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Improving Outcomes in Mechanically Ventilated Adult ICU Patients Following Implementation of the ICU Liberation (ABCDEF) Bundle Across a Large Healthcare System

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OBJECTIVES: To measure how the ICU Liberation Bundle (aka ABCDEF Bundle or the Bundle) affected clinical outcomes in mechanically ventilated (MV) adult ICU patients, as well as bundle sustainability and spread across a healthcare system.

DESIGN: We conducted a multicenter, prospective, cohort observational study to measure bundle performance versus patient outcomes and sustainability in 11 adult ICUs at six community hospitals. We then prospectively measured bundle spread and performance across the other 28 hospitals of the healthcare system.

SETTING: A large community-based healthcare system.

PATIENTS: In 11 study ICUs, we enrolled 1,914 MV patients (baseline $n = 925$, bundle performance/outcomes $n = 989$), 3,019 non-MV patients (baseline $n = 1,323$, bundle performance/outcomes $n = 1,696$), and 2,332 MV patients (bundle sustainability). We enrolled 9,717 MV ICU patients in the other 28 hospitals to assess bundle spread.

INTERVENTIONS: We used evidence-based strategies to implement the bundle in all 34 hospitals.

MEASUREMENTS AND MAIN RESULTS: We compared outcomes for the 12-month baseline and bundle performance periods. Bundle implementation reduced ICU length of stay (LOS) by 0.5 days ($p = 0.02$), MV duration by 0.6 days ($p = 0.01$), and ICU LOS greater than or equal to 7 days by 18.1% ($p < 0.01$). Performance period bundle compliance was compared with the preceding 3-month baseline compliance period. Compliance with pain management and spontaneous awakening trial (SAT) and spontaneous breathing trial (SBT) remained high, and reintubation rates remained low. Sedation assessments increased ($p < 0.01$) and benzodiazepine sedation use decreased ($p < 0.01$). Delirium assessments increased ($p = 0.02$) and delirium prevalence decreased ($p = 0.02$). Patient mobilization and ICU family engagement did not significantly improve. Bundle element sustainability varied. SAT/SBT compliance dropped by nearly half, benzodiazepine use remained low, sedation and delirium monitoring and management remained high, and patient mobility and family engagement remained low. Bundle compliance in ICUs across the healthcare system exceeded that of study ICUs.

CONCLUSIONS: The ICU Liberation Bundle improves outcomes in MV adult ICU patients. Evidence-based implementation strategies improve bundle performance, spread, and sustainability across large healthcare systems.

KEY WORDS: ABCDEF Bundle; critical care outcomes; intensive care unit liberation; implementation science; intensive care; quality improvement

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KEY POINTS

Question: Can evidence-based implementation strategies improve ICU Liberation Bundle (ABCDEF Bundle) compliance and improve outcomes in critically ill patients across a healthcare system?

Findings: A large, multicenter, prospective, observational study demonstrates that implementing the ICU Liberation Bundle (ABCDEF Bundle) significantly reduces the duration of mechanical ventilation and length of stay in adult ICU patients, and helps prevent prolonged ICU stays.

Meaning: Evidence-based implementation strategies, strong leadership support, bundle integration into the electronic health record, and real-time data analytics can help to facilitate bundle adoption, sustainability, and spread across a large healthcare system of community hospitals, and improve ICU patient outcomes.

Severe pain, agitation, and delirium occur commonly in critically ill patients and are associated with worse clinical outcomes and higher costs of care for these patients (1, 2). The ICU Liberation Bundle (ABCDEF Bundle) was developed to facilitate adoption of the Society of Critical Care Medicine's (SCCM's) Pain, Agitation, Delirium, Immobility, and Sleep (PADIS) Clinical Practice Guidelines (**Fig. 1**) (2, 3). This bundle takes an integrated approach to managing pain (A element), sedation (C element), delirium (D element), mechanical ventilation (B element), and mobility (E element) in ICU patients, and engages patients and families in care processes (F element) (4–7). Several studies have shown that this bundle significantly improves ICU patient care and outcomes, and reduces healthcare costs (4–11). The bundle also has a dose-response effect on patient outcomes. Higher levels of bundle compliance are associated with greater reductions in the duration of mechanical ventilation, deep sedation, ICU delirium, and restraint use in ICU patients, along with greater decreases seen in ICU and hospital lengths of stay (LOS), ICU readmissions, hospital mortality, and skilled nursing facility discharges for ICU survivors (4, 5). Improved bundle performance is associated with significant and proportional reductions in ICU and hospital costs (6, 7, 12).

