

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 preventative care bundles for persons at risk of pressure injuries.

Population: Persons with or at risk of developing pressure injuries (PI)

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/caregiver satisfaction [critical]

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

Bibliography: 19, 36, 100, 1010, 1033, 1034

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
Prevalence or incidence rate of pressure injury											
24 ^a	SR of RCTs	Serious ^b	Not serious	Not serious	Not serious	Not detected	n=55 PI events/1679	n=245 PI events/1651	The results showed that the incidence of pressure injuries was lower in the bundle-care intervention group compared with the control group (3.28% vs. 14.84%, OR: 0.19, 95% CI: 0.14–0.26). For every 100 people who receive the bundle-care intervention, 12 less people will have a pressure injury (ranges from 12 less to 11 less).	⊕⊕⊕○ MODERATE	1010: Wang et al (2023)
Health provider compliance											
3	Non-randomized pre-post studies	Very serious ^c	Not serious	Not serious	Not serious	Not detected	n=2963	N/A	In one study, compliance increased by 5%. In another study, compliance to the bundle was high (reported at 78%) however,	⊕○○○ VERY LOW	19: Zhang (2021) 36: Yilmazer (2022) 1033: Pena (2023)

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
									control data was not available. In the final 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 the 594 patients evaluated.		
Person/caregiver satisfaction											
13 ^d	SR of RCTs	Serious ^e	Not serious	Not serious	Not serious	Not detected	N=1047	N=889	Satisfaction with nursing care was higher in the intervention group receiving bundled care than the control group (OR: 5.45, 95% CI: 3.76–7.90)	⊕⊕⊕○ MODERATE	1010: Wang (2023)
Precursor signs and symptoms (measured as stage I pressure injury incidence)											
3	Non-randomized pre-post studies	Very serious ^f	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 ^g .	⊕○○○ VERY LOW	36: Yilmazer (2022), 100 : Aprea (2018) 1034 : Singh (2023)
Adverse events (not measured)											
N/A											

Additional Table- Individual Study Details

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
Outcome: prevalence or incidence rate of pressure injury						
1010: Wang, 2023 ^a	SR and meta-analysis of 24 RCTs	China	Care bundles for stroke patients. Authors note the content of the bundled-care interventions, duration of the intervention and pressure ulcer evaluation criteria differed between individual studies but further details not provided. N=1679	Conventional nursing methods N=1651	Among the intervention group of 1679 patients, 55 developed PIs, whereas in the control group of 1651 patients, 245 developed PIs. The results showed that the incidence of PIs was lower in the bundle-care intervention group compared with the control group (3.28% vs. 14.84%, OR: 0.19, 95% CI: 0.14–0.26). For every 100 people who receive the bundle-care intervention, 12 less people will have a pressure injury (ranges from 12 less to 11 less).	Systematic Review: LOW Individual studies: SERIOUS
Outcome: health provider compliance						
19: 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 ,colour, 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 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
36 : Yilmazer, 022	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)	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	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

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

			Setting: adult neurosurgery ICU	- PI risk assessment was completed on admission to the neurosurgery ICU N=64 (pre-bundle)		
1033 : Pena, 2023	Non-randomized pre-post study Quality improvement design	USA	<p>Bundle details:</p> <ul style="list-style-type: none"> - 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 outline underneath for easy reference by team members. - Iterative changes were made on the basis of team feedback and updates to various skin care or device policies. - In addition to all of 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). <p>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.</p>	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. Postimplementation, compliance with HAPI prevention process measures has been maintained greater than 85% for 594 patients evaluated.	VERY SERIOUS
Outcome: person/caregiver satisfaction						
1010: Wang, 2023 ^d	SR and meta-analysis of 13 RCTs	China	<p>Care bundles for stroke patients. Authors note the content of the bundled-care interventions, duration of the intervention and pressure ulcer evaluation criteria differed between individual studies but further details not provided.</p> <p>N=1047</p>	Conventional nursing methods N=889	The results showed that patient satisfaction with nursing care was higher in the bundle-care intervention group than in the control group (96.59% vs. 84.43%, OR: 5.45, 95% CI: 3.76–7.90), suggesting that patients were more satisfied with the bundle-care intervention than with conventional care.	<p>Systematic Review: LOW</p> <p>Individual studies: SERIOUS</p>
Outcome: precursor signs and symptoms						

