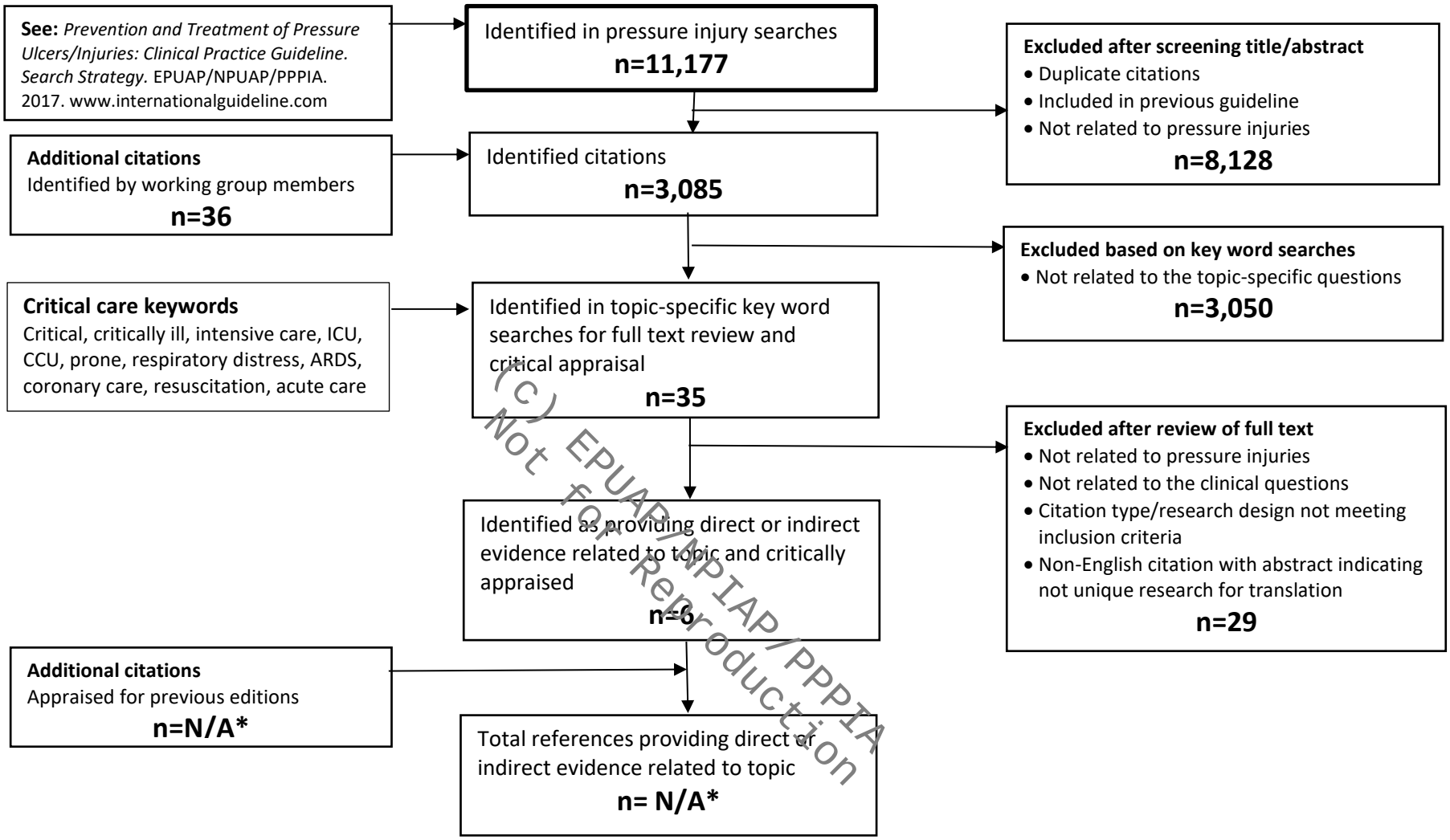
Search results for 2019 International Pressure Injury Guideline: Critically Ill Individuals



* Recommendations related to all special populations are included in the topics to which the recommendation relates (e.g. support surfaces), and the references supporting these recommendations are included in the search reports for those topics.

