EXTRACORPOREAL MEMBRANE OXYGENATION: A PROTOCOL IMPLEMENTATION FOR QUALITY IMPROVEMENT

By

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Abstract

Extracorporeal membrane oxygenation (ECMO) is an aggressive medical intervention that is considered a last-resort care measure. Caring for patients receiving ECMO requires nurses to have a high skill set and demands constant attention to detail. Intensive care unit protocols provide structure, consistency in care and aid in improved patient outcomes. The use of ECMO increased drastically during the COVID-19 pandemic and continues to be used more often for acute respiratory distress syndrome. This quasi-experimental project aimed to implement an evidence-based protocol and evaluate the impact on patient outcomes. Quantitative data was collected, analyzed, and compared to data collected before protocol implementation. Results revealed that sedation scores, nutritional status, and mortality improved post-protocol implementation. ECMO nurses were surveyed pre- and post-protocol implementation to evaluate understanding and confidence in ECMO best practice care. Nurse survey results showed that nurses felt more confident caring for the ECMO population post-implementation. Limitations of the study included a small sample size, time constraints, and the dependency on accurate documentation in the electronic medical record for data collection and analysis. Future projects would benefit from a larger sample size, a prolonged project timeline, and more reliable ways to collect additional specific patient data, such as mobility. A final consideration is to collect patient and hospital cost savings data incurred with this protocol implementation.

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Chapter 1: Introduction

Several patient care and management advances have occurred throughout the project manager's 18-year nursing career in the intensive care unit (ICU). These evidence-based practice changes have reduced mortality and morbidity. A noteworthy example is the fast-track extubation protocol in adult cardiothoracic surgical patients. In a study by Ellis et al. (2021), early extubation of a post-operative cardiothoracic patient occurred in 42% of the population. After the fast-track protocol was implemented, 72.5% of post-surgical patients were extubated within 6 hours after surgery, leading to faster recoveries and earlier discharges to home. Ellis’ example shows that protocols improve outcomes, which helped to establish the aim of this DNP project.

A protocol, created correctly, provides attention to the everyday aspects of a patient with a well-described illness. Wall et al. (2001) stated that a well-formulated ICU protocol does not eliminate the need for clinical decision-making but demands constant attention to patient status details. Also, continual appraisal of the evidence within protocols must occur so that correct modifications arise promptly. Valid and reliable metrics to document expected and unexpected outcomes drive continual improvement in the ICU (Wall et al., 2001).

Statement of Problem

From 2019, the number of patients supported by extracorporeal membrane oxygenation (ECMO) at the project facility quadrupled. In 2019, project facility staff cared for ten ECMO patients. In 2021, the number of ECMO patients increased to over 45 due to the COVID-19 pandemic (J. Morton, personal communication, December 3, 2021). Physician orders were similar among ECMO patients, but there was no set protocol or pathway to follow when admitting and caring for the ECMO population. A lack of specific, consistent sedation, pain medication, and nutritional and physical mobility parameters existed. Caring for these patients without a set protocol led to inconsistency in care and confusion between caretakers and providers.

Purpose/Aim of the Project

This quality improvement (QI) project implemented an evidence-based practice (EBP) protocol for the ECMO population to decrease mortality and improve patient outcomes. The project aimed to implement a protocol for the ECMO population at a Midwestern level II trauma center and evaluate patient outcomes. This project also assessed the nurse's pre- and post-implementation protocol knowledge.

Background/Problem of Interest Supported by the Literature

Venovenous ECMO has recently been used in COVID-19 patients suffering from acute respiratory distress syndrome. During venovenous ECMO, a large volume of venous blood is continually pumped through an oxygenator, removing carbon dioxide. During this process, the lungs are bypassed, and lung-protective ventilation strategies in patients with lung failure, such as patients with ARDS, are facilitated (Nigoghossian et al., 2016). Complications and risks are involved when substantial amounts of blood are circulated continuously through cannulas, thin tubes inserted into the body. Bloodstream infections, central-line-associated bloodstream infections, and coagulopathies are of enormous concern. Another component of caring for ECMO patients is the sedation necessary to provide comfort yet prevent delirium. As such, the care of the ECMO patient is complex. Researchers found improved outcomes with the initiation of ECMO care protocols (Landolf et al., 2020; Polastri et al., 2016). These protocols include the involvement of a critical care nurse liaison and ECMO sedation parameters, among others (Polastri et al., 2016). One finding is that using hydromorphone over fentanyl increases days alive without delirium or coma (Landolf et al., 2020).

