Improving Mechanical Ventilation Management Process Aided with an Analytics Informatics System in the Intensive Care Unit

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Abstract

Objective: The importance of evidence-based guidelines for mechanical ventilation (MV) management is well accepted. However, timely actionable data are costly to generate manually. As part of a structured clinical process improvement, we evaluated the utility of an analytic informatics system on MV process management in an intensive care unit (ICU).

Methods: We used a pre-, post-, observational study design. There were 138 and 140 patients admitted to the ICU requiring MV in the pre- versus post- phases. During the pre-period, a MV management analytics system was implemented for automatic data collection only. During the post-period, a structured process improvement project was implemented supported with computerized reports from the analytics informatics system.

Results: After implementing process changes based on data generated from the MV management analytics system, spontaneous breathing trials occurred earlier in the day (P<0.0001). There was a statistically non-significant trending of shorter duration in the post-period in the milestones leading to extubation as well as a shorter MV duration (median; 97.8 vs 72.4 hours for the pre- versus post- periods; P=0.20).

Conclusions: Computerized ventilation data analytics systems could aid focused clinical process improvement. Continued refinement and effort are needed to further improve ventilator management effectiveness.

Keywords: Quality Improvement, Process Improvement; Electronic Health Record (EHR), Mechanical Ventilation (MV), Intensive Care Unit (ICU), Medical Informatics

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Introduction

The intensive care unit (ICU) is one of the most expensive venues in a hospital. Mechanical ventilation (MV) is a significant component of that cost.[1] Mechanically ventilated patients represent approximately 3% of all acute care hospitalizations and 30% of all ICU admissions,[1-3] incur longer ICU stay than non-ventilated patients (mean, 6.9 vs. 2.9 days) and have greater average costs ($31,574 vs. $12,931).[1] The mean hospital length of stay (LOS) for a ventilated patient was 14 days accounting for 7% of all hospital days and an estimated 12% of all U.S. hospital costs.[3] Although ventilated patients are only a small fraction of hospitalized patients, they represent a disproportionately large share of hospital days and costs.

Despite its efficacy in the management of critically ill patients, MV has iatrogenic complications such as ventilator induced lung injury and ventilator associated pneumonia (VAP). As many as 28% of patients receiving MV may develop VAP,[4] with risk increasing with longer MV duration.[5] Hence, reducing MV duration has clinical impacts on patients' outcomes.

The use of protocols to improve the management of sedation and to implement consistent processes for MV weaning with spontaneous breathing trials (SBT) have demonstrated significantly shorter times to extubation when compared to non-standardized weaning.[6-8] However, without a process for protocol compliance monitoring and automated data feedback, improvements in weaning and extubation through manual data collection are prohibitively expensive and difficult to achieve.[9]

Scientific evidence supports the recommendation that weaning from MV and discontinuation protocols that incorporate non-physician healthcare professionals should be used in ICUs.[8,10] Several weaning and ventilator management protocols have been published and evaluated for use in the ICU.[11,12] Commonly used is the "Wake up and Breathe" protocol.[13] This protocol requires at least one daily spontaneous awakening trial with an appropriate reduction in the administration of intravenous sedation that can facilitate a SBT and subsequent weaning and removal of MV.

Concurrent electronic monitoring and use of data analytics may improve the safety and efficacy of MV. However, most standard ICU monitoring equipment and alarm systems lack the ability to recognize physiologic syndromes associated with ventilator-

induced lung injury, and VAP.[14] A Cochrane review[15] of available studies through 2013 concluded that automated "closed-loop" systems may result in reduced duration of weaning, ventilation and ICU stay; however, there was substantial heterogeneity in trials with very small numbers of patients, most of which had sample size in the lower double digits or even a single digit. Therefore, no firm conclusions could be drawn based on the review.

We conducted a structured process improvement study designed to assure standardized MV weaning procedures were incorporated aided by the use of a computerized analytics system intended to assist ventilation management. The system provides data analytics only; it does not use "closed-loop" intervention. We hypothesized that the computerized MV analytics system would provide timely data and clinical feedback to the providers. Through structured process improvement aided by automated clinical data feedback, providers could identify variations, adopt evidence-based practice, and hence potentially change practice and shorten MV duration.

