**CDR 18: Safety Measure: Serious Side Effects among patients undergoing Treatment with HBOT**

**MEASURE STEWARD:**
US Wound Registry and the Undersea and Hyperbaric Medical Society (UHMS)

This measure was developed via a consensus process in collaboration with the Undersea and Hyperbarics Medicine Society (UHMS) Quality Measure Committee.

**DESCRIPTION:**
Percentage of patients aged 18 years or older undergoing HBOT for any diagnosis

**NUMERATOR:**
Patients who experience a specifically defined serious side effect of HBOT.

**DENOMINATOR:**
Patients aged 18 years or older who
- Have undergone HBOT for any Medicare covered diagnosis.

**DENOMINATOR EXCLUSIONS / EXCEPTIONS**
EXCLUSIONS: NONE
EXCEPTIONS: NONE

**BACKGROUND:**
Hyperbaric oxygen therapy is a safe medical therapy with a low risk of side effects and complications. Hyperbaric oxygen therapy involves placing the entire patient in a pressure vessel (hyperbaric chamber) which is then compressed with air or oxygen, and allowing the patient to breathe oxygen at an atmospheric pressure greater than 1.3 times sea level pressure (atmospheres absolute). Due to the mechanical effects of the atmospheric pressure change and the unique physiologic effects of some gases at increased partial pressure, certain side effects are known to occur. These side effects are not due to improper use of HBOT, to equipment malfunction, or a failure of care. These are known risks associated with HBOT. Certain underlying medical conditions may make patients more likely to experience side effects from HBOT (e.g. fever may predispose to hyperoxic seizure). However, fundamentally these complications occur due to the unique physics of the hyperbaric environment. Some side effects from HBOT may be mitigated by screening patients for specific underlying medical problems. It is also possible to reduce the risk of some side effects by modifying the parameters of the HBOT treatment (e.g. providing HBOT at a slightly lower treatment pressure or providing “oxygen breaks” for patients at greater risk of a hyperoxic seizure).

Even the risk of potentially serious side effects may not be a sufficient reason NOT to perform HBOT. The risk(s) of HBOT side effects must always be evaluated in the context of the potential benefit of HBOT for a given condition. HBOT may be limb or lifesaving depending upon the indication for which it is recommended. For example, even a patient with an increased risk of grand mal seizure due to oxygen toxicity may feel this risk is acceptable if, for example, the reason they are being offered HBOT is to prevent long term brain damage from carbon monoxide poisoning. In such a case, the benefit of HBOT to protect from the long term neurological sequelae of CO poisoning still outweighs the relatively low risk of hyperoxic seizure from which there are no reported long term neurological effects.
POTENTIAL SERIOUS SIDE EFFECTS OF HBOT AND RATIONALE FOR THIS MEASURE

For many years, individual hyperbaric centers, management programs, and other groups have attempted to pool data to ascertain the incidence of side effects and the impact of specific patient risk factors. However, no national database has ever been created to track these data. The UHMS believes that the creation of a clinical quality measure for the reporting of serious side effects, combined with the transmission of patient Continuity of Care Documents (CCDs) to understand patient co-morbid conditions and medications taken, will allow the USWR and the UHMS to better understand the incidence of serious side effects, possible contributing factors, and create patient specific informed consent procedures for HBOT.

For this reason, this per visit measure (per hyperbaric oxygen treatment measure) will be an index of the reported serious side effect in relation to total number of patient treatments (exposures). The USWR will publish national benchmarks.

The serious side effects listed below are not due to improper use of HBOT, to equipment malfunction, or a failure of care. However, their likelihood might be mitigated in some cases by increased screening. Because all of them are rare, not enough is known about the factors that contribute to them. One of the goals of this measure is to obtain better national data to understand possible contributory factors.

