

***7th EUROPEAN CONSENSUS CONFERENCE
ON HYPERBARIC MEDICINE***

LILLE, 3 - 4 DECEMBER 2004

RECOMMENDATIONS OF THE JURY

Introduction

The aim of the Consensus Conferences organized by the European Committee for Hyperbaric Medicine (ECHM) is to reach an agreement on how Hyperbaric Medicine should be delivered with regard to its different aspects: indications, organisational aspects, education and training of personnel, operational rules and procedures, evaluation and quality assurance, research.

The first ECHM Consensus Conference was held in Lille in 1994 and, after 2 days of intense debates, recommendations were issued. At that time, it was found that not many of these recommendations were supported by a high level of evidence according to the methodology of the Evidence-Based Medicine, but as these recommendations were consensually agreed by a large number of experts, they were regarded as a good starting point for further research and experience.

Ten years have elapsed since this first Conference and a tremendous amount of work has been done in Europe and elsewhere. The time has come to review these 1994 recommendations and to elaborate a new synthesis.

The method of Evidence-Based Medicine (EBM) has gained a large agreement and is presently an integral part of modern medical practice. It is typically based on 3 axes : (1) the level of evidence (i.e. quality of available data), (2) interpretation of the evidence (i.e. what the data suggest and how concordant these data are regarding a particular problem), and (3) the type or strength of the recommended practice (i.e. the extent to which a physician is able to recommend a particular intervention on the basis of the first two considerations). This method may be used either by an individual physician or by a group of experts who could be expected to arrive at the same conclusion.

Unfortunately, this method is only applicable when high quality randomized controlled clinical studies exist. When there is a lack of data, the search for a consensus of experts is the method the most widely adopted. This method is regarded as the best surrogate to EBM method to evaluate interventions under the following circumstances. (1) Where a particular intervention, unsupported by a high level of evidence, has become universally accepted to such an extent that it would be considered a violation of accepted standards of care to deny a patient the benefit of the therapy for the purpose of a study. (2) Where the disease or condition of interest is so complex or where there are so many variables that it would be impossible to design a study sufficiently powerful to evaluate any single intervention. (3) Where the application of the therapy is so logical that it would be grossly inappropriate to consider omitting it to establish proof of efficacy. (4) Where no current higher level of evidence exists, but experts are able to report, not only from their own experiences but also by producing comprehensive literature reviews from which consensus can provisionally be reached, pending the outcome of future studies.

Even if an enormous effort has been made by the hyperbaric medicine community in order to achieve high quality clinical studies, we are forced to recognize that in our field, many questions remain without sufficient evidence to give a definite answer. During its debates, the jury was faced with a number of conditions where the evidence was evaluated as insufficient to put them on the list of accepted indications for Hyperbaric Oxygen Therapy (HBO₂). With other conditions, recent data did not convince the Jury of the efficacy of HBO₂. In these cases, the Jury adopted a “conservative” attitude while awaiting future studies. However, far from discouraging us, this must be a strong stimulant to increase our research effort and improve the quality of our practice.

As for the recommendations of the first ECHM Consensus Conference, those issued by the Jury of this 7th ECHM Consensus Conference have to be looked at a new step forward and a new starting point for the next 10 years.

Professor Francis WATTEL
President of the Jury
7th ECHM Consensus Conference

Methodology of 7th ECHM Consensus Conference

Consensus Conferences aim to create an objective and complete review of current literature and knowledge on a particular topic or field. This method has the advantage of involving a diverse group of experts, thus increasing objectivity. Participants in Consensus Conferences are selected from a broad range of relevant backgrounds to provide consideration of all aspects of the chosen topic and maximum objectivity. The opportunity to meet with other experts in the same field and share comments and information is also a valuable aspect of Consensus meetings.

In a Consensus Conference, experts present their review of the literature relating to a specific topic in front of a jury and an audience. Thereafter, the jury gathers in a secluded place to discuss the presentations, and presents its finding in a Consensus Statement that includes recommendations for clinical practice based on the evidence that was presented. These recommendations are published in the medical literature.