Methods

Study Site

The study site is a medical/surgical ICU in a tertiary-care, regional, and community referral hospital. The ICU has 20 beds with approximately 1,200 adult admissions annually. Approximately six patients per day are mechanically ventilated. Typically, two of these patients receive postoperative care; the remainder is treated for medical conditions. Patients requiring MV are under the care of 13 pulmonologists (mostly intensivists), 39 critical care nurses, and 42 respiratory therapists (RTs). The ICU patient to nurse ratio is 2:1 and the ventilated patient to RT ratio is 5:1. Physicians practicing in the ICU are community-based physicians and therefore do not staff the ICU continuously.

The study protocol was developed as a non-interventional, process improvement project and was reviewed and approved by the hospital Institutional Review Board.

Data Source

Ventilation parameters were captured electronically through an automated analytics informatics system (Vyaire Medical vs Becton Dickinson [BD] — formerly CareFusion Corporation, Yorba Linda, CA) which automatically records the starting and ending time periods of MV, spontaneous breathing trials (SBTs), first ready to wean status (RTW), and extubation candidate threshold (ECT). A total of 10 new ventilator systems were installed approximately eight months prior to the current study. Patients monitored with the RKP analytics system were included for the current analysis. We linked clinical ventilation data with the administrative data, which included the patient's demographics, admission source, principal diagnosis, secondary diagnoses, and discharge status. We used administrative data for the following purposes: 1) to identify the mortality status at discharge, 2) to determine the principal diagnosis and comorbidities through standardized codes of the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9CM); and, 3) to determine the source of admission (e.g. transfer from another acute care hospital, nursing home, etc.).

We used the Clinical Classification Software (CCS) and Comorbidity Software (CS) downloaded from the Agency for Healthcare Research and Quality (AHRQ) for the classification of principal diagnosis group and comorbidities, similar as being used by other studies.[16,17]

Study Design

We used a pre-, post-, open-cohort, observational study design incorporating the elements of quality observational design.[18] During the pre-period (February 1, 2013 to August 31, 2013), the RKP automatically collected ventilation analytics parameter data, but the results were not revealed to the clinicians. During the post-period, (September 1, 2013 to March 31, 2014), structured process improvement steps were implemented. The computerized RKP system analytics reports were made available to the clinicians via the Respiratory Care Clinical Practice Committee (the Committee) composed of staff respiratory therapists, lead respiratory therapists and the manager of respiratory therapy with oversight by the medical director. The goal of the Committee was to develop and implement a process improvement plan based on data from the previously blinded pre-implementation period as well as on-going analytics feedback during the post-period. Communication regarding the use of the RKP analytics was shared with the clinical staff through educational sessions as well as one-on-one instruction. The related activities included active engagement of the staff caring for patients (intensivists, nurses, RTs) with assessment of individual patient RKP analytics data as well as periodic review of overall clinical trends. These activities were done in conjunction with changes in ventilator and weaning management practices.

Operational Definitions of Key RKP Parameters

The RKP system allows sites to configure rules and thresholds that are used to identify exceptions to the hospitals policies and protocols. The rules and thresholds were set by clinicians in the study site based on guidelines.[10]

Ready to Wean (RTW): A respiratory rate < 35 breaths per minute (bpm), positive end-expiratory pressure ≤5 cmH_2O, FiO_2 ≤ 0.5, minute ventilation <14 liters per minute, and remained within these settings for at least 60 minutes.

Spontaneous Breathing Trial (SBT): Changing the mode setting on the ventilator from continuous MV to continuous positive airway pressure (CPAP) with pressure support.

Extubation Candidate Threshold (ECT): A rapid shallow breathing index ≤ 105, respiratory rate < 40 bpm, and FiO2 ≤ 0.5.

Ventilator Weaning Process

The software parameters used to identify possible ventilator weaning candidates included a FiO_2 < 50%, Ve < 14 L/min, PEEP <6 and total respiratory rate of < 35 breath/min. A minute ventilation value of < 14 L/min was used as an indication that a patient may be a candidate for weaning. Upon reaching the weaning candidate threshold, each patient was assessed by a RT using the following parameters consistent with the evidence-based guidelines for weaning and discontinuing ventilatory support:[10] a) the patient was free of agitation; b) vital signs were within normal limits; c) SpO_2 ≥ 88%, FiO_2 ≤ 50%, PEEP ≤ 8 cm H_2O; d) the patient demonstrated adequate inspiratory effort; e) the patient was free of myocardial ischemia; f) the patient was free of vasopressor usage; and g) the underlying cause of MV has been resolved. The patient was moved to a SBT only after satisfactory completion of this evaluation by a RT. During the