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

Articles Reviewed for International Pressure Injury Guideline

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

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

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Clinical question one: What are the unique pressure injury risk factors to consider for individuals in critical care?							
(Cox & Roche, 2015)	Retrospective cohort study **exploring association between vasopressor use and development of pressure injuries in intensive care unit (ICU) patients**	Participants were in two medical-surgical and cardiothoracic ICUs in the US (n=306) Inclusion criteria: • Aged ≥18 years • ICU admission ≥ 24 hours • Received a vasopressor in ICU Exclusion criteria: • Aged under 18 years • ICU admission < 24 hours • Did not receive a vasopressor • Pre-existing pressure injury 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	• All participants received a low-air-loss mattress	• Pressure injury incidence determined through retrospective record review	**Pressure injury incidence** • Pressure injury incidence rate 13% (n=41) • Of pressure injuries, 39% were suspected deep tissue injury (DTI), 37% Category/Stage II, 12% Category/Stage I and 12% Unstageable. • 56% sacral, 34% buttocks, 5% heel, 5% other **Significant variables in logistic regression analysis** • Cardiac arrest:; odds ratio [OR] 3.894, 95% CI 0.998 to 15.118, p=0.05 mechanical ventilation longer than 72 hours: OR 23.604, 95% CI 6.427 to 86.668, p<0.001 • 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	• Statistical power for multivariate analysis was achieved • Only considers pressure injuries that developed in participants who took vasopressors so it is unknown how this compares to patients who did not take vasopressin • Unclear how pressure injuries were identified and by whom • Relied on records – length of follow up is not clear	**Level of evidence: 4 (prognostic)** **Quality: Low**
(Coyer et al., 2017)	To explore **the effects of positioning and body**	Participants were recruited in a mixed ICU in Australia, with purposive recruitment based on BMI (n=18) plus healthy adult	• All participants placed on non-powered pressure redistribution mattress or memory	• Measure of interface pressure peak pressure index (PPI) at sacrum and trochanter using	**Interface pressure** PPI values for high and low acuity ICU participants were higher than in healthy volunteers (p=0.093)	• Sample size too small to detect effect size • Feasibility issues	**Level of evidence: 3**

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	mass index (BMI) on interface pressure and tissue reperfusion in individual with high Sequential Organ Failure Assessment (SOFA) scores compared to those with low SOFA scores and healthy people	volunteers (n=9) Recruitment based on BMI: N=9 (6 ICU, 3 volunteer): BMI ≤ 24.9 N=9 (6 ICU, 3 volunteer): BMI ≥ 30 N=9 (6 ICU, 3 volunteer): BMI 25-29.9 Inclusion criteria (ICU participants): • ≥ 18 years of age • Mechanical ventilation projected to continue for 24-48 hours post-recruitment Exclusion criteria (ICU participants) • Burn > 40% total body surface area or burn to hip or sacrum • Unable to be repositioned • Hemodynamic instability (based on clinician judgement) Inclusion (healthy volunteers): • Age ≥ 18 years. Participant characteristics: • Mean age 57 years in ICU and 32 years in health volunteers • Primarily white participants • ICU high and low acuity participants smoked more than healthy volunteers (36.4% and 53.8% vs 0%)	foam. • Participants placed in 2 positions: ○ semi-recumbent supine with HOB at 30◦ and bed knee elevation at 10◦ ○ quarter lateral turn position • Measures in each position were repeated	pressure mapping sensor 20 minutes • Tissue perfusion (measured as peak time (PT); settled time constant (STC) and normalized hyperemic area (NHA) using Doppler Laser blood perfusion monitoring for 5 minutes • Other measures: SOFA score, body and room temperature, Braden scale, APACHE II scale. • Patients were analyzed in 3 groups based on SOFA score: ○ Healthy adults ○ Low acuity critically Ill patients (mean SOFA score 2.9±1.8) ○ High acuity critically ill patients (mean SOFA score 8.0±1.9)	**Factors associated with PPI** • Age was significantly associated with PPI at the sacrum and greater trochanter (p=0.008), older adults having higher PPI when controlling for body position and patient type • No significant associations were found between PPI and body type, patient type, Braden scores, APACHE 2 scores. **Factors associated with tissue reperfusion** • Using 5 different multivariate models, no factors were found to be significantly associated with tissue reperfusion (body position, body temperature, Braden score, APACHE II score, BMI, age)	identified with the use of pressure mapping device in the ICU (difficult to roll under participants) • Pressure mapping and tissue reperfusion measures were not completed in all patients (e.g. pressure mapping was only available in 1/6 high acuity ICU patients) and repeat measures not reported • Non-blinded outcome measurement	**Quality: High**
(Nowicki et al.,	To assess the clinical	Participants were those who were recorded in the incident	• N/A • Data for ICU	• Pressure injury reported on two	**Facility acquired pressure injury incidence change over time**	• Single centre study • use of different	**Level of evidence:**

