Evaluating the Effectiveness of a Multicomponent Care Bundle Among Intubated Patients

by

Sarma Klimanis Givens

Under Supervision of

Lynn Marie Bullock, DNP, RN, NEA-BC

Second Reader

Bridgitte Gourley, DNP, FNP-BC

A DNP Project Manuscript
Submitted in Partial Fulfillment of the Requirements for the
Doctor of Nursing Practice Degree

University of Maryland School of Nursing
May 2022

Abstract

Problem: At a community hospital, the current intensive care unit (ICU) length of stay (LoS) is increasing. In January 2021, the LoS was 3.84 days, and in December 2020, it was 3.0. Also, it is above the average ICU LoS in the United States, which according to the Society of Critical Care medicine, is 3.8 days. Prolonged LoS can lead to ICU delirium, higher hospital bill costs, decreased quality of life, long-term physical impairments, and is associated with increased risk of long-term mortality after hospital discharge. *Purpose*: The purpose of this quality improvement project is to implement and evaluate the effectiveness of the ABCDEF bundle in an adult medical/surgical ICU. ABCDEF stands for: assess, prevent, and manage pain; both spontaneous awakening and breathing trials; choice of analgesic/sedation; delirium: assess, prevent, and manage; early mobility and exercise; and family engagement. It is anticipated that the implementation of this bundle could result in a shortened LoS among intubated patients. *Methods*: Data was collected using an observational checklist adopted from the Society of Critical Care Medicine's website. All nurses were educated on how to use this tool. The tool was completed once a day, around the time of rounds, by charge nurses to assess which of the ABCDEF bundle elements were applied to intubated patients. The observational checklists were collected and analyzed weekly. *Results*: By the end of the implementation phase, 100% of staff nurses have received education on patient eligibility for the bundle, 22.9% of intubated patients (who met criteria) received all components of the ABCDEF bundle, and 67.4% of intubated patients were assessed via Observational Checklist, and the average LoS during the 15 weeks was 7.53 days. *Conclusions*: Though LoS was not decreased, progress was achieved. Nurses demonstrated proficient skills when applying the bundle to patients and nurses gained confidence in initiating SAT/SBTs and early-mobility practices. Post-implementation the SAT/SBT provider

order became available for use in EPIC and the SAT/SBT policy has been updated and published on the institution's intranet. Limitations such as high staff turnover may have negatively impacted this project.

Effectiveness of a Multicomponent Care Bundle Among Intubated Patients

According to the Society of Critical Care Medicine, the national average ICU length of stay (LoS) is 3.8 days. A LoS longer than this could negatively impact patients and their families. Prolonged ICU LoS can lead to ICU delirium, overall longer hospital stays, higher hospital costs, decreased quality of life, long-term physical impairments, and is associated with increased risk of long-term mortality after hospital discharge (*Longer Stay in Hospital ICU Has Lasting Impact on Quality of Life*, 2014; Williams et al., 2010). It has been documented that families of ICU patients with lengthy stays have developed adverse psychological outcomes such as anxiety, acute stress disorder, posttraumatic stress, depression, and complicated grief (Davidson et al., 2012).

The problem that a community hospital is experiencing is that the current ICU LoS is 3.84 days as of January 2021, and in December 2019 it was 3.0 days. It has increased and is above the average ICU LoS in the United States. The problem with this current state is that a prolonged LoS can lead to negative patient outcomes as mentioned above.

The current state of clinical practice regarding application of all six ABCDEF bundle elements is that there is no protocol in place to apply bundle elements to intubated patients. See Appendix A for current process flow map. The purpose of this quality improvement project is to implement and evaluate the effectiveness of a multicomponent care ABCDEF bundle in an adult medical/surgical ICU in an urban, community hospital setting to every intubated patient who meets eligibility criteria. The anticipated outcome of this implementation is to decrease the LoS

in intubated patients, which in turn may decrease ICU delirium, overall longer hospital stays, higher hospital bill costs, long-term physical impairments, and risk of long-term mortality. For this project one of the measurable outcomes will specifically be LoS.

Literature Review

The evidence reviews and synthesis tables include five studies that are relevant to the practice change being implemented, see Tables 1 and 2. The studies include similar target populations (intubated patients), setting/contexts (intensive care units), interventions (multicomponent care bundles), and outcomes (length of stay, delirium, morbidity, and number of ventilator free days). The studies were published within the past 5-10 years. These studies are viewed as project models to support the intervention.

Trogrlić et al. (2015) conducted a systematic review (SR) with meta-analyses which found that reduced mortality and ICU length of stay reduction were statistically more likely with implementation programs that employed six or more implementation strategies and when a framework was used that either integrated current evidence on pain, agitation, and delirium management (PAD) or when a strategy of early awakening, breathing, delirium screening and early exercise (ABCDE bundle) was employed. The SR included analysis of 21 studies, which included randomized control trials (RCTs). There was control and randomization in most of the studies. This is SR had well-defined, reproducible search strategies. Consistent results with sufficient numbers of 21 well-defined studies were included. There was a criteria-based evaluation of overall scientific strength and quality of included studies. Definitive conclusions were outlined in the discussion (decreased LOS and mortality with a bundle-approach).

Devlin et al. (2018) updated the 2013 clinical practice guidelines (CPGs) on pain, agitation, and delirium. Many topics were discussed, but when the panel answered the question

"Should a multicomponent, nonpharmacologic strategy (vs no such strategy) be used to reduce delirium in critically ill adults?" it was recommended that ABCDEF bundle be used to address this question because bundle-compliance was statistically significantly associated with reduced mortality and less ICU days with coma or delirium. This study was CPG with a mix of RCTs, and non-randomized studies. Well-defined, reproducible search strategies were defined. There were consistent results in over 41,000 studies observed. There studies were strong overall in scientific strength and quality.

Pun et al. (2019) conducted a prospective, multicenter, cohort study. The association between complete and proportional ABCDEF bundle performance and three sets of outcomes were investigated. Complete ABCDEF bundle performance was associated with lower likelihood of seven outcomes: hospital death within 7 days, next-day mechanical, coma delirium, physical restraint use, ICU readmission, and discharge to a facility other than home. This study has a sufficient sample size (n=15,226). There was some control (partial- versus total-bundle compliance) performance. Definitive results were drawn using statistical measurement tools. The results were consistent. Recommendations were clear that the bundle-approach was statistically significant affecting positive patient outcomes. However, the design study did not have randomization or control.

Balas et al. (2014) conducted a prospective, cohort, before and after study, evaluating the effectiveness and safety of implementing the ABCDE bundle into everyday practice. The bundle had statistically significant results that number of mechanically ventilated days decreased, hospital mortality was lower, mobilization increased. No significant difference was noted in coma prevalence, or ICU/hospital length of stay. This cohort study had consistent results. Sample size was relatively small (n=296) but with good group homogeneity. Conclusions were definitive

that the ABCDE bundle appears to be a valuable tool in the management of critically ill patients even though length of stay did not significantly decrease (or increase), other outcomes improved significantly. Strengths and limitation were discussed. One strength was the daily assessment of patients' sedation/agitation level and delirium status by trained study staff using valid and reliable screening instruments. Due to the sample size and study design is susceptible to both temporal changes as well as the impact of important unbalanced (or missing) confounders not included in our multivariable adjustment.

