Ventilator-associated Complications In The Mechanically Ventilated Veteran

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VENTILATOR-ASSOCIATED COMPLICATIONS IN THE MECHANICALLY VENTILATED VETERAN

by

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ABSTRACT

Surveillance of ventilator-associated pneumonia (VAP) has been the common outcome measurement used for internal and external benchmarking for mechanically ventilated patients; and although not a clinical definition, it is commonly used as an outcome measurement for research studies. Criteria in the VAP definition include both subjective and objective components, leading to questions of validity. In addition, recent legislation has mandated the public reporting of healthcare-associated infections, including VAP, in many states. Infectious disease experts have recently recommended monitoring a new outcome, ventilator-associated events (VAE), that contain specific objective criteria. The Centers for Disease Prevention and Control (CDC) have refined this definition and released a new VAE protocol and algorithm, replacing the VAP surveillance definition, as a result. The VAE protocol assesses for ventilator-associated conditions (VAC).

The primary aims of this study were to determine the incidence of VAC; and to assess four predictors for VAC, including two VAP prevention strategies (use of the subglottic secretion drainage endotracheal-tube [SSD-ETT]), and daily sedation vacation); and two patient-related factors (alcohol withdrawal during mechanical ventilation, and history of COPD). In addition, the incidence for VAE, using a new national algorithm was determined.

Using a retrospective study design, electronic medical records of 280 veterans were reviewed to identify cases of VAC using the VAE algorithm. The setting was two intensive care units (ICU) at a large Veterans Administration Healthcare System (VAHCS) from October 2009 to September 2011. In addition to demographic information, variables were collected to determine if cases met event criteria (VAC, infection-related ventilator-associated complication

[IVAC], and possible or probable VAP). Incidence rates were calculated for VAC and IVAC. Comparative data between those with and without VAC were assessed with independent sample T-test or non-parametric equivalents.

The study sample was predominantly male (97.1%), Caucasian (92.1%), non-Hispanic (90.7%); with a mean (SD) age of 67.2 (10.4) years. Twenty patients met the VAC definition resulting in a VAC incidence of 7.38 per 1000 ventilator days. There were no statistically significant differences in demographics or disease characteristics found between the two groups (patients with VAC and patients without VAC). Using logistic regression, the impact of the four predictors for VAC was assessed. None of the four explanatory variables were predictive of the occurrence of VAC. Secondary outcomes (e.g. mechanical ventilation days, ICU days, hospital days, and mortality) of veterans with VAC were compared to veterans without VAC. Results indicated that the VAC group was associated with a significantly longer duration of ICU stay, longer mechanical ventilation period, more likely to have a tracheostomy, and had a higher mortality during hospitalization.

Expanding mechanical ventilation quality performance measures to include VAE/VAC provides a better representation of infectious and non-infectious ventilator-associated problems, and provides more accurate morbidity and mortality in this high-risk ICU population. Further research is necessary to explore patient characteristics and prevention strategies that impact the development of all VAC.

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1: INTRODUCTION

Surveillance of healthcare-associated infections (HAI) by the infection preventionist (IP) remains a cornerstone of every acute care Infection Control Program.[1,2] The IP must accurately and timely identify HAIs in the intensive care unit (ICU) and rapidly recognize trends to apply necessary interventions. In addition to infection control surveillance requirements for accreditation, many states have passed legislation to publicly report HAI rates. The Centers for Disease Control and Prevention (CDC) provides HAI definitions that are used by IPs nationally.[3]

Ventilator-associated pneumonia (VAP) is a device-associated HAI that is monitored in the acute care setting, and is associated with a high morbidity and mortality.[2,4,5] Thus, the incidence of VAP has been used as an outcome measure for assessing complications of mechanical ventilation in clinical practice for decades; and has expanded from an internal quality assurance measure to external benchmarking. Unfortunately, the CDC VAP definition was never intended to be used for external benchmarking; and controversy with the subjective components impact reliability and accuracy of case identification.[6,7] Recently, infectious disease experts proposed that ventilator-associated complications rather than VAP, is a superior measure of morbidity and clinical outcomes. Chapter 2 provides the surveillance overview and challenges with outcome measurements in the mechanically-ventilated adult.

The CDC expanded and refined the objective criteria, and developed a protocol for ventilator-associated events (VAE).[8] Identification of ventilator-associated conditions (VAC) assesses deterioration in respiratory status to include both infection-related ventilator-associated complications (IVAC) and non-infectious conditions (i.e. atelectasis, pneumonia, pulmonary embolism, pneumothorax, fluid overload, and barotrauma); all of which impact morbidity and

outcomes. One large civilian study reported ventilator-associated complication incidence rate of 21.2 per 1000 ventilator days compared to a VAP rate of 8.8 per 1000 ventilator days.[9] Further research by CDC refined the respiratory deterioration criteria of the new VAE definition to the current fraction of inspired oxygen (FiO_2) and positive-end expired pressure (PEEP) criteria.[10,11] No studies to date have identified the incidence of VAC or predictors of VAC in the veteran population. Baseline data for comparison is only one civilian study in the U.S.

Study Purpose and Aims

The primary aim of this study was to determine the incidence of VAC in mechanically-ventilated veterans in the ICU; and to identify the predictors of VAC, including two VAP prevention strategies (subglottic secretion drainage endotracheal tube [SSD-ETT] and daily interruption of sedation [sedation vacation], and two patient-related factors (alcohol withdrawal during mechanical ventilation and history of chronic obstructive pulmonary disease [COPD]). Secondary aims included comparing outcomes (mechanical ventilation days, ICU days, hospital days, and mortality) of veterans with VAC to those without VAC; and comparing VAC incidence with the pre-reported VAP rate (obtained from Infection Control database).

The specific research questions were:

- What is the incidence of VAC in mechanically-ventilated veterans in the ICU?
- In mechanically-ventilated veterans identified with VAC, what is the incidence of infectious VAC compared to non-infectious VAC?
- Is the incidence of VAC in mechanically-ventilated veterans influenced, individually or in combination, by a history of COPD, alcohol withdrawal, use of a SSD-ETT, and daily sedation vacation?

Conceptual Model: Pathogenesis of VAE

Critical care patients that require mechanical ventilation are at risk of pulmonary complications. Selection of variables to study was based on the Conceptual Model of the Pathogenesis of VAE (Figure 1). This model was based on the pathogenesis of ventilator-related infections and complications, and infection control strategies for prevention of VAP.[2,5,8,12]

Following insertion of an artificial airway (endotracheal tube [ETT]) to assist in respiration, colonization of the naso/oralpharyngeal tract begins around and within the lumen of this assistive respiratory device.[12] Commonly there is pooling and subsequent leakage of bacteria-laden secretions around the ETT cuff, that results in bacterial exposure to the lower respiratory tract and host defenses.[13] The normal airway and defense mechanisms are compromised with an ETT that is necessary to support mechanical ventilation and sustain respiratory parameters, resulting in colonization, potential ventilator-associated complications, and other adverse events.[2,14,15]

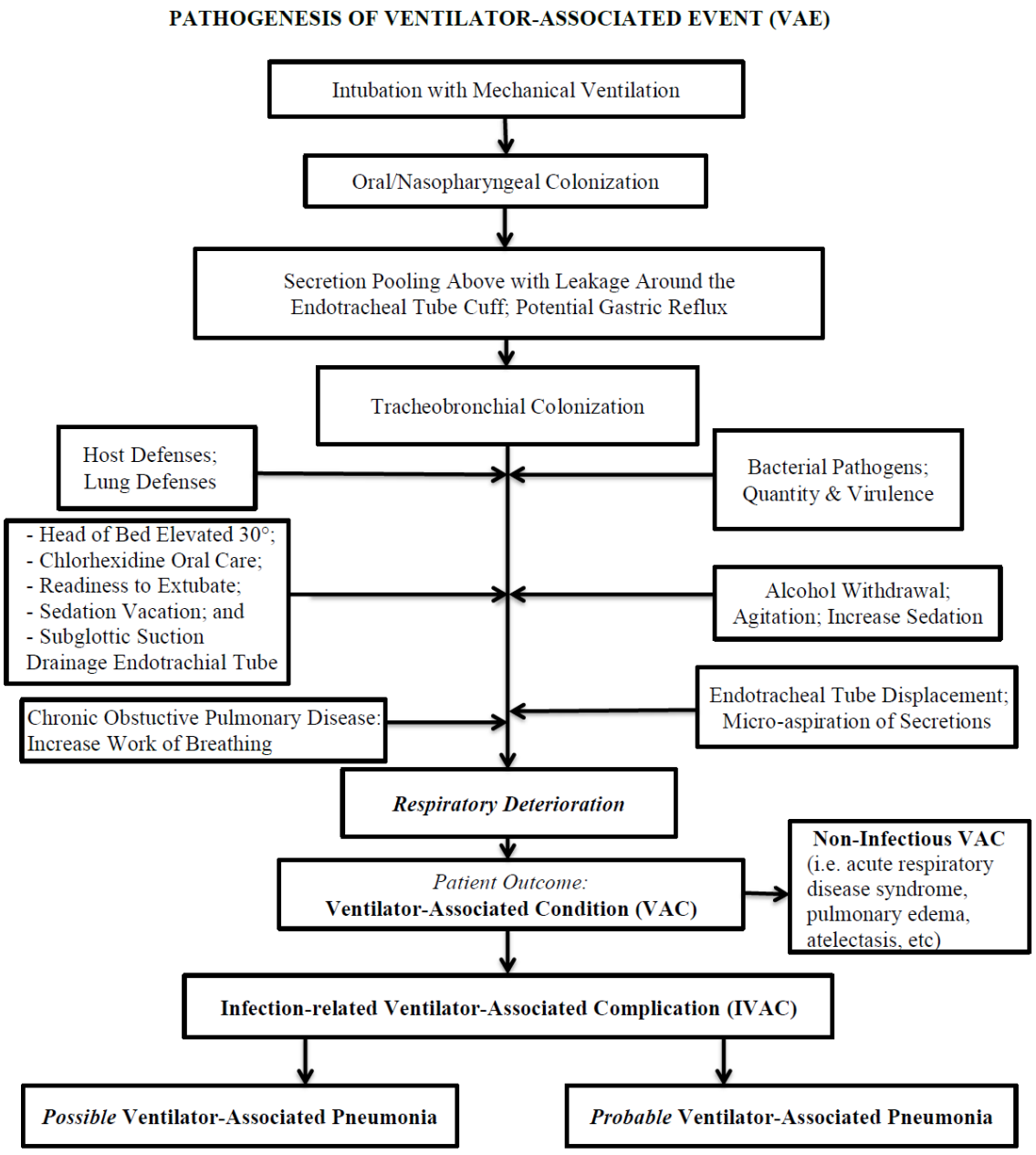

Figure 1: Conceptual Model of VAE

Impact of Prevention Strategies and Patient Factors on VAC

The Institute for Healthcare Improvement (IHI) recommends a set of ventilator prevention strategies that are standard ICU practices: including: elevation of the head of the bed,

peptic ulcer prophylaxis, deep venous thrombosis prophylaxis, oral care with chlorhexidine, and the sedation vacation.[5] The Veterans Administration Healthcare System (VAHCS) adopted implementation of the IHI ventilator bundle, and adherence is monitored. Implementation of the sedation vacation, which includes decreasing patient sedation until spontaneous ventilation occurs, is often difficult due to a variety of medical reasons or contraindications, including alcohol withdrawal.[16-18] Alcohol abuse is a continued problem in the veteran population.[19,20]

During mechanical ventilation, patients require sedation to reduce or prevent agitation that may cause additional airway trauma, ETT displacement, or accidental extubation. Daily interruption of sedation is recommended to assess readiness to wean from mechanical ventilation.[5,21,22] Alcohol withdrawal maybe the primary reason for intubation, thus protecting the airway, and mechanical ventilation is necessary during sedation to decrease agitation. Sedation and alcohol withdrawal scales are frequently used to assess the amount of medication necessary, and many facilities have implemented sedation protocols to facilitate a sedation vacation or daily interruption of sedation.[23] Although a daily sedation vacation is recommended, practices vary depending on individual patient circumstances and there are no studies indicating the impact of sedation vacation or alcohol withdrawal on the incidence of VAC.

The ETT provides a direct pathway for air exchange during mechanical ventilation and for suctioning of lower respiratory tract secretions. The ETT can act as a conduit for microorganisms resulting in airway colonization; as micro-aspiration of bacteria-laden secretions that pool above the ETT cuff may result in a lower respiratory tract infection. While the ETT cuff is inflated in the trachea, channels are created within the ETT cuff folds and increase the risk for micro-aspiration of the pooled oral-pharyngeal secretions above the cuff. In research studies using the SSD-ETT to provide continuous or intermittent removal of pooled secretions, study

results indicate improved patient outcomes and reduced lower respiratory tract infections, specifically VAP.[24-26] The SSD-ETT is available and many patients are intubated with this tube; however many ICU patients are intubated with a standard ETT during surgery or are transferred intubated from another facility. It is recommended that a SSD-ETT be used for mechanical ventilation to prevent VAP[26], but there are no studies indicating the success or failure of this recommendation on the incidence of VAC.

