Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

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

- Identified in pressure injury searches
  - n=11,177

- Identified citations
  - n=3,085

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

- Excluded based on key word searches
  - Not related to the topic-specific questions
  - n=3,066

- Identified as providing direct or indirect evidence related to topic and critically appraised
  - n=4

- Excluded after review of full text
  - Not related to pressure injuries
  - Not related to the clinical questions
  - Citation type/research design not meeting inclusion criteria
  - Non-English citation with abstract indicating not unique research for translation
  - n=15

- Total references providing direct or indirect evidence related to topic
  - n=22

Additional citations
- Identified by working group members
  - n=36

Pain keywords
- Pain, discomfort, nociception, neuropathic, analgesic, analgesia

Additional citations
- Appraised for previous editions
  - n=18


Data Tables: 2019 Guideline Update: Assessment and Treatment of Pressure Injury Pain
### Articles Reviewed for International Pressure Injury Guideline

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


#### Ref | 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?**

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kelly, Bender, Harris, &amp; Casarett, 2014</td>
<td>Retrospective cohort study reporting factors that are associated with pain being controlled within 48 hours of admission to end-of-life care</td>
<td>Participants were recruited through a retrospective review of 1 year of electronic health records from 10 hospices in US (n= 4,157 eligible)</td>
<td>No interventions</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**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

- 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 presence 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