The bundle is supported by strong, high-quality evidence, but widespread bundle implementation remains elusive (1, 2, 13). Bundle performance varies significantly, even in ICUs with large-scale quality improvement (QI) efforts, and overall bundle adoption remains low (14–18). Significant racial disparities in bundle performance also exist (19), and challenges created by the COVID-19 pandemic have dramatically reduced bundle utilization worldwide (20–23). Common barriers to bundle adoption include staff reluctance, knowledge deficits, and safety concerns, staffing shortages, a lack of interprofessional teamwork and collaboration around the bundle, incomplete integration of the bundle into the electronic health record (EHR), and a

ABCDEF Bundle	
A	Assess, prevent, and manage pain
B	Both spontaneous awakening and breathing trials
C	Choice of sedation strategies
D	Assess, prevent, and manage delirium
E	Early mobility and exercise
F	Family engagement and empowerment

Figure 1. The ICU Liberation Bundle (aka ABCDEF Bundle). ABCDEF Bundle elements: A: Assess, prevent, and manage pain in ICU patients; B: Conduct daily Spontaneous Awakening and Breathing Trials (SAT-SBT trials) in mechanically ventilated ICU patients; C: Use non-benzodiazepine sedatives and minimize sedative use in ICU patients; D: Assess, prevent, and manage delirium in ICU patients; E: mobilize and exercise ICU patients early and often; F: engage and empower patients and families in care processes.

lack of ICU and hospital leadership support for the bundle (15, 17, 19, 24–35). Thus, many ICU patients remain deeply sedated and ventilated for longer than necessary, increasing their risk of developing delirium, muscle weakness, ventilator dependency, nosocomial infections, long-term physical and cognitive dysfunction (post-intensive care syndrome), and other preventable harms, especially in the wake of the COVID-19 pandemic (36–46).

Two previous multicenter trials have attempted to demonstrate the impact of the bundle on various ICU patient outcomes in the context of large QI projects (4, 5). Neither study measured the aggregated effects of the bundle on patient outcomes, nor on bundle sustainability and spread across a healthcare system after the QI project ended. We conducted a large, multicenter, prospective, observational cohort study to quantify the effects of bundle implementation on clinical outcomes in mechanically ventilated (MV) adult ICU patients, using evidence-based implementation strategies to accelerate bundle adoption and improve performance, and applied data analytics to EHR data to improve bundle sustainability and spread across a large healthcare system.

MATERIALS AND METHODS

Bundle Implementation

The Dignitiy Health (DH) System (now part of CommonSpirit Health Organized Health Care Arrangement), systematically implemented the ICU Liberation Bundle in their adult ICUs between 2013 and 2019 (**Fig. A**, **Supplemental Digital Content**, http://links.lww.com/CCX/B269). Because this was a large-scale QI effort using only deidentified patient data, the requirement for patient consent was waived in accordance with the ethical standards of the CommonSpirit Health Research Institute's institutional review board (IRB) (CSHRI approval date: June 15, 2023; CSHRI OHRP IRB number: IRB00009715), and with the Helsinki Declaration of 1975.

In 2013, with funding from the Gordon and Betty Moore Foundation (47), DH conducted a pilot study to evaluate the impact of implementing the entire bundle over a 12-month period in 11 adult ICUs within six DH community hospitals in the Sacramento, California region. Study results were then used to inform efforts to spread the bundle to the other 28 DH hospitals with adult ICUs. The grant provided 12 months (April 1, 2014, to March 31, 2015) of full salary support for both a registered nurse to serve as project coordinator (**Table A**, Supplemental Digital Content, http://links.lww.com/CCX/B269) and a physical therapist, depending on the size of the facility. A small stipend was also provided for a physician champion at each hospital. Of note, before this bundle implementation project, DH had individually implemented some of the bundle elements in their ICUs (spontaneous awakening and breathing trials [SATs/SBTs], a palliative care bundle that routinely assessed pain in all patients, and mandated family meetings for all ICU patients with LOS > 5 d).

An ICU steering committee of local subject matter experts developed a list of bundle performance metrics. During the initial implementation period (September 1, 2013, to March 31, 2014), each site formed an interdisciplinary implementation team that adopted universal bundle policies, procedures, and order sets; incorporated bundle performance metrics into the EHR platform; and conducted interdisciplinary staff education. Teams also participated in bundle implementation calls and training webinars.

