THE DEVELOPMENT OF AN AUDITING TOOL TO MEASURE ADHERENCE TO A SEDATION PROTOCOL

by

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As members of the DNP Project Committee, we certify that we have read the DNP Project prepared by Keith Wesley Kent entitled “The Development of an Auditing Tool to Measure Adherence to a Sedation Protocol” and recommend that it be accepted as fulfilling the DNP Project requirement for the Degree of Doctor of Nursing Practice.

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SIGNED: Keith Wesley Kent
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ABSTRACT

Introduction: A protocol for management of sedation and pain for mechanically ventilated patients at Flagstaff Medical Center (FMC) was implemented in August 2013. It was unknown whether the protocol is being adhered to or whether it has had an impact on patient outcomes.

Objectives: To develop an audit and feedback mechanism to monitor adherence to sedation protocol at FMC and determine whether the protocol has impacted patient outcomes.

Methods: A retrospective manual chart review was conducted including all mechanically ventilated adult patients for four, one-month periods: 1) pre-protocol; and 2) one month, 3) six months, and 4) 12 months post-protocol implementation.

Results: 132 total patients were included (32 pre; 100 post-protocol). Mean weighted adherence score for post-protocol study groups were 5.0±0.6, 5.0±0.7, and 5.2±0.7 (p=0.926) out of ten. Time of mechanical ventilation (p=0.003) and hospital length of stay (LOS) (p=0.023) were reduced post (56±58h; 9.8±7.9days) vs. pre-protocol (90±67h; 13±7days). The adherence score was weakly correlated with hospital LOS but not time of mechanical ventilation.

Conclusion: This project demonstrates improvements in patient outcomes from utilization of a sedation protocol. However, this project also highlights several challenges associated with the monitoring of protocol adherence. A lack of audit and feedback may be a factor in the observed unchanged adherence over time. Both research and monitoring activities are impaired by EHR systems that do not allow for the easy extraction of data. Ensuring that adequate audit and feedback strategies are designed and available prior to implementation of new protocols is an essential step in planning the implementation of a new protocol.
CHAPTER 1: INTRODUCTION

Background and Significance

Mechanical ventilation (MV) is a common intervention in healthcare that uses a disproportionate amount of resources and is associated with a high rate of mortality (Wunsch et al., 2010). In 2005, it was estimated that more than 790,000 hospitalizations in the United States involved MV; this represents 2.8% of all hospital admissions and nearly 40% of all patients in intensive care units (ICU) are mechanically ventilated (Wunsch et al., 2013). Mechanically ventilated patients incur between $600-$1500 of incremental costs when compared to non-ventilated patients and in 2005 national expenditures related to MV were estimated at $27 billion, or 12% of all hospital expenses (Wunsch et al., 2010). More than half of these costs are attributable to patients of age ≥ 65 and mortality for all mechanically ventilated patients approaches 35% (Wunsch et al., 2010). The causes of mortality are multi-factorial; nearly half of all mechanically ventilated patients have a major comorbid illness such as diabetes (15.4%) and pulmonary disease (13.2%), and frequently there is concurrent non-respiratory organ involvement led by renal (20.7%) and cardiac (18.4%) dysfunction (Wunsch et al., 2010).

Furthermore, observational studies have shown that with longer duration of MV there are associated increases in mortality and morbidity, including ventilator associated pneumonia (VAP) and ventilator associated lung injury (VALI) (Blackwood et al., 2011).

Given the significant health and economic impacts of MV, quality improvement and cost reduction strategies targeted at this patient population are warranted (Blackwood et al., 2011; Wunsch et al., 2010). Research has shown that protocolized management of sedation for mechanically ventilated patients decreases time of mechanical ventilation, ICU length of stay (LOS), hospital LOS, mortality, and healthcare costs (Abdar et al., 2013; Awissi, Begin, Moisan,
Lachaine, & Skrobik, 2012; Barr et al., 2013; Blackwood et al., 2011; Dale et al., 2014; Hahn, Beall, Turner, Woolley, & Hahn, 2012; Mansouri et al., 2013; Radtke et al., 2012; Skrobik et al., 2010). Components of sedation protocols that result in these improved outcomes include more frequent assessment of level of sedation, more restrictive use of sedation medication, prophylactic interventions for delirium prevention, spontaneous awakening trials, and spontaneous breathing trials. However, a meta-analysis of 11 studies and 1,971 patients evaluating the impacts of ventilator weaning protocols performed by Blackwood et al. (2011) showed mixed results for effect on patient outcomes; time of mechanical ventilation was reduced by 25% (95% confidence interval 9 to 39%, P=0.006; 10 trials), duration of weaning was reduced by 78% (31 to 93%, P=0.009; six trials), ICU length of stay was reduced by 10% (2 to 19%, P=0.02; eight trials), while no difference was found in ICU mortality (odd ratio 0.98, 0.48 to 2.02; four trials, n=508), hospital mortality (odds ratio 1.10, 0.86 to 1.41; six trials, n=1368), or hospital length of stay (overall effect z=0.13; p=0.90). Commonly, in studies investigating this topic there is potential for bias due to the inability to blind those administering the interventions; plus, the control groups usually consist of usual care, which varies widely across settings (Blackwood et al., 2011). Further complicating the interpretation of the findings is the significant heterogeneity ($I^2 = 76\%$, $P<0.01$ for duration of mechanical ventilation, $I^2 = 97\%$, $P<0.01$ for duration of weaning) present in the outcomes that were improved (Blackwood et al., 2011). The variability in research findings and heterogeneity of study characteristics necessitate that researchers provide clear descriptions of contextual factors, such as organizational setting, staffing ratios, and implementation strategies (Blackwood et al., 2011).

In addition to the challenges mentioned above, another factor that significantly affects findings related to implementation of sedation protocols is the level of adherence to individual
components of the protocol and to the protocol as a whole. In general, adherence to protocols in
the ICU is quite low (Burns, 2012; Leone et al., 2012; Radtke et al., 2012) with rates for sedation
protocols falling between 10 to 30% (Burns, 2012). Strikingly, perception of adherence with
protocols does not mirror reality. For example, Burns (2012) found that physicians thought they
were adherent with a sedation protocol at three times the actual rate.

**Knowledge Gaps**

Patients receiving MV is an area of healthcare that warrants investigation due to the
opportunity to improve both clinical outcomes and the economic costs of care. The majority of
available evidence indicates that sedation protocols are effective in improving clinical outcomes
and reducing healthcare costs; however, studies are heterogeneous in multiple facets including:
specific components of the protocol, implementation strategies, monitoring strategies, make-up
and interventions of the control group, and outcomes measured. As a result, little is known about
the relative importance of individual components of sedation protocols. While there are studies
that have investigated the adherence to protocols in the ICU setting, including protocols for
management of sedation of mechanically ventilated patients, the results vary widely and are
difficult to compare due to variations in methodology. The lack of information regarding
essential components of sedation protocols combined with uncertain rates of adherence make
generalizability of research findings more difficult and calls into question whether the full
benefit of sedation protocols is being realized. A more detailed and repeatable analysis of
adherence is needed. This project will develop and apply a numerical adherence score to assess
fidelity to a sedation protocol developed based on guidelines published by the American
Colleges of Critical Care Medicine (ACCM) and designed and implemented specifically for
mechanically ventilated patients in the ICU at Flagstaff Medical Center.
Purpose of Study

There is increasing acceptance that there is a generalized failure to translate new evidence into healthcare practice and that one major factor is the lack of research on implementation and sustainability (Feldstein & Glasgow, 2008; Tabak, Khoong, Chambers, & Brownson, 2012). The study of implementation involves methods to promote the integration of research and evidence into healthcare policy and practice (National Institutes of Health [NIH], 2014). The implementation of a sedation protocol can alter both adherence to the protocol and outcomes resulting from the protocol. However, at FMC there is currently no method for evaluating protocol adherence or patient outcomes. The overall purpose of this project was to develop an audit and feedback mechanism for the sedation protocol at FMC. Through the creation of a numerical adherence score with weighted values for individual components of a sedation protocol, this project developed a system for monitoring the adherence to the sedation protocol. This system allows for both snapshot and time-series analyses of protocol adherence and identification of implementation successes, areas for improvement, and opportunities for additional or repeated education. Specific aims of the study included:

1. Development of an adherence score to evaluate adherence to:
   - Individual protocol elements
   - The protocol as a whole
2. Application of the adherence score using a retrospective chart review.
3. Evaluation of the sedation protocol implementation process.
4. Creation of recommendations to improve adherence.
5. Evaluation of feasibility of automated ongoing auditing.
Secondary project aim included:

1. Tracking outcome data (time of mechanical ventilation, ICU LOS) and evaluate for correlation to adherence score.

**Operational Definitions**

In general, practice guidelines attempt to be as comprehensive as possible, but given the inevitable variation in availability and strength of evidence, most guidelines include incomplete or inconclusive recommendations (Aapro et al., 2008). As a result, many guidelines are difficult to translate and monitor in a systematic method (Aapro et al., 2008). Despite this limitation, Aapro et al. (2008) developed an algorithm, which later evolved into a congruence score (Aapro et al., 2009), to both promote and monitor adherence to published guidelines for the treatment of anemia in cancer patients. The process of developing the congruence score began with an expert review of the individual elements of the algorithm to determine reliability and validity (Aapro et al., 2008). In this DNP project, a similar process was initiated to develop a method to monitor adherence to the sedation protocol at FMC.

