Published in final edited form as:

Crit Care Med. 2016 March ; 44(3): 460–467. doi:10.1097/CCM.0000000000001462.

Evaluation following staggered implementation of the ‘Rethinking Critical Care’ ICU care bundle in a multi-center community setting

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Abstract

Objective—To evaluate process metrics and outcomes following implementation of the ‘Rethinking Critical Care’ (RCC) ICU care bundle in a community setting.

Design, Setting, and Patients—Patients admitted to the intensive care unit (ICU) at three hospitals in the Kaiser Permanente Northern California integrated healthcare delivery system between January 1, 2009 and August 30, 2013.

Interventions and Measurements—The RCC ICU care bundle is designed to reduce potentially preventable complications by focusing on the management of delirium, sedation, mechanical ventilation, mobility, ambulation, and coordinated care. RCC implementation occurred in a staggered fashion between October 2011 and November 2012. We measured implementation metrics based on electronic medical record data and evaluated the impact of implementation on mortality with multivariable regression models.

Main Results—We evaluated 24,886 first ICU episodes in 19,872 patients. After implementation, some process metrics (e.g., ventilation start and stop times) were achieved at high rates while others (e.g., ambulation distance), available late in the study period, showed steep increases in compliance. Unadjusted mortality decreased from 12.3% to 10.9% (p-value<0.01) before and after implementation, respectively. The adjusted odds ratio for hospital mortality after implementation was 0.85 (95% confidence interval, 0.73–0.99) and for thirty-day mortality was 0.88 (95% CI, 0.80–0.97) compared with before implementation. However, the mortality rate trends were not significantly different before and after RCC implementation. The mean duration

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Conflicts of Interest: The authors have no conflict of interest to declare.

The remaining authors have disclosed that you do not have any potential conflicts of interest.

of mechanical ventilation and hospital stay also did not demonstrate incrementally greater declines after implementation.

Conclusions—RCC implementation was associated with changes in practice and a 12% to 15% reduction in the odds of short-term mortality. However, these findings may represent an evaluation of changes in practices and outcomes still in the mid-implementation phase and cannot be directly attributed to the elements of bundle implementation.

Keywords

Critical Care; Mechanical ventilation; Quality improvement; Health plan implementation; Hospital mortality; Outcomes research

INTRODUCTION

Increasing attention has focused on the deleterious long-term effects of care in the intensive care unit (ICU).^{1–6} Commonly recognized complications, especially delirium and immobility, increase hospital lengths of stay, costs of care, morbidity, and mortality and also contribute to long-term functional and cognitive impairment.^{6–11} Fortunately, specific ICU care practices—for example, spontaneous awakening and breathing trials to hasten liberation from mechanical ventilation or early mobilization to prevent ICU-acquired muscle weakness—have been shown to be efficacious at reducing these ICU-related sequelae.^{8,12}

Novel efforts aim to implement these proven ICU care practices together within quality improvement bundles.^{13–15} For example, the Rethinking Critical Care (RCC) program from the Institute of Healthcare Improvement is designed to reduce patient adverse effects from sedation, immobility, and delirium by helping hospitals implement multiple best practices.¹⁶ While bundled care has proven to be an effective strategy for improving the quality of care in other critical care settings, the impact of implementing the RCC program on ICU outcomes has not been well-described.^{15,17–19} Prior studies have primarily relied on pre-post comparisons, which fail to contextualize changes in outcomes within the setting of contemporaneous secular trends. Furthermore, there are no evaluations of the RCC program outside of academic medical centers.

In this study, we evaluate the practices and outcomes in a multi-center sample of community hospitals before and after implementing the RCC program. In a cohort of 24,886 ICU admissions from three ICUs in the Sacramento area of Kaiser Permanente Northern California (KPNC), we describe the RCC implementation process and its impact on mortality, mechanical ventilation, and length of stay.