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2017)	characteristic and outcomes of critically ill patients compared to ward patients with a hospital-acquired pressure injury	reporting system in one Australian hospital as having a facility acquired pressure injury over a 8.5 year period (n=3,860 patients with n=5,280 reports) Inclusion criteria: Had a facility acquired pressure injury in the audit period Exclusion criteria: Not specifically stated Participant characteristics: • predominately cardio-thoracic case-mix • 726 part • Characteristics for each group not summarized	participants (n=726) was compared to data for general ward participants (n=4,554)	different incident reporting systems used in the facility during data collection period • The pressure injury staging system post-2012 was the NPUAP system, for pre-2012 the system is not reported • Pressure injuries were categorized as severe (Category/Stages III, IV and sDTI) and non-severe Catgory/Stage I, II, mucosal and unstageable)	• Pressure injury incidence increased in ICU by mean 2.9/100 separations (95% CI 1.3 to 4.5/100, p=0.0006) • Pressure injury incidence decreased in general ward by mean 2.1/1000 (95% CI 0.9-3.2/1000, p=0.001) • Rate of severe **Comparison between ICU and general ward** • ICU patients had a 10 fold higher facility acquired pressure injury incidence rate • Significantly more occiput, nose, mouth, ear and lip pressure injuries in ICU (p= 0.008) • Severe pressure injury rate higher in ICU than general ward **Author conclusion: Facility acquired pressure injuries in critically ill patients are associated with severity of illness and skin failure, therefore they may be unavoidable**	reporting systems over time • changes in definitions of pressure injury during the study • Voluntary reporting systems • Does not report how pressure injury assessment was conducted in the facility • Reports that 22 ICU participants had severe pressure injuries, but data only presented for 13	**4** **Quality: Low**
(Catala Espinosa et al., 2014)	Case control study to evaluate the association between body mass index (BMI), incidence and severity of pressure injuries in the ICU	• Number of participants: Case: 77 with PI Control: 231 w/o PI with mechanical ventilation • Clinical setting: ICU • Country: Spain • Inclusion criteria: adults admitted on ICU Exclusion criteria: patients with PI present on admission	• N/A	pressure injuries measured on admission and during hospitalization on ICU period of observation15 months Risk factors measured: age, sex, comorbidities, dependency level (Barthel index), BMI, nutritional status, severity on admission (APACHE II and SAPS 3), reason for admission, treatment done, complications, length of stay, use of special	**Pressure injury incidence** 77/1424 = 5.41% • Stage 1 – 29 (37.7%); Stage 2 – 34 (44.2%); Stage 3 – 10 (13%); Stage 4 – 4 (5.2%) **Univariate analysis** • People with pressure injuries had: o higher APACHE II (p = 0.043) o higher SAPS 3 (p = 0.023), o longer length of stay in ICU and mechanical ventilation (MV) (p < 0.001 • BMI ≥ 40 associated with UPP (p = 0.024 OR = 3.23 CI95% 1.17-8.93) • Significant association between Category/Stage, length of stay and mechanical ventilation (p < 0,001) • No association with immobilization	• Study done in one ICU only • Case control study	**Level of evidence: 3 (prognostic)** **Quality: Moderate**

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				mattress.	**Multivariable analysis** • Association between PI and length of mechanical ventilation (MV) (p = 0.013, OR 1.08, CI95% 1.01-1.16) • Association between PI and kidney replacement therapy (p = 0.013, OR 3.55 CI95% 1.31-9.64). • BMI ≥ 40 was a confounding factor **Author conclusions on modeling: PI development and maximum stage are not associated with a worse prognosis**		
Clinical question two: What are the unique pressure injury prevention strategies for individuals in critical care?							
Support surfaces							
(Black, Berke, & Urzendowski, 2012)	Quasi experiment **comparing a low air loss bed with microclimate management to an integrated power air redistribution bed for preventing PU in a cardiovascular ICU unit**	Participants were recruited from a cardiovascular surgical ICU in USA (n=52) Inclusion: • Likely to be ICU for three days • Not receiving palliative care • No pulmonary or wound issues requiring special beds Characteristics: • No significant differences in demographics at baseline • Mean length of stay 7 days, mean length of data collection was 5 days • Mean age 59.1 years • Mean admitting Braden score 11.2 (range 7 to 20)	• Staff training occurred prior to study commencement. • Participants received similar regimens for repositioning and skin care. Participants received either: ○ loss bed with microclimate management (n=31) ○ integrated power air redistribution bed (n=21)	• PU incidence determined through skin assessment every three days • Mean follow up period was 5.7 days	**Pressure injury incidence** Participants on a low air loss bed had significantly less PUs (0% versus 18%, p=0.046)	• No randomization, blinding, study power calculation • Limited baseline demographics • Concurrent management unclear • Short study period • No interrater reliability	**Level of evidence: 2** **Quality: Low**
Repositioning							
(Tsuchiya et al., 2016)	Observational study exploring the	Participants were healthy females (n=9)	Participants were observed on an air mattress designed to all	• 3 point interface sensor with three sensor mats positioned along an	**Interface pressure** Significantly decreased (p<0.05) by 1.3 to 3.9mmHg in 28 different positions	• Healthy volunteers were all young females, which may	**Indirect evidence (PU not an**

