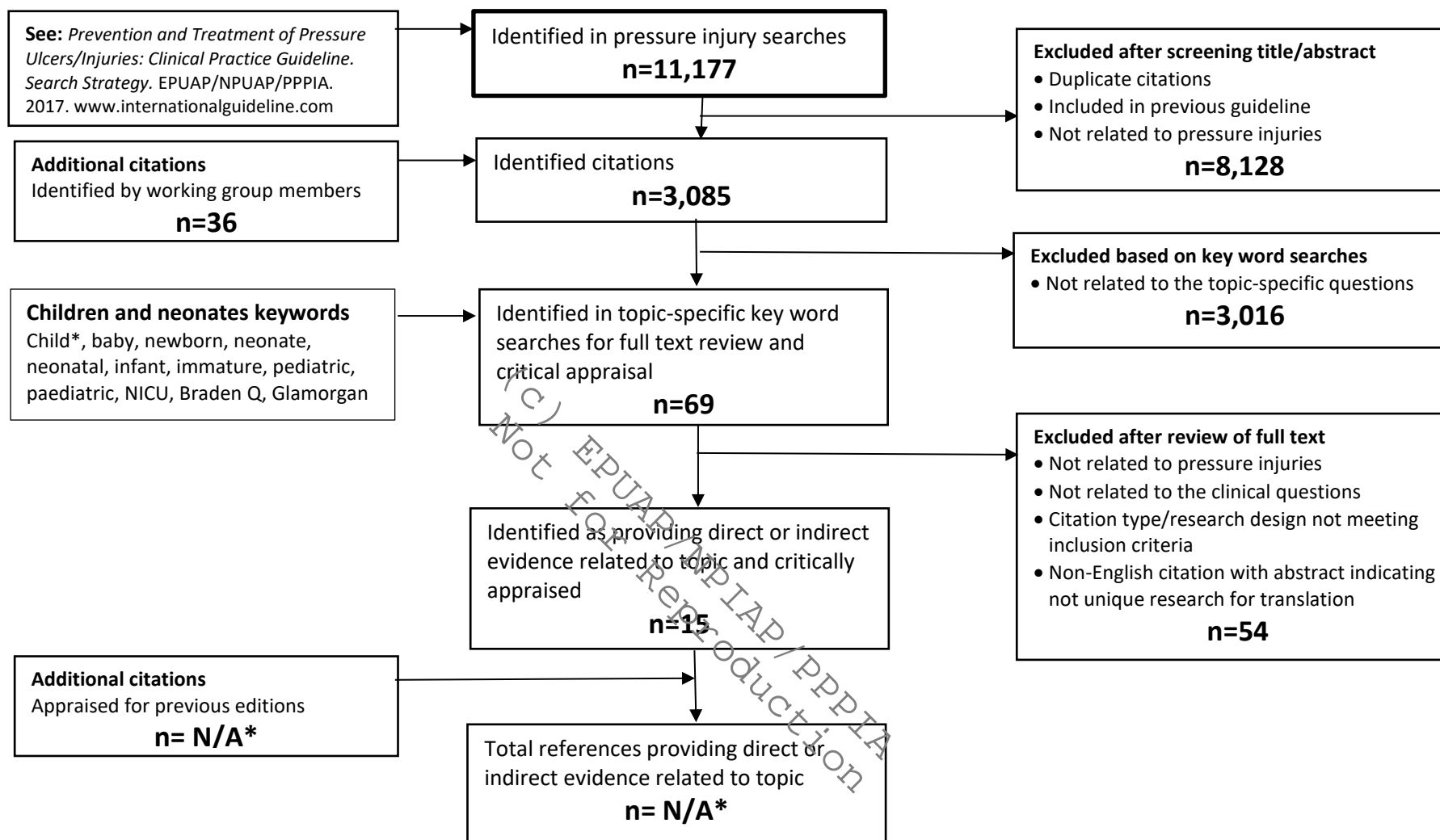


Neonates and Children: data extraction and appraisals

Search results for 2019 International Pressure Injury Guideline: Neonates and Children



* 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

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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	
Risk assessment tools							
Tume, Siner, Scott, & Lane, 2014	Retrospective cohort study to predict validity of the Braden Q	<p>Study was conducted in a 23-bed surgical/medical PICU in the UK over a 12 month period (n=1057 participants, n=891 had Braden Q scores and were analyzed)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Aged > 37 weeks gestation Braden Q score recorded in the first 24h of the PICU admission <p>Exclusion criteria:</p> <p>Preterm infants (<37 weeks gestation)</p>	<p>Patient data included paediatric index of mortality score (validated mortality risk assessment tool for the PICU population) mortality, age, gender, invasive ventilation and length of PIC length and this was summarised for the two age groups</p>	<ul style="list-style-type: none"> Measures of sensitivity, specificity, positive predictive value (PPV), NPV and AUC of the Braden Q in different ages Braden Q is scored every 12 h, the score used for this study was taken from the first 24 h all nurses on the PICU had been trained in the use of the Braden Q scale 	<p>Pressure injury incidence</p> <ul style="list-style-type: none"> Non-device related PUs (all stages EPUAP) incidence= 1.2% Incidence of non-device related PUs (stage 2) = 0.6% <p>Psychometric properties for 3 weeks to 8 years age group</p> <ul style="list-style-type: none"> Braden Q using cut off score ≤ 16 had 100% sensitivity and 73.1% specificity Positive predictive value 2.56, negative predictive value 100 Area under curve (AUC) 0.87 (95% CI 0.75 to 0.98) <p>Psychometric properties birth at term to 14 years</p> <ul style="list-style-type: none"> 75% sensitivity and 72.6% specificity Positive predictive value 1.5, negative predictive value 99.8 Area under curve (AUC) 0.74 (95% CI 0.49 to 0.98) <p>Author conclusions: In a younger age group (less than 8 years) the Braden Q had better properties than when using in children aged up to 14 years</p>	<ul style="list-style-type: none"> Large amount of missing data Retrospective study Braden Q measured at only one time point No MV analysis 	<p>Level of evidence: 3 (prognostic)</p> <p>Quality: low</p>

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
J. Willock, Habiballah, Long, Palmer, & Anthony, 2016	Prospective study comparing the Glamorgan and Braden Q risk assessment scales	<p>Participants were recruited consecutively in two hospitals in Jordan and Australia from general wards, NICU and PICU (n=513)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • No pre-existing PU • Aged < 18 years • In Jordan minimum LOS was 72 hours, in Australian minimum LOS was 2 nights <p>Participant characteristics:</p> <ul style="list-style-type: none"> • 212 participants in Jordan and 301 participants in Australia • 53% males • 51% critical care admissions (100% in Jordan and 16% in Australia) • 7% participants developed more than one PU • 33% participants were located in NICU 	Nurse data collectors received education on pediatric PU and risk assessment tools, PU risk management and conducting skin and PU risk assessment.	<ul style="list-style-type: none"> • In Jordan, one tissue viability nurse collected all data and in Australia clinical nurses collected data • Skin and risk assessments conducted within 24 hours of admission • In Jordan follow up risk assessments were conducted every 2-3 days in first 2 weeks of admission and weekly thereafter. • In Australia risk assessment was conducted daily • Glamorgan and Braden Q scales were used for each risk assessment and NPUPA/EPUAP staging was used. 	<p>Pressure ulcer incidence Overall incidence was 6.8% Jordan incidence 9% Australian incidence 5%</p> <p>Pressure ulcer Category/Stage Jordan: 41.3% Category/Stage I, 48.3% Category/Stage II, 10.3% Category/Stage III Australia: 76% Category/Stage I, 20% Category/Stage II, 4% Category/Stage III</p> <p>Risk assessment tool performance</p> <ul style="list-style-type: none"> • All participants Glamorgan Score: AUC 0.748, 95% CI 0.53 to 0.82, p=0.018 Braden Q Score: AUC 0.827, 95% CI 0.74 to 0.91, p<0.001 • Excluding Category/Stage I Glamorgan Score: AUC 0.77, 95% CI 0.67 to 0.87, p=0.018 Braden Q Score: AUC 0.85, 95% CI 0.77 to 0.93, p<0.001 • PICU populations Glamorgan Score: AUC 0.76, 95% CI 0.61 to 0.91, p=0.006 Braden Q Score: AUC 0.74, 95% CI 0.58 to 0.90, p=0.010 • NICU populations Glamorgan Score: AUC 0.82, 95% CI 0.73 to 0.91, p<0.001 Braden Q Score: AUC 0.82, 95% CI 0.73 to 0.92, p<0.001 • General populations Glamorgan Score: AUC 0.57, 95% CI 0.37 to 0.77, p=0.478 Braden Q Score: AUC 0.83, 95% CI 0.73 to 0.92, p<0.001 <p>Author conclusions:</p>	<ul style="list-style-type: none"> • Small number of PUs in general wards limits the analysis • Slightly different procedures used between the two sites and significantly more critical care admissions in Jordan; however the scales performed equivalently between sites (see paper) • Scales were completed at the same time and this may influence the results • No interrater reliability was conducted • Introduction of PU preventive care reduces the sensitivity of PU risk assessment scales 	<p>Level of evidence: 1 (prognostic)</p> <p>Quality: high</p>