METHODS

This study was approved by the KPNC Institutional Review Board for the Protection of Human Subjects, which has jurisdiction over the study hospitals.

Setting

Our investigation was centered at KPNC, an integrated healthcare delivery system with common information systems across all its hospitals and clinics. We conducted a retrospective study of the practices and outcomes at three KPNC ICUs before and after implementing ICU care bundles modeled after the Institute for Healthcare Improvement's 'Rethinking Critical Care' (RCC) performance improvement program.¹⁶

The 'Rethinking Critical Care' bundle

At KPNC, the RCC performance improvement effort comprises a multidisciplinary and multi-faceted set of care practices that are focused on improving patient outcomes by reducing the potentially preventable complications associated with ICU care. The RCC bundle components are designed to: (1) improve the recognition, prevention, and management of delirium; (2) minimize the use of sedatives (especially benzodiazepines) and the duration of mechanical ventilation; (3) increase the frequency of mobilization and ambulation in critically ill patients; and (4) optimize the coordinated care delivered by multidisciplinary teams through improved rounding strategies. The staged implementation of the RCC program across the three sites began as a pilot project at the first facility in October 2011 followed by implementation in July and November of 2012 at the remaining two sites, respectively.

Bundle implementation at each site was nested within a regional RCC performance improvement effort that included clinician educational and training sessions, changes to standard electronic orders in the medical record, meetings with local and regional quality leaders and improvement advisors, and ongoing 'Plan, Do, Study, Act' cycles designed to improve the implementation of changes (Appendix).²⁰ Local implementation teams consisted of a physician and nurse clinical lead, a dedicated quality improvement advisor and nurse leader, and a respiratory therapy manager; additional quality improvement staff from a regional support team served as advisors. In coordination with these efforts, staged modifications to documentation fields within the electronic medical record were made to enhance the accurate capture and assessment of process measures. In order to foster low latency review of implementation performance metrics, these data were also used to populate monthly RCC performance scorecards which were disseminated and reviewed by local and regional ICU leadership. Scorecard elements, whose number increased over the period of RCC implementation, included aggregated measures of: delirium assessment based on the Confusion Assessment Method ICU (CAM-ICU) test²¹; compliance with ventilator start-stop time documentation; frequency of spontaneous awakening and breathing trials; and frequency and distance of ambulation.

Implementation process measures

We quantified the implementation process metrics for selected elements of RCC based on the aggregated data reported in the RCC monthly scorecards. These data were extracted in a standardized fashion from central data repositories by trained quality improvement staff with specific guidelines for calculating the percentage compliance associated with each measure (Appendix Table 1). We further assessed the administration of common benzodiazepines (midazolam and lorazepam) on a patient-level by linking ICU patients with their

corresponding medication administration records. For each medication, we captured all instances of their continuous, parenteral, or enteral administration and calculated the fraction of all ICU days in which they were administered as well as their total dosage within an ICU episode.

Outcome measures

Our primary outcome was hospital mortality among first-time ICU patients admitted between January 1, 2009 and August 31, 2013. We determined our eligible population by first identifying an inpatient cohort at the three sites comprised of patients aged 18 years whose hospitalizations included an overnight stay, began in a KPNC hospital, and were not for peripartum care.²² From this inpatient cohort, we then identified eligible ICU episodes if they were a patient's first ICU admission during a hospitalization and included critical care based on a patient's physical location within an ICU ward and an electronic order for ICU 'level of care'. We excluded 2,303 episodes (8.5% of the initial sample of 27,189) whose primary reason for hospitalization was neurosurgical observation or treatment (based on International Classification of Diseases, 9th Edition, principal diagnosis codes for intracranial bleeding or skull trauma of 430–432, 800–804, and 850–854) because these patients were not subject to RCC implementation. The majority of these patients were hospitalized at the pilot facility (a regional referral center for neurosurgery) and the final implementing facility (a regional center for trauma; Appendix Table 2).

