility of the National Accreditation Authorities, considering European consensus on quality assurance requirements laid down in the UEMS CME Charter with its Annexes and the guidelines implicit in the data to be submitted. The quality and effectiveness of the accreditation process and of the awarding of international CME credits will be granted at the European level by the European Accreditation Council for CME. The EACCME will liaise with the appropriate UEMS Section for the evaluation of events.

Comment

From the ancient times of Hippocrates, doctors have promised to keep up-to-date their knowledge and skills. The importance of Continuing Medical Education (CME) and Continuing Professional Development (CPD) is self-evident to doctors.

As progress in medicine becomes ever faster, the necessity to up-date ones knowledge is even greater. It has been estimated that about half of all medical knowledge is out of date within five years. It was the great Greek philosopher Socrates who stated: “If you think that education is expensive, you should consider ignorance.”

CME-CPD actually starts from the first day of medical school. However, the longest time in a doctor’s career is the time following specialization. The actual importance of CME-CPD is most relevant during this period which may be 30 years long.

The objectives of UEMS include the promotion of quality patient care through the harmonisation and improvement in the quality of specialists’ medical care throughout the European Union and the encouragement and facilitation of CME for European specialists. UEMS has been very active in the field of CME-CPD. The key message is that CME-CPD is a moral and ethical obligation to doctors.

The medical directives of the EU followed by the directive on professional qualifications have mainly been concerned with basic medical education and postgraduate training. The EU has not demanded any mandatory
system of CME-CPD at European level in spite of the fact that many individual Member States have created obligatory systems.

A major concern of the UEMS has been the structure and facilitation of accreditation of CME-CPD activities with the awarding of appropriate credits (hours) to individual medical specialists throughout Europe. The UEMS established the European Accreditation Council for CME (EACCME®) in order to give Europe a co-ordinated system to facilitate such activity, without encroaching on the responsibility of national organisations where they exist.

Ref. 3 - European Committee for Hyperbaric Medicine (ECHM)

Educational and training standards for the staff of hyperbaric medical centres (1997)

Continuous Medical Education (Quality Control and Competency)

- Medical Director of Hyperbaric Centre

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.

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.

- 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 at least 10 working days in a HBO facility and attendance at two congresses in two years.

Comment

For medical directors of HBO centres ECHM & EDTC in 1997 did not define CME requirements in detail. For Job IIb (= physicians working at HBO centres) CME requirement is defined as “attendance at one national and/or international congress on hyperbaric medicine per year”.

INTERNAL USE ONLY – Not for redistribution
Ref. 4 - COST B14 working group safety - A European code of good practice for hyperbaric oxygen therapy (WGS-S103 V. 11, 20th Sep. 2004)

Competencies and education

- Competencies and education of hyperbaric personnel should follow the standards presented in the ECHM/EDTC document. 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.

Comment

COST B14 Working Group Safety recommended CME for all staff working at HBO centres. CME requirements were not defined in detail, for this was not the main target of this working group.

Ref. 5 - European Committee for Hyperbaric Medicine (ECHM)

COST B14 Standards of education in diving and hyperbaric medicine

(consensus, 1st Dec. 2004)

IIb „Competence in Hyperbaric Medicine“

Continuous education (renewal every 3 years)

- attendance at 3 congresses, conferences or workshops of UHMS, EUBS or ECHM during the last 3 years, alternative events require approval,
- Current certification in advanced life support and defibrillation
- work during the last 3 years or
- successful completion of a 80h hospitation as physician in an approved hyperbaric center

Comment

COST B14 ‘Standards of education’ of 2004 were adopted by ECHM Consensus Conference 2004 in Lille. CME requirement was clearly defined for level IIb (= physicians working at HBO centres): a) attendance at 3 congresses, conferences or workshops within 3 years, b) current certification in advanced life support and defibrillation, c) recent practice as physician at a HBO centre. Were a) is identical to ECHM/EDTC demands of 1997, b) and c) were new demands.
Level 2H „Hyperbaric Medicine Physician“

Renewal at least every 5 years

- Continuing experience in the field of HBO therapy and scientific update by participation in a refresher course, congress or literature studies.
- Reactivation after laps should be on the basis of specifically approved course.
- (See Appendix 6 for details)

Appendix 6. CME Requirements for Level 2H

- Renewal at least every 5 years
- Attendance at at least 5 congresses, conferences or workshops of ECHM, EUBS, SPUMS or UHMS during the last 5 years (alternative events require approval)
- Current certification in advanced life support and defibrillation
- Full time work (or the equivalent number of hours part time) during the last 5 years
- or
- successful completion of a 80h hospitation as physician in an approved hyperbaric centre

Level 3 „Expert in Hyperbaric Medicine“

- Renewal at least every 3 years.
- Proof of continuous clinical, teaching or research activity in his expertise field
- At least 3 events from the following list in the last 3 years:
  - Participation in the international congresses, conferences, workshops or other scientific meetings organized in cooperation with or approved by of the ECHM, EUBS, ICHM, SPUMS, UHMS. Seminars and meetings organised by other scientific bodies or academic institution may be considered by the ECB.
  - Giving lectures on level 2D or 2H courses accredited by the ECB.
  - Being co-author of at least one publication in a peer reviewed journal or a chapter in published books.
  - Other activity in the field of diving or hyperbaric medicine. This includes for example active participation in the international bodies, leadership or active participation in international projects, leadership of hyperbaric centre.
Comment

In ECHM/EDTC ‘education and training standards’ of 2011 CME requirement is clearly defined for level 2H (former level IIb) in appendix 6 of this publication: a) attendance at 5 congresses, conferences or workshops within 5 years, b) current certification in advanced life support and defibrillation, c) recent practice as physician at a HBO centre. The only difference to COST B14 demands of 2004 is the reduced recertification frequency of 5 years instead of 3 years.

Unfortunately the main text mentions a few points that are not defined further in its ‘appendix 6’: it remains unclear what is meant by ‘refresher course’ or ‘literature studies’ with respect to CME, also definition of ‘specifically approved courses’ for ‘reactivation after laps’ remains undefined.

Ref. 7 - British Hyperbaric Association (BHA) - Training and education of hyperbaric unit personnel - report of a working party of BHA (1999)

9. Team roles of staff

Comment

British BHA does not define CME requirements in detail in this publication but uses the expression ‘continuing professional development’ (CPD) instead of CME. For differences in definition between CME and CPD see comment to Ref. 2.
Ref. 8 - German Diving and Hyperbaric Medical Society (GTÜM)

Post graduate education regulations for diving and hyperbaric medicine physicians’ qualifications [Weiterbildungsordnung der GTÜM für tauch- & hyperbarmedizinische Qualifikationen für Ärzte] (1st Jan. 2011)

Diploma IIb 'Hyperbaric Medicine Physician' 
[Druckkammerarzt'-Diplom]

- Valid 5 years after finishing GTÜM approved course IIb
- Renewal for another 5 years after:
  - Proof of attendance at 2 acknowledged congresses / conferences during last 5 years
  - Proof of work as physician at GTÜM acknowledged hyperbaric centres during last 5 years

or

- Proof of 80 hrs work shadowing as physician at GTÜM acknowledged hyperbaric centre
- Application for renewal after expiration of diploma requires new GTÜM approved course IIb instead of 2 acknowledged congresses / conferences during last 5 years

Diploma III ‘Diving & Hyperbaric Medicine Consultant’

[Diplom ‘Tauch- & Hyperbarmedizin’]

- Valid 5 years
- Renewal for another 5 years after:
  - Proof of attendance at 3 acknowledged congresses / conferences during last 5 years
  - Application for renewal after expiration of diploma will be scrutinized like a first application

Comment

German GTÜM education regulations tried to interpret ECHM recommendations during last years and adopt them to the situation in Germany. In its current version GTÜM defines CME requirement for level IIb (equivalent to level ECHM 2H): a) attendance at 2 acknowledged congresses or conferences within 5 years, and b) recent practice as physician at a HBO centre. For level III GTÜM demands: attendance at 3 acknowledged congresses or conferences within 5 years. Frequency of recertification was changed from 3 years to 5 years in 2011, because most other medical qualifications in Germany require a 5 year recertification as well. Right now
GTÜM is discussing an update of its education regulations in consideration of 2011 ECHM/EDTC recommendations.

Ref. 9 - Austrian Society for Diving and Hyperbaric Medicine (ÖGTH)
Post graduate education regulations for diving and hyperbaric medicine physicians’ qualifications [Weiterbildungsordnung der ÖGTH für tauch- & hyperbarmedizinische Qualifikationen für Ärzte] (1st Jan. 2010)

Diploma IIb ‘Hyperbaric Medicine Physician’ [Druckkammerarzt’-Diplom]

- Valid 3 years
- Renewal for another 3 years after:
  - Proof of attendance at 2 acknowledged congresses / conferences during last 3 years
  - Proof of work as physician at ÖGTH acknowledged hyperbaric centres during last 3 years

or

proof of 80 hrs work shadowing as physician at ÖGTH acknowledged hyperbaric centre during last 12 months

- Application for renewal is possible within 12 months after expiration of diploma; a later renewal is not possible. New period of validity will start at last expiry date of diploma.

Diploma III ‘Diving & Hyperbaric Medicine Consultant’ [Diplom ‘Tauch- & Hyperbarmedizin’]

- Valid 3 years
- Renewal for another 3 years after:
  - Proof of attendance at 3 acknowledged congresses / conferences during last 3 years
  - Application for renewal is possible within 12 months after expiration of diploma; a later renewal is not possible. New period of validity will start at last expiry date of diploma.

Comment

Austrian ÖGTH education regulations tried to interpret ECHM recommendations during last years and adopt them to the situation in Austria. In its current version ÖGTH defines CME requirement for level IIb (equivalent to level ECHM 2H): a) attendance at 2 acknowledged congresses or conferences within 3 years, and b) recent practice as physician at a HBO centre. For level III ÖGTH demands: a) attendance at 3 acknowledged congresses or conferences within 3 years.
Ref. 10 - Southern African Underwater and Hyperbaric Medical Association (SAUHMA), Policy on accreditation of hyperbaric treatment facilities

SAUHMA Policy on Accreditation of Hyperbaric Treatment Facilities

In line with international practices, SAUHMA has put in place a hyperbaric chamber accreditation policy that seeks to ensure the achievement of the following goals:

- All facilities are adequately staffed with appropriately-trained staff members
- The Certificate is valid for a period of 4 (four) years from the date of issue, where-after the facility shall require an updated assessment prior to a new certificate being issued. The nature and extent of this updated assessment is dependent on the actual status of the facility.

Comment

South African SAUHMA certification standards for HBO centres demand centre recertification every 4 years. Recertification demands centres to be ‘adequately staffed’ and staff members to be ‘appropriately-trained’. CME requirements are not defined.

Ref. 11 - South Pacific Underwater Medicine Society (SAUHMA) - Diploma of Diving and Hyperbaric Medicine ‘Requirements for Candidates’ (updated October 2008)

No specific information about CME requirements

Comment

South African SAUHMA certification standards for Diving and Hyperbaric Medicine do not contain information about CME requirements.
Ref. 12 - Swiss Undersea and Hyperbaric Medical Society (SUHMS)

Programme of competency in diving medicine [Fähigkeitsausweis ‘Tauchmedizin’]

- Hyperbaric Medicine NOT covered
- Renewal at least every 5 years
- Proof of continuous practical experience in the field of professional diving, e.g. as diving medical consultant of a professional diving company or equivalent activity
- Attention at least at 1 training course or national or international specific congress. SUHMS working group „education“ is responsible for acknowledgement of events.
- Renewal after longer discontinuity is possible after attendance at a course assigned by SUHMS. In case there is no such course, the candidate can put together an alternative education and training programme, which has to be acknowledged by SUHMS working group "education".

Comment

Swiss SUHMS provides certification standards for Diving Medicine but not for HBO therapy. Renewal of diving medicine diploma is possible with: a) attendance at 1 ‘training course’ (not further defined) or national/international diving medicine congress within 5 years, and b) continuous practice as professional diving physician.
Ref. 13 - Undersea and Hyperbaric Medical Society (UHMS) - Clinical Hyperbaric Facility Accreditation Manual - (Revision 1, 2005)

**HYPERBARIC MEDICAL STAFF**

- The Hyperbaric Medicine Director is certified by an appropriate specialty board, or affirmatively establishes comparable competence, through the credentialing process.
- All hyperbaric medical staff personnel participate in continuing education related to the practice of hyperbaric medicine.
- Participation in continuing education activities by hyperbaric medical staff is documented.

**Comment**

US American UHMS certification standards for HBO centres demand all hyperbaric centre staff to ‘participate in continuing education’. CME requirements are not defined in detail.
Ref. 14 - German employer’s liability insurance association [Berufsgenossenschaften] ‘Working safely with therapeutic hyperbaric chambers’ [Sicheres Arbeiten mit therapeutischen Druckkammern]

(BGI 5120, April 2007)

Number and Qualification of appointed Personnel

Organisational structures have to fulfil recommendations of §2 of Regulation for Operators of Medical Devices (German regulation ‘Medizinprodukte-Betreiberverordnung’, inferior to Medical Devices Directive, MDD). According to this therapeutic hyperbaric chambers may be operated only by persons who have completed all necessary courses or have the necessary knowledge and experience (§§ 2 and 5 par. 2 of Regulation for Operators of Medical Devices). Finally it has to be considered that personnel might have to be compressed in the chamber for intensive nursing of patients or in emergency situations. Protection of patients and employers’ obligation to take care for employees determine criteria for number and qualification of personnel. (German) Regulation for Work in Hyperbaric Environments [Druckluftverordnung] gives hints, which should be followed also for operation of therapeutic hyperbaric chambers.

... The Medical Director is responsible for the entire safety engineering, operation, and organisation of the hyperbaric chamber. Therefore he needs knowledge about chamber operation and assessment of safety condition of the hyperbaric system according to manufacturer’s informations, and actual legislative regulations (e.g. technical checklists, occupational-medical health examinations, and regular instructions of personnel.

A Hyperbaric Physician … has to have proof of knowledge about chamber operation.

... Regarding teaching of specific knowledge in diving and hyperbaric medicine for the whole personnel working at a hyperbaric chamber it is referred to professional associations for diving and hyperbaric medicine.

... Comment

German employer’s liability insurance association normally addresses safety of work for employees. In their standards for ‘working safely with therapeutic hyperbaric chambers’ they address a) taking care for employees and b) protection of patients. One important basis of these standards is European MDD (Medical devices Directive), which is national law in all EU member countries. Germany incepted a ‘Regulation for Operators of Medical Devices’ as a national regulation inferior to MDD. ‘Working safely with therapeutic hyperbaric chambers’ is a specific publication in this respect.
Interestingly not only diving and hyperbaric medicine qualification is demanded for HBO physicians but also a qualification as chamber operator. It is argued that being responsible for HBO treatment (according to MDD) needs knowledge about the entire system with regard to safety.

Regarding qualification (and CME) of hyperbaric personnel the publication refers to education standards of national professional associations for diving and hyperbaric medicine (for German physicians: GTÜM).

**Summary**

Until now the European Union (EU) has not demanded any mandatory system of CME or CPD (Continuous Professional Development) at European level in spite of the fact that many individual Member States have created obligatory systems. The ‘European Union of Medical Specialists’ (UEMS) established the ‘European Accreditation Council for CME’ (EACCME) to get to European harmonized CME standards. Up to now CME remains under responsibility of national medical societies and official bodies.

Regarding CME for Hyperbaric Physicians the identified online publications can be separated into two groups: a) Educational standards for hyperbaric medicine diplomas, b) Certification standards for therapeutic hyperbaric centres. None of the screened HBO centre certifications standards provide any details about CME for hyperbaric doctors.

The different national and international educational standards for hyperbaric medicine diplomas vary in their recommendations for CME of physicians working at HBO centres.

ECHM 1997: level 2H
- 1 national or international congress per year

SUHMS 2004: level 2D
- 1 training course or national/international congress within 5 years
- continuous practice as professional diving physician.

ECHM 2004: level 2H
- 3 congresses, conferences or workshops within 3 years
- current certification in advanced life support and defibrillation
- work in hyperbaric centre during last 3 years
or 80h work shadowing in hyperbaric centre

ÖGTH 2010: level 2H
- 2 congresses or conferences within 3 years
- work in hyperbaric centre during last 3 years
or 80h work shadowing at hyperbaric centre during last 12 months
level 3
- 3 acknowledged congresses or conferences within 3 years
GTÜM 2011: level 2H
- 2 congresses or conferences within 5 years
- work at hyperbaric centre during last 5 years
  or 80h work shadowing at hyperbaric centre
level 3
- 3 congresses or conferences within 5 years

ECHM 2011: level 2H
- 5 congresses, conferences or workshops within 5 years
- current certification in advanced life support and defibrillation
- work at hyperbaric centre during the last 5 years
  or 80h work shadowing in hyperbaric centre
level 3
- Renewal at least every 3 years.
- Proof of continuous clinical, teaching or research activity in his expertise field
- At least 3 events from the following list in the last 3 years:
  -- Participation in the international congresses, conferences, workshops or other
    scientific meetings organized in cooperation with or approved by of the ECHM,
    EUBS, ICHM, SPUMS, UHMS.
  -- Seminars and meetings organised by other scientific bodies or academic institution
    may be considered by the ECB.
  -- Giving lectures on level 2D or 2H courses accredited by the ECB.
  -- Being co-author of at least one publication in a peer reviewed journal or a chapter
    in published books.
  -- Other activity in the field of diving or hyperbaric medicine. This includes for
    example active participation in the international bodies, leadership or active
    participation in international projects, leadership of hyperbaric centre.
References


(09) Training of the nurses, operators, technicians and attendants in the Hyperbaric Centre

Peter Atkey (UK)

Introduction

The aim of this paper is to explore some of the origins of training as appropriate to hyperbaric staff; it should be said that although I have traced the origins of some current systems this is by no means the full story. Training and standards have been the subject of much debate for a considerable period of time; in production of this paper I have had to choose to focus on some significant steps but will not have had time or space to mention all of the people and strategies that will have contributed to the formation of our current systems and certainly given time and space would deserve credit for advances made.

Why train staff?

Training is of course an overhead for any organisation and can become extremely expensive and indeed unpopular at all levels of the organisation, so why do we need to conduct training and what are the goals?

Management have responsibility for all staff, patients, public and any other persons that could be affected by actions of the organisation as well as being responsible for protecting the environment.

As part of good management practice, risk assessment must be undertaken for all parts of the organisation, education requirements for staff will form a key part of the considered risk control measures; therefore fundamental risk management of the organisation must include consideration of educational requirements for all staff.

There exists a duty to ensure that all staff are given sufficient training to ensure they properly understand their duties and the consequences of ‘getting it wrong’. No staff member should be put in a situation of their being unsure of the appropriate course of action for all foreseeable eventualities especially where safety could be put at risk by choosing an inappropriate course of action. There are of course consequences to overdoing it as far as training is concerned. Staff can become overburdened by facts and figures, identifying which information is needed will be key, such that training delivered is concise and appropriate.

What are the consequences of getting it wrong?

1. Accidents.
2. Poor or inappropriate outcomes.
3. Low staff moral.
4. Inefficiency.
5. Ineffective procedures.
6. Increased costs.
7. Loss of confidence in the facility.
As has been said above in an ideal world staff members would be prepared for all eventualities they could possibly face during the envisaged operation. Staff members then will feel in control and at ease for the duties with which they have been tasked, on completion they will know that they have conducted the required task safely, efficiently and to required standards achieving expected outcomes.

**Why Training Matters**

Accidents and ill health associated with work lead not just too needless pain and suffering but to huge costs and loss of business continuity. By way of example 171 people were fatally injured in work-related accidents in the UK during 2010/11, over 600,000 work place injuries were reported and 1.2 million people suffered from a work-related illness leading to 26.4 million working days lost.

Ensuring safe, healthy and efficient working has to be a key priority for everyone at work and this requires real competence, not just commitment and good intentions.

All staff from the most senior manager right down to the lowliest staff member will need to be properly trained and competent not only in their own tasks but also to know where they fit in to the overall hierarchy of the organisation.

The way an organisation approaches training speaks volumes about the organisation, its values and professionalism.

**Why Invest in Training?**

- Helps your staff identify hazards and adopt safe, healthy and efficient working practices
- Helps to avoid the pain, anguish and financial costs that use of inappropriate procedures could cause
- Fosters a positive culture, in which unsafe, unhealthy and inefficient working are not tolerated
- Enables and empowers staff to spot ways to improve how the organisation approaches tasks and encourages them all to bring this to the notice of management
- Enables the organisation to meet its statutory and legal duties to protect the health and safety of employees, patients and others

Competence is more than having attended a course; experience is key too; the UK Health and Safety Executive (HSE) Approved Code of Practice (ACoP) state that it is the employer’s responsibility to ensure employment of personnel with appropriate training, certification and experience for the tasks to be undertaken. It is imperative to establish procedures ensuring that the organisation has the right people with the right knowledge and skills to manage the required tasks. Trusting to luck is just too risky.

All businesses have a legal and moral duty to provide information, training and supervision to employees in order to enable them to carry out their work safely and efficiently, this applies not just too front-line staff but also to directors, managers and those in other key roles. Of course, this costs money and time (both of which are likely to be in very short supply). But remember, there are major business benefits to be gained from training. By
cutting accidents and ill health and by helping to ensure faultless operations, appropriate training will be a major contributor to the success of any organisation.

Additionally the current world in which we all operate requires that we demonstrate to commissioners, insurance companies, statutory bodies and others that we operate to high standards; when training is conducted in a structured and repeatable manner it will provide a firm basis from which this assurance can be gained.

Training Needs Analysis

To ensure that limited resources are used appropriately there is a need to analyse requirements for all training to be employed. Consider the roles listed below. Can you be sure you are equipping key staff with the necessary skills and knowledge to play their role in ensuring operations are conducted safely and efficiently, thus preventing accidents and ill health and achieving the desired outcomes?

- Medical Directors
- Senior Managers
- Chamber Team
- Nursing Staff
- All staff including new starters (1)

How can this be achieved?

1. Use only appropriate staff – not all staff will be capable of achieving the required levels of competence. Appropriate pre-requisites for staff attending training must be identified so that only appropriate staff will be brought in to the scheme.

2. Identify required training – investigate precise requirements for the task(s) to be achieved, this will ensure all necessary subjects will be included in training and levels of required competence can be set while ensuring that inappropriate subjects are left out of the training schedules.

3. Allow sufficient time – given the above, reasonable timeframes for training can be set.

4. Competence assessment – identify appropriate methods of competence assessment, it is likely that ‘in-house’ competence assessment will be entirely appropriate and sufficient for a number of tasks but for others it will be important to identify independent competence assessment routes.

5. Certification – where appropriate identify independently accredited certification.

6. Funding – budgets for training and assessment must be established so that training schemes are sustainable.

Why not have highly qualified personnel such as physicians employed at all levels of the organisation?

While this may be a considered option there are several reasons why it would not be appropriate:
1. Job satisfaction – in order for an individual to feel ‘job satisfaction’ they need to utilise their skills at an appropriate level. If doctors were to be employed routinely to clean floors, it is unlikely that they would feel properly utilised or motivated.

2. Aptitude – skills required for the various tasks will differ, while an engineer who is extremely good when maintaining complicated equipment such as compressors, it would be unlikely they would be the right person to assess a patient prior to treatment.

3. Team spirit – in order for a team to work efficiently they will all need to appreciate each others strengths and weaknesses such that they can work together to support one another.

4. Cost – although nobody likes to bring cost into this equation we live in a world where costs have to be taken into account; highly qualified staff are normally also highly paid. In order to make best use of available funds, appropriately qualified members of staff must be employed at all levels of the organisation.

History

In our field training schemes have been evolving for a considerable period, there are currently schemes in Europe, USA, Australia and South Africa to name the more notable examples. The European scheme is the most recent addition and has benefitted from the accumulated experiences of the other schemes; this has produced a firm foundation from which to progress.

Structured training for Operators, Attendants and technicians in the USA commenced in 1981 with the formation of the National Association of Diving Medical Technicians (NADMT), in the early days this was aimed primarily at commercial divers. By the mid 80’s studies were confirming benefits of oxygen therapy for non diving applications; clinical applications grew in number resulting in treatment of DCI being overtaken by clinical applications. On 1st March 1991 NADMT created the National Board of Diving and Hyperbaric Medical Technology (NBDHMT); NBDHMT launched their scheme which was specifically aimed at personnel wishing to work with hyperbaric chambers in the clinical/medical field both inside as attendants and outside as operators. In 1985 the Baromedical Nursing Association (BNA) was created and in conjunction with NBDHMT in 1995 launched examinations aimed specifically at Nurses wishing to work in the hyperbaric field. Currently NBDHMT offer two levels of certification, Certified Hyperbaric Technologist (CHT) and Certified Hyperbaric Registered Nurse (CHRN) (2)

While this is without doubt a very good scheme there are some significant obstacles to its effective use in Europe, there are differing legislation and standards, such as the variation in colours of gas bottles etc., the American system utilises Imperial units which are of course no longer widely used in Europe and of course there are language problems as this system is only available in English.

It became clear that a dedicated European scheme would be preferable so that standards could be harmonised throughout Europe this has taken a lot of work over a protracted period. One of the first attempts at identifying the requirements for hyperbaric units was conducted in the UK by the Faculty of Occupational Medicine who published ‘a Code of Good Working Practice for the Operation and Staffing of Hyperbaric Chambers for Therapeutic Purposes’, this code became known as the ‘Cox Report’ after Dr R. A. F. Cox the chair of the working Party this code was first published in 1994 and was compiled from the work of doctors experienced in the field.
As far as training is concerned the code stated “Personnel concerned with providing hyperbaric treatments come from a variety of disciplines and may have different educational backgrounds. Nevertheless, it is considered that there is a core of knowledge required by all those attending patients undergoing hyperbaric therapy” it went on to recognise that, at the time “There is currently no nationally recognised means of acquiring such knowledge and the Working Party believes that appropriate education and training should be organised as soon as possible” (3).

This code formed the basis for the British Hyperbaric Association (BHA) published text ‘Health and Safety for Therapeutic Hyperbaric Facilities: A Code of Practice’, this was published in 2000 (4).

Clearly the above was aimed specifically at the UK but of course there would be relevance to hyperbaric facilities everywhere. During the late 90’s Mr Robert Houman visited a large number of European HBO facilities (40+) and observed that each had to manage the same types of problems. During this period, it also became clear that there was a very definite need for a Pan-European association representing the interests of HBO teams. During EUBS 2002 in Bruges, others from the hyperbaric community were invited to discuss this opportunity. Following a period of consultation the European Baromedical Association (EBAss) was formed; EBAss exists to represent nurses, operators and technicians and so was in a perfect position to produce a properly structured Pan-European training scheme aimed at education of these staff. EBAss was officially launched during EUBS 2003 in Copenhagen. Part of the original consensus was that it would be imperative for EBAss to work with the European Committee for Hyperbaric Medicine (ECHM founded in 1990) in order to produce material that would avoid any potential clashes; subsequently this partnership has proven to be very productive with the result that the EBAss/ECHM Resource Manual has been robustly defended by this partnership.

The European Underwater and Baromedical Society (EUBS) became the vehicle bringing together experts in the field of HBO forming the Cost Action B14 working group, this was a collaboration of personnel from more than 19 countries in a programme of scientific cooperation; subsequently publishing ‘A European Code of Good Practice for Hyperbaric Oxygen Therapy’, this publication was supported by the European Science Foundation; it drew heavily on the above mentioned BHA documentation as well as acknowledging other European documents, directives and publications which were listed as References. A special mention was made of two documents issued by the ECHM; namely:

- ECHM Educational and Training Standards for the Staff of Hyperbaric Medical Centres (Annex 1) (5)
- ECHM Recommendations for Safety in Multiplace Medical Hyperbaric Chambers (Annex 2) (6)

The Code recognised that these documents were instrumental in the production of the European Code; this code was formally accepted in May 2004 and was subsequently published by the European Journal of Underwater and Hyperbaric Medicine. The code was the result of three years work. Professor D. Mathieu wrote the forward to the code and stated “It (the code) intended to be a reference document for European countries wanting to issue or update their own Guidelines, Regulations, Standards, or Codes of Practice in hyperbaric medicine. Of course, the present document cannot be looked at as definitive and it shall be revised and updated regularly”.

EBAss worked closely with ECHM to produce syllabi for training of nurses, operators and technicians; the result was the document ‘EBAss & ECHM Education of Nurses, Operators and Technicians in hyperbaric facilities in Europe EBAss/ECHM Resources manual’, this document was initially published in September 2008 and is scheduled for regular review.
The Resources Manual identifies several categories of individual with respect to training:

1. Operators
2. Nurses
3. Nurses Intensive Care
4. Attendants Not Nurse

For each of the above the manual specifies preconditions for entry onto the scheme, examples of how competence would be lost and if lost what would be required for competence to be regained. These points show any prospective candidate what they need to do in order to enter the scheme and what they would need to do in order to maintain or potentially regain their competence if lost at any time.

The Resource Manual identifies a number of areas for which competency would be required for all personnel working in a hyperbaric facility these form the ‘Common Module’ in which all operators, nurses and attendants must achieve competence.

Once the disciplines in the common module have been covered the manual then goes on to specify additional competencies required depending on whether nurse, operator or attendant.

Each of the specific topics identified in the resource manual are assigned levels of knowledge and competency to be achieved for both theory and practical training. To ensure comprehension by all parties the following terms have been defined to demonstrate levels of knowledge required.

**DEFINITIONS**

**OUTLINE KNOWLEDGE**

The candidate must be familiar with the subject in outline terms.

He/She should know that the topic exists and what it is applied to. In the context of hyperbaric methods/techniques the candidate would be expected to know what it is, what it does but would not be expected to know the finer points of application of the technique.

**KNOWLEDGE**

The candidate must have a working knowledge of the subject and be able to apply it.

**DETAILED KNOWLEDGE**

The candidate must have a depth of knowledge sufficient to enable him/her to exercise judgment.

Level 1 = Outline Knowledge  = L 1
Level 2 = Knowledge  = L 2
Level 3 = Detailed Knowledge  = L 3 (7)

The EBAss/ECHM Resource Manual draws heavily from the following texts:

2. Recommendations of the ECHM consensus conferences (REC) (9)

3. European Code of good practice of hyperbaric oxygen therapy (CGP) (10)

4. EN 14931 (EN) (11)

Clearly in order to ensure instructors are capable of delivering information at the correct levels it is imperative that appropriate levels of instructor competence are also set, the EBAss/ECHM Resource Manual set the levels as follows:

For level 1 (Outline Knowledge) and Level 2 (Knowledge) depending the topic (medical or technical) a recognised operator or nurse, member of a HBO team.

For level 3 (Detailed Knowledge) on medical topic, a hyperbaric physician (ECHM level IIb) or, under the responsibilities of the hyperbaric physician (level IIb), a registered nurse specialised on HBO.

For level 3 (Detailed Knowledge) on technical and safety topics, a safety manager or a medical director (ECHM level III).

Training is of course the prime necessity however it is also very important to ensure that this training has been successful in bringing the candidate to the required standard; examination of candidates is specified in the EBAss/ECHM Resource Manual and European College of Baromedicine (ECB) as follows:

The examination of the candidate is in two steps: theory and practical.

The theory examination is based on multiple choice questions, each with normally four possible answers as recommended by ECB/EBAss. All questions are set at the required level for the qualification according to the EBAss/ECHM resource manual.

Before progressing to the practical examination, the candidates need to show achievement of more than 70% of the points of the theory examination.

The practical examination consists of practical situations/problems that the candidate would be required to solve.

Following successful completion of the above the candidate can apply for certification from the ECB/EBAss.

**Duration of Training Required by EBAss/ECHM Resource Manual**

**Common Module for Operators and Nurses**

<table>
<thead>
<tr>
<th>Theory</th>
<th>16 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practical</td>
<td>16 hours</td>
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</tbody>
</table>

**Specific Module for Chamber Operator**

<table>
<thead>
<tr>
<th>Theory</th>
<th>16 Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practical</td>
<td>32 Hours</td>
</tr>
</tbody>
</table>

**Specific Module for Hyperbaric Nurse**

<table>
<thead>
<tr>
<th>Theory</th>
<th>16 Hours</th>
</tr>
</thead>
</table>
Practical  –  32 Hours

**Specific Module for Hyperbaric Nurse for Intensive Care (IC)**

Theory  –  8 Hours  
Practical  –  32 Hours

**Module for Attendant (Not Nurse)**

Theory  –  8 Hours  
Practical  –  8 Hours

The following is an excerpt from the EBAss/ECHM Resource Manual and covers guidance for the common module; this shows the subjects to be covered and the levels expected to be achieved:

3.1 Common Module for Operators and hyperbaric nurses (attendant)

<table>
<thead>
<tr>
<th>Theory</th>
<th>Level</th>
<th>Practical</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overview</strong></td>
<td>L1</td>
<td><strong>Hyperbaric chamber and devices</strong></td>
<td>L2</td>
</tr>
<tr>
<td>Types of hyperbaric facilities</td>
<td></td>
<td>Set up of chamber</td>
<td></td>
</tr>
<tr>
<td>History of hyperbarics</td>
<td></td>
<td>Driving chamber - pressure increase</td>
<td></td>
</tr>
<tr>
<td>Hyperbaric facility organisation</td>
<td></td>
<td>Pressure decrease Patient problems</td>
<td></td>
</tr>
<tr>
<td>Basic Technical overview</td>
<td></td>
<td>Locking (personnel and materials)</td>
<td></td>
</tr>
<tr>
<td><strong>Hyperbaric Chamber Technology</strong></td>
<td>L1</td>
<td>Built in breathing system (BiBS)</td>
<td></td>
</tr>
<tr>
<td>Basic chamber technology</td>
<td></td>
<td>Breathing masks and Hood-tent</td>
<td></td>
</tr>
<tr>
<td>Hygiene</td>
<td></td>
<td>Illumination and communication</td>
<td></td>
</tr>
<tr>
<td>Generation of compressed Air (low and high pressure)</td>
<td></td>
<td>Disinfection of chamber and associated devices</td>
<td></td>
</tr>
<tr>
<td>Oxygen supplies, Handling of oxygen</td>
<td></td>
<td>Post treatment shut down</td>
<td></td>
</tr>
<tr>
<td>Oxygen Hazards</td>
<td></td>
<td><strong>Patient education</strong></td>
<td></td>
</tr>
<tr>
<td>Electrical supplies, routine and emergency</td>
<td></td>
<td>Introduction into general rules</td>
<td></td>
</tr>
<tr>
<td><strong>Physics and Physiology in a hyperbaric environment</strong></td>
<td>L2</td>
<td>Fitting of the breathing mask</td>
<td></td>
</tr>
<tr>
<td>Concepts of pressure</td>
<td></td>
<td>Behaviour during chamber treatment</td>
<td></td>
</tr>
<tr>
<td>Boyle, Dalton, Henry, General Gas Laws:</td>
<td></td>
<td>Behaviour in emergency situations</td>
<td></td>
</tr>
<tr>
<td>Pressure/Volume/Temperature etc.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Physio- and Pathophysiology under hyperbaric conditions</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Air filled cavities, Pressure equalisation, Barotrauma,</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Oxygen toxicity, Arterial Gas Embolism, Decompression Illness.

