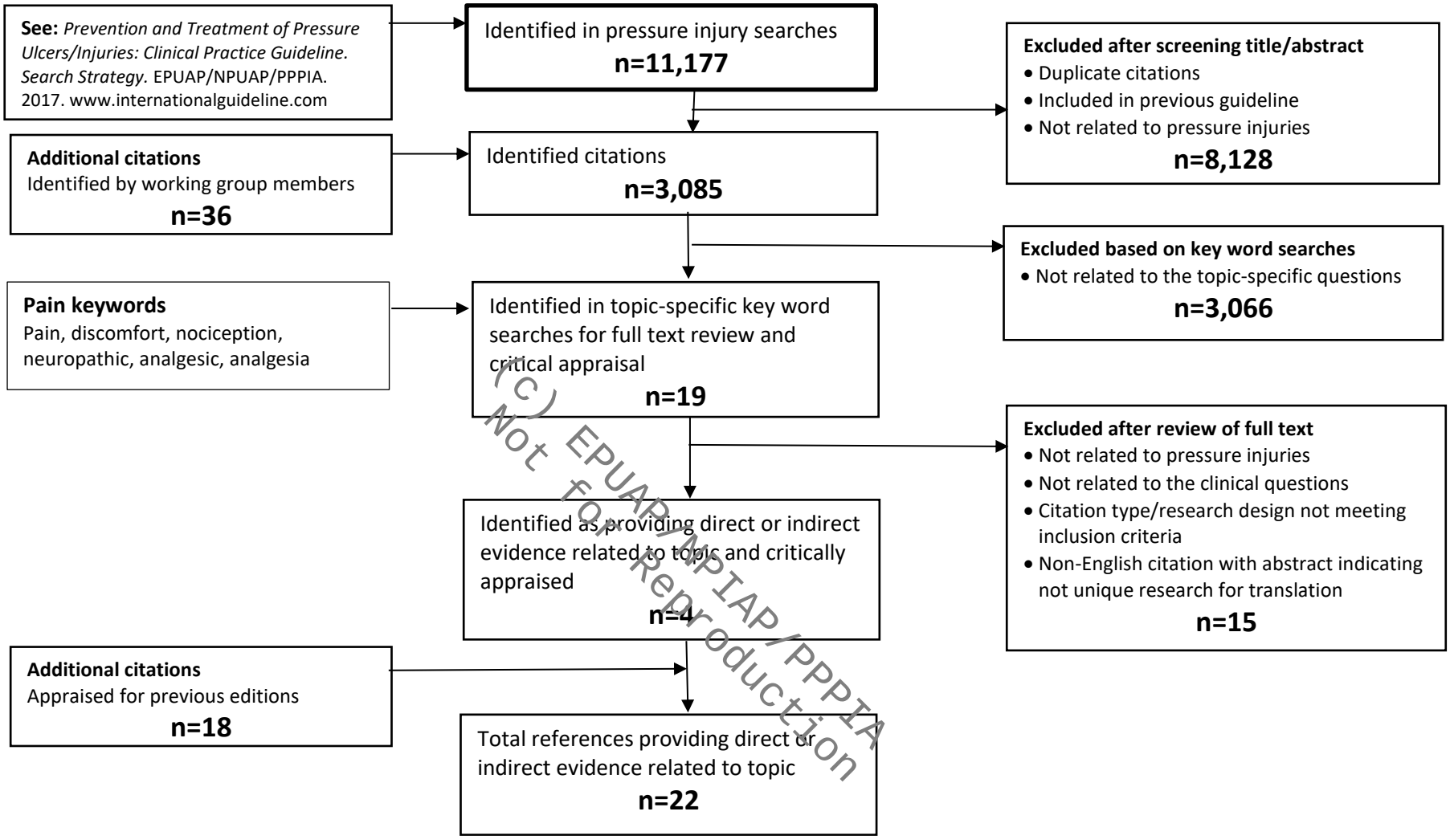
Search results for 2019 International Pressure Injury Guideline: Pressure injury pain



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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	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Clinical question 1: What are accurate and effective methods to assess pressure injury pain?							
Kelly, Bender, Harris, & Casarett, 2014	Retrospective cohort study reporting **factors that are associated with pain being controlled within 48 hours of admission to end-of-life care**	Participants were recruited through a retrospective review of 1 year of electronic health records from 10 hospices in US (n= 4,157 eligible) Inclusion criteria: • Adult • Pain that made participant uncomfortable but pain was controlled within 48 hours Exclusion criteria: • unable to respond to questions about pain • no documentation in EHR Participant characteristics: • Mean age 75 years (range 65 to 87) • 54.5% female • Primarily white • Primarily at home • 97.8% had no pressure injury or a Stage 1 pressure injury	No interventions	• The outcomes measure are #0209 score • Demographics and clinical characteristics • To identify characteristics independently associated with #0209 scores, the research used univariate and multivariate regression models, • At least moderate level of significance ($p<0.25$) was considered sufficient for inclusion in models • Staging system used 1998 EPUAP classification over 13 anatomical sites	**Characteristic associated with pain control within 48 hours of admission** • Presences of Category/Stage II pressure injury was independently associated with worse pain control (odds ratio [OR] 0.63; 95% confidence interval [CI] 0.31 to 0.96, p= 0.012) • Factors associated with better pain control included: ○ Older patient (OR 1.02, 95% CI 1.02 to 1.03, p=0.003) ○ Patients admitted to an inpatient hospice unit (OR 1.28; 95% CI 1.08 to 1.47, p= 0.031) ○ Patient with diagnosis of cancer (OR 1.37; 95% CI 1.20 to 1.53; p= 0.008) ○ The presences of Foley catheter (OR 1.40; 95% CI 1.15 to 1.59, p=0.038) ○ Use of opioid medication at the time of hospice enrollment (OR 1.34; 95% CI 1.03 to 1.74, p=0.027) ○ Palliative performance scale (PPS) score (OR 1.02; 95% CI 1.01 to 1.03, p=0.000) **Author conclusions: Inpatient care may offer better opportunity to control end-of-life pain. There is limited relevance of this study to pressure injury care as most participants had no pressure injury**	• May not be applicable to all patients. • Other factors that influence management of pain were not considered	**Level of evidence: 3** **Quality: Low**

