Implementing a Pressure Injury Care Bundle in Chinese Intensive Care Units

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Background: The incidence of pressure injury (PI) in intensive care units (ICUs) is high with a low compliance rate for PI prevention standard care. Although studies have confirmed that PI are largely preventable, a PI care bundle based on the best evidence in Chinese ICUs is lacking.

Aim: The aims of this study are to assess the effectiveness of our PI care bundle—which is based on the best evidence and designed to prevent the development of ICU PI—and to identify the changes in nurse compliance rates during the implementation process.

Methods: A quasi-experimental, pre- and post-intervention design was used. Implementation strategies included training, auditing the use of the care bundle, and measuring outcome indicators in the ICU. The key elements of the care bundle were risk identification, skin assessment, patient repositioning, skin care, use of a pressure-reducing device, and nutrition. The number and stage of PI were collected at three time points by unit staff. The implementation compliance rate was measured at two time points using a compliance checklist.

Results: Pressure injury rates were reduced significantly from 13.86% to 10.41%. The incidence of new hospital-acquired pressure injuries (HAPI) decreased by 29.5% within 6 months. The compliance rate of nurses increased significantly from 55.15% to 60.15% before and after the implementation of the care bundle ($\chi^2=16.72$, P=0.00); This result may be attributable to the implementation of care bundle training for nurses and the audit.

Conclusion: A standardized care bundle based on the best evidence is indicated to effectively reduce the incidence of PI. The increase in compliance rate after the intervention may benefit from nurses training in the care bundle and the audit during the intervention.

Keywords: pressure injuries, pressure ulcers, intensive care, intensive care unit, care bundle, compliance

Background
Pressure injuries (PIs) usually occur over bony prominences and are local injuries to the skin and/or subcutaneous tissues caused by pressure or pressure combined with shear forces, and it may also be related to medical devices or other objects.1 Studies have shown that hospital-acquired pressure injuries (HAPIs) can reduce the health-related quality of life (HRQOL) of patients, increase the length of hospital stay, workload of nurses, and medical burden. They can also cause medical disputes and even increase mortality.2,3

There are many risk factors for PI in critical-care patients, such as older age, poor perfusion, and changes in mobility.4 An epidemiological investigation showed that the incidence of hospital-acquired pressure injuries is 0.63% (0.20–1.20%) in China, and critical care patients are more likely to develop PI than general hospital patients.5 This
indicates that it is necessary to take targeted measures to prevent the occurrence of PIs in intensive care units (ICUs).

Studies suggest that the use of a care bundle can prevent PIs even more effectively than clinical guidelines. A care bundle is a set of nursing interventions for a particular class or individual patient, each element of which has been clinically proven to improve patient outcomes. The care bundle approach is often used in the clinic because it is usually based on the best evidence and has been shown to benefit the patient’s clinical outcome.

Although studies have demonstrated an association between care bundle and positive outcomes for ICU patients, there is still no uniform and clear definition of a care bundle in the ICU pressure ulcer prevention guidelines. The complexity of the ICU environment and the severity of the patient’s illness present challenges to care bundle implementation. In addition, implementation compliance is also an important factor that needs to be evaluated when using a care bundle. If compliance with intervention guidelines is not considered, the benefits of evidence-based practical intervention cannot be maximized. Measuring the effectiveness of the PI prevention bundle implementation through compliance with the bundle is essential for a comprehensive understanding of the quality of the bundle and its implementation, which is particularly useful in effectiveness trials in a clinical setting. However, to date, few studies have evaluated compliance with care bundles during the intervention.

Considered that the incidence of pressure injuries in China’s ICU is higher than that of other departments and the use of a PI care bundle may improve patient outcomes and reduce the incidence and mortality of PI. This study evaluated the effectiveness of a care bundle in the Chinese ICU. In addition, this study also assessed the compliance rate for care bundle implementation to fully understand the effectiveness of the PI prevention care bundle.