The application of Evidence-Based Medicine methodology to the consensus conference process helps the jury members to reach a consensus and strengthens the recommendation made. Thus, it is proposed each jury member assesses the literature and the evidence presented by the experts, and grades those according to their quality.

We propose each jury member uses the same grading scale, which has been extensively validated.

Basic studies (tissular, cellular or subcellular level)

1. Strong evidence of beneficial action
2. Evidence of beneficial action
3. Weak evidence of beneficial action
4. No evidence of beneficial action, or methodological or interpretation bias precluding any conclusion.

Animal studies with control group

1. Strong evidence of beneficial action
2. Evidence of beneficial action
3. Weak evidence of beneficial action
4. No evidence of beneficial action, or methodological or interpretation bias precluding any conclusion

Human studies

1. Strong evidence of beneficial action based on at least two concordant, large, double-blind, controlled randomised studies with no or only weak methodological bias.
2. Evidence of beneficial action based on double-blind controlled, randomised studies but with methodological bias, or concerning only small samples, or only a single study.
3. Weak evidence of beneficial action based only on expert consensus or uncontrolled studies (historic control group, cohort study,...)
4. No evidence of beneficial action (case report only), or methodological or interpretation bias precluding any conclusion.

ECHM Recommendations

The Jury will issue its recommendations using a 3 grade scale according to the strength each recommendation has been evaluated.

Type 1 : Strongly Recommended. The Jury considers the implementation of the recommendation of critical importance for final outcome of the patient/quality of practice/future specific knowledge.

Type 2 : Recommended. The Jury considers the implementation of the recommendation as positively affecting final outcome of the patient/quality of practice/future specific knowledge.

Type 3 : Optional. The Jury considers the implementation of the recommendation as an option.

The Jury will also report the level of evidence which supports, in its view, the recommendation.

Level A : Recommendation supported by level 1 evidence.

Level B : Recommendation supported by level 2 evidence

Level C : Recommendation supported only by level 3 evidence.

In using such a methodology, we expect every physician reading the jury conclusions will be immediately able to assess the strength of evidence supporting each statement and how it has to be applied in clinical practice.

QUESTION 1

WHAT ARE THE LEVELS OF EVIDENCE PRESENTLY SUPPORTING THE ACCEPTED INDICATIONS OF HBO₂?

- * Recommendations for HBO₂ indication have been issued on the understanding that no personal skill nor technical limitation interferes with the decision to treat with HBO₂.
- * Hyperbaric Oxygen Therapy implies the administration of oxygen under pressures not lower than 2 ATA and for durations not less than 60 minutes.
- * Hyperbaric Oxygen Therapy must be seen as part of a therapeutic continuum, without any interruption of the chain of treatment. It cannot be considered as an isolated treatment modality.
- * Technical competence and personal skills at the hyperbaric facility must be adequate and such that no potential accident, adverse event or problem occurring during the patient's stay in the facility will be likely to worsen the outcome of the patient.
- * Hyperbaric facilities accepting emergency indications in patients potentially requiring Intensive Care should be hospital based and located in or immediately near-by a hospital Intensive or Emergency Care Department.

I - Carbon Monoxide (CO) Intoxication

- * Carbon monoxide intoxications must be treated with normobaric oxygen as a first aid treatment (Type 1 recommendation, level C)
- * Hyperbaric Oxygen Therapy is recommended in patients with diagnosed carbon monoxide poisoning when at high risk of immediate or long term complications. (Type 1 recommendation)

High risk includes :

- Unconsciousness at or before admission (level B)
- Clinical neurological, cardiac, respiratory or psychological symptoms or signs (level B)
- Pregnant women (level C)

- * Treatment delayed beyond 24 hours after the last exposure to poison is not recommended if the patient has become symptom-free. (Type 3 recommendation, level C)
- * In carbon monoxide poisoned patients not at high risk, there is a choice between normobaric oxygen therapy for 12 hours and HBO₂. Until the results of further randomized studies are available, HBO₂ remains optional in these patients (Type 3 recommendation, level C).

