Evidence Profile Rec 3.0: *Pressure injury management: Risk assessment, prevention and treatment*

Recommendation 3.0 Evidence Profile

Recommendation question 3: Should preventive care bundles be recommended or not for the prevention of pressure injuries?

Recommendation 3.0: The expert panel suggests that nurses and health providers implement/do not implement preventative care bundles for persons at risk of pressure injuries.

Population: Persons with or at risk of developing pressure injuries
Intervention: Use of preventive care bundles (any number of interventions bundled together)
Comparison: Use of one intervention alone
Outcomes: Prevalence or incidence rate of pressure injury [critical], Pressure injury precursor signs and symptoms [critical], Health provider compliance with care bundle [critical], Adverse events [important] (not measured), Person/family satisfaction [important]

Setting: All health-care settings, including but not limited to community care, outpatient care, and acute care.

Note: An earlier version of this evidence profile included a systematic review by Wang et al. (2024) which informed information about the outcomes of, 1) prevalence or incidence rate of pressure injury and 2) person/family satisfaction. In 2025, this systematic review was retracted by the journal. The RNAO BPG team conducted a targeted search of the literature and identified a systematic review by Lin et al. (2020). This systematic review now informs the outcomes of prevalence or incidence rate of pressure injury and person/family satisfaction. For more information, please contact the RNAO BPG development team.

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Prevalence or incidence rate of pressure injury (PI)											
1[a]	RCT	Serious[b]	Not serious	Not serious	Very Serious[c]	Not detected	PI events/ participants: 12/70 (any stage of PI) 5/70 (Stage II PI)	PI events/ participants: 37/70 (any stage of PI) 13/70 (Stage II PI)	Prevalence of PI (any stage): RR 0.42 (0.24 to 0.76) For every 100 people who receive the prevention bundle intervention, 31 less people will have a pressure injury (ranges from 13 less to 40 less). Prevalence of Stage II PI: RR 0.38 (0.14- 1.02) For every 100 people who receive the prevention bundle intervention, 12 less people will have a Stage II PI (ranges from 16 less to no more or less).	⊕◯◯◯ Very Low	Lin et al., 2020
19[d]	Non-randomized studies	Very serious[e]	Not serious	Not serious	Not serious	Not detected	N= 1401 PI events (pre-post studies) N=4439 PI events (quality improvement studies)	N= 1144 PI events (pre-post studies) N/A (quality improvement studies)	The 19 NRS that examined bundled care interventions reported decreased PI incidence. An effect estimate was not calculated due to missing details and variation in reporting across studies.[f]	⊕⊕◯◯ Low	Lin et al., 2020

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Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Health provider compliance											
3	Nonrandomized pre-post studies	Very serious[g]	Not serious	Not serious	Not serious	Not detected	n=2963	N/A	In one study, compliance to the bundle pre-implementation had a variable compliance rate averaging 50% across components of the bundle. Post-implementation compliance has been maintained greater than 85% for 594 patients evaluated. An additional study, compliance increased by 5%. In the final study, compliance to the bundle was high (reported at 78.91%). However, control data was not available.	⊕◯◯◯ Very Low	Pena et al., 2023 Yilmazer et al., 2022 Zhang et al., 2021
Person satisfaction											
1[h]	Non-randomized quality improvement study	Very serious[i]	Not serious	Not serious	Serious[i]	Not detected	207/213	N/A	Person satisfaction: 97%.	⊕◯◯◯ Very Low	Lin et al., 2020
Precursor signs and symptoms (measured as stage I PI incidence)											
3	Non-randomized pre-post studies	Very serious[k]	Not serious	Not serious	Not serious	Not detected	n (across 2 studies)=118 Total sample size (across 2 studies): 256	n (across 2 studies)=138	In three studies, the incidence of PI was less after introducing the care bundle compared to pre-implementation[l].	⊕◯◯◯ Very Low	Aprea et al., 2018 Singh et al., 2023 Yilmazer et al., 2022
Adverse events (not measured)											

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Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
N/A											

