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## Major Article

# Implementing the comprehensive unit-based safety program model to improve the management of mechanically ventilated patients in Saudi Arabia



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## Key words:

Ventilator-associated events  
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Safety and quality improvement  
Intensive care unit

**Background:** Ventilator-associated events are common in mechanically ventilated patients. They are associated with more days on mechanical ventilation, longer intensive care unit (ICU) stay, and increased risk of mortality. Theoretically, interventions that prevent ventilator-associated events should also reduce associated morbidity. We evaluated the Comprehensive Unit-based Safety Program approach to improve the care of mechanically ventilated patients.

**Methods:** All mechanically ventilated patients admitted to the ICU between October 1, 2015, and October 31, 2016, were prospectively monitored for the development of ventilator-associated events according to the National Healthcare Safety Network criteria. A process care bundle (endotracheal intubation with subglottic suctioning, head-of-bed elevation  $\geq 30^\circ$ , target sedation scores, daily spontaneous awakening trials, spontaneous breathing trials), daily delirium assessment, and an early mobility protocol were instituted. The bundle compliance, ventilator-associated events rates, ICU length of stay, and mortality rate were noted. The database allowed viewing of current rates, trends, and averages of all participating sites.

**Results:** In the study period, 2,321 patients were admitted to the ICU, and 1,231 required mechanical ventilation (10,342 ventilator days). There were 115 ventilator-associated events: 82 ventilator-associated conditions, 15 infection-related ventilator-associated conditions, and 18 possible cases of ventilator-associated pneumonia. The ICU mortality rate was 13.3%, compared with 28.7% for those mechanically ventilated patients with ventilator-associated events ( $P = .0001$ ). There was increased compliance for spontaneous awakening trials (51.5%–76.9%,  $P = .0008$ ) and spontaneous breathing trials (54.2%–72.2%,  $P = .02$ ) and a decrease in infection-related ventilator-associated conditions (4.2–3.5 per 1,000 days), possible cases of ventilator-associated pneumonia (2.1–1.7 per 1,000 days), ICU mortality (45.3%–19.1%,  $P = .045$ ), and

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Conflicts of interest: None declared.

Author contributions: RK was head of the project and oversaw the analytical plan. M.A. oversaw validation of CAM-ICU score in Arabic. G.B. performed data entry. A.M., V.B., I.T., S.Z., and B.N. oversaw the implementation of the CUSP project in their ICU unit. B.K. oversaw implementation and supervision of the mobility protocol. J.A. oversaw supervision of nursing staff. A.M., V.B., I.T., S.Z., and B.N. monitored bundle compliance. H.A., G.B., J.A., A.M., V.B., I.T., S.Z., and B.N. participated in staff education. R.K., M.A., H.A., and G.B. participated in data collection. R.K., M.A., and Y.A. participated in drafting of the manuscript. All authors participated in critical revision of the manuscript for important intellectual content. All authors participated in approval of the final version to be published. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.

ventilator-associated events associated mortality rates (33.3%–8.3%,  $P < .37$ ). Physical therapy participation and mobility were 60.8% and 26.4%, respectively.

**Conclusion:** The implementation of a multipronged program like the Comprehensive Unit-based Safety Program could improve the care processes and outcomes of mechanically ventilated patients.

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In 2004, the Institute for Healthcare Improvement (IHI) 100,000 lives campaign introduced the concept of a “care bundle” for the prevention of ventilator-associated pneumonia (VAP).<sup>1</sup> A care bundle identifies a set of key interventions that, when implemented together as a best practice approach, are expected to improve patient outcomes.<sup>2</sup> In recent years, approaches to the care of mechanically ventilated patients have evolved from fixating only on VAP prevention to focusing on a more comprehensive strategy based on the recent finding of benefit from the combined approach of the ABCDE bundle (Awakening and Breathing trial Coordination, Delirium management and Early mobilization)<sup>3</sup> and the Wake Up and Breathe Collaborative trial.<sup>4</sup>

Although previous improvement initiatives used VAP rates as the primary outcome measure, it has been increasingly recognized that mechanical ventilation (MV) causes harm beyond just VAP. Hence, wider outcome measures were needed to determine the value and success of safety programs. The Centers for Disease Control and Prevention, together with several critical care societies, convened a group to address the limitations of the National Healthcare Safety Network definition of injury caused by MV, and they proposed a new approach in 2013.<sup>5</sup> Besides VAP, the new algorithm uses objective criteria for the diagnosis of ventilator-associated events and conditions and infection-related ventilator-associated complications. This approach thereby broadens the definition of harm suffered by ventilated patients beyond pneumonia to include pulmonary edema, atelectasis, and acute respiratory distress syndrome.<sup>6</sup>

The Comprehensive Unit-based Safety Program (CUSP) approach was developed by patient safety researchers at the Johns Hopkins Hospital, Baltimore, Maryland.<sup>7</sup> CUSP is designed to improve teamwork and safety culture and to guide organizations to learn from mistakes by using a validated and structured framework.<sup>8</sup> CUSP involves a repetitious process that trains a multidisciplinary team about the science of safety, asking them to identify defects, learn from them, implement improvement tools, and establish a partnership with senior leaders.<sup>9</sup> Key components include identifying evidence-based interventions that improve the outcomes of interest, converting these interventions into behaviors, placing value on the wisdom of frontline staff, and empowering frontline staff to be actively involved in safety improvements. The CUSP intervention has achieved great success in reducing VAP, central line–associated bloodstream infections, catheter-associated urinary tract infections, surgical care complications, mortality, and associated costs.<sup>10,11</sup>

Our hospital's Infection Control and Intensive Care departments implemented a VAP prevention program in 2003, which led to the reduction of VAP rates from 19.1 to 0 per 1,000 ventilator days in 2015.<sup>12</sup> Despite our success in reducing the VAP rates, our data indicated that intensive care unit (ICU) length of stay (LOS) (9.8 vs 8.5 days) and mortality rates (36% vs 28.7%) were both higher in the post-VAP prevention bundles compared with the pre-VAP prevention intervention group,<sup>12</sup> implying that merely decreasing the rate of VAP was not enough. We needed to implement other strategies to optimize patient care to improve outcomes. We joined the Johns Hopkins Armstrong Institute Comprehensive Unit-Based Safety Program for Mechanically Ventilated Patients and Ventilator-Associated Pneumonia (CUSP 4 MVP-VAP) project in October 2015 with the objective of

improving the care delivery process and reducing the mortality of our mechanically ventilated patients. This article describes the impact of implementing the CUSP 4 MVP-VAP project on patient care in our ICUs at the Ministry of National Guard Health Affairs in Riyadh.