Outcomes for eligible MV patients were measured during the 12-month baseline period (July 1, 2011, to June 30, 2012) and the 12-month performance period (July 1, 2014, to June 30, 2015). Bundle compliance was measured during the performance period and was compared with the preceding 3 months of baseline bundle compliance (April 1, 2014, to June 30, 2014). Within 1 year of project completion, the other 28 acute care DH hospitals with adult ICUs implemented the bundle without external grant funding or a project coordinator. Bundle sustainability and spread were then measured over the 12-month bundle sustainability and spread period (July 1, 2018, to June 30, 2019).

Study Population and ICU Outcomes

The study population included all adult (≥ 18 yr) MV and non-MV patients admitted to 11 ICUs for greater than 24 hours up to 30 days, during the baseline and bundle performance periods. Exclusion criteria included ICU LOS greater than 30 days, patients with significant mobility restrictions at baseline, and patients receiving palliative or comfort care only. In this pilot phase, only MV patients were targeted to receive the full bundle, although the following outcomes were recorded for all eligible MV and non-MV patients, using Case Mix Index (CMI) as a measure of patient complexity and severity of illness

(48): ICU and hospital LOS, duration of MV, percentage of patients with ICU LOS greater than or equal to 7 days, hospital mortality, and CMI.

Bundle Compliance

Bundle compliance metrics in MV patients included:

1) Efficacy of opioid treatment for significant pain within 48 hours of ICU admission, using either a numerical rating scale or a nonverbal pain scale (NVPS).
2) Performance of daily SAT/SBT and reintubations within 24 hours.
3) Assessment of sedation q shift using the Richmond Agitation-Sedation Scale (RASS) (49).
4) IV sedatives used (benzodiazepines [midazolam or lorazepam] vs. non-benzodiazepines, [propofol or dexmedetomidine]).
5) Assessment of delirium q shift using the Confusion Assessment Method for the ICU (CAM-ICU) tool (50).
6) CAM-ICU positivity rates.
7) Use of an ICU mobility screen q shift using a modified American Association of Critical-Care Nurses early mobility protocol (51, 52).
8) Percent of patients with an ICU mobility score of greater than or equal to 2 (either sitting on the edge of the bed without assistance, standing, or walking).
9) Level of patient and family engagement assessed as a % of ICU patients having a completed Palliative Care Screening Tool (PCST) less than or equal to 48 hours of admission (**Table B**, Supplemental Digital Content, http://links.lww.com/CCX/B269).

Bundle Sustainability and Spread

Between July 2015, and March 2018, several changes were implemented to help sustain bundle performance in the six study hospitals and to spread the bundle to the other 28 DH hospitals. The CERNER EHR (Oracle Cerner, Austin, TX) was modified, and bundle order sets were created to facilitate documentation and compliance. Aggregated bundle performance and outcomes data were extracted electronically to facilitate bundle QI efforts. The bundle was also identified as a healthcare system priority for FY18 and FY19, which strengthened leadership support and prioritized resource allocation for bundle QI efforts.

Bundle sustainability at the six study sites was assessed during the sustainability and spread period, using a subset of compliance metrics measured in MV patients only (with the same inclusion and exclusion criteria used for the pilot study patient population):

1) Performance of daily SATs/SBTs.
2) Sedative use (benzodiazepine vs. non-benzodiazepine infusions).
3) Delirium assessment and management (bid RASS and CAM-ICU assessments, titration of sedatives to minimize sedation and delirium).
4) Daily mobility assessments and performance, targeting a mobility level greater than or equal to 2.
5) EHR documentation of family engagement (multidisciplinary family meetings held less than or equal to 72 hours of ICU admission).

These same metrics were used to assess bundle spread to the other 28 DH hospitals only in MV ICU patients during this same 12-month period. These metrics were also incorporated into the quality board goals for the entire DH healthcare system to increase facility focus on bundle performance.

Statistical Analyses

Demographics were described for both MV and non-MV patients with ICU LOS of 2–30 days in both baseline and performance periods. For demographic proportions (gender, medical vs. surgical admission), a standard binomial proportion test was used. For multicategory demographic values (race), a chi-square test was used to determine whether the baseline and performance cohorts were from the same distributions. For numerical demographic values (age), an unpaired, two-sample Student *t* test for means was used to determine statistical significance.

