**CDR 19: Process Measure: Completion of a Risk Assessment at the time of HBOT Consultation**

**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 Measures Committee.

**DESCRIPTION:**
Percentage of patients aged 18 years or older undergoing HBOT for any diagnosis for whom an assessment of risk factors for HBOT complications or side effects was documented. This is to be performed one time in the reporting period.

**NUMERATOR:**
Patients who
- Underwent a risk assessment at the time of HBOT Consultation. Patients will be assessed for these specific risk factors so that additional informed consent can be provided.

**DENOMINATOR:**
Patients aged 18 years or older undergoing HBOT.

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

**RATIONALE:**
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, allowing the patient to breathe oxygen at an atmospheric pressure greater than 1.3 times sea level pressure. 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. The potential for side effects and complications from HBOT can be mitigated by screening patients for specific underlying medical problems. HBOT may be limb or lifesaving depending upon the indication for which it is recommended. Thus, 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 for 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 seizures from which there are no reported long term neurological effects. Thus, the risk(s) of HBOT side effects must always be evaluated in the context of the potential benefit of HBOT for a given condition.
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 risk factors, combined with the transmission of a Continuity of Care Document (CCD) will allow the USWR and the UHMS to better understand incidence and risk factors, and then use these data to create more patient specific informed consent for HBOT.

The Rationale for each of the screening risk factors is provided in the Addenda.

**CLINICAL RECOMMENDATION STATEMENTS:**
Patients undergoing HBOT should be assessed for factors which may increase the risk of side effects or complications. When risk factors are identified, the hyperbaric clinician should provide risk specific informed consent to help the patient weigh the risk vs. benefit of HBOT.

**REFERENCES and ADDENDA**

**Addendum A: Bleomycin as a Risk for Oxygen Toxicity**
Bleomycin is an antitumor antibiotic used successfully to treat a variety of malignancies. The major limitation of bleomycin therapy is the potential for life-threatening interstitial pulmonary fibrosis in up to 10% of patients receiving the drug (1). Age over 40, cumulative drug doses ≥ 400 units, renal insufficiency, concomitant use of radiation therapy, cigarette smoking, and exposure to high partial pressures of oxygen are probable risk factors for bleomycin lung toxicity (2).

Prior administration of bleomycin was previously thought to be an absolute contraindication for patients being considered for HBO2 therapy.

Data are conflicting about whether exposure to high concentrations of inspired oxygen increases the likelihood of lung toxicity in patients having received prior bleomycin chemotherapy. In animal models, simultaneous exposure to bleomycin and high FiO2 increases the risk of lung injury (3), while exposure to lower than normal oxygen concentrations appears protective (4).

A study in hamsters showed increased lung toxicity only with simultaneous exposure to bleomycin and high inspired FiO2, and did not occur when bleomycin treatment preceded the oxygen exposure by > one month (5). It is not clear whether this data can be extrapolated to humans.

The evidence that oxygen exposure may increase the risk of pulmonary toxicity is largely anecdotal. A prospective study of 12 patients that had received bleomycin preoperatively, and had removal of retroperitoneal lymph nodes or pulmonary metastases reported no postoperative complications using low concentrations of inspired oxygen during surgery and careful monitoring of fluid replacement in the immediate postoperative period. The study followed 5 postoperative deaths due to pulmonary complications at the same institution (6).

In a similar review of 77 major surgery patients with prior bleomycin-containing chemotherapy, there was no correlation between perioperative oxygen restriction and postoperative pulmonary morbidity or mortality. Intravenous fluid management, including transfusion appeared to be the most significant factor affecting postoperative pulmonary morbidity and overall clinical outcome (7).
The anecdotal human data, combined with the animal data have led to widespread recommendations for lifelong avoidance of high concentrations of supplemental oxygen, including HBOT in patients previously exposed to bleomycin.