II - Decompression Accident (see answer question 2)

III - Gas Embolism

* Hyperbaric Oxygen Therapy is strongly recommended, whatever the presentation of air embolism. (Type 1 recommendation, level C)

IV - Anaerobic or mixed anaero-aerobic bacterial infections

1- Necrotizing soft tissue infections :

Hyperbaric Oxygen Therapy is strongly recommended in the treatment of anaerobic or mixed bacterial necrotizing soft tissue infections (myonecrosis, necrotizing fasciitis, etc...). HBO₂ therapy should be integrated in a treatment protocol comprising adequate surgical and antibiotic therapy (Type 1 recommendation, level C).

The sequential order for HBO₂, antibiotics and surgery is a function of the condition of the patient, the surgical possibilities and hyperbaric oxygen availability. (Type 1 recommendation, level C)

2- Selected cases of organ abscess including intracranial, pleuro-pulmonary, and liver abscess :

Selection criteria may include failure of an appropriate conventional initial therapy, high surgical risk, compromised general condition of the patient. (Type 1 recommendation, level C)

V - Acute Soft Tissue Ischemia

* HBO₂ is recommended in post traumatic crush injury following open fracture Gustilo type III B and C (Type 1 recommendation, level B)

* HBO₂ is optional in reperfusion syndromes following invasive vascular procedure (Type 3 recommendation, level C)

* HBO₂ is recommended in compromised skin grafts and myo-cutaneous flaps (Type 2 recommendation, level C)

* HBO₂ is optional in the re-implantation of traumatically amputated limb segment (Type 3 recommendation, level C)

* In every case, the measurement of transcutaneous oxygen pressure is recommended as an index for the definition of the indication and of the evolution of treatment (Type 1 recommendation, level B)

VI - Radio-induced Lesions

The jury felt the data published since the 5th ECHM Consensus Conference in Lisbon, focused on the role of HBO₂ in the treatment of radio-induced lesions in normal tissues, have not changed the overall evaluation made by the Jury of that Conference. Therefore, it endorses the recommendations issued at that time.

HBO₂ is indicated in :

- * Radionecrosis of the mandible
- * Radio-induced cystitis resistant to conservative treatment
- * Tooth extraction in irradiated tissues (preventive action)
(Type 1 recommendation, level B)

- * Radionecrosis of other bones
- * Radio-induced proctitis/enteritis
- * Radio-induced lesions of soft-tissues
- * Surgery and implants in heavily irradiated tissues (preventive action)
(Type 2 recommendation, level C)

- * Laryngeal radionecrosis
- * Central nervous system radionecrosis
(Type 3 recommendation, level C)

VII – Delayed wound healing

1- Ischemic lesions (ulcer or gangrene) without the possibility of revascularization, or lesions persisting after optimal revascularization:

* In the diabetic patient, the use of HBO₂ is recommended in the presence of a Chronic Critical Ischemia as defined by the European Consensus Conference on Critical Ischemia (*note 1*), if perilesional transcutaneous oxygen pressures measured under hyperbaric conditions (2.5 ATA, 100% Oxygen) are higher than 100 mmHg (Type 2 recommendation, level B)

* In the arteriosclerotic patient, the use of HBO₂ is recommended in case of a Chronic Critical Ischemia (*note 1*), if perilesional transcutaneous oxygen pressures measured under hyperbaric conditions (2.5 ATA, 100% Oxygen) are higher than 50 mmHg (Type 2 recommendation, level C)

note 1 : Chronic Critical Ischemia:

periodical pain, persistent at rest, needing regular analgesic treatment for more than two weeks, or ulceration or gangrene of foot or toes with ankle systolic pressure <50 mmHg in the non-diabetic or toe systolic pressure <30 mmHg in the diabetic (Second European Consensus on Critical Ischemia: Circulation 1991, 84, IV, 1-26)

2- Selected non-healing wounds secondary to inflammatory processes:

* HBO₂ may be used in selected non-healing wounds secondary to inflammatory processes, but only in association with optimized conventional treatment.
(Type 3 recommendation, level C).

