CDR 1: Outcome Measure: Adequate Off-loading of Diabetic Foot Ulcers at each visit, appropriate to location of ulcer

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.

MEASURE STEWARD:
US Wound Registry
[Note: This measure has been under testing as part of the "Do The Right Thing™" initiative in 6 New York state hospitals based outpatient wound centers]

DESCRIPTION:
Percentage of visits in which diabetic foot ulcers among patients aged 18 years and received adequate off-loading during a 12-month reporting period, stratified by location of the ulcer.

The location of the diabetic foot ulcer on the foot (e.g. heel/midfoot vs. toes) determines the type of off-loading device that is appropriate, the patient's risk of falling, the probability of successful off-loading and thus the likelihood of major amputation. The clinician needs to assess the most appropriate off-loading option based on many different factors.

There are three rates reported for this measure.
The three rates will be risk stratified into two buckets (location of wound and/or ulcer) which are the following:

1. Midfoot/heel
2. Toes
3. The average of the two risk stratified buckets which will be the performance rate in the XML submitted.

NUMERATOR:
Visits in which diabetic foot ulcers are documented to have adequate off-loading during the 12-month reporting period

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

DENOMINATOR EXCLUSIONS/EXCEPTIONS
EXCLUSIONS: None

EXCEPTIONS: Adequate off-loading not prescribed for Medical, Patient or System Reasons

RATIONALE:
Offloading the pressure from a diabetic foot ulcer allows the wound to heal by secondary intention when the wound is appropriately dressed because pressure is a causal factor for neuropathic foot ulcers. The gold standard is total contact casting (TCC) in which the entire foot is enclosed in a solid structure that is retained until the wound is healed. However, for many valid medical and patient centered

reasons, TCC may not be feasible or appropriate. Additionally, if the wound is on the non-weight bearing surface of the foot, other methods of protection may be more superior to a TCC.

Principle: In a review of 9 randomized controlled trials of total contact casting (TCC), TCC healed 89% of DFUs on an average of 43 days. Thus, the process of off-loading has been directly linked to the outcome of DFU healing from multiple RCTs. Furthermore, patients treated with TCC experienced a higher percentage of healed ulcers in a shorter period of time than with other advanced therapeutics based on RCTs for other interventions, although direct comparisons with other advanced therapeutics have not been performed since no advanced therapeutic should be used in the absence of appropriate off-loading.

However, when the patient has moderate or severe ischemia this treatment is contraindicated. Additionally, for foot ulcers on the dorsal foot or toes, other protective devices may be superior. An alternative to total contact casting is a removable device such as a CROW walker which still maintains ankle immobility. For patients who are able to use them properly, crutches may be effective. For patients who do not ambulate, the use of a wheelchair may provide effective offloading.

Evidence Based Off-Loading Devices

A recent consensus statement with a systematic review of the literature ranked the overall strength of evidence for diabetic foot ulcer off-loading as moderate. However, off-loading is widely considered the single most important intervention necessary to accomplish wound healing in the management of the diabetic foot ulcers (1-13). Offloading methods with published studies to support their effectiveness include the options listed below, depending on the location of the ulcer.

Generally, a cast shoe will only be acceptable off-loading for ulcers on the dorsal toes.
Reverse IPOS, L'NARD splints, and patella tendon-bearing braces will useful only for posterior heel ulcers.

The following options may work for ulcers on any area of the foot with certain restrictions known to foot expers:

- Total contact cast (any brand)
- CROW (Charcot Restraint Orthotic Walker)
- DH walker
- CAM boot
- Air cast
- Half wedge shoe
- Diabetic shoe
- Shoe modification (custom made temporary footwear)
- Felt and foam
- Prefabricated walker
- Healing sandal
- MBAL shoe