Researchers suggest that a protocol that integrates normal physical mobility, specific sedation parameters, and a core ECMO care team improves the mortality rate of ECMO patients (Polastri et al., 2016). Several successful protocols in ICUs have previously proved effective; one example is the extubation protocol mentioned above (Wall et al., 2001). By using a protocol, such as the one identified by Polastri et al. (2016), that includes physical mobility, sedation, and nutrition guidelines; more patients can recover from organ failure and be discharged to home.

Significance of the Project

Due to COVID-19, ECMO is used significantly more now than ever before. The increase in ECMO use as a treatment for ARDS secondary to COVID-19 has allowed for improved patient outcomes. Thus, more research and implementation of best practices are needed with the additional volume of patients on ECMO therapy. According to the Extracorporeal Life Support Organization (ELSO) (2022), mortality rates at the project facility were below the national average before the project implementation. Implementing a specific ECMO protocol aims to decrease mortality and improve the percentage of ECMO patients discharged from the hospital to either a rehabilitation facility or home (Polastri et al., 2016).

Nursing care for critically ill patients involves combining science with the art of caring and a passion for excellence. An ECMO protocol that entails set sedation parameters, timely nutrition, and mobility expectations provides a standard of care for the

ECMO population to improve outcomes. A consistent protocol for the ECMO population also allows for measuring results and identifying how to decrease barriers.

Impact of the Project

According to ELSO (2022), the national mortality rate for ECMO patients with a COVID-19 diagnosis was approximately 48%. The project facility's mortality rate pre-protocol implementation was nearly 15% higher than the national average (J. Morton, personal communication, December 3, 2021). An expected outcome of implementing the protocol was to decrease the mortality rate at the project's facility site by 10%. Hospital costs are typically reduced with decreased mortality rates and improved patient outcomes. Furthermore, it was expected nurses would demonstrate increased consistency and confidence in the care they provide to the ECMO population with the EBP protocol in place.

Chapter II: Literature and Theory Review

A thorough literature search was conducted to implement a QI project based on evidence. The initial literature search included only articles published within the last five years; however, due to a lack of relevant supporting data in this period, reports published since 2000 were included. The Cumulated Index to Nursing and Allied Health Literature database was used to obtain the literature to support the project.

Literature Review

The main topics researched were ECMO and best practice sedation, ECMO protocols, ECMO and reduced mortality, ECMO and nutrition, and ECMO and mobility. Literature was gathered and placed in a synthesis matrix. Information regarding the type of research, strength and quality rating, sample size, intervention, data collection method, and study results were analyzed.

Importance of Protocols

The importance of standardized care is relative to many aspects of patient care. When considering the ECMO patient population, Conceição et al. (2019) performed a bibliographic study to evaluate the importance of nursing care for the ECMO patient. Categories of importance were ambulation/mobilization, hemodynamic monitoring, prone position, sedation monitoring, and bleeding/coagulation. In all articles analyzed, Conceição et al. (2019) concluded that nursing care directly impacts improvements in the clinical condition of ECMO patients. Nursing care is directly related to the ECMO patient's recovery. For nurses to effectively care for these complex patients, specific skills and standardized protocols are prioritized (Conceição et al., 2019). Conceição et al. (2019) and Wall et al. (2001) agree that a correctly created protocol provides attention to patients' everyday aspects with a well-described illness. Wall et al. (2001) described that a well-formulated ICU protocol does not eliminate the need for clinical decision-making but demands constant attention to patient status details. Also, continual appraisal of the evidence within protocols must occur so that correct modifications arise promptly. Valid and reliable metrics to document expected and unexpected outcomes drive continual improvement in the ICU (Wall et al., 2001). Research suggests that a set protocol that integrates normal physical mobility, specific sedation parameters, and a core ECMO care team improves the mortality rate of ECMO patients (Polastri et al., 2016). Several successful protocols in intensive care units have proved effective; one example is the ventilator weaning, sedation, and analgesia protocol (Wall et al., 2001).