Research indicates that weaning from mechanical ventilation can be a problem in patients with COPD; and patients with COPD have been found to be at high risk for VAP, have increased mechanical ventilation days, and higher mortality.[27-28] The incidence of COPD in the veteran population is high in a recent study, 39% of veterans were active smokers, and the odds of having COPD were 3.18 times greater in smokers than non-smokers. [29] In the recent civilian study, 31% of patients identified with ventilator-associated complications had COPD.[9]

Ventilator-Associated Complications

The conceptual model of VAE (Figure 1) was used to guide the research study to determine the incidence of VAC and to identify the predictors of VAC. Following Institutional Review Board approval, a retrospective study of 280 mechanically-ventilated veterans from two ICUs in a large VAHCS setting was performed. Data were extracted from the electronic medical record. Data and results of the study are discussed in Chapter 3.

By understanding the pathogenesis of VAE, this model can be used to guide research in VAC incidence; and determine the impact of prevention strategies on the development of VAC, IVAC, and VAP. Issues in retrospective assessment of VAE (e.g. mechanical ventilation respiratory parameters, sedation vacation, and SSD-ETT) that could impact results are discussed in Chapter 4.

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CHAPTER 2: OUTCOME MEASUREMENTS FOR COMPLICATIONS OF MECHANICAL VENTILATION

Summary Abstract

The incidence of ventilator-associated pneumonia (VAP) has been a common outcome measure used for assessing complications of mechanical ventilation in clinical practice and research, and for internal and external benchmarking. Although the Centers for Disease Control and Prevention (CDC) VAP definition is commonly used for surveillance, controversy with subjective components impact reliability and accuracy. Recently, researchers studied several combinations of surveillance criteria, and the CDC announced expanding VAP surveillance to capture ventilator-associated events (VAE) based on respiratory deterioration criteria.

Background: VAP Surveillance

Medical treatment in an intensive care unit (ICU) for many critical illnesses and injuries require the assistance of an artificial airway (endotracheal tube [ETT]) and mechanical ventilation for survival. Intubation and mechanical ventilation are often associated with life-threatening pulmonary complications and infections while the airway is compromised.[1] Strategies are aimed at providing supportive care to prevent respiratory tract infections and other complications. Infection control surveillance includes VAP as an outcome measurement, using the widely used CDC VAP definition.[2] Multidisciplinary studies frequently use the presence of VAP as an indicator of the success or failure of nursing, medical, or pharmaceutical interventions in the mechanically-ventilated adult. In addition, quality improvement programs based on evidence-based prevention strategies, termed the ventilator bundle, have become a standard ICU practice with VAP used as the indicator of success.[3,4]

In 2011, the National Healthcare Safety Network (NHSN) reported that VAP ICU incidence ranged from mean 1.0 -1.1 (medical ICU, medical major teaching ICU) to 2.0-2.4 (surgical ICU, surgical major teaching ICU) cases per 1000 ventilator days.[5] Rates have decreased compared to a previous NHSN report, and other reports estimated VAP incidence from 1 to 4 cases per 1,000 ventilator days.[1,6] As a serious healthcare-associated infection (HAI), VAP impacts hospital care and length of stay and is associated with a longer period of mechanical ventilation, ICU stay, and hospitalization. In addition, VAP is associated with an increase in morbidity and mortality with reported attributable cost up to $28,508.[1,7] The economic impact of VAP was reported to have a median hospital cost of $35,480 greater than matched controls in one study.[8]

Over the past several years, there has been an increased public interest in VAP outcomes due to changes in HAI reimbursement regulations and legislature changes in public reporting. Although public reporting has promoted interest in VAP prevention and outcomes, it also creates pressure for the Infection Preventionists (IP) to strictly interpret the definition criteria which may result in artificially decreasing VAP rates.[9] Previous challenges with VAP interpretation and subsequent rates were only experienced with internal committees, but now accountability has expanded to external comparison, public reporting, and hospital revenue.[10-12] The addition of external reporting has forced experts to re-evaluate the VAP definition to standardize criteria to ensure reliability and validity.[13,14]

The VAP definition contains subjective criteria resulting in a high range of inter-observer variability.[1,15,16] Diagnostic components used to distinguish and define VAP include pulmonary criteria, systemic signs and symptoms of infection, and radiographic criteria; but components are without precise criteria for interpretation.[1,2] Microbiologic criteria are also controversial due to

the various techniques in specimen collection and processing, with reports of poor sensitivity and specificity of specimens.[17,18] Although these problems with the VAP definition are well known, VAP incidence based on this definition continues to be used as a performance indicator for hospitals to compare outcomes.[1] Thus, using the current CDC VAP definition to identify cases impacts the validity of any reported VAP incidence rates used both internally and externally as quality benchmarks, and do not accurately reflect quality of care.[19,20]

Process to Improve Outcome Measurements

To circumvent the problems with the CDC VAP definition, researchers began using other end-points to assess the success of interventions on mechanical ventilation outcomes. In an attempt to improve surveillance, a modified VAP definition using specific measurable criteria in an algorithmic approach was used by researchers to evaluate electronic data.[21] The modified VAP definition kept the basic structure of the VAP definition in that two pulmonary criteria, one systemic criterion, and one radiographic criterion would need to be fulfilled. Instead of the subjective criteria in the CDC VAP definition, the modified VAP definition included objective and measurable criteria that could be retrieved from the electronic record (Table 1). For example, specific criteria for a sustained increase in fraction of inspired oxygen (FiO_2) or positive-end expiratory pressure (PEEP) was used instead of the subjective interpretation of a worsening gas exchange (CDC VAP definition). A modified VAP incidence rate of 8.3 per 1000 ventilator days was found, and a 100% positive predictive value when comparing cases to the traditional CDC VAP definition criteria.[21]

Further research on using ventilator-associated complications as a quality indicator was undertaken, and criteria was based on a change in respiratory demand reflected in the need for an increase in ventilator settings (FiO_2 or PEEP) following a two day period of stability. In a

multicenter retrospective study, the ventilator-associated complications definition was used to review data from 600 mechanically ventilated adults in which this incidence was compared to VAP; and other secondary outcome measurements were compared for the two outcomes.[22] A VAP incidence rate of 8.8 per 1000 ventilator days was found compared to a ventilator-associated complication incidence of 21.2 per 1000 ventilator days. The ventilator-associated complication diagnostic criteria used an objective quantitative approach in assessing changes in ventilator settings in determining a change in oxygenation requirements compared to the traditional CDC VAP definition. Top etiologies of ventilator-associated complications reported included: any pulmonary complication (59%), pneumonia (23%), adult respiratory distress syndrome (16%), pulmonary edema (18%), and atelectasis (11%).[22] Thus, ventilator-associated complications encompassed both infectious and non-infectious etiologies, and emerged as a possible superior clinical indicator of mortality compared to VAP.

The CDC began a process of testing a revised VAP definition for adults on mechanical ventilation based on this research.[21,23-25] Initial research and plans to quantify criteria using a streamlined VAP [s-VAP] surveillance definition were presented at national meetings.[24] Specific measurable criteria included adults being mechanically-ventilated for four or more days which included at least two days of stability. The two days of stability were followed by an indicator of respiratory deterioration (minimum daily value of FiO_2 increased at least 0.15 [15 points] or minimum daily PEEP value increased at or above 2 cm H_2O, with either FiO_2 or PEEP remaining at the increased level for two or more calendar days) and indicators of inflammation (fever, leukopenia/leukocytosis, and quantitatively-defined purulent sputum). Reported results indicated that using the s-VAP definition with two indicators of inflammation generated a more

reasonable event rate (7 per 1000 ventilator days) compared to only using one indicator (10 per 1000 ventilator days).

Table 1: Comparison of Assessment Criteria for VAP, Modified VAP, s-VAP, and Ventilator-Associated Complication

Definition	Pulmonary Criteria	Systemic Criteria	Radiographic Criteria
Ventilator-Associated Pneumonia (VAP)[2]	*Any 2* of the following: -New onset of purulent sputum (≥25 neutrophils and ≤10 squamous epithelial cells) or change in character of sputum or increased respiratory secretions or increased suctioning requirements -New onset or worsening cough, dyspnea, or tachypnea -Rales or bronchial breath sounds -Worsening gas exchange (e.g. O_2 desaturations [eg.PaO_2/FiO_2 ≤240]), increased oxygen requirements, or increased ventilator demand	*At least 1* of the following: -Fever (>38°C or >100.4°F) w/no other cause; -Leukopenia (<4000 WBC/mm^3) or leukocytosis (≥12,000 WBC/mm^3); -Adults ≥ 70 years old, altered mental status with no other recognized cause.	Two or more serial chest radiographs w/at least 1 of the following: -New or progressive and persistent infiltrate -Consolidation -Cavitation *Note:* In patients without underlying pulmonary or cardiac disease, one definitive chest radiograph is acceptable.
Modified VAP[21]	*Both* of the following: -Sustained rise in ventilator FiO_2 >15 mm Hg over 48 hours OR sustained rise in ventilator PEEP by ≥5cm H_20 over 48 hours OR simultaneous rise in FiO_2 >10mm Hg AND rise in PEEP > 2.5 cm H_20 sustained over 48 hours. -Gram stain of respiratory secretion sample with ≥ 25 neutrophils per high power field within past 72 hours	*Any 1* of the following: -Fever >38°C (100.4°F) within past 24 hours; -Leukopenia (<4000 WBC/mm^3) or leukocytosis (≥12,000 WBC/mm^3) within past 24 hours	*Any 1* of the following: -Opacity, infiltrate, or consolidation that appears, evolves, or persists over ≥ 72 hours -Cavitation
Modified VAP [s-VAP][24] (CDC 1st Draft)	Mechanically ventilated ≥3 days; - 2 calendar day period of stability or improvement on the ventilator - Sustained (≥2 calendar days) increase FiO_2 ≥15 points OR PEEP increase ≥ 2 cm H_2O.	*Any 1* of the following inflammatory signs -Fever (>38°C or < 36°C) - White Blood Cell Count (>12,000 WBC/mm^3 or <4000 WBC/mm^3) -Quantitatively-defined purulent sputum (≥ 25 neutrophils and ≤ 10 squamous epithelial cells per low power field)	Not applicable

Definition	Pulmonary Criteria	Systemic Criteria	Radiographic Criteria
Ventilator-Associated Complication[22]	Patients must have: -Minimum of 2 days of stable or decreasing daily minimum PEEP or FiO_2. *Followed by*: -Increase in the daily minimum PEEP by 2.5cm H_20 sustained for $\geq$ 2 days OR increase in daily minimum FiO_2 by $\geq$15 points sustained for $\geq$ 2 days.	Not applicable	Not applicable

CDC researchers further evaluated 32 different possible objective definitions that were based on various combinations of indicators of respiratory deterioration and infection.[26] Different indicators of respiratory deterioration based on ventilator settings that were evaluated included: increase in the daily minimum PEEP by at least 2 cm H_2O or the FiO_2 by 15 points sustained for two or more calendar days, increase in the daily minimum PEEP by at least 3 cm H_2O or the FiO_2 by 20 points sustained for two or more calendar days, and increase in the daily minimum PEEP by at least 5 cm H_2O or the FiO_2 by 20 points sustained for two or more calendar days; plus various indicators of infection (abnormal temperature, white cell count, purulent secretions [indicated by gram stain], and culture). In this retrospective study, results indicated that increased hospital mortality was significantly associated with the definitions that required respiratory deterioration criteria.[26] Defining respiratory deterioration with specific parameters of a sustained increase in FiO_2 or PEEP, following a two calendar day period of stability, also predicted an increase in ventilator days and hospital days, although adding systemic infection thresholds did not impact outcomes.[26]

New VAE Surveillance Definition

This evidence-based process to quantify and validate the VAP definition has resulted in a new surveillance definition. In January 2013, the CDC introduced the VAE protocol, and indicated that VAE will replace the widely used VAP definition.[27] The VAE protocol contains three tiers: the first tier is determining ventilator-associated condition (VAC) that is based on respiratory deterioration (FiO_2 or PEEP); and if VAC is met, then the second tier is assessed for the occurrence of an infection-related ventilator-associated complication (IVAC) based on inflammatory signs; if IVAC is met, then the third tier based on microbiology data is assessed for a possible or probable VAP (Figure 2).

CDC experts are already recommending that public reporting and external comparison include VAC and IVAC only, with possible and probable VAP being used for internal quality improvement purposes.[27] The new VAE algorithm contains specific criteria promising for data mining and electronic data extraction for case identification. Expanding the VAE definition to assess for all potential avoidable ventilator occurrences will enable clinicians to begin recognizing trends in other conditions and potential patient safety issues, implement necessary interventions, and improve patient outcomes. Thus, the long term goal to minimize variability across observers with a standard definition and provide a reliable measure with clinical relevance may be achieved; and by using specific measurable objective criteria, data-mining technology using precise algorithms can facilitate immediate case finding.