**Monitoring**
- ECG, NBP, TcPCO2/TcPO2, ExO2 & CO2
- O2-Monitoring of the Chamber

**Relative Humidity**

**Safety**

**Risk Assessment and Management**

**Fire Protection**
- Prevention by limiting materials entering chamber
- Clothes and other possible fuels
- Procedures in case of fire
- Fire extinguishing systems
- Practice of fire extinguishing

<table>
<thead>
<tr>
<th>L2</th>
<th>Prohibited items and devices</th>
<th>L2</th>
</tr>
</thead>
<tbody>
<tr>
<td>L2</td>
<td>Emergency training</td>
<td></td>
</tr>
<tr>
<td>L2</td>
<td>Fire</td>
<td></td>
</tr>
<tr>
<td>L2</td>
<td>Evacuation</td>
<td></td>
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</tbody>
</table>

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**Treatment profiles and decompression tables for patients and personnel**

<table>
<thead>
<tr>
<th>L1</th>
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</table>

**What could be expected of newly qualified Personnel?**

Successful completion of the EBAss/ECHM Chamber Operator programme would demonstrate competence in:

- Operation of the internal and external devices of the Chamber.
- Control and operation of the mechanisms for compression and decompression, and for delivering gas mixtures and oxygen.
- Control and application of the safety regulations concerning prevention of fire, and oxygen toxicity.
- Calculation, application and control of compression and decompression schedules for all chamber occupants, applying decompression stops, when necessary.
- Be available for intervention inside the Chamber under pressure, in order to control or check the correct operation of determined parts of the circuits or devices.
• Adaptation and checking of the medical instruments carried by the patients before being introduced into the Chamber, in order to ensure their correct operation, and to avoid dangerous or undesirable effects.

• Control and checking of the operation of auxiliary facilities to the Chamber: air compressors, sources of compressed air or medical gases, gas/air reserves, pneumatic circuits, control systems etc.

• 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.

• Safe handling of technical emergency situations.

• Check the calibration of technical equipment relating to the hyperbaric facility.

• Steering, Controlling and documentation of the HBO treatment according to prescribed procedure.

• Duties in emergency situations (locking in and out of personnel).

• Adherence to national law of the appropriate member state.

Successful completion of the EBAss/ECHM Nurse programme would demonstrate competence in:

• Nursing measures belonging to the common pathologies of the hyperbaric therapeutics to be applied to the patients in a hyperbaric chamber.

• Nursing assistance of patients inside the hyperbaric chamber, taking special care of the specific conditions of the hyperbaric environment.

• Where possible adaptation of conventional medical techniques and specific treatments of each illness to the hyperbaric environment, so that other treatments the patient is habitually receiving will not need to be interrupted while in the chamber.

• In some cases, operating the external controls of a Monoplace Hyperbaric chamber according to the compression and decompression schedules established.

• Care of patients including sporadic emergency treatments conducted either inside or outside of HBO chamber.

Successful completion of the EBAss/ECHM Nurse Intensive Care programme would in addition to the above demonstrate competence in:

• Nursing assistance of intensive critical care patients during hyperbaric treatment.

Successful completion of the EBAss/ECHM Attendant (Not Nurse) programme would demonstrate competence in:

• Patient care in non invasive, non-specialised medical activities inside and outside the chamber.

• 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.

• Other activities to develop inside or outside the Chamber, indicated by the Medical Director or the Nurse.
Technician Training

Training of hyperbaric technicians is another area where identification of appropriate standards and certification is required; technician training is currently largely catered for by equipment manufacturers conducting courses either at their own facilities or perhaps in-house at the hyperbaric facility. This works very well in the main but of course the same principles apply as with all other training, i.e.

1. Use only appropriate staff – identification of appropriate pre-requisites for staff attending training so that only appropriate staff will be brought on to the scheme.

2. Identify required training – investigate precise requirements for the task(s) to be achieved and levels of competence required. This must also identify appropriate organisations/staff to accomplish the training.


4. Certification – where appropriate identify independently accredited certification.

EBAss have identified the need for a qualification level that will have understanding of all of the above such that safety can be assured for all personnel involved in the hyperbaric operation. With this in mind the next step for the EBAss/ECHM scheme will be introduction of the role of Safety Manager.

Safety Manager

Management of the team as a whole is clearly of ultimate importance and safety should be a major part of the management team for any Hyperbaric Unit. There must be a formal structure within any Hyperbaric Unit and part of that is that there must be an individual responsible for safety. The Medical Director has a right to have a competent person as part of the team who can be relied on to monitor safety in the Hyperbaric Unit; this role will be taken by the Safety Manager who will be ultimately responsible to the Medical Director.

The Safety Manager will be responsible for analysis of situations resolving confusion; the Safety Manager should be qualified and experienced to the specific unit they are to manage and would be appointed by the Medical Director. Introduction of this role will reduce confusion between personnel as far as responsibilities and boundaries are concerned. At this time the Medical Director may have no competent individual to help with complex safety decisions, this could have huge consequences. There needs to be a “Global” approach to management of safety and education within the team.

Introduction of the role of Safety Manager will increase safety and help the medical director minimise risks and manage hazards more effectively thus reducing risks for all persons who enter the Hyperbaric Chamber or the facility in general. They will be able to assist the Medical Director with the effective management of safety and continuing professional development (CPD) of the team as a whole.

Safety Managers will ensure work practices, effective methodology of policies and procedures are developed in order to properly evaluate and therefore reduce risk and to help personnel to work to proven, effective and safe methods. When new equipment or methods for treatment of patients or changes in methods of operation of the hyperbaric facility in general are identified assessment and effective training will be produced with the help of the safety manager. All of the above will enhance confidence in the professionalism of the unit as a whole; thus helping to enhance the patient experience. The Medical Director will be more able to demonstrate that safety and quality of the Hyperbaric Unit is managed effectively.
Functions of the Safety Manager

- The Safety Manager will be qualified and experienced to the specific unit they are to manage and would be appointed by the Medical Director.
- The Safety Manager will be required to maintain a sound professional relationship with the Medical Director.
- The Safety Manager will ensure reduced confusion between personnel; responsibilities and boundaries will be clearer.
- The Safety Manager will support the Medical Director as a competent individual who will be able to help with complex safety decisions.
- The Safety Manager will ensure a “Global” approach to management of safety and education within the team.
- The Safety Manager will ensure there are full and proper written policies for the HBO centre.
- The Safety Manager will be responsible for ensuring comprehensive hyperbaric procedures are in place.
- The Safety Manager will be responsible for ensuring maintenance/repair programs are conducted by legally competent personnel to agreed standards.
- The Safety Manager will be responsible for supervision of effective Quality Assurance within the Hyperbaric Unit.
- The Safety Manager will ensure the HBO centres policies and procedures comply with local, National and European directives.

Education of the Safety Manager

- In addition to the basic hyperbaric education (EBAss European Certification, ECHCO or ECHRN) the Safety Manager should have received specific and recognised advanced education related to the hyperbaric fields (i.e., safety director, fire fighting course, detailed knowledge of rules and regulations, safety culture in Healthcare etc.) and will have presented or will be working toward presentation of work related to safety at a scientific congress on Hyperbaric Medicine.
- Must have received formal specific education in the fields of Risk Assessment/Management, general Health and Safety management and Quality Assurance management.
- Should maintain qualification to Basic Life Support (BLS) level as a minimum.
- It would be advantageous fo r the individual to have received training in the technical aspects of Hyperbaric Systems and Healthcare Management.

Profile of the safety manager

- They will be appointed by the Medical Director.
- They will have received appropriate education.
They will have appropriate experience; this being at least 3 years in the last 5 years working in a Hyperbaric Centre treating the ECHM indications regularly as Operator, Nurse or Doctor.

Recommended that the individual will have attended a recognised HBO national or international congress within the last 5 years.

**Future Work for EBAss**

EBAss will continue to work to ensure nurses, operators and technicians are kept properly informed and that their concerns, thoughts and aspirations are brought to any discussions in the future. In particular EBAss will be revisiting; initial and continued education, rules of good practice, required policies and procedures for the HBO organisation.

**Approach of DDRC to Education of the Hyperbaric Team**

We at DDRC have adopted the above guidance in the training and assessment regime for our team, we ensure that staff training commences as soon as a new staff member sets foot in our centre and never ends. We spend a great deal of time and effort ensuring that staff all have the necessary skills ensuring they are properly prepared for any foreseeable events.

When we started along the path of evolution of our current training regime in 2002 we found that there was considerable opposition to the levels of training being suggested. At the time there were a number of senior staff who had been with the organisation for a considerable time and didn’t feel there was any need for them to undertake training of any sort whether it was externally accredited examination of their skills or any type of continuing professional development. Since that time there has been considerable natural wastage of staff resulting in our workforce being much more receptive to the concept of training.

Initially there was no European training scheme aimed at hyperbaric personnel and therefore we adopted the NBDHMT system of CHT and CHRN for all our chamber staff; while this was a huge step forward it was not the answer for all the reasons stated above.

With the advent of the EBAss/ECHM scheme we found a much more European friendly scheme utilising metric measurements and focussing on rules and regulation that were appropriate to our facility.

We now find our staff are keen to be involved in routine and exceptional training, they are aware that their knowledge needs to be continually refreshed and increased. We find now that staff come to us with suggestions of training they feel will help them and indeed we are continually changing our training regime to take account of new developments; adding some items and dropping others that are no longer appropriate.

**Conclusions**

Training schemes need to continually evolve; the needs and requirements of both the staff and the organisation will change over time with variations in equipment, methods and procedure. Legislation changes will always need to be borne in mind so that the training delivered complies with statutory requirements; it is important that management keep abreast of all regulatory changes so that they can ensure their facility is working to current legal requirements.
The EBAss/ECHM system will continue to ensure proposed changes to regulation are fully and properly discussed and communicated to all HBO facilities in Europe this will ensure that we can be confident that only appropriate changes in legislation will be applied.

Training Centres

In order for the above to work effectively there is an urgent need for a network of properly accredited training centres. EBAss and ECHM are working with the ECB to ensure that centres wishing to conduct training to the required standards can easily achieve accreditation for their courses. Training courses accepted as satisfying required criteria ultimately gain accreditation from the European College of Baromedicine (ECB).

One of the major strengths of the EBAss/ECHM/ECB scheme is that it is multi lingual such that students can undertake required training and examination in their native language (6 languages will be available initially); for this to become a reality we need training centres to become accredited for training. The aim is to have at least one accredited facility in all countries providing training in the local language.

Training centres wishing to apply for accreditation by ECB should initially contact EBAss at accreditation@ebassexam.eu supplying the following information:

- Formal application requesting accreditation.
- Complete Course Curriculum, detailing topics, lecture & practical session duration.
- Course venue + equipment available.
- Candidate’s admission pre-requisites.
- Qualifications of Course Director(s) (C.V.).
- Qualifications of Faculty (with C.V.).
- Cost of the course.
- Disclosure of any conflict of interest.

The above to be provided in English, it is recognised that having to translate all course material into English would be far too onerous and therefore the decision was taken to request the bare minimum information in English in order to ensure the course properly addresses subjects as specified in the EBAss/ECHM Resource Manual. The final proving of the course will be when students sit the EBAss on-line examination where their knowledge will be independently tested.

References

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4. BHA Health and Safety for Therapeutic Hyperbaric Facilities a Code of Good Practice.
5. Certification Scheme for Welding and Inspection Personnel Document No: CSWIP-DIV-9-03
6. ECHM Educational and Training Standards for the Staff of Hyperbaric Medical Centres (Annex 1)
7. ECHM Recommendations for Safety in Multiplace Medical Hyperbaric Chambers (Annex 2)
9. Recommendations of the ECHM consensus conferences (REC)
10. European Code of good practice of hyperbaric oxygen therapy (CGP)
11. EN 14931 (EN), Pressure Vessels for Human Occupancy – Multi-place pressure chambers for hyperbaric therapy, safety requirements and testing
Chapter 4: Hyperbaric equipment
(10) Hyperbaric chamber

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Abstract

Hyperbaric chambers are pressure vessels capable of accommodating one or more persons with the purpose of providing medical treatment. Therapeutic hyperbaric chambers have been in use from the middle of the twentieth century, yet it seems that their design has not reached its full potential. Moreover, they are not compatible with current healthcare facility designs.

The paper will present therapeutic hyperbaric chambers from a Human–Environment–Machine perspective and the implications of their design.

Data was drawn from limited number of publications, primarily from websites of hyperbaric centers and companies for hyperbaric therapeutic chambers. Consequently, this paper basically presents an “observational” study.

It is suggested that adopting a user-centered design rather than an engineering focus in the planning of hyperbaric therapeutic chambers will highlight their suitability as a general medical treatment, and hopefully, improve the image of hyperbaric medicine as a common medical subspecialty.

DEFINITION

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 European code of good practice for hyperbaric oxygen therapy-COST B14, 2004).
HYPERBARIC CHAMBERS OBJECTIVES

The two main objectives of hyperbaric chambers are medical treatment and research.

Medical treatment

Medical treatment is supplied by breathing high oxygen pressure in well-structured predetermined protocols. We can distinguish between two kinds of treatments that may differ in their requirements and might have implications on the design of the hyperbaric chamber.

- Acute, emergency treatments are not planned ahead of time and are organized and implemented in acute situations. By and large, such treatment approximates what happens in an intensive care unit and is characterized by its critical care features.
- Chronic treatments are treatments that are planned according to fixed protocols and mostly extend for several sessions at predetermined time intervals.

Research

There is a great need within the hyperbaric community to strengthen research in order to support the scientific background and compile evidence of the beneficial effects of hyperbaric oxygen therapy. This can be achieved by randomized studies, double blind studies and by conducting multi-center studies with common protocols.

TASK ANALYSIS: THE HUMAN–ENVIRONMENT–MACHINE APPROACH

The following paragraph discusses the nature of therapeutic hyperbaric chambers from a human–environment–machine perspective in order to highlight their specific problems and requirements. Topics such as safety, technical issues, regulations, equipment standards, etc. are omitted.

Indexed publications in this area are scarce and most of the data appearing below has been gathered from professional reports and publications, and Internet sources,(the websites of commercial HBO chamber companies and of hyperbaric centres). The pictures and the information (mostly commercial and marketing) on the websites of hyperbaric centres and chamber companies were used to conduct a type of “remote” observational study for identifying problems and limitations.

All available information from the main hyperbaric chamber companies was sorted into table according to the following categories: morphology, pressure range, number of patients, door type, windows, materials, entertainment, interior design, medical equipment, control panel, etc., without referring to specific company, type of chamber or facility; therefore no pictures will be presented in the manuscript.

HYPERBARIC CHAMBER USERS

Hyperbaric chamber users can be divided into three main groups, which may have different needs that impact on the design and function of the chamber and the nearby surroundings:

1. Hyperbaric medical staff -- who work outside and within the chamber.
2. Technical team - who operate the chamber and the equipment, mostly from outside the chamber.
3. Patients – who stay within the chamber, breathing different gas mixtures with diverse levels of supportive medical treatment given before, during or after the HBO session(s). Most of the time, patients are ‘restrained’ by being connected to a gas source, apart from air breaks in between sessions.

Essentially, the persons accompanying the patient constitute another subgroup, which will not be discussed here. Patients of therapeutic hyperbaric facilities are heterogeneous. They may be of different ages, physical and mental fitness, and language knowledge. Generally, they have restrictions and disabilities unrelated to their initial reason for admission for hyperbaric treatment.

Patients may be impaired by various diseases causing motor dysfunction (e.g., Parkinson's disease, essential tremor, or arthritis), visual decline (e.g., diabetes retinopathy, or cataract), the loss of tactile sensation (e.g., diabetes neuropathy), cognitive impairment (dementia), auditory decay (e.g., phonal trauma, presbycusis, or deafness), speech disabilities (e.g., stroke), and equilibrium disorders. Moreover, chronic patients may have multiple illnesses and disabilities and may go through transient and unpredictable changes in their clinical status and performance during and between HBO sessions.

These patients are different than diving causalities treated at hyperbaric chambers, as divers are essentially healthy people and in good physical condition, apart from the diving accident’s clinical manifestations.

Based on the aging of the population, special consideration should be given to elderly people that are likely to become a major group of users and typically suffer from chronic diseases and a wide array of cognitive and motor disabilities that may significantly disrupt their behavior and treatment outcome.

Common reactions such as anxiety and claustrophobia may also decrease users’ attention and treatment outcomes.

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Main patient categories</th>
<th>Requirements, implications for chamber design</th>
</tr>
</thead>
</table>
| Number of patients treated | - Single patient  
- Several patients | - Separation between patients  
- Need for personal space, privacy - Individual treatment protocols |
| Position – posture | - Sitting  
- Lying | - Chairs, beds, stretcher  
- Different height for wall-attached equipment |
| Conscience level | - Conscious  
- Unconscious | - Easy and comfortable entrance  
- Different options for HBO breathing (mask, hood, free breathing…) |
| Mobility | - Mobile outpatient –walking into chamber  
- Critical care patient must be wheeled/transported | - Easy to walk in entrance,  
- Wide opening to suit stretcher or hospital bed  
- Reserved space for wheelchair |
| Familiarity with facility | - Single treatment = casual user  
- Repeated sessions = dedicated user | - Stress and anxiety reducing environment  
- Stress reducing procedures, tutoring, instructions  
- Auditory pre-warning about changes (temp., noise) |
|--------------------------|------------------------------------|-------------------------------------------------------------------|
| Health status            | - Generally healthy  
- Sick, impaired | - Accessibility  
- Infection control  
- In-chamber close assistant |
| Equipment usage          | - Only HBO breathing  
- HBO + extra monitoring and equipment | - Spacious chamber  
- Extra inlets  
- Non radial equipment arrangement |
| Cooperation with staff   | - Speaking, understanding, following directions  
- Non responsive | - Good communication lines outside-inside, and within chamber (sound control) |
| Claustrophobia           | - Claustrophobia, anxiety  
- Relaxed, calm | - Design reducing claustrophobia  
- Increased transparency (see-through) |
| Age                      | - All ages (from infants on)  
- Elderly | - Adapt sitting options, equipment (mask, hood, etc.) for all ages (height, anthropometry).  
- Personalized (age tailored) entertainment |
| Social needs             | - Sociopath  
- Sociable person | - Personal space, privacy |
| Interest level           | - Self occupied  
- Passive, bored | - Tailored entertainment  
- Suitable condition for reading (e.g., lighting), talking, music (noise, earphones), TV, video, etc. |

The two other groups of users; medical and technical staff will not be discussed herein.

**HYPERBARIC CHAMBER ENVIRONMENT**

Hyperbaric chambers are a closed and isolated environment with specifications and characteristics that might have implication on user needs and chamber design.

- A closed high pressure environment, whose pressure changes (compression and decompression) by using precise and fixed protocols.
- Closed system with potential hazard and threat of fire and burning, explosion and contamination.
- Hyperbaric environment with options for supplying varied gas mixtures at the same ambient pressure for different people simultaneously without the patient or the team being aware of its content (done for scientific research protocols).

- Assortment types of compressed gas breathing apparatuses. Each patient has to be connected to a compressed breathing gas source. The main options are: Free breathing (without a mask), which is practical only for small volume chambers (monoplace), gas mask, hood and intubation.

- Contact. As hyperbaric chambers are disconnected visually and acoustically from the environment, there is a need for good quality communication routes between the internal and external environments (eye and voice contact). Communication is complicated due to voice distortion and no direct visual and eye contact.

- Ability to insert and remove the patient, medical/technical staff or samples during the hyperbaric session without disrupting the treatment for the rest of the patients or causing a pressure drop.

- Lighting – natural light is limited in most situations, and therefore, artificial lighting, suitable for hyperbaric conditions, is needed to care for patients, with the requirements of avoiding glare and heat producing lamps.

- Temperature control is needed for the closed environment of the chamber, sharp changes in temperature during compression and decompression must be especially avoided.

- Noise – acoustic problems especially during compression and decompression.

- Chamber dimensions – Spacious (width and height) for people and equipment, with a possibility for versatility in chamber design arrangement depending on the number of patients in supine or seated positions.

- Infrastructure – Technical support such as electricity and water systems, compressors, and backup systems near the hyperbaric chamber.

- Infection control – mostly hazardous in the confined atmosphere of the hyperbaric chamber.

- Connection to healthcare facility – Medical support mostly for patients treated in hospital departments between HBO sessions, and with physician and patients arriving from ICU, ER and the hospitalizing wards.

## HYPERBARIC CHAMBER CHARACTERISTICS

### Chamber morphology

Curvature forms (shell structures) are the most appropriate structures which resist hydrostatic pressure as can be seen looking at underwater living creatures. It is not surprising therefore that cylinder and sphere were verified as the most common shapes for undersea habitats and pressure vessels. Subsequently, the classical therapeutic hyperbaric chambers followed this image and were by and large of a cylinder structure shape with a horizontal axis.

Horizontal cylinder chambers use a flat bottom technology; the \( \Omega \) omega shape increase the horizontal space, supplying a flat and convenient workable platform, but reduce the overall height of the chamber. Moreover, curved walls add constrains on the equipment arrangement and sitting options of the patients.

Rectangular chambers are starting to gain popularity over the last years. The rectangular shape provides maximal available areas for patients and equipment, regulated uniform height and vertical walls. Moreover rectangular
Chamber materials

Classical materials of hyperbaric chambers of the cylinder shape are steel for the matrix and glass or acrylic for windows and viewing area, with different proportion between the two materials.

Concrete, and recently its advanced version of post tensioned concrete, has been proposed as an alternative material enabling rectangular morphology of multiple rooms and large rectangular doors (Maisan, 1990; Balogh, 1996; Workman & Butler, 1997, Haux, 2000).

The time and cost required to build the concrete prototype were compared to those required to build a welded steel chamber of equivalent size. The prototype concrete chamber was built in less than two month at only 10% of the cost of the steel structure. Moreover, concrete chambers can be erected by a building contractor and makes easier to a hospital architect to incorporate a concrete HBO facility as another room (Haux, 2000).

As therapeutic hyperbaric chambers are not planned to perform at extreme high pressures, it can be built light weighted, using polymers materials ensures high mobility. Moreover it is suggested that use of innovative technologies such as nanotechnology-based materials and extreme textiles (McQuaid, 2005) in which there is dissociation between structure and function. The use of such materials can help in developing new structures and revolutionary forms of therapeutic hyperbaric chambers.

Chamber openings

The main requirements for opening ports of hyperbaric chambers are ease of opening (staff requirement) and comfort of moving through (patient and staff requirement), apart from the technical necessity of forming tight closure to the chamber contour and maintaining the high pressure. Hence, type and shape of the door is dependent on the morphology of the chamber.

Hyperbaric chambers doors should enable fast and easy entrance and exit for free moving people, people supported by wheelchair or crutches and for stretchers and beds pushed by staff on which immobile patients are lying. This requires wide opening, satisfactory height and walkthrough passage; requirements that are not met at many cylinder like hyperbaric chambers.

Rectangle chambers provide much more adaptable opening options- wide doors, possibility of straight comfortable walkthrough passage and sliding door which can accommodate standard hospital doors that are easy for opening.

Viewing and connectivity

Hyperbaric chamber are closed isolated environment and therefore there is a need for a close follow-up of patients both visually and auditory. Multiple windows and expanding the portion of transparent materials in the
outer walls of the chamber are used for better observation and also help in reducing claustrophobia, decreasing isolation feeling and relieving psychological tensions of the patients.

A balance is needed between the need for observing and the privacy of the patients inside the chamber, by deciding on the total amount and proportion of transparent and dense surfaces and their distribution around. Innovative materials having changeable properties of visibility can be used for the windows for adjusting the privacy level. Natural light directed into the chamber may improve viewing and psychological feeling.

Multiple cameras at different angles distributed in the chamber are additional options for improving visibility for the staff, without increasing the number of windows. Using "smart" technologies as miniature sensors (e.g. pressure sensors in the chair, motion sensors etc) will improve and simplify patients inspection.

**Mobility**

Therapeutic hyperbaric chambers can be fixed or movable. The advantage of movable chambers is enabling treatment at the point and at the time of need. The size, configuration, weight of the chamber and its infrastructure determine the potential for mobility. Initial planning of the chamber and its accessories using light and flexible materials can enable possibilities for mobility. Moreover, planning and designing the moving aids as part of the chamber, scheduling the location where the chamber is placed and allowing free accessible pathway for transporting the chamber should be part of the design of any chamber. Movability will also enable storing the chamber if not used.

Another option is division of the hyperbaric chamber into two units; fixed and movable. The infrastructure will be the stable part and installed at several locations at the hospital, while the chamber will be a de-attached unit, which will be moved upon need between the stable locations; a concept similar to a docking station for portable computers.

Further improvement in innovative materials will help to establish an inflatable chamber to mount a single bed, and will be moved to the patient for HBO treatments, rather than moving the patient to the HBO facility.

**Interior Design**

The internal design in most chambers is simple and does not seem to be fully adapted to the users and task. The most frequent furniture elements (sitting elements) seen to be borrowed either from diving facilities (benches) or armchairs common at waiting rooms and the aviation industry. It does not seem that a special effort was directed towards designing a specific sitting or lying options that will support and alleviate the prolonged sitting connected to the different kinds of gas supply apparatus (mask, hood, etc.), while trying to be engaged in activities such as reading or TV watching, not mentioning being connected to physiological parameters monitoring, infusion and more.

Spatial sitting arrangements is another unsolved issue – observations of websites presenting hyperbaric chambers both currently working or chambers for purchasing, reveal that usually the seats and beds are distributed near the walls, as the result of using the breathing system installed and attached to the external chamber envelop. This sort of “fringe” design does not utilize the total area of the chambers effectively and force the patients to face each other. Sitting for prolonged time while facing each other invade the personal space of the patients and does not permit any intimacy. Distributing the breathing apparatus all over the chamber area by inserting the breathing apparatus from the chamber ceiling in a vertical manner will allow distribution of the patients over the
entire chamber area. Intermediate dividing walls will supply a personal intimate space and the divider walls will house the monitoring devices as well as supplying a panel for personal entertainment options.

Innovative technologies such as virtual windows offering a landscape view to patients while staying in windowless isolated environment of the hyperbaric chamber can dramatically improve inner design and the clinical outcome (Ulrich, 1984).

Special care should be given also to the design of the hyperbaric chamber surrounding environment; the waiting area for the accompanying person, the area in which the patients are checked and treated before and after the hyperbaric treatment (e.g., wound treatment), wardrobe, personal lockers and even a drinking water and snake station.

**Research possibilities**

Therapeutic hyperbaric chambers can work as research unit by preplanning and organizing the equipment and the chamber with the relevant infrastructure and facilities. Providing diverse gas mixtures to different patients without awareness of the patient and the medical staff, placebo medications, close follow-up, hemodynamic and respiratory monitoring, options for taking blinded samples from the patient (e.g., blood, urine, saliva, etc.), and coded documentation are some of the requirements (Workman, 2000). Multiple penetrations through the chamber envelope for additional monitoring and recording and taking samples are essential for research chambers.

**Psychological issues**

Hyperbaric chambers are closed space in which people are forced to stay together without moving option of walking out for periods of 1-2 hr and more.

Common activities within the chamber while breathing oxygen are limited; people may doze intermediately while others will read, listen to music with headphones or watch TV. Based on diversity of patients treated, the entertainment options should be personalized and adapted to the users’ profile (e.g., personal screen, video movies, music options etc.). Special concern should be given to accessories and aids for babies and children. There are evidences that good design can reduce anxiety, lower blood pressure, reduce the need for pain medication and shorten the hospital stay, while poor design was found to be linked to anxiety, delirium and more (Ulrich, 1992, 1992).

Isolation, claustrophobia and anxiety may accompany the stay within the old fashioned previous generation of hyperbaric chambers mostly of the cylinder type. Rectangular chambers, large internal space allowing more freedom of movement and projection of landscape and nature through virtual windowing will reduce isolation and improve at ease feeling (Ulrich, 1984).

**SUMMARY AND FUTURE SUGGESTIONS**

Morphology, materials and image of hyperbaric chambers has been taken from the domain of underwater professional and military missions that are aimed at high pressures and extreme environments. Yet, the therapeutic pressure range is much lower and therefore an innovative and original new design detached from the morphology and visual language of the military and commercial underwater objects should be developed.
The use of innovative technologies such as nanotechnology-based materials and extreme textiles (McQuaid, 2005) (e.g., Kevlar) in which there is dissociation between structure and function can help in developing novel structures and revolutionary forms of hyperbaric chambers.

Moreover, the pioneering staff developing the hyperbaric oxygen therapy field, both physicians and technicians, has belonged to the diving community. In our days many people of the hyperbaric community arrive from various clinical disciplines, sharing the rational of using HBO protocols, same as any other drug treatment, without being divers or sea fans.

It is therefore the time that hyperbaric chambers will di-attach themselves from the visual image of the hyperbaric diving world and underwater missions, and fully integrate with the visual language of healthcare facilities. Therapeutic hyperbaric chambers should be comfortable and familiar to patients and serve as an extension of the hospital’s clinical environment. Close collaboration between engineers, architects, designers, psychologists and material engineers is needed to produce novel concept of hyperbaric therapeutic facilities integrated with healthcare domain.

It is suggested building hyperbaric chambers as part of the healthcare facility (e.g., “hyperbaric rooms”) rather as building it as an external facility construction outside the hospital and looking for the right location to place it. This is similar to the newly developing concept of sheltered underground parking lot that can convert in an emergency to a fully protected working hospital. Moreover, based on the current concept of ‘personalized medicine’, it is suggested to design small tailored ‘personalized hyperbaric chambers’ of different configurations, adjuvant to diverse hospital wards, to accommodate varied patients and indications.

Changing the morphology, the materials and the visual image of the hyperbaric chambers will hopefully place HBO as an equal sub-specialty to others and increase the popularity of this field.

REFERENCES


(1) Compressed gas supply system
Francois Burman Pr. Eng. (South Africa)

1. Executive summary

The diversity of requirements adopted around the clinical hyperbaric operating world clearly shows that we have too often drawn on history, or adopted practices that have been researched and developed for other applications. It is considered opportune to review our knowledge of the standards for air quality and the quantity of air required to effect safe treatments, based on realistic and likely scenarios.

A significant amount of information exists in the scientific literature, as well as in national and industry-regulated standards. In many cases, the information has been developed through practices and lessons learned. This data should be carefully heeded in the pursuit of extracting a single series of proposals for the road going forward.

Medical and industrial science, technology and experience have empowered us to better understand the effects of decisions, as well as providing us with better rationale behind making such decisions.

This paper represents a summary of the existing knowledge base, and then presents two proposals based on real or expected situations, rather than using either a best-guess or overly conservative speculative approach.

2. Objectives

There is a need to review the currently available information and then to answer the following two questions:

1. What is an appropriate standard for the quality of air provided to hyperbaric chamber occupants?
   (Most hyperbaric air quality standards are based on occupational health or diving related applications, whereas we are essentially dealing with medical devices.)

2. What is the appropriate quantity of air that should be available to hyperbaric chambers?
   (Internationally accepted practices for ventilation and air storage vary greatly, and consistency based on realistic expectations is required.)

The final intended outcome of this discussion paper will be a proposal for suitable specifications for both the quality and the quantity of air provided to clinical hyperbaric chambers for use in Europe.

3. Introduction

3.1. Background

The technical realm of hyperbaric medicine has traditionally been driven by two main influencing forces, viz. (1) commercial and military diving practices and (2) clinical and hospital-engineering standards. The majority of our new and sector-specific standards and guidance documents have attempted to introduce technical specifications that are based on actual hyperbaric practice requirements, but there are some areas where the older, traditional methodologies have been incorporated without much change.
Medical investigative work has been performed to determine the human impact of common contaminants in breathing air and this has provided a rationale behind the stated carbon dioxide (CO₂) and carbon monoxide (CO) maximum levels in stored breathing gases.

Scientific analysis has been performed on CO₂ levels in closed environments, specifically for helmets and confined diving bells or habitat chambers. Suitable oxygen (O₂) levels in living environments have likewise been investigated, resulting in a degree of consensus regarding the requirements for sufficient air exchange based on these two gases.

Finally, other notable toxic or debilitating elements have found their way into breathing systems, including for example sulphur dioxide (SO₂), nitrous oxide (N₂O), nitrogen dioxide (NO₂), nitrous fumes (NOₓ), methane (CH₄), non-volatile hydrocarbons and even more infrequent compounds such as xylene, toluene and various halogenated solvents (sometimes used in cleaning piping systems). Limits based primarily on health effects are published in occupational health regulations and specifications.

The contaminant elements that require specific consideration include oil and water, both in the form of vapour or condensed liquids. These ‘contaminants’, together with other biological hazards, require some discussion in order to consider suitable limits.

The combined processes of elimination and air exchange should provide a definitive guideline to quality as well as quantity of air required in the clinical hyperbaric environment.

### 3.2. Survey of international practices

Before entering into sensible discussion, a survey is required of the existing practices and established standards that are in force in the various operating and geographical arenas.

Source data is available in standards, specifications, occupational health and clinical regulations, industry practices as well as in the original repositories of knowledge for breathing air (gas) systems, namely the ‘rules’ published by the international maritime classification societies.

The following two tables provide a summary of the available information on both air quality standards, as well as considerations for determining suitable quantities of air. Data is tabulated in the form needed to support the discussion on a suitable proposal and is thus by no means a comprehensive reflection of all the relevant data. Units are not always consistent with those published in the reference sources, as in some cases these needed to be converted to provide easier comparison. Also limits are stated in the literature, with no corrections applied where approximation or interpretation have resulted in deviations from the actual values.
<table>
<thead>
<tr>
<th>Region</th>
<th>Reference</th>
<th>CO₂</th>
<th>CO</th>
<th>H₂O</th>
<th>Oil</th>
<th>Odour</th>
<th>Other</th>
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</thead>
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<td>500 ppm, 5 ppm, 1000 ppm</td>
<td>0.5 mg/m³</td>
<td>NS³</td>
<td>THC 27.2 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>HSE DVIS 9</td>
<td>500 ppm, 3 ppm, 31 ppm</td>
<td>0.5 mg/m³</td>
<td>NS³</td>
<td></td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>LR 5-4 3.1</td>
<td>500 ppm, 10 ppm, 621 ppm</td>
<td>1 mg/m³</td>
<td>None</td>
<td></td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>International</td>
<td>ISO 8573-1 Cl 2†</td>
<td>-</td>
<td>-</td>
<td>-40°C</td>
<td>0.1 mg/m³</td>
<td>-</td>
<td>Partic.³ 1 mg/m³</td>
</tr>
<tr>
<td></td>
<td>ISO 10083</td>
<td>300 ppm, 5 ppm, 67 ppm</td>
<td>0.1 mg/m³</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RAG²</td>
<td>500 ppm, 10 ppm, 500 ppm</td>
<td>5 mg/m³</td>
<td>None</td>
<td>THC 25 ppm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RAG²</td>
<td>500 ppm, 10 ppm, 500 ppm</td>
<td>0.1 mg/m³</td>
<td>None</td>
<td>THC 25 ppm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Maximum limits of contaminating substances in breathing air

Notes to Table 1:

Shaded rows indicate medical air specifications; the clear rows indicate breathing air or other, similar specifications.

The list is not exhaustive and where countries like South Africa have followed specific ISO standards (published with local reference numbers), these standards have not been repeated.

Dew point temperatures are indicated as pressure dew point (PDP) temperatures in the table.