## METHODS

### Study design

This was a prospective quality improvement and patient safety study to describe the impact of implementing the CUSP 4 MVP-VAP in a cohort of patients in our ICUs.

### Setting and organization of the ICUs

This improvement project was performed at King Abdul Aziz Medical City in Riyadh, Saudi Arabia, for all adult patients who received invasive MV in the ICU between October 1, 2015, and October 31, 2016. The ICU had 60 beds and was covered by onsite board-certified intensivists 24 hours per day, 7 days per week, with a nurse-to-patient ratio of approximately 1:1 and a respiratory therapist-to-patient ratio of approximately 1:5. The hospital was a 1,000-bed tertiary-care center accredited by the Joint Commission International, with an active Infection Prevention and Control Program that collaborated with the ICU medical and nursing staff to ensure the implementation and monitoring of infection control practices. The Institutional Review Board and King Abdullah International Medical Research Center Ethics Committee of National Guard Health Affairs, Riyadh, Saudi Arabia, approved this study and waived the requirement for informed consent.

### Team formation

A multidisciplinary CUSP 4 MVP-VAP team was created in September 2015 to implement evidence-based practices for all mechanically ventilated patients. The group was led by an intensivist but included other physicians, nurses, respiratory therapists, physical therapists, infection control practitioners, and quality management personnel.

### Data collection

The team monitors (nurses and research coordinators) were trained on data collection and monitored compliance on a daily basis. They reviewed the electronic charts of all patients on MV in the ICU daily. The implementation of each care process bundle element, along with the Confusion Assessment Method for the ICU (CAM-ICU) score and the maximum level of mobility for that day were recorded on a standard data collection form and entered into the Johns Hopkins Armstrong Institute database, which generated a compliance rate for our hospital. This compliance rate was compared with those of other institutions in the project, so that we could benchmark our performance. If a component of the bundle was not performed, the inspectors used this moment to elucidate any barriers to the implementation of the particular element. The first month (October 2015) was considered the baseline data point.

Diagnosis, definition, and classification of VAP

We defined a ventilator-associated condition (VAC) as an increase in  $FiO_2 \geq 0.2$  or positive end expiratory pressure (PEEP)  $\geq 3$  cm  $H_2O$  sustained for  $\geq 2$  calendar days in a patient on MV for  $> 2$  days with a baseline period of stability or improvement, defined by  $\geq 2$  calendar days of stable or decreasing daily  $FiO_2$  or PEEP values.<sup>13</sup> An infection-related ventilator-associated complication (IVAC) occurred on or after 3 days of MV when a patient met the criteria for a VAC plus both of the following: temperature  $> 38^\circ C$  or  $< 36^\circ C$  and white blood cell count  $\geq 12,000$  or  $\leq 4,000$  cells/ $mm^3$ , as well as a new antimicrobial agent(s) started and continued for  $\geq 4$  calendar days.<sup>13</sup> A possible VAP (PVAP) occurs in a patient with the criteria for an IVAC and 1 of the following: positive culture meeting quantitative or semiquantitative thresholds from endotracheal aspirate ( $\geq 10^5$  colony-forming units [CFU]/mL), bronchoalveolar lavage ( $\geq 10^4$  CFU/mL), lung tissue ( $\geq 10^4$  CFU/g), or protected specimen brush ( $\geq 10^3$  CFU/mL); purulent respiratory secretions ( $> 25$  neutrophils and  $< 10$  squamous epithelial cells per low-power field plus organism identified from sputum, endotracheal aspirate, bronchoalveolar lavage, lung tissue, protected specimen brush); or organism identified from pleural fluid, lung histopathology, *Legionella* tests, or diagnostic test on respiratory secretions for influenza virus, respiratory syncytial virus, adenovirus, parainfluenza virus, rhinovirus, human metapneumovirus, or coronavirus. Ventilator-associated events (VAEs) are the sum of VAC, IVAC, and PVAP. All patients on MV were reviewed prospectively and independently by 2 physicians who confirmed the diagnosis.<sup>13</sup> The incidence of VAE, VAC, IVAC, and PVAP was expressed as cases per 1,000 ventilator-days.

Project overview

The project had 3 arms: daily care process, early mobility, and low tidal volume ventilation. Participation could be in 1, 2, or all 3 of the arms (Fig 1). Our hospital selected daily care process and early mobility, because low tidal volume ventilation was already a standard practice in our ICUs for all patients on MV.

I. Daily Care Process

a. Endotracheal tube with subglottic suctioning (SUB-G EET)

All patients anticipated to need MV for  $> 48$  hours were intubated with a TaperGuard evacuation oral tracheal tube (Covidien, Mansfield, MA). The data collectors inspected patients for the presence of SUB-G EET when indicated and documented whether the subglottic drainage lumen was connected to the wall suction at the appropriate intermittent negative pressure.<sup>12</sup>

b. Head of bed (HOB)  $\geq 30^\circ$

The hospital was equipped with Hill-Rom hospital beds (Hill-Rom, Chicago, IL). The angle of the HOB was measured with an electronic device or built-in protractor present on the bed. Elevation of the HOB was the default order for all patients on MV. Exceptions were hypotension; unstable physiological status; low cardiac index; recent cervical, thoracic, or lumbar surgery or instability; ventricular assist device; intra-aortic balloon pump; open abdomen; and patient refusal.<sup>12</sup> This element required that the data collector directly observe the angle of the HOB.

c.. Spontaneous Awakening Trials (SAT)