Barnes-Daly et al. (2017) conducted a prospective, cohort quality improvement initiative which studied the association between the ABCDEF bundle compliance and outcomes such as delirium-free and coma-free days in the hospital setting. Patients experienced more days alive and free of delirium and coma with both total bundle compliance. Reasonably consistent results using statistical methods for analysis exist and there was a sufficient sample size (n=6,064). Overall, the recommendations concluded were that higher bundle compliance was independently associated with improved survival and more days free of delirium and coma.

Theoretical Framework

After looking at the HS/HSL databases and searching "communication" "theories" and "social" theories, the Self-Efficacy Theory (SET) was chosen. This theory explained what factors contribute to self-efficacy and how it determines behavior. (Bandura, 1989). SET was applied to the QI project. It was useful to realize that the nurses' perceptions of their own self-efficacy affected their likelihood in carrying out a new implementation. Because ICU nursing care is highly autonomous, it was interpreted that the ICU RNs have high perceived self-efficacy. This was important because the higher one's self-efficacy, the more likely one will carry out a behavior, especially in a new/challenging situation. This theory was favorable to consider when

implementing a new innovation in the ICU where the nurses are highly autonomous and possess high self-efficacy. And therefore, the project leader had little doubt that after the implementation phase, this specific group of ICU nurses would continue the process of implementing the ABCDEF bundle to every ICU patient, every day. See Figure 1.

The process framework described by Helfrich et al. (2007) was applied to the specific implementation plan for the QI project. This framework specified the steps which were needed to reach the implementation goals. For example, the QI project required management support/financial resource availability to implement the ABCDEF-bundle. Management helped determine an appropriate innovation-value fit between the organization and the innovation (ABCDEF-bundle). Also, this framework described the factors that may influence outcomes. For example, factors such as unit champions and the assessment of innovation-values fit directly influenced the long-term outcome (LoS) of this QI project. And the implementation's effectiveness was dependent upon the implementation climate (nursing/provider culture, pandemic status, patient population etc.).

Methods

This project took place on a 32-bed inpatient adult ICU in an urban community hospital in Baltimore City, Maryland. Approximately 58 staff nurses were available on the unit to implement the ABCDEF bundle. All patients were included in the intervention including those patients who were a part of the most vulnerable populations including non-English speaking, prisoners, morbidly obese, having numerous surgical drains, and having nutrition tubes.

The practice change was the application of the ABCDEF bundle to intubated patients. The nurses received educated on the inclusion/exclusion criteria for each bundle element. During rounds staff nurses discussed which bundle-elements were applied to their intubated patients.

Charge nurses completed the observational checklist (Appendix A) to document number of bundle elements completed on each patient. Each week, the project leader collected the checklists and audited them with the data management spreadsheet (Appendix B). The implementation team included nurses, the nurse manager, nurse educator, providers, respiratory therapists, physical therapists, and nurse technicians.

To track implementation, the following structure, process, and outcome goals were tracked: 100% of the ICU staff RNs will be educated on the eligibility criteria for patients receiving the ABCDEF bundle, 100% of intubated patients will have received all components of the ABCDEF bundle within 72 hours of admission, 100% of intubated patients will be assessed via observational checklist by a dayshift charge nurse, and 100% of ICU-status patients will achieve a LoS $\leq$3.0 days.

To facilitate the goal of educating ICU staff RNs, the project leader developed educational materials, provided food, and sent thank you letters to staff after education sessions to show appreciation to the nurses. To reach the goal of "100% of intubated patients will have received ABCDEF bundle completeness", the project leader identified and prepared change champions, scheduled group discussions during 11 a.m. nurse huddle, completed data analysis and provided feedback to staff. To reach the goal of "100% of intubated patients were assessed via observational checklist daily", the project leader verbally reminded charge nurses weekly of this task, assisted charge nurses to complete checklist when physically on the unit, and sent reminder e-mails to nurses about what each bundle element stood for and how to implement it. The bedside nurses were responsible for physically applying the bundle elements. For example, the bedside nurses would get intubated patients out of bed, initiate SAT/SBTs, assess sedation/analgesics used, assess the patients' delirium status, and encourage family engagement.

Each day, the charge nurses completed the observational checklist (Appendix A) to document number of bundle elements completed on each patient. Each week, the checklists (Appendix A) were collected and analyzed with the data management spreadsheet (Appendix B). The project leader conducted staff interviews and recorded the outcomes using a data management spreadsheet (Appendix C), to assess if the short-term structure goal of the project was met. At the end of the 15 weeks, a run chart was completed to analyze the data to assess if all of the short-term goals of the project were met. And at the end of the 15 weeks, the finance/revenue staff calculated the LoS with electronic data to see if LoS was changed.

A code key (Appendix D) was created to protect clinicians, patients, and their data by using clinician/patient codes on the spreadsheets. It was filed securely in a password protected laptop which was kept in the project leader's home office which was locked and separate from the data management spreadsheets and only was accessible by the project leader.

By week fifteen, 100% ICU staff nurses were educated on the eligibility criteria for patients receiving the ABCDEF bundle. On the run chart, there was a positive trend, there seemed to be an appropriate number of runs, the data was not too scattered, and a shift occurred at weeks 9-15 where 6 datapoints were above the median. See Figure 3. By week fifteen, 67.4% of total intubated patients were assessed via Observational Checklist by a nurse. There was no trend on the run chart, there seemed to be an appropriate number of runs, the data was not too scattered, no shift existed in the run chart. There was one astronomical point at week three where only 50% of intubated patients were assessed via Observational Checklist. At week 12, the median decreased to 57.5% indicating compliance of nurse use of the Observational Checklist sharply declined. See Figure 4. By week fifteen, 22.9% of patients, who met eligibility criteria, received all components of the ABCDEF bundle within 72 hours of admission. There was no

trend on the run chart, there seemed to be an appropriate number of runs, the data was not too scattered. No shift exists in the chart. See Figure 5.

Results

Changes in structures were made to achieve the goals of this quality improvement project. For example, the implementation team educated 100% of the ICU staff nurses on the eligibility criteria for patients receiving the ABCDEF bundle. This was evidenced by the staff interviews conducted by the Project Leader throughout the implementation phase. The goal of educating 100% of nurses was achieved, though not by the September 30th date as desired. However, the goal was achieved by the end of the implementation phase. There was a correlation seen that as more nurses were educated on the multicomponent care bundle, the more observational checklists were completed, and bundle completeness increased.

Two changes in processes occurred: intubated patients, who meet eligibility criteria, were to receive all components of the ABCDEF bundle implemented by an ICU nurse within 72 hours of admission and intubated patients were to be assessed via observational checklist by a dayshift charge nurse daily. By week 15, 22.9% of intubated patients (who met criteria) received all components of the ABCDEF bundle, and 67.4% of intubated patients were assessed via Observational Checklist. Though the goals of 100% for each process goal was not achieved, significant improvements were made with both changes. This information had not been previously monitored, and therefore significant increases in intubated patients receiving all bundle elements and nurses assessing patients via an Observational Checklist were seen.

It seemed that the initiation of SAT/SBTs and early-mobility practices were major pitfalls for achieving bundle completeness. Despite continuous education and reminder e-mails to nurses on “how to” complete these elements, barriers stood in the way. When asked, one nurse stated

they would prefer SATs/SBTs to occur during day shift versus night shift. Also, high staff turnover rate among respiratory therapists, nurses and providers was a barrier to educating all staff at the beginning of the implementation since some staff were onboarded after the implantation began. Some ICU staff resigned because they were seeking a higher paying position at another institution. Therefore, cost was seen as a barrier to this project since staff were not satisfied with their current wage and higher and more satisfying wages were not offered to staff. The number of staff that left during the implementation phase was not equally replaced in quantity or expertise, and the unit suffered from short staffing issues. This QI project was a new initiative and possibly caused "project-fatigue". Feelings of being over-worked may have existed among the already stretched staff.