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Rutherford, Nixon, Brown, Briggs, & Horton, 2016	Prospective cohort study to **assess psychometric properties of the Leeds Assessment of neuropathic symptoms & signs (LANSS) for people with pressure injury- related pain**	Participants were recruited in nine acute and community hospitals in the UK (n=728) Inclusion criteria: • 18 years or older • Able to report pain • High risk of a pressure injury Exclusion criteria: • Pediatric, obstetric and psychiatric considered ethically or clinically inappropriate Participant characteristics: Mean age 76 years (SD 15.3) 59.1% females 97.1% White 80.6% had pressure injuries	**Assessment tool** • LANSS contains: 5 patient-reported symptoms • 2 clinical sensory items associated with neuropathic pain	• All three study areas tissue viability teams – site initiations pre-survey • Questions about whether pain is experienced and if the patient thinks the pain is related to pressure • Participants experiencing pain were there assessed with the LANSS • Pain assessed using a 0-10 numerical rating scale • Staging system used 1998 EPUAP classification over 13 anatomical sites	**LANSS assessments** 367 assessments conducted, 362 for torso skin and 361 limb skin (19 excluded as being healthy skin) **Validity** • Internal construct validity: inter-item correlations low to moderate (range 0.156 to 0.421) • Convergent validity: low correlation between LANSS and pain intensity visual analogue scale (VAS) (r= –0.21) (i.e. neuropathic pain is not related to pain intensity) • Discriminant validity: LANNS was not biased by age (r<0.3) **Author conclusions:** LANSS items largely measure the same construct across gender, age, setting and skin status but the tool was not supported as a valid measure of neuropathic pain. **LANNS is not suitable as a measure of pressure injury-related neuropathic pain.**	• Useful study to exclude this scale	**Level of evidence: 3** **Quality: Moderate**
Dallam et al., 1995 Same study reported in Freeman, Smyth, Dallam, & Jackson, 2001	Prospective cross-sectional study reporting **assessment/ diagnosis of pressure injury pain**	Participants were recruited in a tertiary med center over 12 months in the US (=132) Inclusion criteria**:** • Aged 18 years or greater • At least one Category/Stage I to IV pressure injury Participant characteristics: • 5% female • average age 71.4 years (range 24-100 • 66% white, 22% black, 11% Hispanic, 2% Asian • 68.9% had a sacral pressure injury, 24% buttock pressure injury,	Not applicable	• Folstein Mini-Mental Status Exam • Beck's Depression Inventory • Faces Pain Rating Scale (FRS) • Visual Analog Scale (VAS) • Tools have previously been reported to have good reliability & validity • Pain defined as "unpleasant sensory & emotional experience with actual or potential tissue damage."	**Pressure injury pain prevalence** • 41% denied pressure injury pain • 68% reported some degree of pain **Pan management** • 2.3% (3/132) had received analgesia for pressure injury pain in preceding 4 hours • 39.4% had received analgesia, narcotics, NSAIDs for other pain in the preceding 4 hours • 8.3% had received other medication that might manage pain (e.g. sedatives, psychotropics) in preceding 4 hours • People receiving analgesics for pressure injury pain had significantly more pain than people not receiving analgesics (p<0.05) **Factors influencing pain** • Maximum pain score was significantly correlated with:	People who could not verbally indicate pain were not included in the tool use (66.67% of participants)	**Level of evidence: 1 diagnostic** **Quality: High**

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		14.4% heel pressure injuries • 35% considered to be at risk of pressure injuries as per Braden scale		• Data collected at 3 month intervals, but most only 1 time total.	○ Age (r=-0.36, p<0.02) ○ FRS (r=0.92, p<0.01) **Pain assessment** • Pressure injury site pain correlated with: ○ generalized pain intensity on VAS (r=0.59, p<0.01) ○ generalized pain intensity on FRS (r=0.53, p<0.01) • Localized VAS significantly correlated with maximum Category/Stage of pressure injury (r=0.37, p<0.01) **Author conclusion: There is a high level of agreement between VAS and FRS for assessing pressure injury pain**		
Roth, Lowery, & Hamill, 2004	Prospective cross-sectional exploring use **of different pain assessment tools in people with wounds**	Participants were recruited in two veteran's centers in the US (n=69) Inclusion criteria: • Inpatient, outpatient or nursing home resident • Category/Stage II to IV pressure injuries or a tissue flap from a pressure injury repair or a diabetic ulcer • No cognitive impairment Exclusion criteria: • Cognitive impairment Participant characteristics: • Mean age 59 (range 2 to 83 years) • About half the participants had pressure injuries (n=39/69) • Average duration of wounds was 4.1 months	Patients followed for up to 6 visits. All patients queried on 1st visit re: wound pain, & if present, took series of pain & other questionnaires.	• McGill Pain Questionnaire (MPG) • Numeric Pain Rating Scale (NPRS) • Brief Symptom Inventory • Center for Epidemiologic Studies Depression Scale • Coping Strategies Questionnaire • NPUAP staging for pressure injuries	**Pain experience** • A greater percentage of people with Category/Stage III and IV pressure injuries had pain compared to people with other types of wounds (35.9% vs 16.7%, p=0.07) • Spinal cord injury status was not related to the experience of pain (p=0.59) • 28% had wound pain unrelated to dressing change **Pain assessment (n=19 people with pain participated)** • Total MPG score correlated with Global Severity Index (r=0.62, p<0.05) • Total MPQ score and NPRS score were not significantly different in people with Category/Stage III and IV pressure injuries	• Small sample • Correlational design - causal direction can be ascertained	**Level of evidence: 3 diagnostic** **Quality: Low**

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Essex, Clark, Sims, Warriner, & Cullum, 2009	Cohort study exploring pain experience and **pilot study on tools for assessing pain**	**Cohort study** • n=2,507, including 218 participants with pressure injuries • Participants with pressure injuries were significantly older (p<0.001, mean age 75.8) than those without (mean age 64.3) • Primarily pressure injuries Cateogry/Stage I or II **Pilot study** Inclusion: • Inpatient in elderly or surgical ward and identified by tissue viability nurse • ≥65 years Exclusion: • Physical or mental incapacity to complete survey Mean age 79 to 80 yrs Primarily Category/Stage II pressure injuries	**Cohort study** questionnaires designed to be self-completed, however, a structured interview method addressed the problem that many patients could not complete the questionnaires. **Pilot study** Health-related Quality of Life (HRQoL) tool designed to be self-completed; however, supplemented by a structured interview	**cohort study** information collected included age, sex, reason for admission, co-morbidities and pressure injury grade; short-form SF-36 (including pain). **Pilot study** • comparison of the findings of measures: EQ-5D, SF-36 and Pain VAS • information collected included demographics; main co-morbidities; PU grade and HRQoL	**cohort study** SF-36 pain • Participants with pressure injuries mean 28.41 (SD 17.00) median 31.0 (IQR 30.0) Score of 0=17 (12.3%) • Participants without PUs mean 32.79 (SD 17.36), median 41.0 (IQR 28.0), score of 0=226 (11.6%) **Pilot study SF-36 pain (any cause)** • Participants with pressure injuries (n=5) mean 46.6 (SD 31.2) • Participants without pressure injuries mean 55.6 (SD 34.51) mean difference 9.0 (95% CI 27.7 to 45.7, p= 0.61) **Pain VAS (anywhere on the body)** • Participants with pressure injuries (n=6) mean 48.6 (SD 22.1) • Participants without pressure injuries mean 24.8 (SD 23.4) • Mean difference –23.9 (95% CI –48.56 to 0.95, p= 0.06)	**Overall** This paper does not report PU pain, rather general pain experienced by the patient with a PU. **Cohort study** • Unclear when HRQOL and pain assessments were undertaken (on admission or during hospital stay) • Described as a cohort study but conducted as a cross-sectional study **Pilot study** • Non-completion of SF-36 • Participant identification and selection process not described • Small sample size with low statistical power represents only a small subset of the population	**Level of evidence: 5 diagnostic** **Quality: Low**
Clinical questions 2 and 3: What are effective non-pharmacological and pharmacological interventions for reducing pressure injury pain?							