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**Level of evidence:**
3

**Quality:**
Low
### Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>Rutherford, Nixon, Brown, Briggs, &amp; Horton, 2016</th>
<th>Prospective cohort study to assess psychometric properties of the Leeds Assessment of Neuropathic symptoms &amp; signs (LANSS) for people with pressure injury-related pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants were recruited in nine acute and community hospitals in the UK (n=728)</td>
<td></td>
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<tr>
<td>Inclusion criteria:</td>
<td></td>
</tr>
<tr>
<td>• 18 years or older</td>
<td></td>
</tr>
<tr>
<td>• Able to report pain</td>
<td></td>
</tr>
<tr>
<td>• High risk of a pressure injury</td>
<td></td>
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<tr>
<td>Exclusion criteria:</td>
<td></td>
</tr>
<tr>
<td>• Pediatric, obstetric and psychiatric considered ethically or clinically inappropriate</td>
<td></td>
</tr>
<tr>
<td>Participant characteristics:</td>
<td></td>
</tr>
<tr>
<td>Mean age 76 years (SD 15.3)</td>
<td></td>
</tr>
<tr>
<td>59.1% females</td>
<td></td>
</tr>
<tr>
<td>97.1% White</td>
<td></td>
</tr>
<tr>
<td>80.6% had pressure injuries</td>
<td></td>
</tr>
<tr>
<td>Assessment tool</td>
<td></td>
</tr>
<tr>
<td>• LANSS contains: 5 patient-reported symptoms</td>
<td></td>
</tr>
<tr>
<td>• 2 clinical sensory items associated with neuropathic pain</td>
<td></td>
</tr>
<tr>
<td>All three study areas of tissue viability teams – site initiations survey</td>
<td></td>
</tr>
<tr>
<td>Questions about whether pain is experienced and if the patient thinks the pain is related to pressure</td>
<td></td>
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<tr>
<td>Participants experiencing pain were there assessed with the LANSS</td>
<td></td>
</tr>
<tr>
<td>Pain assessed using a 0-10 numerical rating scale</td>
<td></td>
</tr>
<tr>
<td>Staging system used 1998 EPUAP classification over 13 anatomical sites</td>
<td></td>
</tr>
<tr>
<td>LANSS assessments</td>
<td></td>
</tr>
<tr>
<td>367 assessments conducted, 362 for torso skin and 361 limb skin (19 excluded as being healthy skin)</td>
<td></td>
</tr>
<tr>
<td>Validity</td>
<td></td>
</tr>
<tr>
<td>• Internal construct validity: inter-item correlations low to moderate (range 0.156 to 0.421)</td>
<td></td>
</tr>
<tr>
<td>• Convergent validity: low correlation between LANNS and pain intensity visual analogue scale (VAS) (r= –0.21) (i.e. neuropathic pain is not related to pain intensity)</td>
<td></td>
</tr>
<tr>
<td>• Discriminant validity: LANNS was not biased by age (r&lt;0.3)</td>
<td></td>
</tr>
<tr>
<td>Author conclusions: LANNS 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.</td>
<td></td>
</tr>
<tr>
<td>Useful study to exclude this scale</td>
<td></td>
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<tr>
<td>Level of evidence: 3</td>
<td></td>
</tr>
<tr>
<td>Quality: Moderate</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dallam et al., 1995 Same study reported in Freeman, Smyth, Dallam, &amp; Jackson, 2001</th>
<th>Prospective cross-sectional study reporting assessment/ diagnosis of pressure injury pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants were recruited in a tertiary med center over 12 months in the US (=132)</td>
<td></td>
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<tr>
<td>Inclusion criteria:</td>
<td></td>
</tr>
<tr>
<td>• Aged 18 years or greater</td>
<td></td>
</tr>
<tr>
<td>• At least one Category/Stage I to IV pressure injury</td>
<td></td>
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<tr>
<td>Participant characteristics:</td>
<td></td>
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<tr>
<td>• 5% female</td>
<td></td>
</tr>
<tr>
<td>• Average age 71.4 years (range 24-100)</td>
<td></td>
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<tr>
<td>• 66% white, 22% black, 11% Hispanic, 2% Asian</td>
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<tr>
<td>• 68.9% had a sacral pressure injury, 24% buttock pressure injury,</td>
<td></td>
</tr>
<tr>
<td>Not applicable</td>
<td></td>
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<tr>
<td>• Folstein Mini-Mental Status Exam</td>
<td></td>
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<tr>
<td>• Beck’s Depression Inventory</td>
<td></td>
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<tr>
<td>• Faces Pain Rating Scale (FPRS)</td>
<td></td>
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<tr>
<td>• Visual Analog Scale (VAS)</td>
<td></td>
</tr>
<tr>
<td>• Tools have previously been reported to have good reliability &amp; validity</td>
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<tr>
<td>• Pain defined as “unpleasant sensory &amp; emotional experience with actual or potential tissue damage.”</td>
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<tr>
<td>Pressure injury pain prevalence</td>
<td></td>
</tr>
<tr>
<td>• 41% denied pressure injury pain</td>
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<tr>
<td>• 68% reported some degree of pain</td>
<td></td>
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<tr>
<td>Pan management</td>
<td></td>
</tr>
<tr>
<td>• 2.3% (3/132) had received analgesia for pressure injury pain in preceding 4 hours</td>
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</tr>
<tr>
<td>• 39.4% had received analgesia, narcotics, NSAIDs for other pain in the preceding 4 hours</td>
<td></td>
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<tr>
<td>• 8.3% had received other medication that might manage pain (e.g. sedatives, psychotropics) in preceding 4 hours</td>
<td></td>
</tr>
<tr>
<td>• People receiving analgesics for pressure injury pain had significantly more pain than people not receiving analgesics (p&lt;0.05)</td>
<td></td>
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<tr>
<td>Factors influencing pain</td>
<td></td>
</tr>
<tr>
<td>• Maximum pain score was significantly correlated with:</td>
<td></td>
</tr>
<tr>
<td>People who could not verbally indicate pain were not included in the tool use (66.67% of participants)</td>
<td></td>
</tr>
<tr>
<td>Level of evidence: 1 diagnostic</td>
<td></td>
</tr>
<tr>
<td>Quality: High</td>
<td></td>
</tr>
</tbody>
</table>
### Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>Data Tables: 2019 Guideline Update: Assessment and Treatment of Pressure Injury Pain</th>
<th>© EPUAP/NPIAP/PPPIA</th>
<th>Page 4</th>
</tr>
</thead>
</table>

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

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### Roth, Lowery, & Hamill, 2004

**Prospective cross-sectional exploring use of different pain assessment tools in people with wounds**

<table>
<thead>
<tr>
<th>Participants were recruited in two veteran’s centers in the US (n=69)</th>
<th>Patients followed for up to 6 visits. All patients queried on 1st &amp; subsequent visits re: wound pain, &amp; if present, took series of pain &amp; other questionnaires.</th>
<th>Participants followed for up to 6 visits. All patients queried on 1st &amp; subsequent visits re: wound pain, &amp; if present, took series of pain &amp; other questionnaires.</th>
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</table>

**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

**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

**Level of evidence:** 3  
**Quality:** Low  
**Small sample**  
**Correlational design - causal direction can be ascertained**
### Data Tables: 2019 Guideline Update: Assessment and Treatment of Pressure Injury Pain