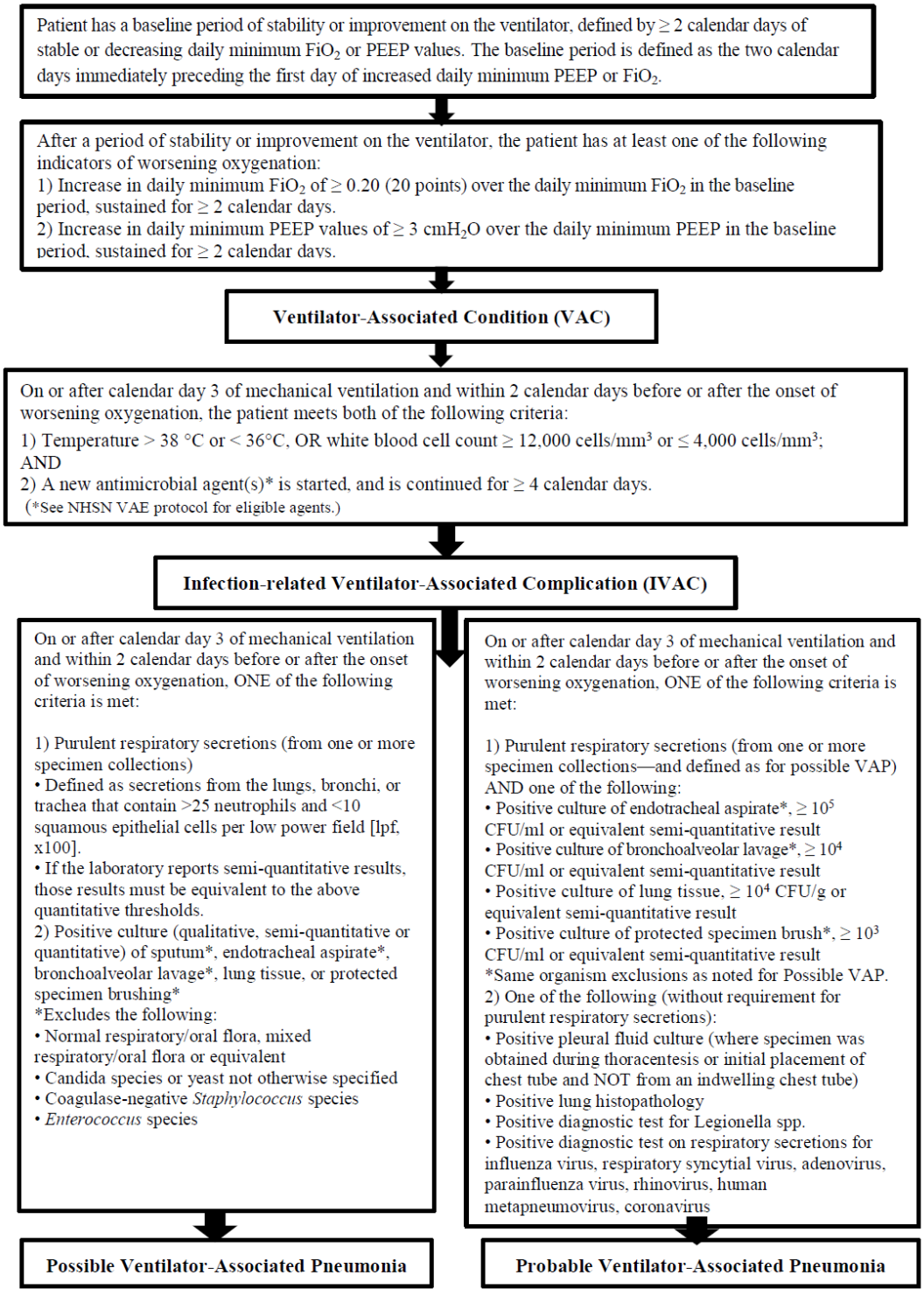

Figure 2: VAE Surveillance Algorithm; from: http://www.cdc.gov/nhsn/acute-care-hospital/vae/

Summary

Expanding and improving mechanical ventilation quality performance measures to VAE will provide a better representation of clinical improvements and challenges, improve data validity, provide a better benchmark for comparison, and eliminate the present confusion with the current VAP definition. The IP will be able to consistently and accurately identify cases with less conflict and analyze data for common factors to reduce the incidence of HAI; and thus reduce morbidity and save healthcare dollars. Using VAE (VAC and IVAC) as an outcome indicator will provide a standard and valid measurement for research and external rate comparison.

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CHAPTER 3: FINDINGS

Abstract

Ventilator-associated pneumonia (VAP) has been the traditional outcome measurement for critically-ill patients on mechanical ventilation. Recently, the Centers for Disease Control and Prevention (CDC) updated and expanded the VAP surveillance definition to include all ventilator-associated events (VAE), specifically addressing ventilator-associated conditions (VAC) that can be either non-infectious related conditions or infectious ventilator-associated complications (IVAC). Further internal quality measurement criteria to identify if an IVAC is a possible or probable VAP are included in the algorithm. The primary aims of this retrospective study was to determine the incidence of VAC; and to assess four predictors for VAC, including two VAP prevention strategies (use of the subglottic secretion drainage endotracheal-tube [SSD-ETT], and daily sedation vacation), and two patient-related factors (alcohol withdrawal during mechanical ventilation, and history of chronic obstructive pulmonary disease [COPD]).

Using a retrospective study design, electronic medical records of 280 subjects were reviewed using the CDC VAE algorithm. The setting was two intensive care units (ICU) in a Veterans Administration Healthcare System (VAHCS). Medical records of those who met inclusion criteria (orally intubated, mechanically-ventilated for a minimum period of two calendar days) from October 2009 to September 2011 were reviewed. In addition to demographic information, variables were collected to determine if cases met VAC event criteria to determine an incidence rate based on 1000 ventilator days. Comparative data between those with and without VAC were assessed with independent sample T-test or non-parametric equivalents. Using logistic regression, the impact of the four predictors for VAC was assessed.

Secondary outcomes (mechanical ventilation days, ICU days, hospital days, and mortality) of veterans with VAC were compared to veterans without VAC.

Twenty patients met the VAC definition resulting in a VAC incidence of 7.38 per 1000 ventilator days. No statistically significant differences in demographics or disease characteristics were found between the two groups (patients with VAC and without VAC). Logistic regression was performed on occurrence of VAC and the four predictors. Results indicated that these four explanatory variables were not predictive of the occurrence of VAC. Secondary outcomes indicated that the VAC group was significantly associated with a longer duration of ICU stay, longer mechanical ventilation period, more likely to have a tracheostomy, and had a higher likelihood for mortality during hospitalization.

Expanding mechanical ventilation quality performance measures to include VAE/VAC provides a better representation of ventilator-associated improvements and complications; and provides more accurate morbidity and mortality in this high-risk ICU population. Further research is necessary to explore patient characteristics and nursing interventions that impact the development of all VAE.

Introduction and Background

Ventilator-associated pneumonia incidence rates have been used for decades as an outcome measurement in mechanically-ventilated patients, although experts acknowledge that VAP surveillance has high inter-observer variability which impacts credibility for external comparison.[1,2] Expanding surveillance from VAP to include other complications has emerged as a superior indicator of mortality.[3,4] The CDC recently announced in January 2013, that a VAE protocol would replace the VAP surveillance definition in adults. Within the VAE algorithm four possible events can be determined for surveillance purposes: 1) VAC, 2) IVAC, 3) possible

pneumonia, and 4) probable pneumonia. The goal of this research-based VAE algorithm was to significantly expand, improve, and standardize surveillance for ventilator-associated infections.[5,6]

A retrospective, descriptive study was designed to apply the new CDC VAE algorithm to critically-ill, mechanically-ventilated veterans. The primary aims were 1) to determine the incidence of VAC; and 2) to assess the predictive ability of two VAP prevention strategies (SSD-ETT, and daily sedation vacation), and two patient-related factors (alcohol withdrawal during mechanical ventilation, and history of COPD) on VAC. Secondary outcomes (mechanical ventilation days, ICU days, hospital days, and mortality) of veterans with VAC were compared to veterans without VAC. In addition, the VAC incidence rate was compared with the pre-reported VAP rate (obtained from Infection Control database), and the etiology of VAC incidence was grouped into infectious and non-infectious complications for comparison.

The Institute for Healthcare Improvement (IHI) recommends a set of ICU ventilator prevention strategies that are expected practices: elevation of the head of the bed, peptic ulcer prophylaxis, deep venous thrombosis prophylaxis, oral care with chlorhexidine, and the sedation vacation.[7,8] The Veteran's Health Administration (VHA) system has adopted implementation of the ventilator bundle, and compliance was monitored.

The first predictor reviewed for this study was the SSD-ETT, which was available at the study site for use; however, many ICU patients are intubated with a traditional endotracheal (ETT) either during surgery or transferred into the ICU intubated from another facility.[9,10] This variation in intubation practices provided an opportunity to assess the effectiveness of the SSD-ETT device in preventing VAC. The second predicator was the sedation vacation, which included decreasing patient sedation until spontaneous ventilation occurred, which may be

difficult to achieve daily due to a variety of medical reasons or contraindications, including alcohol withdrawal. The third and fourth predictors in this study were based on known high risk patient-related factors (alcohol withdrawal and COPD). Soldiers are known to have a higher than average consumption of alcohol and cigarettes (with smoking known as a precursor to development of COPD). These behaviors continue after retirement and discharge and continue to be seen at a higher rate in the veteran population, and influence morbidity.[11-13] This is the first study known to assess the impact of these four factors on VAC.

Methods

Setting and Sample

The setting was a large Veteran Administration Healthcare System (VAHCS) in the Southeastern United States. Subjects received mechanical ventilation in either the surgical or medical ICU between October 1, 2009 and September 30, 2011. The IHI ventilator bundle was implemented in 2007, with chlorhexidine oral care added in 2010. The SSD-ETT was implemented in the ICUs and emergency intubation trays in 2006 (HiLo®Evac ETT). During the spring of 2010 the Mallinckrodt™ TaperGuard™ Evac ETT replaced the HiLo®Evac SSD-ETT.[14] The SSD-ETT was not implemented in the operative area until 2009 when anesthesia providers were encouraged to consider using the SSD-ETT for patients that may require mechanical ventilation post-operatively. The SSD-ETT was not used on every patient, and the sedation vacation was not often done; thus, providing an opportunity to compare the effectiveness of these interventions on the incidence of VAC in this veteran population. The time period selected for the study was after the implementation of the IHI bundle and SSD-ETT in this VAHCS ICU population.

The sample consisted of adult veterans (≥18 years), orally intubated with an ETT or SSD-ETT, who required mechanical ventilation for at least two calendar days. Exclusion criteria included any non-veteran, veterans under age 18, admission with existing tracheostomy, and aspiration documented at time of admission. Subjects were identified from historic infection control data (received from the Respiratory Therapy department that included patients on mechanical ventilation and number of mechanical ventilation days). All patients on mechanical ventilation during the 24 months were screened to verify inclusion criteria, resulting in 280 subjects.

Respective institutional review boards at the VAHCS and the university approved the study, along with waiver of informed consent. All subjects were assigned a random number after meeting inclusion criteria. Data was de-identified during data extraction, therefore only de-identified data were available for analysis.

The method for determining a sample size for the logistic model with a binary covariate was used for the sample size estimation, with data from 300 subjects estimated a-priori to satisfy the inclusion criteria for analysis. This sample size would ensure a Type I error 0.05 and a power of 80% for the primary analysis.[15] Sample size for the logistic regression model with a binary covariate X is determined by B, proportion of samples at X =1; VAC event rate p_1 at X=1, and VAC event rate p_2 at X=0. Table 2 provides sample sizes for various values of p_1, p_2 and B.

Table 2: Sample Size for Logistic Regression with VAC Event Rate p_1 at X=1, VAC Event Rate p_2 at X=0

	B=20% $p_1 = 0.8$	*B=45%* $p_1 = 0.7$	*B=55%* $p_1 = 0.6$	*B=80%* $p_1 = 0.5$
p_2=0.6	31	71	94	262
p_2=0.5	42	81	106	294
p_2=0.4	50	86	110	**300**
p_2=0.3	54	83	105	282

All analyses of predictive VAC risk factors were conducted with a 2-tailed test and at the 0.05 significance level. If one predictive factor was missing the whole record for a patient was excluded from analysis without imputation; there were no missing factors recorded and all subjects were included in data analysis. During the approved study time period, only 280 mechanically ventilated patients met inclusion criteria.

Measures

Demographic and Medical History

Demographic data and medical history were extracted from the electronic medical record (Appendix A). Various demographic and morbidity/mortality data were collected (e.g. age, gender, ethnicity, body mass index [BMI], admitting diagnosis, ICU admission diagnosis, acuity score [Charlson score], surgical procedures related to ICU admission, intubation circumstances [place, type of ETT], and occurrence of mortality).

The CDC VAE algorithm (Figure 3) was used for every patient to determine the occurrence of VAC, IVAC, possible pneumonia, and probable pneumonia and collect the necessary variables (Appendix A).