Additional Table- Individual Study Details

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
Outcome: incidence or prevalence of PI						
Tayyib et al., 2015 (Taken from review Lin et al, 2019)	Two-arm cluster randomized experimental control trial	Saudi Arabia	N=70 Sample: Patients ≥18 years and expected to stay in the ICU for more than 24 hours without existing PI on admission and in the first 24 hours of admission to the ICU Intervention: PI prevention bundle, including: • PI risk assessment • Skin assessment • Skin care • Nutrition assessment • Repositioning • Elevating foot of the bed by 20 degrees • Elevating heels • Mobilizing patients • Using support surface • Securing and repositioning devices • Staff education	N=70 Control: standard care	Prevalence of PIs: difference between the intervention (12/70) and control (37/70) groups (p<0.001) PI cumulative incidence: difference between intervention group (7.1%) and control group (32.9%) (p<0.001)	Systematic review: LOW Individual studies: VERY SERIOUS
Anderson et al, 2015 Avsar et.al, 2018 Azuh et al., 2018 Baldelli et al, 2008 Ballard et al, 2008 Coyer et.al, 2015 De Laat et.al 2007, Donovan et al., 2016 Elliott et at, 2008 Gage, 2015 Gill, 2015	19 non-randomized studies (quality improvement and pre-post studies)	USA (9 studies), Australia (2 studies), UK (2 studies), Turkey (2 studies), UAE, Netherlands, Argentina, Brazil	**Intervention:** N= 1401 (pre-post studies) N=4439 (quality improvement studies) The number of components included in each pressure injury prevention program varied, ranging from 2 to 11. •Common components of pressure injury prevention programs included: clarification of staff roles/introducing new roles dedicated to pressure injury prevention, repositioning/positioning of patients' pressure areas, staff and patient education, support surfaces use, pressure injury risk assessment, skin assessments, nutrition needs assessment, documentation, multi-disciplinary team involvement, and mobilization	**Control:** N= 1144 (pre-post studies) N/A (quality improvement studies) Participants received standard care (risk assessment followed by PI prevention intervention that were not bundled)	Anderson et al, 2015 Before n=181; Cumulative incidence 15.2% After n=146; Cumulative incidence 2.1% Avsar et.al, 2018.: n = 154 Before (n=77) number of PI's: 26 (p-value .002) n of MDRPI: 24 (p-value .000) Cumulative incidence 33.8% After (77) number of PI's: 10 (X2 = 9.281) number of MDRPI: 3 (X2 = 19.806) Cumulative incidence 13% Azuh et al., 2016: n=3233 PI cumulative incidence: decrease from 9.2% in 2011 to 6.2% in 2013	Systematic review: LOW Individual studies: SERIOUS

Hiser et al, 2006 Loudet et.al., 2017 Padula et al., 2008 Richardson et al., 2017 Rogenski., 2012 Swafford et al., 2016 Uzun et.al., 2009 Wolverton et al., 2005 (Taken from review Lin et al., 2019)					Baldelli et al, 2008 n=NR PI cumulative incidence: decrease from 18% in 2005 to 10% in 2006 Ballard et al, 2008 n=NR PI period prevalence: reduced from >30% to <10% Coyer et.al, 2015 n=102 Before Total number of PIs: 64 Cumulative incidence 30.4% (31/102) After Total number of PIs: 24 (t=3.27) Cumulative incidence 18.1% (19/102) De Laat et.al 2007, n=130 Before 1st observation period (baseline) n= 110. PI incidence rate 43% - 54 per 1000 days After (2nd OP) PI incidence rate 37% - 46 per 1000 days; 3rd OP n = 159 & PI incidence rate 28% - 32 per 1000 days Donovan et al., 2016 n=221 PI cumulative incidence: 2.3% (5/221) in the surgical ICU during the 10-week pilot program, below benchmarks Elliott et at, 2008 n=563 PI period prevalence: decrease from 50% in 2003 to 8% in 2005 Gage, 2015 n=NR PI cumulative incidence in each ICU: downward trend from up to 18 incidents to below 2 incidents in 2 years Gill, 2015 n=NR PI cumulative incidence: reduced from 6 incidents to 2 or below in 2013 Hiser et al, 2006 n=NR PI period prevalence: decreased from an average of 29.6% to 0% Loudet et.al., 2017 Before n= 55 PI Incidence: 75% or 41 After n= 69 PI Incidence: 54% or 37 Padula et al., 2008 PI cumulative incidence: a trend toward improvement (pre 9/12 vs post 8/13) Richardson et al., 2017 n=NR PI cumulative incidence: reduced from 8.08/100 patient admissions (baseline) to 2.97/100 patient admissions	

