



## Measuring and reporting outcomes in wound care: The standardization conundrum – creating a new framework to define quality wound healing

As the nation's largest provider of advanced wound care services, Healogics® is committed to data transparency and the standardization and measurement of wound healing outcomes. The Healogics Wound Science Initiative is a collaborative effort that aims to accelerate data-driven improvements, advance insights and perspectives, and identify mechanisms to continuously improve patient outcomes and reduce costs in the treatment of chronic wounds. With a network of 700 hospital-affiliated outpatient Wound Care Centers® that treated more than 300,000 new patients and healed more than two million wounds in 2016, Healogics has the largest repository of patient wound data insights in the industry. The Wound Science Initiative is committed to using the Healogics data to guide the creation of wound outcomes measures that allow for industry-wide standardization and aggregate quality benchmarking.

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## The challenge

- Chronic non-healing wounds are a considerable economic burden to the healthcare system and adversely impact the quality of life for those impacted.
- Patients with chronic wounds are medically and socially complex patients who require specialized care and management for optimal treatment outcomes.
- Along with an aging population and the continued rise in chronic conditions, such as obesity and diabetes, the prevalence of chronic wounds will continue to grow. Yet, the challenges associated with chronic wounds remain underappreciated by the public health and policy communities.
- A recent analysis reported that chronic, non-healing wounds impact nearly 15 percent of Medicare beneficiaries (8.2 million) and total **Medicare spending estimates for all wound types ranges from \$28.1 to \$96.8 billion.**<sup>1</sup>
- Although there are evidence-based guidelines for wound care delivery, there is currently no industry standard for measuring aggregate wound healing outcomes.
- There is a pressing need for the wound care industry to agree on the adoption of a standard method for measuring and reporting healing outcomes.
- Until standardization occurs, quality comparison remains out of reach and the true value of advanced wound care may not be recognized by payers, purchasers and the broader public health community.

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## Quality measurement: if you can't measure it, you can't improve it

Medicare spending on chronic ulcer patients runs into the billions of dollars. A rough prevalence rate for chronic, non-healing wounds in developed countries is one to two percent of the general population; similar to the prevalence rate for **heart failure**<sup>2</sup>. Ulcer rates will continue to rise as our population ages and rates of obesity and diabetes also continue to increase. As wound care gains recognition as a sub-specialty, and with continued movement toward value-based care, industry consensus around standard measures of wound healing is critical. The purpose of this paper is to report on a framework for aggregate wound measurement standardization recently published in **Wound Repair and Regeneration**.<sup>3</sup>

A standard outcome reporting methodology is essential for advancing the delivery of high-quality, cost-effective wound care. To date, publicly reported **wound care outcomes have suffered from a high degree of variability and a lack of transparency in definitions.**<sup>4</sup> Comparisons across clinical research, observational studies utilizing population databases and industry outcomes is not possible due to heterogeneity in reporting methodology and inclusion/exclusion criteria. As a result, it is challenging to identify macro-trends in expected wound outcomes. As in oncology, where coordinated efforts between providers has resulted in an aggregate standardized outcomes framework, the wound care industry must take steps toward consensus-based transparent outcomes reporting.

Healogics has made substantial strides towards transparency in quality through the development and reporting of the comprehensive healing rate, a modified intent-to-treat outcome measure. In this paper, we describe the findings of a recently published study that provides external validation of the comprehensive healing rate through the publication of a coauthored study with leaders in the academic and scientific community.

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## Comprehensive healing rate: a modified intent-to-treat outcome

The comprehensive healing rate was developed using a modified intent-to-treat (mITT) methodology, a conceptual framework. It is an inclusive methodology with a foundation in clinical trials research. ITT outcomes include all patients, regardless of whether the patients complete care. ***Such measures avoid overly optimistic estimates of the effectiveness of a service or treatment by accepting that noncompliance and care deviations are likely to occur in actual clinical practice.***<sup>5</sup> The ITT model also allows for comparisons of published studies from various sources, preserves sample size and limits inferences based on random subgroup reporting. As a result, many, including the Food and Drug Administration (FDA), believe that using an ITT model is the optimal mode for reporting outcomes.

The comprehensive healing rate reports healing for all patients treated at the Wound Care Center. Whereas traditional healing rates often exclude patients who do not complete care, the comprehensive healing rate retains all treated wound care patients. Only patients without a wound present at the time of treatment and those who were seen as consultations, defined as fewer than seven days, first to last assessment, are excluded. Given those exclusions, we define the comprehensive healing rate as a mITT outcome.

The following report describes published data that compares the comprehensive healing rate to the traditional healing rate in two clinical samples; a large cohort of data from over 600 Healogics Wound Care Centers and an academic full-time clinical wound care team. The purpose of the study is twofold. First, to describe the framework and compare the comprehensive healing rate in two settings to demonstrate the benefits achieved through the implementation of an evidence-based, process driven wound care program. Second, to compare the comprehensive healing rate to the traditionally reported healing rate in order to demonstrate the variation between the two measures.