Discussion

During the implementation phase key findings, project impact and relevance were discovered. ICU nurses became much more autonomous with early-mobility- practices. Some nurses had expressed apprehension about getting intubated patients out of bed in the early phases of the implementation, but as the project went on, more and more intubated patients were mobilized. Also, night shift nurses became more autonomous with spontaneous awakening and breathing trials (SAT/SBTs). This policy was non-existent in the early weeks of the project meaning there was no SAT/SBT policy in place. After the policy "went live" and nurses were educated on how to perform SATs/SBTs, more nurses performed this task in the later weeks of the implementation. Overall, as more nurses were educated on the ABCDEF bundle elements, compliance with the observational checklist and bundle completeness increased. And, their confidence was most likely reinforced by seeing this initiative as a "new normal' on the unit.

Some similarities and differences existed between this project's results and result findings found in other publications. For example, the average LoS during the implementation phase did not decrease as had occurred several studies in the literature. The LoS in this community hospital's ICU increased during the implementation phase. However, as was seen in the literature, more bundle elements were completed by the nurses as more education was given on how to complete the bundle elements on intubated patients. The more education was provided, the more bundle completeness was achieved as the weeks progressed during the implementation. Though bundle completeness increased, LoS did not decrease as has been proven in the literature.

There were some possible reasons for differences between observed and anticipated outcomes. For example, there was a high turnover rate of nurses, providers, and respiratory therapists during the implementation of this project. While some staff left during this time, they were not all replaced with new staff which caused the unit to be 'short-staffed'. Due to a lack of staff, the nurses sometimes worked with higher nurse-to-patient ratios than they normally did causing a very fast-paced and stressful work environment. Taking on new initiatives during a stressful time only added additional tasks for the staff and therefore sometimes the observational checklists were not completed on every single intubated patient. Additionally, many nurses from other units were "pulled" to the ICU and were caring for patients. However, the nurses from other units were not educated on the ABCDDEF bundle and therefore they did not know to perform the ABCDEF bundle on their intubated patients. Only permanent ICU staff members were educated on this project.

There were some factors that might have limited internal validity such as bias or imprecision in the project design, methods, measurement. For example, when calculating LoS in

ICU patients, the finance and revenue team calculated the LoS for intubated patients only since this is the population of the unit who received the implementation. The LoS from Dec 2019 included all critical care status patients therefore this included patients were considered critical care status though technically some of those patients may not have been intubated. When calculating average LoS during the implementation, only patients with an intubation charge were included. To minimize and adjust for limitation, the finance and revenue team was sure to only include patients admitted during the dates Aug 30, 2021 – Dec 15, 2021. Some patients who had a late December admit have days counted past December 15th since they were still here. For example, if a patient was admitted on the Dec 15th but discharged on Dec 20th, their 5 days were counted in this data. This information was included because we wanted to reflect any patient who received the implementation up until Dec 15th.

Conclusion

This QI project was useful in many ways to the community hospital's ICU and its staff. The project introduced an evidence-based approach to nursing care for intubated patients. The education provided by the implementation team gave clear instruction on safety criteria for early-mobilization practices and SAT/SBTs. In addition, the project facilitated a multidisciplinary approach to managing intubated patients' ventilator settings/sedation goals, involving the provider, nurse, and respiratory therapist. The goals of this project were to improve patient outcomes by decreasing LoS which in turn can decrease ICU delirium, overall longer hospital stays, higher hospital bill costs, long-term physical impairments, and risk of long-term mortality.

Actions were taken to sustain this practice change after its initial implementation phase. The ABCDEF resource binder is permanently located at the nurse's station for reference. A Spontaneous Awakening and Breathing Trials (SAT/SBT) policy has been updated and

published on the institution's intranet. SAT/SBT documentation is now visible across disciplines allowing providers to see what respiratory therapy (RT) and nursing have documented. All ABCDEF bundle elements can be documented electronically in EMR. And the SAT/SBT provider order is now available for use in EPIC.

Next steps for this project to promote sustainability and further improvements for bundle completeness for intubated patients could be the discussion of ABCDEF bundle during rounds because this may increase bundle completeness as was seen in the literature. Training new staff on ABCDEF bundle intervention is necessary to sustain this practice. And the unit needs a designated staff member to continue documenting the data and reeducating staff as necessary. Once COVID cases decrease, there will be less burden on staff. Eventually the staff may be more dedicated and motivated to put their energy to this initiative once the burden of COVID is reduced.

References

Balas, M. C., Vasilevskis, E. E., Olsen, K. M., Schmid, K. K., Shostrom, V., Cohen, M. Z., ... & Burke, W. J. (2014). Effectiveness and safety of the awakening and breathing coordination, delirium monitoring/management, and early exercise/mobility (ABCDE) bundle. *Critical care medicine*, *42*(5), 1024.

Bandura, A. (1997) Self-Efficacy: The Exercise of Control. W.H. Freeman and Company, New York.

Bandura, A. (1994). Self-efficacy. In V. S. Ramachaudran (Ed.), Encyclopedia of human behavior (Vol. 4, pp. 71-81). New York: Academic Press. (Reprinted in H. Friedman [Ed.], Encyclopedia of mental health. San Diego: Academic Press, 1998).

Bandura, A. (1989). Social cognitive theory. *Annals of child development.*, *6*(), 1 -60. Retrieved from https://www.uky.edu/~eushe2/Bandura/Bandura1989ACD.pdf

Barnes-Daly, M. A., Phillips, G., & Ely, E. (2017). Improving hospital survival and reducing brain dysfunction at seven California community hospitals: implementing PAD guidelines via the ABCDEF bundle in 6,064 patients. *Critical Care Medicine*, *45*(2), 171-178.

Davidson, J. E., Jones, C., & Bienvenu, O. J. (2012). Family response to critical illness: postintensive care syndrome-family. *Critical care medicine*, *40*(2), 618–624. https://doi.org/10.1097/CCM.0b013e318236ebf9

Devlin, J. W., Skrobik, Y., Gélinas, C., Needham, D. M., Slooter, A. J., Pandharipande, P. P., ... & Alhazzani, W. (2018).

Longer stay in hospital icu has lasting impact on quality of life. (2014, April 2). Johns Hopkins Medicine. Retrieved January 10, 2021,

from https://www.hopkinsmedicine.org/news/media/releases/longer_stay_in_hospital_icu_has_lasting_impact_on_quality_of_life

OVP Management Consulting Group Inc. (2018). *Bandura's Self Efficacy Theory*. Retrieved July 12, 2021, from https://www.ovpconsulting.com/weekly/2018/11/16/086p3teoj8d0dbvuwbt51sh7qkc63c

Pun, Brenda, DNP, RN, Balas, Michele, PhD, RN, CCRN-K, FCCM, Barnes-Daly, Mary, et al. (2019). Caring for Critically Ill Patients with the ABCDEF Bundle: Results of the ICU Liberation Collaborative in Over 15,000 Adults. *Critical Care Medicine*, *47*, 3-14. https://doi.org/10.1097/CCM.0000000000003482

Sccm | critical care statistics. (n.d.). Society of Critical Care Medicine (SCCM). Retrieved March 1, 2021, from https://www.sccm.org/Communications/Critical-Care-Statistics

Trogrlić, Z., van der Jagt, M., Bakker, J., Balas, M. C., Ely, E. W., van der Voort, P. H., & Ista, E. (2015). A systematic review of implementation strategies for assessment, prevention, and management of ICU delirium and their effect on clinical outcomes. *Critical Care*, *19*(1), 1-17.

