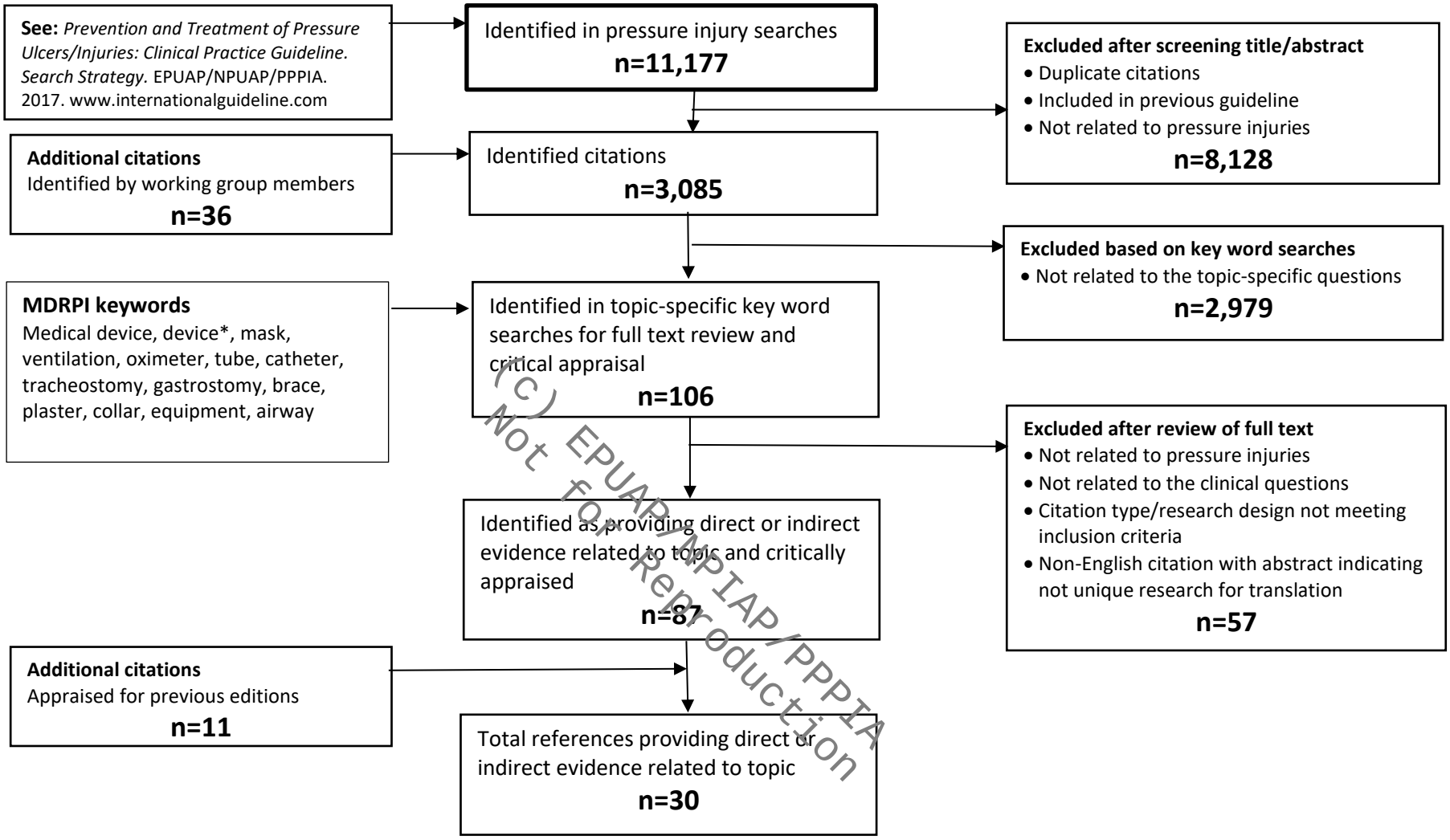
Search results for 2019 International Pressure Injury Guideline: Medical Device Related Pressure Injuries



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 2 (local management strategies): Alternate oxygen therapy delivery options							
Newnam et al., 2015	RCT investigating **frequency and severity of nasal pressure injuries for different neonatal nasal continuous positive airway pressure (CPAP) systems in neonates of extremely low birthweight**	Participants were recruited in a neonatal ICU in US (n=377 screened, n=138 met inclusion, 78 consented) Inclusion criteria: • Preterm infant with birth weight 500 to 1500 g • Required nasal CPAP treatment Exclusion criteria: • Airway or physical anomaly preventing use of nasal CPAP • Nasal break down at enrolment Characteristics: • Continuous mask group had significantly lower weights than other groups (p=0.0) • prong rotation group had significantly higher CPAP flow (p=0.037)	On extubation, randomized using block stratified according to birth weight (<750g; 750 to 1000g; 1001 to 1250g; and 1251 to 1500g) to receive: • A) continuous nasal prong (n=21) • B) continuous mask (n=35) • C) alternating mask and prongs every 4 hours (n=22)	• 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, breakdown and excoriation each graded 1 to 3 giving total score 3 to 9 with higher score indicating worse skin condition • Analysis was performed on measures from baseline, midpoint in infants therapy and endpoint of therapy	**Skin breakdown** • 24.2% of participants • Occurred at nasal septum (85.3%), nasal bridge (29.9%) and forehead (26.6%) **Skin evaluations** • There were significantly higher mean excoriation scores in the continuous mask group [1.19 vs 1.18 (prongs) and 1.10 (rotation group), p=0.007] • There were significantly higher erythema scores in the continuous mask group [1.31 vs 1.28 (prongs) and 1.18 (rotation group), p=0.001] • There was no significant difference in overall NSCS scores (p=0.716) **Factors associated with MDRPI** • Mean post menstrual age (p<0.001) • Number of days on CPAP (p=0.006)	• 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-equivalent birth weight groups • Established reliability of assessment (kappa = 0.74, α=0.721)	**Level of evidence: 1** **Quality: High**

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					Conclusions: there was reduced nasal injuries by using rotation between nasal prongs and mask for babies with birth weights below 1,500g		
Clinical question 2 (local management strategies): Alterative securing devices							
Hampson et al., 2018	Retrospective observational study exploring **impact of alternate ET tube fasteners on incidence of oral pressure injuries**	Retrospective record review for two periods of 2yrs 9mths (pre intervention and post intervention) in one hospital ICU in Australia (n=2008 admissions) Inclusion criteria: Receiving mechanical ventilation during the study timeframe Exclusion: Non stated Participant characteristics: • Median age 56 years (range 47.7 to 72.6) • 66.7% male • 19% malnourished on admission • 14.3% diabetes • 26.2% restricted mobility • There was no significant difference between observation periods for risk factors including Waterlow scale score and length of stay	• First observation period the ET tube securement cloth tapes were used to secure ET tubes, with adjustment every 6 hours (n=1043 admissions) • Second observation AnchorFast™ (Hollister) and cloth tapes were used to secure ET tubes, with the device adjusted every 2 hours (cloth tape remaining at 6 hours)	• Pressure injury location and severity using NPUAP classification system was documented by a nurse	**Pressure injury rate** There were significantly more pressure injuries in people who had the device securement versus the cloth securement (1.98/100 versus 4.03/100, incident rate ratio 2.03, 95% CI 1.17 to 3.51, p=0.02) **Other outcomes** • People with pressure injuries from the device were more likely to have a lip pressure injury (75%) and people with cloth securement were more likely to have a corner mouth injury (53.6%) • Greater compliance with protocols was observed in the second period (64.5% versus 9.1%, p=0.004) • No significant differences in time to pressure injury	• Some pressure injuries were inside the mouth and would qualify as mucosal membrane injuries, these were still classified using the NPUAP system • Single center study • Findings may indicate increased surveillance for pressure injuries due to the study • Relied on medical records	**Level of evidence: 2** **Quality: Low**
Ambutas, Staffileno, & Fogg, 2014	Quasi experiment **comparing conventional**	Retrospective record review in 3 long term care facilities in the US over 12 months (106,722 patient days)	• Participants had a 14 or 16 grade NG tube • Participants received either:	• Unknown how skin was assessed, how often assessments were made or by whom	**PU rate** Significantly fewer individual using the commercial NG tube holder developed a PU compared	• Sample size calculation required 200 participants to detect 2%	**Level of evidence: 2** **Quality:**

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	tape to a commercial device for securing nasogastric tube for reducing PUs	Inclusion criteria: Intubated patients with facial burns ET tube secured using non-twill and/or non- silicone pressure reducing strips methods Exclusion criteria: Incomplete data regarding use of interventions Participant characteristics: • Mean age 59.9 years • Primarily surgical participants	○ Commercial nasogastric holder device (Dale Nasogastric Tube Holder®, n=115) ○ Regular adhesive tape split with a cut down the tape and wrapping the two pieces around the NG tube, with additional tape securing across nose bridge (n=83)		with regular adhesive tape (4% versus 23%, p<0.0001) There was no significant difference in adhesiveness of the two methods **Author conclusions: Commercially design NG tube holders might lead to fewer PUs than regular adhesive tape.**	difference in Pu rate • Minimal information about participants including risk factors (e.g. fever, medical status, nutrition) • No randomization or blinding • Only one particular holder was used in one clinical setting	**Low**
Worsley, Prudden, Gover, & Bader, 2016	Observational study investigating **effect of varying NIV mask design and strap tension and the reaction at the skin interface**	Healthy volunteers (n=13) Participant characteristics: • Mean age 25 years • Mean BMI 24.8±3.2	Participants wore the following masks with Sebutape attached to the nose bridge and cheeks: • Philips Respironics Amara (mask 1) • ResMed Mirage Quattro (mask 2) • Straps tensioned to ensure central position of mask (T1) then incrementally increased tension by 5mm (T2) and then a further 5mm (T3)	• Interface pressure at nose bridge measured after 10 min application • Cytokine concentration before and after mask application • Temperature and humidity	**Interface pressure** • For both masks, bridge of nose interface pressure was higher than cheek interface pressure (p<0.05) • Strap tension was significantly associated with interface pressure for both masks (p<0.01) **Cytokine analysis** There was increase in cytokine ratio with increase in strap tension, particularly IL-1α ratio **Temperature and humidity** • Median temperature at skin-mask interface was 34C (significant compared to ambient temperature, p= not reported)	• The result may be different if applying in hospitalized patients • The data can be used as reference for clinicians for further study	**Indirect evidence (health volunteers)**

