

Wound Care Outcomes and Associated Cost Among Patients Treated in US Outpatient Wound Centers: Data From the US Wound Registry

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Abstract: Data from registries can be especially useful in the evaluation of healthcare effectiveness. Thus, the goal of this study was to report on use of the US Wound Registry to investigate the outcomes of a broad population of patients undergoing treatment. Using a 5-year slice of de-identified data from electronic health records originating from 59 hospital-based outpatient wound centers in 18 states, outcomes, patient and wound variables, and costs for facility and physician fees and procedures were analyzed for 5240 patients with 7099 wounds. Mean patient age was 61.7 years with 52.3% being male and the majority Caucasian (73.1%) and Medicare beneficiaries (52.6%). The mean number of serious comorbid conditions per patient was 1.8, with the most common being diabetes (46.8%), obese or overweight (71.3%), and having cardiovascular or peripheral vascular disease (51.3%). More than 1.6% of patients died in service or within 4 weeks of the last visit. Almost two thirds of wounds healed (65.8%) with an average time to heal of 15 weeks and 10% of wounds taking 33 weeks or more to heal. The average wound surface area was 19.5 cm². Half of wounds that healed did so with only the use of moist wound care (50.8%) and without the need for advanced therapeutics. Mean cost to heal per wound was \$3927 with jeopardized flaps and grafts the most expensive (\$9358). This Registry would seem ideal for comparative effectiveness research in wound care, as it includes patients often excluded from randomized controlled trials and reflects actual practice.

A rough population prevalence rate for chronic nonhealing wounds in the United States is 2% of the general population.¹ A conservative estimate of the staggering cost of caring for these wounds exceeds \$50 billion per year.^{2–5} 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,⁶ unlike heart failure, little is known regarding the outcome of these patients or the comparative effectiveness of the treatments they receive. Randomized controlled trials (RCTs) in wound healing are infrequent compared to problems of similar prevalence,

and almost without exception are funded by the pharmaceutical or wound management industry on the conceptual framework of “is product A better than product B” under rigorously controlled conditions, including a limited portion of the affected population. Although patient care does improve as better products and devices become available, such trials are costly and time consuming, generally exclude patients with serious comorbidities, and are never directed at patients with the hardest to heal wounds (eg, sickle cell ulcers, vasculitis, scleroderma). Patients with chronic wounds suffer from a multitude of comorbid conditions that would have excluded them from nearly every RCT performed in the past 10 years.⁷ 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 (eg, healing rates, time to heal). Some wound care-related businesses 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 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 have been difficult to obtain.

The Institute of Medicine (IOM) has promoted the collection of outcome information as a byproduct of documenting care within electronic health records (EHRs), which could be mined for outcome and other patient-related information.⁸ The Federal Coordinating Council for Comparative Effectiveness Research (CER) Report established that “longitudinal linked electronic health record (EHR) databases or patient registries should be a major area of investment for [comparative effectiveness] research.” The strong external validity of registries is achieved by the fact that, unlike RCTs, they include “typical patients.” As discussed in the AHRQ document on “Registries for Documenting Patient Outcomes, a Users Guide,” registry data can provide a good description of the course of a disease and impact of interventions in actual practice.⁹ Data from registries can approximate the effects of interventions as well as RCTs, and may be particularly useful in the evaluation of health care effectiveness.^{10–12}

Driven by the need for such real world data from patients with chronic wounds, particularly those with multiple comorbid conditions, in 2005 the authors created a

registry of wound care patients from de-identified electronic health records. The registry provides a window on the real world effectiveness of current wound care interventions. Because of the unique ability of the EHR to automate charge calculation and track associated costs, the authors also have access to information regarding resource utilization. Thus, the goal of the present study was to report on use of the US Wound Registry to investigate the outcomes of a broad population of patients undergoing treatment among hospital-based outpatient wound centers across several states. This study is not a cost effectiveness study, although such a study is possible with the registry.

