Improving Hospital Survival and Reducing Brain Dysfunction at Seven California Community Hospitals: Implementing PAD Guidelines Via the ABCDEF Bundle in 6,064 Patients

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Objectives: To track compliance by an interprofessional team with the Awakening and Breathing Coordination, Choice of drugs, Delirium monitoring and management, Early mobility, and Family engagement (ABCDEF) bundle in implementing the Pain, Agitation, and Delirium guidelines. The aim was to study the association between ABCDEF bundle compliance and outcomes including hospital survival and delirium-free and coma-free days in community hospitals.

Design: A prospective cohort quality improvement initiative involving ICU patients.

Setting: Seven community hospitals within California's Sutter Health System.

Patients: Ventilated and nonventilated general medical and surgical ICU patients enrolled between January 1, 2014, and December 31, 2014.

Measurements and Main Results: Total and partial bundle compliance were measured daily. Random effects regression was used to determine the association between ABCDEF bundle compliance accounting for total compliance (all or none) or for partial compliance ("dose" or number of bundle elements used) and outcomes of hospital survival and delirium-free and coma-free days, after adjusting for age, severity of illness, and presence of mechanical ventilation. Of 6,064 patients, a total of 586 (9.7%) died before hospital discharge. For every 10% increase in total bundle compliance, patients had a 7% higher odds of hospital survival (odds ratio, 1.07; 95% CI, 1.04–1.11; $p < 0.001$). Likewise, for every 10% increase in partial bundle compliance, patients had a 15% higher hospital survival (odds ratio, 1.15; 95% CI, 1.09–1.22; $p < 0.001$). These results were even more striking (12% and 23% higher odds of survival per 10% increase in bundle compliance, respectively, $p < 0.001$) in a sensitivity analysis removing ICU patients identified as receiving palliative care. Patients experienced more days alive and free of delirium and coma with both total bundle compliance (incident rate ratio, 1.02; 95% CI, 1.01–1.04; $p = 0.004$) and partial bundle compliance (incident rate ratio, 1.15; 95% CI, 1.09–1.22; $p < 0.001$).

Conclusions: The evidence-based ABCDEF bundle was successfully implemented in seven community hospital ICUs using an interprofessional team model to operationalize the Pain, Agitation, and Delirium guidelines. Higher bundle compliance was independently associated with improved survival and more days free of delirium and coma after adjusting for age, severity of illness, and presence of mechanical ventilation. (*Crit Care Med* 2016; XX:00–00)

Key Words: ABCDEF bundle; delirium; ICU liberation; interprofessional; mobilization; sedation

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Supported, in part, by a grant from the Gordon and Betty Moore Foundation.

Dr. Barnes-Daly has received honoraria from the Society of Critical Care Medicine and a grant from the Gordon and Betty Moore Foundation for the ICU Liberation project. Her institution received funding from the Gordon and Betty Moore Foundation. Mr. Phillips received funding from Sutter Health. Dr. Ely has received honoraria from Abbott Laboratories, Hospira, and Orion for continuing medical education activities and is funded by both the National Institutes of Health (NIH) and Veteran's Affairs Geriatric Research Education Clinical Center. He received support for article research from the NIH and received funding from Orion and Abbott. His institution received funding from the NIH and Hospira.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's website (http://journals.lww.com/ccmjournal).

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DOI: 10.1097/CCM.0000000000002149

Knowledge derived through epidemiologic investigations has contributed to a growing understanding of the far-reaching effects of critical illness (1, 2), emphasizing the need to help mitigate patient suffering and improve quality of care and patient safety both during and after care in the ICU. Society of Critical Care Medicine's (SCCM's) "Clinical Practice Guidelines for the Management of Pain, Agitation, and Delirium in Adult Patients in the Intensive Care Unit" (PAD guideline) is