Williams, T. A., Ho, K. M., Dobb, G. J., Finn, J. C., Knuiman, M., & Webb, S. A. R. (2010). Effect of length of stay in intensive care unit on hospital and long-term mortality of critically ill adult patients. *British journal of anesthesia*, *104*(4), 459-464.

Zimmerman, Jack E. MD, FCCM; Kramer, Andrew A. PhD; McNair, Douglas S. MD, PhD; Malila, Fern M. RN, MS; Shaffer, Violet L. MA Intensive care unit length of stay: Benchmarking based on Acute Physiology and Chronic Health Evaluation (APACHE)

IV*, Critical Care Medicine: October 2006 - Volume 34 - Issue 10 - p 2517-2529 doi: 10.1097/01.CCM.0000240233.01711.D9

Tables

Table 1.

Evidence Review Table

Citation: Trogrlić, Z., van der Jagt, M., Bakker, J., Balas, M. C., Ely, E. W., van der Voort, P. H., & Ista, E. (2015). A systematic review of implementation strategies for assessment, prevention, and management of ICU delirium and their effect on clinical outcomes. *Critical Care*, *19*(1), 1-17.					**Level**: I
Purpose/Hypothesis	Design	Sample	Intervention	Outcomes	Results
"The purpose of this systematic review is to summarize what types of implementation strategies have been tested to improve ICU clinicians' ability to effectively assess, prevent and treat delirium and to evaluate the effect of these strategies on clinical outcomes"	Systematic review (with meta-analyses) of studies including RCTs	**Search Strategy:** Review was performed according to the PRISMA guidelines. PubMed, Embase, Psych INFO, Cochrane and CINAHLwere searched for studies published between January 2000 - April 2014 with no search filter limits. The year 2000 was chosen because a preliminary Pubmed search with the search terms 'delirium', 'implementation', 'ICU', 'critically ill', 'critical care', yielded only one study that year that pertained to the subject of this review and none before. A biomedical information specialist at the medical library of the Erasmus MC - University	**Control**: Controls varied between studies included in the SR (PAD/ABCDE or separate interventions such as delirium screening only and Visual feedback system, delirium prevention program, and Multifaceted sleep promotion program) **Intervention :** Different implementation strategies (ex. "audit and feedback" and "tailored interventions", distribution of educational materials, educational meetings, reminders, mass media, provider-oriented interventions, patient-mediated interventions,	**DV**: Outcomes were distinguished between clinical outcomes (ICU length of stay (LOS) and mortality)) and process outcomes (adherence to screening for the presence of delirium, knowledge of delirium, incidence of delirium, use of antipsychotics) **Measurement tool:** The clinical and the process outcomes were measured pre- and post- intervention, examined with a variety of implementation methods observing for increase or decrease. See Table 3.	**Level of measurement:** Associations between study characteristics and outcomes were assessed with Pearson's chi-square or Fisher's exact test after dichotomization (for example, significant decrease of delirium incidence: yes/no). The number of implementation strategies used in the implementation studies was summarized as median with IQR. The effectiveness of the implementation interventions was expressed as a risk ratio (RR) for dichotomous outcomes by using a DerSimonian and Laird random-effect model and as a weighted mean difference (WMD) for

		Medical Center Rotterdam guided the search. Search terms included intensive care and delirium and were tailored to each database and its indexing. **Eligible studies:** The search focused on clinical studies aimed at implementation of delirium screening, prevention or management in the adult ICU setting. Implementation could be focused on single components of delirium care or delirium screening, prevention and/or management as an integral part of a wider bundle or guideline (for example, ABCDE bundle or PAD guideline. Any type of ICU was included. To be included in the review, the study had to contain a clear description of the implementation processes. **Exclusion Criteria:** Studies that concerned delirium related to alcohol withdrawal	structural interventions, peer review or licensure) Full list of interventions in Table 1. **Protocol:** N/A		continuous outcomes with 95% CIs. Analysis was performed with Microsoft Excel 2013 and IBM SPSS 21.0. Statistical significance was defined as a P-value <0.05. **Outcome data retrieval:** Researchers pooled data from selected articles **Analysis:** Pooled data from four studies reporting ICU LOS after implementation of PAD or the ABCDE bundle approach yielded significantly shorter LOS after implementation compared with not using these approaches (WMD = −1.71; 95% CI −2.45, −0.98 versus WMD −0.55, 95% CI −1.48, 0.38) In the studies that used the PAD guideline or ABCDE approach (n = 6) (Figure 3c) mortality reduction was higher (P = 0.0478) in studies that used a higher number of implementation strategies (RR = 0.73; 95% CI 0.59, 0.88 versus RR = 0.98; 95% CI 0.74, 1.30) **Conclusion:** Reduced mortality/ICU LOS reduction were statistically

		and/or were focused solely on validation of delirium screening tools. Further, the efficacy of the implementation intervention had to be reported in terms of a clearly defined outcome such as mortality, length of stay, and/or adherence to delirium screening. Reviews, opinion papers, editorials and comments on original articles were also excluded. Consensus on final selection was achieved by discussion with a third author. **Accepted:** 21 studies			more likely with implementation programs that employed more (six or more) rather than less, and when a bundle approach as used like the PAD or ABCDE. The findings indicate that multi-component implementation programs with a higher number of strategies targeting ICU delirium assessment, prevention and treatment and integrated within PAD or ABCDE bundle have the potential to improve clinical outcomes.
Citation: Pun, B., Balas, M., Barnes-Daly, M., et al. (2019). Caring for Critically Ill Patients with the ABCDEF Bundle: Results of the ICU Liberation Collaborative in Over 15,000 Adults. *Critical Care Medicine*, *47*, 3-14. https://doi.org/10.1097/CCM.0000000000003482					**Level**: IV
Purpose/Hypothesis	Design	Sample	Intervention	Outcomes	Results
"The relationship between ABCDEF bundle performance and patient-centered outcomes in critical care was evaluated. The association between complete and proportional ABCDEF bundle performance and three sets of outcomes	Prospective, multicenter, cohort study	**Sampling technique:** Convenience **Eligible patients:** Adult patients, whether on or off mechanical ventilation, who were admitted to a participating medical, surgical, cardiac, or neurologic ICU.	**Intervention protocol:** The surveyors measured complete and proportional bundle performance on days when a patient was in the ICU for a full 24 hours. Of those 15,226 patients, 10,840 (72%)	**Dependent Variable:** Patient-related outcomes (mortality, ICU and hospital discharge), symptom-related outcomes (mechanical ventilation, coma, delirium, pain, restraint use), and system-related outcomes (ICU readmission, discharge destination.	**Results:** Complete ABCDEF bundle performance was associated with lower likelihood of seven outcomes: hospital death within 7 days (adjusted hazard ratio, 0.32; CI, 0.17–0.62), next-day mechanical ventilation (adjusted odds ratio [AOR], 0.28; CI, 0.22–0.36), coma