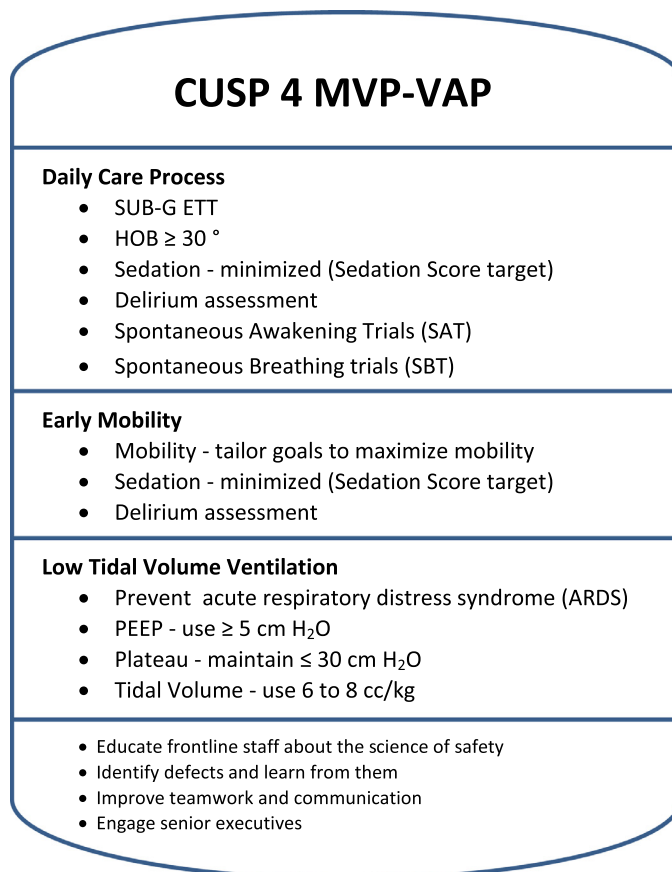


Fig 1. Project overview: improving the care of mechanically ventilated patients.

A nurse-led sedation vacation protocol was implemented that allowed the nurse to stop all sedation at 8:00 a.m. if the patient fulfilled certain criteria.<sup>12</sup> The SAT was continued until either the patient was agitated or fully awake and could be assessed for delirium. For this element, the data collectors asked the bedside nurse whether sedation was interrupted. They then reviewed the patient's daily flow sheet to confirm the nurse's statement. If the chart did not reflect sedation interruption, then this bundle was considered noncompliant.

#### d. Sedation-minimized (Sedation Score target)

Sedation orders were entered via a standardized computer order set, with dosage adjusted based on the patient's weight and renal and hepatic functions. In addition, a target sedation score (Richmond Agitation-Sedation Scale [RASS]) had to be assigned to the patient by the physician before the order could be completed. The targeted RASS was addressed daily in rounds, and the nurse's documentation was examined to determine whether the patient's actual sedation score matched the planned target.

#### e. Spontaneous Breathing Trials (SBTs)

A ventilator weaning protocol was drafted that allowed respiratory therapists to wean all patients on MV starting at 9:00 a.m., 1 hour after the sedation was held. Patients who met the following criteria were weaned to pressure support ventilation:

- Awake or off sedation with RASS  $\geq 3$  or for  $> 1$  hour
- Spontaneous inspiratory efforts
- Oxygen saturation  $> 88\%$
- $FiO_2 \leq 0.5$
- PEEP  $< 8$  cm H<sub>2</sub>O

The spontaneous breathing trial was conducted by placing the patient on pressure support (5–8 cm H<sub>2</sub>O) with or without 5 cm H<sub>2</sub>O PEEP. Both the patient's ICU flow sheet and respiratory therapist's notes were monitored to assess this element.

#### f. Delirium assessment

The CAM-ICU advocated by the Society of Critical Care Medicine was used to evaluate for delirium. In our hospital the assessment tool was translated into Arabic, and, after a validation process of several Plan-Do-Study-Act cycles, staff were trained to perform this appraisal. The CAM-ICU score was recorded at 10 a.m. daily and documented<sup>7</sup>:

- P if the patient is positive for delirium based on CAM-ICU assessment
- N if the patient is negative for delirium based on CAM-ICU assessment
- UTA if unable to assess (ie, RASS =  $-4$  or  $-5$ )
- X if CAM-ICU assessment was not completed

- NK if CAM-ICU was completed, but results are not known
- NK was also used if it was not known whether the CAM-ICU was performed

## II. Early Mobility

### a. Mobility—tailor goals to maximize mobility

All patients admitted to the ICU had standing orders for physical therapy (PT) and occupational therapy as part of the admission order sets. The level of mobility (0 to 8) was recorded: 0: passively rolled or exercised; 1: transfer from bed to chair without standing; 2: sitting in bed/exercising in bed; 3: sitting at edge of bed; 4: standing with or without assistance; 5: transfer from bed to chair with standing; 6: marching in place; 7: walking at least 4 steps; and 8: unknown what level of activity occurred. Additionally, any perceived barrier to achieving a higher level of mobility was documented.

### Communications

There were bimonthly meetings among the CUSP team and monthly webinars with the Armstrong Institute.

### Analysis

Frequencies and percentages were used for categorical variables, whereas means with standard deviations were presented for continuous variables. The Fisher exact test was used to evaluate differences between categorical variables, and the t test was used to evaluate differences between continuous variables. Comparisons for mortality, LOS, and MV days were made, with the first month (October 2015) used as the base line. The unadjusted risk of death from developing a VAE was compared using the Fisher exact test; for those patients receiving MV who did not develop a VAE.  $P < .05$  was considered statistically significant.

## RESULTS

During the study period 2,321 patients were admitted to the ICU; 1,231 (53%) required MV, with 1,399 episodes of MV and 10,342 ventilator days.

