Search results for 2019 International Pressure Injury Guideline: Pressure injury assessment and monitoring

Identified in pressure injury searches  
\( n=11,177 \)

Excluded after screening title/abstract  
- Duplicate citations  
- Included in previous guideline  
- Not related to pressure injuries  
\( n=8,128 \)

Identified citations  
\( n=3,085 \)

Excluded based on key word searches  
- Not related to pressure injuries  
- Not related to the topic-specific questions  
\( n=3,009 \)

Identified in topic-specific key word searches for full text review and critical appraisal  
\( n=76 \)

Excluded after review of full text  
- Not related to pressure injuries  
- Not related to the clinical questions  
- Citation type/research design not meeting inclusion criteria  
- Non-English citation with abstract indicating not unique research for translation  
\( n=71 \)

Identified as providing direct or indirect evidence related to topic and critically appraised  
\( n=5 \)

Additional citations  
Identified by working group members  
\( n=36 \)

Additional citations  
Appraised for previous editions  
\( n=20 \)

Total references providing direct or indirect evidence related to topic  
\( n=25 \)

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### Articles Reviewed for International Pressure Injury Guideline

The research has been reviewed across three editions of the guideline. The terms pressure ulcer and pressure injury are used interchangeably in this document and abbreviated to PU/PI. Tables have not been professionally edited. Tables include papers with relevant direct and indirect evidence that were considered for inclusion in the guideline. The tables are provided as a background resource and are not for reproduction.


#### Ref

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| Palese et al., 2015 | Secondary analysis cohort of data from a multi-center RCT to evaluate PU healing time | Participants were initially recruited for an RCT evaluating topical agents and dressings from 46 Italian hospitals, aged care centers and home care. Inclusion (in this analysis): (n=270) • Aged > 18 years • Stage II PU • Only one PU per participant included (random selection of PU site) • Receiving best available care at time of initial study Exclusion: • Heel PU • Vascular or diabetic ulcers or those associated with radiation therapy Characteristics: Mean age 83.9 years Primary locations were sacral (64.4%) trochanteric (15.1%) and buttocks (14.5%) | N/A | • Weekly evaluation f PU for 10 weeks • Healing time measured as time to reach complete epithelialization with PUSH score =0 • PU healing evaluated by experienced RN (or educated caregiver) using PUSH Tool score o LxW (scored 0 to 10) Exudate amount (scored 0 to 3) o Tissue type (scored 0 to 4) | Baseline PU conditions • Average size 1 to 3 cm² • 44.8% had slight exudate • 64.8% granulation tissue • Average PUSH score 8.04 (95% CI 7.79 to 8.4) Healing times • 15.9% participants excluded from analysis due to death/transfer • 56.7% (n=153) healed within 10 weeks • No PUs worsened from Stage II to Stage III during study time • Average healing time 22.9 days (95% CI 20.47 to 25.37) Factors associated with healing • Surface are < 3.1cm² (PUSH LxW score ≤ 6) significantly more likely to heal than those ≥3.1cm² (p=0.032) • Surface area < 3.1cm² (PUSH LxW score ≤ 6) significantly faster healing time than those ≥3.1cm² (19.2 vs 31 days, p=0.000) • No significant association between healing time and PU location, exudate amount, comorbidities, PU shape, treatment type. | • Potential lack of reliability in data collection and interventions across the 46 sites • Interrater reliability in assessment not established • Caregivers performed assessments in homecare environments but received education. • Sample were older old adults. • Only included Stage II Pus • Weekly evaluations may have influenced the documented healing times | Level of evidence: 3 Quality: high

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### Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals

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| Bliss et al., 2017 | Retrospective cohort study to assess racial and ethnic disparities in the healing of pressure ulcers present at nursing home admission at a 90-day admission endpoint | Participants recruited in nursing homes in US (n=10,862) 60.4% had ≥ two comorbidities, 21.9% had diabetes | N/A | • The outcome of PU healing was defined as the absence of a Stage 2, 3 or 4 PU on the first MDS record at the required 90-day assessment after admission  
  • Data from patient records reviews  
  • PU are staged according to the severity of skin loss according to the guidance manual for the MDS | • 44% of NH admissions healed PU present at admission by the 90-day assessment  
  • The odds of healing a PU present at NH admission within 90 days are significantly lower if the PU is a stage 3 (0.30 (0.25,0.36)) or 95% CI  
  • Stage 4 (0.23 (0.20, 0.28)) than a stage 2  
  • Likelihood of not healing is greater if there are deficits in activities of daily living (0.97, (0.96, 0.99))  
  • Predictors in the model explained 54% of the disparity in PU cure.  
  • Smaller proportion of Black NH admissions had their PU heal than expected had they been part of the White group.  
  • No disparities in PU healing disadvantaged other minority groups  
  • Significant predictors of a nonhealing PU were greater deficits in activities of daily living and PU severity | • Data only generalizable to the cohort under review  
  • Relied on data base entries  
  • Unmeasured NH effects controlled for during modeling by ensuring racial/ethnic minority groups were in same NMs as Whites whose modeling coefficients were applied |
| Gabison, McGillivray, Hitzig, & Nussbaum, 2015 | To examine the agreement between digitized tracing and digital photography methods in measuring wound area and healing rate, and to compare and contrast the methods on feasibility and utility in the measurement of wound area | Participants were recruited in a rehabilitation center in Canada (n = 22, n=20 analyzed) | One assessor independently performed wound photographed  
  And second assessor used wound tracing  
  Both assessors used the same image software to calculate area (Image-J® software) | • Weekly tracing or photographs taken.  
  • One person took all the photographs, one person undertook all the tracings. Each worked out the surface area.  
  • Minimum of three consecutive weekly measurements | Differences between methods on measured wound area  
  Significant difference between methods on measured wound area (<p=0.0001)  
  Results were also significantly different between methods for small (<2.5cm², p=0.0001) and larger (>2.5cm², p=0.0044) wounds | Differences between methods on weekly healing rate  
  Association between improvement ration and week was not significant p=0.9429 indicating there was not significant difference between the methods in measuring the weekly healing rate | Small sample size  
  Area of undermining not visualized only surface area of the ‘exposed hole’ measured.  
  Limited number of wounds with healing trajectories longer than 10 weeks. |

### Pressure injury measurement strategies

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Data Tables: 2019 Guideline Update: Assessment of Pressure Ulcers and Monitoring of Healing © EPUAP/NPIAP/PPPIA Page 3
## Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals

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<td>Bilgin et al., 2013</td>
<td>Examine the levels of agreement among 3 techniques used in wound measurement comparing more spherical versus irregularly shaped wounds</td>
<td>Participants recruited from CV, neurology, neurosurgery in University hospital in Turkey (n=65 with n= 80 pressure ulcers)</td>
<td>N/A</td>
<td>All wounds cleansed and measured using the 3 techniques by the same investigator. This was performed 3 x for each wound.</td>
<td>Conclusion: The two methods are not in agreement on measured wound but are in agreement on the important parameter of healing rate.</td>
<td>The removal of 4 outlier values could possibly affect the results</td>
</tr>
<tr>
<td>Arora et al., 2017</td>
<td>to determine reliability of measuring wound undermining in those with spinal cord injury</td>
<td>30 people with complete or incomplete SCI</td>
<td>N/A</td>
<td>Undermining measured using four points from a clock face (12, 3, 6, 9 with 12 o’clock defined as the head).</td>
<td>Interrater reliability intraclass correlation coefficients ICC=0.996 (95% confidence interval 0.992-0.999). Repeat measurements by different assessor were within 0.3cm of each other 83% of the time.</td>
<td>Studies on reliability of measuring undermining are limited. This contributes to the reliability of this measurement</td>
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**Participant characteristics:**
- Mean age 54 years
- Wounds present for a mean of 29.7 weeks (2 – 312)

**Inclusion criteria:**
- inpatients with a stage 2 or higher PI
- 18 years or older

**Exclusion criteria:**
- does not meet inclusion

**Participant characteristics:**
- Mean age 59.4 years

**Wounds divided into 2 groups 24 were larger and irregularly shaped and 56 smaller and round or oval**

**Higher level of agreement when measuring regularly shaped wounds (ICC=0.95) and lower levels of agreement for irregularly shaped wounds (ICC = 0.75)**

