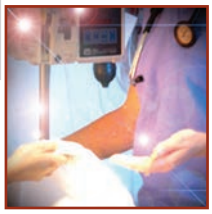

Effects of a National Quality Improvement Collaborative on ABCDEF Bundle Implementation

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Background The ABCDEF bundle (Assess, prevent, and manage pain and Delirium; Both spontaneous awakening and breathing trials; Choice of analgesia/sedation; Early mobility; and Family engagement) improves intensive care unit outcomes, but adoption into practice is poor.
Objective To assess the effect of quality improvement collaborative participation on ABCDEF bundle performance.
Methods This interrupted time series analysis included 20 months of bundle performance data from 15226 adults admitted to 68 US intensive care units. Segmented regression models were used to quantify complete and individual bundle element performance changes over time and compare performance patterns before (6 months) and after (14 months) collaborative initiation.
Results Complete bundle performance rates were very low at baseline (<4%) but increased to 12% by the end. Complete bundle performance increased by 2 percentage points (SE, 0.9; $P=.06$) immediately after collaborative initiation. Each subsequent month was associated with an increase of 0.6 percentage points (SE, 0.2; $P=.04$). Performance rates increased significantly immediately after initiation for pain assessment (7.6% [SE, 2.0%], $P=.002$), sedation assessment (9.1% [SE, 3.7%], $P=.02$), and family engagement (7.8% [SE, 3%], $P=.02$) and then increased monthly at the same speed as the trend in the baseline period. Performance rates were lowest for spontaneous awakening/breathing trials and early mobility.
Conclusions Quality improvement collaborative participation resulted in clinically meaningful, but small and variable, improvements in bundle performance. Opportunities remain to improve adoption of sedation, mechanical ventilation, and early mobility practices. (*American Journal of Critical Care.* 2022;31:54-64)

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Millions of survivors of critical illness worldwide experience profound physical, mental, and cognitive health impairments.[1,2] These short- and long-term impairments are often caused or exacerbated by severity of illness, preexisting comorbidities, and conditions commonly experienced during the course of an intensive care unit (ICU) stay.[3,4] For example, ICU-acquired pain, deep sedation, delirium, and weakness are associated with numerous adverse health outcomes, including increased risk of death, prolonged mechanical ventilation, depression, functional decline, and severe neurocognitive dysfunction.[5,6]

Although the results of numerous well-designed clinical trials suggest that a number of safe and effective ICU symptom management, mechanical ventilation liberation, and mobility interventions exist,[4,6,7] analyses continue to show that many are underused in everyday clinical practice.[8,9] This research-to-practice gap most likely contributes to the high morbidity, mortality, and cost associated with critical care.

The ABCDEF bundle is an integrated, interprofessional approach to optimizing ICU team performance and patient- and family-centered outcomes.[3,4,10] The bundle consists of the following individual elements: (A) assess, prevent, and manage pain; (B) both spontaneous awakening trials (SATs) and spontaneous breathing trials (SBTs); (C) choice of analgesia and sedation; (D) delirium: assess, prevent, and manage; (E) early mobility and exercise; and (F) family engagement and empowerment. Previous investigations demonstrated the safety and effectiveness of incorporating earlier versions of the ABCDEF bundle into everyday care.[11-13] Prior publications also have documented the many challenges that ICU providers experience when trying to deliver the interventions contained in the bundle in a consistent, collective, and coordinated manner.[14-17] Implementation science methods may help address this problem by developing and testing strategies to overcome the known barriers to ABCDEF bundle delivery.

Quality improvement collaboratives (QICs) are used in a variety of health care settings to help facilitate adoption of evidence-based practices. A QIC is an organized and multifaceted implementation strategy that includes multiple health care teams who come together to learn, share improvement tactics, compare benchmark data, and support the dissemination and implementation of clinical evidence or effective models of care.[18-21] Although previous QICs have improved clinical outcomes and/or adherence to targeted care practices for a number of ICU conditions (eg, central catheter–associated bloodstream infections, sepsis, and ventilator-associated pneumonia),[22,23] until recently, none have specifically focused on common ICU syndromes such as pain, delirium, and weakness. Moreover, evidence is currently insufficient to draw conclusions about the overall effectiveness of QICs or their ability to evoke meaningful and sustained change.[18,19,24-26]

The Society of Critical Care Medicine (SCCM) ICU Liberation Collaborative aimed to support the successful implementation of the ABCDEF bundle in a large and diverse group of US ICUs.[10] In a cohort of patients admitted to ICUs that participated in this QIC, ABCDEF bundle performance was associated with significant improvements in clinical outcomes, after relevant covariates were controlled for.[27] However, the effect of QIC participation on important process measures such as overall bundle adoption and delivery of the separate evidence-based interventions contained in

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the bundle remains unclear. The range of impact the QIC had at the individual ICU level is also unknown. These are important knowledge gaps considering the limited empirical data describing current national ABCDEF bundle performance rates, the uncertainty surrounding how long it takes to effectively implement the bundle, and the paucity of detailed descriptions of whether QIC participation effects bundle adoption in some ICUs more than others. The purposes of this study were to evaluate the effect of ICU Liberation Collaborative participation on ABCDEF bundle performance and explore whether bundle performance differed among participating ICUs at the end of the QIC.

The purpose of this study was to evaluate the effect participating in a quality improvement collaborative had on ABCDEF bundle adoption.

Methods

Study Design and Participants

This implementation study used an interrupted time series model to analyze 20 months of ABCDEF bundle performance data in 15 226 critically ill adults admitted to the 68 academic, community, and Veterans Affairs ICUs participating in the SCCM ICU Liberation Collaborative. The Vanderbilt University Medical Center institutional review board (IRB) served as the coordinating center IRB and approved this quality improvement project. All QIC participants acquired site-specific IRB evaluation and approval.

Data Sources and Collection

The study database contained deidentified demographic, clinical, and bundle performance data for critically ill adults with a variety of diagnoses, receiving or not receiving mechanical ventilation, admitted to an ICU participating in the QIC. Excluded from data collection were patients who died, were discharged from a participating ICU within 24 hours of ICU admission, or were undergoing active life support withdrawal and/or receiving only comfort care within 24 hours of ICU admission.