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					• Median relative humidity at skin-mask interface was 84% (significant compared to ambient temperature, p= not reported) • No significant association between strap tension and either humidity or temperature **Comfort** • Participants rated optimal tension as being more comfortable than either tightened tension (p<0.05 for both), with no difference between mask designs **Author conclusion: Increases in strap tension that are small can lead to large difference in interface pressures and biomarker responses**		
Clinical question 2 (local management strategies): Skin moisturizing							
Otero et al., 2017	RCT exploring efficacy of **four different methods of preventing facial pressure injuries**	Participants were recruited in a high dependency unit in Spain (n=220 screened, n=171 randomized, 152 analyzed) Inclusion criteria:	• Participants were randomized to receive: ○ Group1: regular facial mask (n=44 randomized, n=39 analyzed)	• Skin and dressing under mask assessed every 6 hours • Assessment performed independently by two trained evaluators using GNEAUPP staging system	**PUs** • There was no significant difference in PU rate based on age, Norton score or number of hours with NIV • 48.68% of participants developed a facial pressure	• No ITT analysis • Approx 10% drop out that was not equivalent between groups – more drop outs	**Level of evidence: 1** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	including prophylactic dressings and hyperoxygenated fatty acids (HOFA)	• Acute respiratory failure requiring non-invasive ventilation (NIV) • Aged > 18 years • No facial deformity or tissue injury Exclusion criteria: • Facial lesions or deformities • Not consenting Participant characteristics: • Mean Norton score 10.69 (SD 2.85) indicating high risk patients • Average hours with NIV was 14.48, with HOFA having higher average duration than the other three groups • 20.5% taking vasopressors	○ Group 2: adhesive polyurethane thin prophylactic dressing (n=36 randomized, n=35 analysed) ○ Group 3: 2-layered foam prophylactic dressing (n=46 randomized, n=39 analyzed) ○ Group 4: HOFA applied over cheeks, nasal bridge and forehead(n=45 randomized, n=39 analyzed) • Dressings reapplied as required and if required according to hydration status the HOFA was reapplied	• Final assessment conducted 5-10 hours after ceasing NIV	injury, most frequently on the nasal bridge • 5.2% of participants developed > one facial pressure injury • 85% were category 1, 13.5% Category 2, 1.5% Category 3 **Comparison between groups** • Direct mask: 44% PUs, thin prophylactic dressing 57%, foam dressing 72% and HOFA 23% • There was significantly fewer facial PU in the HOFA group compared with the direct mask group (p=0.055), thin prophylactic dressing (p=0.03) and foam dressing (p<0.001) • NNT 2.04 to treat with HOFA to avoid a facial pressure injury **Author conclusion: When reapplied 4-6 hourly, HOFA is an effective strategy to prevent facial MDRPU**	from dressing and HOFA groups • Reached the required recruitment for power calculation based on an approx. 15% decrease in PU • Minimal details re risk factors (e.g. vasopressors, concentrations of oxygen, nutritional profiles) • Non-blinded outcome measures	
Clinical question 2 (local management strategies): Padding of casts							
Murgai, Compton, Patel, Ryan, & Kay, 2018	Retrospective review of patients undergoing lower extremity (LE) casting after elective surgery to determine if	Participants were recruited at a children's hospital in US (n=920 patients, n=2481 casts; n=612 casts had foam padding under cast) Inclusion Criteria: All patients who underwent LE casting after elective surgery	Casts were analyzed as: • having padding (n=612, 24.7%) when foam was applied, it was applied to the heel, patella and padding the top of the cast • Or not having padding (n=1869, 75.3%)	• Types of skin complications and anatomical locations were analyzed for casting with and without foam Skin complications included pressure injury, blister and unspecified skin breakdown Unspecified skin breakdown:	**Incidence of skin complication** • Overall incidence 3.3% • Incidence with A frame case: 8.2% • Incidence with hip spica 4.3% • Incidence with long cast 3.1% • Incidence short leg casts 2.5% • 59.8% of skin complications were described as pressure	Relied on records No staging of pressure injuries and method of assessment was unclear Unclear classifications of skin complications	**Level of evidence: 4** **Quality: Moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	foam padding reduced incidence of skin complication in children	Exclusion criteria: If the patient did not have a minimum of 2 months of follow-up or if their case was split at the time of surgery			injuries, 31.7% were blisters and 8.5% unspecified **Incidence of skin complications: padding vs no padding** • A frame cast skin complications incidence was significantly reduced with padding vs no padding (4.5% vs 13.4%, p=0.03) • Long leg cast skin complications incidence was significantly reduced with padding vs no padding (0.9% vs 4.3%, p=0.02) • Static encephalopathy cast skin complications incidence was significantly reduced with padding vs no padding (0.7% vs 3.6%, p=0.01) • Other types of cast showed no significant difference for skin complication in padded vs no padding **Factors influencing skin complications** Patients with skin complications had a higher mean BMI (p=0.04) Age, number of procedures and performance of osteostomy did not influence incidence of skin complications Author concluded the incidence of skin complication was significantly lower in static	Concurrent management was not reported (particularly positioning of the casted leg and what support surface was used)	

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					encephalopathy, A-frame casts, and long leg casts when padding was used		
Balch Samora, Samora, Dolan, & Klingele, 2018	Quality improvement projectderived from the Plan-Do-Study-Act (PDSA) cycles, **to decrease the cast complication rate**	Participant recruitment methods were unclear (3,559 patients pre-intervention and 13,635 post-intervention) Inclusion criteria: All pediatric patients admitted to an orthopedic assessment. No clear inclusion/exclusion criteria	QI project involving several interventions • Resident casting: education program with a competency "checklist" to ensure that casts are applied, bivalved, and removed in a safe, standardized manner to prevent harm. • Cast safety strips (AquaCast Saw Stop Protective Strips, Newark, DE) were required for every cast • Residents were required to demonstrate competency with 3 cast applications and 3 removals before they were permitted to apply or remove casts independently.	Review of electronic health records The main complications included cast-saw burns and stage 1 and stage 2 pressure ulcers, as defined by the National Pressure Ulcer Advisory Panel. Cast complication rate was measured over a two year period Jan 2015 to Jan 2017 identified patients that had received upper and/or lower extremity casts and had subsequent complication encounters.	**Cast complications** Rate of complications reduced from 5.65/1000 to 0.16 per 1,000 after 18 months of the program This represented a 97.33% improvement (p<0.001) Pressure injuries were reduced by from 22/3559 (0.61%) to 11/13635 (0.08%))	• Similar resources may be unavailable at other institutions. • Multimodal QI project, unclear what specific intervention might have accounted for improvement. • No assessment of severity of fracture, concurrent management or other confounding factors • • Method of assessment and categorization of pressure injuries is not reported	**Level of evidence: 4** **Quality: Low**
Difazio, Harris, Feldman, & Mahan, 2017	Quasi-experiment (prospective interrupted time-series design), quality improvement project to	Project was conducted in a pediatric institution in the USA over 2 years (Pre-intervention 5514 casts applied; post-intervention 11,210 casts applied) Inclusion criteria: Participants aged under 18 years	• Pre-intervention: usual care with cotton lined cast (n=5514 casts applied) • Post-intervention: modifying the lower extremity casting technique to include	• The data collection tool contains 6 domains: o demographic characteristics, clinical characteristics o cast characteristics o casting characteristics o skin complications	**Cast-related skin events** • Pre-intervention, 13.6 per 1000 casts had skin events • Post intervention, 6.6 per 1000 casts had skin events **Cast-related skin events of the heel**	• Reliance on staff reporting for skin complaints • Variation in classification of skin injury between observers	**Level of evidence: 2** **Quality: Low**

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	evaluate introduction of an intervention to decrease cast-associated MDRPI	Requiring a cast Exclusion criteria: • Patients who • sustained cast saw-related injuries Patients with splints	padding, including over the heel. Additionally, staff were provided with education and simulation learning (n=11,200 casts applied)	○ skin interventions. • Skin complications: any patient complaints, anatomic location, description of lesion • NPUAP grading • Data collected over 2 years • Intervention assessed over 15 months of this period.	• Pre-intervention, 17.1 per 1000 casts had skin events • Post intervention, 6.8 per 1000 casts had skin events • Numbers stable from introduction of intervention over time .	• Lack of blinding for the assessors • Key differences in the cohort pre-post-intervention i.e. comorbidities, type of cast applied	
Clinical question 2 (local management strategies): Support surface use in neonates							
Levy, Kopplin, & Gefen, 2016	Laboratory study to **discover mechanical load on supine lying newborn's head in different conditions**	Used 4 finite element computational models to simulate a newborn's head developed by the authors bioengineering laboratory in Israel	Pressure stresses were measured in the following situations: • Weight bearing in Supine position • Lying on flat foam mattress • Medical device (Electode) beneath the head and mattress • Medical device (wire) beneath the head and mattress	Pressure stress on tissues on the newborn head model were evaluated in the biomechanical laboratory	• More pressure stress on tissue from the wire medical device was beneath the newborn model head • Increased stress values were found when donut- shaped headrest was used beneath the head model. **Author conclusions: Medical devices beneath a newborn's head may increase risk for a MDRPI**	• Computational models use animal tissue not human skin • The authors comment that this manuscript is only the 2nd paper on biomechanics of medical device related(MDR) pressure injury in pediatric patients	**Indirect evidence (computational modeling)**
Clinical question 2 (local management strategies: Adapting the medical device							
Limpaphayom, Skaggs, McComb, Krieger, & Tolo, 2009	Retrospective case series **reporting on complications associated with Halo use in children and strategies to address MDRPI**	Participants were those treated in a children's hospital in USA from 1996 to 2005. (n=97 eligible, n=68 with complete medical records included) Inclusion: • Treatment with halo Exclusion:	Halo used for immobilization (n=37), 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	Development of pressure ulcers as a complication. Frequency of assessment, assessment methods or staging are not reported.	• Incidence of pressure injuries was 7.3% (severity not reported) • In no cases did development of a pressure injury require cessation of halo use or surgical intervention. • The authors suggest that "cutting off the offending	• retrospective review • small sample size • 30% eligible records were not reviewed due to being incomplete, which leads to an unreliable	**Level of evidence: 4 Quality: Low**