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	influence of small body changes on interface pressure and blood flow.	Participant characteristics: • All aged 21-22 years • Height range 152.5 to 168.5 cm • BMI 17.7 to 22.1 kg/m^2	small postural changes (e.g. change degree tilt in lateral) rather than large ones (e.g. change from supine to lateral). Changes were similar to using a small pillow to provide support at different anatomical places. Small change air mattress had 6 cell components, each with two compartments. Small change mattress was located underneath a standard alternating air mattress.	arc. • Interface mats had a precision of 4mmHg • Measured interface pressure an contact area on pad. • Lateral alignment measured using stickers and angular calculation to determine angles of greater trochanter, head of fibula and lateral malleoli • Physical sensation during inflation and deflation of small change cells measured as yes or no by respondents	**Contact area** Median contact area with sensor increased significantly in 17 combinations of cells **Physical sensations** Minimal uncomfortable detection of movement by participants **Author conclusions: Small changes in body positioning can alter interface pressures and contact area with the support surface that may influence the risk of PU. Small changes at the buttock region reduced disruptions in body alignment.**	influence alignment factors • PU was not an outcome measure • No safety considerations of use of mattress were explored (e.g. height under another mattress)	**outcome measure)**
(Romero et al., 2009)	Case series **investigating the effect of prone positioning ventilation and reporting pressure injuries as an adverse effect of positioning**	Participants were recruited from an ICU in Chile (n=15) inclusion: • aged over 18 years • severe Acute Respiratory Distress Syndrome (ARDS) • ventilation >72hrs exclusion: • contraindications to prone positioning ventilation • hemodynamic disorders • chronic respiratory insufficiency • likelihood of death within 24hrs Characteristics: • Mean age 46±17 years (range	Prone position ventilation for 48 hours or until the oxygenation index was 10 or less (extended PPV)	Primary: • Barotraumas and/or monobronchial incursion of the orotracheal tube • Arterial and venous blood gas results Secondary: • Development of a new pressure injury as assessed using NPUAP staging	• Prone position ventilation was continuously maintained for 55 ± 7 hours • Two patients (13%) developed Category/Stage II pressure injuries (nasal septum, cheek) • All patients experienced facial edema • No patients experienced ventilation complications in prone position	• No control group • Only 20% of the individuals were older than 60 years • Pressure injury risk factors not reported	**Level: 4** **Quality: moderate**

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		19 to 69) • Mean time for mechanical ventilation 19±9 days (rang 4 to 64) • 40% died					
(Oertwich & Kindschuh, 1995)	Observational experiment to **determine in small body shifts influence interface pressure and blood flow**	Participants were a convenience sample of older adults from 3 long term care facilities in US (n=50) Inclusion and exclusion criteria not reported Participant characteristics: • Primarily Caucasian females • Age range 67 to 97 years • Mean Braden Scale scores 18.58±4.39 • No evidence of pressure injuries	• Baseline measures taken with no loading • Participants had measurements taken on a standard flat mattress in two positions: ○ Trochanter measure: lateral oblique position (side-lying with body plane at 45° to 75° angle to support surface with top leg posterior to midline) ○ Sacrum measure: supine position • In each position, two small body shifts were obtained : ○ by placing a towel beneath thigh ○ by placing towel directly above waistline • Measurements in every position were taken at 5 minute intervals for 15 minutes	• Mini-Texas Interface Pressure Evaluator to measure interface pressure at sacrum and trochanter (interrater reliability was 0.95) • TSI ASERFLO Blood Perfusion Monitor used to measure capillary blood perfusion at trochanter and sacrum	**Interface pressure** • Significant main effect for small shift of body weight in the lateral oblique position: F(1.75, 85.79) = 5.36, p<0.01 • Significant main effect for small shift of body weight in supine position: F(1.38, 67.64) = 3.90, p<0.05 **Blood flow measures** • Significant main effect for small shift of body weight in supine position: F(1.24, 60.54) = 4.85, p<0.05 **Author conclusions: Small shifts in position relieve pressure and increase blood flow**	• Did not establish if change was sufficient to prevent a pressure injury • Unclear if results would be generalizable to other populations beyond older adults at risk of pressure injuries	**Indirect evidence (pressure injury not an outcome measure)**
Reducing sedation							
(Nederga ard,	RCT to assess **whether non-**	Participants were recruited in mixed ICUs in three countries	• All participants placed on air-filled, pressure	• Occurrence of pressure injuries,	**Pressure injury development** • There was no significant difference in	• Staging system is not clear.	**Level of evidence:**