The effects of bundle implementation on patient outcomes were described for both MV and non-MV patients with ICU LOS greater than or equal to 2–30 days in the baseline and performance periods. A sample Student *t* test for 2 means was used to compare the impacts of bundle implementation on ICU/hospital LOS and ventilator days for all MV patients. Binomial probability was used to compare the impact of bundle implementation on mortality rates and LOS greater than or equal to 7 days. To measure patient complexity and illness severity, a sample Student *t* test for 2 means was used to compare CMI for all patients in the baseline and performance periods.

To evaluate bundle compliance in MV patients with ICU LOS greater than or equal to 2–30 days, a binomial probability was determined for each metric by comparing bundle performance over time, versus the 3-month baseline bundle compliance period. Bundle sustainability and spread were assessed using linear regression analyses, with

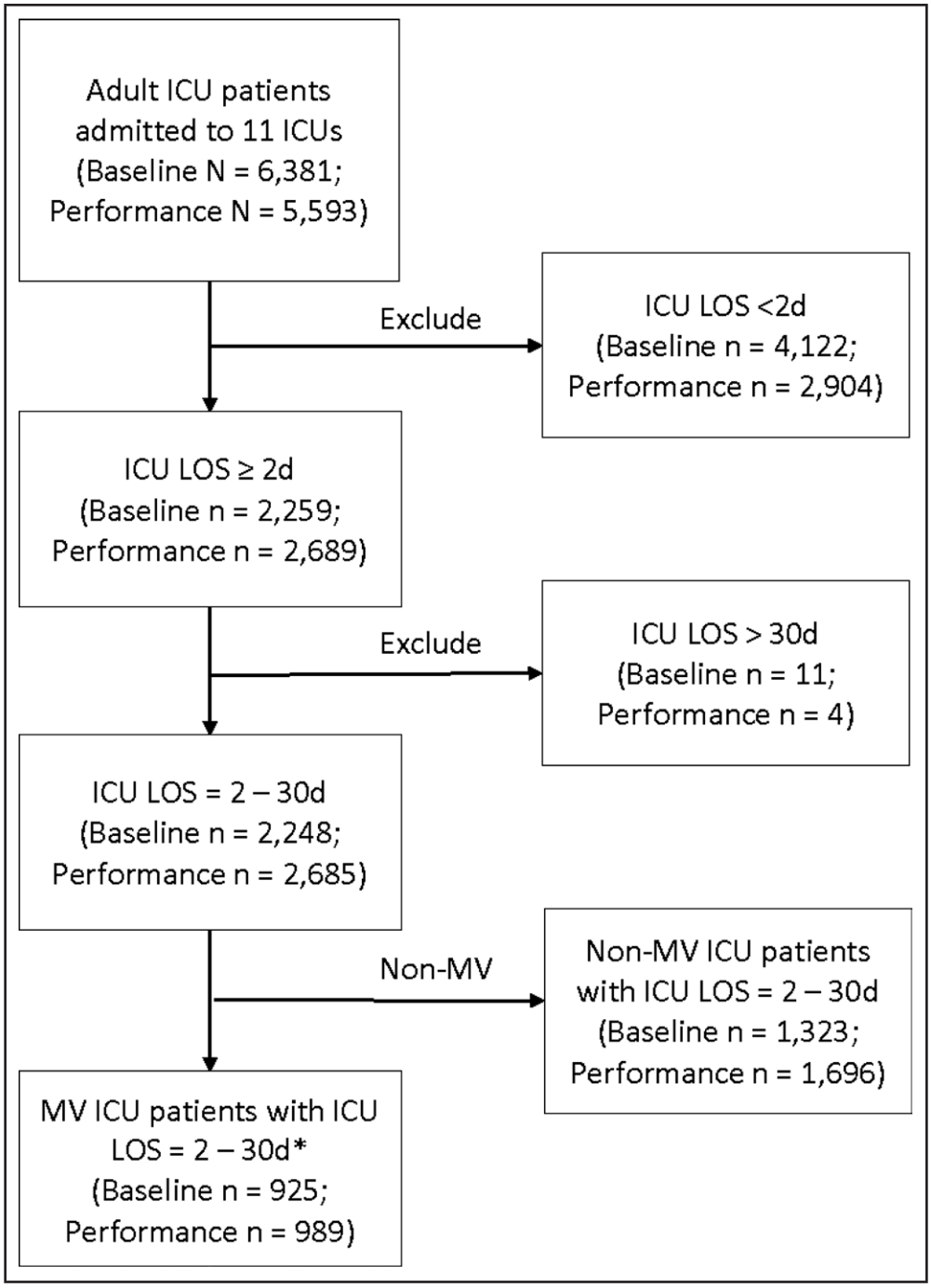

Figure 2. STROBE diagram of study patients. LOS = length of stay, MV = mechanically ventilated, STROBE = STrengthening the Reporting of OBservational studies in Epidemiology.

a 95% CI. Statistical significance for all tests was defined as *p* value of less than or equal to 0.05.