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Neonates and Children: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					Braden Q and Glamorgan Scales have similar validity. Braden Q had slightly better performance in general pediatric populations.		
de Lima, de Brito, Souza, Salome, & Ferreira, 2016	Psychometric study to test the reliability and validity of a translated version of the Neonatal/Infant Braden Q Risk Assessment Scale (RAS)	<p>Participants were recruited consecutively in one NICU in Brazil over one year (reliability sample n=20, validity sample n=30, total n=50)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> No PU on admission Inpatient for > 24 hours <p>Participant characteristics:</p> <ul style="list-style-type: none"> Mean gestations age at birth 31.5±4.4 weeks Mean birth weight 1777±1003g Age range 0 to 28 days Primarily pre-term (83.3%) 80% acquired infection 93% required ventilatory support 	<ul style="list-style-type: none"> Neonatal/Infant Braden Q RAS contains eight subscales. Six subscales (sensory perception, activity, mobility, moisture, nutrition, and friction and shear) are adapted from Braden Q Scale and two additional subscales (tissue perfusion and oxygenation, and gestational age) are added. The original version was translated from English to Brazilian using a back translation process. 30 health professional performed the assessments using the tool 	Psychometric characteristics	<p>PU prevalence 13% (4/30) (Category 2 and 3), with 2 in occipital region and 2 in nasal septum.</p> <p>Interrater reliability first assessment, r =0.98, P < 0.001; last assessment, r =0.99, p< 0.002</p> <p>Intra-rater reliability first assessment, r = 0.87, p< 0.001; last assessment, r=0.84, p<0.001</p>	<ul style="list-style-type: none"> Small sample size Procedure for assessments is minimally reported Experience of raters is not reported Frequency of assessments unknown 	<p>Level of evidence: 4</p> <p>Quality: Low</p>
Leonard, Hill, Moon, & Lima, 2013	Psychometric study comparing performance of two risk assessment tools: Modified Glamorgan Scale (mGS) and Glamorgan Scale (GS)	<p>Participants were recruited in a 19-bed PICU (pediatric intensive care unit) and a 25-bed NNU in Australia over 5 months (n=133 included, n=112 analyzed)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Convenience sample of admissions to the participating units 	<ul style="list-style-type: none"> Testing two risk assessment tools for pressure ulcer injury in two pediatric intensive care settings (mGS = modification of the Glamorgan Scale and GS = Glamorgan Scale) 	<ul style="list-style-type: none"> Primary outcome was allocation of risk category for pressure injury based on mGS and GS Investigator visited NNU and PICU twice per week, data collection was done by nursing staff 	<ul style="list-style-type: none"> Chi square value of 0.982 across the 112 records indicated a very strong agreement between the two tools 111 patients were rated as “high risk” or “very high risk”, only one being rated “at risk” Little difference in risk category allocation between GS and the mGS <p>Author conclusions: Results of the small study demonstrated little</p>	<ul style="list-style-type: none"> Single center study Using a convenience sample Participants with missing data were excluded from statistical analysis Data was collected from medical records rather than as a patient 	<p>Level of evidence: 4</p> <p>Quality: Low</p>

Neonates and Children: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Participant characteristics: <ul style="list-style-type: none"> 51% from PICU and 49% from NNU 			variation between risk categorization between the two tools when data from a medical recorded is used	assessment process and clinical evaluation <ul style="list-style-type: none"> Study did not test psychometric properties or performance of tools in predicting pressure injuries 	
Csoma et al., 2016	Cross sectional study exploring factors relevant to development of skin disorders	Participants were recruited in one pediatric department in Hungary over a 2 year period (n=460) Inclusion criteria: Admission to the NICU in the study period Exclusion criteria: None stated Participant characteristics: mean birth-weight 2,236.86±965.53g (range 500–5,470g) mean gestational age 33.8±4.4 weeks (range 22–41 weeks) Male infants had significantly higher birthweight than feamles (p=0.003)	<ul style="list-style-type: none"> None 	<ul style="list-style-type: none"> Skin assessments conducted by the same two dermatologists 	Prevalence of skin injuries <ul style="list-style-type: none"> Prevalence of iatrogenic skin injury was 18% over 2 years, of which 8.7% were PU Prevalence over 2 years was 9 PU/460 infants =1.9% Mean age for infants with skin injury was significantly lower than those without skin injury (p=0.006) Length of stay significantly longer in infants with skin injury than without (32.2 days versus 18.3 days, p=0.001) No significant difference in mortality between those with and without a skin injury (with skin injury 9.6% versus without skin injury 8.2%) Correlation between skin injury and treatments Individuals with a skin injury (NOT just a PU) were more likely to have: <ul style="list-style-type: none"> Intubation–surfactant–extubation (p=0.006) Surfactant therapy (p=0.003) Umbilical arterial or venous catheter (both p=0.004) Patent ductus arterious (p=0.004) Pulmonary or intracranial hemorrhage (both p=0.002) Bronchopulmonar dysplasia (p=0.01) Positive bacterial swabs (p=0.001) 	<ul style="list-style-type: none"> Classification of Pus not reported Unable to determine specific treatments correlated with PU, only with broad skin injury Management was not discussed 	Level of evidence: 4 Quality: Low

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Neonates and Children: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
J. Willock, 2013	Psychometric study to assess the inter-rater reliability of the Glamorgan scale using overt and covert method	<p>Study was conducted in a Children's hospital in Wales</p> <p>Number of participants:</p> <ul style="list-style-type: none"> Overt: 27 nurses (35 nurses approached, 8 refused to participate) Covert: 41 risk assessments 	<p>Overt: Participants and the researcher independently assess a patient's potential pressure ulcer risk using Glamorgan scale</p> <p>Covert: Researcher and pediatric tissue viability link nurse assess the patient PU risk using Glamorgan scale and compared with the score documented by the bedside nurses</p>	Glamorgan scale – Risk factors identified, total score and category of risk group	<p>Overt assessment</p> <ul style="list-style-type: none"> 88.9% agreement 3 nurses score the patient's nutritional status differently from that of the researcher, however the score did not affect the overall risk category of the patients Spearman's rho: 0.976 Cohen's Kappa: 0.867 (Very good agreement) <p>Covert assessment</p> <ul style="list-style-type: none"> 82.9% agreement (n=34) Item of disagreement (3 records disagree on 2 items): <ul style="list-style-type: none"> 5 Medical device 4 Mobility 1 Pyrexia Spearman's rho: 0.727 Cohen's Kappa: 0.763 (Good agreement) <p>Author conclusions: Scales should be clear and have good interrater reliability</p>	<ul style="list-style-type: none"> Hawthorne effect – Overt study nurses aware that assessments will be compared Covert study, ward manager was informed 1 week prior which may have influenced the results Time lapse between the assessment done by bedside nurse, researcher and tissue viability link nurses may cause the disagreement in scoring No reporting of education levels and training of participants, or whether they reflect general population 	<p>Level of evidence: 4</p> <p>Quality: Low</p>
Sari & Altay, 2017	To determine the validity and reliability of the Turkish Neonatal Skin Risk Assessment Scale (NSRAS) translation	<p>The study was performed in NICU in an university hospital in Ankara in a 1 month period</p> <p>Including 130 neonatal assessments from a total of 17 patients performed by 7 observer nurses</p>	Observer nurses underwent training session for 1 hour in the use of NSRAS with bedside practice performance	<ul style="list-style-type: none"> Bed side nurses will be before the assessment within 20 minutes and the investigator will reassess patients separately using the NSRAS assessment Discriminatory power of the NSRAS was determined by a receiver operating characteristic (ROC) curve analysis 	<p>Psychometric properties</p> <ul style="list-style-type: none"> Cronbach's alpha was 0.88, subarticles were 0.3 to 0.90 indicating good internal validity All subitems had ROC > 0.7; Area under ROC curve = 0.79 Interrater reliability for overall tool, Spearman's correlation 0.95, p<0.001 <p>Author conclusions: the NSRAS is a valid and reliable tool for use in Turkish NICUs.</p>	<ul style="list-style-type: none"> Turkish translation 	<p>Level of evidence: 4</p> <p>Quality: High</p>

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Anthony, Willock, & Baharestani, 2010	Cross sectional study comparing the predictive validity of Glamorgan scale to the Braden Q and Galvin scales	Convenience sample of participants were recruited from 11 pediatric hospitals (n=71, primarily with PU) and from a 12 th pediatric hospital (n=165, primarily without PU). Inclusion: unclear Exclusion: unclear Characteristics: <ul style="list-style-type: none"> • Age, gender, diagnoses and co-morbidities were not reported • PU status: <ul style="list-style-type: none"> ○ No PU n=175 ○ Stage 1 n=15 ○ Stage 2 n=28 ○ Stage 3 n=13 ○ Stage 4 n=5 • PU location: <ul style="list-style-type: none"> ○ Heel n=17 ○ Ear n=11 ○ Sacrum n=11 ○ Occipital n=10 ○ Ischial tuberosity n=9 ○ Other n=27 	Three risk assessment scales were administered on all participants by a special interest group of nurses. <ul style="list-style-type: none"> • Glamorgan scale: scale with 10 sub-scores developed through literature review, statistical analysis of patient data and expert opinion • Braden Q: modification of the adult Braden scale and validated for use in ages 21 days to 8 years • Garvin scale: scale with four risk factors (mobility, sensory perception, nutrition and moisture) with four risk categories 	Chi-square, Mann-Whitney and logistic regression to determine statistically significant risk factors. Receiver operating characteristic (ROC) curves were used to produce area under curve (AUC). It is unclear how many times the risk scales were applied or when they were applied in the sequence of care and PU development.	<ul style="list-style-type: none"> • Glamorgan sub-score The following sub-scores were significant when comparing those with and without PU at p<0.001: anaemia, equipment pressing, mobility, poor peripheral perfusion, pyrexia, serum albumin, surgery in past 4 weeks The following sub scales were not significant: weight < 10th centile, (p=0.105) continence (p=0.628) , nutrition (p=0.960) The following sub-scales were significant by logistic regression: equipment pressing, continence, mobility, pyrexia and serum albumin • Braden Q scale The following sub-scores were significant when comparing those with and without PU: activity (p<0.001), mobility (p<0.001), sensory perception (p<0.001), tissue perfusion (p=0.009), friction-shear (p=0.014) The following sub scales were not significant: moisture (p=0.112). nutrition (p=0.890) The following sub-scales were significant by logistic regression: mobility, moisture, tissue perfusion • Garvin scale The following sub-scores were significant when comparing those with and without PU at p<0.001: mobility, sensory perception 	<ul style="list-style-type: none"> • Cross-sectional design, not prospective • Characteristics of the population (particularly age) not defined • Unclear whether the risk assessments were performed blind to each other and PU status • Inter-rater/intra-rater reliability is unclear • No sample size calculation for establishing clinically relevant difference 	Level of evidence: 3 (prognostic) Quality: low