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Haberlandt, Toft, & Jensen, 2017)	**sedation affects the occurrence of pressure ulcers**	(n=205) Inclusion criteria • Mechanically ventilated • ≥18 years of age Exclusion criteria • Declined to participate • Severe head trauma • Therapeutic hypothermia • Status epilepticus • Pao2/Fio2＜9 • Transferred from another ICU with intubation ＞48h • Comatose at admission Participant characteristics: • No differences between groups for baseline characteristics	reliving mattresses. • All participants mobilized as early and as often as possible • Participants were randomized to receive either: ○ Intervention: receiving no sedation, but bolus morphine for pain or pharyngeal discomfort (n=104), ○ Comparison: continuous sedation to a target of RASS score of –2 to –3 (propofol for the first 48 hours, then midazolam), with bolus morphine for pain and a daily interruption of sedatives(a wake-up call) (n=101)	described by Category/Stage and location (using grades I to IV) • APACHE II, SAPS II • Follow up period not reported	pressure injury rate between sedated and non-sedated groups (43.5% versus 29.8%, p=0.08) • There were no significant differences in characteristics between people who developed pressure injuries within the two groups: (age, p=0.72; gender, p=0.28; BMI, p=0.55, APACHE II score, p=0.49; SAPS II, p=0.75) • Anatomical location of pressure injuries was significantly different between groups, with sedated patients having more pressure injuries on heels and sacrum and non-sedated participants having more pressure injuries related to equipment(p=0.03) **Length of stay in the ICU** • Length of ICU for the whole sample with pressure injuries was a median of 18 days (IQR 9 to 31), no significant difference between groups (p=0.22) **Author conclusions: Non-sedation did not influence pressure injury incidence.**	• How pressure injuries were evaluated is poorly reported (e.g. who conducted assessment, how often and whether interrater reliability was established) • Follow up period duration is not reported • Power calculation not reported • Retrospective data collection	**1** **Quality: Low**
Intravenous albumin							
(Serra et al., 2013)	RCT **evaluating intravenous administration of albumin to reduce the pressure injuries in patients admitted to the ICU**	Participants were recruited in an ICU in Italy (n=21) Inclusion criteria- • Hospitalized in ICU • Hypoalbuminemia • Minimum stay of 24h • No pressure injury on admission Exclusion criteria:	Participants were randomized to receive: • Intervention group: receiving 25g of albumin for the first three days of ICU stay (n=11), or • Comparator group received nothing (n=10)	• Other variable identified: age , sex, LOS in ICU, LOS in hospital, comorbidities, & chronic diseases • Both groups were followed for at least 7 days • Staging system NPUAP/EPUAP	**Pressure injury incidence** • Pressure injuries developed in 27.27% (3/11) participants in intervention group compared with 70% (7/10) I the control group (p=not reported) • Intervention group were primarily Category/Stage I pressure injuries while the control group experienced Category/Stage I to IV pressure injuries **Author concluded that albumin**	• Does not report methods for randomization, allocation concealment or blinding • No mention of training or credentialing for pressure injury assessment	**Level of evidence: 1** **Quality: Low**

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		• not defined Participant characteristics: • Mean age 64±12 • Mean BMI 31.4±5.9 • Mean eGFR(ml/minutes/1.73m^2) 35±20 • 28.57% had complicated cardiac surgery,19.05% subarachnoid hemorrhage, 14.28% cardiogenic shock			**administered I the ICU reduces the occurrence and severity of pressure injuries**	• Does not report frequency of assessments • Very small sample size • No inter-group statistical comparisons	
Multi-faceted interventions							
(Swafford, Culpepper, & Dunn, 2016)	Chart audit to determine the effectiveness of a facility-acquired pressure injury prevention program in an adult ICU	Participants were individuals admitted to a medical/surgical ICU in the USA over a period of 3 years (n=1458) No inclusion or exclusion criteria reported Participant characteristics: • Mean age of participants per audit year ranged from 50.5 to 52.2 years • Mean length of stay per audit year ranged from 14 days to 10.7 days	Pressure injury prevention program included: • Revised skin care protocol • Fluidized repositioners for individuals with Braden Scale score ≤14 • Silicone border wound dressings on pressure points for individuals with Braden Scale score ≤14 • Face to face staff education	• NPUAP pressure ulcer staging system • No follow up period stated • Unclear how skin assessments were performed • Costs of pressure injuries were based on an estimation from the National Database of Nursing Quality Indicators (NDNQI) based on $US 38,700 per facility acquired pressure injury	**Facility-acquired pressure injury incidence** There was a reduction of pressure injury incidence from 10% to 3% over 3 years Estimated costs of pressure injuries Costs of pressure injuries decreased from $US 1.7 million to $US 0.66 million over the 3 year period	• Appears to rely on retrospective chart audit but reporting of data collection is limited • No statistical analyses • Unclear how skin assessments performed • Unclear if there are significant differences in population demographics over time that confound results • Quality improvement program with low quality reporting	**Level of evidence: 4** **Quality: Low**
(Kelleher, Moorer,	Quality improvement	Carried out in a 17 bed surgical ICU (total n=180)	• Nurse-led quality improvement program	• Quarterly facility acquired pressure	• Facility acquired pressure injury incidence rate: 10.6% overall	• Introduction of specialty	**Level: 3**

