Editorial

Prevention does not always improve patient outcomes—use of a ventilator associated events prevention bundle as a quality metric

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Over the last decade, and particularly since the public reporting of the Center for Medicare and Medicaid Service's (CMS) quality based performance evaluation of potentially preventable conditions in hospitalized patients, the incidence of ventilator associated pneumonia (VAP) has taken a sharp drop with several institutions in United States reporting a "zero incidence" (1). Lately this discrepancy between VAP rates among quality monitoring reports and the actual care given to patients has widened, and the accuracy of reporting zero VAP has been questioned. While the application of several infection prevention measures, implemented as a "bundled approach" ,with effective implementation, has been viewed to be an effective measure for decreasing the incidence of VAP, the credibility of these reports has been questioned (2-5). Recognizing the formidable challenge of accurately diagnosing VAP and the existing gaps between surveillance and clinical definitions, the Centers for Disease Control and Prevention (CDC) in 2013 shifted its focus to complications related to ventilation, rather than to identifying infection, through the new surveillance definition—ventilator associated events (VAE) (6). VAE includes ventilator-associated complications (VAC), infection-related ventilator-associated complications (IVAC), as well as possible and probable VAP (PVAP).

Since it is not specific to infection, VAE can be caused by a number of problems, including atelectasis, acute pulmonary edema, acute respiratory distress syndrome (ARDS), as well as pneumonia (7-9). Patients diagnosed with VAC have longer ICU lengths of stay, duration of mechanical ventilation and higher mortality compared to those without, but the diagnosis of VAC is not specific or sensitive for pneumonia and in fact may miss a significant proportion of pneumonia patients with relatively stable oxygenation (8). In order to effectively use VAE definitions in a pay for performance scenario, and as a benchmark quality metric for comparing health care institutions, there has to be substantial evidence to suggest that VAE is preventable.

Muscedere and colleagues retrospectively applied VAE definitions to a prospective data series over four study periods, including 1,320 patients in 11 ICUS, where VAP clinical guidelines were being implemented (10). Increased adherence to VAP prevention guidelines resulted in reduced incidence of VAC and VAP, but not IVAC, over subsequent periods. In a recent study including 20 ICUs with ongoing prospective VAE surveillance, investigators compared protocol based paired daily spontaneous awakening and breathing trials (SATs and SBTs) to surveillance alone (11). In that study, there was a significant reduction in the duration of mechanical ventilation and hospital length of stay in the units following the protocols with a consequent improvement in VAE risk per episode of mechanical ventilation, but no difference in pneumonia rates. Ding and associates evaluated the impact of pre and post VAP bundle implementation in 350 patients using data from electronic medical records in two specific time periods (January 2003 to December 2006—pre bundle period and January 2007 to December 2009—post bundle

period (n=137) (12). The incidence of VAP and VAE were unchanged despite good compliance with the protocol; however the standardized hospital mortality ratio of patients at high risk to develop VAP significantly decreased during the study period. In a randomized controlled trial including 352 patients, use of subglottic secretion drainage (SSD) resulted in fewer microbiologic VAPs (8.8% *vs.* 17.6%, P=0.018) and less antibiotic days (absolute risk reduction of 6.9%), but had no impact on the VAC rate (21.8% *vs.* 22.5%) compared to patients without SSD (13). Thus there are conflicting reports on the benefit of the VAP bundle on VAE prevention.

In the July 2017 issue of *Critical Care Medicine*, Rawat and associates presented the results of a multifaceted intervention program in 38 hospitals across Maryland and Pennsylvania and its impact on VAE rates (14). The study was organized as a collaborative effort and followed a pragmatic approach to evaluate the issues discussed above. The authors hypothesized that VAE rates would decrease from the early intervention phase (October 2012 to March 2013) to the late intervention phase (April 2013 to March 2015), with implementation of the comprehensive unit-based safety program (CUSP) bundle-based approach. The aim was to measure and improve compliance to six evidence based interventions—head of bed elevation (HOB), use of SSD, oral care (OC) six times per day, use of chlorhexidine mouth care (CHG) two times per day, SATs and SBTs. They encouraged setting up a local multidisciplinary team in each participating ICU with a team leader, and addressed barriers to implementation with feedback, quarterly coaching calls and established a web- based platform to educate/disseminate knowledge regarding evidence based interventions. The collected data were uploaded into a web-based portal weekly and VAE data were extracted from the CDC National Healthcare Safety Network (NHSN). The initiative was originally conceived to target VAP and the data collection started in October 2012, prior to publication of the CDC VAE definition.