A series of 15 bleomycin-exposed patients received HBOT at Duke University under a special-precautions protocol. The pre-treatment evaluation included chest x-ray, spirometry, blood gases, a single 2 ATA 120-minutes HBOT treatment and a gradual acceleration over one week to a twice-daily schedule contingent on clinical and lab findings. Total bleomycin doses ranged from 40 to 225u/m2 (mean 103±56) in conjunction with other chemo and radiation. Mean radiation-to-HBOT and bleomycin-to-HBOT latencies were 24 and 32.2 months respectively. There were no persistent post HBO2 pulmonary complications. One patient experienced pleuritic chest pain that resolved with humidification. The authors conclude that evidence may be overstated for increased long-term susceptibility to acute pulmonary toxicity based on synergy of bleomycin and HBOT.

Unanswered questions include whether there is a threshold FiO2 or duration of therapy above which the risk of lung injury increases, or whether there is a time interval following bleomycin treatment after which higher FiO2 exposures will not increase the risk of injury.

**CLINICAL RECOMMENDATION STATEMENTS REGARDING BLEOMYCIN:**
Patients should not be treated simultaneously with bleomycin and HBOT. Patient candidates for HBO2 previously treated with bleomycin should have an initial pre-HBO2 evaluation to include recent chest x-ray, spirometry, and blood gas analysis, and should be reassessed after a single HBO T exposure. Pulmonary consultation as indicated.


**Addendum B: Pregnancy and Hyperbaric Oxygen Therapy**
High concentrations of oxygen have been known to cause retinopathy of the newborn, and an increased arterial PO2 is a stimulus for closure of the patent ductus arteriosus. For these reasons, it was thought that pregnant women should not be exposed to hyperbaric oxygen. It is now known that pregnant women can be successfully treated with HBOT without deleterious effects on the developing fetus.
Extensive published Russian research and experience between 1979 and 1983 of more than 700 women treated with HBOT in all stages of gestation for a variety of maternal and fetal conditions did not result in any complications or mortality. Many pregnant women have been treated with HBOT for carbon monoxide poisoning, and purportedly in some countries for placental insufficiency, but evidence and documentation is limited (1).

Diving and hyperbaric oxygen-related studies have addressed the first (teratogenic effects) and third (effects of DCS and effects of HBOT on the fetal circulatory system) trimesters of pregnancy (2). The developmental abnormalities that have been associated with hyperbaric exposure include low birth weights among the offspring of diving mothers (3-5), fetal abortion in sheep (6), bubbles in the amniotic fluid in sheep (7,8), premature delivery (4), abnormal skull development (9, 4, 10), abnormal heart development (10, 11), changes in fetal circulation (12), limb weakness associated with DCS (13), and blindness (3).

Limited research suggests that there is a greater incidence of birth defects in infants whose mothers engaged in SCUBA diving while pregnant. In a report evaluating field data of 129 women reporting 157 pregnancies over 1,465 dives to investigate any potential link between diving while pregnant and fetal abnormalities, there was insufficient data to establish any significant correlation between diving and fetal abnormalities (14). In a review, the authors recommended that pregnant females should refrain from diving because the fetus is not protected from decompression problems. However, if a woman unaware that she was pregnant completed a dive during early pregnancy, the current evidence is not to recommend an abortion because normal pregnancies have been documented even if diving is continued (15).

Clinical recommendation statement regarding Pregnancy and HBOT:
The literature indicates that while the effect may be small, compressed air diving (such as scuba diving) during pregnancy does increase the risk to the fetus. The prudent course is to avoid diving and elective, non-emergent HBOT therapy while pregnant. Pregnancy testing is recommended for any woman of child-bearing potential being considered for elective HBOT therapy. The absolute risk of any exposure cannot be determined from available data. Due to the ethical challenges of research during pregnancy, it is unlikely that studies will be conducted that establish the absolute risk in the foreseeable future (2). If emergency HBOT is indicated during pregnancy, e.g., to treat carbon monoxide poisoning, evidence suggests that fetal benefit outweighs risk.

REFERENCES