

CDR2 Diabetic Foot Ulcer (DFU) Healing or Closure

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.

2018 OPTIONS FOR INDIVIDUAL MEASURES:

US Wound Registry, SCG Health

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

MEASURE TYPE: Outcome

INSTRUCTIONS:

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.

DENOMINATOR:

All visits of diabetic foot ulcers among patients aged 18 years and older

Denominator Criteria (Eligible Cases):

All patients aged 18 years and older with diabetic foot ulcers

Denominator Exclusions:

Palliative care patients, DFU patients seen less than 5 times over reporting period

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.

WHAT DATA SOURCES ARE USED FOR THE MEASURE? EHR, Registry

STEWARD: US Wound Registry

OF PERFORMANCE RATES TO BE SUBMITTED IN THE XML: 4

Indicate an Overall Performance Rate if more than 1 performance rate is to be submitted:

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.

INVERSE MEASURE: No

PROPORTION MEASURE SCORING OR **CONTINUOUS MEASURE SCORING**

RISK ADJUSTED: Yes

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.

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