<table>
<thead>
<tr>
<th>Essex, Clark, Sims, Warriner, &amp; Cullum, 2009</th>
<th>Cohort study exploring pain experience and pilot study on tools for assessing pain</th>
<th>Cohort study</th>
</tr>
</thead>
<tbody>
<tr>
<td>• n=2,507, including 218 participants with pressure injuries</td>
<td>• Participants with pressure injuries were significantly older (p&lt;0.001, mean age 75.8) than those without (mean age 64.3)</td>
<td>Cohort study questionnaires designed to be self-completed, however, a structured interview method addressed the problem that many patients could not complete the questionnaires.</td>
</tr>
<tr>
<td>• Primarily pressure injuries Category/Stage I or II</td>
<td>• Participants with pressure injuries were significantly older (p&lt;0.001, mean age 75.8) than those without (mean age 64.3)</td>
<td>Cohort study information collected included age, sex, reason for admission, co-morbidities and pressure injury grade; short-form SF-36 (including pain).</td>
</tr>
<tr>
<td>Pilot study</td>
<td>• Participants with pressure injuries were significantly older (p&lt;0.001, mean age 75.8) than those without (mean age 64.3)</td>
<td>Pilot study • comparison of the findings of measures: EQ-5D, SF-36 and Pain VAS</td>
</tr>
<tr>
<td>Inclusion:</td>
<td>• Participants with pressure injuries were significantly older (p&lt;0.001, mean age 75.8) than those without (mean age 64.3)</td>
<td>{Piloto study Health-related Quality of Life (HRQoL) tool designed to be self-completed, however, supplemented by a structured interview.</td>
</tr>
<tr>
<td>• Inpatient in elderly or surgical ward and identified by tissue viability nurse</td>
<td>• Participants with pressure injuries were significantly older (p&lt;0.001, mean age 75.8) than those without (mean age 64.3)</td>
<td>Pilot study Health-related Quality of Life (HRQoL) tool designed to be self-completed, however, supplemented by a structured interview.</td>
</tr>
<tr>
<td>• ≥65 years</td>
<td>• Participants with pressure injuries were significantly older (p&lt;0.001, mean age 75.8) than those without (mean age 64.3)</td>
<td>Pilot study Health-related Quality of Life (HRQoL) tool designed to be self-completed, however, supplemented by a structured interview.</td>
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<tr>
<td>Exclusion:</td>
<td>• Participants with pressure injuries were significantly older (p&lt;0.001, mean age 75.8) than those without (mean age 64.3)</td>
<td>Pilot study Health-related Quality of Life (HRQoL) tool designed to be self-completed, however, supplemented by a structured interview.</td>
</tr>
<tr>
<td>• Physical or mental incapacity to complete survey</td>
<td>• Participants with pressure injuries were significantly older (p&lt;0.001, mean age 75.8) than those without (mean age 64.3)</td>
<td>Pilot study Health-related Quality of Life (HRQoL) tool designed to be self-completed, however, supplemented by a structured interview.</td>
</tr>
<tr>
<td>Mean age 79 to 80 yrs Primarily Category/Stage II pressure injuries</td>
<td>• Participants with pressure injuries were significantly older (p&lt;0.001, mean age 75.8) than those without (mean age 64.3)</td>
<td>Pilot study Health-related Quality of Life (HRQoL) tool designed to be self-completed, however, supplemented by a structured interview.</td>
</tr>
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</table>

#### Clinical questions 2 and 3: What are effective non-pharmacological and pharmacological interventions for reducing pressure injury pain?

- **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%)
  - 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)

- **Pilot study**
  - Participants with pressure injuries (n=5) mean 46.6 (SD 31.2)
  - 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
### 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

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### 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