The following section includes a table of the elements of a numerical adherence score for the sedation protocol at FMC and an explanation for how the elements were chosen and how the point values were determined (Table 1). The concept of a numerical score to monitor adherence has been demonstrated by Aapro et al. (2009) and the initial selection and point-value determination was completed through consultation with physicians, nurses, and nurse educators familiar with the sedation protocol at FMC. Given that there are no published reports of a numerical adherence score for a sedation protocol, the precedent set by Aapro et al. (2008) supports the use of expert opinion in the development of the adherence score in this project.
### TABLE 1. Adherence Score for Sedation Protocol Implementation

<table>
<thead>
<tr>
<th>Responsible Party</th>
<th>Intervention</th>
<th>Quality of Evidence*</th>
<th>Strength of Recommendation*</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered Nurse (RN)</td>
<td>RASS documented at least once per 12-hour shift</td>
<td>B</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>SAT initiation charted once per day</td>
<td>B</td>
<td>1</td>
<td>2.5</td>
</tr>
<tr>
<td></td>
<td>SBT initiation charted once per day</td>
<td>B</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Respiratory Therapist</td>
<td>SBT pass/fail</td>
<td>B</td>
<td>2</td>
<td>2.5</td>
</tr>
<tr>
<td>Provider</td>
<td>Target RASS ordered</td>
<td>B</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>SAT addressed in orders</td>
<td>B</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>Sedation and pain medications with bolus and titration guidelines ordered</td>
<td>B</td>
<td>1</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Total Adherence Score (10 possible) 10

**LEGEND:** RASS – Richmond Agitation Sedation Scale; SAT – Spontaneous Awakening Trial; SBT – Spontaneous Breathing Trial

Evidence Grade:
B – Moderate quality (e.g. randomized-control trials with limitations, high-quality observational studies)
1 – High strength of evidence supports recommendation; 2 – Weak evidence supports recommendation

* Retrieved from Barr, et al., 2013 using Grading of Recommendations, Assessment, Development and Evaluation (GRADE) methodology for the quality of evidence rating while the strength of recommendation was determined as (1) strong or (2) weak.

**Richmond Agitation Sedation Scale (RASS) Scoring**

The RASS was developed by a multidisciplinary team consisting of critical care physicians, nurses, and pharmacists in an effort to create an optimal sedation assessment tool (Sessler et al., 2002). The RASS is the most tested subjective scale available for assessing sedation among sedated and ventilated patients (Jullette-Fantigrassi, 2013) and is one of two assessment tools that has established reliability and validity for monitoring the quality and depth of sedation among critically ill patients (Barr et al., 2013; Jullette-Fantigrassi, 2013). The charting of a RASS at least every two hours by the bedside RN is a validated way to assess if
light, versus deep, sedation is being maintained. Light sedation allows a patient to approximate wake/sleep cycles, participate more in their own care, and reduces the incidence of delirium while decreasing time of MV and reducing ICU length of stay (LOS) (Barr et al., 2013). The concept of ‘light sedation’ has previously not been well defined, but should include more than being “sleepy but arousable.” Instead, light sedation should allow for the evaluation of pain through patient self-report, for assessing patients’ readiness to wean and extubate, for performing delirium assessments, and for implementing early mobility efforts (Barr et al., 2013). The charting of a RASS score at least every two hours demonstrates active management of the patient’s level of sedation.

Another aspect of the sedation protocol requires that the provider order a target RASS. If the provider utilizes the sedation protocol order set, the default value for target RASS is -2 – 0. However, some patients require a deeper level of sedation and it is expected that the provider adjust the target RASS to reflect that individual patient’s needs. The ordered target RASS is an important part of the adherence score as it represents clear instructions from the provider for management of sedation. After discussion regarding the relative importance of the provider and nurse responsibilities related to the RASS, it was determined that the RASS represents 30% (3 points) of the total adherence score.

**Spontaneous Awakening Trial (SAT)**

During a SAT, all sedative and pain medications are reduced or turned off to allow for assessment of the patient’s neurological status, reassessment of the necessary level of sedation, and to allow for a SBT (Jones et al., 2014). While there is good evidence to support the protocolized use of either light sedation or a daily sedation interruption, there is insufficient data to support the use of one over the other, and there is limited evidence as to whether combining
the two approaches would add additional benefit (Barr et al., 2013). One study conducted by Mehta, et al. (2012) compared two groups of patients with sedation managed by the same protocol and the experimental group also receiving a daily interruption of sedation; they found equivalent time of mechanical ventilation and a slight decrease in ICU LOS that was not statistically significant. Despite a lack of evidence showing benefit, the sedation protocol at FMC does utilize both strategies and presents a good opportunity for additional study of this combined approach.

The RASS monitors for the maintenance of light sedation, while monitoring the SAT will track the daily interruption of sedation and what the patient response was. However, while the RASS allows for a continuum of acceptable levels of light sedation, a SAT is a concrete way to ensure that only the necessary amount of pain and sedative medication is administered and that the patient’s response to less sedation is clearly documented. Due to the dual evaluation of both light sedation and a daily sedation interruption, the SAT receives 30% (3 points) of the total adherence score.

**Spontaneous Breathing Trial (SBT)**

A SBT is when a patient is allowed to breathe independently, often with some level of pressure support to account for increased airway resistance of the endotracheal tube and to approximate physiological positive end expiratory pressure (PEEP) (Jones et al., 2014). Tolerance of a breathing trial with assessment of breathing mechanics is one way to wean a patient from mechanical ventilation and assess readiness for extubation. While there are a variety of other methods of weaning, using a protocolized approach for whichever method is utilized results in reduced duration of mechanical ventilation and ICU LOS (Blackwood et al., 2011). While the data for SAT combined with light sedation is equivocal, Girard, et al. (2008) did find
that combined SAT and SBT resulted in improved outcomes for mechanically ventilated patients (reduced time of mechanical ventilation, ICU LOS, hospital LOS, and one-year mortality) and should become part of regular practice. There are many other factors that affect the duration of weaning, but a protocol specifying a daily SBT requires regular assessment of a patient’s readiness for extubation and should result in the earliest appropriate discontinuation of mechanical ventilation. Given that the SBT is the culmination of the SAT, is an important step in the ventilator weaning process, requires an order from the provider and activities by the RT and the bedside RN justifies the highest percentage of points (35%) in the adherence score.

**Sedation and Pain Medication Orders**

The orders for pain and sedation medications set the foundation for maintenance of light sedation, affect incidence of pain, agitation, and delirium, and influence the timing of weaning from the ventilator. It is recommended that analgesia is the first-line therapy for sedation with non-benzodiazepine agents added as needed (Barr et al., 2013). Furthermore, it is essential to have appropriate bolus and titration parameters ordered so that nurses have the necessary tools available for maintaining light sedation while also protecting patient safety. The sedation protocol at FMC includes comprehensive orders for pain and sedation drips, though it is still possible to order these infusions outside of the protocol that do not include the appropriate bolus and titration parameters. Despite the fundamental nature of these orders to the protocol, it can be debated whether the specific parameters of the order influence the behavior of the nurse at the bedside. Given the extensive education that has occurred for all staff involved in the care of mechanically ventilated patients, it is possible that titration and bolusing activities would proceed in a similar manner whether or not the order is input into the EHR. Furthermore, if the appropriate orders are not in the EHR, it is possible that a nurse will bring this to the attention of
the attending provider. Given that the presence of the appropriate order for medications may or may not exert a significant influence on the behavior at the bedside, this component of the adherence score receives 5% of the total score.

**Significance to Advanced Practice**

The APRN role has expanded to include the care of most hospitalized patients, including those that are mechanically ventilated. This project is significant for APRNs in several different ways. First, management of mechanically ventilated adult patients has been shown to improve with the use of protocols for managing sedation. This project highlights the latest evidence in the use of sedation protocols and provides a resource that describes issues surrounding the implementation of these protocols. While the specific protocol implemented at FMC may not be directly transferable to another facility, the scientific underpinnings of the protocol are transferable and aspects of the implementation process can be tailored to a variety of settings.

Secondly, this project provides an example of how to include contextual information about research that will improve generalizability of the findings and assist any researcher that seeks to recreate a similar project. By utilizing a well-defined set of contextual characteristics, this project demonstrates the utility of an expanded description of contextual factors that influence outcomes of the study and have previously been infrequently reported in most medical research. Through knowledge of the importance of this contextual information and following the example set in this project, APRNs will build on a growing body of research that improves the process of implementing evidence-based practice.

Finally, through the creation of a numerical adherence score, this project establishes a foundation for similar projects that create easily interpretable audit and feedback mechanisms and opens the door for other novel uses of electronic health information. As computer systems
become more integrated and sophisticated, healthcare workers will be able to receive more timely and targeted feedback regarding care processes at the bedside. Given their experience both at the bedside and at the provider level and a baseline knowledge of conducting research, APRNs are ideally situated to design and implement innovative systems for improving the implementation and sustainability of quality improvement projects.

**Implementation Model**

The use of a theory or framework in implementation research improves interpretability of study findings and ensures that essential implementation strategies are included (Tabak et al., 2012). Theories and frameworks are distinct concepts, but both enhance the effectiveness of interventions by focusing efforts on individual components during the process of implementation (Tabak et al., 2012). In their systematic review, Tabak et al. (2012) used the term model to encompass both theories and frameworks and evaluated 61 models from Dissemination & Implementation research. The review inventoried, synthesized, and organized the models in a way to facilitate selection of a model for use in future research (Tabak et al., 2012). Each model was evaluated for: 1) construct flexibility; 2) focus on dissemination and/or implementation activities; and, 3) the socioecological framework level. Through review of their results, I chose the Practical, Robust Implementation and Sustainability Model (PRISM) to inform the design and implementation of my project. PRISM focuses more on implementation than dissemination and targets the organizational and individual socioecological level (Tabak et al., 2012). These characteristics make it an appropriate choice to evaluate the implementation of a sedation protocol at a single hospital while considering both organizational and individual factors.

PRISM was developed by building on concepts from existing work such as Diffusion of Innovations, social ecology, the PRECEDE/PROCEED model, RE-AIM, the Chronic Care
Model, and others (Feldstein & Glasgow, 2008). The model emphasizes the consideration of: 1) the perceived relative advantage of adopting new behaviors; 2) the cultural compatibility and complexity of the innovation; 3) observability; 4) trialability; and, 5) reversibility (Feldstein & Glasgow, 2008). PRISM also advocates identifying the one or two most impactful elements at each of multiple levels of influence to narrow the number of areas of focus and maximize intervention effectiveness and efficiency (Feldstein & Glasgow, 2008). Furthermore, PRISM highlights the critical role of clinical information systems to define gaps in care, measure performance change, and provide decision support at the point of care (Feldstein & Glasgow, 2008). Each element of PRISM is defined in greater detail and discussed in relation to this project in Appendix A.

