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A Standardized Approach to Awakening and Breathing Trials

Maureen Awuor Abongo
University of Missouri, St. Louis, maxt5@umsystem.edu

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Maureen A. Abongo

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Nancy Magnuson, DSN, APRN, PCNS, FNP-BC, Chair

Louise C. Miller, PhD, RN, Committee Member

Pam-Hale David, MSN, CCRN, RN, Committee Member

Abstract

Problem: Mechanical ventilation with sedation, are crucial co-therapies for the critically ill. Risks of both, known as Ventilator Associated Events(VAEs), can worsen outcomes. Performing Spontaneous Awakening Trials (SATs), with Spontaneous Breathing Trials(SBTs), is a targeted evidence-based strategy in reducing VAE rates. The Intensive Care Unit (ICU) lacked a coordinated approach to operationalizing SATs with SBTs.

Methods: An observational retrospective study involving a review of VAE and patient data for corresponding months in years before, and after an improvement strategy application, and making comparisons. The multimodal strategy includes filling out checklists outlining criteria for performing a SAT with SBT. Checklists were filled from November 13, 2019, to February 26, 2020. The VAE surveillance algorithm, comprising three definition tiers, namely, Ventilator-Associated Conditions (VAC), Infection Related Ventilator Associated Complication (IVAC), and Possible Ventilator Associated Pneumonia (PVAP), is applied to assess improvement outcomes. Performance is measured by manually counting completely filled checklists.

Results: Noted improvements, calculated as proportions of ventilator days are, 1) VACs (0.013 and 0.007 for January and February 2019, and 0 for January and February 2020), 2) IVACs (0.007 in February 2019 and 0 in February 2020), and 3) PVAP (0.005 in January 2019 and 0 in January 2020). Improvements could not be tied to the strategy. A paired samples *t*-test revealed a significant mean difference in checklists filled versus those not filled ($t(105) = 11.31$, $p < .001$).

Implications for practice: A closer look into strategies to increase adherence with care processes targeting critically ill ventilated patients is warranted.

Mechanical ventilation (MV) is a lifesaving treatment modality for the critically ill. It often requires sedation to both ease and guarantee the humane delivery of care (Aitken et al., 2018). This therapy is, however, not free of adverse events. The likelihood of such complications as Ventilator Associated Pneumonia (VAP), and emboli increase with increasing duration of MV (Kallet, Zhuo, Yip, Gomez, & Lipnick, 2018).

Sedation produces alterations in the body's microcirculatory control mechanisms, compromising both tissue perfusion and nutrient flow. Along this continuum of events is multiorgan failure. The prolonged use of sedation may also compromise esophageal motility, a risk factor for ventilator associated infections (VAIs), (Nseir, Makris, Mathieu, Durocher, & Marquette, 2010).

Complications can mean longer stays in the Intensive Care Unit (ICU) and other inpatient areas, increased morbidity, and mortality, and overall, increased costs of care (Agency for Healthcare Research and Quality [AHRQ], 2017). Targeted strategies that address exposure to both MV and sedation, and their associated complications, are needed. Decreasing ventilatory support starts with weaning, a process aimed at restoring respiratory control to the patient (Blackwood, Burns, Cardwell, & O'Halloran, 2014). The use of sedatives can affect this process, hence a need for approaches that combine MV and sedation (Girard et al., 2008).

Protocols can provide structured guidance on readiness to wean. Protocols that have paired sedation and breathing, namely, Spontaneous Awakening Trials (SATs) and Spontaneous Breathing Trials (SBTs), done daily, have been shown to result in improved outcomes for these patients (Girard et al., 2008). The Infectious Diseases Society of America's (IDSA) revised guidelines on Ventilator Associated Event (VAE) prevention

strategies, include the pairing of SATs with SBTs (Chumpia, Ganz, Chang, & de Peralta, 2019).

There is a notable absence of nationwide aggregate data on the performance of SATs with SBTs (Kallet et al., 2018). Efforts targeting the reduction of VAE rates, hence focus on improved adherence with evidence-based strategies. In Klompas et al.'s (2015) study, for example, increased SAT with SBT performance accounted for a reduction in the VAE rate to 5.2 from 9.7, per 100 episodes of MV. Within the medical surgical ICU, there was the recognition of a lack of a standardized approach to operationalizing SATs with SBTs. The ICU team therefore sought to streamline this process.