**The ruler method tends to over estimate**

**Results closer for the tracing and digital planimetry systems**

**There is no standard for wound measurement**

**Indirect evidence:**
- 3

**Quality:**
- moderate
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<td>Lange mo, Spahn, Spahn, &amp; Chowdry Pinman i, 2015</td>
<td>Observational study of retrospective wound photos to explore precision of wound measurement using the Scout device</td>
<td>Participants recruited at in and outpatient centers (n=40) &lt;br&gt; Inclusion: 60% wound care experts &lt;br&gt; Mixed etiology wounds &lt;br&gt; Aged over 18 years and consenting</td>
<td>N/A</td>
<td>LxW measure using a ruler &lt;br&gt; Wounds measured using Scout ImageCapture and Scout ImageReview &lt;br&gt; o Scout L X W measure &lt;br&gt; o Scout trace area &lt;br&gt; o Scout perimeter trace &lt;br&gt; Camera is a non-contact longwave infrared camera that captures thermal images &lt;br&gt; Software allows measurement of diameter, surface area (SA), wound perimeter and thermal intensity &lt;br&gt; All wounds were measured once &lt;br&gt; Each reader made 3 replicate measures of each wound using the Scout outcome measures</td>
<td>Interrater reliability of Scout measures &lt;br&gt; Average coefficient of variation was &lt; 20% for all wound measurement strategies, with Scout trace perimeter having the high reliability</td>
<td>Unable to compare Scout measures to ruler measures due to patient discomfort and contamination concerns with repeated measures &lt;br&gt; Selection of participants is not reported &lt;br&gt; Wounds with obscured edges not included &lt;br&gt; No discussion of reliability in evaluating undermining/tunneling</td>
</tr>
<tr>
<td>Vereda s, Mesa, &amp; Morente, 2015</td>
<td>Laboratory modeling description of a computer-visual approach to identifying and categorizing wound beds</td>
<td>For development and testing: 322 PU photographic images from 69 patients</td>
<td>N/A</td>
<td>Photographs of PUs were taken in optimal conditions (i.e. well lit, correct distance, high quality tools) &lt;br&gt; Wound specialists (n=5) categorized the pixels on each digital image according to a) location (skin, peri-ulcer, wound bed) and b) type (e.g. Category/Stage 1 PUs “Superbed” refers to all tissue that is non-skin (i.e. peri-ulcer plus wound bed) Two models were tested – a histogram model and a Gaussian-mixture based model</td>
<td>The software was developed to reduce &quot;noise&quot; (i.e. non-wound bed skin) whilst maintaining sufficient per-wound region to maintain ability to distinguish Category/Stage 1 PUs “Superbed” refers to all tissue that is non-skin (i.e. peri-ulcer plus wound bed)</td>
<td>Indirect evidence: computational modeling</td>
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### Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals

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| Cutler et al., 1993| Prospective study     | 17 patients each had at least one full-thickness pressure ulcer (stage III or VI) that had been present for at least four weeks, and approximately 2 to 150 cm² in area, not infected, not include exposed bone or cellulitis around the ulcer, and the patients are not critically ill. | N/A                                                                              | Ulcers assessed by same nurse weekly for four weeks. Computer-assisted planimetry from the tracing and photographs, and calculations from direct measurements determined ulcer areas. Wounds were stratified according to their size. Ulcer volumes were calculated by means of bedside measurements and Jeltrate® volume calculated weight. | Area Under Curve  
Histogram model: superbed 0.94, wound bed 0.94  
Gaussian model: superbed 0.88, wound bed 0.88  
Cohen’s kappa coefficient  
Histogram model: superbed 0.66, wound bed 0.37  
Gaussian model: superbed 0.49, wound bed 0.22  
Conclusions: categorization of PUs using high quality digital photography and computational modeling shows moderate to good reliability but is currently not in clinical use | developed with only Caucasian skin/wound samples  
Algorithm was based on opinion from 5 experts                                                                                   |
| Bryant, Brooks, Schmidt | Laboratory study, exploratory | 16 wound care professional staff; 11 registered nurses and five physicians. | N/A                                                                             | Health professionals measured irregular shaped                                                        | The perpendicular method is generally more accurate than the other two when  
Used low technology method to measure wound, | Level 4, low quality  
No attempt was made to base area calculation on any other shaped differentially.  
Calculated off photographs                                                                                    |
## Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals

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| Mostow, 2001 | Descriptive study, inter-rater reliability study. | Wounds on a prosthetic leg using 3 methods:  
• Their usual method of practice  
• Clockwise method  
• Perpendicular method. The three methods were evaluated gold standard (comparison with a computer assisted measurement) and inter-rater reliability. | Measuring across variety of wound configuration.  
• Range of accuracy is found for each other method depending on the type of wound leading to the conclusion that different measurement methods are better suited to different wound shapes. | The study does not represent true random sampling, and results may not be generalized to all settings or to full thickness wounds. | Pressure injuries |
| Sugama et al., 2007 | Descriptive psychometric study | 10 inpatients with pressure ulcer in a long-term facility  
To test the validity: 30 inpatients with pressure ulcers or develop pressure ulcers during the validity test period, which is 6 months. | N/A | Interrater reliability established by four nurses tracing the wounds using the VISITRAK wound measurement system  
• One assessor carried out the tracing, then the traced wound area was redrawn three times by each assessor onto the digital pad using the accessory pen in laboratory.  
• The digital planimetry as a standard. The wound area in the digital planimetry photographs were measured 3 times each by each assessor with a digital planimetry.  
• Convenience of the VISITRAK was assessed by recording the time it took to calculate wound area | The inter-rater and intra-rater reliabilities for the VISITRAK were excellent (ICC= 0.99-0.75).  
• There was a significant strong positive correlation between the two wound measuring area technique $r=0.99$, $p<0.001$.  
• The VISITRAK is significantly quicker (median = 54 seconds) than the digital planimetry (median = 126 seconds). | Level 4, low quality |
## Data Tables: 2019 Guideline Update: Assessment of Pressure Ulcers and Monitoring of Healing

