CLINICAL MANAGEMENT extra

# A Predictive Model for Pressure Ulcer Outcome: The Wound Healing Index

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## PURPOSE:

**The purpose of this learning activity is to provide information regarding the creation of a risk-stratification system to predict the likelihood of the healing of body and heel pressure ulcers (PrUs).**

## TARGET AUDIENCE:

**This continuing education activity is intended for physicians and nurses with an interest in skin and wound care.**

OBJECTIVES:

**After participating in this educational activity, the participant should be better able to:**

1. **Explain the need for a PrU risk stratification tool.**
2. **Describe the purpose and methodology of the study.**
3. **Delineate the results of the study and development of the Wound Healing Index.**


## ABSTRACT

**OBJECTIVE:** To create a validated system to predict the healing likelihood of patients with body and heel pressure ulcers (PrUs), incorporating only patient- and wound-specific variables.

**DESIGN:** The US Wound Registry data were examined retrospectively and assigned a clear outcome (healed, amputated, and so on). Significant variables were identified with bivariate analyses. Multivariable logistic regression models were created based on significant factors ($P < .05$) and tested on a 10% randomly selected hold-out sample.

**SETTING:** Fifty-six wound clinics in 24 states.

**PATIENTS:** A total of 7973 body PrUs and 2350 heel PrUs were eligible for analysis.

**INTERVENTION:** Not applicable.

**MAIN OUTCOME MEASURE:** Healed PrU.

**MAIN RESULTS:** Because of missing data elements, the logistic regression development model included 6640 body PrUs, of which 4300 healed (64.8%), and the 10% validation sample included 709 PrUs, of which 477 healed (67.3%). For heel PrUs, the logistic regression development model included 1909 heel PrUs, of which 1240 healed (65.0%), and the 10% validation sample included 203 PrUs, of which 133 healed (65.5%). Variables significantly predicting healing were PrU size, PrU age, number of concurrent wounds of any etiology, PrU Stage III or IV, evidence of bioburden/infection, patient age, being nonambulatory, having renal transplant, paralysis, malnutrition, and/or patient hospitalization for any reason.

**CONCLUSIONS:** Body and heel PrU Wound Healing Indices are comprehensive, user-friendly, and validated predictive models for likelihood of body and heel PrU healing. They can risk-stratify patients in clinical research trials, stratify patient data for quality reporting and benchmarking activities, and identify patients most likely to require advanced therapeutics to achieve healing.



**KEYWORDS:** predictive model, pressure ulcers, patient outcome, Qualified Clinical Data Registry, wound registry

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## INTRODUCTION

Lack of a practical and validated method to comprehensively risk-stratify patients with body or heel pressure ulcers (PrUs) has led to the exclusion of patients with serious comorbid conditions from randomized controlled trials directed at the treatment of PrUs, thus limiting generalizability of the results.[1] Patients with serious comorbid conditions, however, are needed in clinical trials in order to simulate a more "real-world" environment.[2] Also, new reimbursement systems focused on healthcare outcomes necessitate a patient risk-stratification system to adjust for differences in health status among patients, making it possible to compare PrU healing provider performance fairly.

To accomplish this, it is necessary to first identify factors that contribute to nonhealing in a real-world data set. The Centers for Medicare & Medicaid Services (CMS) encourages analyzing real-world data,[3] and the Institute of Medicine promotes the mining of electronic health record (EHR) data for clinical research.[4] In wound care, this latter goal has been accomplished with the creation of a national clinical data research network (CDRN) of wound care centers.[5] The CDRN data are submitted to the US Wound Registry (USWR), which has used them to develop and validate the Wound Healing Index (WHI).[6]

Predictive factors of PrU healing have been studied; they include the effect of PrU size (depth, area, and diameter) and patient immobility,[7] PrU stage,[8] malnutrition,[8–10] presence of PrU infection,[11] number of wounds, diabetes and/or other chronic diseases,[12] patient age, and incontinence.[12]

Previously developed PrU scoring systems combined several factors and allocated points to each factor to allow the clinician to estimate healing by examining change in PrU status based on an interpretation of the total score from assessment to assessment. For example, the Pressure Ulcer Scale for Healing (PUSH) score includes PrU factors of surface area, exudate amount, and surface appearance (tissue type) to indicate whether a PrU is healing or not from assessment to assessment.[13–15] The Bates-Jensen Wound Assessment Tool uses 13 items to examine change in PrU status in more detail than the PUSH tool. These items include size (length and width), depth, edges, undermining, necrotic tissue type, necrotic tissue amount, exudate type, exudate amount, skin color surrounding the PrU, peripheral tissue edema and induration, granulation tissue, and epithelialization.[11] The DESIGN-Rating (DESIGN-R) tool is designed to score the severity of PrUs and to monitor their chronological healing.[16–18] This tool classifies PrU severity based on the necessity of treatment or care. The DESIGN acronym is derived from the 7 components of the tool: depth, exudates, size, inflammation/infection, granulation tissue, necrotic tissue, and

pocket. A "P" is added to the acronym when a pocket (undermining) is present. Each item is scored in 3 to 7 grades (points range from 0 to 24 for each item), and the total score is calculated with higher scores indicating greater severity (0 = healed to 66 = greatest severity). DESIGN-R was created using 6 of the DESIGN components (depth was excluded) that were weighted according to their relationship to healing rate determined by Cox hazard analysis.