**Contextual Factors**

Contextual factors are infrequently recorded, analyzed, or reported in published research and this lack of contextual information increases the difficulty of attempts to replicate the research and complicates interpretation of subsequent results (Tomoaia-Cotisel et al., 2013). The resulting inconsistency of context and findings also introduces challenges when attempting to conduct meta-analyses or formulate evidenced-based guidelines (Tomoaia-Cotisel et al., 2013). Historically, research has focused on strengthening internal validity at the expense of external validity (Tomoaia-Cotisel et al., 2013) and investigations into the extent of influence of contextual factors and which contextual factors are most important is nascent and warrants further study (Kaplan et al., 2010; Taylor et al., 2011; Tomoaia-Cotisel et al., 2013).

One model that has been developed by quality improvement experts to describe the effect of context on implementation is the Model for Understanding Success in Quality (MUSIQ) (Kaplan et al., 2012). This model illustrates the relationship between different contextual factors
and allows for greater understanding of the mechanism by which context influences research findings and provides a framework for future researchers to test and refine (Kaplan et al., 2012). Tomoaia-Cotisel et al. (2013) have taken the next step and proposed five domains that researchers should address when reporting findings in order to improve the value, validity, and transportability of results, which include: (1) the practice setting; (2) the larger organization; (3) the external environment; (4) implementation pathway; and, (5) the motivation for implementation (Tomoaia et al., 2013).

This project involves aspects of implementation science, quality improvement, and protocol adherence, each of which is subject to the effects of the contextual factors. As such, it is necessary to describe, in detail, the context in which this project will take place. To promote the consistent reporting of contextual factors, application of the five domains to this project as defined by Tomoaia et al. (2013) is presented in Appendix B.
CHAPTER 2: LITERATURE REVIEW

This chapter examines the existing body of knowledge related to the effects of sedation protocols on clinical outcome measures and clinical protocol adherence in an ICU setting. Articles from several electronic databases were reviewed to evaluate the latest research on these topics and identify knowledge gaps.

Literature Review Process

In order to determine the effect that sedation protocols have on duration of mechanical ventilation and ICU LOS for adult patients in the ICU, a July 2013 literature search restricted to articles published since 2008 was conducted on PubMed and Cumulative Index of Nursing and Allied Health Literature (CINAHL) using keywords: intensive care unit, sedation, and protocol. Articles were excluded if they were not written in English, involved subjects younger than 19 years of age, or were review/meta-analysis papers. The search resulted in 133 articles (60 PubMed; 73 CINAHL) of which five were retained for an evidence synthesis table (Appendix C). These particular articles were retained for their appropriateness of both practice setting and patient population and for reporting of key patient outcome variables important for the determination of benefit of the intervention. Reasons for excluding articles included: a practice setting in a foreign country with a vastly different healthcare system than the U.S., interventions for pediatric patients, interventions that targeted only a specific aspect of clinical management of mechanically ventilated patients, among others.

To investigate the current state of research on adherence to clinical guidelines, an additional literature review was conducted July 2013 in PubMed and CINAHL using keywords ICU, protocol, and adherence, with the following filters: published within 10 years, subjects 19 years and older, and English language. A total of 309 articles (305 PubMed; 4 CINAHL) were
retrieved and four were retained for an evidence table (Appendix D). These four articles were retained for their appropriateness of patient population and/or outcome measures, as a representation of different sampling methods, and to cover a variety of adherence factors that influence protocol implementation success. Articles were excluded when investigation involved inappropriate patient population, interventions for topics vastly different from those covered in this project, evaluating the quality of protocols for other areas of care, among others.

In order to determine if a numerical score approach for the evaluation of the implementation of a sedation protocol has previously been used, a September 2014 literature search was completed in PubMed, CINAHL, and the Cochrane Library. The search terms “sedation protocol adherence score,” “sedation protocol compliance score,” and “sedation protocol congruence score,” with filters for published within the last five years and English language were used. No results were obtained in the searches of the CINAHL and Cochrane databases. One study met the search criteria in PubMed (Leroy et al., 2010), though the specific research involved the creation of a Report Mark (0 - 10 scale) for adherence to guidelines for procedural sedation for pediatric patients. While this study does provide a second example of the utilization of a numerical rating system to evaluate adherence to a guideline, it involves a different intervention and a different patient population, lessening the applicability to this project. However, the findings from this study do highlight the low rates of adherence to guidelines and support the importance of targeted implementation strategies in order to improve adherence (Leroy et al., 2010).
Current State of the Science

Sedation Protocol Effect on Length of Mechanical Ventilation and ICU LOS

Pain, sedation, agitation, and delirium have both short and long-term consequences for mechanically ventilated patients in the ICU (Barr et al., 2013). Methods of administering and titrating medications, as well as choice of medications for management of these symptoms, have been shown to affect patient outcomes (Barr et al., 2013). It is suggested that protocolized management of sedation improves some patient outcomes, including shortening the duration of mechanical ventilation and decreasing overall ICU length of stay (LOS) (Awissi, Begin, Moisan, Lachaine, & Skrobik, 2012; Barr et al., 2013; Blackwood et al., 2011; Hahn, Beall, Turner, Woolley, & Hahn, 2012; Radtke et al., 2012; & Skrobik et al., 2010). In addition to improvements in these clinical measures, a study by Awissi et al. (2012) found that the cost of hospitalization for mechanically ventilated patients decreased by nearly $1,000 (15%) after implementation of a sedation protocol. This study was conducted in Canada, which may suggest cost savings are likely to be even greater in the U.S. where daily ICU charges are significantly higher.

The majority of evidence indicates that utilizing a well-defined protocol for administration of sedation reduces the duration of mechanical ventilation and ICU LOS (Awissi et al., 2012; Barr et al., 2013; Hahn et al., 2012; Radtke et al., 2012; & Skrobik et al., 2010). Several of these studies used pre/post cohort observations to analyze the effect of a new protocol and found that the duration of mechanical ventilation (Awissi et al., 2012; Hahn et al., 2012; & Skrobik et al., 2010) and ICU LOS (Awissi et al., 2012 & Skrobik et al., 2010) decreased post-implementation. The study by Hahn et al. (2012) did not have sufficient power to find statistical significance in the results, though the authors report this was likely a type II error.
In order to investigate a different aspect of sedation protocol use, Radtke et al. (2012) compared the success of two different education strategies for implementation of a new protocol. Despite no significant differences in age, gender, and severity of illness between the study groups, the authors found that an extended training program resulted in a trend towards reduced duration of mechanical ventilation and ICU LOS.

Only one study did not find a difference in the duration of mechanical ventilation and ICU LOS. However, the research question was different than the other articles included in this structured literature review. Mehta et al. (2012) conducted a randomized controlled trial (RCT) to determine the benefits of a daily sedation interruption as part of a sedation protocol versus the same sedation protocol without daily interruption. No difference was found in duration of mechanical ventilation or ICU LOS with the addition of a daily sedation interruption (Mehta et al., 2012). Even though a RCT represents a higher level of evidence versus other observational studies, the particular research question they investigated must be taken into account. By comparing implementation of a sedation protocol versus implementation of a sedation protocol plus sedation interruption, the results do not specifically address protocol versus no protocol. The authors acknowledge other literature that clearly indicates the benefits of using a sedation protocol and propose that no difference was found in their study because a protocol was used in both study groups. Therefore, this article does support the implementation of a sedation protocol, but calls into question as to whether a daily sedation interruption is necessary.

Many of the other studies are observational cohort studies and represent a lower level of evidence than RCT’s; however, cohort studies are typically a good fit for this type of research question. Skrobik et al. (2010) purposely chose this design because it mimics real life clinical situations. Therefore, despite the inherent limitations of this type of study design, the results of
these observational studies, when taken as a whole, are rigorous enough to be considered in nursing practice and introduce little to no risk to the patient.

**Protocol Adherence**

A secondary finding in the study by Radtke et al. (2012) indicates that adherence to a protocol alters the measurable effects of the protocol on patient outcomes. Rates of adherence to clinical care guidelines in an ICU setting vary widely across different studies and, for sedation protocols, generally fall between 10 to 30% (Burns, 2012). In addition to these already low rates of adherence, self-reporting of adherence often overstates actual adherence. A study reported by Burns (2012) found that physicians perceived that they adhered with a sedation guideline 69% of the time while actual adherence was 20%. One study across 66 ICUs in France measured adherence across 13 clinical guidelines and found that 24% of patients received fully compliant care (Leone et al., 2012). At an individual protocol level, adherence rates ranged from 24% to 96% and the number of protocols applicable to each patient played a large role in determining overall level of adherence. For example, the rate of full adherence was >80% in patients eligible for fewer than three protocols while in those eligible for more than three protocols adherence fell to <20% (Leone et al., 2012).

Despite the generally low adherence rates to clinical care protocols, there are studies showing a measurable improvement in protocol adherence through a variety of strategies. Several studies indicate that two important components of achieving higher rates of adherence are a targeted education program for rollout of the clinical care protocol and utilization of a multidisciplinary team (Bird et al., 2010; Burns, 2012; Quenot et al., 2010). Degrado, Anger, Szumita, Pierce, & Massaro (2011) measured sedation protocol adherence through tracking the number of RASS assessments and the percentage of assessments which were charted. The
authors showed improvements in charting of target RASS (85.4 vs. 21.3%) and actual RASS assessments (11.4 vs. 4.7) after implementation of a sedation guideline that included continuous education along with annual competencies for RNs. Radtke et al. (2012) demonstrated that an extended education program resulted in higher rates of adherence to a sedation protocol vs. the hospital’s typical rollout plan. Furthermore, modifying nurse’s attitudes on sedation and the experience of mechanical ventilation may be necessary to change sedation practices (Guttormson, Chlan, Weinert, & Savik, 2010).

