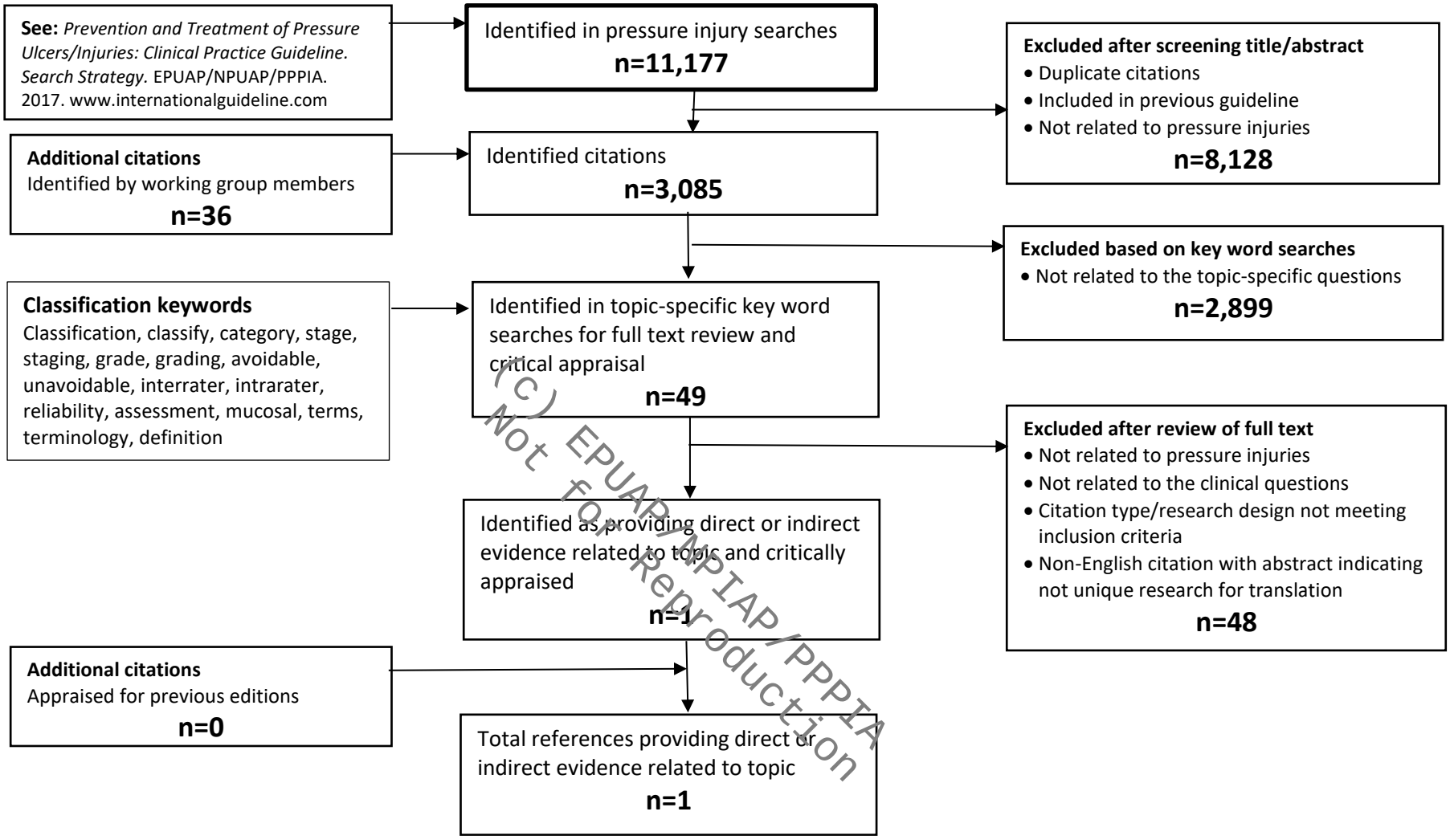
Classification of Pressure Injuries: data extraction and appraisals

Search results for 2019 International Pressure Injury Guideline: Classification



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.