Another effective protocol is the fast-track extubation protocol in adult cardiothoracic surgical patients (Ellis et al., 2021). This study found that early extubation in post-operative cardiothoracic patients occurred in 42% of their population (Ellis et al., 2021). After the fast-track protocol was implemented, 72.5% of post-surgical patients were extubated within six hours after surgery, leading to faster recoveries and earlier discharges to home. More patients can discharge home when a protocol with physical mobility and correct sedation is used.

A retrospective chart review-based study by Dalia et al. (2019) also supports set protocols, guidelines, and a specific ECMO team promoting optimal patient outcomes. Dalia et al. (2019) compared ECMO cases at their facility from 2009 to 2013 to the ECMO cases from 2014 to 2017. Survival to discharge was 37.7% in the first group and 52.3% in the latter group. The difference was that a multidisciplinary ECMO team established protocols and guidelines to care for the ECMO patient (Dalia et al., 2019).

Guidelines included progressive mobility, sedation parameters, and appropriate management of risks and nutrition (Dalia et al., 2019). These studies indicate the importance of using standard protocols, guidelines, and a specific ECMO team to care for complex patients and improve outcomes.

Sedation Best Practice

The literature researched for this project also included many articles supporting the appropriate use of sedation and analgesia for the ECMO patient. These articles supported minimal doses of intravenous sedation, analgesia, and paralytics as best practices for the ECMO patient. Although this research subject is new, commonalities between articles were evident. An international, cross-sectional survey was distributed to over two hundred Society of Critical Care Medicine members in January 2018 (Dzierba et al., 2019). Most commonly, fentanyl and hydromorphone are the opioids of choice, while propofol and benzodiazepines are the most common sedatives. Deep sedation is targeted for the first 24 hours after initiation of ECMO 64% of the time. After 24 hours, light sedation is preferred using dexmedetomidine and propofol. This survey also reported that most ECMO facilities use validated scales and protocols to assess and manage pain, agitation/sedation, and delirium.

Together, these studies indicate that protocols that include minimal doses of intravenous sedation, analgesia, and paralytic guidelines improve patient outcomes. Avoidance of benzodiazepines and regularly scheduled antipsychotics are ways used to prevent delirium (Dzierba et al., 2019; Landolf et al., 2020). In one retrospective observational study, ECMO patients received either fentanyl or hydromorphone (Landolf et al., 2020). The study determined that those who received the continuous hydromorphone drip instead of fentanyl resulted in more days alive without delirium and less use of narcotics overall (Landolf et al., 2020). This guideline indicates that hydromorphone use in ECMO patients should be prioritized in patients that do not have contraindications to its use.

Enhanced Recovery After Surgery (ERAS)

ERAS refers to a patient-centered, evidence-based, multidisciplinary team-developed pathways protocol for a surgical specialty and facility culture to reduce the patient's surgical stress response, optimize their physiologic function, and facilitate recovery (American Association of Nurse Anesthesiology [AANA], 2022). The post-operative ERAS protocol elements relevant to the ECMO population include early nutrition, minimizing opioid usage while providing adequate pain relief, and appropriate sedation (AANA, 2022). Return on investment (ROI) has been proven using the ERAS protocol. A study by Thanh et al. (2020) implemented ERAS guidelines for multiple surgeries and performed an ROI analysis. Results displayed that for every dollar spent on ERAS, the ROI was one to seven times the original amount (Thanh et al., 2020). Patient savings were also significant with the ERAS guideline implementation (Thanh et al., 2020).

ECMO and Nutrition

Several articles researched proposed benefits of early and appropriate enteral nutrition for ECMO patients. Frequently, ECMO patients are prone to a hypermetabolic state, a rapid breakdown of protein, and insulin resistance, all leading to protein energy malnutrition (Dresen et al., 2022). The hypermetabolic state and risk of bowel ischemia, paired with the use of vasoactive agents, steroids, and intravenous sedation, along with a lengthened ICU stay, make the ECMO patient's nutritional needs unique (Dresen et al., 2022; Lu et al., 2018).

Three reviews from differing working teams concluded that early enteral nutrition is attainable, safe, and beneficial to ECMO patients who are not experiencing severe gastrointestinal dysfunction, hemodynamic instability, or shock (Al-Dorzi & Arabi, 2021; Davis et al., 2021; Stoppe et al., 2018). Dresen et al. (2022) noted that the most extensive observational study of ECMO patients concluded that early nutrition versus late nutrition did not pose a higher risk of pneumonia or bowel ischemia. Early nutrition in this study was also associated with lower hospital costs and a decreased 28-day mortality (Dresen et al., 2022).

