Search results for 2019 International Pressure Injury Guideline: Risk Factors and Assessment

- Identified in pressure injury searches: n=11,177
- Identified citations: n=5,843
  - Identified as providing direct or indirect evidence related to topic and critically appraised for risk assessment and risk factors: n=257
    (n=128 for risk factors, n=129 for risk assessment)
  - Identified as providing direct or indirect evidence related to topic and critically appraised: n=31
- Total references providing direct or indirect evidence related to topic: n=104
- Excluded after screening title/abstract:
  - n=8,128
    - Duplicate citations
    - Included in previous guideline
    - Not related to pressure injuries
- Excluded after review of full text:
  - n=226
    - Not related to pressure injury risk
    - 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

Additional references identified in risk factor specific search
- n=2,758

Additional citations
- Appraised for previous editions
- n=73

## Risk Factors and Risk Assessment: data extraction and appraisals

### Articles Reviewed for International Pressure Injury Guideline

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


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<th>Results</th>
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<th>Risk factors</th>
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<tr>
<td>Yoshimura, Iizaka, et al., 2015</td>
<td>Retrospective cohort study investigating risk factors for PU in hospital patients undergoing neurosurgery</td>
<td>Participants in a Japanese hospital having neurosurgery (n=277)</td>
<td>NA</td>
<td>Pressure injuries Stage 1 and greater</td>
<td>Risk factors considered in model: • Perspiration present • Surgery length &gt; 6 hours • Core temperature &gt; 38.1°C</td>
<td>Pressure injury rate 11% Significant factor on Multivariate logistic regression: • Perspiration present OR 3.09 (95% CI 1.07 to 8.58, p=0.037) • Surgery length &gt; 6 hours OR 8.45 (95% CI 3.04 to 27.46, p&lt;0.001)</td>
<td>• Timing of development of perspiration and PU during surgery is unclear • Few risk factors • Poor definition of perspiration • Data derived cut points</td>
<td>• Perspiration present • Surgery length &gt; 6 hours • Core temperature &gt; 38.1°C</td>
</tr>
</tbody>
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| Gonzalez-Mendez, Lima-Serrano, Martin-Castano, Alonso-Araujo, & | Prospective cohort study investigating risk factors for PU in patients in ICU | Participants (n=335) | NA | Pressure injuries Stage 1 and greater | Risk factors considered in model: • Severity SAPS 3 (simplifies acute physiology score) • Days of immobilisation • Complications • Age | Pressure injury rate 24.1% Significant factor on Multivariate logistic regression: | • Insufficient number of events. • Unclear risk factor measurement methods | • Perspiration present • Surgery length > 6 hours • Core temperature > 38.1°C |

Data Tables: 2019 Guideline Update: Risk Factors © EPUAP/NPIAP/PPPIA
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<th>Level of evidence: 3 Quality: Very Low</th>
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<tr>
<td>H. L. Chen, Zhu, Wei, &amp; Zhou, 2018</td>
<td>Retrospective cohort study investigating risk factors for PU in hospital patients</td>
<td>256 (21 missing data) recruited 235 patients with hip fracture at risk on Braden scale exclusion: PU on admission, death</td>
<td>NA</td>
<td>Pressure injuries Stage 1 and greater</td>
<td>The only significant factor on Multivariate logistic regression: Braden Scale score (OR) 1.073 (95% CI 1.025 to 1.14, (p=0.015))</td>
<td>Insufficient number of events. Unclear risk factor measurement methods</td>
<td></td>
<td>3 Quality: Very Low</td>
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<tr>
<td>Lin et al., 2017</td>
<td>Prospective cohort study investigating risk factors for PU in patients undergoing spinal surgery</td>
<td>Patients having posterior lumbar and/or thoracic spinal surgery in the prone position on a Jackson table. (n=209) Exclusion: procedure under sedation or local anaesthesia, existing PU secondary to neuropathic conditions or neglect</td>
<td>NA</td>
<td>Pressure injuries Stage 1 and greater</td>
<td>Risk factors considered in model: Previous skin problems Myelopathy Spinal deformity Operative time &gt;300 mins Levels of surgery &gt; 4 Greater body height Concomitant cancer history Braden scale&lt;20 Previous spinal instrumentation and fusion Increased number significant factor on Multivariate logistic regression: Previous skin problems ((p=0.034)) Myelopathy (OR 4.79, (p=0.013)) Spinal deformity (OR 3.31, (p=0.01)) Operative time &gt;300 mins (OR 8.12, (p=0.005)) Levels of surgery &gt; 4 (OR 9.10, (p=0.006))</td>
<td>Unclear if sufficient number of events. Cut-offs and categorical factors not appropriate and unclear if full sample had complete data</td>
<td></td>
<td>3 Quality: Very Low</td>
</tr>
<tr>
<td>Apostolopoulou et al., 2014</td>
<td>Prospective cohort study investigating</td>
<td>Participants were all admissions to two ICUs in Greece (n=216)</td>
<td>PI risk assessed by trained ICU nurses using Jackson/Cubbin</td>
<td>64 PIs ≥ Category/stage II in 42 patients cumulative incidence</td>
<td>Step-wise logistic regression for factors</td>
<td>Follow-up period of time is unclear</td>
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<td>risk factors for PU in ICU patients</td>
<td>Inclusion criteria: • admitted to ICU • ventilated for &gt; 48 hours • actively monitored for PI until discharge or death Exclusion criteria: • none stated Characteristics: • Mean age 66-68 years • 66.7% of patients with PI had only one, 19% experienced two, 9.5% had three and 4.8% had four PIs</td>
<td>Scale within 12 hours of admission • APACHE on admission Co-morbidity using weighted Charlson co-morbidity index</td>
<td>of 29.6% • 14 cases per 1000 ventilated days Risk factors considered in model: length of stay of ventilation &gt;20 days, APACHE II at admission, Cubbin/Jackson score, Age, diabetes, malignancy, shock, bloodstream infection, hemodialysis, sedatives, inotropic drugs, corticosteroids Risk factors significant in univariate analysis • length of stay of ventilation &gt;20 days (p&lt;0.001) • Age &gt; 70 years (p=0.038) • Diabetes mellitus (p=0.002) • Bloodstream infection (p&lt;0.001) • Hemodialysis (p&lt;0.001) • Inotropic drugs (p=0.041)</td>
<td>statistically significant in univariate analysis Multivariable analysis • risk of PU is 98.5% greater in patients with Cubbin/Jackson scale score ≤29 (OR 0.015, 95% CI 0.005 to 0.050, p=0.001) • Risk of PU is 622.5% greater in patients with length of stay of ventilation &gt;20 days (OR 7.225, 95% CI 2.461 to 21.207, p&lt;0.001)</td>
<td>statistically significant in univariate analysis</td>
<td>• Appears to be missing data (e.g. gender does not add to correct number of participants)</td>
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Ham, Schoonhoven, Schuurmans, & Leenen, 2017a | Prospective cohort study investigating risk factors for PU in an emergency department (trauma) Participants were recruited over 12 months (n=254) in one level 1 trauma center in Netherlands Inclusion criteria: • Aged ≥ 18 years | • Backboard removed on arrival before assessment • Immobilized with extrication color and head blocks in supine position until PU categorized using NPUAP/EPUAP 2009 categories Risk factors collected on admission (n=12): Risk factors: Age, Skin color, Body Mass Index, Time in Emergency | PU incidence after 72 hours 28.3% (72/254) PU incidence after 48 hours from admission 13% (33/254) | MV logistic regression Model 1 (PU in 72 hours) • Age p=0.0 OR 1.05 95% CI 1.03 to 1.07 • female (reference male) p=0.17 OR 1.74 95% CI 0.79 to 3.88 | insufficient events for factors in model | level of evidence: 3 |