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## Data

**Cohort of Healogics Wound Care Centers.** Retrospective data, including wound characteristics, patient demographics and final disposition were collected from 626 outpatient wound care centers nationwide between January 1, 2014 and November 1, 2015. All wounds that met the qualifying inclusion criteria were included in the de-identified file; no other exclusions were applied. A final sample of 1,000,690 wounds were analyzed.

**Academic wound center.** Data from 2006 – 2009 were prospectively collected and retrospectively analyzed. The data was generated from a 200-bed, community hospital-based wound care program staffed by three full-time wound program faculty employed by the non-Healogics-affiliated University of Illinois hospital. A final sample of 2,578 wounds were analyzed.

## Findings

**Table 1. Modified intent-to-treat comprehensive healing rates: Healogics vs. Academic**

Table 1 displays the comprehensive healing rate for both study populations. The 2014 – 2015 data includes wounds from 626 outpatient Healogics Wound Care Centers. The 2006 – 2009 data includes a single outpatient Wound Care Center staffed by a full-time academic wound care team. Overall, the comprehensive healing rates are extremely comparable; 75 percent across the Healogics sample and 78 percent at the single academic center.

	Healogics Cohort	Academic Cohort
	2014–2015	2006–2009
<b>Total # healed wounds</b>	<b>498,113</b>	<b>1,388</b>
<b>Total # wounds</b>	<b>1,006,690</b>	<b>2,578</b>
% healed at population level	49.5	53.8
Exclude – # active at study conclusion	99,301	75
% of total	9.9	2.9
# remaining wounds	907,389	2,503
% healed at level	54.9	55.5
Exclude – # without wound documented	4,080	63
% of total	0.4	2.4
# remaining wounds	903,309	2,440
% healed at level	55.1	56.9
Exclude – # consult and with days first to last assessment <= 7 days	236,018	652
% of total	23.4	25.3
<b>Final – # remaining wounds</b>	<b>667,291</b>	<b>1,788</b>
<b>Comprehensive Healing Rate (%)</b>	<b>74.6</b>	<b>77.6</b>

**Table 2. Comparison of the comprehensive healing rate to the traditional healing rate**

Table 2 compares the comprehensive healing rate to the traditionally reported healing rate. The traditional healing rate excludes patients that did not complete the full wound care episode, as well as patients whose care was classified as palliative. Patient transfers to other facilities or providers accounted for the greatest percentage of exclusions.

	Healogics Cohort	Academic Cohort
	2014–2015	2006–2009
<b>Total # healed wounds</b>	<b>498,113</b>	<b>1,388</b>
<b>Total # wounds</b>	<b>1,006,690</b>	<b>2,578</b>
<b>Comprehensive Healing Rate (%)</b>	<b>74.6</b>	<b>77.6</b>
Exclude – # wounds patients that died	15,867	35
% of total	1.6	1.4
# remaining wounds	651,424	1,753
% healed at level	76.5	79.2
Exclude – # wounds patients that moved	5,520	4
% of total	0.6	0.2
# remaining wounds	645,904	1,749
% healed at level	77.1	79.4
Exclude # wounds patients that transferred providers	24,436	34
% of total	2.4	1.3
# remaining wounds	621,468	1,715
% healed at level	80.2	80.9
Exclude – # wounds patients that transferred facility	66,776	48
% of total	6.6	1.9
# remaining wounds	554,692	1,667
% healed at level	89.8	83.3
Exclude – # wounds patients lost to follow-up	11,771	82
% of total	1.2	3.2
# remaining wounds	542,921	1,585
% healed at level	91.7	87.8
Exclude – # wounds patients that underwent amputation	4,455	47
% of total	0.4	1.8
# remaining wounds	538,466	1,538
% healed at level	92.5	90.2
Exclude # wounds patients converted palliative	1,149	109
% of total	0.1	4.2
<b>Final – # remaining wounds</b>	<b>538,352</b>	<b>1,429</b>
<b>Traditional Healing Rate (%)</b>	<b>92.5</b>	<b>97.1</b>

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## Key takeaways and conclusions

- Using a modified intent-to-treat framework, we find that the average range of the comprehensive healing rate is between 75 – 78 percent. Implementation of an evidence-based, process-driven wound care program achieves outcomes that are consistent with those seen in a highly specialized academic wound care center.
- The comprehensive healing rate is a highly transparent, easily understood measure for reporting wound outcomes.
- Industry-wide adoption of the comprehensive healing rate is a first step towards transparency and comparability in wound healing outcomes.
- Advances in wound patient risk-stratification are the next step in the journey towards wound outcomes reporting.

Consistency and standardization in wound outcomes reporting is essential as the healthcare industry moves towards value-based models. With an aging population and the continued rise in diabetes and obesity, identifying cost-effective, high-quality wound care will be an increasing public health and policy issue. Publicly reported healing rates can be misleading if inclusion and exclusion criteria are not clearly articulated. The comprehensive healing rate is a modified intent-to-treat metric which allows for comparison across multiple settings; it is not subject to proprietary exclusions. The findings of this study indicate that in a well-managed, process-driven, evidence-based wound care center, high-quality outcomes are achievable. However, in order to fully adjust for clinical complexity and further improve comparability, additional work that defines a risk stratification framework for wounded patients is needed.

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