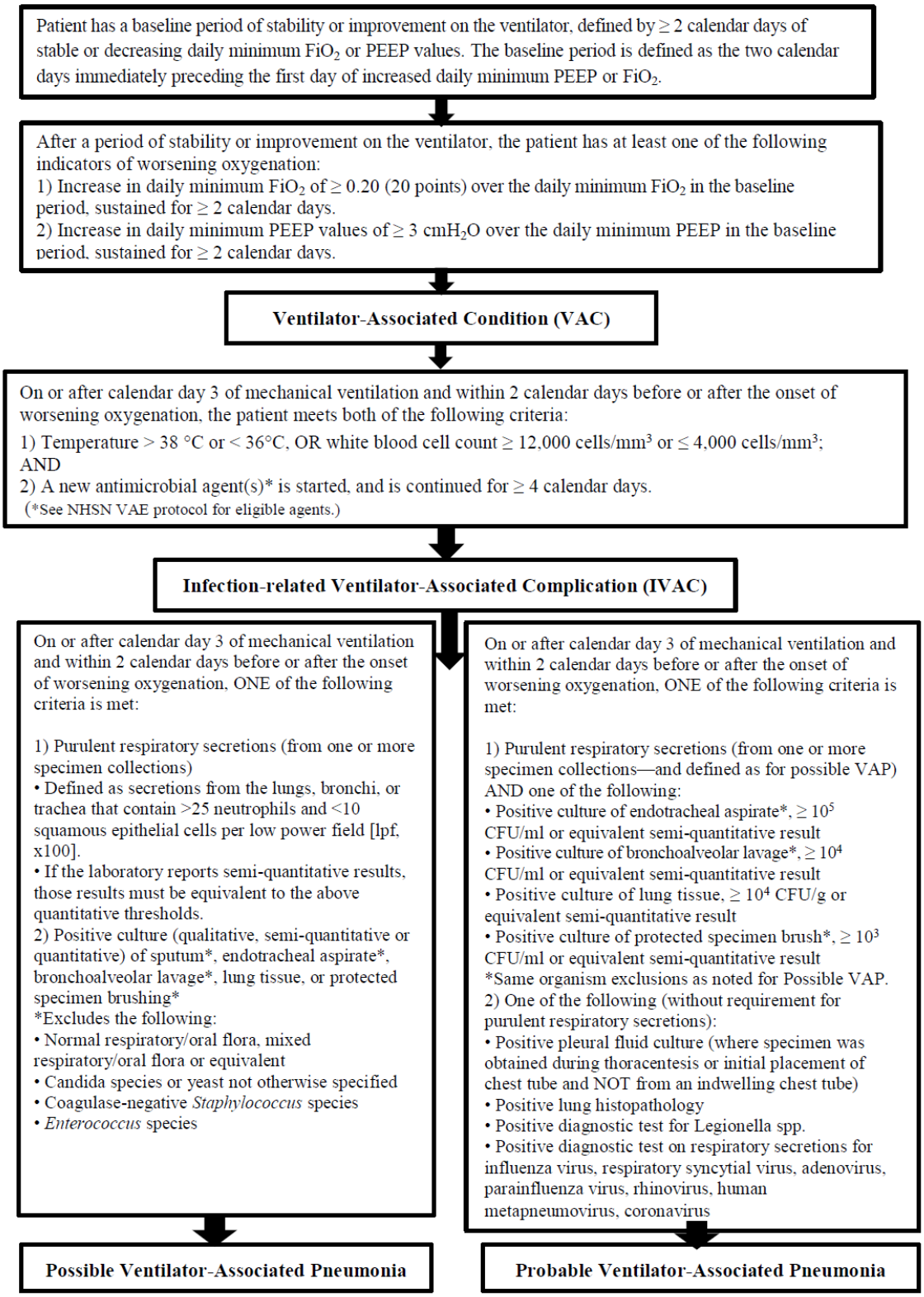

Figure 3: VAE Surveillance Algorithm; from: http://www.cdc.gov/nhsn/acute-care-hospital/vae/

Procedures

Demographic, Medical, and Hospitalization History

Each medical record was reviewed for necessary data. Dates of care were de-identified and recorded numerically during data collection: hospital length of stay (calculated from dates of hospital admission and discharge), ICU length of stay (calculated from dates of ICU admission and discharge), number of days mechanically ventilated (calculated from dates of intubation and extubation), and occurrence and timing of tracheostomy (intubation date and tracheostomy date, if applicable). Although some patients had re-admissions to the ICU, only the ICU length of stay related to the first ventilator event was captured for the purpose of the study.

VAE Algorithm Assessment for Occurrence of VAC

All patients were evaluated using the CDC VAE algorithm (Figure 3) and the inclusion/exclusion criteria for the study. The first tier evaluated for VAC and documentation was assessed for a two calendar day period of decreasing or stable respiratory mechanical ventilator parameters (positive end expiratory pressure [PEEP] and fraction of inspired oxygen [FiO_2]), followed by a sustained increase in the same parameter (Appendix A). An occurrence of VAC was noted with a sustained increase in the minimum PEEP by 3 cm H_20 for $\geq$ 2 calendar days or a sustained increase in the minimum FiO_2 by $\geq$ 0.20 (20 points) for $\geq$ 2 calendar days. In addition, once a VAC was determined, patients were evaluated for occurrence of IVAC, possible VAP, and probable VAP based on NHSN criteria.

Assessment for Predictor Occurrence

Each subject was assessed for the presence of four variables during the mechanical ventilation period, 1) SSD-ETT, 2) sedation vacation, 3) alcohol withdrawal, and 4) history of COPD (Appendix A).

Presence of SSD-ETT

Although research indicates that that use of SSD-ETT prevents VAP, practice modifications to all hospitals and populations lag due to an economic impact.[9,16] At the study site, the SSD-ETT was the only ETT available outside of the operating room (OR), and anesthesia attempted to use the SSD-ETT on select surgical patients that were candidates for post-operative ventilation. In addition, patients on mechanical ventilation were frequently transferred to the VAHCS from other facilities that may not have implemented the SSD-ETT. The type of ETT used during mechanical ventilation was recorded for each patient. The presence of the SSD-ETT or not (standard ETT) was assessed and recorded once. Patients that required re-intubation within 24 hours were noted in the comments if there were two different types of ETT used for that ventilation period. Only one patient met this situation, and did not meet criteria for VAE.

Daily Sedation Vacation

Documentation was reviewed for indication that sedation was lightened daily until the patient was awakened, aroused, and had spontaneous ventilation.[8,17] If any of the notes on each calendar day indicated this occurrence, then a daily sedation vacation occurred. If there was an overall 90% occurrence of a sedation vacation during the mechanical ventilation period, then a positive occurrence was recorded.

Alcohol Withdrawal

Management of alcohol withdrawal in the ICU, especially the veteran population, is challenging, and patients may require intubation and extended mechanical ventilation.[18] Documentation was reviewed for occurrence of alcohol withdrawal during the mechanical ventilation period. Alcohol withdrawal screening and management of symptoms of agitation

were often reported using the Clinical Institute Withdrawal Assessment (CIWA) of Alcohol Scale, yet did not necessarily indicate the diagnosis of alcohol withdrawal. A physician note was required to indicate the presence of alcohol withdrawal for a positive occurrence during the mechanical ventilation period.

History of COPD

Documentation of a history of COPD by a physician was acceptable as a positive history of COPD. Since this was a retrospective study, COPD staging criteria (i.e. GOLD) was not assessed.[19] Therefore, if either the provider generated problem list or physician documentation indicated the presence of COPD, then this was a positive occurrence. In addition, the known COPD risk factor of cigarette smoking was collected for secondary analysis (history of smoking, pack per year history, and current smoking history).

Secondary Outcome Data

Dates were de-identified during data collection and converted directly into numerical data (i.e. days of care) for data entry and analysis. Secondary data included:

Mechanical ventilation days: number of days on the mechanical ventilator.

ICU days: number of patient days in the ICU for the mechanical ventilation event period.

Hospital days: total number of patient days in the hospital, inclusive of ICU days.

Mortality: did the patient expire during the hospitalization (yes or no).

Tracheostomy: days from intubation to tracheostomy (for mechanical ventilation event period).

Study Endpoints

Endpoints of the mechanical ventilation period included: extubation >24 hours, tracheostomy, discharge, or death. If a patient was extubated and re-intubated within 24 hours

for any reason, it was documented in the comments, although time remained inclusive for the mechanical ventilation period. Only the first mechanical ventilation episode per patient was included in the study. Subsequent mechanical ventilation events on the same patient were not assessed for VAE occurrence.

Data Analysis

Data analysis included the overall incidence rate of VAC and IVAC. Incidence rates were calculated based on the number of events per 1000 ventilator days. Comparative data between those with and without VAC were assessed with independent sample T-test or non-parametric equivalents, depending on whether data met assumptions for parametric statistics. Logistic regression was performed on occurrence of VAC and four predictors (use of the SSD-ETT, daily sedation vacation, alcohol withdrawal, and history of COPD). Secondary outcomes (mechanical ventilation days, ICU days, hospital days, and mortality) of veterans with VAC were compared to veterans without VAC. The statistical testing was performed using IBM® SPSS® Statistics 21, and a level of significance of 0.05 was set for all these tests.

Results

Sample

There were 280 subjects that met inclusion criteria. Using the CDC VAE algorithm, 20 patients met the VAC definition, resulting in a 24-month incidence of 7.38 per 1000 ventilator days. Descriptive statistics are reported as a number (percentage) for categorical variables; and as a mean value, standard deviation (SD), and 95% confidence interval (CI) for continuous variables (Table 3). There were no statistically significant differences in demographics or disease characteristics between the two groups (with VAC and without VAC).

Table 3: Sample Demographics and Characteristics of Patients With and Without VAC

Characteristic	Total Sample (n=280)	Without VAC (n=260)	With VAC (n=20)	95% CI	ρ value*
Sex, n (%)					.452
Male	272 (97.1)	253 (97.3)	19 (95.0)		
Female	8 (2.9)	7 (2.7)	1 (5.0)		
Age, years, mean (SD)	67.2 (10.4)	67.2 (10.5)	66.9 (9.4)	-5.060, 4.507	.909
Range	38-89				
Race, n (%)					.110
Black	17 (6.1)	14 (5.4)	3 (15.0)		
White	258 (92.1)	242 (93.1)	16 (80.0)		
Other	5 (1.8)	4 (1.5)	1 (5.0)		
Ethnicity, n (%)					.086
Hispanic	3 (1.1)	2 (0.8)	1 (5.0)		
Not Hispanic	254 (90.7)	235 (90.4)	19 (95.0)		
Unknown	23 (8.2)	23 (8.8)	0 (0.0)		
BMI, mean (SD)	28.4 (7.4)	28.5 (7.5)	27.0 (6.9)	-1.98, 4.81	.413[t]
(Range)	(14.4-50.7)				
BMI Groups:					
BMI< 18.5	16 (5.7)	15 (5.8)	1 (5.0)		.341
BMI 18.5-24.9	88 (31.4)	78 (30.0)	10 (50.0)		
BMI 25-29.9	71 (25.4)	69 (26.5)	2 (10.0)		
BMI 30-39.9	80 (28.6)	75 (28.8)	5 (25.0)		
BMI >40	25 (8.9)	23 (8.8)	2 (10.0)		
ICU type, n (%)					.374
MICU	141 (50.4)	129 (49.6)	12 (60.0)		
SICU	119 (42.5)	111 (42.7)	8 (40.0)		
ICU combination	20 (7.1)	20 (7.7)	0 (0.0)		
ICU diagnosis, n (%)					.569
Medical	71 (25.4)	67 (25.8)	4 (20.0)		
Surgical	73 (26.1)	69 (26.5)	4 (20.0)		
Respiratory Event	136 (48.6)	124 (47.7)	12 (60.0)		
Charlson Score, mean (SD)	5.8 (2.5)	5.8 (2.5)	5.8 (2.8)	-1.11, 1.18	.947[t]
Range	0-13	0-13	0-12		
Coronary Artery Disease, n (%)					.787
Yes	262 (93.6)	243 (93.5)	19 (95.0)		
No	18 (6.4)	17 (6.5)	1 (5.0)		
Renal Disease, n (%)					.404
Yes	123 (43.9)	116 (44.6)	7 (35.0)		
No	157 (56.1)	144 (55.4)	13 (65.0)		

Characteristic	Total Sample (n=280)	Without VAC (n=260)	With VAC (n=20)	95% CI	ρ value*
Diabetes Mellitus (DM), n (%)					.107
Yes	118 (42.1)	113 (43.5)	5 (25.0)		
No	162 (57.9)	147 (56.5)	15 (75.0)		
Insulin-Dependent DM, n (%)					.543
Yes	48 (17.1)	46 (17.7)	2 (10.0)		
No	232 (82.9)	214 (82.3)	18 (90.0)		
Liver Disease, n (%)					.972
Yes	97 (34.6)	90 (34.6)	7 (35.0)		
No	183 (65.4)	170 (65.4)	13 (65.0)		
Cancer History, n (%)					.379
Yes	80 (28.6)	76 (29.2)	4 (20.0)		
No	200 (71.4)	184 (70.8)	16 (80.0)		
Chronic Obstructive Pulmonary Disease, n (%)					.304
Yes	209 (74.6)	196 (75.4)	13 (65.0)		
No	71 (25.4)	64 (24.6)	7 (35.0)		
Smoking History, n (%)					.248
Yes	249 (88.9)	233 (90.0)	16 (80.0)		
No	30 (10.7)	26 (10.0)	4 (20.0)		
Currently Smoking, n (%)					
Yes	113 (40.4)	107 (41.2)	6 (30.0)		.327
No	167 (59.6)	153 (58.8)	14 (70.0)		
Pack per Year- mean (SD)	54.8 (31.6) (n=185)	55.2 (32.0) (n=171)	51.1 (26.1) (n=14)	-13.35, 21.35	.649[t]
Range	2-150				
Alcohol Abuse History, n (%)					.292
Yes	109 (38.9)	99 (38.1)	10 (50.0)		
No	171 (61.1)	161 (61.9)	10 (50.0)		
Alcohol Withdrawal History, n (%)					.395
Yes	24 (8.6)	21 (8.1)	3 (15.0)		
No	256 (91.4)	239 (91.9)	17 (85.0)		

**P* value for $_X{}^2$ or Fisher exact test.
[t] *P* value for Independent Sample T test

The majority of subjects were male (97.1%), Caucasian (92.1%), non-Hispanic (90.7%), with a mean (SD) age of 67.2 (10.4) years. The majority of the ICU admission diagnoses were related to a respiratory event (48.6%). The majority of these subjects had a history of smoking (88.9%) with a mean 47.4 pack year history, and 40.4% reported they continued to smoke

tobacco. Although there was alcohol abuse history noted in 38.9% of the sample, only 8.6% were previously diagnosed with alcohol withdrawal. No significant differences in demographic or disease characteristics (Table 3) were found between the two groups (patients with and without VAC). Categorical variables were analyzed by $_{X}^{2}$ test or Fisher exact test, and independent sample T test was used for continuous variables.