ECMO and Mobility

A resounding theme to successful ECMO outcomes and reduced hospital mortality is to incorporate a plan to mobilize and ambulate the patient as early as possible. Dalia et al. (2019) included progressive mobility and early ambulation in their facility's protocol which assisted in positive patient outcomes. Chavez et al. (2015) developed an advanced mobility guide to promoting ambulation for the ECMO patient at the University of Colorado Hospital. The guidelines provide structure to primary caregivers, promote safe practice and holistic recovery, and facilitate advanced care (Chavez et al., 2015). Wells et al. (2018) performed a retrospective cohort study of ECMO patients at the University of Maryland. Those who participated in early mobilization were more likely to have successful outcomes and be discharged alive from the hospital (Wells et al., 2018). The researchers also supported using a highly trained multidisciplinary team to safely deliver this therapy and care (Wells et al., 2018).

Moreover, hospital mortality and costs are reduced after the initiation of a progressive early mobilization program (Liu et al., 2018. Researchers quickly realized the economic benefit of early ambulation for patients requiring ventilation or ECMO (Liu et al., 2018). After protocol implementation, there was a 27% reduction in hospital costs and significant decreases in in-hospital mortality and organ failure assessment scores at discharge (Liu et al., 2018).

Muhamed Aleef & Labib (2017) conducted a journal review concerning ECMO patients' early mobilization and ICU rehabilitation. Results aligned with Liu et al. (2018); early mobilization and exercises reduce delirium and days on mechanical ventilation, shorten ICU and hospital stays, and reduce healthcare costs (Muhamed Aleef & Labib, 2017). As such, aggregate data suggests that including exercises and early mobilization in an ECMO protocol would benefit patient outcomes.

The literature summarized and synthesized in this review revealed several themes and supported the need for the proposed project. First, protocols and guidelines provide safe, efficient care. Care providers, trained well in the protocols and processes to promote optimal patient outcomes, will be most equipped to care for patients requiring ECMO. Protocols that include sedation and pain management guidelines are encouraged by many ECMO centers (Dzierba et al., 2019; Landolf et al., 2020). The correct sedation parameters and appropriate pain management guidelines also aid in less delirium for patients receiving ECMO. Less agitation provides more awake and alert time, allowing more aggressive mobility. The evidence gathered offered immense support for the early mobility and ambulation of the ECMO patient, along with timely nutrition via an enteral feeding tube. Incorporating a protocol with sedation parameters and aggressive mobility/ambulation of the ECMO patient is validated as vital for successful outcomes.

Review of Theory

The project manager selected the diffusion of innovation for its foundation theory as it best aligned with this EBP project. Everett Rogers' classical theory of change includes the innovation-decision process. This process describes how stakeholders' thoughts about the characteristics of the proposed change influence diffusion of the innovation and the relationship between types of adopters (Mohammadi et al., 2018). Rogers highlighted that the adopter's decision-making is the center of moving toward adoption (Mohammadi et al., 2018). The phases of adoption or rejection are knowledge, persuasion, and decision. First, knowledge is obtained when an individual is provided with information about an existing innovation, but a more significant level of understanding is needed. Persuasion occurs once the individual has formed a view of the innovation. The decision happens when the individual must decide whether to use the innovation. Adoption finally occurs when individuals agree that innovation is beneficial. The diffusion of innovation theory has been proven effective for EBP projects.

Alignment of Theory

This project was guided by Rogers' classical theory of change and the innovation-decision process (Mohammadi et al., 2018). The Iowa model provided more detail on integrating change as it initially evolved based on Roger's theory (Mohammadi et al., 2018). As described in Chapter III, the project manager used the Iowa model (Buckwalter et al., 2017) to aid the project's design.

Rogers' first step of diffusion is knowledge. To determine the knowledge base of nurses caring for ECMO patients at the project facility, a confidential survey using a convenience sample of nurses was used to indicate the necessity of the EBP protocol. Protocol education on the project was provided to ECMO nurses to help them understand the protocol's innovation and implementation in a comprehensive manner.

Persuasion is Rogers' second step of the theory. In this project, the distribution of relevant literature was used to persuade stakeholders and create a sense of buy-in and urgency for the change. The information was provided using a PowerPoint to the project facility during educational sessions. Rogers identified primary influencers as those who spread ideas. There are also other categories of adopters ranging from innovators to laggers (Balas & Chapman, 2018). A project's success depends on all adopters; those willing to quickly make a change and those who ask questions or are more cautious (Balas & Chapman, 2018).