To enhance reliability of data collection, operational definitions for all study variables were created before QIC initiation. These definitions and a step-by-step guide to data collection were communicated to participating sites via a standard operating procedures manual and online webinars. Local staff members, who received formal data collection training and as-needed support from SCCM personnel, manually abstracted data from eligible patients' medical records (either electronic or paper) at their individual institution. The data were then entered into a Research Electronic Data Capture database (grant support UL1 TR000445 from the National Center for Advancing Translational Sciences, National Institutes of Health), a secure, web-based application for validated data entry, transmission, and storage.

We collected 20 months of ABCDEF bundle performance data, including 6 months of baseline (preimplementation) data from January 2015 through June 2015 and 14 months of data collected prospectively during the QIC from January 2016 through February 2017. No changes in usual care were reported during the baseline period. During the 14-month implementation period, sites were encouraged to use the bundle. Data were collected for the first 5 patients (baseline period) or first 15 patients (implementation period) consecutively admitted to the ICU each month. Performance data were collected for each qualifying patient for a maximum of 7 ICU days or until the patient was transferred out of the ICU, was designated as having non-ICU status, or died.

Variables

The implementation outcome examined in this analysis was ABCDEF bundle adoption (performance). The ABCDEF bundle consists of 7 discrete, evidence-based interventions (ie, 7 bundle elements). Eligibility criteria for receipt of bundle elements, definitions of each element, and bundle element performance criteria are provided in the Supplement (available online only at www.ajcconline.org). Consistent with prior work,[27] ABCDEF bundle performance was defined in 2 ways: complete bundle performance and individual element performance. Complete bundle performance was a patient-day in which every eligible bundle element was performed (100% of the bundle was performed). Individual element performance was a patient-day in which an eligible patient received a particular bundle element (eg, a patient receiving mechanical ventilation had an SBT).

Complete and individual bundle element performance was assessed daily for each included patient and aggregated across all patients for each month before and after bundle implementation during the 20-month study period. Performance was measured only on the days the patient was in the ICU for a full 24 hours. The 7 bundle elements, eligibility criteria, and bundle element performance requirements did not change over the course of the QIC.

Collaborative Activities

The history of the SCCM ICU Liberation Collaborative, methods used to recruit QIC sites, requirements

for participation, site selection process, and strategies used to foster evidence adoption are detailed elsewhere[10,28] and summarized in the Supplement (available online only). Briefly, 69 ICUs were officially invited to participate in the QIC after a formal review process. One site declined, leaving 68 adult ICUs from 29 states and Puerto Rico as QIC participants. All 68 sites contributed to the QIC database and completed the entire course of the collaborative. An interprofessional team composed of SCCM staff and experts in critical care, quality improvement, and implementation science led the collaborative. The collaborative consisted of in-person and virtual components in which a variety of improvement methods and implementation strategies were taught and used. All QIC sites were invited to participate in 4 in-person meetings (fall 2015, spring 2016, fall 2016, and spring 2017), monthly combined learning calls, database training sessions, a digital community, selected in-person site visits, and as-needed expert consultation and support. The key components, educational topics, and implementation strategies taught during the QIC are presented in Supplemental Table 1 (available online only).

Statistical Analysis

We assessed characteristics of the overall patient cohort before and during QIC participation. We then calculated the aggregate monthly rates of complete bundle performance and element-specific performance per eligible ICU patient-days across all study sites. Supplemental Table 2 (available online only) provides the definitions of the performance measures and the numerators and denominators for the calculations. The time series data for monthly rates were plotted to illustrate the temporal trends, which were "interrupted" by the adoption of the QIC at the 7th month. Segmented regression analysis for interrupted time series data was used to model the linear trend of rates as a function of time for each study period (months 1-6 for the baseline period and months 7-20 for the implementation period).

From the segmented linear regression models, we derived estimates of level change and slope change for each performance measure. Level change is an estimate of the change in rate from the end of the baseline period to immediately after initiation of the implementation. Slope change is an estimate of the change in trend in the implementation period compared with the trend in the baseline period. A positive impact of QIC participation is indicated by either a significant level increase or a significant slope increase. We accounted for first-order autocorrelation, if indicated by the Durbin-Watson statistic, with the Yule-Walker method for segmented regression models. We examined the goodness of fit of the model by using the coefficient of determination (R^2). In addition, we calculated unit-specific rates of complete bundle performance and element-specific performance for the last month of the QIC. We used descriptive statistics and box plots to illustrate the variability of performance rates across units. All statistical tests were 2-sided with a significance level of .05. Statistical analyses were performed with SAS statistical software, version 9.4 (SAS Institute Inc).

Results

During the 20-month data collection period, 17 228 patients were enrolled. Excluded were 2002 patients with ICU stays of less than 24 hours. The overall study cohort included 15 226 critically ill adults (1713 in the baseline period and 13 513 in the implementation period) who spent 49 018 full days in an ICU. Most patients in the overall cohort were White (72%), male (58%), and admitted to teaching hospitals (63%); the most common admitting diagnosis was sepsis/septic shock or acute respiratory distress syndrome (22%) (Table 1). More than one-third of participants were aged 70 years or older, and more than half (54%) required mechanical ventilation. No clinically meaningful differences between the baseline and implementation cohorts were noted.

Complete bundle performance rates increased from 4% in the baseline period to 12% by the end of the collaborative.

Complete Bundle Performance

Figure 1 presents the monthly percentages of complete bundle performance before (baseline) and after QIC initiation. As illustrated in Figure 1, complete bundle performance rates were very low in the baseline period (<4%). Complete bundle performance increased by 2 percentage points (SE, 0.9 percentage points; $P = .06$) immediately after the start of the QIC. Each month of participation in the QIC was associated with a significantly greater upward trend in complete bundle performance rates (monthly increase, 0.6 percentage points; SE, 0.2 percentage points; $P = .04$), as compared with the relatively flat performance trend in the baseline period. By the end of the final month of the QIC, the complete bundle performance rate was 12%. Table 2 provides the estimates of level and slope changes from our segmented regression analysis of complete bundle performance in the implementation versus baseline periods.

