Georgia State University ScholarWorks @ Georgia State University

Nursing Dissertations (PhD)

School of Nursing

Fall 12-5-2012

The Impact of Nurses' Adherence to Sedation Vacations on Ventilator Associated Pneumonia Prevention

Soraya N. Smith Georgia State University

Follow this and additional works at: https://scholarworks.gsu.edu/nursing diss

Recommended Citation

Smith, Soraya N., "The Impact of Nurses' Adherence to Sedation Vacations on Ventilator Associated Pneumonia Prevention." Dissertation, Georgia State University, 2012. https://scholarworks.gsu.edu/nursing_diss/33

This Dissertation is brought to you for free and open access by the School of Nursing at ScholarWorks @ Georgia State University. It has been accepted for inclusion in Nursing Dissertations (PhD) by an authorized administrator of ScholarWorks @ Georgia State University. For more information, please contact scholarworks@gsu.edu.

ACCEPTANCE

This dissertation, THE IMPACT OF NURSES' ADHERENCE TO SEDATION VACATIONS ON VENTILATOR ASSOCIATED PNEUMONIA PREVENTION by Soraya N. Smith was prepared under the direction of the candidate's dissertation committee. It is accepted by the committee members in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing by the Byrdine F. Lewis School of Nursing and Health Professions, Georgia State University.

> Patricia C. Clark, PhD, RN, FAHA, FAAN Committee Chairperson

Cecelia Grindel, PhD, RN, FAAN Committee Member

Pamela O'Neal, PhD, RN Committee Member

Kenneth V. Leeper, MD Committee Member

Date

This dissertation meets the format and style requirements established by the Byrdine F. Lewis School of Nursing and Health Professions. It is acceptable for binding, for placement in the University Library and Archives, and for reproduction and distribution to the scholarly and lay community by University Microfilms International.

Ptlene Minick, PhD, RN Doctoral Program Coordinator Byrdine F. Lewis School of Nursing and Health Professions

Joan Cranford, EdD, RN Assistant Dean for Nursing Byrdine F. Lewis School of Nursing and Health Professions

AUTHOR'S STATEMENT

In presenting this dissertation as a partial fulfillment of the requirements for an advanced degree from Georgia State University, I agree that the Library of the University shall make it available for inspection and circulation in accordance with its regulations governing materials of this type. I agree that permission to quote from, to copy from, or to publish this dissertation may be granted by the author or, in his/her absence, by the professor under whose direction it was written, or in his/her absence, by the Coordinator of the Doctoral Program in Nursing, Byrdine F. Lewis School of Nursing and Health Professions. Such quoting, copying, or publishing must be solely for scholarly purposes and will not involve potential financial gain. It is understood that any copying from or publication of this dissertation which involves potential financial gain will not be allowed without written permission from the author.

Soraya N. Smith

NOTICE TO BORROWERS

All dissertations deposited in the Georgia State University Library must be used in accordance with the stipulations prescribed by the author in the preceding statement.

The author of this dissertation is:

Soraya N. Smith 5775 Jamerson Drive Atlanta, GA 30349

The director of this dissertation is:

Patricia C. Clark, PhD, RN, FAHA, FAAN Professor Byrdine F. Lewis School of Nursing and Health Professions Georgia State University P.O. Box 4019 Atlanta, GA 30302-4019

Users of this dissertation not regularly enrolled as students at Georgia State University are required to attest acceptance of the preceding stipulations by signing below. Libraries borrowing this dissertation for the use of their patrons are required to see that each user records here the information requested.

NAME OF USER ADDRESS

DATE

TYPE OF USE (EXAMINATION ONLY OR COPYING)

VITA

Soraya N. Smith

ADDRESS:		5775 Jamerson Drive Atlanta, GA 30349		
EDUC	CATION: Ph.D.	2013	Georgia State University Atlanta, Georgia	
	M.S.N.	2005	Emory University Atlanta, Georgia	
	B.S.N.	2003	Clayton State University Morrow, Georgia	
PROFESSIONAL EXPERIENCE:				
TROP	2006 – Present		Acute Care Nurse Practitioner/Intensivist Extender, Emory University Hospital Midtown	
	2003 - 2006		Staff/Charge Nurse, Coronary Care Intensive Care Unit, Emory University Hospital Midtown	
PROFESSIONAL ORGANIZATIONS AND CERTIFICATIONS:				
INOI	2003 – Present		American Association of Critical Care Nurses	
	2005 – Present		Sigma Theta Tau Honor Society	
	2005 – Present		Alpha Epsilon Chapter of Sigma Theta Tau	
	2006 – Presen	ıt	Society of Critical Care Medicine	
	2006 – Presen	ıt	American Academy of Nurse Practitioners	

PROFESSIONAL ORGANIZATIONS AND CERTIFICATIONS, CONTINUED:

- 2003 Present BLS Certification
- 2005 Present CCRN Certification
- 2006 Present ANCC Certification
- 2006 Present CITI Certification
- 2011 Present FCCS Certification
- 2012 Present ACNPC Certification

ABSTRACT

THE IMPACT OF NURSES' ADHERENCE TO SEDATION VACATIONS ON VENTILATOR ASSOCIATED PNEUMONIA PREVENTION

by

SORAYA SMITH

Patients who require mechanical ventilation (MV) are at risk for developing ventilator associated pneumonia (VAP). Nurses' adherence to sedation vacations (SVs) has a direct impact on the development of VAP, because SVs have been shown to reduce patients' average duration of MV and length of stay (LOS) in the intensive care unit (ICU). The purposes of this study guided by Donabedian's (1966) model were to quantify nurses' level of adherence to SVs, in relation to the health outcomes of critically ill patients, and identify the barriers and facilitators to performing SVs.

A correlational design was used. The design included three components: abstraction of patient data from the electronic medical record (EMR) (n=79 with VAP and n=79 without VAP), administration of surveys to ICU nurses (N=34), and vignettes related to SVs. Analyses included descriptive statistics, t-tests, correlations, and analyses of covariance.

Most nurses held a Bachelors degree (70.6%), had \leq 9 years of ICU experience (52.9%), worked in a medical ICU (47.1%), and reported high confidence in managing SVs (*M* =8.88, *SD* =1.25). The majority of patients (*N* =158) were Black (58.2%), males

(56.3%), and on average middle-aged (M =61.5, SD =14.91), with a long ICU LOS (M =15.5, SD =11.84), extended duration of MV (M =9.5, SD =8.47), and high acuity (APACHE III) (M =70.2, SD =25.42).

The nurses' education, advanced certification, and ICU experience were not associated with the appropriate implementation of SVs in the vignettes. On average nurses' had low scores on the vignettes (M =6.97, SD =2.21; possible range =0-14). The adherence rate of nurses' implementation of SVs, determined using EMR data, was also low (M =24%; SD =23%). There were higher rates of SV adherence in patients without VAP (p <.001), with an ICU LOS ≤ 13 days (p < .01), and a duration of MV ≤ 6 days (p =.04).

These findings indicate that even with established protocols, nurses may not consistently implement the evidenced-based interventions that have been shown to prevent nosocomial infections. Future research is needed to improve nursing practice and the quality of care in this patient population.

THE IMPACT OF NURSES' ADHERENCE TO SEDATION VACATIONS ON VENTILATOR ASSOCIATED PNEUMONIA PREVENTION

by

SORAYA N. SMITH

A DISSERTATION

Presented in Partial Fulfillment of Requirements for the Degree of Doctor of Philosophy in Nursing in the Byrdine F. Lewis School of Nursing and Health Professions Georgia State University

Atlanta, Georgia

2012

Copyright by

Soraya N. Smith

2012

ACKNOWLDEGEMENTS

I dedicate this accomplishment to those who mean the most to me. Without the love and support of my mother, father, husband, son, family, and friends this achievement would not have been possible. There were days that I felt weak and believed that I may not be able to complete this journey. There were also days that I felt that I had been presented with insurmountable obstacles, hindering my path. But the love of those closest to my heart has given me the strength and determination to preserver. Moreover, I take solace in knowing that through God's grace and mercy all things are possible.

I would be remiss if I did not also deeply thank Dr. Laura Kimble for starting me on this path of doctoral study and believing in my ability to pursue this academic endeavor. Thanks to, Dr. Pamela O'Neal for your time, encouragement, and expertise. Thanks to, Dr. Kenneth Leeper for your inspiration and support. Thanks to, Dr. Cecelia Grindel for your guidance and encouragement along the way. Most of all, I would like to thank Dr. Patricia Clark for your infinite support, feedback, encouragement, and understanding. I greatly appreciate all that you have done to facilitate this achievement.

To my mother, thank you for always coaching, mentoring, encouraging, inspiring, supporting, helping, guiding, and loving me. To my father, thank you for always believing in me and cheering me on. To my husband, thank you for your patience, understanding, love, and support. You have been by my side every step of the way, and I look forward to a life time of future endeavors that we will conquer together. To my son, let this be a lesson that all things are possible; if you can dream it, you can achieve it. No one can say that it will always be easy, so just remember that it will always be worth it! To all those who come after me, I offer the following words of encouragement:

"When you're up against a trouble, Meet it squarely, face to face; Lift your chin and set your shoulders, Plant your feet and take a brace. When it's vain to try to dodge it, Do the best that you can do; You may fail, but you may conquer, See it through!

Black may be the clouds about you, And your future may seem grim, But don't let your nerve desert you; Keep yourself in fighting trim. If the worst is bound to happen, Spite of all that you can do, Running from it will not save you, See it through!

Even hope may seem but futile, When with troubles you're beset, But remember you are facing, Just what other men have met. You may fail, but fall still fighting; Don't give up, whatever you do; Eyes front, head high to the finish. See it through!"

~Edgar Albert Guest

TABLE OF CONTENTS

Section		Page
List of Tal	bles	xvi
List of Fig	gures	xvii
List of Ab	breviations	xviii
Chapter		
I.	INTRODUCTION	1
	Overview of VAP	2
	Complications of Prolonged Mechanical Ventilation	4
	Patient Factors Associated with VAP	5
	Evidenced-Based Interventions to Prevent the Development of VAP	8
	Nurses' Lack of Adherence to Evidence-Based Practices	9
	Structure, Process, and Outcome Model for Improving Patient	
	Quality of Care	10
	Research Questions and Hypotheses	14
	Hypotheses	15
	Research Questions	15

Section

II.	REVIEW OF LITERATURE	17
	Complications of Sedative Medications	17
	Bundling Groups of Interventions to Improve Patient Outcomes	18
	Efficacy of Adherence to Evidence-Based Strategies	21
	Efficacy of Sedation Vacations in Mechanically Ventilated Patients	22
	Perceived Barriers to Sedation Vacations	27
	Nurses' Perceptions of Sedation	31
	Evidence of Nurses' Suboptimal Adherence to Evidence-Based	
	Protocols	33
	Conclusions	36
III.	METHODOLOGY	39
	Research Design	39
	Rationale for Time Points of Data Collection	40
	Sample	41
	Mechanically ventilated patients	41
	Intensive care nurses	42
	Sample Size	42
	Instruments	43
	Structural-system characteristics	43
	Structural-client characteristics	43
	Clinical process	46
	Patient outcomes	49

Page

Section

Page

	Data Collection Procedure	49
	Mechanically Ventilated Patients	50
	Intensive Care Nurses	50
	Threats to Internal Validity	53
	Data Management	54
	Preliminary Data Analysis	54
	Protection of Human Subjects	55
	Analysis Plan for Specific Aims	56
IV.	RESULTS	60
	ICU Nurse Sample	60
	Nurse Participants Characteristics	61
	Descriptive Statistics for Nurses' Perceptions of Sedation Vacations	62
	Major Study Variables	64
	Nursing-related barriers	64
	Nursing-related facilitators	66
	Association of nursing characteristics and the implementation of	
	sedation vacations	66
	Mechanically Ventilated Patient Sample	69
	Mechanically Ventilated Participants' Characteristics	70

Section 8

V.

Adherence rate of sedation vacations..... 72 Hypothesis Testing..... 73 Evaluation of Adherence to Sedation Vacations and Patient Outcomes... 74 Hypothesis A..... 74 75 Hypothesis B..... Hypothesis C..... 76 Summary..... 78 DISCUSSION AND CONCLUSIONS 79 Health Outcomes of Mechanically Ventilated Patients..... 80 Nursing-Related Barriers and Facilitators..... 82 Association of Nursing Characteristics and Sedation Vacations..... 84 Adherence of Sedation Vacations 86 Limitations of the Study..... 86 Strengths of the Study..... 88 Implications for Practice..... 88 Implications for Research 92 Conclusions..... 93 REFERENCES..... 94

<u>Page</u>

APPENDICES	109
Appendix A: Evaluating Sedation Practices in the ICU Survey	109
Appendix B: Nursing Survey Coding Guidelines	122
Appendix C: Nursing Survey Consent Form	139
Appendix D: Patient Data Abstraction Form	142
Appendix E: Emory IRB Letter	152
Appendix F: Georgia State University IRB Letter	155
Appendix G: Study Site's Complete Sedation Vacation Protocol	158

<u>Page</u>

LIST OF TABLES

<u>Table</u>		Page
1.	Nurse Characteristics	61
2.	Nurses' Survey Responses	63
3.	Nursing-Related Barriers to Implementing the Sedation Vacation Protocol	65
4.	Nursing-Related Facilitators to Implementing the Sedation Vacation Protocol	66
5.	Accuracy of Nurse Participants' Vignette Decisions to Perform a Sedation	
	Vacation	68
6.	Nurse Participants' Vignette Composite Scores	69
7.	Mechanically Ventilated Patient's Characteristics	71
8.	One-Way Analysis of Variance for Nurses' Adherence to Sedation Vacations	
	in each ICU	73
9.	ANCOVA for Patient Outcomes Related to Nurses' Adherence to Sedation	
	Vacations, Controlling for Level of Acuity, Gender, and Age	74

LIST OF FIGURES

Figure	<u>Page</u>
1. Structure, Process, Outcome Model for Evaluating Health Care Quality in	
Relation to the Sedation Vacation Protocol	13
2. Response Rate for Nurse Participants	60
3. Enrollment of Mechanically Ventilated Participants	70

LIST OF ABBREVIATIONS

AaDO2	Alveolar-Arterial Oxygen Tension Difference
ABG	Arterial Blood Gas
ANCOVA	One-Way Analysis of Covariance
APACHE III	Acute Physiology, Age, Chronic Health Evaluation III
ARF	Acute Renal Failure
BUN	Blood Urea Nitrogen
CDC	Centers for Disease Control
CT scan	Computed Tomography scan
DI	Daily Sedative Interruption
DVT	Deep Vein Thrombosis
EMR	Electronic Medical Record
ESPICUS	Evaluating Sedation Practices in the Intensive Care Unit Survey
FiO2	Fraction of Inspired Oxygen
GCS	Glasgow Coma Scale
HIPAA	Health Insurance Portability and Accountability Act
НОВ	Head of Bed
ICD-9	International Statistical Classification of Diseases
ICU	Intensive Care Unit
IHI	Institute of Healthcare Improvement
IRB	Institutional Review Board
LOS	Length of Stay

MAAS	Motor Activity Assessment Score
MV	Mechanical Ventilation
PaO2	Partial Pressure of Arterial oxygen
pCO2	Carbon Dioxide Partial Pressure
PEEP	Positive End-Expiratory Pressure
PDAF	Patient Data Abstraction Form
pH	Acid Base Balance
PI	Principal Investigator
PS	Protocolized Sedation
SAS	Sedation Agitation Scale
SAT	Spontaneous Awakening Trial
Serum Na	Serum Sodium
SBT	Spontaneous Breathing Trial
SV	Sedation Vacation
VAP	Ventilator Associated Pneumonia

CHAPTER I

INTRODUCTION

This chapter provides an overview of the significance of nurses' adherence to sedation vacations and the impact that this evidenced-based practice has on the prevention of ventilator associated pneumonia (VAP). Sedation vacations consist of daily scheduled interruptions in the continuous intravenous infusion of sedative drugs in order to establish patients' readiness for extubation (Efrati et al., 2010; O'Keefe-McCarthy, Santiago, & Lau, 2008; Wip & Napolitano, 2009). The implementation of sedation vacations has been shown to significantly reduce the average duration of mechanical ventilation and intensive care unit (ICU) length of stay in patients who require mechanical ventilation via an endotracheal or tracheostomy tube, thereby diminishing their risk of developing VAP (Bouadma, Wolff, & Lucet, 2012; Kress, Pohlman, O'Connor, & Hall, 2000; Quenot et al., 2007; Ruffell & Adamcova, 2008; Schweickert, Gehlbach, Pohlman, Hall, & Kress, 2004; Sessler & Varney, 2008). Sedation vacations have a direct impact on the development of VAP since the cumulative risk of VAP increases over time, despite the daily hazard rate decreasing after day five of mechanical ventilation (Bouadma et al., 2012; Quenot et al., 2007; Schweickert et al., 2004). Studies have demonstrated that the risk of VAP per day is 3.3% at mechanical ventilation day five, 2.3% at mechanical ventilation day 10, and 1.3% at mechanical ventilation day 15 (Bouadma et al., 2012; Schweickert et al., 2004). Yet, researchers have postulated that sedation vacations are inconsistently implemented by nurses (O'Keefe-McCarthy et al., 2008; Wip & Napolitano, 2009). Thus, this study examined ICU nurses' level of adherence to sedation vacations in relation to the impact on VAP prevention and factors associated with the implementation of this practice. Donabedian's structure, process, outcome model (Donabedian, 1966) was used to guide the selection of variables for this study and examine the process of care, adherence to sedation vacations, and outcomes of patients in the ICU.

Overview of VAP

Hospital-acquired infections represent a major complication in hospitalized patients, particularly in those who are critically ill and require intensive care (Sedwick, Lance-Smith, Reeder, & Nardi, 2012; Sierra, Benitez, Leon, & Rello, 2005). As a result, nosocomial pneumonia is the second most common hospital-acquired infection in the United States, and is the leading cause of death among nosocomial infections (Augustyn, 2007; Sedwick et al., 2012). In contrast to infections of more frequently involved organ systems (e.g. skin and urinary tract), for which mortality is low, ranging from 1 to 4%, the mortality rate for VAP ranges from 24 to 50% and can reach 76% in some specific patient populations (e.g. trauma patients) or when lung infection is caused by high-risk pathogens (e.g. methicillin-resistant *Staphlococcus aureus*) (Chastre & Jean-Yves, 2002; Efrati et al., 2010; Heyland, Cook, Griffith, Keenan, & Brun-Buisson, 1999). VAP is a

form of nosocomial pneumonia that develops in patients receiving invasive mechanical ventilation, either through an endotracheal or tracheostomy tube, for more than 48 hours (Bouadma et al., 2012; Roy, 2007). The development of VAP is generally divided into the subtypes of early and late onset (Roy, 2007). Early-onset VAP occurs between 48 and 96 hours after the initiation of invasive mechanical ventilation and is usually associated with community-acquired, antibiotic-susceptible pathogens such as *Staphylococcus aureus* and *Moraxella catarrhalis* (Esperatti et al., 2010; Roy, 2007). Late-onset VAP occurs more than 96 hours after the initiation of invasive mechanical ventilation and is often associated with hospital-acquired, antibiotic-resistant pathogens such as *Pseudomonas aeruginosa* and *Acinetobacter* species (Esperatti et al., 2010; Roy, 2007).

Microorganisms associated with the pathophysiology of VAP can be dispersed by both direct and indirect modes of transmission, which usually involve two main processes: bacterial colonization of the respiratory and digestive tracts, and microaspiration of contaminated secretions of the upper and lower parts of the airway (Efrati et al., 2010; O'Keefe-McCarthy et al., 2008). The direct mode of transmission includes the bacterial colonization of the lungs due to the dissemination of microorganisms from sources such as the oropharynx, nares, sinus cavities, dental plaque, gastrointestinal tract, patient-to-patient contact, and the ventilator circuit (Lawrence & Fulbrook, 2011; O'Keefe-McCarthy et al., 2008). The indirect mode of transmission includes the presence of invasive devices such as endotracheal or tracheostomy tubes that cause VAP by preventing the mucociliary clearance of secretions and depressing epiglottic reflexes, which leads to the entry of pathogenic microorganisms through microaspiration (Lawrence & Fulbrook, 2011; O'Keefe-McCarthy et al., 2008). These secretions pool and then leak around the endotracheal or tracheostomy tube's inflated cuff, which allows the pathogenic microorganisms to infiltrate the sterile environment of the lower respiratory tract and cause a pulmonary infection (Efrati et al., 2010; O'Keefe-McCarthy et al., 2008; Roy, 2007).

Complications of Prolonged Mechanical Ventilation

VAP is a preventable secondary consequence of the initiation of invasive mechanical ventilation that has been linked to the quality of care provided by healthcare providers (Augustyn, 2007; Fields, 2008; Grap, 2009; Ibrahim, Tracy, Hill, Fraser, & Kollef, 2001; Krein et al., 2008; Kress et al., 2000; O'Keefe-McCarthy et al., 2008; Schweickert et al., 2004; Sedwick et al., 2012). Nurses typically provide more bedside hours of care than other healthcare providers, thus their clinical practices can have a substantial impact on the prevention of VAP in mechanically ventilated patients. Therefore, nurses' adherence to sedation vacation protocols is important given the significant morbidity and mortality that is associated with this disease process (Tseng et al., 2012). VAP complicates the illness course of patients who acquire it by increasing mortality rates (24-80%), healthcare cost, and hospital length of stay by two-fold (Sedwick et al., 2012; Sierra et al., 2005). In the United States, it has been estimated that VAP accounts for 1.75 million excess hospital days and \$1.5 billion in extra healthcare cost annually, which equates to approximately \$29,000-\$40,000 per patient (Fields, 2008; Furr, Binkley, McCurren, & Carrico, 2004; Lawrence & Fulbrook, 2011; Rello et al., 2012; Sedwick et al., 2012). Ninety % of all nosocomial infections that occur in patients who require mechanical ventilation are attributed to VAP (O'Keefe-McCarthy et al., 2008). It is the leading cause of death due to nosocomial infections, exceeding rates of death that are secondary to

respiratory tract infections in non-intubated patients, central line infections, and severe sepsis (Sedwick et al., 2012; Wip & Napolitano, 2009). The risk of a mechanically ventilated patient developing VAP is estimated to be 28%, which increases to approximately 50% for those who remain invasively ventilated for more than 5 days (Bouadma et al., 2012; O'Keefe-McCarthy et al., 2008). The reported incidence of VAP among patients who require invasive mechanical ventilation ranges from 10 to 65% (O'Keefe-McCarthy et al., 2008; Tseng et al., 2012). Therefore, the reduction of this preventable nosocomial infection is of major concern in clinical practice since strategies are needed that effectively facilitate nurses' adherence to VAP preventive interventions, such as the sedation vacation protocol, in order to improve patient outcomes and conserve scarce healthcare resources (Esperatti et al., 2010; Sierra et al., 2005; Wip & Napolitano, 2009). The sedation vacation protocol has a significant impact on VAP prevention, because it leads to a decrease in the duration of mechanical ventilation, thus promoting earlier extubation and shorter ICU length of stay (Bouadma, Wolff, & Lucet, 2012; Kress, Pohlman, O'Connor, & Hall, 2000; Quenot et al., 2007; Ruffell & Adamcova, 2008; Schweickert, Gehlbach, Pohlman, Hall, & Kress, 2004; Sessler & Varney, 2008).

Patient Factors Associated with VAP

Several studies have been conducted to determine the patient characteristics that have been consistently associated with the development of VAP (Ibrahim et al., 2001; Sofianou, Constandinidis, Yannacou, Anastasiou, & Sofianos, 2000; Tseng et al., 2012). However, studies using multivariate analysis have not found the type of patient to be an independent risk factor for the development of VAP (Krein et al., 2008; Sofianou et al., 2000; Vallés et al., 2007). Nonetheless, researchers have shown that the patient characteristics that most influence the development of VAP are level of acuity, gender, and age (Alp & Voss, 2006; Bonten, Kollef, & Hall, 2004; Ibrahim et al., 2001; Kollef, 2004; Pieracci & Barie, 2007; Sofianou et al., 2000; Trouillet et al., 1998). Mechanically ventilated patients who develop VAP typically have a higher level of acuity (e.g. Acute Physiology, Age, Chronic Health Evaluation III score >55) upon ICU admission than patients who do not develop VAP (Andales, 2004; Chastre & Jean-Yves, 2002; Esperatti et al., 2010; Heyland et al., 1999; Kollef, 2004; Rakshit, Nagar, & Deshpande, 2005; Rello et al., 2002; Sofianou et al., 2000; Trouillet et al., 1998). This finding is likely due to a greater risk of infection because of persisting organ failure and preexisting comorbidities (Heyland et al., 1999; Tseng et al., 2012). Several studies have also determined that males are more likely to develop VAP than females (Bonten et al., 2004; Heyland et al., 1999; Kollef, 2004; Rello et al., 2002; Trouillet et al., 1998). In a study by Rello et al. (2002), a logistic regression analysis demonstrated that male gender (AOR, 1.58; 95% CI, 1.36 to 1.83) was independently associated with the development of VAP (Rello et al., 2002). Male gender has been postulated to be a marker for other risk factors, which predispose men to either colonization with pathogenic bacteria or aspiration (Rello et al., 2002). Lastly, studies have indicated that age (> 60 years old) may likely be an independent risk factor for the development of VAP, due to this patient population's propensity for frailty and chronic disease (Alp & Voss, 2006; Chastre & Jean-Yves, 2002; Heyland et al., 1999; Rello et al., 2002; Tseng et al., 2012).

Findings from several studies also suggest that an independent determinant of a patient developing VAP was being intubated for longer than 48 hours (Eng, Malhotra, Saeed, Mark, & Talmor, 2008; Kollef, 2004; Sofianou et al., 2000). An approximation of

the percentage of mechanically ventilated patients who require intubation for more than 48 hours has been established by Eng, Malhotra, Saeed, Mark, and Talmor (2008), who found that 2,583 (15%) of the 17,493 patients who were admitted to their study from 2001 to 2005 required invasive mechanical ventilation for greater than 48 hours (Eng et al., 2008). Therefore, the purpose of a daily sedative interruption, of all hypnotic and analgesic agents, is to accelerate patients' liberation from mechanical ventilation and ICU discharge (Kress et al., 2003; Sedwick et al., 2012). Studies of mechanically ventilated patients' outcomes have documented that the implementation of a daily sedative interruption, until patients were awake and able to follow commands, led to a reduction in the average duration of mechanical ventilation of 2.4 days as well as a reduction in the average ICU length of stay of 3.5 days (Kress et al., 2000; Ruffell & Adamcova, 2008; Schweickert et al., 2004). Sedation vacations are daily scheduled interruptions of continuous intravenous sedation that are based on hospital-based criteria (Wip & Napolitano, 2009). If patients meet these criteria, their continuous sedation is turned off in order to evaluate whether the criteria for extubation have been met (Wip & Napolitano, 2009). If patients meet the criteria for extubation they are subsequently extubated (Wip & Napolitano, 2009). If they do not meet the criteria for extubation they are restarted on the continuous sedative infusion, at one half of the dose, and the infusion is titrated upward until the patient reaches a Motor Activity Assessment Scale (MAAS) score of 2-3. A MAAS score of 2-3 indicates that the patient is responsive to touch or name, and is calm and cooperative (Schweickert et al., 2004).

Evidenced-Based Interventions to Prevent the Development of VAP

Sedation vacations are a vital component of the accepted Centers for Disease Control's (CDC) and Society of Critical Care Medicine's practice guidelines, which recommend the use of VAP bundle practices (i.e. sedation vacations, head of bed elevation, deep vein thrombosis (DVT) prophylaxis, and peptic ulcer prophylaxis) to prevent VAP in mechanically ventilated patients (Bouadma et al., 2012; Cason, Tyner, Saunders, & Broome, 2007; Dodek et al., 2004; Fulbrook & Mooney, 2003; Jacobi et al., 2002; Mehta et al., 2006; Muscedere et al., 2008; O'Keefe-McCarthy et al., 2008; Resar et al., 2005; Tolentino-Delosreyes, Ruppert, & Shiao, 2007; Wip & Napolitano, 2009). While all the components within the VAP bundle directly relate to VAP reduction, only the head of bed elevation and sedation vacations have been shown to have an effect on patient outcomes for VAP (O'Keefe-McCarthy et al., 2008; Resar et al., 2005). Sedation vacations facilitate earlier extubation by allowing healthcare providers to assess patients' neurologic status and ability to wean from the ventilator on a consistent basis (Sedwick et al., 2012; Walker & Gillen, 2006). As a result, daily sedation vacations have major implications for mechanically ventilated patients who are extubated early (Girard et al., 2008; Kollef et al., 1998; Kress et al., 2000; Payen et al., 2007; Schweickert et al., 2004). Even so, researchers have postulated that sedation vacation protocols have been inconsistently implemented by nurses (O'Keefe-McCarthy et al., 2008; Wip & Napolitano, 2009). Consequently, many patients may inadvertently be left intubated for longer periods of time, even though they meet the criteria for extubation, thereby increasing their risk of VAP (Wip & Napolitano, 2009). Therefore, since VAP is the most common type of hospital-acquired infection seen in the medical/surgical ICU, this

population of clinicians represents an important group to study when evaluating patients' outcomes in relation to the implementation of sedation vacations (Krein et al., 2008; Pieracci & Barie, 2007). Yet, little research has examined the implementation of sedation vacation protocols by nurses, thus empirical evidence to unequivocally support that nurses consistently perform sedation vacations and that this consistency is associated with positive patient outcomes is lacking.