an extensive set of evidence-based recommendations addressing key elements of quality and safety and suffering for patients during critical illness (3). The Rethinking Critical Care initiative sponsored by the Institute for Healthcare Improvement and other investigations over the past 20 years have helped hundreds of hospitals focus on patient comfort and safety issues in the ICU related to pain, sedation, delirium, and early mobility, evolving into a bundle of care (4–6). Subsequent investigations of various permutations of this bundle have been favorable (4, 7–13), yet more data are needed. To that end, the revised **A**ssess, prevent, and manage pain; **B**oth spontaneous awakening trials (SATs) and spontaneous breathing trials (SBTs); **C**hoice of Sedation/Analgesia; **D**elirium monitoring and management; **E**arly mobility and exercise; and **F**amily engagement and empowerment (ABCDEF) bundle was developed as an evidence-based strategy to implement the PAD guidelines. The robust nature of the evidence in support of this bundle's individual elements (3–5, 7, 11, 14–37) led the SCCM to begin its national ICU Liberation Collaborative. At the same time, continuing to generate an understanding of the utility of these elements as a bundle in a community setting is important. The quality improvement (QI) initiative described here was designed to utilize an interprofessional team (IPT) model to implement the ABCDEF bundle as configured by Sutter Health in seven community-based ICUs in California (38). The aim was to study the relationship between ABCDEF bundle compliance and outcomes including hospital survival and delirium-free and coma-free days (DFCFDs).

MATERIALS AND METHODS

Study Design

One IPT at each of seven Sutter Health–affiliated ICUs was trained on IPT concepts and the clinical aspects of the ABCDEF bundle. Each ICU-based team consisted of a dedicated registered nurse (RN), an administrative RN, a pharmacist, a physical therapist, a respiratory care practitioner (RCP), and an ICU physician. This project was reviewed by the Sutter Health Institutional Review Board, who considered it a QI initiative that did not require consent.

Timeline

The study period was calendar year 2014. A 12-week IPT training and multiple clinical education programs were provided to each ICU team in a staggered fashion beginning the fourth quarter of 2013 through the second quarter of 2014. The IPT education program, IPT model, and collaborative functionality of the IPT have previously been well-described (38). Additional clinical education was provided to the IPT members through attendance at conferences and lectures given by nationally recognized subject matter experts early in the study period.

Study Sites

The ABCDEF bundle was implemented by the IPT in ICUs ranging from six to 16 beds at seven Sutter Health community hospitals. All units were open, mixed general medical and surgical ICUs, and only the three largest hospitals were staffed with intensivists. All hospitals had care augmentation from the remote electronic ICU (eICU) RN and physician staff.

Study Procedures

The ABCDEF bundle elements were implemented for every patient every day. The elements are described in detail at www.iculiberation.org (39) and by Frimpong et al (40). Note that as part of the 2015–2017 ICU Liberation Collaborative, the bundle letters were adjusted to reflect explicitly the inclusion of assessment, prevention, and management of pain as Element A. Accordingly, we advise the reader to see www.iculiberation.org and www.icudelirium.org (39, 41) for the most current description of the ABCDEF bundle. At the time of this 2014 QI study, we operated with the following rubric: Element A: SAT involved completely turning off all sedative infusions as well as analgesic infusions if the patient was not having active pain. Element B: SBT was considered compliant for patients receiving mechanical ventilation (MV) if they were placed on CPAP/PSV 5/5 or blow-by for a minimum of 30 minutes after having passed a safety screen. Element C1 required the coordination of Elements A and B by actual communication between the RN and RCP performing Elements A and B. This was verbalized in rounds as having happened or not. Element C2 consisted of a statement by the ICU pharmacist that the PAD guidelines for sedation were being followed (i.e., light sedation target, avoidance of benzodiazepines, and an analgosedation [pain-first] approach). Element D was met if the Confusion Assessment Method for the ICU (CAM-ICU) had been used to assess the patient on both the current shift and the prior shift. Element E was met if the patient had been mobilized to maximum potential after passing a mobility safety screen. Element F was met if the patient/family had participated in rounds or a family conference had been held. All of these elements had to be accomplished during the previous 24 hours (rounds yesterday to rounds today) to be considered total compliance for that time period.