All 3 of these measures to predict PrU healing are independent of patient characteristics, setting type, and PrU location. However, patient characteristics and PrU location can strongly affect the likelihood of PrU healing, and complex multivariable mathematical models can be utilized to improve the prediction of PrU healing.[7,8,16–18]

The goal of the present study was to develop a model of PrU healing that is both practical and comprehensive of patient and PrU characteristics and can be used in both PrU research and patient care. The authors have previously published a detailed description of the database used, the approach to the analysis, the variables selected, and an overview of the basic model.[6] The purpose of this article is to describe in detail the creation of a risk-stratification system to predict the likelihood of the healing of body and heel PrUs. The WHI for PrUs is a validated wound/patient risk-stratification tool that was developed using "real-world" data. It is one of the more comprehensive models developed and can be used to risk-stratify patients enrolled in clinical research trials or reported in the Physician Quality Reporting System[19] and to identify patients most likely to require costly therapeutic interventions.

## MATERIALS AND METHODS

### Settings and Database Description

Elsewhere, the authors describe the database used to create the WHI models.[6] In brief, data came from a specialty-specific EHR, which, at the time of analysis, met the standards for Stage 1 of "meaningful use" as defined by the CMS and certified by the Office of the National Coordinator for Health Information Technology under the HITECH (Health Information Technology for Economic and Clinical Health) Act legislation.[20] The Intellicure Research Consortium (IRC) is a national CDRN of hospital-based outpatient wound centers across the United States and Puerto Rico that agree to share deidentified data from patient EHRs in exchange for benchmarking and quality measurement services. The IRC is composed of facilities that contribute data to the registry. The aggregate national database to which these facilities contribute data is known as the USWR. At the initiation of this project, the IRC comprised 56 clinics in 24 states. Since the completion of this project, the IRC has grown to consist of more than 100 clinics in 32 states and provides data to the CMS as part of the Physician Quality Reporting System as a Qualified Clinical Data Registry.

The USWR is registered in the "Registry of Registries"[21,22] and https://clinicaltrials.gov.[23] This extensive database was used to create and validate the WHI. The USWR independent institutional review board (The Woodlands IRB) approved this study and determined that retrospective analysis of HIPAA-deidentified compliant data as described here was exempt from the requirement for patient consent. This study complied with the 1975 Declaration of Helsinki.

The CMS uses the term "pressure ulcer" to refer to chronic skin lesions primarily due to pressure over bony prominences that occlude blood flow to tissues. In this article, the authors will use both the shortened term "wound" or the full expression "pressure ulcer" or "PrU" to refer to pressure ulcers and will specify the location on the body excluding the heel (eg, head, shoulders, arms, hips, sacrum) or heels, because several factors that predict healing differ depending on location. Although the authors realize that the heel is technically part of the "body," it is difficult to find a term that describes all parts of the human anatomy excluding the heels, so the authors will refer to these general locations as PrUs of the "body" versus "heels."

### Identification of Pressure Ulcers

Within the EHR, PrUs were defined by the *International Classification of Diseases, Ninth Revision, Clinical Modification* code. Only PrUs specifically indicated by the clinician as being on the body or heel were included in the data set. Physicians and nurses, all of whom were performing point-of-care electronic charting in the examination room with the patient, also provided "free text" data entries designating the specific body location. Thus, text field searches were used to establish right versus left and exact PrU location.

Further requirements for inclusion in analyses were as follows:

- at least 2 clinical encounters for each PrU
- at least 5 days between first and last encounter
- no gap longer than 90 days between any 2 clinic visits
- at least 1 PrU area measurement or a clinician statement of PrU outcome
- at least 1 PrU assessment with an PrU area larger than or equal to 0.25 $cm^2$
- a date of onset for the PrU
- a specified body location of the PrU

### Dependent Variable

Previously, the authors published a detailed explanation of the way in which healing was defined.[6] In ideal circumstances, at the time of the final wound assessment the clinician would assign an outcome to the PrU (such as healed, not healed, amputated, patient died). In those cases in which no outcome was assigned by the clinician at the final visit, longitudinal data analyses were performed to assess change in PrU size over time and change in

tissue type exposed over the course of care in order to establish which PrUs had healed. Outcomes of amputation and cases of death prior to healing were considered not healed. A hierarchical approach was created to determine whether a PrU had healed. If the clinician did not assign an outcome, the second and third levels were size of last area and change in PrU area from maximum to last. The fourth level of outcome assessment was last PrU depth, and the fifth level was last exposed tissue type with 3 categories of exposed tissue types included in the clinician descriptions: mild = Stage I descriptors, moderate = Stage II descriptors, and severe = Stages III and IV descriptors.[6] The authors used the worst tissue type category if a PrU had descriptions from multiple categories during an encounter.

## Independent Variables

From their prior research, as well as by other researchers, the authors identified the following patient and PrU characteristics as being significantly associated with healing prediction for PrUs[6]: PrU area at first encounter,[7,11,13–18,24] PrU age at first encounter (PrU duration in days),[25] patient chronological age at first treatment,[7,24–26] signs of inflammation and/or infection in the PrU,[11,27] malnutrition,[9,10,26,28] number of concurrent wounds or ulcers, renal failure or transplant, and maximum PrU Stage III or IV.[8,28] Additional significant factors identified by the authors' group included patient requiring hospitalization or a visit to the emergency department (regardless of whether it was associated with the PrU) and ambulatory status of the patient, including the method of arrival to the clinic, such as bed bound, wheelchair, or able to ambulate. These independent variables are defined in detail in Table 1.