VIII - Osteomyelitis

* HBO₂ is recommended in chronic refractory osteomyelitis defined as osteomyelitic lesions persisting for more than six weeks after adequate antibiotic treatment and at least one operative procedure (Type 2 recommendation, level C).

* In cranial (excluding mandible) and sternal osteomyelitis, HBO₂ should be started simultaneously with antibiotics and surgical treatment (Type 2 recommendation, level C).

IX - Post-anoxic encephalopathy

* HBO₂ is optional for the treatment of cerebral anoxia (Type 3 recommendation, level C)

X - Burns

* HBO₂ is optional when burns exceed 20% of body surface and are of second degree or more (Type 3 recommendation, level C)

* If burned areas (excepted for head, hands, perineum) are less than 20% of body surface, HBO₂ is not recommended (Type 1 recommendation, Level C)

XI - Sudden Deafness

* Multiple treatment modalities have been proposed for sudden deafness with no high level evidence for any of those. HBO₂ remains recommended in sudden deafness (Type 2 recommendation, level C) until the results of the on-going European randomized controlled study are published.

XII - Ophthalmological Disorders

* HBO₂ is optional in acute ophthalmological ischemia (type 3 recommendation, level C)

XIII – Neuroblastoma Stage IV

Although there has been no randomized controlled study published, there is convincing accumulation of data showing a beneficial action of HBO₂ combined with conventional therapy. HBO₂ should be considered in combination with other accepted treatment for patients with neuroblastoma stage IV (Type 2 recommendation, level C)

XIV – Pneumatosis Cystoides Intestinalis.

HBO₂ treatment may be used in selected cases of pneumatosis cystoides intestinalis as an alternative to surgery when there is no signs of acute complications, such as perforation, peritonitis and bowel necrosis. (Type 3 recommendation, level C)

XV - Other indications

* Many other indications accepted by other scientific societies or leading representatives have been reviewed but are not currently recognized indications for Hyperbaric Therapy. Various research protocols are currently in progress; and results need to be awaited before issuing definite recommendations.

Table 1 : List of potential and proposed indications for Hyperbaric Oxygen Therapy.

After having listened the experts and with the assistance of literature reviewers, the Jury has graded the existing evidence using the scale used in ECHM Consensus Conferences.

Conditions where the use of HBO₂ was supported by level A, B or C evidence were considered as accepted indications.

Level A : At least 2 concordant, large, double-blind, controlled randomized studies with no or little methodological bias.

Level B : Double-blind controlled, randomized studies but with methodological flaws; studies with only small samples, or only a single study.

Level C : Consensus opinion of experts.

In order to make more transparent the jury discussion and decision, conditions which were not considered as accepted indications for HBO₂ are also reported with the Jury's evaluation of the existing evidence. The scale used in this table is an extension of that used for accepted indications.

Level D : Only uncontrolled studies with no consensus opinion of expert.

Level E : No evidence of beneficial action, or methodological or interpretation bias preclude any conclusion.

Level F : Existing evidence favors not to use HBO₂.