Patient characteristics are shown in **Table 1**. The ABCDEF bundle was addressed each morning during ICU rounds using the IPT collaborative model. Both MV and nonventilated patients were eligible for the bundle in an opt-out fashion. All elements of the bundle were contained in a standardized order set (**Supplemental Fig. 1**, Supplemental Digital Content 1, http://links.lww.com/CCM/C232). Patients were excluded in certain instances such as active ethanol/drug withdrawal, open abdomen, significant hemodynamic or respiratory instability, new coronary ischemia, therapeutic neuromuscular blockade, or intubation within the previous 6 hours without stabilization.

Bundle-specific safety screens were used to exclude patients who were not clinically stable to have the SAT, the SBT, and the exercise/early-mobility protocol (E) (**supplemental data**, Supplemental Digital Content 2, http://links.lww.com/CCM/C233).

Each patient was evaluated for level of arousal/sedation and for the presence of delirium using the Richmond Agitation and Sedation Scale (RASS) and the CAM-ICU (22, 23, 37). Sedation was titrated or removed completely to meet a prescribed RASS target. This target allowed patients to be awake and responsive,

permitting performance of the delirium assessment and completion of the other bundle elements.

During discussion of the implementation of the ABCDEF bundle, the full impact of the bundle was thought to be most evident in patients explicitly seeking recovery and survival. In contrast, patients whose focus of care had shifted to palliation of suffering were expected to be affected less by implementation of the ABCDEF bundle. Therefore, a subgroup analysis of patients with and without a palliative care consult was planned a priori to measure the differential importance of bundle compliance in those two groups of patients related to survival and DFCFDs.

TABLE 1. Patient Demographics and Baseline Clinical Characteristics

Characteristic	Statistic
No. of patients in study, *n*	6,064
Age in years, mean (SD)	63.1 (17.4)
Sex, *n* (%)	
Male	3,236 (53.1)
Female	2,828 (46.6)
Race, *n* (%)	
White	4,468 (73.7)
Black	638 (10.5)
Asian	319 (5.3)
Native American	56 (0.9)
Other/unknown	583 (9.6)
Acute Physiology and Chronic Health Evaluation III, mean (SD)	92.0 (26.0)
Percent with any mechanical ventilation, *n* (%)	1,438 (23.7)
Admit status, *n* (%)	
Elective	627 (10.3)
Emergency	3,957 (65.3)
Urgent/trauma	1,480 (24.4)
Palliative care, *n* (%)	
No	5,471 (90.2)
Yes	593 (9.8)
Affiliate, *n* (%)	
1	495 (8.2)
2	505 (8.3)
3	213 (3.5)
4	1,061 (17.5)
5	1,575 (26.0)
6	1,269 (20.9)
7	946 (15.6)

Acute Physiology and Chronic Health Evaluation III range is 0–299.

Data Collection

Data were collected each day by the IPT RN in each ICU during daily rounds and entered into an electronic data collection tool (MIDAS; Kitware, Clifton Park, NY). To reduce the data burden for the individual units, data collection responsibilities were transitioned to the eICU staff, who participated in rounds remotely as active members of the ICU care team and entered the data in real time. Monthly dashboard reports were generated to track total and partial bundle compliance and patient outcome data.

Statistical Methods

Analyses addressed the relationship between bundle compliance (independent variable) versus hospital survival and DFCFDs (two dependent/outcome variables).

Independent Variables. Bundle compliance was measured in two ways: 1) *total compliance* was defined as the proportion of days during a patient's ICU stay that he or she received all elements of the ABCDEF bundle for which the patient was eligible on a given day and 2) *partial compliance* was an acknowledgment that some effect on outcomes may result from clinicians' using some elements of the bundle even though not all bundle elements could be completed. Thus, partial compliance was used to determine the *dose* of compliance when something less than total compliance was provided to a given patient on a given day. This was calculated in two steps. First, a proportion was generated by taking the number of the individual elements in a particular day that a patient received and dividing that by the number of elements that he or she was eligible to receive. Then the partial compliance was defined as the mean of all of that patient's proportions during his or her ICU stay (i.e., for all ICU days).

Dependent (Outcome) Variables. The two main outcomes variables are: 1) hospital survival was tracked prospectively and calculated as the percent of patients still alive at hospital discharge; 2) DFCFDs were also tracked prospectively using the CAM-ICU (37) and RASS (22, 23) and calculated as the number of days a patient was alive and *free of both* delirium (i.e., CAM-ICU negative) and coma (i.e., any RASS other than –4 or –5) of that person's total ICU duration. CAM-ICU and RASS monitoring were only conducted while patients were in the ICU, thus only ICU days were used to determine the presence or absence of delirium and coma.