**Summary**

While the majority of research findings support the use of sedation protocols for mechanically ventilated adult patients in the ICU, some studies have failed to consistently show a statistically significant improvement in clinical measures of length of mechanical ventilation and ICU LOS after implementation of these protocols (Hahn et al., 2012; Mehta et al., 2012, Radtke et al., 2012). However, the majority of evidence also suggests that adherence rates to such protocols are quite low. The purpose of this project was to develop a numerical method to track overall and individual element adherence to a sedation protocol. This score may be used to identify opportunities for improved adherence to the sedation protocol in the critical care cluster at FMC.
CHAPTER 3: PROJECT PLAN

Design and Methods

This project was performed as a retrospective manual chart review of electronic health record information within the PowerChart by Cerner EHR at FMC. The comparison group consists of mechanically ventilated patients in the adult ICUs at FMC over a one-month period prior to the implementation of the sedation protocol. Intervention groups involve the same patient population grouped by one month, six months, and 12 months post-protocol implementation.

Setting

Flagstaff Medical Center is a non-profit community hospital with approximately 270 beds. This project was conducted with mechanically ventilated patients who received care in either the 20-bed general ICU or the 11-bed CVICU. Medical management of both ICUs is performed by an independent group of intensivists who are on-site 24 hours per day, seven days per week. Staffing ratios are capped at two patients per nurse with a nursing assistant for approximately every 10 patients. A sedation protocol for the care of mechanically ventilated patients was implemented in these ICUs in August 2013. A multidisciplinary team designed the protocol based on the ACCM’s clinical guidelines for the management of pain, agitation, and delirium in the ICU and oversaw the implementation process. Institutional Review Board (IRB) approval from Northern Arizona Healthcare (NAH) was obtained as well as a deferral of oversight to the NAH IRB from the University of Arizona.

Procedures

The attempt was made to utilize automated queries to pull data from the EHR. Challenges encountered during the process (detailed in the discussion section of this project) were
sufficiently prohibitive to require manual extraction of data. The principal investigator and a member of the evidence-based practice (EBP) team at FMC performed the manual data extraction.

Queried data included both demographic and clinical data. Demographic data consisted of: age, gender, and ethnicity. Clinical data included: ICD-9 code for MV, hospital admission and discharge date/time, mechanical ventilation start/stop time, diagnosis-related group severity of illness (DRG-SOI), provider order for target RASS, provider order for SAT, provider order for sedation and pain medication with bolus and titration parameters, each charted RASS value, charted values for the SAT and SBT, and charted value for pass/fail of SBT. Data was evaluated for: one instance of each of the three provider orders per patient, one value charted for RASS every two hours during MV, one value charted for the SAT, SBT, and SBT pass/fail per day of MV. Based on the presence of these charted values a numerical score was assigned per above and both weighted and unweighted adherence scores for the sedation protocol were calculated.

**Information Management and Confidentiality of Data**

After the data was extracted, each patient record was randomly assigned a Patient Identification Number (PIN). The data file with identifiable information was stored on a password protected S: / drive on Northern Arizona Healthcare’s server with access limited to the principle investigator and Alejandra Figueroa, research data analyst at FMC. Subsequently, de-identified data was exported to a separate Excel file and used for data analysis.

**Risks and Benefits to Subjects**

This project was a retrospective chart review and the only risk to subjects was disclosure of protected health information (PHI). All patients have received care before the data was obtained and care was unaffected by the study process or results. The subjects included in the
project also stood to gain no benefit from this project for the same reasons. However, future mechanically ventilated patients at FMC may potentially benefit from opportunities for improved care-delivery processes identified during the course of this project. Additionally, through evaluation of the implementation process, FMC may benefit from lessons learned during the rollout of the sedation protocol that can be applied to future quality improvement projects.
CHAPTER 4: RESULTS

Sample Population

Four study groups were formed based on a query of the EHR system for mechanically ventilated patients in the critical-care areas at FMC. The groups consisted of one pre-sedation protocol implementation group and three post-implementation groups. Each group included all mechanically ventilated patients discharged from critical care areas for a period of one month. A total of 220 patients were obtained in the initial query, of which 88 were excluded for a total study population of 132. Exclusion criteria included: 1) expired while on the ventilator/extubated to comfort care (n=43); 2) tracheostomy tube placement (n=29); 3) intubated less than 24 hours (n=11); 4) coronary artery bypass surgery or valve replacement (n=3); 5) transfer to another facility while on the ventilator (n=1); and, 6) an order to defer the SAT or SBT (n=1). By group, exclusions were 27 (45.8%) in July 2013; 17 (33.3%) in September 2013; 23 (48.9%) in March 2014; and 21 (39.6%) in September 2014.

Demographic data is summarized in Table 2. Mean age of subjects was 51.7 ± 18.2 years with no significant difference between groups (F=1.69; p = 0.174). The gender of the subjects was skewed towards male (64.1%). Over 90% of subjects were split evenly between White and Native American, with Hispanics representing an additional 6.8% of total. The total mean severity of illness (SOI) value (SD) was 3.8 ± 0.5 with no significant difference between groups (F=1.99; p = 0.119).
TABLE 2. *Patient Characteristics*

<table>
<thead>
<tr>
<th>Age, mean (SD) (yrs)</th>
<th>July 2013 (n = 32)</th>
<th>Sept 2013 (n = 44)</th>
<th>March 2014 (n = 24)</th>
<th>Sept 2014 (n = 32)</th>
<th>Total (N=132)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>53.1 (17.4)</td>
<td>48.9 (18.6)</td>
<td>50.4 (16.9)</td>
<td>55.3 (18.3)</td>
<td>51.7 (18.2)</td>
</tr>
</tbody>
</table>

| Male gender | 26 (81.3%)       | 24 (54.5%)       | 17 (70.8%)       | 14 (43.8%)       | 81 (64.1%)    |

| Ethnicity |  |
|-----------|-----------|-----------|-----------|-----------|
| White     | 15 (46.9%) | 21 (47.7%) | 6 (25.0%) | 17 (53.1%) | 59 (44.7%) |
| Native American | 15 (46.9%) | 18 (40.9%) | 14 (58.3%) | 13 (40.6%) | 60 (45.5%) |
| Hispanic  | 4 (9.1%)   | 4 (16.7%)   | 1 (3.1%)   | 9 (6.8%)   |             |
| Other     | 2 (6.2%)   | 1 (2.3%)    | 1 (3.1%)   | 4 (3.0%)   |             |

| DRG SOI, mean (SD) | 3.9 (0.2) | 3.8 (0.5) | 3.6 (0.7) | 3.7 (0.5) | 3.8 (0.5) |

DRG SOI (0-4): Diagnosis-related group severity of illness

a pre-implementation
b post-implementation
c One way ANOVA for difference between groups not significant (p = 0.119)

Results

**Adherence Score**

The primary aim of this project was to design and apply an adherence score to audit the implementation of the sedation protocol at FMC. As shown in Table 3, during the three month-long time periods of study post-implementation, the adherence score was essentially unchanged (p = 0.926). To evaluate whether the weighting applied to each component of the adherence score affected the end result, an unweighted adherence score was also evaluated. No significant trend in the unweighted adherence score was observed either (p = 0.812). Individual components of the adherence score were also examined for significant trends and none were found (Figure 1).

The adherence scores indicate that overall adherence rates were 50% (weighted) and 55% (unweighted) with individual components ranging from a low of 27% (SBT pass/fail) to a high of 77% (RASS charted every two hours). Provider orders were present 66% of the time for all
three orders. Spontaneous awakening trial charting occurred 46% of the time while SBT initiation was charted 40% of the time.

TABLE 3. Adherence Score

<table>
<thead>
<tr>
<th></th>
<th>Sep-13</th>
<th>Mar-14</th>
<th>Sep-14</th>
<th>ANOVA (one way) F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weighted Adherence Score</td>
<td>5.0±2.3</td>
<td>5.0±2.2</td>
<td>5.2±2.4</td>
<td>0.077</td>
<td>0.926</td>
</tr>
<tr>
<td>± SD (10pts)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unweighted Adherence</td>
<td>3.8±1.8</td>
<td>3.7±1.9</td>
<td>4.0±1.8</td>
<td>0.209</td>
<td>0.812</td>
</tr>
<tr>
<td>Score ± SD (7pts)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FIGURE 1. Weighted Adherence Score Over Time

Outcome Measures

In the original project proposal, time of MV and ICU LOS were proposed as the two measures to use in evaluating the impact of the sedation protocol on patient outcomes. However, there was no reliable way to obtain ICU LOS data from the EHR, so hospital length of stay was
used instead. This change is discussed further in the discussion section of this paper. Using one-tailed t-tests to evaluate measures of time of MV and hospital LOS, both were significantly lower (Table 4) after implementation of the sedation protocol. Measured in hours:minutes, time of MV was shortened from 90:08 ± 67:47 to 56:16 ± 58:20 (p=0.0034), representing a mean reduction of 34h. Length of hospital stay was reduced by 3.2 days, 13.0 ± 7.2 to 9.8 ± 7.9 days (p=0.0229). When examining all four study groups using a one-way ANOVA, a significant difference (p=0.049) was found between groups for time of MV, though no two groups were significantly different when tested individually using the Tukey HSD post-hoc test.