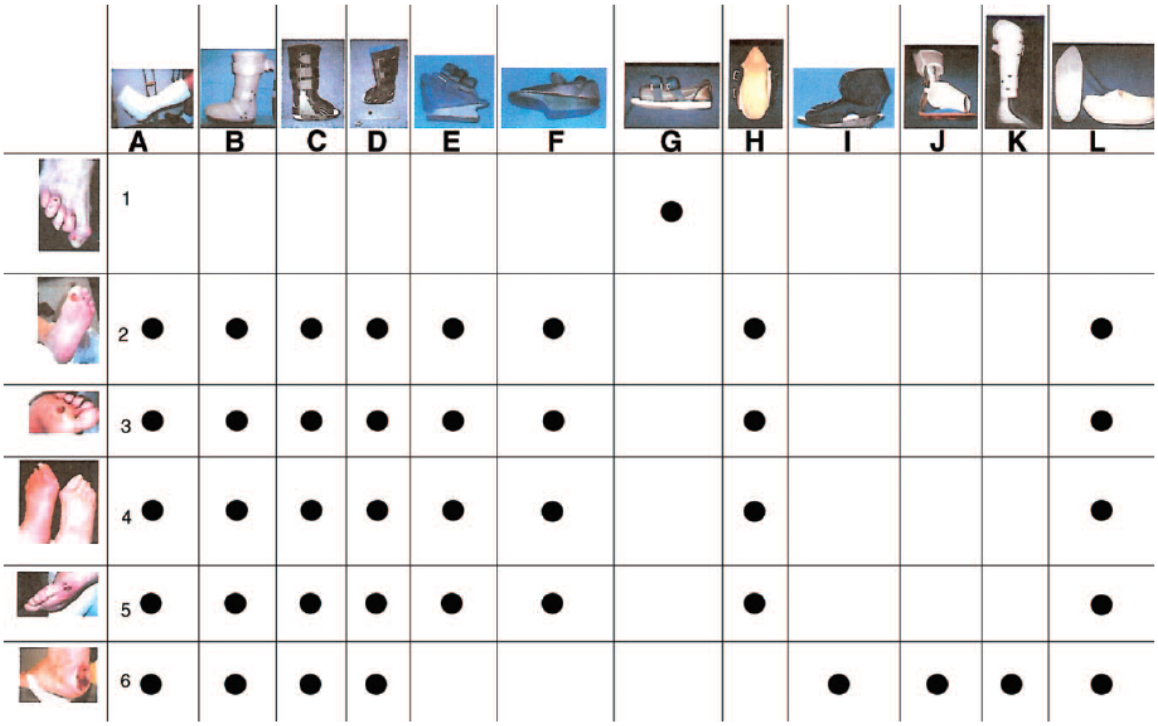

Figure 1. Off-loading algorithm for diabetic foot ulcer showing off-loading methods and ulcer locations. A, Total contact cast; B, Charcot Restraint Orthotic Walker boot; C, prefabricated walker; D, DH walker; E, IPOS shoe; F, OrthoWedge; G, postoperative shoe; H, healing sandal; I, reverse IPOS; J, L'nard splint; K, patella tendon–bearing brace; L, MABAL shoe. 1, Dorsal digit; 2, plantar digit; 3, plantar metatarsal; 4, medial metatarsal; 5, lateral metatarsal; 6, heel. (Reprinted with permission from *Ostomy Wound Management*.[40])

The Gap in Practice for DFU Off-loading

The US Wound Registry (originally called the "Intellicure Research Consortium") began running a registry of patients with wounds in 2005. As far back as 2007 we began studying the gap in practice for DFU off-loading. A diabetic foot ulcer (DFU) off-loading measure was originally developed by the American Society of Plastic Surgery as part of the AMA PQRI Work Group, a process which took place in 2007. It was one of 7 measures the group developed. The off-loading measure required documentation of diabetic foot ulcer off- loading one time per year.

In our first study, the USWR analyzed 108,000 visits made to 18 outpatient wound centers in 16 states. Out of 264 patients with DFUs, only 17 patients (6%) received the gold standard of off-loading with Total Contact Casting (TCC). Furthermore, we were able to document that when TCC was *not* used, the cost of caring for a DFU doubled (from $11,946 per patient to $22,494).(14) In other words, the gap in practice for DFU off-loading was huge, and the type of off-loading significantly affected the cost of DFU treatment. Most worrisome was our finding that DFUs were being treated with expensive cellular and tissue based products in the absence of adequate off-loading.