Statistical Modeling. The two outcomes were regressed on each of the two independent variables (total and partial compliance). Because patients were seen in seven ICUs (affiliates) in the Sutter Health System, the analysis included the specific ICU as a random term in the regression analysis. Random effects logistic regression was used when analyzing hospital survival, whereas random effects negative binomial regression was used when analyzing the number of DFCFDs. Both of these regression methods were run separately when total compliance was

the independent variable and when partial compliance was the independent variable. Negative binomial regression was used as opposed to Poisson regression because the variance was over dispersed. ICU length of stay (LOS) was used as the exposure variable in this regression to control for the variable length of time the patient was in the ICU.

Random effects logistic regression analysis produced hospital survival odds ratios (ORs) for a 0.1 unit increase for both independent (i.e., bundle compliance) variables. Thus the ORs estimate the increase in hospital survival for every 0.1 increase in the bundle compliance proportion. Similarly, random effect negative binomial regression produced incident rate ratios (IRRs) for a 0.1 unit increase for both bundle compliance variables. Here the IRRs estimate the increase in the rate of DFCFDs for every 0.1 increase in the proportion of bundle compliance.

The goal of this investigation was to identify the true relationship between total or partial compliance and hospital survival; therefore, a risk factor (bundle compliance as the independent variable) modeling approach was used to determine which covariates to add to the random effect regression model. The OR and the IRR describe the relationship between the dependent variable (i.e., hospital survival and DFCFDs, respectively) and total or partial bundle compliance in the regression. When determining other covariates to add to the regression model, only covariates that change the total or partial compliance OR or IRR (i.e., confounders) were included. These confounders of the relationship were determined as those that changed the relationship by more than 10% in either direction. Covariates that had a statistically significant interaction with total or partial compliance ($p < 0.05$) were also included in the model as they are effect modifiers. If a confounder or an effect modifier was found, the analysis was adjusted for this covariate.

It was determined a priori that age and Acute Physiology and Chronic Health Evaluation (APACHE) III would be included in all risk-adjusted models regardless of whether or not they were confounders. APACHE III was missing in 2.9% of the observations and was thus imputed using multiple imputation (M = 20) using truncated linear regression where the lower and upper limit of the truncation was set at the observed minimum and maximum values of 7 and 194, respectively. The predictor variables in the imputation included patient age, sex, race, admission status (elective, emergency, trauma, or urgent), whether or not the patient was receiving sedation, hospital LOS, and affiliate location. All analyses were run using Stata 14.1 (StataCorp, College Station, TX).

RESULTS

Demographics and Baseline Characteristics

In total, 6,064 unique patients were included in the study. Patient demographic information and baseline characteristics are summarized in Table 1. Approximately one quarter of the patients were on MV at some point during their ICU stay making them eligible for all ABCDEF bundle elements on those days. Patients who were not receiving MV on a particular day and those who never received MV would not be eligible for the A, B, or C_1 elements of the bundle on those particular days, which was accounted for in assessing bundle compliance.

Patient Outcomes and Compliance Statistics

Table 2 shows that one in 10 patients died before they left the hospital (n = 586 [9.7%]), after a median ICU and hospital LOS of 3 and 5 days, respectively. Table 2 also demonstrates a high rate for both total (all or none; 89%, 95% CI) and partial ABCDEF bundle compliance (95%, 95% CI).