This quality improvement (QI) project's purpose was to ascertain whether an approach to liberating patients from MV mandating that SATs be simultaneously performed with SBTs, daily, was associated with reduced VAE rates. Eligibility for a SAT with SBT required a physician order. SAT eligibility also required an order for a continuous sedative infusion for a period of 24 hours, or greater. SBT eligibility also required at least 24 hours of MV.

The project's aim was to improve interdisciplinary coordination of, and to reinstate consistency in the performance of SATs with SBTs within the medical-surgical ICU ,in order to reduce the VAE rate. The CDC originated VAE surveillance algorithm within which are three definition tiers was applied to this project. Outcomes included the proportion of 1) Ventilator-Associated Conditions (VACs), 2) Infection-related Ventilator-Associated Complications (IVACs), and 3) Possible VAPs (PVAPs)(The Centers for Disease Control and Prevention(CDC), 2020) all, relative to the number of ventilator days. The question of interest (PICO) was, "for patients who were mechanically

ventilated for longer than 24 hours, and determined to be eligible for a SAT with SBT trial, did the performance of a SAT with SBT, as indicated by completely filling out the "Wake Up and Breath" (WUAB) form compared to not performing a SAT with SBT result in 1) Fewer VACs, 2) Fewer IVACs, and 3) Fewer PVAPs ?"

Review of Literature

Searches were executed in PubMed, MEDLINE, PsycINFO, CINAHL and the Cochrane Library. The following keywords and associated abbreviations were used: Paired SATs and SBTs, Awakening and Breathing Coordination (ABC) and Wake Up and Breathe (WUAB) trial. Alternate terms for SATs were Daily Sedation Interruption (DSI) and Sedation Vacation." Weaning" was also used as an alternate term for SBT. There are no known published studies on this specific subject prior to 2008.349 records resulted, with 344 remaining after duplicates were removed. After screening for eligibility, 331 articles were excluded. Twelve final full text articles were considered eligible with one foreign article excluded there being no reliable options for translation. The final tally was eleven articles.

The main theme in the literature was the role of the performance of daily SATs with SBTs in reducing adverse events in the ICU. Barriers to, challenges, as well as the efficacy of the intervention implementation also emerged as themes. Other themes were patient population and clinician types, the former addressing to whom the protocol is well suited and the latter, persons that may direct said protocol.

Girard et al.'s (2008) Awakening and Breathing Coordination (ABC) trial, a large Randomized Clinical Trial is regarded as the pioneer study in this area. In it, the performance of a SAT with SBT is successfully linked with a reduction in MV days. This

study challenged practice norms and set off replicatory studies, and studies seeking to effect change in processes and practice.

In their retrospective review of medical records, Jones, Newhouse, Johnson, & Seidl (2014) were able to successfully replicate Girard et al.'s (2008) results on the duration of MV. Their study also noted improvements in additional outcomes such as the ventilator utilization ratio (VUR). A more recent study by Forson et al. (2019) also found that the adoption and increased adherence to a WUAB protocol corresponded to a decrease in VAE rates from 14.1 to 10.9 per 100.

Two other studies, Jackson et al.'s (2010) multicenter randomized controlled trial and Khan et al.'s (2014) QI study, sought to examine the psychological sequalae of those protocolized with a WUAB protocol. Jackson et al.'s (2010) study additionally challenged the long-held perception of the potential risks of psychological harm associated with lighter sedation. Khan et al.'s (2014) focus was the incidence and prevalence ICU associated delirium in those protocolized. Jackson et al. (2010) found no difference in cognitive, or physical function at three- and twelve-months post discharge as those managed with moderate to heavy sedation. Khan et al.'s (2014) study however failed to find a change in the incidence or prevalence of delirium in those protocolized, thus demonstrating that results as seen in Girard et al.'s (2008) initial work were not always reproducible.