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					<p>The following sub scales were not significant: moisture (p=0.139), nutrition (p=0.652)</p> <p>The following sub-scales were significant by logistic regression: mobility, moisture</p> <ul style="list-style-type: none"> • Area under curve Glamorgan total scale AUC 0.912, standard error 0.017, p<0.001, lower bound 0.878, upper bound 0.946 Garvin total scale AUC 0.641, standard error 0.036, p=0.001, lower bound 0.570, upper bound 0.712 Braden Q total scale AUC 0.694, standard error 0.034, p<0.001, lower bound 0.627, upper bound 0.762 		
Jane Willock, Anthony, & Richardson, 2008	Study reporting the interrater reliability of the Glamorgan risk assessment scale	<p>Raters: Self-selected sample of 15 nurses working in 7 pediatric wards in a tertiary hospital in Wales (n=35 invited, n=15 participated)</p> <p>Sample: children in 7 pediatric wards in a tertiary hospital in Wales (n=15)</p> <p>Inclusion: self-selected Exclusion: not reported Characteristics:</p> <ul style="list-style-type: none"> • Characteristics of children who were not reported • Experience, age, training of nurses is not reported • All nurses had used the Glamorgan scale previously in clinical practice • Nurses worked in a range of specialties including medical (n=4), high 	<p>Each nurse assessed one child (selection not clear) using the scale. A second assessment was conducted on the same child by a researcher blinded to the first assessment within 10 minutes of the first assessment.</p>	Paired score analysis with SPSS analysis	<ul style="list-style-type: none"> • There was 100% agreement on 9 of 10 Glamorgan sub-scales: mobility, equipment, anaemia, pyrexia, poor perfusion, low albumin, low weight, inappropriate incontinence ($\kappa=1.0$ for all) • There was good agreement for the 10th subscale: nutrition ($\kappa=0.63$, p<0.001) • On most of the sub-scales (excepting equipment and mobility), a dichotomous score is allocated (1 if present, 0 if absent) • Agreement for overall Glamorgan score was not reported • Conclusions: There was good agreement between nurses on the scale in a population of children with low PU risk 	<ul style="list-style-type: none"> • Small sample of 15 nurses • Self-selection may favour those who are more confident using the tool • Selection of children was those who primarily had low risk of PU • Characteristics of nurses and children is not reported • Confidence intervals not reported • No sample size calculation for establishing clinically relevant difference 	Level of evidence: 3 (prognostic) Quality: moderate

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		dependency (n=4), NICU (n=3), oncology (n=2), PICU (n=1) and surgical (n=1).					
Kottner, Kenzler, & Wilborn, 2012	Study reporting the interrater reliability of the Glamorgan risk assessment scale	<p>Raters: Participants were all nurses in one unit of a university hospital in Germany (n=27)</p> <p>Sample: convenience sample of children in the ward (n=30)</p> <p>Inclusion: all nurses in the ward</p> <p>Characteristics of nurses:</p> <ul style="list-style-type: none"> • Median work experience 14 years • Median time in this unit 3.5 years <p>Characteristics of children:</p> <ul style="list-style-type: none"> • Median age 5.5 years • Median weight 19.9 kgs • Median VAS score 15.3 (IQR 11.3 to 23.7) • Median Glamorgan scale score 4.8 (IQR 0.3 to 11.0) 	<p>Three nurses assessed one child simultaneously but without consultation with each other using:</p> <ul style="list-style-type: none"> • Glamorgan scale • 100mm VAS for pressure ulcer risk labelled one end 'no risk' and other end 'maximum risk' <p>Each nurse rated approximately 3 children resulting in 90 observations</p>	<p>Interrater agreement calculated by per cent. Interrater reliability calculated using kappa and intraclass coefficient (ICC)</p> <p>Construct validity by scatter plots and Pearsons'r</p>	<ul style="list-style-type: none"> • Agreement for Glamorgan scale was 48% and interrater reliability was ICC=0.34 (95% CI 0.12 to 0.57) • Subscales interrater agreement: <ul style="list-style-type: none"> Mobility 82%, $\kappa=0.15$ (95% CI -0.19 to 0.48) Equipment 91% $\kappa=0.47$ (95% CI 0.10 to 0.82) Anaemia 100% Pyrexia 98% $\kappa=0.31$ (95% CI -0.78 to 1.00) Poor peripheral perfusion 93% $\kappa=0.49$ (95% CI 0.05 to 0.95) Nutrition 94% $\kappa=0.58$ (95% CI 0.13 to 1.00) Serum albumin 99% $\kappa=-0.01$ (95% CI -1.00 to 1.00) Weight < 10th percentile 97% $\kappa=0.63$ (95% CI 0.04 to 1.00) Incontinence 94% $\kappa=0.31$ (95% CI -0.32 to 0.95) • Interrater reliability for VAS was ICC=0.25 (95% CI 0.03 to 0.49) • Correlation between VAS and Glamorgan scale was $r=0.68$ ($r^2=0.46$) • Conclusion: Interrater agreement for Glamorgan scale (strong agreement between nurses) was high but interrater reliability was low (poor differentiation between children), likely due to the low overall PU risk observed in the sample. 	<ul style="list-style-type: none"> • Most children had a low risk of PU 	<p>Level of evidence: 2</p> <p>Quality: high</p>

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Kottner, Schroer, & A., 2012	Study reporting the interrater reliability of the Glamorgan risk assessment scale	<p>Raters: Participants were nurses in one PICU unit of a university hospital in Germany (n=20)</p> <p>Sample: convenience sample of children in the ward (n=20)</p> <p>Inclusion: 24 of 30 nurses</p> <p>Characteristics of nurses:</p> <ul style="list-style-type: none"> • Mean work experience 15.5 years • Mean time in this PICU 8.5 years <p>Characteristics of children:</p> <ul style="list-style-type: none"> • Median age 1 years • Median weight 19.9 kgs • Median VAS score 10 (IQR 6.2 to 14.4) • Median Glamorgan scale score 27.6 	<p>Three nurses assessed one child simultaneously but without consultation with each other using:</p> <ul style="list-style-type: none"> • Glamorgan scale • 100mm VAS for pressure ulcer risk labelled one end 'no risk' and other end 'maximum risk' <p>Each nurse rated approximately 3 children resulting in 60 observations</p>	<p>Interrater agreement calculated by per cent. Interrater reliability calculated using kappa and intraclass coefficient (ICC)</p> <p>Construct validity by scatter plots and Pearsons' r</p>	<ul style="list-style-type: none"> • Interrater reliability for Glamorgan scale was ICC=0.43 (95% CI 0.16 to 0.69) • Subscales interrater agreement: <ul style="list-style-type: none"> Mobility 63%, $\kappa=0.21$ (95% CI -0.21 to 0.35) Equipment 97%, $\kappa=-0.03$ (95% CI -0.28 to 0.22) Anaemia 92%, $\kappa=0.35$ (95% CI -0.09 to 0.59) Pyrexia 95% $\kappa=0.52$ (95% CI -0.26 to 0.77) Poor peripheral perfusion 92% $\kappa=0.35$ (95% CI 0.09 to 0.59) Nutrition 88% $\kappa=0.53$ (95% CI 0.27 to 0.78) Serum albumin 98% $\kappa=0.48$ (95% CI 0.23 to 0.73) Weight < 10th percentile 92% $\kappa=0.56$ (95% CI 0.30 to 0.80) Incontinence 95% $\kappa=0.69$ (95% CI 0.43 to 0.94) • Interrater reliability for VAS was ICC=0.34 (95% CI 0.01 to 0.67) • Correlation between VAS and Glamorgan scale was $r=0.78$ ($r^2=0.61$) <p>Conclusion: Interrater agreement for Glamorgan scale (strong agreement between nurses) was high but interrater reliability was low (poor differentiation between children), likely due to the high overall PU risk observed in the sample.</p>	<ul style="list-style-type: none"> • Most children had a high risk of PU 	Level of evidence: 2 Quality: high
Fujii, Sugama, Okuwa, Sanada, &	Prospective cohort study	<p>Survey of seven NICUs in Japan in 2006 (n=81)</p> <p>Inclusion:</p>	<ul style="list-style-type: none"> • Skin was assessed daily by nurses and researchers 	<ul style="list-style-type: none"> • Skin texture was assessed using Dubowitz neonatal 	<ul style="list-style-type: none"> • Cumulative incidence of PU was 16% • 62% PUs occurred in patients aged <33 weeks gestation • Stage I PU 21.4%; Stage II PU 78.6% 	<ul style="list-style-type: none"> • High level of non-consent (61.8%) led to high exclusion 	Level of evidence: 1 (prognostic) Quality: moderate