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Avoidable vs unavoidable PU							
Baker et al., 2016	Observational study **exploring whether Stage 3,4 and unstageable PUs can occur despite good quality care**	Convenience sample of participants recruited from 7 US nursing homes deemed to provide good quality care (n=20) Inclusion criteria: • Aged > 65 years • Had a facility acquired stage 3,4 or unstageable PU within the preceding 12 months • Deemed by expert panel to have received expert care Exclusion criteria: • Deemed to not have received expert care • Hospitalization or death	• Participants were only recruited from facilities ranked in the top 1/3 of US centers based on CMMSQI • Participants had their care rated by an expert panel to determine if it met the criteria of consistent good quality care • Facilities were audited to ensure there was quality skin check procedures in place and appropriate care was observed	• Demographic data • History of PU development	**Characteristics of individuals developing advanced stage PU despite best quality care** • 65% male • 90% Caucasian • 100% used a mobility aid • 50% ≥ 1 fall in preceding 6 mths • 90% urinary incontinence • 75% fecal incontinence • 85% dementia • 60% depression • 100% had ≥ 1 cardiovascular symptom • 20% diabetes • 90% current or recent diagnosed infection requiring antibiotics **Characteristics of advanced stage PU** • 25% sacral or coccyx, 35% heel • 55% < 4cm^2 • 85% no undermining • 80% no swelling or edema of peripheral tissue • 95% no induration • 80% small or no exudate	• No comparator group • No statistical analysis (e.g. logistic regression) • Potential sampling bias • Small sample size	
Pittman et al., 2016	Retrospective cross-sectional study **to test a tool to distinguish**	31 patient records in 3 major US hospitals Inclusion:	• Psychometric evaluation of the Indiana University Health Pressure Ulcer	• PUPI scale implemented through a retrospective record analysis	**PU status using PUPI tool** • 39% PUs deemed to be unavoidable • Characteristics of patients with HAPU assessed as unavoidable: ○ 83% had LOS> 5 days	• Small sample size and small number of repeated measures	**Level of evidence: 4 (diagnostic)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	avoidable versus unavoidable PU	• HAPU presented with in hospital Exclusion: • None stated Characteristics: • Mean age 58 years (SD 18.5) • Mean length stay (LOS) 12 days (SD6.9) • Mean BMI 28 (SD 6.7) • 68% men • 84% white skin • 39% smokers	Prevention Inventory (PUPI) • Tool was based on NPUAP definition of unavoidable PU and the Braden conceptual scale of PU prevention • Tool assessed whether: ○ PU risk assessment conducted (using the Braden scale, history and physical examination and skin assessment and repeated daily or every shift) ○ Whether appropriate interventions had been implemented to address sensory perception, moisture, activity, mobility, nutrition, friction and shear ○ Whether interventions were evaluated with a skin assessment each shift and revised as required • Tool examines care from the day HAPU occurred and for 3 days prior	• Braden scale also implemented base don retrospective records	○ 58% in critical care ○ 58% fecal incontinence ○ 50% ventilated ○ 42% chemically sedated ○ 42% febrile, 42% hemoglobin <7mg/dl, 42% cancer, 42% nil by mouth ○ 25% procedure length > 4 hrs ○ 21% taking pressor agents **Content validity index** High proportion of experts (n=10) agreed with overall tool (CVI=0.99) and with individual items on scale (CVI ranged from 0.9 to 1.0) with no significant difference sin opinion between wound experts and generalist experts **Construct validity** No significant difference in Braden scale scores between people who did or did not develop a PU based except for mobility on the day immediately before a PU developed (p<0.001) **Interrater reliability** (n=5 patients and n=2 raters) Excellent level of inter-rater reliability (Cohen κ = 1.0, p=0.025) with raters agreeing on 93% of individual iems **Author conclusions: The tool had acceptable psychometric properties and the only risk factor with significant difference between avoidable and unavoidable PU was mobility on the day prior to the HAPU.**	• Selection of participants is poorly reported (? consecutive) • Overall status of patients is unclear (e.g. medical, surgical, diagnoses) so it is unclear how representative they are. Low mean age and length of stay compared with populations susceptible to PU • Based on documentation rather than clinical evaluation • Tool requires specific PU risk assessment tool to be used, which limits its generalisability to other sites	**Quality: Low**
Strategies to promote accurate PU classification							