Quality: Low

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| Ranzani, Simpson, Japiassu, & Noritomi, 2016 | Prospective cohort study exploring predictive ability of Braden scale | Participants were recruited over 6 months in 12 ICUs in 11 hospitals in Brazil (n=9,605) | • standard prehospital spinal immobilization  
• admitted to ED for acute traumatic injuries  
Exclusion criteria:  
• Existing skin breakdown  
• Severe burns (>10%)  
• Transferred from another hospital  
Participant characteristics:  
• Mean age 52 years  
• Mean BMI 26.6  
• 36.6% female  
• Primarily falls and cycle accidents  
• 5.1% had medium to very dark skin | • radiology excluded spinal injury (unconscious patients were admitted to ICU and immobilized)  
• Extrication collar replaced with semi-rigid collar | Department, Injury Severity Score (ISS), Mean Arterial Pressure (MAP), hemoglobin (Hb), Glasgow Coma Score (GCS), admission ward after Emergency Department | • Age p=0.01 OR 1.03 95% CI 1.01 to 1.06  
• female (reference male) p=0.25 OR 1.71 95% CI 0.69 to 4.21  
• skin color (reference dark pigment) p=0.28 OR 0.44 95% CI 0.10 to 1.97  
• BMI p=0.93 OR 1.00 95% CI 0.91 to 1.09  
• Length time in ED p=0.74 OR 1.00 95% CI 0.91 to 1.08  
• ISS p=0.76 OR 1.01 95% CI 0.96 to 1.05  
• MAP p=0.13 OR 0.98 95% CI 0.96 to 1.01  
• Hb p=0.42 OR 0.87 95% CI 0.61 to 1.23  
• GCS p=0.01 OR 1.16 95% CI 1.03 to 1.31  
• Position change (reference no change) p=0.33 OR 0.26 95% CI 0.02 to 3.84  
• Extra nutrition (reference no extra) p=0.68 OR 0.79 95% CI 0.25 to 4.09  
• skin color (reference dark pigment) p=0.64 OR 0.71 95% CI 0.17 to 2.96  
• BMI p=0.66 OR 0.98 95% CI 0.91 to 1.06  
• Length time in ED p=0.41 OR 1.00 95% CI 1.00 to 1.01  
• ISS p=0.03 OR 1.05 95% CI 1.00 to 1.09  
• MAP p=0.11 OR 0.98 95% CI 0.96 to 1.00  
• Hb p=0.27 OR 0.82 95% CI 0.57 to 1.17  
• GCS p=0.00 OR 1.21 95% CI 1.08 to 1.35  
• Position change (reference no change) p=0.34 OR 4.50 95% CI 0.21 to 96.53  
• Extra nutrition (reference no extra) p=0.04 OR 0.20 95% CI 0.04 to 0.94  
• PR mattress (reference none) p=0.68 OR 0.79 95% CI 0.26 to 2.37 | MV analysis using Fine-Gray model  
• Censored after discharge or 30 days in ICU  
• 138 people had 157 Category/Stage 1 or greater pressure injuries (1.43%) or 3.33  
Multivariable analysis (Fine-Gray model)  
• Age (subdistribution hazard ratio) sHR 1.20,  
Data base collection of pressure injury and general diagnostic/dem  
Level of evidence: 3  
Quality: Low |
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<tr>
<td>Joseph &amp; Nilsson Wikmar, 2016a</td>
<td>Prospective cohort study investigating risk factors in trauma patients</td>
<td>Participants were recruited over 12 months in specialized acute care units in South Africa (n=145 included, 141 analyzed)</td>
<td>N/A</td>
<td>Medical complications including pressure injuries screened weekly by medical team; MV regression analysis</td>
<td>29.8% (n=42) developed pressure injury</td>
<td>MV logistic analysis: Motor complete injury (AIS A/B) OR 3.51 95% CI 1.22 to 10.04, p=0.019; Vertebral injury OR 4.41, 95% CI 1.10 to 17.58, p=0.036; UTI OR 2.86, 95% CI 0.90 to 9.09, p=0.075</td>
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**Risk Factors and Risk Assessment: data extraction and appraisals**

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<td>and proposing additional predictive items</td>
<td>First admission only</td>
<td>Exclusion criteria: Subsequent admissions Pressure injury on or within 48 hours of admission</td>
<td>• Pressure injury determined by trained nurses &lt;br&gt; • Uncertain how many risk factors collected</td>
<td>idents/1,000 patient-days in ICU 27.5% Category/Stage I, 68% Category/Stage II, 2.2% Category/Stage III, 0.7% Category/Stage IV and 1.4% unclassified or SDTI 61% coccyx/sacrum, 10.1% buttocks, 7.2% heels</td>
<td>95% CI 1.03 to 1.39, p=0.022 Sex sHR 1.45 95% CI 1.02 to 2.06, p=0.0039 Diabetes sHR 1.48, 95% CI 1.03-2.11, p=0.033 Hematological malignancy sHR 2.63, 95% CI 1.24 to 5.60, p=0.012 Peripheral artery disease sHR 3.21, 95% CI 1.02 to 10.04, p=0.046 Braden score ≤ 13 sHR 3.89, 95% CI 2.46 to 6.13, p&lt;0.001 MAP &lt;60mmHg on admission sHR 1.50, 95% CI 0.94 to 2.40, p=0.089 Mechanical ventilation during first 24 hours sHR 2.14, 95% CI 1.37 to 3.34, p=0.001 Renal replacement therapy 2.16, 95% CI 1.48 to 3.15, p&lt;0.001</td>
<td>Low incidence of pressure injuries</td>
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Data Tables: 2019 Guideline Update: Risk Factors © EPUAP/NPIAP/PPPIA Page 6
### Risk Factors and Risk Assessment: data extraction and appraisals

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<tr>
<td>Nassaji, Askari, &amp; Ghorbani, 2014</td>
<td>Prospective cohort study investigating risk factors for PU in ICU male patients</td>
<td>Participants were recruited over 9 months in one 20 bed ICU in Iran (n=2046 admissions, n=352 met inclusion, n=160 smokers)</td>
<td>PU screening on admission and then assessed daily by researchers Routine PU prevention strategies</td>
<td>Presence of PU if PU present grading (using EPUAP scale)</td>
<td>HAPU incidence 25.6% (n=90) PUs</td>
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<td>Significantly more of smokers experienced a PU than non-smokers (38.8% versus 14.6%, p&lt;0.001)</td>
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<td><strong>Category/stage</strong></td>
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<td>• Stage I: 53.2% of smoker PUs, 85.7% non-smoker PU</td>
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<td>• Stage II: 37.1% of smoker PUs, 14.3% non-smoker PU</td>
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<td>• Stage III: 9.7% of smoker PUs, 0% non-smoker PU</td>
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<td>• Stage IV: none</td>
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<td>Patients with PU were more likely to have:</td>
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<td>• Older age (p=0.001)</td>
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**Participants**

- **Survival ≥ 7 days**
- **Exclusion criteria:** ASIA Impairment Scale E at 7 days post injury

**Participant characteristics:**

- **85.5% males**
- **Mean age at injury 33.5 (SD13.8)**
- **51.7% required spinal surgery**
- **Mean time to surgery 9.93 hrs (SD 9.5)**

**Inclusion:**

- Admitted to ICU in study period

**Exclusion:**

- Female
- No skin assessment within 24 hours of admission

**Characteristics:**

- Length of stay was a mean 10-11 days (smokers longer, p=0.009)
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<tr>
<td>Tayyib, Coyer, &amp; Lewis, 2015</td>
<td>Prospective cohort study investigating risk factors for PU in ICU patients</td>
<td>Participants were all admissions to two ICUs in tertiary hospitals in Saudi Arabia in a 30-day study period (n=90 admissions, n=84 included in study) Inclusion criteria: • admitted to ICU in study time frame and consenting Exclusion criteria: • Pre-existing PU Characteristics: • Mean age 52.8 years (range 18 to 99 years) • 66.6% men • Primarily non-Saudi nationals • 85.7% assessed as being at high risk for Comprehensive skin assessment performed second daily on every participant by the same researcher Presence of PU If PU present: • Grading (using NPUAP/EPUAP scale) and site of PU • Ventilation status • Frequency of repositioning • Sequential Organ Failure Assessment (SOFA) score</td>
<td>HAPU incidence 39.3% (33/84) 41 PUs recorded in the 33 participants Sites: Sacrum 24.3% Heel 29.2% Category/Stage: 1 23/41 (56.09%) 2 15/41 (36.5%) 3 3/41 (7.3%) Incidence of MDRPU 8.3% (7/84) 20% of all PUs and primarily located on ears Risk factors considered in model (n=7) Age, length of stay in ICU, history of cardiovascular disease, infrequent repositioning, emergency</td>
<td>Binary logistic regression model for all stages of PU Age OR=1.254 (95% CI 1.054 to 1.492, p=0.011) Longer stay in ICU OR=1.831 (95% CI 1.014 to 3.309, p=0.045) Infrequent repositioning OR=250.04 (95% CI 5.230 to 11954.16, p=0.005) Binary logistic regression model for PU stages 2 to 4 Length of stay in ICU OR=1.23 (95% CI 1.087 to 1.392, p=0.001) Infrequent repositioning OR=2.96 (95% CI 1.23 to 7.153, p=0.015)</td>
<td>High rate of PU noted</td>
<td>Level of evidence: 3 Quality: Very low</td>
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| Demarre et al., 2015 | Retrospective analysis of a RCT study investigating factors associated with PU in general hospital | Participants recruited in 5 hospitals in Belgium (n=610)  
Inclusion criteria:  
- Braden score < 17  
- Category 2 to 4 PU  
- DO not resuscitate status  
- Bodyweight <30kg or >160kg  
- Not consenting  
Exclusion criteria:  
- Category 2 to 4 PU  
- DO not resuscitate status  
- Bodyweight <30kg or >160kg  
- Not consenting  
Characteristics:  
- Median age 80 years  
- Median Braden score 14.0 (interquartile range 12 to 15)  
- 27.5% bedbound and 61.3% chair bound  
- 15% admitted with non-blanchable erythema (PU Category/Stage 1) | PU (mean Braden score 10±2.12)  
- Participants received an alternating low pressure air mattress (two types used and no significant difference between two for PU rate)  
- Staff received training in differentiating between incontinence associated dermatitis and PU and using Braden scale  
- Transparent plastic disc used to differentiate non-blanchable and blanchable erythema | Skin assessment performed daily by ward nurse and weekly by research team (interrater reliability κ=0.71 to 0.81)  
PU classified using NPUAP/EPUAP classification system  
Follow up period of 14 days | PU incidence  
- 14.6% developed non-blanchable erythema (PU Category/Stage 1)  
- Cumulative PU incidence 5.7% (n=35) including 3.9% PU category/stage II (n=24) and 1.8% Category/stage 3 to 4 (n=11)  
- Of patients with Category/Stage 1 PU on admission, 13.7% developed Category/Stage 2 to 4  
Sites:  
- Sacrum 3.4% (n=22)  
- Heels 1.7% (n=9)  
Risk factors considered in model:  
- Age, weight, length, BMI, blood pressure, Braden score (including subscales)  
- Body temperature, gender, continence status, catheter, ward type, primary diagnosis, medications, type of mattress, incontinence-associated dermatitis (IAD) present | Multivariate analysis with PU Category/Stage 2 to 4 as dependent variable  
- Non-blanchable erythema OR=5.36 (95% CI 2.40 to 11.99, p<0.001)  
- Urogenital diagnosis OR=3.76 (95% CI 1.03 to 13.70, p=0.044)  
- Body temperature OR=1.65 (95% CI 1.02 to 2.66, p=0.041)  
- Catheter insitu OR=2.00 (95% CI 0.92 to 4.37, p=0.081)  
- IAD OR=2.15 (95% CI 0.92 to 4.37, p=0.079)  
- Braden score OR=0.87 (95% CI 0.75 to 1.01, p=0.074) | Low event rate (only 11 PU Category/Stage 3 to 4 PU)  
Level of evidence: 3  
Quality: Low |
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<tr>
<td>Matozinho, Velasquez, Melendez, Tiensoli, Moreira, &amp; Gomes, 2017</td>
<td>Prospective cohort study investigating risk factors for PU in hospitalized patients</td>
<td>Participants were a convenience sample of patients in hospital in a 6 month period in Brazil (n=442)</td>
<td>• Data collection by trained nurses using standardized questionnaire</td>
<td>HAPU incidence 2.42/1,000 people days (95% CI 1.63 to 3.58) Following factors were no statistically significantly related to PU development: • Age being over 60 years • Gender • Skin color • Smoking status • Nutritional status measured (malnourish, eutrophic or overweight defined by BMI ranges) Statistically significant risk factors: Braden Scale score (risk increases as Braden score decreases, p&lt;0.01)</td>
<td>Multivariate regression model • Only significant factor was Braden Scale score (adjusted hazard risk: high risk Braden Scale score 6.31 (95% CI 2.73 to 14.58, p&lt;0.001) Non-significant factors in multivariable model • age over 60 (HR 0.44, 95% CI 0.18 to 1.06, p=not sig value not reported) • Gender (adjusted HR 0.66, 95% CI 0.27 to 1.61, p=not sig value not reported) • Smoker (HR 1.38 (95% CI 0.44 to 4.36, p=not sig value not reported) • Overweight (HR 0.50 (95% CI 0.08 to 2.99, p=not sig value not reported)</td>
<td>• Not entirely clear whether the risk factor preceded the PU in this study • Unclear how PU was identified or categorized • Sample selection not reported, small sample size</td>
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<td>Dhandapani, Dhandapani, Agarwal, &amp; Mahapatra, 2014</td>
<td>Prospective cohort study investigating risk factors in individuals admitted with brain injury</td>
<td>Participants were recruited in a neurosurgery department in India (n=89 met inclusion criteria)</td>
<td>• Daily assessment for sacral or trochanter PU • AHCPR criteria used</td>
<td>PU incidence • 7% at 2 weeks • 16% at 3 weeks Univariate analysis significant factors</td>
<td>Multivariate analysis Significant factors • Enteral feeding for more than 7 days, OR 5.65 (95% CI 1.6 to 19.9, p=0.03) • Mean hemoglobin change at 2 weeks OR -2.07 (95% CI -3.5 to -0.7, p=0.05)</td>
<td>• Unclear who performed assessment for PU • Only assessed for sacral or trochanter PU • High attrition</td>
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</tbody>
</table>
## Risk Factors and Risk Assessment: data extraction and appraisals