RESULTS

Hospital Characteristics and Patient Demographics

The characteristics of hospitals and ICUs varied across the six pilot study sites (**Table C**, Supplemental Digital Content, http://links.lww.com/CCX/B269). They included urban, suburban, and rural community hospitals, and small (< 125 beds), medium (125–250 beds), and large (> 250 beds) facilities. One site had a residency teaching program. ICU size ranged from 8 to 40 beds (median of 15 beds) and included medical, surgical, trauma, and cardiovascular ICUs.

A total of 11,974 patients were admitted to the 11 study ICUs during the baseline (*n* = 6,381) and bundle performance (*n* = 5,593) periods (**Fig. 2**). Eligible patients included 1,914 MV patients (925 baselines and 989 bundle performance), and 3,019 non-MV patients (1,323 baselines and 1,696 bundle performance). The only demographic differences in MV patient cohorts were gender and race, with the baseline group having more females and less ethnically diverse than the bundle performance group (**Table D**, Supplemental Digital Content, http://links.lww.com/CCX/B269). In non-MV patients, except for race, there were no significant differences in non-MV patients between these two groups (**Table E**, Supplemental Digital Content, http://links.lww.com/CCX/B269).

ICU Patient Outcomes

Bundle implementation in MV patients was associated with significant improvements in ICU LOS, days of MV, and the percentage of patients with ICU LOS greater than or equal to 7 days (**Table 1**; and **Table F**, Supplemental

TABLE 1.
Outcomes in Mechanically Ventilated Patients Pre- Versus Post-Bundle Implementation[a], All Hospitals (*N* = 6)

Patient Characteristics	Pre-Implementation[b]	Post-Implementation[c]	*p*
N[a]	925	989	
ICU LOS[d] (d)	5.55 (4.58)	5.09 (4.17)	0.02
Hospital LOS (d)	12.34 (15.67)	11.68 (13.14)	0.32
Mechanical ventilation, expressed as mean (SD) (d)	4.94 (5.50)	4.35 (4.82)	0.01
ICU LOS ≥ 7 d (%)	38.2	23.1	< 0.01
Mortality rate (%)	10.2	8.2	0.14
Case Mix Index, expressed as mean (SD)	3.60 (3.01)	3.47 (2.64)	0.32

LOS = length of stay.
[a]Mechanically ventilated patients with ICU LOS = 2–30 d.
[b]Pre-bundle implementation (baseline period) = between June 1, 2011, and June 30, 2012.
[c]Post-bundle implementation (performance period) = between June 1, 2014, and June 30, 2015.
[d]LOS = length of stay, expressed as mean (SD).

Digital Content, http://links.lww.com/CCX/B269). Average ICU LOS decreased by 0.5 days (8.3%), from 5.55 days to 5.09 days ($p = 0.02$). MV days decreased by 0.6 days (11.9%), from 4.94 days to 4.35 days ($p = 0.01$). The percentage of patients with ICU LOS greater than or equal to 7 days decreased by 18.1%, from 30.4% to 24.9% ($p < 0.01$). There was an insignificant trend toward reductions in hospital LOS, in-hospital mortality, and CMI in MV patients during the bundle performance period. By contrast, non-MV patients showed no differences in outcomes between the two groups (**Table G**, Supplemental Digital Content, http://links.lww.com/CCX/B269).

