

# Quality Assurance for a Hyperbaric Treatment Centre

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## 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?

*(To assure compliance with statutory requirements while achieving good clinical outcomes on a consistent basis.)*

- (4) 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.<sup>[1]</sup> Sometimes simplified as "conformance to specifications".<sup>[2]</sup>
- (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. <sup>[1]</sup>
- (3) Quality Control The inspection & defect detection activities to assure validity, reliability and reproducibility of the hyperbaric treatment program. <sup>[1]</sup>
- (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. <sup>[1]</sup>
- (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. <sup>[1]</sup> *Voluntary*
- (2) Auditing Process of using criteria or standards to assess quality, effectiveness & outcomes of hyperbaric treatments. <sup>[1]</sup> *Internal or external; voluntary*
- (3) Certification Process by which a recognised authority evaluates and recognises that the treatment program has met predetermined requirements. <sup>[3]</sup> 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. <sup>[4]</sup> *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. <sup>[5]</sup> 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. <sup>[6]</sup> 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 <sup>[6]</sup> 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:

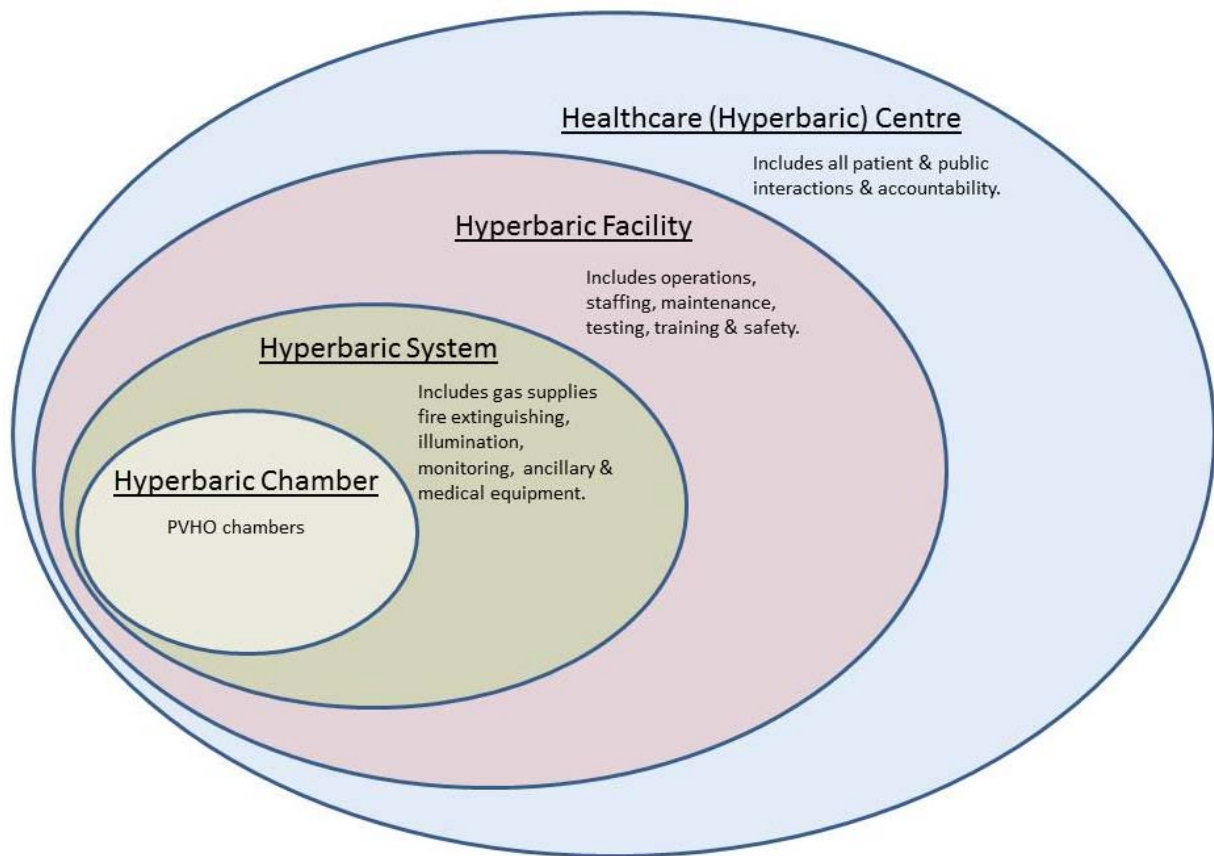
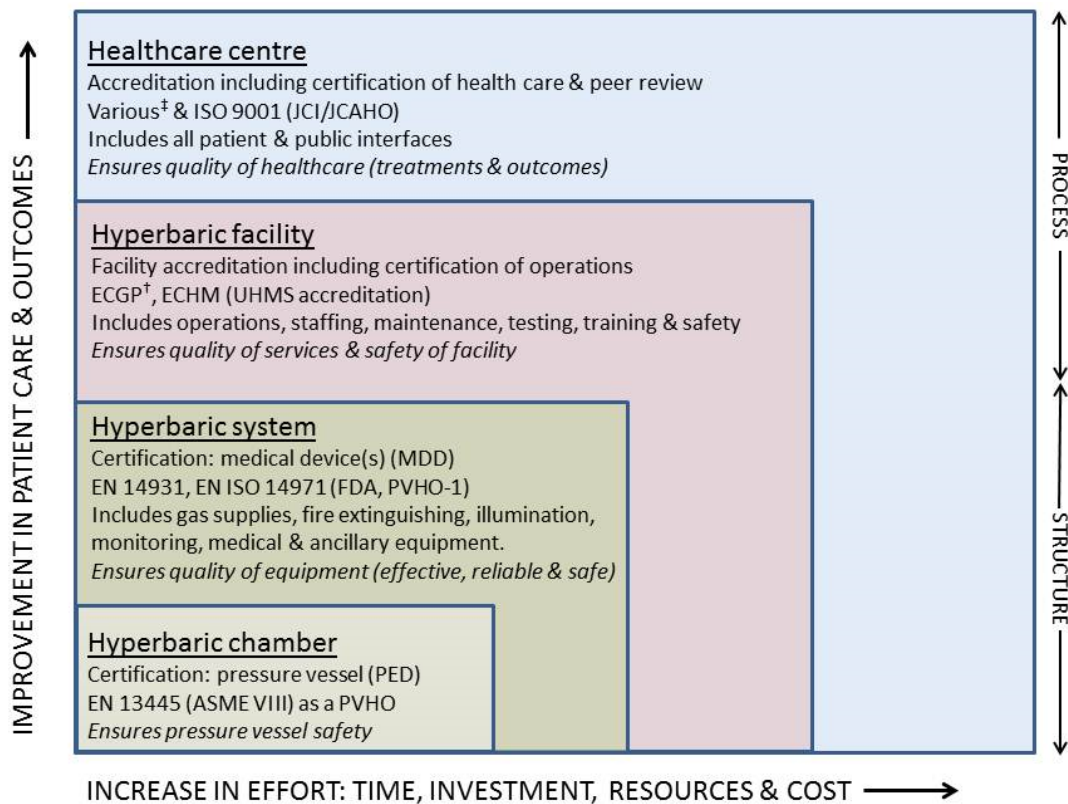