## Data Analysis

The authors conducted bivariate analyses to test the relationship between each candidate predictor and the outcome of healed. For discrete variables, the authors created contingency tables and used $\chi^2$ tests, Fisher exact tests, or Wilcoxon tests (for ordered categories) to determine significance of bivariate associations. For continuous variables, the authors used correlation, 2-sample *t* tests, or analysis of variance. A 2-sided $P < .05$ was considered statistically significant. Once the dichotomous outcome of healed was defined, the authors randomly selected 10% of the body PrUs and 10% of the heel PrUs to use for model validation. The unit of analysis used in this study is the PrU.

The authors performed multivariable logistic regression for the dichotomous outcome of healed on the remaining 90% of PrUs, separately for body and heel PrUs. In addition, the authors used data from 2 time frames: (1) data available at the "first encounter" for 1 model of healing likelihood or (2) data available from the "whole course of care" for the second model of healing likelihood. Some predictor variables from previous literature were not allowed to enter the development model; these included any variables related to documented PrU treatment, as the authors did not want the treatment administered to influence the WHI. The authors' rationale was that if they allowed treatments to enter, then the WHI could not be used to determine which treatments were associated with a greater likelihood of healing because those treatments might already be part of the index. Although treatments were excluded from the models, it is clear that some additional and potentially predictive information became known regarding the patient over the course of care. For example, factors that are clearly associated with a reduced likelihood of healing include the development of new wounds, infection, or the need for hospitalization—any of which could occur during the treatment course.

It is useful to have a predictive model that can risk-stratify patients on their first day of assessment, because this might be used to prioritize patients for advanced therapeutics. However, for retrospective research or benchmarking, a slightly more predictive model that could be performed at the conclusion of all visits is also valuable.

Based on information available in published literature and clinical experience as well as bivariate analysis, potential predictors were allowed to enter the models using stepwise selection, but only significant variables were retained. The authors confirmed through pairwise Spearman correlations that no independent variables in the final models were collinear. All correlations between independent variables were less than 0.75. Discrimination of the models was measured using area under the receiver operating characteristic curve (c statistic) to evaluate how well the model distinguished PrUs that did not heal from PrUs that did heal. This was measured on both first visit and all-visits models using the 90% sample.

The WHI for PrUs is the predicted probability of a specified PrU becoming healed without regard to any time constraint or treatments used. It is created from multiplying the logistic regression parameter estimates by the values of the significant variables for body or heel PrUs and applying the appropriate transformation. The WHI was validated using the 10% validation samples for heel and body PrUs, respectively. In addition, the Hosmer-Lemeshow goodness-of-fit test was used to evaluate the degree of correspondence between WHI-estimated probabilities of achieving the outcome (healed) and the actual outcome proportion over groups spanning the entire range of probabilities (calibration) in the 10% validation model. The Institute for Clinical Outcomes Research team performed analyses as directed by the USWR team members using SAS version 9.2 (SAS Institute, Inc, Cary, North Carolina).

In addition, all PrUs used in the development and validation models were divided into 2 sets by number of PrUs treated by

**Table 1.**
**DEFINITIONS OF VARIABLES USED IN PREDICTING PRESSURE ULCER HEALING**

| Variable | Definition |
|---|---|
| FirstWoundArea | Beginning PrU area in $cm^2$ |
| EpiEndHospER | Caregiver encounter ending with patient sent to emergency department or hospital |
| PATC_Age_atFirstTreatment | Patient chronological age at first encounter |
| WorstArrvScoreGrp3Bed* | Mobility of patient at arrival, patient bed bound at arrival |
| WorstArrvScoreGrp2WC* | Mobility of patient at arrival, patient in wheelchair |
| WorstArrvScoreGrp1Amb[a] | Mobility of patient at arrival, patient able to ambulate |
| NumWounds_Strt_End | Number of wounds or ulcers that started previous to or concurrent with the index PrU, but exist on the patient during the time frame the index PrU is being treated |
| InfectBioBurden2 | Signs of inflammation and/or infection in the PrU as indicated by the words milky, purulent, green, or malodorous describing PrU exudates or the words indurated, edematous, tender to palpation, warm to touch, or erythematous describing the periwound area |
| CSI_Pat_RenalFailure_Transplant | Renal failure or transplant drugs were present if after scanning 5 different database tables containing medical history, surgery summaries, and patient's problems, the following words or word segments were found: ESRD, CHD, chronic renal insufficiency, end-stage renal, dialysis, hemodialysis, kidney and failure, renal and failure, or renal and transplant. |
| FirstUlcer34DTIUnstg | Stage III, Stage IV, deep tissue injury, or unstageable classification at first encounter, as well as the worst during the PrU episode. Each was used in its respective model |
| MaxUlcer34DTIUnstg | |
| MalnutritionInd3 | Patient was said to be malnourished if he/she had an *ICD-9* code of the form 263.XX, 262.XX, or 995.84, Braden nutrition 1 or 2, or a body mass index <18.5 $kg/m^2$ |
| DCDispFacSNF | Patient was said to reside in a nursing home or skilled nursing facility (SNF) if evidence existed of a visit encounter discharge to SNF or facility (if first encounter model, this has to be the first visit; otherwise, it could be any visit in the time continuum) |
| CSI_PAT_Paralysis | Paralysis was present if after scanning 8 different database tables containing initial and follow-up examination information, medical history, surgery summaries, nursing assessments, and patient's problems, the following words or word segments were found: paralysis, spinal cord injury, quadraplegia, paraplegia, tetraplegia, plegi, spina bifida, 741 (*ICD-9* code) |
| CSI_Pat_Insulin_Yes_or_No | Type 1 diabetes was present if patient was said to be on any insulin medications, or if patient had an *ICD* code of the form 250.XX |
| WoundAgeAtFirstEncounter | The number of days from PrU onset to the first encounter date |

Abbreviations: ICD-9, International Classification of Diseases, Ninth Revision; CHD, coronary heart disease; ESRD, end-stage renal disease.
[a]The variables are mutually exclusive and are positive for the worst condition during the PrU episode (whole-course model). A second set of variables was created for use in the first encounter model based on mobility at first encounter arrival.

individual physicians, using physicians with 30 or fewer treated body or heel PrUs, respectively, compared with physicians treating more than 30 body or heel PrUs as the cutoff point. This enabled the authors to examine predicted complete PrU healing according to WHI score versus actual PrU healing rates. For this purpose, the authors used probability breakpoints of less than 33%, 33% to 67%, and greater than 67%.