On patient populations, Kallet et al.'s (2018) study at a large urban level one trauma center involved survivors of acute respiratory distress syndrome (ARDS). These complex patients' high ventilatory demands present weaning challenges. Conversely, Lee et al. (2017), sought to examine the suitability of the protocol within a burn ICU, a cohort

known for failures with other protocolized models of care. Their unique presentation and needs, including numerous operative and wound care interventions often necessitated an increased use of both sedatives and analgesics. Both were retrospective studies with patients divided into a pre- and post-SBT/DSI group. Both Kallet et al. (2018), and Lee et al. (2017) arrived at similar results, finding that the intervention resulted decreased MV days and ICU LOS, thereby concluding that despite the unique characteristics of ARDS and burn patients, a combined SAT with SBT protocol was not only feasible but advantageous.

Hilliard et al. (2016) and Almuslim, Rezk, & Hassan (2011) explored optimizing the use of technology and adding multiple strategies to communicate between disciplines and increase awareness to, and adherence to a combined SAT with SBT protocol. Their combined approaches involved the use of communication boards and texts , the intrahospital wireless system, preprinted daily order sheets, multidisciplinary rounds, and QI monitoring with feedback. An increase was noted in SAT with SBT performance, and an associated decrease observed in the duration of MV, ICU LOS and mortality rates.

Klompas et al. (2015) CDC's prevention epicenters WUAB collaborative, a prospective study involving 3,425 patients in 12 collaborative ICUs and spanning a total of 19 months, focused on the role of a paired SAT and SBT performance in reducing VAE rates, the duration of MV, ICU, and hospital LOS. The study emphasized the significance of proper coordination across disciplines . Stollings et al. (2015) focused on the role of the pharmacist in directing an ABC QI program for improved process measures and adherence. Within the collaborative VAE rates decreased with the increased frequency of SAT with SBT performance. The pharmacy led post-QI screening rates, alongside the

rates at which SATs with SBTs were coordinated and performed, improved for at least eight months, post intervention completion.

To effect change, W. Edwards Deming's principles for continuous improvement consisting of four iterative steps for change, commonly referred to as the Plan–Do–Study–Act (PDSA), cycle, was applied to this project (The W. Edwards Deming Institute, 2020). The first step identified the problem that required improvement. This was noted to be non-standardized weaning practices in the medical-surgical ICU. This stage also involved collecting baseline data around the problem, namely, the number of VACs, IVACs, and PVAPs. Lastly, in this stage, actions that could be undertaken to increase adherence to the protocol were discussed.

In the "Do" phase, the planned improvement intervention began. This included an educational video with a knowledge assessments posttest, and a return demonstration showing that the RN completely filled out a WUAB form. The educational session's aim was to assist staff in overcoming barriers to adherence to performing daily SATs by offering reminders of guidelines, and rationales for a change in behavior. In this phase, regular feedback was offered with reminders to complete the WUAB forms as part of the daily care process.

The Coronavirus Disease (COVID)- 19 pandemic severely affected the continued implementation of this project as it was determined that those with a diagnosis of COVID-19 pneumonia would not be protocolized. Eventually, these patients made up the entirety of the patient population in the ICU. In the "Study" phase therefore, statistical analyses were only performed for the data available, and that which was amenable to such an evaluation. The study phase also involved an assessment of the significance of

findings with the appropriate statistic. This allowed for an additional assessment of how well the plan improved the problem/process targeted for improvement.

In the wake of the pandemic, a decision is yet to be made regarding the interventional strategy's success or failure as needed for the "Act" phase. An agenda for the UNPC meetings, once in person gatherings resume would require the unit to chart a way forward.

Methods

Design

This QI project was an observational retrospective study involving the review of medical records of eligible patients for whom a SAT with SBT was indicated. Data collection was focused on specific time periods before and after the intervention referred to as the pre-QI and post-QI periods. Data was obtained for the number of VACs, IVACs and PVAPs, and the corresponding monthly data on the total number of ventilator days for the pre-QI period. The post-QI period involved data for the corresponding months after strategy implementation. In the post QI period, performance measures were obtained, and in addition, data around notable patient characteristics. The design employed the use of objective measurements by performing statistical analyses of data collected and making comparisons of pre- and post- QI findings.