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<td>(Haghpanah, 2006 #206)</td>
<td>investigated the</td>
<td>40 different pressure ulcers</td>
<td>Four nurses used the system to perform wound tracings on ten pressure ulcers for investigation into the reliability. <strong>Electronic method of wound tracing</strong> comparing two different electronic data collection systems (Visitrak™ and a digital system that is no longer available) to manual linear measurement using a disposable paper ruler. The Visitrak™ system requires clinician to trace the wound using transparent tracing paper, after which the wound tracing is placed on the Visitrak™ tablet and retraced.</td>
<td>The electronic tracing system was found to be more reliable in repeated measures than linear measurement.</td>
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### Monitoring with pressure injury healing rates

| Brown, 2000 | Retrospective analysis | Measurement of fully healed stage IV pressure ulcers (n=10) in the pelvic area of patients (n=9) were examined retrospectively | Wounds treated by eschar removal with sharp debridement, wet-to-dry dressing in some cases, sodium chloride-impregnated gauze as primary dressing with calcium alginate | Wound measurements taken weekly by wound, ostomy, and continence nurse during an 18 months period. Linear measurements used to calculate the area of the wound. Average daily reduction in wound area (initial wound area/days till full healing). Wounds were stratified into 3 groups: small, medium, and large. | The wound healing curves begin on a gradual slope but quickly dive downward as the wound contracts. In the last phase of epithelialization, the rate slows considerably. The time to reach 50% reduction in wound area for the large, medium, and small groups was: 26.7%, 42.2%, and 30.1% of total healing time. As initial wound area increases the, the average daily wound area reduction also increases. | Small study                                                                                                                                   | Level of evidence: 4 Quality: low |       |
### Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals

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<td>van Rijswijk &amp; Polansky, 1994</td>
<td>Secondary analysis</td>
<td>48 patients with full thickness stage III and IV pressure injuries (n=56) that were dressed with hydrocolloid dressing for mean of 56 days prior to the study enrollment. Patients’ characteristics: general health condition, mental statues, mobility, skin condition, activity level, body build and overall skin condition, nutritional status. Wound characteristics: aspects of ulcer margin, the pressure granulation, or necrotic tissue and depth were assessed at baseline and every dressing change.</td>
<td>N/A</td>
<td>To analyze wound healing curves; individual healing curve examined.</td>
<td>Kaplan-Meier time until 100 % healing time curve</td>
<td>Median time to healing 69 days  Median time to reach 100% healing for completely immobile patients was 86 days (no significant difference from 53 days in fully mobile patients, p=0.10).  Healing can be expected in 25% of patients after 50 days and in 75% of patients after 243 days.  A 50% reduction in wound size can be expected after 15 days, and 80% reduction in area after 40 days.  The difference of the healing time between different wound sizes was not significant and not significant difference based on patient age.  Stepwise Cox proportional hazards model  Poor nutritional status at baseline was predictive of healing.</td>
</tr>
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**Limitation:**
- For heavily exuding wounds.
  - Date treatment start considered to be: (1) initial examination with heavy to no fibrous necrotic tissue or slough, if no eschar was covering the wound, or (2) debridement of at least 90% of eschar.
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<td>factors of time until healing 100%. Kaplan-Meier time until healing curves were calculated for time until 50, 80, and 100% healing based on the ulcer tracing obtained.</td>
<td>Age, nutritional status and percent reduction in area were all independently predictive of time to healing after two weeks of treatment</td>
<td></td>
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### Other characteristics assessed in pressure injuries

**Taverna, Pollins, Sindona, Caprioli, & Nanney, 2015**
- Laboratory study reporting proteomic findings in stage IV PUs
- Edge of wound samples from pressure ulcers undergoing surgical excision and flap repair (n=15)
- IMS was used to analyze localized proteins in tissue samples from PUs
- N/A
- Calcium modulated proteins (e.g. calcyclin, calgranulin-A and B and calgizzarin (all S100 proteins) showed different patterns in healing vs intermediate vs chronic wounds
- Small samples size
- Patient variables were not reported or considered (e.g. other chronic disease)
- Indirect evidence: laboratory study