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		• Incomplete medical record Characteristics: • Mean age was 10 years (range 1 to 20 years) • 54% sample male	weeks when used for traction.		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 and ways to adapt a device**	indication of pressure injury incidence • Insufficient detail of Pressure injury preventative strategies used, duration of treatments, participant characteristics, severity and duration of pressure injury or management of pressure injury while halo in use were provided in this study.	
Clinical questions 3 and 4 (prophylactic dressings): Use of prophylactic dressings to prevent MDRPI							
Whitley, Nygaard, & Endorf, 2017	Cohort study exploring reduction in MDRPU **using silicone pressure reducing strips underneath straps securing endotracheal (ET) tubes**	Participants were recruited in a burns center in US (n=115) Inclusion criteria: • Intubated with facial burns • ET tube secured using non-twill and/or non- silicone pressure reducing strips methods Exclusion criteria:	• Phase one (4 years and 10 months): Twill tie to secure the ET tube by securing to tube and wrapping around head (n=77) • Phase one (2 years and 2 months): Apply silicone pressure reducing strips under the twill tie (n=38)	• Skin inspection performed by nursing and respiratory specialists	**MDRPU rate** • Phase 1 (pre-intervention): 25 MDRPU in 16 patients(20.7%) , 21% had ≥1 MDRPU • Phase 1 (post-intervention): 2 MDRPU in 2 patients (5.2%), 5% had ≥1 MDRPU • There was a significant reduction in MDRPIs related to using silicon pressure reducing strips (p=0.032)	• Retrospective comparison – other factors may have been related to change in MDRPU rate • Minimal information on assessment methods	**Level of evidence: 3** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Incomplete data regarding use of interventions Participant characteristics: • Age range 0 to 92 years • Postintervention group (Phase 2) had a larger mean burn area size and higher mortality • Length of stay mean pre vs post was 33 days vs 27, p=0.372 • Mean ventilator days pre vs post 14 days vs 14 days, p=0.997 • Percent facial burns pre vs post was 4% vs 4%, p=0.235			**Author conclusions: silicon pressure reducing strips in conjunction with twill tape is a safe way to secure an ET tube with lower risk of Pus than when using twill alone.**		
Singh, Sood, Kerai, & Puri, 2017	Case series reporting efficacy of a **polyvinyl alcohol foam dressing to prevent nasal PU in individuals with nasotracheal tube**	Participants were recruited in an Indian hospital over 9 months (n=33) Inclusion criteria: • Undergoing prolonged nasotracheal intubation during surgery for oral or maxillofacial carcinoma Exclusion criteria: • Expected tubation > 8 hours Participant characteristics: • Age range 0 to 92 years • Mean nasal intubation duration 26.07±2.2 hours • Mean surgery duration 9±2.9 hours	• Most patent (or right side) nostril selected • After general anesthetic, nasal intubation with flexometallic ETT (size 7.5 for males and 6.5 for females) • Foam dressing (8cms) trimmed to shape of nasal cavity and lubricated with ointment • Foam dressings then used for packing nasal alae forming a cushion around the tube	• PU classified using EPUAP/NPUAP classification system • Assessment immediately post-operative and at 24 hours	**Outcomes** • 1 patient (3%) developed pressure injury • Pre-intervention pressure injury rate reported as 51.4% **Conclusion: Foam dressing is effective in reducing rate of nasal PU from medical device**	• Recruitment strategy is not clear • Participant details are minimal	**Level of evidence: 4** **Quality: Low**
O'Toole et al., 2017	Pretest/ posttest study investigating	Participants were recruited prospectively in a tertiary care center in the US (n=155) and	• In pre-intervention phase no standard	• Suspected pressure injuries reported on a daily basis during daily nursing rounds	**Pressure injuries related to tracheostomy**	• Delays on up to one month for pressure injury	**Level of evidence: 2**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	effectiveness of a **care bundle that included prophylactic dressings to reduce tracheostomy-related pressure injuries**	compared with a retrospective review of cases over 12 month period (pre-intervention) (n=183) Inclusion criteria: • aged > 18 years • Open surgical tracheostomy Exclusion criteria: • Percutaneous tracheostomy or bedside tube placement • Existing tracheostomy on admission Participant characteristics • Equivalent populations in terms of demographics and health history • Mean age 57 to 6 years • Mean length of stay in ICU 18.5 days and 22 days in facility	protocol was used (n=183) • In intervention phase the following interventions were introduced (n=155): ○ Hydrocolloid dressing (DuoDERM Signal) placed under tracheostomy flare in immediate postoperative period ○ At 7 days, suture removal and placement of polyurethane PolyMem foam dressing (Ferris Mfg Corp) with head/neck in neutral position	• NPUAP classification used for staging on a monthly basis by WOCN	• Incidence of pressure injuries reduced after introduction of intervention from 10.93% (20/183) to 1.29% (2/155) (p=0.0003) • Pre-intervention pressure injuries included Stage II (n=5), Stage III (n=9) and unstageable (n=6). In post-intervention phase, unstageable (n=2) • Pressure injuries occurring in the intervention phase were determined to be due to non-implementation of the intervention **Compliance with intervention** • Random audit (n=19) • 95% compliance with dressing regimen on tracheostomy placement, 89% compliance with suture removal at 7 days, 100% compliance with dressing placement on suture removal, 95% compliance with positioning of head/neck and 84% compliance with full intervention **Author conclusions: The care bundle protocol was related to reduction in tracheostomy-related pressure injuries**	staging validation may influence the documented incidence rate • No blinding or randomization • Reliance on medical records for comparison group incidence	**Quality: High**
Clay, Cruz, Ayotte, Jones, &	The purpose of this quality improvement	Participants were children requiring non-invasive ventilation or prone surgery (n=not reported)	In collaboration with the respiratory therapists, an adhesive foam dressing	• Number of device related pressure injuries	• After intervention zero pressure injuries occurred when the adhesive foam	Single site No statistical data presented	**Level of evidence: 3**