Methods

Software. A 5-year slice of data, March 2005 – July 2010, was selected in order to evaluate the effect of time on outpatient resource utilization. The Intellicure electronic health record (EHR) is certified by the ONC (Office of the National Coordinator) of Health Information Technology as a complete ambulatory care electronic health record in accordance with the certification criteria adopted by the Secretary of Health and Human Services (HHS). More than 200 elements of staff work contribute to the facility acuity scoring system which has been separately published and validated (http://www.intellicure.com/Index/Product_iFAST.aspx).¹³ In addition, a “wound care-specific” physician-billing module using the 1997 Center for Medicare and Medicaid Services (CMS) evaluation and Management (E/M) documentation guidelines was developed, which automatically audits the chart using a computer algorithm and then internally calculates the physician charges, including all procedural documentation for interventions, such as debridements or the application of bioengineered skin. The clinician does not “select” the level of service at the completion of the visit. Rather, the EHR informs the clinician of the level of service that is supported by the documentation contained within the chart at the completion of the visit. Thus, compliance between documentation and billed level of service for both the facility and the physician are ensured. Computers are present in every room allowing “point of service” documentation of all aspects of the patient’s care in a prospective fashion. All dressing products are selected from menu options based on facility formulary, and the software generates interval dressing orders to home nursing agencies.

Data are maintained on servers hosted by the vendor, accessed through a secure portal using remote desktop protocols. Clinics agree to participate in the US Wound

Registry from which facilities receive benchmarking reports for the purpose of quality assurance. There is a well-defined vetting process before clinics can contribute to the Registry. Data must meet specific standards for completeness. After 3 days of intensive onsite training prior to initial “go live,” clinics undergo remote chart audits with telemedicine for 6 weeks. For 6 months, charting undergoes a data integrity review process before the site can begin to contribute to the Registry. Periodic chart audits continue and if facilities fail to meet quality standards, contribution to the registry is halted until quality standards are met. Through the registry, de-identified, cumulative data can be evaluated from all centers. While registry information is collected primarily for quality improvement (QI) activities, it can be used for research. The boundary between these two types of activities can be indistinct because they often serve both functions simultaneously. Studies involving human subjects may be exempt from IRB review if the research involves the study of existing data.¹⁴ Furthermore, de-identified data are not protected health information (PHI) and are not subject to the privacy rule if all elements that could be used to identify the individual have been removed. Thus, with the permission of the participating centers, EHR data are HIPAA de-identified and submitted to the US Wound Registry. For this project, 59 hospital-based outpatient wound centers in 18 states using the Intellicure electronic health record (EHR) provided data. While CMS defines “wounds” and “ulcers” as different entities, since a generic term encompassing both does not exist, unless otherwise specified, the authors will use the term “wounds” in this manuscript to indicate all types of chronic wounds and ulcers.

We had access only to outpatient data, so cost information from interval hospitalizations were not available. Furthermore, we did not attempt to include the cost of diagnostic testing (eg, angiograms, bone scans). Elements of cost included the billed advanced practitioner fee for the day’s visit; the billed facility fee for the day’s visit; billed procedure costs that day (eg, bio-engineered skin application, debridement, compression bandaging); the estimated cost of all interval dressings (based on the frequency of dressings ordered until the next visit) if the patients were performing their own dressing changes; the estimated charges for negative pressure wound therapy (based on an average daily rate, multiplied by the days for which NPWT was documented in the chart); and the billed number of hyperbaric oxygen therapy treatments. When patients received home nursing care, we estimated the cost of this on a daily rate or that specified by the CMS

Home Health Prospective Payment System, and assumed this cost included the cost of the applied dressings. This method underestimates the total cost of NPWT and home nursing due to the “billing cycles” used for these services, as addressed more fully in the Discussion. Thus, while most of the costs were actual charges, some were estimated from orders contained within corresponding charts.