Table 1
Patient characteristics by study period (n = 1713 in baseline period, n = 13 513 in implementation period, N = 15 226 overall)[a]

Characteristic	Baseline	Implementation	Overall
Age category, y			
18-29	93 (5)	696 (5)	789 (5)
30-39	108 (6)	826 (6)	934 (6)
40-49	156 (9)	1241 (9)	1397 (9)
50-59	307 (18)	2554 (19)	2861 (19)
60-69	431 (25)	3458 (26)	3889 (26)
70-79	368 (22)	2756 (20)	3124 (21)
80-89	194 (11)	1617 (12)	1811 (12)
≥90	52 (3)	311 (2)	363 (2)
No. of patients with data	1709	13 459	15 146
Race			
American Indian/Alaskan Native	21 (1)	115 (1)	136 (1)
Black/African American	240 (14)	1746 (13)	1986 (13)
White	1170 (68)	9855 (73)	11 025 (72)
Asian	58 (3)	399 (3)	457 (3)
Native Hawaiian/Pacific Islander	9 (1)	83 (1)	92 (1)
Other or not specified	195 (1)	1201 (9)	1396 (9)
Multiple races	6 (<1)	30 (<1)	36 (<1)
No race data entered	14 (1)	84 (1)	98 (1)
No. of patients with data	1713	13 513	15 226
Female sex	728 (43)	5704 (42)	6432 (42)
No. of patients with data	1703	13 451	15 154
Primary admission diagnosis			
Other	313 (19)	2389 (18)	2702 (18)
Sepsis/septic shock or ARDS	355 (21)	3038 (23)	3393 (22)
Respiratory	349 (21)	2137 (16)	2486 (16)
Neurologic	155 (9)	1379 (10)	1534 (10)
Cardiac	155 (9)	1233 (9)	1388 (9)
Gastrointestinal	76 (5)	708 (5)	784 (5)
Trauma	69 (4)	667 (5)	736 (5)
Genitourinary	64 (4)	571 (4)	635 (4)
Surgery	111 (7)	1081 (8)	1192 (8)
Overdose/withdrawal	33 (2)	263 (2)	296 (2)
No. of patients with data	1680	13 466	15 146
Teaching hospital	1047 (61)	8472 (63)	9519 (63)
No. of patients with data	1713	13 513	15 226
ICU type			
Mixed medical/surgical	934 (55)	7535 (56)	8469 (56)
Medical	300 (18)	2439 (18)	2739 (18)
Surgical/trauma	221 (13)	1615 (12)	1836 (12)
Neurologic	74 (4)	693 (5)	767 (5)
Cardiac/surgical	106 (6)	759 (6)	865 (6)
Cardiac	78 (5)	472 (3)	550 (4)
Unclassified	0 (0)	0 (0)	0 (0)
No. of patients with data	1713	13 513	15 226
Ethnicity			
Hispanic	163 (10)	1408 (10)	1571 (10)
Non-Hispanic	1523 (89)	11 920 (88)	13 443 (88)
No ethnicity recorded	27 (2)	185 (1)	212 (1)
No. of patients with data	1713	13 513	15 226
Residence in a facility before admission	347 (20)	2627 (20)	2974 (20)
No. of patients with data	1704	13 447	15 151
Residence in a facility after ICU	625 (45)	5054 (45)	5679 (45)
No. of patients with data	1387	11 327	12 714
Mobility restricted before admission	481 (32)	4205 (34)	4686 (34)
No. of patients with data	1488	12 418	13 906

Continued

Table 1
Continued

Characteristic	Baseline	Implementation	Overall
Mobility restricted after ICU	642 (54)	5622 (53)	6264 (53)
No. of patients with data	1194	10544	11738
APACHE III score,[b] median (IQR)	60 (44-74)	58 (43-77)	58 (43-76)
Ever received invasive mechanical ventilation	928 (56)	7161 (53)	8089 (54)
No. of patients with data	1669	13387	15056
Hours of invasive mechanical ventilation, median (IQR) (n=8089)	70 (25-168)	60 (23-141)	60 (24-144)
ICU length of stay, median (IQR) (n=15159)	4.0 (2.4-7.0)	3.5 (2.5-6.0)	3.5 (2.5-6.0)
Hospital length of stay, median (IQR) (n=15055)	9.0 (5.0-17.0)	8.8 (5.0-15.0)	9.0 (5.0-15.0)
Ever received comfort care in ICU	91 (5)	473 (4)	564 (4)
No. of patients with data	1713	13513	15226
Discharge status			
Died in an ICU during the ICU collaborative admission stay	163 (10)	1209 (9)	1372 (9)
Died in an ICU, but not during the ICU collaborative admission stay	50 (3)	260 (2)	310 (2)
Died during this hospitalization but not in an ICU	66 (4)	458 (3)	524 (4)
Discharged from the hospital alive	1393 (83)	11363 (86)	12756 (85)
No. of patients with data	1672	13290	14962

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; ARDS, acute respiratory distress syndrome; ICU, intensive care unit; IQR, interquartile range; SOFA, Sequential Organ Failure Assessment.

[a] Values are No. (%) unless otherwise specified.
[b] APACHE III scores were available for 950 patients. Additional severity of illness scores available were APACHE II (n=675), median 18, IQR 13-24; APACHE IV (n=775), median 50, IQR 15-69; and SOFA score (n=1) 3.

Individual Bundle Elements

Figure 2 presents the monthly individual bundle element performance rates before and after initiation of the QIC. Performance rates for elements A (pain assessment), C (sedation assessment), and F (family engagement) increased significantly immediately after the QIC was begun and then increased monthly at the same rate at which they had increased during the baseline period (Table 2). The only bundle element with a significant change in slope from the baseline period was element B1 (SAT performance), in which the rate of change actually decreased. All remaining bundle elements had continued performance rate increases that were unchanged from the baseline period.

Variability

Figure 3 demonstrates variation among ICUs in complete and individual element bundle performance rates during the last month of the QIC. Bundle performance varied substantially among ICUs and across performance measures by the end of the QIC. Interquartile ranges were greater than 20% for all performance measures. The 3 elements with the highest variability were elements D (delirium assessment) (IQR, 37.5%-88.6%), B1 (SAT performance) (IQR, 22.2%-68.4%), and F (family engagement) (IQR, 59.3%-100%). By the end of the QIC, elements A (pain assessment), C (sedation assessment), and F were performed most frequently; more than half of the ICUs had performance rates of at least 70% for these elements. For element E (early mobility), most ICUs had a performance rate of less than 40% at the end of the QIC. Although complete performance rates were generally low (median, 7.5%; 75th percentile, 19.0%), a few ICUs reached rates of 53.7% to 71.4% at the end of the QIC.