Logistic regression was performed on occurrence of VAC and four predictors (use of the SSD-ETT, daily sedation vacation, alcohol withdrawal, and history of COPD). A test of the full model against the constant only model was not statistically significant (-2 Log likelihood 142.981, x^2=1.118, p=.891). Variance accounted for in the model was estimated at 1%, and the Hosmer and Lemeshow Test indicated the data were a good fit for the model (x^2=3.781, df=4, p=.437). Table 4 presents the regression coefficients (B), Wald statistics, odds ratio (OR), and 95% confidence intervals (CI). Results indicated that none of these four variables were predictive of the occurrence of VAC.

Table 4: Logistic Regression (LR) Model Results

LR Model Predictors	*B*	S.E.	Wald	OR	95% CI		ρ value
					Lower	Upper	
Subglottic Secretion Drainage Endotracheal Tube	-.205	.652	.099	.815	.227	2.926	.753
Sedation Vacation	-.007	.796	.000	.993	.209	4.725	.993
Alcohol Withdrawal	-.101	.781	.017	.904	.196	4.174	.897
Chronic Obstructive Pulmonary Disease	.510	.502	1.035	1.666	.623	4.454	.309

Outcome Data

During the 24 month period, 20 patients met the VAC definition (incidence of 7.38 per 1000 ventilator days). The VAC event etiology was diagnosed by the provider as pneumonia (9), acute respiratory distress syndrome (5), pulmonary edema (2), pleural effusion (2), atelectasis (1), and severe asthma (1). Using the VAE algorithm, eight of the 20 patients met the IVAC definition (incidence of 2.95 per 1000 ventilator days), with four probable VAPs

identified in this group. During the same time period, the infection preventionist reported a total of 10 VAPs (incidence of 3.69 per 1000 ventilator days) to the VAHCS Infection Control Committee.

The VAC group was associated with a significant longer duration of ICU stay, longer mechanical ventilation period, more likely to have a tracheostomy during ICU stay, and higher likelihood for mortality (Table 5). Although hospitalization stay was not found statistically significant, patients that developed VAC had an average of 5 additional days in the hospital.

Table 5: Secondary Outcomes for Patients With and Without VAC

Outcome	**Total Sample (n=280)**	**Without VAC (n=260)**	**With VAC (n=20)**	**95% CI**	**ρ value***
Hospital LOS, mean (SD) (range 2-94 days)	18.34 (16.13) n=278 median=13.0	17.98 (16.27) n=258	23.00 (13.62)	-12.38, 2.34	.180 [t]
ICU LOS, mean (SD) (range 2-73 days)	10.82 (11.53) n=277 median=7	10.14 (11.19) n=257	19.60 (12.58)	-14.62,-4.30	**<.001** [t]
Ventilator Days, mean (SD) (range 2-74)	5.66 (7.29) median=3	5.01 (6.52)	14.05 (10.97)	-14.22, -3.85	**.002** [t]
Tracheostomy Yes No	19 (6.8) 261 (93.2)	13 (5.0) 247 (95.0)	6 (30.0) 14 (70.0)		**.001**
Mortality during Hospitalization, n (%) Yes No	59 (21.1) 221 (78.9)	48 (18.5) 212 (81.5)	11 (55.0) 9 (45.0)		**.001**

LOS, Length of Stay.
*P value for $_X{}^2$ or Fisher exact test.
[t] P value for Independent Sample T test

Discussion

Expanding surveillance to include VAE provides an improved surveillance tool that rapidly and objectively identifies outcomes in mechanically-ventilated veterans. The new CDC VAE protocol is easy to use with clear objective definitions.[20] Identification of VAE with specific definition criteria allows for the possibility of electronic extraction from the medical

record, although rapid manual screening is a reality using a simple daily line listing (recording the daily minimum FiO_2 and PEEP).[3] The VAE algorithm and protocol provides a reliable and valid tool to identify VAC and IVAC, report and compare rates with confidence, and avoid prior problems noted with the VAP definition.[21] Questions regarding the VAE protocol specific to NHSN reporting continue to be answered by CDC experts.

The sample population reflected the population at this VAHCS (97.1% male, 92.1% Caucasian, 90.7% non-Hispanic, with average age of 67.2). A history of COPD was noted in 74.6% of the sample, with over 88.9% admitting to having a history of cigarette smoking, and 40.4% continuing to smoke. Therefore, it was not surprising that a respiratory event (48.6%) was the reason for majority of the ICU admission diagnoses. The prevalence of COPD was expected to be high in this population, and the odds ratio indicated that subjects with COPD were 1.67 times more likely to have a VAC. This is not unexpected and is supported by other studies that demonstrate that COPD prolongs ventilator weaning thus increases the risk of complications.[22,23] Data were not collected for polysubstance abuse, smoking crack cocaine, or smoking marijuana, and was a limitation to the study.

The VAC incidence rate was 7.38 per 1000 ventilator days for a 24 month period. Data were de-identified immediately; therefore, VAC rates by time periods cannot be obtained. VAC event etiology was diagnosed by the provider as pneumonia (45%), acute respiratory distress syndrome (25%), pulmonary edema (10%), pleural effusion (10%), atelectasis (5%), and severe asthma (5%). This is comparable to a recent study that reported top VAC etiology as any pulmonary complication (59%), pneumonia (23%), acute respiratory distress syndrome (16%), pulmonary edema (18%), and atelectasis (11%).[3] Historically during the same time period, the infection preventionist reported a total of 10 cases of VAP (or an incidence of 3.69 per 1000

ventilator days) to the VAHCS Infection Control Committee which is comparable to the IVAC rate (incidence of 2.95 per 1000 ventilator days) in this study. The CDC VAE criteria for possible VAP and probable VAP contain stricter criteria than the previous VAP definition, which may account for only meeting criteria for four probable VAPs under the new algorithm. In addition, the CDC VAE criteria excludes *Candida* species, coagulase-negative *Staphylococcus* species, and *Enterococcus* species, when isolated from cultures of sputum, endotracheal aspirates, bronchoalveolar lavage, and or protected specimen brushings which may account for differences in case identification under the new criteria for possible VAP or probable VAP.[20]

Another area that impacts case identification is the mode of mechanical ventilation, and this was found to be a limitation in this study. Medical management of patients on mechanical ventilation includes various modes of ventilation that vary based on hospital and available equipment. The major criteria for respiratory deterioration (VAC definition) include changes in either FiO_2 or PEEP, and CDC experts have excluded some modes of ventilation that specifically impact the PEEP criteria (Table 6). For example, airway pressure release ventilation (APRV) is a ventilation mode that the VAE protocol requires only FiO_2 to be used for VAC surveillance, where high-frequency ventilation and extracorporeal life support is excluded from surveillance.[20]

Table 6: Types of Mechanical Ventilation

Type of Mechanical Ventilation	Ventilator-Associated Event (VAE) Surveillance
Controlled Mandatory Ventilation (CMV)	Yes
Assist-Control Ventilation (ACV)	Yes
Synchronized Intermittent Mandatory Ventilation (SIMV)	Yes
Pressure Control Ventilation (PSV)	Yes
Pressure Support Ventilation (PSV)	Yes
Continuous Positive Airway Pressure (CPAP)	Yes
PCV+ without Inverse I:E Ratio (Dräger ventilators)	Yes
Pressure-Regulated Volume Control Ventilation (PRVC)	Yes
Volume Support Ventilation	Yes
Volume-Assured Pressure Support Ventilation	Yes

Type of Mechanical Ventilation	Ventilator-Associated Event (VAE) Surveillance
Adaptive Pressure Control Ventilation	Yes
Mandatory Minute Ventilation (MMV)	Yes
AutoFlow (Dräger ventilators)	Yes
Adaptive Pressure Ventilation (Hamilton GALILEO ventilators)	Yes
Volume Control Plus Ventilation (Puritan-Bennett ventilators)	Yes
Volume Targeted Pressure Control Ventilation	Yes
Pressure Controlled Volume Guarantee Ventilation (General Electric Ventilators)	Yes
Adaptive Support Ventilation	Yes
Proportional Assist Ventilation	Yes
Bi-Level Ventilation without Inverse I:E Ratio (Puritan-Bennett Ventilators)	Yes
Airway-Pressure Release Ventilation (APRV)	Yes* (FiO_2 only)
Pressure-Control Inverse Ratio Ventilation (PC-IRV)	Yes* (FiO_2 only)
Bi-Level Ventilation with Inverse I:E Ratio (Puritan-Bennett ventilators)	Yes* (FiO_2 only)
Bi-Vent Ventilation (Maquet SERVO-i ventilators)	Yes* (FiO_2 only)
PCV+ with Inverse I:E Ratio (Dräger ventilators)	Yes* (FiO_2 only)
DuoPAP Ventilation (Hamilton GALILEO ventilators)	Yes* (FiO_2 only)
Biphasic Intermittent Positive Airway Pressure Ventilation	Yes* (FiO_2 only)
Intermittent Mandatory Airway Pressure Release Ventilation	Yes* (FiO_2 only)
Excluded from VAE Surveillance:	
High Frequency Ventilation (HFV)	No
High Frequency Oscillatory Ventilation (HFOV)	No
High Frequency Jet Ventilation	No
High Frequency Percussive Ventilation	No
Volumetric Diffusive Ventilation (VDR, Percussionaire ventilators)	No
Extracorporeal Life Support (ECLS) with venous-venous cannulation	No
Extracorporeal Life Support (ECLS) with venous-arterial cannulation	No
Extracorporeal Membrane Oxygenation (ECMO)	No

*These types of mechanical ventilation are included in VAE surveillance, but oxygenation changes are assessed using fraction of inspired oxygen (FiO_2) data *only* during the period of time these types of mechanical ventilation are used. Positive End Expiratory Pressure (PEEP) criteria are not used to assess for VAEs when receiving one of these types of mechanical ventilation.

At the study site, the option of Bi-Level Ventilation was recorded for numerous patients and some patients frequently switched from one mode of ventilation to Bi-Level Ventilation and back again; therefore, only the FiO_2 criteria was followed most of the time in many patients. This ventilation exclusion may have limited the identification of VAC cases in the study population. CDC experts are now prospectively asking participating National Healthcare Safety

Network hospitals to submit the mode of ventilation (APRV) to determine the impact of these alternate modes on the VAE algorithm and rates.[20]

This study reported a VAC incidence of 7.38 per 1000 ventilator days (or 7.1%) with study endpoints that may have impacted the lower rate (tracheostomy and first extubation). These study endpoints were necessary to evaluate the impact of the SSD-ETT on the occurrence of VAC. This study VAC rate was lower than a recent retrospective study of 600 mechanically ventilated patients with an overall VAC incidence of 21.2 per 1000 ventilator days (or 23%).[3] However, these patients had a longer duration of ventilation (14.7 days [CI 13.2-16.4]), with an average of 8% VAC rate among ventilated patients less than 7 days, and an average of 37% for patients ventilated more than 7 days.[3]

Although these data were not collected for this study due to the study endpoints of tracheostomy, 80% of VACs occurred within the first seven days on mechanical ventilation. This study was a single setting confined to all 280 patients in a 24 month period compared to a multi-site setting of 600 patients (three hospitals in which each site randomly selected 100 patients ventilated 2-7 days and 100 patients ventilated more than seven days).[3] In addition, the occurrence of VAC was defined slightly different (sustained increase in the minimum PEEP by 2.5 cm H_20 for $\geq$ 2 calendar days or a sustained increase in the minimum FiO_2 by $\geq$15 points for $\geq$ 2 calendar days) than this study, which may account for additional cases meeting criteria. Under the new CDC VAE protocol, patients may have more than one VAE event during a ventilation period (must have 14 days between a VAE event); and in addition to the respiratory deterioration criteria, specific infection criteria for IVAC, possible VAP, and probable VAP are included.[20] Therefore, the VAC incidence rate of this study is limited to the population and available data, and lack generalizability.

Other important limitations include the retrospective nature of the study, and limitation of the nature of the veteran population served at the VAHCS. The study sample was predominantly Caucasian, non-Hispanic male veterans with complex medical morbidities. There were no significant differences in demographics or acuity score (Charlson score) between patients with and without VAC, and morbidities were expected in this veteran population.