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Cox &amp; Roche, 2015</td>
<td>Retrospective cohort study exploring association between vasopressor use and development of PU in UCU patients</td>
<td>Participants were in two medical-surgical and cardiothoracic ICUs in the US (n=306)</td>
<td>• All participants received a low-air-loss mattress</td>
<td>• PU incidence determined through retrospective record review</td>
<td>PU incidence</td>
<td>• Cardiac arrest; odds ratio (OR) 3.894, 95% CI 0.998 to 15.118, p=0.05</td>
<td>• Statistical power for multivariate analysis was achieved</td>
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<td>PU incidence rate 13% (n=41)</td>
<td>• Of PUs, 39% were suspected DTI, 37% Category/Stage II, 12% Category/Stage I and 12% Unstageable.</td>
<td>• Only considers PUs that developed in participants who took vasopressors so</td>
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<td>Level of evidence: 3</td>
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<td>Quality: Low</td>
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</table>

Exclusion criteria:
• Aged > 60 years
• Glasgow Coma Scale (GCS) 3
• Significant systemic disorder

Characteristics:
• 61% aged 18 to 40 years
• 92% male
• 25% had systemic injuries
• 62% had a surgical intervention
• 36% had total enteral feeding for more than 7 days
• 61% had tracheostomy
• 49% had a fever for at least 7 days

GCS, p=0.05
Enteral feeding for more than 7 days (p=0.005)
Mean hemoglobin change at 2 weeks (p<0.005)

Non-significant factors:
• GCS, OR 3.22 (95% CI 1.00 to 10.31 p=0.67)
• Age, OR 5.26 (95% CI -1.7 to 12.3 p=0.33),
• Surgery, OR 1.14 (95% CI 0.35 to 3.7, p=0.92),
• Mean albumin change at 2 weeks, OR -0.16 (95% CI -0.5 to 0.2, p=0.42)

Level of evidence: 3
Quality: Low
### Risk Factors and Risk Assessment: data extraction and appraisals

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<tbody>
<tr>
<td>Van Der Wielen, Post, Lay, Glasche, &amp; Scheel-Sailer, 2016</td>
<td>Prospective cohort study investigating factors associated with development of hospital-acquired PU</td>
<td>Participants were observed in an acute and rehabilitation spinal center in Switzerland for 6 months (n=185)</td>
<td>All participants received best practice for PU prevention based on risk assessment</td>
<td>• Participants were examined every 12 hours during admission and HAPU graded according to EPUAP classification</td>
<td>• 56% sacral, 34% buttocks, 5% heel, 5% other</td>
<td>• hours of MAP &lt;60mmHg while receiving vasopressors: OR 1.096, 95% CI 1.020 to 1.178, p=0.01</td>
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<td></td>
<td>• administration of vasopressin OR 4.816, 95% CI 1.666 to 13.925, p=0.004</td>
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<td></td>
<td>• Cardiac diagnosis at time of ICU admission:, OR 0.035, 95% CI 0.002 to 0.764, p=0.03</td>
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<td></td>
<td>• it is unknown how this compares to patients who did not take vasopressin</td>
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<td></td>
<td></td>
<td>• Unclear how PUs were identified and by whom</td>
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<td></td>
<td></td>
<td>• Relied on records – length of follow up is not clear</td>
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</table>

Van Der Wielen, Post, Lay, Glasche, & Scheel-Sailer, 2016

- Received a vasopressor in ICU

Exclusion criteria:
- Aged under 18 years
- ICU admission < 24 hours
- Did not receive a vasopressor
- Pre-existing PU

Participant characteristics:
Mean age 71 years (SD 13.8) 57% male 78% white skinned Mean ICU length of stay 6.7 days (SD 7.0) 59% admitted for cardiac conditions, 15% admitted for sepsis or infection

- • 56% sacral, 34% buttocks, 5% heel, 5% other

- • hours of MAP <60mmHg while receiving vasopressors: OR 1.096, 95% CI 1.020 to 1.178, p=0.01

- • administration of vasopressin OR 4.816, 95% CI 1.666 to 13.925, p=0.004

- • Cardiac diagnosis at time of ICU admission:, OR 0.035, 95% CI 0.002 to 0.764, p=0.03

It is unknown how this compares to patients who did not take vasopressin

- Unclear how PUs were identified and by whom

- Relied on records – length of follow up is not clear

**Level of evidence:** 1

**Quality:** Moderate

- Does not describe who performed skin assessments
- Does not report wound management strategies
- Small patient group without reporting comorbidities
- >30% PUs unhealed on discharge so no
## Risk Factors and Risk Assessment: data extraction and appraisals

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<tr>
<td>Sternal, Wilczynski, &amp; Szewieczk, 2017</td>
<td>Retrospective cohort study exploring risk factors for PU in palliative care setting</td>
<td>Consecutive participant records over one year from one palliative care ward in Poland were reviewed (n=329 participants) Inclusion criteria: Patient in a participating facility Exclusion criteria: Not stated Participant characteristics: Mean age 70.4±11.8 years 55.3% female 95% had cancer</td>
<td>• Comprehensive PU prevention scale was in place that included regular daily assessment, best practice with respect to support surfaces, positioning, skin care, hydration and nutrition</td>
<td>• Patients were evaluated daily during admission • Waterlow scale within 2 hours of admission and then daily • Risk assigned based on Waterlow score ≥10 for risk, ≥15 high risk and ≥20 very high risk • For analysis, patients were analyzed as no PU developed (group A), admitted with PU (group B) and hospital acquired PU (group C)</td>
<td>Prevalence • 62.3% had no PU • 25.5% admitted with a PU • 11.8% HAPU</td>
<td>Multivariable logistic regression Factors assessed at admission: • Waterlow score at admission (odds ratio [OR] 1.140, 95% CI 1.057 to 1.229, p=0.001) • admitted from another hospital (OR 2.938, 95% CI 1.339 to 6.448, p=0.007) • hemoglobin level at admission (OR 0.814, 95% CI 0.693 to 0.956, p=0.012) • systolic blood pressure at admission (OR 0.976, 95% CI 0.955 to 0.997, p=0.023) Factors assessed during hospitalization: • mean Waterlow score (OR 1.194, 95% CI 1.092 to 1.306, p=0.001) • mean systolic blood pressure (OR 0.956, 95% CI 0.929 to 0.984, p=0.003)</td>
<td>data on complete healing</td>
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## Risk Factors and Risk Assessment: data extraction and appraisals