## RESULTS

There were 15,814 body PrUs and 4184 heel PrUs in the original data set spanning a time frame from July 2003 to July 2011. In addition to those PrUs not meeting the inclusion criteria, some additional PrUs were excluded because clinicians determined that the patient was lost to follow-up. Imposing these restrictions reduced the sample to 7973 body PrUs (50.4% of the original body PrU data set) and 2350 heel PrUs (56.2% of the original heel PrU data set) for analysis (Table 2). The logistic regression development model included 6640 body PrUs, of which 4300 healed (64.8%), and the 10% validation sample utilized 709 PrUs, of which 477 healed (67.3%). There were 624 PrUs missing a first PrU area and thus could not be included in the modeling. For heel PrUs, the logistic regression development model included 1909 heel

**Table 2.**
**REASONS AND NUMBER OF PRESSURE ULCERS NOT INCLUDED IN FINAL ANALYSIS DATABASES FOR BODY AND HEEL PRESSURE ULCERS**

| Step | Cleaning Step | Body PrUs | Heel PrUs |
|---|---|---|---|
| 1 | Starting number of PrUs/wounds | 15,814 | 4184 |
| 2 | PrU location not specified adequately for analysis | −1509 | −400 |
| 3 | No encounter data | −91 | −26 |
| 4 | Delete when encounter date is after resolved date | −2 | −2 |
| 5 | Require >1 PrU encounter | −2395 | −581 |
| 6 | Require that first encounter date is not resolved date | 0 | 0 |
| 7 | Keep wounds where longest gap between encounters is <90 d | −1429 | −285 |
| 8 | Require days between first and last encounter ≥5 | −153 | −47 |
| 9 | Wound outcome group "throw out" (lost to follow-up) | −234 | −60 |
| 10 | Require wound age | 0 | 0 |
| 11 | No areas, no evidence of outcome | −84 | −23 |
| 12 | EvidenceStatus = none and MeasureStat2 = depth or no | −1147 | −282 |
| 13 | Max wound area <0.25 $cm^2$ | −797 | −128 |
| 14 | Encounter date duplicates with nonidentical data—keep worst | −0 | −0 |
| 15 | Encounters after resolved date | −0 | −0 |
| | End number of PrUs | 7973 | 2350 |

PrUs, of which 1240 healed (65.0%), and the 10% validation sample utilized 203 PrUs, of which 133 healed (65.5%). There were 238 PrUs missing first PrU area here.

Table 3 shows descriptive statistics for the patients and PrUs that were included in the database that was analyzed for development and validation of the PrU WHI model. Table 4 shows all the variables that were examined to assess their bivariate association with a PrU being healed for the 7973 body and 2350 heel PrUs that were eligible for analysis. Many were significantly associated with more or less likelihood of the PrU being healed. Table 4 also shows which bivariately analyzed variables were allowed to enter and those that were significant in the final development regression models of body and heel PrU likelihood of being healed.

Models were created using 90% of the data (6640 body and 1909 heel PrUs) and retaining approximately 10% of data (709 body and 203 heel PrUs) for model validation. Variables that significantly predict the likelihood of being healed for these PrUs in multivariable logistic regressions are presented in Table 5. All regression coefficients were negative—meaning all variables were associated with less likelihood of being healed. Variables in Table 5 are ordered from the strongest significant predictor to the weakest significant predictor for each model—whole course and first encounter—using Wald $^2$ as the significance test. Table 6 shows the performance of each PrU model in the 10% validation data

**Table 3.**
**PATIENT CHARACTERISTICS AND MAXIMUM STAGE AND SIZE FOR HEEL AND BODY PRUS DURING ENCOUNTERS WITH CLINICIANS IN WOUND CLINICS**

| Variable | Heel PrUs (n = 2112) | Body PrUs (n = 7349) |
|---|---|---|
| Patient age, mean (SD), y | 70.01 (18.04) | 63.40 (19.26) |
| Gender, female, % | 47.59 | 45.75 |
| Race, % | | |
| Black | 12.31 | 12.56 |
| Asian | 1.89 | 1.42 |
| White | 68.13 | 69.48 |
| East Indian | 0.28 | 0.33 |
| Hispanic | 11.13 | 11.09 |
| Native American | 0.71 | 0.46 |
| Unknown | 5.54 | 4.61 |
| BMI, mean (SD), $kg/m^2$ | 27.55 (8.17) | 28.38 (10.95) |
| Smoker, yes, % | 9.94 | 12.53 |
| Nursing home residents, yes, % | 27.37 | 22.21 |
| Maximum PrU stage, % | | |
| Stage I | 7.62 | 3.14 |
| Stage II | 12.88 | 25.85 |
| Stage III, Stage IV, Unstageable, deep tissue injury | 79.50 | 71.00 |
| Maximum PrU size by stage, mean (SD), cm | | |
| Stage I | 4.54 (5.86) | 9.08 (25.24) |
| Stage II | 6.88 (9.08) | 7.29 (36.58) |
| Stage III, Stage IV, Unstageable, deep tissue injury | 14.84 (115.10) | 15.13 (33.88) |

Abbreviation: BMI, body mass index.