The four predictors (SSD-ETT, sedation vacation, alcohol withdrawal, and history of COPD) were not found significant in this study. Although 17.1% of veterans did not have a SSD-ETT in place, the SSD-ETT was in place majority of time (82.9%), and there was no significant difference between groups (patients with VAC had a SSD-ETT 85.0% compared to 82.7% of patients without VAC). This finding was unexpected since the SSD-ETT is associated with a reduction in VAP. [9,10] One reason may be that VAE identifies many different events in addition to VAP. A limitation to this study is that documentation of the function of the SSD-ETT was not collected. Amount of intermittent or continuous suction based on manufacturer recommendations were not routinely documented, only that the SSD-ETT was in place. Previous research indicated that endotracheal tube-suction lumen dysfunction occurred in 48% of the participants.[24]

There was a high prevalence of COPD in this population (74.6%), and no significant difference between the group with VAC and the group without VAC. The odds ratio with VAC was 1.666 but not statistically significant, although this is clinically important and a larger sample size is needed to detect statistical difference. Data were not collected on the type of ventilation (e.g. APRV), and whether only the FiO_2 criteria was used for assessment of a VAE event. Different ventilation modes may be used for treatment of respiratory events and COPD, and may have been impacted by the VAE protocol.[20]

The provider, nurse, and respiratory therapy notes were reviewed for documentation of a daily sedation vacation when on mechanical ventilation. An overall positive sedation vacation occurred if there was at least 90% daily sedation vacation documented, so the rate may be impacted by the number of mechanical ventilation days. In addition, a documentation template that indicated that nursing and respiratory therapy collaborated on weaning, spontaneous breathing trial, and the occurrence of a sedation vacation was implemented in 2010, and used by nursing. The overall sedation vacation rate indicated a successful IHI VAP prevention strategy at 91.1%.[25]

Although alcohol abuse history was documented in 38.9% of the veterans, polysubstance abuse history was not collected and maybe a limitation to the study. The CIWA scale was used by nurses to document the effects of alcohol withdrawal, and was used whenever there was a physician order (preventative assessment based on prior history or admission of a high alcohol intake).[18] Although the CIWA scale was used in some patients indicating agitation, there was no physician documentation of alcohol withdrawal, which may have impacted the results. This study used physician documentation of alcohol withdrawal as a positive occurrence during mechanical ventilation, with 8.9% of the sample experiencing alcohol withdrawal (group with VAC had 10% with alcohol withdrawal, and group without VAC had 8.8% with alcohol withdrawal). It was noted that several patients were electively intubated and mechanically ventilated to protect the airway at the start of alcohol withdrawal. The timing and effect of this preemptive strategy to prevent complications was not studied. Although only the occurrence of alcohol withdrawal was collected for this study, in reviewing the documentation the patients differed in when symptoms of agitation developed and the level of sedation needed. Thus, this study did not measure the impact of alcohol withdrawal and when it occurred during mechanical

ventilation, nor did it measure the intensity of alcohol withdrawal and the necessary sedation. Individual experiences, early identification, and treatment of alcohol withdrawal were not collected and may impact occurrence of VAC.

This study supported earlier research that VAC was associated with increased mechanical ventilator days of care, increased hospital length of stay, and increased mortality.[3,4] In addition, this study found that patients with VAC were more likely to get a tracheostomy, suggesting further that the VAC criteria are a better indicator for patient outcomes.

There is a large gap in research, across adult mechanically-ventilated populations, with the development of a new VAE protocol. Respiratory deterioration criteria (sustained increase in FiO_2 or PEEP) have emerged as a better indicator of mortality and other patient outcomes, and research is just beginning. Research is needed to determine the impact of the IHI VAP strategies (individually and as a bundle) on the incidence of VAC, and the true economic impact of VAC. New products have flooded the market to prevent VAP, but the impact of VAC is unknown.

Implications for Practice and Research

The incidence of VAP has been used as the outcome measurement for components of the IHI ventilator bundle in numerous studies.[2,8,26] Research is needed to determine the effect of the ventilator bundle on the incidence of VAC in different adult populations. This study is the first known attempt to look at the impact of VAP prevention strategies (use of the SSD-ETT and sedation vacation) on the outcome of VAC in veterans. Study results indicate that compliance to these prevention practices were widely used (SSD-ETT 82.9% and sedation vacation 91.1%). Electronic documentation for sedation vacation varied, although most notes involved used a template to satisfy this strategy. High compliance to use of the SSD-ETT was expected, as it is the only option available to use throughout the study site except the OR. This resulted in 50% of

subjects that lacked an SSD-ETT came from the OR, and 50% were transferred from outside hospitals or intubated in-route by emergency medical staff. Consideration to expand the routine use of a SSD-ETT to the OR would be expensive and was not supported with results from this study, although expanding to select surgical patients maybe a better strategy.

Ventilator management strategies may influence VAC incidence rates. Although CDC experts have managed to provide an objective definition, there may still be some variability and confusion understanding ventilator parameters. The novice infection preventionist will need to develop a collaborative relationship with respiratory therapists and other critical care staff to facilitate collecting and understanding these data elements. The VAE algorithm is recommended as a surveillance tool in adults, and the occurrence of VAC may be infectious or non-infectious in nature. This expands the role of the infection preventionist, as identification and further analysis of VAC etiology may uncover preventable root causes that results in practices changes outside of infection prevention and control.

Future research in identifying predictors of VAC is needed to guide multidisciplinary interventions or changes in the IHI ventilator bundle. This study provides a baseline VAC incidence rate in a veteran population, and supports other research that ICU length of stay, time on mechanical ventilation, and hospital mortality increases with ventilator-associated complications.[2-4,27]

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CHAPTER 4: PREVENTION STRATEGIES IMPACTED BY VAE SURVEILLANCE

Summary Abstract

The Center for Disease Control and Prevention (CDC) recently expanded infection control surveillance definitions to include all ventilator-associated events (VAE).[1] The VAE algorithm identifies ventilator-associated conditions (VAC) based on respiratory deterioration criteria, and replaces the controversial ventilator-associated pneumonia (VAP) definition.[2,3] In a recent retrospective study, VAC incidence was described and four predictors explored. During data collection for this study, a few challenges were faced when extracting variables from the electronic medical record (EMR). These variables (mechanical ventilation parameters, sedation vacation, and subglottic secretion-drainage endotracheal tube [SSD-ETT]) will be discussed and how they impact recommended infection prevention strategies.[4,5]

Mechanical Ventilation

Medical treatment of critically-ill patients may require the assistance of an artificial airway (endotracheal tube [ETT]) and mechanical ventilation to sustain life during a critical illness or acute injury. A mechanical ventilator is a device that is able to assist or control patient respirations in a continuous manner through the ETT. The infection preventionist (IP) collaborates with the critical care multidisciplinary team to minimize the risk of ventilator-associated infections and decrease mechanical ventilation days.[6,7]

Patients are routinely monitored for gas exchange, and the work of breathing (WOB) is an indicator of the workload of the respiratory muscles.[8] This respiratory measurement is a key index that is used during evaluation of respiratory effort, and is actually measured as the transpulmonary pressure change that is necessary to surpass the elastic and resistive components times the volume of air that is moved into and out of the lung. The mechanical ventilator

supplements or performs the WOB during inspiration, while expiration remains passive. During mechanical ventilation, the WOB is reduced when there is synchrony between patient and ventilator, thus creating smooth interaction between the patient's respiratory muscles and the assisted ventilation.[9,10] By reducing the WOB, ventilated patients, or patients with impending respiratory failure, can decrease respiratory muscle demands, conserve energy, and improve respiratory parameters; and successfully wean from mechanical ventilation prior to developing complications associated with being on a ventilator.[9]

Imposed resistive WOB includes the inspiratory resistance that occurs from addition of the ETT and ventilator circuit to the usual pathway of the patient's airway and respiratory tract. Imposed resistive WOB varies between patients and includes: inspiratory flow rate demand, ETT resistance (based on cross-sectional area, secretion and biofilm occurrence), breathing circuit resistance (diameter, humidifier), and ventilator resistance (trigger sensitivity setting, response time). Although mechanical ventilation is medically required to ease the WOB, it can increase WOB and stimulate episodes of patient-ventilator asynchrony, thus delay weaning and put patients at risk for ventilator-associated complications.[11,12]

Recommended strategies to prevent VAP include: conduct active surveillance for VAP, perform daily readiness to wean and use weaning protocols, prevent aspiration, and minimize colonization of equipment.[4] Recently, the CDC updated and expanded the surveillance definition of VAP to include all VAE.

Mechanical Ventilation and VAE

Changes in mechanical ventilator parameters frequently occur for various reasons to manage and wean the critically-ill patient. There are different ventilation modes aimed at minimizing these problems, promoting spontaneous ventilation, and improving patient outcomes;

or these changes may inadvertently increase imposed resistive WOB and patient-ventilator asynchrony.[13-15] The VAE surveillance definition uses the ventilator parameters of the daily minimum fraction of inspired oxygen (FiO_2) or the positive-end expiratory pressure (PEEP) as indicators of stability on the ventilator, and as markers of respiratory deterioration for VAC (Figure 4).[1]

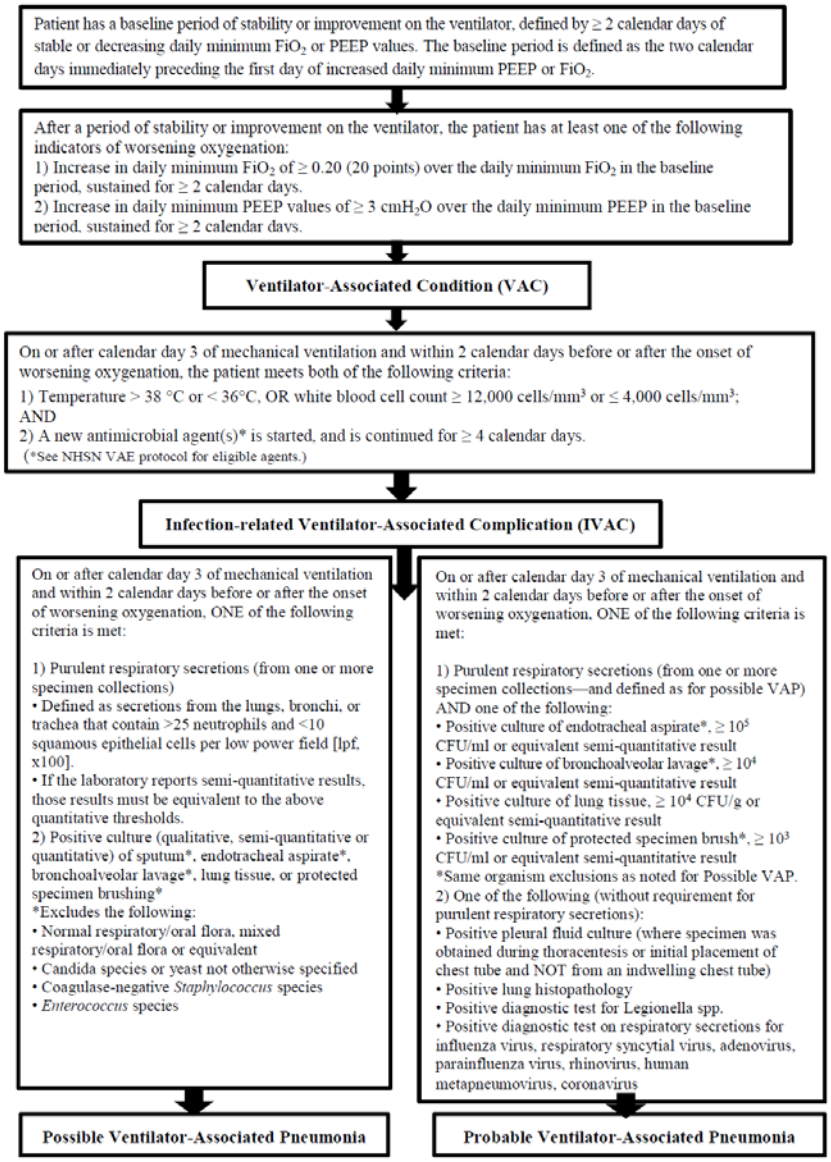

Figure 4: VAE Surveillance Algorithm; from: http://www.cdc.gov/nhsn/acute-care-hospital/vae/

Although treatment of oxygen desaturation and respiratory failure may require sustained increase in FiO_2, the treatment of airflow obstruction frequently requires PEEP to be added to ventilator settings.[16] There are several modes of mechanical ventilation possible to use to facilitate ventilation.

The CDC VAE protocol excludes some ventilation delivery modes (Table 7); and in other modes, such as airway pressure release ventilation (APRV), requires only the assessment of FiO_2 as an indicator of stability or respiratory deterioration.[1] Thus, some modes of ventilation limits VAE assessment to only use the FiO_2 as the respiratory deterioration indicator, and the significance of this exclusion is not known.[1]

Table 7: Types of Mechanical Ventilation

Type of Mechanical Ventilation	**Ventilator-Associated Event (VAE) Surveillance**
Controlled Mandatory Ventilation (CMV)	Yes
Assist-Control Ventilation (ACV)	Yes
Synchronized Intermittent Mandatory Ventilation (SIMV)	Yes
Pressure Control Ventilation (PSV)	Yes
Pressure Support Ventilation (PSV)	Yes
Continuous Positive Airway Pressure (CPAP)	Yes
PCV+ without Inverse I:E Ratio (Dräger ventilators)	Yes
Pressure-Regulated Volume Control Ventilation (PRVC)	Yes
Volume Support Ventilation	Yes
Volume-Assured Pressure Support Ventilation	Yes
Adaptive Pressure Control Ventilation	Yes
Mandatory Minute Ventilation (MMV)	Yes
AutoFlow (Dräger ventilators)	Yes
Adaptive Pressure Ventilation (Hamilton GALILEO ventilators)	Yes
Volume Control Plus Ventilation (Puritan-Bennett ventilators)	Yes
Volume Targeted Pressure Control Ventilation	Yes
Pressure Controlled Volume Guarantee Ventilation (General Electric Ventilators)	Yes
Adaptive Support Ventilation	Yes
Proportional Assist Ventilation	Yes
Bi-Level Ventilation without Inverse I:E Ratio (Puritan-Bennett Ventilators)	Yes
Only FiO_2 is assessed, *when used*:	
Airway-Pressure Release Ventilation (APRV)	Yes* (FiO_2 only)
Pressure-Control Inverse Ratio Ventilation (PC-IRV)	Yes* (FiO_2 only)
Bi-Level Ventilation with Inverse I:E Ratio (Puritan-Bennett ventilators)	Yes* (FiO_2 only)
Bi-Vent Ventilation (Maquet SERVO-i ventilators)	Yes* (FiO_2 only)
PCV+ with Inverse I:E Ratio (Dräger ventilators)	Yes* (FiO_2 only)
DuoPAP Ventilation (Hamilton GALILEO ventilators)	Yes* (FiO_2 only)

Type of Mechanical Ventilation	Ventilator-Associated Event (VAE) Surveillance
Biphasic Intermittent Positive Airway Pressure Ventilation	Yes* (FiO_2 only)
Intermittent Mandatory Airway Pressure Release Ventilation	Yes* (FiO_2 only)
Excluded from VAE Surveillance:	
High Frequency Ventilation (HFV)	No
High Frequency Oscillatory Ventilation (HFOV)	No
High Frequency Jet Ventilation	No
High Frequency Percussive Ventilation	No
Volumetric Diffusive Ventilation (VDR, Percussionaire ventilators)	No
Extracorporeal Life Support (ECLS) with venous-venous cannulation	No
Extracorporeal Life Support (ECLS) with venous-arterial cannulation	No
Extracorporeal Membrane Oxygenation (ECMO)	No

*These types of mechanical ventilation are included in VAE surveillance, but oxygenation changes are assessed using fraction of inspired oxygen (FiO_2) data *only* during the period of time these types of mechanical ventilation are used. Positive End Expiratory Pressure (PEEP) criteria are not used to assess for VAEs when receiving one of these types of mechanical ventilation.