- The requirement for stored air depends on circumstances: (1) Where conditions are unknown, a PDP limit of -11°C applies; or (2) PDP to be 5°C below the lowest likely temperature; or, at atmospheric pressure, the limits are (3) air stored between 40 to 200 bar, 50 mg/m³ (62 ppmv), (4) air stored above 200 bar, 35 mg/m³ (44 ppmv), & (5) air supplied to high pressure cylinders, 25 mg/m³ (31 ppmv).
- NS – not significant
- Free of any other harmful or toxic substances
- NS – not specified
- Determined through condensate on a mirror
- Dew point (atmospheric) to be ±6°C below lowest likely temperature or -54°C for exposure of air in cold regions (24 ppmv).
- Dew point (atmospheric) to be 5°C below lowest likely temperature and -53°C (26 ppmv) for storage above 124 bar
- Volatile hydrocarbons 5 ppmv and halogenated hydrocarbons 5 ppmv,
- Dew point -20°C or less than minimum recorded temperature
- Air stored between 40 to 200 bar, less than 50 mg/m³ (62 ppmv); air stored above 200 bar, 35 mg/m³ (44 ppmv); air supplied to high pressure cylinders, 25 mg/m³ (31 ppmv).
- Expressed as pressure dew point (PDP)
- Maximum particle size 1 micron
- ISO 10083 provides a specification for oxygen-enriched air, implying suitability for use in an oxygen pipeline or with oxygen-rated equipment. This provides good guidance where the breathing air is to be delivered via the oxygen breathing circuit.
- Air supplied to patients and chamber need only meet the 500 mg/m³ requirement. Air stored at pressures up to 200 bar should contain less than 50 mg/m³ (62 ppmv); air stored above 200 bar, is restricted to 35 mg/m³ (44 ppmv).
- Unless otherwise stated, the limits apply to air at standard temperature and pressure (STP) – 0°C & 10¹⁵ Pa.
##参考文献概述和解释所需的最低要求

<table>
<thead>
<tr>
<th>参考文献</th>
<th>总结概述和解释所需的最低要求</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>EN 14931-2006</td>
</tr>
<tr>
<td>2</td>
<td>ECGP-2004</td>
</tr>
<tr>
<td>3</td>
<td>NFPA-99:2012</td>
</tr>
<tr>
<td>4</td>
<td>USN Dive Manual, Rev. 6 2008</td>
</tr>
<tr>
<td>5</td>
<td>UHMS Manual: 2005</td>
</tr>
<tr>
<td>6</td>
<td>CSA: Z275.1-05</td>
</tr>
<tr>
<td>7</td>
<td>AS 4774.2-2002</td>
</tr>
<tr>
<td>8</td>
<td>Nuckols, M.L. 1996</td>
</tr>
<tr>
<td>9</td>
<td>RAG 2010</td>
</tr>
</tbody>
</table>

###海洋分类机构

10 | ABS-2002 | 适合于预定操作的需求，提供氧气和CO2监测 |
11 | DNV-OS-E402 | 适合于预定操作的需求，提供氧气和CO2监测 |
12 | GL-2009 | 每位患者（休息时）每分钟需40公升/分钟（40 acfm）及每小时40公升/分钟（40 acfm） |
13 | LR-1989 | 适合于预定操作的需求，提供氧气和CO2监测 |
14 | NKK 12-480 | 适合于预定操作的需求，提供氧气和CO2监测，加脱脂处理 |
15 | RINA-2011 | 适合于预定操作的需求，CO2 < 5000 ppmv |
16 | RMRS-2004 | 与用户协商确定，监测氧气和CO2，加脱脂处理 |

###表2：空气容量要求

在所有情况下，要求都适用于当个体呼吸的气体系统在舱外（通常称为过板排放）时。

- 在标准气压下（NTP，20°C和101.325 kPa）时，流量以实际升/分钟或正常升/分钟（NTP，20°C和101.325 kPa）表示。

- 只考虑平均值，未考虑气体流速或温度的变化。

- 主要和备用系统的要求仅适用于主案例（更高的要求）。

- 有些规定提供了容量要求，这些要求可能降低到在氧气和CO2监控，以及CO2脱脂之后。

- a. 这个标准还要求连续监控以确保O2 < 23.5%，CO2 < 5000 ppmv，有机物 < 0.5 mg/m³和RH 40–60%。这被视为有机物的特殊情况。

- b. Pmaxb应被视为预定治疗的最大压力，由服务范围定义。

- c. Nuckols等人提出了一个公式，用于计算绝对最小气体交换。这在讨论中，4.2.4章节详细解释。
3.3. Practical considerations

3.3.1. Quality assessment

When establishing specifications for contaminants in air for use in hyperbaric facilities, consideration of the available analytical techniques is necessary to ensure that analysis can be done in practice. Clearly techniques that provide accuracy and resolution appropriate to the limits being imposed is necessary, but analyses that requires remote, expensive and elaborate testing methods are not going to provide practical solutions.

References [2] and [26] are examples where additional information has been provided as to how the analyses need to be done. Assuming the commercially available testing methods, the following data applies:

<table>
<thead>
<tr>
<th>Detection methods</th>
<th>CO$_2$</th>
<th>CO</th>
<th>H$_2$O</th>
<th>Oil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual</td>
<td>Detector tube</td>
<td>Detector tube</td>
<td>Detector tube</td>
<td>Detector tube</td>
</tr>
<tr>
<td>Electronic</td>
<td>Infrared sensor</td>
<td>Electro-chemical sensor</td>
<td>Dew-point meter</td>
<td>Gravimetry</td>
</tr>
<tr>
<td>Accuracy</td>
<td>± 15%</td>
<td>±15%</td>
<td>±20%</td>
<td>N/A$^a$</td>
</tr>
<tr>
<td></td>
<td>±2%</td>
<td>±5%</td>
<td>±0.2°C</td>
<td>±0.2%$^b$</td>
</tr>
<tr>
<td>Lowest detection</td>
<td>100 ppm$_v$</td>
<td>5 ppm$_v$</td>
<td>5 mg/m$^3$</td>
<td>0.1 mg/m$^3$</td>
</tr>
<tr>
<td>Limit</td>
<td>50 ppm$_v$</td>
<td>0 ppm$_v$</td>
<td>$&lt; 10$ ppm$_v$$^c$</td>
<td>0.01 mg/m$^3$$^b$</td>
</tr>
</tbody>
</table>

Table 3: Practical methods for air analysis

Notes to Table 3:
- The lower values apply to the most commonly used method, i.e. the detector tube, while higher values are achieved using electronic (sensor-based) or laboratory-based instruments.
  - a Oil-detection by detector tube or equivalent provides a simple pass or fail outcome only.
  - b On-line oil detection requires highly sophisticated equipment, impractical to use in air-production plant. Gravimetric analysis in a testing laboratory provides greater accuracy for oil contaminant detection, but is not an on-line or real-time method.
  - c The limits of detection expressed in ppm, for a dew point meter reduces with temperature. The value shown is a rough indication that applies at the typical dew point temperatures that are required.

While there are a range of other toxic and debilitating compounds that have been detected in breathing air, it would be deemed impractical to demand analysis except where a risk assessment clearly shows that this is a likely hazard in a specific location or situation.

Theoretical concerns about microbiological or ‘organic compound’ contamination have been raised by concerned practitioners. In general, breathing gas supplied to a hyperbaric environment should be “unexposed” to human or animal environments, apart from any exposure prior to compression. In addition, compressed gases have pO$_2$ values that are toxic to most known pathogens. Microbiological contamination is thus unlikely in terms of ‘unused’ air. Organic compounds should be assessed by risk analysis and if a hazardous situation is likely to exist, there are analytical instruments commercially available to provide monitoring for these compounds.

3.3.2. Quantity assessment

Appropriate means to assess the quantity of air required will be covered in the Discussion, section 4.2. As a general principle, the philosophy of “what is expected” and “what is likely” should be based on assessments of normal and emergency conditions or situations.
This has been the approach taken by the international maritime classification societies that need to accommodate situations that possibly contain even greater opportunities for mishaps when compared to a building on land, supplied by services that are generally always available.

The presiding reason for requiring a minimum specification should not be one of convenience or preference, but for a genuine emergency situation. One such example might be an injured diver requiring recompression therapy; another might be a critically-ill patient requiring immediate hyperbaric oxygen therapy; both presenting during a power outage. These two examples reveal that the worst case is thus not likely to be one of maximum occupancy at maximum pressure, except for a smaller hyperbaric chamber and in this case, the gas requirements are generally less. A realistic approach is needed.

### 3.4. Synopsis

A range of options and approaches has developed over the past 50 or more years, systematically tempered through scientific advances, practical assessments and regulatory efforts.

It is an opportune time to review the standards based on improvements in compression and filtration techniques, advances and improved availability of analytical instruments, but also considering the extended history where incidents and accidents have been examined and assessed.

*Air quality* has traditionally been sub-divided into two distinct camps, viz. (1) air used to pressurise the hyperbaric environment, which has been heavily influenced by the diving industry, but also by the limiting practicalities of dedicated air compression plants; and (2) air provided to chamber occupants, primarily for therapeutic purposes.

The *quantity* of air required to ensure a safe and effective treatment is a product of the size and occupancy of the chamber, the pressure and duration of the intended treatment, and the accepted limits, in terms of contaminants such as CO\textsubscript{2} or excessive oxygen levels, that are introduced inside the hyperbaric environment. The changes over the past decades to offer larger therapeutic chambers, albeit at lower pressures, have perhaps moved the focus to considering ventilation rates on a per occupant basis. Guidelines for these computational variables would be of use to system designers, users and safety personnel.

The issue of suitable quality of air inside the chamber, apart from being an indication of the need to ventilate, is not considered a part of this discussion, and existing general limits for clinical facilities, viz. CO\textsubscript{2} < 5000 ppm, and O\textsubscript{2} < 23.5%, remain as the accepted norms for this industry.

### 4. Discussion

While there is a cross-over between quality and quantity of air, the focus here is on unused air to be introduced into the chamber either for pressurisation and ventilation, or as an individual, therapeutic (or emergency) breathing gas.

The two subjects are thus discussed separately.
4.1. Quality of air

4.1.1. General

The three primary reasons for considering the assessment of air quality in clinical hyperbaric applications, listed in a normally accepted order of concern, include: (1) the risk to human health, (2) the risk of fire, and (3) the risk of equipment failure.

Contaminants can be divided into three levels that represent the likelihood of occurrence, namely: (1) those most commonly found in compressed air (CO₂, CO, H₂O, condensed oil, particles and odour), (2) those found in certain operational areas (volatile hydrocarbons and organic compounds, such as CH₄) and (3) relatively rare but reported toxic substances (for example vapours from cleaning products and halogenated solvents, emissions from motor vehicles, SO₂ and NOₓ fumes).

The production process for compressed air can only introduce oil (vapourised or condensed), particulates, and some amounts of CO₂ and CO. All the other contaminants, including larger amounts of CO₂ and CO, must be available in the environment in order to be present in the final product.

As a general rule, occupational health practices require that we analyse environmental conditions in the vicinity where we are aware of potential hazards. Compressors used to produce air for chamber compression or for breathing air will require a thorough risk analysis prior to selection and purchase. Installation of the compressors, the compressed air lines, and all interface connections will require compliance with the applicable codes and standards governing the installation of gas systems. Site selection of the compressors’ intake should also receive a careful risk analysis with consideration given to weather conditions, potential local toxic fumes and exhaust from buildings or internal combustion engines.

Lubricating oils for breathing air compressors are selected on the basis of their high temperature stability, inertness and acceptability to human exposure.

It remains an accepted fact that we do not monitor or analyse the air that we breathe unless we are have reason to be concerned.

These considerations are mentioned to provide a degree of pragmatism in any debate on the quality of air produced for hyperbaric facilities. In the ideal world, where all the correct selection criteria are applied, and where a thorough risk analysis is made of the operating area, these requirements for analysis and quality control could be reduced by design. Additionally, planned sampling could be limited to where changes or maintenance activities are known to have taken place.

However, the reality is that exposures to contaminants in compressed air have occurred due to a loss of controls, external influences and incidents, and where equipment has been neglected.

Finally, while it is possible to provide a consensus and even mandate of maximum exposure limits for all potential hazardous contaminants, the practicalities of on-line, real-time analysis, affordable measuring instruments, and the accuracy achievable in the field, have in the end a large determining influence on what can and should be required.

A discussion on air quality to derive safe, realistic, achievable and sustainable standards therefore needs to be done in the context of the imperfect world, but with a sensible dose of realism.
### 4.1.2. Main contaminants & detection

#### Group 1: Contaminants always potentially present in compressed air

<table>
<thead>
<tr>
<th>Compound:</th>
<th>Carbon dioxide (CO(_2))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sources:</td>
<td>Ambient environment, internal combustion and cooking processes, human and animal respiration, microbial breakdown of organic matter, conversion of CO to CO(_2) in compressor filters and in motor vehicle exhaust systems.</td>
</tr>
<tr>
<td>Human safety:</td>
<td>Elevated levels stimulate respiratory centre, increasing rate of breathing; increase in depth increases respiratory risk; patients with high PaO(_2) are at greater risk of oxygen-induced seizures with elevated PaCO(_2); elevated levels lead to minor perceptive changes, discomfort, dizziness or stupor and finally to unconsciousness and even death.</td>
</tr>
<tr>
<td>Fire safety:</td>
<td>No concerns</td>
</tr>
<tr>
<td>Equipment:</td>
<td>No concerns</td>
</tr>
<tr>
<td>Detection methods:</td>
<td>Field detection through detector tube or on-line infra-red sensor. Laboratory measurement using GC-M-FID(^1).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound:</th>
<th>Carbon monoxide (CO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sources:</td>
<td>Ambient environment, internal combustion processes, furnaces, gas burners, cigarette smoke or overheated compressor oils.</td>
</tr>
<tr>
<td>Human safety:</td>
<td>Decreases the carrying capacity of hemoglobin resulting in a decreased amount of oxygen available to the tissues leading to hypoxia. A highly toxic contaminant with environmental levels magnified by increased chamber pressure.</td>
</tr>
<tr>
<td>Fire safety:</td>
<td>No concerns</td>
</tr>
<tr>
<td>Equipment:</td>
<td>No concerns</td>
</tr>
<tr>
<td>Detection:</td>
<td>Field detection through detector tube or on-line electrochemical sensor cell. Laboratory detection using GC-M-FID(^1).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound:</th>
<th>Moisture (H(_2)O)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sources:</td>
<td>Ambient environment (humidity), drying process (laundry), some combustion and other processes.</td>
</tr>
<tr>
<td>Human safety:</td>
<td>Elevated levels of moisture are desirable (comfort &amp; reduced dehydration), whereas dry air inhibits growth of bacteria.</td>
</tr>
<tr>
<td>Fire safety:</td>
<td>Very dry conditions enhance production of static electricity.</td>
</tr>
<tr>
<td>Equipment:</td>
<td>Excessive moisture may cause regulators to freeze as adiabatic cooling takes place during pressure reduction. Regulators may fail open, causing downstream over-pressurisation of piping and equipment. Excessive moisture enhances corrosion and oxidation (rust) of air storage vessels. Excessive moisture causes filtration elements &amp; chemicals to saturate, resulting in reduced filtration efficiency and effectiveness, as well as elevated pressure drops. Excessive moisture can interact with some ultra-fine carbon filtration units generating strong chemical odours and resulting in nausea and respiratory irritation.</td>
</tr>
<tr>
<td>Detection:</td>
<td>Field detection through detector tube or dew point meter (electronic hygrometer). Laboratory detection using GC-MS(^2).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound:</th>
<th>Oil (condensed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sources:</td>
<td>Mostly compressor lubricating oil (introduced internally); but also: ambient evaporated oil from compressor oil leaks &amp; surrounding equipment, motor vehicle exhaust fumes, pollens (introduced through the compressor intake) and even contaminated air pipes between the air processing plant and the chamber.</td>
</tr>
<tr>
<td>Human safety:</td>
<td>Larger condensed particles removed by body’s clearance mechanisms; smaller particles are retained and may be hazardous depending on type and amount (symptoms include inflammation or even rupturing of alveoli)(^28).</td>
</tr>
<tr>
<td>Fire safety:</td>
<td>Significant fire concerns, irrespective of type of condensed oil.</td>
</tr>
<tr>
<td>Equipment:</td>
<td>No concerns at the levels usually controlled for. The maximum level of 5 mg/m(^3) equates to a dew point temperature of -64°C, or 6 ppm(_v); significantly lower than the lowest required levels for H(_2)O.</td>
</tr>
<tr>
<td>Detection:</td>
<td>Field detection through detector tube (Impactor(^3)).</td>
</tr>
</tbody>
</table>
### Laboratory detection using gravimetric analysis or GC-MS².

<table>
<thead>
<tr>
<th>Compound:</th>
<th>Particles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sources:</td>
<td>Ambient environment (micro-particles of dust &amp; pollens); breakdown products in compressors, piping systems &amp; filtration media; as well as post-construction debris in pipes and controls.</td>
</tr>
<tr>
<td>Human safety:</td>
<td>Particles smaller than 10 µm have the potential to cause shortness of breath, especially in patients with respiratory conditions (e.g. asthma &amp; bronchitis), as well as a reduction in the ability to resist infection.</td>
</tr>
<tr>
<td>Fire safety:</td>
<td>Large concentrations of particulates can serve as a source of ignitable fuel.</td>
</tr>
<tr>
<td>Equipment:</td>
<td>Larger particles are known causes of failures in pressure regulators, may cause valves not to seal when closed, and may erode valve seats, discs and seals.</td>
</tr>
<tr>
<td>Detection:</td>
<td>Field detection is not a practical option; however, filtration is highly effective where properly sized and located. Laboratory detection using gravimetric analysis. Particle size assessed using microscopy.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound:</th>
<th>Odour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sources:</td>
<td>Ambient environment and cleaning compounds used on air supply systems.</td>
</tr>
<tr>
<td>Human safety:</td>
<td>Generally related to comfort levels only. Odours from volatile, toxic or otherwise harmful substances indicate potential safety issues related to these contaminants.</td>
</tr>
<tr>
<td>Fire safety:</td>
<td>No concerns from odour. Contaminants with fire risks (oils, VOC, etc.) are discussed under the relevant contaminant sections.</td>
</tr>
<tr>
<td>Equipment:</td>
<td>No concerns</td>
</tr>
<tr>
<td>Detection:</td>
<td>Field detection – subjectively through the human sense of smell. Laboratory detection for odours using an olfactometer. Identified odours measured using GC-MS².</td>
</tr>
</tbody>
</table>

### Notes:

1. GC-M-FID: Gas Chromatography - Methaniser - Flame Ionization Detection
2. GC-MS: Gas Chromatography - Mass Spectrometry
3. Impactor is a Dräger Safety product enabling field detection of all oil types with reproducible results expressed in the ranges: <0.1 mg/m³, 0.1 to 0.5 mg/m³ and >1.0 mg/m³.

### Group 2: Contaminants present in specific areas

This group may be significantly larger than discussed here, but the following analysis serves to indicate where potential hazards may exist for clinical hyperbaric facilities.

Volatile hydrocarbons include organic compounds. However, methane is the most commonly occurring of these compounds and is separated from the analysis.

Some standards require that all hydrocarbons be grouped as a total hydrocarbon (THC) limit. This does not allow for easy identification of potential sources.

<table>
<thead>
<tr>
<th>Contaminant:</th>
<th>Volatile hydrocarbons and Volatile Organic Compounds (VOC) – include but are not limited to toluene, xylene, benzene, ethane, styrene and acetone.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sources:</td>
<td>Ambient environment as a result of exposure to building materials, plastic materials, industrial chemicals &amp; cleaning compounds, adhesives, furniture, flooring, heating &amp; combustion processes. Overheating compressors reported as a potential source.</td>
</tr>
<tr>
<td>Human safety:</td>
<td>Generally hazardous in terms of carcinogens, neurological &amp; narcotic effects, organ damage &amp; general distress. Initial symptoms include fatigue, headaches, confusion, numbness, cardiac irritation &amp; depression.</td>
</tr>
<tr>
<td>Fire safety:</td>
<td>Significant fire concerns in terms of low ignition temperature and low flashpoint fuels.</td>
</tr>
<tr>
<td>Equipment:</td>
<td>No significant concerns at the expected levels.</td>
</tr>
<tr>
<td>Detection:</td>
<td>Field detection – odour usually detected through the human sense of smell. Identified compounds measured using detector tubes or GC-MS¹.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound:</th>
<th>Methane (CH₄)</th>
</tr>
</thead>
</table>
| Sources:     | Ambient environment, especially prominent in certain geological areas as well as near decaying or fermenting organic matter, landfills, or domestic animals (cattle). CH₄ may permeate buildings and
enter the compressor intake.

| Human safety: | Not toxic (may be an asphyxiant where oxygen is reduced to below 16%) |
| Fire safety: | Significant fire concerns with \( \text{CH}_4 \) being a highly flammable fuel. |
| Equipment: | No concerns |
| Detection: | Field detection through detector tube or on-line using infra-red sensors. Laboratory detection using GC-M-FID\(^2\). |

Notes:
1 GC-MS: Gas Chromatography - Mass Spectrometry
2 GC-M-FID: Gas Chromatography - Methaniser - Flame Ionization Detection

**Group 3: Rare but reported contaminants**

This group is too diverse and extensive to discuss in a similar fashion to the previous two groups.

Typical contaminants include vapours from cleaning products or solvents not covered under Group 2 above, as well as environmental compounds including hydrogen sulphide (\( \text{H}_2\text{S} \)), \( \text{SO}_2 \), \( \text{NO}_x \), \( \text{NO}_2 \), \( \text{NO}_x \) fumes, ozone, lead compounds, asbestos and many others.

Each of these has specific deleterious effects on humans, but no significant fire or equipment issues – at least not in the concentrations expected in the air.

Nitrogen oxide products, loosely referred to as NOx, are associated with decreases in lung function, increased severity of respiratory problems, chronic inflammation and irreversible structural changes, amongst other related respiratory conditions and complications.

Most occupational health and safety regulations for any public enterprise provide regulations, limits and guidelines for identification and exclusion.

In terms of this discussion, we will exclude several of these from the requirements for acceptable air quality and accept that they will be controlled by occupation hazard identification and risk assessment (HIRA) practices.

**4.1.3. Practical limits**

The following limits have been extracted from the literature based on the effect on human physiology, fire risks and risks to equipment.

Consistent units of measure have been used throughout the table as far as possible for easy of reading, but are not necessarily the units used by some measurement devices.

All human exposure limits are expressed as the surface equivalent value (SEV) and for the purposes of a discussion in clinical hyperbaric facilities, a maximum pressure of 6 ATA is assumed. Limits tabulated are generally stated as the “no-effect level”, that is the dose with no known toxic or debilitating effects.

The exact conditions under which air quality analysis should be done are not discussed, but from a practical perspective, any analysis should be done such that the worst case can be detected. This will ensure that the actual air delivery conditions to the chamber, occupants or sensitive equipment are likely to be less severe.
### Table 4: Contaminant safe limits

<table>
<thead>
<tr>
<th>Contaminant</th>
<th>Human exposure</th>
<th>Fire risk</th>
<th>Equipment risk</th>
<th>Detection limit ¹</th>
<th>Achievable limit ²</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO₂</td>
<td>5000 ppm, for pO₂ ≥ 3 ATA 15000 ppm, for pO₂ ≤ 1.6 ATA</td>
<td>Nil</td>
<td>Nil</td>
<td>100 ppm,</td>
<td>&lt; 350 ppm, Normal air contains ≤ 30 ppm,</td>
</tr>
<tr>
<td>CO</td>
<td>60 ppm, ³</td>
<td>Nil</td>
<td>Nil</td>
<td>1 ppm,</td>
<td>≤ 5 ppm,</td>
</tr>
<tr>
<td>H₂O</td>
<td>RH ²: ≤ 50% – 60% Based on control of bacterial growth RH &gt; 30% Dew point &gt; 3ºC HP: Lowest ambient less 44ºC LP: Lowest ambient less 6ºC Dew point -64ºC based on 5 mg/m³</td>
<td>Nil</td>
<td>Nil</td>
<td>0.1 mg/m³</td>
<td>≤ 0.5 ⁴ mg/m³</td>
</tr>
<tr>
<td>Oil</td>
<td>≤ 5 mg/m³</td>
<td>≤ 0.1 mg/m³</td>
<td>None at ≤ 5 mg/m³</td>
<td>0.1 mg/m³</td>
<td>≤ 0.5 ⁴ mg/m³</td>
</tr>
<tr>
<td>Particles</td>
<td>≤ 50 mg/m³</td>
<td>≤ 5 mg/m³</td>
<td>None at ≤ 5 mg/m³</td>
<td>0.01 mg</td>
<td>0.5 mg/m³ for particles &gt; 5 µm</td>
</tr>
<tr>
<td>Odour</td>
<td>None</td>
<td>None detected</td>
<td>Nil</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>VOC</td>
<td>≤ 5 ppm, Limit 1000 ppm,</td>
<td>LEL ⁵ ≤ 1 %</td>
<td>Nil</td>
<td>5 ppm,</td>
<td>≤ 5 ppm,</td>
</tr>
<tr>
<td>CH₄</td>
<td>≤ 5% (5x10⁴ ppm,)</td>
<td>LEL ⁵ ≤ 5 %</td>
<td>Nil</td>
<td>10 ppm,</td>
<td>≤ 25 ppm,</td>
</tr>
<tr>
<td>H₂S</td>
<td>≤ 50 ppm,</td>
<td>Nil</td>
<td>&gt;&gt; Human limit</td>
<td>1 ppm,</td>
<td>≤ 1 ppm,</td>
</tr>
<tr>
<td>SO₂</td>
<td>≤ 5 ppm,</td>
<td>Nil</td>
<td>Nil</td>
<td>1 ppm,</td>
<td>≤ 1 ppm,</td>
</tr>
<tr>
<td>NO₃ ⁷</td>
<td>≤ 10 ppmv</td>
<td>Nil</td>
<td>Nil</td>
<td>0.5 ppm,</td>
<td>≤ 2 ppm,</td>
</tr>
</tbody>
</table>

Notes to Table 4:

1. Limit applicable to what can be detected in the field – using detector tubes or basic on-line analysers.
2. Limit that can be realistically achieved based on current filtration, catalytic and elimination methods.
3. A SEV value of 60 ppm, at 6 ATA arises from a value of 10 ppm, at 1 ATA.
4. RH: Relative humidity at normal temperature and pressure (20ºC and 101.325 kPa).
5. Some equipment suppliers state the limit contained in EN 12021 ref. [1]. Using available and economically viable equipment, a limit of ≤ 0.1 mg/m³ is realistically achievable.
6. LEL: Lower explosive limit – fire codes usually recommend a limit of ≤ 10% of LEL. 10% of 1% LEL = 0.1% or 1000 ppm,.
7. NO₃ represents all nitrogen oxide compounds.

### 4.2. Quantity of air

#### 4.2.1. General

The primary criteria in determining a suitable quantity of air for the safe and effective treatment of clinical patients have been previously stated as (1) the size and occupancy of the chamber, (2) the pressure and duration of the intended treatment, and (3) the accepted limits in terms of contaminants introduced inside the hyperbaric environment (being primarily CO₂ and excessive O₂ levels).

The requirement for redundancy, due to the critical nature of some treatments, implies that this quantity of air shall be available with due regard to likely equipment failure, power failure or operator error.

Table 2 provides a summary of the air capacity requirements as stated in a variety of reference documents. This discussion will endeavour to provide some rationale behind the process to determine a suitable quantity of
air, based on actual requirements and the likely operational or clinical situations. This applies to both multipurpose and air-driven monoplace chambers.

4.2.2. Criteria for determining air capacity

The actual amount of air used during a treatment is the sum of the air required to:

1. pressurize the chamber to treatment pressure, plus
2. transfer staff, equipment and consumable products into the chamber, plus
3. ventilate the chamber during the treatment in order to condition the environment (reduce excess O₂ from equipment leakage, replenish consumed O₂, remove CO₂ build-up, cool-down and dehumidify the interior, and remove odours).

The first two parts of the computation are determined by chamber size and treatment pressure. The only relatively unknown factor is how many transfers under pressure (TUP) may be required.

Ventilation is more difficult to determine, as this is based on environmental conditions, actual occupancy, chamber type, equipment condition and fit, patient behaviour, potential dynamics of patients and tenders, and significantly, the type of treatment being provided.

In an ideal world, the chamber environment would be monitored for all possible situations of contamination or shortfall, equipment would not fail, power would always be maintained, and operators would not make errors. This would ensure that the lowest air capacity is required. The reality is not quite this simple, but any risk assessment would indicate that the converse is in fact a reality.

A logical approach would thus be a combination of decisions as to the most likely requirements, which would need to be critically re-evaluated in the event of an emergency, together with a realistic assessment of ventilation needs based on a scientific analysis.

4.2.3. Air requirements

The following table indicates the air requirements, expressed as an operation rather than a value, and based on current regulated practices, together with a theoretical approach.

<table>
<thead>
<tr>
<th>Computation</th>
<th>Low regulation</th>
<th>High regulation</th>
<th>Scientific assumption</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Pressurisation</td>
<td>Tx chamber vol. x Tx pressure</td>
<td>1 Tx duration</td>
<td>1 Tx duration</td>
</tr>
<tr>
<td>(2) TUP</td>
<td>TUP vol. x Tx pressure</td>
<td>Not stated</td>
<td>2 TUP excursions</td>
</tr>
<tr>
<td>(3) Ventilation</td>
<td>No. occupants x stated alpm x Tx pressure x Tx time</td>
<td>30 alpm per person for 150 minutes, or adjusted through monitoring of CO₂ &amp; O₂ levels.</td>
<td>2 alpm per patient + 4 alpm per tender for longest Tx duration.</td>
</tr>
</tbody>
</table>

Table 5: Air capacity requirements for clinical treatments

Notes to Table 5:

(1) Chamber volume (vol.) is the actual rated dimensional volume of a chamber, determined by computation or as stated by the manufacturer.

(2) Treatment (Tx) pressure is the actual Tx pressure in absolute atmospheres (ATA) as required by the Tx protocol selected, but taken as the maximum pressure defined by the scope of services. If a 6 ATA Tx is offered in accordance with ref. [15] as a table 6A, then this pressure must be assumed in the worst case scenario planning.

(3) TUP volume requires both locks used for transferring personnel as well as equipment or products to be used, and is the sum of the actual rated dimensional volumes as computed, or as stated by the manufacturer.
Ventilation capacity is computed as aclm x Tx pressure x numbers of occupants x total Tx duration in minutes. The Tx duration shall be the maximum duration offered under the scope of services.

4.2.3. Risk assessment

In most cases, the requirements from the above table should be provided by both the primary as well as the secondary air supply systems.

This requires any low pressure compression packages to be capable of providing an achievable flow rate to pressurise both the treatment lock(s) and the TUP locks to the required pressure in a suitable time. Low pressure compression packages are not generally expected to provide excessive volumes of stored gases, implying that the required capacity is expressed simply in terms of a flow rate (in normal lpm or normal m³/min).

High pressure compression packages general rely on a lower output flow rate and used to fill high pressure storage cylinders. In this case, the total volume of air required needs to be computed in terms of the amount of air (typically in m³) at NTP, and size and number of cylinders determined by this total volume requirement.

The actual risks envisaged in terms of air capacity are that the system is unable to continue with a treatment due to power failure, equipment failure or operator error.

Hospitals generally have electrical generator back-up systems, whereas free-standing facilities are not always expected to have this level of redundancy.

Secondary low pressure air supply systems are required to compensate for equipment failure, although careful attention is also required to ensure that piping and regulating systems have suitable redundancy and by-pass systems built-in.

Operator error should be mitigated through training, specifically for the management of fault or emergency situations.

The situation requiring a degree of consideration is the actual capability of the secondary or back-up system. This may be realistically considered as follows:

1. Where services are offered on a 24 hours per day, 7 days per week basis, and providing for emergency treatments, then the secondary system shall be capable of providing a full treatment as defined by the scope of services. This implies that any emergency treatment can be provided and concluded at all times, even in the event of equipment or power failures. (This would include the ability to commit to any emergency treatment where significant decompression times are part of the treatment profile.)

2. Where clinical treatments do not involve significant decompression times, such as for out-patients, non-emergency patients, non-diving patients or during working-hours, then treatments can be safely stopped at any stage, and the required capacity need only be determined by (a) the acceptable rate of pressurization, and (b) the flow rate required to ensure safe, effective ventilation and Tx termination.

4.2.4. Scientifically determined air exchange requirements

Ref. [18] provides an evaluation for underwater habitats based on several factors, such as the likely O₂ consumption of individuals, CO₂ production, mixing within the environment and acceptable SEV values.
This is expressed in the formula: \( Q_{\text{gas}} \text{ (scfm)} = (P_{\text{TX}} \text{ (ATA)} \times Q_{\text{O2}} \text{ (scfm)} \times \text{RQ} \times F) \div (26.3 \times \text{pCO}_2) \)

Where: 
- \( Q_{\text{gas}} \): the required ventilation flow rate in scfm 
- \( P_{\text{TX}} \): the treatment pressure in ATA 
- \( Q_{\text{O2}} \): the consumed oxygen, per person, in scfm 
- \( \text{RQ} \): the respiratory quotient (ratio of the rates of CO\(_2\) generation to O\(_2\) consumption) used to compensate for the required rate of CO\(_2\) elimination and generally accepted as 0.85 for underwater habitats [18]. 
- \( F \): the mixing factor, generally accepted as 1 for well-designed (complete) mixing in the chamber. 
- 26.3: the conversion factor: slpm (metric, 0°C) to scfm (imperial, 15.6°C). (1 scfm equates to 26.3 slpm). 
- \( \text{pCO}_2 \): the difference between the maximum allowed limit (in ATA) and the expected input value (usually 280 ppm, or 0.00028 ATA).

Substituting the values above provides a required ventilation flow rate of 64 actual slpm per person, determined at treatment pressure and limiting \( \text{pCO}_2 \) to less than 5000 ppm.

### 5. Proposal

Based on the limited but focused literature survey, a discussion of limits in terms of what can be achieved in practice, and applying a clinical hyperbaric-specific risk assessment, the following two proposals are submitted:

### 5.1. Air quality requirements for clinical hyperbaric facilities

| Group 1: Contaminants always potentially present should be limited to: |  |
|-------------------|-------------------|-------------------|-------------------|-------------------|
| CO\(_2\) | Compressed air, Hyperbaric chamber | 1000 ppm, 0.5% SEV (5000 ppm, at 1 ATA) |  |
| CO | Compressed air | 5 ppm, |  |
| H\(_2\)O | Compressed air, Hyperbaric chamber | Stored at 40 - 200 bar: 50 mg/m\(^3\) (62 ppmv) Stored above 200 bar: 35 mg/m\(^3\) (44 ppmv) Supplied to cylinders: 25 mg/m\(^3\) (31 ppmv) | RH: Ideally maintained at 50% – 60% |  |
| Oil | Pressurisation air, Breathing air | 0.5 mg/m\(^3\) 0.1 mg/m\(^3\) |  |
| Particles | Compressed air | 0.5 mg/m\(^3\) for particles > 5 \(\mu\)m |  |
| Odour | Compressed air | None |  |

| Group 2: Contaminants present in specific areas should be limited to: |  |
|-------------------|-------------------|-------------------|-------------------|-------------------|
| VOC | Compressed air, Hyperbaric chamber | ≤ 5 ppm, LEL ≤ 0.1% (1000 ppmv) |  |
| CH\(_4\) | Compressed air, Hyperbaric chamber | ≤ 25 ppmv, LEL ≤ 0.5% (5000 ppmv) |  |

| Group 3: Rare but reported contaminants should be limited to: |  |
|-------------------|-------------------|-------------------|-------------------|-------------------|
| H\(_2\)S | Compressed air | ≤ 1 ppmv |  |
| SO\(_2\) | Compressed air | ≤ 1 ppmv |  |
| NO\(_3\) | Compressed air | ≤ 2 ppmv |  |

Table 6: Proposed Contaminant Limits for Compressed Air

Notes to Table 6:

1. These contaminants should be monitored regularly (every 3 months) by means of either on-site or laboratory analysis.
2. It is deemed preferable that all air meet the higher limit of 0.1 mg/m\(^3\).
A HIRA survey should be used to determine the likelihood of any of these or other potentially toxic elements being present in the environment during the air compression process.

