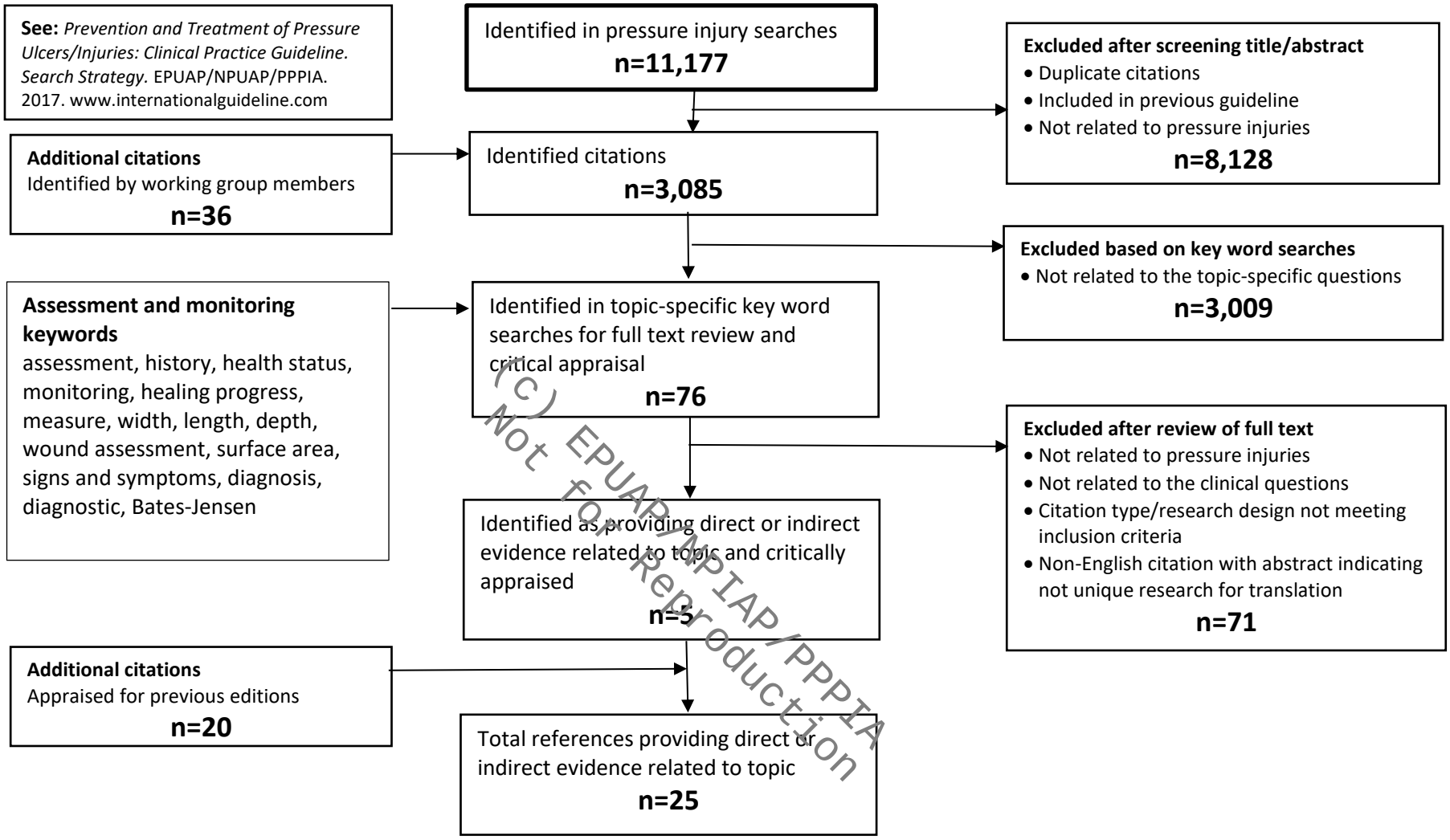
Search results for 2019 International Pressure Injury Guideline: Pressure injury assessment and monitoring



European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA; 2019

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 resources and are not for reproduction.