The last step, the decision, includes the diffusion of knowledge and its power to provide translational research. Is there enough evidence to support adopting the project protocol, and will the adopters confirm it (Balas & Chapman, 2018)? As this QI project implemented an ECMO-based protocol, Rogers' theory was well-suited for this project and aligned well with the steps necessary for a new EBP implementation.

Based on Roger's innovation theory, the Iowa model was used as the design method for this DNP project. Developed by the Iowa hospitals and clinics in 2001, this model has been a framework to guide EBP change and evaluation and incorporate research into the nurse's routine (Buckwalter et al., 2017). The Iowa model provides more detail on integrating change as it initially evolved based on Roger's theory. Four thousand requests to use the Iowa model since 2001 make it an essential guide for EBP (Buckwalter et al., 2017). The discussion below describes the steps involved in this project using the IOWA model.

The Iowa Model Collaborative (Buckwalter et al., 2017) states that EBP projects stress the importance of integrating existing knowledge into healthcare practice. EBP is often implemented by a new protocol or policy, aligning with this project's approach. There is a gap in the knowledge and training of nurses at the chosen facility impacting patient care—specifically, the patient population receiving ECMO. With the new protocol development and implementation, sustained change is expected. The data collected from this project can potentially guide additional program development and evaluation.

Chapter III: Method

The absence of an ECMO protocol was identified as a barrier to best-practice care at the project facility. This project implemented an ECMO protocol to enhance consistency in care, improve patient outcomes, and increase the knowledge and confidence of nurses caring for the ECMO population. Literature suggests that a protocol that integrates EBP improves the mortality rate of ECMO patients (Polastri et al., 2016; Dalia et al., 2019).

Design of the Project

Indiana Wesleyan University Institutional Review Board (IRB) approved this project per a Notice of Exemption (Appendix A). The project facility accepted Indiana Wesleyan University's IRB Notice of Exemption and did not require further review per the IRB Authorization Agreement to initiate the project. The project utilized a quantitative, quasi-experimental pre- and post-survey design to evaluate the effectiveness of nurse education on the newly developed ECMO protocol. ECMO patients' pre- and post-implementation data were compiled and compared for sedation usage, sedation scores, nutritional status, and discharge status. Rogers' theory, along with the Iowa model were found effective tools to the project's design.

Steps of the IOWA Model

The IOWA model first identifies a problem or a knowledge-focused trigger (Buckwalter et al., 2017). In this project, the project manager compared external benchmarking data from the ESLO (2022) to the project facility's data revealing that the facility's ECMO mortality rate in the years 2020-2021 was 15% higher (worse) than the national average (J. Morton, personal communication, December 3, 2021). In 2020, ELSO (2022) provided a separate dashboard about the data of COVID-19 patients on ECMO. ELSO has recorded over 13,000 patients diagnosed with COVID-19 receiving ECMO on this dashboard. The current global mortality rate reported is 47%. More than 8,000 of those cases were reported from North America, which has a mortality rate of 49% (ELSO, 2022). The facility chosen for this project had a staggering mortality rate of 60% in 2020-2021. Year to date, ELSO registered almost 1,300 total ECMO cases in North America, with a current adult mortality rate of 45% (ELSO, 2022).

To further improve patient outcomes, the project manager corresponded with an ECMO center of excellence in a neighboring state whose mortality rate was reportedly 20% lower (better) than the national average (E. Bak, personal communication, March 16, 2022). This facility's success is highly attributed to the prioritization of minimal sedation and increased mobility of patients receiving ECMO (E. Bak, personal communication, March 16, 2022)—the preliminary information received made this topic a priority for the project's chosen facility. The external benchmarking data classify this project as a problem-focused trigger (Buckwalter et al., 2017). Low mortality or high success rate gains trust in caring for ECMO patients within the community.

As the next step of the IOWA process, the project manager assembled a team of physicians, therapists, ECMO coordinators, ICU pharmacists, ICU unit managers, ICU unit educators, and bedside ECMO nurses to serve as the ECMO team. Following the team assembly, relevant literature and evidence were gathered and discussed in chapter two of this project and relayed to the ECMO team. The project was planned with the interdisciplinary collaborative ECMO team, and stages were set to pilot the change in practice. The protocol (Appendix B) was written with the interdisciplinary collaborative

ECMO team and approved by the ECMO physician. The protocol applied best practices from the literature review and many attributes from the post-operative ERAS protocol.