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Faigeles et al., 2013	Observational study **investigating strategies used to manage pain during turning**	Participants were a convenience sample selected in 169 US hospitals (n=1,395) Inclusion: • Aged ≥ 18 years • Able to understand and communicate Exclusion: • Blind or deaf • Receiving neuromuscular blocking medication • Disease/injury that impaired sensory transmission proximal to the procedure site (e.g. peripheral neuropathy) Characteristics: • 86.3% sample were White • Mean age 63.5±3.1 years • 65.9% in a critical care unit • 70.4% were surgical patients	Participant was repositioned once as required by the care team and rated pain during the repositioning.	• Pain associated with turning measured during the turn procedure using a numerical rating scale (0 to 10) • Survey (participant, family and nurse) after the turn procedure regarding use of pain relief interventions during the procedure	• Overall mean pain was 4.9±3.1 during turning. • Participants were primarily turned using a draw sheet (53.6%) • Most participants (69.4%) were given assistance to turn • 12% were premedicated with an opioid prior to turning • The three most used non-pharmacological interventions were a calming voice, providing information and encouraging deep breathing. • Surgical patients more likely than medical to receive information (OR 1.73, 95% CI 1.25 to 2.38) and deep breathing (OR 2.33, 955 CI 1.62 to 3.34)	• Participants did not have pressure injuries • Did not evaluate effectiveness of the interventions	**Indirect evidence (not pressure injury)**
Clinical questions 2: What are effective pharmacological interventions for reducing pressure injury pain?							
Twillman et al. (1999)	Case studies on use of **morphine-infused gel dressing for reducing wound pain**	Consecutive participants recruited in a cancer center (n=9) Inclusion criteria: Not reported Exclusion criteria: Not reported Participant characteristics: • Age range 31-81 years • All participants had major co-morbidities,	• All participants were treated with 0.1% or 0.15% morphine-infused IntraSite® gel • Treatment continued for up to 12 months	• Most pain was measured on an 11-point VAS	**Pain management** • 77.79% of people (7/9) reported substantial relief • 1/9 participant reported a lesser (but still significant) degree of analgesia • 1/9 reported no relief	• Methods of selection and recruitment not reported • No comparator, no blinding • Only 2/9 participants had a pressure injury • Pain assessment method was not clear	**Indirect evidence (mixed etiology)**

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		most of which were also painful					
Paris et al., 2008	Randomized, crossover, multicenter, prospective, open-label, pilot study **comparing morphine to nitrous oxide for PU pain management**	n=34 (33 completed study) Inclusion: • 8 days inpatient stay • PU causing pain during care Exclusion: • Aged <18 years • Pregnancy or desire to be pregnant within 12 months • Intracranial hypertension • Pneumothorax, chronic resp failure • Middle ear or sinus surgery • Alcohol intoxication or delirium tremens • Bullous emphysema gaseous abdominal distention • Facial fracture Median age 84 82% had a PU, 18% varicose ulcer	Crossover protocol requiring each participant to receive three different protocols over six days (every second day) in a randomised order: **Arm 1** morphine subcutaneous 30 mins prior to care at 1mg/10kg body weight or 10% of daily dose if already receiving morphine **Arm 2** nitrous oxide-oxygen mixture inhaled 5 mins before care and throughout procedure at an individualized dose **Arm 3** morphine plus nitrous oxide oxygen mixture both of above	Level of pain following procedure assessed after and before care using: • Evaluation of Pain in Non-communicating Elderly (ECPA) • global hetero-evaluation scale (GHES) • DOLOPLUS-2 scale • This scale measures both out-of-care and in-care observations During all procedures pulse, arterial pressure and pO2 saturation Duration of care	• Duration of care was significantly shorter for arms 2 and 3 than arm 1 (p<0.001) • ECPA average difference after and before care: Arm 1: 5.2 ± 8.6, p<0.001 Arm 2: –0.3 ± 8, p<0.001 Arm 3: –0.6 ± 7.4, p<0.001 Significant difference between arms 1 and 2 (p<0.001) and arms 1 and 3 (p<0.001) but not arms 2 and 3 (p=0.971) • GHES and DOLOPLUS-2: • Similar significant differences (both tests in all arms p<0.01) Significant difference (p<0.001) between arms 1 and 2 and arms 1 and 3, but not arms 2 and 3 (p=0.17) • No differences were found with regard to safety or tolerability • **Conclusions: the study found that nitrous oxide – oxygen mixture was superior to morphine for analgesia when attending PU care in patients aged over 65 years**	• Bias in pain evaluation • Small study	**Level of evidence: 1** **Quality: moderate**
Zeppetella, Paul, & Ribeiro, 2003	Randomized, double-blind, placebo-controlled, crossover pilot study **comparing morphine sulphate to placebo as a**	Participants were hospice patients with advanced cancer (n=5) Inclusion criteria: • Painful sacral pressure injury • Suitable for 1x/day Intrasite® hydrogel	• Treated for 2 days with either: o 10mg morphine sulphate (MSO4) applied topically to pressure injury in morning of day 1 and covered with a Tegaderm dressing	• VAS used twice per day to rate analgesia • Local or systemic side effects	**Effectiveness in reducing pain** 100% participants reported lower VAS scores with MSO4 compared to placebo **Adverse effects** No local or systemic adverse effects attributable to MSO4 No significant difference in use of rescue analgesics during two treatment arms.	• Small sample • Only one application of morphine • Cross-over design may not measure pain accurately as pain may be adequately	**Level of evidence: 1** **Quality: low**