Aims
The aims of this study were to (1) identify the impact of the care bundle on preventing PI, and (2) identify changes in the compliance rate of nurses to the elements of the care bundle at different time points (before and after intervention).

Method
Study Design
This quasi-experimental, pre- and post-intervention study was completed over six consecutive months between April and October 2019 in the ICUs of tertiary hospitals in China.

Participants and Setting
The study involved all critical care units in hospitals from 26 provinces in China, and all hospitals belonged to the China Nursing Quality Promotion Alliance. Before the study, 60 hospitals participated, and new hospitals were accepted during the intervention process. After the study, 97 hospitals participated in data reporting. One hundred sixty-three ICU nursing units participated in this study, including medical, surgical, neurological, trauma, cardiac, and mixed ICUs. All patients over 18 years of age admitted to the ICU during the data collection phase were included in our study. For data collection convenience, 97 hospitals were divided into six groups. Each group was led by a head nurse responsible for supervising, controlling the quality, implementing, and collecting data.

Pressure Injury Care Bundle
We designed a PI care bundle for adults receiving intensive care based on a multi-stage and theory-driven approach. Before the intervention, eight nursing management specialists and four ICU head nurses attended a three-hour meeting with the researchers to develop the care bundle. The key elements of the care bundle were risk identification, skin assessment, repositioning, skin care, use of a medical device, and nutrition (Table 1).

Instrument
A care bundle checklist was specifically designed by researchers for our study to check the compliance of nurses with the care bundle (Table 6). The checklist consists of six dimensions and 10 entries, with a series of yes or no questions. We recorded the care bundle as implemented only when the contents of the checklist were all completed; if more than one item was not implemented, it was recorded as unimplemented. Finally, we scored the nurses’ implementation rate of the PI prevention bundle.

Procedure
The study ran from April 2019 to October 2019 (Table 2).

Pre-Intervention Phase
The pre-intervention data collection phase ran for 2 weeks and consisted of usual care with the nurse staff continuing to complete their standard pressure injury prevention practices (Table 2). There was a two-week period before the nursing staff began to implement the bundle elements to enable the delivery of the training and education session.
Table 1 The PI Prevention Bundle

| Intervention Key Element | PI Prevention Bundle |
|--------------------------|----------------------|
| Risk identification      | Use the Braden risk-assessment scale to assess the risk of PI within 24 hours of admission. |
| Skin assessment          | Use the PI staging assessment tool to assess skin condition within four hours of admission. Assessments included skin defect, defect location, depth, size, color, etc. |
| Patient repositioning    | Visit at least every two hours and turn the patient over. |
| Skin care                | Use pH weak acid/neutral cleansing liquid to clean the skin of patients every day. Protect exposed and damaged skin with a dressing. Use skin protectant to prevent moisture-related skin lesions if the patient has incontinence. |
| Pressure reducing device | Use decompression or pressure redistribution equipment for at-risk patients. |
| Nutrition                | A nutritionist assesses the nutritional status of the patient within 24 hours of admission and provides individualized nutritional guidance. |

(Table 2). We offered training sessions to the nursing staff to maximize attendance and provided a care bundle brochure for those who could not attend.

### Intervention Phase

The care bundle was implemented and used for 24 weeks (Table 2). To compare the nurse staffing before and after the intervention, the ICU nurse-to-patient ratio was obtained in the system. The risk assessment was a mandatory component of our bundle. We provided a harmonized method for conducting the risk assessment and asked the nursing staff to document the risk assessment score for each ICU patient on the bundle sheet. The unit staff were ultimately responsible for unifying the collection of these data and delivering it to nursing institute researchers for auditing purposes.