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Fowler, 2018	(QI) project was to explore incidence of MDRPIs in children, develop and implement a plan to reduce MDRPIs and compare the incidence of MDRPIs pre and post implementation	Inclusion/exclusion criteria not reported	was selected to pad and protect the face under all positive airway pressure masks	between Jan 2014-Dec 2016.	dressings were applied to the potential pressure injury areas. • One intraoperative pressure injury occurred since implementation of the initiative	No clear indication of sample (size or demographic) No indication of confounding factors Very little information regarding how the outcomes were measured/collated.	**Quality: low**
Boesch et al., 2012	Qualitative Plan Do Study Act (PDSA) investigating a multi-faceted intervention in reducing tracheostomy-related pressure injuries (TRPI) in children	Conducted in an academic children's hospital in the US (490 beds) Results included 834 tracheostomy patients and 10,132 tracheostomy patient days. Patient characteristics: • Mean age 2yr 8 mo • 87% ventilator dependent	**Professional intervention** PDSA cycle to implement a bundle that included: • Risk (Braden scale) and skin assessment • Moisture and pressure free device interface • Hydrophilic polyurethane foam dressing (Mepilex Lite®) used under tracheostomy tube to wick moisture away from the stoma and skin surface • Extended tracheostomy tube design • Online nursing education on risk and skin assessment **Organizational intervention**	TPRI rate	**Mean TRPU rate** • Pre-intervention ranged from approx. 3.8% to 16% over 6 months (mean rate 8.1%) • During bundle development and implementation ranged from 0% to 12% over 12 months (mean rate 2.6%) • Post-intervention ranged from 0% to 3% over 10 months (mean 0.3%) • Statistical analysis on effect of extended tracheostomy tube design found a significant reduction in number of TPRIs ($p=0.007$) and number of days with TPRU ($p<0.0001$)	• The study is limited to a single hospital unit design and was not a randomized controlled trial • Measurement periods were different for pre-during and post-intervention which influences mean rates	**Level of evidence: 2** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			• Patient brochures • Engagement with tracheostomy tube manufacturer to develop and deliver extended tracheostomy tube design • Real time TRPI reporting • Incorporation of TRPI interventions into electronic record nursing workflow				
Forni et al., 2011	Historical controlled clinical trial **investigating effectiveness of polyurethane foam applied inside a foot plaster cast for reducing MDRPI**	Participants recruited from an orthopaedic ward in Italy (n=158, 156 completed study). Study used an historical control group. Inclusion: • Orthopaedic disease requiring plaster cast on lower limb and foot, including heel • "Sore skin" (stage I pressure injury) on presentation OR undergoing chemotherapy Exclusion: • Cast not including foot • Pressure injury > stage I • Not having a risk factor of sore skin or chemotherapy Characteristics: • No significant difference in demographics at baseline • Mean age 28 to 30 years • Primarily quick setting plaster cast including spica casts, above	• Study group: received sterile polyurethane foam pad measuring 10 x 10 cm in contact with the skin of the heel before applying the cast (n=71). Treated 2007 to 2009. • Control group: retrospective participants with the same risk factors but not administered the foam prior to cast application (n=85). Treated 2005 to 2006.	• Presence/absence of PU in the treated limb using NPUAP staging	**Participants with stage I pressure injury (sore skin) as a risk** (n=56 in study group, n=49 in control group) • Significantly less in experimental dressing group who presented with stage I pressure injury experienced heel pressure injury on cast removal (3.6% versus 42.9%, p < 0.0005) • Relative risk of heel pressure injury on cast removal was 0.08 (95% CI 0.02 to 0.33) equating to a 92% (95% CI 58% to 97%) reduction in risk associated with the foam heel dressing. • Number needed to treat (NNT) was 3 (95% CI 2 to 4). **Participants with chemotherapy as a risk factor** (n=24 in study group, 54 in control group)	• Historical control • Length of plaster cast insitu is not reported and may be significantly different • Other management strategies (e.g. patient education) were not reported and may vary between groups	**Level of evidence: 2** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		the knee casts and below the knee casts			• From participants undergoing chemotherapy, the study group had significantly less pressure injury (4.2% versus 33.3%, p=0.005) **Conclusions: application of a polyurethane foam in contact with the skin prior to applying a plaster cast covering the foot is associated with a lower rate of heel pressure injury in patients with existing stage I pressure injury or undergoing chemotherapy**		
Weng, 2008	Quasi-experiment investigating **effect of Tegaderm and Tegarsorb in preventing MDRPI of the nasal bridge from oxygen masks**	Participants recruited from a medical ICU and a cardiac ICU in Taiwan (n=90) Inclusion: • Diagnosed with respiratory failure • Using and tolerating with non-invasive face mask • No facial skin breakdown Exclusion: • Not reported Characteristics: • No significant differences between groups at commencement for any demographics including BP and bloods • Primarily classified as having adequate nutrition and no sensory impairment • Majority had no sweating observed	Participants were assigned to one of three groups: • Control group with no dressing (n=30) • Tegasorb™ (hydrocolloid dressing) group (n=30) • Tegaderm™ (transparent film dressing) group (n=30) The materials were used to cover the nasal bridge and patients were observed for pressure injury formation	• Formation of pressure injuries assessed as being one of four grades (grading system not reported, Grade I defined as reddened area lasting more than 30 mins after change of position). • Time until pressure injury formed in minutes	• Incidence of grade I pressure injury lower in transparent film dressing compared with control group (53.3% versus 96.7%, p<0.01) • Incidence of grade I pressure injury lower in hydrocolloid dressing group compared with control group (40%% versus 96.7%, p<0.01) • PUs formed significantly faster in control group (1111±2169 mins) versus the transparent film dressing (2628±1655mins) or hydrocolloid dressing groups (3272±2566 mins, p=0.0) • No significant difference in occurrence duration and time between the hydrocolloid dressing and transparent film dressing group	• Small number of subjects • No blinding, no power calculations • Several factors may influence the findings (e.g. skin colour precluding accurate assessment of pressure injury formation) • Facial formation may influence pressure injury formation • No reporting of skin breaks/damage associated with dressing removal	**Level of evidence: 2** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Mean age approx. 75years			• Transparent film dressing adhered less effectively than hydrocolloid dressing **Study conclusions: A protective dressing was associated with decreased incidence of stage I pressure injury in older adults wearing non-invasive face masks**		
Huang, Tseng, Lee, Yeh, & Lai, 2009	Quasi experiment investigating **effectiveness of a prophylactic dressing in preventing nasal pressure injuries in nasal intubation**	A sample of participants was recruited in China (n=18) Inclusion: • Nasal intubation • head/neck surgery for squamous cell carcinoma Characteristics: • No significant difference between groups for age, length surgery, diameter of endotracheal tube length of tube inserting or operative time • Mean age 60 to 62 years • Mean surgery length 9.8 to 10.4 hours	• Participants were managed with either: • Duoderm® (hydrocolloid dressing) • and Soft Liner used for a custom-made cushioning	• Pressure injury area (strategy for measuring area was not reported)	• Mean pressure injury surface area was less in participants who had protection with hydrocolloid dressing (8.0±9.0 mm^2 versus 35.2±27.5mm^2, p=not reported) • Few participants who had protection with hydrocolloid dressing experienced nasal pressure injuries (60% versus 100%, p= not reported) **Study conclusion: Protective dressing was associated with lower incidence of nasal pressure injuries**	• Recruitment of participants not reported • No statistical analysis • Small sample size • Unclear how outcomes were measured	**Level of evidence: 2** **Quality: Low**
Kuo et al., 2013	Retrospective cohort study record investigating **effectiveness of a preventative dressing under tracheostomy ties**	Participants were children with tracheostomies receiving care in a 6 year period in a US hospital (n = 134) Inclusion: • had a tracheostomy within the retrospective review period Characteristics: • Age range 2 weeks to 16 years	Mepilex® Ag (antibacterial foam dressing) was applied underneath tracheostomy ties for the last 15 months of the retrospective review period. (n=41) Prior to that, no dressing was applied under tracheostomy ties (n=93)	No stated	• No dressing cohort: 11/93 (11.8%) developed some degree of skin breakdown Average time to skin breakdown was 5 days • Dressing cohort: 0/41 (0%) had skin breakdown	• Other care interventions/ changes in ward routine over the 6 year period may have influenced findings • Skin assessment method not reported • Relied on documentation for	**Level of evidence: 3** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• mean age was 3.3 years in no dressing cohort vs 3.9 years in dressing cohort	All participants had the same tracheostomy rube			determination of an event	
Günlemez, Isken, Gökalp, Türker, & Arisoy, 2010	RCT investigating **effectiveness of silicone gel in preventing nasal pressure injuries in neonates**	Participants were recruited in a NICU in India over a 2 year period (n = 179) Inclusion: • premature infant • nasal CPAP Exclusion: • term gestation • nasal deformity • shock • coagulant defect Characteristics: • no significant difference at baseline • mean birth weight approx. 1760 g • Mean age 32 gestational weeks • Mean ventilation duration 5-6 days	Participants were randomized to receive: • 1.8mm thick silicone gel sheeting applied to nares surface during ventilation (n=92) • No sheeting (n=87)	Nasal injuries including: bleeding, crusting, excoriation, columella necrosis assessed daily by the same plastics surgeon 1 month follow up	• Nasal injury incidence was significantly greater in the group that did not have prophylactic gel sheeting (4.3% versus 14.9%, OR 3.43, 95% CI 1.1 to 10.1, p<0.05) • Columella necrosis was significantly greater in the group that did not have prophylactic gel sheeting (6.8% versus 1.08%, OR 6.34, 95% CI 0.78 to 51.6, p<0.05) • Infants with nasal injury had a significantly longer duration of ventilation (19.6 ± 10.6 days) vs those without injury (4 ± 3.3 days) • Nasal injury developed significantly slower in those without gel sheeting (10.8 ±3.1 days vs 16.2 ±3.2 days, p <0.05)	• Minimal reporting of randomization, allocation concealment and blinding • Duration of therapy confounded results • Included no PU in the outcome measure • Unclear how assessment was performed • No a priori power calculation	**Level of evidence: 1** **Quality: moderate**
Clinical question 1 (selecting medical devices): Factors influencing use of oxygen therapy delivery devices							
Visscher et al., 2015	Prospective cohort study exploring **different consideration for selecting facial mask associated pressure injury in children**	Participants were recruited over a 3 year period (n=50) Inclusion criteria: • Children and adult in-patients using facial mask for non-invasive ventilation Characteristics: • Age 10.4±9.1 years (range 0.1 to 32.5 years)	• Masks individually selected for each participant based on ventilation requirements • Mask positioning was assessed 4 hourly • Participants with skin erythema or a pressure	• Skin compromise was evaluated (none, erythema, stages I to IV pressure injury, unstageable pressure injury, DTI) • High resolution color photographs used to visualize sub-epidermal microvasculature	**PU rate** • 28% (n=14) had no visible skin compromise, 28% (n=14) had stage I pressure injury, 24% (n=12) had stage II pressure injury, erythema (14% (n=7), 2% (n=1) stage III pressure injury, 4% (n=2) DTI • Most common sites were nose bridge (39%), left cheek (30%),	• Selection of participants unclear • Assignment of participants to interventions unclear • Patients receiving interventions had displayed erythema	**Level of evidence: 3** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 69% had a diagnosis associated with craniofacial abnormality (e.g. spinal muscular atrophy) • 9% had abnormal facial dimensions	injury were treated with either: ○ Silicone foam dressing (n=18) ○ Hydrogel dressing (n=18) ○ Cloth nasal mask instead of plastic mask (n=44) • Interventions were removed 4 hourly for skin hydration measurement	• Skin hydration measured as capacitive reactance units at mask contact points (nose bridge, upper/lower/ left/right cheeks and chin), except when open wound present • For some participants (n=16) 3-dimensional face imaging was used	right cheek (18%), forehead (10%) and chin (3%) **Skin hydration** • Mean skin hydration under plastic masks with no intervention was greater than normal skin p<0.001 • Hydration was higher than control with both dressings (silicone foam, p=0.005; hydrogel, p<0.001) • Hydration under the cloth mask did not differ significantly from the control (p=0.14). **Facial shape** People with facial abnormalities had higher rate of pressure injury **Study conclusion: The cloth mask led to reduced hydration, and there was no erythema or tissue damage. Skin microclimate studies showed that increased humidity, increased skin temperature, and reduced permeability of materials in contact with skin increased is associated with increased risk of superficial pressure injuries.**	but controls had no erythema	