**Table 4.**

**VARIABLES ALLOWED IN REGRESSION MODELS, THOSE INCLUDED IN BODY AND HEEL PRESSURE ULCER REGRESSIONS, AND *P* VALUES IN BIVARIATE ANALYSES OF HEALED VERSUS NOT HEALED**

| Variable | Allowed in Regression Testing | In Final Regression Models | Body Pressure Ulcers (n = 7973), *P* | Heel Pressure Ulcers (n = 2350), *P* |
|---|---|---|---|---|
| Infection/bioburden | Yes | Yes | (−) <.001 | (−) .002 |
| Patient admitted for acute hospital stay | Yes | Yes | (−) <.001 | (−) <.001 |
| First wound area (− means that healed wound is associated with smaller area) | Yes | Yes | (−) <.001 | (−) <.001 |
| Malnutrition indications | Yes | Yes | (−) <.001 | (−) <.001 |
| Patient age at first treatment (− means that healed wound is associated with younger age), (+ means that wound is associated with older age) | Yes | Yes | (+) .916 | (−) <.001 |
| Patient has insulin-dependent diabetes | Yes | Yes | (+) .005 | (−) <.001 |
| Patient resides in a nursing home or skilled nursing facility | Yes | Yes | (−) <.001 | (−) .070 |
| Patient is paralyzed | Yes | Yes | (−) <.001 | (+) .495 |
| Renal transplant or dialysis | Yes | Yes | (−) .103 | (−) <.001 |
| Patient has had a renal transplant | Yes | Yes | (+) .593 | (−) .052 |
| Mobility of patients at arrival: bed bound or in a wheelchair | Yes | Yes | (−) <.001 | (−) <.001 |
| Wound age at first encounter (− means that healed wound is associated with younger age) | Yes | Yes | (−) <.001 | (−) .005 |
| Previous or concurrent other wounds or ulcers (− means that healed wound is associated with fewer other wounds) | Yes | Yes | (−) <.001 | (−) <.001 |
| Stage III, Stage IV, or unstageable | Yes | Yes | (−) <.001 | (−) <.001 |
| Days from first to last encounter (− means that healed wound is associated with shorter time), (+ means that healed wound is associated with longer time) | Yes | No | (−) <.001 | (+) <.001 |
| Patient is on dialysis | Yes | No | (−) .131 | (−) <.001 |
| Patient takes pain medications | Yes | No | (+) 1.000 | (+) .459 |
| Peripheral vascular disease | Yes | No | (+) .406 | (−) <.001 |
| Worst Braden Score (+ means that healed wounds are associated with higher score = less risk) | Yes | No | (+) <.001 | (+) <.001 |
| Braden malnutrition (+ means that healed wounds are associated with higher score = less risk) | Yes | No | (+) <.001 | (+) <.001 |
| History of autoimmune disease | Yes | No | (+) .013 | (+) .015 |
| Patient on muscle relaxants | Yes | No | (+) .291 | (+) <.001 |
| Any prior amputation | Yes | No | (+) <.001 | (−) <.001 |
| General vascular disease | Yes | No | (+) .354 | (−) .005 |
| Dementia and Alzheimer disease | Yes | No | (−) <.001 | (−) <.001 |
| Autoimmune disease and rheumatoid arthritis | Yes | No | (+) .001 | (+) .014 |
| Patient is incontinent | Yes | No | (−) <.001 | (−) .160 |
| Worst Braden subscore for mobility (+ means that healed wounds are associated with higher score = less risk) | Yes | No | (+) <.001 | (+) .001 |

*(continues)*

**Table 4.**

**VARIABLES ALLOWED IN REGRESSION MODELS, THOSE INCLUDED IN BODY AND HEEL PRESSURE ULCER REGRESSIONS, AND *P* VALUES IN BIVARIATE ANALYSES OF HEALED VERSUS NOT HEALED, CONTINUED**

| Variable | Allowed in Regression Testing | In Final Regression Models | Body Pressure Ulcers (n = 7973), *P* | Heel Pressure Ulcers (n = 2350), *P* |
|---|---|---|---|---|
| Patient has renal failure | Yes | No | (−) .294 | (−) <.001 |
| Patient has diabetes | Yes | No | (+) .001 | (−) <.001 |
| No. of foot pulses obtained by Doppler rather than being palpable (+ means that healing is associated with higher number = less risk) | Yes | No | (+) .010 | (+) .220 |
| Patient has renal insufficiency | Yes | No | (−) .460 | (−) .402 |
| Patient is male | Yes | No | (−) .266 | (−) .730 |
| Patient takes transplant antirejection drugs | Yes | No | (+) .065 | (+) .862 |
| Patient has had any organ transplant | Yes | No | (+) 1.000 | (−) .124 |
| Patent has alcoholic liver disease | Yes | No | (+) .001 | (+) .544 |
| Patient is a current smoker | Yes | No | (−) .643 | (+) .387 |
| Patient has sleep apnea | Yes | No | (+) .271 | (+) .189 |
| Wound on left side | Yes | No | (+) .007 | (−) .762 |
| BMI category of patient at first treatment[a] | Yes | No | <.001 | .402 |
| Patient has history of sickle cell anemia | No | No | (+) .012 | (+) .097 |
| Patient has chronic obstructive pulmonary disease | No | No | (+) .449 | (−) .387 |
| Patient has Crohn or irritable bowel disease | No | No | (+) .884 | (−) .532 |
| Patient has a history of hip fracture | No | No | (+) .259 | (−) .846 |

[a]BMI, body mass index.

set. Both the ''whole course of care'' and ''first encounter'' models validated well. Table 7 lists the 13 questions that are used to produce the WHI for body and/or heel PrUs.

