**CDR 15: Outcome measure: Healing or Closure of Wagner Grade 3, 4 or 5 Diabetic Foot Ulcers (DFUs) Treated 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 diabetic foot ulcers of patients aged 18 years or older with a diagnosis of a Wagner Grade 3, 4, or 5 diabetic foot ulcer (DFU) whose ulcer has achieved healing or closure 6 months after completion of a course of HBOT, stratified by the Wound Healing Index. Healing or closure is defined as an ulcer with epithelial coverage and no continued drainage requiring a dressing.

**NUMERATOR:**
Those diabetic foot ulcers receiving at least 10 HBOT treatments achieving healing or closure within 6 months, stratified by the Wound Healing Index.

**Definition:** Healing or closure is defined as an ulcer with epithelial coverage and no continued drainage requiring a dressing.

**DENOMINATOR:**
Diabetic foot ulcers, graded Wagner Grade 3 or greater, of patients 18 years or older treated with at least 10 HBOT treatments during the reporting period.

**DENOMINATOR EXCLUSIONS / EXCEPTIONS**
**EXCLUSIONS:** Death within 6 months of completing a course of HBOT, Palliative care patients, DFU patients receiving amputation, DFU patients with < 10 HBOT treatments in 30 days
**EXCEPTIONS:** NONE

The CDC estimates that 25.8 million people, or roughly 8.3% of the US population, are affected by diabetes. More than 60% of non-traumatic amputations occur in people with diabetes, and a foot ulcer precedes 85% of lower-limb amputations in patients with diabetes. Contralateral leg amputation follows for 56% of patients within 3-5 years, and the 5-year mortality rate for diabetic patients who have had a single-leg amputation is 60%. This figure is higher than the overall 5-year mortality rate of breast cancer (10%), bladder cancer (19%), colorectal cancer (33%), and all cancers combined (32%).

Examination of the evidence provides eight (8) randomized controlled trials (RCTs), over a dozen observational (OBS) studies, and several meta-analyses. These studies show that HBOT increases wound healing, decreases amputation rates, increases healthcare related quality of life, and improves outcomes of DFU. DFU pose a major public health problem due to their incidences, morbidity, and costs to manage. The systematic review and analysis of the HBOT literature regarding the treatment of DFU using the GRADE methodology showed that HBOT is helpful in preventing amputations and promoting complete healing in patients with Wagner ≥3 DFU who have undergone surgical debridement of the foot as well as in patients with Wagner ≥3 DFU that have not healed after 30 days of conservative treatment.
In patients with Wagner ≤2 DFU, there is no adequate evidence to justify the use of HBO2 as an adjunctive treatment.

The USWR has previously published outcome data on 5,240 patients with 7,099 wounds from 59 hospital based out-patient wound centers (Fife, Carter 2012). The mean age was 61.7 years and 52.6% were Medicare beneficiaries. Over 46% had diabetes. Outcomes were as follows: over 1.6% of patients died in service or within 4 weeks of the last visit, 65.8% healed eventually (mean time to heal 6 months with 10% taking 8 months or more); approximately 3% underwent amputation. Importantly, nearly one third never healed even though they were followed for more than one year. The average patient had at least 2 major co-morbid conditions with 8% being on dialysis and 8% taking steroids or transplant medications. Overall, approximately 10% of these patients underwent hyperbaric oxygen therapy. Some wound care organizations have reported “healing rates” as a measure of the success of their program or product, but these data have been vetted (usually post hoc) by excluding patients retrospectively classified as “palliative care” or those with “anticipated amputations” so that the apparent success of wound care or hyperbaric oxygen therapy is not impacted by patients unlikely to do well. Thus, data regarding “real world outcomes” among outpatients with diabetic foot ulcers, particularly the specific effect of hyperbaric oxygen therapy, has been difficult to obtain.

A recent study by Margolis raised questions as to the effectiveness of HBOT in the treatment of diabetic foot ulcers. However, a major criticism of this study was the challenge of stratifying such complicated patients by disease severity. Many studies over the past 20 years have identified factors known to negatively impact wound healing. Even though these individual factors are known to be important, they have only recently been successfully incorporated into a validated model which can predict the likelihood of wound healing. The Wound Healing Index (WHI) was achieved through a collaboration of scientists at the Institute for Clinical Outcomes (Salt Lake City, UT) and Intellicure, Inc. (The Woodlands, TX) using data from the U.S. Wound Registry (USWR). The WHI is a comprehensive stratification system for patients with wounds that predicts healing likelihood. Complete medical record data on 50,967 ulcers from the United States Wound Registry were assigned a clear outcome (healed, amputated, etc.). Factors known to be associated with healing were evaluated. Logistic regression models were created based on variables that were significant (p<0.05) and subsequently tested on a hold-out sample of data. The predictive factors in the Diabetic Foot Ulcer Wound Healing Index can be obtained by answering the following questions:

**Diabetes WHI Components:**

1. Patient age in years (calculated from date of birth) at first treatment
2. Wound age (duration) in days (calculated from wound onset) at first encounter
3. Wound area in cm2 (calculated from length x width) at first encounter
4. What is the patient’s primary ambulatory method (walks unaided, cane, crutches, walker, roll about, scooter, wheelchair bound, bed bound)?
5. Was the patient admitted to the hospital or the emergency department on the date of service?
6. How many total wounds or ulcers of any type does the patient have?
7. Does this wound have evidence of infection or bioburden (evidenced by: purulent, green, malodorous drainage, peri-wound induration, tenderness to palpation, warmth)?
8. Is the patient on dialysis or status post renal transplant?
9. What is the Wagner Grade of the ulcer (1-5)?
10. Does the patient have peripheral vascular disease (claudication, rest pain, abnormal arterial vascular studies, loss of pulses)?

For the DFU HBOT data reported by clinician each quarter, diabetic foot ulcer outcomes will be stratified using the WHI incorporating both patient and wound factors to classify severity. This will be the first time that real world DFU outcomes have been reported on hyperbaric oxygen treated patients using a validated risk stratification method.

CLINICAL RECOMMENDATION STATEMENTS:
The UHMS Guidelines Committee recommends patients with Wagner ≥3 diabetic foot ulcers that have not healed for 30 days have Hyperbaric Oxygen Therapy added to the Standard of Care to reduce the risk of major amputation and incomplete healing. Urgent HBOT should be added to the standard of care for patients with Wagner ≥3 diabetic foot ulcers who have had surgical debridement of an infected foot (e.g., partial toe or foot amputation, I&D of deep space abscess, necrotizing soft tissue infection) to reduce the risk of major amputation and incomplete healing. In patients with Wagner ≤2 diabetic foot ulcers, The UHMS Guidelines Committee recommends against using Hyperbaric Oxygen Therapy.

REFERENCES