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<tr>
<td>Yoshimura, Nakagami, et al., 2015 (With Nakagami)</td>
<td>Observational cohort study exploring the influence of microclimate on development of PU in operating room</td>
<td>Participants were recruited in a Japanese general hospital (n=35 eligible, n=33 enrolled, n=29 complete data for analysis)</td>
<td>• Monitoring probes attached to patient during surgical procedure to measure microclimate&lt;br&gt;• Patient positioned on a support surface of urethane foam mattress, gel pad and bean bag&lt;br&gt;• Active warming applied to patient</td>
<td>• Erythema assessed by a researcher and confirmed by a nurse in operating room&lt;br&gt;• Patients followed for 7 days following surgery for any new PU in the lateral thorax region&lt;br&gt;• Micromitect observations (skin temperature and perspiration) conducted every 30 mins during surgery then for 30 mins post-surgery&lt;br&gt;• Interface pressure distribution measured every 30 mins with a pressure mapping device</td>
<td>PU rate was 24.1% (all Category 1)</td>
<td>• mean evening body temperature (OR 3.830, 95% CI 1.729 to 8.486, p=0.001)&lt;br&gt;• lowest recorded hemoglobin level (OR 0.803, 95% CI 0.672 to 0.960, p=0.016)&lt;br&gt;• lowest recorded sodium concentration (OR 0.880, 95% CI 0.814 to 0.951, p=0.001)</td>
<td>• Small sample&lt;br&gt;• Only one position for surgery and long surgery duration&lt;br&gt;• Non-blinding of outcome measurement</td>
</tr>
</tbody>
</table>

### Refs

- Yoshimura, Nakagami, et al., 2015 (With Nakagami)

### Inclusion criteria:
- Undergoing surgery in park bench position
- Free from PU before surgery

### Exclusion criteria:
- Repeated surgery, skin disorders or scars in the area observed
- Anhidrosis or autonomic nerve abnormality

### Participant characteristics:
- Monitoring probes attached to patient during surgical procedure to measure microclimate
- Patient positioned on a support surface of urethane foam mattress, gel pad and bean bag
- Active warming applied to patient

### Outcome Measures
- Erythema assessed by a researcher and confirmed by a nurse in operating room
- Patients followed for 7 days following surgery for any new PU in the lateral thorax region
- Micromitect observations (skin temperature and perspiration) conducted every 30 mins during surgery then for 30 mins post-surgery
- Interface pressure distribution measured every 30 mins with a pressure mapping device

### Results
- PU rate was 24.1% (all Category 1)

### Factors associated with developing park-bench position PU (univariate analysis)
- Significantly more likely to be male (85.3% versus 32%, p=0.01)
- More likely to have higher hemoglobin (14.6±1.16g/dl vs 13.0±1.4g/dl, p=0.02)
- Longer surgery (7.6±1.1 vs 6.7±0.9, p=0.04)
- Significantly lower baseline skin temperature 34.9±0.5°C vs. 35.3±0.4°C, p=0.03)
- Greater change in skin temperature over surgery duration (2.7±0.3°C vs. 1.9±0.8°C, p=0.02)

### Multivariate hierarchical logistic regression
- Change in skin temperature (0.1°C): odd ratio (OR) 1.44, 95% CI 1.09 to 2.33
- Average peak pressure (mmHg): OR 1.41, 95% CI 0.96 to 2.54
- Length of surgery (hour): OR 1.57, 95% CI 0.46 to 5.95

### Author conclusions:
- Elevated skin temperatures are an independent risk factor for PU. As temperature increases, local tissue metabolism accelerates and there is reduced oxygen and nutrients where pressure is being applied to the skin leading to PU.
## Risk Factors and Risk Assessment: data extraction and appraisals

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</table>
| Smith et al., 2017 | Prospective cohort study exploring pain as predictor of PUs Category/Sta ge 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]) | N/A | • 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 subscale, presence of skin alterations, presence of Category/Stage 1 PU, clinical setting (hospital vs community) | 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 rating  
  • 14.4% of skin sites had PU pain at baseline, 10.3% of these developed a Category/Stage ≥2 PU | Multivariable (MV) logistic regression:  
  • 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)  
  • Pressure area related pain (OR 1.56, 95% CI 0.93 to 2.63 p=0.0931) | Blinded end point not possible, but assessments performed by independent clinical staff  
  • Low loss to follow-up |

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,  
- Aged <18 years  
- Two or more existing Category/Stage 2 PUs or greater on sacrum, buttocks, heels or hips  
- Mean age approx. 44.4±13.2 years  
- 44.8% male  
- 100% had ASA category 1 or 2  
- Most patients were undergoing cerebellopontine angle tumor removal  
- Mean surgery length 6.9±1.0 hours  
- Higher mean baseline, end and average peak interface pressure (119.1±36.8 mmHg vs. 94.5±23.1 mmHg, p=0.04)  
- Non-significant factors were presence of perspiration and amount of perspiration

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<tr>
<td>Brienza, Krishnan, Karg, Sowa, &amp; Allegretti, 2017</td>
<td>Identify characteristics of newly injured SCI persons associated with PU that developed during acute-care &amp; inpatient rehabilitation</td>
<td>Retrospective analysis of prospective cohort study with recruitment of participants (n=104) within 24-72 hours of hospital admission to specialized SCI unit. Participants later were transferred to SCI rehab unit. Study conducted in USA. Inclusion criteria: • new SCI patients who received acute medial &amp; surgical treatment or admitted to inpatient rehab • ≥18 year</td>
<td>Routine acute traumatic SCI care</td>
<td>Outcome: first pressure ulcer PU measured by research nurse every 3 days in acute care and weekly in rehab Risk factors analyzed univariately: • ASIA p&lt;0.01 • Mechanical ventilation p=0.01 • Pneumonia p=0.01 • Age p=0.22 • Gender p=0.79 • UTI p=0.09 • Steroid p=0.78 • Diabetes p=0.43</td>
<td>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 PU pain had development of a Category/Stage ≥2 PU 2.28 times faster compared to those without baseline PU pain (95% CI 1.59 to 3.27)</td>
<td>Author conclusion: Pain increases risk of PU at that clinical site, and pain decreases the time until PU development</td>
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Data Tables: 2019 Guideline Update: Risk Factors © EPUAP/NPIAP/PPPIA
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</table>
| Borghardt, Prado, Bicudo, Castro, & Bringuente, 2016 | Identify the incidence of PU, describe the factors associated with its development | Participants recruited in ICUs in a university hospital in Brazil (n=77) | N/A | Rate of pressure injuries | MV analysis significant factors:  
- Risk level Waterlow scale (p=0.397)  
- Risk level on Braden (p=0.003) | • Mechanical ventilation p=0.25 OR0.51 (CI0.16-1.60)  
Author concluded: High-injury severity increase pressure ulcer risk in SCI patients. Pneumonia is associated with new PU formation. |

Exclusion criteria:  
- preexisting disease that affected inflammatory response to SC;  
- prior SCI or neurological disease that affected motor or sensory function  
- diabetics were excluded but included after the first year.

Inclusion criteria:  
- Adults > 18 years,  
- free of PU on admission

Exclusion criteria:  
- Patients without metabolic profile lab tests

Participant characteristics:  
- Primarily surgical patients since emergency department closed  
- Length of stay 5 – 110 days (Mean: 31.5 days)

Researcher collected the data from admission to discharge or patient’s death. NPUAP staging system used for assessment and classification of PUs. Sociodemographic/clinical variables: age, length of stay, body mass index (BMI), history of diabetes mellitus, smoking and congestive heart failure. Metabolic data: hemoglobin, hematocrit, lymphocyte cell count, albumin, transferrin. Factors related to PUs: number, location, categories, Waterloo and Braden scores.

Univariate analysis: Incidence of PUs: Divided the number of new PU cases in the units evaluated by the number of patients who were hospitalized in intensive care units during the study period.

Bivariate analysis: Conducted to identify significant variables with p<0.20. The significant results were submitted to logistic regression analysis with p<0.05