### Data Collection

We conducted two assessments, one in April and one in October 2019, to analyze differences in the compliance of nurse implementation of the PI prevention bundle before and after the intervention (Table 2). In addition, we

| Pre-Intervention Phase | Intervention Phase | Post-Intervention phase |
|------------------------|--------------------|-------------------------|
| 2-Week Pre-Intervention Period | Consisted of: -Usual care with the care staff continuing to complete their standard PI prevention. Data Collection (1st timepoint): -RN compliance with implementation of the PU care bundle (1st check). -Baseline ICU data average nurse-patient ratio -PI incidence: the number of patients with PI the documented development of any new HAPI stage of PI | Consisted of: -All group leaders learned about the elements of the PI care bundle through meetings provided by the researcher. -All RNs learned about the elements of the PI care bundle through one-to-one bedside education provided by group leaders. -All RNs were provided with brochures containing elements of the PI care bundle (risk identification, skin assessment, patient repositioning, skin care, pressure-reducing device, nutrition) | Consisted of: -Provide care bundle elements for patients at risk of PI. Data Collection (2nd timepoint) -Baseline ICU data average nurse-patient ratio -PI incidence: the number of patients with PI the documented development of any new HAPI stage of PI |
| 2-Week Training Period | Consisted of: | Data Collection (3rd timepoint) |
| 24-Week Intervention Period | -ICU RN compliance with implementation of the PI care bundle (2nd check). -Baseline ICU data average nurse-patient ratio -PI incidence: the number of patients with PI the documented development of any new HAPI stage of PI |
conducted three timepoint surveys at 10 AM and 10 PM on April 9, August 8, and October 30 to measure the prevalence and stage of PIs in different periods (before, during, and after intervention).

Data Analysis
We analyzed data using IBM SPSS (version 21; SPSS, Chicago, IL). We used descriptive statistics (frequency and percentage) to summarize the number of patients with PIs and HAPIs, the development of PIs and HAPIs, and the stage of PIs. Chi-square test was used to compare the difference of PI prevalence and new HAPIs across three time points (before, during, and after the intervention). We used Poisson’s regression to examine the level of PI prevalence before and after the intervention. We measured nursing staff adherence to the elements using the PI prevention bundle compliance checklist. All-or-none measurements were used to measure the ratio of patients who actually received all of the care elements to the number of patients eligible to receive the care elements. We calculated adherence to the individual elements using an item-by-item measurement in which the denominator was the total number of ICU patients per bed day, and the numerator was the number of patients who received the element fully per day.

Ethics
Ethical approval to conduct this study was obtained from the Medical Ethics Committee of Shandong Provincial Hospital Affiliated to Shandong University (NO.2016–130). All patients participating in this study signed an informed consent form. For patients who are unconscious and unable to obtain informed consent, the family members of the patients will sign it instead. Our study was conducted in accordance with the Declaration of Helsinki.

Results
Incidence and Stage of PIs
The results of timepoint surveys showed that the prevalence of pressure injuries decreased significantly from 13.86% to 10.41% ($\chi^2=21.183$, $P<0.01$) (Table 3). The prevalence of HAPI also decreased after the intervention, but the difference was not statistically significant ($\chi^2=4.46$, $P=0.04$) (Table 4).

The incidence of HAPI after the intervention was 0.705 times that before intervention (Table 5). There was a relative rate reduction of 29.5% over the intervention period. The reduction was seen in stage I to stage II and deep tissue PIs but not for unstageable PIs (Figure 5).