European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA; 2019

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Factors influencing wound healing							
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 ○ LxW (scored 0 to 10) ○ Exudate amount (scored 0 to 3) ○ Tissue type (scored 0 to 4)	**Baseline PU conditions** • Average size 1 to 3 cm^2 • 44.8% had slight exudate • 64.8% granulation tissue • Average PUSH score 8.04 (95% CI 7.79 to8.4) **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 are < 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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		60.4% had ≥ two comorbidities, 21.9% had diabetes					
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 Inclusion criteria • Age >65 years • Stage 2,3 or 4 PI present on admission • Race & Ethnicity defined by MDS classifications American Indian and Native Alaskan (AIAN), Asian and pacific islander (API), black non-Hispanic (Black), white on-Hispanic (White) and Hispanic Exclusion criteria • Not stated	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 disadvantaging 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 entires • Unmeasured NH effects controlled for during modeling by ensuring racial/ ethnic minority groups were in same NHs as Whites whose modeling coefficients were applied	**Level of evidence: 3 (prognostic)** **Quality: high**
Pressure injury measurement strategies							
Gabison, McGilliv ray, Hitzig, & Nussba um, 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	Participants were recruited in a rehabilitation center in Canada (n = 22, n=20 analyzed) Inclusion criteria: • Aged over 18 years • SCI • Category/Stage II or higher pressure injury • received inpatient care for three consecutive weeks. Exclusion criteria: • not stated	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 (<2.5cm^2, $p<0.0001$)) and larger (>2.5cm^2, $p=0.0044$) 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.	**Level of evidence: 4** **Quality: low**

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	patient care and research	Participant characteristics: • Mean age 54 years Wounds present for a mean of 29.7 weeks (2 – 312)			**Conclusion: The two methods are not in agreement on measured wound but are in agreement on the important parameter of healing rate.**	• The removal of 4 outlier values could possibly affect the results	
Bilgin & Güneş, 2013	Examine the levels of agreement among 3 techniques used in wound measurement comparing more spherical versus irregularly shaped wounds	Participants recruited from CV, neurology, neurosurgery in University hospital in Turkey (n=65 with n= 80 pressure ulcers) 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	N/A	• All wounds cleansed and measured using the 3 techniques by the same investigator. This was performed 3 x for each wound. • Ruler method: sterilized paper ruler, measured widest and longest calculated in square dimensions • Wound tracing method: Transparency placed directly over the ulcer and wound margins traced with an indelible pen • Digital Planimetry method: measured with digital planimetry, calculates the area of a wound based on wound tracing	• 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**
Arora et al., 2017	to determine reliability of measuring wound undermining in those with spinal cord injury	30 people with complete or incomplete SCI Inclusion: undermining pressure ulcer	N/A	• Undermining measured using four points from a clock face(12,3,6, 9 with 12 o'clock defined as the head). • Inter-rater reliability tested by comparing undermining scores from 2 assessors. • Intra-rater reliability was tested by comparing scores	**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 **Intrarater reliability** ICC =0.998 (0.996-0.999).	• Studies on reliability of measuring undermining are limited • This contributes to the reliability of this measurement	**Level of evidence: 4** **Quality: low**