**TABLE 4. Outcome Measures**

<table>
<thead>
<tr>
<th></th>
<th>Pre-protocol</th>
<th>Post-protocol</th>
<th>T-Test (one-tail)</th>
<th>ANOVA (one way)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of MV (mean±SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(h:mm)</td>
<td>90:08±67:47</td>
<td>56:16±58:20</td>
<td>65:54 0.0034*</td>
<td>64:29 0.049*</td>
</tr>
<tr>
<td>Hospital LOS (mean± SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(days)</td>
<td>13.0±7.2</td>
<td>9.8±7.9</td>
<td>2.0 0.0229*</td>
<td>1.780 0.154</td>
</tr>
</tbody>
</table>

*a Analysis for between-group significance using all four study groups
*b Overall between-group difference was significant, but no significant difference found between any individual groups with Tukey HSD Post-hoc test
*p < 0.05

**Relationship Between Adherence Score and Outcomes**

Both the weighted and unweighted adherence scores were also evaluated for correlation with the outcome measures of time of MV and hospital LOS (Table 5) using Pearson correlations. Neither score correlated with time of MV and there was a weak, negative correlation between both the weighted (r = -0.245; two-tailed p = 0.001) and unweighted (r = -0.310; two-tailed p = 0.014) adherence scores and hospital LOS.
<table>
<thead>
<tr>
<th></th>
<th>Pearson's Correlation (r)</th>
<th>Weighted Adherence Score</th>
<th>Unweighted Adherence Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of MV</td>
<td></td>
<td>-0.057</td>
<td>-0.066</td>
</tr>
<tr>
<td>Hospital LOS</td>
<td></td>
<td>-0.245*</td>
<td>-0.310*</td>
</tr>
</tbody>
</table>

* p < 0.05
CHAPTER 5: DISCUSSION

Significant Findings

Generally, findings from this project are similar to previous research. The decrease in time of MV and hospital LOS are consistent with many other studies that have demonstrated improved patient outcomes through the protocolized management of mechanically ventilated patients in the ICU (Abdar et al., 2013; Awissi et al., 2012; Barr et al., 2013; Blackwood et al., 2011; Dale et al., 2014; Hahn et al., 2012; Mansouri et al., 2013; Radtke et al., 2012; & Skrobik et al., 2010). In the context of PRISM, these improved outcomes demonstrate the relative advantage of the sedation protocol when compared to the previous standard of care. In addition to improved clinical outcomes, it is reasonable to infer a positive economic impact of the protocol related to decreases in cost of medications and cost associated with shorter LOS and decreased time of MV as previously demonstrated by Awissi et al. (2012). However, a cost analysis would be needed to determine this.

Also of significance is the contribution this project makes to the body of knowledge regarding adherence to protocols in the ICU. Generally, full adherence to sedation protocols fall between 10-30% while partial adherence may climb as high as 80% (Burns, 2012; Leone et al., 2012), yet the level of adherence in this project was quite stable around 50%. While the results in this project indicate that adherence was higher than in many other reports, there is still significant room for improvement. Several components of PRISM, including the perceived relative advantage of the intervention, cultural compatibility with the change, and complexity of the intervention speak to factors that may influence adherence; these factors are detailed by research that has found that some of the factors include caregiver perception, complexity of protocols, buy-in, education, lack of comfort with a new assessment, and the number of protocols.
applicable to a particular patient (Andrews, Silva, Kaplan, & Zimbro, 2015; Burns, 2012; Gutierrez et al., 2010; Leone et al., 2012).

In addition to the overall rate of adherence, another interesting finding is the consistency of adherence over time. There are several possible explanations for this consistency. First, it must be recognized that, with the exception of the provider orders, the adherence score measures what was charted, not necessarily what was done. As part of the education for the sedation protocol, classes were held that included instruction on new charting related to the protocol. Different employees, based on their level of familiarity with the EHR and willingness to adopt new practices likely came away with differing levels of comfort with the new charting processes. It is possible that a certain percentage of RNs and RTs are performing the appropriate bedside activities as outlined in the protocol, yet they do not successfully chart their actions due to difficulties with the charting. Additionally, there are also caregivers who know what they should be charting and will chart accordingly regardless of their actions at the bedside. PRISM highlights the impacts of the complexity of the intervention and it could be that the consistency of the adherence score is a consequence of charting behaviors as opposed to actual behaviors. Inconsistencies with documentation of a newly implemented ICU protocol were recently demonstrated by Andrews et al. (2015).

PRISM highlights the importance of observability of a new intervention and another potential contributing factor to the consistency in the adherence score over time is that the lack of an established audit and feedback mechanism did not promote a change to existing behaviors. Timely feedback has been shown to be an integral component to improve adherence (Andrews et al., 2015; Bird et al., 2010, Sinuff, Muscedere, Cook, Dodek, & Heyland, 2008; Zaydfudim et al., 2009). At FMC there has been no method of audit and feedback, timely or otherwise. Thus,
those performing the components of the sedation protocol have had no information regarding their, or other members of the healthcare teams’, success in implementing the protocol and consequently, no motivation to change behaviors. Behaviors that were present after the initial education and rollout of the protocol have perhaps continued unchanged due to lack of feedback or additional education.

Areas for Future Research and Recommendations for Improved Adherence at FMC

Several topics researched in this DNP Project warrant further investigation. The sedation protocol at FMC was based on recommendations from the ACCM regarding the management of pain, agitation, and delirium; the lack of integrated delirium prevention, assessment, and management constitutes a significant gap between the evidenced-based recommendations and the sedation protocol that was implemented. Plans for adding in a delirium component to the protocol are ongoing at FMC and additional study of the relationship between the protocol and patient outcomes will be warranted and could even be used to elucidate the relative importance of delirium management. Despite recent findings that the addition of delirium monitoring to a sedation protocol did not improve patient outcomes (Andrews et al., 2015), this area warrants additional research at FMC, especially given the wealth of prior research summarized by Barr et al. (2013) that demonstrates the importance of delirium as a predictor of outcomes.

Another area for further research involves strategies to improve adherence to the sedation protocols. Since the initial implementation, there has been little follow-up education, feedback, or reinforcement of the principles of the sedation protocol. One strategy that has repeatedly proven successful at improving adherence is the utilization of daily multidisciplinary rounds with specific checklists for protocols (Bird et al., 2010; Burns, 2012; Quenot et al., 2010). FMC currently conducts multidisciplinary rounds on Mondays, Wednesdays, and Fridays but there is
no established format for the content to be discussed. Furthermore, respiratory therapists are not regular participants in rounds. Additional education with bedside rounding and annual competencies may also be warranted and have been shown to improve adherence to protocols (Degrado et al., 2011; Radtke et al., 2012). These measures will reinforce already understood concepts, address issues that have arisen while performing the steps of the protocol at the bedside, and provide initial education for new staff members. The challenge with this strategy is that significant investment in time and resources is necessary to conduct this type of extended education. Finally, addressing nurses’ attitudes on sedation and the patient experience of MV may be necessary to successfully modify sedation practices (Guttormson et al., 2010).

Based on the results of this project it is clear that, while adherence is greater than in many other studies, there is room for improved adherence to the sedation protocol. However, this project does not investigate why adherence remained steady at around 50%. Reasons for poor adherence are multiple, some of which have been discussed in this project, and include: challenges with the computerized charting system, caregiver attitudes regarding light sedation during MV, lack of coordination between disciplines, lack of knowledge regarding the protocol or how to perform it, failure to input orders for all the components of the protocol, among others (Andrews et al., 2015; Bird et al., 2010; Burns, 2012; Quenot et al., 2010). Through knowledge of the specific reasons for non-adherence, interventions to improve adherence could be more targeted for the specific needs of individual nurses and the facility as a whole. A first step in this process may include a survey of personnel integral to the performance of the sedation protocol to identify barriers to implementation.

Another area of potential investigation includes the monitoring of adherence to protocols other than the sedation protocol to determine if rates of adherence at FMC are similar between
protocols or if there are particular protocols that present unique challenges. Through knowledge of adherence rates both across and between different protocols, information regarding potential interventions could be gained. If, for example, all protocols demonstrate similar levels of adherence it indicates a more global trend that requires interventions to improve the overall culture of excellence and the general process of quality improvement. On the other hand, if only individual protocols demonstrate low adherence, efforts can be focused on identifying and correcting barriers specific to those protocols.

The difficulties encountered in efficiently gathering the data necessary to audit the adherence to the sedation protocol and resultant outcomes highlights limitations of the EHR system at FMC. Most concerning is the inability to obtain reliable ICU LOS data as this is an outcome measure frequently used to evaluate the success of interventions in critical care. It is highly recommended that FMC address this deficiency so that in future studies this measure can be easily and reliably retrieved. Furthermore, the inability to extract the variety of data necessary to track adherence to the protocol represents an additional opportunity for improvement. Continuing to investigate the existing capabilities of the EHR and exploring the possibility of expanding data extraction tools through upgrades to the software are warranted to facilitate future reporting and research tasks.

Another option for specifically addressing the challenges with adherence to the sedation protocol would be to implement a visual feedback tool as described by Kastrup et al., (2011). In their study, the authors utilized an almost fully automated computerized feedback system for auditing adherence to sedation, analgesia, and delirium protocol that provided summarized color-coded feedback the following day. The computer output was marked green if fully completed and red if incomplete and was available within the computerized charting system. This feedback
tool resulted in significantly improved adherence to assessment of pain and delirium and to a ventilator weaning protocol (Kastrup et al., 2011). The authors propose that reducing the time before the feedback is viewable may result in further improvements to adherence (Kastrup et al., 2011) and ideally this feedback system would be real-time, allowing staff to track adherence during the current shift.

**Limitations**

Limitations of this study include the retrospective design and lack of a true control group, although a comparison group was used. A significant percentage of patients were excluded which limits the impact of findings on the overall care of mechanically ventilated patients at FMC. But, exclusions were high for all study groups and the exclusions provide the most accurate representation of patients subject to the sedation protocol. Furthermore, the results are dependent on the quality of charting retrieved from the EHR and may not accurately represent what actually happened at the bedside, though this would be the case for any research based on a chart review. Furthermore, despite similar severity-of-illness scores for all study groups, interpretation of outcome measures must be taken with caution as their tends to be seasonal and annual variations in the type and severity of illness resulting in the need for MV, though including study groups from more than a calendar year may limit this effect. An additional limitation is that the weighting of the adherence score is based on expert opinion and has not undergone a rigorous validation process.