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Mizokami, 2010		<ul style="list-style-type: none"> • Neonate in an incubator • No pre-existing skin breakdown • Consent given <p>Characteristics: 51.9% sample female low birth weight most common reason for admission (74.1%) Mean age 32.5 weeks gestation (range 24 to 41) mean birth weight 1745 g (range 478 to 4122)</p>		maturity assessment scale	<p>Body sites:</p> <ul style="list-style-type: none"> • 86% of PUs were associated with CPAP or DPAP • 50% PU nose • 28% PU labrum and dorsal foot • 7.1% PUs occipital <p>Risk factors associated with PU (p<0.05):</p> <ul style="list-style-type: none"> • birth weight • skin texture • incubator temperature • incubator humidity • support surface • limited position changes • endotracheal intubation <p>Multivariate analysis risk factors:</p> <ul style="list-style-type: none"> • skin texture immaturity odds ratio (OR) 7.6 (95% CI 1.58 to 36.71, p=0.012) • endotracheal intubation OR 4.0 (95% CI 1.04 to 15.42, p=0.047) 	<ul style="list-style-type: none"> • Most neonates were not extremely underweight (<500g) • No congenital heart disease or exacerbated circulation • Potential Hawthorne effect as researcher visited hospitals to directly assess and observe • Does not report PU classification scale used 	
Schindler et al., 2011	Retrospective – sectional database review	Survey of nine PICUs in trauma centers in USA All patients in the center between March 2006 and December 2007 were included. (n=5346)			<ul style="list-style-type: none"> • Aggregate incidence 10.2% (range 0.8% to 17.5% by PICU site) • Aggregate incidence per 10000 patient days was 24.35 (range 2.47 to 57.10 by PICU site) <p>Stages</p> <p>Stage I PUs 63% Stage II PUs 32% Stage III PUs 4% Stage IV PUs 1%</p> <p>Multivariate analysis risk factors:</p> <ul style="list-style-type: none"> • stay ≥ 4 days OR 5.68 (95% CI 4.481 to 7.21, p<0.001) • bilevel or CPAP OR 2.004 (95% CI 1.509 to 2.661, p<0.001) • mechanical ventilation OR 1.334 (95% CI 1.031 to 1.726, p=0.03) 	<ul style="list-style-type: none"> • Did not reach sample size based on power calculation (15 sites) • Site may have influenced risk factor analysis as there was differing use of support surfaces between facilities • Inter-rater reliability not established • Does not report PU classification scale used 	Level of evidence: 3 (prognostic) Quality: moderate

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Neonates and Children: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					<ul style="list-style-type: none"> • high frequency oscillatory ventilation OR 2.057 (95% CI 1.208 to 5.134, p=0.01) • extracorporeal membrane oxygenation OR 2.490 (95% CI 1.208 to 5.134, p=0.01) • Pediatric Index of Mortality 2 score OR 1.132 (95% CI 1.055 to 1.215, p<0.001) <p>Body sites:</p> <ul style="list-style-type: none"> • 17% buttocks • 10% neck • 6% perineum • 6% occipital • 6% sacrum • 5% shoulders • 4% forehead • 4% back 		
McCord, McElvain, Sachdeva, Schwartz, & Jefferson, 2004	Prospective case control study investigating PU risk factors in children	<p>Participants were recruited over a 10 month period from a 30-bed PICU in US (n = 118)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> • Child included in PU group when a PU was identified <p>Characteristics:</p> <ul style="list-style-type: none"> • 48% sample male • aged from less than 1 year to greater than 14 years 	<ul style="list-style-type: none"> • Risk factor assessment 	<ul style="list-style-type: none"> • Risk assessment tool was based on Braden scale and included 45 indicators (content validity and interrater reliability is reported). • Braden scale • Assessment and staging using NPUAP system. 	<ul style="list-style-type: none"> • Skin breakdown related to medical devices occurred. • 36% PU occurred in aged < 1 years, 30% in 1-3 yrs, 9% in aged 3-8 years, 18% in 8-14 years, 7% in > 14 years • Significant risk factors: (0.002 < p < 0.05 was considered significant): <ul style="list-style-type: none"> ○ Edema (p=0.0016) ○ Length of stay , 96 hrs (p=0.0011) ○ Increasing positive end expiratory pressure (p=0.002) ○ Nut turning/turned by low air loss bed (p=0.0001) ○ Weight loss (p<0.0001) 	<ul style="list-style-type: none"> • Does not indicate how controls were selected and assessed • Unclear if ongoing assessments were conducted • Demographics and similarities of groups not reported • Participants were not weight-matched • No confidence intervals are reported 	Level of evidence: 3 Quality: low
Risk factors							
Schluer, Schols, & Halfens, 2014	Cross sectional study reporting factors associated with	Participants were recruited in 13 pediatric hospitals in Switzerland (n= 268 recruited, n= 204 analyzed)	N/A	<ul style="list-style-type: none"> • Pressure injury risk measured by the Braden Scale 	<p>Pressure injury rates</p> <ul style="list-style-type: none"> • 26.5% had ≥ one pressure injury • most frequently was category/stage 1: 83.3% 	<ul style="list-style-type: none"> • participation rate varied between 43% and 100% by hospitals 	Level of evidence: 4 Quality: moderate

Neonates and Children: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	the occurrence of pressure injuries in hospitalized children	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> Aged 1 year to 18 years Hospitalized for at least 1 day <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Hospitalization in psychiatric wards <p>Participant characteristics:</p> <ul style="list-style-type: none"> 67% had been hospitalized for less than 14 days, the average length of stay was 5 days (SD =75.1), median stay of 5 days Male = 113 (55.4%) 		<ul style="list-style-type: none"> Pilot studies in all sites with more than 2 rater pairs were conducted to access the inter-rater reliability for grading and risk assessment 34 rater pair (1 internal & 1 external rater for each hospital unit) rater were trained nurses at least 2 years' experience in working with neonates and infants Overall: inter-rater-reliability for the grading of PUs was sufficient 	<ul style="list-style-type: none"> leg/foot (34.1%) most common location 38.5% were medical device related <p>Pressure injury risk scores</p> <ul style="list-style-type: none"> mean PU risk according Braden Scale was 20 (SD=3.3), median of 22, range of 9 to23 32% patients with "at risk" (mean of 16.5 and a median of 17 (SD = 2.8) Patients not at risk had a mean Braden Score 22 and a median of 23 (SD 0 1.0) <p>Factors influencing pressure injury risk</p> <ul style="list-style-type: none"> no differences were find between girls and boys (χ^2 0.03, $p=$ 0.43) age and type of department was significantly related to being at risk (χ^2 25.8, $p=$ 0.001) 	<ul style="list-style-type: none"> the results were gathered on one day and provide no information about the development of pressure injuries over time Braden Scale is not validated for use in pediatric populations no assumptions can be made, when the highest risk levels within a patient's hospital stay occur, or which represent the highest risk of PU development 	
August & Kandasamy, 2016	Retrospective case-control study exploring association between administration of antenatal steroids and skin injury in neonates	<p>Participants were recruited from a neonatal unit in one hospital in Queensland Australia (n=1624 eligible admissions, n=247 analyzed)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Neonate admission Mothers were administered antenatal steroids Pressure injury or epithelial stripping <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Skin injuries from the following sources: 	<p>Neonates with pressure injuries were divided into two groups for analysis:</p> <ul style="list-style-type: none"> Those whose mothers had received glucocorticoids either a complete or partial course before delivery Those whose mothers had not received any glucocorticoids. 	<ul style="list-style-type: none"> Skin assessments were conducted by two auditors. Assessments included injury size and description Both auditors decided on the stage of the pressure injury or epithelial stripping Perinatal medical records examined to identify use of antenatal glucocorticoids 	<p>Pressure injury cases</p> <p>77 had documented pressure injuries and 170 had no documented injury, prevalence rate was 31.2%</p> <p>Administration of antenatal steroids</p> <ul style="list-style-type: none"> 66% of 77 pressure injury cases had received antenatal steroids 53% of those with no pressure injury had received antenatal steroids <p>Multivariate association between pressure injury and antenatal steroids adjusted for age</p> <ul style="list-style-type: none"> In the full sample, there was no significant difference in risk of pressure injury (odds ratio [OR] 0.59, 	<ul style="list-style-type: none"> Retrospective study and some data may not have been captured. Injury results may have been unreported as suspected deep tissue injury and unstageable pressure injury classifications were not recognized until 2012 Information on other risk factors (e.g. nutrition, medications) not analyzed Selection of participants not 	Level of evidence: 3 Quality: moderate