5.2. Air capacity requirements for clinical hyperbaric facilities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Available 24/7 for emergency cases, including diving accidents:</th>
<th>Outpatient, non-emergency &amp; no diving patients with suspected AGE:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Primary</td>
<td>Secondary</td>
</tr>
<tr>
<td>Pressurisation</td>
<td>1 excursion to maximum Tx pressure</td>
<td>1 excursion to maximum Tx pressure</td>
</tr>
<tr>
<td></td>
<td>1 excursion to maximum Tx pressure</td>
<td>1 excursion to maximum Tx pressure</td>
</tr>
<tr>
<td></td>
<td>1 excursion to maximum Tx pressure</td>
<td>Nil</td>
</tr>
<tr>
<td>Lock transfer (TUP)</td>
<td>2 TUP to maximum Tx pressure</td>
<td>1 TUP to maximum Tx pressure</td>
</tr>
<tr>
<td></td>
<td>1 TUP to maximum Tx pressure</td>
<td>2 TUP to maximum Tx pressure</td>
</tr>
<tr>
<td></td>
<td>1 TUP to maximum Tx pressure</td>
<td>Nil</td>
</tr>
<tr>
<td>Ventilation¹</td>
<td>64 alpm per person for longest Tx duration.</td>
<td>64 alpm per person for longest Tx duration.</td>
</tr>
<tr>
<td></td>
<td>64 alpm per person for longest Tx duration.</td>
<td>64 alpm per person for longest Tx duration.</td>
</tr>
<tr>
<td></td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>

Table 7: Proposed Air Capacity Requirements for Hyperbaric Facilities

1 Actual ventilation rate, or the amount of stored air to ensure venting, may be reduced through on-line CO₂ & O₂ monitoring.

Where the air supply for the primary chamber system is provided from stored gas banks (typically using 200 or 300 bar, 50 litre cylinders), it is not suggested that the air supply system requires dual redundancy in terms of available air.

Only one total air volume to provide a full, emergency treatment is required. A risk assessment should be performed to determine the actual, worst case scenario (treatment duration, pressure and number of occupants) and the total air volume requirement determined from this.

6. Concluding remarks

The information presented in this paper has been extracted from available literature and combined with personal experiences in this industry. Medical effects stated are as presented in the scientific media and have not been based on any current human-based research.

It is not considered practical to base contaminant limits (or associated gas analysis), or capacity requirements only on incidents or accidents, unless these can be shown to occur with significant frequency. In some cases, the lack of reported accidents should not allow for the removal of, or reduction in a specific limit. Basic risk theory, where the actual risk is the product of the severity, the likelihood and the frequency of an accident, is a more suitable means of considering adjustment or even removal.

In specific regions, where local or other mandated regulations apply, these should always take precedence. It is likely that these are based on actual environmental conditions. Where the limits and requirements proposed exceed these, then it would be considered prudent to adopt the stricter levels.

In each and every case, there remains a place for specific risk assessments to be performed in order to accommodate individual and unique operational situations or requirements.
7. References & Relevant Literature

7.1. References


7.2. Relevant literature


(12) Safety and fire fighting system

Roly Gough-Allen (UK)
Operations, Training, Safety & Quality Manager
Hyperbaric Health 119-123, Woodlands Drive, Braeside, Victoria 3195, Australia

Introduction

This account details an overview of some International English written hyperbaric specific Standards, Norms, Guides and Codes of Practice and is a summary of the issues most likely to cause concern.

In an ideal hyperbaric world there would be one set of standards in one language and one system of measurement. In reality, there are many papers of relevance to the general well being for a safe hyperbaric workplace. However, the following eight documents concentrate on actual hyperbaric safety and especially fire safety.

Europe has three fairly recent publications, which have all been published since 2004 and cover this topic well for clinical multi-place chambers. The UK also has several well-respected British Hyperbaric Association (BHA) documents and the USA has many excellent UHMS & NFPA publications. NFPA & UMHS publications have been updated regularly and the last edition of NFPA 99 was published in 2012. In Australia and New Zealand two publications are often quoted when addressing clinical hyperbaric facilities.

1. ECHM - A European code of good practice for hyperbaric oxygen therapy (May 2004)
2. EN14931 Pressure vessels for human occupancy (PVHO) – Multi-place pressure chamber systems for hyperbaric therapy – Performance, safety requirements and testing. (Jan 2006)
3. EN16081 hyperbaric chambers – Specific requirements for fire extinguishing systems – Performance, installation and testing. (March 2010)
Common standards & accreditation

It is important to agree on what makes a good design for a new hyperbaric facility, a new multi-place chamber, its optimum location and what training is needed for all the team.

A new facility may need to be fitted out with new approved safe tested hyperbaric equipment that complies with the new Norms and Standards. A third party group of accreditors may need to inspect the chamber to give the whole establishment a seal of approval and award an accreditation certificate to enable medical treatment to commence. All of this requires a good quality multi-skilled team to work towards and maintain high standards. However, this in turn increases the cost of delivering the service and raises concerns that the bar may be too high for smaller facilities in under developed countries to afford to offer basic, safe hyperbaric care. What is good in one country may not work in another. There are considerations like costs and attitude to health and safety to consider. Keep it simple, safe and cheaper may be the best approach. Flexibility is needed to allow facilities to demonstrate they are safe. Accreditation needs to be helpful with guidance and not over enforcement. Standards & Regulations can be too strong; guidance, codes and Quality Assurance may be a better alternative.

Consider the KISS principle (“Keep It Short & Simple”) or even maybe substitute an “S” for Stupid or Straight but the meaning remains much the same.) We often find “experts” write such a lot in more words than necessary and make those words more complicated and difficult to understand, and that’s assuming the words in the first place are even in their own first languages.

Many countries refer to the NFPA publications when needing guidance on a huge range of technical safety issues. In this account we will only consider from USA the NFPA 99 chapter 14 hyperbaric facilities, against other international publications for Europe, UK, Australia and New Zealand. In Australia and New Zealand two publications are often quoted when addressing clinical hyperbaric facilities however AS/NZS 2299.1 2007 states within its text under the heading “1.3 Application, Notes”. “Work in pressurized atmospheres in tunnels or caissons or in hyperbaric treatment facilities in hospitals are not covered by this Standard.” There is however some useful information in AS2299.1 on gauge accuracy and breathing gas quality, which we will consider later. The other important point is that AS/NZS 2299.1) is an approved standard in both Australia and New Zealand unlike AS 4774.2, which is only an Australian Standard.

Table 1 at the end this document is a brief summary and comparison of some of the important safety issues found in: the European Norms 16081 & 14931, NFPA 99 chapter 14, BHA guides & codes and AS4774.2. The reader must realise that there are many other documents, which cover the material and so further research, and comparisons can be continued. For example just because a column does not appear to cover an issue does not mean that there is not another document from that region that might give more information. NFPA and UHMS both produce many documents too numerous to summarize in this text.

Hyperbaric facilities need staff that will ask questions, think for themselves quickly and appropriately and react when needed. So much in our world is routine and can easily become boring to the point that “does it matter or that will do, or that is good enough” becomes the norm.

A major concern is that; can we all afford the level of health care we are now prescribing/requesting or will just a little pressure and a little 02 suffice?

Maybe we need less bureaucracy, more common sense and good self-discipline to do our jobs well and to a high standard.
Consider a scenario a technician/trainer finds themselves in; The Technician has just finished a 12 month service and training visit to a remote recompression chamber site. The equipment all works well, but the staff showed very little interest, have other full time jobs, not enthusiastic to learn, had trouble understanding the important issues and lacked management support. Would you allow your child to be sent to that remote facility for the treatment of DCI without hesitation? Maybe if you are in doubt then perhaps that technicians work there remains unfinished and they need to stay longer and try to force some change before they can depart for home.

Years ago there was a huge surge in interest in hyperbaric accreditation in Europe and USA, while small countries were still struggling to even offer safe basic hyperbaric care. We may need to reconsider some accreditation schemes and perhaps go back a few steps and remember we need to keep it simple and safe. At some sites just trying to clean BIBS effectively is incredibly difficult and would not stand up to scrutiny in the western world.

Hospital Accreditation schemes and Medicare (Australian Health funding scheme) all require extensive auditing, which is expensive and time consuming and then if we add to that other overlapping accreditation or regulation schemes, we find ourselves awash with hurdles to jump and different points of view to answer. The same is true all over the “civilised” world. One set of Regulations or Norms says we must do “x” while another equally important Standard says we must do ‘y’. What can we do to keep all these different auditors happy? External audits of all departments of a facility whether it is a stand-alone unit or part of a large hospital (private or government owned) are all well and good, but again keep it safe, simple and straightforward. Facilities are at risk of spending too much time chasing paper and not treating patients safely or well.

Consider whether an external body, saying they need to do something in a particular way just because it may be a good idea in another country or another branch of medicine, over policed facilities. There are considerations like costs and attitude to health and safety to consider. We are all different and we need to accept what we individually consider works safely for us in our local environment. There are many ways to do all sorts of things, but often one way is more straightforward and simple, let’s try and learn from others and not over complicate matters.

Consider words or phrases like: may like to consider, may adopt, may demonstrate rather than words like will, should or must. We need to be flexible in our approach and allow facilities to demonstrate they are safe.

Some thoughts
Accreditation - should we give sticks to others to beat us with?
Accreditation – needs to be helpful with guidance and not over enforcement unless absolutely necessary for organisations which are not caring for their patients well.

Be broad-minded and consider other avenues, look after your patients, as they are your future.

Standards & Regulations are often too strong maybe it’s better to have guidance and codes.

There a many ways to do things, but usually one way is easier, better & safer for all.

Quality Assurance (QA) – concentrate on areas not covered by others and avoid duplication, make decisions early on, on what standards/codes etc. the facility will be governed or operate by.
General hyperbaric safety

HBOT is merely the delivery of oxygen (02) at pressure: how expensive, large or safe the hyperbaric chamber is depends on many issues but mostly, comes down to how much cash the customer (hospital or stand alone client) has. Sydney’s new four-lock square chamber facility is rumoured to have cost in the region of 7 million Euros and yet other small diving chambers may have been installed (admittedly into an existing building) for less than 200,000.00 Euros. They both treat many similar patients with the same pressure and 02. These are of course the two extremes.

Most of the safety problems in HBOT are related to the staff and the procedures used (or not) and the precautions enforced during the day-to-day work.

Merely listing lots of international safety documents and then pointing out the differences (Table 4) may not help very much. Most of us work to just a few sets of regulations, codes, standards and guidance, so does it really matter exactly what someone else said in some other country. Of course on the other hand someone else may have much more experience, that we can learn from and maybe we could adopt their method with good reason. Let’s consider the main or perhaps some controversial issues.

Imagine again you are responsible for the technical or safety matters within a facility, you should be aware of all the key national or international documents concerning hyperbaric technical issues and also perhaps know the main key differences and why. The really important safety matters around the facility should not need to be looked for and found in some regulation or guidance document, they should be known by the end of a knowledgeable persons first day or two in any facility. The national and international documents may then be referred to for advice and consideration and maybe compared to allow us to have enough information to formulate a local policy for ourselves based on best available practice which may after all that be, just adopt the document we found most appropriate at the time. For example we are technically not allowed to modify medical devices for use inside the chamber (Medical Device) unless we gain CE, FDA or TGA approval which is extremely difficult, time consuming and therefore expensive if not impossible. Lots of facilities however do modify ventilators, syringe drivers, infusion pumps and much more and normally with excellent results, however it is they who carry the risk of using non approved medical equipment. We all know the problem. There is not a large enough market for the manufacture of good quality hyperbaric approved medical equipment and therefore these “home made” modifications are essential even though not approved. A step in the right direction would be for some large creditable organisation (like perhaps the US Navy or UHMS) to publish a standard procedure /Risk Assessment on how to test all medical equipment to assess whether it is, or can be made safe for use in the hyperbaric environment. This way we can all use the same procedure whether we are in Europe, USA, Micronesia or Australia and then share our technical results and opinions at international meetings, giving us interesting technical things to discuss.

In Australia, Hyperbaric Health (HH) are the distributors for a mono-place chamber made in USA, HH discovered early on that in their view the safety of the chamber operator and the patient could be greatly improved, if they altered the chamber in two simple areas, so with the manufacturers permission, HH set about making some modifications, which HH then had to have approved by the Therapeutic Goods Act (TGA) (similar to CE medical devices) and the manufacturer. Eventually the TGA and the manufacturer both signed off the two improvements, but of course the improvement approvals were only for this range of chambers for use only in Australia. The two improvements were:
1. Adding a fire suppression system

2. Adding a lock down (twist to cancel) emergency decompression button meaning that the operator no longer needed to stand/sit and hold down the decompression button for 110 seconds while a potential fire burnt inside the chamber and right in front of their face. If they now feel the need to run away at least water spray and emergency decompression will continue.

The end result may be that patients and operators in the above example may be safer in Australia than in USA or Europe. Surely we are a small enough industry to share this experience.

**USA & Europe approach very different, will either accept the other?**

In the NFPA 99 hyperbaric chapter 14, fire deluge water delivery volumes based on an apparent (See figure 1) chamber floor area have always been the over ruling parameters required to comply as far back as the 1970’s if not before. For a manufacturer to have their chamber “comply with NFPA 99” it had to deliver sufficient water volume per lock floor area. Another apparent problem was that this adopted water volume requirement, was reputed to be based on poor scientific evidence. However it was accepted and many went along with the policy and there was little else to challenge it.

To discover the apparent floor area of a lock at we need to know the width of the lock 25% up on the internal diameter of a chamber which can be easily calculated or simply measured. This measurement is required to calculate the water volume to be delivered regardless of the actual floor size. For example a 2-metre diameter and 6-metre long lock will have an apparent floor width of 1.73 metres when in fact it may have a real floor width of only 600 mm. The water delivery required to comply with NFPA 99 will be: 1.73 x 6 =10.38 M2 therefore 10.38 x 81.5 litres = 846 litres required as a minimum for one minute for this one lock alone. To this the designer would be wise to add a safety factor to allow for the air pressure driving supply and other factors.

Years later, Europe with a major input from Germany had quite an opposite approach to the NFPA 99 and this was basically to allow the use of whatever medium the designer wished (not necessary water), prove it to be...
efficient, safe and effective on real fires at pressure, with high % values of 02 concentration and to exact specifications, have their results witnessed, videoed and measured by a notified body and then continue to deliver that volume at the subsequent service tests thought the life of the chamber.

The European option may be a better one based purely on a technical or scientific basis, but also it must be very much more expensive. These new European Norms (EN’s) may now mean that Europe will no longer accept NFPA 99 compliant chambers and USA may not accept chambers built and tested to the new EN’s simply because they will no longer deliver enough water volume.

**Risk management**

Virtually all occupational health and safety issues all over the world are now based on Risk Assessments (RA’s). If kept reasonably practical these help many see the problems they have around the facility for themselves so they can solve the issues simply and efficiently.

According to EN ISO 14971 it is the responsibility of the chamber manufacture to perform the risk management of the medical device (Chamber and all it’s equipment). Also see Annex 3 of the EGCP for a comprehensive list of the most likely risks to be considered when installing a new facility.

Good design is easy, but often it is easier to those with a large capital budget.

Good Team work is essential, it can also help if staff can be given some job variety, which means having a multi skilled team to reduce work boredom. Why not teach your nurses and doctors how to be chamber operators, and your chamber operators to be inside attendants, you may be surprised, nurses may be better operators than your retired commercial divers.

**Air quality**

C02 levels in the atmosphere are on the increase, yet air quality standards have remained unchanged for many years. See Figure 2 below for international standards for compressed air for divers.

![Figure 2. Compressed air for divers.](image)

Many chamber operators understand so little about Carbon Dioxide (C02) where it comes from, that safe levels vary with depth, it is seldom zero and in fact often we have more than allowed according to the gas quality
standards we work with before we even compress the gas. Operators need to flush their chambers regularly if no automatic flush is installed and need to be even more vigilant if no CO2 analyser is fitted.

See Figure 3 below for suggested maximum CO2 values for different chamber pressures.

Air quality needs to be checked at least every six months on all gas supplies, water content is less important to the end user, however too much moisture causes freezing up issues at regulators and corrosion in Low Pressure (LP) receivers and High Pressure (HP) cylinders. AS2299.1 suggests water content in a 200 bar HP air cylinder should be below 50mg/m, 30mg/m for 300 bar cylinder and 100mg/m for LP air.

<table>
<thead>
<tr>
<th>PRESSURE (MSW)</th>
<th>ATA</th>
<th>MAX % CO₂</th>
<th>MAX PPM CO₂</th>
<th>SEV</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>1.9</td>
<td>0.26</td>
<td>2600</td>
<td>0.45</td>
</tr>
<tr>
<td>10</td>
<td>2</td>
<td>0.25</td>
<td>2500</td>
<td>0.5</td>
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<td>14</td>
<td>2.4</td>
<td>0.21</td>
<td>2100</td>
<td>0.54</td>
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<td>18</td>
<td>2.8</td>
<td>0.18</td>
<td>1800</td>
<td>0.54</td>
</tr>
<tr>
<td>30</td>
<td>4</td>
<td>0.125</td>
<td>1250</td>
<td>0.2</td>
</tr>
<tr>
<td>50</td>
<td>6</td>
<td>0.025</td>
<td>833</td>
<td>0.45</td>
</tr>
</tbody>
</table>

Carbon dioxide levels must be closely monitored, as elevated levels of inspired CO₂ will cause signs and symptoms of Carbon Dioxide poisoning.

Figure 3. Maximum allowable CO2 limits.

While on the subject of standards for gas quality we should consider language.

It is difficult enough for some to have to do their reading in a language other than their own, so why use so many different English words to mean the same thing.

How can a low-pressure air receiver also be called?

- A tank
- A flask
- A vessel
- A LP pig
An accumulator

Or a high pressure air or O2 cylinder be called:

- A tank
- A bottle

Tanks hold water or have tracks and a large gun, flasks hold hot or cold fluids, Pigs live on a farm, Accumulators are for stopping the hammer in pipes, and of course bottles are for beer!

**BIBS**

There are some chambers where the technician only has oxygen available for the BIBS, which is not ideal, but that’s it. There should be a set of BIBS for every occupant inside the chamber, not just the patients breathing oxygen. If a chamber only has O2 available then it may have to be limited to 18 MSW (2.8 ATA), even if the pressure hull is rated to 50 MSW (6 ATA). Then there comes the question of medical air to BIBS switch over, is it needed? How clean must the air be? What standards should we apply in Europe and/or some remote island in the Pacific or Indian Ocean? Should these standards be the same? I am sure others will discuss this. Filling an "Oxygen Clean" cylinder with air to the CGA Grade "E" standard may introduce hydrocarbon contamination so that the cylinder is no longer considered O2 clean and may no longer be used for partial pressure blending which means it’s not suitable for supplying medical air to BIBS.

In remote sites: How can we achieve good quality BIBS medical air without an oil free air compressor? (We require a better quality than normal values in Figure 2 above)

Ideally we need a set of BIBS for every chamber occupant and medical quality air to all BIBS which may be needed in the event of the chamber environment becoming contaminated or in the case of a inside chamber fire.

**02, C02 & CO Analysers**

Some technicians know little about how their gas analysers work and why they are so important. No gas flow though the analyser flow meter, or numbers that are “too high they must be wrong” so the analyser is then turned off have been observed! This does not just happen in some remote location but has been observed in Europe. Some international standards require 02 and C02 analysers as standard on the control panel, where others only require a 02 analyser.

**Pressure gauges & vessels**

In AS2299.1 it is stated that chamber depth/pressure gauges should be checked against a master gauge every three months, the best way to comply with this is to fit a master gauge to both locks and compare these gauges against each other every three months (the local technician can do this) and then once every 12 months calibrate both the master gauges against a certified test gauge when conducting a 12 month service visit. It is also stated that for an operational working range exceeding 30 MSW and less than 200 MSW then the gauge should have an accuracy of 0.5%. (1% is OK for ranges up to 30 MSW).
Pressure vessel inspections

It appears the guidance on who performs and when a pressure vessel should be inspected varies hugely across the world and even between states or territories in the same country.

Normally a pressure vessel is made to a code (ASME/Lloyds/ABS/DNV) and may also if desired or specified (but not essential) be third party inspected during the build and/or hydrostatic testing. After a pressure vessel is put into service it may also require additional in service examination and a local pressure vessel inspector normally conducts this, but again a competent person can in many sites complete this task. The inspection intervals and requirements for the registration of pressure vessels vary hugely and someone at a facility needs to be aware of this in order to maintain a safe pressure system and comply with the law. It can easily be overlooked.

Monoplace fire suppression

In Australia the AS4774.2 tells us “NFPA 99 may be used for guidance”. But also states that mono-place chambers (air or 02 filled) shall be equipped with a suitable fire suppression system. It has been shown that there may be up to a 10 second window of opportunity for staff to react to start fire fighting procedures in a 100% oxygen filled mono-place chamber. Why would we not bother to install something, rather than give up before we have even started?

Clothing

It is well known that 100% cotton scrubs with NO pockets are what we all need to wear when inside the chamber and yet some of the largest suppliers of hyperbaric equipment are still ONLY supplying sets of scrubs with four pockets, and when asked why, they say, its too expensive or difficult to change, its time we ALL insisted on 100% cotton pocket less chamber clothing and not just pay this advice lip service. How difficult can it be? Make a change, go back to your facilities and sew up all your chamber-clothing pockets and don’t buy any more scrubs with pockets. It must be cheaper, safer and easier for every one and how much time will staff save by not having to check everyone’s pockets at the start of every treatment? There are suppliers in USA of 100% cotton, no pockets scrubs, so no excuses and they are well priced at less than $18.00 a set. We need to make sure that the treatment chamber is kept at a comfortable temperature so we do not have to constantly make exceptions to the 100% cotton clothing and bedding rule.

Fire extinguishers

Normal fire extinguishers do not function correctly inside our pressurised chambers. Test your extinguishers at the maximum pressure of the chamber. Some of us are buying “hyperbaric” extinguishers that have been relabelled by the supplier and the working pressure (WP) increased by the addition of a sticky label and a new Pressure Relief Valve (PRV) Pressure vessels can not simply have there Working Pressure (WP) increased beyond the original manufactures WP simply by adding a sticker and higher value PRV?

Water fire extinguishers should expel their full contents in a given time and may not achieve this in a chamber at 50 MSW (6ATA). These same extinguishers however may still be good for systems working at lower pressures than 50 MSW (6ATA)
Team sizes

Many safety issues are related to what competent staff are available close (sight & sound) to the chamber.

In the EGCP, it states for a multi-place facility a minimum of three staff need to be present at all times to cover the four skills and the location is “remain in the facility and immediately available”.

For the mono-place sites there are three skills and a minimum of two staff can cover these and same location position above applies.

Overall responsibility Medical Director (MD) or Hyperbaric Therapeutic Provider (HTP)?

In the UK it is the HTP who is responsible for the overall administrative control of the facility. The HTP employs the team and makes sure that competent technical and medical staff are employed and on duty. The HTP shall ensure so far as is reasonably practicable that the operation of the therapeutic hyperbaric facility is planned, managed and conducted in a manner which protect the health and safety of all persons involved.

The HTP must be appointed in writing and may be the medical director if desired.

If there were to be a non-medical accident then, it would be them that would be answerable to any enquiry.

In the EGCP it is quite different, the overall responsibility for the facility, medically and technically rests totally with the Medical Director, whether they have the technical skills or not. This difference must be a huge concern to some. Are we convinced all medical directors have the skills and knowledge needed to know whether the technical issues of the facility are well cared for?

Most Medical Directors are unlikely to know very much about the inner workings of the machinery that supplies gases, heating, cooling, humidity control, fire fighting, 02 & C02 monitoring and adjustment, electrical safety and how and when it is all serviced and by who and at what cost.

In USA it would be the Safety Director who would be responsible in the event of a technical mishap. Of course the MD in all cases should take an active interest in all matters, but ultimately how can the MD be responsible for matters outside their direct control, knowledge or experience?

Emergency Procedures (EP’S) and their regular practice

Facilities must really not keep putting off the regular practice of all the facility EP’s. Practice makes perfect and to video record your training is a useful future training aid.

For years we have been told by many that all EP’s must be developed and be unique to each facility and now let’s question this advice. It can mean that in some cases the staff just don’t get around to ever writing their EP’s, let alone there practice. Teams ask, “Can I have a copy of your EP’s, so I can translate them”? Are the staff becoming lazy? Or don’t they have enough self-confidence or experience to write their own EP’s? Some facilities write a few pages on what each staff member should do so they have section headings like: 1. Duty Physician, 2. Operator / Technician & 3. Attendant. All nicely presented for the many considered emergencies and they look good for the upcoming accreditation but in truth who reads it? Maybe better options are to KISS’S Keep it straight & simple & share it!

Example:
Fire inside the chamber

1. Use fire hose / Turn on fire suppression system
2. Start emergency decompression
3. Switch BIBS or chamber supply (if mono-place) to Medical air
4. Shout for local help
5. Call for assistance & call fire brigade /service inform building reception/switch

And that is all, if a mistake is made, so what, a few people get wet and maybe a little angry or cold. Every one is however well. This could not be simpler and would work at any facility in the world.

One possible excuse for not having standard EP’s is: The operator does not know how or where these controls are. Quotes like “Our system is very different to others”. The answer to that is then retrain them or consider giving them another “job” in some far away remote place looking after less important matters!

Next task perhaps for the ECHM may be for us to develop say 20 common EP’s and share them amongst us all. There are more than 20 facilities represented here today, so with less than one each we could be finished by tomorrow morning before the conclusions for the Jury tomorrow. It will always be easy to write lots and explain everything in detail for all skills, but who will read it or more importantly remember it or find it when needed. This way we can mount all 20 EP’s under clear acrylic on the control panel. You really don’t want your staff to be looking for an emergency manual when they have an emergency.

Paul Sheffield & David Desautels demonstrated that fires in chambers are mostly extinguished with a fire hose, so do we even need a spray or deluge system? Of course it is preferable but we certainly need fire hoses.

On a recent examination of a new multi-place chamber (two-lock 2400 mm dia and 7200 mm long) made in China, but being installed in Vietnam it was interesting to see a total of three normal room fire sprinkler heads and no fire hoses or fire extinguishers inside. The chamber’s WP was 20 MSW (3ATA).

Prohibited items

In Paul Sheffield and David Desautels original paper and including their updated paper, they state “it brings the total known human fatalities to 91 from 40 hyperbaric facility fires occurring between 1923-1997”. Their updated conclusion supports their previous report, and that was: that recent chamber fires have been caused by prohibited sources of ignition, that we allowed an occupant to carry into the chamber being the primarily cause.

I am sure every country has their own list of prohibited items, but why have we not all agreed on one list and translated it and made a picture version of it. In London at one time a facility was asked to translate all their patient material into seven languages. Needless to say they refused and adopted the policy of having an English-speaking relative attend with any patient who could not understand.

Is it reasonable to have more than two languages available? A picture speaks a thousand words so perhaps facilities should try and use pictures to explain things where possible in much the same way as flat pack furniture instructions now come with pictures.
Pipe work materials

What materials should we use in this day and age - Plastics, copper or stainless steel? Or a mixture? Steel rusts, aluminium corrodes, but they both need to get wet first. Galvanising or epoxy coating the inside of a water receiver may be a good idea, but then let us consider protecting them with an anode just like we do with our expensive yachts. How often should we test our pressure vessels especially those filled with water? Consider where does the water come from that we fill our fire receivers with, is it high in chlorine content and if yes, then this may cause us other problems if we have a stainless steel receiver. In some remote island sites, Fire deluge receivers have been filled with salt water as it was cheaper and then the deluge nozzles become thick with salt deposits. When the fire suppression system is activated the water flow may be badly effected and inadequate.

Chamber operator/Technician training and experience

It is important that we find the right staff and train them well and keep them. A good example of this was when recently an ex commercial diver who then became a helicopter pilot, stared their training as part time technician at the Darwin clinical chamber and every day he was climbing all over the chamber asking what does this do, why is this like this, where does this pipe go, why is it made this way, what happens if this breaks or that and so on and so forth. Consider how confident you and he would be in just a few days and whether he would be a great safe clinical chamber technician.

IDAN for example teach chamber technician/ operators to carry out basic low pressure 02 cleaning on site; this must be a good idea. In fact the IDAN nuts and bolts course for chamber technicians is a wonderful idea and will help Medical Directors have more confidence in their technicians. Any additional training that can be offered to operators/ technicians must be encouraged and especially in remote sites where they gain little regular chamber operation experience.

In Australia facilities can only employ Chamber technicians who are ex commercial (ADAS 3) or military divers with supervisor experience as a pre entry requirement to be a clinical chamber technician. This standard is very restrictive and limits a facilities ability to expand. Consider how these commercial divers will maintain their skills and at what financial cost to the clinical facility. It has also been suggested that the offshore Life Support Technician (LST) qualification should be encouraged for clinical chamber technicians, but again the skills learnt in this training are seldom put into practice and soon forgotten in the clinical situation. To qualify as a full LST also takes years after completing a 2-week (theory only) Assistant LST course and obtaining enough qualify hours offshore.

In the UK we can train Nurses and Doctors to run clinical chambers if we wish. I wonder, which trade/skill, has the better empathy with the patient?

An international accepted, achievable and accredited realistic training program and qualification is urgently needed for the position of clinical chamber operator/technician.

AS 4774.2 States: “The hyperbaric technical officer (HTO) is responsible for the safe operation of the hyperbaric chamber and the safety of all occupants. An HTO will need both theoretical and practical knowledge of the management, supervision and operation of multi place hyperbaric chambers and the skills to assume the responsibilities for operating the chamber and care for patients in a hyperbaric environment.”

The standard also requires that an HTO shall have one of the following pre-requisites.
1. Be qualified as a Life Support Technician (LST) and certified by the International Marine Contractors Association (IMCA).

2. Have at a minimum an Australian Diver Accreditation Scheme (ADAS) Part 3 certificate of competency for diving supervisor.

3. If from a military background, have attained the minimum rank of Petty Officer Clearance Diver.

These pre-requisites attempt to ensure that all technical officers have relevant chamber operator skills and should have a working grasp of the essential skills and knowledge assumed in the qualification. It is intended to ensure that an HTO is a competent chamber operator, with a better than working knowledge of diving physics and physiology before starting work in the healthcare context.

If the pre-requisites are studied carefully it can be seen that apart from experience, the main thrust is towards supervision. The whole point about the prerequisites is that an HTO can come into a clinical hyperbaric setting and, after orientation, conduct chamber operations unsupervised.

These pre-requisites are all well and good but they are all occupational dive/chamber operator qualifications with no healthcare experience required and they are not uniform in their teaching or experience. While AS4774.2 was being developed there was a lot of discussion in the Hyperbaric Technicians and Nurses Association (HTNA) regarding a nationally recognised training scheme for hyperbaric technical officers.

It is very important to notice that even given all the above in AS4774.2 a Medical Director may acknowledge in writing that a person they wish to employ as a clinical technician / operator and who has equivalent training and experience to an appropriate level as listed in the standard may be employed in that position.

**Conclusion**

From the above it is noticed that most safety issues are in fact due to human operational issues and/or over burdening facilities with bureaucracy and duplicating requirements.

In reading the conclusion from the 1998 ECHM paper “Recommendation for Safety in Multi-place Medical hyperbaric Chambers (informative) 1998 by D. Mathieu”. The conclusion may be the same now as then (see below).

“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 centres 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.
References


7. EN 16081, (2010) Hyperbaric chambers - Specific requirements for fire extinguishing systems - Performance, installation and testing.