Given the consistency over time of the adherence score and patient outcomes post-implementation, there is limited potential to determine if the score actually could predict outcomes. While the adherence score did correlate with hospital LOS, the correlation was quite weak, likely due to little variability in the adherence score over time. Additional trials of the
adherence score where there exists a significant change over time would be needed to observe for a stronger correlation. As in this project, low levels of adherence are frequently reported in existing research (Andrews et al., 2015; Burns, 2012; Kastrup et al., 2011) yet much of the same research still shows improvements in patient outcomes. This introduces the possibility that there is a relatively low threshold of adherence above which improved outcomes may be observed; but, the question remains if adherence is improved to higher levels will outcomes correspondingly improve.

It must also be noted that the sedation protocol at FMC includes recommendations for early mobilization with physical therapy for all intubated patients who pass both the spontaneous awakening trial (SAT) and spontaneous breathing trial (SBT). This mobilization involves activities such as dangling from the bedside, sitting in a chair, and walking, with the level of mobilization depending on the ability of the patient to tolerate such activities. This mobilization is not included in the adherence score due to the difficulty of obtaining reliable data for if, and what, interventions were completed. This constitutes a significant limitation to this project and to the adherence score as a whole. For future implementation of an adherence score, every effort should be made to include all interventions that are part of the protocol in order to best represent and track adherence and to allow for analysis of the relative importance of each, and all, individual components.

A significant proportion of the studies cited in this project included delirium as a component of patient management and currently, the protocol at FMC does not include this aspect of care. Delirium affects up to 80% of mechanically ventilated patients and has been shown to be an independent predictor of negative outcomes such as increased mortality, hospital LOS, cost of care, and long-term cognitive impairment (Barr et al., 2013). So, the omission of
delirium in both the sedation protocol at FMC and this project limits the ability to identify
causative factors for the improved outcomes that were observed. It may be that rates of delirium
decreased with the implementation of the sedation protocol, but without consistent monitoring
this relationship cannot be elucidated. However, the role of delirium is brought into question by a
recent study by Andrews et al. (2015) that did not show a difference in patient outcomes after
implementing the use of the Confusion Assessment Method for ICU.

Finally, the inability to retrieve accurate data on ICU LOS represents a significant
omission. For many interventions in the critical care environment, ICU LOS is a commonly used
outcome measure that represents the success of medical management, policies/procedures, and
financial activities. While hospital LOS is a previously used outcome measure in similar
research, there are myriad additional factors that make it a less reliable indicator of activities in
the critical care environment than ICU LOS.

**Evaluation of Project Plan**

There were two notable deviations from the project plan and the eventual execution of the
project: 1) an inability to utilize automated queries of the EHR to extract data; and, 2) the lack of
reliable data for ICU LOS. A discussion follows of the factors involved in these deviations.

There are multiple methods available to extract data from the EHR at FMC and
dependning on the type of data, different strategies must be employed. For this project, a variety
of data types were needed: provider orders, charting by RNs and RTs, patient location within the
hospital during the admission, patient disposition upon discharge, procedures during admission,
among others. No single data extraction strategy available could capture this variety of data.

Multiple meetings were held with members of the EBP office and data analysts to try to
coordinate varied strategies of data extraction that could be combined. However, through a
combination of inconsistent charting within the EHR, time constraints related to completing the project in a timely manner, and challenges related to prioritization of work for FMC employees, automated data extraction was not achieved. As a result, all data for provider orders, time of mechanical ventilation, and all charted values needed for the adherence score were manually extracted. While this does not alter the obtained results, it does diminish the potential ongoing impact of the project for future auditing of the sedation protocol.

The second significant deviation from the project plan involved the inability to gather reliable ICU LOS data. ICU LOS data was found using two different strategies: 1) through a query utilized for other hospital reporting; and, 2) in a section of the EHR that indicates the patient location within the hospital during the admission. However, there were inconsistencies between the two sources of data and, with manual chart comparison, there was disagreement between the ICU LOS data and other obtained information such as dates/times of mechanical ventilation, nurses notes for transfers to another unit, and RT charting on ventilator data. Due to these discrepancies the decision was made to not include this outcome measure and instead use hospital LOS. Hospital LOS has been used as an outcome measure in previous studies involving management of pain, agitation, and delirium in the ICU (Barr et al., 2013; Skrobik et al., 2010) justifying its use in this project.

**Implications for Advanced Practice**

While many areas of this project failed to show significant results, there are important take-home points to consider. First, this project adds to the body of research that demonstrates improved outcomes with the use of a sedation protocol and the use of light vs. deep sedation. Perhaps more importantly, this project demonstrates improved outcomes while also including information regarding contextual factors that influenced the implementation process and will
provide future researchers with a more nuanced understanding of the findings and facilitate the repetition of the results (Tomoaia-Cotisel et al., 2013). Additionally, 50% adherence to a complex sedation protocol represents a significant achievement, making the strategies used at FMC (Appendix B) a source of ideas for other facilities looking to implement a similar protocol. These adherence scores and outcomes may also serve as a positive reinforcement tool to encourage continued use of the protocol and promote improvement where possible.

Further implications involve the lessons learned regarding data extraction and issues surrounding acquisition or maintenance of an EHR. An aim of this project was to set up an automated method to track adherence to the sedation protocol, but this was not achieved. There were too many hindrances involving the complexity of the EHR, multiple methods needed for extracting different types of data, and a shortage of personnel due to competing priorities. Electronic health records are intended to ease access and improve quality of data available for research (CMS.gov, 2014), but in this particular instance, the use of the existing EHR was insufficient for efficiently extracting the needed data. This may, in part, be due to the diversity and complexity of information necessary to evaluate an implementation project, but given the increasing emphasis placed on this type of research, EHRs must evolve. While it would be impossible to design EHR software in a way that predicts all future research interests, it is important to utilize an EHR system that is flexible enough to accommodate novel investigations.

Additionally, APNs, who are educated to facilitate and conduct research in the clinical setting, need to be cognizant of the capabilities of an existing EHR system and ensure that when a new innovation is implemented, there are adequate methods for a feasible audit and feedback mechanism. This project provides an example of the potential consequences of not including an audit and feedback mechanism in the initial implementation process for a new protocol. The
omission of an audit and feedback mechanism from the planning process may be avoided by following an established model or framework such as the PDSA cycle, PRISM, RE-AIM, among many others; a helpful tool in choosing an appropriate model is the paper published by Tabak et al. (2012) which had the explicit intent of assisting future researchers with the model selection process.

Furthermore, through the creation of a numerical adherence score, this project establishes a foundation for similar projects that create easily interpretable audit and feedback mechanisms and opens the door for other novel uses of electronic health information. As computer systems become more integrated and sophisticated, healthcare workers will be able to receive more timely and targeted feedback regarding care processes at the bedside. Given their experience both at the bedside and at the provider level and a baseline knowledge of conducting research, APRNs are ideally situated to design and implement innovative systems for improving the implementation and sustainability of quality improvement projects.

This project offers an example of one method of including contextual information that will improve generalizability of research findings and assist any researcher that seeks to recreate a similar project. By utilizing a well-defined set of contextual characteristics, this project demonstrates the utility of an expanded description of contextual factors that influenced outcomes of the study and have previously been infrequently reported in most medical research. Through knowledge of the importance of this contextual information and following the example set in this project, APNs will build on a growing body of research that improves the process of implementing evidence-based practice.
Conclusion

This project demonstrates improvements in patient outcomes from utilization of a sedation protocol in the management of mechanically ventilated adult patients in an ICU setting. However, this project also highlights several challenges associated with the monitoring of adherence to protocols and describes opportunities to improve the implementation, auditing, and feedback mechanisms for new or existing care protocols. The lack of an established audit and feedback mechanism for the sedation protocol may be a contributing factor to the unchanged adherence observed over time. Both research and monitoring activities are impaired by EHR systems that do not allow for the easy extraction of data. Furthermore, ensuring that adequate audit and feedback strategies are designed and available prior to implementation of new protocols would facilitate the ongoing evaluation of the success of protocol implementation and the effect on patient outcomes. This project provides additional rationale for protocolized management of sedation for mechanically ventilated patients and lessons learned may be useful for those considering the implementation of sedation, or other, protocol.
APPENDIX A:

