

**USWR16: Outcome measure: Major Amputation in 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 of 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 an outcome of major amputation 6 months after completion of a course of HBOT, stratified by the Wound Healing Index.

**NATIONAL QUALITY STRATEGY DOMAIN:** Effective Clinical Care

**MEASURE TYPE:** Outcome, High Priority

**MEANINGFUL MEASURE AREA:** Appropriate Use of Healthcare

**INVERSE MEASURE:** Yes

**PROPORTIONAL MEASURE:** Yes

**RISK ADJUSTED:** No

**NUMERATOR:**

Those diabetic foot ulcers receiving at least 10 HBOT treatments undergoing an **above the ankle** amputation 6 months after completed a course of HBOT, stratified by the Wound Healing Index.

**Definition:** Major amputation is defined as a below the knee or above the knee amputation, or any amputation occurring above the medial and lateral malleolus.

**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 with < 10 HBOT treatments in 30 days

**EXCEPTIONS:** NONE

**RATIONALE:**

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 (RCT), 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  $\geq 3$  DFU who have undergone surgical debridement of the foot as well as in patients with Wagner  $\geq 3$  DFU that have not healed after 30 days of conservative treatment. In patients with Wagner  $\leq 2$  DFU, there is no adequate evidence to justify the use of HBOT as an adjunctive treatment.

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). It 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 cm<sup>2</sup> (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. The goal is to understand the outcome of major amputation among DFUs treated with HBOT, given the wound's

predicted likelihood of healing. This knowledge will foster a better understanding on whether there is an effect of HBOT treatment number on amputation among patients with similar risk stratification, and whether there are risk categories of patients for whom HBOT is either not likely to be beneficial or should be prioritized.

**CLINICAL RECOMMENDATION STATEMENTS:**

The UHMS Guidelines Committee recommends patients with Wagner  $\geq 3$  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  $\geq 3$  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.

**REFERENCES:**

1. Estimating the applicability of wound-care randomized controlled trials to general wound care populations by estimating the percentage of individuals excluded from a typical wound care population in such trials. Carter MJ, Fife CE, Walker D, Thomson B. *Adv Skin Wound Care*. 22:316-24, 2009.
2. Wound Care Outcomes and Associated Cost Among Patients Treated in U.S. Outpatient Wound Centers: Data from the U.S. Wound Registry, Fife, CE, Carter MJ, Walker D, Thomson B. *Wounds* 2012; 24(1) 10-17.
3. Development of a Wound Healing Index for Patients with Chronic Wounds; S Horn, C Fife, R Smout, R Barrett, B Thomson, *Wound Rep Regen* (2013) 21 823-832