Implementation Compliance of the PI Care Bundle
Baseline ICU Characteristics
Before the intervention, 156 ICU nursing units participated in data collection; 163 participated after the intervention. A total of 2021 ICU patients participated in verification before the intervention, and 2329 participated after the intervention. Three timepoint surveys showed that the nursing and patient ratio in the ICUs before and after the intervention was relatively stable. The above results indicated that the ICU baseline data of 97 hospitals did not change significantly before and after the intervention and were comparable (Figures 1–4).

| Table 3 Incidence of HAPI |
|--------------------------|
| Time | Number of HAPI (n) | Number of Patient (n) | The prevalence Rate (%) | $\chi^2$ | P |
| 1st timepoint | 73 | 3246 | 2.25 | 4.46 | 0.04 |
| 2nd timepoint | 60 | 3043 | 1.76 |
| 3rd timepoint | 69 | 4352 | 1.59 |

| Table 4 Incidence of PI |
|--------------------------|
| Time | Number of PI (n) | Number of Patient (n) | The Prevalence Rate (%) | $\chi^2$ | P |
| 1st timepoint | 450 | 3246 | 13.86 | 21.18 | 0.00 |
| 2nd timepoint | 455 | 3043 | 13.37 |
| 3rd timepoint | 453 | 4352 | 10.41 |

| Table 5 Poisson Regression Analysis of the Incidence of HAPI |
|--------------------------|
| Group | IRR | SE | z | P | 95% CI |
| Pre-intervention | - | - | - | - | - |
| Post-intervention | 0.705 | 0.118 | -2.08 | 0.037 | 0.507 | 0.980 |
Compliance Rate of Car Bundle

The ICU staff compliance rate for the PI care bundle increased from 55.15% to 60.15% before and after the intervention, and the difference was statistically significant ($\chi^2 = 17.62, P<0.01$) (Table 6). However, no significant improvement was observed for compliance with the use of pH weak acid/neutral cleaning liquid to clean the skin of patients and provide individualized nutritional guidance.

**Table 6 Implementation Compliance of the PI Care Bundle**

| Implementation Complaince of the PI Prevention Bundle | 1st Time Point | 2nd Time Point | $\chi^2$ | P |
|-------------------------------------------------------|----------------|----------------|---------|---|
| 1. Skin assessment Completed skin assessment use PI staging assessment tool and record. (yes) (n/%) | 2013; 98.29 | 2069; 99.31 | 17.52 | 0.00 |
| 2. Patient repositioning Completed turn the patient over every two hours. (yes) (n/%) | 1953; 96.83 | 2375; 99.37 | 40.26 | 0.00 |
| 3. Skin care 3.1 Use pH weak acid/neutral cleansing liquid to clean the skin of patients. (yes) (n/%) | 1820; 91.46 | 2304; 92.87 | 3.06 | 0.08 |
| 3.2 Keep the skin dry and clean. (yes) (n/%) | 1904; 94.87 | 2325; 97.28 | 17.28 | 0.00 |
| 3.3 Use skin protectant to prevent moisture-related skin lesions if the patient has incontinence. (yes) (n/%) | 1532; 76.79 | 2173; 87.27 | 34.33 | 0.00 |
| 4. Care of medical devices Use decompression or pressure redistribution device for patients at risk. (n/%) | 1547; 95.61 | 2324; 97.24 | 7.73 | 0.00 |
| 5. Nutrition 5.1 Provide individualized nutritional guidance. (n/%) | 2219; 92.85 | 2219; 92.84 | 0.00 | 1.00 |
| 5.2 Regular monitoring of nutritional indicators. (n/%) | 1984; 98.02 | 2295; 96.02 | 14.77 | 0.00 |
| Implementation rate of the PI prevention bundle. (n/%) | 1644; 55.15 | 2163; 60.15 | 17.62 | 0.00 |

**Discussion**

**Prevalence of Pressure Injuries**

This was a quasi-experimental, pre- and post-intervention design study conducted in the ICUs of 97 general hospitals...
in China. The purpose of our study was to explore the effectiveness of the developed PI prevention care bundle. The results of the study showed that the prevalence of PIs and HAPIs decreased after using the PI care bundle. This is consistent with previous studies\(^9\),\(^12\) and further proves that the bundle approach is more effective than single methods in Chinese ICUs.