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	topical analgesia	• Receiving a stable analgesic regime for at least 48 hours Exclusion criteria: • Infected or covered by necrotic tissue Participant characteristics: Pressure injuries ranged from 4.5 – 14 $cm^{2,}$	○ Placebo gel applied topically and covered with Tegaderm • After a two-day wash out, participants crossed over groups • Rescue analgesia available.		**Conclusions: Study suggests morphine sulphate added topically is effective in producing local analgesia, is well tolerated without any negative effects.**	addressed by the time participant crosses-over	
Flock, 2003	Randomized, double-blind, placebo-controlled crossover pilot trial **investigating effectiveness of diamorphine gel for managing pressure injury pain**	Participants were recruited in an inpatient hospice in the US (n=13, recruited, n=7 completed trial) Inclusion criteria: • Category/Stage II or III painful pressure injury • Inpatient for at least one week Exclusion criteria: • Category/Stage I or IV painful pressure injury • No pressure injury Participant characteristics: • Mean age 77 years • 77% females • Primarily sacral pressure injuries with one pressure injury • 62% Category/Stage II pressure injuries with a mean size 9cm^2	• Random assignment to receive either: ○ 3 days of IntraSite® hydrogel applied daily followed by 3 days of 0.1% diamorphine/hydrogel or ○ 3 days of 0.1% diamorphine/Ihydrogel followed by 3 days of ○ hydrogel • All participants had pressure relieving support surfaces and repositioning	• Prior to study entry pressure injury size, location, stage was recorded. • Pain assessed before, 1, & 12 hours after gel application • Pain assessment conducted by blinded nursing staff Patients rated pain as none, mild, moderate, or over- whelming (translated to scores of 0=no pain to 4=overwhelming) • Nurses checked daily for skin irritation, pruritus, constipation, nausea and/or vomiting, drowsiness, hallucinations, myoclonus jerking, respiratory rate. Follow-up was 3 and 6 days.	Reduction in pressure injury pain • Pain scores were similar between groups at baseline • Pain scores improved significantly at 1 hour after application (p=0.003) and 12 hours after application (p=0.005) after diamorphine gel application compared with placebo/baseline. • Four patients were pain free after 1 hour; 3 patients were pain free after 12 hours. Adverse events • No significant difference in occurrence of side effects between groups at 1 or 12 hours. • No difference in systemic pain medication use in the 2 groups. • Symptoms of opioid toxicity similar in both groups.	• Methods of randomization and allocation concealment not reported • Very small sample size • High attrition rate (almost 50%) primarily due to acute illness after randomization	**Level of evidence: 1** **Quality: low**

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Abbas, 2004	Retrospective observational study **investigating pain management with diamorphine hydrogel gel**	Participants were selected by unknown methods over 30 months in a hospice in the UK (n=17) Inclusion criteria: • incurable malignancy • Category/Stage II pressure injury Exclusion criteria: None reported Participant characteristics: • Mean age 68 years (range 47-89 years) • 53% females	• All pressure injuries treated with diamorphine 5-10 mg & Intrasite® on a dressing • Dressing changed every 12-24 hours	Patients evaluated severity of pain on a visual analogue scale (VAS) ranging from 0 to 10 (0 = asymptomatic) on admission and after 5 days.	Participant outcomes • 12% (2/17) died of progressive illness within 7 days of having dressing applied • 70.5% participants (12/17) improved by 4+ points on the VAS over 5 days • Mean VAS improved from 9.4 to 4.6 after the treatment (p<0.02) **Author conclusions: Diamorphine-hydrogel dressing is effective in reducing pain in open pressure injuries in palliative care patients.**	• 12% who died were excluded from analysis • Diamorphine acts on nociceptors in superficial skin • No consideration to concurrent illness contributing to pain • No consideration not other interventions that may have been used	**Level of evidence: 4** **Quality: low**
Prentice, Roth, & Kelly, 2004	Randomized, double-blind, placebo-controlled trial exploring **effectiveness of an anti-inflammatory cream in reducing pressure injury pain**	Participants were recruited in three palliative care units in the UK (n=31) Inclusion criteria: • Pain related to a pressure injury • Inpatient for at least 24 hours • Able to consent Participant characteristics: • Mean age = 66.5 years • All participants had a cancer diagnosis • Most participants were receiving oral analgesics for pain	• Participants randomized to receive either ○ benzydamine hydrocholoride cream (3% Difflam®) applied to the skin surrounding the pressure injury (i.e. not on open skin; n=17), or ○ Placebo gel (n=13)	• 11-point VAS • Numeric Pain Scale (NPS) • Pain assessments done 24 hours prior to & immediately following application, and at 2, 6, 12 & 24 hours after cream application. Both tools considered to have good reliability & validity & equivalent in assessing pain.	**Effectiveness in managing pain** • Maximum pain reduction was not significantly different between the experimental and control group (23.5mm±22.5 vs 15.8±22.5mm, p=0.41) • Average pain rating over 24 hours was not significantly different between the experimental and control group (27.8±14.1mm vs 36.0±14.1mm, p=0.17) **Adverse events** No adverse events experience	• Small sample limited ability to reach statistical significance • Used ITT analysis • Does not report methods of allocation concealment or randomization • Does not report severity of pressure injuries • Funded by pharmaceutical company	**Level of evidence: 1** **Quality: Moderate**
Background: Experience of pressure injury pain							

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Ahn, Stechmiller, Fillingim, Lyon, & Garvan, 2015	Retrospective cross-sectional study **investigating the relationship between pain experience and pressure injury stage in nursing home (NH) residents aged over 64 years**	Record review of Minimum Data Set (MDS) 3.0 data completed over 3 months in 2012 (843,616 cases screened, 41,680 met inclusion criteria) **Inclusion criteria:** • Aged ≥ 65 years • Pressure injury present • Pain intensity interview recorded • Only one nursing home entry per resident was included if multiple admissions **Exclusion criteria:** • Unable to verbalize pain **Characteristics:** • Mean age 81.15±8.3 years • Mean Brief Interview for Mental Status (BIMS) 13.55±11.82 • 64.4% female • 59% had painful comorbidities • 39.7% used analgesia	N/A	• Pain intensity measured using numeric rating scale (NRS) or verbal descriptor scale (VDS) • Scores on NRS or VDS were summarized on a 4-point ordinal scare of 1=mild or no pain, 2=moderate pain, 3=severe pain and 4=excruciating pain. • Pressure ulcer categorized/staged as I-4 or SDTI (interrater reliability for staging reported as 0.94)	**Bivariate analysis of pain intensity** *Unadjusted odds ratio (OR) compared to Category/Stage I Pressure Injury* • Category/Stage II pressure injury: OR 1.14 (95% CI 1.09 to1.19, p<0.001) *i.e person with a PU Stage 2 is 14% more likely to have pain than a person with PU Stage I* • Category/Stage III pressure injury: OR 1.21 (95% CI 1.12 to 1.30, p<0.001) • Category/Stage IV pressure injury: OR 1.38 (95% CI 1.25 to 1.52, p<0.001) • Suspected Deep Tissue Injury: OR 1.23 (95% CI 1.16 to 1.30, p<0.001) **Factors associated with increased pain intensity** (multivariate logistic regression) • Category/Stage II pressure injury: OR 1.11 (95% CI 1.06 to 1.16, p<0.001) • Category/Stage III pressure injury: OR 1.14 (95% CI 1.06 to 1.23, p<0.001) • Category/stage IV pressure injury: OR 1.24 (95% CI 1.012 to 1.38, p<0.001) • Suspected Deep Tissue Injury: OR 1.22 (95% CI 1.15 to 1.30, p<0.001) • Presence of comorbidities: OR 1.32 (p5% CI 1.27 to 1.57, p<0.001) • Use of analgesia: OR 1.51 (95% CI 1.56 to 1.57, p<0.001) • Age: OR 0.97 (95% CI 0.97 to 0.98) • Female: OR 1.13 (95% CI 1.08 to 1.18) • Cognitive function, marital status, functional impairment were no significant	• Does not include people unable to verbalize pain • Duration of PU is not reported • Relies on data records • No analysis by facility – there could be variability in assessment and documentation	**Level of evidence: 3 prognostic** **Quality: moderate**
Ahn, Stechmiller, & Horgas, 2013	Retrospective cross-sectional study **exploring pressure injury-related pain in nursing home**	Participants were recruited over 12 months via a review of MDS 3.0 data for nursing homes in the US in 2009 (197,097 cases screened, 56,577 met inclusion criteria) Inclusion criteria:	• Cognitive impairment was classified as mild (group 1, n=15,955; 28.2%) moderate (group 2, n=21,657; 38.3%) or severe	• All measures collected from MDS 2.0 data set (a multidimensional questionnaire to assess nursing home residents in in the United States • The MDS-PrU item used to assess presence and	**Pain experience** • Pain was reported for 36.9% of residents with dementia • mild pain (72.6% of participants), moderate pain (25.1%), and excruciating pain (2.4%) **Relationship between pain and pressure injuries**	• secondary analysis of MDS data, may have variability due to different MDS coordinator styles/skills	**Level of evidence: 3 prognostic** **Quality: moderate**

