Feasibility and Effectiveness of a Delirium Prevention Bundle in Critically Ill Patients

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Background Strategies for preventing delirium include early identification and avoiding or modifying patient, environmental, and iatrogenic factors. Minimal research exists on a prescriptive delirium prevention bundle that details elements or strategies for each bundle component. Even less research has been focused on nurse-driven interventions or components.

Objective To evaluate the effectiveness of a delirium prevention bundle in decreasing delirium incidence in 2 medical-surgical intensive care units in a large Texas medical center.

Methods Researchers used the Confusion Assessment Method for the Intensive Care Unit to assess delirium incidence by using a controlled interventional cohort design with 447 delirium-negative critically ill patients. Bundle components consist of sedation cessation, pain management, sensory stimulation, early mobilization, and sleep promotion.

Results The intervention, analyzed by using a logistic regression model, reduced the odds of delirium by 78% (odds ratio, 0.22; P = .001).

Conclusions The delirium prevention bundle was effective in reducing the incidence of delirium in critically ill medical-surgical patients. Further validation studies are under way. (American Journal of Critical Care. 2017; 26:19-27)
Delirium is a preventable medical condition that is a symptom of acute brain dysfunction. It occurs in 60% to 80% of critically ill patients who are receiving mechanical ventilation and in 20% to 50% of critically ill patients who are not receiving mechanical ventilation. These percentages mean that more than 40,000 patients receiving mechanical ventilation in intensive care units (ICUs) in the United States experience delirium every day. Patients receiving mechanical ventilation present a different set of risk factors for development of delirium; those factors include multi-system illness, comorbid conditions, and medications. Delirium has both short-term and long-term adverse effects on patients’ levels of function and cognition.

Delirium continues to plague patients across the care continuum, often resulting in an increase in morbidity and mortality and a longer hospital stay. As 1 of the 6 leading causes of preventable injury in patients aged 65 years or older, delirium adds approximately 10 days to the patients’ mean length of stay in the hospital. Each additional day spent in delirium is independently associated with a 20% increased risk for prolonged hospitalization, and a 10% increased risk of death. Delirium often develops in patients who have 2 to 6 multifactorial causes and commonly develops in critically ill patients due to advanced age, critical illness, and multiple medical-surgical interventions. In this study, delirium incidence is defined as a change in the patient’s delirium assessment from delirium-negative to delirium-positive.

Delirium remains unrecognized in 66% to 84% of patients in ICUs, acute care, and emergency departments and is underdocumented and undertreated. The national approximation may be grossly underestimated, resulting in poorer outcomes for patients, higher costs, and a staff shortage. As health care braces for the anticipated surge in aging patients, the incidence of delirium is expected to soar. Hospital costs continue to climb, with predictions that delirium will nearly double patients’ hospital costs and will increase US health care costs between $6 billion and $20 billion annually. In the ICU, delirium incidence increases cost per case to $9,000 or more per patient.

Delirium prevention outweighs available delirium treatment options. Key strategies for preventing delirium and decreasing its duration include early identification and avoiding or modifying patient-related, environmental, and iatrogenic factors. If hospital staff are able to consistently implement preventive measures on an ongoing basis, delirium incidence may decrease, resulting in improved outcomes for patients and hospitals. Although some research has addressed the feasibility of having ICU nurses assess for delirium, little research has tested the feasibility of nurses consistently adhering to all components of a delirium prevention bundle (DPB). The purpose of this article is to report findings from a controlled interventional cohort study that tested the effectiveness of a prescriptive, nonpharmacological, nurse-led DPB in reducing delirium incidence in critically ill patients in medical-surgical ICUs.

The research questions for the study were as follows:
1. Does consistent use of an intervention bundle consisting of sedation cessation, pain management, sensory stimulation, early mobilization, and sleep promotion reduce delirium incidence in critically ill patients?
2. Are any of the components of the intervention bundle problematic to achieve?
3. Which components of the intervention bundle contribute significantly to reducing delirium in critically ill patients?