ELEMENTS OF PRISM* AND CORRESPONDING PROJECT INFORMATION
<table>
<thead>
<tr>
<th>PRISM Element</th>
<th>Components</th>
<th>In this Project</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Program (Intervention)</strong></td>
<td>Readiness</td>
<td>In general, FMC has a positive culture of quality improvement that is fostered through continued efforts to refine practice.</td>
</tr>
<tr>
<td>Organizational Perspective (leaders, management, and staff)</td>
<td>Strength of evidence</td>
<td>The evidence to support the implementation of the new sedation protocol is robust and written by an influential academic body (ACCM).</td>
</tr>
<tr>
<td></td>
<td>Addresses barriers to frontline staff</td>
<td>All departments and levels of staff were offered an opportunity to participate in the implementation process from the beginning.</td>
</tr>
<tr>
<td></td>
<td>Coordination across departments</td>
<td>Costs of implementation are limited to human capital for education and changes to the EHR.</td>
</tr>
<tr>
<td></td>
<td>Burden (complexity and cost)</td>
<td>Given the significant changes in practice inherent in the implementation of this protocol, it is not realistic to reverse those changes; however, the protocol may be subject to further evolution based on observed outcomes.</td>
</tr>
<tr>
<td></td>
<td>Usability and adaptability</td>
<td>The ability to monitor results was not well established before implementation of the new protocol, and this project aims to improve the ability to track outcomes related to the implementation.</td>
</tr>
<tr>
<td></td>
<td>Trialability and reversibility</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ability to observe results</td>
<td></td>
</tr>
<tr>
<td><strong>Patient Perspective</strong></td>
<td>Patient centeredness</td>
<td>The process of implementation did not involve a patient representative.</td>
</tr>
<tr>
<td></td>
<td>Provides patient choices</td>
<td>Patient and family perspectives related to lighter sedation during mechanical ventilation include both positive and negative reactions and knowledge of this aspect of patient care is important to consider during day-to-day management of this patient population.</td>
</tr>
<tr>
<td></td>
<td>Addresses patient barriers</td>
<td></td>
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<tr>
<td></td>
<td>Seamlessness of transition between program elements</td>
<td></td>
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<tr>
<td></td>
<td>Service and access</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Burden (complexity and cost)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Feedback of results</td>
<td></td>
</tr>
<tr>
<td><strong>External Environment</strong></td>
<td>Payor satisfaction</td>
<td>Implementation of this protocol does not have any direct consequences on payors or reimbursement. However, as payment is moving towards fixed-sum payouts based on diagnosis and non-payment for certain complications, anticipated reductions in the time of mechanical ventilation and length of ICU stay should result in a favorable effect on the hospital’s budget as well as reduce overall healthcare costs.</td>
</tr>
<tr>
<td></td>
<td>Competition</td>
<td>The potential for decreased hospital acquired infections related to decreased time of MV could impact reimbursement from Medicare/Medicaid.</td>
</tr>
<tr>
<td></td>
<td>Regulatory environment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reimbursement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Community resources</td>
<td></td>
</tr>
<tr>
<td><strong>Implementation and</strong></td>
<td>Performance data</td>
<td>A dedicated multi-disciplinary team performed the implementation process, but there is not designated team for</td>
</tr>
</tbody>
</table>
| PRISM Element | Components                                                                 | In this Project                                                                                                                                
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Sustainability Infrastructure</td>
<td>• Dedicated team&lt;br&gt;• Adopter training and support&lt;br&gt;• Relationship and communication with adopters&lt;br&gt;• Adaptable protocols and procedures&lt;br&gt;• Facilitation of sharing of best practices&lt;br&gt;• Plan for sustainability</td>
<td>continued evaluation of sustainability. The CNS at the hospital has made efforts to give feedback to the staff regarding impacts of the protocol on patient outcomes (time of MV, length of ICU stay), but that communication has been limited by the difficulty in obtaining reliable and accurate data. &lt;br&gt;• This project aims to provide an easier way to track sustainability and provide information that may allow for targeted interventions to improve/maintain sustainability. &lt;br&gt;• Issues with the implementation of the protocol have been identified, but there is no dedicated team to address them.</td>
</tr>
<tr>
<td>Recipients Organizational Characteristics</td>
<td>• Organizational health and culture&lt;br&gt;• Management support and communication&lt;br&gt;• Shared goals and cooperation&lt;br&gt;• Clinical leadership&lt;br&gt;• Systems and training&lt;br&gt;• Data and decision support&lt;br&gt;• Staffing and incentives&lt;br&gt;• Expectation of sustainability</td>
<td>Currently, the organizational health and culture is mixed; anecdotally, most employees appreciate their jobs and feel well compensated, but there is also significant turmoil in upper management and a feeling of disconnect between stated organizational goals and actions of management. &lt;br&gt;• FMC participates in the Kaizen initiative for smaller changes and the Six Sigma Greenbelt project improvement process for larger quality improvement projects. &lt;br&gt;• As a result of the above stated lack of consistent leadership, clinical leaders are put in a difficult place of trying to navigate the difficult terrain between managers and staff. &lt;br&gt;• One area where quality improvement has not necessarily received adequate support is in data and decision support. While training for existing IT capabilities is adequate, adding new capabilities to the EHR system is met with resistance due to increased costs. &lt;br&gt;• Staffing ratios are capped at 2:1. &lt;br&gt;• Education on the new protocol was paid time.</td>
</tr>
<tr>
<td>Patient Characteristics</td>
<td>• Demographics&lt;br&gt;• Disease burden&lt;br&gt;• Competing demands&lt;br&gt;• Knowledge and beliefs</td>
<td>Specific patient characteristics have not been relevant for the implementation of the new protocol nor will they be for this project. Both the protocol and the project apply to all adult patients who are mechanically ventilated, minus exclusions. &lt;br&gt;• One area where knowledge and beliefs plays an important role is with patient and family education regarding the care of a mechanically ventilated patient while they are under light sedation. At times, something as simple as a cough can be quite disturbing to a family member yet is an appropriate and clinically beneficial response. Patient/family education and encouraging patient and family participation in their own care is one area of positive response to light sedation and should be included as part of the implementation.</td>
</tr>
</tbody>
</table>
APPENDIX B:

DESCRIPTION OF CONTEXTUAL FACTORS
**Domain** | **Description of Context**
---|---
The practice setting | This project will be conducted using patients from a 20-bed ICU and an 11-bed cardiovascular ICU (CVICU). This CVICU also takes non-cardiac patients. Medical management of the ICU is performed by an independent physician group comprised of eight physicians who are all critical care board certified and are on-site 24 hours/day. Occasionally, patients are admitted to the ICU under different services (trauma, hospitalist, surgery, neurosurgery, etc.) though the intensivists are almost always consulted if the patient is intubated. There is a Clinical Nurse Specialist (CNS) who coordinates quality improvement and education functions throughout the entire hospital with a focus on critical care. Both the ICU and CVICU have unit-based nurse educators. Nurse-to-patient ratios are capped at 1:2 with rare exceptions of 1:1 for the most critically ill patients. Approximately one nursing assistant is staffed for every 10 patients.

The larger organization | Flagstaff Medical Center (FMC) is a not-for-profit community hospital with over 270 beds, 200 physicians, and around 2,000 employees. It is a level-1 trauma center and serves a large geographic area spanning most of northern Arizona and parts of Utah, New Mexico, and Colorado. FMC is part of Northern Arizona Healthcare that consists of two hospitals and two clinics in four different cities in northern Arizona. No nurses’ union is active in the organization and nurses’ pay raises are merit-based.

The external environment | FMC is the major medical center for much of northern Arizona. Flagstaff is a city of approximately 70,000 people, nearly 20,000 of which are students at Northern Arizona University (NAU). The city is very near the border of the largest and most populous Native American reservation in the country, the Navajo Nation. Outside of Flagstaff, the area is rural and FMC is designated as a federally medically underserved area. FMC was founded in 1936 and is a major part of the Flagstaff community as its second-largest employer (NAU is the largest).

Implementation pathway | The process for implementing the new sedation protocol was managed by the CNS at FMC. The CNS formed a multidisciplinary committee consisting of nurse educators within the critical care cluster, any staff RNs within the cluster who had interest (of which four were consistent attendees, including the principal investigator of this study), two respiratory therapists, a physical therapist, and targeted participation of a representative from the intensivist physician group, the Director of Critical Care, the Director of Pharmacy, the Director of Respiratory Therapy, a representative from IT responsible for changes to the electronic health records (EHR) system, and a pharmacist who managed programing of IV pumps. The committee met on a bi-weekly or monthly basis to write a new sedation protocol for the hospital, develop an implementation plan, identify potential challenges to implementation, design and evaluate changes to the EHR, discuss interdisciplinary strengths and weaknesses, design and implement an education plan for staff, and plan the rollout. Staff education was conducted by each individual discipline and included classroom instruction on the research foundations of the new protocol, bedside processes, and changes to the EHR. Additional training consisted of rounding on the floor by members of the committee to facilitate implementation of the protocol at the bedside. The classroom education was conducted over a month-long period prior to the ‘go live’ date, and bedside rounding was performed for one month after rollout and on an as needed basis after that.