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				from same assessor on 2 different days.	Repeat measurements by the same assessor were within 0.3cm of each other, 80% of the time		
Langemo, Spahn, Spahn, & Chowdry Pinnamaneni, 2015	Observational study of retrospective wound photos to explore precision of wound measurement using the Scout device	Participants recruited at in and outpatient centers (n=40) Inclusion: • Aged over 18 years and consenting • Mixed etiology wounds Exclusion: • Obscured wound edges • Blurred images • Images taken not at 18inch distance or not perpendicular to external wound Clinicians (n=5) Characteristics: • 60% wound care experts • 40% previous experience with Scout device, but not wound care experts • All staff received training prior to product use.	N/A	• LxW measure using a ruler • Wounds measured using Scout ImageCapture and Scout ImageReview ○ Scout L X W measure ○ Scout trace area ○ Scout perimeter trace • Camera is a non-contact longwave infrared camera that captures thermal images • Software allows measurement of diameter, surface area (SA), wound perimeter and thermal intensity. • All wounds were measured once • Each reader made 3 replicate measures of each wound using the Scout outcome measures	**Interrater reliability of Scout measures** Average coefficient of variation was < 20% for all wound measurement strategies, with Scout trace perimeter having the high reliability **Intrarater reliability of Scout measures** Average coefficient of variation was < 10% for all wound measurement strategies, with Scout trace perimeter having the high reliability	• Unable to compare Scout measures to ruler measures due to patient discomfort and contamination concerns with repeated measures • Selection of participants is not reported • Wounds with obscured edges not included • No discussion of reliability in evaluating undermining/ tunneling	**Indirect evidence: Mixed etiology wounds** **Quality: moderate**
Veredas, Mesa, & Morente, 2015	Laboratory modeling description of a computer-visual approach to identifying and categorizing wound beds	For development and testing: 322 PU photographic images from 69 patients	N/A	• Photographs of PUs were taken in optimal conditions (i.e. well lit, correct distance, high quality tools) • 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.	• The software was developed to reduce "noise" (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) • Two models were tested – a histogram model and a Gaussian-mixture based model	• The same photographs used to develop the visualization algorithm were used to test the program • The computer visualization program was	**Indirect evidence: computation-al modelling**

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				pigmented, necrosis, slough etc.)	**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	
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 cm^2 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.	• Areas determined from all methodologies were very similar (coefficient > 0.94, p= 0 .01) • Photographs and tracing slightly over-estimated the ulcer area when compared to area obtained by computer-assisted planimetry (mean difference about 1.5 cm^2) • There was good agreement between volumes calculated from measurements and determined by impression (*r*=.892). Impression volumes tended to yield smaller measurements especially in larger than 10 cm^3 wounds. • tendency for impression volume to over predict calculated volumes in smaller wounds less than 10 cm^3	• Area calculated from the dimension measurements assumed all ulcers were elliptical in shape. • No attempt was made to base area calculation on any other shaped differentially. • Calculated off photographs	**Level 4, low quality**
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,	**Indirect evidence (not**

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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 and intrarater reliability established by four nurses tracing the wounds using the VISTRAK wound measurement system • One assessor carried out the tracing, then the traced wound area weas 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-o.75). • There was a significant strong positive correlation between the two wound measuring area technique s(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**

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{Haghpanah, 2006 #206}	investigated the reliability of the Visitrak™ system	40 different pressure ulcers	N/A	• Four nurses used the system to perform wound tracings on ten pressure ulcers for investigation into the reliability • electronic method of wound tracing 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.	• The electronic tracing system was found to be more reliable in repeated measures than linear measurement		**Level 4**
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**

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			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 escher	• To analyze wound healing curves; individual healing curve examined.			
van Rijswijk & Polansky, 1994	Secondary analysis	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.	N/A	• The relationship between outcome (time to healing deep pressure ulcer) and the covariates were assessed (patient and wound characteristics). • Several analysis methods developed and used on secondary data: • Area reduction calculated as reduction in area % from baseline, controlled by baseline area. • Median time to healing calculated for all patients combined and as a function of each patient and ulcer characteristics at baseline and after two weeks of treatment. • A stepwise Cox proportional hazards' model for prognosis	**Kaplan-Meier time until 100 % healing time curve** • 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.		**Level of evidence: 4** **Quality: low**

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				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.	• Age, nutritional status and percent reduction in area were all independently predictive of time to healing after two weeks of treatment		
Other characteristics assessed in pressure injuries							
Tavern a, 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)**