The VAE algorithm uses at least a two calendar day of stable or improving FiO_2 or PEEP values as an indicator of patient stability or improvement. Following this, an occurrence of VAC is based on a two calendar day of worsening oxygenation indicated by specific changes in FiO_2 or PEEP (Figure 4). If APRV or similar mode is used, then only the FiO_2 is assessed during VAE surveillance for stability and changes, so any changes in levels of airway pressure or PEEP (high or low) to treat the patient's condition are not assessed as a predictor of change.[14,17] These alternative ventilation modes, such as APRV, may be used to treat respiratory failure, improve oxygenation, and minimize patient-ventilator asynchrony.[17] Thus while promoting spontaneous ventilation and maintaining FiO_2 levels, adjustments are usually necessary in the positive pressure (divided into two time periods: high airway pressure and low airway pressure) and auto PEEP (result of a short release time between pressures resulting in residual volume).[14,17] Compared to conventional modes, APRV may be used to improve alveolar recruitment in hypoxemic respiratory failure, maintain intrinsic PEEP, and increase pulmonary blood flow, while enabling spontaneous ventilation.

It was noted during data collection for clinical research, that some patients were switched from a conventional mechanical ventilation mode with traditional PEEP to a Bi-Level mode, which is an excluded ventilation mode and requires only assessment of the FiO_2 for VAE (Table 7).[1] Reviewing electronic documentation indicated that these patients were able to maintain oxygenation during BiLevel ventilation mode; thus, the FiO_2 criterion was not met for a VAC, but physician diagnosis indicated treatment of a VAC in a few cases. This change in ventilation mode may exclude VAE cases with the current algorithm, and could be one explanation of the lower VAC incidence (7.4 per 1000 ventilator days) found in the study, compared to a previous study (21.2 per 1000 ventilator days).[18]

Challenges with VAE Criteria

The VAE algorithm includes objective criteria for VAC (with specific measurements for FiO_2 or PEEP), criteria for infection-related ventilator-associated condition (with specific measurements of white blood cell count or fever, and start of new antimicrobial therapy), and specific microbiologic criteria to quantify purulent sputum and cultures.[1] Although the VAE protocol is an improvement to the VAP definition, there are still potential problems with the definition. For example, during mechanical ventilation the FiO_2 and PEEP settings may temporarily change during weaning, thus creating a minimum value that is not reflective of the true clinical picture. In another example, clinicians may temporarily adjust the PEEP to zero during spontaneous breathing trials (SBT), and then the patient is placed back to a particular pre-SBT level. In this case, the patient will always have a zero recorded for a minimum PEEP value.

Unfortunately, there is still opportunity to manipulate the VAE rate, as there was with VAP rates.[2] For example, since there is no minimum time period required to be counted as the minimum daily value for FiO_2 or PEEP, ventilator settings can be purposely lowered in an

attempt to minimize VAC rates. In addition, if the criteria are extracted from the EMR, the IP may never realize the patient is only temporarily on the settings for weaning. During data collection, these potential problems were not encountered since the data was retrospectively collected, but some patients had several ventilation changes during the course of treatment.

During the assessment of infection-related ventilator-associated condition (IVAC) criteria, in addition to white blood cell count or fever, the evaluation of whether a new antimicrobial agent meets the definition criteria may be somewhat complex.[1] The IVAC criteria were not intended only to assess for VAP, but for other infectious processes, and the antimicrobial list is reflective of this and may be confusing to some IP.[18] Specific criteria includes timing of starting the antimicrobial agent two days before or after the day of VAC event, verifying that the antimicrobial agent is eligible for inclusion, and verifying four consecutive qualifying antimicrobial days (QAD). Challenges include addressing acceptable variations in the QAD when the patient has renal insufficiency or renal failure, and addressing antibiotic changes during the four consecutive QAD.[1] During data collection, there usually were no problems meeting the QAD when the antibiotic was started within the five day window, although incomplete QAD occurred when the patient was transferred to hospice or expired.

Assessment of possible VAP and probable VAP include specific microbiologic criteria, and explanations of the variations that may be reported and encountered in practice.[1] Not all healthcare facilities are able to process respiratory specimens the same, and the intent of the VAE algorithm is to provide measurable objective criteria.[18,19] Thus, purulent sputum is defined quantitatively in an attempt to ensure validity. Some laboratories may need to change their methods or reporting practices to ensure that the results are easily interpreted for VAE criteria. In addition, normal oral flora and common oral pathogens (e.g. Candida, enterococcus) are

excluded from the probable VAP definition.[1] For example, during data collection even though gram stain met criteria, any sputum culture of Candida was not assessed for VAP.

IHI Ventilator Bundle and Sedation

National quality improvement initiatives in critical care units include the Institute for Healthcare Improvement (IHI) ventilator bundle.[6] Although this bundle is not inclusive of all possible preventative strategies for mechanically-ventilated patients, these evidence-based practices have become an intensive care unit (ICU) standard of care. When implemented as a bundle, these interventions have better patient outcomes than single interventions; thus ventilator bundle checklists have been adopted in the ICU and daily adherence is frequently monitored on multidisciplinary daily rounds.[20] Compliance is achieved when all five elements are met (elevation of the head of the bed 30°, peptic ulcer disease prophylaxis, deep venous thrombosis prophylaxis, chlorhexidine daily oral care, and daily sedation vacation and assessment of readiness to extubate).[6]

A significant component of the IHI ventilator prevention bundle is the sedation vacation and assessment of readiness to extubate.[6] Sedation is used to reduce pain, agitation, anxiety, maintain patient-ventilator synchrony, and reduce WOB; and can be given as a continuous infusion or intermittent dose, with attention to dosing to avoid possible metabolite accumulation and over sedation.[9,21,22] Combinations of barbiturates, sedatives, analgesics, and/or neuromuscular agents are used to decrease pain and agitation, and reduce oxygen consumption during mechanical ventilation, resulting in limiting the patient's communication so dosing is often at the nurses' discretion or based on a sedation scale.[23]

Documentation of the patient's sedation level may be based on an ICU sedation protocol and scale, or subjective documentation that evaluates levels of sedation. It is recommended that

sedation is lightened daily until the patient is awakened and aroused, and during this time patients are assessed neurologically for readiness to extubate.[24] Sedation interruption with a spontaneous breathing trial has been found to decrease ventilator days; and the use of sedation protocols in addition to spontaneous breathing trials to manage ventilator patients is recommended.[22,25,26] Although complete success of this intervention occurs when the patient's sedation level is lightened enough for spontaneous ventilation to occur; this maneuver is not without risk of self extubation, desaturation, and patient-ventilator asynchrony.[24] Daily interruption of sedation and spontaneous breathing trials are not done automatically and irrespective of clinical state, but in collaboration with the multidisciplinary team. [24,25,27] Compliance to this IHI ventilator bundle component may be achieved when the team only discusses the overall weaning interventions, since the performance of a sedation vacation or spontaneous breathing trials may be contraindicative.[26,28,29]

During data collection for the retrospective study of 280 mechanically ventilated patients, it was noted that nursing ICU notes included templates for documentation of the IHI ventilator bundle components in the EMR. It was difficult to ascertain whether a sedation vacation was undertaken or if it was only discussed based on documentation, since a general template note was used to meet the compliance intent of the bundle. For example, the ICU nursing template referred to collaborating with respiratory therapy to "assess for readiness to wean and sedation vacation", this was done daily in addition to a nursing sedation scale note each shift. In general, the respiratory therapist documented ventilator changes on a flow sheet and provided one general note per shift, but there was no indication when a "sedation vacation" was occurring based on ventilator changes. On occasion, the ICU nurse would expand from the template and provide further details regarding the sedation vacation and whether it was

contraindicated, but this was not consistent. Daily multidisciplinary team rounds are conducted in the ICU, and the IHI ventilator bundle components are discussed, although retrospectively interpreting whether the patient had a sedation vacation from the EMR was difficult due to the electronic template in use at the time. Improvements to the electronic template to include mandatory components to assess and follow-up whether the sedation vacation was successful or contraindicated would improve the documentation of this compliance measure.

Subglottic Secretion Drainage-Endotracheal Tube (SSD-ETT)

During mechanical ventilation, the ETT creates a conduit for bacteria in and around the tube to migrate down the respiratory tract and put the patient at risk for respiratory infections.[30] Recent innovations in the cuff and tube design of the ETT are aimed at decreasing microaspiration of oral/pharyngeal secretions.[31-33] Recommended strategies to prevent aspiration include the use of subglottic suction and to maintain 20 cm H_2O cuff pressure.[4,33,34]

The purpose of the SSD-ETT is to remove subglottic secretions that pool above the ETT cuff, and maintain continuous or intermittent suction. Although healthcare facilities have implemented the SSD-ETT, all populations may not be included (e.g. operating room) and there are no guidelines to monitor compliance. In a recent study, malfunction of the subglottic suction port was reported at 48%, and subglottic suction may predispose or cause tracheal injury.[31,35] During review of 280 mechanically-ventilated patients EMR in a recent study, no documentation on the function of the SSD-ETT was found, only that the patient had a SSD-ETT placed. In addition, when patients are transferred from another facility, or intubated during emergency management service, there were no procedure noted that changed the ETT to a SSD-ETT, and there are no recommended guidelines.

The SSD-ETT is used as a VAP prevention strategy, and documentation of appropriate function should be standard to ensure effectiveness of the SSD-ETT. In addition, if a facility has implemented the SSD-ETT but excluded some populations, it would be prudent to do a risk assessment and assess infection risk.[5] Based on the infection control risk assessment, changes in practice and procedure should be implemented to ensure that patients requiring longer periods of mechanical ventilation are given the same VAP prevention measures.[4,33]

Implications

Strategies to prevent VAP include VAP surveillance, although now surveillance has expanded to include all VAE and problems with the definition may not capture all cases. Experts at CDC are aware of the potential problem with the VAE criteria, and want CDC National Healthcare Safety Network (NHSN) users to provide prospective data on the use of APRV and alternative modes of ventilation impacted by exclusion of PEEP.[1] In the meantime, hopefully the algorithm does not promote an inconsistent reporting of VAC incidence based on these ventilator parameters (FiO_2 and PEEP), or provide a way to decrease reported VAC incidence.[2] In addition, the IP will need to review the new antimicrobial and microbiological criteria, and implement any necessary changes the CDC makes in the future. Regardless, this algorithm is an improvement over the subjective VAP definition, and provides the IP the opportunity to identify and analyze the incidence of infectious and non-infectious ventilator-associated complications.[18]

Although literature supports the success of the ventilator prevention bundle, the level of compliance may impact achievable outcomes, and further research on the impact of evidence-based bundles on the incidence of VAC is needed.[20,28,36,37] Daily sedation vacation or sedation interruption, along with assessment for readiness to wean, and spontaneous breathing trial, are

grouped together as one bundle component but each component should be addressed separately. This research study noted a possible disparity in the use of a template for EMR documentation of a "discussion" of a sedative interruption with whether there was an actual performance of a sedation vacation.

National guidelines recommend the use of SSD-ETT to prevent aspiration, thus reducing VAP, although specific populations are not addressed and the standard ETT is still available for use.[4] Universal implementation would be costly, for example, every patient having a surgical procedure with general anesthesia does not necessarily need a SSD-ETT.[38] Concerns over improper use of the SSD-ETT, and the necessity to follow manufacturer's recommendations for safety, prompt the recommendation to document use of the SSD-ETT, monitor and document compliance to suction, and document function.

Challenges in ICU nursing electronic documentation include the inclusion of various nursing standards, patient education, performance measures, and compliance to IHI bundle interventions. Collaboration is needed between ICU nursing and respiratory therapy to ensure that the required documentation for ventilator bundle, SSD-ETT management, and other ventilator management and weaning documentation is achieved. Further clarification and education of staff on the IHI ventilator bundle, sedation vacation and weaning components, maintenance of the SSD-ETT, electronic documentation and use of templates, and impact on outcomes is necessary to ensure success of infection prevention strategies. The CDC continues to refine and clarify the VAE algorithm, and those conducting surveillance need to identify issues and report concerns. Changes in monitoring practices may be necessary, and flexibility is important as the new VAE definition evolves.

