

**CDR2: Outcome measure: Diabetic Foot Ulcer (DFU) Healing or Closure**

**MEASURE STEWARD:**

Alliance of Wound Care Stakeholders, the US Wound Registry, and Plastic Surgery

**DESCRIPTION:**

Percentage of diabetic foot ulcers among patients age 18 or older that have achieved healing or closure within 6 months, stratified by the Wound Healing Index. Healing or closure is defined as complete epithelialization without drainage or the need for a dressing over the closed ulceration, although venous compression would still be required.

**NATIONAL QUALITY STRATEGY DOMAIN:** Person and Caregiver Centered Experience and Outcomes

**MEASURE TYPE:** Outcome, High Priority

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

**HIGH PRIORITY:** Yes

**INVERSE MEASURE:** No

**TRADITIONAL MEASURE:** Yes

**PROPORTIONAL MEASURE:** Yes

**RISK ADJUSTED:** Yes

There are four rates reported for this measure.

Three of the rates will be risk stratified into three buckets (minimum-maximum) which are the following:

1. 0.00 – 62.42
2. 62.42 – 73.19
3. 73.19 – 93.45
4. The average of the three risk stratified buckets which will be the performance rate in the XML submitted.

**NUMERATOR:**

Diabetic Foot Ulcers within the denominator that achieved healing or closure within 6 months of its initial encounter.

The ICD-10 and CPT codes for the Numerator will consist of all patients meeting the criteria described in the denominator.

**DENOMINATOR:**

All Diabetic Foot Ulcers of patients aged 18 years and older.

**DENOMINATOR EXCLUSIONS / EXCEPTIONS**

**EXCLUSIONS:** Death, Palliative care patients, DFU patients receiving amputation, DFU patients seen for consultations only, DFU patients with <2 visits in 30 days.

**EXCEPTIONS:** *NONE*

## **RATIONALE:**

Diabetes affects 26 million people in the US and up to 25% of those with diabetes will develop a foot ulcer (Singh, Armstrong, Lipsky. J Amer Med Assoc 2005). The yearly incidence of diabetic foot ulcers (DFUs) ranges from 2% to 32%, depending on ADA risk classification (Boulton, Armstrong, et al, Diabetes Care 2008, Lavery , et al, Diabetes Care 2008, Sibbald, et al, Adv Skin Wound Care, 2012). The DFUs contribute to approximately 80% of the 120,000 nontraumatic amputations performed yearly in the United States (Armstrong et al. Amer Fam Phys 1998).

DFUs also take a long time to heal with the median time to healing for diabetic foot wounds: being 147 days, 188 days, and 237 days for toe, midfoot and heel ulcers (Pickwell, et al, Diabetes Metab Res Rev, 2013). Patients with chronic wounds including DFUs suffer from a multitude of co-morbid conditions that would have excluded them from nearly every RCT pertaining to wound care products and devices performed in the past 10 years (Carter, Fife 2009). RCTs in wound care have also consistently failed to provide data on the most vulnerable populations such as those with dementia, the disabled, racial minorities, and the very elderly. Nevertheless, most of what we know about wound “outcomes” in relation to advanced therapeutic interventions has been derived from these studies.

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 programs is not impacted by patients unlikely to do well. Thus, data regarding “real world outcomes” among outpatients with chronic wounds has been difficult to obtain. 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 of the patients was 61.7 years and 52.6% were Medicare beneficiaries with nearly 5% being dual eligible (Medicare Medicaid). 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.

We think that the USWR data published to date represents the most accurate look at real world data on chronic wounds and ulcers, particularly DFUs in relation to co-morbid disease. The growing burden of diabetes in the USA makes this segment of chronic ulcers, estimated to contribute 80% of overall wound related costs, of primary interest to the QCDR for wound care.

The above data have the following implications:

- 1) Outcomes from wound care related RCTs fail to provide an accurate picture of real world outcomes for diabetic foot ulcers or other wound types because RCTs a priori exclude patients with serious co-morbid conditions
- 2) Outcomes reported by many wound care organizations do not reflect real world realities because they post hoc vet data (reported healing rates > 80% unstratified by risk are unlikely to be realistic).
- 3) Data from the USWR emphasize the importance of proper risk stratification in reporting outcomes.

### **Risk Stratification with the Wound Healing Index:**

Many studies over the past 20 years have identified factors known to negatively impact healing. Even though these individual factors are known to be important, they have only recently been successfully been 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).

We developed 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. Seven models were developed because a different model predicted healing for each wound type (e.g., diabetic foot ulcers, pressure ulcers, venous ulcers). Factors in each model differ, depending on the type of wound, but may include:

- Initial wound surface area
- Severity of wound (e.g., Wagner grade or NPUAP stage, or tissue type exposed)
- Age of wound
- Patient age
- Renal failure or organ transplant
- A patient whose course of care includes hospitalization or ED visit
- The presence of wound infection/bioburden
- The number of concurrent wounds
- Ambulation method
- Malnutrition
- Peripheral vascular disease

For example, **the Diabetes WHI** contains the following 10 factors:

<b>Number</b>	<b>Question</b>
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)?
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**For the DFU data reported by clinician each quarter, we will stratify diabetic foot ulcer outcome using the WHI which contains both patient and wound factors to stratify severity.** This will be the first time that real world DFU outcomes have been reported using a validated risk stratification method.

**EVIDENCE:**

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.