

Decision process to assess medical equipment for hyperbaric use.

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Burman F, Sheffield R, Posey K. Decision process to assess medical equipment for hyperbaric use. *Undersea Hyperb Med* 2009; 36(2):137-144. There are very few items of medical equipment specifically designed for hyperbaric use; and little information is available about medical equipment already tested for hyperbaric use. Hyperbaricists are usually left to their own devices in making a determination about the safe and effective use of standard medical equipment in the hyperbaric setting. This article proposes a logical and systematic process to arrive at this determination. The process involves seven steps beginning with a need assessment and ending with endorsement by appropriate individuals. The discussion of decision steps includes identifying risk elements, compliance with safety standards, testing, and documentation.

BACKGROUND

There are very few items of medical equipment designed specifically for use in a hyperbaric facility. Therefore, when a hyperbaricist needs medical equipment, it must be determined if standard medical equipment is safe for use in the hyperbaric setting. This presents several challenges. First, one must understand and mitigate the potential risks associated with using the equipment during hyperbaric treatment. Second, one must understand the machine functions that may be affected by the hyperbaric environment and be able to test for proper function. Third, one must be able to identify and compensate for any variances in accuracy or performance. Equipment modifications are frequently involved. Unfortunately, there is little guidance on testing and modification available.

To use medical equipment during a hyperbaric treatment, there are essentially two options: 1) Take the entire piece of medical equipment into the hyperbaric chamber or 2)

Leave the energized and/or control components of the equipment outside the chamber and find a way to split the equipment so the patient interface is inside the chamber. The second option is more likely to be used with monoplace hyperbaric chambers because of the strict limits on energy inside the chamber. If the entire piece of equipment is inside the chamber, there are concerns about fire safety, pressure integrity of the equipment, release of toxic substances, and accuracy of the equipment. If the energized components remain outside, there are still concerns about pressure integrity of the inside components, pressure integrity of the penetration through the chamber, and accuracy of the equipment. It is necessary to have a methodical and practical means to assess the safety of the medical equipment.

This article proposes a decision process to assess medical equipment for use during hyperbaric treatment. It includes a decision tree (Figure 1) and an explanation of the key decision points in this process.

DISCUSSION

The goal of the decision process is to reach one of two endpoints: place the equipment on a “go list” or place the equipment on a “no-go list”. Most steps of the process have a decision point. If one can move forward through all of the decision points, the equipment has been approved for use and is added to the “go list”. If one drops out of the process at any decision point, the equipment is added to the “no-go list”. Documentation of the decision process should be kept regardless of which endpoint is reached.

The decision process involves assessing equipment components for safety and potentially modifying the equipment to mitigate risk. Assessment and modification can be technically complex. Therefore, it is important to involve an engineer or biomedical equipment expert in this process. Any equipment modification will likely void the manufacturer warranty.

The entire decision process is divided into seven steps.

1. Need assessment: Is the equipment necessary? (See opposite page for Figs 1-3).

The concept of need is subjective. In order to determine need, one is really asking the following question: how important is this piece of equipment to the hyperbaric department? The answer falls somewhere on a relative scale. To identify the level of importance, it helps to break the issue down into more specific elements: effect on patient outcome, frequency of use, cost, complexity, and alternatives. Each of these elements falls somewhere on a relative scale. The need assessment should not be unilateral. As a minimum, the medical director and safety director of the hyperbaric department should be involved. The patient care staff may also have valuable input. After weighing the input from the entire care team, the motivation may not be strong enough to pursue the rest of the decision process. If this

is the case, one should document the rationale for the decision and add the equipment item to the “no-go list”.

2. Review existing literature: Has someone already tested and approved this equipment for hyperbaric use?

It may be possible to find equipment designed for hyperbaric use through regulatory agencies. In the US, medical device manufacturers are expected to register with the Food and Drug Administration⁽¹⁾ and show in their documentation the intended use of the equipment. In Europe a similar process is used through Notified Bodies certifying devices to the European Medical Directive⁽²⁾. Unfortunately, few items of medical equipment are specifically designed for hyperbaric use.