Neonates and Children: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<p>dermatitis, surgical wounds, venipuncture, capillary puncture, indwelling catheter entry sites, incisions, chemical burns intravenous extravasation, EB, delivery mode injuries and genetic conditions.</p> <p>Participant characteristics: Mean age 28±4.1 gestational weeks Mean birth weight 1155±2678 grams</p>			<p>95% confidence interval [CI] 0.29 to 1.21, p=0.148)</p> <ul style="list-style-type: none"> • Antenatal steroids had a protective effect against the risk for pressure injury in female neonates (OR=0.317, 95% CI 0.105 to 0.96, p=0.041) • No statistical difference in characteristics between cases and control male babies <p>Conclusion: Female neonates who received antenatal steroids have reduced likelihood of developing a pressure related skin injury, although the reason is unknown</p>	reported – only 15% of eligible participants included	
Manning, Gauvreau, & Curley, 2015	Retrospective study investigating factors associated with occipital pressure injuries in critically ill infants and children	<p>Records for admissions to PICU in a US children's hospital over 4.25 years were reviewed (n=60)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Admitted in audit period • Acquired an occipital pressure injury <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Pressure injuries on admission to hospital • No documented skin assessments before discovery of occipital pressure injury <p>Participant characteristics:</p> <ul style="list-style-type: none"> • Avg age 12 months (range 3 to 28) • 55% white, 10% black, 23% not documented 	N/A	<p>Braden Q was calculated based on data recorded within 72 hours of a pressure injury and based on information recorded on the day pressure injury was discovered</p>	<ul style="list-style-type: none"> • 60 cases of occipital pressure injuries • The median Braden Q score was 16 on day closest to pressure injury discovery • On day of discovery: <ul style="list-style-type: none"> ○ 63% were being repositioned ○ 25% had been out of bed/held ○ 40% had neuromuscular block ○ 20% were sedated ○ 32% agitated ○ 72% receiving opioids ○ 65% receiving benzodiazepines ○ 18% had fever above 38C ○ 32% were receiving sufficient calories for age <p>Author conclusions: Infants and children at risk for occipital pressure ulcers can be prospectively identified, allowing implementation of nursing interventions to prevent pressure injuries</p>	<ul style="list-style-type: none"> • Retrospective study relying on medical record data • Changes in staging pressure injuries and patterns of prevention over time. • No logistic regression analysis • No comparison to a non-pressure injury cohort 	Level of evidence: 3 Quality: moderate

Neonates and Children: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<ul style="list-style-type: none"> 53% had a cardiovascular diagnosis 28% had weight lower than 5th percentile for age 40% stage I, 12% stage II, 30% unstageable, 18% deep tissue Injury. 					
Cohen, Scanlon, Bermanian, & Schindler, 2017	To identify and describe the phenomenon of skin failure as a component of multiple organ dysfunction syndrome (MODS) in critically ill children	<p>Study was conducted over two years in one PICU in USA (n=19 reported participants)</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> Admitted to PICU Developed a serious skin injury including stage 3-4 pressure injuries, unstageable pressure injury, suspected deep tissue injury (SDTI) <p>Exclusion criteria: None</p> <p>Participant characteristics:</p> <ul style="list-style-type: none"> Median age 13 years (IQR 1.8 to 18.5) 42% of participants died 	N/A	<ul style="list-style-type: none"> Pressure injuries staged as per National Pressure Ulcer Advisory Panel definitions Injuries reported in hospital electronic software for event monitoring 	<ul style="list-style-type: none"> All patients reported as having a pressure injury had pressure injury prevention strategies in place prior to developing a pressure injury All PI were full thickness on day identified 18 of the 19 patients MODS in the week leading up to the reported injury Children older than 10yrs most affected Occiput and coccyx most common site for pressure injury <p>Author conclusions: In critically ill children who experience multiple organ dysfunction syndrome, skin failure is unavoidable</p>	<ul style="list-style-type: none"> Small study at only one site, unclear what percent of patients were included No comparisons to other patient groups Data collection methods changed during the study so some data may not be available Relied on medical records to attain information 	Level of evidence: 4 Quality: High
Support surfaces							
Niles et al., 2013	Study to determine if a crib mattress with dual pressure redistribution can be used during chest	N/A	<ul style="list-style-type: none"> Two pressure redistribution support mattresses were compared for stability during chest compressions: 	50 chest compressions for a total of 200 compressions were analyzed: SM with a backboard, without a backboard and the PR and PR/CPR mattress with and	<p>Mattress displacement during chest compression</p> <ul style="list-style-type: none"> With the backboard, the SM mattress had more mattress displacement compared to dual mode mattress (mean difference 16.5±1.4mm, p<0.0001) 	<ul style="list-style-type: none"> Mattress deflection was not studied for each CC depth The adult manikin was utilized Only 2 crib mattresses were evaluated without 	Indirect evidence: (healthy volunteers and lab study)

Neonates and Children: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	compression and prevent skin injury		<ul style="list-style-type: none"> ○ single mode pressure reduction mattress (SM) and ○ dual mode PR/CPR mattress ○ Both mattresses compared with and without a backboard ● Chest compressions were conducted using adult size manikin 	without the use of a backboard. Interface mapping was used to evaluate pressure	<ul style="list-style-type: none"> ● Same results shown without the backboard, but the displacement was greater (mean difference 31.7±1.5mm, p< 0.0001) <p>Interface pressure Both mattresses had interface pressure ≤ 50mmHg</p> <p>Conclusion: Chest compressions performed on a dual mode crib mattress resulted in less mattress deflection compared to the single mode mattress and it had good skin pressure injuries capabilities</p>	assessing variation inpatient weight <ul style="list-style-type: none"> ● Pressure mapping was conducted on healthy subjects 	
Higer & James, 2016	Observational study to evaluate the pressure-redistributing properties of various support surfaces used for hospitalized children	Healthy children in the community in US were recruited (n=22) Inclusion criteria: <ul style="list-style-type: none"> ● Aged < 6 years Participant characteristics: <ul style="list-style-type: none"> ● Age range 4.5 months to 5.5 years ● Weight range 10 to 46 lbs ● Height range 21 to 44 inches 	<ul style="list-style-type: none"> ● A standard pediatric mattress and 4 commercial pressure-redistributing support surfaces: gel, air, foam and fluidized were evaluated ● Mattress was placed on the floor ● Measure of pressure was taken for 30 sec using a 45cmx45cm pressure mapping system (XSensor, X3 Medical Seat System) with 1296 sensels 	<ul style="list-style-type: none"> ● Occipital interface pressure measured using pressure mapping system for 30 seconds at 0.5Hz recording frequency ● Reported mean interface pressure, peak pressure index (PPI), mean to peak pressure index ration and contact area 	Air surface had a significantly lower PPI than all other surfaces (p<0.005) Air surface had highest mean-to-mean pressure ratio (0.61) compared to all other surfaces (p<0.005) suggesting it is most homogenous surface Pediatric mattress had significantly higher PPI than all other surfaces (p<0.005) Gel surface and air surface had significantly higher contact areas than all other surfaces, but were not statistically different from each other <p>Author conclusions: Based on the findings, the authors suggest using an air support surface to redistribute occipital pressure. However, it is unclear if all air surfaces are equivalent and no product names were reported</p>	<ul style="list-style-type: none"> ● The products were evaluated were not described and product names not reported – unclear if the results from one unknown product can be extrapolated to other products ● Products were not used according to specifications (placed on floor instead of a bed frame) ● Results applicable to hospitalized children ● It would be useful to measure pressure-redistribution over longer time periods 	Indirect evidence: (healthy volunteers)
Turnage-Carrier, McLane, &	Quasi-experimental investigating	Participants were recruited from an inpatient level II	<ul style="list-style-type: none"> ● All participants were positioned on 5 different support 	<ul style="list-style-type: none"> ● Interface pressures obtained under the occiput using an 	<ul style="list-style-type: none"> ● No significant differences between the readings for participants 	<ul style="list-style-type: none"> ● Infant movement could alter interface pressures 	Indirect evidence: (indirect)

Neonates and Children: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Gregurich, 2008	interface pressure between occiput and different support surfaces in children	<p>hospital nursery (n=13, n=11 completed study)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> • healthy premature infants of post-menstrual age (PMA) 35 to 37 weeks • feeding and gaining weight • in an open crib • within 1 to 3 weeks of discharge • no history or diagnosis of a skin disorder <p>Exclusion:</p> <ul style="list-style-type: none"> • Supplemental oxygen • Apnea, bradycardia, active infection, cardiopulmonary disease, congenital abnormality, skin disorder, trauma, hydrocephaly, cephalohematoma, caput succedaneum or birth injury of head/neck. <p>Characteristics:</p> <ul style="list-style-type: none"> • Mean age 30.2 gestational weeks, mean PMA 36.1 weeks • Mean weight 2556.9g 	<p>surfaces in a random order for 3 to 5 minutes.</p> <ul style="list-style-type: none"> • The 5 bed surfaces were: <ul style="list-style-type: none"> ○ Standard crib mattress with 2.75" foam overlay ○ Standard crib mattress without foam overlay ○ Gel pillow ○ Gel mattress ○ Water pillow – 288mL water • Crib blanket was placed over the standard crib mattress, the gel mattress and the foam overlay and a new disposable cover was placed over the gel pillow. 	<p>interface (IF) pressure evaluator and recorded in mmHg</p> <ul style="list-style-type: none"> • Three measurements were taken on each surface 	<ul style="list-style-type: none"> • A significant difference in the mean of the IF pressures between each mattress and the standard crib mattress was established ($p < 0.001$) • Mattress with foam overlay had the lowest IF pressure (mean 31mmHg) and standard mattress had the highest IF pressure (86.9mmHg) • Study conclusions: A foam mattress overlay is associated with lower occipital IF pressure in babies 	<ul style="list-style-type: none"> • Observable differences in head shape could have influenced the IF pressures 	outcome measure)
García-Molina et al., 2012	Cross sectional survey investigating incidence of HAPU in a children nursed on continuous and reactive low pressure mattresses	<p>Participants were admitted over a 2 year period to the 5 bed Paediatric ICU in a Spanish hospital (n=30 children)</p> <p>Inclusion: aged 1 day to 10 years</p> <ul style="list-style-type: none"> • Admitted for > 24 hours 	<ul style="list-style-type: none"> • All participants received standard PU prevention including application of hyperoxygenated fatty acid oil to skin 8 hourly, and protective hydrocellular dressings) • Participants of interest to survey were nursed on one of two 	<ul style="list-style-type: none"> • Presence of PU determined by daily skin assessment 	<ul style="list-style-type: none"> • 63.3% participants did not receive any repositioning due to their clinical condition • There was a significantly lower incidence of non-device related HAPU in the study participants compared with the estimated incidence in the previous year (3.3% versus 20%, 95% CI 0.08% to 17.2%, $p = 0.021$) 	<ul style="list-style-type: none"> • Small sample size • Comparison cohort was not described and reported as an estimated incidence • Severity of PUs prior to admission not reported 	Level of evidence: 4 Quality: low