Setting

The setting was a medical-surgical ICU of a medium sized suburban midwestern acute care hospital with a total capacity of 462 beds, and an ICU capacity of 30 beds with two ICU patients per nurse, and 24-hour coverage by one to three critical care physicians. The hospital had over 20,000 inpatient admissions in 2018 (AHD, 2020). The hospital

provides a full continuum of medical and surgical services to both inpatients and outpatients. The hospital's location, within a suburban metropolitan area and at the intersection of two major highways provides a relative ease of access from the outer regions, thus capturing an ethnically, racially, and regionally diverse group of patients with a wide variability in age, and diagnoses. Patients under 18 years of age are not admitted to the medical-surgical ICU.

Sample

In the post QI period beginning November 13, 2019, to February 26, 2020, a total of 142 unique patients were determined to be eligible for the protocol. The sample comprised male and female patients with an age range of 21 to 91 years old. The average patient age was 63.45 years. The patients had an average of 1.94 other presenting diagnoses, in addition to acute hypoxemic, or hyper carbic respiratory failure. Patients spent an average of 3.93 days on the ventilator. MV days ranged from one, to a maximum of 16 days. Patients eventually transferred to a different facility for any reason were excluded from the sample.

For de-identification, privacy, and anonymity purposes, the Department of Health and Human Service's (DHHS) Safe Harbor approach was applied to the data management process. This approach mandates that certain patient identifiers including information on employers, or familial or household relations be removed. These include 1) Names, 2) All elements of dates (except year), 3) Telephone numbers, 4) Social Security Numbers (SSNs), 5) Medical record numbers, and 6) Full-face photographs and any comparable images (U. S. Department of Health and Human Services (DHHS), 2012).

Procedures

The intervention, the daily performance of a SAT with SBT, is rooted in the work of Girard et al. (2008) who showed in a randomized controlled trial (RCT) that an approach of paired sedation and ventilator weaning for managing critically ill mechanically ventilated patients was not only safe, but effective in reducing adverse events. This approach henceforth has continued to provide objectivity and structure to the conduct of SATs and SBTs.

The critical care team convened in their monthly Unit Practice Council (UNPC) meeting in October of 2019. This team included critical care physicians (CCPs), the ICU Quality Assurance (QA) manager, critical care nurses, respiratory therapists (RTs) and the infection control staff. The need for reinstating the WUAB checklist that was created by a multidisciplinary team and that had previously been adopted by the ICU but was no longer in use, to collect clinically useful data, was discussed. The checklist was touted for its simplicity providing an easy-to-follow guide in implementing the SAT with SBT protocol. The team agreed upon a reinstitution date of November 3, 2019.

An educational session was provided by one of the CCPs to address the knowledge gap. The session was recorded and made available via an ICU iPad for those not at the meeting. There was a required knowledge posttest that included the ability to completely fill the WUAB form. A score of 90% on the posttest and a completely filled out WUAB form demonstrated competency.

The team addressed performance feedback that would be given regularly. Adjuncts that included reminders through communication boards, post it notes on workstations, and a screensaver developed in coordination with the hospital's

informational technology (IT) team offering reminders were also discussed. The intervention, it was determined, would be both RN and RT driven.

Data Collection

Adherence was assessed by manually counting and recording the number of WUAB forms completely filled. VAE data was obtained from the Infection Control Department. Demographic and clinical data necessary for analysis was extracted from the patient's health record, and only after IRB approval was granted. Patient names were replaced with anonymous identifiers based on a combination of the patient's name, and randomly generated alpha numeric characters. Data was saved and stored as a spreadsheet in Microsoft Excel. This Microsoft Excel file is password protected. This file is only available in the author's personal password protected computer. Files will not be shared for reuse. Data will be stored for a maximum of seven years after project completion then destroyed.

Data Analysis

Data was analyzed using Intellectus Statistics(Intellectus Statistics, 2020), an online computer software. Data was examined for single point outliers that differed from the rest of the observations or missing observations. These were eliminated. All patients were assumed to be unique, and the Pre-QI and Post QI data independent of each other.

Approval Processes

This was a QI project focused on the improvement of daily care processes within the ICU and as such, mandated by the institution as part of its operations, and as a means to improve the quality of care provided. This project did not involve randomization of human subjects to particular treatments. Institutional Review Board (IRB) exempt status

was sought from the facility IRB and the University of Missouri St. Louis IRB. The project was determined to meet accepted ethical standards for the protection of human subjects of research and the necessary permissions granted.