were investigated: patient-related (mortality, ICU and hospital discharge), symptom-related (mechanical ventilation, coma, delirium, pain, restraint use), and system-related (ICU readmission, discharge destination."		**Exclusion criteria**: Patients who: 1) died or were discharged from the participating ICU within 24 hours of ICU admission or 2) were undergoing active life support withdrawal and/or "comfort care-only" within 24 hours of ICU admission. **Accepted**: n= 15,226 adults with at least one ICU Day **Group homogeneity:** see Table 1 **Control:** None **Intervention groups:** Patients with Complete (vs Incomplete) ABCDEF Bundle Performance	had two consecutive 24-hour ICU days and were thus eligible to be included in our symptom-related outcome models (33,689 patient-days); 12,756 (84%) survived hospitalization and thus were eligible for ICU readmission and discharge destination models.	**Measurement tools:** The patient-related outcomes (time to ICU discharge, hospital discharge, and death) were analyzed by Cox proportional hazards models with time-varying covariates. Patients with one 24-hour day in the ICU were included when observing the symptom-related outcomes (significant pain episodes, coma, delirium, physical restraint use, and mechanical ventilation). Significant pain episodes were recorded using a pain numeric rating scale score > 3, Behavioral Pain Scale (39) score > 5, or Critical Care Pain Observation Tool (40) score ≥ 3. Logistic regression was used to analyze these outcomes. The surveyors summarized ABCDEF bundle performance over the entire original collaborative ICU stay and, using logistic regression, analyzed the association between bundle performance, ICU readmission, and ICU discharge to a destination other than home among survivors (i.e., system-related outcomes). In all models, a robust sandwich estimation was, clustered by	(AOR, 0.35; CI, 0.22–0.56), delirium (AOR, 0.60; CI, 0.49–0.72), physical restraint use (AOR, 0.37; CI, 0.30–0.46), ICU readmission (AOR, 0.54; CI, 0.37– 0.79), and discharge to a facility other than home (AOR, 0.64; CI, 0.51–0.80). There was a consistent dose-response relationship between higher proportional bundle performance and improvements in each of the above-mentioned clinical outcomes (all $p < 0.002$). Significant pain was more frequently reported as bundle performance proportionally increased ($p = 0.0001$).

				study site to adjust variances, accounting for correlation among observations from the same site. The R Project for Statistical Computing software version 3.4 was used for all analyses.	
Citation: Devlin, J. W., Skrobik, Y., Gélinas, C., Needham, D. M., Slooter, A. J., Pandharipande, P. P., ... & Balas, M. C. (2018). Clinical practice guidelines for the prevention and management of pain, agitation/sedation, delirium, immobility, and sleep disruption in adult patients in the ICU. *Critical care medicine*, *46*(9), e825-e873.					**Level**: I
Purpose/Hypothesis	Design	Sample	Intervention	Outcomes	Results
The purpose of these clinical practice guidelines is, "To update and expand the 2013 Clinical Practice Guidelines for the Management of Pain, Agitation, and Delirium in Adult Patients in the ICU."	Clinical practice guidelines with a mix of RCTs, and non-randomized studies.	**Search Strategy**: Evidence searches focused on the highest quality evidence available per outcome and per question in keeping with GRADE guidance. Content experts, methodologists, and ICU survivors were represented in each of the five sections of the guidelines: Pain, Agitation/sedation, Delirium, Immobility (mobilization/rehabilitation), and Sleep (disruption). Each section created PICO questions based on perceived clinical relevance. Once the list of questions was finalized, a university-based librarian conducted a literature review of five electronic	**Control:** Implementation practices for the management of pain, agitation, and delirium in adult ICU patients **Intervention**: More than one intervention was researched and suggested in the nursing management of pain, agitation, and delirium (ex. ABCDEF bundle, use of the 0–10 Numeric Rating Scale self-report pain, CPOT and the BPS pain scales for assessing pain adults unable to self-report, using acetaminophen and low-dose ketamine a as an adjunct to an opioid, using dexmedetomidine for delirium in	**Dependent variable**: adult ICU patients' level of pain, agitation, and delirium, immobility and sleep disruption **Measure**: Prevention/decrease in adult ICU patients' Pain, Agitation/sedation, Delirium, Immobility (mobilization/rehabilitation), and Sleep (disruption)	The Pain, Agitation/Sedation, Delirium, Immobility (mobilization/rehabilitation), and Sleep (disruption) panel issued 37 recommendations (three strong and 34 conditional), two good practice statements, and 32 ungraded, nonactionable statements. Three questions from the patient-centered prioritized question list remained without recommendation. In sections added to these guidelines since their last 2013 version were to rehabilitation/mobility and sleep. Some recommendations worth noting (see exhaustive list of recommendations in article) were the recommendation of the

		databases from 1990 to October 2015 based on priority topics voted on by the members and revised by critical illness survivors. For each PICO questions, the librarian searched the best available evidence (preferably RCTs), determined its quality, and formulated recommendations as "strong," "conditional," or "good" practice statements based on GRADE principles. In addition, evidence gaps, and clinical caveats were explicitly identified. The librarian finalized the relevant search terms with the groups and extracted literature based on these prioritized topics. **Eligible Studies:** Studies were limited to capturing studies examining the 'critical care' environment, defined for guideline purposes as any environment capable of providing mechanical ventilation and invasive	mechanically ventilated adults where agitation is precluding weaning/extubation, etc.)		ABCDEF bundle. Bundle-compliance was significantly associated with reduced mortality and more ICU days without coma or delirium.

		hemodynamic monitoring. **Excluded:** **Environment** could not be t a post-operative recovery room, **s**tudies performed in centers where long-term mechanical ventilation and weaning might take place (e.g., a long-term acute care hospital (LTACH). Case series were not included unless a large case series was the only source of literature for a particular question/particular outcome or an appropriate form of evidence for a specific outcome (e.g., safety). Any study with a sample size ≤ 10 was excluded. **Accepted:** Over 41,000 references were included in the study database.			
Citation: Balas, M. C., Vasilevskis, E. E., Olsen, K. M., Schmid, K. K., Shostrom, V., Cohen, M. Z., ... & Burke, W. J. (2014). Effectiveness and safety of the awakening and breathing coordination, delirium monitoring/management, and early exercise/mobility (ABCDE) bundle. *Critical care medicine*, *42*(5), 1024.					**Level**: IV
Purpose/Hypothesis	Design	Sample	Intervention	Outcomes	Results
"The purpose of this study was to evaluate the effectiveness and	Eighteen-month, prospective,	**Sampling technique:** Convenience	**Control Protocol:** Not treated with ABCDE bundle	**Dependent Variable:** The primary outcome for mechanically ventilated	**Statistical Results:** Mechanically ventilated patients post-