Neonates and Children: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		<ul style="list-style-type: none"> Braden score indicating at risk of developing PU (Braden-Q ≤ 16, Neonatal Skin Risk Assessment Scales ≤ 13) <p>Exclusion:</p> <ul style="list-style-type: none"> Admitted < 24 hours Aged > 10 years No consent Not received the pressure mattress support surface PMSS <p>Characteristics:</p> <ul style="list-style-type: none"> Primarily aged from 1 month to 3 years (73.3%, n=22) Average Braden score for those aged > 1 month 10.4 ± 2.4 Average Braden score for those aged < month 13.2 ± 3.03 About half participants were sedated and had vasoactive medication (n=15) 33.3% had a PU on admission to study 	<p>mattresses provided in the unit for children at risk for PU</p> <ul style="list-style-type: none"> Both mattresses classified as continuous and reactive low-pressure special surfaces consisting of double air-cell construction that reacts to pressure in three different compartments (head, body, trunk) but maintains same level of support in each section (i.e. not alternating pressure). First mattress (Cartio Neo®): designed for children weighing 500g to 6kg (n=4) Second mattress (Cartio Juve®): designed for children weighing ≥ 6 Kg (n=26) <ul style="list-style-type: none"> Participants were placed on the study mattresses for a mean of 7 ± 7 days (range 1 to 25 days) 		<ul style="list-style-type: none"> 66.6% of participants admitted with a PU healed before discharge from the PICU Study conclusions: the continuous and reactive low-pressure support surface was associated with a lower incidence of new PU in children in the absence of regular repositioning 	<ul style="list-style-type: none"> Participating nurses were trained informally Concurrent use of several local pressure-management devices in certain high-risk anatomical locations 	
De Raeve et al., 2001	Randomized trial comparing ability of neonates to maintain their body temperature on a visco-elastic	<p>Participants were recruited over a one year period at a NICU in Brussels (n = 72)</p> <p>Characteristics:</p> <ul style="list-style-type: none"> gestational age 24 to 41 weeks (mean 32 ± 3.7 weeks) 	<ul style="list-style-type: none"> babies were admitted on a radiant warmer and transferred to the incubator with support surface when stabilized randomized to receive either: 	<ul style="list-style-type: none"> Settings of air flow systems Settings of humidifiers PU – does not state how this was measured, or how often assessed 8 month study period 	<ul style="list-style-type: none"> Hyperthermia occurred more frequently than hypothermia Mode of ventilation and temperature of the environment had an influence on hypothermia Temperature setting in the humidifier was lower when babies were on a viscoelastic mattress, 	<ul style="list-style-type: none"> Methods of randomization and allocation concealment are poorly described Outcome measures were poorly described 	Level of evidence: 1 Quality: low

Neonates and Children: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	foam compared to a gel mattress , also reports PU	<ul style="list-style-type: none"> weight 535g to 3,600g (mean 1,692±741g) 78% low-birth weight, 16% respiratory distress syndrome babies with cold stress were considered a subgroup 	<ul style="list-style-type: none"> viscoelastic polyurethane foam mattress (Tempur®) (n=41) 43% on a gel mattress (Premat®) (n=31) 		<p>suggesting they could better regulate body temperature</p> <ul style="list-style-type: none"> There was no PU in the time of the study 	<ul style="list-style-type: none"> Unclear how PU was assessed No statistical analysis for PU outcome Unclear if sample size was sufficient 	
Solis, Krouskop, Trainer, & Marburger, 1988	Observational study comparing interface pressure between a standard mattress and a foam overlay	<p>Participants were healthy volunteers (n =13)</p> <p>Characteristics:</p> <ul style="list-style-type: none"> age range 10 weeks to 13.5 years 	<ul style="list-style-type: none"> Participants lay on a standard hospital mattress and a hospital mattress with a 2" or 4" foam overlay 	<ul style="list-style-type: none"> Interface pressure (IP) was measured at the occiput, scapula and sacrum 	<ul style="list-style-type: none"> There was significant differences in IP between occiput and sacrum (p < 0.001) <ul style="list-style-type: none"> Age 0 to 2: mean occiput IP was 45.7 mmHg, mean sacral IP 17 mmHg Age 2 to 10 years mean occiput IP was 54.3 mmHg Aged > 10 yrs: mean occiput IP was 78 mmHg; mean sacral IP 34 mmHg There was a significant reduction in mean IP with the foam overlay compared with a standard mattress alone at the occiput <ul style="list-style-type: none"> aged 0 to 2 years, 22.3 mmHg versus 45.7 mmHg aged 2 to 10 years, 30.5 mmHg versus 54.3 mmHg 10 to 14 years, 42.4mmHg versus 78mmHg 	<ul style="list-style-type: none"> Healthy volunteers, indirect outcome measures 	Indirect evidence: indirect outcome measure
McLane, Krouskop, McCord, & Fraley, 2002	Observational study comparing interface pressure between a standard mattress and a foam overlay, gel pillow and low air loss bed	<p>Participants were healthy volunteers (n = 54)</p> <p>Characteristics:</p> <p>0 to <2yrs (n=13) 2 to <6 yrs (n=8) 6 to < 10yrs (n=16) 10 to <14yrs (n=10) 14 to 16 yrs (n=7)</p>	<ul style="list-style-type: none"> Participants lay on: Neonates (n = 13) <ul style="list-style-type: none"> standard crib mattress crib mattress were a 2.75" foam overlay crib mattress with a gel pillow crib mattress with 2.75" foam overlay and a donut pillow 	<ul style="list-style-type: none"> Interface pressure (IP) was measured at the occiput, coccyx and heel (occiput only in < 6 yrs) 	<p>Neonates (n =13) occiput IP</p> <ul style="list-style-type: none"> all 4 modified surface types had lower occiput IP than crib mattress (61±19mmHg) (p<0.001) foam overlay had lower occiput IP than the gel pillow (mean 26±6mmHg vs 32±10 mmHg, p = 0.018) and the low air loss bed (mean 26±6mmHg vs 32 ±13mmHg, p=0.059) no significant difference between foam and foam + gel pillow (mean 	<ul style="list-style-type: none"> Healthy volunteers, indirect outcome measures No description of standard mattress 	Indirect evidence: indirect outcome measure

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Neonates and Children: data extraction and appraisals

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			<ul style="list-style-type: none"> ○ low-air-loss bed ● aged >2 years (n=41) ○ low air loss bed ○ standard mattress ○ standard mattress with 3.5" foam overlay ○ standard mattress with gel pillow ○ standard mattress with 3.5" foam overlay and gel pillow 		<p>26±6mmHg vs 26±9 mmHg, p =0.834)</p> <p>2 to 16 years (n = 41) occiput IP</p> <ul style="list-style-type: none"> ● age had no effect on IP ● all 4 modified surface types had lower occiput IP than standard mattress (53±27mmHg) (p=0.00) ● gel pillow had significantly lower IP than low air loss bed (24±10mmHg vs. 32±17mmHg p=0.12) ● gel pillow + overlay had significantly lower IP than low air loss bed (26±12mmHg vs. 32±17mmHg p=0.032) ● no significant difference between foam overlay and low air loss bed (28±14mmHg vs. 32±17mmHg p=0.78) ● no differences between foam overlay, gel pillow or gel pillow + overlay. <p>6 to 16 years (n = 33) coccyx IP no significant difference between standard mattress, delta foam overlay and low air loss bed (p=0.159)</p> <p>6 to 16 years (n = 33) heel IP delta foam overlay had significantly lower IP than standard mattress (71±17mmHg vs. 81±22mmHg p=0.014) low air loss bed had significantly lower IP than standard mattress (66±20mmHg vs. 81±22mmHg p=0.014) no significant difference between foam overlay and low air loss bed.</p>		
Skin rounds							
Nist et al., 2016	Prospective cohort study evaluating	<ul style="list-style-type: none"> ● Observation occurred in a NICU in the US 	A skin team was formed to conduct weekly skin	<ul style="list-style-type: none"> ● Weekly skin rounds by skin team and twice a day skin 	<ul style="list-style-type: none"> ● 9025 assessments conducted ● Pressure injury rate: 11.8% ● 406 incidents of pressure injuries: 	<ul style="list-style-type: none"> ● Not all patients were assessed every week 	Level of evidence: 3