It is possible the original equipment manufacturer, a hyperbaric chamber vendor, some other organization, or a hyperbaricist has documentation of testing for hyperbaric use. The equipment manufacturer is a good first step. No one knows the equipment better than the manufacturer; and even if they have not tested the equipment for hyperbaric use, one can obtain information (e.g. drawings, wiring diagrams, specifications, operating parameters, and technical advice) that may be useful in later steps of the decision process.

The US Navy (USN)⁽³⁾ has published information on their testing of hyperbaric equipment. Other organizations such as Norwegian Underwater Technology Centre⁽⁴⁾ may also have relevant information. If a fellow hyperbaricist has tested hyperbaric equipment, the information may have been submitted to one of the hyperbaric medicine journals published by the Undersea and Hyperbaric Medical Society (UHMS)⁽⁵⁾, South Pacific Underwater Medicine Society (SPUMS)⁽⁶⁾, or European Underwater and Baromedical Society (EUBS)⁽⁷⁾. If one is comfortable with the information found in existing literature, proceed directly to process step 6 – Documentation.

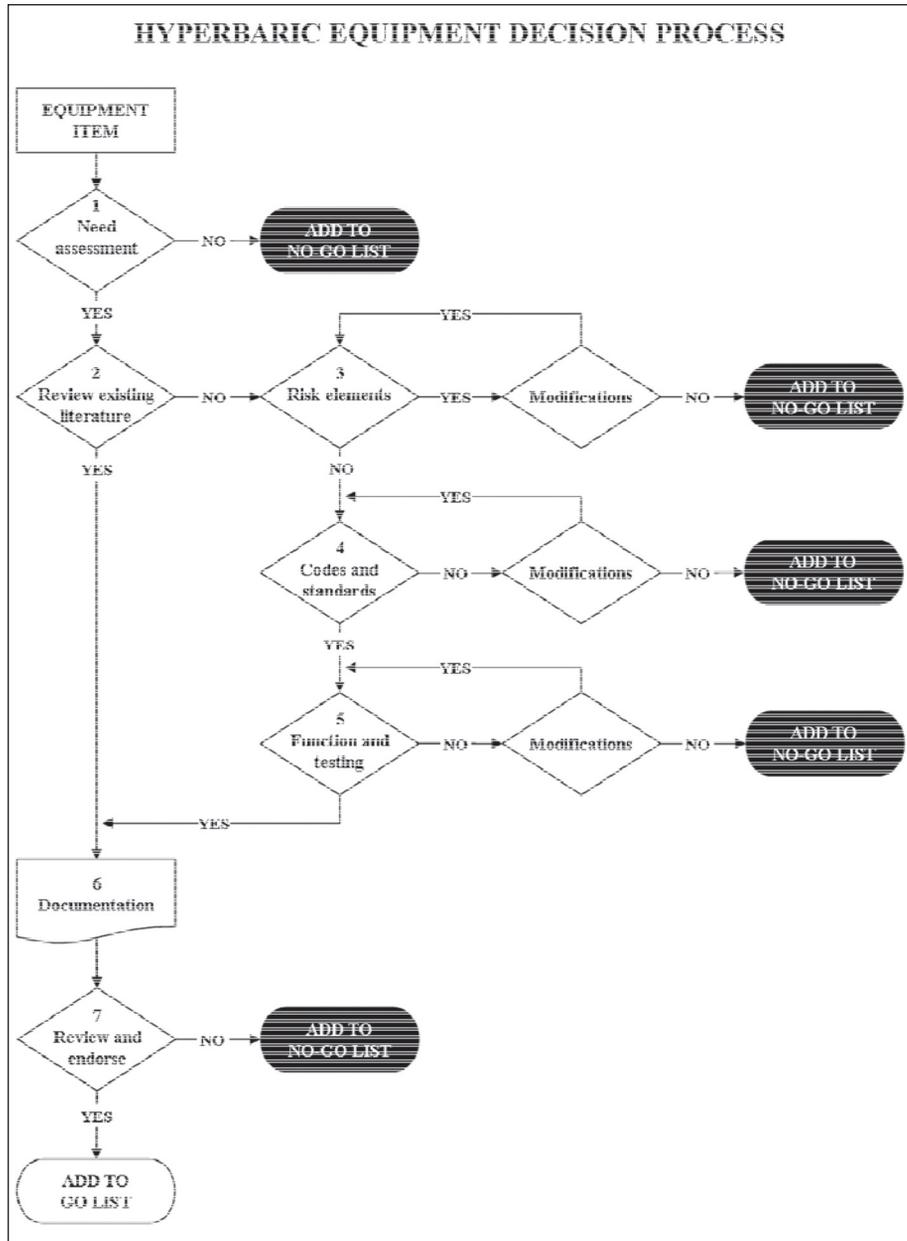


Fig.1

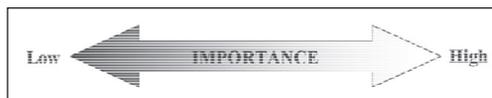


Fig.2

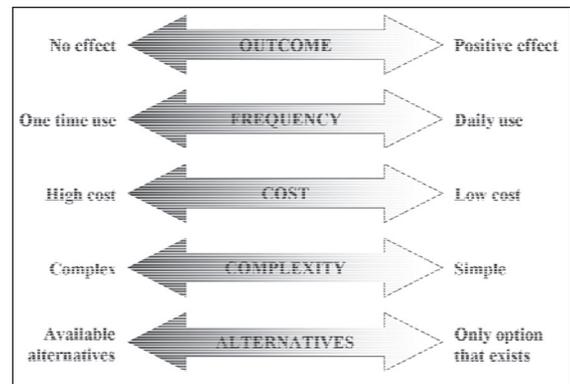


Fig.3

3. Risk elements: Are there areas of concern?

This step of the process involves analyzing the equipment carefully to determine the main sources of risk. Any equipment component or accessory introduced into the chamber, passed through the pressure boundary, or used to sense chamber pressure can be affected. This includes internal, external, and functional issues. Some risks will only arise under hyperbaric conditions. This risk assessment should address concerns about fire, pressure, toxic substances, and physical issues.

Fire concerns

For a fire to occur there must be sufficient quantities of oxygen, fuel, and energy present. Inside of any hyperbaric chamber, there will be sufficient oxygen to support combustion; and the higher partial pressure of oxygen (pO_2) in the chamber will cause an existing fire to spread faster and produce more heat. However, the primary risk issue is initiation of combustion (ignition); and the single greatest influence on ignition temperature is the oxygen percentage (not the pO_2). As the oxygen percentage rises, ignition temperature decreases. Therefore, preventing higher percentages of oxygen