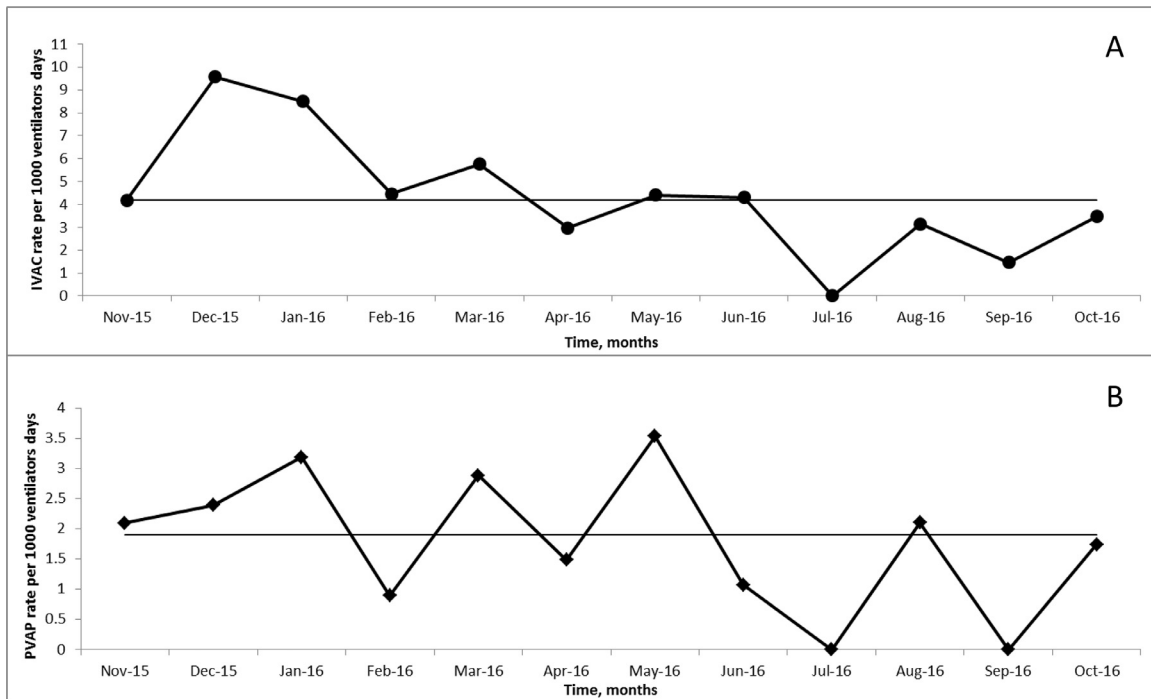
There were 115 VAEs, of which 82 were VACs, 15 IVACs, and 18 PVAPs (Table 1, Fig 2). The overall ICU mortality rate was 13.3% compared with 28.7% for those with development of a VAE ( $P = .0001$ ). The ICU mortality rate for mechanically ventilated patients decreased from 32.8% to 19.1% ( $P = .045$ ), whereas the mortality rate associated with VAEs decreased from 33.3% to 8.3% ( $P = .37$ ) over the study period (Fig 3). There were significant increases in MV days and ICU LOS for patients with VAEs (Table 1).

The mean care bundle compliance for all the elements was 82.8%. The compliance rates for endotracheal intubation with subglottic

**Table 1**  
CUSP 4 MVP VAP outcomes

	MV patients	VAE	VAC	IVAC	PVAP	P value
Episodes		115	82	15	18	
		11.12	7.93	1.45	1.74	
Rates per 1000 ventilator days		21.18 $\pm$ 13.34	20.78 $\pm$ 7.83	17.55 $\pm$ 8.69	25.25 $\pm$ 18.54	
MV days $\pm$ SD	7.46 $\pm$ 2.29					$< .0001$
ICU LOS, days $\pm$ SD	8.32 $\pm$ 2.57	25.43 $\pm$ 15.05	23.86 $\pm$ 13.15	21.27 $\pm$ 9.41	36.92 $\pm$ 19.98	$< .0001$
Mortality rates, %	24.6	28.7	31.7	26.7	16.7	NS
Unadjusted risk of mortality, OR (95% CI, P value)		1.23 (0.86–1.58, 0.39)	1.42 (0.87–2.31, 0.19)	1.07 (0.34–3.45, 0.15)	0.59 (0.17–2.07, 0.77)	

CI, confidence interval; CUSP 4 MVP VAP, Comprehensive Unit-Based Safety Program for Mechanically Ventilated Patients and Ventilator-Associated Pneumonia; ICULOS, intensive care unit length of stay; IVAC, infection-related ventilator-associated complications; MV, mechanical ventilator; NS, nonsignificant; OR, odds ratio; PVAP, possible ventilator-associated pneumonia; SD, standard deviation; VAC, ventilator-associated conditions; VAE, ventilator-associated events.

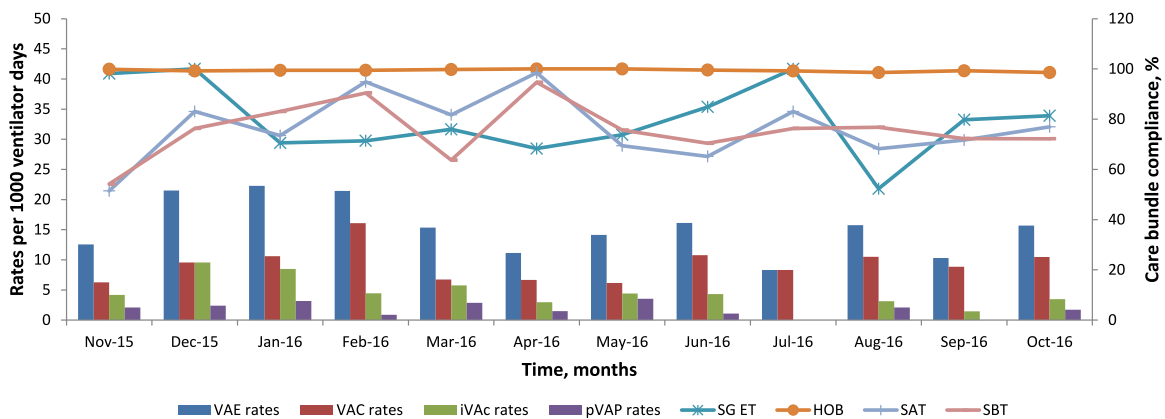


**Fig 2.** Run chart. (A) IVAC rates per 1,000 ventilator days, (B) PVAP rates per 1,000 ventilator days (horizontal line is the median). IVAC, infection-related ventilator-associated complications; PVAP, possible ventilator-associated pneumonia.