ABCDEF Bundle Compliance Versus Hospital Survival

Figure 1, *A* and ***B*** encompass the data demonstrating the effect of the ABCDEF bundle on survival analyzed by all-or-none compliance in Figure 1*A* and by partial compliance (dose response) in Figure 1*B*. Two models were used for each analysis to consider the relative difference in the bundle effect on the overall patient group (model 1) as well as on the patients who were or were not transitioned into palliative care (model 2). These results are also presented in **Supplemental Table 1** (Supplemental Digital Content 3, http://links.lww.com/CCM/C234). Model 1 shows that with each 10% incremental increase in total bundle compliance, the odds of hospital survival increase to 7% (OR, 1.07; 95% CI, 1.04–1.11; $p < 0.001$). Model 2 shows that, as suspected, total bundle compliance in patients receiving palliative care did not demonstrate improved survival benefit; however, patients not receiving palliative care demonstrated a 12% increase in survival with each 10% incremental increase in total bundle compliance for nonpalliative care patients (OR, 1.12; 95% CI, 1.07–1.17; $p < 0.001$).

Figure 1*B* shows that with each 10% increase in partial bundle compliance, the odds of hospital survival increase to 15% (OR, 1.15; 95% CI, 1.09–1.22; $p < 0.001$). Again, model 2 demonstrates that for patients not receiving palliative care, the odds of hospital survival increase to 23% (OR, 1.23; 95% CI, 1.14–1.32; $p < 0.001$). These results are also presented in **Supplemental Table 2** (Supplemental Digital Content 4, http://links.lww.com/CCM/C235).

ABCDEF Bundle Compliance Versus DFCFDs

Figure 2, ***A*** and ***B*** encompass the data showing the association of bundle compliance with DFCFDs, that is, a day during which the patient was alive and both not delirious (CAM-ICU negative) and not in a coma (RASS, –3 or higher). These results are also presented in **Supplemental Table 3** (Supplemental Digital Content 5, http://links.lww.com/CCM/C236). In 483 of the patients, DFCFDs could not be calculated because these patients' records did not include either RASS scores or delirium assessments (CAM-ICU). The presence or absence of coma and/or delirium was unknown; thus, the number of observations used in the analysis is 5,581. These data show that for every 10% increase in total bundle compliance, patients had a 2% increase of DFCFDs (IRR, 1.02; 95% CI, 1.01–1.04;

TABLE 2. Patient Outcomes and Compliance Statistics

Characteristic	*n*
Hospital survival, *n* (%)	
No	586 (9.7)
Yes	5,478 (90.3)
ICU LOS in days, median (IQR)	3.0 (3.0–5.4)
Hospital LOS in days, median (IQR)	5.0 (3.0–8.8)
Delirium- and/or coma-free days, mean (95% CI)[a]	1.61 (1.55–1.67)
Proportion of days mechanically ventilated, mean (95% CI)	0.180 (0.171–0.189)
Proportion total compliance, mean (95% CI)[b]	0.891 (0.884–0.897)
Proportion partial compliance, mean (95% CI)[c]	0.952 (0.949–0.957)

IQR = interquartile range, LOS = length of stay.

[a]*Delirium- and coma-free days* were also tracked prospectively using the Confusion Assessment Method for the ICU (CAM-ICU) (37) and Richmond Agitation Sedation Scale (RASS) (22, 23) and calculated as the number of days a patient was alive and *free of both* delirium (i.e., CAM-ICU negative) and coma (i.e., RASS other than −4 or −5) of that person's total ICU duration. CAM-ICU and RASS monitoring were only conducted while patients were in the ICU, thus only ICU days were used to determine the presence or absence of delirium and coma.

[b]*Total bundle compliance* was defined as the proportion of days during a patient's ICU stay that he or she received all elements of the Awakening and Breathing Coordination, Choice of drugs, Delirium monitoring and management, Early mobility, and Family engagement bundle for which the patient was eligible on a given day.

[c]*Partial bundle compliance* was an acknowledgment that some effect on outcomes may result from clinicians' using some elements of the bundle even though not all bundle elements could be completed. Thus, partial compliance was used to determine the *dose* of compliance when something less than total compliance was provided to a given patient on a given day. This was calculated in two steps. First, a proportion was generated by taking the number of the individual elements in a particular day that a patient received and dividing that by the number of elements that he or she was eligible to receive. Then the partial compliance was defined as the mean of all of that patient's proportions during his or her ICU stay.

$p = 0.004$), and for every 10% increase in partial bundle compliance, there was a 15% increase in DFCFDs (IRR, 1.15; 95% CI, 1.09–1.22; $p < 0.001$).