Theoretical Framework
The theoretical framework for the study was Virginia Henderson’s Theory of Need. Henderson described the unique function of the nurse as one who assists sick or well patients to perform activities that they would normally perform themselves, if they possessed the strength, desire, or knowledge to...
do so. Said activities are those that contribute to patients’ health, recovery, or peaceful death in such a way as to help patients regain their independence.18 The nurse strives to assist each patient to become independent as quickly as possible, thereby decreasing the patient’s need for the nurse.

In essence, the nurse using the DPB intervenes to provide nursing care in 5 specific domains that contribute to patients’ recovery. During patients’ ICU stay, most have neither the ability nor the desire to perform such activities on their own. The DPB aligns with many of Henderson’s 14 components of basic nursing care, which make up the Theory of Need. Domains within the DPB include sedation cessation, pain control, sensory stimulation, early mobility, and sleep promotion. Components from Henderson’s theory that mirror those in the DPB include the patients’ need to breathe normally, move and maintain desirable positions, sleep and rest, avoid environmental dangers and the injury of others; communicate with others in expressing emotions, needs, fears, or opinions; and participate in various forms of recreation18 (Table 1).

Methods

The study was approved by the nursing research council and institutional review board at the study site. Researchers conducted a controlled interventional cohort study in 2 similar medical-surgical ICUs in a large medical center in Houston, Texas. Patients admitted to an 18-bed medical-surgical ICU were in the control group and received standard ICU care. Patients admitted to a 10-bed medical-surgical ICU were in the intervention group, for whom the nursing staff consistently implemented the entire DPB. Using both didactic and practical methods, researchers taught the licensed staff in both groups to administer the Confusion Assessment Method for the ICU (CAM-ICU) and the Richmond Agitation-Sedation Scale (RASS) at least once per shift.19 Interrater reliability was established. Licensed and unlicensed staff received training on the DPB in the intervention unit. The research team delayed data collection for approximately 4 weeks to enable the staff to become proficient in the use of the CAM-ICU and to ensure adoption by at least 4 of 5 categories of adopters.

Nurses in the control group provided standard ICU care. The study groups had similar patient acuity, ICU length of stay, and comorbid conditions (Table 2). Nurses collected patient data (N = 447) every shift during patients’ ICU stay, not to exceed 30 days. Nurses assessed patients for delirium at least twice daily, resulting in 1533 observations. Patients were considered delirium-positive if assessed as positive for delirium at least once during a 24-hour period.

Because the control group has fewer patients receiving mechanical ventilation, researchers theorized that the census in that larger unit would compensate for the smaller percentage of ventilator-dependent patients. The 2 groups were configured similarly, including a combination of medical and surgical patients, study-supporting leaders, willing staff nurses, and a homogeneous patient mix with projected high rates of delirium.

Researchers randomized by group rather than by participant because of the likelihood that the
The patient for agitation or arousal is the first step in the delirium assessment. One cannot assess the “attentive” and “disorganized thinking” features of the CAM-ICU if the patient is deeply sedated or highly arousable. The RASS is a valid and reliable instrument for the measurement of arousal and is stable over time.21

The CAM-ICU is a valid and reliable tool that is widely used to assess critically ill patients for the presence or absence of delirium.2,6 It is easy to use and quick to administer and has an administration time of approximately 2 minutes.2 The instrument is used to assess changes in 4 key criteria: acute change from baseline or fluctuating course, inattention, disorganized thinking, and altered level of consciousness.11

Nurses used a researcher-generated patient data collection tool to document demographics, comorbid conditions, risk factors, and significant clinical events. The research team authenticated and recorded daily compliance with DPB components via weekly random audits. Compliance regularly ranged from 80% to 88%.

