



HYPERBARIC OXYGEN THERAPY

The Issue

While hyperbaric oxygen therapy is recognized as an effective treatment for 13 specific conditions listed below, the operators of some private clinics claim it can also be used to treat such conditions as multiple sclerosis, cerebral palsy, cancer, AIDS, stroke and migraine headaches. There is no scientific proof to support these claims.

- necrotizing soft tissue infections (flesh-eating disease)
- osteomyelitis (bone infection)
- delayed radiation injury (e.g., radiation burns that develop after cancer therapy)
- skin grafts and flaps that are not healing well
- thermal burns (e.g., from fire or electrical sources)

Background

Hyperbaric oxygen therapy is a well established medical treatment. In April 2005, the Undersea and Hyperbaric Medical Society recognized the therapy as an effective treatment for 13 specific conditions:

- embolisms (air or gas bubbles in the bloodstream, which may travel to the brain or lungs)
- carbon monoxide poisoning (from inhaling smoke or car exhaust)
- gas gangrene
- crush injury, Compartment Syndrome and other acute traumatic problems where blood flow is reduced or cut off (e.g., frostbite)
- decompression sickness (the bends)
- enhancement of healing for wounds such as diabetic foot ulcers
- exceptional blood loss (anemia)
- intracranial abscess (an accumulation of pus in the brain)

How Hyperbaric Treatment Works

The therapy promotes healing in these 13 conditions by delivering a high concentration of oxygen quickly and deeply into the affected areas of the body.

During treatment, a patient goes into a closed chamber. The atmospheric pressure inside the chamber is increased. When the pressure reaches the level prescribed for the treatment, the patient is given 100 percent oxygen to breathe for a set amount of time. The patient breathes the oxygen through a hood and is advised when to take "breaks" and breathe the regular air inside the chamber. Regular air is 21 percent oxygen.

Some hyperbaric chambers hold only one patient. Others can accommodate two or more people. On occasion, a care-giver will go into the chamber with a patient.

The duration of each treatment, the number of treatments and the pressure used all vary, depending on the patient's



condition. Hyperbaric oxygen therapy treatments normally take place in hospitals or private clinics.

The Safety of Hyperbaric Chambers

Hyperbaric chambers are medical devices and require a licence from Health Canada. Before granting a licence, Health Canada experts review technical information to ensure that the medical device is safe and effective when used for specific conditions.

Health Canada has reviewed the scientific evidence related to hyperbaric chambers. The evidence shows that chambers are effective in treating the 13 conditions recognized by the Undersea and Hyperbaric Medical Society. Therefore, Health Canada has issued medical device licences for hyperbaric chambers to treat only these 13 conditions. No device licences have been issued for the use of hyperbaric chambers to treat other conditions.

Unproven Claims about Hyperbaric Oxygen Therapy

Be skeptical of anyone who advertises or offers hyperbaric oxygen therapy to treat conditions such as multiple sclerosis, cerebral palsy, cancer, AIDS, stroke or migraine headaches. At present there is no scientific proof that this therapy is useful in treating these other conditions.

It is very expensive to have treatments at a private clinic. People who pursue hyperbaric oxygen therapy for these other conditions may spend a lot of money for little or no benefit. Even worse, they may delay, or in some cases not receive, proven treatments that could help them or their loved ones.

Potential Risks

When used to treat recognized medical conditions, hyperbaric oxygen therapy is generally safe, as long as:

- the chamber is properly installed according to municipal and provincial regulations;
- operators and attendants are properly trained; and,
- a certified hyperbaric physician is either on site, or can be reached easily and quickly.

However, there are risks. Before consenting to treatment, you should consider these factors:

- Pressure inside the chamber can damage the middle and inner ear, nasal sinuses, lungs and teeth in both adults and children.
- Some people experience claustrophobia inside the chamber.
- The therapy may affect your eyes, for example by promoting nearsightedness or or cataract growth.
- Because hyperbaric oxygen therapy affects blood sugar levels, diabetics should have their levels checked before and after treatment.

- A high concentration of oxygen can cause serious complications in some children who have congenital heart disease.
- Too much oxygen can sometimes, although rarely, lead to overload that can cause seizures and lung problems. This is usually prevented by having the patient take breaks to breathe normal air instead of pure oxygen.
- High concentrations of oxygen at elevated pressures can pose a risk of fire.

There is also a risk the chamber might explode if it has not been properly installed or if the staff is not properly trained. In addition, it may be difficult or impossible for operators to deal with medical emergencies that may come up when patients are isolated inside the closed chamber.

Minimizing Your Risk

If you decide to pursue this therapy on the advice of your doctor, Health Canada recommends the following steps:

- Make sure your medical condition is on the list of recognized conditions that respond to hyperbaric oxygen therapy. (See the Need More Info? section below for more on this.)
- Be candid with the hyperbaric physician who interviews you. The doctor needs all the facts to determine whether you are medically capable of undergoing treatment.



- Make sure the hyperbaric chamber has been licensed by Health Canada. You can do this on the Internet by searching Health Canada's database of approved medical devices.
- If your treatment is going to be at a private clinic:
- Verify that the installation and operation of the hyperbaric chamber comply with recognized safety standards.
- Ensure that operators are trained and capable of dealing with a medical emergency that might arise during treatment. Ask about emergency procedures.
- Check that a certified hyperbaric physician will either be on site or can be reached easily and quickly if needed.

Finally, report any problems caused by hyperbaric oxygen therapy to Health Canada's Medical Devices Hotline, at 1-800-267-9675 (toll-free in Canada).

Health Canada's Role

Hyperbaric chambers must be licensed by Health Canada before they can be imported and sold in Canada. The Medical Devices Regulations require that the medical devices imported and sold in Canada are safe, effective, and of quality manufacture. This is achieved by a combination of a pre-market review prior to licensing, and post-market surveillance of adverse events.

Need More Info?

For details and updates about recognized indications for HBOT, visit the Undersea & Hyperbaric Medical Society Web site:
<http://www.uhms.org/Indications/indications.htm>

To check the credentials of a doctor running a facility, call the College of Physicians and Surgeons in your province or go to the Royal College of Physicians and Surgeons at:
http://rcpsc.medical.org/main_e.php?vtype=gp

For general information about medical devices, contact:

Manager, Device Evaluation Division
Medical Devices Bureau,
Health Canada
Tunney's Pasture 0301H1
Ottawa, ON K1A 0K9
E-mail:
ded_manager@hc-sc.gc.ca

Medical Device Licence Listing:
www.mdall.ca

Also, see Health Canada's Medical Devices Web site at
http://www.hc-sc.gc.ca/dhp-mps/md-im/index_e.html

For additional articles on health and safety issues go to the It's Your Health Web site at:
www.healthcanada.gc.ca/iyh
You can also call toll free at 1-866-225-0709
or TTY at 1-800-267-1245*