Bundle Compliance—Performance Period

Figures B(i-xii), Supplemental Digital Content (http://links.lww.com/CCX/B269) include run charts depicting bundle metric compliance over time for all six hospitals during the 3-month baseline bundle compliance period immediately preceding the 12-month bundle performance period. **Table 2** summarizes across-hospital R^2 and p values for each of these metrics, comparing bundle compliance at baseline to bundle compliance during the performance period. Compliance with pain assessment and management within 48 hours of ICU admission was high at baseline (> 90%) and did not significantly change ($p = 0.11$, $R^2 = 0.18$). Compliance with daily SATs/SBTs was also high at baseline (> 90%) and did not significantly change ($p = 0.49$, $R^2 = 0.04$ for both SATs and SBTs). Reintubation rates were very low at baseline (< 2%) and did not significantly increase ($p = 0.23$, $R^2 = 0.11$). RASS assessments significantly increased ($p < 0.01$, $R^2 = 0.45$). Use of benzodiazepine infusions for sedation significantly decreased ($p < 0.01$, $R^2 = 0.57$); non-benzodiazepine use did not significantly change over time ($p = 0.49$, $R^2 = 0.04$). CAM-ICU delirium screening significantly increased ($p = 0.02$, $R^2 = 0.36$); the prevalence of ICU delirium significantly decreased ($p = 0.02$, $R^2 = 0.35$). Routine mobility screening decreased ($p = 0.03$, $R^2 = 0.32$); the percentage of patients with a mobility level greater than or equal to 2 did not significantly change over time ($p = 0.24$, $R^2 = 0.11$). Family engagement initially increased, then decreased over time, but the change was not significant ($p = 0.75$, $R^2 = 0.01$).

Bundle Sustainability and Spread

Table 3 summarizes bundle sustainability in the 11 study ICUs, and bundle spread to the other 28 DH hospitals. Nearly 3 years post-bundle implementation in the study ICUs, bundle compliance in MV patients still varied considerably. SAT/SBT compliance decreased by nearly half, from 86% and 92%, respectively, to only 45% and 53% during the sustainability period. Preferential use of non-benzodiazepine sedation remained high (86%), and routine sedation and delirium assessments and active titration of sedation also remained high (83%). Daily assessments of patient mobility and mobilization remained low (28%).

TABLE 2.
Comparing Baseline Versus Performance Period Bundle Compliance in Mechanically Ventilated ICU Patients, All Hospitals ($N = 6$)[a]

Bundle Element	Bundle Metric	R^2	p
A: Assess, Manage, Prevent Pain	Pain assessed, managed ≤ 48 hr	0.18	0.11
B: SAT/SBT	Daily SAT	0.04	0.49
	Daily SBT	0.04	0.49
	Reintubation < 24 hr	0.11	0.23
C: Choice of Sedation Strategies	Richmond Agitation-Sedation Score assessment Q shift	0.45	< 0.01
	Sedation with benzodiazepine infusions	0.57	< 0.01
	Sedation with non-benzodiazepine infusions	0.04	0.49
D: Delirium: Assess, Prevent, Manage	CAM-ICU assessment Q shift	0.36	0.02
	CAM-ICU Positive Rate	0.35	0.02
E: Early Mobility and Exercise	Mobility Screening Q Shift	0.32	0.03
	ICU Mobility Score[b] ≥ 2	0.11	0.24
F: ICU Family Engagement, Empowerment	Palliative care screening tool[c] completed ≤ 48 hr	0.01	0.75

CAM-ICU = confusion assessment method for the ICU, SAT = spontaneous awakening trial, SBT = spontaneous breathing trial.
[a]Bundle compliance: 1) baseline bundle compliance period = between April 1, 2014, and June 30, 2014; 2) bundle performance period = between July 1, 2014, and June 30, 2015.
[b]American Association of Colleges of Nursing (AACN) mobility score.
[c]Palliative care screening tool (family engagement = identification of healthcare decision-maker, verification of patient's code status, completion of advance healthcare directive, distribution of ICU family brochure, scheduling of family meeting).

Measures of family engagement fell slightly, from 68% to 57%.

During this same period, there was a significant bundle spread to MV patients admitted to ICUs at the other 28 DH hospitals. High compliance was seen with preferential use of non-benzodiazepines for sedation (82%) and with routine assessment and management of sedation and delirium in patients (86%). SAT/SBT compliance was 46% and 58%, respectively. Mobility assessments and mobilization of MV patients and multidisciplinary family meetings were somewhat higher in these ICUs than in the study ICUs (37% and 61%, respectively).