**Ou et al., 2015**
- Observational study in mice investigating role of KL4 and MDSCs in wound healing
- The study is conducted in mice
- Exploration of healing in mice using biomarkers
- One trial explores influence of a plant-derivative, Mexicanin I administered via intraperitoneal injection on wound healing.
- Wound healing
- Myeloid derived suppressor cells (MDSCs) are bone-marrow derived cells that have an immunosuppressive function
- Kruppel-Like Factor (KL4) is a transcription factor involved in monocyte differentiation and is known to be involved in skin healing (this role is previously unclear)
- The study provides some support for the theory that KL4 promotes wound healing by regulating differentiation of MDSCs
- Animal model requiring significantly more work before intervention would be relevant to humans

### Nursing diagnoses related to pressure injury identification and classification

**Menna Barreto, Swanson, &**
- Focus group study to validate Nursing Outcomes Classifications
- The study was conducted with invited participant nurses in two large city hospitals in Brazil (n=9)
- Inclusion criteria:
- Focus groups were discussed to discuss each proposed Nursing
- Validated NOCs required 100% consensus
- Validated NOC related to nursing diagnosis Impaired Tissue Integrity in Adults with PU
- Wound healing: primary intention
- Wound healing: secondary intention
- Limited information about the purpose of this study and how
- Indirect evidence (PU not an outcome measure)
**Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals**

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| de Abreu Almeida, 2016 | related to impaired tissue integrity | • At least 2 years nursing in surgical, clinical or ICU during past 5 years  
• Clinical practice in skin care for individuals with PU  
• Participation in a skin care study group for at least 6 months of the preceding 5 years  
• Familiar with nursing process and standardized nursing terminology  
Exclusion criteria:  
• None  
Participant characteristics:  
• 56% had ≥ 20 years’ experience in nursing  
• 33% had ≥ 22 years’ experience in skin care for PUs  
• 33% had ≥ 12 years’ experience in skin care study groups  
• 56% had specialization qualifications, 22% had Master’s degree | Outcomes Classifications  
• 16 outcomes from NOC were evaluated |  
Tissue integrity: skin and mucous membranes  
Allergic response: localized  
Nutritional status  
Self-care: hygiene  
Immobility consequences: physiological  
Knowledge: treatment regimen  
Risk control: infectious process  
Fluid overload severity  
**Non-validated NOCs**  
• Allergic response: localized  
• Hydration  
• Sensory function: cutaneous  
• Knowledge: infection management  
• Infection severity  
• Tissue perfusion: peripheral  
• Thermoregulation | Author conclusion: Standardized language should be used in health records to define nursing outcomes. Nine outcomes were validated for PU assessment. | the NOCs would be used  
• Limited information about the consensus process and how equal participation was promoted  
• No information about criteria to define each NOC  
• No exploration of the practical clinical use of NOCs |
| Choi, Chin, Wan, & Lam, 2016 | An observational study assessing the diagnostic accuracy of PUSH tool compared with nurse judgement for evaluation | Participants were recruited over 3 months in two outpatient primary care clinics in Hong Kong (n=541)  
Inclusion criteria:  
• Enrolled in a participating service  
• Diagnosed with a wound type included in study (VLU, PU, neuropathic ulcer, burn/scald,  
• All wounds were assessed on admission to the service and discharged from the service using the PUSH tool  
• At discharge the assessing nurse categorized the wounds | • All wounds were assessed on admission to the service and discharged from the service using the PUSH tool  
• Nurse judgement score  
• PUSH tool | **Comparison between judgement and PUSH score**  
Kappa coefficient 0.9719  
**Responsiveness of PUSH tool to wound change by multiple linear regression**  
• In wounds classified as improved static or worsened: change coefficient = 8.14, 95% CI = 5.78 to 10.50, p<0.001 |  
• The same nurses conducted the PUSH assessment and rated the wound as healed or otherwise.  
Conducting the first assessment with the PUSH tool may have influenced their judgments |

**Pressure injury assessment tools**

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Conducting the first assessment with the PUSH tool may have influenced their judgments |

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Data Tables: 2019 Guideline Update: Assessment of Pressure Ulcers and Monitoring of Healing © EPUAP/NPIAP/PPPIA

Page 11
### Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td></td>
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<td></td>
<td></td>
<td>In wounds classified as improved but not healed: change coefficient $-5.42$, 95% CI $-5.99$ to $-4.84$, $p&lt;0.001$</td>
<td></td>
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<tr>
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<td></td>
<td>In pressure ulcers: change coefficient $-1.66$, 95% CI $-3.68$ to $0.36$, $p=0.107$</td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td>Age $p=0.025$</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Gender not significant</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Author conclusions: the PUSH tool can help nurses who are not specialized in wound care to measure different wound types</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Use of the 3-point rating system.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No measure of interrater or intrarater reliability of the tool.</td>
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</tr>
</tbody>
</table>