Nurses' Lack of Adherence to Evidence-Based Practices

There are numerous examples from daily nursing practice that illustrate that the consistent implementation of evidence-based practice is often not accomplished (Maskerine & Loeb, 2006; van Achterberg, Schoonhoven, & Grol, 2008; Waltman, Schenk, Martin, & Walker, 2011; Whitby & McLaws, 2004). For example, most studies published in the past 20 years on hand-hygiene practices consistently indicate that healthcare providers are adherent with hand-hygiene protocols in less than 50% of all relevant patient care interactions (Maskerine & Loeb, 2006; Petroudi, 2009; van Achterberg et al., 2008). Although nurses tend to be somewhat more adherent with handhygiene than their physician counterparts, the overall low rate of adherence is a serious threat to patient safety considering the well-established evidence in this area (van Achterberg et al., 2008). Consequently, in response to nurses' divergence from current evidence-based practices that are associated with standard infection control precautions, Gammon, Morgan-Samuel, and Gould (2008) reviewed the literature and found that there was agreement among researchers as to the range of reasons for non-adherence to infection control practices which included: lack of means, lack of time, putting patients at risk, precautions not warranted, interfering with patient care, forgetfulness, patient not a

risk, and lack of knowledge (Gammon, Morgan-Samuel, & Gould, 2008). Similarly, the immediate goal of this study was to identify the most salient factors that are associated with nurses' adherence to sedation vacations, in patients who require invasive mechanical ventilation, so that the level of adherence to the sedation vacation protocol could be quantified and barriers and facilitators to performing sedation vacations could be identified. Identification of these factors will facilitate the development of interventions aimed at improving nurses' adherence to evidence-based practices, such as sedation vacations, in view of the fact that these interventions are known to reduce the incidence and prevalence of nosocomial infections such as VAP. Thus, this study was an important component of a program of research that is focused on evaluating nurses' adherence to evidence-based practices in relation to the health outcomes of critically ill patients. The long-term goal of the program of research is to develop and test quality improvement measures that are directed toward improving patient outcomes by reducing the morbidity and mortality that is associated with patients who develop nosocomial infections.

Structure, Process, and Outcome Model for Improving Patient Quality of Care

The evaluation of healthcare quality is imperative in facilitating effective nursing interventions to improve the healthcare outcomes of critically ill patients who require the initiation of invasive mechanical ventilation (Mitchell, Ferketich, & Jennings, 1998). For the purposes of this study, healthcare quality was defined as a reflection of current evidence-based medicine in peer-reviewed research literature and in the larger medical care system of which it is a part (Donabedian, 1966). More specifically, for this study, healthcare quality was examined in the context of facilitating the consistent implementation of an evidenced-based intervention, such as the sedation vacation

protocol, to reduce the incidence of nosocomial infections such as VAP (Mitchell et al., 1998). The focus of this study was directed toward evaluating the healthcare quality of nursing-directed patient care in intensive care situations and improving patient outcomes with a focus on the performance of sedation vacations as an intervention and its associated health outcomes (development of VAP, ICU length of stay, and duration of mechanical ventilation) (Kress et al., 2000; Mitchell et al., 1998). Although there are other evidenced-based interventions that are part of the VAP bundle, this specific intervention was chosen because it has been shown to be one of only two interventions (elevation of the head of bed and sedation vacations) that have been demonstrated to have a direct effect on patient outcomes for VAP (O'Keefe-McCarthy et al., 2008; Resar et al., 2005).

The linear model implied by Donabedian's 1966 traditional framework of structure, process, and outcome has been used in several studies that have focused on health outcomes research, and therefore was also used to guide this study (Closs & Tierney, 1993; Hong, Morrow-Howell, Proctor, Wentz, & Rubin, 2008; Kunkel, Rosenqvist, & Westerling, 2007; Wubker, 2007). The traditional structure, process, outcome model has four major components: system characteristics, client characteristics, nursing interventions (process), and outcomes which influence healthcare quality. The structure of the model is comprised of the system characteristics and client characteristics, which gives direction to the provision of healthcare resources (Wubker, 2007). The hospital environment and nursing characteristics which include the size of the hospital facility, hospital policies, hospital culture, available patient care technologies, and skill mix of the nursing staff (education, level of intensive care experience) are conceptualized as the

system characteristics that interact with nursing interventions to affect the healthcare outcomes of patients (Mitchell et al., 1998). However, for the purposes of this study, the system characteristics of the hospital environment (which include the size of the hospital facility, hospital policies, hospital culture, and available patient care technologies) were not directly evaluated due to lack of feasibility. These were controlled by conducting the study at one hospital. The patient characteristics which include the patient's level of acuity, gender, and age are conceptualized as the client characteristics of the patients to whom the nursing interventions are directed (Mitchell et al., 1998).

The process of the model refers to an evidence-based clinical intervention performed by the nursing staff, which affects the outcomes of patient care. The nursing intervention, which was comprised of nurses' performance of the sedation vacation protocol, was conceptualized as the clinical process that was delivered during the direct nursing-based patient care interventions performed in the ICU (Mitchell et al., 1998; O'Keefe-McCarthy et al., 2008). The outcome of the structure, process, outcome model refers to the changes in a patient's state of health that can be ascribed to the nursing intervention (Wubker, 2007).

Outcome was conceptualized as a change in status or patient outcome that was confidently attributable to antecedent care, such as facilitating the reduction of the ICU length of stay, duration of mechanical ventilation, and development VAP in intubated patients (Wubker, 2007). These outcomes are thought to be influenced by nurses' practices of using a hospital-based sedation vacation protocol that has been empirically associated with earlier extubation in patients who require invasive mechanical ventilation (Bond & Thomas, 1991; Kress et al., 2000). The conceptualizations of Donabedian's 1966 structure, process, and outcome model in the context of evaluating healthcare quality in relation to the sedation vacation protocol can be seen in the following diagram.

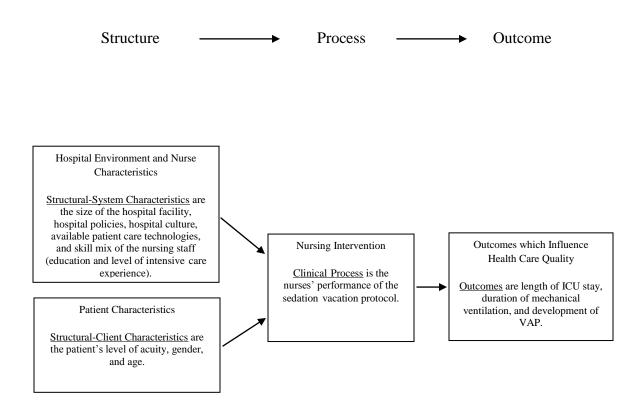


Figure 1. Structure, process, outcome model for evaluating health care quality in relation to the sedation vacation protocol. From "Quality Health Outcomes Model," by P.H.
Mitchell, S. Ferketich, and B.M. Jennings, *Image: Journal of Nursing Scholarship, 30(1)*, p.43. Copyright 1998 by Sigma Theta Tau International.

Thus, by using Donabedian's structure, process, outcome model to evaluate the healthcare outcomes and identify the most salient factors that are associated with patient care in relation to nurses' implementation of the sedation vacation protocol, we were able to specify and test the relationships that were associated with the nursing intervention in order to assess how they directly relate to the quality of clinical care provided to mechanically ventilated patients (Mitchell et al., 1998). Therefore, the linear model presented for the purposes of this research was considered to be broad enough to facilitate the development of quality improvement measures that are directed toward facilitating nurses' adherence to evidence-based protocols (Mitchell et al., 1998). The model also provides a framework for performing health outcomes research related to VAP prevention and clinical nursing interventions that are directed toward improving the quality of care provided to critically ill patients receiving invasive mechanical ventilation (Mitchell et al., 1998).

Research Questions and Hypotheses

Hence, the purposes of this study were to evaluate patient outcomes and identify the most salient factors that are associated with nurses' implementation of a sedation vacation protocol, in a consecutive number of medical/surgical patients requiring invasive mechanical ventilation for greater than 48 hours, within a large metropolitan hospital. The specific aims of this study were to:

I: Evaluate the health outcomes (development of VAP, ICU length of stay, and duration of mechanical ventilation) of mechanically ventilated patients in relation to intensive care nurses' practices of implementing the sedation vacation protocol.

Hypotheses:

A: There will be a relationship between the percentage of sedation vacation days performed and the development of VAP in patients who require invasive mechanical ventilation, controlling for patient characteristics (level of acuity, gender, and age).

B: Greater adherence to sedation vacation days will be related to shorter ICU length of stay in patients who require invasive mechanical ventilation, controlling for patient characteristics (level of acuity, gender, and age).

C: Greater adherence to sedation vacation days will be related to a shorter duration of intubation in patients who require invasive mechanical ventilation, controlling for patient characteristics (level of acuity, gender, and age).

II: Identify nursing-related barriers and facilitators that are associated with the consistent (daily) implementation of the sedation vacation protocol in mechanically ventilated patients.

<u>Research Question</u>: What are nurses' perceptions of the barriers and facilitators to implementing the sedation vacation protocol in patients who require invasive mechanical ventilation?

III: Determine whether nursing characteristics are associated with the consistent (daily) implementation of the sedation vacation protocol in mechanically ventilated patients.

<u>Research Question</u>: Are nursing characteristics (education, level of intensive care experience) associated with the appropriate implementation of the sedation vacation protocol in patients who require invasive mechanical ventilation? **IV:** Determine whether nurses' adhere to the sedation vacation protocol consistently (daily) in mechanically ventilated patients.

<u>Research Question</u>: What was the adherence rate of sedation vacations in sedated mechanically ventilated patients in the ICU?

The specific aims enumerated above served to evaluate the clinical outcomes and identify the factors that are associated with nurses' consistent implementation of sedation vacations in patients who require invasive mechanical ventilation. Evaluating ICU nurses' adherence to the sedation vacation protocol in relation to the clinical outcomes of critically ill patients provided data about the impact that non-adherence to evidence-base practices has on preventing nosocomial infections such as VAP.

CHAPTER II

REVIEW OF LITERATURE

This chapter provides an overview of the literature regarding the utility of bundling preventative interventions to improve patient outcomes, the efficacy of sedation vacations in mechanically ventilated patients, the significance of suboptimal adherence to evidence-based protocols, and the perceptions of nurses in relation to sedation. A brief review of the significance of sedative medications and the value of adherence to evidence-based strategies are discussed. Gaps in the literature are identified.

Complications of Sedative Medications

Most patients who require invasive mechanical ventilation are treated with sedative medications such as benzodiazepines, opiates, and propofol (Quenot et al., 2007; Sessler & Varney, 2008; Weinert & Calvin, 2007). These medications are given to reduce the physiologic and psychological stress of respiratory failure, improve patients' tolerance of invasive mechanical ventilation, decrease oxygen consumption, and facilitate nursing care (Kress et al., 2003; Kress et al., 2000; Salluh et al., 2009; Schweickert et al., 2004; Weinert & Calvin, 2007). However, the continuous infusion of these sedative drugs in patients who require intubation may prolong the duration of mechanical ventilation, prolong the length of hospital stay, impede efforts to perform daily neurologic examinations, and increase their need for diagnostic testing to assess alterations in mental status (Kress et al., 2000; Salluh et al., 2009; Strom, Martinussen, & Toft, 2010). Furthermore, over-sedation is associated with long-term neuropsychiatric dysfunction, more neurologic investigations for coma, and slower awakening (Salluh et al., 2009). Delirium is a form of acute brain dysfunction that can occur in up to 80% of mechanically ventilated patients and is a strong predictor of adverse outcomes in patients who are critically ill (e.g. posttraumatic stress disorder and increased long term mortality) (Jacobi et al., 2002; Salluh et al., 2009; Sessler & Varney, 2008). Delirium is typically characterized by fluctuating levels of arousal throughout the day, which is associated with sleep-wake cycle disruption and worsened by reversed day-night cycles (Jacobi et al., 2002). Delirium may be associated with altered mental status and various motoric subtypes: hypoactive, hyperactive, or mixed (Jacobi et al., 2002). Hypoactive delirium, which has the worst prognosis, is characterized by psychomotor retardation that is manifested by a calm appearance, decreased mobility, inattention, and obtundation in extreme cases (Jacobi et al., 2002). Hyperactive delirium is readily recognized by combative behaviors, agitation, progressive confusion, and lack of orientation after sedative therapy (Jacobi et al., 2002). There is emerging evidence that many cases of hyperactive and mixed delirium in mechanically ventilated ICU patients are related to the sedative effects of anxiolytic and analgesic drugs (e.g. benzodiazepines) that ICU nurses are responsible for managing (Jacobi et al., 2002; Sessler & Varney, 2008). Thus, strategies that facilitate nurses' adherence to sedation vacations may help avoid these subtypes of delirium (Jacobi et al., 2002; Sessler & Varney, 2008).

Bundling Groups of Interventions to Improve Patient Outcomes

Bundles are a method used to facilitate providers' adherence to evidence-based clinical guidelines (Curtin, 2011; Fulbrook & Mooney, 2003; Wip & Napolitano, 2009).

Bundling is a term used to reflect a grouping of best practices that, when used separately, are found to be effective (Curtin, 2011; Wip & Napolitano, 2009). The bundling of evidence-based strategies was first conceptualized in 2002 in a seminal study, conducted by Berenholtz et al., that demonstrated that the grouping of best-evidence interventions could facilitate strategies that were aimed at preventing the morbidity and mortality associated with hospital-acquired complications, such as VAP (O'Keefe-McCarthy et al., 2008). The Institute for Healthcare Improvement (IHI) advocated the use of bundles and in 2006 developed the ventilator bundle (also known as the VAP bundle), which consists of the following: elevation of the head of bed to 30-45 degrees, daily sedation vacations, peptic ulcer disease prophylaxis, and DVT prophylaxis (Lawrence & Fulbrook, 2011; Wip & Napolitano, 2009). Each of the four interventions within the VAP bundle is backed by medical evidence and independently affects patient morbidity and mortality (Ibrahim et al., 2001; Kress et al., 2000; Lawrence & Fulbrook, 2011; Morris et al., 2011; O'Keefe-McCarthy et al., 2008; Rello et al., 2012; Resar et al., 2005; Wip & Napolitano, 2009). However, only the strategies of HOB elevation and sedation vacations have been shown to effectively improve the outcomes of VAP when VAP bundles have been evaluated (Ibrahim et al., 2001; Kress et al., 2000; O'Keefe-McCarthy et al., 2008; Resar et al., 2005; Wip & Napolitano, 2009).

Although included within the VAP bundle, peptic ulcer disease prophylaxis is not a specific intervention for VAP prevention (O'Keefe-McCarthy et al., 2008; Wip & Napolitano, 2009). It was included in the VAP bundle as an intervention to prevent stress-related mucosal disease of the gastrointestinal tract, because mechanical ventilation is a significant risk factor (Wip & Napolitano, 2009). In addition, mechanically ventilated patients who receive sedation are at an increased risk for DVT (Wip & Napolitano, 2009). Therefore, DVT prophylaxis is a vital component of the standard of care for this patient population (Wip & Napolitano, 2009). Similar to stress ulcer prophylaxis, DVT prophylaxis has not been shown to reduce patients' risk of developing VAP. Nonetheless, it remains part of the VAP bundle in order to prevent other complications that could increase the morbidity and mortality of mechanically ventilated patients (e.g. pulmonary embolism and stroke) (O'Keefe-McCarthy et al., 2008; Wip & Napolitano, 2009)

Conversely, researchers have demonstrated that positioning patients in a semirecumbent position with the head of bed elevated 30 to 45 degrees decreases the incidence of VAP by reducing gastroesophageal reflex and the subsequent aspiration of nasopharyngeal, oropharyngeal, and gastrointestinal secretions (Grap, 2009; O'Keefe-McCarthy et al., 2008; Tolentino-Delosreyes et al., 2007; Wip & Napolitano, 2009). This was first found in 1999 in a landmark study by Drakulovic et al., which randomly assigned mechanically ventilated patients from one medical and one respiratory ICU in a tertiary care university hospital to either semi-recumbent (n=39) or supine (n=47) body position (Abbott, Dremsa, Stewart, Mark, & Swift, 2006; Ruffell & Adamcova, 2008; Wip & Napolitano, 2009). The frequency of microbiologically confirmed and clinically suspected VAP was assessed in both groups (Wip & Napolitano, 2009). The frequency of the microbiologically confirmed VAP was lower in the semi-recumbent group than in the supine group [semi-recumbent 2 of 30 (5%) versus supine 11 of 47 (23%), 95% confidence interval (CI) 4.2-31.8, P = 0.018]. This finding was also true for clinically suspected VAP [3 of 39 patients (8%) versus 16 of 47 patients (34%), 95% CI 10.0-42.0, P = 0.003] (Abbott et al., 2006; Wip & Napolitano, 2009). Similarly, in a descriptive

study of 360 adult ICU patients, Metheny et al. (2006) demonstrated that low back-rest elevation was an independent risk factor for both pneumonia (p = .02) and aspiration (p = .02) (Wip & Napolitano, 2009).

Efficacy of Adherence to Evidence-Based Strategies

Several studies have demonstrated that sedation vacations are an integral component of the VAP bundle, in that patients who are extubated early are at decreased risk of VAP and sedation-related delirium (Bouadma et al., 2012; Kress et al., 2000; Quenot et al., 2007; Ruffell & Adamcova, 2008; Schweickert et al., 2004; Sessler & Varney, 2008). Therefore, the focus of this study was placed on the sedation vacation component of the VAP bundle, given that the literature on the consistency with which nurses' adhere to sedation vacation protocols is relatively non-existent. Despite the known importance of implementing sedation vacations, there are only a few studies that have empirically evaluated nurses' implementation of daily sedation vacations (Arias-Rivera et al., 2006; Weinert & Calvin, 2007). However, there are numerous studies that have demonstrated that when healthcare providers' adhere to evidenced-based practices patients' outcomes improve (Ruffell & Adamcova, 2008). For instance, in a study of preventative VAP interventions, Hixson and Sole (1998) listed 20 evidence-based strategies (e.g. oral hygiene, prevention of unplanned extubation, and semi-recumbent positioning) that improved patient outcomes when applied to nursing practice (Ruffell & Adamcova, 2008). The subsequent year Kollef (1999) listed a similar number of nonpharmacological VAP preventative evidence-based strategies that also improved patients' outcomes when consistently applied by healthcare providers (Ruffell & Adamcova, 2008). Consequently, the movement toward evidence-based medicine has changed the

way in which nurses deliver healthcare in the recent years, though very few studies have evaluated the consistency with which nurses' adhere to sedation vacation protocols (O'Keefe-McCarthy et al., 2008).

Efficacy of Sedation Vacations in Mechanically Ventilated Patients

To evaluate the use of continuous sedation in mechanically ventilated patients Kollef et al. (1998) conducted a landmark prospective observational cohort study that involved 242 adult ICU patients, in which they determined that the use of continuous intravenous sedation was associated with the prolongation of mechanical ventilation (Kollef et al., 1998). The duration of mechanical ventilation was significantly longer for patients receiving continuous intravenous sedation compared with patients who did not receive continuous intravenous sedation (185 \pm 190 hours versus 55.6 \pm 75.6 hours; p<0.001) (Kollef et al., 1998). Similarly, the lengths of ICU (13.5 \pm 33.7 days versus 4.8 \pm 4.1 days; p < 0.001) and hospital stays (21.0 \pm 25.1 days versus 12.8 \pm 14.1 days; p < 0.001) were found to be significantly longer in patients who were receiving continuous intravenous sedation (Kollef et al., 1998). However, the researchers did not evaluate the use of daily sedative interruptions in this study.

In a seminal randomized, controlled trial that involved 128 adult patients who were receiving mechanical ventilation and continuous infusions of sedative drugs in a medical ICU, Kress, Pohlman, O'Connor, and Hall (2000) found that patients who received a daily interruption in their sedative-drug infusions had a significant reduction in the duration of mechanical ventilation and length of stay in the ICU, as compared to those patients who had their continuous sedation interrupted per the usual practices of the ICU team (Kress et al., 2000; Ruffell & Adamcova, 2008; Strom et al., 2010). In the intervention group, the continuous sedative infusions were interrupted on a daily basis until the patients were awake and could follow instructions or until they became uncomfortable or agitated and were deemed to require the resumption of sedation (Kress et al., 2000). The sedative infusions were started again after the patient was awake or, if agitation prevented the patient from successful waking, at half the previous rates and were titrated according to the patient's need for sedation (Kress et al., 2000). The nurses adjusted the rate and dosage of the continuous sedative infusions according to the standard procedures at the study site (e.g. the Ramsay sedation scale) (Kress et al., 2000). The patients in the control group were monitored each day by the research staff, and the total doses of continuous sedative drug infusions were recorded (Kress et al., 2000). The adjustments of the dosage of the sedative drugs in the control group were left to the discretion of the ICU team (Kress et al., 2000). The median duration of mechanical ventilation was 4.9 days in the intervention group, as compared to 7.3 days in the control group (p = 0.004); and the median length of stay in the ICU was 6.4 days in the intervention group as compared to 9.9 days in the control group (p = 0.02) (Kress et al., 2000).

These findings were further substantiated when Schweickert, Gehlbach, Pohlman, Hall, and Kress (2004) performed a secondary data analysis of their previously published, prospective, randomized-controlled study of daily sedative interruption in critically ill patients undergoing mechanical ventilation using a blinded, retrospective chart review (Schweickert et al., 2004). Their subsequent investigation determined that the daily interruption of sedative infusions in mechanically ventilated patients reduced ICU length of stay (3.5 days) and the incidence of complications of critical illness associated with prolonged invasive mechanical ventilation (Schweickert et al., 2004). Patients who underwent daily interruptions in sedative infusions experienced 13 complications (2.8%) versus 26 (6.2%) in those who underwent conventional sedation techniques (p = 0.04) (Schweickert et al., 2004).

Moreover, in a randomized, controlled trial that involved 336 mechanically ventilated patients who were receiving continuous infusions of sedative drugs in the ICU, Girard et al. (2008) found that patients in the intervention group (n=168; that paired daily interruption of sedatives with daily spontaneous breathing trials) spent more days breathing without the assistance of mechanical ventilation (14.7 days versus 11.6 days, 95% CI 0.7 to 5.6; p = 0.02) during the 28 day study period than did those in the control group (n=168; sedation per usual care plus daily spontaneous breathing trials) (Girard et al., 2008). Additionally, patients in the intervention group were discharged from the ICU (median duration of time in the ICU 9.1 days versus 12.9 days; p = 0.01) and the hospital (median duration of time in the hospital 14.9 days versus 19.2 days; p = 0.04) earlier than the control group (Girard et al., 2008). Furthermore, patients in the intervention group were less likely to die as compared to the patients in the control group (hazard ratio 0.68, 95% CI 0.50-0.92, *p* = 0.01) (Girard et al., 2008; Wip & Napolitano, 2009). In accordance with the spontaneous awakening trial (SAT) protocol (i.e. sedation vacation), patients in the intervention group were assessed every morning with a SAT safety screen (Girard et al., 2008). SATs were prescribed by protocol only for the mechanically ventilated patients in the intervention group, although patients in the control group were not prevented from undergoing SATs if the managing healthcare provider deemed that they were indicated (Girard et al., 2008). Patients who failed the SAT safety screen, due

to active seizures, agitation, or need for neuromuscular blockers, were reassessed the following morning (Girard et al., 2008). Patients who passed the safety screen underwent a SAT, which entailed interrupting all sedatives and analgesics used for sedation (Girard et al., 2008). Patients were monitored for up to four hours (Girard et al., 2008). Patients who passed the SAT by opening their eyes to verbal stimuli or tolerating sedative interruption for four hours or more without exhibiting study-based failure criteria were immediately managed with the spontaneous breathing trial protocol (Girard et al., 2008). When patients failed a SAT, they were started at half the previous dose and then their sedative infusions were titrated to achieve patient comfort (Girard et al., 2008).

As evidenced by these findings, these studies provide strong evidence that daily sedation vacations with spontaneous breathing trials result in better outcomes for mechanically ventilated patients in the ICU as compared to the standard approaches used in practice that do not implement the routine use of sedation vacation protocols (Girard et al., 2008; Kress et al., 2003; Mehta et al., 2006; Wip & Napolitano, 2009). Thus, researchers have demonstrated that sedation vacations are important in improving healthcare outcomes in patients who require invasive mechanical ventilation, because they help to establish patients' readiness for ventilator weaning thereby facilitating early extubation (O'Keefe-McCarthy et al., 2008). However, how nurses implement the sedation vacation protocol in routine practice has not received much attention, even though studies have demonstrated that for evidence-based interventions to be effective they must be implemented according to an established protocol. Evidenced-based protocols have been shown to provide a systematic approach that reduces the practice variations among practitioners (Mehta et al., 2006; O'Keefe-McCarthy et al., 2008;

Walker & Gillen, 2006). Despite this knowledge, surveys of sedation administration in ICUs reveal widely varying practice patterns with regard to the types of medications, sedation monitoring, and method of administration (Martin et al., 2005; Mehta et al., 2006; O'Connor, Bucknall, & Manias, 2010; Walker & Gillen, 2006).

In a cross-sectional mail survey of Canadian intensivists conducted by Mehta et al. (2006), researchers found a wide variation in self-reported practice patterns. The intensivists' reported that their use of interventions, including sedation protocols, delirium scales, sedation scoring systems, and daily sedative interruption, differed depending on the clinicians' age, training, size of the ICU, and whether they practiced in a university-affiliated or community hospital (Mehta et al., 2006). A total 273 of 448 (60%) eligible ICU physicians responded to the survey (Mehta et al., 2006). Twenty-nine % of the intensivists responded that a protocol guideline for the use of sedatives or analgesics was currently in use in their ICU (Mehta et al., 2006). In the ICUs that did not use a sedation vacation protocol, decisions regarding dosing of sedative agents were primarily made by attending physicians (73%), nurses (33%), and residents (22%) (Mehta et al., 2006). Daily interruptions of continuous infusions of sedatives or analgesics were practiced by 40% of the intensivists within the study (Mehta et al., 2006). However, 63% of those intensivists stated that they interrupted sedative infusions in only some patients (Mehta et al., 2006). Eight-six % of intensivists stated that they interrupted sedative infusions before morning rounds (Mehta et al., 2006). If needed, sedative infusions were restarted at the previous dose by 20%, at half the previous dose by 19%, and 56% of respondents had no standard approach (Mehta et al., 2006). A sedation scoring system was used by 49% of the respondents (Mehta et al., 2006). Only 3.7% of

the intensivists reported that they used a delirium scoring system in their ICU (Mehta et al., 2006). Intensivists who worked in university-affiliated hospitals were more likely to employ a sedation vacation protocol (p < .0001), as were intensivists who worked in larger ICUs (≥ 15 beds, p < .01) (Mehta et al., 2006). Intensivists with anesthesiology training (without formal critical care training) were more likely to use a protocol and sedation scale, and intensivists trained in critical care were more likely to practice sedation vacations (Mehta et al., 2006). Younger intensivists (< 40 years old) were more likely to practice daily interruptions (p = .009) (Mehta et al., 2006). Hence, it is clear that a large gap exists between published evidenced-based practices and actual intensivist practice, given the tremendous variability that exists in clinicians' sedation practices (Mehta et al., 2006).

Perceived Barriers to Sedation Vacations

Research that is focused on identifying the barriers and facilitators to implementing the sedation vacation protocol may help to reduce the variability with which ICU nurses administer sedative infusions, titrate and monitor them, and discontinue them when they are no longer needed, thus having a significant impact on the health outcomes of mechanically ventilated patients (Tanios, Wit, Epstein, & Devlin, 2009). In consideration of the potential barriers to implementing sedation vacations, a prospective, multicenter, randomized, pilot trial conducted by Mehta et al. (2008) examined the safety and feasibility (e.g. protocol adherence and work-load) of daily sedative interruptions (DI) in the setting of protocolized sedation (PS) among nurses and respiratory therapists in the ICU (Berry & Zecca, 2012; Mehta et al., 2008). In the study, 65 mechanically ventilated adults receiving continuous infusions of sedatives and

analgesics were randomly assigned to study groups that compared PS and DI (intervention group) to PS alone (control group) (Mehta et al., 2008). The researchers determined that both sedation strategies (PS and PS + DI) could be safely used in this patient population (Mehta et al., 2008). Participants experienced a similar number of adverse events, which included self-extubation (9% in both study groups) and catheter removal (two participants in each group removed their nasogastric tube; and one participant in the PS group removed their central venous catheter) (Mehta et al., 2008). Feasibility was determined by using a visual analog scale (VAS), whereby nurses and respiratory therapists were asked to rate their patient management on a scale from 1 ("very easy") to 10 ("extremely difficult") (Berry & Zecca, 2012; Mehta et al., 2008). Based on the VAS, the workload imposed on the nurses and respiratory therapists was found to be similar between the two groups and was acceptable (Mehta et al., 2008). Bedside nurses rated patient management as "very easy" to "fairly easy" in 77.6% of assessments in the PS group and 82% of assessments in the PS + DI group; the respiratory therapists' corresponding values were 82.5% and 80.4%, respectively (Berry & Zecca, 2012; Mehta et al., 2008). Protocol adherence was determined to be reasonable as evaluated by the Sedation Agitation Scale (SAS), which was within target range (3-4) in 60% of the PS measurements and 57.3% of PS + DI measurements (Mehta et al., 2008). SAS values were within an acceptable range (2-5) in 82.8% of the PS measurements and 84.1% of the PS + DI measurements (Mehta et al., 2008). In both groups, there were very few episodes during which participants were noted to be "very agitated" (SAS score 6, <1.5%) or experienced "dangerous agitation" (SAS score 7, (0.3%) (Mehta et al., 2008). In the PS + DI group, continuous sedative infusions were

interrupted on 82.2% of the eligible study days (Mehta et al., 2008). The most common reasons for non-interruption of sedative infusions were "not specified" (21.4%), "palliation" (21.4%), "physician request" (16.1%), and "the bedside nurse forgot" (16.1%) (Mehta et al., 2008).