The evidence-based ABCDEF bundle was implemented with high levels of compliance in all seven hospitals (**Supplemental Table 4**, Supplemental Digital Content 6, http://links.lww.com/CCM/C237), which showed that the findings from Figures 1*A* and 2*A* held up even when the bundle was not implemented completely. Distribution of patients by compliance range for both total and partial compliance is shown in **Supplemental Table 5**, which shows that the bulk of the data for compliance by decile fall in the higher ranges of compliance.

DISCUSSION

This large-scale QI project in more than 6,000 patients at seven community hospitals demonstrated the value of implementing the PAD guidelines using a bundle of evidence-based steps through interprofessional teamwork. Incorporating the evidence of the PAD guidelines that appears in the ABCDEF bundle demonstrated that compliance with the bundle was independently associated with better patient survival and more days alive and free of delirium and coma even after adjusting for age, severity of illness, and MV (Figs. 1*A* and 2*A*). Importantly, these findings held up even when the bundle was not implemented completely. That is, the ABCDEF bundle *dose*, as measured by partial compliance, data shown in Figures 1*B* and 2*B* were strikingly positive for both the survival and the brain dysfunction outcomes of delirium and coma. These partial bundle compliance figures showed that both ICU survival and DFCFDs displayed steeper increases than total compliance figures. Partial compliance was likely a more sensitive indicator of these relationships as it demonstrated the dose-effect of the bundle, whereas the total compliance had only two variables, all or none.

This study adds the largest cohort to date on this topic and is complementary to and consistent with findings from previous studies, which have shown that different approaches to this evidence-based bundle have been associated with favorable clinical outcomes (7–13, 17). Balas et al (8) conducted a cohort study using the earlier ABCDE bundle and demonstrated improvements in ventilator-free days, delirium rates, adoption of early mobility, and trends toward improved 28-day survival. In that study, bundle compliance was an independent predictor of reducing delirium by half and doubling mobility. A Centers for Disease Control and Prevention–led QI initiative that implemented the bundle's ABC portion in more than 5,000 ventilated patients successfully reduced nosocomial, infectious-related complications (11). The 51-hospital Keystone initiative showed that ICUs that implemented SATs and delirium screening were 3.5 times more likely to exercise ventilated patients, concluding that their data were "another layer of evidence that for the ABCDEs, the whole is greater than the sum of the parts." (12)

Some hospitals criticize the bundle specifically because it does have so many "parts," claiming that this makes effecting lasting change too difficult. Trogrlić et al (13), in a study of 21 previous publications examining the assessment, prevention, and management of ICU delirium, found that it was the number of implementation strategies used (in fact, six or more, equal