CONDITION	ACCEPTED			NON ACCEPTED		
	Level of Evidence			Level of Evidence		
	A	B	C	D	E	F
Type I						
CO poisoning		X				
Crush syndrome		X				
Prevention of osteoradionecrosis after dental extraction		X				
Osteoradionecrosis (mandible)		X				
Soft tissue radionecrosis (cystitis)		X				
Decompression accident			X			
Gas embolism			X			
Anaerobic or mixed bacterial anaerobic infections			X			
Type II						
Diabetic foot lesion		X				
Compromised skin graft and musculocutaneous flap			X			
Osteoradionecrosis (other bones)			X			
Radio-induced proctitis / enteritis			X			
Radio-induced lesions of soft tissues			X			
Surgery and implant in irradiated tissue (preventive action)			X			
Sudden deafness			X			
Ischemic ulcer			X			
Refractory chronic osteomyelitis			X			
Neuroblastoma Stage IV			X			

CONDITION	ACCEPTED			NON ACCEPTED		
	Level of Evidence			Level of Evidence		
	A	B	C	D	E	F
Type III						
Post anoxic encephalopathy			X			
Larynx radionecrosis			X			
Radio-induced CNS lesion			X			
Post-vascular procedure reperfusion syndrome			X			
Limb replantation			X			
Burns >20 % of surface area and 2nd degree			X			
Acute ischemic ophthalmological disorders			X			
Selected non healing wounds secondary to inflammatory processes			X			
Pneumatosis cystoides intestinalis			X			
Others indications						
Post sternotomy mediastinitis				X		
Stroke				X		
Sickle cell disease				X		
Malignant otitis externa				X		
Acute myocardial infarction				X		
Femoral head necrosis				X		
Retinitis pigmentosa					X	
Tinnitus					X	
Interstitial cystitis					X	
Facial (Bell's) palsy					X	
Cerebral palsy						X
Multiple sclerosis						X
Fetoplacental insufficiency						X

QUESTION 2

WHAT ARE PRESENTLY THE RECOMMENDATIONS CONCERNING THE PREVENTIVE MEASURES AND THE TREATMENT OF THE ACCIDENTS INDUCED BY HYPERBARIC PRESSURE?

I - Primary prevention: preventing onset of disease

In that field, common sense, existing legislation, and accepted standards of practice have to palliate the lack of studies following the Evidence-Based Medicine criteria. It is felt that the role of this Jury lies primarily in recommending the harmonization of standards and guidelines for both working and recreational divers, as well as hyperbaric workers, as promulgated by bodies such as ECHM, EDTC, etc.

This applies to: Fitness to Dive Assessment and Re-assessment, Risk Assessment, Safety and Emergency Procedures, and Diving Procedures in general.

1- Fitness-to-dive and Medical re-assessment :

* The joint ECHM-EDTC fitness-to-dive criteria are an agreed standard for all categories of diving and hyperbaric work, and should be periodically reviewed for currency. National standards may require modifications.

* Medical re-assessment includes periodic and post illness/accident assessments.

* Assessment outcomes may include: unfitness, fitness or conditional fitness. Diving/hyperbaric workers have the right to appeal against these decisions.

2- Risk Assessment, Safety and Emergency Procedures :

* EN ISO 14971 defines the risk management process as being made up of three steps: risk analysis; risk evaluation; and risk control. These are to be applied to all diving and hyperbaric activities.

* No single failure should result in a serious accident and this has to be implemented through appropriate safety plans.

* All responsibilities should be clearly defined and properly assigned or delegated before any operation.

* For all activities, written current Emergency Procedures (EPs) as well as Standard Operating Procedures (SOPs) should be prepared in advance in order to minimize the consequences of failure/accidents; they should be readily available and practiced regularly.

* Both the Regulations and their intent should be observed through education, development of a safety-oriented culture, reporting, and obtaining informed consent from participants.

3- Diving Procedures :

Current statements on safety of Diving/hyperbaric exposure are based on the incidence of clinical DCI; sub-clinical, unreported events, or the biological effects of bubble production remain unexamined.

The Jury recommends that these parameters/markers are considered in the evaluation of future diving procedures as by field bubble detection, bubble-induced biological effects, prospective epidemiological surveys and data collection.

4- Medical Hyperbaric Workers :

Medical hyperbaric workers have unique occupational safety issues - DCI incidence is low, particularly with routine HBO₂, and unrelated to gender. With increasing depth, DCI risk increases. Oxygen breathing and staff rotation are useful preventive measures.