Author conclusions: Author asserts that all factors

Level of evidence: 1

Quality: Moderate
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<th>Quality</th>
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<tr>
<td>Bly, Schallom, Sona, &amp; Klinkenberg, 2016</td>
<td>Retrospective record review to identify risk factors for pressure injuries in critically ill adults</td>
<td>Record review of all patients listed on monthly prevalence records over a 10 month period in two ICUs in a US hospital (n=435 admissions, 345 included)</td>
<td>N/A</td>
<td>• 41 variables collected</td>
<td>Pressure injury incidence ICU-acquired pressure injury incidence 109 patients (31%) Mean days to pressure injury was 9.3 (SD 7.2)</td>
<td></td>
<td>a typo, ” 77 were excluded” (vs. included) in the study</td>
<td>3</td>
<td>Very Low</td>
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<tr>
<td></td>
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<td>Inclusion criteria:</td>
<td></td>
<td>• Included 19 variables as risk factors</td>
<td>Logistic regression of all significant factors for first admissions (n=306)</td>
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<td>Admitted to the ICU in the study period</td>
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<td>o Oxygenation variables (n=9)</td>
<td>• Any transport off unit OR 2.79 (95% CI 1.08 to 7.25, p&lt;0.05)</td>
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<td>Included repeat admissions in the same period (analyzed first admissions separately)</td>
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<td>o Perfusion variables (n=4)</td>
<td>• Number of days to bed change OR 2.89, 95% CI 1.26 to 6.63, p&lt;0.05</td>
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<td>Exclusion criteria:</td>
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<td>o Comorbidity variables (n=6)</td>
<td>• Systolic blood pressure &lt;90mmHg OR 5.12, 95% CI 1.41 to 18.65, p&lt;0.05</td>
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<td></td>
<td>None</td>
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<td>• Use of &gt; 1 vasopressor OR 3.71, 95% CI 1.42 to 9.69, p&lt;0.05</td>
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<td>Pressure injuries present on admission not included in analysis</td>
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<td>• History of pulmonary disease OR 2.37, 95% CI 1.07 to 5.24, p&lt;0.05</td>
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<td>Participant characteristics:</td>
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<td>Logistic regression of 20 significant factors in bivariate analysis for all admissions (n=397)</td>
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<tr>
<td></td>
<td></td>
<td>55% males</td>
<td></td>
<td></td>
<td>• Any transport off unit OR 2.28 (95% CI 1.11 to 4.70, p&lt;0.05)</td>
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<td></td>
<td>73% Caucasian, 26% African American</td>
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<td></td>
<td>• Number of days to bed change OR 1.93, 95% CI 10.99 to 3.75)</td>
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<td>Mean age 60.5 (SD 15.8) years</td>
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<td></td>
<td>• Systolic blood pressure &lt;90mmHg OR 3.50, 95% CI 1.24 to 9.91</td>
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<tr>
<td>Chiari et al, 2017</td>
<td>Evaluate the incidence of PU in older adults with fragile proximal hip fracture from hospital admission to discharge and to evaluate predictors of PU, categorized as medical, nursing and rehab care, and organizational</td>
<td>Consecutive patients presented with fragility hip in 3 Italian hospitals were recruited (1130 met inclusion, 1083 agreed to enroll)</td>
<td>Inclusion: &gt;65 years; Diagnosis fragility hip fracture</td>
<td>Pressure injuries measured daily with inspection of skin using NPUAP criteria; All data collected until discharge or PU developed</td>
<td>Incidence any pressure injuries: 22.7%; Incidence category/Stage II pressure injuries 11.4%</td>
<td>Logistic Regression: Age p=0.015 OR 1.030 (CI 1.006-1.054), Absence of bed railing p=0.026 OR 1.668 (CI 1.062-2.622)</td>
<td>Use of &gt; 1 vasopressor OR 3.71, 95% CI 1.42 to 9.69; Feeding tube OR 5.68, 95% CI 1.19 to 27.11</td>
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<td></td>
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<td></td>
<td>Exclusion: Periprosthetic or pathological fractures; presence of a PU</td>
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<td>Failure to use BMI to evaluate patient constitution</td>
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<td>Characteristics: Length of stay: mean 10.9 days; Deaths during study N=16 (1.48%); Time from fracture to arrival at ER: mean 23 hours</td>
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<td>Level of evidence: 3 Quality: Low</td>
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**Chiari et al., 2017**

Evaluate the incidence of Pressure Ulcer (PU) in older adults with fragile proximal hip fracture from hospital admission to discharge and to evaluate predictors of PU, categorized as medical, nursing and rehab care, and organizational factors.

- **Inclusion:**
  - >65 years
  - Diagnosis fragility hip fracture

- **Exclusion:**
  - Periprosthetic or pathological fractures
  - Presence of a PU

- **Characteristics:**
  - Length of stay: mean 10.9 days
  - Deaths during study N=16 (1.48%)
  - Time from fracture to arrival at ER: mean 23 hours

- **Outcome Measures & Length of Follow-up:**
  - Pressure injuries measured daily with inspection of skin using NPUAP criteria

- **Results:**
  - Incidence any pressure injuries: 22.7%
  - Incidence category/Stage II pressure injuries 11.4%

- **Logistic Regression:**
  - Age p=0.015 OR 1.030 (CI 1.006-1.054)
  - Absence of bed railing p=0.026 OR 1.668 (CI 1.062-2.622)
  - Daily postop positioning p=0.008 OR 0.897 (CI 0.828-0.971)
  - Days with urinary catheter p<0.0005 OR 1.013 (CI 1.008-1.018)
  - Days with partial presence of caregiver p=0.012 OR 0.994 (CI 0.990-0.999)
  - Days with a foam valve p<0.0005 OR 1.025 (CI 1.018-1.032)
  - Days with pain p=0.008 OR 1.008 OR 1.008 (CI 1.002-1.014)
  - Wearing diaper p=0.061 OR 1.555 (CI 0.980-2.467) (not significant but improved predictive value of model when other factors held constant)

- **Limitations and comments:**
  - Failure to use BMI to evaluate patient constitution

*Level of evidence: 3 Quality: Low*
### Risk Factors and Risk Assessment: data extraction and appraisals

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<tr>
<td>Shaw, Chang, Lee, Kung, &amp; Tung, 2014b</td>
<td>Cohort study exploring the context of immediate and thirty-minute-later incidence of and associated risk factors for pressure injuries</td>
<td>Participants were recruited in a teaching hospital in Taiwan (n=297)</td>
<td>N/A</td>
<td>• Pressure injuries were measured using the NPAUP/EPUAP staging system</td>
<td>Pressure injury incidence</td>
<td>• Age p=0.002 OR 1.068 (CI 1.024-1.114)</td>
<td>Immediate pressure injuries: • Operation age (OR=1.03, 95% CI 1.00-1.08) • type of anesthesia (general anesthesia) [yes vs no, OR=17.06, 95% CI: 2.09-49.43] • type of operation position (nonsupine vs supine, OR=32.06, 95% CI: 4.48-48.79) • type of surgery (orthopedic surgery vs general surgery, OR=3.33, 95% CI: 1.05-10.61) • admission Braden score (OR=0.95, 95% CI: 0.91-0.99) • number of nursing intervention (OR=0.9, 95% CI: 0.90-0.98) 30-minute post-operatively: Level of evidence: 3 Quality: Low</td>
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## Risk Factors and Risk Assessment: data extraction and appraisals

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| Lin et al., 2017 | Retrospective cohort study investigating risk factors for pressure injury in people undergoing posterior lumbar and/or thoracic surgery | Participants were recruited in one spine service in Singapore (n=209) | N/A             | • Pressure injury Stage 1 or greater assessed using NPUAP staging system  
  • Skin assessments conducted at immediate postop, 24 hours postop, 48 hours postop  
  • Daily Braden scale score  
  • Multivariate logistic analysis  
  • Risk factors collected: (n=27) including gender, smoking, diabetes, cancer, antiplatelet use, previous skin problems, Braden | Pressure injury incidence 23% (48 Category./Stage I PU and 2 Category/Stage II pressure injuries)  
  • Previous skin problems OR not reported, p=0.034  
  • Myelopathy, OR 4.79, p=0.013  
  • Spinal deformity, OR 3.31, p=0.010  
  • Operative time >300 mins, OR 8.12, p=0.005  
  • Levels of surgery > 4, OR 9.10, p=0.006 | • Operation age (OR=1.06, 95% CI 1.00-1.12)  
  • type of operation position (nonsupine vs supine, OR=18.16, 95% CI: 1.32-52.63)  
  • type of surgery (orthopedic surgery vs general surgery (OR=9.29, 95% CI: 1.05-28.50; cardiac surgery vs general surgery, OR=22.60, 95% CI: 1.2-43.85)  
  • number of nursing interventions (OR=0.95, 95% CI: 0.91-0.99) | Insufficient number of events  
  Cutoffs and categorical factors not clearly defined  
 Unclear if full sample included in analysis | Level of evidence: 3  
 (prognostic)  
 Quality: Very Low |
### Risk Factors and Risk Assessment: data extraction and appraisals

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<td>scale score, myelopathy, radiculopathy, non-specific numbness, spinal deformity, lumbar prolapse, cervical myelopathy, lumbar spinal stenosis, spondylolisthesis, spinal metastasis, anterior surgical approach, posterior surgical approach, surgery with fusion, ASA grade, height, weight, BMI, operative time, number of screws, levels of surgery</td>
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### Risk Assessment

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<tr>
<td>Gunes &amp; Efteli, 2015</td>
<td>Prospective cohort study investigating validity and reliability of Turkish version of Risk Assessment Pressure Sore</td>
<td>Prospective enrolment of new admissions to a Turkish university hospital ICU over 12 month period (n=146 screened, n=122 participated)</td>
<td>Assessment with the RAPS scale</td>
<td>RAPS scale: 9 variables (general physical condition, physical activity, mobility, moisture, food intake, fluid intake, sensory perception, body temperature and serum albumin level) rated on a 4 point scale and friction/shear measured on a 3 point scale. Conducted</td>
<td>Pressure injury incidence Category/Stage 1 PU n=21 Category/Stage 2 PU n=9 Category/Stage 3 PU n=1</td>
<td>Single site study Tool not compared to other tools</td>
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### Risk scales

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<td>Single site study Tool not compared to other tools</td>
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**Validity of RAPS scale for different cutoff scores**  
- Score ≤ 26: area under curve 0.50, sensitivity 69.3%, specificity 36.4%, positive predictive value (PPV) 37.2%, negative predictive value (NPV) 90.8%
## Risk Factors and Risk Assessment: data extraction and appraisals