Dataset preparation. Within the 5-year data slice, the initial registry database consisted of 11,664 patients. Since the goal was to assess both outcomes and resource utilization, 759 patients who underwent a consultation only and 1352 patients who were lost to follow-up were excluded. In addition, 484 patients who had no wound (eg, those seen for edema or lymphedema) were deleted, leaving 9069 patients. The data format was then converted from Microsoft SQL Server to PASW 19 (SPSS, Inc., Chicago, IL). Two cases were then found with patient age but no other data, such as wound measurements or assigned outcome. Data for 15 other patients were deleted because of miscoded data pertaining, for example, to body mass index (BMI).

At the wound level of data, some missing data were imputed as follows: 1619 wounds not associated with NPWT, and 451 wounds which were associated with NPWT had no initial tissue depth described at the base of the wound. These missing data were imputed using a maximum likelihood algorithm based on A) maximum depth of tissue exposed at any visit, and/or B) initial depth of wound. The 1204 wounds with incomplete ICD-9 coding were removed, along with 6001 wounds associated with NPWT in which it was too difficult to impute the missing data, leaving 11,740 wounds among the 9069 patients before conversion to PASW 19.

Sixty-one wounds were found with NPWT-type data attached but not coded as having had NPWT; these were recoded to the NPWT category. Forty-eight NPWT cases were found with no associated type of NPWT and were recoded to no NPWT. The following issues also resulted in exclusion of some cases or data: 1) the type of tissue at the wound bed was not recorded at the final visit (5842 values deleted); 2) 12 unknown values for maximum wound surface area were converted to missing values; 3) 175 cases with initial depth of < 0.1 cm were deleted; 4) 2311 cases with an initial wound surface area between 0 and 1 cm² were also deleted, leaving 9254 wounds to be analyzed. During the merging of patient variables with wound variables, 1775 cases did not have matching keys, (a wound case had been deleted and thus could not be matched to patient variables or vice versa), which result-

ed in the deletion of 1775 wounds, leaving 7459 wounds in the merged dataset.

Using a boxplot for initial area and initial depth, 6 and 19 unique wounds, respectively, were identified as having exceptionally high values and these cases were deleted after effect on primary wound characteristics had been ascertained (area > 400 cm² and depth > 9 cm). In addition,⁴⁹ cases had no NPWT duration for wounds treated with NPWT (these cases were deleted), and 293 cases had 0–4 days for duration of NPWT treatment (these cases were deleted), leaving 7099 wounds in 5240 patients to be analyzed.

Statistical Analysis

Descriptive statistics were analyzed using PASW 19. One way ANOVA was performed for cost of nonhealing wounds categorized by time in service (0–0.5 years, 0.51–1.0 years, 1.01–2 years, and ≥ 2 years) using Games-Howell for post hoc adjustment for multiple comparisons. Cost to heal by number of comorbidities was analyzed using t test with number of comorbidities categorized as 0 or 1 vs ≥ 2.

A general linear model (GLM) analysis to identify factors that affected the cost to heal was carried out in which the cost to heal was log transformed and all available factors and covariates were entered into the model with subsequent refinement, including main effects and 2-factor interactions. When comparing factors, adjustments were made for multiple comparisons using Sidak adjusted P value calculations.

Results

In the prepared dataset the 5240 patients exhibited 7099 wounds for an average of 1.3 wounds per patient. These patients made 119,786 visits over the time 5-year time frame, a mean of 16.8 visits per wound, but the range was very large (1–374). The mean patient age was 61.7 years (standard deviation [SD]: 17.42; range 19–103 years) with 52.3% of the dataset being male, 47.7% female. The preponderance of patients were Caucasian (73.1%) with Hispanics representing 10.7%, African-Americans 9.3%, and other races 1.7%. As might be expected from the age data, the majority of patients were Medicare beneficiaries (52.6%), with healthcare coverage for the remainder provided by private insurance in 36.2%, Medicaid in 3.2%, and worker's compensation or self pay in 8.0%. These 5240 patients accrued a total “cost to the system” of \$29,249,500 for their outpatient care.