Results

142 patients were determined to be eligible for the protocol. Of these, 82 were male (57.75%) and 60 female (42.25%). Patients had an average age of 63.45 years and spent an average of 3.93 days on the ventilator. The patients had an average of 1.94 major diagnoses. Summary statistics for age, ventilator days, and the number of major diagnoses are shown in Table 1.

VAE data per month, were measured as a proportion of the individual numerical values, divided by the associated ventilator days. Pre and Post QI comparisons were made for months with available data as displayed in Figure 1. For the months of January and February 2019, the VAC proportions were 0.013 and .007 respectively, compared to 0 for both January and February of 2020. IVAC proportions were 0 and .007 for January and February 2019 compared to 0 for January 2020 and .005 for February 2020. The proportion of PVAPs were 0.005 and 0 for January and February 2019 respectively, compared to 0 for both January and February of 2020.

SATs, (n = 141, 58%) as well as SBTs (n = 140, 58%), were done in more instances than not. Chi-Square tests for association was performed to assess the relationship between the outcome of both a SAT and SBT, and extubation. Extubation at the earliest possible time was the optimal goal. The Chi-Square values were found to be significant ($\alpha = 0.05$, $\chi^2(4) = 43.94$, $p < .001$) for a SAT, and ($\alpha = 0.05$, $\chi^2(4) = 154.89$, p

< .001) for a SBT, suggesting a relationship between the outcome of both a SAT and SBT, and the likelihood of the patient being extubated.

Performance outcomes were measured as a ratio of actual forms filled daily divided by the number of forms that could have been filled for that day. Of the 142 eligible patients, forms were only filled for 97 patients. Variables were placed into four categories as shown in Figure 2 to simplify analyses. Each range signifies a proportion of forms filled over the entire data collection period. The most frequently observed category of proportion of forms filled, represented as "Proportion of Done" in Figure 2, was 50-74% (n = 34, 32%).

A two-tailed paired samples t-test was further conducted to examine whether the mean difference of forms available to be filled for specific date noted as "ELIGIBLE" versus forms actually filled for the corresponding date, indicated by "DONE" was significantly different from zero. The result of the two-tailed paired samples t-test was significant based on an alpha value of 0.05, $t(105) = 11.31$, $p < .001$. This finding suggests the difference in the mean of "ELIGIBLE" and the mean of "DONE" was significantly different from zero. The results of the two-tailed Wilcoxon signed rank test were also significant based on an alpha value of 0.05, $V = 3916.00$, $z = -8.19$, $p < .001$. This indicates that the differences between "ELIGIBLE" and "DONE" are not likely due to random variation.

Discussion

Both the two-tailed paired samples t-test and the two-tailed Wilcoxon signed rank test reveal evidence of insufficient compliance in filling out the WUAB form. Ensuring that a specific improvement initiative achieves its intended purpose can be a challenge,

especially in high stress critical care areas. Such environments can either foster or undermine efforts to improve practice at any stage. Changes require preparation, continued nurturing, and support, being careful to remove competing interests that can choke its development (Alspach, 2017). Failure in any one of these areas could have hindered the full adoption of the protocol.

Within the QI period, emphasis was placed on filling out the checklist as evidence of performance of a WUAB action. Checklists are meant to identify a series of evidence-based strategies and can be employed as tools to support practices among staff individually and collectively. In and of themselves, they do not improve care(Avery, Pierce, & Gazarian (2015). The extra step committed to manually filling out the checklist, may inadvertently create an undue burden to the nurse's workflow, especially if some of those aspects of care, has previously been committed to memory.

This ICU was one of 12 that participated in Klompas et al. (2015) CDC's prevention epicenters WUAB collaborative. The behaviors set forth henceforth may explain the low VAC, IVAC, and PVAP numbers in the pre-QI period. Still, the facility managed, to show a decline in these numbers from the pre to the post-QI period. While it may be that a renewed focus on the performance of a SAT with SBT was responsible for this improvement, it was difficult to tie the results to the interventional strategy as variables were not amenable to any statistical analysis that would have allowed for the establishment of such a relationship. Regarding performance, the unit was able to show a commitment to actionable processes that required a daily evaluation of the likelihood of extubation for each and every mechanically ventilated patient. The unit's most common performance rate for the process measure was in the range of 50-74%, revealing an above

average buy in on the part of frontline staff. This performance data aptly provides a benchmark which is largely missing in literature, for future research in this area.