In a study by Tanios et al. (2009) the researchers used a multidisciplinary, webbased survey to determine the current use of sedation protocols and daily sedation vacations in mechanically ventilated patients and identify the perceived barriers toward the use of each among 904 critical care physicians (60%), nurses (14%), and pharmacists (12%) (Tanios et al., 2009). More than half of the participants had 10 years or greater of ICU experience, 45% worked in a university hospital and 62% in large ICUs with > 11beds where 50% or more patients required mechanical ventilation (Tanios et al., 2009). Most participants (64%) worked in ICUs where sedation protocols were implemented with 67% having participated in the development of their institution's protocol (Tanios et al., 2009). Sedation protocols were more likely to be used in ICUs that had > 20 beds as compared to ICUs with < five beds (72% versus 43%, p = .03) (Tanios et al., 2009). More pharmacists (81%) were involved in developing sedation protocols than either physicians (68%, p = .04) or nurses (50%, p = .03) (Tanios et al., 2009). The patient populations that were determined not to be candidates for the sedation protocol included patients admitted to neurology/neurosurgery (23%), cardiothoracic surgery (5%), and trauma (5%) services (Tanios et al., 2009). Of the participants who had a sedation protocol at their institution, the three most common perceived barriers preventing its use was a lack of a physician order for the sedation protocol (38%), a nursing preference to not use the sedation protocol (15%), and cases where the ICU healthcare provider wanted

to have more control over the patients' sedation than the protocol afforded (Tanios et al., 2009). Use of a daily sedation vacation was used in 50% or more of mechanically ventilated patients by 40% of participants, although the use varied greatly with 23% of the total participants using sedation vacations frequently (>75%) of mechanically ventilated patients) and 37% of participants rarely or never using sedation vacations (< 25% of mechanically ventilated patients) (Tanios et al., 2009). The percentage of healthcare providers who had never heard of daily sedation vacations was low (5%) (Tanios et al., 2009). When compared to pharmacists (35%), nurses (50%, p = .007) and physicians (44%, p = .03) were more frequent users of daily sedation vacations (Tanios et al., 2009). Although nurses and physicians used sedation vacations more often than pharmacists, the percentages were still lower than optimal (Tanios et al., 2009). Participants from institutions with a sedation protocol in place were more likely to use daily sedation vacations (Tanios et al., 2009). Of the participants who did not have a sedation protocol at their institution, the three most common perceived barriers to the use of daily sedation vacations included the potential for respiratory distress (26%), the lack of nursing acceptance (22%), and concern for patient-initiated device removal (20%) (Tanios et al., 2009). The findings of this multidisciplinary survey identified a number of important barriers to sedation protocols and the use of daily sedation vacations (Tanios et al., 2009). Further exploration of this topic is warranted, thus the current study explored the reasons for ICU nurses' level of adherence to sedation vacations; so as to facilitate the development of quality improvement measures that are directed toward improving the health outcomes of mechanically ventilated patients (Tanios et al., 2009).

Nurses' Perceptions of Sedation

How the nurse practices in relation to sedation management directly affects the quality of care provided to mechanically ventilated patients (Walker & Gillen, 2006). Thus, nurses' perceptions of their own use of continuous sedation were evaluated in a cohort study conducted by Weinert and Calvin (2007). The study included 274 adult patients who were receiving mechanical ventilation in medical and surgical ICUs (Weinert & Calvin, 2007). The study's purpose was to measure the epidemiology of sedative use and patient behavior, and to define the factors that influenced nurses' estimates of sedation adequacy (Weinert & Calvin, 2007). They found that nurses' perceived that their patients were inadequately sedated 17% of the time, with under sedation occurring five times more often than over sedation (Weinert & Calvin, 2007). In addition, the factors that influenced nurses' judgment of sedation adequacy included time of day, patients' level of consciousness, and patients' spontaneous motor activity (Weinert & Calvin, 2007). During the daytime hours nurses were the healthcare providers that were significantly (p < .001) more likely to judge patients as being over-sedated; even though there were minimal differences between the actual amount of sedatives administered during the day versus the nighttime hours (Weinert & Calvin, 2007). Furthermore, the study also found that nurses were the healthcare providers who were significantly (p <.001) more likely to rate patients, when assessing their level of consciousness and spontaneous motor activity, as being over-sedated when they were unable to be aroused with moderate tactile stimuli and had no spontaneous movement (Weinert & Calvin, 2007).

Walker and Gillen (2006) also examined a convenience sample of 107 registered nurses in the ICU, to explore nurses' perceptions of their role in sedation management (Walker & Gillen, 2006). The nurses in the study agreed that the nurse contributes to the plan regarding the patients' target level of sedation (78%, n=72). They also found that the nurse plays a major role in the sedation management of critically ill patients, given that sedation is titrated by the nurse in collaboration with the physician (Walker & Gillen, 2006). The ICU physician was primarily responsibility for prescribing the sedative drugs that intubated patients receive while in ICU (Walker & Gillen, 2006). However, the ICU nurse normally manages the dose and rate of the sedative infusion, within the prescribed limits, according to the level of sedation and the patient's requirements (Walker & Gillen, 2006). In the study, both the sedation scoring and the nurses' judgment (90%, n = 82) were considered to be the best measure of patients' level of sedation (Walker & Gillen, 2006). Nurses' perception of patients' ideal level of sedation during the day was seen to be less than their ideal level at night. The authors' findings demonstrated that the nurses believed that during the daytime hours patients should be aware but calm (82%, n=74)while at nighttime it was acceptable for patients to be more sedated as long as they could be aroused to voice (81%, n=73) (Walker & Gillen, 2006). The nurses were also asked to identify on a scale from 1 to 10 (1= low confidence to 10 = high confidence) their level of confidence when managing patients' sedation (Walker & Gillen, 2006). The nurses' mean confidence score was 7.1, which demonstrated that they perceived themselves to be confident about managing patients' sedation with 51% (n=46) scoring at the high confidence level (scoring 8, 9, or 10) (Walker & Gillen, 2006). Even so, less than half of the nurses said that they would stop (40%, n=37) and restart sedation (48%, n=44), within

the prescribed limitations of their orders, depending on their patients' sedation score (Walker & Gillen, 2006). When the authors analyzed the nurses' statements about their practices of stopping and restarting sedation, they found that there was a significant difference in practice within groups of nurses with low, medium, and high levels of confidence (Walker & Gillen, 2006). Nurses who indicated higher confidence levels were more likely to stop (low to high confidence p = 0.012; medium to high confidence p=0.023) and restart (low to medium confidence p = 0.04; low to high confidence p = 0.03) sedation; with the most notable differences being between the nurses with low and high confidence levels for each statement (Walker & Gillen, 2006). The study also found that nurses who were more confident typically had more experience in the ICU and had achieved (or were currently undertaking) a post registration qualification in intensive care (p = 0.001) when compared to those who had less experience and had not taken a post registration qualification (p = 0.35) (Walker & Gillen, 2006). Therefore, these results support the evidence that nurses are the healthcare providers who manage the dose and frequency of patients' sedation (Walker & Gillen, 2006; Weinert & Calvin, 2007).

Evidence of Nurses' Suboptimal Adherence to Evidence-Based Protocols

As demonstrated in the literature nurses play a pivotal role in implementing evidence-based patient care interventions, because they are the healthcare providers who are primarily responsible for performing the bedside protocols that are aimed at optimizing the healthcare outcomes of critically ill patients (Roy, 2007). Unfortunately, there are numerous examples from daily nursing practice that demonstrate how the implementation of evidence in clinical practice is often not accomplished (Cabana et al., 1999; Cochrane et al., 2007; Lam, Lee, & Lau, 2004; Mathai, George, & Abraham, 2011; Rao et al., 2009; van Achterberg et al., 2008). For instance, most studies published in the past 20 years on hand-hygiene have consistently indicated that healthcare providers are adherent to hand-hygiene protocols in less than 50% of all relevant occasions (Maskerine & Loeb, 2006; Petroudi, 2009; van Achterberg et al., 2008). In a study by Grap and Munro (1997), 90% of nurses who were surveyed reported that they were adherent to their institutions' hand-washing protocol, however when those nurses were observed only 22% were actually adherent (Cason et al., 2007). Cason, Tyner, Saunders, and Broome (2007) found that 18% of nurses reported that they did not always wash their hands between patient contacts, and 23% reported that they did not use gloves when providing oral care. A study by Rigbe, Almedom, Hagos, Albin, Mutungi (2005) found that 50% of the nurses interviewed admitted that they do not change their gloves between patient contacts and perceived the use of gloves as protective devices for themselves rather than their patients (Petroudi, 2009).

Similar difficulties are also found in other areas of nurses' adherence to and practice of standard precautions to reduce the spread of infectious organisms transmitted by airborne, droplet, and contact means of spread (Gammon et al., 2008; van Achterberg et al., 2008). Furthermore, many research studies have indicated that nurses' adherence to standard precaution measures are commonly deficient, and practice interventions to improve adherence are generally limited in their effect (Creedon, 2005; Gammon et al., 2008). For instance, researchers have concluded that healthcare providers' hand washing adherence rates are difficult to modify as demonstrated in most studies by adherence (Creedon, 2005; Gammon et al., 2008). A review of the literature by Gammon, Morgan-

Samuel, and Gould (2008) illustrated that studies that evaluated the adherence rates of healthcare providers use of gowns/aprons or other protective clothing was on average 62%, and the adherence rate for the use of face masks was 30%. The research review demonstrates that nurses' adherence to infection control precautions is internationally suboptimal, and confirms that healthcare providers' rates of adherence do not consistently improve after a structured intervention, such as an education-based training program or a multidisciplinary intervention (Gammon et al., 2008).

Although there has been no empirical evidence found to unequivocally support the claim that the sedation vacation protocol is inconsistently implemented by nurses, there are numerous examples from daily nursing practice that demonstrate how the implementation of other evidence-based practices are often also suboptimal (O'Keefe-McCarthy et al., 2008; van Achterberg et al., 2008; Wip & Napolitano, 2009). Nonetheless, researchers must acknowledge when considering this association that the primary difference between standard infection control precautions and sedation vacations is the significant threat for patient safety (Wip & Napolitano, 2009). For example, there is a possibility that patients may harm themselves through the removal of invasive devices due to altered mental status during the implementation of sedation vacations; therefore close nursing supervision is required to prevent this occurrence (Payen et al., 2007; Wip & Napolitano, 2009). Despite this dissimilarity, both areas of nursing practice illustrate the gap between evidence-based guidelines and nurses' clinical practices of adherence. Both areas also emphasize nurses' role in preventing hospital acquired infections. Consequently, nurses' adherence to standard infection control precautions can likely be linked to their adherence to sedation vacations in light of the well-established evidence of

non-adherence in similar areas and the impact that both have on the prevention of hospital acquired infections (Creedon, 2005; Gammon et al., 2008; O'Keefe-McCarthy et al., 2008; Rigbe, Almedom, Hagos, Albin, & Mutungi, 2005; van Achterberg et al., 2008; Wip & Napolitano, 2009). Therefore, since nurses' adherence to sedation vacation protocols has received relatively no attention, this study provides greater understanding of the most salient factors that are associated with nurses' non-adherence; which provided important insight into how intensive care nurses' clinical practices affect patients' health care outcomes (Cochrane et al., 2007; van Achterberg et al., 2008).

Conclusions

In summary, the empirical research presented for the purposes of this study demonstrates the magnitude of VAP, importance of implementing sedations vacations, and the significance of suboptimal adherence to evidence-based protocols. The cumulative evidence presented within this manuscript is supported by the use of methodologically robust research designs in the studies reviewed. However, there are several limitations in the studies reviewed. First, most of the studies were solely performed within medical ICUs (Kollef et al., 1998; Kress et al., 2000; Schweickert et al., 2004). Therefore, the results of these studies may not be directly applicable to ICUs that care for different populations of critically ill patients (Kollef et al., 1998; Kress et al., 2000). Second, the studies reviewed did not assess the adequacy of sedation from the patients' perspective; therefore patients' quality of life could not be measured (Kollef et al., 1998; Kress et al., 2000; Schweickert et al., 2004; Weinert & Calvin, 2007). Lastly, most of the studies evaluated did not contact the physicians to obtain their indications for the administration of continuous intravenous sedation (Arias-Rivera et al., 2006; Kollef et al., 1998; J. P. Kress et al., 2000; Schweickert et al., 2004). Therefore, the researchers were unable to assess the number of patients receiving continuous intravenous sedation who could have been treated without this mode of therapy (Kollef et al., 1998; Kress et al., 2000).

Additional methodological problems in the current sedation vacation literature include: a lack of studies that evaluate nurses' level of adherence to the sedation vacation protocol in patients who require invasive mechanical ventilation; a lack of studies that evaluate the most salient factors that are associated with nurses' adherence to the sedation vacation protocol in patients who require invasive mechanical ventilation; a lack of studies that evaluate the clinical outcomes of mechanically ventilated patients in relation to intensive care nurses' practices of implementing the sedation vacation protocol; a lack of studies that identify the frequency with which sedation vacations must be performed in order to demonstrate improvement in patients' health care outcomes; and a lack of a theoretical basis. These issues have been addressed in the current study by: a) evaluating patients' electronic medical records; b) using self-report surveys to evaluate the major factors that are associated with nurses' adherence to the sedation vacation protocol; c) collecting patient data regarding the clinical outcomes of length of ICU stay, duration of mechanical ventilation, and the development of VAP; d) examining the study findings to determine if there is an association between the frequency with which sedation vacations are performed and patients' healthcare outcomes; and e) designing the study and selecting well-established measures conceptualized around a theoretical healthcare quality model.

The current study adds to the body of research by filling two primary gaps in the literature. First, this study evaluated the implications of nurses' clinical practices of

37

adherence to a sedation vacation protocol. Specifically, the study considered issues such as the association between the percentage of sedation vacation days performed and the development of VAP, length of ICU stay, and duration of mechanical ventilation within a large metropolitan hospital that has a documented nurse-driven sedation vacation protocol. Secondly, the study broadens the literature base by adding to the empirical body of research, which has previously demonstrated the utility of evidence-based practice standards such as sedation vacations, with the study's findings that addressed the most salient factors that are associated with nurses' adherence to their institution's sedation vacation protocol. Thus, by identifying the most salient factors that are associated with ICU nurses' adherence to evidence-based practices, this study will facilitate the Principal Investigator's long-term goal of developing and testing quality improvement measures. These measures would be based on evidenced-based recommendations that are aimed at improving the consistent use of protocols known to reduce the incidence and prevalence of nosocomial infections, such as VAP, by ICU nurses.

CHAPTER III

METHODOLOGY

This chapter describes the study's research design. A description of the sample, instruments, and procedures are included. A discussion of the data analysis plan has been provided.

Research Design

A correlational design was used to evaluate the patient outcomes and identify the most salient factors that are associated with the nurses' implementation of a sedation vacation protocol. The design included three main components. The first component was the abstraction of data from the electronic medical record (EMR) of 158 medical/surgical mechanically ventilated patients (79 with VAP and 79 without VAP), meeting eligibility criteria over a one year time period, in a large metropolitan hospital that had four medical/surgical ICUs. The second component was the administration of self-report surveys to ICU nurses to obtain information about their characteristics, barriers to implementing sedation vacations, and perceptions of their practice of implementing sedation vacations. The third component consisted of vignettes of patient scenarios related to ICU nurses' implementation of sedation vacations, to determine their adherence to the sedation vacation protocol and rationale for implementation in standardized case presentations. These vignettes were administered as part of the nurses' survey.

Retrospective data were abstracted from the EMRs of eligible mechanically ventilated patients who were admitted to a medical/surgical ICU during the fiscal year of 2010 (September 2009 through August 2010) to evaluate the clinical outcomes of patients' length of ICU stay, duration of mechanical ventilation, development of VAP, and nurses' adherence to the sedation vacation protocol. In addition, 100 anonymous self-report surveys for bedside ICU nurses who provide direct patient care were distributed in order to obtain descriptive data about nurses' perceptions of sedation vacations and barriers/facilitators to implementing sedation vacations. Included in the self-report surveys were vignettes that describe seven patient scenarios and represented the nurses' evidenced-based implementation of sedation vacations in relation to their clinical decision-making and ability to follow the sedation vacation protocol.

Rationale for Time Points of Data Collection

The abstraction of data from the EMR was selected based on the study's feasibility of resources, and need to minimize possible threats to the internal validity of the study. It was determined that the data of eligible participants would be retrospectively abstracted from the EMRs of mechanically ventilated patients who were admitted during the fiscal year of 2010, in order to limit the threat of history caused by ongoing changes in clinical practice that are attributed to a recent reorganization of the study site's infrastructure. Bedside ICU nurses were also recruited, over a two month period, to participate in a one-time anonymous self-report survey to obtain their perspective on their current clinical practices related to sedation vacations.

Sample

Mechanically ventilated patients. Initially, the EMR sample was to include a consecutive number of medical/surgical patients requiring invasive mechanical ventilation for greater than 48 hours, who were patients in the ICU during the period of September 2009 to August 2010, in one large metropolitan hospital. As necessitated by the study's preliminary data analysis the PI requested an Institutional Review Board (IRB) amendment to the protocol's design, which pertained to the abstraction of patient data from the EMR. The volume of mechanically ventilated patients was far greater than initially thought and thus it was not feasible to collect data on all patients. The design was revised to include the 79 patients known to have VAP per ICD-9 code during the fiscal year of 2010. The non-VAP patients were then randomly selected based on the number of VAP cases in each ICU using a table of random numbers that was generated from Research Randomizer (Urbaniak & Plous, 2011). For example, the PI abstracted data on the known 31 VAP patients in the medical ICU and then randomly sampled 31 non-VAP patients from the same medical ICU census. This methodology was then duplicated in each of the ICUs within the study site, which yielded a total of 158 patient abstractions.

The primary criteria for inclusion into the study were that the mechanically ventilated participants be identified as: 1) patients who were admitted to a medical/surgical ICU for a minimum of 24 hours during the time period of September 2009 to August 2010; 2) patients who were at least 18 years old; and 3) patients who required invasive mechanical ventilation for greater than 48 hours, in association with the administration of a continuous intravenous infusion of a sedative drug, while in a medical/surgical ICU. For the purposes of this study, continuous intravenous sedation was considered to be present

whenever a participant received a constant intravenous infusion of an analgesic or sedative class of agents (e.g. major tranquilizers, narcotics, propofol, or benzodiazepines) (Kollef et al., 1998). Mechanically ventilated participants were excluded: 1) if they died within 24 hours of being admitted to a medical/surgical ICU; and 2) if they had contraindications to receiving sedations vacations as indicated by the physician's/midlevel's orders (e.g. receiving a sedative infusion for active seizures or alcohol withdrawal; receiving escalating doses of a sedative as a result of ongoing agitation; receiving neuromuscular blocking agents; evidence of active myocardial ischemia in the previous 24 hours; and/or evidence of increased intracranial pressure) (Berry & Zecca, 2012; Kress et al., 2000).

Intensive care nurses. Bedside ICU nurses who provide direct patient care for a minimum of 24 hours per week, within a medical/surgical ICU in a large metropolitan hospital, were surveyed. All nurses who met eligibility criteria (approximately 100 bedside ICU nurses) were recruited for the survey and vignette portion of the study. Nursing participants were included in the study: 1) if they were ICU nurses who participated in independent, direct bedside patient care for a minimum of 24 hours per week; 2) if they had completed the hospital's orientation for new hires; and 3) if they were at least 21 years old. Nursing participants were excluded from the study if they indicated on the self-report survey that they did not perform sedation vacations on patients.

Sample size

Calculations to estimate sample size were conducted based on a moderate effect size and the correlational design of the study. Based on *t*-test computations using the standard alpha level of .05 and a minimum power of .80, a projected sample size of 102 mechanically ventilated participants was determined to be adequate to address the specific aims of the study (Soper, 2010).

Instruments

Measurement of the Concepts in the Structure, Process, Outcome Model

Structural-system characteristics. Nursing characteristics have been defined within the model as the skill mix of the nursing staff, and were comprised of two main components: education and level of intensive care experience. The "Evaluating Sedation Practices in the Intensive Care Unit" Survey (ESPICUS) is a 23-item survey that was originally developed and validated by Tanios et al. (2009) (see Appendix A for the ESPICUS). The survey was used to obtain ICU nurses' level of education, ICU experience, barriers/facilitators to implementing sedation vacations, and confidence in performing sedation vacations. Vignettes were added to the survey and are described later. Education was determined by: the highest nursing degree held (e.g. 1=ADN [lowest], 2=BSN, 3=MSN, 4=PhD [highest]); and the achievement of a post registration qualification in intensive care (e.g. CCRN, PCCN, CCNS, and/or ACNP), which was dichotomously coded as "1=Yes" or "0=No". Level of intensive care experience was defined as the total number of years of clinical critical care practice in any ICU as a registered nurse.

Structural-client characteristics. Patient characteristics have been conceptualized within the model as the client characteristics, and are comprised of three key components: gender, age, and level of acuity. A Patient Data Abstraction Form (PDAF) developed by the PI was used to abstract data from the EMR regarding the patient characteristics of gender, age, level of acuity, and nurses' adherence to sedation vacations which are discussed later in this section (see Appendix D for the PDAF). Content validity of the entire PI developed PDAF was ensured by having a panel of four experts that have experience in instrument development, critical care, and the performance of sedation vacations to evaluate the instrument. The panel of experts reviewed the instrument and confirmed that the individual items included were appropriate, accurate, and representative of the content domain being evaluated within the study. Furthermore, intrarater reliability of the data obtained via the PDAF were ensured by randomly selecting 10% of the EMRs to be re-coded until a 90% agreement was achieved on two separate occasions prior to study completion, so that the overall consistency of data abstraction could be evaluated (Dilorio, 2005). Intrarater reliability of the data transcribed from the ESPICUSs was also achieved by recoding all the returned surveys on two separate occasions prior to data analysis.

Patient <u>gender</u> was collected as a dichotomous variable coded with categories of male or female as indicated in the EMR. Patient <u>age</u>, in years, was abstracted from the EMR admission date to the ICU. The <u>level of acuity</u> was determined by using the Acute Physiology, Age, Chronic Health Evaluation III (APACHE III) to predict an adult (age 18 years or older) patient's level of acuity/risk of hospital mortality after the first day of ICU treatment (Knaus et al., 1991). The APACHE III scoring system is comprised of the sum of three components: an age score, an acute physiology score, and a chronic health problems score (Knaus et al., 1991). Scores range from 0 to 299 (age, 0 to 24; physiology, 0 to 252; chronic health evaluation, 0 to 23), with higher scores implying a more severe disease and higher risk of death (Knaus et al., 1991). The APACHE III

scoring system stipulates that the patient's age and chronic health history are worth up to 47 points (Knaus et al., 1991). The APACHE III score was calculated based on the clinical data that were documented in the EMR, within the first 24 hours of ICU admission, using a web-based scoring tool (QuesGen Systems Inc., 2012). Seventeen physiologic variables was measured using the first set of relevant lab values documented in the EMR, which may add up to a maximum of an additional 252 points (Knaus et al., 1991). Any missing physiologic values were assigned a weight of zero (Knaus et al., 1991). The resulting total score, in combination with prior patient treatment location (i.e. ICU readmission versus emergency room) and primary ICU diagnosis provided the level of acuity/ predicted mortality for each patient (Knaus et al., 1991). The total scores were interpreted as follows: 0 to 4 points = 4% mortality rate; 5 to 9 points = 8% mortality rate; 10 to 14 points = 15% mortality rate; 15 to 19 points = 25% mortality rate; 20 to 24 points = 40% mortality rate; 25 to 29 points = 55% mortality rate; 30 to 34 points = 75%mortality rate; and greater than 34 points = 85% mortality rate (Knaus et al., 1991). After the initial score had been determined for the first 24 hours of ICU admission, no new score was calculated during the patient's hospital stay (Knaus et al., 1991). This scoring system has been used to evaluate and improve ICU performance, optimize ICU resource allocation, and better manage the care of critically ill patients (Knaus et al., 1991). The APACHE III has been documented to have a good overall explanatory power ($r^2=0.41$ and ROC= .90; correct classification at a 0.50 risk level of 88.2%) compared to that of previous versions of APACHE and other prognostic scoring systems (Knaus et al., 1991). APACHE III was selected over the APACHE II (ROC= 0.85; correct classification at a

0.50 risk level of 85.5%) for its established increase in explanatory power for patient's level of acuity (Knaus et al., 1991).

Clinical process. The nursing intervention has been conceptualized as nurses' adherence to the implementation of sedation vacation protocols. Nurses' implementation of the sedation vacation protocol was determined using the percentage of nurses' adherence to sedation vacations from the EMR data and the vignettes in the self-report surveys. First, nurses' adherence to the key steps of the sedation vacation protocol was coded dichotomously as "performed=1" or "not performed=0" by using the PDAF to abstract the following data from the EMR: 1) whether the nurse completely turned off the patient's continuous intravenous sedation during the designated morning hours of 7 am to 10 am; and 2) whether the nurse restarted the patient's continuous intravenous sedation at half the previous dose and titrated the agent(s) upward as needed after the completion of the sedation vacation (see Appendix G for the study site's complete sedation vacation protocol). Data were abstracted from day 1 of invasive mechanical ventilation to a maximum of day 14. A total score for each sedation vacation was computed with one point for each of the key steps performed. Total scores for the implementation of the sedation vacation protocol ranged from 0 to 2, with a score of "2" indicating adherence and a score of "< 2" indicating non-adherence to the sedation vacation protocol. In addition, the following data were abstracted from the EMR to ensure that a patient was eligible to receive a sedation vacation and calculate the nurses' adherence rate: the dosage(s) at which the continuous intravenous sedative medication(s) was restarted after completion of the sedation vacation; the duration (in minutes) of the sedation vacation; the type(s) of continuous intravenous sedative medication(s) used; the dosage(s) of

continuous intravenous sedative medication(s) used prior to the sedation vacation; whether or not a spontaneous breathing trial was performed; the duration (in minutes) of the spontaneous breathing trial; the number of spontaneous breathing trials that were performed; and the reason(s) that a sedation vacation was not performed as indicated by the documentation of a nurse and/or physician/midlevel provider.

The second way in which <u>nurses' implementation of the sedation vacation protocol</u> was evaluated was by using multiple-choice questions and vignettes on the ESPICUS to evaluate their level of adherence and perceptions of sedation vacations. Two closed-ended questions on the ESPICUS were used to provide self-report data about nurses' implementation of the sedation vacation protocol. The questions asked nurses to numerically describe the frequency with which they perform sedation vacations for the mechanically ventilated patients under their care using a range of six predetermined responses.

As part of the survey, nurses received seven vignettes developed by the PI and reviewed by experts for content validity. The vignettes were initially administered to two ICU nurses, which were asked to provide feedback on the clarity and clinical relevance of the patient scenarios. Minor revisions were made based on feedback and all vignettes were viewed as clinically relevant. The vignettes described typical clinical situations in the ICU for mechanically ventilated patients in order to determine the clinical judgments that an ICU nurse might make in a patient care situation. The vignettes allowed for the evaluation of a patient situation with a pre-determined outcome and provided the ability to make comparisons of nurses' decisions based on similar clinical findings of the patients presented. The use of vignettes also allowed the PI to examine the relationship of nurses' education and level of ICU experience with the appropriateness with which they implemented the sedation vacation protocol in patients who require invasive mechanical ventilation. For five of the vignettes nurses had to make a decision about whether or not to implement a sedation vacation given the patient information presented (dichotomous coding), and also provide their rationale for that decision. For two of the vignettes, the nurses had to select the action they would take from multiple choices and provide their rationale for that decision. Responses to the vignettes were coded by an expert in critical care. Extensive coding details are provided to guide the scoring of the vignettes, and these details can be found in Appendix B. In general, both the dichotomous score response and the rationale were used to determine the scoring of the vignettes. For example, if the decision to perform a sedation vacation or not was correct and the rationale met the specified written criteria, then the item was scored correct and received a score of "2". If the decision was correct, but the rationale indicated a wrong thought process the item was scored incorrect and received a score of "0". If the decision was correct and the rationale provided justification for the decision, but not all the essential points in the criteria were presented, then a partial score was given and the item was scored a "1". Once the vignettes were coded by the expert, a total score was obtained by summing the value for the coded patient scenarios within the survey. The possible scores ranged from 0-14, with higher scores indicating greater accuracy in following the sedation vacation protocol.

Furthermore, <u>nurses' perceptions of nursing-related barriers/facilitators to</u> <u>implementing sedation vacations</u> were determined by three closed-ended questions on the survey. The close-ended questions allowed the participants to select a response based on a list of choices that included an option for an open-ended response, so as to evaluate the reasons for nurses' level of adherence to the sedation vacation protocol.