10. AS 4774.2-(2002) Work in compressed air and hyperbaric facilities – Hyperbaric oxygen facilities


12. AS 1210-(2010) Pressure vessels. Includes unfired, human occupancy vessels

13. AS ISO 13845 Medical Devices- Quality Management Systems – Requirements for regulatory purposes


17. ISO 14971:2000 Medical devices. - Application of risk management to medical devices
Table 1. Comparison of EN 16081, EN 14931, BHA Guidelines & Codes, NFPA 99 Chapter 14 & AS 4774.2

<table>
<thead>
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<tr>
<td>1</td>
<td>Multiplace only</td>
<td>Yes</td>
<td>Both Mono &amp; Multi</td>
<td>Multiplace only</td>
<td>Includes Monoplace</td>
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<td>2</td>
<td>Therapeutic use only</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>3</td>
<td>Performance &amp; Testing Speciation’s for fire fighting system quoted</td>
<td>Yes</td>
<td>Yes</td>
<td>No operational guidelines only</td>
<td>Use NFPA 99 for guidance</td>
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<td>Extinguishing medium allowed or quoted</td>
<td>Any</td>
<td>Water</td>
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<td>Stated fire fighting volume requirements</td>
<td>No</td>
<td>Yes exactly volumes to be delivered for deluge &amp; hand held hoses</td>
<td>No Specification except hand held hose &amp; extinguisher guidelines</td>
<td>Use NFPA 99 for guidance</td>
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<td>6</td>
<td>All chamber compartments covered</td>
<td>Yes</td>
<td>Yes all compartments designed for manned operations unless purely transfer locks</td>
<td>Very brief guidelines only so too general</td>
<td>Use NFPA 99 for guidance</td>
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<tr>
<td>7</td>
<td>Manual release available from Control panel</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Use NFPA 99 for guidance</td>
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<td>8</td>
<td>Independent water release inside and out</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Use NFPA 99 for guidance</td>
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<tr>
<td>9</td>
<td>Warning signal at console</td>
<td>Yes</td>
<td>Yes</td>
<td>Visual only, noise will hinder communications</td>
<td>Use NFPA 99 for guidance</td>
</tr>
<tr>
<td></td>
<td>Main fire risk area under consideration</td>
<td>Seats &amp; Beds in all locks</td>
<td>Apparent floor area 25% up from bottom of hull.</td>
<td>Reasonably uniform &amp; adequate coverage in all compartments</td>
<td>Use NFPA 99 for guidance</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------------------</td>
<td>--------------------------</td>
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<td>------------------------</td>
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<tr>
<td>10</td>
<td>Other area coverage</td>
<td>50% of stated volumes to other areas</td>
<td>All manned locks same volume required</td>
<td>Reasonably uniform &amp; adequate coverage in all compartments</td>
<td>Use NFPA 99 for guidance</td>
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<tr>
<td>11</td>
<td>Receiver adequately protected against corrosion</td>
<td>No mention</td>
<td>No mention, guidelines only</td>
<td>No mention</td>
<td>No mention</td>
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<td>12</td>
<td>Controllable level indicator</td>
<td>Yes</td>
<td>Yes</td>
<td>No mention, guidelines only</td>
<td>No mention</td>
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<td>13</td>
<td>Display at panel to show level + pressure</td>
<td>No</td>
<td>1 second for activation only</td>
<td>No mention, guidelines only</td>
<td>Use NFPA 99 for guidance</td>
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<td>14</td>
<td>Automatic switch off when empty</td>
<td>Yes</td>
<td>No</td>
<td>No mention, guidelines only</td>
<td>No, not required</td>
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<td>15</td>
<td>Manual off/on/off/on function</td>
<td>Yes</td>
<td>Yes</td>
<td>No mention, guidelines only</td>
<td>Use NFPA 99 for guidance</td>
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<td>16</td>
<td>Calculated time of fire suppression flow</td>
<td>1 minute</td>
<td>1 minute</td>
<td>For complete extinguishment</td>
<td>Use NFPA 99 for guidance</td>
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<td>Protected against freezing</td>
<td>Yes</td>
<td>No mention</td>
<td>No mention</td>
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<td>18</td>
<td>Notified body for witness &amp; approval required</td>
<td>No 3rd party witness required</td>
<td>No mention, guidelines only</td>
<td>Use NFPA 99 for guidance</td>
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<td>19</td>
<td>Test interval</td>
<td>As per the approved design</td>
<td>6 monthly</td>
<td>No mention</td>
<td>6 monthly</td>
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<tr>
<td>20</td>
<td>Minimum test number, type when new and interval after commissioning</td>
<td>By manufacturer at build and 6 monthly thereafter recording water volumes only. Initial test at 1 ATA and max WP. Records kept with chamber</td>
<td>No mention</td>
<td>6 monthly after commissioning</td>
<td>Use NFPA 99 for guidance</td>
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<tr>
<td>21</td>
<td>Fire test conditions</td>
<td>Approved test with EN compliant dummies. Very exact test</td>
<td>Measure water volume only 81.5 L/min/M² with no area less than</td>
<td>Use NFPA 99 for guidance</td>
<td></td>
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</tbody>
</table>

**Use NFPA 99 for guidance**
<p>| | | | | |</p>
<table>
<thead>
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<td>24</td>
<td>Thermo couplers required for tests</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<tr>
<td>25</td>
<td>Time from ignition to activation allowed</td>
<td>Yes, fire to be at the upper shoulders of dummies</td>
<td>No hot fire tests required</td>
<td>No mention</td>
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<tr>
<td>26</td>
<td>Increase in temperature requirements</td>
<td>Yes 2 x 100°C above starting temperature</td>
<td>N/A</td>
<td>No mention</td>
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<td>27</td>
<td>Film of the fire test required</td>
<td>Yes</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>28</td>
<td>Test parameters required</td>
<td>All temp sensors below 50°C within 20 secs and pressure back to start point &amp; fire out within 40 secs</td>
<td>Is the water flow per M² sufficient for the calculated floor area (25% up on the diameter)</td>
<td>N/A</td>
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<tr>
<td>29</td>
<td>Suppression flow rates criteria</td>
<td>Per seat</td>
<td>Per M² of apparent floor area (floor = 25% up from diameter of hull)</td>
<td>Fire fighting equipment to be fitted to all compartments</td>
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<tr>
<td>30</td>
<td>On site wet testing at 2 bar &amp; witnessed by notified body for each compartment</td>
<td>Yes</td>
<td>Not required</td>
<td>No mention</td>
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<tr>
<td>31</td>
<td>Risk Analysis outline</td>
<td>Included in EGCP</td>
<td>Fire risk table included and also covered in C of P</td>
<td>Yes section 6</td>
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<tr>
<td>32</td>
<td>Mention of chamber earth requirements and testing</td>
<td>Yes</td>
<td>Yes lots of reference</td>
<td>Yes in Electrical guidelines</td>
</tr>
<tr>
<td>33</td>
<td>Manually operated fire hoses</td>
<td>To be considered</td>
<td>Essential in all locks with 2 in main lock (12.7 mm dia with ¼ turn) with flow of 18.9 L/min</td>
<td>Yes in all compartments and pressure to be 7 bar over max</td>
</tr>
<tr>
<td></td>
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<tr>
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<td></td>
</tr>
<tr>
<td>34</td>
<td>Hand held extinguisher requirement</td>
<td>Yes EN 14931</td>
<td>Positive paragraph on NOT to be installed</td>
<td>Fire fighting equipment so OK if water filled</td>
</tr>
<tr>
<td>35</td>
<td>List of prohibited materials quoted</td>
<td>Yes quoted in EGCP for example and to be posted above doors &amp; also included in EN 16081</td>
<td>Specific list of 4 items and also mention of makeup, cosmetics, lotions, oils, hair sprays, oils &amp; dressings etc to be removed.</td>
<td>Yes full example supplied as appendix</td>
</tr>
<tr>
<td>36</td>
<td>Position descriptions, education &amp; training</td>
<td>2 x paragraphs included in annex but also covered in ECGP</td>
<td>No</td>
<td>Brief position descriptions &amp; responsibilities in C of P</td>
</tr>
<tr>
<td>37</td>
<td>Who is responsible for Technical issues &amp; faults in the system</td>
<td>Medical Director</td>
<td>Safety Director</td>
<td>Hyperbaric Therapy Provider (HTP)</td>
</tr>
<tr>
<td>38</td>
<td>Chamber room fire protection and doors</td>
<td>Not covered</td>
<td>Yes 2 hr construction &amp; doors 1.5 hr</td>
<td>Same as ICU or operating department of hospital</td>
</tr>
<tr>
<td>39</td>
<td>Fire evacuation practiced</td>
<td>Not covered</td>
<td>Yes annually</td>
<td>No mention</td>
</tr>
<tr>
<td>40</td>
<td>¼ turn isolation allowed on PRV</td>
<td>No mention</td>
<td>No mention</td>
<td>No mention</td>
</tr>
<tr>
<td>41</td>
<td>Emergency lighting required</td>
<td>Yes 90 lux</td>
<td>Yes</td>
<td>Very brief mention</td>
</tr>
<tr>
<td>42</td>
<td>Chamber lighting from UPS</td>
<td>Yes main 300 lux + spot 500 lux</td>
<td>Effectively yes</td>
<td></td>
</tr>
<tr>
<td>43</td>
<td>Depth gauge calibration &amp; accurate</td>
<td>Internal 1% accurate</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control panel 0.25% accurate</td>
<td>No mention</td>
<td>No mention</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>44</td>
<td>BIBS pressure limits covered</td>
<td>Exact inhalation and exhalation pressure stated</td>
<td>No mention</td>
<td>No mention</td>
</tr>
<tr>
<td>45</td>
<td>Double up on essential electrical circuits required</td>
<td>Yes IEC-60364-7-710</td>
<td>Yes. All facilities to have two independent electrical supplies, see NFPA 70</td>
<td>Lots of reference to other standards in Electrical guidelines</td>
</tr>
<tr>
<td>46</td>
<td>Breathing Apparatus required for the chamber operator</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes + training required</td>
</tr>
<tr>
<td>47</td>
<td>Full activation testing for fire suppression system required</td>
<td>Yes</td>
<td>Yes 6 monthly</td>
<td>2.11 at regular intervals</td>
</tr>
<tr>
<td>48</td>
<td>Humidity levels required</td>
<td>No mention</td>
<td>No mention</td>
<td>Greater than 40%</td>
</tr>
<tr>
<td>49</td>
<td>Clothing required</td>
<td>Yes Exact specification</td>
<td>Silk, wool, synthetic textiles materials prohibited, 100% cotton or cotton/polyester blend permitted</td>
<td>100% cotton materials</td>
</tr>
<tr>
<td>50</td>
<td>Maintenance requirements</td>
<td>Covered in ECGP</td>
<td>PRV testing listed</td>
<td>Yes brief outline</td>
</tr>
<tr>
<td>51</td>
<td>Chamber room fire sprinkler systems required</td>
<td>Not covered</td>
<td>Yes as per NFPA 13 since 1968</td>
<td>No not required in UK hospital at that time</td>
</tr>
<tr>
<td>52</td>
<td>Pipe systems to comply with</td>
<td>EN 13348</td>
<td>ANSI/ASME PVHO-1</td>
<td>Many references</td>
</tr>
<tr>
<td>53</td>
<td>Pressure vessel code</td>
<td>Medical Device CE marked since</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1998</td>
<td>ANSI/ASME PVHO-1</td>
<td>BS5500</td>
<td>that hosts country</td>
</tr>
<tr>
<td>---</td>
<td>------</td>
<td>------------------</td>
<td>--------</td>
<td>-------------------</td>
</tr>
<tr>
<td>54</td>
<td>Floor construction &amp; bilge access required. Plates bolted down and electrical ground</td>
<td>No mention</td>
<td>Yes</td>
<td>Yes. See Electrical guidelines</td>
</tr>
<tr>
<td>55</td>
<td>Paint inside</td>
<td>Compatible with hyperbaric conditions</td>
<td>Epoxy non combustible + min cure time between coats to off gas</td>
<td>No mention</td>
</tr>
<tr>
<td>56</td>
<td>Electrical circuits housings</td>
<td>IEC 60364-7-710</td>
<td>Waterproof both inside and outside chamber</td>
<td>See Electrical guidelines</td>
</tr>
<tr>
<td>57</td>
<td>Lighting levels stated</td>
<td>Yes at seated head height 300 lux 500 lux on spot 90 lux for emergency</td>
<td>Outside chamber, fibre optic or designed for internal use, heat output below viewport temperature rating</td>
<td>See Electrical guidelines</td>
</tr>
<tr>
<td>58</td>
<td>Chamber ventilation</td>
<td>30 litres per min per person x absolute pressure</td>
<td>0.085 m³ min per occupant not on BIBS</td>
<td>No mention</td>
</tr>
<tr>
<td>59</td>
<td>Viewports</td>
<td>ASME-PVHO</td>
<td>ANSI/ASME/PVHO-1</td>
<td>No mention</td>
</tr>
<tr>
<td>60</td>
<td>BIBS available and gas supply types</td>
<td>Independent from chamber supply, medical air and O₂</td>
<td>For every chamber occupant &amp; independent of the chamber supply and to function at all possible pressures &amp; switchable to independent suitable air supply</td>
<td>For every occupant for all foreseeable situations inc emergencies</td>
</tr>
</tbody>
</table>
|   | Gas quality monitoring and specification | Max O₂ 23.5% | Every 6 months as per Fig 2. OK for chamber supply but higher spec for medical air for BIBS | Mentioned but not exact requirements  
Max O₂ allowed 24% | Every 6 months  
AS2568 & NOHSC 1003 also see AS/NZ 2299.1 2007  
Max O₂ 23.5%  
Max CO₂ 0.5 % (A) |
|---|----------------------------------------|--------------|-----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| 61 | Gas volume/pressure supply required     | Two sources required and list of what is considered sufficient is included  
2 x oil lubricated or oil free compressors OK with separate electrical branch supplies |  
Refers to other UK standards/codes | Adequate to support protocols & emergency operations |
| 62 | Temperature & Humidity control required | No mention | Water/Glycol mixture in radiators with air flow over normally 22°C  
+/- 2°C | No mention  
3.4 once stabilised not greater than 30°C  
Monitoring systems for both incorporated |
| 63 | Compression/Decompression rates        | Yes  
Pressure rate 80 kPa/min minimum  
Max 300 kPa /min maximum | Deco 3 ATA to surface within 6 mins | No mention  
10 kPa /min accuracy |
| 64 | Temperature specifications             | Yes  
Ambient + 7°C except on compression + 10 mins  
Deco ambient -5°C except on deco.  
Max 40°C on compression  
Max operating 32°C | 22°C +/- 2°C | No mention  
3.4 once stabilised not greater than 30°C |
<table>
<thead>
<tr>
<th></th>
<th>Noise specifications</th>
<th>Yes</th>
<th>70 dB (A) at seated head height with ventilation max 90 dB</th>
<th>No mention</th>
<th>No mention</th>
<th>Not interfere with normal conversation once at pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>66</td>
<td>Other chamber equipment</td>
<td>Chamber pressure recorder required at 1 min intervals</td>
<td>All to be rated, tested and documented for hyperbaric use</td>
<td>No mention</td>
<td>No mention</td>
<td>No mention</td>
</tr>
<tr>
<td></td>
<td>Main door 1.55 M ht x 0.7M wide</td>
<td>Paper bins to be provided &amp; metal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Seat size 0.5M wide &amp; 0.4 deep</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Entry lock to have 2 seats</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No ¼ turn ball valves on O₂ over 20 bar</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>67</td>
<td>Wires and cables</td>
<td>IEC 60364-7-710</td>
<td>To comply with UL 1685 and all in waterproof installations, see NFPA 70</td>
<td>Lots quoted</td>
<td>AS/NZS 3000, 3200 &amp; 3551</td>
<td></td>
</tr>
<tr>
<td></td>
<td>UPS required</td>
<td></td>
<td>See Electrical guidelines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>68</td>
<td>Maximum voltages and amps</td>
<td>42 volt</td>
<td>28 volts &amp; 0.5 amps under normal use &amp; under circuit fault conditions.</td>
<td>24 V dc</td>
<td>+ Circuit breakers</td>
<td>No mention</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Switches intrinsically safe</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>69</td>
<td>Batteries</td>
<td>No mention</td>
<td>No lithium or lithium ion</td>
<td>No unprotected leads</td>
<td>No mercury</td>
<td>No mention</td>
</tr>
<tr>
<td>70</td>
<td>Electrical grounding</td>
<td>Yes</td>
<td>All chambers + inside equipment to be grounded as per NFPA 70 and ground will not exceed 1 ohm</td>
<td>2.7 See Electrical guidelines</td>
<td>No mention</td>
<td></td>
</tr>
<tr>
<td>No.</td>
<td>Item</td>
<td>Requirement</td>
<td>Notes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----</td>
<td>-------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>72</td>
<td>Gas Analysers</td>
<td>Control panel O₂ &amp; CO₂ partial pressure and if chamber over 12 person then 2 x O₂ analysers required with alarms at 23% + switch O₂ to air on BIBS</td>
<td>O₂ analysers with audible &amp; visual alarms, CO₂ only required when ventilation not used No exact speciation’s listed O₂ &amp; CO₂ No alarms quoted</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>73</td>
<td>CCTV/Viewports</td>
<td>Must have good view from viewports</td>
<td>No mention No mention No mention No mention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>74</td>
<td>Exhausts</td>
<td>Deco rates 40 kPa to 20 kPa in 1 min &amp; 20 secs + emergency deco 200 kPa to surface max 2 mins</td>
<td>All to be piped outside the building with fine mesh filter and labelled oxygen exhaust No mention No mention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>75</td>
<td>Safety Director</td>
<td>No mention</td>
<td>Must appoint a person Position covered by Hyperbaric Therapy Provider (HTP) unless appointed separately No mention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>76</td>
<td>Emergency procedures</td>
<td>Yes</td>
<td>Must be established &amp; practiced by all team annually Must be established Must be established</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>77</td>
<td>Lubrication</td>
<td>No mention</td>
<td>Only O₂ compatible lubricant inside the chamber 0₂ compatible, however also a variety of lubricants will be required Only lubricants for O₂ rich environment + persons familiar with principles of use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>78</td>
<td>Cylinders allowed inside the chamber</td>
<td>No mention</td>
<td>Yes if prior approved by the facility safety director No mention No mention No mention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Building fire detection equipment</td>
<td>Not covered</td>
<td>Yes 14.2.1.1 section included + to be tested every week</td>
<td>To be tested every week</td>
<td>As per NFPA 99 + adequate number of fire extinguishers + emergency lighting</td>
<td></td>
</tr>
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<td>---</td>
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<td>------------------------------------------------------</td>
<td>-------------------------</td>
<td>------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>79</td>
<td>Staff Medicals</td>
<td>Not covered</td>
<td>No mention</td>
<td>Recommended &amp; valid for a maximum of 12 months</td>
<td>Initial &amp; Periodic</td>
<td></td>
</tr>
</tbody>
</table>
(13) European regulations and normalisation

Harald Pauli (Germany)
Head of Department Pressure and Underwater Technology
Germanischer Lloyd SE

1. Foundation for the assessment of Hyperbaric Equipment

Germanischer Lloyd (GL) tests and certifies medical treatment chambers used for hyperbaric oxygen therapy and specialised medical devices for use inside chambers according to the European standard EN 14931 and other internationally recognised standards.

In close cooperation with manufacturers and medical experts, we also supports in new requirements such as the development of a goal-based standard for fire-fighting systems in hyperbaric chambers.

Hyperbaric treatment chambers that are intended for use in Europe have to be built and certified according to the European Directives 93/42/EEC “Medical Devices” and 97/23/EC “Pressure Equipment” to ensure that they comply with the relevant European health and safety requirements. Since the certification requires expertise in both fields, clients are well advised to authorize a highly reputable and experienced independent society with international medical and pressure technology know-how.

After all, product development in combination with the certified quality of hyperbaric equipment products helps to strengthen company’s reputation.

To assist this process manufacturer are well advised to use more than 30 years of experience in risk-based classification and certification in the field of underwater technology especially in hyperbaric medical treatment technology. In addition, experience from the activities as chair of the European Standardisation Committee for Hyperbaric Chambers and member of the American Society of Mechanical Engineers (ASME) - both equipped with manufacturers, operators and representatives of the medical profession - provides practical regulatory for evaluation of hyperbaric equipment.

In order to give an overview about some hyperbaric equipment, applicable standards, news and solutions for technical questions following some examples are specified.
2. Medical devices used in hyperbaric chamber systems

Medical devices defined as any item of equipment required for the treatment of the patient are increasingly part of the interior of hyperbaric medical treatment chambers. The increasing demand of medical devices for hyperbaric chambers leads to a challenge for the manufacturer to find applicable regulations and support by third party companies.

2.1. General regulatory requirements

The following regulations concern medical devices for use in hyperbaric chambers:

**EN 14931:2006 Annex B**

Annex B of the European Standard EN 14931:2006 describes the potential hazards which certain medical devices represent, the risk induced by medical devices likely to be used within hyperbaric chamber systems intended for hyperbaric oxygen therapy and the recommendations for manufacturers of medical devices and users of hyperbaric chamber systems, in order to achieve the highest possible level of safety for the patients and personnel.

The European Standard clearly highlights the two main hazards caused by the special environment in hyperbaric chambers:

- **Pressure**
  
  A hyperbaric chamber realises an environment where the internal pressure is increased over the atmospheric pressure. Potential risks for any medical device intended to be used in hyperbaric environment are present, e.g. displays may deteriorate, keyboard pads may be blocked and crushed, implosions or explosions of certain components are possible due to the variation of pressure.

- **Oxygen**
  
  The partial pressure of oxygen within the hyperbaric chamber’s atmosphere increases proportionally with the pressure level inside the chamber. Patients treated inside the hyperbaric chamber breathe pure oxygen and/or over-oxygenated mixtures via half-masks or breathing systems which cannot guarantee a perfect tightness. The higher oxygen partial pressure and/or oxygen content causes aggravating factors of fire risks if associated with a combustible product or with a source of ignition, e.g. sparks.

Furthermore the European Standard EN 14931:2006 describes possible environmental conditions within pressure chambers for therapeutic use and lists typical medical equipment which may be required for critical care inside a hyperbaric chamber.


The National Fire Protection Association, an International Codes and Standards Organization, deals in chapter 20 ‘Hyperbaric Facilities’ with requirements on portable patient care-related electrical appliances and battery-operated devices.
The Code points out that equipment or equipment components installed in or used in the chamber shall not pose an explosive or implosive hazard under the conditions of hyperbaric use and shall be rated, or tested and documented, for intended hyperbaric conditions prior to use. Only the electrical equipment necessary for the safe operation of the chamber and for required patient care shall be permitted in the chamber. Furthermore portable patient care-related electrical appliances shall have a maximum operating surface temperature less than 85°C and the electrical and mechanical integrity of the appliance shall be verified and documented through an ongoing maintenance program. In addition detailed requirements regarding battery-operated devices are listed.

2.2. Special requirements for electronic devices

The applicable European Standard for medical devices used in hyperbaric chambers is EN 14931:2006. However, additional national requirements also apply.

Sometimes national regulations are contra productive to agreed and recognized European standards.

As an example: Presumably, due to a series of serious accidents in pressure chambers filled with pure oxygen - 1987 a four year old child died in Italy, in 2009 in Broward, Florida an Italian child and his grandmother died - the Italian authorities became very cautious and required compliance with Directive 94/9/EC and EN 60079-11 (Explosive atmospheres - Part 11: Equipment protection by intrinsic safety "i") for electronic devices.

This requirement is not conform to the European Standard EN 14931:2006 Annex B because an explosion proofed electronic device may be destroyed under pressure or may cause other hazards (e.g. grease incorporated, no pressure compensation). According to EN 14931 any potential for crushing, implosion and explosion of any electronic device and device components is to be eliminated. Therefore pressure compensated or pressure resistant components are required.

This example shows clearly that national requirements may not conform to an international recognized standard from the safety point of view. To ensure an objective evaluation of the relevant case third party experts consider applicable requirements, combined with long-term practical experience.

2.3. Type Approval procedure for safety integrity

To consider possible hazards and dangers caused by an electronic device or a medical device used in hyperbaric pressure chambers an evaluation and approval of each device intended to be used in hyperbaric atmosphere should be carried out by an independent third party.

In this function we performed several ‘Type Approvals’ on electronic devices and medical devices for the use in hyperbaric pressure chambers to provide safety integrity of each device in this special environment.

The type approval procedure includes the

- evaluation of potential risks of the individual device to the human body
- pressure and functional tests of the device or device components respectively
- extended tests in pure oxygen atmosphere.

Additionally included is an approval of the documentation (e.g. instruction manual, risk analysis and safety concept of battery management system, etc.) and the issuance of a GL Type Approval Certificate (see Fig. 2).
The medical equipment intended to be used in hyperbaric chambers needs to be certified according to the European Medical Device Directive. During this certification process an examination related to the special requirements for use in hyperbaric and oxygen enriched environment as well as an evaluation of the measures to provide repeatable manufacturing quality of any device for the use in hyperbaric chambers has to be carried out.

For this Type Approval procedure the medical or electronic device intended to be used in hyperbaric chambers has to undergo several tests like cyclic pressure exposure (see Error! Reference source not found.) and functional tests under pressure (see Error! Reference source not found.).

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**Figure 1.** Hyperbaric (HBO) Monitoring unit, Patient box and pacer unit during pressure testing in hyperbaric chamber

**Figure 2.** GL Type Approval Certificate

**Figure 3.** Pressure profile: Cyclic pressure testing of a medical device according to GL Rules
During testing and approval of several medical devices potential risks may caused by a non-suitable medical device used in hyperbaric chambers were determined:

- Respiratory devices showed serious malfunctions,
- high power capacitors for defibrillators exploded during pressure exposure,
- battery management systems failed as a result of destroyed electronic components during pressure exposure and
- reliable automatic non-invasive blood pressure measurements as well as CO₂ measurements (depending on partial pressure) showed malfunctions during pressure variations.

Due to these serious risks we strongly recommend evaluation of medical and electronic devices intended to be used in hyperbaric chambers by a qualified expert / third party.

3. Fire extinguishing system for hyperbaric chambers

According to EN 14931:2006 any hyperbaric chamber shall be equipped with a fire-extinguishing system in all compartments. This chapter gives a short introduction in the applicable requirements and the type approval procedure for fire extinguishing systems.

3.1. Regulatory requirements

Criteria for design and performance of fire extinguishing systems are given in EN 16081:2011 and NFPA 99.

**EN 16081:2011**

This European Standard is applicable to the performance and safety requirements of fire extinguishing systems and their associated test methods for hyperbaric chambers and requires type approval of each fire extinguishing system by a Notified Body and on site acceptance test carried out by a Notified Body or a manufacturer certified according to MDD Annex II.
Figure 5. Burning and extinguishing test (hot test) according to EN 16081:2011


The National Fire Protection Association covers in chapter 20 ‘Hyperbaric Facilities’ the requirements on fire protection systems. In comparison to the European Standard, NFPA requires a specific spray density as a performance indicator for the fire extinguishing system instead of an examination of burning and extinguishing tests.

**3.2. Type Approval Procedure**

As you may know we have certified several different fire extinguishing systems for hyperbaric chambers in recent years to provide maximum safety for human occupants. Systems certified according to the expired Standard DIN 13256-3 have been successfully evaluated and re-certified according to the new European Standard EN 16081:2006.
Figure 6. Functional test of fire extinguishing system during periodical survey

The type approval procedure according to EN 16081:2006 includes burning and extinguishing tests (hot tests) for each type of fire extinguishing system and on site acceptance tests (wet tests) for each hyperbaric chamber installation.

4. Regulatory Requirements for the design of acrylic windows

4.1. Application of current standards

The use of acrylic windows in medical treatment chambers is commonly good practice. However, these windows could be a safety critical component of the pressure hull. The acrylic windows should be treated with a higher accurateness as the pressure hull.
The following standards are to be observed:

- ASME PVHO-1-2007
- Safety Standard for Pressure Vessels for Human Occupancy
- GL Rules I-5-1, 2, 3 Annex C Rules for Classification and Construction, Ship
- Technology Underwater Technology, Annex C Acrylic Windows
- Annex of Pressure Equipment Directive 97/23/EC,
- Manufacturer’s Processing Standards of acrylic for scientific and other special applications

Only the latest revision of each standard should be used for construction and verification of acrylic windows. New revisions can cause a necessary design modification of the pressure chamber flanges or / and windows for a renewal of windows after e.g. 10 years.

**Example:**

The windows of a medical pressure chamber (construction year 1999) have to be renewed after maximum lifetime (10 years for flat disc windows). The customer orders the flat disc windows from an approved manufacturer via pattern (old demounted windows). During the periodical safety check by a third party according to the new revised standard, it was detected that these new windows shall not be further operated with the maximum working pressure of the chamber.

According to the latest revisions the flange bearing contact area and the required thickness of the viewport needs to be increased. Without these measures this could have the consequence that the chamber pressure needs to be reduced from a maximum working pressure of actually 5 bar to a maximum working pressure of 3.5 bar. This reduction would be not critical for HBO / medical oxygen therapy. However, this pressure reduction may lead to a non-suitable chamber for treatment of divers. Therefore it is recommended to consider the actual status of standards or to involve independent expert support.
4.2. Failure causation, failure mode and failure detection

For the evaluation of failure characteristics as well as critical dimensions, locations and population of failures in acrylic windows international standards (e.g. ASME PVHO-1-2007 and GL Rules) are to be considered.

**Technical reasons for damaged windows:**

Mechanical influences such as:

- Scratching (with fingernail noticeable recess)
- Incorrect integration in the pressure hull
- Frequent stress (often pressure changes)
- Mechanical hits
- Use of non-suitable gasket material

Chemical / physically influences such as:

- Solvent-based cleaners
- Permanently ultra violet light
- High variation of the ambient temperature

**Example I:**

An acrylic window is non-suitable mounted in the flange of the pressure hull. Mechanical stress is generated in the sealing area of the window. This influence in combination with cyclic pressure stress can determine micro tearing in the window (structurally cross linking damage in the interior, see also Error! Reference source not found.). This defect increases continuously and could cause crack or collapse of the window in the worst case.

**Example II:**

The use of unsuitable solvent for cleaning of acrylic windows can cause permanent damage of the window and can lead to irreparable intercrystalline corrosion (corrosion inside of the meshing) of the acrylic material especially in addition with mechanical stresses. The material strength is strongly negatively influenced and may lead to a spontaneous collapse of the window.

![Figure 10. Chemical links between molecule chains \([C_5H_8O_2]_n\). Polymethylmethacrylat](image)

![Figure 11. Micro crazing (Source: Payne plastics)](image)

**Preventive measures for safety operation of acrylic windows:**

In order to avoid damages due to improper installation of seals, gaskets or incorrect flange geometries, a drawing approval according to applicable standards and constructional tests should be performed.

Visible damages (crazing see Error! Reference source not found.) indicate irreparable deterioration and lead to appropriate measures to provide a safe operation of the hyperbaric chamber.
Internal material stress can be detected by an analysis of the material via UV light or with polarisation foil.

Also important is the correct manufacturing process (cutting, polishing etc.) of the raw material and the subsequent correct annealing process. The quality of the manufacturing process has a very important influence to lifetime and safety integrity of the window in the hyperbaric chamber system. As you may know we implement this by company audits. Furthermore comprehensive tests according to international standards (e.g. ASME PVHO-1-2007, EN ISO 6507:2005, ASTM D638 and D790) as part of new manufacturing and treatment processes have to be carried out and supervised by a third party expert.

New manufacturing methods for acrylics provide new design possibilities for hyperbaric chambers.

5 Conclusion

Previously mentioned explanations regarding the use of electronic equipment and medical devices in hyperbaric chambers demonstrate the potential risk that may caused by a non-suitable medical device used in hyperbaric chambers. Each device shall undergo an examination against the requirements for safe use in hyperbaric environment.

The presented examples of hyperbaric equipment and associated components with possible failures show the need for examination and periodical surveys by a third party according to recognized standards.
Next to the technical safety related aspects also the quality management system of a Hyperbaric Centre including the qualification of the involved personnel is essential to cover a safe operation of the chamber and the Hyperbaric Equipment. It is recommended to perform the annual quality audit by an independent party to support in implementation of applicable standards.

References

1. GL Rules for Underwater Technology – Part 5 – Chapter 1 “Diving Systems and Diving Simulators”
2. GL Rules for Underwater Technology – Part 5 – Chapter 1, Annex C – Acrylic Windows
6. EN 14931 - Pressure vessels for human occupancy (PVHO) - Multi-place pressure chamber systems for hyperbaric therapy - Performance, safety requirements and testing
7. EN 16081 - Hyperbaric chambers - Specific requirements for fire extinguishing systems - Performance, installation and testing

(14) Medical equipment inside hyperbaric chamber

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Introduction

The selection and utilization of medical devices for hyperbaric medicine practice presents special challenges – related not just to physical compatibility and safety but also because of the legal and regulatory environment in which healthcare operates. This presentation does not aim to provide detailed information about any particular device, nor provide a recommended testing and approval pathway. Instead, the first section aims to provide an overview of the legal principles applicable and the second section provides a series of issues to be considered in assessing safety, with a number of observations and recommendations that may be of assistance to those establishing or refining their medical device safety processes.

Medical Device Regulation

Medical Devices are an essential part of the provision of healthcare and there are a range of laws, regulations, standards and licensing requirements in every country to ensure that medical devices are safe and effective. Worldwide, the definition of just what qualifies as a Medical Device does vary somewhat but the principles remain the same – anything that is specifically designed and marketed for use in caring for a patient. Thus a standard waiting room chair with armrests that is placed in the foyer of a hospital would not be considered a Medical Device but a similar chair with strong armrests used to assist patients with limited mobility is a Medical Device because it is designed and marketed for clinical use.

There are several main European Community Directives that guide the Medical Device regulatory environment within Europe and the United Kingdom. As with many EC Directives, these Directives have a primary aim of creating open and competitive markets in addition to the patient safety aims of such regulation. Compliance with these directives requires member countries to have legislation and administrative systems in place to enable approval of Medical Devices by a “Competent Authority” which can then approve “CE Marking” to allow use with patients across Europe. CE marking is the most widely recognized medical device approval system in the world, although many other jurisdictions have robust systems, with the United States and Japan being notable developers and manufacturers of Medical Devices under their own regulatory systems. Council Directive 93/42/EEC is the primary ruling for members of the European Community and it’s provisions have been taken up into legislation in each country, albeit with some important differences in how oversight of the Medical Device market is provided. It provides the overarching principles for Medical Device approvals, the
classification matrix and is harmonized with the critical European and ISO Standards that cover Medical Devices. Critical international standards for medical devices include ISO 14971 - Application of risk management to medical devices and ISO 13485 Quality management standard for medical devices. This latter standard is harmonized with the more generic ISO 9000 series of quality standards. Another set of critical documents with much more specific information about various types of devices is the International Electrotechnical Commission IEC 60601 series of standards.

The practical implementation of these Directives is administered slightly differently in different countries. In some, the regulatory authority has its own inspectorate that directly examines the design and manufacture of devices and then provides Medical Device approval if warranted. Others, by contrast, use private, third party agencies to assess the competence of the manufacturer to design and manufacture a medical device. Acknowledging that the greatest expertise in medical device engineering often resides within the manufacturers company, a substantial focus is on audit of quality assurance systems, including quality assurance over company management as well as device design, safety testing and manufacture. Once approval is received by a company under such quality based arrangements, it is often possible for the company to manufacture new devices which are declared as “substantially similar” and therefore able to be CE marked and marketed using an existing approval, rather than having to undergo a new inspection.

Medical Devices are categorized according to the perceived risks associated with the device. The categorization rules are complex but in overview, Class I Medical Devices are typically non invasive devices that do not deliver drugs and this class includes passive objects like chairs and bedpans. Class IIa devices include most surgical instruments, infusion pumps and equipment that can act physically upon the body but in a non hazardous way. Class IIb devices include lower risk implantable devices and all devices which can deliver potentially dangerous energy to the body or modify physiology or drug actions. This includes hyperbaric chambers. Class III devices are those categorized as carrying the highest risk, such as implantable pacemakers and invasive neuro-monitoring equipment.

In recent years, there have been many developments in the regulation of Medical Devices. New ISO standards have been developed, often originating from previous EuroNorms. There are a number of ISO committees working on international standards to replace previously varying country by country standards. One such important committee is ISO TC121 – Anaesthesic and respiratory equipment, where a debate has been initiated as to whether hyperbaric medicine deserves a specific subcommittee within this Technical Committee.

There have also been significant revisions and developments with respect to the IEC 60601 series of standards, which provide the most detailed template for the design, manufacture and safety testing of Medical Devices involving electrical components. Most Medical Device regulatory authorities and most countries laws call for compliance with IEC 60601, although in some cases only older versions or specific parts are called up at this time.

Much work remains necessary with respect to international harmonisation, given that the market for most Medical Devices is worldwide and it is presently difficult for manufacturers to gain approval in multiple markets, given so many different and often complex, slow and expensive administrative pathways. Most companies with a new medical device will engage specialists to help assemble the paperwork or to provide the auditing required to gain approval to “go to market”.
Overall, regulation is getting stricter and part of this trend is that some equipment that was not historically defined as a Medical Device is now clearly covered by regulation. In Australia, for instance, monoplace hyperbaric chambers have long been classified to be Medical Devices, but multiplace chambers, by contrast, were considered mechanical installations within hospitals that were guided by pressure vessel and occupational diving standards. In 2002, however, multiplace chambers were specifically identified as “Class IIb” medical devices and compliance with the Medical Device requirements was mandated from 2007. As is often the case with new laws, this mandate applied to new hyperbaric chambers only, and becomes applicable to older chambers only when they are substantially overhauled to the extent that they are considered “re-manufactured”. In the Europe, hyperbaric chambers are also clearly defined as Medical Devices and thus require CE marking. As a result, we have the unusual, but not unique, situation of wanting to use Medical Devices inside another Medical Device. (Providing ECG monitoring whilst a patient undergoes a CT scan would be another example)

“Composite” medical devices have created challenges for regulators in recent years – especially when consumer devices are used as part of the operation of a medical device. An example might be a transcutaneous monitor which has a laptop computer and printer connected, all powered from a small computer UPS, connected with “off the shelf” power cords. From a patient safety point of view, the whole assembly needs to be considered as one system but the TCOM manufacturer has only provided one part of the system – the Hospital staff have purchased the rest of the items, assembled them on a trolley and then put the whole system into service. In this setting, the Hospital staff can be considered to have become “The Manufacturer” from a legal point of view unless the TCOM manufacturer has specifically identified that the selection and connection of each of the ancillary components is part of the design for which they gained approval.

Similar considerations come in to play whenever a modification is made to a Medical Device, for instance to make it hyperbaric compatible. If work is conducted on the Device by a manufacturer trained technician and according to the technical manual, then this can be considered normal practice that does not void the device’s warranty or its Medical Device approval and CE marking. This is the case when a hospital employed Biomedical Engineer has been trained and approved for the maintenance of a particular device, although not all manufacturers facilitate this. If a significant change is made to the device in any way that is not approved by the original manufacturer, the employer of the engineer making the modification can be considered to be the new “Manufacturer” who is now legally responsible for the device.

Fortunately, there are provisions that may allow Hospitals to avoid the cost, delays and paperwork involved in seeking Medical Device registration themselves for such modifications or for assembly of composite device systems – Medical Device regulation primarily controls the “marketing” of medical devices. If there is no “marketing” then the regulations may not apply, and this can be considered the case when a Hospital’s Biomedical Engineering Department manufactures or modifies a device for use in the hyperbaric chamber. Note, however, that supplying a successful custom made device to another hospital would be considered “marketing” in most jurisdictions, whether payment is made or not. Also important to note is that general safety and liability provisions of law always continue to apply – it is only the registration and CE marking component of law that can be avoided.

Medical Device “labeling” is another important issue. For a device to be approved, the Manufacturer must document not only safety and operating information, but also the indications for use. This must be submitted to the Competent Authority and included in the operating manual or on the “label”. The information submitted by

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to the Medical Device regulatory agency will define what is “on-label” versus “off-label” use. Included in the manufacturer’s documentation will be the environmental operating conditions that are allowed and this will only rarely include hyperbaric pressure. In some cases there may be a reference to hyperbaric use being either allowed or specifically not recommended. Off-label use is usually considered to be use for an indication other than recommended by the manufacturer but is can also be considered to apply to use of the device in an environment that falls outside the manufacturers specific “operating environment”, for instance at pressure inside a hyperbaric chamber. In at least one instance, these different “label” considerations are not in alignment – the Cardinal Alaris modular infusion pump system has operating conditions specified as including pressures of 0 – 6000hPa (full vacuum to 6 bar absolute) but it is specifically not approved for hyperbaric oxygen chamber use. Presumably the warranty is not voided by having the pumps used in the chamber but any use on patients is clearly “off-label”.