The average number of serious comorbid conditions

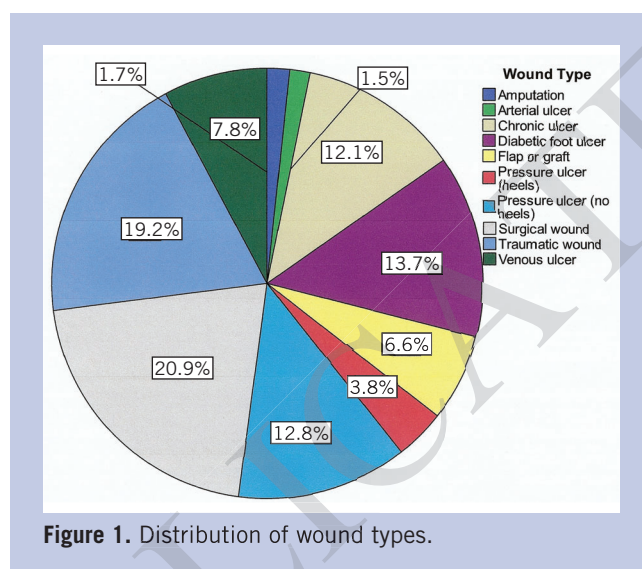


Figure 1. Distribution of wound types.

per patient was 1.8 (range 0–9). The most common serious comorbid condition was diabetes, present in 46.8% of patients (including 33.1% of patients who had ulcers not identified as diabetic foot ulcers). A surprising 71.3% of patients were classified as obese or overweight (BMI > 25), and 51.3% had diagnoses indicating cardiovascular or peripheral vascular disease. Of note, 7.5% of patients were on dialysis or had undergone renal transplantation, and 8.5% of patients were taking prednisone, a drug likely to inhibit normal healing processes.

The distribution of wound and ulcer types is depicted in Figure 1. Nonhealing surgical wounds represent the largest category at 20.8% of the total, followed by pressure ulcers on the body (eg, sacrum, trochanter, ischium) at 19.2%. Pressure ulcers on the heels represented 3.8% of the total dataset, with these data being maintained separately due to their association with peripheral vascular disease. Diabetic foot ulcers were the next most common ulcer type at 13.7% of the total, followed by traumatic wounds or chronic ulcers which are not otherwise classified (12.8% and 12.1%, respectively). These traumatic wounds were often associated with diabetes or vascular disease, and the generic “chronic ulcers” were often due to sickle cell anemia, scleroderma, vasculitis, or other disease states, but the ICD-9 classification system does not allow providers to identify ulcers as being caused by these diseases so they remain in a nonspecific class. Venous ulcers represented 7.8% of the dataset, and arterial ulcers and nonhealing amputations 1.5% each.

Almost two thirds of wounds (65.8%) had an “outcome” of “healed” or the measurements in the chart indicated that the wound was no longer present at the fi-

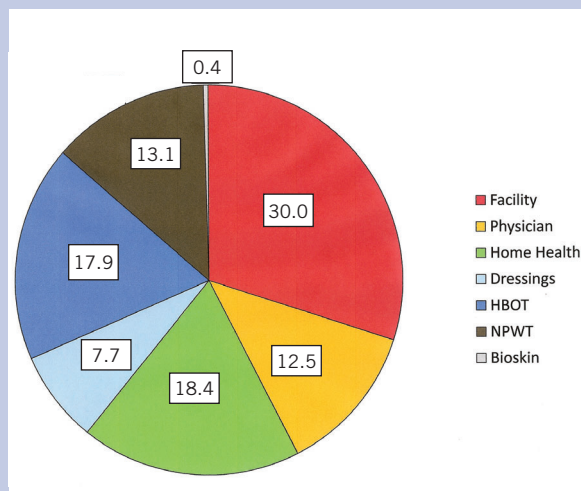


Figure 2. Breakdown of cost to heal by various factors.

nal visit. The average time to heal in those wounds that healed was 15 weeks (107 days; SD: 150.29) but the range was very large (< 1 week to 5 years) with 10% of wounds taking 33 weeks or more to heal. The average wound surface area was 19.5 cm² (SD: 39.71; range: 1–480 cm²). An outcome of “amputated” was found for 1.38% of wounds (highest for diabetic foot ulcers at 6.4%, but also high for arterial ulcers at 4.0%), leaving 31.2% of wounds whose benefit from treatment was unclear despite considerable resource utilization. Of note, 1.63% of patients died in service or within 4 weeks of the last visit.