#### Banks et al., 2016

**Pilot RCT exploring a high protein/high energy supplement with arginine, vit C and zinc**

- Participants were recruited from a hospital in Australia ($n=185$ identified, $n=50$ eligible and randomized)
- **Inclusion criteria:**
  - Existing Category/Stage 2 or greater PU
- **Exclusion criteria:**
  - Unable to receive enteral or parenteral nutrition
  - Inappropriate for intensive nutrition support
  - Unable to follow nutritional advice (e.g. cognition level)
- **Participant characteristics:**
  - Median length of stay 14 days (range 1 to 70)
  - Mean age approx. 62-65 years
  - Approx. 20% had BMI $<20$kg/m$^2$
  - Approx. 40% of participants had $>1$ PU

- Participants were randomized (stratified by PU Category/Stage) to receive:
  - Standard nutrition care including review by dietitian, standard hospital diet or high protein/energy diet ($n=25$ randomized, $n=17$ analyzed)
  - Intensive individualized diet including dietitian, high protein/energy diet aimed at 1.2g protein/kg/bod

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  - Standard nutrition care including review by dietitian, standard hospital diet or high protein/energy diet ($n=25$ randomized, $n=17$ analyzed)
  - Intensive individualized diet including dietitian, high protein/energy diet aimed at 1.2g protein/kg/bod

- **Change from baseline in PU in PUSH score at day 15**
- **Change from baseline in PU size measure using wound tracings of area at day 15 (using VISITRACK)**

**Results related to PU monitoring**

- All PUSH scores and PU area measurements were strongly correlated ($p<0.01$).
- Change in PUSH score at day 15 did not correlate with PUSH score on recruitment
- PU area change at day 15 correlated with PU area on recruitment ($p=0.00$) – larger initial area, the larger the change in area measurement

**Results related to PU monitoring**

- The pilot was designed to test feasibility of study design so not powered to measure an effect
- The PUs in control group were larger and had greater opportunity for improvement using percent reduction in size

- The pilot was designed to test feasibility of study design so not powered to measure an effect
- The PUs in control group were larger and had greater opportunity for improvement using percent reduction in size

#### Level of evidence: 1 Quality: low

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## Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals

| Ref                      | Type of Study                                                                 | Sample                                                                 | Intervention(s)                                                                                                                                                                                                                                                                                                                                 | Outcome Measures & Length of Follow-up                                                                                   | Results                                                                                                           | Limitations and comments |
|--------------------------|------------------------------------------------------------------------------|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Thoma son et al., 2016  | Quality improvement project aimed at introducing a PU assessment tool into SCI facilities | Spinal Cord/Disorders Centers in Veterans Affairs facilities in the US (n=23)  | No facility characteristics reported                                                                                                                                                                                                                                                                                                                                                     | Pre-post knowledge test (n=51)  
  - 3/10 questions answered correctly by ≥ 85% participants in pre test  
  - 10/10 questions answered correctly by ≥ 95% participants in post test  
  
  **Staff engagement**  
  - 30 sites were high adopted with 76-100% of staff receiving education and using SCI-PUMT  
  - More than half the facilities reported ,50% of Pus were assessed with SCI-PUMT  
  - Only 3 sites used all components of the SCI-PUMT kit  
  - 3,254 downloads of kit components from website  
  
  **Facilitators**  
  - Improvement in wound care costs  
  - Integrated documentation system  
  - Education and standardized documentation improved  
  - Interprofessional involvement  
  - Use of a trajectory graph made identification of stagnate wounds easier  
  - Weekly wound rounds facilitated interprofessional approach  | PU prevalence was not an outcome measure  
  - No reporting of facility characteristics  
  - Connection between intervention and improved patient care or improved knowledge is indirect  | Indirect evidence (PU not an outcome measure) |
## Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals

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| Iizaka et al., 2014 | To evaluate the relationship between nutritional status, anemia, diabetes and granulation tissue colour of PUs by color | Participants recruited in 10 settings in Japan over two time periods (n=42 pts with 51 full thickness PU; second period 59 pts with 68 full thickness PUs) | • Guideline for overcoming barriers to implementation  
• Implementation strategy included 15-day educational and strategy conference with clinical champions  
• Availability of kit from website  
• Condensed video conference training offered  
• Five year follow up with conference calls and ongoing PDSA QI cycle planning at national level with clinical champions | Wound assessment was undertaken by a trained specialist wound nurse using the DESIGN-R tool (range 0-66, >18 = severe pressure injury)  
• Depth was assessed separately ranked by:  
Association between measurements and granulation tissue  
• Hemoglobin levels were positively associated with granulation red index %GR180 (percent of granulation tissue exceeding a red index of 80) p=0.260  
• Interaction between diabetes and protein intake was significantly associated with %GR180 in adjusted model p=0.010 | Barriers  
• Lack of patient availability on ward rounds  
• Lack of integration into electronic document system  
• Low access to training manikin  
• Lack of buy in from some wound care nurses/teams  
Time and work load constraints | • Pooling of data not able to identify differences between cohorts  
• Small numbers  
• Incomplete data collection and risk of bias with Level of evidence: 3 (prognostic)  
Quality: low |

### Wound color measurement

<table>
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| Iizaka et al., 2014 | To evaluate the relationship between nutritional status, anemia, diabetes and granulation tissue colour of PUs by color | Participants recruited in 10 settings in Japan over two time periods (n=42 pts with 51 full thickness PU; second period 59 pts with 68 full thickness PUs) | • Guideline for overcoming barriers to implementation  
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• Availability of kit from website  
• Condensed video conference training offered  
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• Incomplete data collection and risk of bias with Level of evidence: 3 (prognostic)  
Quality: low |
## Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals

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|     | analysis of digital images in the clinical setting | • Exclusion criteria:  
- If wound surface was covered in necrotic tissue or skin graft, were bleeding, or had a wound bed that was difficult to evaluate i.e. Undermining or tunneling  
Participant characteristics:  
9 pts diagnosed with diabetes (21.4%) | | o D1 = persistent redness  
o D2 = dermal wounds  
o D3 = wounds extending to subcutaneous tissue  
o D4 = wounds extending to muscle tissue  
o D5 = wounds extending to bone  
o DU = unstageable wounds  
- Nutrition status assessed by anemia status, acute-phase proteins, glycemic control, anthropometry, nutritional intake, blood tests  
- Wounds images - all images calibrated and calculation of granulation tissue was done using image-editing software and a researcher manually selecting the region of granulation tissue  
- This study was taken over two time periods | They found there was a positive correlation in hemoglobin levels, diabetes and color of granulation tissue but this was not present in the adjusted model (p=0.260) | assessment process  
• No identification of malnourish status – this would have impacted on the pts ability to create granulation tissue – confounder |

**Ultrasound assessment**

<table>
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</tr>
</thead>
</table>
| Aliano, Low, Stavrides, Luchs, & Davenport, 2014 | To confirm superficial pressure ulcers will have a greater depth of injury than predicted | • Participants were recruited in a hospital in US (n=20)  
Inclusion:  
- Patients with Category/Stage I, II and SDTI sacral pressure injuries  
- Exclusion  
- Category/Stage III and IV pressure injuries | N/A | • All patients with pressure ulcers were staged according to the NPUAP PU staging system on admission  
• Ultrasonic wound assessment undertaken showing evidence of:  
- Of the 8 pts with Stage I 63% had disruption of the epidermal dermal interface:  
  - 3 had all three US abnormalities  
  - 1 had two US abnormalities  
  - 4 had one US abnormality  
- Of the 4 patients with Stage II:  
  - 100% had disruption of the epidermal dermal interface  
  - 1 patient had one abnormality | • Small sample size  
• No statistical assessment was undertaken  
• Not all areas would have access to ultrasound | Level of evidence: 3 (prognostic)  
Quality: low |
## Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals

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<tbody>
<tr>
<td></td>
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<td></td>
<td>o deep tissue injury – loss of dermo epidermal interface</td>
<td>• 3 pts had two abnormalities • 0 pts had all three abnormalities</td>
<td>assessment by wound radiologist who have expertise in looking at wound ultrasounds</td>
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<tr>
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<td>o presence of hypoechoic lesions in subcutaneous fat and/or deep muscle</td>
<td>Of the 8 pts with SDTI: • 100% had disruption of the epidermal dermal interface • 5 had all three abnormalities • 3 had only two findings</td>
<td></td>
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<tr>
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<td></td>
<td>• 3 pts had two abnormalities • 0 pts had all three abnormalities</td>
<td>Conclusion: Category/stage II and II ulcers have a deeper extent of injury on US examination than on clinical examination</td>
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</tbody>
</table>