Patient outcomes. Patient outcomes have been conceptualized within the proposed model as the outcomes which influence health care quality, and are comprised of three major components: length of ICU stay, duration of mechanical ventilation, and the development of VAP. The PDAF was used to abstract data from the patients' EMRs regarding the three components that comprise the patient outcomes being evaluated in the study. The length of ICU stay, in days, was calculated by determining the date and time of ICU admission and the date and time of transfer out of the ICU or death, and summing the total number of days. In addition, since ICU patients who go to surgery typically return to their designated ICU for recovery, the time (in hours and minutes) spent in surgery was counted as part of the total length of ICU stay. The duration of mechanical ventilation, in hours, was calculated by determining the date and time that each participant was intubated and the date and time of extubation or death, and then summing the total number of hours on mechanical ventilation. The development of VAP was determined by abstracting the associated ICD-9 code, which demonstrates that a participant has been diagnosed by a physician/midlevel provider as having developed VAP. The variable was dichotomously coded as "1=Yes" or "2=No" for the development of VAP.

Data Collection Procedures

Prior to the initiation of data collection, all procedures and instruments were refined, protocol guidelines were established, and IRB approvals were obtained.

Mechanically Ventilated Patients

Data collection began by identifying eligible mechanical ventilated participants in the EMR from a census, provided by the study site's infectious disease nurse, of the patients, with and without VAP, who were previously admitted to a medical/surgical ICU during the time period of September 2009 to August 2010. The PI obtained a Health Insurance Portability and Accountability Act (HIPAA) waiver from the IRB prior to retrieving deidentified study related data from the EMR without the informed consent of the eligible patients due to the nature of the study. The PI solely performed all the abstraction of data from the EMR to ensure consistency in data collection. Retrospective data were collected on all eligible mechanically ventilated patients, for the first 14 days of invasive mechanical ventilation, by abstracting pertinent study related information from the EMR using the PDAF. Patients with VAP were identified from the existing census and then patients without VAP mere randomly selected from each ICU based on the number of patients with VAP from that ICU.

Intensive Care Nurses

Over a two month period, all eligible nursing participants from one large hospital, working in one of five ICUs, received a survey packet in their mailbox to complete anonymously. Consent was indicated by the return of the surveys. The time for each nurse to complete the self-report survey was estimated at approximately 30 minutes. To improve the survey's response rate, the PI implemented the principles of Dillman's Total Survey Method (Rosenbaum & Lidz, 2007) which include: making the survey respondent-friendly, including a stamped return envelope for the paper questionnaires, using five varied contacts with survey recipients, providing an incentive in the same solicitation as the survey itself, and personalizing the correspondence. The PI distributed a respondent-friendly survey by: using a structured survey instrument that was directly associated with nurses' sedation practices in the ICU; and being clear and concise in the design of the survey, given that the participants would not have the opportunity to clarify the questions that were being asked within the questionnaire (Rosenbaum & Lidz, 2007). In addition, the PI placed the answers to the patient scenarios in the nurses' work mailbox approximately 8 weeks after study completion.

The PI also automatically enrolled every participant into an anonymous drawing for a \$100.00 Visa gift card. Two numbered raffle tickets were enclosed with each survey, one of which the participants were asked to keep and the other was to be returned in the self-addressed envelope provided. The nurses' participation in the raffle was not contingent on their participation in the study and they remained eligible for the raffle even if they withdrew from the study or did not complete every question on the survey. At the completion of the study, one ticket was randomly selected and the winning ticket number was posted on flyers in the conference room of each ICU. The participant who possessed the winning ticket number notified their unit director, who contacted the PI for receipt of the gift card. After the gift card was awarded, flyers were posted in the conference room of each ICU in order to let the nursing staff know that the prize had been claimed.

The initial participant contact included a white sealed envelope, with Georgia State University's crest embossed on the front left hand corner, which was distributed to all the medical/surgical ICU nursing staff by placing a single envelope into each of their mailboxes located in the conference room of every ICU. The sealed envelope included: (1) a consent form requesting the nurses' participation in the study; (2) a token gift of a retractable, blue ball point syringe pen that is shaped like a hypodermic needle; (3) two numbered raffle tickets that were used in a random drawing for a \$100.00 Visa gift card; (4) a paper questionnaire; (5) a stamped return envelope for the paper questionnaire; and (6) a predetermined individualized code number with a prefix that designated the ICU that the survey was distributed to. The individualized code numbers were printed on each consent form and paper questionnaire. The prefix that was included as part of the predetermined individualized code numbers provided the PI with the means to identify the ICU locations of the participants who had successfully returned their surveys, so that the ICUs with low response rates could be tracked as needed. The consent form clearly described the purpose of the study and explained why the participant's opinion was being sought (see Appendix C for consent form). The participant contacts were personalized by the PI hand signing each consent form in blue ink so it was clear that signatures were not electronically printed, and adhering individual stamps to all return envelopes instead of using automatic bulk mailing (Rosenbaum & Lidz, 2007). The participants were instructed in the consent form to either return the survey via mail or a locked bin that was centrally located in each ICU's conference room. One week after the sealed envelopes were distributed an e-mail reminder was sent out to all the medical/surgical ICU nursing staff. Three to four weeks after the initial contact was made the ICUs with the lowest number of responders were sent a second e-mail reminder, and paper reminders were placed in the nurses' work-mailboxes. ICUs that continued to have low response rates after six weeks were sent a final e-mail reminder.

Threats to Internal Validity

A fundamental component of this study is its attention to internal validity. Multiple strategies to control for potential extraneous factors that could affect the study were instituted. First, individualized code numbers were used on the nursing surveys as anonymous identifiers, so as to track the response rates of the nurses in each ICU in order to focus recruitment efforts. Secondly, nurses who are invited to complete the ESPICUS were instructed in the cover letter of the specific inclusion/exclusion criteria, with the intention of minimizing the likelihood that ineligible participants would complete the survey. Thirdly, the hospital environment that has been conceptualized within the proposed model as the system characteristics (size of the hospital facility, hospital policies, hospital culture, and available patient care technologies) was not directly evaluated in the proposed study due to lack of feasibility; however, using only one hospital enabled the PI to control for the consistent use of institutional policies and procedures. Fourth, the PI only abstracted data that pertained to the patients' initial intubation. Data that pertained to re-intubation or the re-initiation of mechanical ventilation via tracheostomy were not evaluated given that the resumption of invasive mechanical ventilation is an independent risk factor for the development of VAP (Ibrahim et al., 2001). Additionally, data were only abstracted for the first 14 days that the patient required invasive mechanical ventilation due to lack of feasibility and resources. Fifth, due to the history threat, a retrospective method of data collection was selected so that ongoing changes in clinicians' clinical practice would not inadvertently influence the data obtained from the EMR. Sixth, due to the retrospective method of data collection, there may have been a different cohort of nurses who completed the selfreport survey than those who recorded data in the EMR during the fiscal year of 2010. Therefore, the nurses were asked in the self-report survey how long they have worked in their primary ICU in order to determine if there was overlap. Lastly, the PI abstracted all data from the EMRs of the patients within the study to make certain that there was consistency in this method of data collection.

Data Management

Preliminary Data Analysis

Preliminary analysis included a systematic plan for data entry into SPSS Statistics 20, which was designed to reduce errors during the data entry phase by using a code book (Burns & Grove, 2005). Data entry was followed by the standard data cleaning, which included randomly checking the accuracy of the data points (Burns & Grove, 2005). As a second check of the accuracy of the data, a computer analysis of the frequencies of each value of every descriptive variable related to the study's sample was performed (Burns & Grove, 2005). Distributions and patterns of missing data were then examined, and a determination of whether the information could be obtained and entered into the data file was made (Burns & Grove, 2005). Missing data that could not be obtained were handled by estimating missing data through imputation as appropriate (Munro, 2005). Exploratory analysis of the data was conducted, and based on the evaluation of the analysis there were appropriate steps taken to correct any issues. Outliers in the data were identified by evaluating box plots (Munro, 2005). Outliers in the data were handled by making a determination of whether they represented errors in coding or a failure in the data collection, and if either was present then those observations were either discarded or corrected (Munro, 2005). If the outliers were determined to represent actual values or

their occurrence in the distribution could not be explained, the data were analyzed in two ways: with the outliers in the distribution, and with the outliers removed (Munro, 2005). If the results of the analysis were similar, results with outliers were reported. If the results of the analysis were dissimilar, then a statistical analysis that was resistant to outliers was used (e.g. trimmed mean, winsorized mean) (Munro, 2005). Estimates of central tendency, dispersion, and normality for the variables that are relevant to the study's sample population were examined, and the variables in the theoretical model were screened for singularity and multicollinearity (Burns & Grove, 2003). In addition, descriptive statistics were used to evaluate the characteristics of the study's sample population and major study variables (Burns & Grove, 2005).

Protection of Human Subjects

All risks, benefits, and costs were discussed with the nursing participants prior to their participation in the study via the consent form that was included with the survey. Nursing participants were assured in the consent form that their decision of whether or not to participate in the study would not cause any adverse work-related penalties. In addition, the survey was completely anonymous so that the nursing participants could be reassured that their responses would not cause any damage to their financial standing, employability, or reputation. Nursing participants were also reassured that there would be confidentiality in the maintenance and dissemination of the study's research findings. Study related data were only available to the PI and PI's dissertation committee.

All study-related data obtained from the EMR were coded with individualized participant identification numbers and kept in a locked file cabinet in the PI's personal office. The original PDAFs and ESPICUSs were also kept in a locked file cabinet in the PI's personal office. In addition, no identifying participant information was recorded on the PDAFs or ESPICUSs (Burns & Grove, 2005). The master list of participants' names and code numbers from the EMR was kept separate from the data collected, and no identifying information was attached to any of the instruments used in the study (Burns & Grove, 2005). Furthermore, the data collected from the EMR using the PDAF's "tear sheet" was destroyed after the de-identified data had been abstracted. The data collected for the purposes of the study were entered into computerized files with the use of code numbers for participant identification (Burns & Grove, 2005). After study completion, all study related data were kept in a locked file cabinet in the PI's personal possession.

Analysis Plan for Specific Aims

The following section describes the approach for the statistical analysis of the specific aims, hypotheses, and research questions that were presented for the purposes of this study.

I: Evaluate the health outcomes (development of VAP, ICU length of stay, and duration of mechanical ventilation) of mechanically ventilated patients in relation to intensive care nurses' practices of implementing the sedation vacation protocol.

<u>Hypotheses I a:</u> There will be a relationship between the percentage of sedation vacation days performed and the development of VAP in patients who require invasive mechanical ventilation, controlling for patient characteristics (level of acuity, gender, and age).

<u>Analysis Approach for Hypothesis I a related to Specific Aim I</u>: The percentage of sedation vacation days performed was determined by dividing the number of sedation vacation days performed on each participant by the number of days that each sedated

participant in the study received invasive mechanical ventilation and multiplying by 100%. Analysis of covariance was conducted to evaluate the relationship between the percentage of sedation vacation days performed and the development of VAP in patients who require invasive mechanical ventilation, controlling for the patient characteristics of level of acuity, gender, and age.

<u>Hypotheses I b:</u> Greater adherence to sedation vacation days will be related to shorter ICU length of stay in patients who require invasive mechanical ventilation, controlling for patient characteristics (level of acuity, gender, and age).

<u>Analysis Approach for Hypothesis **I b** related to Specific Aim **I**: The length of ICU stay was determined by summing the total number of days that each mechanically ventilated patient remained in the medical/surgical ICU. Analysis of covariance was conducted to evaluate the relationship between the percentage of sedation vacation days performed and the length of ICU stay in patients who require invasive mechanical ventilation, controlling for the patient characteristics of level of acuity, gender, and age.</u>

<u>Hypotheses **I** c</u>: Greater adherence to sedation vacation days will be related to a shorter duration of intubation in patients who require invasive mechanical ventilation, controlling for patient characteristics (level of acuity, gender, and age).

<u>Analysis Approach for Hypothesis **I c** related to Specific Aim **I**: The duration of mechanical ventilation was determined by summing the total number of hours that each participant required invasive mechanical ventilation in the medical/surgical ICU. Analysis of covariance was conducted to evaluate the relationship between the</u>

percentage of sedation vacation days performed and the duration of intubation in patients who require invasive mechanical ventilation, controlling for the patient characteristics of level of acuity, gender, and age.

II: Identify nursing-related barriers and facilitators that are associated with the consistent (daily) implementation of the sedation vacation protocol in mechanically ventilated patients.

<u>Research Question related to Specific Aim II</u>: What are nurses' perceptions of the barriers and facilitators to implementing the sedation vacation protocol in patients who require invasive mechanical ventilation?

<u>Analysis Approach for the Research Question related to Specific Aim II</u>: The concepts identified by the closed-ended items in the ESPICUS were descriptively analyzed using frequencies. The concepts identified by the open-ended items in the ESPICUS were content coded and reported based on their frequency of occurrence.

III: Determine whether nursing characteristics are associated with the consistent (daily) implementation of the sedation vacation protocol in mechanically ventilated patients.

<u>Research Question</u>: Are nursing characteristics (education, level of intensive care experience) associated with the appropriate implementation of the sedation

vacation protocol in patients who require invasive mechanical ventilation?

<u>Analysis Approach for the Research Question related to Specific Aim III</u>: One-sample *t* tests were conducted to examine the functional relationships between nursing characteristics (education and level of intensive care experience) and the implementation of the sedation vacation protocol as evaluated through the nurses' vignette scores.

IV: Determine whether nurses' adhere to the sedation vacation protocol consistently (daily) in mechanically ventilated patients.

<u>Research Question</u>: What was the adherence rate of sedation vacations in sedated mechanically ventilated patients in the ICU?

<u>Analysis Approach for the Research Question related to Specific Aim IV</u>: The adherence rate of sedation vacations in sedated mechanically ventilated patients was determined by dividing the total number of participants who had sedation vacations by the total number of days (up to 14 days) ventilated and receiving sedation, then multiplying by 100%. The shape of the data distribution, measures of central tendency, measures of dispersion, and the frequency of specific values were evaluated.

CHAPTER IV

RESULTS

This chapter presents the results of this correlational study to evaluate patient outcomes and identify the most salient factors that are associated with nurses' implementation of a sedation vacation protocol. Descriptions of the sample characteristics, findings from the measurements used in this sample, and results of hypotheses testing and research questions are reported.

ICU Nurse Sample

Between July and September 2012, 100 medical/surgical ICU nurses in this study in a mid-size urban city at a large metropolitan hospital were invited to participate. The overall survey response rate was 35% (see Figure 2).

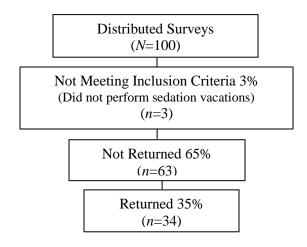


Figure 2. Response Rate for Nurse Participants

Nurse Participants' Characteristics

Table 1 summarizes the descriptive statistics for the characteristics of nurse participants. Most nurses held a Bachelor of Science in Nursing, had at least nine years of clinical critical care experience, worked in a medical ICU, and rated their confidence when managing continuous intravenous sedation in mechanically ventilated patients as high. Most nurses also reported that a large percentage of the patients who they cared for were mechanically ventilated. The majority of the nurses had not completed a post registration qualification in intensive care (e.g. CCRN, PCCN, and CCNS). Additionally, the majority of nurses worked in the primary ICU in which they were currently practicing for less than 10 years.

Table 1

Nurse Characteristics (n = 34)

Range (observed)	M(SD)	%	<i>(n)</i>
		26.5	(9)
		70.6	(24)
		2.9	(1)
		20.6	(7)
		14.7	(5)
		17.6	(6)
		17.6	(6)
		2.9	(1)
		26.5	(9)
	Kange (observed)	Kange (observed) M (SD)	26.5 70.6 2.9 20.6 14.7 17.6 17.6 2.9

(Table 1 continues)

(Table 1 continued)

Type of ICU		
Medical ICU	47.1	(16)
Coronary ICU	11.8	(4)
Neurosurgical ICU	20.6	(7)
Cardiothoracic ICU	11.8	(4)
Medical-Surgical ICU	8.8	(3)
Years worked in the primary ICU in which they practice		
0-3 years	35.3	(12)
4-6 years	29.4	(10)
7-9 years	11.8	(4)
10-12 years	5.9	(2)
13-15 years	2.9	(1)
20 + years	14.7	(5)
Achievement of a post registration qualification in intensive care		
No	64.7	(22)
Yes	35.3	(12)
Level of confidence when managing sedation		
6-10 8.88 (1.25)		
1-3=Low confidence	0	(0)
4-7=Medium confidence	14.7	(5)
8-10=High Confidence	85.3	(29)
Percentage of patients under their care who are mechanically ventilated		
0-25%	5.9	(2)
26-50%	55.9	(19)
51-75%	23.5	(8)
76-100%	14.7	(5)

Note. ¹For all other analysis, Masters Degree was included with Bachelor's Degree

Descriptive Statistics for Nurses' Perceptions of Sedation Vacations

Table 2 summarizes descriptive statistics for the nurse participants' perceptions of sedation vacation implementation in the ICU. Most nurses felt that there was an association between the sedation administered and the patient outcomes for mechanically ventilated patients under their care. When asked about the most commonly used sedation

regimens, the majority of nurses reported "Midazolam + Fentanyl" as the most frequently used regimen for their patients who required invasive mechanical ventilation and "Diprivan, as a single agent," as the second most common. Most nurses also reported that they used the sedation vacation protocol for the majority of the intubated patients under their care, and that all mechanically ventilated patients should be managed with this protocol. Though, 20.6% of the nurses either did not know that the clinical site had an established sedation vacation protocol or were unsure. Of the nurses (17.6%, n = 6) who reported that the sedation vacation protocol should not be routinely used in all mechanically ventilated patients, all felt that patients admitted to the neurosurgical ICU should be excluded.

Table 2

Nurses' Perceptions	s of Sedation	Vacations in	ICU(n=34)
---------------------	---------------	--------------	-----------

	%	(<i>n</i>)
Association between sedation administered and patient outcome	e	
Yes	73.5	(25)
No	8.8	(3)
Unsure	14.7	(5)
Percentage of patients who the sedation vacation protocol is use	ed for	
\leq 25%	17.6	(6)
> 25-75%	14.7	(5)
>75-100%	58.8	(20)
Unfamiliar with this strategy	2.9	(1)
Does the ICU have a sedation vacation protocol?		
Yes	79.4	(27)
No	11.8	(4)
Unsure	8.8	(3)

(Table 2 continues)

(Table 2 continued)

Should all intubated patients be managed with a sedation vacation prote	ocol?	
Yes	82.4	(28)
No	17.6	(6)
Most frequently used sedation regimen		
Midazolam + Fentanyl	61.8	(21)
Diprivan, as a single agent	29.4	(10)
Other (e.g. Dexmedetomidine, Lorazepam, Morphine)	8.8	(3)

Major Study Variables

Prior to addressing the hypotheses and research questions, data were examined for errors of data entry, normal distribution, presence of outliers, and missing data as outlined by Field (2009). The results from the following study variables were positively skewed: length of ICU stay, duration of mechanical ventilation, and sedation vacation adherence rate. Data transformation did not improve the distributions (Field, 2009). There were three nurses who had a missing composite score due to an omission of one or more of their vignette responses. Therefore, their missing values were replaced with the mean scores of all other participants for that variable (George & Mallery, 2009).

Nursing-related barriers. Table 3 summarizes descriptive statistics for the ICU nurses' perception of the nursing-related barriers to implementing the sedation vacation protocol. To address the research question related to specific aim II, participants were asked to identify the three most important reasons that a daily interruption of sedation therapy was not used for all mechanically ventilated patients under their care in the ICU. The nurses reported that the three most common primary perceived barriers to the implementation of the sedation vacation protocol were the possibility of respiratory compromise, possibility of patient-initiated device removal, and inconvenience of

coordinating with observers' availability. To further evaluate the perceived barrier of patient-initiated device removal, nurses were asked to report the percentage of daily interruptions of sedation therapy that they felt were associated with an adverse event (e.g. self-extubation or central line removal) in mechanically ventilated patients. The majority of nurses (61.8%, n = 21) estimated the percentage of adverse events to be relatively low (1-10%). However, 58.8% (n = 20) of nurses reported that they had personally experienced an adverse event when they were implementing a daily interruption in sedation therapy for a mechanically ventilated patient under their care. Of the adverse events that nurses had personally experienced, self-extubation (50%, n = 17) was the most common.

Table 3

Nursing-Related Barriers t	• Implementing the Sedation	<i>Vacation Protocol</i> $(n = 34)^1$
----------------------------	-----------------------------	---------------------------------------

	%	<i>(n)</i>
Possibility of respiratory compromise	70.6	(24)
Possibility of patient-initiated device removal	55.9	(19)
Inconvenient to coordinate with observers' availability	29.4	(10)
Possibility of compromising patient comfort	26.5	(9)
Possibility of cardiac ischemia	17.6	(6)
Nursing staff preferences	8.8	(3)
No Proven Benefit	5.9	(2)
Patients get over-sedated	5.9	(2)
Patients get under-sedated	5.9	(2)
Need for more control of sedation use	2.9	(1)

Note. ${}^{1}n$ varied due to nurses being able to select more than one option

Nursing-related facilitators. Table 4 summarizes descriptive statistics for the ICU nurses' perception of the nursing-related facilitators to implementing the sedation vacation protocol. To further address the research question related to specific aim II, nurses were asked to identify the strategies that would most effectively improve their implementation of daily interruptions of sedation therapy in mechanically ventilated patients. Nurses reported that the three most common perceived facilitators to implementing the sedation vacation protocol were improving the convenience of implementing sedative interruptions (e.g. a nurse driven buddy system to help monitor patients), avoiding excessive workload and/or staff shortages, and implementing multimodal interventions (e.g. a combination of staff education, posters, and audits). Table 4

Nursing-Related Facilitators to Implementing the Sedation Vacation Protocol $(n = 34)^{1}$

	%	(<i>n</i>)
Improving the convenience of implementing sedative interruptions	50	(17)
Avoiding excessive workload and/or staff shortages	35.3	(12)
Multimodal interventions	20.6	(7)
Individual performance feedback from nurse managers/unit directors	2.9	(1)

Note. ¹Percents add to more than 100 because nurses were able to select more than one option

Association of nursing characteristics and the implementation of sedation vacations. To address the research question related to specific aim III, parametric and non-parametric analysis were both evaluated and the results were determined to be similar. Therefore, the results of independent-samples *t* tests are reported for the comparison of nursing characteristics (level of nursing education and completion of a

post registration qualification in intensive care) with the appropriate implementation of the sedation vacation protocol (indicated by the nurses' vignette composite scores) in patients who require invasive mechanical ventilation. There was no significant difference in adherence to the sedation vacation protocol for nurses with baccalaureate or higher education (M = 7.04, SD = 2.34) and those with an associate's degree (M = 6.78, SD =1.92; t(32) = .30, p = .77), or for those nurses who had completed a post registration qualification in intensive care (M = 6.00, SD = 2.22) and those who had not (M = 7.50, SD = 2.06; t(32) = 1.98, p = .06). The results of a Pearson's correlation coefficient are reported for the relationship between nurses' years of ICU experience and their appropriate implementation of the sedation vacation protocol in intubated patients. Nurses' years of ICU experience was not associated with the appropriate implementation of sedation vacations using the standardized vignette scores, r = -.05, p = .78.

Vignette scores were computed two ways. First, a total score of whether the nurse had made the correct decision that a sedation vacation was needed or not was obtained. This score had a possible range of 0-7. On average nurses got M = 4.97(SD=1.11) of the vignettes correct with an observed range of 3-7. The percent of nurses who got the correct answer to the simple dichotomous (Yes, No) decision of whether to conduct a sedation vacation is included in Table 5.

	Correct 9	% (n)	Incorrect	% (n)
Intubated for elective knee surgery (V1)	100	(34)	0	(0)
Intubated for Acute Respiratory Distress Syndrome (V2)	50	(17)	50	(17)
Intubated for drug overdose (V3)	91.2	(31)	8.8	(3)
Intubated for active seizures (V4)	61.8	(21)	38.2	(13)
Intubated for an allergic reaction (V5)	79.4	(27)	20.6	(7)
Restless and agitated (V6)	58.8	(20)	41.1	(14)
Responsive only to noxious stimuli (V7)	55.9	(19)	35.2	(12)

Accuracy of Nurse Participants' Vignette Decisions to Perform a Sedation Vacation (n = 34)

Note. n varied due to missing data

Secondly, scoring of the vignettes was completed by including the rationale for the decision provided by the nurse. The nurse could receive no credit, full credit, or partial credit with this scoring, with the possible total score ranging from 0-14. On average nurses scored M = 6.97, SD = 2.21 with an observed range of 3-12. The percent of nurses getting each item correct, incorrect, or partially correct when including the rationale in the scoring is illustrated in Table 6.

Table 6

Nurse Participants' Decision Making for Sedation Vacation Vignettes (n = 34)

	Correct		Partially Correct		Incorrect	
	%	(<i>n</i>)	%	(<i>n</i>)	%	<i>(n)</i>
Intubated for elective knee surgery (V1)	29.4	(10)	50	(17)	20.6	(7)
Intubated for Acute Respiratory Distress Syndrome (V2)	20.6	(7)	14.7	(5)	64.7	(22)
Intubated for drug overdose (V3)	58.8	(20)	23.5	(8)	17.6	(6)
Intubated for active seizures (V4)	61.8	(21)	0	(0)	38.2	(13)
Intubated for an allergic reaction (V5)	29.4	(10)	38.2	(13)	32.4	(11)
Restless and agitated (V6)	17.6	(6)	32.4	(11)	50	(17)
Responsive only to noxious stimuli (V7) Note. n varied due to missing data	38.2	(13)	17.6	(6)	35.3	(12)

Mechanically Ventilated Patient Sample

Between July and September 2012, 158 patients were enrolled in this study by obtaining a census, from the study site's infectious disease nurse, of the mechanically ventilated patients who were previously admitted to a medical/surgical ICU in a large metropolitan hospital during the fiscal year of 2010. Figure 3 provides details about the enrollment of the mechanically ventilated participants.

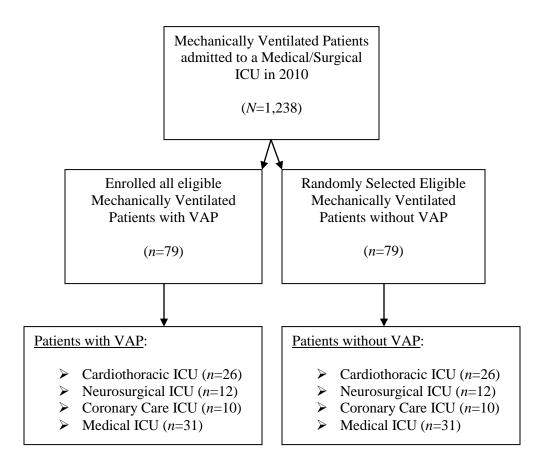


Figure 3. Enrollment of Mechanically Ventilated Participants

Mechanically Ventilated Participants' Characteristics

Table 7 summarizes the descriptive statistics for the characteristics of the mechanically ventilated participant sample. The majority of patients were Black, male, and middle-aged, although ages ranged from 18-94. Most patients also had a long ICU length of stay and duration of mechanical ventilation. Additionally, mechanically ventilated patients were predominately admitted to the medical ICU with a high level of acuity. There were no significant statistical differences between the patient characteristics of those participants with VAP and those without VAP.

Table 7

Characteristics	Range (observed)	M (SD)	%	(<i>n</i>)
Age (years)	18-94	61.5(14.91)		
Gender				
Male			56.3	(89)
Female			43.7	(69)
Ethnicity				
American Indian/Alas	kan		1.3	(2)
Asian/Pacific Islander	•		2.5	(4)
Black, not Hispanic			58.2	(92)
Hispanic			0.6	(1)
White, not Hispanic			35.4	(56)
Other			1.9	(3)
Type of ICU				
Medical ICU			39.2	(62)
Coronary Care ICU			13.3	(21)
Neurosurgical ICU			15.2	(24)
Cardiothoracic ICU			32.3	(51)
Level of Acuity	11-151	70.2(25.42)		
ICU Length of Stay	2-97	15.5(11.84)		
Duration of Mechanical Vent	ilation 2-47	9.5(8.47)		
Adverse Events				
Self-Extubation			3.0	(4)
Catheter Removal			0	(0)

Mechanically Ventilated Patient's Characteristics (n = 158)

Adherence rate of sedation vacations. To address the research question related to specific aim IV, the following criteria were initially examined to evaluate nurses' implementation of the sedation vacation protocol using data abstracted from the EMR: 1) whether the nurse completely turned off the patient's continuous intravenous sedation during the designated morning hours of 7 am to 10 am; and 2) whether the nurse restarted the patient's continuous intravenous sedation at half the previous dose and titrated the agent(s) upward as needed after the completion of the sedation vacation. However, during the preliminary analysis it was determined that for 88% of the ventilator days that sedation vacations were to be performed, nurses did not implement both designated criteria. Therefore, the decision was made to use only the criterion of whether the nurse completely turned off the patient's continuous intravenous sedation during the designated time to represent that a sedation vacation was performed. This was summed and divided by the number of days (up to 14 days) ventilated and receiving sedation. Using this criterion, the total adherence rate of sedation vacations in sedated mechanically ventilated patients in the ICU was considered to be low (observed range= 0-100%; M = 24%; Mdn =20%; SD = 23%). A one-way analysis of variance (ANOVA) was also conducted to evaluate the relationship between each type of ICU (factor) and nurses' rate of adherence to sedation vacations (dependent variable). There were no significant differences in nurses' adherence to the sedation vacation protocol within any of the ICUs evaluated, F (3, 154) = 1.08, p = .36. The means and standard deviations for nurses' adherence to sedation vacations in each ICU are presented in Table 8.