This Jury recommends customized tables to account for these differences, appropriate fitness standards, and provision of oxygen/enriched oxygen breathing mixtures.

II – Secondary prevention : Shortening duration of disease / Improving outcome

Decompression Accidents are true medical emergencies that should receive the benefit of specialised treatment in dedicated centres as soon as possible. A specialized centre is considered a hospital-based recompression facility with permanent and adequately trained medical and paramedical staff.

- On-site 100% oxygen first aid treatment (Type 1 recommendation, level C)
- On-site fluid administration (Type 1 recommendation, level C)
- After immediate stabilization and medical evaluation, the victims of a decompression accident should be immediately directed to the closest specialized centre (Type 1 recommendation, level C)
- In water recompression should never be performed as the initial recompression (Type 1 recommendation, level C)
- Major accidents should be treated with hyperoxygenated tables either at moderate pressure (USN T6) or at high pressure (Cx 30 HeOx). Minor decompression accidents (pain only) can be treated with only oxygen recompression tables at 2.8 ATA maximum. (*note: this is based on the experience and the good results observed in commercial diving*). (Type 1 recommendation, level C)

As an extension of these general principles the following specific recommendations are presented by the Jury

Table 2 : Management of Dysbaric Diseases:

On Site		
First Aid	Recommendation	Evidence level
On Site First Aid – Oxygen 100%	Type 1	C
On Site First Aid – Fluids (oral)	Type 1	C
On Site First Aid – Fluids (IV)	Type 1	C
No In-Water Recompression	Type 1	C
Hospital-based Therapy		
HBO	Recommendation	Evidence level
Hyperbaric Tx Hyperoxygenated Tables	Type 1	C
Recompression with other Tables (USN 6A, Sat) for CAGE** or recalcitrant cases	Type 3	C
Fluids		
Fluid Therapy in General (Hospital Based)	Type 2	C
No Fluid Therapy D5W	Type 1	C
Fluid Therapy LR/crystalloids(Pain only/mild)	Type 2	C
Fluid Therapy LR/crystalloids (Chokes)	Type 2	B
Fluid Therapy LR/crystalloids (Neuro DCI)	Type 1	C
Fluid Therapy LR/crystalloids (AGE)	Type 2	B
Fluid Therapy Colloids (Pain)	Type 1	C
Fluid Therapy Colloids (Chokes)	Type 2	C
Fluid Therapy Colloids (Neuro)	Type 1	C
Fluid Therapy Colloids (AGE)	Type 2	C
Drug Therapy	Recommendation	Evidence Level
Life Support Drug Therapy	Type 1	C
Drug Therapy in General	Type 3	C
Aspirin	Type 3	C
NSAIDs (AGE and Chokes)	Type 3	C
NSAIDs (pain only & neurological)	Type 3	C
Anti-coagulants(AGE,Neurological)* Chokes)	Type 3	C
<u>No</u> Anticoagulants (pain only)	Type 1	C
Anticoagulants (DVT prevention leg immobility)*	Type 1	A
<u>No</u> Corticosteroids	Type 1	C
Lidocaine (AGE)	Type 2	B
Lidocaine (neuro DCS)	Type 3	C
<u>No</u> Lidocaine (pain only, chokes)	Type 1	C

* avoid complete decoagulation

** The use of USN 6A table should be limited to cases of CAGE caused by emergency ascent procedure without any previous compressed gas exposure leading to gas tissue supersaturation.

III – Tertiary prevention : Reducing long-term morbidity

Treatment of Persistent or Residual Symptoms :

At this time a maximum of 10 additional hyperbaric treatment sessions are recommended, based on clinical response, after the initial recompression.

If a clinical plateau has not been achieved by 10 treatments, and there is objective evidence of ongoing improvement, HBO₂ may be continued.