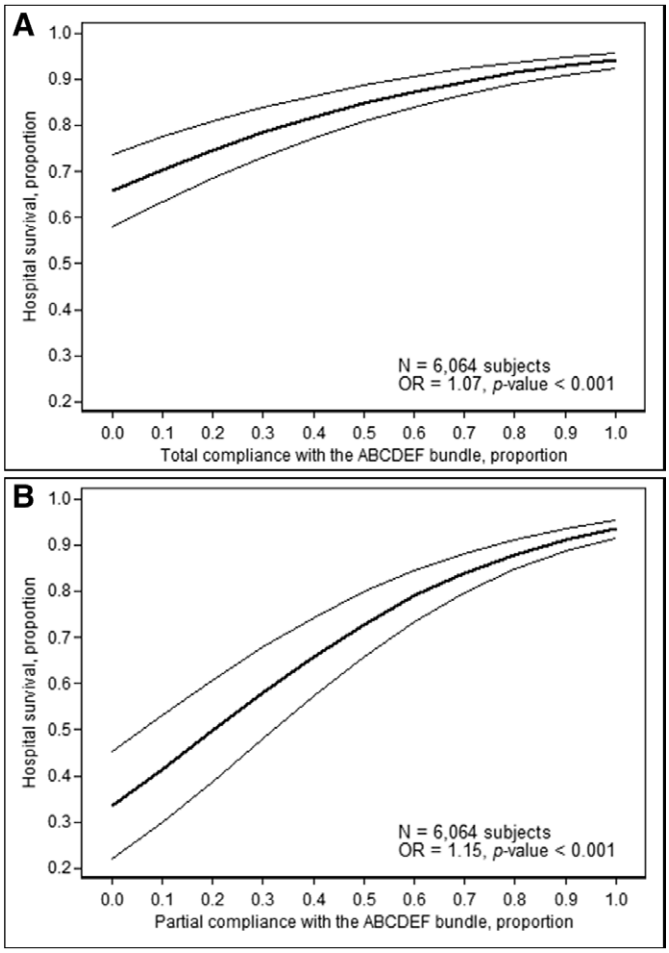

Figure 1. A, Hospital survival plotted in relationship to *total compliance* with the Awakening and Breathing Coordination, Choice of drugs, Delirium monitoring and management, Early mobility, and Family engagement (ABCDEF) bundle after adjusting for patient age, Acute Physiology and Chronic Health Evaluation (APACHE) III, and the proportion of days a patient was mechanically ventilated. **B**, Hospital survival plotted in relationship to *partial compliance* with the ABCDEF bundle after adjusting for patient age, APACHE III, and the proportion of days a patient was mechanically ventilated. Point estimates and confidence limit per decile of compliance increase are detailed in the *Results* section. OR = odds ratio.

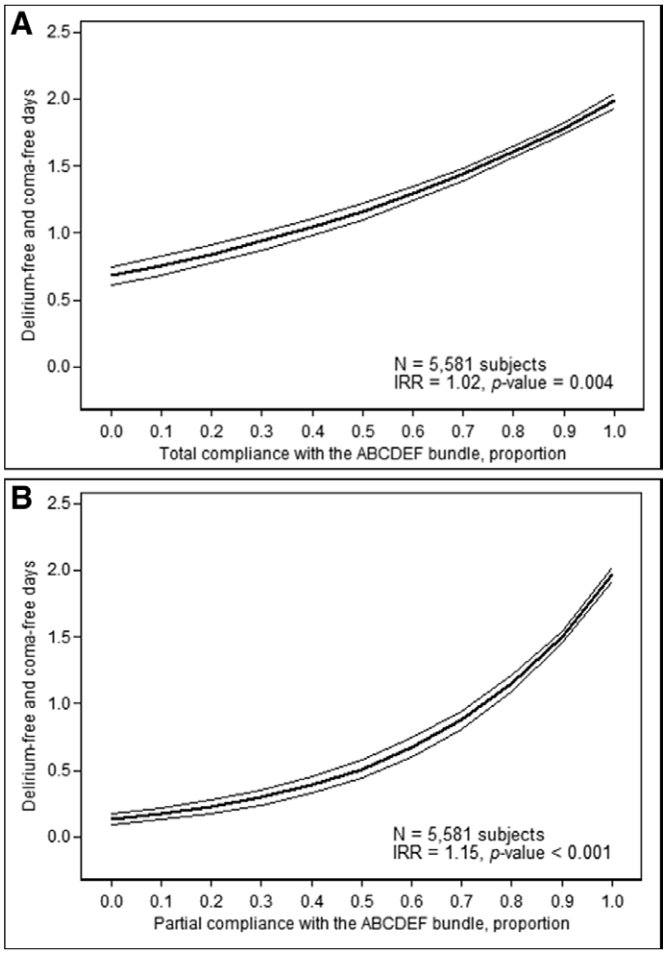

Figure 2. A, Delirium-free and coma-free days (DFCFDs) plotted in relationship to *total compliance* with the Awakening and Breathing Coordination, Choice of drugs, Delirium monitoring and management, Early mobility, and Family engagement (ABCDEF) bundle after adjusting for patient age, Acute Physiology and Chronic Health Evaluation (APACHE) III, and the proportion of days a patient was mechanically ventilated. **B**, DFCFDs plotted in relationship to *partial compliance* with the ABCDEF bundle after adjusting for patient age, APACHE III, and the proportion of days a patient was mechanically ventilated. Point estimates and confidence limit per decile of compliance increase are detailed in the *Results* section. IRR = incident rate ratio.

to the number of steps in the ABCDEF bundle) that statistically predicted reductions in ICU LOS and mortality. This quality improvement project, unlike others previously undertaken, ascribed equal importance to both the clinical improvements as well as IPT collaboration. The tenets of the IPT model, the training provided to the unit-based teams, and the opportunity given to team members to practice and embed the behaviors of collaboration and shared decision making into everyday practice were felt to be the key components contributing to success in improving patient outcomes. The use of dedicated team members was also important, as these individuals were true champions for the project and the patients. Real-time data collection and feedback were achieved each day in ICU rounds. This facilitated focus on bundle element performance as a priority of ICU care.