Half of the wounds that healed did so with only the use of moist wound care (50.8%) and without the need for advanced therapeutics (AT) defined as hyperbaric oxygen therapy (HBOT), bioengineered skin (eg, Apligraf or Dermagraft), or negative pressure wound therapy (almost exclusively provided in this dataset by the V.A.C.[®], KCI, San Antonio, TX). Moist wound care in these clinics consisted of a variety of sophisticated dressing products (eg, alginates, hydrocolloids, hydrofibers, antimicrobial and collagen-containing dressings), but these were not considered “advanced” wound care. However, when advanced therapeutics were utilized, they represented significant cost drivers since these interventions are relatively expensive with 19.7% of patients receiving HBOT, 34.4% receiving NPWT, and 5.3% receiving bioengineered skin; the corresponding percentages of wounds receiving these advanced therapeutics were 21.9% with HBOT, 31.0% with NPWT, and 5.9% with bioengineered skin.

The distribution of major cost drivers for healed wounds is depicted in Figure 2. Although hyperbaric ox-

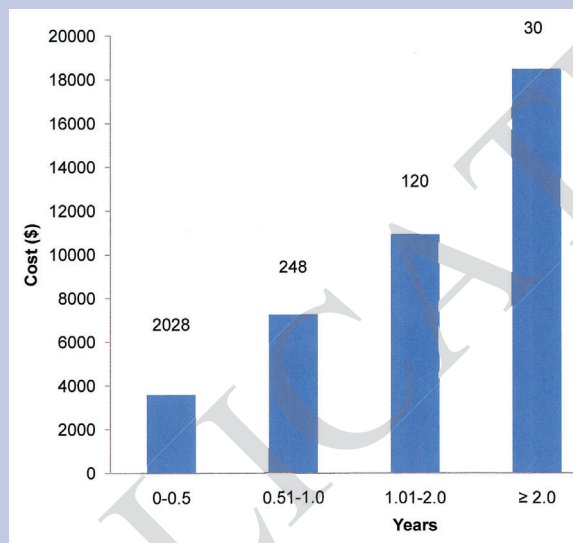


Figure 3. Cost of unhealed wounds increases with longer length of time in service. Numbers in boxes represent number of wounds for each column. P values for difference between means: 0–0.5 years and 0.51–1.0 years: < .0001; 0–0.5 years and 1.01–2.0 years: < .0001; 0–0.5 years and ≥ 2.0 years: .005; 0.51–1.0 years and 1.01–2.0 years: .022; 0.51–1.0 years and ≥ 2.0 years: .045; 1.01–2.0 years and ≥ 2.0 years: .291.

xygen therapy charges and bioengineered skin are both usually billed as part of hospital-based outpatient wound center charges, we have separated them here in order to visualize how these advanced therapeutics contribute to outpatient costs. We see that one of the most significant cost contributors is home nursing (18.4% of total cost) because so many patients are unable to perform self-care. These costs were estimated based on the weeks over which orders for home health appeared in the chart and the frequency of visits ordered. Physician charges represent 12.5% of resource utilization, with dressings at only 7.7%. In this dataset, bioengineered skin (“Bioskin” in the graph) also represented a relatively small percentage of resource utilization (less than 6% of total charges).

There were wide variations in resource utilization among wounds which healed when analyzed by wound type. The average cost to heal per wound was \$3927. Jeopardized flaps and grafts were the most expensive wound type with a mean cost to heal per wound of \$9358. Diabetic foot ulcers were the most expensive type of chronic ulcer and were twice as expensive as other types with an average cost per patient of \$5391. The average cost per wound for pressure ulcers was \$3349.