safety of implementing the Awakening and Breathing Coordination, Delirium monitoring/management, and Early exercise/mobility (ABCDE) bundle into everyday practice"	cohort, before-after study	**Eligible**: n=617 (age ≥ 19 years, managed by the institutions' medical or surgical critical care service) **Excluded:** n=317, did not meet inclusion criteria, declined to participate, imminent patient demise, patient or legal representative did not speak English, or unable to obtain consent with 48 hours of ICU admission **Accepted:** n= 296 patients (146 pre- and 150 post-bundle implementation), age ≥ 19 years, managed by the institutions' medical or surgical critical care service **Control:** 146 (pre-intervention group) **Intervention:** 150 (post-implementation group) **Group Homogeneity:** Patients in the pre-implementation phase were older (pre-age mean 59.2 +/−16.1 vs. post-age mean 55.6 +/−14.9; p = 0.05), but	**Intervention Protocol:** Treated with ABCDE bundle **Treatment Fidelity:** All patients were to receive the intervention on a daily basis unless a licensed prescriber wrote an order not to have the patient participate in certain components of the ABCDE bundle (opt-out method) Trained research personnel (all RNs) were hired to enroll patients, perform daily sedation/ agitation and delirium assessments, and conduct standardized medical record reviews. Interrater reliability checks for delirium and sedation/agitation screenings were 100% for all four research personnel. The research personnel had no role in administering any parts of the ABCDE bundle. The decision to perform daily SATs, SBTs, delirium monitoring/ management, and early	patients was ventilator-free days (VFDs). The surveyors secondarily examined outcomes across the entire ICU population (i.e., mechanically ventilated and non-mechanically ventilated patients), including the prevalence, duration, percent of ICU days of delirium and coma. **Measurement**: Initial comparisons between pre- and post-groups were made using t tests (or Wilcoxon test) for continuous variables, chi-square (or Fisher's exact test) for categorical variables and log-rank tests for time-to-event variables. Differences in outcomes between pre- and post-groups were analyzed after adjusting for age, sex, mechanical ventilation status, APACHE II, and Charlson Comorbidity Index using logistic regression for binary outcomes and Cox regression for time-to-event outcomes. SAS version 9.2 was used for all summaries and analyses. The statistical	implementation spent more days breathing without mechanical ventilator assistance than those pre-implementation (pre-median 21 days [IQR 0 to 25] vs. post-median 24 days [IQR 7 to 26]; p = 0.04) Patients treated with the ABCDE bundle had twice the odds (95% CI, 1.30–3.45; p = 0.003) of mobilizing out of bed at least once during their ICU stay compared to the pre-implementation group. Unadjusted hospital mortality was significantly lower in the post-implementation group (p = 0.04), while ICU mortality showed a non-statistically significant reduction (p = 0.07) No significant difference was noted in coma prevalence, coma duration, percentage of ICU days spent in coma, or mean RASS score between the pre- and post-implementation period in unadjusted or adjusted analyses. No significant difference was observed in the time to ICU or hospital discharge between the pre-

		otherwise shared similar baseline characteristics to patients in the post-implementation period. See table 2.	exercise/mobility was made solely by the ICU team.	level of significance was set at < 0.05 (2-sided alpha). Delirium monitoring was measured with a CAM-ICU and RASS assessment tools. Awakening and Breathing Coordination was measured by staff. They recorded the total 24-hour dose of sedative medications daily. Early Exercise/Mobility was recorded daily (whether patients received physical therapy consultation/if they were mobilized out of bed anytime in the previous 24 hours).	and post-implementation periods **Conclusions:** In a diverse group of critically ill patients, implementation of the ABCDE bundle resulted in reduced time on the ventilator, less delirium, and more time spent out of bed compared to patients not treated with the bundle. These improvements were achieved despite little difference in medication exposure and incomplete bundle adherence. The ABCDE bundle appears to be a valuable tool in the management of critically ill patients.

Table 2.

Synthesis Table

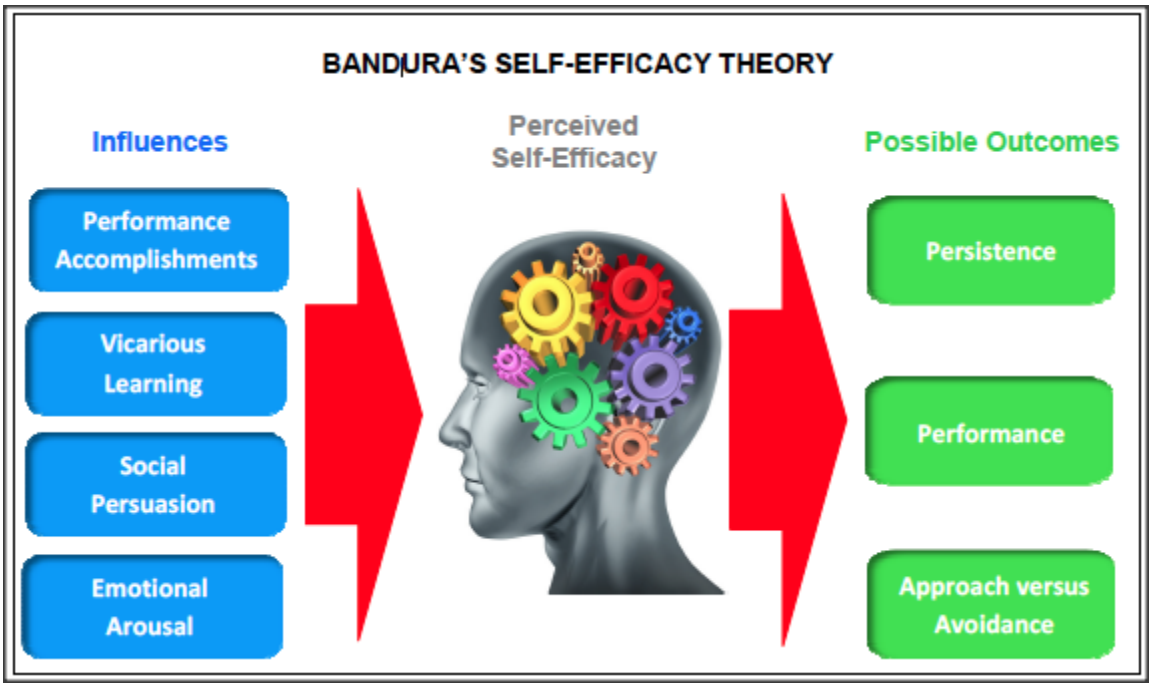
Evidence Based Practice Question (PICO): Can a multicomponent bundle, such as the ABCDEF bundle, (versus no strategy) decrease average length of stay in critically ill adults?			
Level of Evidence	**# Of Studies**	**Summary of Findings**	**Overall Quality**
I	**2**	Trogrlić et al. (2015) conducted a systematic review (SR) with meta-analyses which found that reduced mortality and ICU length of stay reduction were statistically more likely with implementation programs that employed more (six or more) rather than less implementation strategies and when a framework was used that either integrated current evidence on pain, agitation and delirium management (PAD) or when a strategy of early awakening, breathing, delirium screening and early exercise (ABCDE bundle) was employed. Devlin et al. (2018) updated their 2013 clinical practice guidelines (CPGs) on pain, agitation, and delirium. Several PICO questions were researched. When the panel answered the PICO question "Should a multicomponent, nonpharmacologic strategy (vs no such strategy) be used to reduce delirium in critically ill adults?" it was recommended that ABCDEF bundle be used to address this question because bundle-compliance was statistically significantly associated with reduced mortality and less ICU days with coma or delirium.	A, this study was a systematic review, which included meta-analyses. The SR included analysis of 21 studies, which included RCTs, so there was control and randomization in at least some of the studies. This is SR had well-defined, reproducible search strategies. Consistent results with sufficient numbers of well-defined studies (21 studies) were included. There was a criteria-based evaluation of overall scientific strength and quality of included studies. Definitive conclusions were outlined in the discussion (decreased LOS and mortality with a bundle-approach). A, this study was CPG with a mix of RCTs, and non-randomized studies. Well-defined, reproducible search strategies were defined. There are consistent results with sufficient numbers of well-defined studies (n= over 41,000 studies). Criteria-based evaluation of overall scientific strength and quality of included studies exists. The panel followed the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group's methodology for clinical practice guideline development. Consensus was defined as greater than 80% agreement with greater than 70% response rate. Panel consensus was needed to include a guideline. Definitive evidence-based conclusions were drawn for each PICO question asked by the panel.
IV	**3**	Pun et al. (2019) conducted a prospective, multicenter, cohort study. The association between complete and proportional ABCDEF bundle performance and three sets of outcomes were investigated. Complete ABCDEF bundle performance was associated with lower likelihood of seven outcomes: hospital death within 7 days, next-day mechanical, coma delirium, physical restraint use, ICU readmission, and discharge to a facility other than home.	B**,** sufficient sample size (n=15,226) There was some control (partial- versus total-bundle compliance) performance. Definitive results were drawn using statistical measurement tools. The results were consistent. Recommendations were clear that the bundle-approach was statistically significant affecting positive patient outcomes. However, the design study did not have randomization or control.