DISCUSSION

Bundle Performance Versus ICU Outcomes

In this study, the ICU Liberation Bundle in MV adult ICU patients was associated with significant reductions in the duration of mechanical ventilation, ICU LOS, and the percentage of MV patients experiencing ICU LOS greater than or equal to 7 days. These improvements occurred even though bundle element compliance varied considerably. Most of these improvements can be explained by improvements in sedation and delirium management (C and D bundle elements), with a significant reduction in delirium prevalence during the performance period, which may be explained by the decreased use of benzodiazepines during the performance period. Compliance with pain management and SAT/SBT (A and B elements) was high at baseline and remained high throughout the performance period, making observed outcome differences between baseline and performance periods likely smaller than they would have been (5). Baseline compliance with early mobility efforts and family engagement (E and F elements) was low and did not significantly change during the performance period. Following bundle implementation, only about one-third of MV patients achieved a mobility score greater than or equal to 2 (sitting on the edge of the bed without assistance, standing, or walking), which is a strong predictor of core muscle strength and patients' ability to successfully wean from MV (53–55). More robust efforts to mobilize patients to this level of activity would have likely improved clinical outcomes even further. Family

TABLE 3.

Bundle Compliance in Mechanically Ventilated[a] ICU Patients During the Bundle Sustainability and Spread Period[b]

Facility	Daily Spontaneous Awakening Trials (%)	Daily Spontaneous Breathing Trials (%)	Choice of Sedation (Non-Benzodiazepine [Propofol, Dexmedetomidine]) (%)	Daily Sedation and Delirium Assessment/ Management (%)	Daily Mobility Assessment/ Mobilization (%)	Family Meeting < 72 hr of ICU Admission (%)	*N*
A	42.6	57.7	78.9	71.5	27.6	46.3	771
B	45.6	50.6	93.6	90.5	26.7	61.9	1,168
C	41.1	69.9	21.8	70.5	31.6	64.6	440
D	33.7	27.5	86.5	81.1	31.3	88.6	148
E	50.0	46.7	75.9	94.8	38.0	41.2	58
F	63.6	51.5	82.5	91.2	24.6	51.6	57
All study sites (*N* = 6)	44.5	53.2	86.3	83.1	28.0	56.7	2,332
Non-study sites (*N* = 28)	46.1	58.2	82.0	86.4	36.5	60.5	9,717
All sites (*N* = 34)	45.8	57.4	82.9	85.8	34.7	59.9	12,049

[a]Mechanically ventilated patients greater than or equal to 18 years, mechanically ventilated greater than or equal to 24 hours; excluded: patients with significant burns, comfort care, ethanol dependence, seizures, significant neurologic disease or deficits, unstable spine, long-bone fractures, no identified healthcare surrogate decision-maker, or in-ICU mortality.
[b]Bundle sustainability and spread period (between June 1, 2018, and June 30, 2019).

engagement significantly improved during the first 6 months of the performance period, then plateaued and declined between January and March 2015, which coincided with the loss of the registered nurse (RN) project coordinators at each study site at the end of the grant period.

These results are consistent with previous bundle implementation studies showing that higher bundle performance is associated with greater improvements in ICU patient outcomes (bundle dose-response effect) (4, 5). But unlike previous studies that measured the effects of bundle implementation on the next-day likelihood of an individual outcome, our study describes the cumulative effects of bundle implementation on reductions in the duration of MV, ICU LOS, and the percentage of patients with ICU LOS greater than or equal to 7 days. These reductions are both statistically and clinically significant and cannot be explained by either demographic or acuity differences between the pre-implementation and post-implementation groups. In contrast to previous studies, outcome improvements in this study were seen only in MV patients. The lack of improved outcomes in non-MV patients likely reflects the fact that non-MV patients were not targeted to receive the bundle. Previous studies in which both MV and non-MV ICU patients received the bundle have shown significant outcome improvements in both groups (4, 5).

Bundle Compliance

Bundle element compliance varied significantly during the performance period. Bundle elements implemented 2 years previously had become a routine part of the ICU culture (managing acute pain and performing daily SATs/SBTs) and had very high baseline compliance rates that were sustained throughout the performance period. Newly introduced bundle elements (sedation and delirium assessment and management, early mobility, and family engagement) had more variable compliance trajectories, even though evidence-based implementation strategies were used to integrate the bundle into everyday ICU practice over a 7-month period before compliance data were collected. This reflects the fact that not all bundle elements can be performed with equal ease. For example, pain, sedation, and delirium are almost exclusively assessed by the ICU bedside nurse. Clinicians' choice of ICU analgesics and sedatives can be driven by order sets overseen by ICU pharmacists. Improved compliance with these bundle elements was statistically significant. By contrast, SAT/SBT, mobilizing patients, and communicating and coordinating care with family members require effective intraprofessional communication, collaboration, and care coordination. Staffing shortages in one or more specialties create additional challenges for implementing these more complex bundle elements (28). The loss of a project coordinator or clinical champion can also negatively impact bundle performance.