Table 8

 Type of ICU	M (SE)
Medical ICU	26% (3%)
Coronary ICU	28% (5%)
Neurological ICU	24% (4%)
Cardiothoracic ICU	20% (3%)

One-Way Analysis of Variance for Nurses' Adherence to Sedation Vacations in each ICU

Hypothesis testing. To address the hypotheses related to specific aim I, one-way analysis of covariance (ANCOVA) was used to evaluate the health outcomes (development of VAP, ICU length of stay, and duration of mechanical ventilation) of mechanically ventilated patients in relation to intensive care nurses' practices of implementing the sedation vacation protocol (see Table 9). Table 9

Patient Outcome	Adherence to Sedation Vacations Adj. <i>M</i> (<i>SE</i>)	F	<i>p</i> -value
Development of VAP			
No VAP $(n = 79)$	31% (3%)	14.17	<.001
Diagnosed VAP $(n = 79)$	17% (3%)		
Length of ICU stay			
≤ 13 days (<i>n</i> = 80)	29% (3%)	8.55	< .01
>13 days ($n = 78$)	19% (3%)		
Duration of mechanical ventilation			
≤ 6 days ($n = 84$)	28% (3%)	6.37	.04
>6 days ($n = 74$)	19% (3%)		

ANCOVA for Patient Outcomes related to Nurses' Adherence to Sedation Vacations, Controlling for level of acuity, gender, and age

Evaluation of Adherence to Sedation Vacations and Patient Outcomes

There will be a relationship between the percentage of sedation vacation days performed and the development of VAP in patients who require invasive mechanical ventilation, controlling for patient characteristics (level of acuity, gender, and age) (Hypothesis A).

A one-way analysis of covariance was conducted. The independent variable, development of VAP, included two levels: diagnosis of VAP and no diagnosis of VAP. The dependent variable was the percentage of sedation vacation days performed and the covariates were level of acuity, gender, and age. A preliminary analysis evaluating the homogeneity-of-slopes assumption indicated that the relationship between the covariate, level of acuity, and the dependent variable did not differ significantly as a function of the independent variable, F(1, 150) = 4.61, MSE = .05, p = .06, partial $\eta^2 = .03$. Moreover, the homogeneity-of-slopes assumption indicated that the relationship between the covariate, gender, and the dependent variable did not differ significantly as a function of the independent variable, F(1, 150) = 2.33, MSE = .05, p = .13, partial $\eta^2 = .02$. The homogeneity-of-slopes assumption indicated that the relationship between the covariate, age, and the dependent variable also did not differ significantly as a function of the independent variable, F(1, 150) = .61, MSE = .05, p = .44, partial $\eta^2 = .004$. The ANCOVA was significant F(1, 153) = 14.17, MSE = .05, p < .001. The strength of relationship between the development of VAP factor and dependent variables was moderately strong, as assessed by a partial η^2 , with the development of VAP factor accounting for 9% of the variance of the dependent variable, holding constant the level of acuity, gender, and age. The mean of the percentage of sedation vacation days performed adjusted for initial differences was ordered as expected across the two groups. The group with no diagnosis of VAP had a significantly larger adjusted average of adherence to sedation vacations than the group with the diagnosis of VAP (see Table 9). Thus, the hypothesis was supported.

Greater adherence to sedation vacation days will be related to shorter ICU length of stay in patients who require invasive mechanical ventilation, controlling for patient characteristics (level of acuity, gender, and age) (Hypothesis B).

A one-way analysis of covariance was conducted using a median split of the participants' ICU length of stay. The independent variable, ICU length of stay (observed range= 2-97; M = 15.45; Mdn = 13; SD = 11.84), included two levels: ICU length of stay ≤ 13 days (n = 80) and ICU length of stay >13 days (n = 78). The dependent variable was nurses' adherence to sedation vacation days and the covariates were level of acuity, gender, and age. A preliminary analysis evaluating the homogeneity-of-slopes assumption indicated that the relationship between the covariate, level of acuity, and the

dependent variable did not differ significantly as a function of the independent variable, F(1,150) = 4.45, MSE = .05, p = .06, partial $\eta^2 = .03$. Moreover, the homogeneity-ofslopes assumption indicated that the relationship between the covariate, gender, and the dependent variable did not differ significantly as a function of the independent variable, F(1,150) = .01, MSE = .05, p = .92, partial $\eta^2 = .00$. The homogeneity-of-slopes assumption indicated that the relationship between the covariate, age, and the dependent variable also did not differ significantly as a function of the independent variable, F(1, 1)150 = 3.57, *MSE* = .05, *p* = .06, partial η^2 = .02. The ANCOVA was significant *F* (1, 153) = 8.55, MSE = .05, p < .01. The strength of relationship between the ICU length of stay factor and dependent variables was small, as assessed by a partial n^2 , with the ICU length of stay factor accounting for 5% of the variance of the dependent variable, holding constant the level of acuity, gender, and age. The group with an ICU length of stay < 13days had a significantly larger adjusted average of adherence to sedation vacations than the group with an ICU length of stay >13 days (see Table 9). Thus, the hypothesis was supported.

Greater adherence to sedation vacation days will be related to a shorter duration of intubation in patients who require invasive mechanical ventilation, controlling for patient characteristics (level of acuity, gender, and age) (Hypothesis C).

A one-way analysis of covariance was conducted using a median split of the participants' duration of mechanical ventilation. The independent variable, duration of mechanical ventilation (observed range= 2-47; M = 9.50; Mdn = 6; SD = 8.47), included two levels: duration of mechanical ventilation ≤ 6 days (n = 84) and duration of mechanical ventilation > 6 days (n = 74). The dependent variable was nurses' adherence

to sedation vacation days and the covariates were level of acuity, gender, and age. A preliminary analysis evaluating the homogeneity-of-slopes assumption indicated that the relationship between the covariate, level of acuity, and the dependent variable did not differ significantly as a function of the independent variable, F(1,150) = 1.95, MSE = .05, p = .16, partial $\eta^2 = .01$. Moreover, the homogeneity-of-slopes assumption indicated that the relationship between the covariate, gender, and the dependent variable did not differ significantly as a function of the independent variable, F(1,150) = .01, MSE = .05, p = .67, partial $\eta^2 = .001$. The homogeneity-of-slopes assumption indicated that the relationship between the covariate, age, and the dependent variable also did not differ significantly as a function of the independent variable, F(1, 150) = 2.37, MSE = .05, p = .13, partial $\eta^2 =$.02. The ANCOVA was significant F(1, 153) = 6.37, MSE = .05, p = .04. The strength of relationship between the duration of mechanical ventilation factor and dependent variables was small, as assessed by a partial n^2 , with the duration of mechanical ventilation factor accounting for 4% of the variance of the dependent variable, holding constant the level of acuity, gender, and age. The group who had a duration of mechanical ventilation < 6 days had a significantly higher adjusted average of adherence to sedation vacations than the group who had a duration of mechanical ventilation > 6days (see Table 9). Thus, the hypothesis was supported.

Summary

This chapter presented the results of a correlational study to evaluate patient outcomes (development of VAP, ICU length of stay, and duration of mechanical ventilation) and identify the most salient factors that are associated with nurses' implementation of a sedation vacation protocol. A description of participants' characteristics, descriptive statistics of survey responses, and results of hypothesis testing were reported.

CHAPTER V

DISCUSSION AND CONCLUSIONS

This chapter presents a discussion of the study findings and conclusions. A discussion of the study limitations, strengths of the study, future research, and implications for practices are also presented for consideration.

Nurses' adherence to implementing the sedation vacation protocol was low. On average, sedation vacations were implemented about one-fifth of the expected time. This was with adjusting the criteria to only meet one of the key steps of the sedation vacation protocol. These findings are consistent with several other studies that have demonstrated that the implementation of other evidence-based practices, such as hand-hygiene and oral care, are often also suboptimal (O'Keefe-McCarthy et al., 2008; Sedwick et al., 2012; van Achterberg et al., 2008; Wip & Napolitano, 2009). When the sedation was turned off, nurses often did not resume the sedation at one-half the previous dose as stipulated in the protocol. Returning the sedation to the full, previous dose is problematic because it can potentially lead to over-sedation, which can cause delirium, more neurologic investigations for altered mental status, and delayed awakening (Salluh et al., 2009). Furthermore, when nurses' decision making about their rationale for implementing the sedation vacations was evaluated through the use of standardized vignettes, most nurses did not make accurate decisions. This is the first study known to date that assessed ICU nurses' decision making related to implementing sedation vacations in mechanically ventilated patients. Thus, this study adds to the limited body of literature related to

nurses' implementation of a sedation vacation protocol by quantifying nurses' level of adherence to this evidenced-based practice, in relation to the health outcomes of critically ill patients, and identifying the barriers and facilitators to performing sedation vacations.

Health Outcomes of Mechanically Ventilated Patients

In this sample of mechanically ventilated patients who generally had a high level of acuity and experienced a long ICU length of stay and duration of mechanical ventilation, those who developed VAP had a lower percentage of sedation vacations implemented according to the established protocol. The finding of significantly lower adherence rates in patients with VAP compared to those that did not develop VAP is consistent with the literature in that they had a longer length of ICU stay and duration of mechanical ventilation. These findings are congruent with several studies that have demonstrated that the implementation of routine interruptions of continuous intravenous sedation leads to a decrease in the development of VAP, ICU length of stay, and duration of mechanical ventilation (Bouadma et al., 2012; Girard et al., 2008; J. P. Kress et al., 2000; Morris et al., 2011; Quenot et al., 2007; J. Rello et al., 2012; Ruffell & Adamcova, 2008; Schweickert et al., 2004; Sessler & Varney, 2008).

Conversely, the findings of the current study contrast with those of a randomized controlled trial of 430 critically ill, mechanically ventilated adults conducted by Mehta et al. (2012) in 16 tertiary care medical and surgical ICUs in Canada and the United States between January 2008 and July 2011. The purpose of this multicenter randomized controlled trial was to compare protocolized sedation with protocolized sedation plus daily sedation interruption in critical ill mechanically ventilated patients (Mehta et al., 2012). Nurses' rate of adherence with daily sedation interruption was substantially higher

than our study findings, with protocol adherence being 72.2% of all eligible study days for an average patient and 85.6% for all eligible patient days (Mehta et al., 2012). The authors also found that there were no between-group differences in patients' median time to successful extubation, ICU or hospital length of stay, hospital mortality, delirium, rates of unintentional device removal, ICU neuroimaging, barotrauma, organ dysfunction, or tracheostomy placement (Mehta et al., 2012). Nonetheless, in a small pre-specified subgroup analysis, surgical and trauma patients who were randomized to protocolized sedation plus daily interruption of sedation were found to have a significantly shorter time to successful extubation than those randomized to the protocolized sedation alone (control group) (6 versus 23 days; hazard ratio 2.55; 95% CI, 1.40 to 4.55), whereas there was no difference among the study's medical patients (9 versus 8 days; hazard ratio, 0.92; 95% CI, 0.72 to 1.18; P value for the interaction=.004) (Mehta et al., 2012). These findings should be considered in the context of several methodological differences between the current study and this randomized controlled trial. First, the purposes of the studies differ in that Mehta et al.'s (2012) primary study outcome was to assess patients' time to successful extubation. Second, this study consisted of both medical patients and a diverse sample of surgical patient populations, which included medical-surgical, cardiothoracic, and neurosurgical participants. Third, the sedation protocols used in both studies differed in that the protocol implemented in their randomized controlled trial prioritized pain assessment, whereas in this study the protocol prioritized the adequacy of patients' level of wakefulness (Mehta et al., 2012). Fourth, the nurses in this study used a different sedation scale (i.e. MAAS) than those who participated in the randomized control trial (i.e. Sedation-Agitation Scale or the Richmond Agitation Sedation Scale) to

titrate the patients' sedative infusions (Mehta et al., 2012). Fifth, the data of patients who were no longer receiving a continuous intravenous sedative infusion were excluded from this study's analysis, whereas oral or bolus intravenous therapy was used as needed in patients that did not require the use of continuous sedation in the randomized controlled trial (Mehta et al., 2012). Sixth, our study included the use of Propofol and Dexmedetomidine, while these agents were not used in the randomized control trial (Mehta et al., 2012). Lastly, the results of their randomized controlled trial contrast with those of several earlier trials that support the use of daily interruptions of sedative infusions in mechanically ventilated patients (Bouadma et al., 2012; Girard et al., 2008; Kress et al., 2000; Morris et al., 2011; Quenot et al., 2007; Rello et al., 2012; Ruffell & Adamcova, 2008; Schweickert et al., 2004; Sessler & Varney, 2008). Therefore, future research is needed to discern the discrepancy between the results of the recent randomized control trial and studies that demonstrate that the use of sedation vacations reduce patients' duration of mechanical ventilation and ICU length of stay.

Nursing-Related Barriers and Facilitators

Most nurses in this study were educated, experienced in critical care, and confident in their ability to manage continuous intravenous sedation in mechanically ventilated patients. The three most common perceived barriers to their implementation of the sedation vacation protocol included the possibility of respiratory compromise, possibility of patient-initiated device removal, and inconvenience of coordinating with observers' availability. These findings support the results of a study by Tanios et al. (2009), which reported that the three most common primary perceived barriers to the use of daily sedation interruption among their study respondents included the potential for

respiratory compromise (26%), the lack of nursing acceptance (22%), and concern about patient-initiated device removal (20%). Similarly, Ricart, Lorente, Diaz, Kollef, & Rello (2003) found that the most important barriers to nursing adherence with evidenced-based guidelines for preventing VAP included: unavailability of resources (37%), patient discomfort (8.2%), disagreement with the interpretation of reported studies (7.8%), and fear of potential adverse events (5.8%). Since the perceived barrier of patient-initiated device removal has been demonstrated to be a common safety concern for nurses (Berry & Zecca, 2012; Efrati et al., 2010; Ricart et al., 2003), in this study participants were also asked to report the percentage of daily interruptions of sedation therapy that they felt were associated with an adverse event in mechanically ventilated patients. Most nurses estimated the overall percentage of adverse events to be low. Of the mechanically ventilated participants evaluated in this study, only 3% (n = 4) experienced self-extubation and there were no documented occurrences of catheter removal in the EMR data. Similar findings have also been demonstrated in several other studies, which reported no significant difference in adverse events (e.g. self-extubation and removal of central venous catheters) between groups that received sedation vacations and groups that did not (Berry & Zecca, 2012; Girard et al., 2008; Kress et al., 2000; Mehta et al., 2008; Quenot et al., 2007). Nonetheless, most nurses in this study reported that they had personally experienced an adverse event during the implementation of a sedation vacation. This is perhaps explained by the fact that most individuals have an increased recollection of events that are deemed to be traumatic, though they acknowledge that the actual occurrence of adverse events is minimal. This finding may be important in nurses' willingness to "take a risk" with implementing a sedation vacation, if they expect that an

adverse event may occur. A nurse's personal experience with an extubation may contribute to him/her being over cautious with future patients. Little is known about how nurses deal with low occurring adverse events that are related to sedation interruption and how these may affect practice.

Most nurses reported that the three most common perceived facilitators to their implementation of the sedation vacation protocol included improving the convenience of implementing sedative interruptions, avoiding excessive workload and/or staff shortages, and implementing multimodal interventions. These findings support previous literature that has demonstrated the utility of similar strategies to effectively facilitate evidencedbased nursing practice, which include: multimodal interventions, interventions that are aimed at improving the accessibility/convenience of evidenced-based practice, and interventions that provide performance feedback (Hugonnet, Perneger, & Pittet, 2002; Leasure, Stirlen, & Thompson, 2008; Mathai et al., 2011; McLaws, Pantle, Fitzpatrick, & Hughes, 2009; O'Keefe-McCarthy et al., 2008; Petroudi, 2009; Picheansathian, Pearson, & Suchaxaya, 2008; Rao et al., 2009; Rigbe et al., 2005).

Association of Nursing Characteristics and Sedation Vacations

None of the nursing characteristics (education, level of intensive care experience) evaluated were found to be related to the nurses' ability to appropriately implement the sedation vacation protocol in mechanically ventilated patients. When evaluating both their decision about whether or not to implement a sedation vacation and their rationale for that decision, many nurses had low scores indicating that nurses may not fully understand how to assess a patient for the appropriate use of sedation vacations. When only the accuracy of their (Yes, No) decisions to perform a sedation vacation was evaluated, the majority of nurses' exhibited appropriate decision making in most instances. However, there is a fifty/fifty chance to guess the answer correctly. This makes the inclusion of the nurses' rationale for his/her decision essential to fully understand the basis of the decision making. Including the rationale for making a decision may also help inform the development of future interventions that include focused education to increase nurses' understanding of the indications for sedation vacations. The lack of a difference between years of ICU experience, nursing education levels, and advanced certification and the nurses' ability to appropriately implement the sedation vacation protocol are inconsistent with earlier studies. Typically nurses' level of experience has been found to be associated with better quality of sedation and the tendency to sedate patients less often (Walker & Gillen, 2006).

Although nurses had relatively low scores on the standardized vignettes, the majority of nurses' rated their confidence when managing continuous intravenous sedation in mechanically ventilated patients as high. This indicates that the nurses surveyed are likely overconfident in their ability to appropriately implement sedation vacations. Similar findings were demonstrated in a study by Walker and Gillen (2006), which also found that nurses reported a high confidence level when managing patients' sedation. However, less than half of the nurses within that study said that they would stop (40%, n=37) and restart sedation (48%, n=44), within the prescribed limitations of their orders, depending on their patients' sedation score (Walker & Gillen, 2006). These findings may indicate that although nurses are confident in their ability to manage sedation in mechanically ventilated, there is discordance with the appropriateness in

which they implement sedation vacations. Also, if nurses are confident in their ability, it is not likely that they will seek education about how to improve their practice in this area.

Adherence of Sedation Vacations

Nurses' adherence to the sedation vacation protocol was determined to be exceptionally low, when compared to a similar study by Ricart et al. (2003) that assessed nurses' adherence to non-pharmacologic evidenced-based guidelines for preventing VAP. In that study the overall rate of adherence to the guidelines was reported to be 77.7% (Ricart et al., 2003). This substantial difference may be attributed to their evaluation of non-pharmacologic interventions (i.e. hand-washing, tooth-brushing, and chest physiotherapy) or the implementation of their study in a European country that may have different nursing practices. Nonetheless, the findings of the current study may still be representative of nurses' adherence to sedation vacations in other large metropolitan hospitals given that several studies have demonstrated that nurses' adherence to similar evidenced-based practices is internationally suboptimal; on average ranging from 18-50% (Cochrane et al., 2007; Lam et al., 2004; Mathai et al., 2011; Pincock, Bernstein, Warthman, & Holst, 2012; Rao et al., 2009; van Achterberg et al., 2008).

Limitations of the Study

The study findings must be considered in the context of some limitations. The first limitation is that the study was performed in a single, large metropolitan hospital. Therefore, the results may not translate to patients from small community hospitals. However, by using one hospital, there was control in the administrative policies for nursing practice and a standard protocol. The second limitation is that we were unable to assess the potential influence of the different mechanisms of action and pharmacokinetics of the sedative agents used in the sedation vacations. For example, there are numerous studies demonstrating that the continuous infusion of benzodiazepines has been associated with a longer duration of mechanical ventilation when compared to propofol therapy (Carson et al., 2006; Fong, Kanji, Dasta, Garpestad, & Devlin, 2007; Jakob et al., 2012). There are a number of possible explanations for this difference in outcome, which may include the rapid decline in plasma concentrations when propofol infusions are held (Carson et al., 2006). The pharmacokinetics of benzodiazepines are typically stable with continuous administration, but the plasma clearance rate has been shown to be slower than that of propofol (Carson et al., 2006). Therefore, even though sedation vacations were performed with each class of sedatives, because of differences in drug clearance, patients in the propofol group, for instance, may have had a more rapid or effective awakening, which resulted in better SBTs and earlier extubation (Carson et al., 2006). The third limitation is that the diagnosis of VAP was made retrospectively and was based on those patients who were clinically treated for VAP as noted by ICD-9 coding. As a result, there is a difference between the clinical site's surveillance rate of VAP (n = 10) and its' clinical rate of VAP. This difference exists because the CDC's surveillance definition has been designed to compare disease frequency overtime, measure population disease burden, and compare disease frequency between different institutions (Klompas, 2012). To serve this purpose, the surveillance definition was designed to maximize objectivity and positive predictive value, which often sacrifices its' sensitivity (Klompas, 2012). Conversely, clinical diagnoses are primarily intended to guide patients' management, thus favoring sensitivity over specificity, since small delays in appropriate therapy increase patients' risk of mortality (Klompas, 2012).

Strengths of the Study

This study had several strengths. First, this study used a well-established model to examine patient outcomes related to nursing-directed patient care in ICU situations. Second, it sampled nurses from five medical/surgical ICUs to increase the representativeness of the sample of ICU nurses implementing sedation vacations. Third, due to the majority of nurses having worked in the primary ICU in which they were currently practicing for at least 9 years, there was likely an overlap between the nurses who recorded data in the EMR during the fiscal year of 2010 and those who completed the self-report survey, which further substantiates our findings regarding nurses' sedation vacation adherence. Fourth, this study was the first reported to use vignettes to empirically evaluate the implications of nurses' clinical practices of sedation vacation adherence in relation to the health outcomes of mechanically ventilated patients. Lastly, it adds to the knowledge about the most common perceived barriers and facilitators to nurses' adherence to a sedation vacation protocol.

Implications for Practice

Nurses play a pivotal role in implementing sedation vacations, because they are the healthcare providers that are primarily responsible for titrating and/or interrupting these medications (Roy, 2007). It is well-established that nurses can improve patients' outcomes through their consistent use of evidenced-based practices. Accordingly, nurses need to have a working knowledge of the interventions that they are responsible for implementing. In this study, the researcher found that most nurses exhibited a lack of knowledge about the reasons to perform or not perform sedation vacations. Additionally, they demonstrated a lack of appropriate clinical decision making to aptly implement the sedation vacation protocol in mechanically ventilated patients, despite their high confidence in sedation management. Furthermore, their adherence to the sedation vacation protocol was very low (using EMR data) and considered suboptimal for high quality patient care. These findings indicate the need for additional education that specifically addresses the lack of knowledge and awareness, the overconfidence in implementing evidence-based practice, and the possible lack of "risk-taking" behavior to implement a sedation vacation even if they previously experienced a patient having an adverse event associated with sedation interruption. Several studies have demonstrated that focused education is necessary to increase nurses' adherence to evidenced-based practices (Helder, Brug, Looman, van Goudoever, & Kornelisse, 2010; Lam et al., 2004; Martin-Madrazo et al., 2009). This education should be based on the most commonly perceived facilitators to sedation vacation adherence, such as those identified in this study.

Though many researchers have found it challenging to improve nurses' adherence to evidenced-based practices, several strategies very similar to those identified in this study have been shown to effectively change nursing practice. The most successful are those that are multimodal, those that are aimed at improving the convenience of implementing evidenced-based practice, and those that provide performance feedback (Hugonnet et al., 2002; Mathai et al., 2011; McLaws et al., 2009; O'Keefe-McCarthy et al., 2008; Petroudi, 2009; Picheansathian et al., 2008; Rao et al., 2009; Rigbe et al., 2005). Nurses are typically consumed with documentation, technology, learning new procedures, and constant changes in the delivery of care, which leaves little time to provide basic nursing care to critically ill patients (Roy, 2007; Wip & Napolitano, 2009). Therefore, the implementation of strategies to improve the convenience with which nurses' perform sedation vacations will likely improve their compliance with this guideline (Bingham, Ashley, Jong, & Swift, 2010; Lam et al., 2004; Mathai et al., 2011; Roy, 2007). For instance, an intervention could be implemented that included the use of a buddy system. This system would use several nurses to help monitor patients that were undergoing sedation vacations in order to prevent self-extubation and other safety concerns caused by altered mental status during scheduled sedative interruptions (Wip & Napolitano, 2009). Helping nurses realize that if they experienced a relatively low occurring adverse event, they need to not have this limit their future use of evidencebased practices may be helpful.

Lastly, interventions that provide performance feedback have also been demonstrated to significantly improve nurses' compliance with evidence-based practices, such as hand hygiene (Furr et al., 2004; Hugonnet et al., 2002; Mathai et al., 2011; McLaws et al., 2009; O'Keefe-McCarthy et al., 2008; Petroudi, 2009; Picheansathian et al., 2008; Rao et al., 2009; Rigbe et al., 2005; Westwell, 2008). Therefore, this approach could also be successful in improving nurses' compliance with sedation vacations. The efficacy of this intervention has been demonstrated in several studies, which found that nurses' hand hygiene compliance could be improved by providing performance feedback in the form of posters, daily memos about their hand washing frequency, and motivation from nurse managers (Helder et al., 2010; Huang & Wu, 2008; Lam et al., 2004; Mathai et al., 2011; Picheansathian et al., 2008). Hence, to sustain improvement researchers must implement strategies to regularly evaluate nurses' compliance with evidenced-based practices and provide consistent performance feedback when designing interventions to change nursing practice (Lam et al., 2004).

Furthermore, the identification and implementation of effective approaches to facilitating and sustaining practice change are imperative (Abbott et al., 2006). To accomplish this goal nurse administrators, nurse educators, clinical nurse specialists, and nurse researchers must work together to change the nursing practice of nurse clinicians through the use of identified barriers and facilitators (Abbott et al., 2006). It is also recommended that nurse administrators facilitate sustained behavior change by creating work environments that encourage and support change in nursing practice (Abbott et al., 2006; Helder et al., 2010; Picheansathian et al., 2008). They can offer incentives, improve systems to simplify the effects of change, and decentralize nurses' decision making (Abbott et al., 2006; Helder et al., 2010; Picheansathian et al., 2008). Using adult education, system change, and marketing theories nurse educators can improve upon educational interventions that have been shown to result in sustained behavior change (Abbott et al., 2006; Huang & Wu, 2008). Clinical nurse specialists are in a unique position to observe practice, reinforce, teach, and model effective behaviors (Abbott et al., 2006; Picheansathian et al., 2008). Last of all, nurse researchers have an obligation to guide and assist in the evaluation and testing of evidenced-based interventions for improved adoption in clinical practice (Abbott et al., 2006; Burns & Grove, 2005). Hence, nurse researchers should consider the use of proven interventions from similar areas of research, such as hand hygiene, in order to change other areas of nursing practice, such as sedation vacations, through the implementation of interventions that have been shown to be successful (Abbott et al., 2006; Gammon et al., 2008). In doing

so, nurse researchers will be able to effectively influence nurse clinicians' compliance with evidenced-based guidelines through the selection of interventions and evaluation of related methodologies that have been demonstrated to significantly change nursing practice (Abbott et al., 2006; Mathai et al., 2011).

Implications for Research

The findings of this study provide guidance for future investigation. First, this study should be replicated on a larger scale in order to include a larger sample of ICU nurses and mechanically ventilated patients. Little is known about the factors that are associated with nurses' adequate implementation of sedation vacations in mechanically ventilated patients. Further identification of these factors will promote a broader understanding, thereby facilitating the development of interventions aimed at improving nurses' adherence to evidence-based practices.

Secondly, future research is needed to develop and test quality improvement measures that specifically address other barriers and facilitators to nurses' adherence to sedation vacations. These measures should be based on strategies that have been empirically shown to effectively change nursing practice. In doing so, attention must be given to strategies that might facilitate nurses' process of implementing evidence-based practice. One of the first issues to deal with may be how to address nurses' overconfidence in their implementation of standardized protocols and decision making.

Finally, in extending research in this patient population, additional studies are needed to evaluate the level of nursing adherence needed to demonstrate a significant decrease in the development of VAP. In this study, the average percentage rate of adherence to sedation vacations was significantly higher in those patients who did not have a diagnosis of VAP, which would imply that even minimal adherence to the protocol may be beneficial. Though, there are no studies that have specifically addressed this individual component of the VAP bundle or the minimal adherence needed to prevent VAP.

Conclusions

This study adds to the body of literature regarding nurses' adherence to sedation vacations. Nurses typically play a central role in implementing evidence-based patient care interventions, because they are the healthcare providers who are primarily responsible for performing the bedside protocols that are aimed at optimizing the healthcare outcomes of critically ill patients. Implementing evidence-based practice is essential for high quality patient care. These study findings identify the most salient factors that are associated with nurses' implementation of a sedation vacation protocol, and accentuate the need for strategies that are directed toward improving patient outcomes in this patient population.

REFERENCES

- Abbott, C. A., Dremsa, T., Stewart, D. W., Mark, D. D., & Swift, C. C. (2006). Adoption of a ventilator-associated pneumonia clinical practice guideline. *Worldviews on Evidence-Based Nursing*, 3(4), 139-152.
- Alp, E., & Voss, A. (2006). Ventilator associated pneumonia and infection control. Annals of Clinical Microbiology and Antimicrobials, 5(7), 1-10.

 Andales, S. A. A. (2004). The occurrence of late-onset ventilator associated pneumonia in the manila doctors hospital ICU: Risk Factors and clinical outcomes. *The Philippine Journal of Microbiology and Infectious Disease*, 33(1), 7-27.