The consequences of off-label use vary somewhat in different jurisdictions but as a general principle, a physician is entitled to use a device “off-label” in several circumstances. In an emergency, the physician (and his or her employer if relevant) can take responsibility for off-label use. Off-label use may also be permitted for “special” or “compassionate” purposes. Such off-label use will usually require a special application or at least notification to the medical device authority – in some jurisdictions for every case where the device is used.

The other pathway for using medical devices off-label or for using non-approved devices is via Clinical Trial Notification, where the oversight and approval for the off-label use is provided by a Human Research Ethics Committee (called an “IRB” in USA). The application for such an approval may relate to clinical research designed to test the medical device prior to registration, or to using an unapproved medical device for some physiological or clinical research that can only be conducted with a device that does not yet have approval for general clinical use.

**Footnotes to Medical Device Regulation section**

A good source of overview information on medical device regulation is the website of the UK’s Competent Authority, the Medicines and Healthcare products Regulatory Agency (MHRA) which publishes Bulletins which explain the requirements and clarify various issues in straightforward language. It should, of course, be remembered that the MHRA advice represents the UK legal situation and both law and its interpretation will be somewhat different in other jurisdictions, despite harmonisation.

Readers should note the above Section attempts to summarise some general principles from the point of view of the author who is a clinician without legal training. The legal position applying in each reader’s jurisdiction will depend upon the jurisdiction’s relevant laws and any Standards and Codes called up, as well as local interpretation and the administration processes of the relevant authorities.

**The Physical and Safety Challenges**

Most medical devices are designed with the assumption that they will operate in a hospital at fixed altitude. As for consumer and industrial goods, the assumption is therefore generally that they must work at pressures from sea level (1.0 atmospheres absolute / 1.0ATA) to altitudes of no more than around 3000M (10,000 feet) although most devices are designed to cope with transport by aircraft when packaged up and in a non operating condition. Many devices will actually work during altitude exposure and some are actually designed for aeromedical
transport use, which requires tolerance of pressure change but it is important to note that the rate of change in
pressure during aircraft flight is a fraction of that experienced in the hyperbaric chamber. A normal commercial
aircraft cabin will depressurize to around 0.8ATA over a period of about 20 minutes – a pressure change rate of
approximately 1 kPa per minute. Slow hyperbaric chamber pressurisations are 10 times faster than this and many
chambers are capable of pressurization at 100kPa/min or faster.

Accepting any device into the hyperbaric chamber will always require a local risk assessment process. The
complexity of this will depend upon the item and whether it is approved and CE marked for hyperbaric use (best
case) or locally modified, custom built, or only capable of modified or limited operation in the chamber (more
difficult). The fundamental principles of device risk assessment are to assess whether the environment can affect
the device and whether device creates risk for the environment (including the patient), in each case during either
normal operation and during failure modes, including human behavior failure modes. The raised oxygen
availability and its consequences for fire safety are always critical risks to be assessed.

Testing

Many hyperbaric centres have developed their own testing programs for hyperbaric compatibility of
commercially manufactured medical devices as well as custom modified or locally manufactured items. In
addition, manufacturers who have approved devices for hyperbaric use have presumably undertaken their own
risk assessments and testing programs. Unfortunately there is no standardized approach at this time.
Development of expert agreement on a recommended testing pathway would be ideal as this might facilitate
manufacturers to consider hyperbaric use of their devices, especially if such a document could subsequently be
published as a European or ISO Standard. At this time, however, each institution and manufacturer must develop
their own program, guided by the principles listed in the relevant laws and standards and by the experience of
those centres which have made their experience public.

Testing will, in most cases, require the involvement of biomedical engineers, who often have access to technical
documents and risk information from manufacturers, as well as advice from their professional networks. It is
worthwhile having a final risk evaluation committee which includes professionals from all relevant disciplines,
including persons who were not involved in the testing process.

The following considerations are aimed at assisting hyperbaric team members in understanding some of the
issues that must be addressed in developing a risk assessment and testing process for medical devices that are not
CE marked for hyperbaric use.

Manufacturer cooperation

Risk assessment and testing will be easiest and most robust if the manufacturer is prepared to cooperate by
making a test device available, complete with access to technical manuals and ideally to original test data.
Fortunately, detailed design and software programming information is rarely critical to the risk assessment given
that these are often the most secret intellectual property of the manufacturer. Unfortunately, it is often necessary
to proceed without manufacturer support as many suppliers are too concerned about corporate risk associated
with such cooperation, even if cooperation were just supplying a technical manual.
The chamber manufacturer should be considered an important source of expertise and opinion, and may be prepared to provide input into testing or risk assessment processes, especially if this is only in an advisory role with the hyperbaric unit taking the legal responsibility.

Single device vs multiple

One strategic decision necessary is whether testing of a single device is adequate. In many cases, this will be all that is practical but an assessment must be made as to whether the single device tested will be adequately representative of all devices.

Individual device approval or type approval

When a particular device is approved, a decision must be made as to whether the approval is valid only for the particular device or set of devices tested, or whether approval can reasonably be extended to all identical models of device from the same manufacturer, or even to a whole class of devices. This will depend upon the nature of the device and whether the manufacture of any one type of device can be relied on to remain identical over time. It is important to note that many consumer electronic devices can be sold with different electronic components from different suppliers, even though the brand, the model number and the external features of the device remain unchanged.

Hyperbaric specific devices or generic device approval

A related issue is whether to restrict devices inside the chamber to only those devices that are dedicated to the hyperbaric unit or whether to allow approved device types to enter the chamber, even if they have come from another part of the Hospital. Portable devices that travel to the chamber from other areas carry a particular risk of arriving at the hyperbaric unit with un-reported damage or in an unsafe condition, such as having been recently cleaned with an alcohol solution. Although it may be clinically ideal to provide continuity of beds, infusion devices and monitors, the reduction of clinical risk by avoiding changes carries with it an increased risk of a damaged or contaminated device or a contraband article entering the chamber. There are no obvious right or wrong choice here – the risks and benefits will vary with individual devices, institutions and clinical situations.

Failure Modes and Effects Analysis for electronics

Failure mode and effects analysis (FMEA) is an important risk assessment technique and a critical part of assessing hyperbaric compatibility of medical devices. It is important not just to assess the risk of the hyperbaric device to the chamber environment and the effects of the chamber environment upon the device during normal operation of the device in a normal hyperbaric setting. The potential failure modes of the device and potential abnormal operations of the chamber (emergency decompression, deluge activation etc.) must be considered. A thorough internal inspection of a device by an experience biomedical electronics engineer will usually identify the most likely potential failure points in circuit boards and components, enabling consideration of whether any ignitable materials are nearby to any potential hot spots. Ideally, the manufacturer’s original safety test data will be available – most electrical devices have undergone extensive failure modes and effects testing, including flame testing to identify components which may melt, distort or ignite. This information is, unfortunately, rarely
made available and the critical testing may have been done by a component manufacturer, not the company that finally assembles and tests the device. It is important to remember that ignitability and flammability are enhanced in oxygen rich, pressurized environments and this needs to be taken into account.

**Destructive failure modes testing**

It must be accepted that testing of medical devices for hyperbaric compatibility may destroy the device, or at least make it unusable with patients. This can occur when a plastic casing has to be damaged to open up the device for inspection or a pressure test may damage internal components. If the ignitability and flammability of critical internal components is impossible to assess from inspection or manufacturer’s data, it can be argued that some electrical devices will need flame testing and/or over-voltage testing in a hyperbaric fire test chamber.

**Pressure testing**

Pressure testing must include the range of pressure scenarios possible. This will include the maximum chamber pressure and the maximum rate of pressure change possible. For some smaller devices, this may include passing through the medical lock which will expose the device to very dramatic pressure and temperature fluctuations. Although pressure is the main focus, rapid cooling can also cause damage via component cracking. In some cases, a medical device will only work normally in a restricted pressure range and this will need to be clearly identified in labeling and operational procedures. In some cases, devices which demonstrate a non-critical failure with abnormal pressure exposure might be acceptable – as an example, the author’s institution allows a certain pneumatic mattress inside the chamber which works satisfactorily during normal therapeutic profiles but damage will occur to the mattress bladder if an emergency decompression is undertaken. Saturation exposure testing can also be useful in some circumstances, even if saturation profiles are not used therapeutically. An overnight pressure exposure followed by a sudden depressurization will provide an extreme provocation for gas dissolving into the materials within “sealed” wheel bearings or hydraulic or pneumatic lift cylinders on beds and trolleys, for instance.

**Functional testing under pressure**

Functional testing under pressure can be time consuming. In some cases, preliminary function testing of parameters such as infusion pump flow rates can be carried out without human presence inside the test chamber but it will usually be necessary at some stage to have a staff member test all of the likely operating functions of the device during pressurization, constant pressure and depressurization phases. Specific test equipment may be necessary, for instance to test volumetrically correct flow rates of ventilators or the vacuum flows and pressures of suction systems. For infusion control devices, it is important to make accurate low flow tests across the range of operating conditions, to ensure that paediatric doses or critical vaso-active drugs are not delivered in a dangerously inaccurate or variable manner. Timed gravimetric methods are probably the most accurate, where small volumes are delivered via a needle tip into a series of labeled and individually pre-weighed containers which are then weighed to determine volume of fluid gathered.
Some specific technical considerations

Installing devices without modification

When medical devices require any act of installation inside the chamber, it is preferable if this can be done without modifying the manufactured medical device in any way. Examples are where cable connections are required to pass through the chamber hull between electrophysiological monitor modules inside and external monitors, or the provision of a dedicated low voltage power supply via custom hyperbaric power connectors. If the manufacturer makes extension cables available, as utilized in hospital installations, these can usually pass through the chamber pressure hull via “split bolt” penetrators that clamp tight onto the cable or which use a sealant compound, thus not requiring biomedical cables to be cut and soldered or crimped onto a commercially manufactured pressure proof aviation or marine electrical penetrator. Although a “make-shift” pressure penetration around a medical device cable may not be completely leak proof, it can be pressure tested and the risks arising from minor air leakage may be more acceptable than the risks incurred by electrically disrupting data or physiological electrical signal cables and thus possibly making the electronic technician responsible into the “manufacturer” of the medical device. The same concerns about cutting and rewiring electronic cables apply for many video signal formats – non-standard cables and connectors often interfere with the video image and it is preferable to use commercial penetrators and connectors or else unbroken cables secured into a pressure penetrator as described above. Fortunately many signals can now be transmitted by wireless technology (Bluetooth, Wifi etc) or via an Ethernet cable and off-the-shelf Ethernet pressure penetrators which are now readily available.

Accepting abnormal operation

Some medical devices, most notably ventilators and end tidal CO2 monitors, will operate in the hyperbaric chamber but will function in an abnormal way, but an abnormal way which is predictable and clinically acceptable, in the absence of a superior device. Any abnormal function or abnormal measurement display must be well characterized and acceptable to clinicians operating the equipment and caring for the patient. In some cases, the abnormal operation may be a limitation – for instance a maximum minute ventilation volume that is significantly reduced compared to normal.

Physiological response differences at pressure

Ventilation and response to vasopressors are two of many areas where a patient’s physiological response under pressure may vary from that expected at sea level and it is important that this is not confused as indicating a medical device malfunction. Sometimes it is difficult to separate these issues however, for instance if minor changes occur in vasopressor requirements it can be difficult to determine whether this is a drug delivery rate variation or a physiological response.

Electrical safety overview

Electrical safety covers a range of aspects. In general, the hyperbaric environment does not create any special considerations with respect to electro-magnetic radiation, electrical shock risk or the clinical impact of a device
ceasing function. Most hyperbaric facilities now choose to make the chamber’s medical electrical installations and chamber power supply systems compatible with only “Body Protected” standards rather than “Cardiac Protected” although cardiac protection is possible, using isolation transformers and line isolation monitoring. As intracardiac procedures are not usually undertaken in the chamber, using standards applicable for emergency resuscitation rooms and lower acuity intensive care cubicles is probably reasonable but further consideration of this is beyond the scope of this paper. The main electrical safety concerns are whether any particular medical device is pressure tolerant, whether it functions normally under pressure and whether the device is capable of producing heat that might initiate a fire in either normal operation or in any particular failure mode. Pressure change may damage the device, gas density change may alter cooling characteristics, predisposing to overheating and oxygen levels may change ignitability and flammability. The potential for electrical failure to initiate a fire is thus the principal risk to be assessed, although not the only risk possible, of course.

The voltage issue

Even the smallest of batteries contains enough electrical energy to risk triggering a cardiac arrhythmia in a patient with pacemaker leads or a conductive fluid pathway to their heart. With respect to fire safety, 6-12 volt batteries can produce a powerful spark if short circuited. Consumer dry cell batteries of 1.3-1.5 volts can be made to generate sparks if connected to the right electronics – pocket Tasers and lasers being the most extreme examples. A common electronic circuit voltage carrying a few milli-amps at 5 volts can deliver enough energy to overheat a small component, generating temperatures that could ignite an alcohol vapour – oxygen mix. Short circuit and component failure temperatures can be high enough to ignite fluff, paper or some plastics. By contrast, there are many examples of 400 plus volt, three phase, high amperage motors driving equipment safely in potentially explosive environments, such as exhaust fans and hydrocarbon gas compressors on oil rigs and in petrochemical plants. Safety in these situations is dependent upon “explosion proof” technology which can safely contain and dissipate both heat and gas expansion in a safe manner in the worst case scenarios. Simplistic electrical safety formulae that merely specify a maximum safe voltage and / or power (wattage) therefore make little sense for hyperbaric chambers – in all cases, a proper safety assessment must be made of risks that might arise from normal operations in conditions of high heat and operating intensity, as well as during the various failure modes that can be identified for each component of the device.

Batteries

Batteries represent one of the major hazards associated with medical device use in the chamber. There are, however, many precedents for the use of suitable batteries, which are most commonly sealed lead acid gel or nickel-metal-hydride (NiMH) rechargeables for devices with relatively high energy requirements such as ventilators, infusion pumps and wireless communications sets; single use carbon-zinc or “alkaline” dry cells for wireless headsets and small size single use “button” or circuit board mounted batteries that operate implanted devices or maintain the memory and timeclock functions of other devices when the main power is switched off. These latter types are often based upon silver or non-rechargeable lithium chemistry.

Each of these battery types should carry relatively little risk in normal operation. The main risks of overheating and fire ignition arise from charging or from excessively rapid discharge. Batteries should never be charged in
the chamber (some types produce hydrogen gas). Batteries should not be changed over inside the chamber and all battery powered devices should have inbuilt protection against excessive discharge or short circuit.

Lithium-ion and lithium polymer batteries have created major challenges for hyperbaric safety in recent years as the majority of portable devices and nearly all consumer electronics incorporate these technologies and nearly all agree that there are too many risks and unknowns to allow these types of batteries into the chamber. When this battery technology first appeared, there were significant instances of spontaneous fire and many recalls resulted for devices such as laptop computers and mobile phones. The safety of this technology has since improved dramatically but in ways that may not necessarily provide adequate hyperbaric safety. A significant part of the interior volume of most lithium based rechargeable batteries is occupied by “add on” safety technology, such as micro-chip electronic monitoring circuits that protect against excessive rates of charge, excessive discharge or excessive temperature and the casing is fitted with tiny valves to vent excessive internal pressure or allow air ingress during pressurization, for instance during descent in an aircraft. Manufacturing quality control has been important to reduce the likeliness of “hot spots” occurring at thin points and to prevent leaks in internal membranes, particularly in lithium ion cells, which have semi-liquid electrolytes inside. Physical deformation is a specific risk, as if the layers inside the cell are distorted, creating a hot spot or electrolyte leak, the heat generated can be sufficient to trigger spontaneous and self perpetuating combustion. When this occurs, lithium cells have the dangerous characteristic that in many cases, the chemistry for combustion can be fully provided from within the cell, without any need for external oxygen. Combustion can therefore continue underwater and the temperatures generated can be easily sufficient to melt metal. Air transport of lithium batteries of any significant size is highly restricted, with only small batteries for cameras, computers and phones allowed in the aircraft cabin.

There are many different lithium ion chemistries and some are probably safer than others. It is claimed that recent phosphate based chemistry has intrinsically better fire safety. It seems likely that lithium polymer cells are also inherently safer, as the electrolyte is bound within polymer sheets within the flat pack style cells and large capacity lithium polymer batteries have been used to power underwater vehicles with the batteries exposed to pressure. Most expert opinion nevertheless holds that none of these technologies are yet ready for in-chamber use.

As lithium batteries have the highest stored energy density readily available to date, they are popular and it can be difficult to find suitable non-lithium options and this is presently limiting the choice of medical devices for hyperbaric use. In some cases batteries can be replaced, for instance with NiMH, but this may void the manufacturers warranty unless this is a specifically available option. It is hoped that in future there will be new battery technologies that are intrinsically safer, such as perhaps, silver or zinc-air units.

**Waterproofness and electrical isolation**

The water based fire suppression systems of hyperbaric chambers make it necessary assess the effects of water spray or fog on any medical device. Most devices have an “IP” rating that includes rating against water ingress or submersion but the risk of failure or of electrical hazard when wet should also be assessed. Any electrical systems within the chamber which are not “intrinsically safe” and waterproof should have their power automatically disconnected upon activation of the fire suppression system. For stand-alone devices not connected electrically to the patient, such as infusion pumps, the main risk is cessation of operation – “runaway”
pumping is probably unlikely. Devices such as ECG monitors that are electrically connected to the patient are in theory of more concern as there is a direct electrical pathway to the patient’s now wet skin. In practice this risk is probably negligible as all devices that have direct electrical connection, such as ECG monitors, external pacemakers, cardiac output monitors etc have design features to prevent electrical shock in all normal operation and in failure modes. In the author’s facility, we have assessed the hazards associated with our monitoring system during inadvertent activation of the fire deluge during whilst an intensive care treatment is underway (which has occurred). During the physiological shock of sudden drenching with cold water we felt it was most important for vital signs monitoring to continue and our automatic electrical isolation system is therefore designed to shut off power to the low voltage power outlets in the chamber and to the in-chamber video screens but not to the monitoring system which has its central processing unit outside the chamber. The external display of physiological parameters thus stays “live” and low voltage power will still be present within the modules which operate the ECG, blood pressure transducers, end-tidal CO2 monitor and oxygen saturation probe.

**Robust or readily replaceable?**

In many cases, the cost of water and pressure tolerant devices is high, and a waterproof or totally pressure tolerant device may be more complex to install and/or operate than more commonly used devices which are not so robust. In these cases it can be a valid choice to select a device which will most likely fail in case of saturation by the fire deluge – it can be removed or covered with plastic wrap for fire deluge testing but will probably have to be replaced in case of an unplanned deluge. This seems a valid choice provided replacement units are readily available or held as a spare part.

**Sealed but air filled components**

Many devices have gas containing spaces within them which are sealed to keep out water and dust. The sealed container is generally designed to be strong enough to resist depressurization during air shipping but this will often not be adequate to prevent crushing during hyperbaric chamber pressurization. Modern computer hard drives and old electronic capacitors are two common examples where deformation of the casing may temporarily or permanently disrupt function of the device. Most modern implanted pacemakers and pacemaker/defibrillators fortunately have been manufactured with a casing sufficiently strong to retain function during either hyperbaric oxygen therapy or scuba diving but it remains important to check the characteristics of each device implanted in our patients.

**Risks of vented devices**

Most biomedical devices are pressure tolerant because they are not sealed. Large vents may be required for cooling or there may be only small leaks in casing materials. Some devices which were sealed may be modified with a vent (perhaps just a small drill hole) to make them pressure tolerant.

Large cooling vents suggests the device generates heat and is dependent upon cooling and the hazards of the heat source will need careful assessment, especially if the device has cooling fans which may fail to work normally under pressure or which are not be pressure safe and therefore need to be inactivated. The result may be overheating of the device unless another source of cooling is provided. A semi-sealed device with only small
leaks may tolerate slow pressurization but may deform if pressurized or depressurized too fast – in this case a choice must be made to risk damage during emergency pressure change or alternatively to make the vent larger. It is arguable whether a small vent in the casing of a device such as an infusion pump would invalidate the Medical Device approvals for the device. The manufacturer would almost certainly deny warranty in case of failure but it is normal practice for biomedical engineers to take casings apart for repairs or servicing and casings are often damaged resulting in cracks which do not stop the device working. In such cases, a small vent hole may be considered consistent with “expected and “non critical” damage.

An important hazard with all vented devices is that there will be significant ingress of air with each pressurization and depressurization cycle and this may carry small amounts of dust and fibre into the device, from skin, bedding, clothing and the like. It is common to find such contamination inside ductwork and on exhaust filters of hyperbaric chambers and contamination can also build up within vented devices. Such fine material probably represents the second most ignitable material of concern in the hyperbaric chamber, after flammable vapours. Fine cotton fibre, for instance, is readily ignitable and a fire could be initiated by a relatively minor short circuit or component failure. There are several strategies to keep the interior of a vented electrical device clean. One approach is to have a regular inspection and cleaning program but this may be impractical if disassembly is required. Preventive strategies to keep dust and fluff outside the device or just the components at risk include:

- potting in a solid resin
- encasing with a pressure proof housing
- venting the housing via a fine filter
- purging the casing with air or nitrogen at a flow rate that prevents chamber air ingress during normal pressurisation

The purging issue

A common strategy to reduce an unacceptable fire ignition risk is to purge the device with either air or nitrogen. Although combustion is still accelerated in a pressurized air environment compared with sea level pressure, air purging has certain advantages: it excludes oxygen build up and thus keeps ignition potential close to normal, it prevents ingress of dust and fluff and being readily available, relatively high flows can be used if needed to provide cooling or to exclude oxygen and contaminants from “leaky” housings and ductwork. Nitrogen purging has the added advantage of essentially eliminating any combustion risk, provided there are no oxidants present, for instance in battery chemistry or in the form of oxygen pipework passing through the purged space. In order to flush air out of a space, significant nitrogen flow will be required for a period of time and higher flows of nitrogen carry some risks – if the flow continues when the chamber is unventilated, for instance overnight, there could be a hypoxic environment in the chamber when staff enter to set the chamber up for the first treatment session of the day.

Although they are rarely used in hyperbaric engineering, sophisticated purging control units are available, designed for explosive atmospheres. These units interlock nitrogen flow with the electrical power to the device and only switch power on after an initial period of high flow purging. After power is activated and the initial purge achieved, a lower flow continues during operation. If nitrogen supply fails, the power is cut. The author of
this paper suggests that if nitrogen purging is required to provide both cooling and fire safety, then such explosion proof technology should be used as a failure of a simpler nitrogen purge system would bring about both overheating and failure of purging safety. More practical in most cases will be to deny the use of any such high risk device in the clinical hyperbaric chamber.

“Potting”

One alternative approach to safeguarding against pressure damage, water and contaminants simultaneously is to completely flood an assembly with a “potting compound” which is often an epoxy resin, although other resins, liquid or solid silicone sealant, and various plastics are sometimes used. Ideally, the potting compound should be non ignitable and it is important that this sealing strategy does not result in a risk of overheating failure of components inside, such as electronic power supplies. If potting is present in a manufactured device being assessed, the oxygen fire safety should still be assessed. The right potting compound will be both heat tolerant and will also absorb heat and conduct it away fast enough to reduce any hazard without increasing the risk of electronic failure within the potted components. If users are considering potting a potentially hazardous component themselves, great care is necessary in selecting the potting compound and then in testing the temperatures and functions in worst case scenarios.

Motors

Many medical devices incorporate small electrical motors and solenoids, for instance in infusion pumps, to control gas flow in ventilators, to operate non-invasive blood pressure cuff inflation or to spin the infra-red beam “chopper” within older analogue end tidal CO2 monitors. Although most such motors will have been selected for safety, there are significant fire ignition risks attached to motors with commutators which can produce sparks. In addition, any spinning shaft can produce friction and thus heat if there is contamination or bearing wear. Motors such as “stepper” motors which do not have commutators are generally preferred and in some cases an unacceptable motor may be the only reason for “failing” a device for hyperbaric use. Some assessors have felt the risk of a small motor is minimal if the motor is deep within an isolated space with non flammable materials in proximity, no way of alcohol contaminating the interior and perhaps exclusion of oxygen or even nitrogen purging.

Pressure transducers

As with analogue pressure gauges, electronic pressure transducers are available in both absolute and gauge (differential) pressure type. Most pressure transducers in modern electronic devices are solid state items that are pressure tolerant, even if they do not measure the pressure range required for hyperbaric operations. The differential pressure transducers used in both invasive and non-invasive blood pressure monitoring devices can be expected to function normally and accurately. Absolute pressure measuring transducers in medical devices often have an inadequate range for hyperbaric exposure, however. A common problem preventing modern ventilators from functioning under hyperbaric conditions is the presence of an accurate absolute pressure transducer designed to correct volume measurements and calculations for the small variations in atmospheric pressure each day. The change in pressure in a hyperbaric chamber will normally greatly exceed either the
software settings or the physical pressure range of such transducers, either triggering an alarm state or incorrect function.

**Flow meters and volumeters**

Electronic devices to measure gas flow and volume are at the heart of modern ventilators. There are a range of technologies that can be used but the most commonly used are subject to varying output as gas density changes with pressure or different gas mixtures. As noted above, accurate absolute pressure measurement can be used to enable correction of volume readings for small variations in ambient pressure and this is often a point of failure in hyperbaric compatibility. In principle, however, a suitable pressure transducer and the right computer software algorithm can correct any flowmeter or volumeter for varying ambient pressure. The ventilator volumes we wish to have delivered at pressure are, of course, the actual physical volume at the therapeutic pressure – not the equivalent amount of gas at sea level pressure (often called “standard” volume or flow). Fortunately oxygen and nitrogen are close enough to each other in density such that oxygen fraction makes relatively little difference to delivered or measured volumes, however pressure variations and use of helium can both induce significant changes, usually in the direction of under-delivery of volume by the ventilator. This results because the flowmeter measures higher than expected flow, leading the control electronics to reduce flow until the “right” electronic output is obtained from the flowmeter which matches the sea level volume settings. The most commonly used flowmeters are those based upon differential pressure measurement across a restriction or screen, upon heat absorption by the passing gas, or upon force measured by a strain gauge stretched by gas flowing across a small paddle in the airflow. All of these technologies will measure high with increasing gas density (and heat capacity). Technologies not significantly affected by gas density include some turbine wheels (as in “Wright’s” spirometers), bellows or piston displacement volumeters, ultrasonic velocity meters and some Coriolis mass flow devices with pressure correction.

**Touch pad and touch screen control**

It is well known that only some membrane touch pads are designed with in-built venting to avoid activation by pressure. The keys of standard sealed touchpads will be depressed as pressure increases, activating all of a devices control keys. It is possible to modify such keypads by venting each key’s membrane with a small drill hole however this destroys waterproofness if drilled from the exterior, risking the ingress of water that may lead to corrosion or of alcohol cleaning agents that may create a fire risk. Accessing the keypad from behind may be possible but often involves separating glue layers. Spare keypads are often available for repairing devices however.

Increasingly, devices are controlled by touch screens. Some of these are activated by pressure which brings membranes together under the finger or stylus and these may or may not prove problematic with pressure. Inductive technology screens do not have this problem but may not operate if gloves are worn.

**Video display screens**

Flat screen video displays are increasingly used inside chambers for entertainment display, electrophysiological monitoring, and display or even control of chamber operating systems. In assessing risks associated with these
devices, it is important to note that older LCD screens are illuminated by cold cathode fluorescent tubes around the perimeter – these require several thousand volts to initiate luminescence and several hundred to operate, generated internally even if the input power to the device is only 12 volts. Newer LED illuminated LCD screens require only a few volts to operate the illumination and the whole monitor operates at much lower power, producing much less heat. The risk assessment conclusions drawn with respect to LCD screens seem to differ widely - it appears some chamber manufacturers have installed standard consumer screens for entertainment without any special protection, whilst others completely enclose and purge their screens. There are probably safety advantages to using specially selected industrial, marine or medical screens which have frames and housings made of metal rather than plastic and much more robust components. In some cases suitable “explosion proof” units may be available but these will still require hyperbaric safety assessment.

**Stiction**

Stiction is an engineering term derived from “static friction” and “sticking”. It refers to the concept that in many circumstances it is necessary to use a brief increase in force to initiate movement because of various surface forces other than inertia, adhesive bonds or magnetism etc. These forces can be related to matters like surface characteristics (roughness) or electrostatic forces or the plasticity of lubricants. In syringe pump infusion devices, stiction is often evident as a small lag in the commencement of infusion after a new setting is activated – the syringe driver motor must run for a while, building up pressure on the syringe plunger, before movement of the plunger actually commences. A number of centres have documented changes in low flow function of syringe infusor devices in hyperbaric conditions and this can be due to increased stiction – the flow diminishes at the start of pressurization and flow may then increase at the end of depressurization as stiction decreases. A likely source of this is the gas space between the two sealing rings of many types of syringes – this space is air filled and will be subject to Boyles Law forces which may distort the plunger seal, causing it to bind more tightly against the syringe barrel.

**Ongoing safety assessments over device life**

After a device has been assessed as safe for hyperbaric chamber use, it cannot be assumed it will stay that way for the life of the device. Daily inspections should occur for damage and a scheduled formal inspection and servicing plan must be in place. In some cases, devices have been noted to be prone to premature failure after regular hyperbaric use. Some batteries will exhibit shorter times to discharge than expected or reduced number of re-charges before failure.

**Conclusion**

Ideally, medical device manufacturers would all specify their devices as either hyperbaric compatible or not and chamber manufacturers would list all compatible medical devices approved within their chambers. In practice, few medical device manufacturers consider hyperbaric use and those that do most often try to avoid liability by advising they do not approve hyperbaric use, even if a device may be compatible. Likewise, few chamber manufacturers are interested in taking liability for medical device safety inside their chambers. Most,
understandably, take a very cautious and restrictive approach, which may include providing support only for their own branded devices.

For optimal care we would have access to the best available equipment. In practice, it seems the hyperbaric community will need to continue our own testing, modifications and risk acceptance processes into the foreseeable future. Hopefully the recent marketing of some new hyperbaric compatible devices herald the start of a greater willingness to assist us by providing more examples of CE marked hyperbaric medical care equipment. If this trend can continue, it would enable a focus on research and development of new devices rather than our present dilemma which is often to decide which item of old or modified technology is the least incompatible with hyperbaric use.
Chapter 5: Quality assurance / accreditation
(15) Quality assurance

Francis Burman (South Africa)

1. Executive summary

We all wish to provide our patients with the highest quality of healthcare. The term “quality” implies a variety of metrics, including service, safety, sound practice and cost-effectiveness. Providing a clear path to ensure all of these in a way that can be quantified is quite challenging; the process is complicated by language barriers, cluttered by rules, regulations, expectations and, not infrequently, confounded by misinformation and miscommunication. So, before we are able to address quality of healthcare services, it is essential to standardise and clarify the language we use, the terms of reference we apply and the methods of communication we employ.

Dedicated efforts in a few regions around the world have seen the development of structures and methods that allow hyperbaric medicine practice to be assessed, improved and ultimately established as a reliable, reproducible, safe and effective health intervention. Europe’s diversity of language and culture and its long history of producing regulatory instruments make the task of consolidation and finding uniformity in this respect especially challenging.

The broader field of quality management is a moving target. As service industries have grown, so also have the models for defining, monitoring, improving and validating them.

In this paper, we will attempt to define more clearly the common terms used to communicate quality, offer a review of where we currently stand and where other international hyperbaric treatment programs stand, and then analyse suitable ways to connect all the existing elements in an effort to provide a suitable pathway forward.

2. Objectives

We would like to answer the following questions:

1. What do we mean with the term Quality Assurance?
   (We need consistency in the definition of our quality related terms and concepts.)

2. What do we really need from Quality Assurance?
   (We need safe, ethical and cost-effective healthcare that is offered in a harmonised, integrated and achievable system which is able to address the myriad of requirements across the regions.)

3. Why do we need this?

4. (To assure compliance with statutory requirements while achieving good clinical outcomes on a consistent basis.) How can we do this?
   (By firstly achieving consensus on a suitable model for Quality Assurance, or at the least, agreeing on the criteria for a proposal that will ensure a balanced focus on technical issues, operations and patient outcomes.)

This paper is dedicated to providing substance and meaning to these initial answers so that we can achieve greater clarity and intentionality for the path forward.
3. Introduction

3.1. Background

The organic growth of the hyperbaric medicine service industry in Europe has generated an abundant supply of regulatory and guidance documents. Some of these are already harmonised as European standards, but there are many other legacy documents from individual member countries that remain in force in these countries – either by local regulatory adoption or simply through expectation.

The majority of these documents contain valuable guidance towards assuring safe, effective and appropriate practices. However, few, if in fact any, can be regarded as suitable to bear the title of a true guide to the quality assurance of a hyperbaric treatment centre in the broadest sense of this concept.

Most forms of external quality review provide essential safeguards and independent means for assessing the appropriateness, effectiveness and professionalism of healthcare practices. What is needed, however, is a consistent approach that accounts for the multitude of issues surrounding hyperbaric medicine and that engenders a culture within operating centres that leads towards compliance from within, rather than imposed from the outside.

All service industries require the assurance that the quality of their efforts meets client expectations if they are in fact to grow and thrive amidst a changing healthcare climate. Hyperbaric medical centres have many unique characteristics, in terms of the equipment, human and organisational resources; the treatments provided; and the eventual improvement in the condition of the patients. Providing a means of assessing and then improving such quality implies that a very specific approach is required. In addition, errors or accidents can have devastating consequences to patients, staff and the healthcare centres. Hyperbaric risks do not always fall into the regular categories of healthcare facility hazards and require specific identification and risk management.

Quality assurance in healthcare facilities has received much attention over the past 5 decades and this is clearly evident in the number of both national and international accreditation programs. Quality assurance in hyperbaric centres, however, has yet to be defined in such a way that quality improvement models and external review processes can be developed systematically.

3.2. Definition of quality and related terminology

It is important to consider a uniform view of the many terms employed in describing “quality” as this applies to hyperbaric treatment centres. The following list and definitions are specifically appropriate to how such terms are viewed in this specific service sector. Three broad categories are employed to show intended application.

The meaning of the term “quality” may appear self-evident. However, the assumed understanding by readers, institutions or individuals is anything but certain. Even where definitions are provided, these are usually designed to differentiate what the term means rather than how it is to be achieved or assured consistently.
3.2.1. Quality related terms

(1) Quality
The extent to which a treatment program meets its patients’ needs and expectations.[1]
Sometimes simplified as “conformance to specifications”. [2]

(2) Quality Assurance
The activities used to monitor the quality of the treatment program, focusing on systems & processes, analysing service delivery and enabling problem solving & quality improvement. [1]

(3) Quality Control
The inspection & defect detection activities to assure validity, reliability and reproducibility of the hyperbaric treatment program. [1]

(4) Quality Improvement
The effort to improve the level of performance of a key process, involving measuring current performance, finding ways to improve and implementing methods to facilitate improvement. [1]

(5) Quality Management System
The organizational structure, procedures, processes and resources needed to assure consistent quality.