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

36 : Yilmazer, 2022	Non-randomized pre-post study	Turkey	<p>Bundle details: The bundle comprises 8 interventions:</p> <ul style="list-style-type: none"> - Participation in PI education - PI risk assessment - Skin assessment - Skin care - Nutrition management - Activity management - Moisture management, and - Support surfaces management <p>Sample size: 104 patients (total) N= 40 (post-bundle)</p> <p>Setting: adult neurosurgery ICU</p>	<p>Pre-intervention data with standard care as control</p> <p>Standard care:</p> <ul style="list-style-type: none"> - 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 <p>N=64 (pre-bundle)</p>	<p>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.</p> <p>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 intervention, 13 less people will have Stage 1 pressure injury (ranges from 22 less to 6 more).</p>	VERY SERIOUS
100: Aprea, 2018	Non-randomized pre-post study	Argentina	<p>Bundle details:</p> <ul style="list-style-type: none"> -Training program for physicians, nurses, physical therapists -Skin care -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. <p>Total Sample size: 152 N=78 (post-intervention)</p> <p>Ages: older than 1 month Setting: PICU</p>	<p>Pre-intervention data with standard care as control (not cited)</p> <p>N=74 (pre-intervention)</p>	<p>70 precursor signs and symptoms (stage 1 PI) were observed over 1000 days of hospitalization in the pre-intervention group and 26 precursor signs and symptoms (stage 1 PI) observed over 1000 days of hospitalization in the post-intervention group.</p>	VERY SERIOUS
1034: Singh, 2023	Non-randomized pre-post study Quality improvement design	USA	<p>Bundle Care:</p> <p>Heels: Protect them by floating on Z-Flo positioner, place Mepilex dressings or use the Z-Flex boots.</p> <p>Sacrum: Turn/Reposition every 2hours as tolerated while making sure patient is off the sacrum, using the Tortoise turn and position system; place Mepilex Sacral Dressing.</p> <p>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.</p> <p>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.</p>	<p>Pre-intervention: Standard care.</p> <p>Pre-intervention was in 2018.</p>	<p>Incidence of stage 1 PI</p> <p>2018: 0 2019: 17 2020: 6 2021: 0 2022: 0</p>	VERY SERIOUS

			<p>Face: With bilevel or continuous positive airway pressure, try to alternate pressure points using different interface and place gel pads or foam dressing under points of contact.</p> <p>Bony prominence: Protect with a Mepilex foam dressing (think elbows, knees, spinal process).</p> <p>Moisture: InterDry in the skin folds, under tracheostomy ties, around tubing; skin barrier ointment, adult briefs, skin care.</p> <p>PIPB go-live was 11 February 2019. The ICU were converted to all low air loss mattress on advanced frames. All units were stocked with turn and position overlays, pressure relieving heel floating boots, bordered foam sacral and heel dressings, skin protectant, moisture wicking fabric. In-servicing was provided every 6 weeks throughout 2019 to 2022 with monthly reminders for implementing the PIPB.</p> <p>Sample Looked at 4 years of postintervention data using one-tailed t-test, comparing the number of HAPI pre-implementation (2018).</p> <p>Ages: Over the age of 18 years.</p> <p>Setting: Urban 260- bed hospital with an average yearly census of 65,000 patient days in Northern California</p>		
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Acronyms

- CI: Confidence interval
- ICU: intensive care unit
- NA: not applicable
- NR: not reported
- NRS: non-randomized study
- PI: Pressure Injuries
- PICU: pediatric intensive care unit
- RCT: randomized control trial
- RR: risk ratio
- ROB: risk of bias
- SR: systematic review
- vs: versus

References

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Explanations

^a 24 studies were included from a systematic review (Wang, 2023).

^b The authors assessed individual studies using the Cochrane Risk of Bias 2.0 tool. Majority of studies were rated as “some concerns”. Reasons for concerns were lack of blinding, unclear allocation concealment and randomization. We downgraded by 1.

^c 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.

^d 13 studies were included from a systematic review (Wang, 2023).

^e The authors assessed individual studies using the Cochrane Risk of Bias 2.0 tool. Majority of studies were rated as “some concerns”. Reasons for concerns were lack of blinding, unclear allocation concealment and randomization. We downgraded by 1.

^f 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.

^g Unable to calculate summary statistic due to heterogeneity across studies and unclear denominator in one study.