Lemyze et al., 2013	Prospective observational study exploring **outcomes for individuals**	Participants were recruited in a ICU in US (n=74) Inclusion criteria: • Acute respiratory failure	• All general management was similar for all participants	• Progress • Pressure injuries	• When participants were changed from face mask to total face mask it was most likely to occur early in treatment (in total 36/74	• Minimal details about risk factors • Cohorts were not equivalent regarding time spent with mask	**Level of evidence: 4** **Quality: Moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	treated with different oxygen delivery systems	• Do not intubate order Exclusion criteria: • respiratory or cardiac arrest • vasopressors • facial burns, trauma or surgery Characteristics: • Mean age 75 yeas (range 64 to 80) • 70% male • Mean BMI 27 • No difference in medical conditions based on type of mask	• Participants received non-invasive ventilation (NIV) • Participants received either a face mask or a total face mask and treatment was changed as required		participants changed mask and 21 changed mask early) • Most common reasons for changing from facial mask to total face mask were failure on NIV treatment and skin breakdown • There were fewer pressure injuries in participants who were switched to a total face mask early versus switching mask late (24% versus 87%, p=0.0002) • No difference in length of NIV based on type of mask used **Author conclusions: Switching to a total face mask early in therapy could reduce pressure injuries**	and changed therapies during study • Small sample size at one facility	
Chidini, Calderini, & Pelosi, 2010	Quasi experiment **comparing a CPAP delivery devices (face mask versus helmet) and reporting on complications including pressure injuries**	Participants were recruited from a PICU in Italy and experimental participants were matched to controls for age, organ failure, $PaCo_2$ and PaO_2:$F10_2$ (n=40) Inclusion: • PaO_2:$F10_2 \leq 300$ • bilateral lung infiltrates on chest x-ray • Venturi mask for 15 minutes provided no significant improvement in function • absence of other organ failure Exclusion:	Participants had CPAP delivered via either • 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	Primary outcome was improvement in gas exchange Secondary outcome included pressure injuries assessed on a four point scale of severity	• There was significantly more stage 1 pressure injuries 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	• Small sample size • Of 97 potential participants, only 20 met the selection criteria to use the helmet • Non-blinded, non-randomised study	**Level of evidence: 2** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• endotracheal tube or tracheostomy prior to PICU • facial deformities • wide range of respiratory system exclusion criteria upper airway obstruction Characteristics: • 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	transparent latex-free polyvinyl chloride secured to a soft collar that adheres to the child's neck (n=20)		difference between the groups. • Other adverse events (CPAP associated outcomes and eye irritation, gastric distension) were equivalent between the groups • Intolerance of the device leading to sedation was higher in the facial mask group (70% versus 5%, p=0.001) **Conclusions: The report highlights the potential of stage 1 pressure injuries associated with oxygen delivery medical devices in children, and options for different devices.**		
Clinical question 2 (local management strategies: Device deign and tension							
Worsley, Stanger, Horrell, & Bader, 2018	Randomized cross-over trial to fit 15 healthy volunteers with **two difference cervical collars (StifNeck versus Aspen) to measure interface pressures and inflammatory biomarkers at the skin**	Participants were healthy volunteers (n=15) Participant characteristics: • aged 18-65, mean age 24 years • 9 males and 6 females	• Participants were fit with either a StifNeck or Aspen collar at three randomly • applied tensions (low, optimal, high). • Collars were applied for 15 minutes. • A 10-minure refractory period was imposed between each application to enable adequate soft tissues recovery.	• Sebutape was applied to the chin for the duration to enable biomarker analysis • Interface temperature and humidity measurements were recorded • Researchers regularly checked • for skin blanching in accordance with NPUAP/EPUAP guidelines.	Interface pressure • Significant increase in interface pressures with greater collar tension – low, optimal, high ($p<0.01$, for both collar designs), with the highest pressures measures at the occiput which were higher in each tension in the StifNeck collar. • Asymmetries noted on the left and right mandible for optimal and high tensions for both collars. • No significant association between interface pressures	• Healthy volunteers in lab conditions • Results of skin assessment using the NPUAP/EPUAP guidelines not reported	**Indirect evidence (healthy volunteers)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					and BMI or neck circumference (p>0.05) **Temperature and humidity** There were no significant differences for either temperature or relative humidity values (p>0.05) between collars Outcome 3 There were statistically significant differences in the cervical ROM for both flexion and total rotation between all three tensions (p<0.001), with the StifNeck demonstrating slightly more restriction (non-significant) **Authors comments: Increased strap tension and collar height generated higher interface pressures at all contact sites, with the occiput recording the greatest values**		
Background: Risk factors for MDRPI							
Hanonu & Karadag, 2016	Cross-sectional prevalence survey **exploring risk of MDRPI in ICUs**	ICUs in Turkey selected due to their high PU point prevalence rate (>15%) in the year prior to the study (n=5) Selection methods for individual participants for the study is not reported (n=175) Inclusion criteria: Admitted to a participating ICU (anesthesia reanimation, neurosurgery, cardiovascular	• Participants were recruited within 24 hours of ICU admission • Skin observation was conducted at 48-hour intervals including a head-toe inspection that included removal of medical devices to check underlying tissues • NOTE: for MDRPI, only re-checked under the	• Braden Scale • NPUAP/EPUAP Classification System • Patient Characteristics Form (demographics) • Assessments were made by researcher and wound/stoma nurse	**HAPU prevalence** • 15.4% developed at least one a non-MDRPI • 40% developed at least one MDRPU • 9% had a non-MDRPI on admission and 8% had a MDRPU on admission **Devices related to MDRPI** • 45% related to endotracheal tubes, 40.4% continuous positive airway pressure	• The study required 150 participants to achieve statistically significant results • Likely underestimation of MDRPU prevalence in this population as only followed sites with a device attached within first 24 hours	**Level of evidence: 3 (prognostic)** **Quality: High**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		surgery, general surgery and intern medicine) Exclusion criteria: None stated Participant characteristics: • Mean age 62.5±16.6 yrs (range 20 to 97) • 42.8% female • 36% had hypertension, 27% diabetes,25% respiratory diagnoses, 24% cardiac diagnoses, 10% chronic renal failure, 3% obesity • 17.1% vasopressors, 78% taking antibiotics, 56% steroids	device if the device was present on the first inspection (i.e. devices attached after 24 hours were not checked underneath)		(CPAP) masks, 8% arterial oxygen saturation (SpO_2) probe, 6.6% nasal cannulas. **Stages of MDRPI** • 42.6% Stage 2, 37.9% Stage 1, 17.5% unstageable and 1.9^ deep tissue injury **Locations** 44% lips, 15.6% nose, 7.5% fingers, 6.1% ears and 17.6% other locations including buccal mucosa, genitalia and tongue. **Risk factors for MDRPI** • Having a non-MDRPI (OR 6.6, 95% CI 1.21 to 15.12, p<0.05) • Receiving enteral feeding (OR 2.12, 95% CI 0.79 to3.13, p=0.045) • High Braden risk score (OR 1.81, 95% CI 1.03 to 3.21, p<0.05) • Type of ICU also significantly related to having a MDRPI • No significant increased risk associated with older age, mechanical ventilation, steroids, anticoagulants, sedatives, low albumin or low hemoglobin.	• Possible non-generalizable results as sites selected due to previously high HAPU rates	
Coyer, Stotts, & Blackman, 2014	Prospective **cross sectional study exploring**	Participants were recruited in two ICUs in Australia and the USA over	• N/A	• MDRPI data collection tool used to collect data about MDR-S (skin) and MDR-	**Devices used in ICU** • Respiratory, vascular lines, gastrointestinal or urinary,	• Prospective non-blinded study	**Level of evidence: 4**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	PU prevalence and progression	1 day per month for 6 months (n=483) Inclusion criteria: • Admitted to ICU • > 16 years in AU and greater than 18 in USA • Consent opted in in USA and opted out in AU Exclusion criteria: • No consent Participant characteristics: • Mean age 56 years • 52% male • 79.9% White skinned, 10% Black, 7% Asian • Mean ICU admission 8.2 days • Mean Braden score 15.6 • Mean BMI 28		MM (mucous membranes) pressure injuries • Collected information on device, pressure injury stage and type, associated pain and infection, blood clot (for MDRPI-MM) • Staging with NPUAP/EPUAP classification system • Braden scale for pressure injury risk • Pain rated on 11 point VAS • PU healing measured using size x length, tissue type, exudate over time • Followed for 7 days after pressure injury development	monitoring devices and preventive devices • Mean device per patient was 7.6 (SD 1.9) **Pressure injury rate and prognosis** • Prevalence of all pressure injuries in ICU (including MDRPU) was 9.9% • Significantly more pressure injuries occurred in Australian cohort (12.8% versus 8.8%, p<0.05) • 3.1% MDRPI rate (6.1% in AU and 2.0% in USA • 20 MDRPI occurred in 15 participants • MDRPI most often stage 2 ranging from 0.06 to 2.0 cm^2 • Most frequent interventions were repositioning, padding, cleansing and moisturizing • Over 2-7 days, 4/11 MDRPIs were healed, 4/11 stayed the same, 3/11 became smaller	• Minimal information about intervention or length of time using devices • Minimal information about participant-level risk factors	**Quality: Moderate**
Yamaguti et al., 2014	Prevalence study reporting **facial pressure injuries associated oxygen delivery systems**	Retrospective record review in an ICUs and a semi-ICU in a hospital in Brazil over 12 months (n=414) Inclusion criteria: • Aged > 18 years • Respiratory failure requiring non-invasive ventilation (NIV) or continuous positive airway pressure (CPAP) od >2 hours	• All participants had oronasal mask or a total face mask • Protective dermal sheet over nasal bridge • Mask with secure head straps avoiding air leak or tight fit	• Frequency of "skin breakdown" classified as stage I and Stage II on EPUAP-NPUAP system • Skin inspection 45 mins following therapy • Variables collected from medical records	**Rate of pressure injuries** • 13.1% developed Stage 1 pressure injury • 1.3% developed stage 2 pressure injury **Factors related to pressure injury** • In univariate analysis, no significant difference	• Selected individuals at risk of pathologic tissue changes associated with pressure injuries (>2 hours of acute respiratory failure) • Relied on medical records • Single site study	**Level of evidence: 3 (prognostic)** **Quality: High**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Acute moderate-to-severe dyspnea Exclusion criteria: • Glasgow scale < 8 • Death during hospitalization • Pre-existing skin breakdown • Sleep apnea Participant characteristics: • Mean age 75 to 78 years • 42.5% male			between those with or without a pressure injury based on age, BMI, gender, type of respiratory therapy or primary medical diagnosis **Multivariate analysis** • Using an oronasal mask was significantly associated with pressure injury (p<0.001) • Length of respiratory therapy longer than 24 hours significantly associated with pressure injury (p=0.001)	• Minimal data on participant risk factors (e.g. nutritional status, hydration, medication not reported)	