Table 1. Patient characteristics*

Variable	Pre-Period	Post-Period	*P* value
Number of discharges	138 (100.0)	140 (100.0)	
Age			
Mean (standard deviation)	62.6 (16.0)	64.2 (15.4)	0.4060
Median (1st, 3rd quartiles)	63.5 (53, 75)	65 (57, 74)	0.4089
Gender			
Female	66 (47.8)	76 (54.3)	0.2804
Male	72 (52.2)	64 (45.7)	
Admission Source			
Ambulatory setting	97 (70.3)	75 (53.6)	0.0104
From another acute care hospital	24 (17.4)	44 (31.4)	
From nursing home or other facility	17 (12.3)	21 (15.0)	
Medicare	67 (48.6)	69 (49.3)	0.9024
Principal Diagnosis-based Clinical Group (CCS)+			
Respiratory failure	33 (23.9)	39 (27.9)	0.4523
Septicemia	24 (17.4)	27 (19.3)	0.6831
Pneumonia	11 (8.0)	9 (6.4)	0.6188
Other	70 (50.7)	65 (46.4)	0.4732
Secondary Diagnosis-based Comorbidities (CS)‡Sorted by Frequency			
Fluid and electrolyte disorders	88 (63.8)	79 (56.4)	0.2102
Weight loss	71 (51.4)	73 (52.1)	0.9078
Hypertension	62 (44.9)	64 (45.7)	0.8953
Chronic pulmonary disease	53 (38.4)	63 (45.0)	0.2638
Deficiency anemia	48 (34.8)	44 (31.4)	0.5522
Renal failure	40 (29.0)	34 (24.3)	0.3749
Congestive heart failure	36 (26.1)	35 (25.0)	0.8354
Hypothyroidism	19 (13.8)	31 (22.1)	0.0671
Coagulopathy	24 (17.4)	23 (16.4)	0.8306
Obesity	23 (16.7)	23 (16.4)	0.9574
Other neurological disorders	13 (9.4)	23 (16.4)	0.0796
Liver disease	8 (5.7)	5 (3.6)	0.4084

* Note: Data were presented as number (%), unless otherwise specified; +CCS: Clinical Classification System by the Agency for Healthcare Research and Quality (AHRQ); ‡CS: Comorbidity Software by the AHRQ). Comorbidity categories with high frequencies were presented.

study, a SBT was defined as either placing the patient on 5 cm H_2O of Pressure Support and 5 cm H_2O of CPAP or a t-tube.

Staff Training

RT staff training included but was not limited to the following: defining RKP clinical markers for the identification of possible ventilator weaning candidates; identification of patients with ventilator settings outside of our protective lung limitation threshold values, adverse effects, and appropriate corrective actions.

Storyboard displays, demonstrations of the RKP, and sharing of electronic educational materials were used for nurse education in the post-period. Engagement of the nursing staff resulted in question-and-answer sessions with active exchange of ideas regarding the use of data obtained from monitoring the RKP. Activities for pulmonologists included one-on-one demonstrations of the RKP as well as informational sessions during meetings of the critical care, quality improvement advisory, and pulmonary leadership committees. Consequently, staff members would take ownership of the care process.

Outcome Measures

MV process parameters included the duration from the first RTW to the first SBT as well as from the first SBT to the first ECT and other parameters. The outcomes included changes in timing of SBTs and total MV duration. The study was powered for a 1.47 days detectable difference in MV duration, a 35% reduction. We analyzed the MV duration on patients discharged alive because mortality may affect the duration of MV and confound this outcome. We also analyzed the entire study cohort including those expired in the hospital as a comparison.

Statistical Analysis

We conducted univariate analysis on all outcomes using the χ^2 test for dichotomous variables and the t-test and Wilcoxon