					Rogenski., 2012 Before n= 78 PI Incidence before 41.02% After n=78; PI Incidence after 23.1% Swafford et al., 2016 PI cumulative incidence: reduced from 10% (45/461) in 2011 to 3% (17/563) in 2013 Uzun et.al., 2009 Before n = 93 Number of patients with PIs/incidence 34 (37%) After = 93 Number of patients with PIs/Incidence 16 (17%) X2 = 8.86; df=1; p<.01 Wolverton et al., 2005 PI cumulative incidence: decreased from 33% to 13.7%	
Outcome: health provider compliance						
Pena, 2023	Non-randomized pre-post study Quality improvement design	USA	Bundle details: - The interprofessional team created a standardized one-page HAPI prevention bundle for general HAPI prevention as well as specialty care populations such as tracheostomy patients. - The top of the bundle consists of evidence-based interventions needed for all patients to prevent HAPIs. - Specialty devices or patient populations requiring additional HAPI prevention strategies are outlined underneath for easy reference by team members. - Iterative changes were made based on team feedback and updates to various skin care or device policies. - In addition to all the standards of care already in place, this bundle highlighted the new practice of the CTICU becoming a "back off" unit and the team utilized right and left turns only. - This HAPI prevention bundle was placed in each patient room to improve access to reference materials for all team members. - A multipronged educational approach was implemented. - For Bundle see: (see Supplemental Digital Content Figure 1, available at: **http://links.lww.com/JNCQ/B148** Sample size: The cohort included patients on the unit between November 2019 and June 2022. Setting: This project included all adult postoperative patients located within the CTICU. The surgical populations included patients with coronary artery bypass graft, valve repair/replacement, aortic surgical procedures, heart transplant, lung transplant, and mechanical circulatory support. The cohort included patients on the unit between November 2019 and June 2022.	Pre-intervention: Standard HAPI prevention bundles were available.	Prior to implementation, the CTICU had a variable compliance rate averaging 50% across components of the bundle. Post-implementation, compliance with HAPI prevention process measures has been maintained greater than 85% for **594** patients evaluated.	VERY SERIOUS

Yilmazer, 2022	Non-randomized pre-post study	Turkey	Bundle details: The bundle comprised 8 interventions: - Participation in PI education - PI risk assessment - Skin assessment - Skin care - Nutrition management - Activity management - Moisture management, and - Support surfaces management Sample size: 104 patients (total) N= 40 (post-bundle) Setting: adult neurosurgery ICU	Pre-intervention data with standard care as control Standard care: - Individual PI prevention interventions including daily skin assessments, skin care, and regular turning and positioning were completed twice daily - PI risk assessment was completed on admission to the neurosurgery ICU N=64 (pre-bundle)	Levels of compliance based on direct observation were similar. The 3-month average of the compliance level in the post-care bundle stage was 78.91 (SD = 7.93). This finding indicates that in 78.91% of observations, nurses were found to comply with the PI prevention care bundle.	VERY SERIOUS
Zhang, 2021	Non-randomized pre-post study	China	Bundle details: - Risk identification: using Braden scale (assess within 24 hours of admission) - Skin assessment: Use PI staging tools to assess skin condition within four hours of admission (Assessment included skin defect, location, depth, size, color, etc.) - Patient repositioning: Visit at least Q2H and turn the patient over - Skin care: Use pH weak acid or neutral cleansing liquid to clean the skin every day. Protect exposed or damaged skin with a dressing. Use skin protectant to prevent moisture related skin lesions if a patient has incontinence - Pressure reducing device: Use decompression or pressure redistribution equipment for at-risk patients - Nutrition: Assess nutritional status withing 24 hours of admission and provide individualized guidance Sample size: 2329 people Setting: Adult ICU	Pre-intervention data as control: Data collection ran for 2 weeks and consisted of usual standard care (details of standard care not available).	The ICU staff compliance rate for the PI care bundle increased from 55.15% to 60.15% before and after the intervention.	VERY SERIOUS
Outcome: person satisfaction						
Azuh, 2016 (Taken from review Lin et al, 2019)	Non-randomized quality improvement study	USA	n=3233 Sample: patients admitted to ICU with Braden Scale score < 19 Intervention: Early mobilization program • Assessing patients' mobility level • Introducing a new staff role: patient mobility assistant • Mobilizing patients: repositioning, sitting on edge of bed/on chair, walking with/without assistance • Staff education • Patients/family education	NA	Patient satisfaction: 97% (207/213). A total of 213 patients were surveyed for this item.	Systematic review: LOW Individual studies: VERY SERIOUS
Outcome: precursor signs and symptoms						
Aprea, 2018	Non-randomized pre-post study	Argentina	Bundle details: -Training program for physicians, nurses, physical therapists -Skin care	Pre-intervention data with standard care as control (not cited)	70 precursor signs and symptoms (stage 1 PI) were observed over 1000 days of hospitalization in the preintervention group and 26 precursor signs and	VERY SERIOUS