Amirah, Rasheed, PJ, Nu'man, & Muteb, 2017	Cross-sectional study **reporting prevalence of MDRPI in an intensive care unit (ICU)**	The study was conducted in an ICU in a tertiary hospital in Saudi Arabia over 6 months (n=431) Inclusion criteria: admitted to one of 4 ICU wards during the study period Exclusion criteria: Aged ≤16 years	No intervention	• Demographic characteristics collected by the investigator from patient's medical records • No staging system used	**Prevalence data** • 26.7% admissions developed at least one MDRPI • 32.4% of pressure injuries caused by a medical device • 37% of MDRPIs were secondary to endotracheal tube, 37% to Foley catheter, 12.5% to neck collar, 9.4% to nasogastric tube and 4.6% to other devices • Medical devices caused injury to lips, penis, nose, occipital area, nick, ankle, clavicle and fingers **Factors associated with MDRPI** • Statistically significant association between gender and developing MDRPI (males had 2.8 times the risk of MDRPI compared to	• Retrospective – relied on accurate medical records. • Inability to determine if the PI was hospital or community-acquired due to a lack of medical records' documentation • This study did not consider the stage of PIs.	**Level of evidence: 4** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					females, prevalence 32.5% vs 14.4%) • No statistically significant correlation between MDRPIs and the majority of demographic factors (patient's age, gender, nationality, BMI), unit, hospital length of stay before the ICU admission		
Moura et al., 2017	Cohort study **reporting PUs associated with continuous EEG electrode related pressure injury**	Participants were recruited over 22 months in an academic hospital in US (n=1519) Inclusion criteria: • Undergoing continuous EEG in routine management Exclusion criteria: • Repeated cEEEG sessions with same patient within 24 hours of previous session • Temporary of emergency set up of cEEEG equipment Participant characteristics: • 84.3% were aged >18 years with a mean age of 59 years • 15% aged <18 years with a mean age of 5.5 years • 55% male • 19.4% taking vasoconstrictors • 88.5% had a feeding tube • 36.6% had skin allergies • 22.6% had a fever • 99% had a head wrap	• Participants were undergoing cEEG for a range of different clinical purposes including investigation of epilepsy, pre-surgical analysis • Electrodes were standard international 10-20 electrode placement using either plastic or metal (gold, silver or silver chloride) disk electrodes • Skin was cleaned with abrasive gel before application • Electrodes fixed with Micropore tape • Application of equipment by technicians with > 2 years' experience • Daily skin care protocol while	• Development of any EERPU, which was reported as a skin lesion appearing at or near the cEEEG site • Time to EEEG appearance • Documentation of potential risk factors included fever, vasoconstrictive medication, nutrition interventions	• 7.8% developed a pressure injury • Mean duration of continuous EEEG was 1.8±.7 days • 92.4% of pressure injuries occurred in adults, 46.6% in females • 92.3% Stage/Category 1, 6.7% Stage/Category 2, 0.8% Stage/Category 3 **Multivariate analysis** • Aged older (71 to 80 years) was associated with increased risk (hazard ratio HR 6.84, 95% CI 1.95 to 24, p<0.01) • No other variable was a significant prognostic factor **Author conclusions: cEEEG related pressure injury is not common and if it occurs, more likely to be of mild severity.**	• No details on diagnoses that may be related to risk factors • Interventions were not reported or considered (some patients had the electrodes moved during treatment to prevent pressure injuries) • Assessment methods not reported • Presence of pressure injury before intervention not reported • Excluded approx. 25% of EEEG participants due to methods of treatment (see exclusion criteria)	**Level of evidence: 1 (prognostic)** **Quality: Moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			undergoing EEEG evaluation				
Turjanica et al., 2011	Descriptive correlational design **reporting characteristics associated with development of ear pressure injury**	Convenience sample recruited from a medical-surgical unit in the US (n=100) Inclusion: • receiving oxygen via nasal cannula during hospital admission Exclusion: • non- English-speaking Characteristics: • Not reported	• A graduate student and the patient's staff nurse jointly assessed the skin condition around the patient's ears • If skin breakdown was present the nurses appropriately staged and documented the lesions on the Turjanica Pressure Ulcer of the Ear Data Collection Tool	• Skin assessment aided by the Turjanica PU of the Ear Data Collection Tool used to assess skin, patient discomforts at the ears, length of time using oxygen, eyeglasses, skin diagnoses that may influence skin condition	**Prevalence/incidence** • The incidence of skin breakdown was 37% (range 28 to 47%) • Only one patient exhibited ear pressure injury on admission • Predominately Stage I pressure injury, no stage III or IV pressure injury **Factors associated with ear pressure injury** • No statistically significant associations existed between skin integrity and patient demographics (use of glasses, fever, other skin conditions, Braden scale • Lack of oxygen use at home predicted the presence of ear pressure injuries (χ^2 = 6.113, p = 0.013)	• Used a non-validated data collection tool • No multivariate analysis • Unclear how pressure injury was assessed and staged	**Level of evidence: 4** **Quality: Low**
Fujii, Sugama, Okuwa, Sanada, & Mizokami, 2010	Prospective cohort study	Survey of seven NICUs in Japan in 2006 (n=81) Inclusion: • Neonate in an incubator • No pre-existing skin breakdown • Consent given Characteristics: • 51.9% sample female • low birth weight most common reason for admission (74.1%)	Clinical audit of pressure injuries	• Skin was assessed daily by nurses and researchers • Skin texture was assessed using Dubowitz neonatal maturity assessment scale	• 86% of pressure injuries were associated with CPAP or DPAP **Risk factors associated with pressure injuries** (p<0.05): • endotracheal intubation **Multivariate analysis risk factors for pressure injury** • endotracheal intubation OR 4.0 (95% CI 1.04 to 15.42, p=0.047)	• High level of non-consent (61.8%) led to high exclusion • Most neonates were not extremely underweight (<500g) • Potential Hawthorne effect as researcher visited hospitals to	**Level of evidence: 1 (prognostic)** **Quality: Moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Mean age 32.5 weeks gestation (range 24 to 41) • mean birth weight 1745 g (range 478 to 4122)				directly assess and observe	
Schindler et al., 2011	Retrospective database study	Survey of nine PICUs in trauma centers in USA All patients in the center between March 2006 and December 2007 were included. (n=5346)	Clinical audit of pressure injuries		**Multivariate analysis risk factors for pressure injuries:** • 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) • 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)	• 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 pressure injury classification scale used	**Level of evidence: 3 (prognostic)** **Quality: Moderate**
Background: Prevalence of MDRPI							
Kayser, VanGilder, Ayello, & Lachenbruch, 2018	Cross sectional prevalence study **evaluating MDRPI in US and Canadian facilities**	Record review in 115 facilities (mixed clinical types) (	• N/A	• NPUAP staging system		• Relied on records • Unclear how often MDRPIs assessed	**Level of evidence: 4** **Quality: High**
Arnold-Long, Ayer, & Borchert, 2017	Cross sectional prevalence study **evaluating**	Retrospective record review in 3 long term care facilities in the US over 12 months (106,722patient days)	• N/A	• Records reviewed by WOC Nurses • WOC nurses verified MDRPU before entering in	**Characteristics of MDRPI** • Across three centers, 142 MDRPUs over 12 months	• Each facility had a different monitoring system	**Level of evidence: 4** **Quality:**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	MDRPI in aged care settings	Inclusion criteria: Not reported Exclusion criteria: None stated		to data base but it is unclear how this occurred given retrospective collection of data	• Per cent of PUs that were related to medical devices ranged from 35% to 50% across the three facilities • MDRPU were most often Stage 2 (51% of MDRPUs) followed by Stage 1 (18%) and SDTI (18%) • Most commo site was ear (71%), flank (14%) and ankle (14) • Splints and brace was most common cause (20%) followed by oxygen tubing (15%) and catheter tubing (15%)	• No inclusion/exclusion stated • Unclear how PUs were graded and how skilled assessors were • Unclear how representative of full sample those that got pressure injuries were • No confounders reported	**Low**
Asti et al., 2017	Retrospective prevalence study exploring **MDRPIs from nasogastric (NG) tubes in individuals having surgery**	Retrospective record review in a hospital in Italy over 5 years (n=4,278 surgeries, n=2,136 meeting inclusion criteria) Inclusion criteria: • Individuals have abdominal or thoracic surgical procedures • General anesthetic Exclusion criteria: • Emergency surgery • No NG tube placed	• N/A	• Unknown	**MDRPI rate** • 4.8% of individuals with NG tube developed a nasal pressure injury • Length of operative time was significantly and positively related to prevalence of PUs: surgery < 2 hours, prevalence 2.3% (95% CI 1.6 to 3.4); surgery > 4 hours, prevalence 12.6% (95% CI 9.2 to 17.1) • Age, gender, type of NG tube size, ASA score, duration of NG tube and hospital length of stay were not significantly associated with risk of PU in univariate analysis	• Single site study • Unclear how pressure injuries were assessed • Relied on retrospective medical records	**Level of evidence: 4** **Quality: Moderate**
Hobson et al., 2017	Prevalence study **exploring MDRPIs from**	Retrospective record review in a hospital in three ICUs in one	• N/A	• Weekly rounds conducted by WOC nurse and nursing	**MDRPI rate** • 7.2% of individuals developed PIs	• Single hospital, but results in three units were similar	**Level of evidence: 4**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	compression stockings	hospital in US over 14 months (n=1,787 patients) Inclusion criteria: • All patients in ICU in the audit period • Compression stocking related pressure injuries were injury of interest Exclusion criteria: • PU on the heel was not categorized as compression-stocking related Participant characteristics: • Mean age 64.7 years • 47.5% male • 44.5% obesity, 42.5% diabetes, 45% mechanical ventilation, 40% receiving vasopressors for >48 hours		team as part of a quality improvement initiative • Classification using NPUAP staging system	• 2.2% of patients developed compression stocking related PIs (prevalence was similar in all 3 units) • Of those with compression stocking related PI, 45% Category/Stage 1, 15% Category/Stage 2, 40% DTI **The authors suggest reviewing need for compression stockings when other forms of prophylaxis are in use**	• Relied on retrospective medical records	**Quality: High**
Bonell-Pons, García-Molina, Balaguer-López, Montal, & Rodríguez, 2014	Retrospective prevalence study exploring **facial pressure injuries in neonates in ICU**	Participants were recruited in a neonate ICUs in Spain for unknown period of time (n=41 or 47??) Inclusion criteria: • Admitted to ICU Exclusion criteria: • Pre-existing pressure injury Participant characteristics: • 87% born > 37-week gestation	• NA	• Neonatal Skin Risk Assessment Scale (NSRAS) • Unknown the scale used for PU severity or how assessments were made	**MDRPI rate** • 31.7% experienced at least one pressure injury • Incidence density was 2.2 pressure injuries per 100 neonate days • 22.7% experienced a pressure injury related to masks delivering non-invasive ventilation	• Small sample size in a single unit • No information about management strategies	**Level of evidence: 4** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Bakhshi, Kushare, Banskota, Nelson, & Dormans, 2015	Retrospective observational study **investigating complications associated with the pinless halo in children**	Retrospective record review identified all patients in one US institution treated with pinless halo over a period of 9 years (n = 61) **Inclusion:** • Treated with pinless halo device **Exclusion:** • Aged > 18 years • < 3 months follow up **Characteristics:** • 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: ○ post operative immobilization of congenital muscular torticollis ○ immobilization o for atlantoaxial rotatory subluxation ○ post operative immobilization of cervical spinal fusion ○ stable cervical spine fractures	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)	• Complication rate 13/61 (21%) of patients. • 2 patients experienced a pressure injury as a 'major complication' (anatomical location scalp and chest) • 1/61 experienced occipital redness as a 'minor complication' **Conclusion: pressure injuries occurred at a rate of 4.9% in children with pinless halo**	• Relied on record review • Cofounding factors not considered • Method of diagnosis and assessment of pressure injury not reported • No Category/Stage reporting	**Level of evidence: 4** **Quality: Moderate**