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APPENDIX A: DATA COLLECTION TOOLS

Data Collection: Study Variables

Participant #
DOB
Age
Gender
Height
Weight
BMI
Race
Ethnicity
Marital status
Coronary Artery Disease Hx
Rheum Hx
Liver Disease Hx
Diabetes Mellitus (DM) Hx
Insulin Dependent DM Hx
Renal Disease Hx
Cancer HX
Chronic Obstructive Pulmonary Disease HX
Smoking Hx
Pack per Year
Currently Smoking
Alcohol Abuse HX
Alcohol Withdrawal Hx
Charlson Score
Admission Diagnosis
Admission Ward
Expired?
Hospital LOS (number of days from hospital admission date to hospital discharge date)
ICU Diagnosis
ICU type
ICU LOS (number of days from ICU admission date to ICU discharge date)
Intubation to Vent (number of days from intubation to ventilator)
Vent Days (number of days on ventilator)
Where intubated
ETT type
SSD-ETT
Surgery (number of days from surgery to ETT)
Surgery Type
Tracheostomy?
ETT to Trach Days (number of days from intubation to trach)
Stable on Vent $\geq$ 2D
Stable on Vent $\geq$ 3D
T$\geq$38 or$\leq$36?
WBC$\geq$12000 or $\leq$4000?
New Antimicrobial and continues $\geq$4D
Purulent Secretions $\geq$25 neutrophils
Organism
Culture Source
Culture Comments
SSD-ETT?
Daily Sedation Vacation?
Alcohol Withdrawal?
COPD?
VAC event?
Days from Vent Start to VAC
Type of VAC event
VAE event?
Days from Vent Start to VAE
IVAC event?
Days from Vent Start to IVAC
Possible VAP event?
Probable VAP event?
Comments

CDC Surveillance for Ventilator-Associated Events (VAE) in Adults

Surveillance Definitions for VAE:

- For use in acute and long-term acute care hospitals and inpatient rehabilitation facilities.
- For use in patients ≥ 18 years of age who are on mechanical ventilation for ≥3 calendar days.
- NOTE: patients on rescue mechanical ventilation (e.g., HFV, ECMO, mechanical ventilation in prone position) are EXCLUDED.

Patient has a **baseline period of stability or improvement on the ventilator**, defined by **≥ 2 calendar days of stable or decreasing FiO_2 or PEEP**. Baseline FiO_2 and PEEP are defined by the minimum daily FiO_2 or PEEP measurement during the period of stability or improvement.

After a period of stability or improvement on the ventilator, the patient has at least one of the following indicators of worsening oxygenation:

1) Minimum daily FiO_2 values increase ≥ 0.20 (20 points) over baseline and remain at or above that increased level for **≥ 2** calendar days.

2) Minimum daily PEEP values increase ≥ 3 cmH_2O over baseline and remain at or above that increased level for **≥ 2** calendar days.

Ventilator-Associated Condition (VAC)

On or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation, the patient meets both of the following criteria:

1) Temperature > 38 °C or < 36°C, OR white blood cell count ≥ 12,000 cells/mm^3 or ≤ 4,000 cells/mm^3.

AND

2) A new antimicrobial agent(s) is started, and is continued for ≥ 4 calendar days.

Infection-related Ventilator-Associated Complication (IVAC)

On or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation, ONE of the following criteria is met:

1) Purulent respiratory secretions (from one or more specimen collections)

- Defined as secretions from the lungs, bronchi, or trachea that contain >25 neutrophils and <10 squamous epithelial cells per low power field [lpf, x100].
- If the laboratory reports semi-quantitative results, those results must be equivalent to the above quantitative thresholds.

2) Positive culture (qualitative, semi-quantitative or quantitative) of sputum*, endotracheal aspirate*, bronchoalveolar lavage*, lung tissue, or protected specimen brushing*

*Excludes the following:

- Normal respiratory/oral flora, mixed respiratory/oral flora or equivalent
- Candida species or yeast not otherwise specified
- Coagulase-negative *Staphylococcus* species
- *Enterococcus* species

Probable Ventilator-Associated Pneumonia

On or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation, ONE of the following criteria is met:

1) Purulent respiratory secretions (from one or more specimen collections—and defined as for possible VAP) AND one of the following:

- Positive culture of endotracheal aspirate, ≥ 10^5 CFU/ml or equivalent semi-quantitative result
- Positive culture of bronchoalveolar lavage, ≥ 10^4 CFU/ml or equivalent semi-quantitative result
- Positive culture of lung tissue, ≥ 10^4 CFU/ml or equivalent semi-quantitative result
- Positive culture of protected specimen brush, ≥ 10^3 CFU/ml or equivalent semi-quantitative result

2) One of the following (without requirement for purulent respiratory secretions):

- Positive pleural fluid culture (where specimen was obtained during thoracentesis or initial placement of chest tube and NOT from an indwelling chest tube)
- Positive lung histopathology
- Positive diagnostic test for *Legionella* spp.
- Positive diagnostic test on respiratory secretions for influenza virus, respiratory syncytial virus, adenovirus, parainfluenza virus

Possible Ventilator-Associated Pneumonia

Data Collection: VAE Parameters **Subject#_____**

Mechanical Ventilation Day#	Minimum PEEP	Minimum FiO_2	Minimum Temperature	Maximum Temperature	Minimum WBC	Maximum WBC	Antibiotic	Specimen Type	Gram Stain (Poly/Epis)	Organism
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										

Minimum PEEP= daily minimum positive-end expiratory pressure (PEEP); Minimum FiO_2= daily minimum fraction inspired oxygen (FiO_2); WBC=white blood cell count; antibiotic=antimicrobial agents; polys/epis=polymorphonuclear leukocytes and squamous epithelial cells

Data Collection: Assessment of Predictors

SUBJECT#_____				
Mechanical Ventilation Day#	**SSD-ETT* (Y/N)**	**Daily Sedation Vacation (Y/N)**	**Alcohol Withdrawal* (Y/N)**	**COPD History* (Y/N)**
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				

**Positive occurrence only needs to be documented once*

APPENDIX B: BAY PINES VAHCS IRB APPROVAL

Human Studies Subcommittee
Bay Pines VA Healthcare System
Research & Development Service (151)
10000 Bay Pines Blvd. • Bay Pines, FL 33744 • 727-398-6661 • Fax: 727-398-9467

IRB APPROVAL - Initial Review

Date: November 14, 2012
From: Angel R. Cruz, M.D.
Investigator: Joan Grano, MS, RN

Angel Cruz Digitally signed by Angel Cruz DN: cn=Angel Cruz, o, ou, email=angel.cruz2@va.gov, c=US Date: 2012.11.15 15:51:35 -05'00'

Protocol: Ventilator-Associated Complications in the Mechanically-Ventilated Veteran
ID: 02833 Prom#: N/A Protocol#: N/A

The following items were reviewed and approved at the 11/08/2012 meeting:

- Research Protocol (10/12/2012)
- Abstract (11/01/2012)
- UCF IRB approval (05/31/2012)
- VA Research Project Application Form (10/29/2012)
- VA IRB Application Form (11/01/2012)
- Waiver or Alteration of Informed Consent and/or HI (10/11/2012)
- Conflict of Interest Form - Grano (10/29/2012)
- Conflict of Interest Form - McGuirt (10/04/2012)

Approval is granted for a period of 12 months and will expire on 11/07/2013. Your Continuing Review is scheduled for 10/10/2013, and the requirements are attached.

The protocol was determined to have the following level of risk:
Minimal

IRB Federal Wide Assurance# 00000979

As Principal Investigator, you retain full responsibility for the proper conduct of the study and for all reporting activities required by regulations, directives, and policies.

The following other committee reviews are scheduled:
Research & Development Committee [11/28/2012]

Approval by each of the following is required prior to study initiation (unless Exempt):
Human Studies Subcommittee
Research & Development Committee

Approval for study initiation is contingent upon your compliance with the requirements of the Research

Service for the conduct of studies involving human subjects.

Bay Pines VA Healthcare System
Research & Development Service

NOTIFICATION OF STUDY APPROVAL (Initial Review)

Principal Investigator:	Joan Grano, MS, RN
Study Title:	Ventilator-Associated Complications in the Mechanically-Ventilated Veteran
R&D File #:	2833

This study requires initial review and approval by the following R&D Subcommittees and ancillary reviewers:

- ☒ IRB (Human Subjects Subcommittee)
- ☐ IACUC (Institutional Animal Care and Use Subcommittee)
- ☐ SRS (Subcommittee on Research Safety)
- ☐ Radiation Safety Committee
- ☐ IBC (Institutional Biosafety Committee)
- ☒ Privacy Officer
- ☒ Information Security Officer
- ☐ Facility Safety Officer
- ☐ BPF Executive Director (CRADA/Funding)

By signing, I certify that the above referenced study has satisfied the requirements for initial approval as required in applicable policies and regulations (respectively):

Review	*Approval Date*	*Comments (if any)*	*Signature*	*Date*
IRB	☐ Expedited ☒ Full Committee		Angel R Cruz /for x John Hoeldtke John Hoeldtke, Pharm. D. IRB Chairperson	11/16/12
IACUC	☐ Designated ☐ Full Committee			
SRS	☐ Designated ☐ Full Committee			
Radiation Safety				
IBC				
Privacy	Deanna Szczeuski			11/28/12
Information Security	Deedra Jones		Deedra Jones	11/30/12
Facility Safety Officer				
BPF Executive Director				

Bay Pines VA Healthcare System
Research & Development Service

NOTIFICATION OF STUDY APPROVAL (Initial Review)

Principal Investigator:	Joan Grano, MS, RN
Study Title:	Ventilator-Associated Complications in the Mechanically-Ventilated Veteran
R&D File #:	

R&D Committee Approval:

The R&D Committee was notified of the above R&D Subcommittee and ancillary review approvals, which were presented to the R&D Committee at the regularly scheduled meeting held on (date)_____. I certify that the initial review for the above referenced study was approved by the R&D Committee.

Comments (if any):

Rechtine, Glenn, M.D. R&DC Chairperson **Date** 11-28-12

ACOS/RD Approval:

I certify that the above referenced study has secured all approvals required for study initiation, and as such the investigator is hereby approved to conduct research-related activities as approved by the applicable committees/individuals identified above.

Comments (if any):

Allison E. Williams, Ph.D., Acting ACOS/RD **Date** 30 Nov 2012

APPENDIX C: UNIVERSITY OF CENTRAL FLORIDA IRB APPROVAL

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Approval of Human Research

From: **UCF Institutional Review Board #1**
FWA00000351, IRB00001138

To: **Joan T. Grano**

Date: **December 17, 2012**

Dear Researcher:

On 12/17/2012, the IRB approved the following human participant research until 12/16/2013 inclusive:

Type of Review:	UCF Initial Review Submission Form Expedited Review Category #5 This approval includes a Waiver of Consent
Project Title:	Ventilator-Associated Complications in the Mechanically-Ventilated Veteran
Investigator:	Joan T Grano
IRB Number:	SBE-12-08984
Funding Agency:	
Grant Title:	
Research ID:	N/A

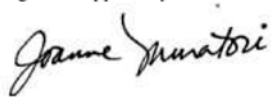
The Continuing Review Application must be submitted 30days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form **cannot** be used to extend the approval period of a study. All forms may be completed and submitted online at https://iris.research.ucf.edu .

If continuing review approval is not granted before the expiration date of 12/16/2013, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in iRIS so that IRB records will be accurate.

In the conduct of this research, you are responsible to follow the requirements of the Investigator Manual.

On behalf of Sophia Dziegielewski, Ph.D., L.C.S.W., UCF IRB Chair, this letter is signed by:

Signature applied by Joanne Muratori on 12/17/2012 01:05:42 PM EST



IRB Coordinator

APPENDIX D: CITI TRAINING

CITI Collaborative Institutional Training Initiative

Resources | Main Menu | Institution Menu | Select Language | Logoff

Modules Completed for Stage

Learner: Joan Grano (ID: 2904794)
Institution: Bay Pines, FL-516
Group: VA Human Subjects Protection and Good Clinical Practices
Stage: 1. Basic Course (Ref #: 8151739)

Required Modules	Date Completed	Score
Pre-Course Evaluation	06/20/12	No quiz
History and Ethical Principles	06/20/12	6/6 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	06/20/12	5/5 (100%)
Informed Consent	06/20/12	4/4 (100%)
Social and Behavioral Research for Biomedical Researchers	06/21/12	4/4 (100%)
Records-Based Research	06/21/12	2/2 (100%)
Genetic Research in Human Populations	06/25/12	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	06/25/12	4/4 (100%)
FDA-Regulated Research	06/25/12	5/5 (100%)
Human Subjects Research at the VA	06/25/12	3/3 (100%)
Conflicts of Interest in Research Involving Human Subjects	06/25/12	4/5 (80%)
Good Research Practices for Protection of Human Subjects, Module 3: Good Clinical Practice and VA Research	06/25/12	4/4 (100%)
Good Research Practices for Protection of Human Subjects, Module 5: Monitoring Subject Safety	06/25/12	5/5 (100%)
Good Research Practices for Protection of Human Subjects, Module 6: Records and Reports	06/25/12	4/4 (100%)
Good Research Practices for Protection of Human Subjects, Module 7: Managing Investigational Products	06/25/12	4/4 (100%)
Good Research Practices for Protection of Human Subjects, Module 8: Patient Privacy and Confidentiality	06/25/12	3/4 (75%)