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& Makic, 2012)	project **investigating bedside rounds in the ICU to decrease pressure injury incidence**	Average number of patients per quarterly prevalence survey was 15	• All nurses received a education resource on pressure injuries. • Main intervention: ○ Weekly bedside rounds by nurse managers and WOCNs to engage nurses in discussion on pressure injury risk factors, Braden score subscales and prevention plans ○ Bed side rounds used question format to guide discussion (included in article) and focused on patient specific issues	injury incidence rates were tracked from January 2008-December 2010 • Prevention measures in use commenced in Q6 • Validation of pressure injury staging systems not reported	• Pre-intervention facility acquired pressure injury incidence rate (over 5 quarters, 1 to 5): 0% to 26.7% • Post-intervention facility acquired pressure injury incidence rate (over 7 quarters, 6 to 12) ranged from 0% to 27.1% • From quarters 9 to 12, the highest prevalence was 6.3% • Observations of the following prevention strategies improved with 100% compliance observed from Q 9 to Q 12: ○ Use of a prevention surface ○ Repositioning ○ Nutrition ○ Moisture Management	beds/mattresses and wicking under-pads during the study period may have affected the HAPU rate • Small number of patients per quarter	**Quality: moderate**
(Gray-Siracusa & Schrier, 2011)	Descriptive study reporting on **a multifaceted quality improvement (QI) intervention in the ICU to prevent pressure injuries**	QI project in a 27-bed cardiovascular and coronary care ICU in USA Participants in pre-QI intervention stage (2007 to 2008)(n=554) Mean age 69.3±21.97 61.9% sample male Participants in post-QI intervention stage (2008 to 2009) (n=645) Mean age 66.8±19.10 56.4% sample male	• Introduced a pressure injury bundle (PIB) including: ○ Risk assessment conducted every 12 hours ○ Mobility – lighting and chimes every 2 hours to indicate repositioning time ○ Minimal head of bed elevation ○ Heel elevation ○ Nutritional screening on admission and daily ○ Skin assessment using NPUAP staging ○ Sacral cleanse and moisturize	• fFcility acquired pressure injuries identified through skin assessments and using EPUAP staging system	• No significant difference between pre-PIB and post-PIB for facility acquired pressure injury incidence rates (p=0.11) • Comparison of quarterly rates showed decreasing trend: ○ Pre-PUB quarterly facility acquired pressure injury incidence rates: QI 5.7% Q2 0% Q3 5.2% Q4 0% ○ Post-PUB quarterly facility acquired pressure injury incidence rates: QI 0% Q2 ~0.8% Q3 0% Q4 0%	• Small number of participants each quarter • Only one site	**Level: 3** **Quality: low**

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(Dibsie, 2008)	Descriptive study reporting on **a QI project aimed at standardising skin and wound care products**	QI project commenced in the adult surgical ICU and expanded to multisite (2) academic medical centers	• Nurse driven protocol to improve skin and wound care within a Standardization of all products related to the prevention of skin breakdown and care of partial-thickness wounds based on nurse recommendations Consistent and correct completion of order sets, education provided on new products and skin care, identification and staging of pressure injuries, assessment and treatment. • Electronic reporting of all skin issues and PUs • Daily reminder systems for use of reporting system • Weekly evaluation of wounds and skin by clinical specialists • Management support and funding for the project • Organizational support including financial reward associated with strategic goals	• Prevalence of pressure injuries quarterly over 2 years • Pressure injuries validated by wound care nurses	Prevalence data reflect steady decreases in the rate of facility acquired Category/Stage II or greater pressure injuries Data from surgical ICU showed: • ~16.5% at baseline (Q4 2005) • ~ 6% at second measure (Q4 2006) • ~ 12.5% at third measure (Q1 2007) • ~ 6.5% at fourth measure (Q2 2007) • ~6% by fifth measure (Q3 2007)	• Interventions might be specific to organizational structure and culture of study site, and might not be generalizable. • No statistical analysis • No reporting of baseline education level, experience of nursing staff	**Level: 3** **Quality: moderate**
Clinical question three: What are the unique pressure injury treatment strategies for individuals in critical care?							
No studies							