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	implementation of a standardized system for assessment, documentation and tracking of skin injuries among hospitalized neonatal patients	<ul style="list-style-type: none"> All skin assessments conducted in the 43.5 project timeframe were included 	<p>rounds to assess the NICU patients.</p> <p>During the skin rounds, the members also provided bedside teaching to the RNs and demonstrate proper skin care.</p> <ul style="list-style-type: none"> A skin rounding log was used by the skin team members to report assessment findings and demographic data <p>Interventions were implemented on detecting skin injury</p>	<p>assessment by bedside nurses</p> <ul style="list-style-type: none"> All skin injuries were recorded including the type of injuries, its appearance, location and cause. NPUAP 2007 staging system was used Both prevalence and incidents rate were recorded 	<ul style="list-style-type: none"> Stage 1: 29.8% Stage 2: 39.4% Stage 3: 1.2% Stage 4: Nil Unstagnable: 1.7% SDTI: 12.6% 60.1% due to respiratory devices 86.6% were device related PU <p>Pressure injury rate Pre-intervention detection rate (excluding stage 1) was 0.49 injuries per 1000 patient days versus Post-intervention detection rate (excluding stage 1) 3.32 injuries per 1000 patient days</p> <p>Author conclusion: The QI project has helped to increase detection and reporting of pressure injuries</p>	<ul style="list-style-type: none"> Number of participants in each analysis period is not reported No confounding factors reported Uncertain how similar participants are pre and post intervention Education on pressure injuries did not lead to reduction in their rates over 3.5 years 	Quality: Low
Local wound care							
Schlürer, Schols, & Halfens, 2013	Cross sectional study reporting on the types of pressure injury treatments used in hospitalized pediatric patients	<p>Observation was conducted in A Swiss hospital (n=412 participants)</p> <p>Differences in the treatment of severe PIs stage 2-4 according to demographic characteristics of patients?</p> <p>Inclusion criteria: Children in all departments, PICUs, neonatal intensive care units, surgical units, medical, pediatric rehabilitation care Age 24 hours to 17 years</p>	N/A	Dutch National Prevalence Measurement of Care Problems used for data collection Collected by local nurses	<p>Pressure injury rate 8.5% had a pressure injury 94.1% of pressure injuries were Stage 1</p> <p>Types of wound care</p> <ul style="list-style-type: none"> Stage 1 management included nothing and high lipid ointment Stage II management included hydrocolloid dressings, and paraffin gauze dressings Stage 3 and 4 management included Foam dressing, alginate dressing and hydrocolloid dressing <p>Author conclusions: There is a need for an evidence-based pediatric-specific guideline regarding the treatment of pressure injuries</p>	<ul style="list-style-type: none"> Lost data for over >30% of participants No evaluation of effectiveness of interventions being used Data collected by nurses working at their respective hospitals, which may have caused bias Only checked treatments once – did not account for changing regimens 	<p>Level of evidence: 4</p> <p>Quality: Moderate</p>

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Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Hospitalized for at least 1 day Exclusion criteria: Hospitalization in psychiatric units					
Implementing quality improvement							
Luton et al., 2017	To report on a quality improvement project designed to achieve zero HAPI in NICU in patients with receiving therapeutic hypothermia for hypoxic-ischemic encephalopathy (HIE)	Program occurred in a US Children's Hospital	Interprofessional team collaborated to expand existing evidence-based standards of care and revise protocols, optimize product selection, hardware assessment practices, and refine documentation	Interprofessional team (EEG technologists, neurophysiology, bedside nurses, wound care nurses, neurologist) used PDSA cycles and data collection applying some changes in the existing protocol <ul style="list-style-type: none"> • Skin assessment performed by EEG technologists with bedside nurse 	A zero HAPI rate in the HIE population was achieved Important components of quality improvement project were identified as: using collaborative approach to identifying, testing, and implementing population-specific solutions	<ul style="list-style-type: none"> • Could not replicate intervention from study report • Does not report participants or pressure injury outcomes, this reports on implementation of a program 	Indirect evidence (evaluates implementation plan, not intervention)
Medical device related pressure injuries prevalence							
Newnam et al., 2015	RCT investigating frequency and severity of nasal PU for different neonatal nasal continuous positive airway pressure	Participants were recruited in a neonatal ICU in US (n=377 screened, n=138 met inclusion, 78 consented) Inclusion criteria: <ul style="list-style-type: none"> • Preterm infant with birth weight 500 to 1500 g • Required nasal CPAP treatment Exclusion criteria:	On extubation, randomized using block stratified according to birth weight (<750g; 750 to 1000g; 1001 to 1250g; and 1251 to 1500g) to receive: <ul style="list-style-type: none"> • A) continuous nasal prong (n=21) • B) continuous mask (n=35) 	Serial skin evaluation conducted during routine care with 8 hours of extubation and then every 8 to 12 hours using the validated Neonatal Skin Condition Scale that includes dryness, erythema and breakdown/excoriation each graded 1 to 3 giving total score 3 to 9 with	Skin evaluations <ul style="list-style-type: none"> • There was significantly higher excoriation scores in the continuous mask group [1.10 vs 1.18 (prongs) and 1.10 (rotation group), p=0.007] • There was significantly higher erythema scores in the continuous mask group [1.131 vs 1.28 (prongs) and 1.18 (rotation group), p=0.001] • There was no significant difference in overall NSCS scores (p=0.716) 	<ul style="list-style-type: none"> • Power analysis indicated requirement for n=24 in each group (not quite met) • Some infants defaulted to mask group due to being the incorrect size for well-fitted nasal prongs (n=11) leaving non- 	Level of evidence: 1 Quality: Moderate

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	(CPAP) systems	<ul style="list-style-type: none"> Airway or physical anomaly preventing use of nasal CPAP Nasal break down at enrolment <p>Characteristics:</p> <ul style="list-style-type: none"> Continuous mask group had significantly lower weights than other groups (p=0.0) prong rotation group had significantly higher CPAP flow (p=0.037) 	<ul style="list-style-type: none"> C) alternating mask and prongs every 4 hours (n=22) 	higher score indicating worse skin condition Analysis was performed on measures from baseline, midpoint in infants therapy and endpoint of therapy	Conclusions: there was reduced nasal injuries by using rotation between nasal prongs and mask for babies with birth weights below 1,500g	equivalent birth weight groups <ul style="list-style-type: none"> Established reliability of assessment (kappa = 0.74, $\alpha=0.721$) 	
Bakhshi, Kushare, Banskota, Nelson, & Dormans, 2015	Retrospective observational study investigating complications associated with the pinless halo	<p>Retrospective record review identified all patients in one US institution treated with pinless halo over a period of 9 years (n = 61)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> Treated with pinless halo device <p>Exclusion:</p> <ul style="list-style-type: none"> Aged > 18 years < 3 months follow up <p>Characteristics:</p> <ul style="list-style-type: none"> 57% sample male Average age 6.04 years Average duration of pinless halo 32.68 days (range 7 to 142 days) Indications for pinless halo: <ul style="list-style-type: none"> post operative immobilization of congenital muscular torticollis immobilization o for atlantoaxial rotatory subluxation 	Pinless halo device (ring connects to a molded vest or body cast and immobilizes the cervical spine)	Complications including pressure ulcers (method of assessment and Category/Stage not reported)	<ul style="list-style-type: none"> Complication rate 13/61 (21%) of patients. 2 patients experienced a pressure ulcer as a 'major complication' (anatomical location scalp and chest) 1/61 experienced occipital redness as a 'minor complication' <p>Conclusion: pressure ulcers occurred at a rate of 4.9% in children with pinless halo</p>	<ul style="list-style-type: none"> Relied on record review Confounding factors not considered Method of diagnosis and assessment of PU not reported No Category/Stage reporting 	<p>Level of evidence: 4</p> <p>Quality: low</p>

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		<ul style="list-style-type: none"> ○ post operative immobilization of cervical spinal fusion ○ stable cervical spine fractures 					
Managing device related pressure injuries							
McEvoy et al., 2017	Prospective cohort study to evaluate effectiveness of a tracheotomy-related pressure injury prevention protocol	<p>Participants were recruited over a 4 year period in one Children's hospital in US (n=121)</p> <p>Inclusion and exclusion criteria: None reported</p> <p>Participant characteristics: Not reported</p> <p>Cohort was compared to a retrospective cohort covering preceding 2 years</p>	<ul style="list-style-type: none"> • Prior to wound care regimen introduction, no standard wound care procedure was used (n=161 procedures) • The wound care regimen start in operating room and included: (m=121 procedures) <ul style="list-style-type: none"> ○ cleaning neck skin and dry then using Cavilon™ No Sting Barrier Film (3M). ○ Mepilex Lite™ (Molnlyke Health Care) applied around tracheotomy tube flanges and under to collar ○ Daily dressing changes until first tracheostomy change • All wounds that occurred within the 7 days post-operatively were treated with Mepilex Ag™ (Molnlyke Health Care) and other appropriate interventions 	<ul style="list-style-type: none"> • a team of otolaryngology and wound care experts performed daily dressing changes and circumferential neck inspection • Any wound identified was graded by the wound care nurse using the National Pressure Ulcer Advisory Panel criteria. Comparisons between • the baseline group and treatment group were performed using Chi-square and Fisher's exact test 	<p>Rate of any new pressure injuries In 2 years prior to protocol introduction 22.4% In 4 years post new protocol, 99.9% (significant reduction, p=0.0064)</p> <p>Rate of new stage 1 or 2 pressure injuries In 2 years prior to protocol introduction 15.5% In 4 years post new protocol, 9.9% (no significant change)</p> <p>Rate of new stage 3 or 4 pressure injuries In 2 years prior to protocol introduction 6.8% In 4 years post new protocol, 0% (significant reduction, p=0.0014)</p> <p>Conclusion: Introducing a standardized protocol for managing tracheotomies was successful in reducing HAPI.</p>	<ul style="list-style-type: none"> • Intervention used prior to change in protocol is not reported • Participant characteristics are poorly reported – cohorts may not be equivalent, however study over long period suggests there is likely similarities • Selection of participants and management or missing data is not reported 	<p>Level of evidence: 3 Quality: Low</p>
Limpaphayom, Skaggs,	Retrospective case series	Participants were those treated in a children's	Halo used for immobilization (n=37),	Development of pressure ulcers as a complication.	<ul style="list-style-type: none"> • Incidence of pressure ulcers was 7.3% (severity not reported) 	<ul style="list-style-type: none"> • retrospective review • small sample size 	<p>Level of evidence: 4</p>