3.2.2. Assessment related terms

(1) Accreditation
Process used by an external agency to determine the extent of the meeting of predetermined standards – to assure the reaching of optimal standards. Applies to facility performance & competence. [1] Voluntary

(2) Auditing
Process of using criteria or standards to assess quality, effectiveness & outcomes of hyperbaric treatments. [1] Internal or external; voluntary

(3) Certification
Process by which a recognised authority evaluates and recognises that the treatment program has met predetermined requirements. [3] Also applies to specific equipment and personnel. Voluntary

(4) Compliance
Being in accordance with established regulations, codes, standards, specifications or guidelines. Mandatory or voluntary

(5) Licencing
Statutory mechanism to grant permission for a hyperbaric treatment centre to provide clinical services. [4] Mandatory

(6) Risk Management
Including Hazard Identification & Risk Assessment (HIRA): Identifying, monitoring, controlling and minimising risks to patients, staff and facilities. Voluntary

3.2.3. Documentation terms

(1) Codes of practice
Written guidelines issued by a recognised body or association to assist in the compliance with the profession’s ethical, safe and/or effective standards. Voluntary

(2) Guidelines
Systematically developed statements to provide guidance regarding appropriate practices, operations and activities in hyperbaric treatment programs. Voluntary

(3) Regulations
Issued by national government and prescribing minimum acceptable standards. Compliance is generally mandatory

(4) Specifications
Established, common norms that define good practice. Voluntary

(5) Standards
An agreed, repeatable way of doing something and containing exact criteria designed to be used consistently as a rule or guideline. Usually suggested by professionals, then tested empirically, and finally accepted by consensus as the appropriate balance between what is ideal and what is real. Mandatory or voluntary
3.3. Navigating a confusing landscape

Growth in most healthcare sectors leads to a striving to establish suitable standards, specifications, codes of practice and guidelines. Regulators then add requirements for compliance and regulation. The public likewise demands that services must be of suitable quality, safe and available to all.

Documented efforts, quality programs and safety standards are all essential to meet these goals and expectations, but with the added complexity of many nations gathered under a single union, the result is an endless myriad of requirements.

The clearest postulation of appropriate quality in healthcare remains the enduring Process-Structure-Outcome model. [5] We ultimately want to provide our patients with the highest quality of medical care, so to apply this model in terms of the hyperbaric treatment programme, we achieve such quality through the structure of the facilities and the interaction between the healthcare workers and the patients, in order to lead to an improvement in the health of the patient.

Most efforts in healthcare focus on the process (i.e. treatments) rather than the structure (i.e. equipment, resources and operational practices).

Hence it could be stated that Quality Assurance for a Hyperbaric Treatment centre is essentially the understanding, application and implementation of, as well as compliance with, all the above stated requirements.

Yet we need to do this in a less confusing manner to ensure consistency, appropriateness and compliance. In addition, we need to determine a way to assess our progress, to provide tools so that we can not only assess where we are, but how we can improve and then make progress in improving, often by means of an iterative, continuous loop process.

The previous work done to achieve a uniform approach to quality assurance in hyperbaric treatment centres resulted in the publication of a European Code of Good Practice (ECGP) in 2004. [6] What we will now endeavour to achieve is further clarification of the concepts of quality assurance and accreditation, and then to render a proposal to take this forward.

To initiate this, one must also clearly distinguish between the terms quality assurance and accreditation as these apply to a hyperbaric treatment program. We already know from 3.2.1 (2) above, that quality assurance comprises a series of quality monitoring activities, while from 3.2.2 (2) above, accreditation is an external reviewing process. Quality assurance is also continuous whereas accreditation is episodic. By way of analogy – accreditation is like an annual medical fitness assessment whereas quality assurance is similar to ongoing performance assessment and health surveillance. The ECGP [6] provided a pictorial representation of the various layers of a hyperbaric treatment program, expanding from the hyperbaric chamber to the complete treatment centre. Using the same expression, we can visualise the equipment, human and organisational resources as follows:
This clearly shows the relative development and location of “structure”, but we need to add applicable, current standards and a progressive assurance of safety and quality. In addition, we would like to see where the terms certification (applicable to equipment, training, procedures), hyperbaric facility accreditation (applicable to equipment, resources and processes), and eventually healthcare facility accreditation (which incorporates outcomes) lie in relation to this model.

Reworking the diagram into a progress-indicating format provides us with the following visual representation:
† ECGP \[6\] sought to provide guidelines to fulfill the requirements for criteria spanning all operational activities required to provide effective hyperbaric oxygen therapy.
‡ There are currently over 25 different accreditation systems in place.
EN 13445 \[7\], ASME VIII \[8\], EN 14931 \[9\], EN ISO 14971 \[10\], PVHO-1 \[11\] & ISO 9001 \[12\]
MDD – Medical Device Directive (Europe)
PED – Pressure Equipment Device (Europe)
The rather well defined standards, regulatory and peer-review structures currently in place in the United States of America are included in parenthesis.
PVHO – Pressure Vessel for Human Occupancy
FDA – Food and Drug Administration: Agency of the USA
UHMS – Undersea and Hyperbaric Medical Society (USA)
JCI/JCAHO – Joint Commission International and Joint Commission on Accreditation of Healthcare Organizations: Not-for-profit based organisation (USA).

The current situation in Europe remains confusing, and while the USA prefers a more prescriptive approach, it has at least allowed for the more uniform development of the overall quality management of the provision of hyperbaric medicine. Australia provides a clear picture in terms of quality assurance (but not as yet hyperbaric-specific accreditation), but their social dynamics are singular rather than the multiple systems of Europe. Africa and Latin America are as yet developing, although there are some effective systems already in place. Asia remains relatively unknown to the European region, primarily due to the significant language and communication differences.

As an aside, but perhaps providing a degree of common understanding, the USA comprises 50 States, each with the authority to accept standards, codes and guidelines as their regulatory authorities deem fit. The Food & Drug Administration (FDA) and the Occupational Safety and Health Administration (OSHA) are federal (national) bodies with jurisdiction across all the States; however, the Undersea and Hyperbaric Medical Society (UHMS) is
true the only peer review structure that has the ability to reach across State lines and play an influencing, uniform and ultimately determining role in steering the industry sector in a relatively consistent direction.

3.4 Review of approaches elsewhere:
The pursuit of a suitable and practical quality assurance system for Europe should heed the progress, achievements and lessons learned in other parts of the world.

However, before looking elsewhere, one should at least consider that there are in excess of 25 different national organisations already providing accreditation programs to healthcare facilities within Europe. This implies a wealth of experience in assessing quality assurance and quality improvement activities, and a review needs to consider the models for quality of care already in place. The process of providing hyperbaric medicine may be unique, but it has sufficient similarities with many other forms of medical treatments.

As in Europe, the amount of literature available internationally is extensive, although very few, if in fact any, of the available articles or publications focus purely on quality assurance. Using the definition provided in 3.2.1 (2), we are able to refine the available resources to glean quality assurance models rather than following boarder concepts of quality in healthcare and in patient care.

A leader in the hyperbaric medical sector remains the United States with its lattice of codes, standards, guidelines and then the integrating effect of the peer group led accreditation system. Most of these documents and systems are well known. The only additional comment to offer would be that while their accreditation does achieve many of the quality assurance goals, quality assurance itself is not a clearly identified and demarcated management system. As such it cannot be used pro-actively in a consistent way, at least not until uncovered and analysed during the accreditation process. In addition, this accreditation system is prescriptive beyond the accepted philosophy of a higher degree of self-governance accepted in Europe.

Extending the search to focussed quality assurance models elsewhere reveals interesting cases in Southern and West Africa, as well as in Australia.

The Australian hyperbaric sector has well defined quality assurance documents that meet many of the requirements. However, this sector currently lacks an accreditation model, implying that there are distinct gaps in hyperbaric quality assurance monitoring activities. Healthcare accreditation models are in place and access to some of the required evaluation information would be available.

South Africa has a somewhat unique hyperbaric accreditation system that is a less prescriptive blend of self-and statutory-regulated approaches. The strength of the peer review body, the Southern African Undersea and Hyperbaric Medical Association (SAUHMA), provides both push and pull forces to the extent that all medical treatment facilities submit willingly to accreditation. However, once again there are gaps in the monitoring of processes and patient outcomes to the extent needed to facilitate quality improvement. However, quality assurance is simplified to statutory compliance and then fitness-for-purpose and risk management processes.

The applicable references referred to in this literature survey are included in 7. below.
3.5. Synopsis

We have endeavoured to provide greater clarity as well as a degree of substantiation to the terms used, what quality assurance means and why we need it. However, what remains as a gap is how one goes about putting this in place and then how it is monitored, assessed and maintained.

Clearly quality assurance is measured through assessing how things perform to pre-determined standards. If a standard is met, why then should we seek to improve?

Quality improvement then takes us forward to improve levels of performance of the process of providing treatments.

Based on this premise, we recommend a process of:

A. Certification to record at a given time point that the established standards of quality assurance have been met, whereas

B. Accreditation is used to record that (1) quality assurance requirements are met, (2) processes are conducted safely, (3) quality improvement is on-going, and finally, using the general term peer review, (4) that overall professional performance is achieved.

What is needed to achieve this are the required criteria for quality assurance for a hyperbaric treatment program and the ways they should be met so that a sensible proposal can be made.

4. Recommended criteria for a conceptual quality assurance model

The path to trying to postulate a single model is littered with challenges. Providing the general criteria that need to be considered, together with the means to apply these to this specific healthcare sector, does allow for many of the shortcomings to be addressed.

While there is usually a best method for a given situation, we also need consistency; the range of requirements is confusing enough.

Interestingly, statistical evidence suggests that up to 85% of quality problems are caused by system flaws, whereas only 15% of problems arrive as a result of individual performance.\(^{(13)}\) Quality improvement falls outside the scope of this article, but this statistic certainly prompts us to pay particular attention to our processes. In addition to this, risk management techniques applied to case reviews of incidents and accidents will ensure that our processes eliminate causes of quality-related failings.

The primary criteria for consideration in the quality assurance model include:

1. Management of resources (both human and technical), also referred to as “structure”.

2. Implementation of processes (operations & healthcare).

3. Evaluation and monitoring of processes and outcomes.


5. Incorporation of patient perspectives.
These criteria may, in a large part, be met through:

1. Compliance with standards, resulting in certification of equipment and procedures
2. Compliance with guidelines, codes of practice and specifications, resulting in certification of processes
3. Auditing, to determine effectiveness and on-going compliance through structured review
4. HIRA using a risk assessment, mitigation and removal process
5. Accessing the results of external accreditation surveys

While all the above can be achieved using internal methods, expert external authorities can be contracted either by the hyperbaric centre or the healthcare centre to perform these functions. Processes such as those envisaged under the ISO 9001 and the Joint Commission International (JCI) models (if applied to the healthcare centre), or dedicated hyperbaric centre accreditation surveys such as the UHMS system or a suitably developed model for the European hyperbaric sector will provide access to patient perspectives.

Suitable, existing standards, guidelines, codes of practice, specifications and even risk assessment guides are all available in Europe and need only be compiled into a single, quality assurance “system” that can then be consistently applied to all those who elect to participate.

At this stage, as accreditation is always going to be the externally applied compliance review process, it is necessary to at least take cognisance of these efforts as a well-structured, appropriate and effective quality assurance “system” will make up a key element of any accreditation system.

Europe currently has access to various country or region-specific healthcare accreditation systems, none of which encompass hyperbaric medicine much beyond medical practices and basic equipment requirements. However, there are three possible models that could be used in such a way as to focus attention on the specific equipment, practices and processed used by our sector, viz. ISO 9001, a system that addresses a quality management system; JCI, an international healthcare accreditation scheme; and a dedicated scheme established by a peer group such the European Committee for Hyperbaric Medicine (ECHM), following on from the example set by the UHMS.

Table 1 below is an attempt to assemble and list the relevant, existing European documents into a single quality assurance system. The notable gaps are identified in bolded, italicised text.

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<tr>
<th>Documents</th>
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<th>Notes</th>
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<td>CE marking</td>
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<td>Pressure vessel</td>
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<td>Hyperbaric system</td>
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<td>Reports</td>
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</table>

Table 1: How Quality Assurance Criteria may be met using existing documents
5. Proposal

We have existing and well-established quality assurance documentation; we have mechanisms for achieving certification; and we have at least a core of appropriate criteria for a quality assurance system that can be effectively met. What we lack are firstly a cohesive program or compiled system that presents this in a uniform and comprehensive manner, and then we have noted gaps in terms of hyperbaric-specific accreditation, quality monitoring, comprehensive system risk assessment and patient monitoring structures.

Until such time as an appropriate European Norm for hyperbaric facility accreditation can be established, it is proposed that the ECHM consider a solution to the requirement for a uniform quality assurance system by establishing an experienced sub-group with a mandate to:

1. **Review the analysis** contained in this paper and provide final recommendations for criteria for acceptance by the ECHM.

2. **Select an interim practical and incremental approach** towards identifying, achieving and endorsing appropriate QA methods within hyperbaric systems using other existing internationally available schemes and risk assessment principles as a guide whilst meeting applicable statutory requirements. In doing so, the ultimate choice of accreditation schemes will better assure and monitor actual quality and meet patient expectations.

3. **Draft a consensus document** that contains the updated data for Table 1 as an overall quality assurance model, together with suggested structured output documentation so that consistency during external accreditation can be encouraged.

6. Concluding remarks

For as long as we fail to provide clear processes and structured means to address quality assurance, we will miss the target of providing safe, effective and reliable hyperbaric treatments.

The analysis provided in this paper should have provided some clarity as to where quality assurance applies to a hyperbaric treatment program, the span of the term quality improvement, and how this all gamers structure (equipment) and process (operations) towards an increase in the improvement of outcomes (patient care and improved outcomes) - the enduring Donabedian quality process.

Quality assurance in hyperbaric medicine is no different to that for other medical, industrial or service sectors, and includes the identification of clear objectives, ensuring compliance with the accepted requirements, monitoring the outcomes and then re-adjusting both technical and operational aspects to ensure we meet our objectives.

We should follow the well proven path that lead to the adoption of our existing standards: utilising professional input, testing a system empirically, carefully considering the sense of the results, and then accepting a final approach through consensus of our peers.

Effective quality assurance will allow us to progress towards quality improvement and will ultimately ensure that we achieve the desired patient care and outcomes.
7. References, Relevant Literature

7.1. References


7.2. Relevant Literature


8. UHMS Clinical Hyperbaric Facility Accreditation Manual (Rev. 1). *Undersea and Hyperbaric Medical Society, USA, 2005.*


(16) Quality assurance, appraisal and accreditation in UK hyperbaric treatment facilities

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Introduction

This account details an appraisal tool that has been adopted as a standard method for providing a measure of the quality of service provision for differing types of hyperbaric treatment for a range of treating facilities in the United Kingdom (UK). However, the appraisal scheme operates within a framework where there is little specific regulation against which UK hyperbaric facilities must formally comply with regards to operational and practical safety apart from the paramount requirements to comply with UK and/or EU regulations of general health and safety in the workplace (Sayer, 2012a).

Nearly all the chambers in the UK are privately owned and operated; this may be on a form of commercial basis although some facilities have charitable status. Even though there is a split between patients whose treatments are funded by the National Health Service (NHS) and those funded privately (either by the individuals themselves or through private healthcare companies/insurers), overall evaluation of the quality of the delivery of healthcare is usually driven by the state-funded body, the NHS.

The NHS provides a comprehensive range of health services, the vast majority of which are free at the point of use to residents of the United Kingdom. Following UK Devolution in 1998, the responsibilities for providing and regulating publicly-funded healthcare were decentralized. The NHS remains a mutual term for three of the four publicly funded healthcare systems but only the English NHS is officially called the National Health Service. The other systems are NHS Scotland, NHS Wales and Health and Social Care (HSC) in Northern Ireland. Other forms of healthcare provision exist for the self-governing British Crown Dependencies of Guernsey, Jersey and the Isle of Man. Each system operates independently, and is politically accountable to the relevant form of independent, devolved or centralized government. Inevitably, each provider of healthcare has generated its own method of regulating and inspecting healthcare services. Therefore, at present, safety and quality of service provision in UK hyperbaric facilities is being evaluated in different ways and to different standards depending on the location of the facility.

In England, service delivery in hyperbaric facilities is assessed by the Care Quality Commission (CQC); however, the CQC only examines criteria related to areas such as treating people with dignity and respect, making sure food and drink meets people’s needs, making sure that the environment is clean and safe, and the management and staffing of services. Following Devolution, NHS Scotland established a registration service for hyperbaric medicine (though principally for emergency recompression) with continued registration being dependent on a successful specific appraisal of medical and nursing provision but also the technical appropriateness and safety of the facility (Ross and Sayer, 2009). The British Hyperbaric Association (BHA) represents the vast majority of hyperbaric facilities in the UK providing treatment of approved indications for
hyperbaric oxygen; the overall objective of the BHA is to promote understanding and safe practice in the
delivery of hyperbaric medicine. In 2010, the BHA adopted a modified version of the Scottish appraisal tool for
hyperbaric facilities; initially it has been employed for chambers intending to join the Association but from 2012
onwards the tool will be used to review all member facilities. It is hoped that the CQC will incorporate the BHA
appraisal into future evaluations of English facilities; likewise, Healthcare Improvement Scotland (HIS), which
was formed in 2011 to regulate the quality of healthcare across Scotland, will consider retaining a version of the
appraisal tool when they start evaluating hyperbaric units.

Appraisal methodology

Appraisal Team

The appraisal team consists typically of three people who have specific knowledge and experience in the
respective fields of hyperbaric medicine, hyperbaric nursing and the technical delivery of a hyperbaric service.
Preferably, the medical representative will be a practicing medical director of a hyperbaric facility, the nursing
representative will be a team leader for nursing in a hyperbaric facility, and the technical representative will have
current or recent management responsibility for all the practical issues related to running a hyperbaric facility. In
some cases where staffing a team of three has not been possible, it has proved feasible for the medical
representative to also adopt the role of nursing representative, and so the appraisal team has numbered only two
people.

Appraisal Format

The appraisal is organized around eight main sections (see below). Some of the information is supplied to the
appraisal team before the on-site visit but much of this will be verified during the visit. The appraisal will
typically start with a round-table discussion between the appraisal team and the host representatives where the
appraisal process is outlined and the timetable for the appraisal discussed and agreed. Although there are sections
of the appraisal tool that are specific to the respective specialties of the appraising team, it is normal practice for
the team to initially move through the sections as a team because of the likelihood that some issues may impact
across the three disciplines. The initial review is often carried out with members of the operating team of the host
facility present. Following this initial examination, it is normal practice for the team to then split into the three
main discipline areas for detailed assessment; again, these examinations will often include staff from the host
facility.

On completion of the detailed review, the appraisal team will typically withdraw from the facility being assessed
in order to compare notes and to draft an initial report highlighting the main issues and including an development
plan for any improvements or changes to be made. The draft is then presented to the host team for open
discussion specifically at that stage in order to ensure that all the issues raised are factually correct. The open
discussion may also generate an agreed timetable for the implementation of any changes with an agreed
methodology for how these are assured. The aim is for both parties to sign off a final document that has, where
necessary, a list of improvements or changes that should be made to the operation of the facility by the time of
the next appraisal visit. The relative significance of the changes or improvements to be made will influence the
timing of the next visit.

The eight sections of the appraisal are detailed below:

**Section 1. Hyperbaric Unit Details**

The initial part of the appraisal process collates basic information on the Hyperbaric Unit including: the official
name of the unit; the registered address (and contact address if different); the name and business address of the
owner; and the name and business address of the operator. The appraisal also asks for a list of people or
organizations having an interest in the operation of the unit with a contact address (the list could include both
individual and corporate financial backers).

A record is made of the date of the appraisal and the operational capacity of the unit is indicated through
recording the number of patients recompressed in the calendar year up to the date of the appraisal. This metric is
supplemented by obtaining information on the total number of patient-treatments and/or treatment runs
performed. For diving recompressions, data on the numbers of divers treated against those examined but not
recompressed is also gathered. The operational methodology of the host unit is obtained through requesting
details of whether a 24 hour emergency recompression service is provided along with the number of days the
facility (or parts of) were off-line (planned or unplanned) in the calendar year up to appraisal. The type of
hyperbaric operation will, of course, influence some aspects of the remainder of the appraisal (e.g. a 24-h
emergency recompression facility capable of receiving the critically ill against a monoplace-based facility only
treating elective indications during normal working hours).

The host facility is also asked whether it is a member of British Hyperbaric Association during this initial
section.

**Section 2: Building and Pressure Chamber System**

The purpose of this section is to establish the adequacy of the hyperbaric unit building, the recompression
chamber and its systems.

It would be expected that all relevant insurance certificates and chamber certification documents should be
available during the whole appraisal. Specific checks are made of a fire prevention plan or policy; a valid Public
Liability insurance certificate; and a valid Employer's Liability insurance certificate.

The building is inspected for ambulance access where appropriate. The patient reception area is inspected for
adequate heating, adequate lighting and that there is an area to accommodate relatives of the patient during a
treatment. The patient examination/resuscitation/preparation area is inspected to ensure that there are sufficient
facilities dedicated to all three requirements; it is fit for purpose; there are adequate working surfaces; there is
100% oxygen available (where applicable); there is cardiac arrest equipment and drugs available if supporting
critical care; there is adequate lighting (including emergency back-up); there is adequate heating and ventilation;
and that the area is clinically clean (including the floor).

For each chamber in the facility, there is direct inspection to insure that there is a valid manufacturer's certificate
of conformity; in-date pressure test certificate; adequate earthing of electrical equipment; one view port per lock;
a planned maintenance schedule for the pressure system; and adequate fire-fighting equipment or a fire suppression system (Sayer, 2012a).

Each chamber is inspected for carbon dioxide and oxygen monitoring (including the direct examination of the equipment plus an examination of the calibration record/protocols) and the internal lighting is measured with a light meter (a minimum of 70-75lux would be expected). The following are inspected and should be demonstrated where necessary: two-way voice communication; back-up communication (e.g. sound-powered phone); an appropriate system for delivery of therapeutic breathing gas (with quality assurance records).

**Section 3: Management, Technician and Attendant Staffing**

The purpose of this section is to identify key managers and to provide a structure for appraisal of the unit’s management structure and standard operating procedures. It also allows for the appraisal of technical and chamber attendant staffing levels and competencies. The types of evidence anticipated are detailed below but alternative sources may be entirely appropriate and dependant upon the unit’s practice (Sayer, 2012b).

For each facility there should be an agreed named Hyperbaric Therapy Provider. This person is defined as being the person in overall administrative control of facility with overall responsibility for the safety, suitability and correct maintenance of all plant and equipment. The Hyperbaric Therapy Provider also has responsibility for providing adequate and correctly maintained medical equipment. The structure of responsibility should be highlighted in the facility Standard Operating Procedures (SOP); the SOP should also provide an overview of the occupational health provision for all team members and the appraisal team should be able to view the details of the health monitoring arrangements that are in place and examine the staff records.

The Hyperbaric Facility Manager should also be named in the SOP. This is the person responsible for the general administration of the facility, personnel management, and the overall supervision of non-clinical staff. The Facility Manager would also have responsibility for all the health and safety aspects of plant, equipment and buildings. The appraisal team should check that there is documentary evidence of a formal appointment for this position with an adequate job description. There should be staff records that detail the qualifications and records of continued education in hyperbaric technology for the Facility Manager.

There should be an assessment of the number of available chamber attendant/internal tenders also needs to be conducted and again these numbers need to be assessed against the operational requirements / capacity of the facility. It would again be expected that there be records maintained for these staff that outline and record all relevant qualifications and ongoing training (e.g. first aid proficiency (to at least the level of Basic Life Support) and continued education in hyperbaric technology). The same type of assessments would be required for assistant chamber operators where relevant.

This section would also cover an evaluation of relevant and ongoing staff training. Evidence of attendance of a specific certified course or an in-house training application would be expected for Basic Life Support;
defibrillator use; patient moving and handling; patient violence and aggression; infection control; patient monitoring; drug administration; intra-venous fluid administration; and oxygen administration.

Section 4: Medical Staffing and Training

The purpose of this section is to describe the medical cover of the unit and to define the adequacy of training, experience and record keeping. In the UK, the General Medical Council (GMC) appraisal process documentation would constitute evidence of competence.

It would be expected that there be a single named Medical Director for the unit and that they should be employed to a level of, or equivalent to, NHS Consultant or Principal in General Practice. They should possess full GMC Registration and have Medical Indemnity insurance that covers the treatment of divers.

The SOP should be examined to ensure that there is a written structure of responsibility for medical staff members, with details of how an on-call rota is maintained if the facility is providing a 24-hour service. Documentary evidence of attendance and/or revalidation certificates should be examined to provide confirmation of regular refresher courses of appropriate disciplines. The personal files of all medical staff should be made available and may be checked to ensure that they are part of an ongoing appraisal and revalidation process. All chambers in Scotland that were part of the national registration process were included as part of an ongoing clinical audit and, as such, an appraisal visit provides an opportunity to cross-check some of the audit returns against the chamber usage record. For appraisals outside of Scotland, there could be a spot-check of some selected patient records against the main treatment record to ensure that a proper account of the treatments was being maintained.

The unit’s Medical Director should be able to provide evidence of appropriate levels of hyperbaric medicine training (record of course attendance, CV, revalidation documents), continuing professional development (record of activity, evidence of course/meeting attendance, revalidation documents), and clinical experience (audit returns, patient records or something similar). Similar types of evidence should also be available and be checked for all the duty hyperbaric doctors.

The appraisal team needs to ensure that adequate medical records are being kept; this is done through inspection of representative records. The team would expect that the records are kept securely and that the unit has a confidentiality policy in place. The medical records have to be maintained in a way that also ensures that they can be available to the duty doctor when required.

Section 5: Standard Operating Procedures

This section documents the unit’s standard operating procedures (SOP) for routine and emergency procedures. The appraisal team would examine the SOP (sometimes provided in advance of the on-site visit) to ensure the following general areas have the appropriate levels of information included. The SOP is also examined from the viewpoint of this being a practical and useful information tool that needs to be easy and, in some cases, quick to find and use.

Chamber operation: the SOP would be expected to have the appropriate information to explain what to do in a number of chamber leak scenarios; how to maintain and deliver all therapeutic gases; what items were prohibited from being allowed in the chamber; methods of compression and decompression; and
details of all the hyperbaric therapies currently in use (to include all the supporting literature plus bail-out procedures).

Policies and Procedures for Medical Emergencies: the SOP would be expected to detail the actions to be taken in the event of: cardiorespiratory arrest, safe defibrillation, convulsions (including oxygen toxicity), loss of consciousness, pneumothorax, vomiting, pressure-related injuries (e.g. barotraumas), oxygen toxicity (chronic and acute), and decompression illness in patients or staff.

Policies and Procedures for Technical Emergencies: the appraisal team would examine the SOP to ensure that procedures were in place and had been documented for uncontrolled gain in pressure, uncontrolled loss of pressure, a loss of gas supply, a contaminated atmosphere (including carbon dioxide), a high oxygen level in chamber, temperature regulation of chamber, a fire in the chamber, a fire in the chamber building or buildings close to the hyperbaric facility, a loss of voice communications, a power failure in some or all of the facility, and the threat of a terrorist attack.

**Section 6: Medical equipment and supplies**

This section documents the medical equipment available to the unit. Where equipment is not stored at the unit, it would be expected that evidence should be provided to include information on the location and availability of the equipment or supplies.

The appraisal team would examine the unit’s inventory but would specifically inspect that the following were present and available: a suitable stretcher or bed (inside and outside the chamber); indirect blood pressure measurement equipment available; a stethoscope; a auroscope/ophthalmoscope; a thermometer (not mercury) normal range and low reading; neurological assessment equipment; an urinary catheterisation kit; chest drainage equipment for long and short term; airway management equipment; suction equipment; a defibrillator; an adequate selection of needles and syringes; various intravenous cannulae; sufficient and appropriate IV fluid giving sets; and appropriate range of IV fluids; a range of appropriate drugs; various dressings; plus a number of other miscellaneous (e.g. blankets, urine bottles; bed pans etc.). In all cases there should be checks performed to ensure that all disposables were maintained in date.

**Section 7: Care of the Critically Ill**

Occasionally, hyperbaric facilities receive critically ill patients. These cases require appropriate clinical support and would receive critical care if at a District General Hospital. Critical Care is subject to nationally accepted guidelines but these are inappropriate for emergency treatment units with a low throughput of critically ill patients. Nevertheless there are certain requirements for the treatment of these cases even in units operating out-with hospital premises. This section provides a framework for documentation of the unit’s critical care response capability if, in fact, the unit accepts critically ill patients for treatment. In discussion, a unit may be guided to have a policy in place where critically ill patients will not be admitted but will be diverted to the most appropriate alternative treatment facility.

In units that are receiving the critically ill, the appraisal team needs to ensure that the clinical staff attending a critically ill patient can provide certificated evidence of Advanced Trauma Life Support (ATLS) proficiency for the attending hyperbaric doctor with the possibility that a doctor experienced to Specialist Registrar level (or equivalent) in either Anaesthetics or Intensive Treatment Unit (ITU) Medicine should be available to help if
required. It should be checked that the internal tender is certified to at least the level of Intermediate Life Support (ILS).

The appraisal team should ensure that there is sufficient equipment available to the unit for use in the chamber at short notice but not necessarily kept at the unit. There should be an Inventory List in place and the team should undertake a visual inspection of all relevant procedures and protocols for use in a hyperbaric environment with the associated maintenance records. The list of equipment that could be considered appropriate for the treatment of the critically ill is: ECG monitoring, pulse oximetry, capnography, automated blood pressure monitoring, mechanical ventilator, syringe drivers, and re-warming equipment.

Each facility should have a written protocol for how the unit would deal with a critically ill patient covering the following: mobilisation of the necessary staff and equipment resources; fluid resuscitation; measurement of haematocrit; partial drowning; hypothermia; and airway management.

It is important that the appraisal team ensures that each facility has a written guideline for the level of care that can be undertaken locally including the clinical criteria that would necessitate immediate transfer of the patient to the most appropriate facility without recompression locally. Those guidelines should cover patients first presenting at the unit and patients who are obviously critically ill on referral to the hyperbaric unit from an accident location and before emergency transport is arranged.

Section 8: Support Services

The appraisal would examine the following support services and assess how they are delivered (to include their relevant entries in the SOP): radiology (with the appropriate written procedures plus the location of services); laboratory investigations (including details of their location and how samples and patients are to be transported); cleaning; laundry; catering; suppliers (including a list of approved suppliers in some cases); toilets; and sluice facilities.

Where there is a possibility of transporting patients who are critically ill, policies and procedures should outline any agreements in place with ambulance services, the availability of adequate equipment to attempt a transfer, and the conformity of the procedures with Intensive Care Society (ICS) guidelines.

Appraisal outcomes

Each appraisal visit produces a list of recommendations as to how the quality of existing service delivery may be improved or enhanced. It is always the intention that this list is presented to the host facility at the end of the appraisal visit so that each recommendation can be discussed and agreed to in a face-to-face situation. Invariably, each recommendation that is agreed will also have an agreed action plan attached to it, with a realistic timeframe for implementation. The list of recommendations effectively becomes an accepted “Development Plan” for the unit.

Following the site visit, a full draft appraisal is developed by the appraisal team. This is sent to the appraised unit for comment. There may be a series of iterations to ensure that the final version of the appraisal document is a true record. Once there is agreement then the appraisal document with the agreed development plan is signed off and dated by the full appraisal team and a representative of the appraised hyperbaric unit. There may be
instances where other parties contributed to the appraisal process and their names are also included in the sign-off section along with an indication as to the capacity of their contribution.

The next phase of the appraisal process is very much dependent on the types of recommendation included in the development plan. If all the recommendations are fairly minor in significance, then the development plan becomes an internal document for the appraised facility against which they implement and sign-off any changes to their own satisfaction. However, it would be expected that the development plan forms the basis for review at the next appraisal visit. Where more significant recommendations are being suggested, there may be a requirement for the appraisal team, or a specific appraiser, to revisit the facility to ensure that the changes have been implemented. The timescale for doing this will probably be dictated by the significance of the required improvement; periods of 6 and 12 months have been used in the past. Where omissions are particularly serious, then the appraisal team may recommend that operations are suspended until the relevant improvements are made. It is unlikely that a final appraisal document could be signed off until the appraisal team was satisfied that the development plan was being addressed diligently by the appraised facility.

Both the NHS Scotland and BHA appraisal schemes lack any legal status and so there are potentially no formal consequences associated with a unit’s failure to comply with the agreed development plan. In the very rare instances of this being the case, there has often been a discussion of the potential implications for the unit continuing to operate while the development plan was not being addressed (or cannot be addressed for lack of funds), and in all cases, the operators decided to withdraw from accepting NHS patients to their facility. The NHS Scotland scheme does have the capability to recommend that a unit be withdrawn from the registration service. The BHA currently has two tiers of membership: full and probationary. Probationary membership is for those facilities that have applied or re-applied for BHA membership; acceptance for full membership is dependent on the appraisal. Appraisal of the existing BHA membership has only started in 2012 and so it is unclear, at present, what action would be taken for a failing full member. However, if full BHA membership is to attain a quality-assurance status then an action such as demotion from full- to probationary-membership, may be a consequence of a failed appraisal.

**Discussion**

The current hyperbaric facility appraisal mechanism running in the UK has created a method of standardized assessment of quality assurance in service delivery. There have been instances where the appraisal process has identified units that would require significant levels of investment in order to achieve the basic levels of quality; all of those units took the decision to no longer accept NHS patients. In other cases, appraisals have identified short-, medium- and long-term improvement requirements. In general, this generated a series of development plans that were discussed and agreed with the unit management and/or owners, and compliance with those plans has resulted in more acceptable standards of care. Discussion of the management of the critically ill has, in some areas of the UK, resulted in the development and adoption of integrated management plans for those types of patient.

Very rarely, there have been instances where the appraisal team has identified practices that were causes of immediate concern. Invariably, these concerns were addressed as matters of priority when conducting the discussions between the appraisal team and the host facility at the end of the appraisal visit. Even in Scotland,
where appraisal is funded by NHS Scotland, the current UK appraisal process has no legal status and no formal authority, and so any improvements to be made can only be recommended. However, where there is a very real concern for safety, then the unit management/owners may be reminded of their legal responsibilities to comply with relevant health and safety legislation for at work activities. In the very few cases where this has been an issue, the unit has usually agreed to suspend operations pending making the recommended changes and re-submitting the facility to an appraisal review.

The lack of any legal authority for the current appraisal scheme means that there is currently no formal accreditation process running in the UK for hyperbaric facilities. Accreditation is a process in which certification of competency, authority, or credibility is presented. Organizations that issue credentials or certify third parties against official standards are themselves formally accredited by accreditation bodies (such as UKAS, The United Kingdom Accreditation Service); hence they are sometimes known as “accredited certification bodies”. The accreditation process ensures that their certification practices are acceptable, typically meaning that they are competent to test and certify third parties, behave ethically and employ suitable quality assurance. There is no intention, at this time, for the Scottish or BHA appraisal schemes to attain this status and so the process is set to remain one of appraisal. It remains unknown as to what status the appraisal process may attain if it is adopted or incorporated into the CQC or HIS procedures. Once all current and pending membership of the BHA have been appraised (which could, realistically be by 2015-16), then BHA membership will be an indicator of delivery of service to an agreed minimum standard.

The time taken for the BHA to conduct a full appraisal of all its member facilities (circa 4 years) is indicative of the major constraints to the introduction of a quality assurance scheme: time and cost. The BHA membership is currently 14-16 facilities. Four of those facilities are in Scotland and are quality-assured through the NHS Scotland scheme. Even conducting three appraisals a year is a significant challenge to the BHA because the scheme is reliant on a small number of appraisers and the costs for each appraisal are more than the BHA membership fee. The membership of the appraisal team is, at present, based on the membership of the NHS Scotland appraisal team. One reason for that is previous experience (the Scottish appraisal scheme has been running since 1999; the BHA scheme started in 2010), but there is also the issue of perceived independence and the lack of any conflict of interests. The respective availabilities of a relatively small pool of appraisers definitely causes many scheduling problems and this is compounded by the fact that presently the BHA scheme cannot afford to fund any salary costs associated with a site visit plus the report writing process. This is not the case in Scotland where the appraisal scheme is funded in full.