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	residents with cognitive impairment	• Pressure injury present • Cognitive impairment with Alzheimer disease or other dementia. • Non-comatose • Aged ≥65 years Exclusion criteria: • Duplicate records Participant characteristics: • Mean age 84.37±7.43 years • 67.7% female, primarily white • Average Charlson Comorbidity Index 3 years (range, 1–16 years) • Category/Stage I (n = 4351; 42.5%); Category/Stage II (n = 3307; 32.3%); Category/Stage III (n = 649; 6.3%); Category/Stage IV (n = 1920; 18.8%)	(group 3, n=18,931; 33.5%)	stage of pressure injury (reliability coefficient reported) • Charlson Comorbidity Index (CCI), and sociodemographic characteristics (eg, age, gender, marital status, education, and race/ethnicity)	• Pressure injury Category/stage was significantly correlated with pain severity $X^2 = 775.74$, p<.001). • Logistic regression to predict pain severity: ○ People with mild cognitive impairment with a Stage 2 pressure injury has 29% more severe pain than someone with no pressure injuries (OR 0.29, p<0.0001), with a stage 4 pressure injury this increases to 50% more severe (OR 1.50, p<0.0001) ○ People with moderate cognitive impairment with a Stage 2 pressure injury has 53% more severe pain than someone with no pressure injuries (OR 0.53, p<0.0001), with a stage 4 pressure injury this increases to 68% more severe (OR 1.68, p<0.0001) ○ People with severe cognitive impairment with pressure injury has the most severe pain (Stage 2 pressure injury OR 1.96, p<0.0001; Stage 4 pressure injury OR 2.36, p<0.0001) **Conclusions: Individuals with dementia with more severe pressure injuries exhibited more severe pain. In individuals with cognitive impairment, pain not be effectively expressed and careful assessment and treatment is warranted.**	• Study is not designed to examine causal relationships • Role of analgesia not considered, analgesia may have been given before and/or after treatment - this might account for lower pain levels	
McGinnis, Nelson, Gorecki, & Nixon, 2015	Qualitative study **exploring the experiences of patients with multiple sclerosis (MS) with pressure injuries**	Participants were recruited by purposive sampling of people who had been admitted to acute and primary care settings in the UK (n=6) Inclusion criteria: • Aged ≥ 18 years • Pressure injuries Category/Stage 1 or greater • Able to consent • Diagnosed with MS	Not relevant	• Data collected via interviews guided by themes around health-related quality of life • Cross-case thematic analysis • Case-based explanatory thematic content analysis	**Pain experiences** • Most experiences some degree of pain • No participants reported pain influencing their sleep • Family identified as a source to help cope with pain • Participants reported that nurses rarely asked about pain • Pain was related to movement, pressure injury treatments and repositioning equipment	• Very small study with wide range of themes and experiences	**Level of evidence: 5 (qualitative)** **Quality: High**

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		• Exclusion criteria: • None reported Participant characteristics: • 80% females • Age range 48 to 61 years • Half had superficial and severe pressure injuries • Primary pressure injury location was sacrum and others					
Jackson et al., 2017	Qualitative study **exploring the experiences of patients with pressure injuries living at home**	A convenience sample of participants was recruited through the National Health Service in a small district I the UK (n=12, 38% response rate from invited population) Inclusion criteria: • Aged ≥18 years • Community based and not receiving 24-hour care • Pressure injury that was not acquired in a facility • Able to communicate • Exclusion criteria: • End-of-life care • Inability to consent Participant characteristics: • Age range 31 to 92 years • 75% female • Pressure injuries ranged from 2 month to 20 year duration • Comorbidities included arthritis, diabetes, obesity, respiratory disease and heart failure.	Not relevant	• Interviewed by an experienced researcher • Open-ended questions focused on experience of pain that were validated by clinical nurses • Thematic analysis by 3 researchers and 1 patient	**Prevalence of pressure injury pain** 91.7% (11/12) participants experienced pressure injury related pain, with the final participant having paraplegia leading to lack of sensation **Themes associated with pain** • Poorly controlled pain: 'I just want the pain to go away' ○ Pain is dominant and unrelenting ○ Powerlessness ○ Normal movement worsens pain, reducing mobility ○ Sitting and lying worsens pain ○ Pain management unachievable ○ Dressings worsen pain ○ Pain impacts ability to sleep • Uncertainty for the future: 'it almost seems insurmountable' ○ Strong understanding of difficulty in healing pressure injuries ○ Doubt and uncertainty about getting better ○ Fear that pressure injury won't heal ○ Frustration with slow healing **Author conclusions: Pain is a serious problem that impacts quality of life, social and emotional well-being**	• Patients validated transcripts • Patient expert reviewed themes • Small study that does not consider the different management strategies used in the communities of the participants	**Level of evidence: 5 (qualitative)** **Quality: High**