Su & Nan, 2014	Case series of **babies wearing brace fixation following surgery for clubfoot deformity in children**	Participants were consecutive admissions in one department over a 4 year period in China (n=32 with 56 deformities) Inclusion criteria: • Undergoing manipulation for club foot deformity	• Brace worn after surgery, then when in maintenance phase brace worn at night for 3-4 years • No information about the brace, padding (if any) or skin care	• Initial skin check every 2 to 3 hours • Pirani's scoring to assess foot deformity • Followup ranged from 12 to 48 months (mean 29 month)	**MDRPI rate** Two participants (6.25%) had PU	• Insufficient information about the intervention • Unknown how long therapy was for, how brace was fitted or how skin was cared for • Unclear if brace applied by parents	**Level of evidence: 4** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Exclusion criteria: • PU on the heel was not categorized as compression-stocking related Participant characteristics: • 24 participants had bilateral deformity • Primarily males • Mean age 38 days (range 0 days to 5 months)				or healthcare professionals	
Schallom, Prentice, Sona, Arroyo, & Mazuski, 2018	Observational study exploring use of oximetry in critically ill people	Participants were critical ill adults (n=43)	• Study explores accuracy of oximetry devices • Used forehead sensor, (n=26), nasal sensor (n=31) and digital sensor (n=31) •	• Daily assessment • NPUAP categorization • All PIs confirmed by a second nurse	**Pressure injuries** Forehead sensor was associated with significantly more pressure injuries (13/26) compared to nasal sensor (3/31) (p=0.006) **Mean time of device use** Forehead sensors used for a mean 37.4 hours versus nasal sensor mean 66.2 hours	• Primarily focuses on efficacy of the sensors • No confounding factors reported	**Level of evidence: 4** **Quality: high**
Wilbrand et al., 2012	Retrospective observational study **reporting rates of adverse events including pressure injury associated with helmet therapy**	Participant group for record review, location and selection of records was not reported (n = 410 children) Exclusion: • records without adequate follow up Characteristics: Children categorized as plgiocephaly (n=230), brachycephaly (n = 32) or both (n148)	• All records were analyzed for adverse effects	• Complications: ○ Pressure sores ○ Local ethanol erythema ○ Skin infection ○ Bacterial abscess ○ Helmet fitting issues ○ Failure to achieve therapeutic success • Did not state how often or by whom the participants were inspected	• Complications were seen 22.4% of the cohort. • Pressure injuries were found in 43 cases (10.5%) • Local ethanol related erythema found in 26 cases (6.3%) • Deficient fitting of the helmet was noted in 24 cases (5.9%) • Pressure injuries primarily seen in initial phase of therapy • In the discussion the researchers provided expert opinion that firm manual	• Categorization of adverse events was unclear e.g. a deficit fitting of the helmet could lead to pressure injuries • Did not report pressure injury stages • Did not report how differentiation was made between local erythema and stage I pressure injury	**Level of evidence: 4** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					pressure applied to the inner surface of the helmet at the site of PU for several minutes each day helps resolve the pressure injury (this was not investigated in the research)	• Unclear how cases were selected	
Black et al., 2010	Secondary analysis of incidence and prevalence study data	Prevalence rates measured in a subset of participants at one US hospital (n=2079) Exclusion: • psychiatric and obstetric patients with length of stay < 3 days • Patients not available due to surgery, medical tests • declined consent • aged < 17 years • Pressure injury on admission to hospital Inclusion: • ICU, medical, surgical and stepdown wards	• No intervention, prevalence survey	• Hospital acquired pressure injury (HAPI) determined by identifying if a pressure injury was documented on admission report • Wound nurse confirmed pressure injury	• The overall rate of HAPI was 5.3% • Medical device related HAPI 1.3% • Proportion of HAPI that were related to medical devices was 34.5% **Risk with a medical device** • Patients with a medical device were significantly more likely to develop a pressure injury (p = 0.008). • Patients with a medical device were 2.4 times more likely to develop a pressure injury of any kind (95% CI 1.2 to 4.8, p = 0.10) **Types of medical device HAPI** • Stage I – 35% of HAPI • Stage III – 3% of HAPI • Unstageable – 24% of HAPI • 43% of HAPI were on head (primarily ears)	• Specific medical devices were not recorded • Procedures for performing survey were not reported	**Level of evidence: 4** **Quality: Low**
Jaryszak, Shah, Amling, & Peña, 2011	Retrospective case series **reporting on wound complications associated with**	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).	Clinical audit of pressure injuries in tracheostomy patients	Number of participants developing wound complications as assessed using the NPUAP PU staging system Type of tracheostomy tube	• 29.2% participants developed a post-operative wound complication • No significant difference in age between those with and without wound complications	• Retrospective review, records may be unreliable • Small sample size • Insufficient detail of pressure injury	**Level of evidence: 4** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	tracheostomy in children	Inclusion: • Coded for tracheostomy • Electronic medical record in audit period Characteristics: • Mean age at time of tracheostomy was 45±8.7 months • Most common indication was pulmonary disease (36.9%)		Wound cultures conducted from 2 weeks before until 2 weeks after tracheostomy	(mean age 39.3 versus 47.4 months, p=0.068) • Higher wound complication rate in participants aged < 1 year compared with those > 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 associated with wound complications. • Type of tracheostomy tube was associated with wound complications (p=0.02) with a Bivona® Flex-Tend™ predicting wound complications (likelihood ration 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. **Conclusions: Highlights potential of wound complications associated with medical device use in children.**	preventative strategies used, duration of treatments, participant characteristics, severity and duration of pressure injury or management of pressure injury were provided in this study. • As a result of wound complication rates, facility instituted a specialty trained tracheostomy nurse, use of barrier protection between tube flange and skin and aggressive wound care to prevent progression, but evaluation of these interventions is not reported.	
Schluer, Halfens, & Schols, 2012	Cross-sectional clinical	Participants recruited in 14 paediatric hospitals including paediatric intensive care units (PICU), neonatal intensive care	Clinical audit of pressure injuries	Classification using EPUAP staging	• Overall pressure injury prevalence 35%	Category 1 pressure injuries may be over- or underdiagnosed in this study remains	**Level of evidence: 4**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		units (NICU), surgical, medical and rehabilitation in Switzerland in 24-hour period in June 2009. (n= 412) Inclusion criteria: • hospitalised children (ages 24 hours to 18 years) • hospitalised for at least 1 day Exclusion criteria: • psychiatric wards, no consent or refusal			• The prevalence of PUs for patients with an external device (tubes, IVs, continuous positive airways pressure, splints, and other installations) was 40%	unclear, although the interrater reliability suggest the scores are reliable.	**Quality: Moderate**
Background: Knowledge of nurses regarding MDRPI							
Barakat-Johnson, Barnett, Wand, & White, 2017	A qualitative study **exploring MDRPI in a large Australian tertiary hospital**	Participants were recruited in a large urban tertiary Australian hospital (n=50 patients for a head-to-toe assessment; n=22 nurses were interviews) Inclusion criteria for patient participants: • Had a MDRPI Inclusion criteria for nurse participants: • Not stated, although assumed to be caring with a patient with a MDRPI Only patient characteristics reported.	• A prospective clinical review and once-only head-to-toe assessment of consenting patients with a reported MDRPI • A prospective review of the health record outlining PI prevention and treatment strategies. • Semi-structured interview with nurses (voluntary) to explore current practice for patients with mechanical devices.	• Based on a once-only assessment of consenting patients • Overall incidence (n, %) of MDRPI, with injury due to specific medical devices reported • Type of medical device was also cross-referenced with anatomical location, mean age and gender of participating patient. • NPUAP/EPUAP classification used – Stages 1, 2 & 3 as well as mucosal' where appropriate	Nurses noted importance of various interventions, but also noted that this did not always happen. Practices reported included: • Checking under devices • Correct sizing of devices • Moving/rotating devices Nurses referred to new interventions being used including: • Silicone gel pads under devices • Educating nurses • Finding new ways to secure devices Author conclusions: Findings add to the literature and confirm previous studies that suggest that medical device related pressure	• Omission of indwelling urinary catheters and their securements as a medical devices • Focus in critical care setting where patients receive one-on-one care, rather the general medical-surgical patient, is a limitation • Potential bias related to nurse self-selection without a process of informed consent. • No information about nurse participants	**Indirect evidence: qualitative study** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					injury is a continuing clinical problem.	• No recommendation made about type of education needed to modify clinician behaviour	
Mucosal membrane pressure injuries							
Zaratkiewicz et al., 2010	Quality improvement report/ retrospective review of electronic records **to describe change in oral pressure injury rates associated with practice changes**	Participants were those who had been critical care patients at a level I trauma center in the US • Pre-intervention: March - July 2007 n=1571 • Post-Intervention Aug – Dec 2007 n=1522 • Follow up post Intervention Jan – Dec 2009 n=3010 Inclusion: Mechanical ventilation and intubation with an oral endotracheal (ET) tube Exclusion: • Aged ≤ 17 years • Facial burns • Prone positioning • Pressure injury on admission or wound unrelated to pressure	• In July 2007 the unit was using two ET tubes, Hollister™ ETAD and B&B Medical Universal Bite Block™ • In December 2007 months the ETAD was discontinued and a new device the Hollister™ Anchor Fast was introduced	• Pressure ulcers rates associated with ET tubes • Analysis of the number of PUs on the lips, mouth, gums, and tongue of orally intubated patients pre-intervention (phase 1) group compared to post-intervention (phases 2 and 3) groups • No staging was conducted in line with the NPUPAP policy for mucosal PU	**Pre-intervention (March – July 2007)** • Total n=1517 (ventilator days: 7175) Oral/lip PUs: 19 **Post intervention (Aug – Dec 2007)** • Total n=1522 (ventilator days: 7592) Oral/lip PUs: 2 **Follow up Jan – Dec 2009** • Total n=3010 (ventilator days: 14328) Oral/lip PUs: 2 • **Study conclusion: change in ET tube model was associated with a reduction in pressure injury incidence**	• No statistical analysis • Patient demographics not reported • Method of identifying a pressure injury was not reported • Unclear if other practices also changed • Relates to mucous membrane pressure injuries that are not a focus of the Guideline	**Level of evidence: 2** **Quality: Low**
Jatana et al., 2010	Cross-sectional study investigating **effect of nasal**	Participants were a consecutive sample enrolled in NICU over a one year period (n=100, n=200 nasal cavities)	• External nasal examinations and anterior nasal endoscopy (0°	• Incidence and characteristics of internal and external nasal finings categorized as ulceration,	• Nasal complications were seen in 12 of the 91 patients (13.2%)	• Unclear how often endoscopies were performed or duration of therapy	**Level of evidence: 4**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	continuous positive airway pressure (CPAP) and cannula use in neonates	Inclusion: • younger than 12 months in age • at least 7 days of CPAP or cannula use Excluded: • Pyriform aperture stenosis • choanal atresia • cleft lip/palate • previous nasotracheal intubation or nasal surgery Characteristics: • Nasal CPAP use (n=182 nasal cavities), • Nasal cannula (n=18 nasal cavities)	telescope) and digital photographic documentation	granulation or vestibular stenosis • Vestibular stenosis graded as mild, moderate or severe	• Nasal complications from CPAP were associated with lower Apgar scores at one minute (p=0.02) and 5 minutes (p=0.06) and no association with gestational age, birth weight, CPAP setting or CPAP duration **Internal examination** • Ulceration in 3.3% of nasal cavities • Granulation in 1.6% cavities • Vestibular stenosis in 2.2% nasal cavities • All abnormalities located wt the top of the CPAP nasal prong and occurring as early as 8 days after administration of CPAP **External examination** 5.5% of participants who used CPAP had columellar necrosis occurring 5 to 25 days after exposure	at time endoscopy performed	**Quality: Moderate**