Table 2. Pre- verus post-period ventilation management parameters comparison

Weaning Parameter Duration Variables (all values in hours)	Unadjusted Descriptive Statistics				Adjusted Estimate on Pre- vs Post-Period Differences	
	Pre-Period, hours		Post-Period, hours			
	Mean (standard deviation)	Median (1st, 3rd quartiles)	Mean (standard deviation)	Median (1st, 3rd quartiles)	Estimated reduction in duration, hours (95% CI)	*P* value
From 1st RTW* to 1st SBT†	37.0 (42.9)	23.3 (11.8, 44.5)	30.0 (31.2)	17.8 (9.0, 45.1)	-8.2 (-19.9, 3.6)	0.174
From 1st SBT to 1st ECT‡	26.0 (104.1)	0.0 (0.0, 4.3)	17.7 (36.1)	0.0 (0.0, 20.2)	-10.9 (-38.2, 16.4)	0.435
From 1st RTW to 1st ECT	53.6 (103.5)	24.1 (7.9, 58.1)	36.8 (40.7)	22.1 (9.1, 48.6)	-20.9 (-47.2, 5.4)	0.121
From MV initiation to 1st ECT	70.4 (123.0)	38.7 (17.7, 78.1)	56.2 (50.0)	36.1 (15.8, 88.7)	-17.2 (-47.1, 12.8)	0.262
From 1st ECT to discontinue MV	84.7 (105.3)	34.6 (15.8, 120.1)	82.0 (114.0)	30.4 (11.4, 115.0)	-11.2 (-45.4, 23.1)	0.523
From extubation to discharge	169.3 (205.6)	132.0 (21.9, 214.0)	128.6 (159.7)	78.7 (6.6, 172.4)	-33.9 (-81.3, 13.6)	0.163
Total duration of MV	138.1 (152.7)	97.8 (32.9, 192.2)	119.6 (129.3)	72.4 (21.5, 171.3)	-23.8 (-60.5, 13.0)	0.206

Note: *RTW (Ready to Wean): a respiratory rate < 35 breaths per minute (bpm), positive end-expiratory pressure ≤5cm H_2O, FiO_2 ≤ 0.5, minute ventilation <14 liters per minute, and remained within these settings for at least 60 minutes. †SBT (Spontaneous Breathing Trial): changing the mode setting on the ventilator from continuous mechanical ventilation to continuous positive airway pressure (with or without pressure support). ‡ECT (Extubation Candidate Threshold): a rapid shallow breathing index ≤ 105, respiratory rate < 40 bpm, and FiO2 ≤ 0.5. MV: mechanical ventilation.

non-parametric test for the continuous variables. We developed multivariable models to control for confounders, by first conducting univariable analysis of candidate variables: demographics, principal diagnosis, and comorbidity in relation to the mortality outcome. We then fit a logistic regression model, using variables significant at $P<0.05$ in the univariable analysis as covariates. Finally, we fit multivariable general linear models for MV duration. Given the frequently skewed distributions of time variables, we conducted a sensitivity analysis using logarithmic transformations for the MV duration and refit the model to compare the direction of the parameter estimate and the associated P-value. All data analyses were conducted using SAS (V9.1, SAS Institute Inc., Cary, NC). A two-tailed P value <0.05 was considered statistically significant.

Results

Patient Characteristics

A total of 138 (pre-period) versus 140 (post-period) patients were included in the analysis. Patients in the two periods were similar in age, gender, and the distribution of specific diagnoses (Table 1). There was a significant increase in the number of admissions from transfers in the post period, from 17.4% to 31.4% in transfers from other acute care hospitals and from 12.3% to 15.0% in transfers from nursing homes or other facilities (P=0.01). The top three principal diagnoses were respiratory failure, septicemia, and pneumonia.

Process Management Change Assisted by the RKP Analytics System

At the transition from the pre- to post-period, the Committee reviewed the RKP data collected during the pre-period. The data patterns from the RKP, suggested a lack of night shift staff involvement (1900-0700) in the weaning process. The Committee considered this as a quality improvement opportunity and suggested conducting SBTs at earlier times of the day to allow adequate time for the attending physicians to evaluate patients prior to morning rounds. This suggestion to move the weaning time was approved by the medical director.

As can be seen in Figure 1, during the pre-period, SBTs occurred between 0700 and 1300 hours, peaking at 0800. In the post-period, SBTs expanded to a wider window between 0300 to 1600 hours, peaking at 0300 as intended. The shift of SBT time to earlier hours of the day was statistically significant at P<0.0001.

Duration of Key Ventilation Process Parameters

Descriptive statistics are in Table 2. For the pre- versus post-periods, the mean (standard deviation) of the duration from the first ready to wean to the first spontaneous breathing trial was 37.0 (42.9) versus 30.0 (31.2) hours, with an adjusted estimate of 8 hours reduction (-8.2, 95% confidence interval: -19.9, 3.6; P=0.17). The corresponding duration of MV was 138.1 (152.7) versus 119.6 (129.3) hours, with an adjusted estimate of 23.8 hours reduction (-23.8, 95% CI: -60.5, 13.0; P=0.20). The adjusted estimates of pre- versus post- changes and 95% CIs for all MV parameters are illustrated in Figure 2. All parameters showed a positive trend in MV management with shorter durations in the sequence of milestones leading to extubation in the post-period, albeit not statistically significant.