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Not for Reproduction
### Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>Study Reference</th>
<th>Design</th>
<th>Participants</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>Protocol</th>
<th>Outcome Measures</th>
<th>Findings</th>
</tr>
</thead>
</table>
| 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 respiratory failure  
• Middle ear or sinus surgery  
• Alcohol intoxication or delirium tremens  
• Bullous emphysema  
• Gaseous abdominal distention  
• Facial fracture | 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-evalution scale (GHES)  
• DOLOPLUS-2 scale  
During all procedures pulse, arterial pressure and pO2 saturation |  
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 treatment for Pressure Ulcers (PU) | Participants were hospice patients with advanced cancer (n=5) | • Inclusion criteria:  
• Painful sacral pressure injury  
• Suitable for 1x/day Intrasite® hydrogel | • Exclusion:  
• Painful conditions requiring systemic analgesia  
• Patients with an active infection or bleeding risk  
• Current use of a local anesthetic or corticosteroids  
• History of hypersensitivity to morphone  
• Concurrent treatment with other systemic analgesics  
• Pregnancy or breastfeeding | Treated for 2 days with either:  
• 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  
Neutral in these respects | Level of evidence: 1  
Quality: low |
### Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>topical analgesia</th>
<th>Randomized, double-blind, placebo-controlled crossover pilot trial investigating effectiveness of diamorphine gel for managing pressure injury pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants were recruited in an inpatient hospice in the US (n=13, recruited, n=7 completed trial)</td>
<td>Participants 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 9cm²</td>
</tr>
<tr>
<td>Exclusion criteria: • Category/Stage I or IV painful pressure injury</td>
<td>Random assignment to receive either: o 3 days of IntraSite® hydrogel applied daily followed by 3 days of 0.1% diamorphine/hydrogel or o 3 days of 0.1% diamorphine/hydrogel followed by 3 days of hydrogel</td>
</tr>
<tr>
<td>Inclusion criteria: • Category/Stage I or III painful pressure injury • Inpatient for at least one week</td>
<td>All participants had pressure relieving support surfaces and repositioning</td>
</tr>
<tr>
<td>• Painful pressure injury</td>
<td>Prior to study entry pressure injury size, location, stage was recorded.</td>
</tr>
<tr>
<td>• No pressure injury</td>
<td>Pain assessed before, 1, &amp; 12 hours after gel application</td>
</tr>
<tr>
<td>Inclusion criteria: • Category/Stage II or III painful pressure injury • Inpatient for at least one week</td>
<td>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)</td>
</tr>
<tr>
<td>Exclusion criteria: • Category/Stage II or III painful pressure injury</td>
<td>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.</td>
</tr>
</tbody>
</table>

**Conclusions:** Study suggests morphine sulphate added topically is effective in producing local analgesia, is well tolerated without any negative effects.

**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
<table>
<thead>
<tr>
<th>Authors</th>
<th>Study Design</th>
<th>Description</th>
<th>Participants</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Conclusion</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbas, 2004</td>
<td>Retrospective study</td>
<td>Investigating pain management with diamorphine hydrogel gel</td>
<td>Participants were selected by unknown methods over 30 months in a hospice in the UK (n=17)</td>
<td>All pressure injuries treated with diamorphine 5-10 mg &amp; Intrasite® on a dressing</td>
<td>Patients evaluated severity of pain on a visual analogue scale (VAS) ranging from 0 to 10 (0 = asymptomatic) on admission and after 5 days.</td>
<td>Diamorphine-hydrogel dressing is effective in reducing pain in open pressure injuries in palliative care patients.</td>
<td>4</td>
<td>Low</td>
</tr>
<tr>
<td>Prentice, Roth, &amp; Kelly, 2004</td>
<td>Randomized trial</td>
<td>Exploring effectiveness of an anti-inflammatory cream in reducing pressure injury pain</td>
<td>Participants were recruited in three palliative care units in the UK (n=31)</td>
<td>Participants randomized to receive either benzydamine hydrochloride cream (3% Difflam®) applied to the skin surrounding the pressure injury (i.e. not on open skin; n=17), or placebo gel (n=13)</td>
<td>11-point VAS</td>
<td>Maximum pain reduction was not significantly different between the experimental and control group (23.5±22.5 vs 15.8±22.5 mm, p=0.41) Average pain rating over 24 hours was not significantly different between the experimental and control group (27.8±14.1 mm vs 36.0±14.1 mm, p=0.17) No adverse events experience</td>
<td>1</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
### Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>Authors</th>
<th>Study Design and Setting</th>
<th>Methodological Details</th>
<th>Key Findings</th>
<th>Level of evidence</th>
<th>Quality:</th>
</tr>
</thead>
</table>
| 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  
- 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 scale 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 to 1.19, 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  | 3 prognostic  

| 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 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  | 3 prognostic  