Diagram 1: Layered Structure of the Hyperbaric Treatment Program

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:



**Diagram 2: Patient Outcome vs. Organisational Effort**

<sup>†</sup> ECGP <sup>[6]</sup> sought to provide guidelines to fulfill the requirements for criteria spanning all operational activities required to provide effective hyperbaric oxygen therapy.

<sup>‡</sup> There are currently over 25 different accreditation systems in place.

EN 13445 <sup>[7]</sup>, ASME VIII <sup>[8]</sup>, EN 14931 <sup>[9]</sup> EN ISO 14971 <sup>[10]</sup>, PVHO-1 <sup>[11]</sup> & ISO 9001 <sup>[12]</sup>

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 truly 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 broader 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.<sup>[13]</sup> 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.
- (4) Hazard identification and risk assessment (HIRA).
- (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 processes 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 as 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.

	<b>Documents<sup>†</sup></b>	<b>Validation</b>	<b>Notes</b>
<b>Structure</b>			
<u>Hyperbaric chamber</u>	PED 97-23-EC MDD 93-42-EEC <i>(ASME PVHO-1)</i>	CE marking <i>(Nameplate)</i>	Pressure vessels in Europe require CE marking. In addition, all medical devices require CE marking.
Pressure vessel	EN 13445 <i>(ASME VIII)</i>	Certification <i>(U-stamp)</i>	Several other pre-existing vessel design & construction codes & specifications still exist in practice.
Acrylic windows	ASME PVHO-1	Certification	PVHO-1, a USA publication, is recognised for use in Europe. DIN 7080 is sometimes referred to.
<u>Hyperbaric system</u>	MDD 93-42-EEC EN ISO 14971 <i>(ASME PVHO-1)</i>	CE Marking Report <i>(Nameplate)</i>	The completed hyperbaric chamber with all systems also requires CE marking. EN ISO 14971 requires that a risk assessment report be issued prior to release of the medical device.
System design	EN 14931 <i>(NFPA 99)</i>	Certification, CE Marking	This standard contains minimum requirements for new chambers.
Air quality	EN 12021 <i>(NFPA 99)</i>	Certification	Contains maximum contaminant amounts for breathing air.
Fire extinguishing	EN 16081 <i>(NFPA 99)</i>	Certification	Allows for compliance with NFPA-99 deluge system requirements, as well as other systems.
<b>Process</b>			
<u>Hyperbaric facility</u>			
	ECGP <i>(NFPA 99)</i>	Certification	Contains requirements for staff, operational and emergency procedures, maintenance, safety and equipment monitoring.

	ECHM recommendations (UHMS guidelines)	Certification	Contains recommendations for facility management, equipment and procedures.
<b>Hyperbaric centre</b>			
<b>Accreditation</b>	ISO 9001, JCI, other accreditation schemes (UHMS accreditation manual)	Certification	There are <b>no hyperbaric centre-specific documents</b> currently available; a significant gap in the European hyperbaric sector. The UHMS Accreditation manual fills this role in the USA.
<b>Evaluation</b>	ECGP, ECHM, facility manuals (NFPA 99)	Reports & certification	A <b>second gap in the current European hyperbaric sector</b> . Elements exist and some external certification bodies offer this as a service.
<b>HIRA</b>	ECGP (ATMO: Risk Assessment Guide)	Reports	The ECGP contains a degree of guidance in risk assessment <b>but other publications</b> <sup>[14]</sup> <b>contain more comprehensive hyperbaric facility assessment approaches</b> .
<b>Outcomes</b>			
Patient perspectives	ISO 9001, JCI, other accreditation schemes (UHMS accreditation manual)	Reports	There are <b>no hyperbaric-specific documents that assemble this information</b> . Some healthcare accreditation schemes, ISO 9001 and JCI do require this information and would be a suitable source for quality assurance purposes.

Table 1: How Quality Assurance Criteria may be met using existing documents

<sup>†</sup> Closest applicable US regulating or guidance document noted in parenthesis under the application European document.

## 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 garners 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.

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