When PrUs were grouped by the number of PrUs treated by individual physicians, the percentages of PrUs healed according to the WHI categories (<33%, 33%–67%, >67%) for physicians who had treated 30 or fewer PrUs were 14.9%, 45.3%, and 74.0% for body PrUs and 29.2%, 54.5%, and 76.7% for heel PrUs, respectively. In contrast, for physicians treating 31 or more PrUs, the corresponding figures were 27.5%, 55.3%, and 82.3% for body PrUs and 38.1%, 54.6%, and 79.7% for heel PrUs, respectively, for the same WHI categories. The results for the first WHI category (<33%) for heel PrUs may have considerable imprecision as only 42 heel PrUs were in the first category for the group of physicians treating 31 PrUs or more.

## DISCUSSION

Determination of factors to describe PrU healing has occupied PrU care researchers for many decades. The PUSH tool and Bates-Jensen Wound Assessment Tool have been used widely to predict time to heal depending on PrU measurements and characteristics.[11,13–15] However, patient characteristics are not included in either model.

The WHI models for body and heel PrUs perform well as predictors of healing likelihood, as measured by c statistics and Hosmer-Lemeshow tests, and have utility for clinicians in overall assessment of patient comorbidities and PrU severity factors that can impact PrU healing. In general, prior efforts to develop a predictive PrU healing score have been hampered by insufficient data (such as small sample numbers of patients and PrUs), as well as limited access to potentially important clinical variables related to patient condition due to the burden of collecting such data.

The WHI for PrUs is one of the more comprehensive validated PrU/patient risk-stratification tools. It can be embedded within an EHR so that calculation of the WHI can occur upon completion of an initial patient assessment, assuming all necessary data for calculations are obtained during the encounter. The authors' results indicate that when a physician treats larger numbers of body and/or heel PrUs there is a trend toward better healing

outcomes. This does not mean that most physicians who treat small numbers of PrUs in their practice do poorly in healing their patients' PrUs. However, such results could be used to provide feedback to physicians in the form of a "dashboard" to show where an individual physician performs in regard to other physicians treating patients with a similar level of PrU severity. Thus, risk-stratifying PrUs with the WHI in conjunction with reported outcomes (eg, healed or resolved PrUs) and adherence to clinical practice guidelines in the form of quality measures may provide a useful window on physician standard of practice as the healthcare system moves from "volume based" reimbursement to a system based on quality of care.

**Table 5.**
**WHOLE COURSE AND FIRST ENCOUNTER HEALING LIKELIHOOD MODELS FOR BODY AND HEEL PRESSURE ULCERS**

| | Body PrU | | | | Heel PrU | | | |
|---|---|---|---|---|---|---|---|---|
| | No. of PrUs = 6640; No. Healed (%) = 4300 (64.8%) | | | | No. of PrUs = 1909; No. Healed (%) = 1240 (65.0%) | | | |
| | 90% Whole Course Model; c Statistic[a] = 0.736 | | 90% First Encounter Model; c Statistic[a] = 0.702 | | 90% Whole Course Model; c Statistic[a] = 0.703 | | 90% First Encounter Model; c Statistic[a] = 0.697 | |
| Variable | Wald Order[b] | *P* | Wald Order[b] | *P* | Wald Order[b] | *P* | Wald Order[b] | *P* |
| PrU Stage III, Stage IV, DTI, or unstageable[c] | 1 | <.0001 | 1 | <.0001 | 2 | <.0001 | 2 | <.0001 |
| Wound age at first encounter | 2 | <.0001 | 2 | <.0001 | 7 | .0092 | 7 | .0082 |
| First wound area | 3 | <.0001 | 3 | <.0001 | 1 | <.0001 | 1 | <.0001 |
| Infection/bioburden | 4 | <.0001 | | | | | | |
| Paralysis | 5 | <.0001 | 5 | <.0001 | | | | |
| Malnutrition | 6 | <.0001 | 4 | <.0001 | 9 | .0113 | 5 | .0018 |
| Patient admitted for acute hospital stay or emergency department visit | 7 | <.0001 | 11 | .0421 | 5 | .0073 | | |
| No. of previous or concurrent other wounds or ulcers | 8 | .0003 | | | | | | |
| Patient age at first treatment | 9 | .0005 | 8 | .0039 | 4 | .0003 | 4 | .0007 |
| Mobility of patients at arrival—bed bound | 10 | .0009 | 6 | <.0001 | 8 | .0107 | 3 | .0005 |
| Renal transplant or dialysis | 11 | .0017 | 7 | .0034 | 6 | .0086 | 6 | .0037 |
| Mobility of patients at arrival—wheelchair | 12 | .1552 | 10 | .0151 | | | | |
| Patient resides in a nursing home or skilled nursing facility | | | 9 | .0147 | | | | |
| Patient has insulin- dependent diabetes | | | | | 3 | .0001 | | |

Abbreviation: DTI, deep tissue injury.
All estimates are negative.
[a]c Statistic: performance metric of model discrimination equivalent to the area under the receiver operating characteristic curve.
[b]Most significant = 1 to least significant.
[c]For the whole-course model, this is the max PrU stage; for the first encounter model, this is the first PrU stage.