Data Tables: 2019 Guideline Update: Assessment and Treatment of Pressure Injury Pain  
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### Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>residents with cognitive impairment</th>
<th>Pain experiences</th>
<th>Study is not designed to examine causal relationships</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pressure injury present</td>
<td>• Most experiences some degree of pain</td>
<td>• Role of analgesia not considered, analgesia may have been given before and/or after treatment - this might account for lower pain levels</td>
</tr>
<tr>
<td>• Cognitive impairment with Alzheimer disease or other dementia.</td>
<td>• No participants reported pain influencing their sleep</td>
<td></td>
</tr>
<tr>
<td>• Non-comatose</td>
<td>• Family identified as a source to help cope with pain</td>
<td></td>
</tr>
<tr>
<td>• Aged ≥ 65 years</td>
<td>• Participants reported that nurses rarely asked about pain</td>
<td></td>
</tr>
<tr>
<td>Exclusion criteria:</td>
<td>• Pain was related to movement, pressure injury treatments and repositioning equipment</td>
<td></td>
</tr>
<tr>
<td>• Duplicate records</td>
<td>Data collected via interviews guided by themes around health-related quality of life</td>
<td></td>
</tr>
<tr>
<td>Participant characteristics:</td>
<td>Cross-case thematic analysis</td>
<td></td>
</tr>
<tr>
<td>• Mean age 84.37±7.43 years</td>
<td>Case-based explanatory thematic content analysis</td>
<td></td>
</tr>
<tr>
<td>• 67.7% female, primarily white</td>
<td>Pain experiences</td>
<td></td>
</tr>
<tr>
<td>• Average Charlson Comorbidity Index 3 years (range, 1–16 years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stage of pressure injury (reliability coefficient reported)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Charlson Comorbidity Index (CCI), and sociodemographic characteristics (eg, age, gender, marital status, education, and race/ethnicity)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pressure injury Category/stage was significantly correlated with pain severity $X^2 = 775.74, p&lt;.001$</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Logistic regression to predict pain severity:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 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&lt;0.0001), with a stage 4 pressure injury this increases to 50% more severe (OR 1.50, p&lt;0.0001)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 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&lt;0.0001), with a stage 4 pressure injury this increases to 68% more severe (OR 1.68, p&lt;0.0001)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• People with severe cognitive impairment with pressure injury has the most severe pain (Stage 2 pressure injury OR 1.96, p&lt;0.0001; Stage 4 pressure injury OR 2.36, p&lt;0.0001)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

**Data Tables: 2019 Guideline Update: Assessment and Treatment of Pressure Injury Pain**

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### Data Tables: 2019 Guideline Update: Assessment and Treatment of Pressure Injury Pain

<table>
<thead>
<tr>
<th>Jackson et al., 2017</th>
<th>Qualitative study exploring the experiences of patients with pressure injuries living at home</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exclusion criteria:</td>
<td>None reported</td>
</tr>
<tr>
<td>Inclusion criteria:</td>
<td>Aged ≥18 years</td>
</tr>
<tr>
<td>Participant characteristics:</td>
<td>Age range 31 to 92 years</td>
</tr>
<tr>
<td></td>
<td>75% female</td>
</tr>
<tr>
<td></td>
<td>Pressure injuries ranged from 2 month to 20 year duration</td>
</tr>
<tr>
<td></td>
<td>Comorbidities included arthritis, diabetes, obesity, respiratory disease and heart failure.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interviewed by an experienced researcher</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open-ended questions focused on experience of pain that were validated by clinical nurses</td>
</tr>
<tr>
<td>Thematic analysis by 3 researchers and 1 patient</td>
</tr>
</tbody>
</table>

#### 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

<table>
<thead>
<tr>
<th>Level of evidence: 5 (qualitative)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality: High</td>
</tr>
</tbody>
</table>
## Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Measures</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Szor &amp; Bourguignon, 1999</td>
<td>Descriptive cross-sectional study exploring the experience of pressure injury pain</td>
<td>Participants were recruited by nurses in acute, home and extended care settings in one health care system in US (n=32)</td>
<td>No intervention</td>
<td>Pain measured at rest and during wound dressing change using McGill Pain Questionnaire (MPQ)</td>
<td>Pain experienced by 87.5% of participants, 84.4% at rest and 43% experienced no pain. 92% of Category/Stage II, 100% of Category/Stage III, and 75% of Category/Stage IV had pain. Severity of pain was often described as mild to discomforting, with 75% of Category/Stage II, 84% of Category/Stage III, and 72% of Category/Stage IV reporting constant pain. Pain management was poor, with only 6% receiving pain medication.</td>
</tr>
<tr>
<td>Gunes, 2008</td>
<td>Descriptive observational study reporting the pain experience of pressure injuries</td>
<td>Participants recruited from a university hospital in Turkey (n=47)</td>
<td>Completion of FRS-R and 4 parts of MPQ</td>
<td>PU stage, location and cause of pain, Pain descriptors from MPQ, Present pain intensity subscale of MPQ (0 to 5 scale), Pain occurrence</td>
<td>Pain experienced by 92% of Category/Stage II, 100% of Category/Stage III, and 75% of Category/Stage IV. Pain was more constant in Category/Stage III and IV compared to Category/Stage II. Pain management was poor, with only 6% receiving pain medication.</td>
</tr>
</tbody>
</table>