from interacting with fuel sources or energized equipment components is a concern. This additional oxygen might come from increased oxygen levels inside the chamber, leakage of a hood or mask placed near the equipment, or equipment that contains piped oxygen (e.g. ventilator, or gas analyzer). Active ventilation (or purging) with either air or nitrogen is a means to prevent oxygen percent from rising.

Fuel sources in equipment include any material or ignitable gas. Almost any fuel source introduced into a chamber will burn as a vapor combustion reaction. The fuel source needs to be heated to the temperature where a sufficient quantity of vapor is released (flashpoint), then it can be ignited. Each material has a different flashpoint. Materials with low flashpoints are

a concern. Volatile and flammable materials (e.g. alcohol, acetone) are the greatest concern. Also, situations where fuel vapor is either introduced into the chamber or trapped inside the equipment should be avoided. Dust particles behave like a vapor and are very easy to ignite. This emphasizes the need for good housekeeping practices.

Preventing ignition by controlling energy sources is a primary concern. Energy sources associated with equipment can include static charge, exothermic reactions, current leakage, and powered components. Even if the equipment does not have a power source, it is possible to have a static charge. This is typically addressed by using static-dissipating materials and grounding. The higher pO_2 in the chamber may also cause accelerated oxidation of materials. Some materials are susceptible to rapid oxidation, which produces heat. Therefore, oxygen compatibility of materials and materials intended to oxidize (e.g. fuel cells, or analyzer cells) are a concern. When the equipment has a power source, all potential sources of heat or spark must be considered. Motors, relays, thermostats, switches, batteries, power supplies, connections, and wiring must be scrutinized for sparking/arc potential. Purging with nitrogen or removing the sparking component are potential means to address this concern. Motors, lamps, circuit boards, and ionizing filaments are sources of heat. Also, battery life may be shorter and some components become hotter under hyperbaric conditions because of the additional work load. Active ventilation, addition of a heat shield (thermal barrier), or addition of a heat sink are potential means to address this concern.