**Table 6.**
**VALIDATION STATISTICS FOR WHOLE COURSE AND FIRST ENCOUNTER HEALING LIKELIHOOD MODELS**

| | Body PrU | | | | | |
|---|---|---|---|---|---|---|
| | No. of PrUs = 709 No. Healed (%) = 477 (67.3%) | | | | | |
| | 90% Whole Course Model | | | 90% First Encounter Model | | |
| Variable | *P* | Hosmer Lemeshow *P* | c Statistic[a] | *P* | Hosmer Lemeshow *P* | c Statistic[a] |
| Wound Healing Index | <.0001 | .3977 | 0.726 | <.0001 | 0.9067 | 0.674 |
| | Heel PrU | | | | | |
| | No. of PrUs = 203 No. Healed (%) = 133 (65.5%) | | | | | |
| | 90% Whole Course Model | | | 90% First Encounter Model | | |
| Variable | *P* | Hosmer Lemeshow *P* | c Statistic[a] | *P* | Hosmer Lemeshow *P* | c Statistic[a] |
| Wound Healing Index | <.0001 | .6145 | 0.712 | <.0001 | .7283 | 0.705 |

[a]c Statistic: performance metric of model discrimination equivalent to the area under the receiver operating characteristic curve.

In this study, the authors report models validated for PrUs, which facilitate use of ''real-world'' data to predict healing likelihood. The WHI for PrUs considers not only parameters incorporated in other PrU scores, such as PrU size, tissue type, and duration, but also other parameters associated with the patient, such as mobility, age, diabetes, malnutrition, paralysis,

**Table 7.**
**QUESTIONS TO PRODUCE BODY AND HEEL PRESSURE ULCER WOUND HEALING INDEX (SEE TABLE 1 FOR MORE DETAIL)**

| Number | Question |
|---|---|
| 1 | Patient age in years (calculated from date of birth) at first treatment |
| 2 | PrU age (duration) in days (calculated from PrU onset) at first encounter |
| 3 | PrU area in $cm^2$ (calculated from length x width) at first encounter |
| 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 PrU have evidence of infection or bioburden? (evidenced by purulent, green, malodorous drainage, periwound induration, tenderness to palpation, warmth) |
| 8 | Is the patient on dialysis or status post renal transplant? |
| 9 | What is the Stage of the PrU (I-IV) at first encounter? Worst stage throughout the course of treatment time continuum? |
| 10 | Does the patient have paralysis (words in chart of paralysis, spinal cord injury, quadraplegia, paraplegia, tetraplegia, plegi, spina bifida, 741 [*ICD-9-CM* code])? |
| 11 | Is the patient malnourished? (*ICD-9* code of the form 263.XX, 262.XX, or 995.84, Braden nutrition 1 or 2, or a BMI <18.5 $kg/m^2$) |
| 12 | Does patient reside in a nursing home or skilled nursing facility? (Yes if evidence exists of a visit encounter discharge to SNF or facility [if first encounter model, this has to be the first visit; otherwise, it could be any visit in the time continuum]). |
| 13 | Does patient have insulin-dependent diabetes? Insulin-dependent diabetes is present if patient was said to be on any insulin medications, or if the patient had an *ICD* code of the form 250.XX. |

Abbreviations: BMI, body mass index; *ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification*; SNF, skilled nursing facility.

and renal transplant and dialysis. It was made possible by the fact that the entire EHR of all patients from all participating clinics was transmitted to the registry (eg, patient social history, medical history, surgical history, functional assessments, nutritional assessments, physical examination, medications, PrU history, hospitalizations) using structured data to facilitate subsequent data analysis. On the clinical side, data capture occurred in a uniform fashion because all clinics used the same EHR and performed point-of-care charting (in the room with the patient). As a result, numerous potential factors could be explored systematically.

An advantage to the CDRN is that 100% of all patients seen at each clinic become part of the registry; thus, there is no selection bias in patient enrollment. Because the data represent the patient's actual medical record, there is no post hoc vetting of outcome information in order to improve the clinic's reported ''healing rate'' for purposes such as marketing; thus, outcomes were not artificially inflated to appear better than they were.

This study was designed to identify those characteristics inherent to the patient (paralysis, malnutrition, patient admitted for acute hospital stay or emergency department visit, number of previous or concurrent other wounds or PrUs, patient age at first treatment, mobility of patients at arrival—bedbound or wheelchair, renal transplant or dialysis, patient resides in a nursing home or skilled nursing facility, and patient has type 1 diabetes) and the PrUs that are associated with likelihood of healing and *not* to assess the impact of treatments. Therefore, it was not necessary to control for variations in care that undoubtedly existed among the clinics. The PrU WHI model confirms the importance of several previously reported PrU and patient factors on the healing process. However, it finally allows the impact of factors such as debility or the need for renal dialysis to be quantified in relation to their impact on healing.