To quantify patients' severity of critical illness, we used a previously developed electronic adaptation of the Simplified Acute Physiology Score, version 3 (eSAPS3).²³ The eSAPS3 incorporates 20 predictor variables based on clinical and physiologic data available within the 1 hour before and after ICU admission; variable scores are summed into a single score with a theoretical maximum value of 217. A KPNC-calibrated version of the eSAPS3 demonstrated excellent discrimination (c-statistic: 0.82) for predicting hospital mortality in KPNC ICU patients.²³ We ascertained hospital and 30-day mortality based on data available within the electronic medical record and death records.²²

Our secondary outcomes included thirty-day mortality, the duration of mechanical ventilation, and the length of ICU and hospital stay. To determine the duration of mechanical ventilation, we incorporated electronic data from ventilator documentation flowsheets in a series of algorithms that assessed time-stamped data denoting ventilator equipment names, modes of ventilation, endotracheal tube characteristics, and clinician-entered start and stop times when available. We compared our electronic estimates based on these algorithms with manually calculated estimates in a randomly selected set of 150 patient records drawn from different medical centers throughout the study period. In the manual sample, the mean duration of ventilation was 101.1 hours with a standard deviation of 158.4 hours. The mean absolute difference between the electronically- and manually-derived intervals was 3.4 hours corresponding to a mean difference of 6.2% in overall duration (Appendix Figure 1) with a correlation coefficient of 0.96. We quantified ICU and hospital lengths of stay based on bed history records and time stamps.

Statistical analysis

Descriptive data are presented as mean $\pm$ standard deviation or as number (percent). To assess the impact of RCC implementation on hospital and thirty-day mortality among ICU patients, we compared unadjusted mortality rates among patients treated in the pre- and post-implementation phases. We then fit 4 multivariable logistic regression models to estimate a combined intervention effect defined as the change in mortality among patients treated before and after the intervention across the three facilities. Each model incrementally added predictor variables beyond pre- versus post-implementation. Our base model (Model 1) was unadjusted while Model 2 added facility-level adjustment as fixed effects. Model 3 added patient-level predictors including patient age, gender, comorbid disease burden (based on the Comorbidity Point Score version 2, COPS2), acute severity of critical illness (eSAPS3), need for mechanical ventilation, and resuscitation care order at hospital entry (full code, partial code, or do not resuscitate/comfort care).²² To adjust for secular trends and seasonal variation, Model 4 added study month number as a continuous variable over the entire study period and calendar month as a categorical variable. Lastly, we fit a fifth model that included facility-specific mortality trends (slope) and effects (intercepts) following implementation in addition to the variables included in Model 4.²⁴ Values are reported as odds ratios and 95% confidence intervals (CI) where an odds ratio less than one indicates a reduction in mortality effect associated with RCC implementation.

Finally, we compared pre- and post- intervals of mechanical ventilation and lengths of stay first with the Student's t-test and then with a multivariable linear regression including the variables listed above. For the length of mechanical ventilation, we truncated values to a maximum of 3 weeks. We considered a p-value of <0.05 to be significant. Analyses were conducted using Stata/SE, version 11.2 and SAS version 9.2.

RESULTS

Our total sample included 24,886 first ICU episodes occurring in 19,872 patients (Table 1); the distribution of ICU patients in the sample was roughly equivalent across the three facilities (ranging from 30.4% to 35.7%), however, because of the staggered implementation process, the pilot facility accounted for just under half of patients in the post-implementation period. Mean patient age was 64 ± 17 years. Mean predicted hospital mortality based on the KP-calibrated eSAPS3 score was $9.3\% \pm 11.4\%$. The most common reason for hospitalization was sepsis (18.1%; $n = 4,452$).