- Arias-Rivera, S., Sanchez-Sanchez, M., Sanchez-Izquierdo, R., Santos-Diaz, R., Gallardo-Murillo, J., & Frutos-Vivar, F. (2006). Does sedation practice delay time to extubation? *Intensive and Critical Care Nursing*, 22, 378-382.
- Augustyn, B. (2007). Ventilator-associated pneumonia: Risk factors and prevention. *Critical Care Nurse*, 27, 32-36.
- Berry, E., & Zecca, H. (2012). Daily interruptions of sedation: A clinical approach to improve outcomes in critically ill patients. *Critical Care Nurse*, *32*(1), 43-51.
- Bingham, M., Ashley, J., Jong, M. D., & Swift, C. C. (2010). Implementing a unit-level intervention to reduce the probability of ventilator-associated pneumonia. *Nursing Research*, 59(1S), S40-S47.

- Bond, S., & Thomas, L. H. (1991). Issues in measuring outcomes in nursing. *Journal of Advanced Nursing*, *16*, 1492-1502.
- Bonten, M. J. M., Kollef, M. H., & Hall, J. B. (2004). Risk factors for ventilatorassociated pneumonia: From epidemiology to patient management. *Clinical Infectious Diseases, 38*(8), 1141-1149.
- Bouadma, L., Wolff, M., & Lucet, J.-C. (2012). Ventilator-associated pneumonia and its prevention. *Current Opinion in Infectious Diseases*, 25(4), 395-404.
- Burns, N., & Grove, S. K. (2003). Understanding Nursing Research. Philadelphia, PA: Saunders.
- Burns, N., & Grove, S. K. (2005). The practice of nursing research: Conduct, critique, and utilization. St. Louis, MO: Elsevier Saunders.
- Cabana, M. D., Rand, C. S., Powe, N. R., Wu, A. W., Wilson, M. H., Abboud, P.-A. C.,
 & Rubin, H. R. (1999). Why don't physicians follow clinical practice guidelines?
 Journal of the American Medical Association, 282(15), 1458-1465.
- Carson, S. S., Kress, J. P., Rodgers, J. E., Vinayak, A., Campbell-Bright, S., Levitt, J., ... Hall, J. (2006). A randomized trial of intermittent lorazepam versus propofol with daily interruption in mechanically ventilated patients. *Critical Care Medicine*, 34(5), 1326-1332. doi: 10.1097/01.CCM.0000215513.63207.7F
- Cason, C. L., Tyner, T., Saunders, S., & Broome, L. (2007). Nurses' implementation of guidelines for ventilator-associated pneumonia from the centers for disease control and prevention. *American Journal of Critical Care*, 16, 28-38.
- Chastre, J., & Jean-Yves, F. (2002). Ventilator-associated pneumonia. *American Journal* of Respiratory and Critical Care Medicine, 165, 867-903.

- Closs, S. J., & Tierney, A. J. (1993). The complexities of using a structure, process and outcome framework: The case of an evaluation of discharge planning for elderly patients. *Journal of Advanced Nursing*, 18, 1279-1287.
- Cochrane, L. J., Olson, C. A., Murray, S., Dupuis, M., Tooman, T., & Hayes, S. (2007).
 Gaps between knowing and doing: Understanding and assessing the barriers to optimal health care. *Journal of Continuing Education in the Health Professions*, 27(2), 94-102.
- Creedon, S. A. (2005). Healthcare workers' hand decontamination practices: Compliance with recommended guidelines. *Journal of Advanced Nursing*, *51*, 208-216.
- Curtin, L. J. (2011). Preventing ventilator-associated pneumonia: A nursing-intervention bundle. *American Nurse Today*, 6(3), 9-11.
- Dilorio, C. K. (2005). Measurement in health behavior. San Franciso, CA: Jossey-Bass.
- Dodek, P., Keenan, S., Cook, D., Heyland, D., Jacka, M., Hand, L., . . . Brun-Buisson, C. (2004). Evidence-based clinical practice guideline for the prevention of ventilator-associated pneumonia. *Annals of Internal Medicine*, *141*(4), 305-313.
- Donabedian, A. (1966). Evaluating the quality of medical care. *Millbank Memorial Fund Quarterly, 44*, 166-206.
- Efrati, S., Deutsch, I., Antonelli, M., Hockey, P. M., Rozenblum, R., & Gurman, G. M.
 (2010). Ventilator-associated pneumonia: Current status and future
 recommendations. *Journal of Clinical Monitoring and Computing*, 24, 161-168.
- Eng, X. J., Malhotra, A., Saeed, M., Mark, R. G., & Talmor, D. (2008). Risk factors for acute respiratory distress syndrome in patients mechanically ventilated for greater than 48 hours. *Chest*, 7, 1-29.

- Esperatti, M., Ferrer, M., Theessen, A., Liapikou, A., Valencia, M., Saucedo, L. M., . . . Torres, A. (2010). Nosocomial pneumonia in the intensive care unit acquired by mechanically ventilated versus nonventilated patients. *American Journal of Respiratory and Critical Care Medicine*, 182, 1533-1539.
- Field, A. (2009). Discovering statistics using SPSS (3rd ed.). Los Angeles, CA: Sage.
- Fields, L. B. (2008). Oral care intervention to reduce incidence of ventilator-associated pneumonia in the neurologic intensive care unit. *Journal of Neuroscience Nursing*, 40, 291-298.
- Fong, J. J., Kanji, S., Dasta, J. F., Garpestad, E., & Delvin, J. W. (2007). Propofol associated with a shorter duration of mechanical ventilation than scheduled intermittent lorazepam: A database analysis using project IMPACT. *The Annals* of Pharmacotherapy, 41, 1986-1991. doi: 10.1345/aph.1K296
- Fulbrook, P., & Mooney, S. (2003). Care bundles in critical care: A practical approach to evidence-based practice. *Nursing in Critical Care*, 8(6), 249-255.
- Furr, L. A., Binkley, C. J., McCurren, C., & Carrico, R. (2004). Factors affecting quality of oral care in intensive care units. *Journal of Advanced Nursing*, 48, 454-462.
- Gammon, J., Morgan-Samuel, H., & Gould, D. (2008). A review of the evidence for suboptimal compliance of healthcare practitioners to standard/universal infection control precautions. *Journal of Clinical Nursing*, 17, 157-167.
- George, D., & Mallery, P. (2009). SPSS for Windows step by step (9th ed.). Boston, MA: Pearson Education.
- Girard, T. D., Kress, J. P., Fuchs, B. D., Thomason, J. W., Schweickert, W. D., Pun, B. T., . . . Ely, E. W. (2008). Efficacy and safety of a paired sedation and ventilator

weaning protocol for mechanically ventilated patients in intensive care: A randomized controlled trial. *Lancet*, *371*, 126-134.

- Grap, M. J. (2009). Not-so-trivial pursuit: Mechanical ventilation risk reduction. *American Journal of Critical Care, 18*(4), 299-309.
- Helder, O. K., Brug, J., Looman, C. W. N., van Goudoever, J. B., & Kornelisse, R. F. (2010). The impact of an education program on hand hygiene compliance and nosocomial infection incidence in an urban neonatal intensive care unit: An intervention study with before and after comparison. *International Journal of Nursing Studies*, 47, 1245-1252. doi: 10.1016/j.ijnurstu.2010.03.005
- Heyland, D. K., Cook, D. J., Griffith, L., Keenan, S. P., & Brun-Buisson, C. (1999). The attributable morbidity and mortality of ventilator-associated pneumonia in the critically ill patient. *American Journal of Respiratory and Critical Care Medicine*, 159, 1249-1256.
- Hong, S., Morrow-Howell, N., Proctor, E., Wentz, J. D., & Rubin, E. (2008). The quality of medical care for comorbid conditions of depressed elders. *Aging & Mental Health*, 12, 323-332.
- Huang, T., & Wu, S. (2008). Evaluation of a training programme on knowledge and compliance of nurse assistants' hand hygiene in nursing homes. *Journal of Hospital Infection*, 68, 164-170. doi: 10.1016/j.jhin.2007.11.020
- Hugonnet, S., Perneger, T. V., & Pittet, D. (2002). Alcohol-based handrub improves compliance with hand hygiene in intensive care units. *Archives of Internal Medicine*, 162, 1037-1043.

- Ibrahim, E. H., Tracy, L., Hill, C., Fraser, V., & Kollef, M. H. (2001). The occurrence of ventilator-associated pneumonia in a community hospital: Risk factor and clinical outcomes *Chest*, 120, 555-561.
- Jacobi, J., Fraser, G. L., Coursin, D., Riker, R., Fontaine, D., Wittbrodt, E. T., . . . Lumb,P. D. (2002). Clinical practice guidelines for the sustained use of sedative and analgesics in the critically ill adult. *Critical Care Medicine*, *30*(1), 119-141.
- Jakob, S. M., Ruokonen, E., Grounds, R. M., Sarapohja, T., Garratt, C., Pocock, S. J.,... Takala J. (2012). Dexmedetomidine vs midazolam or propofol for sedation during prolonged mechanical ventilation. *Journal of the American Medical Association*, 307(11), 1151-1160.
- Klompas, M. (2012). Is a ventilator-associated pneumonia rate of zero really possible? *Current Opinion in Infectious Diseases, 25*(2), 176-182.
- Knaus, W. A., Wagner, D. P., Draper, E. A., Zimmerman, J. E., Bergner, M., Bastos, P.G., . . . Harrell, F. E. (1991). The APACHE III prognostic system. Risk prediction of hospital mortality for critically ill hospitalized adults. *Chest*, 100, 1619-1636.
- Kollef, M. H. (2004). Prevention of hospital-associated pneumonia and ventilatorassociated pneumonia. *Critical Care Medicine*, *32*(6), 1396-1405.
- Kollef, M. H., Levy, N. T., Ahrens, T. S., Schaiff, R., Prentice, D., & Sherman, G. (1998). The use of continuous IV sedation is associated with prolongation of mechanical ventilation. *Chest*, 11, 541-548.
- Krein, Sarah L., Kowalski, C. P., Damschroder, L., Forman, J., Kaufman, Samuel R., & Saint, S. (2008). Preventing ventilator-associated pneumonia in the United States:

A multicenter mixed-methods study. *Infection Control and Hospital Epidemiology*, 29(10), 933-940. doi: 10.1086/591455

- Kress, J. P., Gehlbach, B., Lacy, M., Pliskin, N., Pohlman, A. S., & Hall, J. B. (2003). The long-term psychological effects of daily sedative interruption on critically ill patients. *American Journal of Respiratory and Critical Care Medicine, 168*, 1457-1461.
- Kress, J. P., Pohlman, A. S., O'Connor, M. F., & Hall, J. B. (2000). Daily interruption of sedative infusions in critically ill patients undergoing mechanical ventilation. *The New England Journal of Medicine*, 342, 1471-1477.
- Kunkel, S., Rosenqvist, U., & Westerling, R. (2007). The structure of quality systems is important to the process and outcome, an empirical study of 386 hospital departments in Sweden. *BMC Health Services Research*, 7, 1-8.
- Lam, B. C. C., Lee, J., & Lau, Y. L. (2004). Hand hygiene practices in a neonatal intensive care unit: A multimodal intervention and impact on nosocomial infection. *Pediatrics*, 114(5), 565-571. doi: 10.1542/peds.2004-1107
- Lawrence, P., & Fulbrook, P. (2011). The ventilator care bundle and its impact on ventilator-associated pneumonia: A review of the evidence. *Nursing in Critical Care, 16*(5), 222-234.
- Leasure, A. R., Stirlen, J., & Thompson, C. (2008). Barriers and facilitators to the use of evidence-based best practices. *Dimensions of Critical Care Nursing*, 27(2), 74-82.
- Martin-Madrazo, C., Canada-Dorado, A., Salinero-Fort, A., Abanades-Herranz, J. C., Arnal-Selfa, R., Garcia-Ferradal, I., . . . Soto-Diaz, S. (2009). Effectiveness of a

training programme to improve hand hygiene compliance in primary healthcare. *BMC Public Health*, *9*(469), 1-8. doi: 10.1186/1471-2458-9-469

- Martin, J., Parsch, A., Franck, M., Wernecke, K. D., Fischer, M., & Claudia, S. (2005). Practice of sedation and analgesia in German intensive care units: Results of a national survey. *Critical Care*, 9, R117-R123.
- Maskerine, C., & Loeb, M. (2006). Improving adherence to hand hygiene among health care workers. *Journal of Continuing Education in the Health Professions*, 26, 244-251.
- Mathai, A. S., George, S. E., & Abraham, J. (2011). Efficacy of a multimodal intervention strategy in improving hand hygiene compliance in a tertiary level intensive care unit. *Indian Journal of Critical Care Medicine*, 15(1), 6-15. doi: 10.4103/0972-5229.78215
- McLaws, M.-L., Pantle, A. C., Fitzpatrick, K. R., & Hughes, C. F. (2009). Improvements in hand hygience accross New South Wales public hospitals: Clean hands save lives, part III. *The Medical Journal of Australia, 191*(8).
- Mehta, S., Burry, L., Cook, D., Fergusson, D., Steinberg, M., Granton, J., . . . Meade, M. (2012). Daily sedation interruption in mechancially ventilated critically ill patients cared for with a sedation protocol. *Journal of the American Medical Association, 308*(19), E1-E8. doi: 10.1001
- Mehta, S., Burry, L., Fischer, S., Martinez-Motta, J. C., Hallett, D., Bowman, D., . . .
 Cook, D. J. (2006). Canadian survey of the use of sedatives, analgesics, and neuromuscular blocking agents in critically ill patients. *Critical Care Medicine*, 34(2), 374-380.

- Mehta, S., Burry, L., Martinez-Motta, J. C., Stewart, T. E., Hallett, D., McDonald, E., . . . Cook, D. J. (2008). A randomized trial of daily awakening in critically ill patients managed with a sedation protocol: A pilot trial. *Critical Care Medicine*, *36*(7), 2092-2099.
- Mitchell, P. H., Ferketich, S., & Jennings, B. M. (1998). Quality health outcomes model. *Image -The Journal of Nursing Scholarship*, *30*, 43-46.
- Morris, A. C., Hay, A. W., Swann, D. G., Everingham, K., McCulloch, C., McNulty, J., .
 . Walsh, T. S. (2011). Reducing ventilator-associated pneumonia in intensive care: Impact of implementing a care bundle. *Critical Care Medicine*, *39*(10), 2218-2224.
- Munro, B. H. (2005). *Statistical methods for health care research*. Philadelphia, PA: Lippincott.
- Muscedere, J., Dodek, P., Keenan, S., Fowler, R., Cook, D., & Heyland, D. (2008). Comprehensive evidence-based clinical practice guidelines for ventilatorassociated pneumonia: Prevention. *Journal of Critical Care, 23*, 126-137.
- O'Connor, M., Bucknall, T., & Manias, E. (2010). Sedation management in Australian and new Zealand intensive care units: Doctors' and nurses' practices and opinions. *American Journal of Critical Care, 19*, 285-295.
- O'Keefe-McCarthy, S., Santiago, C., & Lau, G. (2008). Ventilator-associated pneumonia bundled strategies: An evidence-based practice. *Worldviews on Evidence-Based Nursing*, *5*, 193-204.

- Payen, J.-F., Chanques, G., Mantz, J., Hercule, C., Auriant, I., Leguillou, J.-L., . . .
 Bosson, J.-L. (2007). Current practices in sedation and analgesia for mechanically ventilated critically ill patients. *Anesthesiology*, *106*, 687-695.
- Petroudi, D. (2009). Nosocomial infections and staff hygiene. *Journal of Infection in Developing Countries*, *3*, 152-156.
- Picheansathian, W., Pearson, A., & Suchaxaya, P. (2008). The effectiveness of a promotion programme on hand hygiene compliance and nosocomial infections in a neonatal intensive care unit. *International Journal of Nursing Practice*, 14, 315-321. doi: 10.1111/j.1440-172X.2008.00699.x
- Pieracci, F. M., & Barie, P. S. (2007). Strategies in the prevention and management of ventilator-associated pneumonia. *The American Surgeon*, 73(5), 419-432.
- Pincock, T., Bernstein, P., Warthman, S., & Holst, E. (2012). Bundling hand hygiene interventions and measurement to decrease health care-associated infections. *American Journal of Infection Control*, 40, 518-527.
- Quenot, J.-P., Ladoire, S., Devoucoux, F., Doise, J.-M., Cailliod, R., Cunin, N., . . . Charles, P. E. (2007). Effect of a nurse-implemented sedation protocol on the incidence of ventilator-associated pneumonia. *Critical Care Medicine*, 35(9), 2031-2036.
- QuesGen Systems Inc. (2012). Apache III calculation (Version 64) [Online Software]. Retrieved from <u>http://www.quesgen.com/ApacheIII.php</u>
- Rakshit, P., Nagar, V. S., & Deshpande, A. K. (2005). Incidence, clinical outcome, and risk stratification of ventilator-associated pneumonia- a prospective cohort study. *Indian Journal of Critical Care Medicine*, 9(4), 211-216.

- Rao, G. G., Jeanes, A., Russell, H., Wilson, D., Atere-Roberts, E., Sullivan, D. O., & Donaldson, N. (2009). Effectiveness of short-term, enhanced, infection control support in improving compliance with infection control guidelines and practice in nursing homes: A cluster randomized trial. *Epidemiology and Infection, 137*, 1465-1471. doi: 10.1017/S0950268809002210
- Rello, J., Afonso, E., Lisboa, T., Ricart, M., Balsera, B., Rovira, A., . . . Diaz, E. (2012).
 A care bundle approach for prevention of ventilator-associated pneumonia. *Clinical Microbiology and Infection*. doi: 10.1111/j.1469-0691.2012.03808.x
- Rello, J., Ollendorf, D. A., Oster, G., Vera-Llonch, M., Bellm, L., Redman, R., & Kollef,
 M. H. (2002). Epidemiology and outcomes of ventilator-associated pneumonia in a large US database. *Chest*, 122, 2115-2121.
- Resar, R., Pronovost, P., Haraden, C., Simmonds, T., Rainey, T., & Nolan, T. (2005).
 Using a Bundle Approach to Improve Ventilator Care Processes and Reduce
 Ventilator-Associated Pneumonia. *Journal on Quality and Patient Safety*, *31*(5), 243-248.
- Ricart, M., Lorente, C., Diaz, E., Kollef, M. H., & Rello, J. (2003). Nursing adherence with evidence-based guidelines for preventing ventilator-associated pneumonia. *Critical Care Medicine*, 31(11), 2693-2696.
- Rigbe, S., Almedom, A., Hagos, G., Albin, S., & Mutungi, A. (2005). Promotion of handwashing as a measure of quality of care and prevention of hospital-acquired infections in Eritrea: The keren study. *African Health Sciences*, 5, 4-13.
- Rosenbaum, J., & Lidz, C. W. (2007). Maximizing the results of internet surveys. *Center* for Mental Health Services Research, 4(2), 1-2. Retrieved from

Roy, G. (2007). Interventions by critical care nurses reduce VAP. Dynamics, 18, 28-33.

- Ruffell, A., & Adamcova, L. (2008). Ventilator-associated pneumonia: Prevention is better than cure. *Nursing in Critical Care, 13*, 44-53.
- Salluh, J. I. F., Dal-Pizzol, F., Mello, P., Friedman, G., Silva, E., Teles, J. M. M., . . . Soares, M. (2009). Delirium recognition and sedation practices in critically ill patients: A survey on the attitudes of 1015 Brazilian critical care physicians. *Journal of Critical Care*, 24, 556-562.
- Schweickert, W. D., Gehlbach, B. K., Pohlman, A. S., Hall, J. B., & Kress, J. P. (2004).
 Daily interruption of sedative infusions and complications of critical illness in mechanically ventilated patients. *Critical Care Medicine*, *32*, 1272-1276.
- Sedwick, M. B., Lance-Smith, M., Reeder, S. J., & Nardi, J. (2012). Using evidencebased practice to prevent ventilator-associated pneumonia. *Critical Care Nurse*, 32(4), 41-51.
- Sessler, C. N., & Varney, K. (2008). Patient-focused sedation and analgesia in the ICU. *Chest*, 133(2), 552-565.
- Sierra, R., Benitez, E., Leon, C., & Rello, J. (2005). Prevention and diagnosis of ventilator-associated pneumonia: A survey on current practices in southern spanish ICUs. *Chest 128*, 1667-1673.
- Sofianou, D. C., Constandinidis, T. C., Yannacou, M., Anastasiou, H., & Sofianos, E.
 (2000). Analysis of risk factors for ventilator-associated pneumonia in a multidisciplinary intensive care unit. *European Journal Of Clinical Microbiology* & *Infectious Diseases, 19*, 460-463.

- Soper, D. S. (2010). The free statistics calculators website [Online software]. Retrieved January 12, 2010, from <u>http://www.danielsoper.com/statcalc/</u>
- Strom, T., Martinussen, T., & Toft, P. (2010). A protocol of no sedation for critically ill patients receiving mechanically ventilation: A randomised trial. *Lancet*, 375, 475-480.
- Tanios, M. A., Wit, M., Epstein, S. K., & Devlin, J. W. (2009). Perceived barriers to the use of sedation protocol and daily sedation interruption: A multidisciplinary survey. *Journal of Critical Care*, 24, 66-73.
- Tolentino-Delosreyes, A. F., Ruppert, S. D., & Shiao, S. P. K. (2007). Evidence-based practice: use of the ventilator bundle to prevent ventilator-associated pneumonia. *American Journal of Critical Care, 16*(1), 20(28).
- Trouillet, J.-L., Chastre, J., Vuagnat, A., Joly-Guillou, M.-L., Combaux, D., Dombret, M.-C., & Gibert, C. (1998). Ventilator-associated pneumonia caused by potentially drug-resistant bacteria *American Journal of Respiratory and Critical Care Medicine*, 157, 531-539.
- Tseng, C.-C., Huang, K.-T., Chen, Y.-C., Wang, C.-C., Liu, S.-F., Tu, M.-L., . . . Lin, M.-C. (2012). Factors predicting ventilator dependence in patients with ventilatorassociated pneumonia. *The Scientific World Journal*, 1-10. doi: 10.1100/2012/547241
- Urbaniak, G. C., & Plous, S. (2011). Research Randomizer (Version 3.0) [Computer software] Retrieved September 2, 2012, from <u>http://www.randomizer.org/</u>

- Vallés, J., Pobo, A., Garca-Esquirol, O., Mariscal, D., Real, J., & Fernández, R. (2007). Excess ICU mortality attributable to ventilator-associated pneumonia: the role of early vs late onset. *Intensive Care Medicine*, 33(8), 1363-1368.
- van Achterberg, T., Schoonhoven, L., & Grol, R. (2008). Nursing implementation science: How evidence-based nursing requires evidence-based implementation. *Journal of Nursing Scholarship*, 40, 302-309.
- Walker, N., & Gillen, P. (2006). Investigating nurses' perceptions of their role in managing sedation in intensive care: An exploratory study. *Intensive and Critical Care Nursing*, 22, 338-345.
- Waltman, P. A., Schenk, L. K., Martin, T. M., & Walker, J. (2011). Effect of student participation in hand hygiene monitoring on knowledge and perception of infection control practices. *Journal of Nursing Education*, 50(4), 216-221. doi: 10.3928/01484834-20110228-06
- Weinert, C. R., & Calvin, A. D. (2007). Epidemiology of sedation and sedation adequacy for mechanically ventilated patients in a medical and surgical intensive care unit. *Critical Care Medicine*, 35, 393-401.
- Westwell, S. (2008). Implementing a ventilator care bundle in an adult intensive care unit. *Nursing in Critical Care, 13*(4), 203-207.
- Whitby, M., & McLaws, M. L. (2004). Handwashing in healthcare workers: Accessibility of sink location does not improve compliance. *Journal of Hospital Infection*, 58, 247-253.
- Wip, C., & Napolitano, L. (2009). Bundles to prevent ventilator-associated pneumonia: How valuable are they? *Current Opinion in Infectious Diseases*, 22, 159-166.

Wubker, A. (2007). Measuring the quality of healthcare: The connection between structure, process, and outcomes of care, using the example of myocardial infarction treatment in Germany. *Disease Management Health Outcomes*, 15, 225-238. Appendix A

Evaluating Sedation Practices in the Intensive Care Unit Survey

Evaluating Sedation Practices in the Intensive Care Unit Survey

The purpose of this survey is to learn more about nurses' practices of caring for mechanically ventilated patients. The survey is divided into two parts. In <u>Part I</u> you will be asked to answer questions regarding the implementation of daily interruptions of sedation therapy (also known as sedation vacations) using patient scenarios. In <u>Part II</u> you will be asked to provide information about your characteristics and perceptions of this clinical practice. Thank you for taking part in this study! It should not take more than 30 minutes to complete this survey.

Please do not discuss your answers with others.

First, please circle the answer to the questions below to see if you are eligible to participate in the survey. *** If you answered "<u>No</u>" to any of the following four questions, <u>do not</u> complete this survey, please return it with the raffle ticket in the stamped self-addressed envelope provided or the locked bin that is located in each ICU's conference room after circling your answers. ***

 Do you participate in direct bedside patient care for a minimum of 24 hours per week?

NIO

	Yes	or	No		
2)	Are you at least 21 years old?				
	Yes	or	No		
3)	Have you completed the hospital's orientation for new hires?				
	Yes	or	No		
4)	Do you perform sedation vacations on mechanically ventilated patients?				
	Yes	or	No		

~ **

Vac

If you answered "<u>Yes</u>" to all the questions above, please continue with the survey.

Part I: Scenarios of Patients Receiving Mechanical Ventilation

A nurse working in the intensive care unit is assigned to the patients who are represented in the following scenarios. Please read the patient scenarios and answer the questions below as per the example:

Example: A 56 year old female patient is receiving mechanical ventilation and continuous intravenous sedation after being intubated for pneumonia. During the nurse's morning assessment, the patient is found to be receiving a neuromuscular blocking agent and is unresponsive to noxious stimuli. The patient's ventilator settings include the following: Assist Control, Tidal Volume 400, PEEP 5, and FiO2 35%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 122/81, Heart Rate 64, Respiratory Rate 20, Oxygen Saturation 99%, and Temperature 97.8 °F. She has a medical history of diabetes that is being managed with insulin therapy.

- A. Should the nurse perform a daily interruption of sedation therapy? (circle one) Yes or No
- B. Please explain your reason(s) for making this decision. <u>It is mandatory that the nurse does not interrupt the infusion of sedation if the patient is</u> <u>receiving neuromuscular blockade therapy. Patients who are receiving neuromuscular blockade</u> <u>therapy must receive adequate sedation and analgesia medications as continuous intravenous</u> infusions.
- A 42 year old male patient is receiving mechanical ventilation and continuous intravenous sedation after being intubated for an elective knee surgery. During the nurse's morning assessment, the patient is found to be responsive to touch and his name. The patient's ventilator settings include the following: Assist Control, Tidal Volume 450, PEEP 5, and FiO2 30%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 119/78, Heart Rate 74, Respiratory Rate 16, Oxygen Saturation 99%, and Temperature 97.5. He has a medical history of osteoarthritis that is being managed with Ibuprofen for pain relief.
 - A. Should the nurse perform a daily interruption of sedation therapy? (circle one)

or No

Yes

B. Please explain your reason(s) for making this decision.

- 2. A 64 year old male patient is receiving mechanical ventilation and continuous intravenous sedation after being intubated for Acute Respiratory Distress Syndrome (ARDS). During the nurse's morning assessment, the patient is found to be calm and cooperative. The patient's ventilator settings include the following: Assist Control, Tidal Volume 340, PEEP 8, and FiO2 45%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 122/74, Heart Rate 69, Respiratory Rate 18, Oxygen Saturation 91%, and Temperature 98.0. He has a medical history of deep vein thrombosis that is being managed with Lovenox.
 - A. Should the nurse perform a daily interruption of sedation therapy? (circle one)

Yes or No

B. Please explain your reason(s) for making this decision.

- 3. A 28 year old male patient is receiving mechanical ventilation and continuous intravenous sedation after being intubated for a drug overdose. During the nurse's morning assessment, the patient is found to be responsive only to noxious stimuli. The patient's ventilator settings include the following: Assist Control, Tidal Volume 450, PEEP 5, and FiO2 28%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 114/69, Heart Rate 61, Respiratory Rate 12, Oxygen Saturation 98%, and Temperature 98.4. He has no known medical history.
 - A. Should the nurse perform a daily interruption of sedation therapy? (circle one)

Yes or No

B. Please explain your reason(s) for making this decision.

- 4. A 37 year old male patient is receiving mechanical ventilation and continuous intravenous sedation after being intubated for active seizures. During the nurse's morning assessment, the patient is found to be having some jerking movements and is unresponsive to his name. The patient's ventilator settings include the following: Assist Control, Tidal Volume 425, PEEP 8, and FiO2 40%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 136/86, Heart Rate 90, Respiratory Rate 24, Oxygen Saturation 100%, and Temperature 98.1. He has a medical history of epilepsy that is being managed with antiseizure medications.
 - A. Should the nurse perform a daily interruption of sedation therapy? (circle one)

Yes or No

- B. Please explain your reason(s) for making this decision.
- 5. A 65 year old female patient is receiving mechanical ventilation and continuous intravenous sedation after being intubated for an allergic reaction that caused airway edema. During the nurse's morning assessment, the patient is responsive to touch only. The patient's ventilator settings include the following: Assist Control, Tidal Volume 400, PEEP 5, and FiO2 35%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 127/83, Heart Rate 88, Respiratory Rate 18, Oxygen Saturation 92%, and Temperature 97.8. She has a medical history of hypothyroidism that is being managed with Synthroid.
 - A. Should the nurse perform a daily interruption of sedation therapy? (circle one)

Yes or No

B. Please explain your reason(s) for making this decision.

- 6. A 51 year old female patient, who is receiving mechanical ventilation, has been placed on a daily interruption of sedation therapy. During the sedative interruption, the nurse finds that the patient is restless and agitated. The patient's ventilator settings include the following: Assist Control, Tidal Volume 350, PEEP 10, and FiO2 45%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 172/98, Heart Rate 117, Respiratory Rate 32, Oxygen Saturation 93%, and Temperature 98.1. She has a medical history of gout that is being managed with Colchicine.
 - I. What should be the <u>initial</u> nursing action for the patient? (circle one)
 - A. Notify the respiratory therapy staff that the patient can be placed on a spontaneous breathing trial to evaluate for extubation.
 - B. Hold the sedative infusion until the patient is calm and cooperative, and then resume $\frac{1}{2}$ of the prior infusion dose.
 - C. Resume the infusion of sedation medication(s) at $\frac{1}{2}$ the previous dose and titrate as needed.
 - D. Resume the infusion of sedation medication(s) at the previous dose.
 - II. Please explain your reason(s) for making this decision.

