CDR6: Venous Leg Ulcer outcome measure: Healing or Closure

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

This measure was developed via a consensus process in collaboration with the Alliance of Wound Care Stakeholders Member Organizations, which include 16 wound care related clinical associations.

DESCRIPTION:
Percentage of venous leg ulcers among patients age 18 or older that have achieved healing or closure within 12 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
CARE SETTING: Outpatient Services
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. 0.00-73.24
2. 73.24 – 80.26
3. 80.26 – 87.21
4. The average of the three risk stratified buckets which will be the performance rate in the JSON XML submitted.

NUMERATOR:
Venous Leg Ulcers within the denominator that achieved healing or closure within 12 months of its initial encounter.

DENOMINATOR:
All venous leg ulcers of patients 18 or older with an encounter during the measurement period.

DENOMINATOR EXCLUSIONS/EXCEPTIONS
EXCLUSIONS: Death, Palliative care patients, VLU patients who have an amputation, VLU patients seen for consultations only, VLU patients who are lost to follow-up, VLU patients with <2 visits
EXCEPTIONS: NONE

RATIONALE:
A rough population prevalence rate for chronic non-healing wounds in the USA is 2% of the general population. Ulcers caused by chronic venous insufficiency constitute 70%–90% of all lower extremity ulcers. A conservative estimate of the staggering cost of caring for chronic wounds in the USA exceeds $50 billion dollars per year. This is 10 times more than the annual budget of the World Health Organization. Despite the fact that the prevalence rate of chronic wounds is similar to that of heart failure, unlike heart failure, little is known regarding the outcome of these patients. Patients with chronic wounds suffer from a multitude of co-morbid conditions that would have excluded them from nearly every RCT 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" has been derived from these studies (e.g., healing rates, time to heal).

Some wound care-related 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 the program 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). Other USWR studies focused exclusively on venous ulcer patients have showed that approximately 30% of patients with venous stasis ulcers had diabetes as a co-morbid condition and 70% were obese or morbidly obese. When the USWR evaluated the activities of daily living in 500 patients with venous ulcers, we found that 60% of them were not able to dress their lower bodies unaided (Limitations of Daily Living Activities in Patients With Venous Stasis Ulcers Undergoing Compression Bandaging: Fife, et al, Wounds, Volume 26 (1) Jan 2014 http://www.woundsresearch.com/article/7891). This further emphasizes the importance of the interventions provided by wound care clinicians such as compression bandages.

When the outcomes of patients with chronic leg ulcers were evaluated from 59 hospital outpatient wound centers, **nearly one third never healed, even though they were followed for more than one year**. The average leg ulcer patient had at least 2 major co-morbid conditions with 10% having peripheral arterial disease and 8% taking steroids or transplant medications.
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 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). For example, **the Venous ulcer WHI** contains the following 7 factors:

Number	Question
1	Wound age (duration) in days (calculated from wound onset) at first encounter
2	Wound area in cm^2 (calculated from length x width) at first encounter
3	Does the patient have peripheral vascular disease (for example, symptoms like claudication, rest pain, gangrenous changes or other findings suggestive of leg ischemia, or studies confirming vascular disease)?
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)

We will stratify the venous ulcer outcome measure using the WHI which contains both patient and wound factors to stratify risk.

This is the first risk stratification system available for patients with venous ulcers and offers a new method of reporting venous ulcer outcome. For the first time, it allows VLU outcome to be truthfully reported for venous ulcers as well as other types of wounds. Truthful reporting of healing rates among wound care patients has never occurred in the field of wound healing.

No doubt most wound care clinicians would *prefer* to continue to report fabricated healing rates of 98%. However, we have made the case to our colleagues that the way to identify the most skilled physician is to find practitioners with the best healing rate in the category of wounds with the lowest predicted likelihood of healing. Certainly this is the way for *patients and payers* to identify the most skilled EPs.

Risk Stratification Data for USWR #6 2014 -2016
Table 1 shows the result of EPs reporting USWR #6 for the past 3 years. The WHI was developed by the USWR and we continue to evaluate the best way to use it, including determining where the "break points" should be in the stratification system. If there are too many groups then the number of wounds in each category will be too small to be meaningful.

Table 1: EPs reporting VLU Outcome by WHI

VLU WHI Stratification*	No. of Providers 2016	Performance Rate % 2016
1	206	19%
2	342	35%
3	412	54%

Table 2. Results of EPs Reporting USWR #6: Risk Stratified Venous Ulcer Closure

Stratification	Number of Physicians	Performance Rate	Number of Physicians	Performance Rate	Number of Physicians	Performance Rate
	2014		2015		2016	
1	161	14%	196	12%	206	19%
2	259	27%	318	26%	342	35%
3	315	52%	387	48%	412	54%

Based on Table #2, the following are apparent regarding USWR #6:
- Each year in increasing number of EPs have reported this measure
- The is an increasing likelihood of VLU healing with each stratification "bucket"
- A minority of EPs see the most challenging VLU patients. EPs who have better than predicted outcomes among these patients may be the most skilled.
- If the "most likely to heal" stratification bucket (3) still has only a slightly higher than 50% likelihood of healing, this group may need to be divided further with some patients allocated to group 2, so that it brings up the healing likelihood in group #2 slightly, but

the sicker patients in group 2 are removed, raising the healing likelihood in group #3 to at least 75%.

The WHI Can Enable CMS to Identify Patients Most In Need of Advanced Therapeutics
Without the WHI for venous ulcers, it is not possible to identify which venous ulcers actually need advanced therapeutics such as cellular products or radiofrequency ablation. **However, the WHI allows us to separate the patients with a lower likelihood of healing and determine whether an intervention was necessary or changed their predicted healing likelihood.** The USWR risk stratified venous ulcer healing measure is being reported by an increasing number of EPs each year and shows promise at being able to establish the need for certain advanced therapeutics and provide justification for high resource use patients.

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.

4. Limitations of Daily Living Activities in Patients With Venous Stasis Ulcers Undergoing Compression Bandaging: Fife, et al, Wounds, Volume 26 (1) Jan 2014 http://www.woundsresearch.com/article/7891

5. Bolton L, Corbett L, Bernato L, et al. Development of a content-validated venous ulcer guideline. Ostomy Wound Manage. 2006;52(11):32–48.