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<p>McComb, Krieger, & Tolo, 2009</p>	<p>reporting on complications associated with Halo use in children</p>	<p>hospital in USA from 1996 to 2005. (n=97 eligible, n=68 with complete medical records included)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> • Treatment with halo <p>Exclusion:</p> <ul style="list-style-type: none"> • Incomplete medical record <p>Characteristics:</p> <ul style="list-style-type: none"> • Mean age was 10 years (range 1 to 20 years) • 54% sample male 	<p>halo traction (n=12) or halo traction followed by halo vest (n=19). Mean duration of treatment was 12 weeks when used for immobilization and 3 weeks when used for traction.</p>	<p>Frequency of assessment, assessment methods or staging are not reported.</p>	<ul style="list-style-type: none"> • In no cases did development of a pressure sore require cessation of halo use or surgical intervention. • The authors suggest that “cutting off the offending portion of the halo vest” may reduce discomfort. (expert opinion) • The authors recommend routine skin checks by parents at home and during clinic visits, but do not detail frequency or assessment strategies. (expert opinion) • Study conclusions: The report highlights the potential complications associated with medical device use in children 	<ul style="list-style-type: none"> • 30% eligible records were not reviewed due to being incomplete, which leads to an unreliable indication of PU incidence • Insufficient detail of PU preventative strategies used, duration of treatments, participant characteristics, severity and duration of PU or management of PU while halo in use were provided in this study. 	<p>Quality: low</p>
<p>Jaryszak, Shah, Amling, & Peña, 2011</p>	<p>Retrospective case series reporting on wound complications associated with tracheostomy in children</p>	<p>Participants were those identified from the Children’s National Medical Center database in the USA as being coded for tracheostomy over a 15 month period (2008 to 2009) (n=65).</p> <p>Inclusion:</p> <ul style="list-style-type: none"> • Coded for tracheostomy • Electronic medical record in audit period <p>Characteristics:</p> <ul style="list-style-type: none"> • Mean age at time of tracheostomy was 45±8.7 months 	<p>Tracheostomy</p>	<p>Number of participants developing wound complications as assessed using the NPUAP PU staging system Type of tracheostomy tube Wound cultures conducted from 2 weeks before until 2 weeks after tracheostomy</p>	<ul style="list-style-type: none"> • 19/65 (29.2%) participants developed a post-operative wound complication • There was no significant difference in age between those with and without wound complications (mean age 39.3 versus 47.4 months, p=0.068) • There was a higher rate of wound complications in participants aged less than 1 year compared with those aged over 1 year (39% versus 17%, p=0.04) • Use of extended mechanical ventilation (p=0.58), weight (p=0.55), positive preoperative wound culture (p=0.06), positive postoperative wound culture (p=0.28) and maturation of stoma at time of surgery (p=0.14) were not 	<ul style="list-style-type: none"> • Retrospective review • Small sample size • Records may be unreliable • Insufficient detail of PU preventative strategies used, duration of treatments, participant characteristics, severity and duration of PU or management of PU were provided in this study. 	<p>Level of evidence: 4 Quality: low</p>

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		<ul style="list-style-type: none"> Most common indication was pulmonary disease (36.9%) 			<p>associated with wound complications.</p> <ul style="list-style-type: none"> Type of tracheostomy tube was associated with wound complications (p=0.02) with a Bivona® Flex-Tend™ predicting wound complications (likelihood ratio 4.9, p=0.03) compared with a Standard Bivona® or a Shiley™. Wound complications were not associated with increased hospital length of stay or readmission. As a result of wound complication rates the facility instituted a specialty trained tracheostomy nurse, use of barrier protection between tube flanges and the skin and aggressive wound care to early wound complications to prevent progression. The success of these interventions is not reported. Study conclusions: The report highlights the potential of wound complications associated with medical device use in children 		
Chidini, Calderini, & Pelosi, 2010	Quasi experiment comparing a CPAP delivery devices (face mask versus helmet) and reporting on complications including PUs	<p>Participants were recruited from a PICU in Italy and experimental participants were matched to controls for age, organ failure, PaCO₂ and PaO₂:FIO₂ (n=40)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> PaO₂:FIO₂ ≤ 300 bilateral lung infiltrates on chest xray Venturi mask for 15 minutes provided no significant improvement in function 	<p>Participants had CPAP delivered via either:</p> <ul style="list-style-type: none"> facial mask chosen to provide optimal fit to the contour of the child's face, with nasal masks used as facial masks in the smallest children. Colloid dressing was applied to facial pressure points to reduce risk of pressure injury. (n=20) helmet: an infant helmet made of transparent latex-free 	<p>Primary outcome was improvement in gas exchange</p> <p>Secondary outcome included PUs assessed on a four point scale of severity</p>	<ul style="list-style-type: none"> There was significantly more stage 1 PUs associated with the facial mask compared with the helmet (75% versus 0%, p=0.002) Participants with facial mask CPAP delivery had significantly less hours wearing the delivery device compared with the helmet group (6.4±1.8 versus 10.8±2.0 hours, p=0.001) CPAP delivered via both the helmet and the mask led to significant improvements in gas exchange, with no difference between the groups. Other adverse events (CPAP associated outcomes and eye 	<ul style="list-style-type: none"> Small sample size Of 97 potential participants, only 20 met the selection criteria to use the helmet Non-blinded, non-randomised study 	<p>Level of evidence: 2</p> <p>Quality: moderate</p>

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	<ul style="list-style-type: none"> • absence of other organ failure <p>Exclusion:</p> <ul style="list-style-type: none"> • endotracheal tube or tracheostomy prior to PICU • facial deformities • wide range of respiratory system exclusion criteria upper airway obstruction <p>Characteristics:</p> <ul style="list-style-type: none"> • Age range 3 to 11 months • Primarily requiring CPAP due to community-acquired pneumonia or post-operatively • No significant differences between groups in oxygen/respiratory variables, weight, age, body temperature 	<p>polyvinyl chloride secured to a soft collar that adheres to the child's neck (n=20)</p>		<p>irritation, gastric distension) were equivalent between the groups</p> <ul style="list-style-type: none"> • Intolerance of the device leading to sedation was higher in the facial mask group (70% versus 5%, p=0.001) • Study conclusions: The report highlights the potential of stage 1 PUs associated with oxygen delivery medical devices in children, despite the use of hydrocolloid preventative dressing. 		
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Table 1: Level of Evidence for Intervention Studies

Level 1	Experimental Designs <ul style="list-style-type: none"> • Randomized trial
Level 2	Quasi-experimental design <ul style="list-style-type: none"> • Prospectively controlled study design • Pre-test post-test or historic/retrospective control group study
Level 3	Observational-analytical designs <ul style="list-style-type: none"> • Cohort study with or without control group • Case-controlled study
Level 4	Observational-descriptive studies (no control) <ul style="list-style-type: none"> • 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

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CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL

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
10765	(de Lima, de Brito, Souza, Salome, & Ferreira, 2016)	Y	N	U	Y	Y	U	NA	N	N	U	4	Low
12778	(Csuma et al., 2016)	Y	Y	Y	Y	Y	U	NA	N	N	U	4	Low
2920	(D. L. August, Edmonds, Brown, Murphy, & Kandasamy, 2014)	Y	N	Y	N	Y	N	NA	N	Y	Y	4	Low
14409	(Cohen, Scanlon, Bemanian, & Schindler, 2017)	Y	Y	Y	N	Y	Y	NA	Y	Y	Y	4	High
6147	(Leonard, Hill, Moon, & Lima, 2013)	Y	N	U	N	Y	N	Y	U	N	N	4	Low
6612	(Schluer, Schols, & Halfens, 2014)	Y	Y	Y	Y	Y	N	Y	N	U	N	4	Low
1314	(Schlüer, Schols, & Halfens, 2013)	Y	Y	Y	Y	Y	Y	Y	U	N	Y	4	Moderate
1368	(Willock, 2013)	Y	Y	U	Y	Y	Y	NA	N	N	N	4	Low
15878	(Sari & Altay, 2017)	Y	Y	Y	Y	Y	Y	NA	Y	Y	Y	4	High

COHORT STUDIES

ID	Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrollment	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment: blinded, or discuss potential	Valid, reliable assessment with supporting	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Level of evidence	Quality
10853	(Willock, Habiballah, Long, Palmer, & Anthony, 2016)	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	Y	1	High (prognostic)
16248	(Nist et al., 2016)	Y	U	N	N	N	N	Y	N	Y	N	N	N	N	N	3	Low

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PROGNOSTIC STUDIES

	Author/year	Adequate description of baseline characteristics	Satisfactory study attrition	Clear outcome measures/prognostic factors	Range of prognostic factors/confounders measured identified and	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 per factor)	Level of evidence	Quality
8225	(Manning, Gauvreau, & Curley, 2015)	Y	NA	Y	Y	Y	N	N	Y	NA	Y	Y	Y	3 (Prognostic)	Moderate
2836	(Tume, Siner, Scott, & Lane, 2014)	Y	NA	Y	N	Y	U	Y	Y	NA	Y	Y	N	3 (Prognostic)	Low

CASE CONTROL STUDIES

	Author/year	Focussed question	Comparable source populations	Same exclusion cases and controls	Per cent drop out in study arms is reported	Comparison btw participants and non-participants	Cases clearly defined	Established that controls are non-cases	Knowledge of primary exposure not influence case ascertainment	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Level of evidence	Quality
11073	(D. August & Kandasamy, 2016)	Y	Y	Y	Y	NA	Y	Y	U	Y	N	Y	Y	N	3	Moderate

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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 included studies ⁶	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
161 24	(D. L. August, New, Ray, & Kandasamy, 2017)				Y			N		N		NA		N	NA		Exclude
1517 7	(Courtwright et al., 2017)				N			N		N		NA		N	NA		Exclude

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