Limitations of this report should be acknowledged. First, this QI project lacked the strict protocols found in randomized, controlled trials. The IPT RNs, in their role as initial data collectors, were invested in the performance of their unit and team. This could have affected data integrity; however, random audits were performed to combat this as well as basic human error. In addition, very strict and well-defined data definitions and compliance rules were used for analysis. The bundle was applied across the entire patient cohort, in some cases including patients receiving palliative care. This resulted in bundle elements being used on the very ill and the lesser critically ill ICU patients alike, thus making it impossible to predict how compliance would factor into clinical outcome analyses. Real-world issues affecting bundle compliance included non-IPT physician buy-in and patient and family acceptance. Also, this was not a randomized controlled trial; thus, causation has not been ascribed to the outcome benefits. The strength of the experience lies in the very fact that it was *not* a randomized trial. This real-world experience can and should lend

confidence to many hospitals that want to implement the PAD guidelines. These new outcomes data for the bundle as a whole can additionally help support quality improvement initiatives.

Additional limitations that should be acknowledged include the following: the design and sample size benefits of our investigation do not necessarily trump other statistical concerns. For example, it is helpful that our multivariable analysis allowed us to adjust for covariates and determine point estimates for the independent relationship between a dose response for bundle implementation and outcomes, thus building both on the data provided for individual bundle elements by prior randomized controlled trials and on data from the pre-post implementation of those individual elements once bundled by previous investigators. In addition, though, it is important to consider for future work that more advanced study designs such as interrupted time series or stepped-wedge approaches would be valuable methods by which to gain an understanding of the relationship among the bundle elements, compliance, and clinical outcomes. It is reasonable to imagine that outcomes are a function both of compliance *dose* as well as severity of illness, clinician uptake and acceptance, and eICU versus bedside rounds implementation. Although we used palliative care as a barometer of severity of illness and aggressiveness of treatment to bolster our analysis beyond just APACHE III scores, future work could also incorporate an ongoing measure of severity such as daily Sequential Organ Failure Assessment scores.

It was not possible to determine all the effects of the staffing model on compliance or the effect of implementation over time across an individual hospital or in relationship to other sites. In a future investigation, either a model that does not, for example, treat hospital as the random effect or another nuanced approach of assessing hospital, size, staffing, and the effect of time course on clinical outcomes could be studied. Some might consider it a limitation that we have not reported on the individual contributions of the bundle itself versus IPT. We considered these inextricably linked in the overall process of patient management and resultant clinical outcomes, and thus in our methodology, we did not attempt to conduct this large QI project in a way that would measure the effect of one versus the other, but rather take them as parts of a whole. Finally, although some view the lack of a rigorous study protocol as a weakness, this experience in the community hospital setting demonstrated the ability of community hospitals to implement evidence-based changes successfully.

CONCLUSIONS

The SCCM's PAD guidelines can be implemented using the evidence-based ABCDEF bundle with significant and marked associated improvements for both in-hospital survival and days alive and free of delirium and coma even after adjusting for age, severity of illness, and MV. Further, even when delivered incompletely, bundle implementation results demonstrate that perfection is not required to see improvements in patient outcomes. This project complements other recent publications in collectively providing the needed framework for large-scale quality improvement programs across a spectrum of hospital models.

ACKNOWLEDGMENTS

We thank the Gordon and Betty Moore Foundation for enabling conduct of this project. Sutter Health, Sacramento-Sierra Regional and Affiliate-Based ICU liberation teams' dedication to the project allowed us to show the value of application of the bundle. Rebecca Petrella was instrumental as she provided data management and analysis. Deborah McBride's editorial direction was invaluable.

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