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Additional data: Assessing pressure injuries in critical care settings							
(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) Inclusion criteria: • Admitted to ICU Exclusion criteria: • PU on admission to ICU • PU developed within 48 hours of ICU admission	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 of any stage 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 1, 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 **Characteristics between PU and no-PU cohorts** • PU cohort were significantly older (65.7±18 vs 59.6±20 years, p<0.001) • PU cohort more likely to be male (60% vs 49%, p=0.008) • PU cohort more likely to have admission for emergency surgery (p=0.0076) • PU cohort more likely to have higher Charlson score (p<0.001) and be more dependent (p<0.001 • PU cohort more likely to have chronic kidney disease (p=0.005), chronic heart disease (p=0.006), COPD (p=0.004), chronic arterial disease (p=0.019) • PU cohort more likely to be admitted for cardiovascular reason (p<0.001) or sepsis (p<0.001) • PU cohort more likely to require mechanical ventilation (p<0.001), vasoactive drugs (p<0.001) and renal replacement therapy (p<0.001) • PU cohort more likely to have ICU or hospital death both (p<0.001) **Braden scale** • PU cohort had significantly lower mean	• 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** Note: This study also for review by risk SWG

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					Braden scores (11.2±2.7 versus 15.1±3.5, p<0.001) • Discrimination of Braden scale was 0.753 (95% CI 0.712 to 0.795) • Discrimination of Braden scale was 0.642 (95% CI 0.591 to 0.689) for individuals with mechanical ventilation, 0.634 (95% CI 0.0.584 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 • Significant variables in multivariate analysis included age, gender, diabetes, hematological malignancy, PAD, Braden score ≤13, MAP < 60mmHg, mechanical ventilation and renal replacement therapy (subdistribution hazard ratio and p values provided) • Cut off score for Braden scale in critical care proposed at ≤13 **Author conclusions: Braden scale has good predictive ability in critical care, but a lower cut off score for risk is proposed**		
(Delmore, Cox, Rolnitzky, Chu, & Stolfi, 2015)	Retrospective case-control study **exploring predictive factors for acute skin failure (ASF) and differentiating from pressure injuries**	Cases were identified from review of admissions at two US hospitals in a two year period (validation set 102 participants of which 34 with PU; main analysis 450 participants of which 150 had PU) Patients with PUs were purposively selected and control patients without PUs were selected randomly. Inclusion criteria: • Aged ≥ 18 years	• N/A	• Variables considered in modeling: ○ impaired nutrition (BMI < 18.5 kg/m^2, C-reactive protein > 10mg/dL, unintentional weight loss before admission) ○ respiratory failure, renal failure, cardiac failure, and/or liver failure ○ limited tissue	Regression analysis to determine significant and independent predictors of acute skin failure • Peripheral arterial disease (PAD) odds ratio (OR) 3.8, 95% CI 1.64, to 8.66, p=0.002 • mechanical ventilation > 72 hrs OR 3.0, 95% CI 1.78 to 5.05, p<0.001 • respiratory failure OR 3.2, 95% CI 1.82 to 5.40, p<0.001 • liver failure OR 2.9, 95% CI 1.05 to 8.08, p=0.04 • severe sepsis OR 1.9, 95% CI 1.14 to 3.20, p=0.02	• A 3-day length of stay was chosen, as time frame considered adequate to detect development of a new PU • Retrospective design relying on records	**Level of evidence: 3 (prognostic)** **Quality: High**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• admitted into the critical care for at least 3-day ICU stay Exclusion criteria: • preexisting PU • lack of PU prevention measures without justification for non-adherence • actively dying/end of life Participant characteristics: • Mean age 71 years (SD 15.6) • Mean ICU stay 9.8 days • Mean Braden score 14 (SD 3.5) • Most PUs were SDTI, most commonly on sacrum and majority occurred in first 7 days in ICU		perfusion (MI, severe anemia, vasopressor use resulting in peripheral necrosis, PAD, cardiac arrest) ○ sepsis ○ diabetes ○ immobility ○ surgery > 3 hrs duration ○ hypotension > 48 hrs ○ vasopressors used in ICU ○ mechanical ventilation > 72 hrs ○ baseline variables including age, race, gender, diagnosis, Braden score, APCHE score	Area under curve (AUC) 0.793 indicating good predictive accuracy **Study conclusion: PAD, mechanical ventilation >72 hours, respiratory failure, liver failure, and severe sepsis/septic shock were significant independent predictors of ASF. Current pressure injury prevention/intervention strategies should be considered when diagnosing ASF. ASF cannot be accurately distinguished from pressure injuries if the standard of pressure injury prevention has not been maintained.**		