Components of the DPB
Prevention is currently the best method of delirium treatment. The DPB consists of 5 components, each of which contains evidence-based nursing interventions. The etiology of delirium is multifactorial; therefore, researchers devised a multifaceted prevention strategy. The 5 components of the DPB are (1) sedation cessation for patients receiving mechanical ventilation, (2) pain management, (3) sensory stimulation, (4) early mobilization, and (5) sleep promotion. Researchers organized the DPB to mimic the flow of nursing care during a typical ICU day (Table 3). Implementing all components leads to a more positive result than if individual components are implemented independently.1 The consistent practice of all component elements is critical in reducing delirium incidence.

Sedation Cessation for Patients Receiving Mechanical Ventilation. Delirium occurs in patients who recover from a sedated or oversedated state.22 The depth of sedation is independently associated with the duration of mechanical ventilation, in-hospital mortality, and 180-day death rates.23 Sedation cessation is an evidence-based ventilator management protocol for patients undergoing mechanical ventilation. It incorporates a spontaneous awakening trial that is performed daily on nonexcluded patients. For qualifying patients, nurses stop administration of sedatives for 1 hour. If patients open their eyes to verbal

...
stimuli without exhibiting any of the criteria for a failed spontaneous awakening trial, then respiratory therapists initiate a spontaneous breathing trial. Failure criteria for a spontaneous breathing trial include a RASS score of +2 to +4 during sedation cessation, a respiratory rate greater than 35/min for 5 minutes or longer, acute dysrhythmia, or 2 of more of the following: heart rate greater than 100 or less than 60 beats per minute; using accessory muscles; paradoxical abdominal movement; diaphoresis; or marked dyspnea. In failure cases, the nurse restarts the sedation at half the previously ordered rate and notifies the physician.

Pain Management. Pain is the most common memory patients have of their experience in the ICU, and sedatives and analgesics are the most commonly administered ICU drugs. Short-term consequences of unrelieved pain are higher energy expenditure and immunomodulation. Unrelenting pain leads to post-traumatic stress disorder in the long term. Nurses routinely assessed and documented pain by using a numeric rating scale of 0 to 10. Nurses recorded patient-reported comfort goals (0-10), patients’ perceived pain scores (0-10), time of analgesic administration, and patients’ follow-up pain score 1 hour later. Patients’ comfort goals were compared with their follow-up pain scores to assess pain management. Pain was considered adequately managed if the comfort goal was within 1 unit of the follow-up level.

Sensory Stimulation. Sensory stimulation includes visible and accurate clocks and calendars, opening and closing window blinds during daytime and nighttime hours, and orienting patients to time, place, and date. Wearing personal vision and hearing aids improves patients’ sensorium. Age-appropriate television and radio programs that are suited to patients’ personal taste are important, as is offering slow, soothing music to reduce pain and anxiety, foster relaxation, and improve mood and movement.

Early Mobilization. Weakness and muscle wasting often occurs in ICU patients who lack physical activity, which may result in marked consequences. ICU patients may lose up to 20% of muscle strength in 1 week of bed rest. The effectiveness of an ICU mobility protocol in preventing delirium has not been studied; however, a mobility program for elderly non-ICU patients realized a 40% reduction in delirium.

The patients’ clinical condition determined the amount and type of exercise introduced. Early ICU mobilization included frequently turning bed-bound patients, conducting passive and active range-of-motion exercises, having patients dangle their legs at the edge of the bed with feet planted, actively transferring patients to a chair, and ambulating patients. Nurses and unlicensed staff were primarily responsible for implementing early mobilization. Clinical instability generally precludes mobility progression beyond passive range-of-motion exercises. Early mobility, a DPB component, includes mobilizing patients undergoing mechanical ventilation with a fraction of inspired oxygen less than 70% and a positive end-expiratory pressure that is 10 cm H₂O or less; patients with multiple catheters, tubes, wires, and drains, including orally intubated patients; and patients undergoing continuous renal replacement therapy. Early mobilization requires a team approach of licensed and unlicensed nursing staff along with other nonnursing disciplines.