We next analyzed an even larger USWR dataset from 96 outpatient wound centers in 23 states. Data from 11,784 patients with 25,114 DFUs demonstrated that off-loading was documented in only 2.2% of patient visits specifically for the purpose of TREATING those DFUs.(15) The most common off-loading

option was the postoperative shoe, a treatment with no published evidence of effectiveness. There were significantly more amputations within 1 year for non-TCC-treated DFUs compared with TCC-treated DFUs (P = .001). Also, infection rates were significantly higher for non-TCC-treated DFUs compared with TCC-treated DFUs (2.6 vs 1.6; P = 2.1 × 10).

When the USWR submitted PQRS data for providers, we looked at off-loading and venous compression data from eligible providers (EPs) reporting through us and evaluated their performance based on whether the metric for either one was "once per 12 months" vs. "per visit." We found that had the metric of DFU off-loading been whether off-loading was provided ONE time in a year, more than 80% of patients would have been assessed as having been provided off-loading. However, if the metric was whether it is done at each visit, only 2.2% of patients would have been assessed as having adequate off-loading. In other words, it seemed clear that a DFU off-loading measure had a reporting period of ONCE per year, more than 80% of providers would pass it and the measure would "top out," despite the fact that providers would NOT be providing appropriate care.

The USWR Pilot Tested a PER VISIT DFU Off-loading Measure in 2011

In 2012, the USWR piloted a per visit DFU off-loading measure in 6 hospital based outpatient wound centers as part of the USWR "Do the Right Thing™" initiative. The impact on patient care was dramatic. In an article published in 2013, within these 6 clinics, DFU off-loading at each visit increased from 11.7% to 69.2%.(16,17) None of these projects had funding from any source, including the pilot testing of the "per visit" measure. The small size of off-loading studies continues to prevent them from being eligible for NQF endorsement, but since wound care lacks the funding of pharmaceutical trials, larger studies will not be forthcoming.

An Expert Panel recommended a per-visit Off-loading Measure

In 2014, an expert panel met to develop a comprehensive, evidence-based consensus on the optimal use of off-loading in DFU treatment.(18) The panel was deeply concerned that the 5-year mortality rate of diabetics after an amputation is 45%, and 85% of lower extremity amputations are preceded by a diabetic foot ulcer. Because DFUs are a major and costly complication of diabetes that can reduce quality of life and result in amputations and death, and because published data clearly demonstrated the gap between evidence and practice with regard to the use of off-loading in the treatment of DFUs, a consensus on the use of off-loading was needed. The panel developed the following evidence based recommendations which were published in the Journal of the American Podiatric Medical Association:

- Adequate off-loading increases the likelihood of DFU healing.
- There currently exists a "gap" between the evidence supporting the efficacy of DFU off-loading and what is performed in clinical practice.
- Evidence consistently shows that **when off-loading is integrated into the patient encounter process and provided *at each visit***, the likelihood of DFU healing increases and the chance of complications decreases.
- The panel supported the development of a per-visit offloading quality measure to address the gap between evidence of offloading and its current use in clinical practice.

Although TCC is the gold standard for off-loading, some DFUs are on the non-weight bearing part of the foot and a TCC is not needed. Additionally, there are many patients for whom a TCC is ill advised due to mobility issues, or who are not ambulatory due to a prior amputation. We felt that a better approach

would be to select a method of off-loading that is evidence based and appropriate to the location of the ulcer and the needs of the patient. The USWR decided to use the recommendations of the Expert Consensus Panel on Off-loading which provided a table of evidence based off-loading options based on wound location.

The Success of the USWR Per Visit DFU Off-loading Measure

Since CMS recognized the USWR per visit DFU off-loading measure in 2014 through the USWR QCDR, a small but growing number of EPs have been reporting it. Among eligible providers reporting this measure, per visit off-loading of DFUs is now achieved 59 % of the time, a significant improvement from our published data of 11.7% prior to the availability of this measure. It is the plan of the USWR, when sufficient data have accrued, to analyze whether this more demanding measure has been associated with a significant decrease in the rate of diabetic limb amputations, or a significant improvement in DFU risk stratified outcome.

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