- 7. A 69 year old male patient, who is receiving mechanical ventilation, has been placed on a daily interruption of sedation therapy. During the sedative interruption, the nurse finds that the patient is responsive only to noxious stimuli. The patient's ventilator settings include the following: Assist Control, Tidal Volume 500, PEEP 5, and FiO2 30%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 108/74, Heart Rate 62, Respiratory Rate 12, Oxygen Saturation 99%, and Temperature 97.8. He has a medical history of iron deficiency anemia that is being managed with iron supplementation.
 - I. What should be the <u>initial</u> nursing action for the patient? (circle one)
 - A. Notify the respiratory therapy staff that the patient can be placed on a spontaneous breathing trial to evaluate for extubation.
 - B. Hold the sedative infusion until the patient is calm and cooperative, and then resume $\frac{1}{2}$ of the prior infusion dose.
 - C. Resume the infusion of sedation medication(s) at $\frac{1}{2}$ the previous dose and titrate as needed.
 - D. Resume the infusion of sedation medication(s) at the previous dose.
 - II. Please explain your reason(s) for making this decision.

Part II: Characteristics and Perceptions of Clinical Practice

For the following questions, please respond as directed.

- 8. What is the highest nursing degree that you currently hold? (circle one)
 - a. Associate Degree in Nursing (ADN)
 - b. Bachelor of Science in Nursing (BSN)
 - c. Master of Science in Nursing (MSN)
 - d. Doctor of Philosophy in Nursing (PhD)

- 9. Have you completed a post registration qualification in intensive care? (circle all that apply)
 - a. CCRN (critical care nursing certification)
 - b. ACNP (acute care nurse practitioner certification)
 - c. CCNS (acute care clinical nurse specialist certification)
 - d. PCCN (progressive care nursing certification)
 - e. CSC (cardiac surgery subspecialty certification)
 - f. CMC (cardiac medicine subspecialty certification)
 - g. Do not have a post registration qualification in intensive care
- 10. Years in clinical critical care practice as a registered nurse in the intensive care unit (post training/preceptorship)? (circle one)
 - a. 1-3 years
 - b. 4-6 years
 - c. 7-9 years
 - d. 10-12 years
 - e. 13-15 years
 - f. 16-19 years
 - g. 20 + years
- 11. What is the setting of your primary intensive care unit? (circle one)
 - a. Medical intensive care unit
 - b. Coronary intensive care unit
 - c. Neurosurgical intensive care unit
 - d. Cardiothoracic intensive care unit
 - e. Step-down intensive care unit
 - f. Other, please specify: _____

- 12. How many years have you worked in the primary intensive care unit in which you practice? (circle one)
 - a. 0-3 years
 - b. 4-6 years
 - c. 7-9 years
 - d. 10-12 years
 - e. 13-15 years
 - f. 16-19 years
 - g. 20 + years
- 13. What percentage of patients in your primary intensive care unit do you estimate are mechanically ventilated? (circle one)
 - a. 0-25%
 - b. 26-50%
 - c. 51-75%
 - d. 76-100%
- 14. In your opinion, is there an association between sedation administered and patient outcome for mechanically ventilated patients in the intensive care unit? (circle one)
 - a. Yes
 - b. No
 - c. Unsure
- 15. Does your intensive care unit use multidisciplinary rounds, which include identifying mechanically ventilated patients who can have a daily interruption of sedation therapy? (circle one)
 - a. Yes
 - b. No
 - c. Unsure
- 16. Does your intensive care unit have a sedation vacation protocol? (circle one)
 - a. Yes
 - b. No
 - c. Unsure

- 17. The sedation vacation protocol is used for what percentage of mechanically ventilated patients <u>under your care</u>? (circle one)
 - a. None
 - b. 1-25%
 - c. 26-50%
 - d. 51-75%
 - e. 76-100%
 - f. I am not familiar with this strategy
- 18. From the following list of sedation regimens, please choose the five regimens that are most frequently used for your intubated and mechanically ventilated patients (with number 1 being the most frequently used and number 5 being the fifth most frequently used regimen)
 - ____ Morphine; as a single agent
 - ____ Fentanyl; as a single agent
 - ____ Lorazepam (Ativan); as a single agent
 - ____ Lorazepam (Ativan) + Morphine
 - ____ Lorazepam (Ativan) + Fentanyl
 - ____ Midazolam (Versed); as a single agent
 - ____ Midazolam (Versed) + Morphine
 - ____ Midazolam (Versed) + Fentanyl
 - ____ Propofol (Diprivan); as a single agent
 - ____ Propofol (Diprivan) + Morphine
 - ____ Propofol (Diprivan) + Fentanyl
 - ____ Dexmedetomidine (Precedex); as a single agent
 - ____ Dexmedetomidine (Precedex) + Morphine or Fentanyl
 - ____ Other agent(s), please specify: _____

19. In your opinion, what percentage of daily interruptions of sedation therapy is associated with an adverse event (e.g. self-extubation; central line removal) in mechanically ventilated patients?

a.	< 1%
b.	1-5%
c.	6-10%
d.	11-15%
e.	16-25%
f.	Other, please
	specify:

Has a mechanically ventilated patient under your care ever experienced an adverse event (e.g. self-extubation; central line removal) when you were implementing a daily interruption of sedation therapy?

a.	Yes If Yes, what was the adverse		
	event:		
b.	No		
c.	Unsure		

- 20. From the list below select the three (3) most important reasons that a daily interruption of sedation therapy is NOT utilized for all mechanically ventilated patients under your care in the intensive care unit? (circle all that apply)
 - a. Inconvenient to coordinate with observers' availability
 - b. No proven benefit
 - c. Possibility of patient-initiated device removal
 - d. Possibility of cardiac ischemia
 - e. Possibility of posttraumatic stress disorder
 - f. Possibility of respiratory compromise
 - g. Possibility of compromising patient comfort
 - h. Nursing staff preferences
 - i. Need for more control of sedation use
 - j. Patients get over-sedated
 - k. Patient get under-sedated
 - 1. Other, please specify:

- 21. In your opinion, which of the following populations of mechanically ventilated intensive care unit patients should NOT be managed with a sedation vacation protocol? (circle all that apply)
 - a. Medical intensive care unit
 - b. Coronary intensive care unit
 - c. Neurosurgical intensive care unit
 - d. Cardiothoracic intensive care unit
 - e. Step-down intensive care unit
 - f. All intensive care unit populations should be managed with a sedation protocol
 - g. Other, please specify:_____
- 22. In your opinion, which of the following strategies would MOST effectively improve nurses' implementation of daily interruptions of sedation therapy in mechanically ventilated patients? (circle one)
 - a. Individual performance feedback from nurse managers/unit directors (e.g. daily memos)
 - b. Improving the convenience of implementing sedative interruptions (e.g. a nurse-driven buddy system to help monitor patients)
 - c. Multimodal interventions (e.g. a combination of staff education, posters, and audits)
 - d. Avoiding excessive workload and/or staffing shortages
 - e. Other, please specify:
- 23. Please circle the number, from 1=low confidence to 10=high confidence, on the scale below that best indicates your level of confidence when managing continuous intravenous sedation in mechanically ventilated patients.

From "Perceived barriers to the use of sedation protocol and daily sedation interruption: A multidisciplinary survey," by Tanios, M. A., Wit, M., Epstein, S. K., & Devlin, J. W., 2009, *Journal of Critical Care*, 24, p. 71-72. Copyright by Elsevier Inc. Adapted with permission.

Thank you for completing this survey. The answers to the patient scenarios will be placed in your work mailbox in approximately 8 weeks. In addition, please remember to return the survey and one of the numbered raffle tickets in the stamped selfaddressed envelope provided or the locked bin that is located in each ICU's conference room.

Do you have any additional feedback that you would like to convey regarding this survey?

Appendix B

Nursing Survey Coding Guidelines

Nursing Survey Coding Guidelines

Vignette Rationale Coding

- 1=Overall stability/Hemodynamically stable
- 2=Neurological checks
- 3=Ventilator settings
- 4=MAAS score/Patient behavior (level of wakefulness, sedation, or responsiveness)
- 5=Following sedation vacation protocol/No contraindications
- 6=Vital signs
- 7=Assess ability to be weaned off ventilator
- 8=Patient's co-morbidities
- 9=Appropriate contraindication (i.e. seizures)
- 10-Patient's diagnosis/Reason for intubation
- 11=Cardiopulmonary distress/instability
- 12=Need to check with MD/Need MD order
- 13=Need for additional diagnostic test (i.e. ABG, CT scan)
- 14=Need to assess need for continued IV sedation

Survey Coding

- If the participant does not rank the medications as directed, the data will be excluded for question #18.
- If the decision is correct but the rationale has not been given, the vignette will be scored partially correct (=1).
- If in the rationale provided the participant specifies that the sedation vacation should be done to "assess/check mental/neurologic status" and the decision is deemed to be correct, the nurses' reasoning will be scored as correct (=2).

- A 42 year old male patient is receiving mechanical ventilation and continuous intravenous sedation after being intubated for an elective knee surgery. During the nurse's morning assessment, the patient is found to be responsive to touch and his name. The patient's ventilator settings include the following: Assist Control, Tidal Volume 450, PEEP 5, and FiO2 30%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 119/78, Heart Rate 74, Respiratory Rate 16, Oxygen Saturation 99%, and Temperature 97.5. He has a medical history of osteoarthritis that is being managed with Ibuprofen for pain relief.
 - A. Should the nurse perform a daily interruption of sedation therapy? (circle one)

[X] Yes =1 or No=0

B. Please explain your reason(s) for making this decision.

The nurse's reasoning is <u>CORRECT</u> if: =2

-The response selected for "should the nurse perform a daily interruption of sedation therapy" is "Yes" (correct answer).

- The reason includes one of the following essential points:

- Patients are to have daily awakening from sedation while on continuous intravenous sedation in the intensive care unit, if they do not have contraindications to sedation vacations (i.e. active seizures or alcohol withdrawal; escalating does of sedative as a result of ongoing agitation; neuromuscular blocking agents; evidence of active myocardial ischemia in the prior 24 hours; and evidence of increased intracranial pressure), in order to assess their level of wakefulness.
- The sedation awakening trail is done regardless if the patient meets criteria for spontaneous breathing trial.

The nurse's reasoning is **<u>PARTIALLY CORRECT</u>** if: =1

- The response selected for "should the nurse perform a daily interruption of sedation therapy" is "Yes"
- The reason does not include the essential points in the correct answer but does provide support for the correct answer.
- I.e.-indicates that a daily interruption of sedation therapy is important, and that it should be performed because of the patient's normal vital signs and/or the patient's level of consciousness.

The nurse's reasoning is <u>INCORRECT</u> if: =0

• The response selected for "should the nurse perform a daily interruption of sedation therapy" is "No"

OR

• The response is "Yes" but the reasoning does not include either of the essential points in the correct answer and provides information that does not preclude the performance of a daily interruption of sedation therapy.

- I.e.- indicates that their reasoning is due to the lack of a physician's order, lack of an indication for a sedation vacation, patient's ventilator settings, patient's demographics, patient's past medical history, patient's medication regimen, patient's readiness for extubation, or patient's reason for intubation.
- 2. A 64 year old male patient is receiving mechanical ventilation and continuous intravenous sedation after being intubated for Acute Respiratory Distress Syndrome (ARDS). During the nurse's morning assessment, the patient is found to be calm and cooperative. The patient's ventilator settings include the following: Assist Control, Tidal Volume 340, PEEP 8, and FiO2 40%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 122/74, Heart Rate 69, Respiratory Rate 18, Oxygen Saturation 91%, and Temperature 98.0. He has a medical history of deep vein thrombosis that is being managed with Lovenox.
 - A. Should the nurse perform a daily interruption of sedation therapy? (circle one)

[X] Yes =1or No=0

B. Please explain your reason(s) for making this decision.

The nurse's reasoning is <u>CORRECT</u> if: =2

-The response selected for "should the nurse perform a daily interruption of sedation therapy" is "Yes" (correct answer).

- The reason includes one of the following essential points:
 - Patients are to have daily awakening from sedation while on continuous intravenous sedation in the intensive care unit, if they do not have contraindications to sedation vacations (i.e. active seizures or alcohol withdrawal; escalating does of sedative as a result of ongoing agitation; neuromuscular blocking agents; evidence of active myocardial ischemia in the prior 24 hours; and evidence of increased intracranial pressure), in order to assess their level of wakefulness.
 - The sedation awakening trial is done regardless if the patient meets criteria for spontaneous breathing trial.

The nurse's reasoning is <u>PARTIALLY CORRECT</u> if: =1

- The response selected for "should the nurse perform a daily interruption of sedation therapy" is "Yes"
- The reason does not include the essential points in the correct answer but does provide support for the correct answer.
- I.e.-indicates that a daily interruption of sedation therapy is important, and that it should be performed because of the patient's normal vital signs and/or the patient's level of consciousness.

The nurse's reasoning is **INCORRECT** if: =0

• The response selected for "should the nurse perform a daily interruption of sedation therapy" is "No"

OR

- The response is "Yes" but the reasoning does not include either of the essential points in the correct answer and provides information that does not preclude the performance of a daily interruption of sedation therapy.
 - I.e.- indicates that their reasoning is due to the lack of a physician's order, lack of an indication for a sedation vacation, patient's ventilator settings, patient's demographics, patient's past medical history, patient's medication regimen, patient's readiness for extubation, or patient's reason for intubation.
- 3. A 28 year old male patient is receiving mechanical ventilation and continuous intravenous sedation after being intubated for a drug overdose. During the nurse's morning assessment, the patient is found to be responsive only to noxious stimuli. The patient's ventilator settings include the following: Assist Control, Tidal Volume 450, PEEP 5, and FiO2 28%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 114/69, Heart Rate 61, Respiratory Rate 12, Oxygen Saturation 98%, and Temperature 98.4. He has no known medical history.
 - A. Should the nurse perform a daily interruption of sedation therapy? (circle one)

[X] Yes =1 or No =0

B. Please explain your reason(s) for making this decision.

The nurse's reasoning is <u>CORRECT</u> if: =2

-The response selected for "should the nurse perform a daily interruption of sedation therapy" is "Yes" (correct answer).

- The reason includes one of the following essential points:
 - Patients are to have daily awakening from sedation while on continuous intravenous sedation in the intensive care unit, if they do not have contraindications to sedation vacations (i.e. active seizures or alcohol withdrawal; escalating does of sedative as a result of ongoing agitation; neuromuscular blocking agents; evidence of active myocardial ischemia in the prior 24 hours; and evidence of increased intracranial pressure), in order to assess their level of wakefulness.
 - The sedation awakening trail is done regardless if the patient meets criteria for spontaneous breathing trial.

The nurse's reasoning is **PARTIALLY CORRECT** if: =1

- The response selected for "should the nurse perform a daily interruption of sedation therapy" is "Yes"
- The reason does not include the essential points in the correct answer but does provide support for the correct answer.
 - I.e.-indicates that a daily interruption of sedation therapy is important, and that it should be performed because of the patient's normal vital signs and/or the patient's level of consciousness.

The nurse's reasoning is <u>INCORRECT</u> if: =0

• The response selected for "should the nurse perform a daily interruption of sedation therapy" is "No"

OR

- The response is "Yes" but the reasoning does not include either of the essential points in the correct answer and provides information that does not preclude the performance of a daily interruption of sedation therapy.
 - I.e.- indicates that their reasoning is due to the lack of a physician's order, lack of an indication for a sedation vacation, patient's ventilator settings, patient's demographics, patient's past medical history, patient's medication regimen, patient's readiness for extubation, or patient's reason for intubation.
- 4. A 37 year old male patient is receiving mechanical ventilation and continuous intravenous sedation after being intubated for active seizures. During the nurse's morning assessment, the patient is found to be having some jerking movements and is unresponsive to his name. The patient's ventilator settings include the following: Assist Control, Tidal Volume 425, PEEP 8, and FiO2 40%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 136/86, Heart Rate 90, Respiratory Rate 24, Oxygen Saturation 100%, and Temperature 98.1. He has a medical history of epilepsy that is being managed with antiseizure medications.
 - A. Should the nurse perform a daily interruption of sedation therapy? (circle one)

Yes =1 or **[X]** No =0

B. Please explain your reason(s) for making this decision.

The nurse's reasoning is <u>CORRECT</u> if: =2

-The response selected for "should the nurse perform a daily interruption of sedation therapy" is "No" (correct answer).

-The reason includes the following essential point:

 A daily interruption of sedation therapy is contraindicated in patients that are receiving a sedative infusion for active seizures that is exhibited by jerking movements and unresponsiveness.

The nurse's reasoning is <u>INCORRECT</u> if: =0

• The response selected for "should the nurse perform a daily interruption of sedation therapy" is "Yes"

- The response is "No" but the reasoning does not include the essential point in the correct answer and provides information that does not preclude the performance of a daily interruption of sedation therapy.
 - I.e.- indicates that their reasoning is due to the lack of a physician's order, lack of an indication for a sedation vacation, patient's ventilator settings, patient's demographics, patient's past medical history, patient's medication regimen, patient's readiness for extubation, or patient's reason for intubation.
- 5. A 65 year old female patient is receiving mechanical ventilation and continuous intravenous sedation after being intubated for an allergic reaction that caused airway edema. During the nurse's morning assessment, the patient is responsive to touch only. The patient's ventilator settings include the following: Assist Control, Tidal Volume 400, PEEP 5, and FiO2 35%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 127/83, Heart Rate 88, Respiratory Rate 18, Oxygen Saturation 92%, and Temperature 97.8. She has a medical history of hypothyroidism that is being managed with Synthroid.
 - A. Should the nurse perform a daily interruption of sedation therapy? (circle one)
 - **[X] Yes** =1 or No=0
 - B. Please explain your reason(s) for making this decision.

The nurse's reasoning is <u>CORRECT</u> if: =2

-The response selected for "should the nurse perform a daily interruption of sedation therapy" is "Yes" (correct answer).

- The reason includes one of the following essential points:
 - Patients are to have daily awakening from sedation while on continuous intravenous sedation in the intensive care unit, if they do not have contraindications to sedation vacations (i.e. active seizures or alcohol withdrawal; escalating does of sedative as a result of ongoing agitation; neuromuscular blocking agents; evidence of active myocardial ischemia in the prior 24 hours; and evidence of increased intracranial pressure), in order to assess their level of wakefulness.
 - The sedation awakening trail is done regardless if the patient meets criteria for spontaneous breathing trial.

The nurse's reasoning is <u>PARTIALLY CORRECT</u> if: =1

- The response selected for "should the nurse perform a daily interruption of sedation therapy" is "Yes"
- The reason does not include the essential points in the correct answer but does provide support for the correct answer.
 - I.e.-indicates that a daily interruption of sedation therapy is important, and that it should be performed because of the patient's normal vital signs and/or the patient's level of consciousness.

The nurse's reasoning is <u>INCORRECT</u> if: =0

• The response selected for "should the nurse perform a daily interruption of sedation therapy" is "No"

OR

- The response is "Yes" but the reasoning does not include either of the essential points in the correct answer and provides information that does not preclude the performance of a daily interruption of sedation therapy.
 - I.e.- indicates that their reasoning is due to the lack of a physician's order, lack of an indication for a sedation vacation, patient's ventilator settings, patient's demographics, patient's past medical history, patient's medication regimen, patient's readiness for extubation, or patient's reason for intubation.
- 6. A 51 year old female patient, who is receiving mechanical ventilation, has been placed on a daily interruption of sedation therapy. During the sedative interruption, the nurse finds that the patient is restless and agitated. The patient's ventilator settings include the following: Assist Control, Tidal Volume 350, PEEP 10, and FiO2 45%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 172/98, Heart Rate 117, Respiratory Rate 32, Oxygen Saturation 93%, and Temperature 98.1. She has a medical history of gout that is being managed with colchicine.

I. What should be the initial nursing action for the patient? (circle one)

- A. Notify the respiratory therapy staff that the patient can be placed on a spontaneous breathing trial to evaluate for extubation.
- B. Hold the sedative infusion until the patient is calm and cooperative, and then resume $\frac{1}{2}$ of the prior infusion dose.
- C. Resume the infusion of sedation medication(s) at ¹/₂ the previous dose and titrate as needed.
- D. Resume the infusion of sedation medication(s) at the previous dose.
- II. Please explain your reason(s) for making this decision.

The nurse's reasoning is <u>CORRECT</u> if: =2

• The response selected for "what should be the initial nursing action for the patient" is "C" (correct answer).

AND

• The nurse's reasoning for making this decision includes the following essential point: If agitation prevents successful awakening, the nurse is to resume the infusion of sedation medication at ¹/₂ the previous dose and titrate as needed as per the study site's sedation vacation protocol.

The nurse's reasoning is **<u>PARTIALLY CORRECT</u>** if: =1

- The response selected for "what should be the initial nursing action for the patient" is "C".
- The reason does not include the essential point in the correct answer but does provide support for the correct answer.
 - I.e.-indicates that resuming the infusion of sedation medication(s) at ¹/₂ the previous dose and titrating as needed is important, and that it should be performed because of the patient's level of wakefulness/MAAS Score and abnormal vital signs (elevated heart rate, blood pressure, and respiratory rate).

The nurse's reasoning is **INCORRECT** if: =0

• The response selected for "what should be the initial nursing action for the patient" is "A, B, or D".

OR

- The response is "C" but the reasoning does not include the essential point in the correct answer and provides information that does not preclude the resumption of the infusion of sedation medication at ½ the previous dose, to be titrated as needed.
 - I.e.- indicates that their reasoning is due to the lack of a physician's order, lack of an indication for a sedation vacation, patient's ventilator settings, patient's demographics, patient's past medical history, patient's medication regimen, patient's readiness for extubation, or patient's reason for intubation.
- 7. A 69 year old male patient, who is receiving mechanical ventilation, has been placed on a daily interruption of sedation therapy. During the sedative interruption, the nurse finds that the patient is responsive only to noxious stimuli. The patient's ventilator settings include the following: Assist Control, Tidal Volume 500, PEEP 5, and FiO2 30%. On these ventilator settings the patient's vital signs are as follows: Blood Pressure 108/74, Heart Rate 62, Respiratory Rate 12, Oxygen Saturation 99%, and Temperature 97.8. He has a medical history of iron deficiency anemia that is being managed with iron supplementation.
 - I. What should be the initial nursing action for the patient? (circle one)
 - A. Notify the respiratory therapy staff that the patient can be placed on a spontaneous breathing trial to evaluate for extubation.
 - **B.** Hold the sedative infusion until the patient is calm and cooperative, and then resume $\frac{1}{2}$ of the prior infusion dose.
 - C. Resume the infusion of sedation medication(s) at ¹/₂ the previous dose and titrate as needed.
 - D. Resume the infusion of sedation medication(s) at the previous dose.
 - II. Please explain your reason(s) for making this decision.

The nurse's reasoning is <u>CORRECT</u> if: =2

• The response selected for "what should be the initial nursing action for the patient" is "B" (correct answer).

AND

• The nurse's reasoning for making this decision includes the following essential point: If over sedation prevents successful awakening, the nurse is to hold the infusion of sedation medication until at a goal Motor Activity Assessment Score (MAAS) of 2-3 (MAAS 2= responsive to touch and name; MAAS 3= calm and cooperative) and then resume ½ of the previous infusion dose as per the study site's sedation vacation protocol.

The nurse's reasoning is <u>PARTIALLY CORRECT</u> if: =1

- The response selected for "what should be the initial nursing action for the patient" is "B".
- The reason does not include the essential point in the correct answer but does provide support for the correct answer.
 - I.e.-indicates that holding the sedative infusion until the patient is calm and cooperative, and then resuming ½ of the previous infusion dose is important, and that it should be performed because of the patient's level of wakefulness/MAAS Score and normal vital signs.

The nurse's reasoning is **INCORRECT** if: =0

• The response selected for "what should be the initial nursing action for the patient" is "A, C, or D".

OR

- The response is "B" but the reasoning does not include the essential point in the correct answer and provides information that does not preclude holding the sedative infusion until the patient is calm and cooperative, and then resuming ½ of the previous infusion dose.
 - I.e.- indicates that their reasoning is due to the lack of a physician's order, lack of an indication for a sedation vacation, patient's ventilator settings, patient's demographics, patient's past medical history, patient's medication regimen, patient's readiness for extubation, or patient's reason for intubation.
- 8. What is the highest nursing degree that you currently hold? (circle one)
 - a. Associate Degree in Nursing (ADN) =1
 - b. Bachelor of Science in Nursing (BSN) =2
 - c. Master of Science in Nursing (MSN) =3
 - d. Doctor of Philosophy in Nursing (PhD) =4

- 9. Have you completed a post registration qualification in intensive care? (circle all that apply) *Composite score:* 1=Yes, *RN does have a certification;* 0=No, *RN does not have a certification*
 - a. CCRN (critical care nursing certification)
 - b. ACNP (acute care nurse practitioner certification)
 - c. CCNS (acute care clinical nurse specialist certification)
 - d. PCCN (progressive care nursing certification)
 - e. CSC (cardiac surgery subspecialty certification)
 - f. CMC (cardiac medicine subspecialty certification)
 - g. Do not have a post registration qualification in intensive care
- 10. Years in clinical critical care practice as a registered nurse in the intensive care unit (post training/preceptorship)? (circle one)
 - a. 1-3 years =1
 - b. 4-6 years =2
 - c. 7-9 years =3
 - d. 10-12 years =4
 - e. 13-15 years =5
 - f. 16-19 years =6
 - g. 20 + years = 7
- 11. What is the setting of your primary intensive care unit? (circle one)
 - a. Medical intensive care unit =1
 - b. Coronary intensive care unit =2
 - c. Neurosurgical intensive care unit =3
 - d. Cardiothoracic intensive care unit =4
 - e. Step-down intensive care unit =5
 - f. Other, please specify: =6

11 Oth. (String) 0= Not Applicable; 1=Medical-surgical intensive care unit

- 12. How many years have you worked in the primary intensive care unit in which you practice? (circle one)
 - a. 0-3 years =1
 - b. 4-6 years =2
 - c. 7-9 years =3
 - d. 10-12 years =4
 - e. 13-15 years =5
 - f. 16-19 years =6
 - g. 20 + years = 7
- 13. What percentage of patients in your primary intensive care unit do you estimate are mechanically ventilated? (circle one)
 - a. 0-25% =1
 b. 26-50% =2
 c. 51-75% =3
 d. 76-100% =4
- 14. In your opinion, is there an association between sedation administered and patient outcome for mechanically ventilated patients in the intensive care unit? (circle one)
 - a. Yes =1
 - b. No =2
 - c. Unsure =3
- 15. Does your intensive care unit use multidisciplinary rounds, which include identifying mechanically ventilated patients who can have a daily interruption of sedation therapy? (circle one)
 - a. Yes =1b. No =2c. Unsure =3
- 16. Does your intensive care unit have a sedation vacation protocol? (circle one)
 - a. Yes =1
 - b. No =2
 - c. Unsure =3

- 17. The sedation vacation protocol is used for what percentage of mechanically ventilated patients <u>under your care</u>? (circle one)
 - a. None =1
 - b. 1-25% =2
 - c. 26-50% =3
 - d. 51-75% =4
 - e. 76-100% =5
 - f. I am not familiar with this strategy =6
- 18. From the following list of sedation regimens, please choose the five regimens that are most frequently used for your intubated and mechanically ventilated patients (with number 1 being the most frequently used and number 5 being the fifth most frequently used regimen) 0=Not Applicable; 1-5=Rank As Indicated
 - ____ Morphine; as a single agent- 18#1

____ Fentanyl; as a single agent-18#2

____ Lorazepam (Ativan); as a single agent-18#3

____ Lorazepam (Ativan) + Morphine- 18#4

____ Lorazepam (Ativan) + Fentanyl- 18#5

____ Midazolam (Versed); as a single agent-18#6

____ Midazolam (Versed) + Morphine-18#7

- ____ Midazolam (Versed) + Fentanyl- 18#8
- ____ Propofol (Diprivan); as a single agent- 18#9
- ____ Propofol (Diprivan) + Morphine- 18#10
- ____ Propofol (Diprivan) + Fentanyl- 18#11
- ____ Dexmedetomidine (Precedex); as a single agent- 18#12
- ____ Dexmedetomidine (Precedex) + Morphine or Fentanyl- 18#13
- ____ Other agent(s), please specify:-18#14 (String); 0=Not Applicable____

- 19. a. In your opinion, what percentage of daily interruptions of sedation therapy is associated with an adverse event (e.g. self-extubation; central line removal) in mechanically ventilated patients?
 - a. < 1% =1
 b. 1-5% =2
 c. 6-10% =3
 d. 11-15% =4
 e. 16-25% =5
 - f. Other, please specify: =6
- 19 Other. (String) 0=Not Applicable; 1=Unsure____

19. b. Has a mechanically ventilated patient under your care ever experienced an adverse event (e.g. self-extubation; central line removal) when you were implementing a daily interruption of sedation therapy?

a. Yes =1
b. No =2
c. Unsure =3

19bAE. If Yes, what was the adverse event: 0=Not Applicable

1=Self-Extubation

2=Catheter Removal

3=Cardiopulmonary Instability

4=Agitation

- 20. From the list below select the three (3) most important reasons that a daily interruption of sedation therapy is NOT utilized for all mechanically ventilated patients under your care in the intensive care unit? (circle all that apply) 0=No 1=Yes
 - a. Inconvenient to coordinate with observers' availability- 20#1
 - b. No proven benefit- 20#2
 - c. Possibility of patient-initiated device removal-20#3
 - d. Possibility of cardiac ischemia- 20#4
 - e. Possibility of posttraumatic stress disorder- 20#5
 - f. Possibility of respiratory compromise- 20#6
 - g. Possibility of compromising patient comfort- 20#7
 - h. Nursing staff preferences- 20#8
 - i. Need for more control of sedation use- 20#9
 - j. Patients get over-sedated- 20#10
 - k. Patient get under-sedated- 20#11
 - 1. Other, please specify:- 20#12 (String) 0=Not Applicable;1=Poor cardiopulmonary

status; 2=Not indicated for neuro patients; 3= MD

order; 4=Protocol needed; 5=Neuromuscular

blockade therapy

21. In your opinion, which of the following populations of mechanically ventilated intensive care unit patients should NOT be managed with a sedation vacation protocol? (circle all that apply)

0=No 1=Yes

- a. Medical intensive care unit- 21#1
- b. Coronary intensive care unit- 21#2
- c. Neurosurgical intensive care unit- 21#3
- d. Cardiothoracic intensive care unit-21#4
- e. Step-down intensive care unit- 21#5
- f. All intensive care unit populations should be managed with a sedation protocol-21#6
- g. Other, please specify:- 21#7 (<u>String</u>) 0=Not Applicable; 1=Inappropriate situation

22. In your opinion, which of the following strategies would MOST effectively improve nurses' implementation of daily interruptions of sedation therapy in mechanically ventilated patients? (circle one) 0=No1 = Yes

- a. Individual performance feedback from nurse managers/unit directors (e.g. daily memos)- 22#1
- b. Improving the convenience of implementing sedative interruptions (e.g. a nurse-driven buddy system to help monitor patients)- 22#2
- c. Multimodal interventions (e.g. a combination of staff education, posters, and audits)-22#3
- d. Avoiding excessive workload and/or staffing shortages-22#4
- e. Other, please specify- 22#5

22 Other. (String) 0=Not Applicable; 1=Availability of multidisciplinary staff to ensure safety; 2=Performs sedation vacations per protocol unless contraindicated; 3=Increased accountability; 4=Educate nursing staff on evidence based research; 5=Provide feedback about the effects of sedation vacations

23. Please circle the number, from 1=low confidence to 10=high confidence, on the scale below that best indicates your level of confidence when managing continuous intravenous sedation in mechanically ventilated patients.