**Patient Characteristics:**
- 8 had Category/Stage I
- 4 had Category/Stage II pressure injuries
- 8 had SDTI

- 3 pts had two abnormalities
- 0 pts had all three abnormalities

- Of the 8 pts with SDTI:
  - 100% had disruption of the epidermal dermal interface
  - 5 had all three abnormalities
  - 3 had only two findings

**Conclusion:** Category/stage II and II ulcers have a deeper extent of injury on US examination than on clinical examination.
Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals

Table 1: Level of Evidence for Intervention Studies

<table>
<thead>
<tr>
<th>Level</th>
<th>Study Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Experimental Designs</td>
</tr>
<tr>
<td></td>
<td>• Randomized trial</td>
</tr>
<tr>
<td>Level 2</td>
<td>Quasi-experimental design</td>
</tr>
<tr>
<td></td>
<td>• Prospectively controlled study design</td>
</tr>
<tr>
<td></td>
<td>• Pre-test post-test or historic/retrospective control group study</td>
</tr>
<tr>
<td>Level 3</td>
<td>Observational-analytical design</td>
</tr>
<tr>
<td></td>
<td>• Cohort study with or without control group</td>
</tr>
<tr>
<td></td>
<td>• Case-controlled study</td>
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<tr>
<td>Level 4</td>
<td>Observational-descriptive studies (no control)</td>
</tr>
<tr>
<td></td>
<td>• Observational study with no control group</td>
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<tr>
<td></td>
<td>• Cross-sectional study</td>
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<td></td>
<td>• Case series (n=10+)</td>
</tr>
<tr>
<td>Level 5</td>
<td>Indirect evidence</td>
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</tbody>
</table>

Table 2: Levels of evidence for diagnostic studies in the EPUAP-NPUAP-PPPIA guideline update

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Individual high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding among consecutive persons.</td>
</tr>
<tr>
<td>Level 2</td>
<td>Non-consecutive studies or studies without consistently applied reference standards.</td>
</tr>
<tr>
<td>Level 3</td>
<td>Case-control studies or poor or non-independent reference standard.</td>
</tr>
<tr>
<td>Level 4</td>
<td>Mechanism-based reasoning, study of diagnostic yield (no reference standard). Low and moderate quality cross sectional studies.</td>
</tr>
</tbody>
</table>

Table 3: Levels of evidence for prognostic studies in the EPUAP-NPUAP-PPPIA guideline update

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>A prospective cohort study.</td>
</tr>
<tr>
<td>Level 2</td>
<td>Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.</td>
</tr>
<tr>
<td>Level 3</td>
<td>Case-series or case-control studies, or low quality prognostic cohort study, or retrospective cohort study.</td>
</tr>
</tbody>
</table>

APPRAISAL FOR STUDIES PROVIDING DIRECT EVIDENCE (i.e. ELIGIBLE FOR SUPPORTING AN EVIDENCE-BASED RECOMMENDATIONS)

Each criteria on the critical appraisal forms was assessed as being fully met (Y), partially met or uncertain (U), not met/not reported/unclear (N), or not applicable (NA). Studies were generally described as high, moderate, or low quality using the following criteria:

• High quality studies: fully met at least 80% of applicable criteria
• Moderate quality studies: fully met at least 70% of applicable criteria
• Low quality studies: did not fully meet at least 70% of applicable criteria
### Assessment of Pressure Injuries and Monitoring of Healing: data extraction and appraisals

#### CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Focussed question</th>
<th>Sampling method</th>
<th>Representative sample</th>
<th>States number invited participants</th>
<th>Clear outcome measures</th>
<th>Valid reliable outcome measurement</th>
<th>Comparable results for multiple sites</th>
<th>Confounders identified and accounted for</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>6697</td>
<td>Palese et al., 2015</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>4</td>
<td>high</td>
</tr>
<tr>
<td>7940</td>
<td>Langemo et al., 2015</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N/A</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>indirect</td>
<td>moderate</td>
</tr>
</tbody>
</table>

#### RCTS

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Focussed question</th>
<th>Assignment randomised</th>
<th>Adequate concealment method</th>
<th>Subjects and investigators blinded</th>
<th>Groups comparable at commencement</th>
<th>Only difference btw groups was treatment</th>
<th>Valid, reliable outcome measure</th>
<th>% drop out in study arms is reported and acceptable</th>
<th>Intention to treat analysis</th>
<th>Comparable results for multiple sites</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>13368</td>
<td>Banks et al., 2016</td>
<td>Y</td>
<td>U</td>
<td>U</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N/A</td>
<td>N</td>
<td>1</td>
<td>Low</td>
<td></td>
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References


Brown, G. (2000). Reporting outcomes for stage IV pressure ulcer healing: A proposal. *Advances in Skin & Wound Care, 13*(6), 277-283