Implementation metrics

Figure 1 and Appendix Figure 2 display the elements of the RCC scorecard that were available over time as well as the aggregate and facility-level compliance with each metric. Metrics primarily demonstrating compliance with documentation (CAM-ICU testing and ventilator duration) were available early during the implementation process and were achieved at high rates. In comparison, metrics related to spontaneous awakening and breathing trials and ambulation became available later in the process and showed steep increases in compliance through the end of the study period. The uptake patterns of metric compliance were similar across facilities (Appendix Figure 2). The percentage of ICU days

in which a benzodiazepine was administered decreased after RCC implementation (Appendix Figure 3), with the mean total dose among patients receiving midazolam, for example, decreasing from 15.8 ± 57.4 mg to 10.5 ± 60.3 mg ($p < 0.01$).

Mortality

Figure 2 shows quarterly hospital mortality rates over the study period; overall mortality was 12.3% for patients in pre-implementation periods compared with 10.9% for those in post-implementation periods (χ^2 p-value < 0.01). Unadjusted hospital mortality rates decreased from 13.3% to 10.9% at Facility 1 ($p < 0.01$), 12.5% to 11.3% at Facility 2 ($p = 0.12$), and 11.2% to 9.9% at Facility 3 ($p = 0.20$) before and after implementation. Odds ratios for mortality for the combined intervention effect between all regression models were of similar magnitude (Table 2). For example, the adjusted odds ratio for hospital mortality in the post-implementation period was 0.85 (Model 4; 95% confidence interval [CI], 0.73–0.99; $p = 0.04$). The odds ratio for thirty-day mortality was 0.88 (95% CI, 0.80–0.97; $p = 0.01$). The fifth model showed a significant decrease in the adjusted odds of hospital mortality in Facilities 1 and 2 following implementation; however, the implementation had no effect on Facility 3 and facility-specific mortality trends ($p = 0.18$ – 0.41) relative to the pre-implementation period.

Secondary outcomes

Figure 3 shows the trends in duration of mechanical ventilation over the study period as well as the number of patients receiving ventilation. Mean ventilator duration in 2009 was 93.4 ± 120.6 hours; in 2013, it was 74.9 ± 95.5 hours. Ventilator duration was statistically significantly different in unadjusted ($p = 0.03$) pre and post comparisons, but not in adjusted ($p = 0.46$) comparisons. Facility-level mean ventilator duration was not significantly associated with compliance with spontaneous awakening and breathing trials ($p = 0.13$ – 0.72 for each facility; Appendix Figure 3). Similarly, length of stay in the ICU and hospital also decreased steadily throughout the study period, however, adjusted comparisons ($p = 0.54$) did not reach statistical significance.

DISCUSSION

In this study, we conducted an evaluation of the ICU practices and outcomes of three community-based medical centers before and after implementing the ‘Rethinking Critical Care’ performance improvement program. Following implementation, we found that ICU practices changed resulting in an increased frequency of benzodiazepine-free days, assessments for delirium, spontaneous awakening and breathing trials, and ambulation. However, we also found that the rate of adoption for individual practices varied over time with the frequency of some practices appearing to be rising sharply late in the study period. Overall, RCC implementation was not associated with incrementally greater decreases in the length of ventilation or hospitalization, however, it was independently associated with a 15% reduction in the adjusted odds of hospital mortality and a 12% decrease in the odds of thirty-day mortality. At the same time, based on the design of this study of an ongoing quality improvement program, this decrease could not be directly attributable to specific elements of the RCC care bundle.

Several prior studies have shown that individual elements comprising the RCC program improve short- and long-term outcomes in critically ill patients.^{8,12} As a result, increasing attention has focused on improving ICU care by implementing these elements together through bundled care initiatives.^{13–15} For example, the Rethinking Critical Care and ‘ABCDE’ bundles—an acronym based on **A**wake and **B**reathing trial coordination, **C**hoice of sedatives and analgesia, daily **D**elirium monitoring, and early **E**xercise and mobility—focus on reducing the morbidity and mortality resulting from critical care and ventilation.^{25,26} However, the efficacy of these initiatives on ICU outcomes when bundled together has not been well-described, especially when placed within the context of secular trends that predate implementation.¹⁵ And, most studies of the individual practice elements have occurred within the confines of randomized clinical trials at academic medical centers which may impact their effectiveness when deployed in other care settings.