The final General Linear Model predicted a significant portion of the variance in wound healing outcomes, with an $r^2 = 0.348$, and an overall model P value of $< .0001$. However, there was a significant limitation in the model due to violation of Levene's test of equality of error variances, meaning that the variance between groups for several factors was significantly different. Significant factors that increased cost to heal included the presence of diabetes ($P = .007$), the need for systemic antibiotics ($P = .003$), renal failure (particularly if prescription narcotic pain medication was required; $P = .028$), immunocompromise (eg, use of prednisone or medications associated with organ transplantation; $P = .02$), and current smoking ($P = .02$). When patients had 0 or 1 comorbidity the cost to heal the wound was significantly less than when they had ≥ 2 comorbidities (mean: \$3601 vs \$4282; [SD: 5226.96 and 5727.59]; $P = .000024$).

For those wounds which did not heal, the average time in service was 16 weeks. This suggests that the majority of patients who failed to achieve healing did not continue to be followed in the outpatient wound center. However, 10% of patients who failed to heal were still being followed at 39 weeks. Among patients followed for long periods, the cost of care increased as treatment duration lengthened. Figure 3 shows the cumulative cost of care in relation to years in treatment where these data were available. Although ≥ 2 -year data were available in only 30 patients, the cost of care per patient was more than \$18,000.

Discussion

These data confirm previous studies demonstrating that chronic wound patients have multiple comorbidities that would have excluded them from RCTs. While they are likely to heal with the interventions available, the "cost to heal" a chronic wound increases as the number of comorbid conditions increases. Not all wounds achieve healing and nonhealing wounds are among the most expensive. Among nonhealing patients for whom 3 or more years of data are available, the cost of care continues to increase in a near linear fashion, and the costs associated with nonhealing wounds would seem to be a significant savings opportunity. After some point, additional expenditures in patients with nonhealing wounds do not seem to produce measurable benefit but there may be cost savings, which are not visible (eg, hospitalizations which are prevented). While "palliative care" was an option as a "goal of therapy," fewer than 3% of patients were designated as palliative. Thus, it seems likely that some

of the patients followed over long time frames (eg, more than a year) were actually receiving palliative care even though they were not designated as such. Further analysis of these data is warranted to determine how limited resources can be best directed. Diagnosis related groups (DRGs) effectively "capped" the cost of inpatient care by limiting reimbursement based on the number and severity of diagnoses. In contrast, the "fee for service" model of outpatient care has continued to reward both physicians and hospitals for performing high cost, advanced therapeutics without a feedback mechanism for quality or outcomes of care. This appears to be the intent of proposed programs such as "accountable care organizations," but the mechanism by which reimbursement will be linked to quality and outcomes is not clear.

Limitations. This study suffers from the usual limitations of retrospective data analysis, as well as limitations regarding certain cost factors. These data are affected by the quality of clinical documentation. Thus, lack of thorough documentation would affect our estimations of prevalence of comorbid disease as well as certain treatment interventions. The inability of the ICD-9 coding system to identify wounds unusual etiologies, or in some cases correctly assign even common ulcer types to the correct category is a serious limitation. For example, there is no ICD-9 code for a "diabetic foot ulcer," these ulcers are identified by linking "chronic ulcer" to the underlying diagnosis of diabetes. The same is true for arterial ulcers. In addition to the lack of specific ICD-9 codes for most wounds and ulcers, in some cases, even the most experienced clinician may be challenged to correctly classify a wound/ulcer when multiple etiologies may apply (eg, a heel ulcer in a patient with severe arterial disease and diabetes). There is an extreme lack of functionality of the ICD-9 coding system (not improved with the upcoming ICD-10) in classifying wounds and ulcers. These shortcomings may indirectly affect quality of care (making it difficult to standardize treatment protocols if diagnosis coding is confusing) and poses serious impediments to wound healing research. In addition, in our desire to assess longitudinal care, and the exclusion of patients with certain missing data fields may have skewed our dataset towards patients who received advanced therapeutics. Evaluating a multiyear picture of care may account for what appears to be a relatively high percentage of patients who received modalities such as NPWT and HBOT. Furthermore, practice trends may change over a 5-year time frame (clinicians might increase or decrease utilization of advanced therapeutics over several years).