Outcomes

The unadjusted in-hospital mortality was 26.1% versus 37.1% (P=0.05) for the pre- versus post- period. After adjusting for age, transfer-in status, principal admission diagnosis of respiratory failure, pneumonia, or septicemia, (variables significantly associated with the outcome,) the mortality was not statistically different for the pre- versus post-period (P=0.11). For the patients discharged alive, the unadjusted mean (SD) of the total duration of MV was 8.99 (9.47) versus 7.95 (8.72) days (P=0.43) for the pre- versus post- period respectively. The risk adjusted duration of MV was 1.2 days shorter in the post-period, but the P-value did not reach

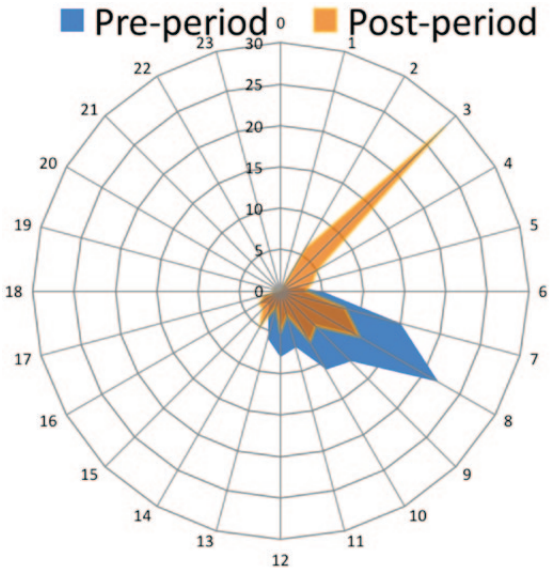

Figure 1. Chronological frequency distribution of spontaneous breathing trials (SBT).

During the pre-period, SBTs occurred between 0700 and 1300 hours, peaking at 0800. During the post- period, SBTs expanded to a wider window between 0300 to 1600 hours, peaking at 0300 hours. The shift of SBT time to earlier hours of the day was statistically significant at P<0.0001.

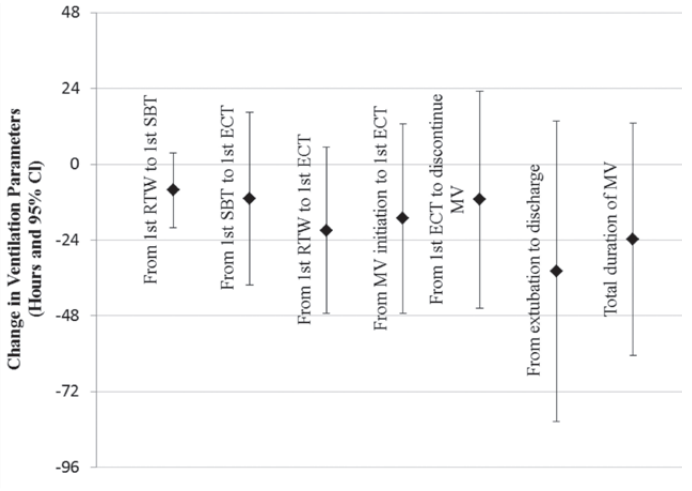

Figure 2. Improvement of ventilation parameter duration in the post-period.

The diamond represents the point estimate of the change in the post- period compared to the pre-period with zero indicating no change between the pre- versus post period. A negative number indicates a shorter duration of the parameters in the milestones leading to extubation. The whisker shows the 95% confidence interval for the estimate. The figure shows that the point estimates were generally in the favorable (shortened) direction and trending towards statistically significant improvement of MV management. MV: Mechanical ventilation; RTW: ready to wean; SBT: spontaneous breathing trial; ECT: extubation candidate threshold.

statistical significance (95% CI: -3.8, 1.4; *P*=0.38). The log-transformed MV data yielded the same direction (shorter MV duration in the post- versus pre-periods) and slightly better P-value (estimate: -0.24 [log-scale], 95% CI; -0.52, 0.05; *P*=0.10). For the entire study population, the MV duration was 1.5 days shorter in the post-periods (95% CI: -3.5, 0.6; *P*=0.16).