In a recent study, Balas and others evaluated the outcomes of 296 general ICU patients before and after implementation of the ‘ABCDE’ program at a single academic medical center.^{15,26} Following implementation, patients were significantly more likely to undergo spontaneous awakening and breathing trials, to be mobilized even when mechanically ventilated, and to not receive benzodiazepines during their ICU stay. The corresponding changes in outcomes following implementation were substantial. Patients spent more days free of mechanical ventilation over a 28-day period and demonstrated a 45% reduction in their odds of delirium during their ICU stay. Implementation was also associated with an impressive 44% reduction in 28-day hospital mortality.¹⁵

In our much larger study, we found the impact of RCC implementation to be more modest. For example, while our metrics to evaluate the use of mechanical ventilation differed, we found that differences in the mean length of ventilation between the pre- and post- phases were not significant when accounting for the secular trend towards shorter ventilation that was already present prior to implementation. Comparisons of ICU and hospital length of stay yielded similar findings. Despite these non-significant findings in presumed intermediate outcomes, we did note a modest reduction in adjusted hospital and thirty-day mortality.

The more modest impact of RCC implementation on outcomes in our study could have resulted from several factors. First, the ICU case-mix differed between studies; for example, 63% of ICU patients in the Balas et al sample were mechanically ventilated compared with 18% in our sample.¹⁵ Not surprisingly, baseline mortality was 20% in Balas et al’s pre-implementation sample, compared with 12% in the current study. Second, Balas et al found that prior to ‘ABCDE’ implementation many patients were already receiving individual bundle elements. For example, 47% of mechanically ventilated patients were already being mobilized out of bed and 71% of patients underwent a spontaneous breathing trial. Although the metrics in our study differed, even our post-implementation compliance appeared lower potentially raising the possibility that the benefits of bundle implementation manifest in a stepwise, rather than linear, fashion requiring a ‘critical mass’ for improvement.

Third, our metrics for awakening and breathing trials and ambulation showed rapid increases from 2013 forward suggesting that the number of patients who were in the post-

implementation phase and also receiving these care elements was still increasing. Thus, the current study may be capturing only the partial impact of a multi-faceted and complex performance improvement program still in the process of maturing. The facility-specific mortality analysis shows that the impact of implementation period was most prominent in the two earlier implementing facilities. At the same time, however, it was clear that at a facility-level, individual bundle elements, as seen in the example of spontaneous awakening and breathing trials at Facility 3, were already underway even before the facility formally entered the implementation period. Finally, while the RCC and 'ABCDE' programs bear many similarities, there may have been differences in the implementation strategies used at study hospitals.

The primary strength of our study is that we evaluated a very large sample of ICU patients from a multi-center sample of community hospitals. Thus, our findings help to address critical gaps in our understanding of how efficacious but complex practices in the ICU can be translated into effective real-world practice.²⁷ Outside of carefully scripted clinical trials, implementation of multidisciplinary bundled programs requires broad institutional and stakeholder commitment that needs to be balanced against the competing demands of other challenging quality improvement efforts. In a recent study of 4 hospitals, Carrothers and others found that numerous structural and cultural elements were relevant for reliably implementing the ABCDE bundle including stable ICU leadership with multidisciplinary representation and a commitment to a culture of quality improvement as well as access to resources (both training materials and trainers).²⁸ Our study suggests that these commitments result in improved risk-adjusted mortality, however, additional study is necessary to understand which facets of the program and implementation process mediated the improvement. Our study also benefits from baseline data preceding the implementation period allowing us to evaluate RCC implementation against the background of steadily improving outcomes over time.