1. **Pulmonary Oxygen Toxicity**

   Breathing oxygen at increased atmospheric pressure can cause pulmonary oxygen toxicity, manifested in severe cases as pain on inspiration and reduction in FEV₁. Pulmonary symptoms are almost never produced by daily exposures to oxygen at the treatment pressure and duration used for clinical hyperbaric oxygen therapy (e.g. 2.0 or 2.4 atm abs for 120 or 90 min). There are no cases of pulmonary oxygen toxicity resulting from the routine clinical use of HBOT with the single exception of a patient having undergone Bleomycin chemotherapy which is a known sensitizing agent.

2. **Pulmonary Barotrauma**

   Pulmonary barotrauma with pneumothorax during decompression may rarely occur. As the atmospheric pressure in the chamber decreases at the end of the treatment, gas expands according to Boyl's Law. If gas is trapped in the lung, a segment of the lung may over-inflate and thus rupture. Patients with airway obstruction probably are at an increased risk for pulmonary barotrauma during decompression. Significant air trapping and a history of spontaneous pneumothorax are also causes for concern and mandate a careful analysis of potential benefit from hyperbaric oxygen therapy versus the associated risk. Only 2 cases of pulmonary barotrauma in association with clinical hyperbaric oxygen therapy have been reported in the literature. The need for HBOT in patients with known obstructive lung disease must be weighed against the risk of pulmonary barotrauma which, although low, could be fatal due to the risk of tension pneumothorax and/or subsequent arterial gas embolism.

3. **Central nervous system oxygen toxicity**

   The incidence of central nervous system oxygen toxicity varies widely depending on the atmospheric pressure at which oxygen is inspired (the total oxygen partial pressure), breathing apparatus, and acuity (level of illness) of the patient. Among stable patients treated at 2.0 ATA the incidence is approximately 1:30,000. However, among very unstable patients treated at higher pressures the incidence may be as
high as 2%. When oxygen convulsions do occur, there are no residual effects if mechanical trauma can be avoided.

4. Flash Pulmonary Edema
A less well understood side effect of HBOT is “flash pulmonary edema”. This is presumed to be due to an increase in peripheral vascular resistance from oxygen induced vasoconstriction, increasing intracardiac pressures and leading to cardiac overload among patients with pre-existing cardiac disease and decreased ejection fraction (EF). However, no EF threshold has been identified that would exclude patients from HBOT. This problem is usually manifested as the sudden onset of shortness of breath during HBOT. However, fulminant congestive heart failure symptoms have been reported.

Minor Complications of HBOT (not part of this measure)
Middle ear barotrauma is the most common side effect of hyperbaric oxygen (HBOT) therapy. This is usually manifested as ear pain but tympanic membrane rupture can occur. The incidence of otic barotrauma is reported between 2% and 10% of patients undergoing HBOT. It is prevented in most patients by teaching autoinflation techniques or by use of tympanostomy tubes for those who cannot autoinflate their middle ear compartment. Sinus barotrauma or pain is seen less frequently than middle ear barotrauma. Both of these problems are due to the change in volume of gas with atmospheric pressure changes. They can be avoided or reduced by gradual changes in the hyperbaric treatment pressure. Because barotrauma to the ears and sinuses is painful but not fatal, it is not considered a major complication of therapy. Claustrophobia or confinement anxiety, present in about 2% of the general patient population, may cause some degree of anxiety among patients undergoing HBOT. Mild sedation may be required for patients to tolerate treatments. This is not considered a major complication. Progressive myopia has been observed in some patients undergoing prolonged periods of daily HBOT therapy. Although the exact mechanism remains obscure, it is apparently lenticular in origin and usually reverses completely within a few days to several weeks after the last therapy. Vision change is therefore not considered a major complication of therapy.

CLINICAL RECOMMENDATION STATEMENTS:
1. Patients undergoing HBOT should be monitored throughout the treatment for serious side effects of HBOT.
2. These side effects are not due to improper utilization of HBOT but the UHMS hopes through the collection of national data to establish national benchmarks for rare side effects and understand risk factors that might contribute to their development.

REFERENCES:


31. Hampson NB, Atik DA. Central nervous system oxygen toxicity during routine hyperbaric oxygen therapy. Submitted