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Szor & Bourguignon, 1999	Descriptive cross-sectional study e**xploring the experience of pressure injury pain**	Participants were recruited by nurses in acute, home and extended care settings in one health care system in US (n=32) Inclusion criteria: • Category/Stage II-IV pressure injurie • Cognitively intact to sense and report pain Exclusion criteria: • Category/Stage I pressure injury • Non-English speaking Participant characteristics: • Mean age 74.7 years (range 47 to 95) • Category/ Stage II = 12, Category/ Stage III = 8, Category/ Stage IV = 12.	No intervention	• Pain measured at rest and during wound dressing change using • McGill Pain Questionnaire (MPQ)	**When did pain occur** • 87.5% participants reported pain at wound dressing change • 84.4% experienced pain at rest • 12.5% reported no pain. • 43% reported pain as continuous, occurring at rest and during wound dressing change **Severity of pain** Of the 28 with pain, 75% rated it mild to discomforting, 18% as horrible or excruciating. **Pain by Category/Stage** • 92% of people with Category/Stage II pressure injuries reported pain, • 100% of people with Category/Stage III pressure injuries had pain • 75% of people with Category/Stage IV pressure injuries reported pain. • Number of word descriptors used to describe pain increased directly in relation to Category/Stage. • People with Category/Stage III and IV pressure injuries reported more constant pain, Category/Stage II more transient pain **Pain management** Only 6% of people had received pain med for their pressure injury pain. **Conclusions: People with Category/Stage II, III & IV pressure injuries experience pain which is often severe & constant.**	No control for types of dressings, use of pressure reducing products, pain meds, etc. Small sample size. Some subjects who were acutely ill had difficulty completing MPQ.	**Level of evidence: 5 diagnostic** **Quality: high**
Gunes, 2008	Descriptive observational study reporting **the pain experience of pressure injuries**	Participants recruited from a university hospital in Turkey (n=47) Inclusion: • ≥18 yrs of age • Category/Stage II, III or IV pressure injury	Completion of FRS-R by selecting the face reflecting degree of pain felt at PU site Completion of 4 parts of MPQ:	• PU stage, location and cause of pain • Pain descriptors from MPQ • Present pain intensity subscale of MPG (0 to 5 scale) • Pain occurrence	**Experience of pain** 44 participants reported experiencing pain 6 participants received pain medication **Pain experience by Category/Stage of pressure injury** • Category/Stage II pressure injury– 3 of 6 • Category/Stage Stage III pressure injury – 32 of 32	• Size of the study • Dressing type, administration of pain medication and air	**Level of evidence: 5 diagnostic** **Quality: moderate**

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		• Ability to sense and report pain • Able to complete McGill Pain Questionnaire (MPQ) and Faces Rating Scale Revised (FRS-R) Exclusion: • Sensory-motor deficits • Peripheral neuropathy Participant characteristics: • Primarily men (62%) • Aged 38 to 72 years (mean 60.1 ±8.23) • Primarily neurological disorders • 74% had only one PU • Primarily stage II PUs of sacrum	• mark the location of pain on a line drawing • choose most appropriate from 78 pain descriptors • select description that best applies • assess present pain intensity based on a 0 to 5 scale	• Faces Rating Scale-Revised (FRS-R) • MPQ	• Category/Stage Stage IV pressure injury – 9 of 9 **Time of pain occurrence** • 41 participants reported no typical time for occurrence of pain • 32 participants dressing change aggravated pain • 9 participants movement of the afflicted area aggravated pain • 3 participants had pain at rest • There was significant difference in present pain intensity based on ulcer duration (F=9.56, p<0.05), with longer duration having greater pain • There was significant difference in present pain intensity between at rest vs having dressing changed (F=6.12,p<0.05) with dressing changes being more painful • Dressing type (F=1.35, p>0.05 and number of pressure injuries (F=1.15, p>0.05) were not related to pain intensity • PPI was significantly associated with FRS-R (r=0.90, p<0.001) **Word descriptors for pressure injury pain** • 13 words were used to describe PU pain • Participants with stage IV ulcers chose three times as many word descriptors as those with stage II PU and 1.5 times as many as those with stage III PU **Pain intensity:** • Category/stage II pressure injury: 3 of 6 rated their pain as "discomforting" • Category/Stage III pressure injury: all 32 rated pain as "distressing" • Category/Stage IV pressure injury: all 9 rated pain was "horrible" • Mean FRS-R pain intensity score 6.04 ± 2.78 corresponding to a moderate pain rating	mattress were not standardised	
Kapp & Annells, 2010	Hermeneutic qualitative pilot study reporting	7 participants • 4 men and 3 women • No cognitive impairment	• unstructured in-depth interviews averaging 50 minutes duration	Interview questions: • Tell me what it is like having a pressure injury	**Themes** • To live with discomfort: Participants spoke about the soreness and pain they experienced	• Generalizability of small sample	**Level of evidence: 5** **Quality: low**

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	themes associated with living with a pressure injury	• All were receiving home-based care for a pressure injury • Mean age 73 yrs	were conducted by the same researcher • All interviews were audio-taped and then transcribed verbatim by the researcher who conducted the interviews	and to be living at home? • How do you feel about that? • Can you tell me more about that? Thematic analysis process suggested by van Manen (1990) guided interpretation of data	•To live with differing interests: living with a PU at home required involvement from more than one community-based health professional •To live with restrictions: living with a pressure injury meant that adaptation may be required to accommodate physical restrictions imposed by wound •To place trust and have faith in the nurse: all participants trusted the home nurses and had faith in their wound management skills	• Patient selection not detailed • Justification of the method very limited • Unclear if informed consent required • Potential for researcher bias not discussed • Statements suggest evidence of researcher bias	
Fox, 2002	Descriptive phenomenology study **exploring the experience of pressure injury pain**	Participants were recruited in the community (n=5) Participant characteristics: • Ages 31 to64 years old, • 80% male • Pressure injury duration 4-36 months	No intervention	Semi-structured interview	Three main themes/sub-themes emerged: • Physical (pain, exudates, loss of independence) • Psychological (emotional factors, worry about healing, relationships, body image) • Social (social isolation). Pain experience • Pain was dominant physical factor & recurring themes throughout the interview. • Pain varied in level of intensity & disturbed sleep. Deep ulcers were painful.	• Very small sample size • May not be generalizable worldwide	**Level of evidence: 5**
Bale, Dealey, Defloor, Hopkins, & Worboys, 2007 Also reported in Hopkins, Dealey, Bale, Defloor, &	Qualitative pilot study using Heideggarian phenomenology exploring the experience of pain	Participants were recruited from 4 centers in England and Belgium (n=8) Inclusion criteria: • Older adult • Category/Stage III or IV pressure injuries Exclusion criteria: • Spinal cord injury	No intervention	Unstructured interviews which acknowledged the contribution of both the participant & researcher	**Three main themes:** • Endless pain • Restricted lifestyle • Coping with the pressure injuries **Endless pain theme** • Pain was constant & severe feature • Analgesia not always effective • Pain prevented proper rehab in some. • Cycle of pain (not pain itself) was endless. • Severity of pain not always recognized by doctors • Pain decreased by repositioning (conflicts with best evidence on frequent repositioning),	• Limited to older adults and limited number of participants. • May not be generalizable worldwide.	**Level of evidence: 5**