The prevention care bundle is considered a success as the prevalence of PIs decreased significantly from 13.86\% to 10.41\%. However, it is worth noting that the ICU incidence of PI is still not as low as that in other general departments. This may be due to the long hospitalization of critically ill patients or nurse deviation from the PI care bundle. A longer hospital stay may increase the risk of PIs or the existence of disease burden and secondary skin failure, making it extremely difficult to completely eradicate PIs. Furthermore, the high incidence of PIs may be related to the lower nurse-to-patient ratio (ie, 1:1.96 or 1:3.24). A lower nurse–patient ratio means that ICU nurses have to take care of more patients; the high nursing workload may result in infrequent repositioning of these high-risk patients, thus accelerating the development of PIs.

Although other countries have lower nurse-patient ratios, the ICU nursing organization structure is different. For example, the ICU in the United States is managed by a multidisciplinary team, including respiratory therapists, nutrition consultants, and physicians.\(^13\),\(^14\) Many studies report that a high nurse–patient ratio is significantly associated with high-quality, safe, and positive patient outcomes.\(^15\)–\(^17\)

In addition, the results of this study show that the use of the prevention care bundle reduces the severity of PIs, which is consistent with other research.\(^9\) After the intervention, the incidence of stage I, stage II, stage III, and deep-tissue PIs all decreased, but the prevalence of unstageable PIs increased. This difference may be due to the nurses’ inconsistent identification standards for PI staging. This suggests that we should strengthen the training of nurses in identifying and staging PIs in future research.

### Implementation Compliance

The results of this study show that nursing staff have a high compliance rate for the prevention care bundle. The implementation rate of some bundle elements was significantly higher after the intervention than before it. This may be due to many factors. The first may be training of nurses before the intervention. Previous studies have shown that education and training can increase adherence
to interventions, which may empower nurses and increase their confidence in realizing positive changes in practice.\textsuperscript{18} Therefore, we have reason to believe that pre-intervention training increased nurses’ familiarity and confidence in the implementation of nursing packages and further enhanced nurses’ compliance. In addition, studies have found that review and feedback related to any summary of clinical manifestations is one of the most successful interventions to change professional behavior.\textsuperscript{19} We designed a checklist for clustered nursing measures requiring nurses to check the implementation of the PI care bundle elements when caring for every patient at risk of PI. This audit behavior in the implementation process may be another important factor underlying the high compliance of nurses in care bundle implementation in our study. Finally, the care bundle approach serves as a strategy based on the individual needs of the patient. The literature points out that this method can increase compliance with the intervention.\textsuperscript{20}

**Limitations**

Our study has some limitations. First, the before and after study design is susceptible to time changes which may affect the results. The positive results may be explained by the Hawthorn effect as there is no control group. Second, we did not collect demographic characteristics of everyone at the patient level, so we could not analyze the impact of interventions on patients with different characteristics (age, gender, disease severity, etc.). Third, we did not consider the impact of nurse compliance rate on the intervention effect, because previous studies reported that PU incidence is not influenced by the compliance level of nursing staff.\textsuperscript{21} In addition, the nurse shortage and their heavy workload in ICUs may affect the implementation of the PI bundle care. Finally, the PI care bundle, based on the latest evidence of PI prevention strategies, combined several measures for risk factors. Therefore, we cannot evaluate the effect of every preventive measure.\textsuperscript{22}

**Conclusions**

To the best of our knowledge, this report describes the first multi-site intervention study in China for a care bundle for PI prevention. This study adopted a comprehensive intervention method including a standardized evidence-based PI preventive care bundle, training of nurses before the intervention, and audit of the nurse’s implementation rate during the intervention. This research suggests that the combination of the care bundle with training and auditing of nursing staff may be more beneficial to the transformation of practice.

**Funding**

This work was supported by Key R&D Projects in Shandong Province (2016GSF201224).

**Disclosure**

The authors declare no conflicts of interest for this work. The authors declare that they have no known competing financial interests or personal relationships that influenced the work reported in this paper.

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