Motivation for implementation | The impetus for implementing a new sedation protocol began with the publishing of new clinical guidelines for the management of pain, agitation, and delirium for patients in the ICU by the American College of Critical Care Medicine (ACCM). The CNS read the guidelines and saw an opportunity to improve care of this patient population. An early mobilization program spearheaded by the Physical Therapy Department had already been informally implemented in the ICU and there was an opportunity to expand on this program with a comprehensive protocol that clearly and thoroughly described the expected care of this patient population.
APPENDIX C:
EVIDENCE SYNTHESIS TABLE FOR DURATION OF MECHANICAL VENTILATION AND ICU LOS IN ADULT ICU PATIENTS PRE- AND POST- SEDATION PROTOCOL IMPLEMENTATION
<table>
<thead>
<tr>
<th>Citation, incl. Funding and Country of Study</th>
<th>Research Design and Sample</th>
<th>Intervention Agent</th>
<th>Procedure</th>
<th>Results</th>
<th>Study Limitations and Strengths</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awissi, (2012) Montreal, Canada. No funding source listed</td>
<td>Prospective – observational cohort study Sample: sequentially admitted adult patients to the ICU requiring mechanical ventilation. n=1214 (604 pre--; 610 post-protocol). Mean age = 63.3±15 years. Men = 59% Setting: Single-center study at Maisonneuve-Rosemont Hospital</td>
<td>Implementation of a protocol for management of sedation, analgesia, and delirium</td>
<td>Pre and post-protocol implementation measures including duration of mechanical ventilation</td>
<td>A multivariate analysis was conducted for multiple variables: duration of mechanical ventilation decreased (p &lt; 0.009) post-protocol (5.95 ± 6.8 days; median = 4.00) vs. pre (7.27 ± 9.09 days; median = 4.00) ICU LOS in days was shorter (P&lt;0.004) post-protocol (5.43±6.43) vs. pre-protocol (6.39±8.05)</td>
<td>Limitations: Study is single-center making the results subject to specific standard of practice and local conditions that may or may not apply to other facilities. A pre/post design limits inter-cohort reliability; though the only significant difference between cohorts was Apache II scores; which were most likely not clinically relevant. Verification of pre and post-protocol changes in practice was not possible. Strengths: large sample size</td>
<td>Level IV</td>
</tr>
<tr>
<td>Hahn, (2012) Birmingham, AL, USA No financial support was received to conduct this research.</td>
<td>Pre/post-implementation review involving a retrospective chart review Sample: patients &gt; 19 yrs. admitted to the ICU, required mechanical ventilation for more than 24hrs, and required sedation. N=42. Mean age = 67 years. %male: pre = 58; post=33. Setting: Single-center study at Saint Vincent’s Birmingham</td>
<td>Implementation of a sedation protocol</td>
<td>Chart review of pre and post-implementation measures of duration of mechanical ventilation</td>
<td>Power &lt; 0.80. A 2-independent samples t test was conducted: mean duration of mechanical ventilation was less, but not statistically significant (p=0.259) in the post-protocol group (3.78 ± 3.21days) vs. pre (6.39 ± 5.24 days).</td>
<td>Limitation: small sample size limited power of study to detect a difference. Retrospective study cannot account for many variables including adherence to new protocol.</td>
<td>Level IV</td>
</tr>
<tr>
<td>Citation, incl. Funding and Country of Study</td>
<td>Research Design and Sample</td>
<td>Intervention Agent</td>
<td>Procedure</td>
<td>Results</td>
<td>Study Limitations and Strengths</td>
<td>Level of Evidence</td>
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<tr>
<td>Mehta, (2012) Canada and USA</td>
<td>RCT of 413 critically ill, mechanically ventilated adults conducted in 16 tertiary care medical and surgical ICUs in Canada and the United States between January 2008 and July 2011. Mean age: Protocol plus daily interruption (57; IQR: 46-70); protocol (60; IQR: 49-70). % female: 43.5 and 44.</td>
<td>Two randomized groups; sedation managed by protocol vs. sedation managed by protocol and daily sedation interruption. There was no masking of groups.</td>
<td>Primary outcome was time to extubation as measured by time of randomization to time of extubation.</td>
<td>Power = 0.90, α = 0.05</td>
<td>Using a 2-sample t test, the median time to successful extubation was 7 days in both groups; interruption group (7, IQR = 4-13) protocol only group (7, IQR = 3-12) (hazard ratio, 1.08; 95% CI, 0.86-1.35; P=.52).</td>
<td>Strengths include multi-center design with a broad mix of patients and sufficient sample size for adequate power. Limitations include not blinding caregivers and possible limitation in patients receiving different medications for sedation.</td>
</tr>
<tr>
<td>Radtke, (2012) Germany</td>
<td>Prospective experimental cohort study</td>
<td>Comparison of two training strategies for implementation of a sedation, analgesia, and delirium management protocol</td>
<td>Pre, post, and 12 month measures for each of the three ICUs of duration of mechanical ventilation. Two of the three ICU’s received additional training between the post and 12 month follow up measures while one ICU did not.</td>
<td>OR with 95 % CI were determined in univariate and multiple logistic regressions. Duration of mechanical ventilation decreased in both ICU’s that received the extended training program. ICU-1 (pre: 355 ± 697 hours vs. @ 12 months: 265 ± 495h; p = .51) and ICU-2 (pre: 7 ±12h vs. @ 12 months: 4 ± 9h; p = 0.06). Neither result was statistically significant, though when compared to ICU-3, which only received the standard training program, it can be seen in</td>
<td>Limitations to this study include: non-homogenous patient group sizes, exclusion of patients with ICU length of stay &lt; 3 days, and the possibility for staff turnover to have affected the effectiveness of training.</td>
<td>Strengths include a large sample size and the inclusion of three different ICU’s.</td>
</tr>
<tr>
<td>Citation, incl. Funding and Country of Study</td>
<td>Research Design and Sample</td>
<td>Intervention Agent</td>
<td>Procedure</td>
<td>Results</td>
<td>Study Limitations and Strengths</td>
<td>Level of Evidence</td>
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<tr>
<td>Skrobik, (2010) Canada</td>
<td>Prospective observational cohort study</td>
<td>Implementation of analgesia, sedation, and delirium protocol</td>
<td>Pre and post-protocol implementation chart review for measures including duration of mechanical ventilation</td>
<td>that duration of MV increased over the 12 month period (pre: 117 ± 196h vs. @ 12 months: 149 ± 244h; p = 0.74). ICU LOS differed significantly for ICU-2 (4±3 @ 12 months vs. 8±7 pre p&lt;0.01).</td>
<td>Limitations include being an observational study, of pre/post design in a single ICU. The pre/post populations were heterogeneous, thus comparisons between them should be considered exploratory and may not be generalizable.</td>
<td>Level IV</td>
</tr>
</tbody>
</table>

**LEGEND:** CI – Confidence Interval; ICU – Intensive Care Unit; IQR – Interquartile ratio; LOS – Length of Stay; OR – Odds Ratio; RCT – Randomized Control Trial

**Level of Evidence***:

I Large RCTs with clear cut results
II Small RCTs with unclear results
III Cohort and case-control studies
IV Historical cohort or case-control studies
V Case series, studies with no controls

APPENDIX D:

EVIDENCE SYNTHESIS TABLE FOR ADHERENCE TO EVIDENCE-BASED PRACTICE

CARE PROTOCOLS IN AN ADULT ICU SETTING
<table>
<thead>
<tr>
<th>Citation, incl. Funding and country of study</th>
<th>Research Design and Sample</th>
<th>Intervention Agent</th>
<th>Procedure</th>
<th>Results</th>
<th>Study Limitations and Strengths</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bird, (2010) Boston, MA No funding source listed</td>
<td>Retrospective public database review Sample: Ventilated patient admitted to the trauma ICU or surgical ICU at Boston Medical Center between 3/1/2006 and 5/31/2009. Number of subjects not reported. Setting: Surgical ICU at Boston Medical Center</td>
<td>Implementation of a protocol for prevention of ventilator associated pneumonia.</td>
<td>Pre- and post-protocol implementation measure of percent compliance with VAP prevention bundle including: HOB &gt; 30°, daily sedation break, peptic ulcer prophylaxis, and DVT prophylaxis</td>
<td>An X^2_ test was used to compare compliance rates with improvement in both ICUs each year (SICU: 53% to 91%, no p-value reported; TICU: 63% to 81%, no p-value reported)</td>
<td>Limitations: Study is single-center making the results subject to specific standard of practice and local conditions that may or may not apply to other facilities and the study did not account for other infection-prevention campaigns implemented during the study period. A pre/post design limits inter-cohort reliability and no data for the sample population was presented to allow for comparison of study groups. Verification of pre and post-protocol changes in practice was not possible. Strengths: large sample size (Approx. 4000)</td>
<td>Level IV</td>
</tr>
<tr>
<td>Burns, (2012) USA No Funding source listed</td>
<td>Literature review of articles published between 1998-2011 including 12 articles on adherence to sedation guidelines and 5 articles on the efficacy of sedation protocols.</td>
<td>Examination of adherence to sedation protocols in mechanically ventilated patients.</td>
<td>Literature review</td>
<td>Despite perceptions to the contrary, adherence to sedation protocols is not good. Multiple reasons for lack of adherence are suggested: complex decision making steps in guidelines, unique education, perceptions, culture, and philosophy of each care setting, lack of monitoring, and the protocols must be ‘owned’ by the staff.</td>
<td>This article is written by a single author opening up the potential for individual bias to affect the information presented. However, a thorough literature search was conducted and research with conflicting results was included.</td>
<td>Level II</td>
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<tr>
<td>Citation, incl. Funding and country of study</td>
<td>Research Design and Sample</td>
<td>Intervention Agent</td>
<td>Procedure</td>
<td>Results</td>
<td>Study Limitations and Strengths</td>
<td>Level of Evidence</td>
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<td>Leone, (2012) France</td>
<td>1-day chart audit across 66 ICUs in 39 institutions. Between January and May 2009 a 1-day audit was conducted without prior knowledge of the medical staff. N = 625. Mean age = 62; 63% male.</td>
<td>Measurement of compliance with 13 clinical guidelines.</td>
<td>Number of patients in whom the guideline was applied versus number of eligible patients.</td>
<td>Compliance rates ranged from 24% (sedation monitoring) to 96% (identification of closest relative and bacteriological sampling before onset of antibiotics). Compliance rates were &gt;80% in patients with less than three eligible guidelines, but dropped to &lt;20% in patients with at least three guidelines.</td>
<td>One strength of this study is the global approach to protocol compliance, independent of specific disease. Furthermore, an independent resident conducted the chart audits limiting the effect of provider bias. A limitation is the lack of consensus on certain guidelines.</td>
<td>Level IV</td>
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<td>DeGrado, (2011) Boston, MA</td>
<td>Retrospective study of patients receiving mechanical ventilation in a 20-bed medical ICU at Brigham and Women’s Hospital from February to March 2006 (pre-guideline) and February to March 2007 (post-guideline). N = 111. Mean age = 63.3; 62.3. Male = 44%; 48%</td>
<td>Implementation of a sedation, pain, and neuromuscular blockade protocol.</td>
<td>Two primary endpoints where frequency of documentation of RASS goal in orders for sedation and analgesia and frequency of documentation of RASS by nurses.</td>
<td>Goal RASS ordered increased from 21 to 85% (P &lt;0.001) and number of charted RASS assessments per 24 hours increased from 4.7±4.9 to 11.4±2.9 (p&lt;0.001).</td>
<td>Limitations include non-randomized, retrospective design, significant difference in severity of illness of the two study groups, and the implementation of a CPOE intervention for target RASS.</td>
<td>Level IV</td>
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<td>Citation, incl. Funding and country of study</td>
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LEGEND: CPOE – Computerized Physician Order Entry; DVT – Deep Vein Thrombosis; HOB – Head of bed; ICU – Intensive Care Unit; RASS – Richmond Agitation Sedation Scale; SICU – Surgical ICU; TICU; Trauma ICU; VAP – Ventilator Associated Pneumonia

**Level of Evidence:**
- I  Large RCTs with clear cut results
- II Small RCTs with unclear results
- III Cohort and case-control studies
- IV Historical cohort or case-control studies
- V Case series, studies with no controls

REFERENCES