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| (RAPS) Scale in ICU | • Expected length of stay (LOS) ≥ 7 days  
• No pressure ulcer (PU) on admission  
Characters:  
• Mean age 56.5±18.6 yrs  
• Mean LOS 10.4 ± 5.3 days  
• Mean length of follow up 18.2 ± 4.9 days  
• 42.6% sample was male  
• 48.3% had a primary diagnosis of respiratory failure  
Skin assessment using NPUAP Pressure Ulcer Classification System Conducted at baseline and weekly thereafter. | at baseline (within 24 hours of admission) by nurses. | • Score ≤ 27: sensitivity 74.2%, specificity 31.8%, positive predictive value (PPV) 38.7%, negative predictive value (NPV) 91.3%  
• Score ≤ 30: sensitivity 17.4%, specificity 36.4%, positive predictive value (PPV) 29.1%, negative predictive value (NPV) 96.3%  
• Score ≤ 31: area under curve 0.50, sensitivity 100%, specificity 0%, positive predictive value (PPV) 25%, negative predictive value (NPV) 100%  
• Best balanced cut off score was ≤ 27 | Reliability  
Cronbach’s alpha 0.81  
Interrater reliability ICC 0.58 to 0.92 |  
| Fulbrooke & Andersson, 2016 | Psychometric study exploring interrater reliability of COMHON Index | Convenience sample in an Australian ICU (n=26 patient participants)  
Self-selected ICU nurses to conduct assessments (n=5)  
Participant characteristics:  
• Mean age 69.1 years (SD 17.2, range 37 to 87)  
• Primarily male sample (69%)  
• Primarily post-operative cardiac patients (62%)  
Rater characteristics:  
• 4-8 years’ experience in ICU | Five nurse raters assisted patients using:  
COMHON index includes 5 items (consciousness level, mobility, haemodynamics, oxygenation, nutrition)  
Braden Scale  
Norton Scale  
Waterlow Score  
Procedures for performing assessments (e.g. gap for each assessor in using each scale) and gap between raters seeing each patient is not reported | Interrater reliability  
• Braden scale sum score: ICC 0.60, 95% CI 0.50 to 0.80  
• COMHON Index sum score: ICC 0.90, 95% CI 0.83 to 0.95  
• Norton Scale sum score: ICC 0.77, 95% CI 0.65 to 0.88  
• Waterlow sum score: ICC 0.47, 95% CI 0.22 to 0.79  
Correlation between tools  
• COMHOM had strong correlation with Braden scale (r=0.70, p<0.001)  
• COMHOM had moderate correlation with Norton scale (r=0.66, p<0.001)  
• COMHOM had no correlation with Waterlow score (r=0.10, p=0.25)  
• Braden scale had strong correlation with Norton scale (r=0.77, p<0.001)  
• Power analysis for sample size met  
• Self-selected raters may have different skills to the general nurse population  
• Duration between assessments between nurses and scales was unclear – it is possible clinical risk changed in the time frame  
• ICU nurses may have more experience assessing the components included on the COMHON  
• No training was provided in using | Level of evidence: 4 (reliability study)  
Quality: Moderate |
### Risk Factors and Risk Assessment: data extraction and appraisals

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<td>Dijkstra, Kazimier, &amp; Halfens, 2015</td>
<td>Cross sectional study evaluating the Care Dependent Scale (CDS) as a risk screening tool for people in home or aged care</td>
<td>Convenience sample of people receiving home care (n=2639), living in residential homes (n=4077) or admitted to a nursing home (n=6917) in the Netherlands (total n=13,633)</td>
<td>Patients were assessed using the CDS</td>
<td>CDS that covers eating/drinking, incontinence, body posture, mobility, day/night pattern, un/dressing, body temperature, hygiene. Avoidance of danger, communication social contact, sense of rules/values, daily activities, learning activities and recreational activities</td>
<td>PU prevalence&lt;br&gt;Home care 4.4%, Residential care 3.2%, Nursing homes 8.8%&lt;br&gt;Comparison between PU group versus no-PU group&lt;br&gt;• No significant difference in age in home care (79.8 vs. 79.3 yrs, p=0.769), or nursing homes (82.8 vs. 82.4, p=0.153)&lt;br&gt;• In residential home group, people with Pus were significantly older (85.5 vs. 85.2, p = 0.019)&lt;br&gt;• Women in all locations were more likely to have PU than men&lt;br&gt;Receiver Operator Curves: Area under curve (AUC)&lt;br&gt;Residential homes 0.79, AUC nursing homes 0.63, AUC home care 0.70&lt;br&gt;Sum score cutoff for CDS identifying PU risk&lt;br&gt;Home care: CDS sum score of ≤72 (identifying 89% true positives and 35% true negatives for PU)&lt;br&gt;Residential homes: CDS sum score of ≤65 (83% true positives and 54% true negatives for PU)&lt;br&gt;Nursing homes: CDS sum score of ≤58 (90% true positives and 24% true negatives for PU)&lt;br&gt;Odds ratio</td>
<td>Waterlow scale as this was the tool already used&lt;br&gt;Author conclusions: COMHON Index has good interrater reliability in the ICU and is consistent with assessments using Braden and Norton scales.&lt;br&gt;It is not clearly documented that the CDS was conducted before clinical assessment for PU, and limitation suggest it may not have been as causality direction is stated as unclear (e.g. PU may have led to restricted mobility vs restricted mobility increasing risk for PU)&lt;br&gt;Level of evidence: 4 (prognostic) Quality: moderate</td>
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| Park & Choi, 2016 | A prospective cohort study exploring the performance of the Incontinence-Associated Dermatitis Severity (IADS) instrument in predicting PU in patients with fecal incontinence | Participants were recruited in 5 ICUs in South Korea (n=131 eligible, n=120 completed and analyzed) | IADS tool was used to evaluate skin                                                                 | Assessments conducted by trained wound care nurses (ICC of IADS was 0.96, ACC for BWAT was 0.92) | All the variables on the CDS had a significant (p<0.01) odds ratio (OR for pressure ulcers versus no pressure ulcers in all three locations. e.g.  
• un/dressing: OR home care 3.0 (95% CI 1.9 to 4.6), OR residential home 11.9 (95% CI 5.5 to 25.5), OR nursing home 4.6 (95% CI 2.9 to 7.2)  
• body temp: OR home care 3.1 (95% CI 2.1 to 4.6), OR residential home 5.1 (95% CI 3.4 to 7.4), OR nursing home 2.4 (95% CI 1.9 to 3.1) | In home care OR ranged 2.1 to 4.0 across variables, in residential care 2.6 to 11.9, in nursing homes 1.3 to 4.6  
Conclusions: AUC values are insufficient to use CDS as a predictive tool  
Participant outcomes  
• Average IADS score 9.30±7.42  
• 33% participants (n=40) developed a PU  
• Mean BWAT score was 23.3±3.84  
IADS tool  
• Higher IADS score was associated with greater likelihood of PU (OR 1.22, p<0.001)  
• AUROC 0.79 (95% CI 0.701 to 0.869)  
• Optimal cutoff score was 8/9 (9 has higher probability, sensitivity 72.5%, specificity 71.2%)  
Author conclusions: IADS could be used to predict PU development in patients with fecal incontinence |  
• Power calculation sample size was 97  
• IADS tool is limited in anatomical area so would not be predictive of PU in other regions  
• Nurses were not blinded to the scores on other tools  
Level of evidence: 1 (prognostic)  
Quality: moderate |
Risk Factors and Risk Assessment: data extraction and appraisals