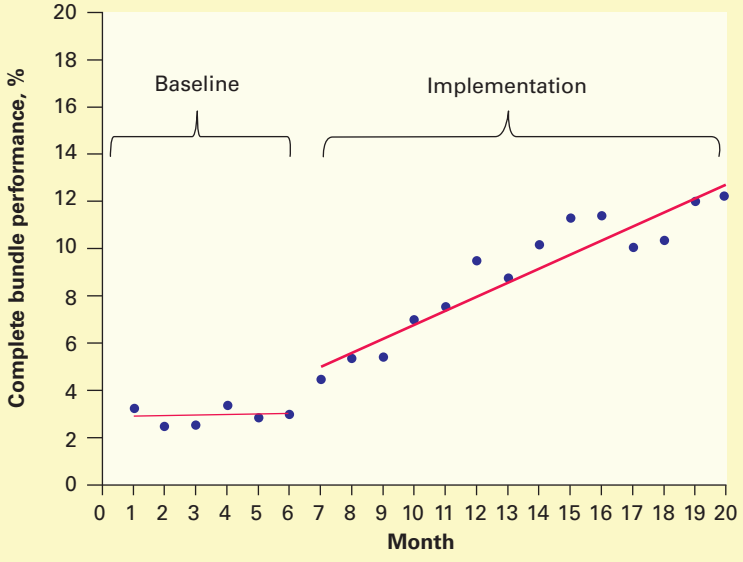

Figure 1 Monthly percentage of complete ABCDEF bundle performance in the baseline (months 1-6) and implementation (months 7-20) periods.[a]

[a] Please refer to the Methods section and Supplemental Table 2 of the online-only supplement for a full description of the ABCDEF bundle components, eligibility requirements, and performance definitions.

Table 2
Estimates of level and slope changes of ABCDEF bundle performance (complete bundle and individual bundle elements), implementation period versus baseline period[a]

	Level change[b]			Slope change[c]			
Element	Estimate	SE	*P*	Estimate	SE	*P*	R^{2d}
Complete	0.020	0.009	.06	0.006	0.002	.04	0.921
A	0.076	0.020	.002	0.003	0.005	.55	0.946
B1 (SAT)	0.014	0.016	.40	–0.013	0.004	.003	0.970
B2 (SBT)	0.027	0.014	.08	–0.001	0.003	.71	0.929
C	0.091	0.037	.02	0.002	0.010	.81	0.829
D	0.040	0.035	.27	–0.010	0.009	.28	0.875
E	0.018	0.013	.18	–0.002	0.003	.60	0.932
F	0.078	0.030	.02	0.014	0.007	.07	0.946

Abbreviations: SAT, spontaneous awakening trial; SBT, spontaneous breathing trial.

[a] Estimates were derived from segmented linear regression models. The baseline period was months 1 to 6 and the implementation period was months 7 to 20.
[b] Level change estimates the change in rate from the end of the baseline period to immediately after initiation of the implementation.
[c] Slope change estimates the change of trend in the implementation period compared with the trend in the baseline period.
[d] R^2 value ranges from 0 to 1, and a higher value indicates better fit of the model. It is interpreted as the proportion of variance explained. For example, an R^2 of 0.921 for complete performance suggests that our model explained 92.1% of variance in complete performance.

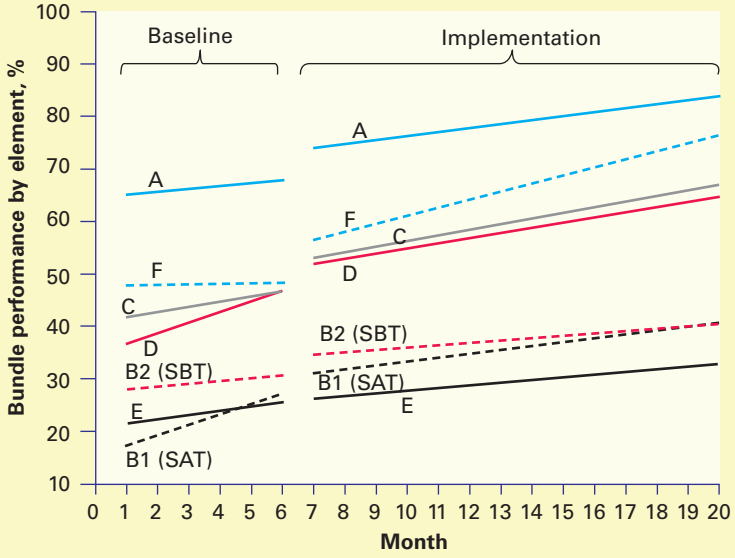

Figure 2 Monthly percentage of individual ABCDEF bundle element performance in the baseline (months 1-6) and implementation (months 7-20) periods. Bundle elements: A, assess, prevent, and manage pain; B, spontaneous awakening trials (SATs) and spontaneous breathing trials (SBTs); C, choice of analgesia and sedation; D, delirium assessment, prevention, and management; E, early mobility and exercise; and F, family engagement and empowerment.[a]

[a] Please refer to the Methods section and Supplemental Table 2 of the online-only supplement for a full description of the ABCDEF bundle components, eligibility requirements, and performance definitions.

Discussion

Our study has 4 key findings. First, our analysis suggests that QICs are an effective, yet limited, way of increasing the adoption of a variety of evidence-based ICU practices. In this large national sample, QIC participation was associated with an 8% absolute increase in complete ABCDEF bundle performance. Second, although measurable process improvements occurred over the course of the QIC, opportunities remain to further enhance ABCDEF bundle adoption. At the end of this national QIC, complete ABCDEF bundle performance rates reached a mere 12%. Third, the low complete bundle performance rates appear to be explained by the bundle elements SAT, SBT, and early mobility (elements B1, B2, and E), which were performed in less than 40% of eligible patients by the end of the QIC. Fourth, we found substantial variability in ABCDEF bundle performance among ICUs. This variability presents the opportunity to learn the characteristics of high and low performers to enhance ABCDEF bundle performance and ultimately improve the short- and long-term physical, cognitive, and psychological outcomes of critically ill adults.