Barnard &	Observational study testing use of an aid for	Tissue viability nurses in the UK (n=20)	• Participants were provided with 15 PU	• Accurate classification/diagnosis of PU	**Pre-intervention** • Accurate diagnosis/classification without visual aid was 70-80%	• No information on recruitment strategy for participants	**Level of evidence: 4**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Copson, 2016	classifying pressure injuries	Characteristics: No characteristics (e.g. education level ,experience with PU) were provided for participants	and 5 moisture lesion images • Participants classified the ulcers/lesions without an aid • Participants repeated the classification using the PUG wheel – a visual aid for pressure ulcer classification	• Change in PU incidence or prevalence (not reported clearly)	• PU incidence was 4-14 Stage 2 PUs/month and 1-5 stage 3 PU prior to the introduction of the visual aid **Post-intervention** • Accurate diagnosis/classification without visual aid was 100% • PU incidence was 3-13 Stage 2 PUs and 2-3 stage 3 PUs after the introduction of the visual aid **Author conclusions: The author asserts that introduction of the visual aid led to more accurate diagnosis and classification and greater awareness, leading to decrease in PUs.**	• Unclear if the same images were used for both tests and the amount of time between images • No formal inter/intra rater reliability was conducted • Unclear if this resource would be accurate to classify real wounds versus images • No methods for determining incidence/prevalence are reported • Assertion that the tool raised awareness, leading to decreased incidence is not supported by the methods and results	**(diagnostic)** **Quality: Low**
Dowsett, Swan, & Orig, 2013	Observational case series study investigating use of a using a monofilament fibre pad to aide accurate categorization of pressure injuries	• Participants recruited (n=13) Inclusion and exclusion criteria: Not reported • Participant characteristics: • Various pressure injury location (e.g. Chest, Hip and Penis etc) were identified	• Mechanical debridement with monofilament fiber pad • Pressure ulcer at various location were debrided with the monofilament fibre pad (Debrisoft, Activa Health Care)	• Data on anatomical location, estimated Category/Stage prior to debridement • Actual Category/Stage following debridement • Time to debride the wound • Digital camera image or the Eykona Wound Measurement	**Classification** (8/13) or 61.5% of cases were re-categorized as grade 2 after debridement **Time to use device** No more than 4 minutes of debridement with monofilament fibre pad were required to reveal the wound bed The use of the monofilament fiber pad in the debridement of pressure injuries allow clinician to clearly view the wound bed (correct categorization) and therefore appropriate treatment can be provided.	• A one-off debridement with monofilament fibre pad on wound containing thick, tenacious slough is unlikely to completely remove. • A number of consecutive treatments with the monofilament fibre pad may be necessary. • Very small study • Inter rater reliability not established	**Level of Evidence: 4** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
				System 3D imaging system			
Characteristics of different ulcer types							
Zaratkiewicz, Whitney, Baker, & Lowe, 2015	Retrospective cohort study exploring prognosis of unstageable PUs	Records for a 3.5 year period for all HAPUs classified as unstageable were reviewed in one trauma/burn center in US (n=unknown number patients, n=194 ulcers, n=120 excluded) Exclusion criteria: • Missing data (n=5) • Wound incorrectly categorized as a PU and later changed to a different etiology (n=7) • Wound base obscured by slough or eschar at discharge/completion of nursing note entries (n=108)	• Not applicable	• Healing trajectory was reviewed and unstageable wounds were categorized as having a "full thickness trajectory" or "partial thickness trajectory" based on nursing notes • Nursing notes completed weekly	**Characteristics of HAPUs included** • 33.78% of PUs were categorized as partial thickness • 66.21% of PUs were categorized as full thickness • Of wound that were classified as partial thickness trajectory, 34% had eschar when unstageable, 65% had slough and 1% had both • There was no significant difference in time from admission to development of an unstageable HAPU based on healing trajectory (mean 18.9±11 days for full thickness vs 15.8±11 days for partial thickness, p=0.26) • There was no significant difference in healing trajectories based on gender (p=0.78) or ethnicity (p=0.12) **The author concludes that not all PUs classified as unstageable have full tissue loss**	• Record review relied on database records • Large number of cases excluded • One facility, may be bias in the use of the unstageable terminology • No definition given of "full thickness trajectory" or "partial thickness trajectory" • No consideration of role of infection in wound trajectory • No clear indication of length of time from classification as unstageable until removal of eschar/slough	**Level of evidence: 3 (prognostic)** **Quality: Low**