The flow of gas is also a potential heat source. Heat is caused by the impact of gas molecules or particles inside piping. This is a concern where gas flow speed exceeds safe limits for oxygen and air, where there are cycling components, where there are solenoid

valves, where shock waves or resonant cavities exist, and where there are particles or dirt in the gas stream.

It is critical that sparks do not interact with oxygen and fuel sources. It is also critical that heat generated by the equipment is strictly limited and cannot ignite materials inside or near the equipment.

Pressure concerns

The increase or decrease in ambient pressure can affect both physical and operational aspects of equipment, leading to concerns about implosion, explosion, failure, and false information. The ability of equipment to resist or compensate for ambient pressure changes needs to be assessed, including equipment housings and sealed volumes or spaces (e.g. keypads, internal sealed components, relay housings, etc.). Gas flow components will be affected by pressure changes, causing variations in flow meter readings, and volumetric changes in ventilators. The increased gas density in the chamber increases the work load on motors, bearings and moving parts. Measuring devices may be inaccurate, especially where reference pressure or gas concentration is relevant (e.g. blood pressure monitors, gas analyzers, or pressure gauges).

Toxic concerns

Due to the confined nature of a hyperbaric environment, even small amounts of toxic gas or vapor may be a problem. The primary concern is off-gassing of any toxic or volatile substances from analyzer cells, batteries, lubricants, sealing compounds, lamps, sealed devices, or materials not compatible with oxygen.

Physical issues

There are a wide variety of physical issues. These include concerns about trip hazards, non-secure mounting of objects,

obstructions to movement, obstructions to line of sight, and entanglement. If additional penetrations or pass-throughs are necessary, these may require blow-out protection, check valves to prevent reverse flow, or security from accidental damage. If devices are electrically powered, it is necessary to have protection from electric shock. In addition, the hyperbaric environment causes an increase in the power and transmission of sound. Therefore, all sources of noise must be assessed. There are also infection control concerns with equipment; and it must be possible to clean the equipment effectively. Cleanliness is also a fire safety concern if dust or other potentially combustible materials could build up inside the equipment. Finally, the level of redundancy must be assessed because the ability to change-out equipment during a hyperbaric treatment may be limited. In the event of equipment failure, some type of back-up or alternative arrangement is necessary.

If the risk elements cannot be adequately managed, one should add the equipment item to the “no-go” list.

4. Codes, standards, and guidelines: Does the equipment comply with applicable standards?

Codes and standards serve a regulatory purpose. It is important to be aware of and understand the standards enforced in one’s jurisdiction (applicable standards). More importantly, codes, standards, and guidelines are a rich source of information. The applicable standards may not address all of the concerns identified in the previous process step; and information about good practice may be obtained from other standards or guidelines.

The following publications contain information relevant to hyperbaric medical equipment. Some are guidelines and others are mandatory in certain jurisdictions.

- NFPA 99: Standard for Health Care Facilities⁽⁸⁾ (requirements for medical gas piping, medical equipment, and hyperbaric facilities)

- NFPA 70: National Electrical Code⁽⁹⁾ (requirements for electrical systems)
- NFPA 53: Recommended Practice on Materials, Equipment, and Systems Used in Oxygen-Enriched Atmospheres⁽¹⁰⁾
- Handbook of Compressed Gases⁽¹¹⁾ (gas specifications, handling of gas cylinders)
- Standards produced by the ASTM^(12,13,14,15) (suitability of materials for oxygen environments)
- ASME PVHO-1: Safety Standard for Pressure Vessels for Human Occupancy⁽¹⁶⁾ (requirements for changes to pass-throughs or acrylic windows)
- European PVHO standard⁽¹⁷⁾ (performance, safety requirements, testing)
- Maritime Certification Society Rules^(18,19,20,21) (applications for human occupancy)
- Risk Assessment Guide for the Installation and Operation of Clinical Hyperbaric Facilities⁽²²⁾

Based on contents of the above documents, the following list contains general guidelines for safe practice. This list is not all-inclusive; and different jurisdictions may have additional requirements.