### Data Tables: 2019 Guideline Update: Assessment and Treatment of Pressure Injury Pain

### (c) EPUAP/NPIAP/PPPIA

**Descriptive Cross-Sectional Study**
- **Participants:** 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 injury
  - 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

### Data Tables: 2019 Guideline Update: Assessment and Treatment of Pressure Injury Pain

### (c) EPUAP/NPIAP/PPPIA

**Descriptive Observational Study**
- **Participants:** Recruited from a university hospital in Turkey (n=47)
- **Inclusion:**
  - ≥18 yrs of age
  - Category/Stage II, III or IV pressure injury
- **Measures:**
  - 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 MPQ (0 to 5 scale)
    - Pain occurrence

### Data Tables: 2019 Guideline Update: Assessment and Treatment of Pressure Injury Pain

### (c) EPUAP/NPIAP/PPPIA

**Level of Evidence:** 5 diagnostic
**Quality:** high

**Level of Evidence:** 5 diagnostic
**Quality:** moderate
## Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>Kapp &amp; Annells, 2010</th>
<th>Hermeneutic qualitative pilot study reporting</th>
<th>7 participants</th>
<th>unstructured in-depth interviews averaging 50 minutes duration</th>
<th>Interview questions: Tell me what it is like having a pressure injury</th>
<th>Themes: To live with discomfort: Participants spoke about the soreness and pain they experienced</th>
<th>• Generalizability of small sample</th>
<th>Level of evidence: 5 Quality: low</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

- 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**
### Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>Themes associated with living with a pressure injury</th>
<th>All were receiving home-based care for a pressure injury</th>
<th>All interviews were audio-taped and then transcribed verbatim by the researcher who conducted the interviews</th>
<th>and to be living at home?</th>
<th>To live with differing interests: living with a PU at home required involvement from more than one community-based health professional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fox, 2002</td>
<td>Participants were recruited in the community (n=5)</td>
<td>No intervention</td>
<td>Semi-structured interview</td>
<td>Patient selection not detailed</td>
</tr>
</tbody>
</table>
| Description and phenomenology study exploring the experience of pressure injury pain | Participant characteristics:  
- Ages 31 to 64 years old,  
- 80% male  
- Pressure injury duration 4-36 months | 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 |
| Bale, Dealey, Defloor, Hopkins, & Worboys, 2007 | Participants were recruited from 4 centers in England and Belgium (n=8) | No intervention | Unstructured interviews which acknowledged the contribution of both the participant & researcher | Limited to older adults and limited number of participants.  
- May not be generalizable worldwide. | Level of evidence: 5 |
| Also reported in Hopkins, Dealey, Bale, Defloor, & | Inclusion criteria:  
- Older adult  
- Category/Stage III or IV pressure injuries | 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), | Level of evidence: 5 |
| Qualitative pilot study using Heideggarian phenomenology exploring the experience of pain | Exclusion criteria:  
- Spinal cord injury | Unstructured interviews which acknowledged the contribution of both the participant & researcher | | |
<p>| Level of evidence: 5 | | | | |</p>
<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Type</th>
<th>Participants</th>
<th>Data Collection</th>
<th>Findings</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worboys, 2006</td>
<td>Qualitative</td>
<td>Inability to provide informed consent.</td>
<td>No intervention</td>
<td>• Pain was restricting feature with significant impact on life &amp; feelings regarding self&lt;br&gt;• Pain contributed to being worried, depressed, feeling burdensome, inadequate &amp; sense of powerlessness.</td>
<td>5</td>
</tr>
<tr>
<td>Langemo, Melland, Hanson, Olson, &amp; Hunter, 2000</td>
<td>Qualitative</td>
<td>Non-probability, purposive sample recruited in US (n=8)</td>
<td>Unstructured, face to face, audio-taped interview.</td>
<td>Seven themes:&lt;br&gt;• Perceived etiology of pressure injury&lt;br&gt;• Life impact &amp; changes (physical, financial &amp; social)&lt;br&gt;• Psycho-spiritual impact (body image changes, struggle with stereotypes, desire/struggle for control &amp; independence, spiritual impact)&lt;br&gt;• Extreme painfulness with pressure injuries (pain intensity &amp; duration, analgesic use)&lt;br&gt;• Need for knowledge &amp; understanding (knowledge of prevention, physiologic processes &amp; lack of knowledge)&lt;br&gt;• Need for and effect of numerous stressful treatments (self-care, treatment regimens &amp; multiple surgeries, complications, length of healing time)&lt;br&gt;• Grieving process (denial, depression, anger, bargaining, acceptance)&lt;br&gt;22 themes and 1 constitutive pattern identified.</td>
<td>5&lt;br&gt;• Limited to Caucasians, young or middle age. Need replication in other ethnic groups&lt;br&gt;• Not followed longitudinally</td>
</tr>
<tr>
<td>Rastinehad, 2006</td>
<td>Phenomenological, qualitative</td>
<td>Purposeful sampling of acute care patients with a pressure injury (n=10)</td>
<td>No intervention</td>
<td>• Limited to 10 subjects</td>
<td>5</td>
</tr>
</tbody>
</table>
### Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Participants</th>
<th>No intervention</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spilsbury et al., 2007</td>
<td>Qualitative study exploring the experience of pressure injury pain</td>
<td>Purposive sample of hospitalized patients (n=23)</td>
<td>No intervention</td>
<td>• Majority of the pressure injuries were sacral • Scientific study exploring the experience of pressure injury pain • Participant characteristics: • Primarily female • Age range 33-92 years (median 78 years) • Highest pressure injury locations heel &amp; sacrum. • Pressure injuries Category/Stages II to IV pressure injuries • No intervention • Semi-structured interviews: Identification of themes &amp; sub-themes</td>
</tr>
</tbody>
</table>