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Worboys, 2006		• Inability to provide informed consent. Participant characteristics: • Age range 68-101. • Participants had other co-morbidities			• Pain was restricting feature with significant impact on life & feelings regarding self. • Pain contributed to being worried, depressed, feeling burdensome, inadequate & sense of powerlessness.		
Langemo, Melland, Hanson, Olson, & Hunter, 2000	Qualitative study using Spiegelberg's phenomenology methods to explore experience of pressure injury pain	Non-probability, purposive sample recruited in US(n=8) Participant characteristics: • 4 people had a current pressure injury and 4 people had experienced a pressure injury I the past • People had experience with Category/Stage II to IV pressure injuries • Four people had SCI, 5 people had surgical flap reconstruction • Primarily males • Mean age 35.7 years	No intervention	Unstructured, face to face, audio- taped interview.	Seven themes: • Perceived etiology of pressure injury • life impact & changes (physical, financial & social), • Psycho-spiritual impact (body image changes, struggle with stereotypes, desire/struggle for control & independence, spiritual impact) • Extreme painfulness with pressure injuries (pain intensity & duration, analgesic use) • Need for knowledge & understanding (knowledge of prevention, physiologic processes & lack of knowledge), • Need for and effect of numerous stressful treatments (self-care, treatment regimens & multiple surgeries, complications, length of healing time) • Grieving process (denial, depression, anger, bargaining, acceptance)	• Limited to Caucasians, young or middle age. Need replication in other ethnic groups • Not followed longitudinally	**Level of evidence: 5**
Rastinehad, 2006	Phenomenological, qualitative study exploring the experience of pressure injury pain	Purposeful sampling of acute care patients with a pressure injury (n=10) Participant characteristics: • Primarily females • 30-90 years of age • 8 had pre-existing pressure injuries and 2 had a hospital-acquired pressure injury • Most had Category/Stage II pressure injuries, 2 had Category/Stage III pressure injuries & 1 had Category/Stage IV pressure injuries	No intervention	• Semi-structured interviews using decision trail • Analysis reviewed by 10 researchers & 2 WOCN nurses • Data collection over 8 months and analysis over 16 months	**22 themes and 1 constitutive pattern identified.** • Multiple terms used to describe pain • Majority of patients with a pressure injury experience pain of varying intensities, many severe, which was consistent with other studies • Emotions of frustration, depression, anger and rage also reported. • The pain experience from a pressure injury permeates their existence.	• Limited to 10 subjects	**Level of evidence: 5**

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		• Majority of the pressure injuries were sacral					
Spilsbury et al., 2007	Qualitative study exploring the experience of pressure injury pain	Purposive sample of hospitalized patients (n=23) Participant characteristics: • Primarily female • Age range 33-92 years (median 78 years) • Highest pressure injury locations heel & sacrum. • Pressure injuries Category/Stages II to IV pressure injuries	No intervention	• Semi-structured interviews Identification of themes & sub-themes	• 91% (21/23) said pressure injury treatment affected lives emotionally, physically, mentally & socially. • Dependent on others to treat, manage, and care for pressure injury • Pain, discomfort and distress of pressure injury not acknowledged by nursing staff. • 7 patients blamed health care professionals for getting pressure injuries, 8 blamed it on comorbidities, 3 on poor hygiene practices or lack of knowledge. • 91% had pressure injury pain, 2 who didn't either had neuro condition or were unaware of pressure injuries • Pressure injuries were associated with pain, fluid leakage & smell, discomfort, & mobility difficulties.	• Impossible to separate effect of pressure injuries from chronic condition.	**Level of evidence: 5**
Pain as a prognostic factor							
Smith et al., 2017	Prospective cohort study **exploring pain as predictor of PUs Category/Stage 2 or greater**	Participants were recruited in 26 hospital and community based centres in UK over two years (n=634, n=602 completed [7863 potential skin sites]) Inclusion criteria: • Aged ≥18 years • Able to report if they have pain • At high risk of PU (based on Braden scale, existing Category/Stage 1 PU, experiencing localized skin pain) • Acutely ill Exclusion criteria: • Obstetrics patients,	No intervention	• Development of a Category/Stage 2 PU or greater • Time to PU development • Baseline and twice weekly skin assessment • Follow up for maximum of 30 days or until not classified of having high risk of PU • Univariate logistic regression for: age (as both categorical and continuous variable), presence of pain, weight loss, Braden score on mobility	**Patient outcomes** • 25.2% developed at least one PU • 77.1% had a PU related to pain • Pain was more frequently reported with more severe skin status rating • From evaluable skin sites (n=7483), 3% developed a Category/Stage ≥2 PU • Proportion of skin sites developing a Category/Stage ≥2 PU increased with severity of baseline skin status • 14.4% of skin sites had PU pain at baseline, 10.3% of these developed a Category/Stage ≥2 PU **Multivariable (MV) logistic regression for Category/Stage II pressure injury** • Presence of category 1 PU (OR 3.25, 95% CI 2.17 to 4.86, p<0.0001) • alterations to intact skin (OR 1.98, 95% CI 1.30 to 3.00, p=0.0014)	• Blinded end point not possible, but assessments performed by independent clinical staff • Low loss to follow-up	**Level of evidence: 1 (prognostic)** **Quality: high**

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		• Aged <18 years • Two or more existing Category/Stage 2 PUs or greater on sacrum, buttocks, heels or hips Participant characteristics: • Hospital based care (m=397) and community based (n=205) • Mean age 77 years • 37% had no PU on entry • 91% using analgesia on entry		subscale, presence of skin alterations, presence of Category/Stage 1 PU, clinical setting (hospital vs community) for • Overdispersion model included gender, BMI, Braden scale domains, presence of Category/Stage ≥2 PU, chronic wound, type of mattress	• pressure area related pain (OR 1.56, 95% CI 0.93 to 2.63 p=0.0931) **Time to PU development** • People with baseline Category 1 PU had development of a Category/Stage ≥2 PU 2.32 times faster compared to those without baseline Category 1 PU (95% CI 1.73 to 3.12) • People with baseline pressure injury pain had development of a Category/Stage ≥2 PU 2.28 times faster compared to those without baseline pressure injury pain (95% CI 1.59 to 3.27) **Author conclusion: Pain increases risk of PU at that clinical site, and pain decreases the time until PU development**		
Background: Prevalence of pressure injury-related pain							
Briggs et al., 2013	Cross sectional study **investigating prevalence of unattributed pressure injury related pain** (defined as pain, soreness or discomfort reported by patients, on an "at risk" or pressure injury skin site.)	Participants were recruited over 2 years in routine pressure injury prevalence audits nine teaching hospitals in two NHS Trusts (n=3,397 participants, 2,010 of whom responded to pain questions) Inclusion criteria: • Aged ≥ 18 years • Inpatient in hospital during prevalence survey Exclusion criteria: • Obstetric, pediatric or psychiatric ward • Imminent death • Unable to communicate pain • Participant characteristics (full population of 3397): • Mean age 65.8 years (range 18 to 103)	No interventions	• Trained nurse conducted skin assessment, pressure injury classification using EPUAP 1998 system • Tissue viability team member asked two questions about pain: one focused on if the person has pain at any time and the second asked the person if the pain was related to pressure	**Prevalence of pressure-related pain** Of 3,397 patients, 2,010 (58.9%) were asked about presence of pain 1,769 patients (88%) had no pressure injuries (12% had pressure injuries) Unattributed pressure injury related pain prevalence was 12.6% in people without pressure injuries (223/1769) Unattributed pressure injury related pain prevalence was 43.2% in people without pressure injuries (104/241) **Author conclusions: The study supports monitoring and management of pressure-related pain. An important minority of patients without pressure injuries reported pressure-related pain.**	• Skin assessment data has inherent limitations • Pain questions have not been validated, one question was leading • Pain recorded are not related by skin site, so it was not possible to assess the level of pressure injury pain • Pain management may differ between various clinical	**Level of evidence: 4** **Quality: Moderate**