Conclusion

Over the years, improved outcomes have been observed in the care of mechanically ventilated patients. Such are the result of years of research with multiple foci. This can explain the improvements observed in numbers, in spite of less-than-optimal compliance. The protocol itself was easily integrated into practice and provided team members with a tool to collaborate with one another. A closer look into factors contributing to poor adherence is warranted. Gathering more data for this project ended with the arrival of, and eventual intubation of our first COVID-19 patient to the ICU. COVID -19 patients remain a difficult to wean population. Future studies can investigate the ease and role of paired SATs with SBT in successfully weaning these patients, and thus, improve their survivability.

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Table 1

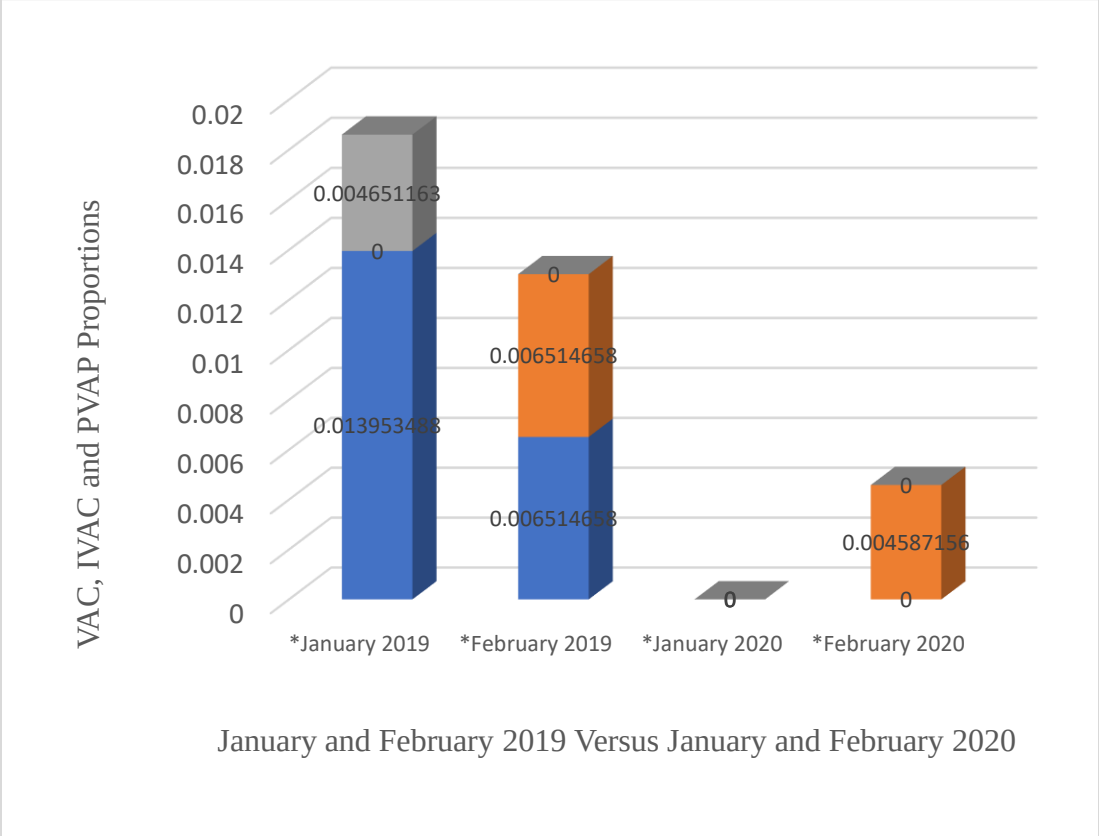
Summary Statistics Table for Patient Characteristics/Demographic Variables