Table 1: Level of Evidence for Intervention Studies

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

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

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

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

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

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

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

- High quality studies: fully met at least 80% of applicable criteria
- Moderate quality studies: fully met at least 70% of applicable criteria
- Low quality studies: did not fully meet at least 70% of applicable criteria

RCTS

Endnote ID	Author/year	Focussed question	Assignment randomized using appropriate method	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measure	% drop out in study arms is reported and acceptable	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Level of evidence	Quality
15073	(Nedergaard, Haberlandt, Toft, & Jensen, 2017)	Y	N	U	N	Y	Y	N	Y	Y	Y	N	Y	1	Low
1568	(Serra et al., 2013)	Y	N	N	N	U	U	N	U	U	NA	U	U	1	Low

COHORT STUDIES

	Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Level of evidence	Quality
15181	(Coyer et al., 2017)	Y	Y	Y	Y	Y	N	Y	N	Y	N	Y	Y	Y	Y	3	High

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL

Endnote ID	Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Level of evidence	Quality
13814	{Swafford, 2016 #13814}	Y	Y	Y	U	Y	U	NA	U	N	N	4	Low
15092	{Nowicki, 2017 #15092}	Y	Y	Y	U	Y	Y	NA	N	Y	N	4	Low

PROGNOSTIC STUDIES

	Author/year	Adequate description of baseline characteristics	Satisfactory study attrition	Clear outcome measures/prognostic factors	Range of prognostic factors/confounders	Method of measuring prognostic factor is reported, valid and reliable	Same method of measure of prognostic factor for all	Continuous variables or appropriate cut offs	Percent participants with complete data acceptable	Appropriate imputation method	Confounders/prognostic factors accounted for in analysis	Selective reporting avoided	Adequate sample size (10 PIs/ factor)	Level of evidence	Quality
9509	(Delmore, Cox, Rolnitzky, Chu, & Stolfi, 2015)	N	U	Y	Y	Y	Y	U	Y	U	Y	Y	Y	3	moderate
6497	{Catala Espinosa, 2014 #6497}	Y	NA	Y	Y	U	Y	Y	Y	Y	Y	Y	Y	3	high

SYSTEMATIC REVIEWS FOR DISCUSSION

RATING CRITERIA:
1 Partial yes: states review question, search strategy, in/exclusion criteria and risk of bias were a-priori; full yes: meta-analysis/synthesis plan, investigation of heterogeneity and justification for protocol deviation
2 Partial yes: At least 2 databases, provides keywords and search, justifies publication restrictions; full yes: searched reference lists of included studies, searched trial registries, consulted experts in field, searched grey literature, search within 24 months of review completion
3 At least two reviewers independently agreed on selection of studies to include or reviewers achieved 80% agreement on a sample of studies
4 Either two reviewers did data extraction and had >80% agreement, or two reviewers reached consensus on data to extract
5 Partial yes: list of all relevant studies that were read and excluded; full yes: every study that was excluded is independently justified
6 Partial yes: described populations, interventions, comparators, outcomes and research design; full yes: detailed descriptions of same plus study setting and timeframe for follow-up
7 FOR RCTS Partial yes: appraised risk of bias from unconcealed allocation and lack of blinding; full yes: appraised risk of bias on true randomisation, selection of reported result from multiple measurements/analyses
FOR non randomised studies: Partial yes: appraised confounding and selection bias; full yes: appraised methods to ascertain exposures and outcomes, selection of reported result from multiple measurements/analyses
8 Must include reporting of the source of funding of individual studies, or reports that the reviewers considered this even if individual funding sources aren't listed in review

Endnote ID	Author/year	PICO research question and inclusion criteria	Explicitly states a-priori protocol[1]	Rationale for selection of study designs	Comprehensive search[2]	Duplicate study selection[3]	Duplicate data extraction[4]	Excluded studies listed[5]	Adequate description of	Risk of bias assessed[7]	Source of funding reported[8]	Appropriate meta-analysis including weighting and adjustment for heterogeneity	Meta-analysis considers risk of bias of studies	Discussion consider risk of bias of studies	Assessment of publication bias if quantitative analysis is done	Potential conflicts of interest of authors reported and managed	Review Quality
8108	(Park et al., 2015)				Y			N		Y		Y		Y	Y		Exclude
14657	(Tayyib & Coyer, 2016)				Y			N		Y		N		Y	N		Exclude

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