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		• 48.7% men • 72.5% of the pain population had Grade I pressure injury, 20.4% had grade 2 pressure injury, 3.7% had grade IIII, 2% hade Grade IV • 39.7% medical patients, 25.6% surgical, 11.2% geriatric medicine, 9% orthopedics, 6% oncology, 5% critical care				areas and influence patient experience • Large number (almost 40%) considered too sick to respond to questions about pain	
McGinnis et al., 2014	Cross sectional study to estimate **prevalence of pressure injury related pain**	Participants were recruited at two community NHS sites in the UK (combined population 566,726, n=287 had pressure injuries, n=176 asked about pain) Inclusion criteria: • Aged over 18 years • On community nursing case load • Had a pressure injury of any Category/Stage Exclusion criteria: • Pediatric, obstetric or psychiatric patients • Imminent death Participant characteristics: • Mean age 72.6 years (SD 15.31) • 70% of participants were in their own home • 75.7% females • 100% white British	No intervention	• Participants were asked if they experienced pain, and if they believed the pain was related to pressure • Individuals reporting pain were asked to rank pain intensity (for most severe pain over past week) for all pressure sites using a numerical rating scale of 0–10 • Participants also rated their most painful torso and limb skin sites • Leeds Assessment Neuropathic Symptoms and Signs (LANSS) Pain Scale was used • Data collection by community nurses trained in assessment (no inter-rater reliability conducted)	**Prevalence of pressure injury related pain** • Prevalence of pain was 75.6% (133/176) **Detailed assessment** • 27.8% (n = 37/133) of the population reporting pain consented to full assessment • Of the 481 skin sites assessed, 11.2% (54/451) had pressure injury area (mean 1.5 per patient, SD 0.65) • Grade 1 pressure injuries (37.0%; n = 20/54), Grade 2 (31.5%; n = 17/54) and Grade 3/4/U (31.5%; n = 17/54) • 98.1% of sites with pressure injury were rated as painful by patients. • Mean pain intensity 6.4 (SD 2.53) (range 1–10, median 7.0) • There is a slightly skewed distribution of pain intensity with very similar pain levels for each grade of pressure injury **Neuropathic pain assessment** • 31 patients identified one or more skin site for LANSS assessment (n=22 torso and n=18 limb assessments) • 54.5% (n = 12/22) of torso pressure injuries and 61.1% (n = 11/18) of limb pressure injuries scored ≥12 on the LANSS assessment (indicating	• Identifying cases of pressure injury was done differently in the two regions • Almost 30% of pressure injury individuals were not asked about pain, primarily due to confusion or end-of-life • Management of pain and other confounding factors were not considered • LANSS is reported elsewhere (see Rutherford et al 2016) as being inappropriate	**Level of evidence: 4** **Quality: high**

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				• 1998 EUAP classification scale used	neuropathic pain was slightly dominant over inflammatory pain) **Study conclusions: Prevalence of pain associated with pressure injuries was 75.6%.**	for assessing pressure injury pain	
Quirino et al., 2003	Exploratory, descriptive and cross-sectional study **describing pressure injury pain prevalence and characteristics**	Participants were recruited in 3 acute care settings in Brazil Inclusion criteria: • 18 years or older • Presence of pressure injury • Cognitive & communication abilities to respond to a questionnaire • Consent to participate Exclusion criteria: • Inability to communicate • Inability to complete study tools Participant characteristics: • Mean age 57.25±19.32 years (range 19 to 80) • 70% white, 15% black, 15% Asian • 75% males • Orthopedic, cancer, drama, cardiac and neurological diseases	No interventions	• Pain characterization • Short version of the McGill Pain Questionnaire Pain Intensity Numerical Rating Scale • Intensity of pain measured with Numerical Rating Scale represented by a line numbered from 0 to 10 where 0=no pain and 10=worst possible pain	**Pain characteristics** • All patients reported pressure injury pain • 80% reported constant pressure injury pain , not limited to a particular time of day • Mean pain intensity was 5.8 ±2.93, characterizing a moderate pain level • Burning was most frequently used to describe pressure injury pain • Significant associations were observed between painful condition and ethnic origin (p=0.034), ethnic origin and impaired appetite (p=0.014), age and impaired walking (p=0.002), and preferential time of day and number of pressure injuries (p=0.013). **Conclusion: This study may contribute to breaking the myth of the absence of pain in pressure injuries, and encourage health care professionals to manage pressure injury pain**	Small study	**Level of evidence: 4**

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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

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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
8067	Ahn et al., 2015	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	4	High
1538	Ahn et al., 2013	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	4	High
2786	McGinnis et al., 2014	Y	Y	U	Y	Y	Y	Y	Y	Y	Y	4	High
1561	Briggs et al., 2013	Y	Y	Y	Y	Y	N	Y	N	Y	U	4	Moderate

PROGNOSTIC STUDIES

	Author/year	Baseline sample adequately described	Study attrition (<20% lost to follow-up)	Clear definition of risk factors	Were continuous variables used/ appropriate cut-point	RF measure/method valid and reliable	*Adequate % sample with complete data	Method/setting of measurement same for all	Appropriate imputation method	Appropriate classification for outcome	Potential confounders accounted in study design	Potential confounders accounted in analysis	Data adequate to assess adequacy of analysis	Appropriate strategy for model building	Model adequate for design	Adequate sample size (rule of thumb >10 events per risk factor)	No selective reporting	Level of evidence	Quality
14318	Smith et al., 2017	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	1 (prognostic)	high

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QUALITATIVE STUDIES

Endnote ID	Author/year	Clear statement of aims	Qualitative method is appropriate	Appropriate research design	Recruitment appropriate to research and sample justified	Clear, explicit and appropriate methods for data	Researchers role in data collection and analysis and potential	Ethics clearance	In-depth description of analysis technique indicates rigorous	Clear findings stated	Research contributes to the existing knowledge	Level of evidence	Quality
14414	Jackson et al., 2017	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	5	High
8369	McGinnis et al., 2015	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	5	High

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	Other relevant topics
7494	Kelly et al., 2014	Y	NA	Y	N	Y	NA	Y	N	N	N	N	Y	Y	Y	3	Low	
13806	Rutherford et al., 2016	Y	Y	Y	NA	Y	NA	Y	N	Y	NA	Y	Y	Y	Y	3	Moderate	

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