Limitations

This study was implemented in a single center. Its application to other types of ICUs needs to be further tested. We attempted to incorporate the STROBE guidelines[18] into our study structure and reporting of results. Despite the sample size limitation, our study had a larger number of patients than any of the reported studies in the Cochrane review.[15] For the very sick patients who need MV, the science and technology continuously evolve while new challenges and opportunities continuously present.

Our findings are ecological in nature, and not necessarily causal. Nevertheless, measuring the impact of change in clinical practice is a benchmark of process improvement. Without automated analytics, it is costly to gather data manually. Without data feedback, it is difficult to track practice variation and persuade clinicians to change their behavior. Data analytics per se will not automatically bring changes if practitioners do not buy-in and take ownership of the care process. Hence, staff training aided with data analytics feedback is an important aspect of the structured care process improvement.

Discussion

There is a wide variation among institutions in procedures used by clinicians to discontinue sedation and wean patients from MV. Physicians often have favorite weaning methods that may differ from each other. RTs may have variation in their performance of weaning patients. Nurses may have variations in the practice of controlling delirium and delivery of sedation. Variations can also be related to the timing at which events occur. These variations often create a practice of weaning that may not be optimal.

We evaluated the impact of a structured process improvement plan on MV management aided by the computerized MV management data analytics. We found that the RKP analytics systems aided many changes of the MV management process. However, the observed reductions in MV duration did not reach statistical significance, in part, due to the limited sample size and lack of power to detect the significance. We powered the study assuming a 35% reduction, based on literature, as the effect size and only a 25% reduction was observed. This sample size and statistical power issue was also observed in the Cochrane review[15] in which results of only 3 out of 16 published studies reached statistical significance.

Girard, et al [13] demonstrated the value of a paired sedation and ventilator weaning protocol which produced better outcomes. Our study site implemented the "Wake-up and Breathe" protocol for patients receiving MV in our ICUs several years before the present study was conducted. However, not all processes associated with weaning patients were standardized. Others[9] have demonstrated that protocols alone, without active compliance monitoring, are not likely to improve extubation processes. Our study demonstrates that the availability of patient-specific data on the MV process from a computerized MV analytics informatics system combined with focused process improvement helped standardization of weaning protocols. Our data demonstrates a significant shift of SBT times to earlier in the day and an expanded window for SBT. These changes were triggered by a review of pre-period RKP analytics data and highlighted the value of using a computerized analytics system in reviewing and implementing process improvements.

Our process improvement activities included the frequent sharing of detailed performance data in a group setting, which might enhance accountability, especially when this is done with the entire team of intensivists, RNs, and RTs. During the post-period the respiratory therapy team leaders reviewed ventilator weaning data daily. The addition of early morning ventilator

weaning by the night shift staff was reinforced through the feedback of the RKP analytics system. Failed early morning SBTs were easily identified. Variations were promptly communicated. We invested significant time in the education of intensivists, RNs, RTs, and team leaders. This training enhanced the understanding and utility of respiratory dynamics in patients requiring MV for all the clinical staff, as shown in the significantly improved coordination and timing of SBTs. Dasta et.al.[1] demonstrated the daily cost for ICU patients receiving MV is at least $3,759/patient/day. Continued efforts to reduce MV can have a positive effect on hospital financial outlays for clinical care.

Conclusions

A computerized, ventilation data analytics system can aid staff training and timely feedback aimed at improvement in MV process management in the ICU setting.

Implications

Structured process improvement plans are often difficult to implement and monitor in daily clinical practice without an automated tool. Although we observed process changes with an automated tool, continued concerted effort among clinicians and application of technology are needed to further achieve improvement in ventilator care.

List of Abbreviations

MV: mechanical ventilation
LOS: length of stay
ICU: intensive care unit
EHR: electronic health record
VAP: ventilator associated pneumonia
RKP: Respiratory Knowledge Portal
SBT: spontaneous breathing trials
SAT: spontaneous awakening trials
RTW: ready to wean status
ECT: extubation candidate threshold
RT: respiratory therapist
RN: registered nurse
PEEP: Positive end-expiratory pressure
FiO_2: Fraction of inspired oxygen
Ve: Minute volume
SpO_2: Peripheral capillary oxygen saturation
H_2O: Water
CPAP: Continuous Positive Airway Pressure

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