Our findings should also be noted in light of the study's limitations. First, we conducted a retrospective analysis of electronic data collected in the course of routine clinical care. As a result, important metrics related to some bundle elements were not available through the entire period limiting our ability to comprehensively evaluate the program's implementation. Thus, in the current study, we were not able to conduct specific sub-analyses associating individual metric compliance with outcomes. Future studies should address the relative importance of different bundle elements on outcomes improvement. Second, bundle implementation was initiated in late 2011 in a pilot site but was still being undertaken through the data collection period limiting our ability to measure the full impact of implementation especially in a mature phase marked by increased compliance. Third, our study was not designed to look at additional variables of interest including the frequency of delirium in our population or changes in discharge disposition that are thought to be important risk factors or outcomes in assessing ICU complications. Fourth, our study does not account for changes in practice and outcomes resulting from other contemporaneous quality improvement efforts, although RCC implementation was the major focus of regional quality improvement after our sepsis performance improvement efforts matured in mid-2010. Finally, our study used aggregate measures of clinical staff documentation of

RCC metrics which may not have accurately captured true bundle implementation or performance.

CONCLUSION

In conclusion, we found that the staged implementation of the Rethinking Critical Care ICU care improvement program in a multi-center community hospital setting was associated with changes in practice and a 12% to 15% reduction in the odds of short-term mortality in interim analysis. However, our findings may represent an evaluation of changes in practices and outcomes still in the mid-implementation phase and cannot be directly attributed to the elements of bundle implementation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The authors would like to recognize the hard work and dedication of hundreds of clinicians providing care in the intensive care units throughout the implementation period. The authors would also like to thank members of the Kaiser Permanente Northern California regional quality improvement staff who led and assisted with the implementation process including Melinda Skeath, Carmen Adams, Elizabeth Scruth, Lorelle Poropat, Jay Soule, Alexander Mustille, Preetpaul Bajwa, and Robby Thompson.

Financial Disclosure: This work was funded by the Gordon and Betty Moore Foundation, The Sidney Garfield Memorial Fund, The Permanente Medical Group, Kaiser Foundation Health Plan and Hospitals. Vincent Liu received support from NIH K23GM112018.

Copyright form disclosures: Dr. Liu received grant support from The Gordon and Betty Moore Foundation, is employed by The Permanente Medical Group, received grant support from the National Institutes of Health (NIH), and received support for article research from the NIH. His institution received grant support from The Garfield Memorial Fund. Dr. Herbert provided expert testimony for the California Medical Board. His institution received grant support from the Gordon and Betty Moore Foundation. Dr. Marelich is employed by The Permanente Medical Group, Inc (physician/administrator). Dr. Patel is employed by Kaiser Permanente. Dr. Whippy is employed by The Permanente Medical Group. His institution received grant support from the Garfield memorial fund (innovation grant). Dr. Turk is employed by the Kaiser Permanente Division of Research. His institution received grant support from the Gordon and Betty Moore Foundation and Garfield Memorial Fund. Dr. Ragins is employed by Kaiser Permanente and received support for article research from the Betty & Gordon Moore Foundation. Her institution received grant support from the Betty & Gordon Moore Foundation. Dr. Escobar is employed by the Permanente Medical Group. His institution received grant support from the NIH and from the Betty & Gordon Moore Foundation. The remaining authors have disclosed that you do not have any potential conflicts of interest.

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Figure 1. The timing and compliance with Rethinking Critical Care implementation program metrics

Data collected by quality improvement staff using standardized criteria (Appendix Table 1). Abbreviations include: Vent time (ventilator start-stop time); CAM-ICU (Confusion Assessment method Intensive Care Unit); SAT/SBT (spontaneous awakening and breathing trial); Amb 1' (ambulation of at least 1 foot); Amb 20' (ambulation of at least 20 feet).