Despite the widespread use of QICs, questions remain regarding their effectiveness for improving health care quality and safety. These questions persist because much of the QIC literature to date consists of case studies, single-site evaluations, and/or qualitative descriptions of implementation success.[18-20] Our study addresses some of these important concerns. We used a rigorous evaluation technique that is less vulnerable than other techniques to secular trends and can examine both the immediate and sustained effects of the QIC intervention. Moreover,

the QIC we evaluated involved a large number of ICUs from diverse academic, community, and Veterans Affairs hospitals. These sites collected thousands of days of documented, rather than perceived, bundle performance data. These conditions allow us to conclude, with a reasonable amount of certainty, that participation in a QIC was an effective but limited way of increasing ABCDEF bundle performance. This finding is important considering the amount of practice change, interprofessional communication, and teamwork needed to deliver this intervention.

Although we observed a significant increase in complete bundle performance during the relatively short data collection period, this improvement was slow (2 percentage points monthly) and far from complete (12% by QIC end). This low complete bundle performance is most likely explained by the limited delivery of daily SATs, SBTs, and early mobility interventions. Complete bundle performance depends on the delivery of all of the individual elements that a patient is eligible to receive, even the most challenging elements. In addition, some bundle elements are more interdependent than others. For example, early mobility requires that a patient be at least somewhat cognitively alert and physically engaged. Therefore, performing bundle element E would be more difficult in patients who have not undergone an SAT (element B1) or who remain physically tethered to mechanical ventilation because of nondelivery of an SBT (element B2). Complete bundle performance also requires the greatest amount of resources and care coordination among doctors, nurses, pharmacists, and respiratory, physical, and occupational therapists. Therefore, more time is likely required to reach larger gains in complete bundle performance because successful implementation depends on the interaction of multiple disciplines. It is also possible that elements B1 (SATs), B2 (SBTs), and E (early mobility) are less responsive to QIC participation.

Suboptimal complete bundle performance findings may also be explained by how the performance of certain bundle elements was defined. Normally, SATs, SBTs, and early mobility episodes are guided by safety screens that help clinicians determine if performing a particular intervention is prudent. In an effort to promote local adoption, each QIC site was allowed to develop its own SAT, SBT, and mobility safety screen criteria. The diversity in (and in some cases the lack of) safety screen criteria precluded determination of when an SAT, SBT, or mobility episode was appropriately not performed. For this reason, performance in this analysis was defined with a simple yes or no, meaning that either the patient did or did not have a SAT (if receiving continuously infused or intermittently scheduled sedatives), SBT (if receiving mechanical ventilation), or mobility episode (if in the ICU). Given this operational definition, achieving 100% complete bundle performance would indeed be difficult because of the high likelihood that some patients would be in too unstable a condition to receive certain bundle elements. Although a "dose-response" relationship between higher bundle performance and improvements in patient outcomes was previously demonstrated,[12,27] the ideal complete bundle performance rate remains to be determined.

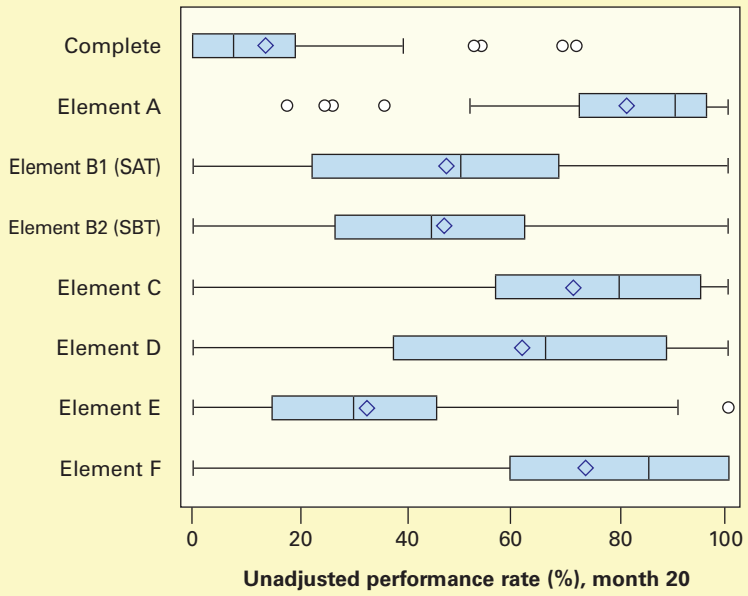

Figure 3 Variation among intensive care units in unadjusted frequency of ABCDEF bundle performance during the last month of the collaborative.[a]

Abbreviations: SAT, spontaneous awakening trial; SBT, spontaneous breathing trial.

[a] Each box plot shows mean (diamond), median (line in shaded box), IQR (shaded box), points within 1.5 times the IQR (error bars), and any outliers (open circles) for unit-level performance rates.

We found impressive and relatively quick improvements in the documented performance of pain and agitation/sedation assessments and family engagement (bundle elements A, C, and F). Because pain and agitation/sedation assessments are most often the responsibility of a single ICU profession (nursing), it is reasonable that these particular elements would be the first to improve and would be performed more often than the other bundle elements. Less clear is how QIC participation led to an improvement in family engagement. It is possible that QIC activities improved health professionals' knowledge of the importance of engaging family members as active participants in ICU care or that interaction

across QIC teams generated normative pressure and an opportunity to make changes in this area.

We found that the slope of change actually decreased for SAT performance (element B1) in the intervention phase compared with baseline. With newly competing processes as part of the entire bundle, the prior SAT momentum might have been attenuated by QIC participation. In addition to element complexity and competing bundle elements, acceptance or understanding of the benefits of this particular intervention might have been lower. For example, some debate remains about the benefit of performing SATs when patients are maintained at sedation levels reflecting both arousability and comfort while receiving continuously infused medications,[29] and results from the initial trial showing the benefits of early mobility[30] have yet to be replicated in other randomized trials.[31,32] Continued improvement in ABCDEF bundle performance will require a much greater understanding of the factors associated with effective bundle adoption.