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| Krishnan et al., 2016 | Retrospective study to determine cut-off point for SCIPUS and to assess risk for PU development at varying time points | Participants were recruited in a rehabilitation center offering acute care and inpatient rehab care in US (n=104 eligible, n=34 included, n=23 analyzed) | SCIPUS (includes 15 items – age, tobacco use, residency, level of activity, mobility, completeness of SCI, incontinence, autonomic dysreflexia, diabetes, comorbidities, impaired cognition, hypoalbuminemia, low hematocrit | SCIPUS was conducted on initial visit  
2-3 day skin assessment: n=18 individuals, n=2 PUs (11.1%)  
mean SCIPUS score individuals with PU 17.5±2.1  
mean SCIPUS score individuals without PU 13±3.6  
5-7 day skin assessment: n=23 individuals, n=6 PUs (26%)  
mean SCIPUS score individuals with PU 14.6±3.7  
mean SCIPUS score individuals without PU 13.4±3.5  
In inpatient setting: SCIPUS cut off score of 15 had sensitivity 100%, specificity 75%, 22.2% positive predictive value, 4% negative predictive value when skin assessment conducted at 2-3 days | Acute hospitalization  
2-3 day skin assessment: n=18 individuals, n=2 PUs (11.1%)  
mean SCIPUS score individuals with PU 17.5±2.1  
mean SCIPUS score individuals without PU 13±3.6  
5-7 day skin assessment: n=23 individuals, n=6 PUs (26%)  
mean SCIPUS score individuals with PU 14.6±3.7  
mean SCIPUS score individuals without PU 13.4±3.5 | Does not state how skin assessment was conducted or by whom  
Management strategies were not clear  
No categorization or details regarding PUs | Level of evidence: 4 (prognostic)  
Quality: moderate |
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| Xie, Peel, Hirdes, Poss, & Gray, 2016 | Cross sectional study to validate InterRAI Pressure Ulcer Risk Scale (PURS) | Data was collected from 3 cohort studies conducted over 5 years in 11 hospitals in Australia (n=1418 participants, n=1,371 with complete data) | No intervention | 14-21 day skin assessment:  
- n=14 individuals, n=3 PUs (21.4%)  
- mean SCIPUS score individuals with PU 9.6±0.5  
- mean SCIPUS score individuals without PU 10.9±3.1  
In inpatient setting: SCIPUS cut off score of 9 had sensitivity 66.7%, specificity 45.5%, 14.3% positive predictive value, 0.7% negative predictive value when skin assessment conducted at 2-3 days | **Mean SCIPUS score individuals without PU 9.9±2.6**  
**14-21 day skin assessment:**  
- n=14 individuals, n=3 PUs (21.4%)  
- mean SCIPUS score individuals with PU 9.6±0.5  
- mean SCIPUS score individuals without PU 10.9±3.1  
In inpatient setting: SCIPUS cut off score of 9 had sensitivity 66.7%, specificity 45.5%, 14.3% positive predictive value, 0.7% negative predictive value when skin assessment conducted at 2-3 days |  
- Recruitment unclear  
- Retrospective design  
- Length of admission unclear  
- Management strategies unclear  
- Similarity between different facilities unclear  
**Level of evidence: 4 (prognostic)**  
**Quality: moderate**  
**Prevalence and incidence**  
- 6.2% had a PU on admission  
- 3.3% developed a PU during hospitalization  
**Psychometric qualities of PURS**  
- Prevalence including Category/Stage 1: AUC 0.81 (standard error 0.02, 95% CI 0.76 to 0.86)  
- Incidence: c-statistic 0.70 (SE0.04, 95% CI 0.63 to 0.77)  
- At cut-off value PURS score of 3 sensitivity for prevalence 72.9%, specificity 71.3%  
- At cut-off value PURS score of 3 sensitivity for incidence 50%, specificity 72% |  
- Recruitment unclear  
- Retrospective design  
- Length of admission unclear  
- Management strategies unclear  
- Similarity between different facilities unclear  
**Level of evidence: 4 (prognostic)**  
**Quality: moderate** |
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| Ranzani, Simpson, Japiassu, & Noritomi, 2016 | Prospective cohort study to validate the Braden scale in critical care and determine appropriate cut off score | Data was collected in 12 ICUs in Brazil over a 12 month period (n=9,605) | All ICU nurses received training prior to study commencement on risk screening, PU classification and PU prevention Preventive equipment including protective cushions, translucent film dressings, dynamic support surfaces were provided to IUCs and 2 hourly repositioning was reinforced | • Daily collection of PU development  
• ICU nurses conducted skin assessments and classifications  
Primary outcome was PU developing in an ICU between 48 hours and 30 days of ICU admission  
The analysis model accounted for competing risk events i.e. events that could occur due to similar risk factors but that even precludes a PU developing (i.e. death, which is more likely to occur in mechanically ventilated patients, as PU is)  
• PU incidence  
• 157 PUs developed, incidence rate of 3.3/1,000 patient-days  
28.7% Stage I, 66.2% Stage II, 3.2% Stage III, 0.7% Stage IV, 1.2% unstageable/ DTI  
Mean time to first PU 9±8 days  
58% coccyx/sacrum, 10.2% buttocks, 8.9% heels | PU incidence  
• Participants with PU within 48 hours were excluded as the cause may have originated external to the ICU  
• Braden score was conducted on admission to ICU and not updated thereafter, even if clinical condition altered  
• No interrater reliability for PU assessment was conducted  
| Level of evidence: 1 (prognostic)  
Quality: high |
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<td>(p=0.006), COPD (p=0.004), chronic arterial disease (p=0.019)</td>
<td>PU cohort more likely to be admitted for cardiovascular reason (p&lt;0.001) or sepsis (p&lt;0.001)</td>
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<td>PU cohort more likely to require mechanical ventilation (p&lt;0.001), vasoactive drugs (p&lt;0.001) and renal replacement therapy (p&lt;0.001)</td>
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<td>PU cohort more likely to have ICU or hospital death both (p&lt;0.001)</td>
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<td>Braden scale</td>
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<td>PU cohort had significantly lower mean Braden scores (11.2±2.7 versus 15.1±3.5, p&lt;0.001)</td>
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<td>Discrimination of Braden scale was 0.753 (95% CI 0.712 to 0.795)</td>
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<td>Discrimination of Braden scale was 0.642 (95% CI 0.591 to 0.689) for individuals with mechanical ventilation, 0.634 (95% CI 0.584 to 0.689) for individuals with vasoactives, 0.660 (95% CI 0.557 to 0.730) for individuals with renal replacement therapy, 0.697 (95% CI 0.558 to 0.842) for surgical patients</td>
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<td>Significant variables in multivariate analysis included age, gender, diabetes, hematological malignancy, PAD, Braden score ≤13, MAP &lt; 60mmHg, mechanical ventilation and renal replacement therapy (subdistribution hazard ratio and p values provided)</td>
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<td>Cut off score for Braden scale in critical care proposed at ≤13</td>
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<td>Author conclusions: Braden scale has good predictive ability in critical care, but a lower cut off score for risk is proposed</td>
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Data Tables: 2019 Guideline Update: Risk Factors
## Risk Factors and Risk Assessment: data extraction and appraisals

<table>
<thead>
<tr>
<th>Ref</th>
<th>Type of Study</th>
<th>Sample</th>
<th>Intervention(s)</th>
<th>Outcome Measures &amp; Length of Follow-up</th>
<th>Results</th>
<th>Limitations and comments</th>
<th>Level of evidence</th>
<th>Quality</th>
</tr>
</thead>
</table>
| Gadd & Morris, 2014 | Retrospective chart review to determine whether pressure injury prevention interventions are implemented when a total Braden Scale score reflects that the patient is at risk | Participants were recruited in community hospitals (n=322) in the USA (n=20 participants) | N/A | at risk versus not-at-risk patients on Braden Score | Consistency of implementing practice  
- Significant difference in Braden scores for people receiving interventions the day before a pressure injury developed compared to those not receiving an intervention (13.7±2.8 vs 18.5±2.3, p=0.001)  
- 20% of pressure injury interventions were not implemented in the patient population deemed at risk  
- When patients were at no-risk with low subscale scores they were less likely to receive preventative interventions | • Could have expanded review of literature and discussion | 5 | Low |
### Table 1: Level of Evidence for Intervention Studies

<table>
<thead>
<tr>
<th>Level</th>
<th>Design Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Experimental Designs</td>
</tr>
<tr>
<td></td>
<td>• Randomized trial</td>
</tr>
<tr>
<td>Level 2</td>
<td>Quasi-experimental design</td>
</tr>
<tr>
<td></td>
<td>• Prospectively controlled study design</td>
</tr>
<tr>
<td></td>
<td>• Pre-test post-test or historic/retrospective control group study</td>
</tr>
<tr>
<td>Level 3</td>
<td>Observational-analytical designs</td>
</tr>
<tr>
<td></td>
<td>• Cohort study with or without control group</td>
</tr>
<tr>
<td></td>
<td>• Case-controlled study</td>
</tr>
<tr>
<td>Level 4</td>
<td>Observational-descriptive studies (no control)</td>
</tr>
<tr>
<td></td>
<td>• Observational study with no control group</td>
</tr>
<tr>
<td></td>
<td>• Cross-sectional study</td>
</tr>
<tr>
<td></td>
<td>• Case series (n=10+)</td>
</tr>
<tr>
<td>Level 5</td>
<td>Indirect evidence:</td>
</tr>
<tr>
<td></td>
<td>• Studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models</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>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Individual high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding among consecutive persons.</td>
</tr>
<tr>
<td>Level 2</td>
<td>Non-consecutive studies or studies without consistently applied reference standards.</td>
</tr>
<tr>
<td>Level 3</td>
<td>Case-control studies or poor or non-independent reference standard.</td>
</tr>
<tr>
<td>Level 4</td>
<td>Mechanism-based reasoning, study of diagnostic yield (no reference standard). Low and moderate quality cross sectional studies.</td>
</tr>
</tbody>
</table>

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

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

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
### RISK FACTOR STUDIES

<table>
<thead>
<tr>
<th>CRITERIA 1-8</th>
<th>QUALITY DOMAINS 1-4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. Is there sufficient number of events (rule of thumb: more than 10 events per risk factor)?</td>
</tr>
<tr>
<td></td>
<td>2. Is there sufficient presentation of data to assess the adequacy of method and analysis?</td>
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<tr>
<td></td>
<td>3. Is the strategy for model building (i.e., inclusion of variables) appropriate and based upon a conceptual framework?</td>
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<tr>
<td></td>
<td>4. Is the selected model adequate for the design?</td>
</tr>
</tbody>
</table>

1. The baseline study sample is adequately described for key characteristics.
2. A clear definition/description of the risk factor measured is provided and a clear definition/description of how the risk factor was measured is provided.
3. Continuous variables used or appropriate (i.e. not data-dependent) cut-points for continuous data.
4. An adequate proportion of sample has complete data for risk factors.
5. Range of potential risk factors are measured.
6. Range of potential risk factors are accounted for in the analysis.
7. Appropriate imputation.
8. No selective reporting.

<table>
<thead>
<tr>
<th>COLUMN 12</th>
<th>COLUMN 1, 3, 7, 8, 11</th>
<th>COLUMN 3, 4, 7, 8, 9, 10, 11</th>
<th>COLUMN 3, 4, 8, 9, 10, 11</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