The introduction of a quality-assurance scheme into Scotland has, over just 10 years, produced a stream-lined and much-improved hyperbaric service. The BHA appraisal scheme will, it is hoped, bring about similar changes while enhancing the value and significance of BHA membership. It remains to be seen how both schemes are treated if or when they are incorporated into more formal assessment procedures managed by government-funded healthcare quality assurance organisations.

References


Chapter 6: Miscellanea
**Introduction**

This presentation is based on my seven year experience as technical/safety manager at the Karolinska University Hospital but is kept as wide as possible to apply to most HBO facilities. Proper management of maintenance routines is necessary to keep technical complicated and expensive equipment in good working order. During the latest years the HBO treatment of critically ill patient has increased.

In that scenario there are also an increased numbers of antibiotic resistant bacteria that implement a raised level of staff knowledge of nosocomial transmission of bacteria as well as hygiene routines to keep inanimate surfaces at lowest possible contamination. Education, clear hygiene and cleaning routines will be mandatory to keep up a high level in this aspect.

So this presentation folds in three parts

1. Management of maintenance of chamber and auxiliary medical technical equipment
2. Monoplace, Multiplace, syringe pumps, defibrillator and ventilator
3. Hygiene routines, prevention of bacteria transmission and culture sampling

**Technical maintenance**

In order to have a good overview on these matters the immediate response should be connected to the technical manager of the HBO unit. This function is recommended to be organized directly under the Medical director of the HBO department whatever the rest of staff organization. Routines for this work is done in cooperation with the producer of the chamber or other medical technical equipment

Procedures are often divided in Yearly maintenance and Preventive maintenance. The first is often done by the producer by agreement and the latter is performed by the technical manager in cooperation with the hospital Biomedical Engineering department.
Here we must also consider whether we belong to a hospital with a biomedical engineering department to connect to and also have a possibility to do some development work. This of course maybe more difficult in smaller hospitals or in standalone HBO centers without physical connections to a hospital.

In the user manual and training schedule for the chamber system there is also maintenance schedule provided. This makes it easy for the technical/safety manager to organize the maintenance work together with the chamber operators and when suitable in cooperation with the hospital biomedical engineering department.

**Monoplace chambers**

The Hyperbaric Facility; Safety and Installation guidelines, Gas supply interface.

Firefighting installation & emergency plan.

The gas supply interface is Medical grade oxygen 5.1bar and Medical breathing air 4, 9 bar.

Gas piping should be arranged in a manner that to every monoplace chamber there is a manifold point where both oxygen and breathing air could be shut off.

![Emergency gas supply shut off valve](image)

The treatment room should be a fire cell separated by fire safety door with at least 30 minutes delay in case of fire.

The Monoplace facility consists of the HBO treatment room which should be separated from other activities like dressing rooms etc. The producer of a monoplace chamber also provides a large document about the installation guidelines.

A maintenance protocol for a monoplace chamber could be performed like below.

Daily function control by the chamber operator before use.
Weekly: door safety lock device, no obstruction in the vent line

A half year control of compression and decompression rates vs. time is recommended

And a yearly maintenance by the producer of the device

It is also recommendable to install at least on oxygen sensor in the treatment room for an early warning of oxygen > 23%.

Medical technical equipment

Should be subject to Yearly preventive maintenance or whenever malfunction is at hand.

Documentation of modification and declaration of conformity must be accessible for inspection and should be signed by the Medical Director.

Safety protocols

**Multiplace chambers**

Installation regulation

Following directives should be mandatory for installation and use of the chamber

- EC-directive 93/42 (June 1993)  medical device directive (for medical treatment chambers)
- EC-directive 97/23 (may 1997)  Pressure equipment directive
- EN-14931  Pressure vessels for human occupancy (PVHO)
- EN 12021  Compressed air for breathing apparatus

Germanischer Lloyd  Enclosures for medical equipment
Gas supply interface

The above schematic drawings displays a standard large hospital gas supply system where one compressor plant supply the whole hospital need of compressed air.

When the HBO facility goes on the second compressor is engaged whereas the third compressor is redundant. For flawless gas flow at the user position the gas is brought to receiver canisters from which the gas is drawn without any fluctuations from compressor works.

The responsibility for function & maintenance belongs normally the hospital.

Hospital redundancy systems (electrical & medical gas)

Firefighting room & system

The firefighting system is regarded as a part of the multiplace chamber and shall only be served by the producers authorized personnel except from filling gas bottles to the demand pressure.

Electrical UPS supply backup

System normally included in the hospital redundancy system, tested twice a year and during yearly maintenance by the producer.

Chamber maintenance

The maintenance protocol and periodically schedule is mostly provided by the producer of the chamber system.

Normally the schedule is divided into daily controls (before and after treatment) and this is normally done by the chamber operator. Monthly and other periodically controls are made by the technical/safety manager together with chamber operators or in some cases in cooperation with the biomedical engineering team.

The Yearly Maintenance program me is mostly done by the manufacturer of the device.
As for example the Karolinska HBO site staff from the hospital biomedical engineering department follows the workers from the producer as part of the education for the HBO –Biomedical engineering team. Members from this team work together with the HBO facility technical manager/safety manager in this maintenance protocol.

It is useful to have a document as a “Malfunction list” for the chamber, where every deviation from the normal pattern is reported. This document is firstly a platform of for safety management to evaluate if there is any repeatedly malfunction in the system.

Of course the safety manager must discuss this document together with the rest of the staff to eliminate user failure of the chamber system.

Table 1. Malfunction list

<table>
<thead>
<tr>
<th>Date</th>
<th>Position</th>
<th>Readings/disorder</th>
<th>Adjustment</th>
<th>Responsible</th>
<th>ok date</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011-09-09</td>
<td>LL</td>
<td>speed of door High speed reported</td>
<td>none</td>
<td>pk</td>
<td>2011-09-19</td>
</tr>
<tr>
<td>2011-09-09</td>
<td>LL</td>
<td>Et CO2 sample flow low</td>
<td>adjust to 58ml sample flow</td>
<td>pk pe MT</td>
<td>2011-09-19</td>
</tr>
<tr>
<td>2011-09-02</td>
<td>LL</td>
<td>noise from gas outlet at 1,4bar</td>
<td>change gas outlet springs</td>
<td>pk pe MT</td>
<td>2011-09-19</td>
</tr>
<tr>
<td>2011-09-26</td>
<td>all</td>
<td>air cond not warm, air in water cirk</td>
<td>YIT (Locum)</td>
<td>pk</td>
<td>2011-10-25</td>
</tr>
<tr>
<td>2011-09-19</td>
<td>SL</td>
<td>jammed motor for quick outlet valve SL</td>
<td>exchanged to new motor</td>
<td>pk s.huisman</td>
<td>2011-10-07</td>
</tr>
<tr>
<td>2011-12-02</td>
<td>SL</td>
<td>noise from gas outlet at 1,4bar</td>
<td>change gas outlet springs</td>
<td>pk</td>
<td>2011-12-13</td>
</tr>
<tr>
<td>2011-12-14</td>
<td>all</td>
<td>alarm low high press handlinetank</td>
<td>topped airbottle to 200bar w. compressor</td>
<td>pk</td>
<td>2011-12-14</td>
</tr>
<tr>
<td>2011-12-14</td>
<td>test</td>
<td>haux mmt-to GE clinisoft</td>
<td>hauxmmt values out but GE driver needs check</td>
<td>pk nb</td>
<td>2011-12-14</td>
</tr>
<tr>
<td>2011-12-19</td>
<td>LL,SL</td>
<td>culture test ex1 &amp; condens watertry</td>
<td>sent to bact.lab</td>
<td>pk</td>
<td>2011-12-29</td>
</tr>
<tr>
<td>2012-01-02</td>
<td>SL</td>
<td>partial misalignment round ventilation knob</td>
<td>adjustment and reposition of locknut</td>
<td>pk</td>
<td>2012-12-02</td>
</tr>
<tr>
<td>2012-02-01</td>
<td>SL,BL</td>
<td>Single doors irregular function</td>
<td>resetting pressure at sea level,-0.006B</td>
<td>pk+Haupteles pport</td>
<td>2012-02-03</td>
</tr>
<tr>
<td>2012-04-10</td>
<td>SL,BL</td>
<td>Doors not function, red sign, level0.023B</td>
<td>resetting pressure at sea level, 0.000B</td>
<td>pk+Haupteles pport</td>
<td>2012-04-10</td>
</tr>
</tbody>
</table>
The Maintenance schedule is exemplified by one page from the Haux maintenance document.

<table>
<thead>
<tr>
<th>ser. device / part of device no.</th>
<th>performing works / remarks</th>
<th>terms d m y</th>
<th>carried out by</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. chamber wall</td>
<td>check on corrosion, blind plugs, air tight, penetrations, threaded joints air tight, touching up paint damages</td>
<td>3 user</td>
<td></td>
</tr>
<tr>
<td>2.1 chamber floor</td>
<td>cleaning</td>
<td>a 3 user</td>
<td></td>
</tr>
<tr>
<td>2.2 chamber floor</td>
<td>repair of floor-covering</td>
<td>1 HAUX</td>
<td></td>
</tr>
<tr>
<td>3. sealing surfaces</td>
<td>clean, without corrosion</td>
<td>3 user</td>
<td></td>
</tr>
<tr>
<td>4.1 chamber doors</td>
<td>see 1., inspection of bearing, hinges, door handles, door stopper</td>
<td>1 HAUX</td>
<td></td>
</tr>
<tr>
<td>4.2 doorway chains</td>
<td>apply thin film of silicone spray</td>
<td>14 user</td>
<td></td>
</tr>
<tr>
<td>4.3 light barrier</td>
<td>check function</td>
<td>b user</td>
<td></td>
</tr>
<tr>
<td>4.4 safety edge</td>
<td>check function</td>
<td>1 user</td>
<td></td>
</tr>
<tr>
<td>5.1 door seals</td>
<td>inspection of seals</td>
<td>b user</td>
<td></td>
</tr>
<tr>
<td>5.2 door seals</td>
<td>apply thin film of silicone spray</td>
<td>1 user</td>
<td></td>
</tr>
<tr>
<td>5.3 door seals</td>
<td>replacement of seals</td>
<td>5 HAUX</td>
<td></td>
</tr>
<tr>
<td>6.1 medical locks</td>
<td>check seals, function light barrier</td>
<td>b user</td>
<td></td>
</tr>
<tr>
<td>6.2 medical locks</td>
<td>check safety edge</td>
<td>1 user</td>
<td></td>
</tr>
<tr>
<td>6.3 medical locks</td>
<td>inspection / maintenance safety</td>
<td>1 HAUX</td>
<td></td>
</tr>
<tr>
<td>6.4 medical locks</td>
<td>system, valves, seals</td>
<td>1 user</td>
<td></td>
</tr>
<tr>
<td>6.5 medical locks</td>
<td>replacement of seals</td>
<td>5 HAUX</td>
<td></td>
</tr>
<tr>
<td>7.1 windows</td>
<td>cleaning</td>
<td>1 user</td>
<td></td>
</tr>
<tr>
<td>7.2 windows</td>
<td>inspection surfaces</td>
<td>1 HAUX</td>
<td></td>
</tr>
<tr>
<td>7.3 windows</td>
<td>replacement of panes and seals</td>
<td>10 HAUX</td>
<td></td>
</tr>
<tr>
<td>8. seats</td>
<td>inspection of attaching of the adjusting and locking device, sliding means</td>
<td>1 HAUX</td>
<td></td>
</tr>
<tr>
<td>9. trolley</td>
<td>wheels, attaching, insp. of looking device</td>
<td>1 HAUX</td>
<td></td>
</tr>
<tr>
<td>10. sound absorber</td>
<td>inspection of corrosion</td>
<td>1 HAUX</td>
<td></td>
</tr>
<tr>
<td>11. safety valves</td>
<td>inspection of function</td>
<td>1 HAUX / TÜV</td>
<td></td>
</tr>
<tr>
<td>12. identifications</td>
<td>complete / to be completed if necessary</td>
<td>1 HAUX</td>
<td></td>
</tr>
</tbody>
</table>

Terms: d = daily, a = after operation; b = before operation; a = after operation; m = after ... months; y = after ... years; B = as required
Syringe pumps

Since 12 V supply system racks for syringe pumps always is built for charging the pumps

It is some circuits that work with higher voltage than the labeled 12 V, normally around 20 V

Charging of batteries creates increased temperature which is not desired inside the chamber

Therefore it is advisable to keep charging circuits outside of the chamber. Another solution is to electrically bypass the charging circuit to avoid the problem.

Defibrillator

This device could be positioned outside of the chamber locked in on demand by the chamber operator. Prior to every start of a multiplace treatment the batter is checked – OK according to the operators checklist.

Ventilators

If the HBO ventilator is used also for transportation of the patient from ICU ward to the chamber it is mandatory that the expiration outlet is connected to the exhale system of the chamber before starting the treatment or else the oxygen level will increase very fast in the chamber.

Medical technical equipment receiving control-preventive maintenance

Performance control is performed during the yearly maintenance procedure or whenever a report of malfunctioning is reported to the technical/safety manager. There should be a list of malfunction including date of report, action carried out, by whom and a date for check/ok. This report is intended to be sent to the producer prior the next yearly maintenance.

Modifications of medical technical equipment

Modifications of medical technical equipment is a widely used procedure concerning devices that are intended to work in hyperbaric environment. This could be done for the own facility or with the aim to have the device certified by a notified body (Dekra, GL etc) together with a letter of conformity signed by the medical director of the HBO facility.

The documentation includes test protocols, verifications on modification, risk analysis, risk assessment and the risk reductive work that have been done.

This will also act as a platform together with a producer want to perform a CE label for the intended use for hyperbaric environment.

Here is an example of certification from a notified body for a PDMS system in Karolinska HBO.
Procedures like this could only be performed in hospitals with a biomedical engineering department that is large enough to include different sections as development and manufacturing capacity as well as quality assurance group used to work with risk analysis.
Hygiene procedures cleaning & disinfection procedures

I would stress the role of inanimate surfaces as mediators of pathogen transmission. These surfaces is mostly monitoring cables ECG cables etc. that have contact with the patient in bed during treatment and transport from and to the HBO facility. Cables, monitoring devices gloves.touch screens are a perfect area for pathogens to reside on.

Together with many helping hands, too much hurry we can even spread the bacteria to other patients in close vicinity.

In short the risk of contamination

- Multipatient treatment
- Go between patients
- Mixed use of equipment
- Not changing gloves & aprons between patients

Who is responsible for bacteria transmission?

- We – the educated staff!!!!!

Why?

- Bad planning
- Wrong dress code
- Mixing equipment between patients
- Contaminated device assumed to be disinfected but……
- No preventive surface disinfection schedule
The net result is

- Transmission of nosocomial pathogens

How to reduce risk of pathogen transmission

- Keep barriers
- High education
- Training procedures
- Patient transport routines

Surface disinfection – where to start

Cleaning and then disinfection of

Syringe pumps, ECG cables, any other cable, keyboards, touch screens, PDMS cables, headset telephones etc etc.

Please note

- Cleaning & disinfection will not be performed in less than 30 minutes if properly done
- Also transportation equipment must be disinfected between utilization
- Gloves must be changed more often than we think.
- The longer a nosocomial pathogen persists on a surface – the longer it is a source of transmission

Culture sampling
The disinfectant agent

Since fire hazard is obvious there has been a need for a non flammable disinfectant agent.

Desisoft is a water-soluble, nonflammable solution; chemically it is (PHMG) Polyhexamethylenebiguanidinehydrochloride.

This agent creates a thin film that isolates the pathogens from the surrounding environment. When PHMG adheres to the pathogen its iontransmission through the cell membrane is not working any more.

The desisoft disinfecting agent is suitable for most bacteria including MRSA, fungi and virus.
Note! Correct dress code and disinfection

Please note that there is a difference between cleaning and disinfecting.

The former procedure is done with a surface reducing agent and water.

The latter procedure should be carried out on a clean surface.
References

Folke Lind, MD, PhD, Peter Kronlund, Technologist, Perfusionist, RN.

Hyperbaric Medicine, Dept of Anesthesiology & Intensive Care
Karolinska Universitet Hospital, Stockholm, Sweden

Organisation of a Clinical Hyperbaric Therapy Centre and Related Health Management Issues

Since 1991, we have successfully performed hundreds of HBO treatments using hospital level equipment. 

• Power voltage-powered Servo 300C, ventilator's integrated main-stream and dual CO2 analyser (Siemens/Sensormedics) to avoid hyperventilation of CO2 saturation monitors (Nellcor/Algo)
Practical Guidelines for Infection Control in Health Care Facilities

World Health Organization
Regional Office for Western Pacific, Manila
Regional Office for South-East Asia, New Delhi
Research article: How long do nosocomial pathogens persist on inanimate surfaces? A systematic review

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Abstract

Background: Inanimate surfaces have often been described as the source for outbreaks of nosocomial infections. The aim of this review is to summarize data on the persistence of different nosocomial pathogens on inanimate surfaces.

Methods: The literature was systematically reviewed in MedLine without language restrictions. In addition, cited articles in a report were assessed and standard textbooks on the topic were reviewed. All reports with experimental evidence on the duration of persistence of a nosocomial pathogen on any type of surface were included.

Results: Most gram-positive bacteria, such as Enterococcus spp. (including VRE), Staphylococcus aureus (including MRSA), or Streptococcus pyogenes, survive for months on dry surfaces. Many gram negative species, such as Acinetobacter spp., Escherichia coli, Klebsiella spp., Pseudomonas aeruginosa, Serratia marcescens, or Shigella spp., can also survive for months. A few others, such as Bordetella pertussis, Haemophilus influenzae, Proteus vulgaris, or Vibrio cholerae, however, persist only for days. Mycobacteria, including Mycobacterium tuberculosis, and spore-forming bacteria, including Clostridium difficile, can also survive for months on surfaces. Candida albicans as the most important nosocomial fungal pathogen can survive up to 4 months on surfaces. Persistence of other yeasts, such as Torulopsis glabrata, was described to be similar (5 months) or shorter (Candida parapsilosis, 14 days). Most viruses from the respiratory tract, such as corona, coxsackie, influenza, SARS or rhino virus, can persist on surfaces for a few days. Viruses from the gastrointestinal tract, such as astrovirus, HAV, polio- or rota virus, persist for approximately 2 months. Blood-borne viruses, such as HBV or HIV, can persist for more than one week. Herpes viruses, such as CMV or HSV type 1 and 2, have been shown to persist from only a few hours up to 7 days.

Conclusion: The most common nosocomial pathogens may well survive or persist on surfaces for months and can thereby be a continuous source of transmission if no regular preventive surface disinfection is performed.

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(18) **Ergonomy**

Dr. WAJ Meintjes (South Africa)

**Introduction**

Many aspects of hyperbaric oxygen therapy follow examples set within the commercial diving industry. One example related to ergonomical factors being addressed in the diving environment is a research paper presented at the 23rd EUBS conference by Bolstad, Ryvarden and Benum[1]. To some extent this is appropriate, since the equipment used in diving operations and the equipment used for the provision of HBO therapy are similar in many respects. However, the type of person entering a HBO chamber for treatment (by definition an ill individual) is different to the person entering a diving chamber as part of a commercial diving project (by definition a healthy person). Because there are vast differences in the persons entering the hyperbaric environment for HBO treatment, special consideration should be given to ergonomical hazards that may complicate the treatment. Ergonomical and hyperbaric chamber design considerations for use in HBO treatments have also been discussed at a previous international conference[2], in publications related to the design of healthcare facilities[3, 4] and published in engineering journals[5].

In order to perform a proper ergonomical assessment, one needs to involve persons who regularly use the equipment and involve specialists with ergonomic know-how. This approach has been used in the hyperbaric field before[6]. The input of chamber operators and chamber attendants can be used to develop a set of design requirements for HBO chambers. Contrary to what one would expect, many ergonomical aspects could be improved by simple means and at a relatively low cost. The outcome would be a safer, more efficient environment, with greater comfort for patients and all personnel involved in the treatment session.

**Ergonomics definition**

In order to ensure that everyone is on the same page, we need to define the term “Ergonomics”. Although various definitions exist, it is ultimately a description of the interface between man, equipment, the environment and organization. The term comes from the words “ergo” (meaning work) and “nomos” (meaning laws) – thus the “laws of work”. The main aim of an ergonomic assessment is to design workstations that are both healthy and efficient. Rather than make the user fit a machine, the aim is to make a machine fit for the user thereof. A comprehensive assessment is performed, with recommendations in order to reduce discomfort and/ or improve safety. Both mental and physical stressors are addressed in the process. Due to time constraints, this paper cannot cover a comprehensive assessment of all ergonomic issues associated with HBO treatments. The paper will be limited to a number of aspects related to the hyperbaric system, with little reference to other components of a center for hyperbaric medicine.

The “operating unit” being described in this paper consists of staff (e.g. the chamber operator, doctor, chamber attendant), the chamber and other equipment, as well as the environment and organization. All of these together
need to be seen as a functional unit and within this functional unit one needs to apply anatomical, physiological and psychological principles in order to solve problems that arise from the interaction between these units.

There are very few existing guidelines that address ergonomics in the hyperbaric chamber environment and even those that exist (e.g. through the Facility Guidelines Institute in the USA[4], the EU Norms on Pressure Vessels for Human Occupancy[7] and others[8, 9]) do not provide a lot of detailed ergonomical design requirements.

The very first point to consider when looking at a hyperbaric chamber is the choice of the chamber. There are obviously many different kinds of hyperbaric chambers (diving chambers, recompression chambers, decompression chambers, etc.), but not all these chambers are suitable for HBO. The main reasons for this include restricted access, restricted space inside, lack of essential safety systems (specific to HBO treatments), the absence of medical support and equipment and the fact that many of these chambers are in unsuitable locations.

Even when considering a specific HBO chamber, the configuration would determine the type of treatment one would be able to provide in the chamber, whether routine HBO treatments (ambulatory patients) or emergency HBO treatments (with acute patients). Monoplace chambers have different capabilities than multiplace chambers and even multiplace chambers could be single-lock or double-lock and thus determine how these could be used.

Another part of the functional unit is the staff and their equipment. Their ability to deal with a certain type of patient will (like the chamber itself) also impact on the type of patient the facility could manage.

The ergonomic assessment

The ergonomic assessment should start with a description and analysis of all the tasks to be performed in the hyperbaric facility, including routine HBO treatments, emergency HBO treatments, etc. All the sub-tasks (such as routine operating procedures and emergency operating procedures) should also be entered into a workflow pattern. This is followed by an analysis of the traffic flow – the idea being to avoid too much traffic and hence decide on the placement and location of equipment and facilities. It is important to ensure that interference between different functions (particularly during emergency procedures) is avoided. After the functional analysis (which determines WHAT is required), the last step in the process is to move from function to design. The quantified function is thus taken into consideration for the design of the facility.

Because this process would be different for each facility (dependent on the specific functions performed at the facility), the ergonomical design for each facility may be different. However, a few generic critical control points are worth discussing and these would be present in most facilities:

1. Loading or transfer of patients into and out of the chamber

Nursing care in general is associated with back problems. The same is true for all hyperbaric facilities that use diving chambers (with round man-way doors) for HBO treatments. When considering the type of patients being treated in a hyperbaric facility – whether it be routine HBO treatments (such as a patient with a diabetic foot) or emergency treatment (such as gas gangrene), there are very few, if any, patients who are able to climb into or out of the chamber themselves. This is not only relevant during emergencies (meaning that it is very difficult to
rapidly get the patients out of the chamber), but also causes significant ergonomical stress on personnel during routine treatments when loading or transferring patients into and out of the chamber.

The most obvious solution to the problem is to have a rectangular entrance door to the main lock and to have the chamber flooring flush with the facility floor (or loading ramp). The door should allow wheelchair and gurney access with ease and the minimum width should thus be 700mm. Wider doors provide easier access and it is worth noting that chambers with rectangular doors wide enough to allow ICU bed access have been manufactured. There should be a minimum of 2,6m free space in front of the door to allow maneuvering of a gurney or stretcher. If the chamber door is not flush with the facility floor, a loading ramp should be used and the incline should be as small as possible. Even if the door is flush with the facility floor, there is usually a small step on the inside of the chamber (to allow a seal of the door) and this step should be as small as possible.

Loading of a patient into a monoplace chamber should also require the minimum effort. Some of the older chambers have blocks on which the gurney slides into the chamber, which requires considerable effort to load a patient. The newer monoplace chambers have gurney wheels, which reduce the effort considerably.

2. The internal free (working) space

Head space should be a minimum of 1.8m to 2m from the floor and careful consideration should be given to the placement of fire extinguishing nozzles and other equipment that could cause an injury to the head. Too much headspace would again introduce ergonomical hazards, since operating equipment (e.g. quick-connectors or valves) with the arms high above shoulder height could also lead to injury.

The passageway should allow a minimum of 600mm, but allow for more free space if procedures are to be performed inside the chamber. An acutely ill, stretcher-bound patient should be accessible from both sides and sufficient space should be available for resuscitation. ICU-level chambers are manufactured with an internal chamber width of up to 3,5m. The EU norms\(^7\) require a minimum of 1m\(^3\) per person (excluding equipment), although some manufacturers would allow for 100ft\(^3\) per person (about 2.8m\(^3\)).

3. Chamber seating

Benches in the chamber (such as metal benches in diving chambers) are not ergonomically appropriate for the treatment of ill patients. Chambers should be equipped with an individual chair for each patient. These should be ergonomically contoured for adequate comfort and to accommodate treatment times. Minimum dimensions are contained in existing standards, which include the height of the seats being at 450mm (but being adjustable), the seat depth being 400mm and a width of 500mm.

Such ergonomic seats will have armrests, be curved to provide cervical and lumbar supports, have adequate cushioning and even provide fold-out footrests. There should be no contact with hot or cold or sharp materials.

The interior of the chamber should have the ability to be quickly removed and changed out to allow for efficient customization of the interior in order to meet the treatment requirements. The materials should be high quality, flame retardant, water repellant and easy to clean. Careful consideration should be given to the colour-selection inside the chamber. Lighter colours for the walls and ceilings give an impression of more space. Darker colours
could be used for the flooring, while more cheerful colours could be used for temporary fittings, e.g. upholstery of the seating.

4. Compression procedures and compression rates

Middle ear barotrauma is the most common injury suffered in a hyperbaric facility. It is therefore important for operators (and attendants) to have absolute control over the compression of the chamber and be able to stop it at any moment. Engineering controls should ensure a compression rate that is slow enough and control panels should allow immediate intervention by the chamber operator, as well as the chamber attendant inside the chamber.

5. Built-in Breathing Systems (BIBS)

BIBS are used for almost every treatment and both attendants and patients being treated in a facility would readily be able to relate to common problems associated with the use of BIBS. The aviator mask is commonly used with heavy piping. It is also associated with increased breathing resistance – especially at low pressures, where exhalation is generally against higher pressures. This is also a heavy piece of equipment and thus puts strain on the neck of the patient or attendant. Furthermore, the piping itself causes obstruction or entanglement – leading to a tripping and falling hazard.

Ergonomically designed BIBS should be lightweight and have a very low resistance and work of breathing. No more than 0.3kPa should be required to open the inhalation and/or exhalation valves.

Newer chambers use masks that are exceptionally light and they use corrugated piping (similar to the piping used for hood systems) and these are ergonomically placed to reduce the risk of it causing obstruction and reduce the likelihood of neck strain.

From the field of occupational medicine we know that many persons do not have adequate protection from masks – especially if these have not been fit-tested. The same principle would apply to patients using masks during chamber treatments, which means that leaks could be quite common, especially in patients with facial hair, head and neck surgery, etc. This may lead to oxygen leakage into the chamber atmosphere and hence a fire hazard, which in turn requires continuous measurement of the chamber atmosphere oxygen percentage and a means of flushing the chamber continuously or on a “as-needed” basis.

All chambers should have access to oxygen hoods for patients who are not able to have a good seal with the mask, or those who cannot tolerate a mask on their face (e.g. with burn wounds).

6. Lighting in the chamber

The general illumination in the chamber should be 300Lux and be able to dim to 10Lux as required. For more specific activities (e.g. surgical procedures, siting a drip, etc.) 500Lux of focused light would be required, with local control of the light source (e.g. using flexible spotlights). Emergency lighting should allow a minimum of 90Lux.

The placement of the lights should conform to known ergonomical design principles to minimize glare, including not placing light sources in the line of vision, but keeping them 30 degrees above the line of vision.
7. Noise

Noise can be a considerable problem in a chamber and all noise sources should be controlled and minimized to ensure compliance with existing recommendations. These differ between different standards – usually ranging from between 40 – 65 dB(A) to a maximum of 70dB(A) when breathing treatment gas, while a maximum of 90dB(A) is allowed during compression. Gas flow noise can be adequately addressed by the use of diffusers, sound attenuators and using appropriate differential pressures.

Any other noise source (e.g. loose deck plates) should be controlled at source.

8. Temperature and humidity

Changes in temperature and humidity should be well controlled in the chamber. Chambers that are too cold inside usually require the occupants to take blankets or additional clothing into the chamber, which allows for additional fuel in the chamber (in case of a fire) and can also cause obstruction (e.g. in case of an emergency evacuation).

The temperature control should allow the internal temperature to be the same as the ambient temperature (with variation of a maximum of +7°C allowed during compression and -5°C allowed during decompression). Irrespective of the ambient temperature, the internal temperature of the chamber should never rise above 40°C (operationally the maximum temperature is usually 32°C). The chamber operator should be able to regulate the internal temperature in accordance with the occupants’ comfort and this should be operationalised without the need of “flushing” the chamber, which is usually a relatively noisy procedure. Chambers should therefore be fitted with control systems that would allow careful control of the temperature, but these should not directly blow either hot or cold air onto the occupants.

9. Atmospheric control

The chamber ventilation should keep oxygen levels below 23.5% and CO2 levels below 0.5ATA. Flushing the chamber manually is usually associated with pressure changes and an automatic ventilation system (such as those used in monoplace chambers) should preferably be used if flushing is required. This would generally be sufficient to address any other contamination in the chamber (provided that the chamber supply is free of contaminants). Administrative control measures should be implemented to prevent chamber air contamination from equipment or procedures (e.g. anaesthesiology) performed in the chamber.

10. Patient monitoring

Vital data monitoring is an integral part of patient safety. The layout in the chamber should allow for placement of monitoring equipment in such a way that a direct line of vision is possible. If the monitors can not be placed inside the chamber, it should be placed in a viewport with a direct line of vision for the attendant, without the need for the attendant to change his position in the chamber.

Patient monitoring systems that would function inside the hyperbaric chamber are available (including transcutaneous oxygen, transcutaneous carbon dioxide, expiratory oxygen/ carbon dioxide, capnography, ECG, EEG, CVP, NIBP, Pulse oximetry, temperature, etc.).
11. Piping and cabling

Pipes and cables of the chamber should not interfere negatively with any other task. This means that these should all be as short as possible and if piped from the outside of the chamber it should penetrate the chamber as close as possible to the instrument or equipment it will serve. Pipes should therefore (as far as possible) run on the outside of the chamber, but if it runs on the inside it should run as close as possible to the chamber wall. Furthermore, to ensure it is out of the way, it should be located above head level or on floor level (away to the side) and/or behind other equipment or installations.

Electrical installations should be minimized and therefore the use of wireless and bluetooth technology should be used where possible.

12. Emergency procedures and internal control panel

Each hyperbaric facility should perform emergency drills on a regular basis. Many ergonomical problems are identified during such drills. The following are common problems identified when visiting chamber facilities:

- An emergency oxygen shut-off valve must be readily available both inside and outside the multiplace chamber. For a monoplace chamber such a shut-off valve should be available right next to the chamber. These valves are normally sealed in the open position and the seals should be easy to break. Some chambers use “cable ties” that are found during emergency drills to be quite difficult (and in some cases impossible) to break.

- During a loss of internal pressure (e.g. burst pipe) or increase in internal pressure, the chamber attendant should be able to prevent further gas flow. The chamber thus requires emergency valves on the inside of the chamber.

It is simply not possible for the chamber operator to manage emergencies alone on the outside, leaving the occupants fully dependent on his or her actions. Although this seems to work on paper, experience tells us that in emergency situations there will often be problems that arise. Many of these become evident when performing emergency drills. Furthermore, there have been numerous cases where the chamber operator left his/her workstation or became incapacitated by illness or injury – resulting in trapped occupants. Although this is a controversial topic, it is the opinion of this author that all multiplace chambers should have a control panel inside the chamber, which allows the chamber attendant to take control and assist during emergency procedures. Most of these valves will be sealed in the “open position” during normal operations – to prevent unintentional use.

The internal control panel should include a caisson gauge, should have valves that are well-marked and accessible in an emergency. It should be in a position where it can be easily observed and operated from a single location. The ideal location for such a control panel is behind the chamber door. This area is usually “dead space” when the chamber door is opened (during loading of patients), but would be accessible when the chamber door is closed and the chamber pressurized. The chamber attendant’s seat can be directly opposite this internal control panel, giving him or her easy access to seal or open the door at the beginning or end of the treatments and also to operate the internal control panel in an emergency.
All the controls, signals and displays on this control panel should be organized in functional groups and be logically ordered. The valves and other controls should be clearly marked, including indications of the direction of closure. All the protrusions and sharp edges should be avoided or alternatively adequately padded. Operation of the valves should require smooth and minimal movements and require minimal effort (consume minimal energy). The controls themselves should conform to hand anatomy. The controls and background colour should be carefully selected for the required psychological effect – e.g. marking emergency valves in bright red. The shape and size of the controls should encourage the desired force to be used during operation, so that excessive energy is not required for operation, neither would the controls themselves be damaged.

13. Additional locks

All multiplace facilities should have an entry lock to allow the egress and ingress of personnel while the occupants are under pressure. However, entry of patients into the main lock should not be via the entry lock, but as stated above be directly into the main lock, which should have a rectangular door.

A supply lock should be placed in a position where it will be easily accessible for both the chamber attendant on the inside of the chamber, as well as the chamber operator on the outside.

14. Additional ergonomical considerations when treating acute patients

Customization of the chamber interior is an important consideration when treating an acutely ill patient. An anaesthetist/ intensivist station, with some storage space for equipment and some workspace will be required. There should also be sufficient space available at the head of the patient for monitoring purposes. Again, the monitoring equipment, its immediate availability and ability to use these in the chamber, as well as the direct lines of vision to such equipment is essential.

15. Decompression, emergency decompression and evacuation

Normal decompression of the chamber should be at a safe rate. During emergency decompression it should be possible to rapidly surface the chamber. An emergency valve could be used for this purpose and surfaces the chamber from a pressure of 200kPa to the surface should not exceed 2 minutes.

Rapid removal of occupants from the chamber should not restrict removal from another chamber or from the facility. This requires careful consideration to be given to the placement of doors and emergency exits. Again, this is another reason for patients to have direct access into the main lock of the chamber and not requiring exiting via an entry lock first.

Storage space in hyperbaric facilities is often restricted, so some of the larger monoplace facilities share chamber loading trolleys (e.g. one loading trolley for every two chambers). This can be problematic in case of an emergency, where removal of a patient from the chamber is interfering with removal of another patient from the chamber.
16. Ablution facilities

Patients being treated for prolonged periods (e.g. for decompression sickness) and patients with limited bladder capacity (e.g. being treated for radiation cystitis) often require a visit to the toilet during a hyperbaric treatment. This can be problematic if ablution facilities are not available. The large new chambers are fitted with a toilet and wash-basin in the entry lock (providing privacy).

17. Ergonomic programme

All chamber facilities should have a proper programme by which ergonomical considerations are continuously assessed and improved upon. Chamber operators and attendants, as well as patients are all able to (within a short period) provide valuable information on ergonomical problems associated with the treatments.

The monitoring programme should include advice from staff members and also capture injuries reported and problems experienced when emergency drills are practiced.

References

7. EN 14931:2006 - Pressure vessels for human occupancy (PVHO) - Multi-place pressure chamber systems for hyperbaric therapy - Performance, safety requirements and testing.