During the study period (divided into 8 quarters) 73% of the participating 52 ICUs provided VAE data. The reported incidence of VAE decreased from 7.34 cases in the first quarter to 4.58 cases per 1,000 ventilator days at the end of the 8th quarter (P=0.007); at the same time, IVAC and possible/probable VAP decreased by 1.59 and 1.1 per 1,000 ventilator days, respectively. The authors did multiple sensitivity analyses to account for missing data with similar results. At the same time the compliance with each of the six interventions improved from the early to the late phase, and the composite measure compliance rate was associated with a 12% VAE decrease. However, there was no significant relationship between possible/probable VAP and the composite compliance measure. As pointed out by the authors, tracking of individual bundle components over the study period, there was very high compliance with HOB elevation from the early to late phase and poor compliance with SSD. On the contrary, participating units did perform significantly more SAT, OC and SBTs from the early to late phase. Investigators used a common surveillance system and standardized definitions to avoid a Hawthorne effect (reduced incidence when surveillance is performed to improve unit performance satisfaction).

One problem with this study is that the clinical impact and clinical benefit of the findings are not clear. For example, to fulfill the criteria for VAE, the patient needs to be ventilated at least for 4 days. Decreasing the duration of ventilation with daily SAT and SBT could potentially decrease the duration of ventilation and possibility the development of VAE, a clear benefit to the patient. However the study by Rawat was not designed to collect information on the duration of mechanical ventilation, ICU length of stay, mortality rate and use of antibiotics, from the pre and post intervention period, or between hospitals participating and the control group of non-participating hospitals. Thus, there are no consistent data available to show meaningful consequences to the interventions undertaken other than decreasing VAE rates. One can argue that the overall objective should be to lower the complications of ventilation and thereby decrease the duration of mechanical ventilation and VAE rates. VAE prevention may include low tidal volume ventilation, conservative fluid strategy, conservative transfusion thresholds, early mobility, SATs and SBTs in addition to VAP prevention bundle (8). All prevention efforts may not mean better care unless the effective intervention strategies are aimed at potential causes of preventable VAE. Further, the VAE incidence and etiology may not be homogenous across all types of ICUs and the definitions are subject to algorithmic manipulation of PEEP and FiO_2 (15). In the study, VAE rate was reduced by using a VAP prevention bundle, but it is not clear which specific types of VAE (pneumonia *vs.* other types of VAE) were prevented by the use of this bundle.

In another study, investigators adjudicated all VAC episodes to identify potentially preventable events (9). They considered preventable events to include inappropriate antibiotic therapy, procedure-related adverse events, aspiration of enteral feedings, ventilation with potentially

injurious tidal volumes, pulmonary edema from excess IV fluid, excess sedation, or potentially avoidable infection such as catheter-associated blood stream infection, wound infection, urinary catheter-associated infection, or probable VAP per CDC criteria. A non-preventable VAC was defined as an unavoidable injury caused by the patient's underlying disease process, associated with appropriate medical care (9). In that study, the authors concluded that less than 40% of all VAC's were preventable.

Using the VAE measure as a reportable "pay for performance" endpoint may not be fair to hospitals or units caring for patients with higher severity of illness and comorbid conditions. Health-care bundles in the form of daily goal sheets and educational sessions may in fact decrease the incidence of VAE or VAP surveillance rates, but it is unclear that all types of VAC are equally preventable, that all bundle measures add to this reduction, and that those reductions truly reflect an improvement in care. In addition, some elements of the bundle, such as head of the bed elevation and use of oral chlorhexidine have been questioned as being effective by themselves for preventing VAP. Perhaps the biggest challenge is improving bundle compliance. As seen in the study by Rawat and others, even with repeated attempts to modify behavior in the ICUs, there were multiple deficiencies in adopting evidence based guidelines (14,16). A reliable performance indicator should be able to identify poor quality of care and adherence to benchmarks that have shown to improve or prevent complications related with mechanical ventilation.

While the study by Rawat and colleagues shows that VAE rates can be reduced using a bundle, it does not show that all the bundle elements are necessary, and it does not show that a reduction in VAE led to meaningful improvement in relevant patient outcomes. As shown by Sevransky and associates, meaningful patient outcomes such as ICU and hospital mortality, length of stay and use of mechanical ventilation may not be different in ICUs following rigorous protocol based care as opposed to ICUs with a low number of protocols (17). To truly improve patient outcomes, further efforts are needed to differentiate preventable harm from events that are unavoidable (18). The focus should be to develop tools that distinguish patient populations, who develop ventilator related complications without receiving appropriate prevention efforts, using standardized evidence based protocols, from those who developed complications despite following the protocol. In addition, when applying ventilator bundles, it is important to continually evaluate each element, and the data supporting its application, in an effort to simplify bundles to their most effective elements.

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Footnote

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