		Balas et al. (2014) conducted a prospective, cohort, before and after study, evaluating the effectiveness and safety of implementing the ABCDE bundle into everyday practice. The bundle had statistically significant results that number of mechanically ventilated days decreased, hospital mortality was lower, mobilization increased. No significant difference was noted in coma prevalence, or ICU/hospital length of stay.	B, this cohort study had consistent results. Sample size was relatively small (n=296) but with good group homogeneity. There was a control. Conclusions were definitive that the ABCDE bundle appears to be a valuable tool in the management of critically ill patients even though length of stay did not significantly decrease (or increase), other outcomes improved significantly. Strengths and limitation were discussed. One strength was the daily assessment of patients' sedation/agitation level and delirium status by trained study staff using valid and reliable screening instruments. Due to the sample size and study design, it is susceptible to both temporal changes as well as the impact of important unbalanced (or missing) confounders not included in our multivariable adjustment.
		Barnes-Daly et al. (2017) conducted a prospective, cohort quality improvement initiative which studied the association between the ABCDEF bundle compliance and outcomes such as delirium-free and coma-free days in the hospital setting. Patients experienced more days alive and free of delirium and coma with both total bundle compliance after adjusting for age, severity of illness, and presence of mechanical ventilation.	B, reasonably consistent results using statistical methods for analysis exist. There was a sufficient sample size (n=6,064). There was some control (partial- versus total-bundle compliance). Definitive conclusions were made. Reasonably consistent recommendations were discussed: higher bundle compliance was independently associated with improved survival and more days free of delirium and coma. However, the study design weakens the overall quality.

Figures

Figure 1.

Theoretical Framework: Self Efficacy Theory



(OVP Management Consulting Group Inc., 2018)

Figure 2.

Current Process in Place

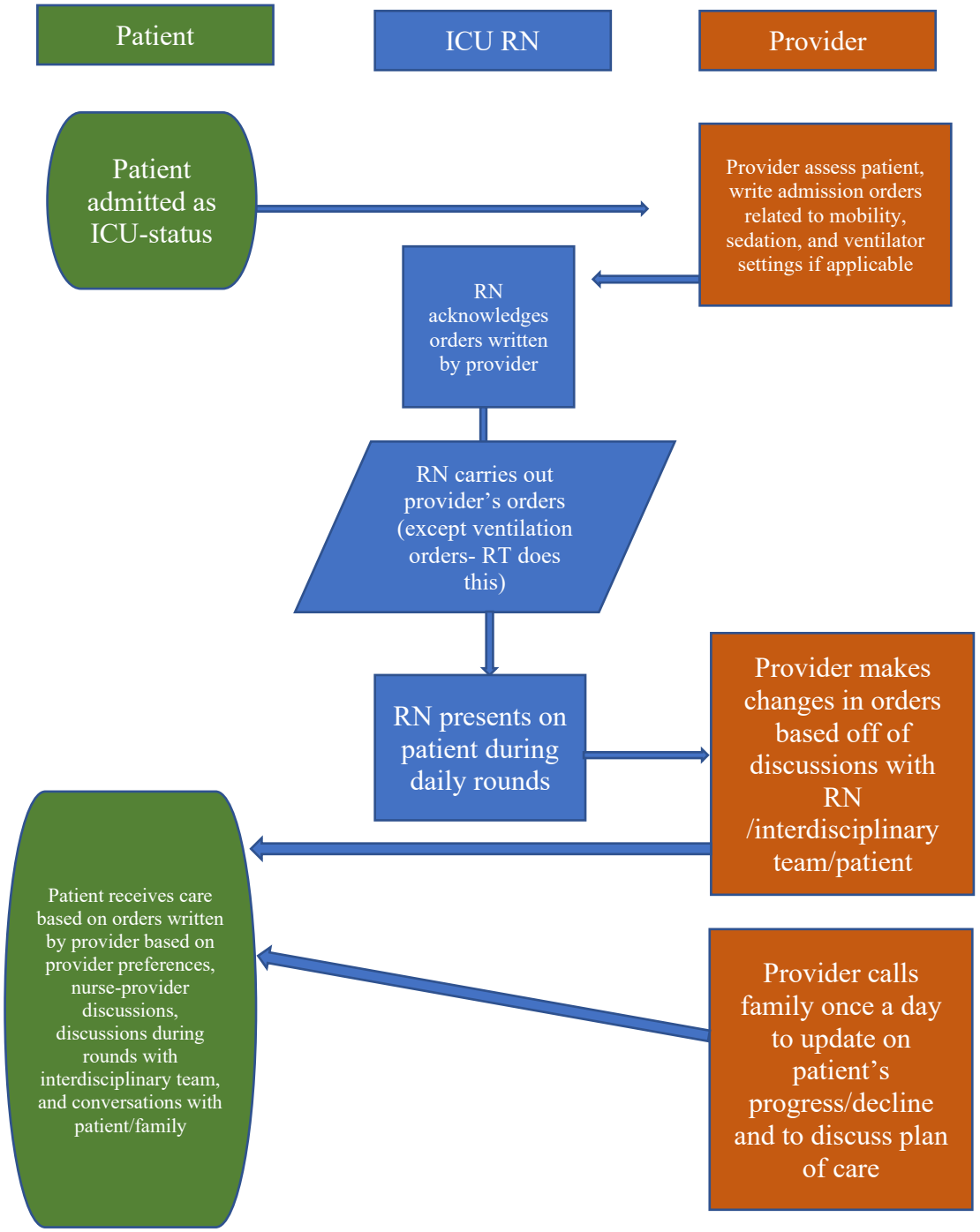


Figure 3.

Percentage of Nurses Educated Weekly

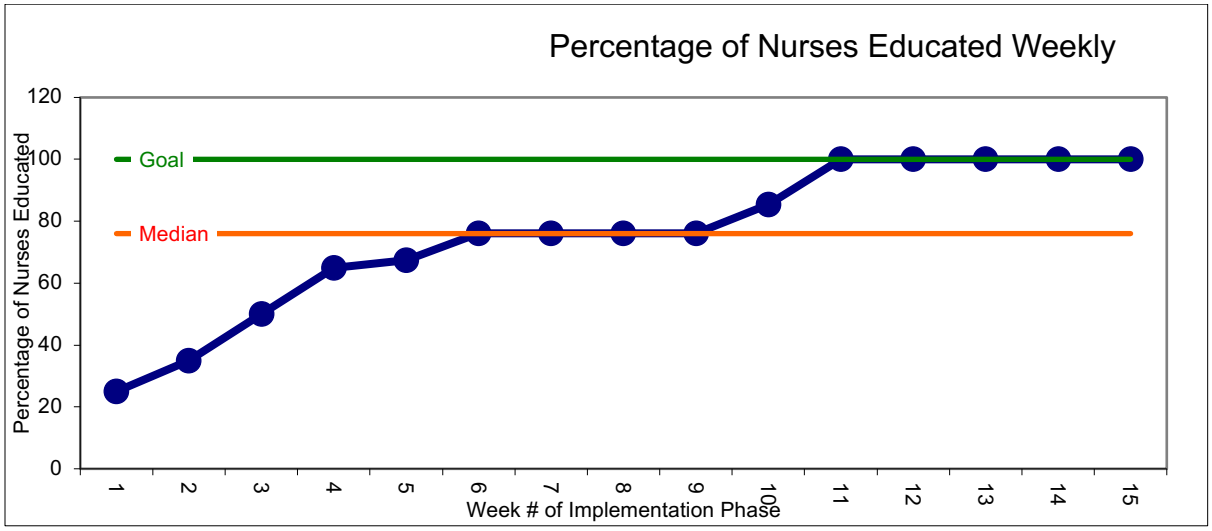


Figure 4.