- No sparking or high temperatures.
- No materials unsuitable for use in oxygen-enriched environments.
- No hydrocarbons or volatile materials.
- No off-gassing of any toxic compounds.
- No trip hazards, obstructions, or access restrictions.
- Use only secure electrical connections.
- Enclosures must be vented or designed for the maximum chamber pressure.
- Noise limited to 85 dBA unless hearing protection is provided.
- Air flow speeds kept below 30 meters per second (100 feet per second).
- Oxygen flow speeds kept below 7 meters per second (23 feet per second).
- High pressure gases regulated at the source and only low pressure gases (less than 500

psi) allowed inside the chamber.

For multiplace chambers:

- DC voltage limited to 28 volts under normal or fault conditions, unless wiring is totally contained.
- AC power cords conduct less than 2 amps under normal and fault conditions.
- Maximum power limited to 48 watts.
- Maximum surface temperature of any component is limited to 85°C (185°F).

For monoplace chambers:

- Power used only for communications and sensors.
- DC voltage limited to 28 volts.
- Maximum power limited to 0.5 watts.
- Maximum surface temperature of any component is limited to 60°C (140°F).

If the equipment does not meet or cannot be modified to meet the general guidelines for safe practice listed above, one should add the equipment item to the “no-go” list. If the equipment or its modifications do not meet a local safety standard, one might be uncomfortable with the liability and should consider adding the equipment item to the “no-go” list.

5. Function and testing: Does the equipment function to specifications?

Although risk issues should have been identified and addressed in the assessment of risk elements, others may arise during testing. Functional testing carries the greatest opportunity for equipment damage or personal injury. It is important to be mindful of all the potential hazards during the testing process.

The purpose of this step is to ensure the equipment functions properly in the hyperbaric chamber and to identify any variance from normal operation. Depending on the type of equipment, different tests will be required. Consider using a biomedical engineer or expert user (e.g. respiratory therapist for ventilator testing) to help set test parameters. The testing

must include all features and operating modes of the equipment through the entire pressure range of the hyperbaric chamber. Fault conditions must also be tested to ensure no hazard is created in the event of equipment failure. It is important to test the equipment several times to ensure the equipment performs consistently.

If the equipment does not fully function through the entire pressure range, it may be necessary to make modifications or to set limits on use of the equipment. If modifications are made, it is necessary to retest the equipment. Because of pressure or gas density changes, there may be operational variances (e.g. an IV pump may not deliver the set flow rate, a ventilator may not deliver the set volume). If these variances are predictable, it is possible to simply compensate for them. If operational limits are too severe, one should add the equipment item to the “no-go” list. Similarly, if operational variances are too great or unpredictable, one should add the equipment item to the “no-go” list.

6. Documentation:

It is important to keep detailed records of each step of the decision process. This documentation is the primary resource in the decision to endorse the use of the equipment. It also serves as evidence of due diligence. Documentation of the decision process should include:

Need Assessment Report. This report details the importance of the equipment. It should include who participated in the assessment, what decision was reached, and why.

Existing Literature (if available). This includes any articles, test data, or manufacturer statements used in this decision process. Be sure to have all information in writing.

Risk Assessment Report (if performed). This report details all of the potential risk elements considered, including risk elements

not present. It should also indicate how risk elements were managed.

Modifications Report (if performed). This report details any modifications made to the equipment or the hyperbaric chamber, including any schematics or technical drawings.

Test Report (if performed). This report details the test parameters and results obtained. It should also indicate any variances from normal operation.

Instructions for Use. These instructions should include manufacturer operating instructions, special instructions for hyperbaric setup and use, and any adjustments or compensations necessary for operational variances. Instructions should be detailed and clear. Photographs or diagrams may help with clarification. Because of the high probability there will be special issues with the equipment setup and operation, it is important to establish a formal competency process for the hyperbaric staff. Also consider any special patient instructions that may be appropriate.

7. Review and endorse: Have the relevant parties in your organization approved the decision to use this equipment?

There should be a formal document, with relevant signatures, endorsing the use of the equipment. This document should be kept with the rest of the decision process documentation. As a minimum, endorsement from the hyperbaric safety director and the hyperbaric medical director should be obtained before using the equipment. Consider others within the hospital/organization who should also endorse this decision. These may include: safety officer, biomedical engineer, infection control nurse, risk manager, or legal counsel. If endorsement is not unanimous, one should add the equipment item to the “no-go” list. After all relevant endorsements are obtained, the hyperbaric staff can be trained, competencies can be established, and the equipment can be placed in service.

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