While we had access to actual cost and charge data, our calculations represent underestimations of real costs. The method by which negative pressure wound therapy and home nursing are actually charged to the payer is not on a per diem basis but in 30- or 90-day cycles. We estimated costs based on daily rates over the time of known use based on physician orders, likely underestimating by a significant margin since charges to the payer are usually rounded up to the next 30 days. Our lack of access to the costs associated with diagnostic or laboratory testing is another area of underestimation.

One advantage of using this particular EHR for data collection is that since the EHR automatically abstracts the chart to calculate charges, and charges determine both the clinic and physician revenue, all clinicians are highly incentivized to perform thorough documentation. The use of EHR data has some other advantages in this setting. Because all the medical data are collected for each patient, it is possible to analyze any aspect of care, as opposed to a “metrics of interest” method for most prospective registries. Because the data are derived from the medical chart and all the charts contribute automatically to the registry, 100% of the patients seen at the clinic become part of the registry. Thus, there is no selection bias in patient enrollment. Registries that require separate data entry may discourage the enrollment of patients with large numbers of wounds or complex histories. De-identified EHRs also guarantee clinician participation. Since the clinicians must do their medical charting anyway, the data needed for the registry are collected at the same time the medical record is created. This provides access to a broad cross-section of practice types, without regard to individual physician or facility motivation for research or quality measures.

It is likely that the quality of care varies highly from one facility to another. However, the point of this study was to determine outcome and costs in the “real world” setting, and since variations in quality of care are drivers of cost, it was not necessary to control for this factor. However, quality of care likely does affect outcome. For this reason, outcome measures such as “healing rates” would seem to be poor quality of care indicators. We have demonstrated that many, if not most chronic wound patients have serious comorbid conditions, which might negatively impact healing. One could argue that the most skilled centers would become referral points for the most complex patients, eventually decreasing their healing rates (unless risk adjusted) rather than increasing them. Thus, better measures of “quality” in the wound care industry would

seem to be process measures such as diabetic foot off-loading, venous ulcer compression, or vascular screening. Quality measures like these might help standardize practice and facilitate future pooled data analysis.

Despite the limitations of these data, registries created from pooled, de-identified EHRs may represent a way to determine the real world effectiveness of wound care treatments once efficacy has been established in RCTs. However, true “comparative effectiveness” studies of the expensive modalities used among chronic wound patients will require a method to stratify patients by severity of illness.

Conclusion

Although the authors recognize the limitations of this project, several statements may be made about wound “outcomes” among outpatients in the United States:

1. Patients with chronic wounds frequently have serious comorbid conditions that distinguish them from the subjects of wound care RCTs.
2. Despite these comorbid conditions, nearly two thirds of patients seen at hospital based outpatient wound centers heal their wounds. A healing rate of 66% may be a realistic estimation of “healing rates” in these compromised patients.
3. Nearly one third of patients in hospital based outpatient wound centers may not heal their wounds even though they are cared for over a long period of time (outcomes include amputation, death, and uncertain).
4. Several factors can be defined that increase the duration and cost of wound care, including wound etiology, as well as several specific patient factors. These patient factors likely impact the effectiveness of advanced therapeutics in ways which cannot be ascertained by RCTs.
5. The longer patients with nonhealing wounds continue to be seen in the outpatient wound center, the greater their cost of care. (These expenditures may prevent hospitalization or other complications, but further research is needed to explore these hypotheses).

The authors believe that this registry demonstrates that outcome information can be a byproduct of documenting care with EHRs, as promoted by the IOM. This Wound Registry would seem to offer ideal opportunities for comparative effectiveness research in wound care, since it includes typical patients often excluded from RCTs, and reflects actual practice.

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