Table 1: Level of Evidence for Intervention Studies

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

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

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

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

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

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

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

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

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
2273	Bakhshi et al., 2015	Y	Y	Y	Y	Y	N	NA	N	Y	U	4	Moderate
10762	Hanonu & Karadag, 2016	Y	U	Y	Y	Y	Y	Y	Y	U	Y	3 (prognostic)	High
16832	Amirah et al., 2017	Y	Y	U	N	Y	N	NA	N	Y	N	4	Low
6674	Coyer et al., 2014	Y	N	U	N	Y	Y	Y	Y	Y	U	4	Moderate
1848	Lemyze et al., 2013	Y	N	U	Y	Y	Y	NA	N	Y	Y	4	Moderate
7419	Bonell-Pons et al., 2014	Y	Y	U	N	Y	U	NA	N	N	N	4	Low
14405	Arnold-Long et al., 2017	Y	Y	U	N	Y	N	U	N	N	U	4	Low
14232	Asti et al., 2017	Y	U	Y	N	Y	Y	N	Y	Y	Y	4	Moderate
13959	Hobson et al., 2017	Y	Y	Y	Y	Y	Y	U	Y	Y	Y	4	High
17252	Murgai et al., 2018	Y	Y	Y	Y	N	U	NA	N	Y	Y	4	Moderate
17558	Balch Samora et al., 2018	Y	N	U	N	Y	Y	NA	N	U	N	4	Low
17568	Schallom et al., 2018	Y	Y	U	Y	Y	Y	NA	N	Y	Y	4	high
17153	Kayser et al., 2018	Y	Y	Y	Y	Y	U	Y	Y	Y	Y	4	High

RCTS

Endnote ID	Author/year	Focussed question	Assignment randomised	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	Other relevant topics
6437	Newnam et al., 2015	Y	Y	Y	N	Y	Y	Y	Y	Y	NA	Y	U	1	High	pediatrics
14020	Otero et al., 2017	Y	Y	N	N	U	U	Y	Y	N	NA	Y	U	1	Low	prophylactic

CASE SERIES

	Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and	Valid, reliable outcome measurement	Per cent drop out reported and acceptable	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Level of evidence	Quality
13987	Singh et al., 2017	Y	N	Y	U	Y	N	N	N	N	N	NA	U	Y	4	Low
2736	Su & Nan, 2014	Y	Y	Y	Y	Y	N	Y	U	N	N	NA	Y	Y	4	Low

QUALITATIVE STUDIES

Endnote ID	Author/year	Focussed question	Appropriate qualitative methodolo	Recruitment appropriate to research and sample	Methods for data collection	Researcher's role in data collection and analysis	Ethics clearance	Sufficiently rigorous data analysis	Clear statement of findings	Research contributes to the existing knowledge	Level of evidence	Quality
14697	Barakat-Johnson et al., 2017	Y	Y	N	Y	N	N	Y	Y	N	Indirect	Low

QUASI EXPERIMENTAL STUDIES

	Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent 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
3015	Ambutas et al., 2014	Y	N	U	U	U	N	N	U	N	N	2	low
16132	Difazio et al., 2017	Y	U	N	N	N	N	N	N	U	U	2	low
15823	O'Toole et al., 2017	Y	N	Y	Y	Y	Y	Y	NA	Y	Y	2	high
17778	Hampson et al., 2018	Y	N	U	N	Y	Y	Y	U	N	N	2	low

PROGNOSTIC STUDIES

	Author/year	Baseline sample adequately described	Study attrition (<20% lost to follow-up)	Clear definition of risk factors	Range of potential risk factors been used (i.e.	RF measure/method valid and reliable	Method/setting of measurement same for all	Were continuous variables used/ appropriate cut-	Adequate % sample with complete data	Appropriate imputation method	Potential confounders accounted in	Adequate sample size (rule of thumb >10 events per risk factor)	No selective reporting	Level of evidence	Quality
6481	Yamaguti et al., 2014	Y	Y	Y	Y	Y	Y	Y	Y	NA	Y	Y	Y	3	High (prognostic)

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 by 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
14284	Moura et al., 2017	Y	Y	Y	N	Y	N	Y	N	Y	U	Y	Y	Y	Y	1 (prognostic)	Moderate
9518	Visscher et al., 2015	U	Y	N	Y	Y	NA	Y	N	Y	Y	N	N	N	N	3	Low
14216	Whitley et al., 2017	Y	Y	Y	N	NA	NA	Y	N	N	N	Y	N	N	Y	3	Low
17697	Clay et al., 2018	Y	U	N	N	N	N	Y	N	U	N	N	N	N	N	3	Low

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
1489	Newnam et al., 2013				N			N		Y		NA		N	N		exclude
17421	Alqahtani & Alahmari, 2018				N			N		N		N		N	N		exclude

QUALITY IMPROVEMENT STUDIES - reporting

	Author/year	Title/abstract is accurate with information to guide searching	Introduction summarizes problem, significance, known information, rationale for study	Specific project aims	Methods outlines context	Methods includes detailed description of intervention and how it was implemented	Reports how methods were assessed and how sustainability was measured over time	Results reports observed associations, unintended consequences and missing data	Ethical issues addressed	Impact of intervention discussed	Results compared to other studies	Cost effectiveness reported	Reports limitations	Funding sources reported	Level of evidence	Quality
16132	Difazio et al., 2017	Y	Y	Y	Y	Y	N	Y	N	Y	N	N	Y	N	2	Quasi-experiment, low quality

Full reference list of citations in tables:

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