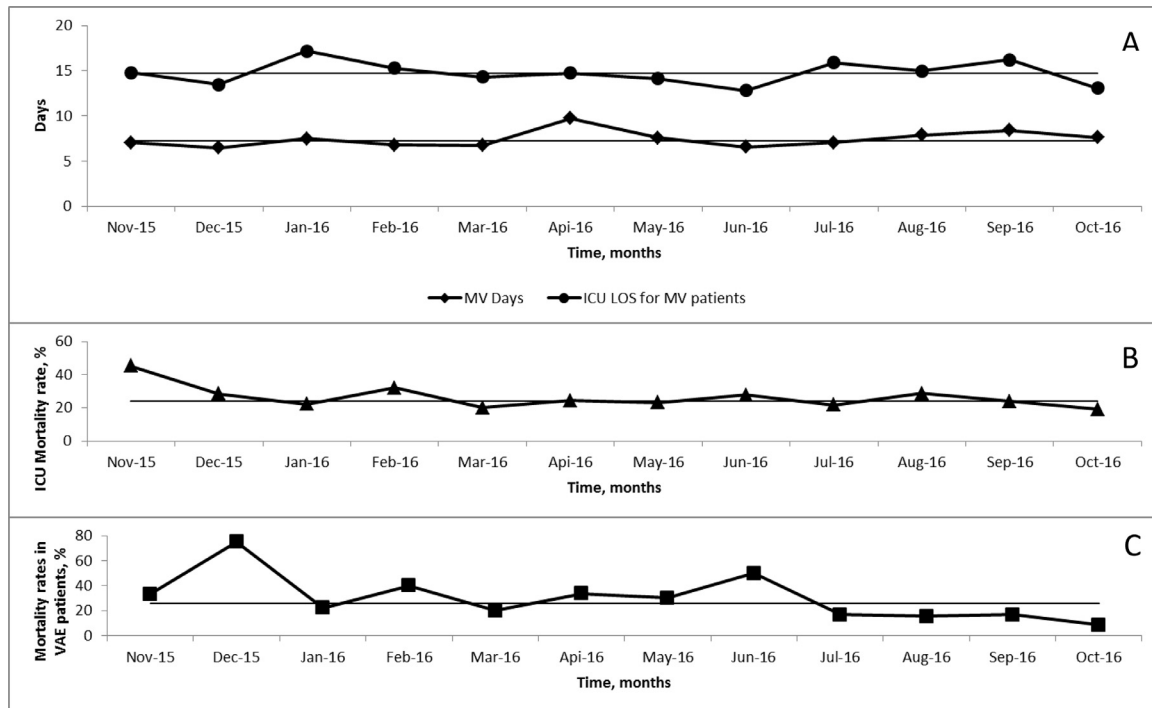
suctioning, HOB elevation  $\geq 30^\circ$ , daily SATs, and SBTs were 79.7%, 98.6%, 76.95%, and 72.2%, respectively. The greatest improvement was seen in SATs, which increased from 51.5% in November 2015 to 76.9% in October 2016 (25.49% absolute increase,  $P = .0008$ ). This was followed by SBTs, which increased from 54.2% to 72.2% (18% absolute increase,  $P = .02$ ). The compliance of endotracheal intubation with subglottic suctioning decreased by 16.8% ( $P = .0006$ ), whereas for HOB it remained around 99% throughout the project (Fig 4).

The target RASS was achieved in 52.8% of mechanically ventilated patients, whereas 40.6% had a RASS of  $-1$  to  $+1$ . However, 90.5% of patients had their SBT done off sedation, and the percentage of mechanically ventilated patients without sedation increased from 36.1% to 50.9% ( $P = .06$ ). The delirium assessment compliance rate was 97.3%, with 82.8% reporting a negative CAM-ICU. The percentage of incorrectly reported CAM-ICU scores was 38.3%, which significantly decreased from 67.5% (November 2015) to 10.7% (October 2016) ( $P = .0001$ ).

The PT and occupational therapy participation rates were 60.8% and 26.4%, respectively. Only 1.8% of mechanically ventilated patients were moved from bed to chair. The most frequent level of mobility achieved was 0 (passively rolled or exercised [83.2%]). The other levels were 1 (transfer from bed to chair without standing [4.8%]); 2 (sitting in bed/exercising in bed [6.9%]); 3 (sitting at edge of bed [0.9%]); 4 (standing with or without assistance [0.1%]); 5 (transfer from bed to chair with standing [0.4%]); 6 (marching in place [0.2%]); walking at least 4 steps [0.9%]; and 8 (unknown what level of activity occurred [0.7%]). The most common perceived barriers to mobilization were the following: patient weakness (20%), hemodynamic instability (18.6%), low RASS on sedation (15.6%), low RASS off sedation (11%), and the patient labeled comfort care (9.5%). However, the most documented adverse event was circulatory or respiratory instability (22.7%).



**Fig 3.** Run charts. (A) Mechanical ventilation (MV) days and intensive care unit length of stay (ICU LOS) for MV patients; (B) Intensive care unit mortality rate; (C) Mortality in VAE patients. Horizontal lines are medians. HOB, head of bed; IVAC, infection-related ventilator-associated complication; PVAP, possible ventilator-associated pneumonia; SAT, spontaneous awakening trials; SBT, spontaneous breathing trial; SG ET, endotracheal tube with subglottic suctioning; VAC, ventilator-associated conditions; VAE, ventilator-associated events; VAP, ventilator-associated pneumonia.



**Fig 4.** Care bundle compliance with VAE, VAC, IVAC and PVAP rates per 1,000 ventilator days. ICU, intensive care unit; ICU LOS, intensive care unit length of stay; IVAC, infection-related ventilator-associated complication; MV, mechanical ventilation; PVAP, possible ventilator-associated pneumonia; VAC, ventilator-associated conditions; VAE, ventilator-associated events.

## DISCUSSION

In our study the implementation of the multifaceted CUSP 4-MVP VAP approach resulted in an increase in SAT (51.5%-76.9%,  $P = .0008$ ) and SBT (54.2%-72.2%,  $P = .02$ ) compliance; an increase in the number of mechanically ventilated patients without sedation (36.1%-50.9%,  $P = .06$ ); and a decrease in IVACs (4.2-3.5 per 1,000 MV days), PVAP (2.1-1.7 per 1,000 MV days), ICU mortality rates (45.3%-19.1%,  $P = .045$ ), and VAE mortality rates (33.3%-8.3%,  $P < .37$ ). Finally, we found that our compliance with PT participation and mobility were suboptimal.

In 2013, the Centers for Disease Control and Prevention replaced their VAP surveillance definitions with VAE objective criteria, in response to a series of concerns about the traditional VAP definitions, including their complexity, subjectivity, burden on surveyors, lack of comparability between institutions, narrow focus, and limited association with adverse outcomes.<sup>14</sup> Furthermore, VAP did not consistently identify patients at increased risk for poor outcomes, and interventions that reduced VAP rates often had no effect on patient-centered outcomes, such as duration of MV or hospital mortality.<sup>15</sup> This is demonstrated in our previous VAP prevention project, in which, in spite of the rate of VAP decreasing from 19.1 to 0 per 1,000 ventilator days, the days on MV remained unchanged, whereas the ICU LOS and ICU and hospital mortality rates all significantly increased in the postbundle implementation group.<sup>12</sup> The failure of most VAP prevention strategies to yield better outcomes for ventilated patients raises the question of whether VAP is the best target to drive surveillance and safety prevention programs, because quality improvement initiatives must focus on identifying and preventing objective complications that are unambiguously associated with poor outcomes.<sup>15</sup> Thus the explicit intent of the a VAE criteria was to broaden the focus of quality surveillance beyond just pneumonia.