Although QIC participation may advance ABCDEF bundle adoption, QIC participation alone is most likely not a sufficient approach to implementation. For example, early mobility often depends on the presence of a trained physical therapist or additional personnel who may not be readily available in many ICUs. Staffing has been reported as a key barrier to early mobility in the ICU.[14,33] Performance of SATs and SBTs similarly depends on nurse and respiratory therapist involvement. Unfortunately, SATs and SBTs are felt to increase workload in both of these professions.[33] In addition to staffing and workload, culture and leadership are believed to be critically important to adoption of ABCDEF practices.[15,16] For example, safety culture, staff receptivity to change, and prior QIC involvement were found to be associated with the use of SATs in a study of 386 US hospitals.[34] Future cost-effectiveness research is required to better understand the financial implications of ABCDEF implementation to potentially support the necessary staffing levels to enhance implementation.

> Participation in a quality improvement collaborative resulted in small, but meaningful improvements in ABCDEF bundle adoption.

Applying a positive deviance approach to efforts to implement the ABCDEF bundle may help facilitate the complex changes that are necessary to establish a culture of evidence-based practice. Instead of concentrating on what goes wrong, why errors occur, and the underlying cause of a problem, the positive deviance approach focuses on the behaviors, processes, and systems that contribute to safe and high-quality health care practices.[35] Our data suggest that an opportunity exists to use such an approach in the ICU setting with QIC sites that demonstrated either high or low bundle performance rates. As shown in Figure 3, many ICU Liberation Collaborative sites met these criteria. By the end of the QIC, consistent variability in complete and individual bundle element performance among ICUs and across measures was observed. Although most sites had disappointingly low complete bundle performance rates at the end of the QIC, a few outliers achieved complete bundle performance rates of up to 71% in this period. Unfortunately, our current data cannot show the source of this variability. Future research should investigate the role that variables at the patient, clinician, and organizational levels play in ABCDEF bundle performance.

Our study had several limitations. As with all observational studies, residual confounding cannot be excluded as an explanation for the observed changes in bundle performance, although the length of follow-up and the heterogeneity of hospitals reduces the likelihood of residual confounding. In addition, although ICUs demonstrated improvements during a 20-month period, we cannot make any conclusions about longer-term sustainability. Because study participation was voluntary, our findings may have had volunteer bias, resulting in higher performance than would occur at nonparticipating sites. This possibility would mean that an even greater opportunity exists for improvement outside of the collaborative. Finally, the factors that contribute to the observed variability in unit-level bundle performance at the end of the QIC remain unclear.

Conclusions

Successful treatment of an acute illness is only one of the elements that leads to positive outcomes for ICU patients. Cognitive, functional, and mental health outcomes require attention toward common practices related to ICU symptom management, mechanical ventilation, and early mobility. Our findings and prior research suggest that adoption of the ABCDEF bundle is one way to improve these practices and that participation in a QIC may yield modest but clinically meaningful improvements in complete bundle performance. Nevertheless, substantial opportunities to improve the delivery of contemporary evidence-based ICU interventions remain. Examining units with the greatest and least

gains in performance may provide a unique opportunity to understand key facilitators of and barriers to effective QIC implementation and to learn strategies for effective ABCDEF bundle adoption.

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SEE ALSO

For more about ABCDEF bundle implementation, visit the *Critical Care Nurse* website, **www.ccnonline.org**, and read the article by Stollings et al, "Implementing the ABCDEF Bundle: Top 8 Questions Asked During the ICU Liberation ABCDEF Bundle Improvement Collaborative." (February 2019).

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CE 1.0 Hour Category A

Notice to CE enrollees:

This article has been designated for CE contact hour(s). The evaluation demonstrates your knowledge of the following objectives:

1. Evaluate the effects of quality improvement collaborative participation in ABCDEF bundle performance.
2. Examine monthly individual ABCDEF bundle element performance rates before and after quality improvement collaborative initiation.
3. Identify which bundle elements were least likely to improve with quality improvement collaborative participation.

To complete the evaluation for CE contact hour(s) for this article #A223113, visit www.ajcconline.org and click the "CE Articles" button. No CE evaluation fee for AACN members. This expires on January 1, 2024.

eMethods

A detailed description of the Society of Critical Care Medicine's (SCCM's) Intensive Care Unit (ICU) Liberation Collaborative, the evidence-based implementation strategies used to foster effective teamwork and ABCDEF bundle adoption, and the performance/outcome metrics used to monitor progress over time in the quality improvement collaborative (QIC) are detailed elsewhere.[1,2] The relationship between ABCDEF bundle performance and patient-centered outcomes in critical care[3] and the challenges and potential solutions to effective bundle adoption also have been described.[4,5]

Collaborative Formation and Key Activities

Briefly, the SCCM initially developed its ICU Liberation Initiative to improve patient outcomes after an ICU stay by "liberating" patients from the harmful effects of pain, agitation/sedation, delirium, mechanical ventilation, and immobility through the adoption of evidence-based practices. In late 2014, the Gordon and Betty Moore Foundation provided a grant to the SCCM to form a QIC aimed at disseminating and implementing the ABCDEF bundle in a variety of diverse ICUs throughout the United States.

QIC Inclusion Criteria

Sites were recruited for QIC participation via annual ICU scientific meetings and a variety of social media and communication platforms. To participate in the QIC, each site was required to (1) identify a core interprofessional implementation team consisting of at least 1 medical doctor, 1 registered nurse, and 1 or 2 additional team members (pharmacist, physical/respiratory/occupational therapist); (2) partake in all planned QIC activities and data collection efforts; and (3) obtain a signed commitment letter from 2 senior administrators verifying that the hospital was willing to provide the necessary implementation resources. Experience with ABCDEF bundle implementation was not a requirement for participation.

Site Selection

Of the 108 QIC applications received, 96 were complete. Staff members from the SCCM screened all completed applications and determined that each provided a sufficient description of their unit's readiness for change, met eligibility criteria, and was ready to be advanced to the next level of review. Next, the applications were blindly ranked (ie, without site identification) by the SCCM president, president-elect, and the QIC's project managers. The rankings were based on a 6-point scoring system where 1 point each was awarded for evidence of (1) interprofessional team composition, (2) administrative support, (3) resources necessary to collect data, (4) plan for education and rollout, (5) nurse and intensivist champion involvement, and (6) innovation description.