- High quality studies: ‘yes’ for all quality domains
- Moderate quality studies: ‘yes’ for quality domain 1 and at least two other quality domains
- Low quality studies: ‘no’ for criteria 1 and ‘no’ or ‘partial yes’ for two other quality domains
- Very low quality studies: ‘no’ for criteria 1 and ‘no’ or ‘partial yes’ for all three remaining quality domains
# Risk Factors and Risk Assessment: data extraction and appraisal

| Author/year | Baseline sample adequately described | Study attrition acceptable (<20% lost to follow up) | Clear definition of risk factors | Range of risk factors / potential confounders measured | Risk factor measurement method valid and reliable | Method of measurement same for all | Appropriate continuous variables or cut-point | Adequate sample with complete data | Adequate imputation method | Potential confounders accounted in analysis | No selective reporting | Adequate sample size (rule of thumb >10 events per risk factor) | Is there sufficient presentation of data to assess the adequacy of method and analysis? | Is the strategy for model building (i.e., inclusion of variables) appropriate and based upon a conceptual framework? | Is the selected model adequate for the design? | Level of evidence | Quality |
|-------------|--------------------------------------|-----------------------------------------------|---------------------------------|-------------------------------------------------|-----------------------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-------------------------------|---------------------------------|------------------------------|-------------------------------------------------|-------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------|-----------------------------------------------------------------|
| Apostolopoulou et al., 2014 | Y | U | Y | Y | Y | Y | N | U | U | Y | Y | N | Y | PY | N | 3 (prognosis) | Low |
| Bly et al., 2016 | Y | U | N | Y | Y | Y | Y | U | NA | Y | Y | N | PY | PY | PY | 3 (prognosis) | Very low |
| Borghardt et al., 2016 | Y | U | Y | Y | Y | Y | Y | U | U | Y | U | Y | PY | PY | PY | 1 (prognostic) | Moderate |
| Brienza et al, 2017 | Y | U | Y | Y | Y | Y | U | NA | Y | Y | N | PY | PY | PY | 3 (prognostic) | Very low |
| H.L. Chen et al, 2018 | Y | Y | Y | Y | N | Y | U | NA | Y | Y | N | PY | PY | PY | 3 (prognostic) | Very low |
| Chiari et al, 2017 | Y | Y | Y | Y | U | Y | N | U | NA | Y | U | Y | N | Y | P | P | 3 (prognostic) | Low |
| Cox & Roche, 2015 | Y | U | Y | Y | N | Y | Y | U | NA | Y | Y | N | Y | Y | PY | 3 (prognosis) | Low |
| Demarre et al., 2015 | Y | Y | Y | Y | Y | Y | Y | U | NA | Y | Y | N | Y | Y | Y | 3 (prognosis) | Low |
| Dhandapani et al., 2014 | Y | Y | Y | Y | N | U | N | U | NA | Y | Y | N | PY | PY | PY | 3 (prognosis) | Very low |
| Gonzalez-Mendez et al., 2018 | Y | Y | Y | Y | Y | Y | U | NA | Y | Y | N | Y | PY | PY | PY | 3 (prognosis) | Low |
| Ham, Schoonhoven, Schuurmans, & Leenen, 2017b | Y | Y | Y | Y | Y | Y | Y | U | NA | Y | Y | N | Y | Y | N | 3 (prognostic) | Low |
| Joseph & Nilsson Wikmar, 2016b | Y | Y | Y | Y | Y | Y | Y | NA | Y | Y | N | Y | Y | PY | PY | 3 (prognostic) | Low |
| Lin et al, 2017 | Y | U | Y | Y | Y | N | U | NA | Y | N | U | N | N | N | N | 3 | Very Low |
### Risk Factors and Risk Assessment: data extraction and appraisals

| Author/year | Baseline sample adequately described | Study attrition acceptable (<20% not to follow up) | Clear definition of risk factors | Range of risk factors/potential confounders measured | Risk factor measurement method valid and reliable | Method of measurement same for all | Adequate sample with complete data | Appropriate imputation method | No selective reporting | Adequate sample size (rule of thumb >10 events per risk factor) | Is there sufficient presentation of data to assess the adequacy of method and analysis? | Is the strategy for model building (i.e., inclusion of variables) appropriate and based upon a conceptual framework? | Is the selected model adequate for the design? | Level of evidence | Quality |
|-------------|-------------------------------------|-----------------------------------------------|---------------------------------|----------------------------------|-----------------------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|----------------------------------|----------------------------------|----------------------------------|-----------------|--------|
| Matozinhos et al., 2017 | Y | U | Y | N | Y | Y | Y | U | NA | N | Y | N | PY | PY | PY | Very low |
| Nassaji et al., 2014 | Y | U | Y | N | U | Y | Y | U | NA | Y | Y | U | N | N | PY | 3 (prognosis) | Very low |
| Ranzani, Simpson, Japiassu, Noritomi, & Amil Critical Care, 2016 | Y | Y | Y | Y | N | Y | N | U | NA | Y | Y | N | Y | PY | PY | 3 (prognosis) | Low |
| Shaw, Chang, Lee, Kung, & Tung, 2014a | Y | Y | Y | Y | Y | Y | Y | Y | NA | Y | Y | N | Y | Y | Y | 3 (prognosis) | Low |
| Smith et al., 2017 | Y | Y | Y | Y | Y | Y | Y | U | NA | Y | Y | Y | Y | Y | Y | 1 (prognosis) | High |
| Sternal et al., 2017 | Y | U | Y | Y | N | Y | U | NA | U | N | U | PY | PY | PY | 3 (prognosis) | Very Low |
| Tayyib et al., 2015 | Y | Y | Y | Y | PY | Y | N | U | NA | Y | Y | N | PY | PY | N | 3 (prognosis) | Very Low |
| Van Der Wielen et al., 2016 | Y | Y | Y | N | Y | Y | N | U | NA | N | Y | Y | Y | PY | PY | 1 (prognosis) | Moderate |
| Yoshimura, Nakagami, et al., 2015 | Y | Y | Y | Y | Y | N | Y | NA | N | Y | N | Y | PY | N | 3 (prognosis) | Low |
| Yoshimura, Iizaka, et al., 2015 | Y | Y | N | Y | N | Y | N | Y | NA | Y | Y | Y | PY | PY | N | 3 (prognosis) | Moderate |
# Risk Factors and Risk Assessment: data extraction and appraisals

## CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>Focussed question</th>
<th>Sampling method</th>
<th>Representativeness of sample</th>
<th>States number invited</th>
<th>States dropouts and 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>9626</td>
<td>Dijkstra et al., 2015</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>U</td>
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<td>N</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
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<td>moderate</td>
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<tr>
<td>12974</td>
<td>Xie et al., 2016</td>
<td>Y</td>
<td>U</td>
<td>U</td>
<td>Y</td>
<td>Y</td>
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<td>U</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>U</td>
<td>4</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

## COHORT STUDIES

| Author/year | Focussed question | Comparable source | States number invited | Likelihood of outcome at enrolment | Dropout of participants in study | Clear outcome measures | Assessment blinded, or discussed, or 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 |
|-------------|--------------------|--------------------|------------------------|----------------------------------|---------------------------------|----------------------|---------------------------------|---------------------------------|-------------------------------|---------------------------------|----------------|-----------------|------------------|---------|
| 8087        | Gunes & Eftel, 2015 | Y                  | Y                      | Y                                | Y                               | N/A                  | Y                               | Y                              | N                        | N                               | N            | U               | 1                | high   |
| 10694       | Park & Choi, 2016   | Y                  | Y                      | Y                                | Y                               | N                    | Y                               | Y                              | Y                          | Y                               | Y            | Y               | 1                | High   |
| 13718       | Ranzani, Simpson, Japiassu, & Noritomi, 2016 | Y                  | Y                      | Y                                | Y                               | N                    | U                               | Y                              | Y                          | Y                               | Y            | U               | 1                | High   |
| 12971       | Krishnan et al., 2016 | Y                  | Y                      | Y                                | NA                              | NA                  | Y                               | U                              | U                          | U                               | N            | U               | 4                 | moderate |
## Risk Factors and Risk Assessment: data extraction and appraisals

### Diagnostic Studies

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Nature of test is defined</th>
<th>Test compared to a gold standard</th>
<th>Where no gold standard exists, compared with valid reference standard</th>
<th>Clear population from which independent measurement of test and standard was drawn</th>
<th>Test and standard measured as close in time as possible</th>
<th>Results for all patients reported</th>
<th>Pre-test diagnosis reported</th>
<th>Minimal bias</th>
<th>Reliable conclusions</th>
<th>Level of evidence</th>
<th>Quality</th>
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</thead>
<tbody>
<tr>
<td>Fulbrook &amp; Anderson, 2016</td>
<td>Y</td>
<td>Y</td>
<td>N/A</td>
<td>N</td>
<td>Y</td>
<td>U</td>
<td>Y</td>
<td>N/A</td>
<td>N</td>
<td>U</td>
<td>Level 4</td>
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</table>

### Systematic Reviews for Discussion

<table>
<thead>
<tr>
<th>Endnote ID</th>
<th>Author/year</th>
<th>PICOT research question and inclusion criteria</th>
<th>Explicitly states a priori protocol</th>
<th>Rationale for selection of study designs</th>
<th>Duplicate study selection</th>
<th>Duplicate data extraction</th>
<th>Excluded studies listed</th>
<th>Adequate description of included studies</th>
<th>Risk of bias assessed</th>
<th>Source of funding reported</th>
<th>Appropriate meta-analysis including weighting and adjustment for heterogeneity</th>
<th>Meta-analysis considers risk of bias of studies</th>
<th>Discussion consider risk of bias of studies</th>
<th>Assessment of publication bias if quantitative analysis is done</th>
<th>Potential conflicts of interest of authors reported and managed</th>
<th>Review Inclusion/Exclusion</th>
</tr>
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<tbody>
<tr>
<td>14491</td>
<td>Alderden, Rondinelli, Pepper, Cummins, &amp; Whitney, 2017</td>
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<td>H.L. Chen, Shen, Liu, &amp; Liu, 2017</td>
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<table>
<thead>
<tr>
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<th>Author/year</th>
<th>PIC research question and inclusion criteria</th>
<th>Explicitly states a priori protocol?</th>
<th>Rational for selection of study designs</th>
<th>Comprehensive search?</th>
<th>Duplicate study selection?</th>
<th>Duplicate data extraction?</th>
<th>Excluded studies listed?</th>
<th>Risk of bias assessed?</th>
<th>Source of funding reported?</th>
<th>Appropriate meta-analysis including weighting and adjustment for heterogeneity</th>
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<th>Discussion consider risk of bias of studies</th>
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<th>Potential conflicts of interest of authors reported and managed</th>
<th>Review Inclusion/Exclusion</th>
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<tbody>
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<td>Kang &amp; Zhai, 2015</td>
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