Sleep Promotion. Sleep deprivation is a common ICU problem that may induce delirium. The mean sleep time for an ICU patient may be as little as 1 to 2 hours per day, with less than 6% of ICU patients achieving rapid eye movement sleep. Environmental factors such as noise, crowded conditions, and bright lights contribute to sleep deprivation. The DPB promotes uninterrupted sleep by clustering patient care interventions (eg, measurement of vital signs, radiographs, phlebotomy) around the designated sleep period (midnight to 4 AM); not administering hypnotic agents after 2 AM; dimming overhead lights; closing window blinds; and minimizing ambient noise (<80 decibels) by turning off televisions and radios. A Sound Level Meter (RadioShack) was used to monitor ambient noise level. Sleep promotion was achieved if at least 4 of 5 interventions were documented.

Results

Comparison of patients’ admitting demographic, morbidity, and comorbidity characteristics indicated no significant difference between the control and intervention groups (Table 2). Consistent with published reports, the adjusted logistic regression model indicated that delirium was more likely to develop in patients who were receiving mechanical ventilation, were in restraints, were more than 64 years of age, or who had spent more than 3 days in the ICU (Table 4). The number of patients who were unable to be assessed did not differ significantly between the 2 groups. The median RASS score was 1 in the intervention group and 2 in the control group.

The bundle consisted of sedation cessation, pain management, sensory stimulation, early mobilization, and sleep promotion strategies.
Longitudinal (repeated-measures) multivariate logistic regressions (Table 5) indicate that patients in the intervention group experienced highly significant reductions (78%) in the relative risk for delirium (odds ratio, 0.22; 95% CI, 0.08-0.56; \( P < .001 \)).

Additionally, increases in age, length of stay in the ICU, and use of mechanical ventilation and restraints were associated with significant increases in the relative risk of delirium. Patients’ race, number of comorbid conditions, and sex were not significant risk contributors.

Staff nurses from the control group crossed to the intervention group for 6 shifts during the 244 days (488 shifts) of data collection (January through August 2012), and intervention group nurses crossed to the control group for 7 shifts. This results in a 2.7% (13/488) possibility of crossover.

Discussion

Descriptive statistics validate the randomization of the study sample and that participants were representative of the hospital’s ethnic distribution. Study findings are consistent with published reports that the incidence of delirium is higher in patients receiving mechanical ventilation than in patients who do not require ventilator support.\(^2,4,11\) Findings from this study indicate that the odds of delirium developing are more than 3 times (\( P < .001 \)) as high in patients receiving mechanical ventilation as in patients not receiving it. Likewise, study findings further suggest that patients in restraints are 2.82 times more likely (\( P = .002 \)) to have delirium develop than are patients who have been liberated. Although not an aim of the study, 1 other predisposing factor for delirium emerged from the analysis. Patients with an ICU stay greater than 3 days were 3 times more likely (\( P = .007 \)) to have delirium develop than were patients with shorter ICU stays. Variables that contributed to a reduction in the odds of delirium include the DPB and age less than 64 years, and variables that increase the likelihood of delirium developing include treatment-specific items such as use of mechanical ventilators and restraints and an ICU stay longer than 3 days. Patients’ race, number of comorbid conditions, and gender did not exhibit any significant effect.

The DPB was effective in reducing delirium incidence and preventing delirium. Some DPB components, however, were problematic to achieve because of limiting factors. Sensory stimulation was problematic because many family members refused to leave hearing aids and eyeglasses in patients’ rooms to avoid losing them. Nurses’ comments on the patient data collection form validated the limitation, “Patients and family members were reluctant to bring and/or leave patients’ glasses or hearing aids for fear of losing the expensive assistive devices.” As a result, patients who normally wore such devices had difficulty with sensory stimulation. Despite efforts to encourage family members to provide the patients’ sensory devices, few were available for patients to use. The