			-Pressure relief -Assessment of risk for PIs: risk assessment was completed on admission to PICU: Braden Q scale, PI staging from the 4-stage system from the National Advisory Group. Total Sample size: 152 N=78 (post-intervention) Ages: older than 1 month Setting: PICU	N=74 (pre-intervention)	symptoms (stage 1 PI) observed over 1000 days of hospitalization in the post-intervention group.	
Singh, 2023	Non-randomized pre-post study Quality improvement design	USA	Bundle Care: Heels: Protect them by floating on Z-Flo positioner, place Mepilex dressings or use the Z-Flex boots. Sacrum: Turn/Reposition every 2 hours as tolerated while making sure patient is off the sacrum, using the Tortoise turn and position system; place Mepilex Sacral Dressing. Ears: Use the Z-Flo positioner and make a well for the ear, use the positioner to support the head and keep the endotracheal tube from resting on the face. Devices: Rotate your device position every 2 hours if possible—even a micro change helps, wrap foam dressing cut in thin strips around nasal cannulas; get creative—the key is to change the position, wick up any moisture.	Pre-intervention: Standard care. Pre-intervention was in 2018.	Incidence of stage 1 PI 2018: 0 2019: 17 2020: 6 2021: 0 2022: 0	VERY SERIOUS
Yilmazer, 2022	Non-randomized pre-post study	Turkey	Bundle details: The bundle comprises 8 interventions: - Participation in PI education - PI risk assessment - Skin assessment - Skin care - Nutrition management - Activity management - Moisture management - Support surfaces management Sample size: 104 patients (total) N= 40 (post-bundle) Setting: adult neurosurgery ICU	Pre-intervention data with standard care as control Standard care: - Individual PI prevention interventions including daily skin assessments, skin care, and regular turning and positioning were completed twice daily - PI risk assessment was completed on admission to the neurosurgery ICU N=64 (pre-bundle)	The incidence of precursor signs and symptoms (stage 1 PI) per 1000 patient-days was 15.11 (95% CI, 6.18-24.04) versus 6.79 (95% CI, 2.20-15.86) before and after the introduction of the PI prevention care bundle. This difference was not significant. More than a quarter (n=18; 26.9%) of the PIs were precursor signs and symptoms (stage 1 PI) in the pre-care bundle stage, whereas this value dropped to 13% (n=6) in the post-care bundle stage. RR 0.53 (0.23 – 1.23). For every 100 people who receive an intervention, 13 less people will have Stage 1 pressure injury (ranges from 22 less to 6 more).	VERY SERIOUS

Acronyms
CI: Confidence interval
CTICU: Cardiothoracic intensive care unit
ICU: intensive care unit
NA: not applicable
NR: not reported
PI: Pressure Injuries
RCT: randomized control trial
RR: risk ratio
ROB: risk of bias
vs: versus

References

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Explanations

[a] One RCT was included (Tayyib, 2015) from a systematic review (Lin et al., 2020).
[b] Review authors assessed using the MMAT tool. This study had serious risk of bias as it did not meet the criteria for groups comparable at baseline. We downgraded by 1.
[c] Total number of events was less than the optimal 300 (n=49). We downgraded by 1.
[d] 19 non-randomized studies were included from a systematic review (Lin et al., 2020).
[e] The review was assessed using the ROBIS tool for systematic reviews and had low risk of bias. Review authors assessed included studies using the MMAT and Quality Improvement Minimum Quality Criteria Set (QI-MQCS) tools. Most of the included papers (n=8, 62%) met ≥13 of 16 QI-MQCS criteria (81%), and the remaining met 10-12 of 16 criteria. However, studies are non-randomized and did not control for confounding. We downgraded by 2.
[f] Due to missing details and variation in reporting across studies, unable to calculate an effect estimate. See individual study details table.
[g] Studies were assessed using the ROBINS-I tool. Both studies were rating as critical risk of bias due to confounding, lack of blinding and potential for co-interventions. We downgraded by 2.
[h] One non-randomized quality improvement study was included (Azuh, 2016) from a systematic review (Lin et al., 2019).
[i] Study is a non-randomized quality improvement study. Patient satisfaction is only reported in after data. Review authors rated the study 13/16 using the Quality Improvement Minimum Quality Criteria Set (QI-MQCS). We downgraded by 2.
[j] Total number of participants was less than the optimal 800 (n=213). We downgraded by 1.
[k] Studies were assessed using the ROBINS-I tool. Studies were rating as critical risk of bias due to confounding, lack of blinding and potential for co-interventions. We downgraded by 2.
[l] Unable to calculate summary statistic due to heterogeneity across studies and unclear denominator in one study.