(Type 3 recommendation, level C)

Regarding neurological DCI, as with any neurological injury, conventional rehabilitation should be started as soon as possible.

(Type 1 recommendation, level C)

However, there are no scientifically valid data on which to base firm recommendations as to the best modalities/procedures to be adopted. Further research is required using standardised disability recording systems.

QUESTION 3

WHAT ARE PRESENTLY THE RECOMMENDATIONS CONCERNING THE ORGANIZATION AND PRACTICE IN A THERAPEUTIC CHAMBER?

* The Jury strongly recommends that the European Code of Good Practice for Hyperbaric Oxygen Therapy (ECGP) be the minimum requirement to be fulfilled by European hyperbaric centres, as it was established by a large consensus between internationally recognized European experts. (Type 1 recommendation, level C)

* The hyperbaric therapeutic facilities enter one of the following categories:

- hospital based or hospital connected.
- stand-alone.

Stand-alone facilities can treat patients not critically ill, but must be capable of providing care in case of clinical complications. Facilities standing on diving sites can treat patients suffering from acute decompression illness, provided their staff and equipment comply with minimum education and safety levels according to ECGP. (Type 2 recommendation, level C)

* The operations must be conducted under Standard Operation Procedures described in a specific manual. Each hyperbaric centres must develop emergency procedures on the same way. The staff must review these regularly, and should be trained in these procedures. (Type 2 recommendation, level C)

- * There is a large consensus to state the minimum team size for a hyperbaric session:
 - 3 persons for a multiplace chamber:
 - physician
 - attendant
 - operator
 - 2 persons for a monoplace chamber:
 - physician
 - operator.

(Type 1 recommendation, level C)

Furthermore, a person for emergency assistance must be available in the vicinity.
(Type 2 recommendation, level C)

* It is the duty of a hyperbaric centres to actively participate in continuous education and training of personnel. (Type 1 recommendation, level C)

* Hyperbaric centres should cooperate in research in hyperbaric and/or diving medicine. (Type 3 recommendation, level C)

* Hyperbaric centres should participate in education and examination of hyperbaric workers and divers (preventive medicine) and act as a referral for employees and contractors as centres of competencies, in respect of their national regulations. (Type 3 recommendation, level C)

* Every hyperbaric centre must develop and maintain a high level of safety for patients, staff and environment, based on risk prevention, education and appropriate procedures. (Type 1 recommendation, level C)

QUESTION 4

WHAT ARE PRESENTLY THE REQUIREMENTS CONCERNING THE DESIGN AND THE SAFETY OF THERAPEUTIC HYPERBARIC CHAMBERS AND THEIR RELATED MEDICAL DEVICES?

* A therapeutic hyperbaric chamber shall be considered a medical device according to the European Council Directive 93/42 “medical products”.

* The performance, testing and safety requirements of new therapeutic multiplace chamber systems shall conform with the new European norm prEN 14931 CEN TF 127 . All new chambers will be CE marked. Existing chambers should strive to reach the same safety levels as required by that norm. (Type 1 recommendation, level C).

* Quality assurance should be implemented in hyperbaric centers. (Type 1 recommendation, level C)

* Approval of medical devices for hyperbaric use is a worldwide problem. With a few exceptions, there is a lack of CE marked medical devices for use in the hyperbaric chamber. A risk evaluation according to the European norm ISO 14971 should be performed before bringing medical equipment into the chamber. Publishing and sharing experience and information on risk analyses between European HBO₂ centres is recommended. The manufacturers shall be encouraged to extend the CE approval of their medical devices for hyperbaric use. (Type 1 recommendation, level C)

* Oxygen filled “monoplace chambers” may be accepted and used according to internationally accepted guidelines. (Type 3 recommendation, level C)

QUESTION 5

WHAT ARE PRESENTLY THE REQUIREMENTS CONCERNING THE MANAGEMENT OF PATIENTS TREATED WITH HBO₂?