### Pain as a prognostic factor

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Participants</th>
<th>No intervention</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith et al., 2017</td>
<td>Prospective cohort study exploring pain as predictor of PUs Category/Stages 2 or greater</td>
<td>Participants were recruited in 26 hospital and community based centres in UK over two years (n=634, n=602 completed (7863 potential skin sites))</td>
<td>No intervention</td>
<td>• Development of a Category/Stages 2 PU or greater • Time to PU development • Baseline and 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</td>
</tr>
</tbody>
</table>

**Data Tables: 2019 Guideline Update: Assessment and Treatment of Pressure Injury Pain**

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### Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>Participants</th>
<th>No/Interventions</th>
<th>Prevalence of pressure-related pain</th>
<th>Author conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aged &lt;18 years</td>
<td>Trained nurse conducted skin assessment, pressure injury classification using EPUAP 1998 system</td>
<td>Of 3,397 patients, 2,010 (58.9%) were asked about presence of pain</td>
<td>The study supports monitoring and management of pressure-related pain. An important minority of patients without pressure injuries reported pressure-related pain.</td>
</tr>
<tr>
<td>Two or more existing Category/Stage 2 PUs or greater on sacrum, buttocks, heels or hips</td>
<td>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</td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>Hospital based care (m=397) and community based (n=205)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age 77 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>37% had no PU on entry</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>91% using analgesia on entry</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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

- 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

#### 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.
## Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>Study</th>
<th>Cross sectional study to estimate prevalence of pressure injury related pain</th>
<th>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)</th>
<th>No intervention</th>
<th>Participants were asked if they experienced pain, and if they believed the pain was related to pressure</th>
<th>Prevalence of pressure injury related pain</th>
<th>Prevalence of pain was 75.6% (133/176)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Inclusion criteria:</strong></td>
<td><strong>Detailed assessment</strong></td>
<td><strong>No intervention</strong></td>
<td><strong>Participants were asked if they experienced pain, and if they believed the pain was related to pressure</strong></td>
<td><strong>Prevalence of pressure injury related pain</strong></td>
<td><strong>Prevalence of pain was 75.6% (133/176)</strong></td>
</tr>
<tr>
<td></td>
<td>• Aged over 18 years</td>
<td>• 27.8% (n = 37/133) of the population reporting pain consented to full assessment</td>
<td></td>
<td>• 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</td>
<td>• Prevalence of pain was 75.6% (133/176)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• On community nursing case load</td>
<td>• 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)</td>
<td></td>
<td>• Participants also rated their most painful torso and limb skin sites</td>
<td>• Detailed assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Had a pressure injury of any Category/Stage</td>
<td>• 98.1% of sites with pressure injury were rated as painful by patients.</td>
<td></td>
<td>• Leeds Assessment Neuropathic Symptoms and Signs (LANSS) Pain Scale was used</td>
<td>• Detailed assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Exclusion criteria:</strong></td>
<td>• Mean pain intensity 6.4 (SD 2.53) (range 1–10, median 7.0)</td>
<td></td>
<td>• Data collection by community nurses trained in assessment (no inter-rater reliability conducted)</td>
<td>• Detailed assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Pediatric, obstetric or psychiatric patients</td>
<td>• There is a slightly skewed distribution of pain intensity with very similar pain levels for each grade of pressure injury</td>
<td></td>
<td></td>
<td>• Detailed assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Imminent death</td>
<td><strong>Neuropathic pain assessment</strong></td>
<td></td>
<td></td>
<td>• Detailed assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Participant characteristics:</strong></td>
<td>• 31 patients identified one or more skin site for LANSS assessment (n=22 torso and n=18 limb assessments)</td>
<td></td>
<td></td>
<td>• Detailed assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mean age 72.6 years (SD 15.31)</td>
<td>• 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</td>
<td></td>
<td></td>
<td>• Detailed assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 70% of participants were in their own home</td>
<td><strong>Level of evidence:</strong> 4</td>
<td></td>
<td></td>
<td>• Detailed assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 75.7% females</td>
<td><strong>Quality:</strong> high</td>
<td></td>
<td></td>
<td>• Detailed assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 100% white British</td>
<td></td>
<td></td>
<td></td>
<td>• Detailed assessment</td>
<td></td>
</tr>
</tbody>
</table>