Klompas et al,<sup>16</sup> in a retrospective study of 20,356 episodes of MV found that VAEs were associated with more days to extubation (relative risk, 3.12 [95% confidence interval {CI}, 2.96-3.29]), more days to hospital discharge (relative risk, 1.46 [95% CI 1.37-1.55]), and higher hospital mortality risk (odds ratio, 1.98 [95% CI 1.60-2.44]). Similarly, Zhu and associates<sup>17</sup> in a prospective study of 2,356 MV patients observed that,

compared with patients without VAEs, those with VAEs had longer ICU LOSs (by 6.2 days), longer duration on MV (by 7.7 days), and a higher hospital mortality rate (50.0% vs 27.3%). More recently, in a multivariable hazard analysis IVAC was independently associated with a higher hospital mortality rate (hazard ratio 2.42, [95% CI 1.39-4.20],  $P = .002$ ).<sup>18</sup> Our data also demonstrated that VAEs are associated with increased mechanical ventilator days, ICU LOS, and ICU mortality, highlighting the point that a VAE appears to be a clinically important event.

The synthesis of the VAE criteria has created a new opportunity for health care facilities to reexamine their approach to preventing complications and improving outcomes of mechanically ventilated patients. VAE surveillance has a quality metric character and appears to identify potential safety opportunities to improve care and outcomes for patients.<sup>19</sup> Theoretically, interventions most likely to prevent VAEs are those that help patients avoid intubation, minimize the duration of MV, or prevent the conditions that most commonly trigger a VAE (pneumonia, volume overload, acute respiratory distress syndrome, and atelectasis).<sup>20</sup> Use of high-flow nasal oxygen for hypoxemic and noninvasive ventilation for hypercapnic respiratory failure may avoid intubation. Minimizing sedation, performing daily coordinated SATs and SBTs, and perhaps early mobility are strategies to decrease the duration of MV. Strategies to prevent pneumonia, volume overload, acute respiratory distress syndrome, and atelectasis include HOB elevation, conservative fluid management, conservative blood transfusion thresholds, low tidal volume ventilation, and early mobility.<sup>14</sup> These interventions are consistent with the best care practices advocated by the ABCDEF bundle, the Surviving Sepsis Campaign, and the Society for Healthcare Epidemiology of America's recommendations to prevent VAP.<sup>21-23</sup> Growing data support that implementing and optimizing these practices can lower VAE rates and improve patient outcomes. The CUSP 4MVP-VAP project was engendered to continue this wider focus of implementing an evidence-based practice bundle while caring for MV patients.

Our study showed that SAT and SBT rates were 76.5% and 76%, respectively. This is similar to data published from 56 ICUs in Maryland and Pennsylvania with 69,417 ventilated patient-days in which compliance with SAT and SBT was 77.5% and 71%, respectively.<sup>24</sup> Our ICUs

have a nurse-led sedation vacation protocol and target sedation scores for all sedated patients. Furthermore, we have an SBT protocol that is respiratory therapist driven. Our low compliance rates could highlight the difficulty of translating evidence-based practice to bedside, or they may represent a defect in our protocol design preventing meaningful change in the practice behavior and culture of our front-line staff.

Our data demonstrated that 1.8% of mechanically ventilated patients were mobilized into a chair, and only 60.1% were evaluated by a physical therapist while receiving MV. Early and progressive mobilization has been demonstrated to be both safe and feasible for patients admitted to critical care.<sup>25</sup> Implementing early mobility programs has led to improvements in physical function and mobility levels, significant reductions in both ICU and hospital LOS, and ventilation days and a reduction in both the incidence and duration of delirium.<sup>26</sup> In fact, the ABCDE bundle is centered on approaches to implement the Integrated pain, agitation, and delirium clinical practice guidelines to reduce delirium and weakness related to oversedation, prolonged mechanical ventilation, and immobility in mechanically ventilated critically ill patients.<sup>27</sup> Despite this, point prevalence surveys have shown that rehabilitation levels remain low. Goddard and colleagues,<sup>28</sup> using a Theoretical Domains Framework of behavior change, found that the social influences domain (local champions, ICU leadership, discord between team members and family members) and behavioral regulation domain (feedback and having a unit protocol) may act as barriers or facilitators to early rehabilitation. Based on these findings, we formulated a multidisciplinary team and a mobility protocol to provide tools to standardize the care of our patients (Appendix 1).

The strengths of our study include the use of prospective collected data, a large sample size with all patients observed daily until ICU discharge, and a common surveillance system using standardized definitions with a Web-based portal for real-time reports. Despite its strengths, our study has several potential limitations. First, a reduction in VAE rates might be beyond the effect of just implementing the bundle, because the VAE rates might have decreased secondary to other simultaneous infection control projects in our ICUs. Second, this was not a preintervention and postintervention study, so analyzing the full effect of the bundle is difficult. Third, despite having standardized data collection techniques and sources, team members might be motivated to demonstrate improvement and potentially could bias results. Fourth, we report VAE rates per 1,000 ventilator days, and any intervention that decreases ventilator days may paradoxically increase VAE rates and underestimate the impact of the intervention on VAE outcomes. Fifth, ICU LOS may depend on multiple complex factors and not only VAEs. Finally, the data represent a cohort study from a single center, and our inventions might not be generalized to other institutions.