* A hyperbaric facility should be hospital based or functionally linked to a hospital. (Type 1 recommendation, level C)

* Standard operating procedures for the management of patients treated in hyperbaric facilities should follow the European Code of good practice for HBO₂ therapy. (Type 1 recommendation, level C)

* Appropriate monitoring equipment for selecting, supervising and follow-up of patients and their clinical response to HBO₂ treatment is required. (Type 1 recommendation, level C)

* HBO₂ treatment of intensive-care patients (with one or more organ failures that threaten vital functions) requires continuing monitoring and management according to standard European intensive care recommendations. The hyperbaric facility shall be located as close as possible to the Intensive Care Unit to minimize risks. (Type 1 recommendation, level C)

QUESTION 6

WHAT ARE PRESENTLY THE REQUIREMENTS CONCERNING THE INITIAL AND CONTINUOUS EDUCATION OF THERAPEUTIC HYPERBARIC CENTRE STAFF?

- * Co-operation between the ECHM and the EDTC has been fruitful.
- * A curriculum drawn up for different categories of hyperbaric personnel, describing the levels of competence according to the professional job, is strongly recommended. (note 1). (Type 1 recommendation, level C)
- * A core curriculum of modular teaching, applicable to all hyperbaric personnel (medical and non-medical) is strongly recommended. (note 2). (Type 1 recommendation, level C)
- * Education based on a modular system should be obtainable in different teaching institutions throughout Europe, with mutual recognition to the core standard. A system of credits, based on the minimal duration and emphasis of teaching elements, is strongly recommended. Entry criteria for the education of hyperbaric medical personnel will depend on the competency ultimately required for the category of the job. (note 3). (Type 1 recommendation, level C)
- * For the education of a hyperbaric medical expert, an in-depth study of particular aspects of hyperbaric medicine (ie a dissertation) is strongly recommended. (Type 1 recommendation, level C)
- * The European College of Baromedicine, as supported by the ECHM, should provide validation and accreditation for education and training in European countries. (note 4). (Type 1 recommendation, level C)
- * A programme for the education and training of non-medical hyperbaric personnel should be developed by an association of non-medical professionals (for example EBASS) in collaboration with the ECHM. (Type 1 recommendation, level C)
- * Continuing professional development using a format such as Continuing Medical Education (CME) is essential. (Type 1 recommendation, level C)

note 1. A curriculum has been drawn up by the COST Action B14 Education Working Group, based on the ECHM/EDTC proposals.

note 2. The core curriculum will be the result of the current work arising from COST Action B14 Education Working Group, due to be published through the ECHM.

note 3. Precise entry criteria for all hyperbaric personnel are being developed through the COST Action B14 Education Working Group, based on the recommendations of the ECHM/EDTC.

note 4. The accreditation body should work according to robust and transparent principles, with representation from the participating countries.

QUESTION 7

WHAT MAY BE PRESENTLY RECOMMENDED CONCERNING THE RESEARCH IN HYPERBARIC MEDICINE FOR THE NEXT FUTURE?

* It is strongly recommended that personnel (member) of hyperbaric facilities will associate into multi-disciplinary teams with specialist in other fields and basic scientists (Type 1 recommendation, level C)

* It is strongly recommended that medical staff involved in Hyperbaric Medicine receive training in basic and clinical research methods on a continuously regular base (e.g. CME). (Type 1 recommendation, level C)

* It is strongly recommended that a network of multicentric basic and clinical research is implemented. (Type 1 recommendation, level C)

* It is strongly recommended that European Ethical and Research Committees have to be continued within the European Committee for Hyperbaric Medicine with 2 priorities :

- establishment of a directory of centers and teams involved in clinical and basic research related to hyperbaric medicine.
- organization of seminars and workshops dedicated to clinical and basic research training.

(Type 1 recommendation, level C)

* It is strongly recommended that information and personnel exchange policies between hyperbaric facilities are implemented (Type 1 recommendation, level C)