APPROVED MEDICAL EQUIPMENT FOR THE HYPERBARIC ENVIRONMENT: *THE ONGOING DILEMMA*

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SAFETY REPORT

News from the Safety Commitee

Everyone who has been trained in hyperbaric medicine understands the problem: Providing medical support for hyperbaric oxygen patients is challenging!

Quite apart from medical and environmental issues, and obvious concerns about fire or potential equipment malfunction due to pressure changes, there is an additional unresolved dilemma:

How does one obtain assurance, endorsement or approval to use a specific medical device in a hyperbaric environment when it has not been designed for this purpose?

The reality is that the need for suitable medical devices in hyperbaric facilities is not being met at present, nor is it likely to be for the foreseeable future. There simply isn't enough duly certified equipment to go around anymore.

As frustrating as the situation may be, however, we cannot really take issue with device manufacturers: The volume of equipment used in hyperbaric facilities is simply too low to justify the onerous and expensive certification requirements; the significant liability involved also serves as an additional disincentive.

As a result, there is now a critical shortage of medical devices being produced specifically for hyperbaric use. Existing device models are being withdrawn, with no replacements on offer. Moreover, some former manufacturers of hyperbaric equipment are withdrawing their previous endorsements. Last, but not least, FDA clearance for the use of medical devices in hyperbaric chambers has become almost non-existent.

So, how long will our practices be able to survive with our being dependent on aging, irreplaceable equipment, for which the approved use and spare parts are becoming increasingly scarce?

The answer is: not indefinitely! Ultimately we have to find a better way to determine the appropriate, safe use of new devices for ourselves, without depending on the manufacturer's certification or endorsement.

But what will this look like? Traditionally our approach to hyperbaric equipment safety has been one of absolute compliance: the purchase of regulatory-approved devices and reliance on the manufacturers to check all the boxes. This is not unique to North America. Europe faces the exact same dilemma, and with its predominantly hospital-based, multiplace, intensive-care-oriented hyperbaric facilities, the need is even greater.

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One potential solution, not well explored but certainly well documented, is a risk-based approach undertaken by a facility once the equipment has been purchased. Manufacturers are not typically enthusiastic about this approach: They understand that their product is to be used outside its official application, its approved use and its current market approval as a medical device. Many medical facilities are equally reluctant to make decisions about such use when these could, potentially, incur liability for complications.

Two publications offer guidance on this approach, however, and add confidence to a more situational risk-assessment process [1,2]. To date several medical support teams have used this approach to assess devices, and render them safe, in spite of their not being approved for hyperbaric use.

What has been the basis for their courage? Primarily, they were able to assess and mitigate all the relevant risks and operational requirements. There was also usually an urgent need for the device. Failures were

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pre-empted and could be managed in a responsible manner. And, most importantly, the medical director was prepared to endorse the application of the device based on a sound technical and patient-treatment risk analysis.

Of course any specific technical code (safety) requirements had to be met, including the limitations on maximum power, fire and electrical safety considerations, and functional reliability [3]. However, this did not render the device approved for use outside that specific healthcare facility.

Did this approach remove all liability exposure? Certainly not, but then it is intrinsic to medical practice to take certain calculated risks for a patient's benefit. And this is what they did. It just happened to involve the 'off-label' use of a device, rather than a pharmaceutical or procedure. So, does this approach represent the light at the end of our equipment tunnel?

A major U.S. medical facility's legal team has recently crafted an opinion, cognizant of the FDA requirements, that has paved a way to mitigate both the regulatory and liability concerns. Their assessment is summarized:

The **off-label use of a medical device**, marketed and sold for specific operating environments, but subsequently **identified for the hyperbaric environment**, with its higher ambient pressure, possible oxygen-enriched gas exposure, restricted access and other collective hazards, may be permitted by means of an appropriate decision-making approach. **Physicians have a duty to provide the best care for their patients**. Where available devices and medications are legally available but are not labeled for a hyperbaric medical indication, the physician may decide to use such a product. Of course there are restrictive considerations: safety is paramount, so any identified risk must be mitigated; there must be a clear patient need that requires the use of the device; the effect of the unintended operation and the behavior of the device must be known; detailed records must be kept. However, **in such an application, with the full knowledge and endorsement of the medical director**, combined with the intent to practice medicine, a new submission to the regulatory authorities is not deemed necessary [4].

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Clearly there are residual risks, even when following this approach: There is the risk of losing the device warranty. The physician or even the healthcare facility may still be held liable in the event of an adverse outcome. But, how does this truly differ from the practice of medicine as a whole? Is it not the very nature of medicine to make informed risk-benefit decisions? Don't health care practitioners make these decisions on a daily basis? If so, how do those decisions differ from the ones made regarding the useof a medical device in a hyperbaric chamber?

The answer is: **Knowledge and experience are lacking, and therefore the confidence to make these decisions**. This creates a significant amount of uncertainty, and each reported hyperbaric accident adds to this unquantified concern.

It is therefore the main objective of this article to introduce you to a better solution to the problem on how to overcome the situation in a responsible way.

This proposed risk-assessment approach is medico-legally defensible. The management of the healthcare facility should, of course, be fully informed as to any decisions taken, and their approval may be required. However, the pivotal decision is to be made by the responsible hyperbaric physician or medical director. It is primarily 'their call.' As such, it is very important to state that **this approach is not intended to promote the unspecified use of modified or risk-assessed equipment outside of a specific hyperbaric facility where its use has been duly approved**: ***The decision is physician- and facility-specific***.

The risk-assessment approach is not a cure-all. However, ignoring the problem will not resolve it. We therefore need to raise our knowledge and awareness of the actual risks, and then make responsible decisions based on appropriate risk-benefit assessments. Understanding the risk is the key: We can no longer afford an attitude of blind **compliance** in the place of true **comprehension**.

References

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