There were significant limitations to this project. Only approximately 50% to 55% of the original body and heel PrU data sets were analyzed in this study. The data may be affected by the quality and consistency of clinical documentation. More than 100 clinicians provided point-of-care charting at the facilities contributing data for this project. Thus, although the methodology of data collection was standardized via discrete vocabularies, variability in patient *assessment* almost certainly existed. In fact, the terms under which data are shared for the purposes of this research mandate that no attempt is made prospectively to influence the interaction with the patient at the point of care. Clinicians were able to document PrUs by stage defined simply as unstageable, Stage I, Stage II, Stage III, or Stage IV. There being no national agreement with regard to the vocabulary for reporting patient outcomes, for the purpose of this project, it is of more importance that all clinicians were provided with the same set of choices for assigning outcome. Whether the outcome selected was ''healed'' or ''closed'' was not the focus of this project. However, inconsistency in clinical documentation may be the reason that some comorbid conditions or patient factors previously reported to be important were not found to be significant in this study, such as Braden Score and incontinence. In addition, many of these patients had Stages III and IV PrUs for which incontinence may be less of a significant contributor than for Stage II PrUs. The authors' inability to validate these factors does not negate their possible impact on the healing process or their possible value in subsequent models. However, the fact that this particular EHR internally audits the chart to determine both the facility and physician level of service provides an incentive for charting completeness without regard to individual physician or facility motivation for research. It should be noted that on average, 8 comorbid conditions were recorded per patient. It is hoped that the progressive governmental requirements of ''meaningful use'' of certified EHRs (currently at Stage II) will expand the data available to the CDRN as clinicians and hospitals are incentivized to create interfaces with laboratory data and other repositories of electronic healthcare information. Finally, although the USWR is national, this does not automatically generalize results to the US population despite the fact that studies published using data from the USWR tend to agree with results in the literature.

It is expected that the next stage of EHR certification will also advance the use of EHRs for clinical research. The Federal Coordinating Council for Comparative Effectiveness Research (CER) strongly supports longitudinally linked EHR databases as a source of data for CER.[29] Given the PrU treatment costs (likely $9.1–$11.6 billion) in the United States annually,[30] there is an urgent need to better understand comparative effectiveness of PrU treatments. Unfortunately, despite the financial and social burden of PrUs, federal funding for the creation of a CDRN focused on PrUs has not been forthcoming. However, this privately funded CDRN, focused on issues unique to wound care, may represent an efficient way forward for CER in PrU treatment.

Previous attempts at the creation of predictive models have been criticized because they have not been found to be of clinical utility. The WHI for PrUs has a variety of real-world clinical uses. A primary one is that it can be used to stratify PrUs by severity for PQRS outcome reporting. The CMS requires that risk stratification be utilized in outcome reporting so that providers who care for the sickest patients are not penalized by appearing to have ''worse'' outcomes. The factors needed to complete the WHI for diabetic foot ulcer outcome reported through the USWR have

been made available as an electronic clinical quality measure.[31] The elements of the WHI for PrUs can be captured similarly with an electronic clinical quality measure, should an outcome measure for PrUs be developed through a Qualified Clinical Data Registry. As stated previously, clinicians and researchers can access the predictive model on the USWR website.[22]

The authors anticipate that these PrU WHI predictive models will be used in a variety of ways and thus create 2 models. The first model may be used in clinical practice on the initial visit to identify hard-to-heal PrUs, perhaps to prioritize those most in need of advanced therapeutics. Models are more challenging to utilize in clinical practice than simple scoring tools because they involve more complex calculations. The authors' answer is to provide access to the model via the USWR website.[22] Clinicians and researchers can access the predictive model by inputting the answers to the questions in Table 7. The ''initial visit'' PrU WHI is now part of the EHR associated with the CDRN, and in the future, clinicians will have access to its predictions upon the completion of a PrU patient's first encounter. The second, slightly more predictive, model can be used in retrospective data analysis as part of CER. Access to the WHI information can allow clinicians, payers, and healthcare systems to identify the patients who are most at risk of failure and most in need of aggressive intervention. The WHI can also be used to stratify patients enrolled in prospective trials to ensure appropriate allocation of study and control groups.

## CONCLUSIONS

To the authors' knowledge, this study is among the largest PrU healing studies of its type and represents a significant advance in terms of the volume of data analyzed and completeness of the data set. The WHI for PrUs may be seen as one of the early dividends of widespread EHR adoption, facilitated by an advanced degree of specialty-specific structured language programming and a unique commitment on the part of users to the value of a shared data repository. These data confirm that certain patient and PrU factors affect the likelihood of healing of PrUs in a predictable way.

Registries created from pooled EHR data, including data transmitted to satisfy ''meaningful use'' requirements under HITECH, represent a way to determine real-world effectiveness of PrU treatments once efficacy has been established by randomized controlled trials. True ''comparative effectiveness'' studies of expensive modalities used among chronic PrU patients have been limited by the absence of a method to stratify patients by severity of illness; the PrU WHI may now help to overcome this obstacle, allowing patients with more comorbid diseases to be enrolled in effectiveness studies, thus enabling trials that are more generalizable to real-world patients.

## PRACTICE PEARLS

- Both patient and wound characteristics are necessary to accurately predict the likelihood of PrU wound healing.
- Different patient and wound characteristics predict the likelihood of healing body PrUs compared with heel PrUs. For example, the presence of paralysis is an important factor in predicting the outcome of body PrUs but not PrUs on the heel.
- The PrU Wound Healing Indices provide a method to risk stratify wounds for realistic reporting of outcomes and quality measures. Thanks to the WHI, clinicians caring for the most difficult wounds will not be penalized for lower healing rates as healthcare reform moves toward quality-based reimbursement.
- The WHI can facilitate the design of more generalizable clinical trials. Patients with comorbid conditions affecting healing can be enrolled in prospective trials because it is now possible to match patients by level of illness and predict the impact of diseases on healing likelihood.
- The WHI can be used to select wounds most likely to require advanced therapeutic interventions to effect healing, allowing better use of scarce healthcare resources.

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