Bundle Sustainability and Spread

Providing system-wide Information Technology support to fully integrate all bundle metrics into the EHR platform and to provide real-time, dashboard-driven data analytics helped to facilitate bundle sustainability and spread across the entire healthcare system. Leadership support for implementing the bundle and making it a healthcare system QI priority further helped to accelerate bundle adoption at the other 28 DH hospitals.

A similar pattern of variable bundle element compliance was seen in both study and non-study ICUs, with higher compliance rates for the assessment and management of sedation and delirium than for SATs/SBTs, early mobility, and family engagement. These findings are similar to results of previous bundle implementation studies and worldwide surveys of bundle element compliance (5, 16, 17, 21). Some of the observed differences in bundle element compliance in our study may also be explained by differences in data collection practices and changes made to compliance metric definitions during the performance and sustainability/spread periods.

In study hospitals during the performance period, the RN Study Coordinator would verify daily compliance with SATs and SBTs, whereas during the sustainability/spread period, the data extraction of SAT/SBT performance from the CERNER EHR was automated. The automated data extraction process was heavily dependent on RNs and Respiratory Therapists accurately charting all aspects of the SATs and SBTs in the EHR. If any part of the data documentation for either SATs or SBTs was incomplete, then they were deemed noncompliant with SAT/SBT for that day, even if the SAT/SBT

had actually been performed. This under-reporting error occurred similarly at both study and non-study hospitals during the sustainability/spread period only, with both cohorts showing comparable low levels of compliance with SATs and SBTs (45% and 53% compliance, respectively at study hospitals, and 46% and 58% compliance, respectively, at non-study hospitals).

Somewhat different metrics were used to measure ICU Family Engagement (F element) during the performance and sustainability/spread periods, which may account for some of the observed differences in the F element during these two periods. In 2014, there was no agreed upon evidence-based definition for ICU Family Engagement (F bundle element), so completion of the DH PCST less than 48 hours of ICU admission was used as a surrogate F element metric. As new evidence about best practices for ICU family engagement became available (56), in 2017 DH adopted early and routine family meetings (< 72 hr of ICU admission) as the new standard for family engagement across all ICUs, which replaced the PCST as the F bundle metric tracked across all hospitals during the sustainability/spread period.

Study Limitations

This study has several limitations. First, bundle compliance, sustainability, and spread data were only collected for MV patients because of personnel and other resource limitations. As a result, outcome improvements were not observed in non-MV patients. Second, assessments of illness severity using either Acute Physiology and Chronic Health Evaluation or Sequential Organ Failure Assessment scores were not available. The use of CMI as an indirect measure of illness severity has several limitations. Most notably, it is based on data collected retrospectively at the time of hospital discharge, not prospectively at the time of admission (48). Patients receiving the bundle during the performance period could have had lower CMIs because they benefited from the bundle and had better outcomes, potentially masking any acuity differences between baseline and performance groups. Third, DH bundle performance metrics predated the SCCM's creation of a standardized set of bundle metrics (minimum dataset), that have since been fully integrated into the CERNER (Oracle Cerner, Austin, TX) EHR platform (57). These DH-created metrics were less granular than current SCCM bundle metric requirements. For example, they only tracked pain management for the first 48 hours, using a behavioral pain assessment tool (NVPS) not recommended by the SCCM guidelines (58, 59). And they assessed sedation and delirium only once a shift. If pain, sedation, and delirium had been assessed more frequently over the entire ICU stay, as recommended in the PADIS guideline (2), even greater improvements inpatient outcomes would have been expected, given the dose-response effect of the bundle.

CONCLUSIONS

This study demonstrates that the ICU Liberation Bundle significantly reduces MV duration and ICU LOS, and prevents prolonged ICU stays in MV adult ICU patients. Use of evidence-based implementation strategies, strong leadership support, integration of the bundle into the EHR, and real-time data analytics can help facilitate bundle adoption, sustainability, and spread across large healthcare systems. Because 80% of adult ICU beds in the United States reside in community hospitals, we believe these findings are generalizable to ICUs in community hospitals nationwide (60–62). These results are particularly important considering that worldwide bundle compliance has decreased significantly in the wake of the COVID-19 pandemic (20).

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