Although the original grant from the Gordon and Betty Moore Foundation financially supported the participation of 50 ICUs, because of the quality, high rankings, and enthusiasm for the applications received, the SCCM made the decision to cover the costs of including an additional 19 sites (69 total). One site declined QIC acceptance, leaving 68 adult ICUs from 29 states and Puerto Rico that varied in size and admitting patient populations as QIC participants. For logistical purposes, the sites were divided into 3 regions (East, West, and Midwest). All 68 sites completed the entire course of the QIC.

Conceptual Framework and Key QIC Activities

The QIC, whose development and evaluation was guided by the Consolidated Framework for Implementation Research,[6-8] consisted of in-person and virtual components in which a variety of concepts and implementation strategies were taught. In the fall of 2015, the QIC launched with a 2-day in-person meeting. This meeting was followed by monthly regional virtual combined learning sessions, access to a website that allowed for sharing of documents, and formation of a digital community. The second and third regional collaborative in-person meetings were held in the spring and fall of 2016. The final regional in-person meeting, which marked the official end of the QIC, was held in the spring of 2017. The believed key components of the QIC, educational topics covered, and implementation interventions taught to QIC members are provided in Supplemental Table 1.[8,9]

ABCDEF Bundle Operational Definitions and Measurement

The ABCDEF bundle is based on hundreds of peer-reviewed investigations published in high-impact journals.[2] The ABCDEF bundle consists of 7 individual elements. Element A focuses on the assessment, prevention, and management of pain. Elements B1 and B2 represent the daily use of spontaneous awakening trials (SATs) and spontaneous breathing trials (SBTs). Element C is the choice of analgesic and sedative medications used to maintain target sedation levels. Element D focuses on the assessment, prevention, and management of delirium. The E element focuses on the use of early mobility and exercise interventions. Finally, element F represents the use of strategies aimed at family engagement and empowerment.

The operational definitions for ABCDEF bundle–related study variables that were used in the QIC were developed from the randomized controlled trials conducted on the bundle's individual elements, the SCCM's pain, agitation/sedation, delirium, immobility, and sleep disruption (PADIS)[1,10] and family-centered care[11] guidelines, and expert consensus. Because this was the first project to use the newly developed bundle, significant attention was paid to the clarity of operational definitions in terms of to whom the bundle element applied; what assessment tools should be used for pain, delirium, and level of arousal assessment; the frequency in which the elements should be applied; and what the intervention entails. These details are described below and outlined in Supplemental Table 2.

Bundle Element A: Assess, Prevent, and Manage Pain

Bundle element A was considered performed if there was documentation in the patient's medical record that the patient received at least 6 pain assessments in a 24-hour period using a valid and reliable instrument (ie, via self-report, numeric rating scale for pain, Behavioral Pain Scale,[12] or Critical Care Pain Observation Tool).[13]

Bundle Elements B1 and B2: Both Spontaneous Awakening Trials (SATs) and Spontaneous Breathing Trials (SBTs)

Bundle elements B1 and B2 were considered performed if it was documented in the patient's medical record that a patient received an SAT or SBT, respectively. To determine this, we first assessed if the patient received any continuously infused and/or intermittent intravenous sedative and/or opioid medications during the preceding 24 hours. If the patient received any continuously infused or intermittent sedative (ie, benzodiazepine, propofol, or dexmedetomidine) and/or opioid medications during the 24-hour period, we then determined the frequency. These frequency options included (1) continuously infused (defined as an intravenous medication that was set at a constant set rate [ie, anything other than 0]), (2) intermittently scheduled (defined as administering intravenous medications at specific intervals [eg, every 2 hours]), and (3) PRN (defined as administering intravenous medications on an as-needed or only-when-necessary basis).

Continued

Supplement Details on methods, collaborative formation and key activities, and ABCDEF bundle components.

ABCDEF Bundle Operational Definitions and Measurement (*continued*)

Bundle Elements B1 and B2: Both Spontaneous Awakening Trials (SATs) and Spontaneous Breathing Trials (SBTs) (*continued*)

For the purpose of this QIC, an SAT was defined as the purposeful interruption in the administration of intravenous medications used to provide sedation in critically ill patients. For an SAT to be considered performed, all continuously infused and intermittently scheduled intravenous medications being administered for the purpose of sedation (ie, opioids, benzodiazepines, propofol, dexmedetomidine) must have been completely turned off (ie, stopped). In the case of intermittently scheduled sedative medications, to meet the qualification for completing an SAT, it must have been clear from the medical record that the scheduled intermittent doses were not given (ie, were withheld). Simply lowering the dose, or titrating sedative medications to a certain level of arousal, was not considered an SAT. The administration of continuously infused and/or scheduled intermittent opioid medication for the treatment of active pain during an SAT was allowed. That is, analgesics were allowed to remain infusing *if* there was documentation of active ongoing pain.

When entering the data on SATs, clinicians were given 3 options to check: (1) Yes, SAT performed: it was documented in the patient's medical record that an SAT was performed; (2) No, patient failed the safety screen/contraindicated: there was documentation in the medical record that an SAT was not performed either because the patient failed the SAT safety screen or an SAT was contraindicated for some other reason, or (3) No, other reason/not documented: there was no documentation in the medical record that the patient underwent an SAT or there was another reason given for not performing an SAT. Because each site was allowed to develop its own SAT safety screen criteria, we considered an SAT to have been performed only if the first option was checked acknowledging that in a certain percentage of patients this "nonperformance" was most likely appropriate.

Next, we determined if the patient was receiving invasive mechanical ventilation during the preceding 24 hours. Mechanical ventilation was defined as a method to mechanically assist or replace spontaneous breathing for a patient through a machine called a ventilator. For this project, we tracked SBT performance only in patients receiving invasive mechanical ventilation. Invasive mechanical ventilation was defined as delivering the ventilation through an instrument that penetrates the mouth or nose (an endotracheal tube) or the skin (a tracheostomy tube). Episodes of noninvasive mechanical ventilation involving positive airway pressure ventilators via a nasal or face mask were not considered in this definition. If the patient received mechanical ventilation during the previous 24 hours, we next determined if an SBT had been performed. An SBT was defined as a purposeful interruption in mechanical ventilation for the purpose of determining whether or not mechanical ventilation can be discontinued. Specifically, the SBT was defined as discontinuation of active ventilator support (rate = 0) so that the patient is allowed to breathe through a T-tube circuit or the ventilator circuit with continuous positive airway pressure (CPAP)/positive end-expiratory pressure (PEEP) ≤ 7.5 cm H_2O and pressure support of ≤ 7 cm H_2O. For patients with a tracheostomy, a tracheostomy collar trial also counted as an SBT.