Indirect evidence

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Wound assessment (Classification)							
Ham, Schoonhoven, Schuurmans, Veugelers, &	Pre/post observational study investigating **skills in PU classification of**	Convenience sample of all registered nurses and physicians in one emergency department in The Netherlands (n=54) Inclusion:	• Education intervention to improve ability to identify and classify normal skin, erythema and Pus in Category/Stage 1 to 4 • Participants completed identification and	• Identification (PU or not PU) • Classification (EPUAP PU classification scale)	**Interrater reliability for identification** Pre-education(10 photos): κ=0.63 Post-education: 10 photos κ=0.83, 20 photos κ=0.82	• No demonstration of sustained influence of the education program (excluded from *Health Professional Education* section)	**Indirect evidence: PU not an outcome measure** **Quality:**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Leenen, 2015	**health professionals**	• RN/physician in ED Characteristics: • 75.9% nurses, 24.1% physicians • Mean years' experience in health care: 20 (nurses) and 3.3 (physicians)	classification using PUCLAS2: ○ Pre-education 10 photos ○ Post education (45 mins after pre-test) 20 photos (10 from original set included)		**Interrater reliability for classification** Pre-education(10 photos): κ=0.43 Post-education: 10 photos κ=0.67, 20 photos κ=0.58	• No consideration to professional status, previous education and experience • Potential contamination between participants • Photos may not have been clear enough for reliable appraisal • Photos only included Caucasian skin types	**high**
Tschannen, McKay, & Steven, 2016	Quasi-experiment **investigating effect of intense training in PU staging on identification of PU stages**	Convenience sample of nursing students in a foundational class attending two universities (n=180 enrolled, 158 participated) Inclusion criteria: Attending the university course Participant characteristics: None reported	• All participants received 2 hours of education on skin integrity, PU prevention, risk factors, staging and wound healing • Control group received only the standard lecture (n=103) • Participants were assigned or volunteered for the intervention group that received Pressure Ulcer Active Learning Intervention (n=55) • Intervention included participation in a Skin Day at local hospital that included skin assessment on every patient, 4 modules on PU staging, wound types, surveying and HAPUs,	• Completion of a photo PU staging tool that consisted of 29 questions • Staging questionnaire was trialed on 3 WOCNs for content accuracy	**PU staging results** • Average score on tool was 64% (SD 15.3%, range 14 to 93%) • The intervention group scored higher in identifying every Category/Stage and significantly better overall (69.47% versus 60.29%, p<0.0001) • The results were significantly better in intervention group for: ○ Stage II PU (68.36% versus 52.62%, p=0.001) ○ SDTI (77.09% versus60%, p=0.006) **Author conclusions: Overall accuracy remained lowed, although significantly improved, following an intense training session for PU staging.**	• No participant characteristics reported • No randomization or blinding • Relied on photographs for the knowledge test • No reliability testing of evaluation tool • Unclear if students in control group could have been exposed to intervention • Intervention group students were volunteers who may have had higher knowledge and/or motivation	**Indirect evidence: PU not an outcome measure** **Quality: low**
Terminology							
Ayello, Cordero, &	Consensus voting study **exploring agreement with**	Convenience sample of attendees at a Mexican wound conference (n= ? invited, n=60		Participants responded to an 11-item survey asking yes/no/no response on	• Latin American respondents agreed to all definitions with rates at > 82%	• Characteristics of respondents is unknown – their	**Indirect evidence: consensus**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Sibbald, 2017	**new NPUAP terms**	responded) and students in a wound course in Canada (n=79 invited, n=68 responded)		agreement with definitions and descriptions of stages	• Canadian respondents agreed with definitions at rates > 85%	education level, background and nationality might influence results • Individuals agreeing to definitions may be more likely to self-select to participate	**opinion study, but may be relevant to the chapter**
Garcia-Fernandez et al., 2016	Consensus panel discussion				• The Spanish Pressure Ulcer and Chronic Wounds Advisory Panel proposal includes wounds classified by etiology (pressure and shear; moisture; friction or grazing and several factors) • The Panel proposes pressure lesions be categorized as Category I Non-blanchable erythema; Category II partial thickness ulcer; Category III full thickness skin loss; Category IV full thickness tissue loss; and Deep tissue lesion. • Full definitions for each category are presented in the paper.	•	**Indirect evidence: this is a discussion paper, but may be relevant to the chapter**