### Table 4

<table>
<thead>
<tr>
<th>Variable</th>
<th>No delirium incidents (n = 369)</th>
<th>≥1 Delirium incident (n = 78)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days of mechanical ventilation, mean (SD)</td>
<td>0.18 (0.58)</td>
<td>3.79 (7.07)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Days in restraints, mean (SD)</td>
<td>0.02 (0.21)</td>
<td>2.32 (4.87)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Stay in ICU &gt; 3 days</td>
<td>107 (29)</td>
<td>56 (72)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>No. of comorbid conditions</td>
<td></td>
<td></td>
<td>.02</td>
</tr>
<tr>
<td>&lt;3</td>
<td>157 (42)</td>
<td>22 (28)</td>
<td></td>
</tr>
<tr>
<td>3-5</td>
<td>147 (40)</td>
<td>33 (42)</td>
<td></td>
</tr>
<tr>
<td>&gt;5</td>
<td>65 (18)</td>
<td>23 (29)</td>
<td></td>
</tr>
<tr>
<td>Female sex</td>
<td>181 (49)</td>
<td>39 (50)</td>
<td>.82</td>
</tr>
<tr>
<td>Age category, y</td>
<td></td>
<td></td>
<td>&lt;.001</td>
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<tr>
<td>&lt;45</td>
<td>74 (20)</td>
<td>4 (5)</td>
<td></td>
</tr>
<tr>
<td>45-64</td>
<td>156 (42)</td>
<td>26 (33)</td>
<td></td>
</tr>
<tr>
<td>65-74</td>
<td>68 (18)</td>
<td>20 (26)</td>
<td></td>
</tr>
<tr>
<td>75-84</td>
<td>53 (14)</td>
<td>15 (19)</td>
<td></td>
</tr>
<tr>
<td>≥85</td>
<td>18 (5)</td>
<td>13 (17)</td>
<td></td>
</tr>
<tr>
<td>Days of mechanical ventilation &gt;0</td>
<td>43 (12)</td>
<td>33 (42)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Days in restraints &gt;0</td>
<td>6 (2)</td>
<td>29 (37)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

* Values in second and third columns are number (percentage) of patients in group unless otherwise indicated in first column.

Patients who received the delirium prevention bundle experienced 78% less incidence of delirium.
use of personal assistive devices is a fundamental strategy for improving sensory stimulation in the prevention of delirium.

Sedation cessation, the first step in the delirium prevention bundle, was difficult to achieve because physicians infrequently used the sedation cessation protocol. A protocol led by a nurse or respiratory therapist may make sedation cessation more achievable. Sedation cessation is commonly used to decrease mechanical ventilator days, ICU length of stay, and patient mortality rates.23

Despite efforts to promote sleep in the ICU at night by reducing environmental noise and clustering patient care, that DPB component was difficult to achieve. Sleep promotion suffered from a large amount of missing data on hypnotic agents administered after 2 AM. The aim of the sleep promotion component was to ensure patients got at least 4 hours of sleep per night. Patients had trouble not only falling asleep, but also staying asleep because of the lights and sounds in the ICU.

Likewise, missing data on pain management items compromised findings on nearly 70% of patients. Missing data elements included patients’ comfort goals, reported level of pain, analgesia administration time, and number of analgesic doses administered relative to patients’ complaint of pain.

Mobilizing patients was problematic because of staffing challenges, incongruity between physical therapy and aggressive mobilization guidelines, and lack of appropriate mobilization equipment. Aggressive mobilization efforts by the nursing staff in the intervention group produced impressive, significant results. The nurse manager and unit staff accomplished aggressive mobilization without additional equipment or personnel resources. The nurse manager spent approximately 30% of the workday physically assisting the nursing staff with mobilization of patients and securing additional equipment as needed.