Figure 2. Quarterly hospital mortality rates
Dashed lines indicates the timing of Rethinking Critical Care implementation program beginning at Facility 1 (1), Facility 2 (2), and Facility 3 (3).

Figure 3. Mean length of mechanical ventilation and number of ventilator episodes by quarter
 Solid line represents mean value and short dotted lines represent 95% confidence limits of mean duration of mechanical ventilation in hours. Long dashed lines and circles represent the number of quarterly mechanically ventilated patients.

Table 1
Baseline characteristics of critically ill patients based on implementation period

Comorbidity score based on the Comorbidity Point Score, version 2. The severity of illness is based on the electronic adaptation of the Simplified Acute Physiology Score, version 3. Principal diagnosis based on International Classification of Disease, 9th Edition.

		Implementation Period	
	Overall	Pre-implementation	Post-implementation
Number of ICU episodes	24,886	18,114	6,772
Age	64 ± 17	64 ± 17	63 ± 17
Male	12,775 (51.3)	9,327 (51.5)	3,448 (50.9)
Comorbidity score	45 ± 45	45 ± 44	43 ± 47
Severity of illness	47 ± 13	47 ± 13	46 ± 13
Mechanically ventilated	4,581 (18.4)	3,325 (18.4)	1,256 (18.6)
Facility 1 (1 st site to implement)	8,434 (33.9)	5,053 (27.9)	3,381 (49.9)
Facility 2 (2 nd site)	8,878 (35.7)	6,665 (36.8)	2,213 (32.7)
Facility 3 (3 rd site)	7,574 (30.4)	6,396 (35.3)	1,178 (17.4)
Principal diagnosis			
Most common Septicemia	4,452 (18.1)	3,079 (17.1)	1,373 (20.7)
Second most common Respiratory failure	1,222 (6.4)	1,199 (6.7)	368 (5.5)

Table 2
Multivariable logistic regression models to evaluate the association between the
Rethinking Critical Care implementation period and mortality

Model 1 includes no covariables. Model 2 includes ICU facility indicators. Model 3 variables include Model 2 and patient age, gender, resuscitation care order at hospital entry, eSAPS3 (electronic Simplified Acute Physiology Score version 3) severity of critical illness score, need for mechanical ventilation, and COPS2 (Comorbidity Point Score version 2) comorbidity score. Model 4 variables include Model 3 and continuous month variable over the study period and categorical calendar month. Model 5 is a segmented regression analysis to evaluate the possibility of both a mortality effect (Facility-specific estimates, show in Table) as well as an effect on the mortality trend (slope) following implementation.

Model	Odds ratio	95% CI	p-value
HOSPITAL MORTALITY			
Model 1 (unadjusted)	0.87	0.80 – 0.95	<0.01
Model 2 (Model 1+ facility adjustment)	0.85	0.77 – 0.93	<0.01
Model 3 (Model 2 + patient-level variables)	0.83	0.75 – 0.92	<0.01
Model 4 (Model 3 + secular trend and seasonality)	0.85	0.73 – 0.99	0.04
Model 5 (Model 4 + facility-specific effects)			
Facility 1	0.73	0.55 – 0.96	0.02
Facility 2	0.71	0.51 – 0.99	0.04
Facility 3	0.94	0.61 – 1.45	0.78
THIRTY-DAY MORTALITY			
Model 1 (unadjusted)	0.90	0.83 – 0.98	0.01
Model 2 (Model 1 + facility adjustment)	0.88	0.81 – 0.96	<0.01
Model 3 (Model 2 + patient-level variables)	0.88	0.80 – 0.97	<0.01
Model 4 (Model 3 + secular trend and seasonality)	0.88	0.80 – 0.97	0.01
Model 5 (Model 4 + facility-specific effects)			
Facility 1	0.87	0.68 – 1.12	0.29
Facility 2	0.74	0.55 – 1.01	0.06
Facility 3	1.02	0.68 – 1.54	0.91