Edsberg et al., 2016	Consensus voting study **exploring agreement with new NPUAP terms**	A literature review was used to unpin the revision of the PU staging system	Validation by an interdisciplinary consensus meeting in the US (n=400 attendees) After agreement on PU Staging definitions, participants viewed photos and classified the wounds		• Agreement for photos using the staging system ranged from 92% to 95% for non PUs	• No references used in staging system despite it being based on the literature • Consensus participants were likely to have higher levels of knowledge in the field so provide more valid feedback •	**Indirect evidence: this is a discussion paper, but may be relevant to the chapter**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Tew et al., 2014	Systematic literature review **identifying uses of terminology to describe PUs**	Database search identified 22 references referring to "PU recurrence", "recidivism" and "healed"			• Progression of healing model indicated that: • Open PU incorporated inflammation and proliferation stages • Closed PU indicated remodeling phase • Healed PU and mature resolved PU refer to remodeling phase • Recurrent or reopening refer to return to Inflammation or proliferation phase	• No consensus process, based on comprehensive literature review	**Indirect evidence: this is a discussion paper, but may be relevant to the chapter**
Skin failure							
Delmore, Cox, Rolnitzky, Chu, & Stolfi, 2015	Retrospective case-control study **exploring predictive factors for acute skin failure (ASF) and differentiating from PUs**	Cases were identified from review of admissions at two US hospitals in a two year period (validation set 102 participants of which 34 with PU; main analysis 450 participants of which 150 had PU) Patients with PUs were purposively selected and control patients without PUs were selected randomly. Inclusion criteria: • Aged ≥ 18 years • admitted into the critical care for at least 3-day ICU stay Exclusion criteria: • preexisting PU • lack of PU prevention measures without justification for non-adherence • actively dying/end of life Participant characteristics:	• N/A	• Variables considered in modeling: ○ Impaired nutrition (BMI < 18.5 kg/m^2, C-reactive protein > 10mg/dL, unintentional weight loss before admission) ○ respiratory failure, renal failure, cardiac failure, and/or liver failure ○ limited tissue perfusion (MI, severe anemia, vasopressor use resulting in peripheral necrosis, PAD, cardiac arrest) ○ sepsis ○ diabetes ○ immobility ○ surgery > 3 hrs duration ○ hypotension > 48 hrs	Regression analysis to determine significant and independent predictors of acute skin failure • Peripheral arterial disease(PAD) odds ratio (OR) 3.8, 95% CI 1.64, to 8.66, p=0.002 • mechanical ventilation > 72 hrs OR 3.0, 95% CI 1.78 to 5.05, p<0.001 • respiratory failure OR 3.2, 95% CI 1.82 to 5.40, p<0.001 • liver failure OR 2.9, 95% CI 1.05 to 8.08, p=0.04 • severe sepsis OR 1.9, 95% CI 1.14 to 3.20, p=0.02 Area under curve (AUC) 0.793 indicating good predictive accuracy **Study conclusion: PAD, mechanical ventilation greater than 72 hours, respiratory failure, liver failure, and severe sepsis/septic shock emerged as significant independent predictors of ASF. Consideration for the diagnosis ASF must also**	• A 3-day length of stay was chosen, as time frame considered adequate to detect development of a new PU • Retrospective design relying on records	**Level of evidence: 4 (prognostic)** **Quality: Moderate** **Primary SWG: Critical care**

		• Mean agew 71 years (SD 15.6) • Mean ICU stay 9.8 days • Mean Braden score 14 (SD 3.5) • Most PUs were SDTI, most commonly on sacrum and majority occurred in first 7 days in ICU		○ vasopressors used in ICU ○ mechanical ventilation > 72 hrs ○ baseline variables including age, race, gender, diagnosis, Braden score, APCHE score	**take into account the presence of current PU prevention/ intervention strategies as ASF cannot be accurately distinguished from a PU if the current standard of PU prevention has not been maintained. Failure to accurately distinguish clinical factors that lead to a PU from factors that can result in ASF can result in financial/ legal consequences.**		

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
16192	Barnard & Copson, 2016	Y	N	U	Y	N	N	NA	N	N	N	4 (diagnostic)	low
13678	Baker et al., 2016	Y	U	U	Y	Y	Y	U	N	U	U	4	Low
1886	Dowsett et al., 2013	N	U	N	U	U	Y	N	N	N	N	4	Low

COHORT STUDIES

	Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Level of evidence	Quality
13830	Zaratkiewicz et al., 2015	Y	NA	N	NA	NA	NA	N	U	U	U	N	N	Y	U	3 (prognosis)	Low

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