Confidence Level:

- 1-3=Low confidence
- 4-7=Medium confidence
- 8-10=High confidence •

Appendix C

Nursing Survey Consent Form

Georgia State University

Byrdine F. Lewis School of Nursing

Informed Consent

Title: The Impact of Nurses' Adherence to Sedation Vacations on Ventilator Associated Pneumonia Prevention

Principal Investigator: Patricia Clark, PhD, RN, FAHA, FAAN

Student Investigator: Soraya N. Smith, MSN, RN, CCRN, ACNP-BC

Purpose:

You are invited to take part in a research study. The purpose of the study is to examine the most salient factors that are associated with intensive care unit (ICU) murses' practice of using sedation vacations when caring for patients who require mechanical ventilation. You are invited to be in the study because you are an ICU nurse who gives direct bedside care to mechanically ventilated patients. As many as one hundred ICU nurses will be asked to be in this study. The study will require about 30 minutes of your time.

II. <u>Procedures</u>

If you are willing to take part in this research study, you will be asked to answer a 23-item survey. The questions will be about your level of education, your intensive care experience, and your reasons for performing or not performing sedation vacations in specific cases. You will also be asked some general questions about your clinical practices. The survey can be completed at a time that is convenient for you. No one except the research team will view the survey.

III. <u>Risks</u>:

In this study, you will probably not have any more risks than you would in a normal day of life. However, it is possible that talking about your workplace may cause you to be upset. You are free to refuse to answer any question at any time or seek counseling at your own expense. However, Georgia State University and Emory Healthcare have not set aside funds to pay for this care or to compensate you if you need care.

IV. Benefits:

Taking part in this study will not benefit you personally. We want to gain information about nurses who implement sedation vacations in mechanically ventilated patients. The study may help to identify ways to reduce the occurrence of ventilator associated pneumonia for mechanically ventilated patients in the future.

V. <u>Voluntary Participation and Withdrawal</u>:

Taking part in research is voluntary. You have the right not to be in this study. If you decide to be in the study and change your mind, you have the right to drop out at any time. You may skip questions or stop being in the study at any time. Whatever you decide, you will not lose any benefits to which you are otherwise entitled.

VI. <u>Confidentiality</u>:

Information may be shared with those who make sure the study is done correctly (Georgia State University's Institutional Review Board and the Office for Human Research Protection). However, we will keep your responses private to the extent allowed by law. We will do this even if outside review occurs. We will use a study number to identify which ICU you practice in, rather than your name on the survey. The survey is anonymous which means your responses cannot be linked to you in any way. Your name and other facts that might point to you will not appear when we present this study or publish its results. The findings will be summarized and reported in group form. You will not be identified personally.



Consent Form Approved by Georgia State University IRB June 27, 2012 - June 26, 2013

VII. Costs:

There are no known costs to you for taking part in this study except you time.

VIII. Compensation:

You can keep the retractable ball point pen that was with the survey whether you participate or not. In addition, you will be automatically enrolled into a drawing for a \$100.00 Visa gift card. Two numbered raffle tickets will be enclosed with the survey, one of which you will keep and the other you should return in the self-addressed envelope provided. Your participation in the raffle is not contingent on your participation in this study and you may remain eligible for the raffle even if you withdraw from the study or do not complete every question on the survey. At the completion of the study one ticket will be randomly selected and the winning ticket's number will be posted on flyers in the conference room of each ICU. The participant that possesses the winning ticket number can then notify their unit director for receipt of the gift card. After the gift card has been awarded, flyers will be posted in the conference room of each ICU in order to let the nursing staff know that the prize has been claimed.

IX. Contact Persons:

Contact Soraya Smith, MSN, RN, CCRN, ACNP-BC, the Student Investigator at 404-284-2566 or Patricia C. Clark, PhD, RN, FAHA, FAAN, the Principal Investigator, at 404-413-1180 or by email at <u>ssmith165@student.gsu.edu</u> or <u>pclark@gsu.edu</u> if you have questions, concerns, or complaints about this study. You can also call if think you have been harmed by the study. Contact Susan Vogmer in the Georgia State University Office of Research Integrity at 404-413-3513 or <u>svogtner1@gsu.edu</u> if you want to talk to someone who is not part of the study team. You can talk about questions, concerns, or suggestions about the study. You can also call Susan Vogtner if you have questions or concerns about your rights in this study.

X. Copy of Consent Form to Subjects:

You can keep this copy of the consent form for your records. Completion and return of the survey via the stamped, self-addressed envelope provided or the locked bin that will be located in each ICU's conference room will indicate your willingness to take part in the study.

Student Principal Investigator

Date



Consent Form Approved by Georgia State University IRB June 27, 2012 - June 26, 2013

Appendix D

Patient Data Abstraction Form

Patient Data Collection Form (PDAF)

Tear Sheet (For confidential patient demographics)

1.	Patient's Financial Identification Number (FIN)[] [] [] [] [] [] [] [] [] [] []
2.	Patient's NameLast: [][][][][][][][][][], First:[][][][][][][][][][][][][][][][][][][]
3.	Patient's Date of Birth (Mo/Day/Yr)[][]/[][]/[][]/[][]/[][]/[][]/[][]
4.	Date Abstracted (Mo/Day/Yr)

Inclusion Criteria *** (If the answer is no to any of the following questions, stop abstracting data, the patient is excluded from the study) ***

1. Was the patient admitted to a medical/surgical ICU for greater than 24 hours? (circle one) Yes1 No2
 Is the patient 18 years of age or older? (circle one)
Yes1
No2
3. Did the patient require invasive (endotracheal/ tracheostomy tube) mechanical ventilation for
greater than 48 hours, in association with the administration of a continuous intravenous infusion
of a sedative drug (e.g. Versed, Fentanyl, Propofol, Precedex, Ativan, Morphine), while in a
medical/surgical ICU? (circle one)
Yes1
No2
Exclusion Criteria *** (If the answer is yes to any of the following questions, stop abstracting, the patient is excluded from the study) ***
4. Did the patient die within 24 hours of being admitted to a medical/surgical ICU? (circle one) Yes1 No2
5. Did the patient have any of the following contraindications to receiving sedations vacations documented by a physician/midlevel: (Circle all the apply) No

Patient Data

1.	Patient's ID Code:	
2.	Patient's Age (in Years)	
3.	Patient's Gender: (Circle One)	
	Male	1
	Female	2
4.	Patient's Ethnicity: (Circle One)	
	American Indian/Alaskan Native	1
	Asian/Pacific Islander	2
	Black, not Hispanic	3
	Hispanic	4
	White, not Hispanic	5
	Other, Specify	6
	No data	7
5.	Length of ICU stay	
	Date/Time of ICU admission	.00/00/00 / 00:00
	Date/Time of ICU discharge or death	.00/00/00/00:00
	Total number of days in the ICU	[][]]

6. Type of ICU: (Circle One)
Medical ICU1
Coronary ICU2
Neurosurgical ICU
Cardiothoracic ICU4
7. Level of Acuity (APACHE III score)[][][]
8. Number of ventilator days:
Date/Time of intubation[][]/[][]/[][]/[][]/[][]/[][]/[][]
Date/Time of extubation or death[][]/[][]/[][]/[][]/[][]/[][]/[][
Total number of ventilator days[][][]
9. Does the patient have a diagnosis of VAP [as indicated by ICD-9 code
997.31]: (Circle One)
Yes1
No2

1	.48

Patient Data	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Nurse ID Code														
Versed dose before SV/ Versed dose after SV (mg/kg/hr)														
Fentanyl dose before SV/ Fentanyl dose after SV (mcg/kg/hr)														
Propofol dose before SV/ Propofol dose after SV (mg/kg/hr)														
Precedex dose before SV/ Precedex dose after SV (mcg/kg/hr)														
Ativan dose before SV/ Ativan dose after SV (mg/kg/hr)														
Morphine dose before SV/ Morphine dose after SV (mg/hr)														
Was a SV performed? (date/time)														
Duration of SV (time started to time ended)														
Was the sedation turned off during the designated time (7am to 10am)?														
Was the sedation restarted at ½ the previous dose, and then titrated up as needed after the SV?														
Was a SBT performed? / How many SBT's were performed?														
Duration of the SBT (time started to time ended)														
Was the patient extubated after the SBT? / Did the patient self-extubate during the SV?														
Reason that a SV was not performed as indicated by a RN and/or MD/ML														

<u>Patient</u> Data	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Serum Creatinine/ Ideal Body Weight														
Creatinine Clearance														
FiO2														
PEEP														
Static Compliance														
MAAS														

APACHE III

Pulse	
Mean Blood Pressure	
Temperature (C)	
Respiratory Rate	
PaO2 (mmHg)	
AaDO2 (mmHg)	
Hematocrit (%)	
White Blood Cell Count (cu/mm) x 1000	
Serum Creatinine without ARF (mg/dl)	
Serum Creatinine with ARF (mg/dl)	
Urine Output (cc/day)	
Serum BUN (mg/dl)	
Serum Na (mEq/L)	
Serum Albumin (g/dl)	
Serum Bilirubin (mg/dl)	
Serum Glucose (mg/dl)	
Age	
Primary Co-morbidity	
(AIDS, Hepatic Failure, Lymphoma, Metastatic Cancer, Leukemia/Multiple Myeloma, Immune Compromised, Cirrhosis)	
pCO2	
Hq	
GCS Visual	
(normal response, response to voice, response to pain, no	
GCS Speech	
(oriented, confused, inappropriate words, incomprehensible	
speech, no response)	
GCS Motor	
(obey commands, localize to pain, flexion withdrawal, flexion abnormal, extension, no response)	

Abbreviations

- SBT=Spontaneous Breathing Trial
- SV=Sedation Vacation
- Nurse ID Code=Identifier for the nurse documented, in the electronic medical record, to have performed the sedation vacation
- Creatinine Clearance=using the Cockcroft-Gault method
- FiO2=Fraction of Inspired Oxygen
- PEEP=Positive End-Expiratory Pressure
- PaO2= Partial Pressure of Arterial oxygen
- AaDO2=Alveolar-arterial oxygen tension difference
- BUN=Blood Urea Nitrogen
- Serum Na=Serum Sodium
- pCO2= carbon dioxide partial pressure
- pH=acid base balance
- GCS-Glasgow Coma Scale
- APACHE III=Acute Physiology, Age, Chronic Health Evaluation III scoring system which provides predicted mortality in critically ill patients
- ARF=Acute Renal Failure
- MAAS=Motor Assessment Activity Scale
- Time started to time ended=Hour and minutes using military time (e.g. 13:30 to 14:46)
- Date/Time= Date using calendar years / Hour and minutes using military time (e.g. 12/21/2013 / 16:55)
- MD/ML=Physician/Midlevel Provider
- RN=Nurse

Legend of Responses

- Y=Yes
- N=No
- N/A=Not applicable

Appendix E

Emory IRB Letter

inspirational Review Board

TO: Kenneth Leeper Jr., MD Principal Investigator MedPulm

DATE: July 3, 2012

RE: Expedited Approval

IRB00059051

The Impact of Nurses' Adherence to Sedation Vacations on Ventilator Associated Pneumonia Prevention

Thank you for submitting a new application for this protocol. This research is eligible for expedited review under 45 CFR.46.110 and/or 21 CFR 56.110 because it poses minimal risk and fits the regulatory category F(5) as set forth in the Federal Register. The Emory IRB reviewed it by expedited process on 06/30/2012 and granted approval effective from 06/30/2012 through 06/29/2013. Thereafter, continuation of human subjects research activities requires the submission of a renewal application, which must be reviewed and approved by the IRB prior to the expiration date noted above. Please note carefully the following items with respect to this approval:

- A complete waiver of HIPAA patient anthorization has been granted by the Emory University IRB. This waiver was reviewed and approved under the review precedure noted above. The approval is granted based on this beard's determination that all criteria for waiver of authorization have been met.
- A request to waive informed consent has been reviewed and approved under 45 CFR. 46.116(d); 1) the research is no more than minimal risk; 2) the waiver will not adversely affect the rights and wolfare of the subjects; 3) the research could not practicably be carried out without the waiver; and 4) whenever appropriate, the subjects will be provided with additional information about their participation in the research. This research is not FDA-regulated.

Document reviewed with this application:

Emory IRB - Protocol Version Date: 06/21/2012

Any reportable events (e.g., unanticipated problems involving risk to subjects or others, noncompliance, breaches of confidentiality, HIPAA violations, protocol deviations) must be reported to the IRB according to our Policies & Procedures at <u>www.irb.emory.edu</u>, immediately, promptly, or periodically. Be sure to check the reporting guidance and contact us if you have questions. Terms and conditions of sponsors, if any, also apply to reporting.

https://cresearch.emory.cdu/Emory/Doc/0/9TVSAPVS5BD43C10R20ILRS859/fromString..., 7/3/2012

Page 2 of 2

-0.0 million

Before implementing any change to this protocol (including but not limited to sample size, informed consent, and study design), you must submit an amendment request and secure IRB approval.

In future correspondence about this matter, please refer to the IRB file ID, name of the Principal Investigator, and study title. Thank you,

Carol Corknan, MPH, CIP Senior Research Protocol Analyst This letter has been digitally signed

CC: Smith Seraya MedPolm

Emmy University 1995 United Roce, 5th Flass – Adamie, Georgie 39542 Tel: 434 51 20236 - Fast (e)4.222 (1358 - Basili, ideffections of a - Web, <u>franziswaw alternary of a</u> discrete appearance, official accession

Appendix F

Georgia State University IRB Letter



INSTITUTIONAL REVIEW BOARD

 Mail:
 P.O. Box 3999
 In Person:
 Alumni Hall

 Atlanta, Georgia
 30302-3999
 30 Courtland St, Suite 217

 Phone:
 404/413-3500
 Fax:
 404/413-3504

June 27, 2012

Principal Investigator: Clark, Patricia

Student PI: Soraya Smith

Protocol Department: B.F. Lewis School of Nursing

Protocol Title: The Impact of Nurses' Adherence to Sedation Vacations on Ventilator Associated Pneumonia Prevention

Submission Type: Application H12510

Review Type: Expedited Review, Category 7

Approval Date: June 27, 2012

Expiration Date: June 26, 2013

The Georgia State University Institutional Review Board (IRB) reviewed and approved the above referenced study in accordance with 45 CFR 46.111. The IRB has reviewed and approved the

research protocol and any informed consent forms, recruitment materials, and other research materials that are marked as approved in the application. The approval period is listed above.

Federal regulations require researchers to follow specific procedures in a timely manner. For the protection of all concerned, the IRB calls your attention to the following obligations that you have as Principal Investigator of this study.

- For any changes to the study (except to protect the safety of participants), an Amendment Application must be submitted to the IRB. The Amendment Application must be reviewed and approved before any changes can take place
- 2. Any unanticipated/adverse events or problems occurring as a result of participation in this study must be reported immediately to the IRB using the Unanticipated/Adverse Event Form.
- 3. Principal investigators are responsible for ensuring that informed consent is properly documented in accordance with 45 CFR 46.116.
 - A Waiver or Alteration of Consent has been approved for this study in accordance with the requirements set forth in 45 CFR 46.116 d.
 - A Waiver of Documentation of Consent has been approved for this study in accordance with the requirements set forth in 45 CFR 46.117 c.
- 4. For any research that is conducted beyond the approval period, a Renewal Application must be submitted at least 30 days prior to the expiration date. The Renewal Application must be approved by the IRB before the expiration date else automatic termination of this study will occur. If the study expires, all research activities associated with the study must cease and a new application must be approved before any work can continue.
- 5. When the study is completed, a Study Closure Report must be submitted to the IRB.

All of the above referenced forms are available online at <u>https://irbwise.gsu.edu</u>. Please do not hesitate to contact Susan Vogtner in the Office of Research Integrity (404-413-3500) if you have any questions or concerns.

Sincerely,

Jusan K. Lawy

Susan Laury, IRB Chair

Federal Wide Assurance Number: 00000129

Appendix G

Study Site's Complete Sedation Vacation Protocol

Protocol: Sedation/Analgesia Guidelines for Patients Requiring Mechanical Ventilation

Status:	Active	
Activation Date:	04/06/2009	
Last Review Date:	04/06/2009	By: Carolyn K. Holder
Entity: Responsible Dept/Group:	Emory Hospitals Nursing, Respiratory Care	
Database:	Patient Care Protocols	
Category:	CPOE, Diagnostic/Therapeutic/	Preventive
Level:	Dependent	
Content:		

Purpose

The purpose of this protocol is to provide guidelines for staff in providing care to patients who require sedation and analgesia while receiving mechanical ventilation. The physician determines the appropriate medications used for sedation and analgesia. The goal of sedation for most critically ill patients is to maintain a level of comfort with a Motor Activity Assessment Score (MAAS) score of 2-3 or as directed by the physician's orders. Analgesia will be provided to a satisfactory pain level for the patient with a pain scale or with appropriate assessment of nonverbal indicators of pain.

General Guidelines

- 1. A physician's order is required for the initiation or discontinuation of specific medications.
- 2. A physician's order is required for a change in dose orders when original order is written to titrate to a specific MAAS score.
- 3. A physician's order is required for dose increases above the written guidelines.
- 4. Refer to the Neuromuscular Blockade Protocol for patients receiving this therapy.

Content

 Motor Activity Assessment Score (MAAS) will be assessed q 4 hours and prn for adequate level of wakefulness. The scale is as follows:
 Unresponsive

U	Uniespunsive	
1	Responsive only to noxious stimuli	Opens eyes OR raises eyebrows OR turns
		head toward stimulus OR moves limbs with
		noxious stimulus
2	Responsive to touch or name	Opens eyes OR raises eyebrows OR turns
		head toward OR moves limbs when touched or name is spoken loudly

- 3 Calm or cooperative No external stimulus is required to elicit movement AND patient is picking at sheets No external stimulus is required to elicit 4 **Restless & cooperative** movement AND patient is picking at sheets OR uncovering self and follows commands No external stimuli is required to elicit 5 Agitated movement AND attempting to sit up OR moves limbs out of bed AND does not consistently follow commands No external stimulus is required to elicit 6 Dangerously agitated movement AND patient is pulling at tubes or catheters OR thrashing side to side OR striking at staff OR trying to climb out of bed AND does not calm down when asked
- 2. If patient is agitated with a MAAS score of 5 or 6, further assessment will be made by the nurse. Causes of agitation that should be considered include:
 - a. Pulmonary endotracheal tube malposition or patency, mode of ventilation, pneumothorax, hypoxia, hypercarbia
 - b. Metabolic hypoglycemia, hyponatremia, acute renal or hepatic failure
 - c. Emotional upset with information or awarenesss of critical condition, prognosis, need for surgical or invasive procedures, other interventions or complications, family or personal stressors
- 3. The goal of neuromuscular blockade and sedation/analgesia in the mechanically ventilated patient is to improve ventilation, oxygenation, and hemodynamic stability. **Patients who are receiving neuromuscular blockade therapy must receive adequate sedation and analgesia medications as continuous IV infusions.**
- 4. Neuromuscular blocking agents (NMBA) have no effect on level of consciousness or pain response. It is mandatory that deep sedation (to the point of unresponsiveness) be induced before these drugs are given, and be continued for the duration of paralysis. The patient's Motor Activity Assessment Scale (MAAS) score must be 0-1.

5. Refer to drug guidelines in Lotus Notes and Sedation algorithm on MD support page

Propofol	initial loading dose:	50 mg over 2 minutes (DO NOT BOLUS) Patients must be on continuous mechanical ventilation with a rate
	continuous infusion:	5-10 mcg /kg / min titrate 5-10 mcg/Kg/min q 5- 10 minutes to achieve MAAS of 2-3 as needed usual dose range = 5-80 mcg/Kg/min
		For ICP reduction/burst suppression, may give 100 mcg/Kg/min dose above 100 mcg/Kg/min must be approved by neurointensivist
Midazolam	initial loading dose: continuous infusion:	1-4 mg IV over 1-2 minutes Start infusion at 1mg/h and increase by 1 mg/h q 30 minutes with a 2 mg re-bolus as needed to achieve a MAAS of 2-3 Usual dose range= 0.5 mg-10 mg/h

Lorazepam	initial loading dose:	1-4 mg IV over 1-2 minutes, then 1-4 mg IV q 2- 6
	continuous infusion:	consider IV continuous infusion if requiring more than q 2h
		Discuss with MD possible continuous infusion at 2mg/h, increase by 1 mg/h q 30 minutes.
		Re-bolus with 2 mg with each increase to achieve a MAAS of 2-3
		NOTE: if converting from propofol to lorazepam, rebolus with 2 mg IV; No bolus if midazolam was
		used

- 6. A pain assessment is conducted q 4h and prn. The level of pain should be determined as satisfactory by the patient. If the patient is unable to communicate pain level, the nurse will assess for nonverbal indicators including facial grimacing, moaning, tachypnea, tachycardia, hypertension, diaphoresis, etc.
- 7. For pain management, analgesia medications are determined by MD. Fentanyl is the drug of choice for patients requiring continuous infusion or those who are hemodynamically unstable. Morphine may be given to those who are hemodynamically stable and who require intermittent pain medication. Continuous infusions of Morphine may be recommended for patients who are receiving comfort care as part of the End of Life (EOL) pathway.

8. Refer to Drug guidelines and the sedation/analgesia guidelines on the MD support page

Fentanyl	initial loading dose: continuous infusion:	50-150 mcg IV q 5minutes until pain is controlled Begin IV infusion at 1 mcg/Kg/h, increase by 0.5 mcg/Kg/h q 30 minutes A re-bolus of 100 mcg may be given. For patients with moderate to severe pain
Morphine	initial loading dose: dosing:	2-4 mg IV q 10 minutes until pain is controlled 2-4 mg IV q 2-4 hr prn pain or continuous infusion for patients on comfort care for EOL

Daily Sedation Awakening Trial (SAT) from IV Continuous Sedation/Analgesia

- 1. Patients are to have daily awakening from sedation while on continuous IV sedation in the ICU. Follow unit guidelines with timing of daily awakening.
- 2. The sedation awakening trial (SAT) is done regardless if the patient meets criteria for spontaneous breathing trial (SBT).
- 3. Criteria for passing the SAT is the patient opened their eyes to verbal stimuli or tolerated sedative interruption without exhibiting failure criteria. Patients fail the SAT if they develop sustained anxiety, agitation, or pain, a respiratory rate of 35 per minute for 5 minutes or longer, an Sp02 less than 88% for 5 minutes or longer, an acute cardiac dysrhythmia, two or more signs or respiratory distress including tachycardia, bradycardia, use of accessory muscles, diaphoresis or marked dyspnea.

- 4. Respiratory therapy staff must verify with nurse that continuous IV sedation is off prior to placing patient on a SBT. Exceptions include patients receiving Precedex (Dexmedetomidine) or neuromuscular blocking agents or on the oscillator ventilator
- 5. **DO NOT Interrupt infusion of sedation or analgesia medications** if patient is receiving neuromuscular blockade therapy.
- 6. Monitor level of wakefulness until patient is awake and follows commands (MAAS 2-3) or patient becomes uncomfortable or agitated (MAAS 5- 6).
- 7. If agitation prevents successful awakening, resume infusion of sedation medication at ¹/₂ the previous dose and titrate as needed.
- 8. Patient may require bolus depending on the MAAS score and pain score with medications as ordered.
- 9. If over sedation prevents successful awakening, hold infusion until at goal and resume ½ of prior infusion rate/dose.
- 10. If patient becomes hypotensive with loading dose of these medications, notify physician for IV fluid bolus if not ordered.

Agitation

- 1. Assess patient for underlying causes for increased agitation.
- 2. Opiates may be given for pain and dyspnea.
- 3. Lorazepam, midazolam or propofol may be given for anxiety or withdrawal symptoms.
- 4. Consider home or medication regimen prior to ICU admission that could lead to withdrawal symptoms if not given.
- 5. Follow Delirium protocol and orders for management of ICU delirium or refractory agitation.
- 6. Neuromuscular blockers cisatracurium or vecuronium may be given for asynchrony with mechanical ventilation resulting in hypoxia or severe refractory hypoxemia.

Related Policies/Procedures:

Key Words for Search: References:

- Brook, AD, et al. Effect of a nursing- implemented sedation protocol on the duration of mechanical ventilation. Critical Care Medicine 1999; 27:12, 2609-2615.
- Devlin, JW. et al. Motor Activity Assessment Scale: A valid and reliable sedation scale for use with mechanically ventilated patients in an adult surgical intensive care unit. Critical Care medicine 1999.27:7, 1271-1275.

- Girard, TD. et al. Efficacy and safety of a paired sedation and ventilator weaning protocol for mechanically ventilated patients in intensive care(Awakening and Breathing Controlled trial) a randomized controlled trial. Lancet 2008; 371, 126-134.
- Kress, JP. et al. Daily interruption of sedation infusions in the critically ill patients undergoing mechanical ventilation. New England Journal of Medicine 2000. 342:1471-1477.
- Hoffman, L. et al. Interrator Reliability of 2 sedation scales in a Medical Intensive Care Unit. American Journal of Critical Care. March 2001; 10-2, 79-83.
- Jacobi, J. Clinical practice guidelines for the sustained use of sedatives and analgesics in the critically ill adult. Critical Care Medicine. 2002; 30:1, 119-141.

Stravitz, MD, R. Todd et al. Intensive care of patients with acute liver failure: Recommendations of the U.S. Acute Liver Failure Study Group. Crit Care Med 2007, Vol. 35, No. 11.



Review/Approval

Lead Reviewer: Carolyn K. Holder Reviewers: Georgia F. Jackson, Mary D. Still, Mary J. Zellinger, Vicki C. Morelock, Carol Batchelder, Ann M. Huntley, Alley Killian, Stacey L. Folse Groups:

 Reviewer Approval
 Stacey L. Folse
 03/31/2009 01:14:26 PM

 Mary D. Still
 04/01/2009 02:46:31 PM
 04/06/2009 12:20:44 PM

Approved By Nurse Executive Team