**CONCLUSION**

Sustaining a safety culture should be a public health priority of all health care facilities. A strategic framework for preventing VAEs is to pair clinical bundle with practice behavior and culture change interventions. The implementation of a multipronged program like the CUSP 4MVP-VAP that places ownership on front-line staff, reduces

**APPENDIX A Early mobility protocol**

Ministry of National Guard Health Affairs, Riyadh ICU Department Mobility Protocol					
Initial Patient Assessment	LEVEL I	LEVEL II	LEVEL III	LEVEL IV	LEVEL V
Assess ALL patient's mobility level within 24 hours of admission to the ICU and reassess every 24 hours.					
Start at Level II if the patient meets all of the criteria below, otherwise start at Level I.	RASS -5 to -3	RASS -2 to -1	RASS -1 to 0	RASS 0 to +1	RASS 0 to +1
<b>Mobility Assessment Criteria</b> <b>Neurological</b> <ul style="list-style-type: none"> <li>RASS &gt; -3 (that is: -2, -1, 0, +1,)</li> <li>Follows 3-4 commands</li> <li>ICP &lt; 20cmH<sub>2</sub>O</li> </ul> <b>Respiratory</b> <ul style="list-style-type: none"> <li>PEEP &lt;10mmHg or FiO<sub>2</sub>&lt;60%</li> <li>SpO<sub>2</sub>&gt;90%</li> <li>RR between 5 and 40/min</li> </ul> <b>Cardiovascular</b> <ul style="list-style-type: none"> <li>HR between 50 and 140/min</li> <li>MAP between 55 and 140mmHg</li> <li>SBP between 90 and 180mmHg</li> <li>Small dose of vasopressors: Norepinephrine(NE) ≤0.5mcg/kg/min or Dopamine(DOP) ≤10mcg/kg/min</li> <li>No increase in dose of vasopressor in last 2 hours i.e. NE by ≥0.1mcg/kg/min or DOP by 5mcg/kg/min</li> <li>No myocardial infraction (within the last 24 hours)</li> </ul> <b>Others</b> <ul style="list-style-type: none"> <li>No Active bleeding</li> <li>No open abdominal wound</li> <li>No unstable spinal or limb fractures</li> <li>No femoral sheath</li> </ul>	<b>Goal:</b> <ul style="list-style-type: none"> <li>Passive ROM</li> </ul>	<b>Goals:</b> <ul style="list-style-type: none"> <li>Sitting upright</li> <li>Move arms against gravity</li> <li>Transfer to chair</li> </ul>	<b>Goals:</b> <ul style="list-style-type: none"> <li>Increase trunk strength</li> <li>Move legs against gravity</li> <li>Transfer to chair</li> <li>Access readiness to weight bear</li> </ul>	<b>Goals:</b> <ul style="list-style-type: none"> <li>Stand with assistance</li> <li>Weight bear</li> <li>Transfer to chair</li> </ul>	<b>Goals:</b> <ul style="list-style-type: none"> <li>Stand with little assistances (1 person)</li> <li>March in place</li> <li>Ambulation</li> <li>Perform ADL</li> </ul>
	<b>Body Positioning</b> HOB ≥ 30° Turning every 2 hours	<b>Body Positioning</b> •HOB ≥ 30° •Turning every 2 hours •Passive transfer to chair	<b>Body Positioning</b> •HOB ≥ 30° •Sitting at edge of bed •Passive transfer to chair	<b>Body Positioning</b> •HOB ≥ 30° •Active transfer to chair •Standing with assistance	<b>Body Positioning</b> •HOB ≥ 30° •Active transfer to chair •Stand and ambulate
	<b>Activity</b> <ul style="list-style-type: none"> <li>Passive ROM x2/d</li> <li>Continuous lateral rotation therapy</li> <li>Reverse trendelenburg 20° daily for 15min.</li> </ul>	<b>Activity</b> <ul style="list-style-type: none"> <li>Passive/active ROM x3/d</li> <li>HOB 45 x15min</li> <li>HOB 45, legs dependent position x 15min</li> <li>Full chair mode for 20min x2/d</li> <li>Passive transfer to chair</li> </ul>	<b>Activity</b> <ul style="list-style-type: none"> <li>Passive/active ROM x3/d</li> <li>Resistance training x1/d</li> <li>Arm cycle in bed x1/d</li> <li>Full chair mode for 60min x2/d</li> <li>Sitting at edge of bed with legs dangling</li> <li>Transfer to chair if demonstrate trunk stability for 20min x2/d</li> </ul>	<b>Activity</b> <ul style="list-style-type: none"> <li>Passive/active ROM x3/d</li> <li>Resistance training x1/d</li> <li>Arm cycle in bed x1/d</li> <li>Full chair mode—remove footboard 60min x2/d</li> <li>Transfer to chair for 30min x2/d</li> <li>Stand attempt if patient can move leg against gravity</li> <li>Transfer to chair</li> </ul>	<b>Activity</b> <ul style="list-style-type: none"> <li>Passive/active ROM x3/d</li> <li>Resistance training x1/d</li> <li>Stands for &gt;1min x3/d</li> <li>Marches in place x2/d</li> <li>Ambulate to chair x2/d</li> <li>Encourage ADL</li> </ul>
	<b>Who to do?</b> Nurse, PCT and care technician (PCT)	<b>Who to do?</b> Nurse, PCT and RT if on ventilator	<b>Who to do?</b> Nurse, PCT, PT and RT if on ventilator	<b>Who to do?</b> Nurse, PCT, PT and RT if on ventilator	<b>Who to do?</b> Nurse, PCT, PT and RT if on ventilator
	<b>Advance to Level II when:</b> <ul style="list-style-type: none"> <li>Acceptable vitals and vent setting</li> <li>Tolerating level I activities</li> </ul>	<b>Advance to Level III when:</b> <ul style="list-style-type: none"> <li>Tolerating level II activities</li> <li>Tolerates active ROM</li> <li>Tolerates leg dependent position</li> </ul>	<b>Advance to Level IV when:</b> <ul style="list-style-type: none"> <li>Tolerating level III activities</li> <li>Actively assist in q2 turning</li> <li>Tolerates full chair position</li> </ul>	<b>Advance to Level V when:</b> <ul style="list-style-type: none"> <li>Tolerating level IV activities</li> <li>Tolerates full chair position</li> <li>Tolerates partial weight bearing</li> </ul>	Progressively increase ambulation distance
<b>DO NOT perform PROM if there is:</b> (Get PT evaluation before nurse imitate PROM) 1. Limb Contractions 2. Spasticity 3. Flaccidity 4. Fractures 5. Patient resisting 6. Documented history of osteoporosis/osteopenia	<b>Start Level I</b>	<b>Start Level II</b>			
	<b>Dr. Yaseen Arabi</b> Chairman, Department of Intensive Care	<b>Mr. John Alchin</b> Director of Clinical Nursing, Nursing Administration		<b>Mr. Emad Mofthah</b> Supervisor Physiotherapy, Department of Rehabilitation	



complexity, provides standardized tools, engages executives, and uses communication tools to strengthen teamwork could improve the care processes and outcomes of mechanically ventilated patients.