Compliance With Completing Observational Checklist On every Intubated Patient

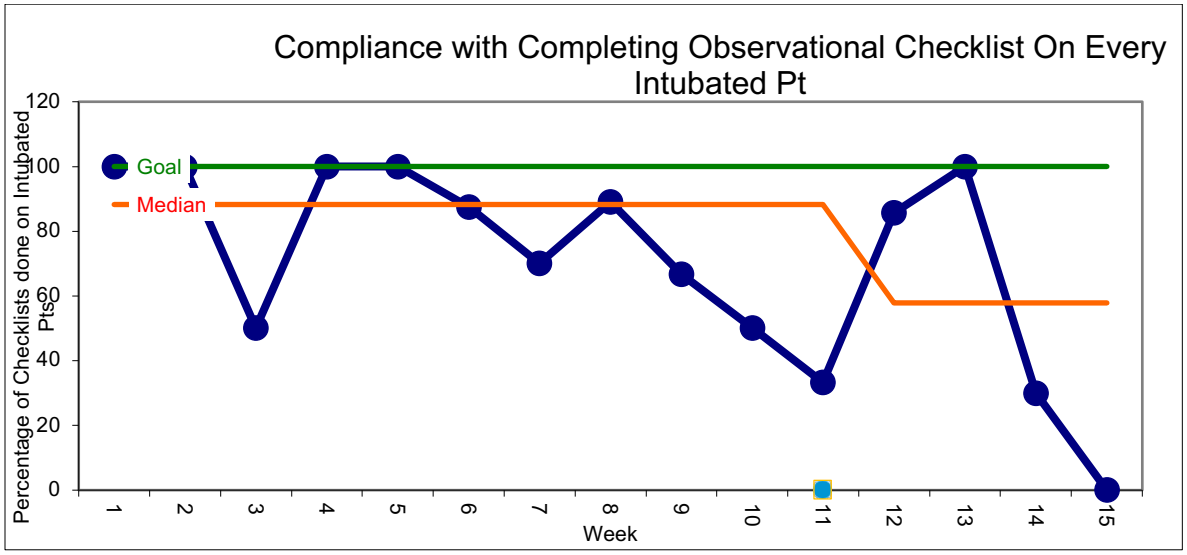
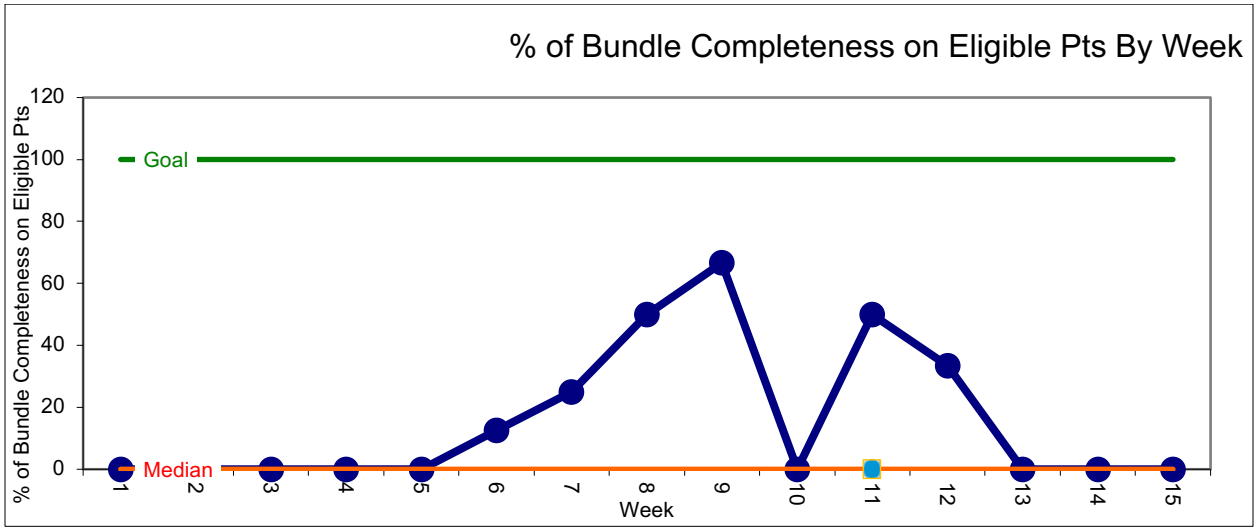


Figure 5.

Percentage of Bundle Completeness



Appendix A

<table>
<tr><td colspan="5">Date:
Pt's admission date & time:</td><td>Comment</td></tr>
<tr><td colspan="3">Awake</td><td>RASS</td><td>Target:
Actual:</td><td></td></tr>
<tr><td colspan="3"></td><td>Did the patient sleep overnight?</td><td>Yes:
No:</td><td></td></tr>
<tr><td>Breathing</td><td>SAT/SBT</td><td colspan="3">Performed- response:
Not performed- reason:</td><td></td></tr>
<tr><td colspan="2">Choice of Analgesia and/or Sedation</td><td colspan="3">Pain Level Goal:
Pain Score (pick 1 scale) 0-10 numerical:
CPOT:
RASS Target:
Actual:
Current analgesia/sedation dose/rates:</td><td></td></tr>
<tr><td colspan="2">Delirium</td><td colspan="3">CAM-ICU score:</td><td></td></tr>
<tr><td colspan="2">Early Mobility</td><td colspan="3">PT Ordered (Y/N)?
Current Activity Order:
Today's mobility target:</td><td></td></tr>
<tr><td colspan="2">Family</td><td colspan="3">Called/in-person meeting (circle one)</td><td></td></tr>
</table>

** THESE ASSESSMENTS ARE ONLY FOR INTUBATED PATIENTS***

Appendix B

ABCDEF Quality Improvement Project Data Management Spreadsheet							
Case Code	**De-identified patient Code**	**Admission date**	**Admission time**	**Complete bundle performed ≤72 hours of admission**	**Did Patient meet eligibility criteria?**	**Comments**	**Code for RN**
				Yes=1 No= 2	**Yes=1 No=2**		
001							
002							

Appendix C

Staff Interviews on Patient Eligibility by Project Leader **Data Management Spreadsheet**	
Code for RN	**Educated on patient eligibility for bundle** **Yes= 1 No=2**

Appendix D

ABCDEF Quality Improvement Project

Code Key

(To be filed securely and separate from the Data Management Spreadsheet)

Deidentified Patient Code	Medical Record #	Code for RN	Nurse Name