When entering the data on SBTs, clinicians were given 3 options to check: (1) Yes, it was documented in the medical record that the patient underwent an SBT; (2) No, patient failed the safety screen/contraindicated: it was documented in the medical record that an SBT was not performed because the patient failed the SBT safety screen or an SBT was contraindicated; or (3) No, other reason/not documented: the information could not be obtained from the patient's medical record documenting that the patient underwent an SBT or that an SBT was not performed for a reason other than a failed safety screen. Similar to SATs, because each site was allowed to develop their own SBT safety screen criteria, we considered an SBT performed only if the first option was checked acknowledging that in a certain percentage of patients this "nonperformance" was most likely appropriate.

Element C: Choice of Analgesia and Sedation

Bundle element C was considered performed if there was documentation in the patient's medical record that the patient received at least 6 sedation/agitation assessments in a 24-hour period using a valid and reliable instrument (ie, Richmond Agitation Sedation Scale [RASS][14] and/or Sedation/Agitation Scale [SAS]).[15]

Bundle Element D: Delirium Assessment, Prevention, and Management

Bundle element D was considered performed if there was documentation in the patient's medical record that the patient received at least 2 delirium assessments in a 24-hour period using a valid and reliable instrument (ie, Confusion Assessment Method for the ICU [CAM-ICU][16] or Intensive Care Delirium Screening Checklist [ICDSC][17]). Delirium assessments derived by other means (eg, nurse judgment) or other delirium assessment tools were not included.

Bundle Element E: Early Mobility and Exercise.

Bundle element E was considered performed if there was documentation in the patient's medical record the patient received early mobility/ exercise interventions in the preceding 24-hour period. For the purpose of this QI project, we defined early mobility/exercise interventions as a patient dangling legs at the edge of the bed, standing at the side of the bed, walking to a bedside chair, marching in place, and/or walking in the room or hall. Active or passive range-of-motion exercises, autorotating beds, turning, elevating the head of the bed, beds with chair positions, and passive transfer to a place other than the bed were NOT considered exercise or mobility interventions.

Bundle Element F: Family Engagement and Empowerment

Bundle element F was considered performed if there was documentation in the patient's medical record that a family member and/or significant other was educated on the ABCDEF bundle and/or participated in at least 1 of the following: ICU rounds, conference, plan of care, or ABCDEF bundle–related care. For the purposes of this QI project, we used a broad definition of family, which included direct family members as well as other people who hold significance for the patient. This person may be a close friend, member of the patient's spiritual community/church, or anyone who has had a close relationship with the patient.

All variables collected on the daily data collection form were referent to a 24-hour period of 00:00 (midnight) to 23:59 on a given date.

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Supplement *Continued*

Supplemental Table 1

Components, educational topics, and implementation interventions used in the Society of Critical Care Medicine's Intensive Care Unit (ICU) Liberation Collaborative

Key collaborative components	Educational topics	Implementation interventions
Multiple, diverse academic, community, and federal ICUs	Purpose and goals of quality improvement collaborative	Formation of interprofessional ICU teams
Topic selected clinically relevant	Science and history of ABCDEF bundle	Use of established quality improvement methods
Topic selected on the basis of best available evidence	Prevalence and etiology of post–intensive care syndrome	Audit and feedback
Variability in ABCDEF bundle performance	Operational definitions for new ABCDEF bundle and its individual elements	Identification of barriers and facilitators of practice change
Theory guided	Description of quality improvement collaborative surveys and their purpose	Change documentation forms
Benchmarking efforts	Evidence-based implementation strategies	Develop and implement tools for quality monitoring
Identification of best practices	Research supporting ABCDEF bundle	Distribution of educational materials
Variety of measures used and outcomes followed (eg, process, teamwork, organizational, clinical)	System change	Identify and prepare champions
Capturing and sharing of ideas	Quality improvement strategies	Identify early adopters
Used tested model for improvement	Interprofessional communication	Involve patients/consumers and family members
Identification and consolidation of relevant knowledge	ICU rounding processes	Obtain formal commitments
Interprofessional focus	Bundle-related documentation	Promote adaptability
Teams set measurable targets and collected data	Family-centered care practices	Provide ongoing consultation
Frequency of in-person and virtual educational meetings	Sustainability strategies	Clinician reminders
Sponsorship	Valid and reliable pain, agitation, and delirium screening tools	
Senior leadership support	Evidence-based sedative and analgesic medication selection	

Supplemental Table 2
ABCDEF bundle components, eligibility requirements, and performance definitions

Component	Patient-ICU days eligible for component (denominator)	Performance definition[a] (numerator)
A: assess, prevent, and manage pain	All days	Days when a patient received ≥6 pain assessments using a valid and reliable instrument (ie, numeric pain rating scale, Behavioral Pain Scale, or Critical Care Pain Observation Tool)
B1: spontaneous awakening trial (SAT)	Only days when patients received continuous and/or intermittent sedation	Days when a patient received an SAT
B2: spontaneous breathing trial (SBT)	Only days when patients received invasive mechanical ventilation	Days when a patient received an SBT
C: choice of analgesia/sedation	All days	Days when a patient received ≥6 sedation/agitation assessments using a valid and reliable instrument (ie, Richmond Agitation-Sedation Scale or Sedation-Agitation Scale)
D: delirium assessment, prevention, and management	All days	Days when a patient received ≥2 delirium assessments using a valid and reliable instrument (ie, Confusion Assessment Method for the ICU or Intensive Care Delirium Screening Checklist)
E: early mobility and exercise	All days	Days when a patient received mobility activities that were higher than active range-of-motion (ie, dangling legs at edge of bed, standing at side of bed, walking to bedside chair, marching in place, walking in room or hall)
F: family engagement and empowerment	Only days when patients had family members present	Days when a family member/significant other was educated on the ABCDEF bundle and/or participated in at least 1 of the following: rounds, conference, plan of care, ABCDEF bundle–related care

Abbreviation: ICU, intensive care unit.

[a] In the past 24 hours, this component was documented in the patient's medical record.