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### References

- Eom JS, Lee MS, Chun HK, Choi HJ, Jung SY, Kim YS, et al. The impact of a ventilator bundle on preventing ventilator-associated pneumonia: a multicenter study. *Am J Infect Control* 2014;42:34–7.
- Cinel I, Dellinger RP. Guidelines for severe infections: are they useful? *Curr Opin Crit Care* 2006;12:483–8.
- Pandharipande P, Banerjee A, McGrane S, Ely EW. Liberation and animation for ventilated ICU patients: the ABCDE bundle for the back-end of critical care. *Crit Care* 2010;14:157.
- Klompas M, Anderson D, Trick W, Babcock H, Kerlin MP, Li L, et al. The preventability of ventilator-associated events. The CDC Prevention Epicenters Wake Up and Breathe Collaborative. *Am J Respir Crit Care Med* 2015;191:292–301.
- Aad G, Abajyan T, Abbott B, Abdallah J, Abdel Khalek S, Abdelalim AA, et al. Search for direct top squark pair production in final states with one isolated lepton, jets, and missing transverse momentum in  $\sqrt{s} = 7$  TeV pp collisions using 4.7 fb<sup>-1</sup> of ATLAS data. *Phys Rev Lett* 2012;109:211803.
- Klompas M. Complications of mechanical ventilation—the CDC's new surveillance paradigm. *N Engl J Med* 2013;368:1472–5.
- Aad G, Abbott B, Abdallah J, Abdelalim AA, Abdesselam A, Abidinov O, et al. Observation of a new  $\chi(b)$  state in radiative transitions to  $\Upsilon(1S)$  and  $\Upsilon(2S)$  at ATLAS. *Phys Rev Lett* 2012;108:152001.
- Pronovost PJ, Berenholtz SM, Goeschel CA, Needham DM, Sexton JB, Thompson DA, et al. Creating high reliability in health care organizations. *Health Serv Res* 2006;41(Pt 2):1599–617.
- Richter JP, McAlearney AS. Targeted implementation of the Comprehensive Unit-Based Safety Program through an assessment of safety culture to minimize central line-associated bloodstream infections. *Health Care Manage Rev* 2018;43:42–9.
- Khan RM, Aljuaid M, Aqeel H, Aboudeif MM, Elatwey S, Shehab R, et al. Introducing the Comprehensive Unit-based Safety Program for mechanically ventilated patients in Saudi Arabian Intensive Care Units. *Ann Thorac Med* 2017;12:11–6.
- Pottenger BC, Davis RO, Miller J, Allen L, Sawyer M, Pronovost PJ. Comprehensive Unit-based Safety Program (CUSP) to improve patient experience: how a hospital enhanced care transitions and discharge processes. *Qual Manage Health Care* 2016;25:197–202.
- Khan R, Al-Dorzi HM, Al-Attas K, Ahmed FW, Marini AM, Mundekkadani S, et al. The impact of implementing multifaceted interventions on the prevention of ventilator-associated pneumonia. *Am J Infect Control* 2016;44:320–6.
- Centers for Disease Control and Prevention. Ventilator-Associated Event (VAE). Available from: [https://www.cdc.gov/nhsn/pdfs/pscmanual/10-vae\\_final.pdf](https://www.cdc.gov/nhsn/pdfs/pscmanual/10-vae_final.pdf). Accessed October 12, 2017.
- Klompas M. Ventilator-associated events 5 years later. *Respir Care* 2017;62:1501–3.
- Cocoros NM, Klompas M. Ventilator-associated events and their prevention. *Infect Dis Clin North Am* 2016;30:887–908.
- Klompas M, Kleinman K, Murphy MV. Descriptive epidemiology and attributable morbidity of ventilator-associated events. *Infect Control Hosp Epidemiol* 2014;35:502–10.
- Zhu S, Cai L, Ma C, Zeng H, Guo H, Mao X, et al. The clinical impact of ventilator-associated events: a prospective multi-center surveillance study. *Infect Control Hosp Epidemiol* 2015;36:1388–95.
- Kobayashi H, Uchino S, Takinami M, Uezono S. The impact of ventilator-associated events in critically ill subjects with prolonged mechanical ventilation. *Respir Care* 2017;62:1379–86.
- Klompas M, Berra L. Should ventilator-associated events become a quality indicator for ICUs? *Respir Care* 2016;61:723–36.
- Klompas M. Potential strategies to prevent ventilator-associated events. *Am J Respir Crit Care Med* 2015;192:1420–30.
- Barnes-Daly MA, Phillips G, Ely EW. Improving hospital survival and reducing brain dysfunction at seven California community hospitals: implementing PAD Guidelines via the ABCDEF bundle in 6,064 patients. *Crit Care Med* 2017;45:171–8.
- Rhodes A, Evans LE, Alhazzani W, Levy MM, Antonelli M, Ferrer R, et al. Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016. *Crit Care Med* 2017;45:486–552.
- Klompas M, Branson R, Eichenwald EC, Greene LR, Howell MD, Lee G, et al. Strategies to prevent ventilator-associated pneumonia in acute care hospitals: 2014 update. *Infect Control Hosp Epidemiol* 2014;35(Suppl 2):S133–54.
- Rawat N, Yang T, Ali KJ, Catanzaro M, Cohen MD, Farley DO, Lubomski LH, Thompson DA, Winters BD, Cosgrove SE, et al. Two-State Collaborative Study of a Multifaceted Intervention to Decrease Ventilator-Associated Events. *Crit Care Med* 2017;45:1208–15.
- Nydahl P, Sricharoenchai T, Chandra S, Kundt FS, Huang M, Fischill M, et al. Safety of patient mobilization and rehabilitation in the intensive care unit. systematic review with meta-analysis. *Ann Am Thorac Soc* 2017;14:766–77.
- McWilliams D, Jones C, Atkins G, Hodson J, Whitehouse T, Veenith T, et al. Earlier and enhanced rehabilitation of mechanically ventilated patients in critical care: A feasibility randomised controlled trial. *J Crit Care* 2018;44:407–12.
- Sosnowski K, Mitchell ML, White H, Morrison L, Sutton J, Sharratt J, et al. A feasibility study of a randomised controlled trial to examine the impact of the ABCDE bundle on quality of life in ICU survivors. *Pilot Feasibility Stud* 2018;4:32.
- Goddard SL LF, Koo E, Rose L, Fan E, Kho ME, Needham DM, et al. Barriers and facilitators to early rehabilitation in mechanically ventilated patients—a theory-driven interview study. *J Intens Care* 2018;6:4.