**Data Tables:** 2019 Guideline Update: Assessment and Treatment of Pressure Injury Pain © EPUAP/NPIAP/PPPIA
### Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
<th>Participants</th>
<th>Interventions</th>
<th>Pain characteristics</th>
<th>Level of evidence</th>
</tr>
</thead>
</table>
| 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 | 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 | Small study | Level of evidence: 4 |
| | | 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 | | | |

**Study conclusions:** Prevalence of pain associated with pressure injuries was 75.6%.

**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.
Assessment and treatment of pressure injury Pain: data extraction and critical appraisal

Table 1: Level of Evidence for Intervention Studies

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

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

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

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

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

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

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

- High quality studies: fully met at least 80% of applicable criteria
- Moderate quality studies: fully met at least 70% of applicable criteria
- Low quality studies: did not fully meet at least 70% of applicable criteria
## CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Focussed question</th>
<th>Sampling method</th>
<th>Representative sample</th>
<th>States number invited</th>
<th>Participants</th>
<th>Clear outcome measures</th>
<th>Valid reliable outcome measurement</th>
<th>Comparable results for multiple sites</th>
<th>Confounders identified and accounted for</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>8067</td>
<td>Ahn et al., 2015</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>High</td>
<td>4</td>
</tr>
<tr>
<td>1538</td>
<td>Ahn et al., 2013</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>High</td>
<td>4</td>
</tr>
<tr>
<td>2786</td>
<td>McGinnis et al., 2014</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>High</td>
<td>4</td>
</tr>
<tr>
<td>1561</td>
<td>Briggs et al., 2013</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
<td>Moderate</td>
<td>4</td>
</tr>
</tbody>
</table>

## PROGNOSTIC STUDIES

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Baseline sample adequately described</th>
<th>Study attrition (&gt;20% lost to follow-up)</th>
<th>Clear definition of risk factors used/ appropriate cut-point and reliable RF measure/methodology</th>
<th>Adequate sample with co-morbidity</th>
<th>Appropriate imputation</th>
<th>Appropriate classification for outcome</th>
<th>Appropriate classification for outcome</th>
<th>Potential confounders accounted in study design</th>
<th>Potential confounders accounted in analysis</th>
<th>Data adequate to assess adequacy of analysis</th>
<th>Appropriate strategy for model building</th>
<th>Model adequate for design</th>
<th>Adequate sample size (rule of thumb &gt;10 events per risk factor)</th>
<th>Non-selective reporting</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>14318</td>
<td>Smith et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>1 (prognostic)</td>
<td>high</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## QUALITATIVE STUDIES

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Clear statement of aims</th>
<th>Qualitative method is appropriate</th>
<th>Appropriate research design</th>
<th>Recruitment appropriate to research and sample justified</th>
<th>Clear, explicit and appropriate methods for data collection and analysis and potential ethical issues</th>
<th>Findings stated clearly</th>
<th>In-depth description of data collection technique indicates rigor</th>
<th>Clear conclusions</th>
<th>Research contributes to the existing knowledge</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>14414</td>
<td>Jackson et al., 2017</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>5</td>
<td>High</td>
</tr>
<tr>
<td>8369</td>
<td>McGinnis et al., 2015</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>5</td>
<td>High</td>
</tr>
</tbody>
</table>

## COHORT STUDIES
### Assessment and treatment of pressure injury pain: data extraction and critical appraisal

| Author/year | Focused 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 | Assesment 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                                    |                                          |                                          |                      |                                          |                                          |                             |                               |                               |                  |                     |                               |       |                       |

### References


Assessment and treatment of pressure injury Pain: data extraction and critical appraisal