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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	
Pressure injury assessment tools							
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 discharge from the service using the PUSH tool • At discharge the assessing nurse categorized the	• PUSH tool • Nurse judgement score •	**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 –9.78 to –6.50, 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	**Indirect evidence (mixed wound types, PU only 2% of wounds)**

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	chronic and acute wounds	skin tear, surgical wound, traumatic wound) Exclusion: Arterial ulcer, malignant wounds Participant characteristics: • Mean age 57.7 years (SD 18.5) • 42.1% female • Mean time in program 41.7 days (SD 44.7) • 2% PUs, 15.5% VLUs, 3.1% neuropathic ulcers, 79.3% acute wound types	wound as healed, improved but not healed or wound static or worsened (judgement)		• In wounds classified as improved but not healed: change coefficient –5.42, 95% CI –5.99 to –4.84, p<0.001 • In pressure ulcers: change coefficient –1.66, 95% CI –3.68 to0.36, p=0.107 • Age p=0.025 • Gender not significant **Author conclusions: the PUSH tool can help nurses who are not specialized in wound care to measure different wound types**	use of the 3-point rating system. • No measure of interrater or intrarater reliability of the tool.	
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: **Participant characteristics:** • Median length of stay 14 days (range 1 to 70) • Mean age approx. 62-65 years • Approx. 20% had BMI <20kg/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	• 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) • Data collected by research nurse on baseline and days 5,10,15,22 and 29 and then weekly until discharge	**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	• 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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		Approx. 45% PUs were Category/Stage 2	yweight/day plus 30kcal/kg body weight/day plus enrichment with arginine, vitamin C and zinc (n=25 randomized, n=14 analyzed)				
Thomason 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	• SCI-PUMT kit designed to increase use of the Spinal Cord Impairment Pressure Ulcer Monitoring Tool (SCI-PUMT) in SCI facilities • Kit includes: ○ 4 video presentations ○ A training flyer ○ The SCI-PUMT ○ Staff knowledge and competency tests ○ Two training mainkans ○ Guides to using SCI-PUMPT ○ Healing continuum graphs ○ Facility implementation plan	• Staff engagement in SCI-PUMT education (number of tool kit downloads from website) • Facilitators and barriers (comments from clinical champions) • Knowledge levels (pre/post test knowledge conducted at a conference) using a previously validated knowledge tool with 10 questions •	**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)**

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			○ 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		**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		
Wound color measurement							
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) Inclusion criteria: • All pts who had one full-thickness pressure ulcer	N/A	• 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	• 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**

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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%)		○ D1 = persistent redness ○ D2 = dermal wounds ○ D3= wounds extending to subcutaneous tissue ○ D4= wounds extending to muscle tissue ○ D5 = wounds extending to bone ○ 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							
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**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Patient Characteristics: 8 had Category/Stage I, 4 had Category/Stage II pressure injuries and 8 had SDTI		○ deep tissue injury – loss of dermo epidermal interface ○ presence of hypoechoic lesions in subcutaneous fat and/or deep muscle •	• 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 by wound radiologist who have expertise in looking at wound ultrasounds •	

Table 1: Level of Evidence for Intervention Studies

Level 1	**Experimental Designs** • Randomized trial
Level 2	**Quasi-experimental design** • Prospectively controlled study design • Pre-test post-test or historic/retrospective control group study
Level 3	**Observational-analytical designs** • Cohort study with or without control group • Case-controlled study
Level 4	**Observational-descriptive studies (no control)** • Observational study with no control group • Cross-sectional study • Case series (n=10+)
Level 5	**Indirect evidence**: studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models

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

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

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

Level 1	A prospective cohort study.
Level 2	Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.
Level 3	Case-series or case-control studies, or low quality prognostic cohort study, or retrospective cohort study.

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

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL

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

RCTS

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

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