Variable	*M*	*SD*	*n*	SE_M	Min	Max	*Mdn*	Mode
AGE	63.45	15.05	142	1.26	21.00	91.00	66.00	68.00
VENT_DAY	3.93	2.81	142	0.24	1.00	16.00	3.00	2.00
X_OF_MAJ_DX_INCL_SEPSIS_1	1.94	0.97	142	0.08	0.00	7.00	2.00	2.00

Note. '-' indicates the statistic is undefined due to constant data or an insufficient sample size. “AGE” is measured in years. “VENT_DAY” is calculated in days. Variable “X_OF_MAJ_DX_INCL_SEPSIS_1” refers to the number of major diagnoses that the patient has. A diagnosis of septic shock is included in the count for this variable. Calculations were done with the help of help of Intellectus Statistics [Online computer software]. (2021). Intellectus Statistics. https://analyze.intellectusstatistics.com/

Figure 1

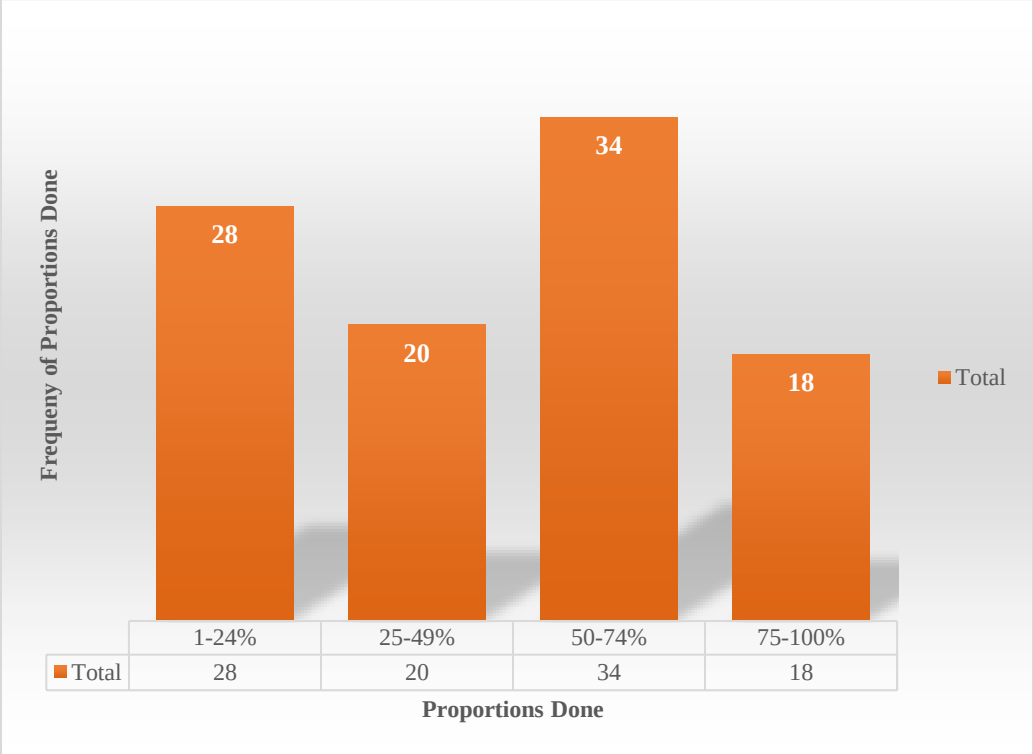
VACs, IVACs, and PVAPs for January and February 2019 Versus 2020.



Note. Proportions were calculated as the number of VACs, IVACs and PVAPs for a specific month, divided by the corresponding number of ventilator days for that month. Calculations were done with the help of Intellectus Statistics [Online computer software]. (2020). Intellectus Statistics. https://analyze.intellectusstatistics.com/

Figure 2

Proportion of Forms Filled Divided by Total Available.



Note. Due to rounding errors, percentages may not equal 100%. Forms actually filled and those that could have been filled were recorded daily. Calculations were obtained for the number of forms filled divided by those eligible to be filled daily. These were then represented as proportions. To simplify analyses, the proportions were divided into four categories, noted here as Proportions_Done_Categories, a nominal variable, Frequencies, and percentages were then obtained for each nominal variable as shown in the table above. Calculations were done with the aid of Intellectus Statistics [Online computer software]. (2020). Intellectus Statistics. https://analyze.intellectusstatistics.com/