Limitations

One might consider the study design as a limitation because researchers randomized by patient care unit, instead of by individual patients. Researchers intentionally randomized by unit to minimize crossover of the DPB into the control group. Although

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of patients (observations)</th>
<th>Odds ratio(^a) (95% CI)</th>
<th>(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unadjusted model(^b) ((P&lt;.001))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention unit(^c)</td>
<td>447 (1578)</td>
<td>0.21 (0.08-0.53)</td>
<td>.001</td>
</tr>
<tr>
<td>Total adjusted model(^b) ((P&lt;.001))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention unit(^c)</td>
<td>433 (1533)</td>
<td>0.22 (0.08-0.56)</td>
<td>.001</td>
</tr>
<tr>
<td>Age category(^a), (y)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>45-64</td>
<td></td>
<td></td>
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<td>65-74</td>
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<td>75-84</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>(\geq 85)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race(^e)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>1.79 (0.81-3.96)</td>
<td>.15</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>1.28 (0.34-4.80)</td>
<td>.72</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1.85 (0.35-9.89)</td>
<td>.47</td>
<td></td>
</tr>
<tr>
<td>No. of comorbid conditions(^f)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-5</td>
<td>1.26 (0.54-2.98)</td>
<td>.59</td>
<td></td>
</tr>
<tr>
<td>(&gt; 5)</td>
<td>1.72 (0.64-4.65)</td>
<td>.28</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1.22 (0.59-2.52)</td>
<td>.59</td>
<td></td>
</tr>
<tr>
<td>Mechanical ventilation</td>
<td>3.15 (1.67-5.97)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Restraints</td>
<td>2.82 (1.48-5.35)</td>
<td>.002</td>
<td></td>
</tr>
<tr>
<td>(&gt; 3) days in intensive care unit</td>
<td>3.02 (1.35-6.80)</td>
<td>.007</td>
<td></td>
</tr>
</tbody>
</table>

\(a\) Odds ratio is defined as ratio of the odds of a delirium incident in the test group relative to the odds of a delirium incident in the comparison group, also known as “relative risk.”

\(b\) Includes adjustment with “days of stay” term and “day x ICU unit” interaction term.

\(c\) Intervention unit uses category “Control unit” as comparison group.

\(d\) Age odds ratios use category “<45” as comparison group.

\(e\) Race odds ratios use category “White, non-Hispanic” as comparison group.

\(f\) Comorbidity conditions odds ratios use category “<3” as comparison group.
efforts were made to minimize crossover, the nurses in the control group were occasionally pulled to work in the intervention group, where they encountered the DPB. This situation increased the likelihood that the DPB may have influenced those nurses’ nursing practice once they returned to work in the control group.

The lack of a daily sedation cessation protocol for patients receiving mechanical ventilation that was led by a nurse or a respiratory therapist was a limitation of the study, as was the failure of the data collection tool to capture data regarding pain management. The unavailability of patients’ assistive sensory devices limited study findings, and finally, the clinical needs of the critically ill patients made adherence to the designated sleep time challenging.

Research Implications

The study design did not allow for study of the relative contribution of the individual bundle elements to the reduction of delirium risk. In future research, one should consider exploring the contribution of each bundle element to avoid excessive staff burden. Revision of the pain management data elements will provide richer, more meaningful, measurable data, after which one should consider replication and validation of study findings. Future research should include refining the DPB to include the use of unlicensed workers who are not part of the nursing staff to support the direct-care nurses and unlicensed support staff in early mobilization of critically ill patients. Researchers should consider a multisite design that includes community hospitals. Replicating the study in specialized critical care units (e.g., cardiovascular surgery ICU, pulmonary ICU, neuroscience ICU) is another area for future research, as is the use of the DPB as the standard of care while testing a revised DPB.

Clinical Implications

Effective mobilization is burdensome for unit staff to accomplish, particularly for patients receiving mechanical ventilation, who may have multiple catheters, wires, tubes, and drains. Physical therapists do not necessarily participate in the mobilization of such patients because of the lack of a requisite skill that is required in billing for their service. The engagement of trained nonnursing staff to facilitate strength building, endurance, and mobilization may provide a more individualized prescriptive approach to early mobilization.

It is feasible for staff nurses to use the CAM-ICU to assess patients for delirium. Use of the DPB is an effective and feasible strategy to prevent delirium in medical-surgical ICU patients. Hospitals should consider implementing a core model of delirium prevention care that combines evidence-based strategies with nursing interventions that integrate into routine ICU care.

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REFERENCES


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