As part of the design process, a survey developed by the project manager was administered to ECMO nurses in the project facility. The validity of the survey and checking internal consistency was established by the statistician using Cronbach's alpha coefficient. The questions remained the same in the pre-and post-implementation survey. The Likert-style survey gave answers ranging from 1-5, 1 equaling strongly disagree, to 5 equaling strongly agree with the statement. (See Table 1). This survey was administered pre- and post-implementation to measure the nurse's confidence and knowledge of ECMO best practice care.

The project protocol included setting sedation parameters for the ECMO patient using the Richmond Agitation Sedation Scale (RASS), shown in Appendix C. Developed by an interdisciplinary team at Virginia Commonwealth University in Richmond; the RASS is a 10-point scale with scores ranging from +4 to -5. A score of 0 equates to an alert and calm patient. Positive RASS scores indicate alert to aggressive behavior, while negative RASS scores denote sedate to comatose states (Sole et al., 2021). The RASS is known to have interrater solid reliability and be a consistent tool that assesses the patient's sedation level over consecutive days in the ICU. RASS also correlates with the amount of sedative and analgesic medications administered (Sole et al., 2021). Measurable goals of the protocol included increased awake and calm time while receiving ECMO, increased mobility, timely nutrition administration, as-needed orders for pain and anxiety, and an overall reduced mortality rate at or better than the current national average.

The project manager introduced the protocol to key stakeholders, who approved moving the project forward. To prepare and train nurses, the project manager held information sessions during shift change huddles and sent an email with a PowerPoint attached describing the implementation process. The approved protocol was distributed on all ECMO carts and dispersed as a Google Doc via email so all on the project unit could access it easily. Copies of the protocol were available to all ECMO RNs and providers as a Google Doc and placed on all ECMO machines. The Google Doc was also sent to all ECMO healthcare providers via email. Healthcare providers included physicians, ECMO RNs, therapists, unit pharmacists, unit managers, and unit educators. ECMO RNs at the project facility cared for ECMO patients for four months during the protocol implementation. At the end of the fourth month, a post-survey was given to a convenience sample of RNs to gauge the level of increased understanding and decision of protocol adoption. The project manager could not determine if the same nurses completed the pre-and post-implementation surveys.

After the EBP guidelines were implemented, the process and outcomes were evaluated. During the review, modifications from stakeholders and project findings were made. The protocol was implemented after the evaluation showed that the project plan was appropriate and beneficial. Continuous monitoring and analyses of the structure, process, and outcome data occurred during the project.

Setting

The project facility was a 400-bed-level II trauma center in Northeast Indiana. The protocol was implemented in this facility's forty-two-bed cardiovascular intensive care (CVIC) unit. The CVIC unit has beds available for major and minor vascular and thoracic surgical patients, patients requiring ventricular assist devices, heart transplant patients, and all patients requiring ECMO. The CVIC unit admits 30-45 ECMO patients per year.

Population

The participants involved in this practice change were the healthcare professionals that care for ECMO patients. All nurses trained to care for patients requiring ECMO therapy used the new protocol developed for this project. All participants were over the age of 18.

There was minimal risk projected during this project. Data were de-identified during collection and analysis. This was a QI protocol implementation. No new research was conducted for this project. Minimal to no harm was projected for participants as the EBP change was implemented in the protocol. There was no additional cost to participants.

Participants were not incentivized in any way for this study. The benefits of this research include a more profound knowledge of the value of a well-developed protocol as increased optimal patient outcomes were expected.

The EBP protocol implementation aimed to decrease mortality, improve RASS scores, and optimize the nutritional status of ECMO patients. The protocol education also aimed for improved the understanding and confidence of the nurses caring for the ECMO population.

The project manager worked closely with the ECMO coordinators and ECMO physician who manages the care of this patient population. Other vital stakeholders included unit intensivists, hospital unit managers, educators, pharmacists, and physical therapists. Ethical considerations for patient privacy and patient integrity were prioritized throughout this project. The data was unidentifiable to specific patients. Open lines of communication between team members assisted in maintaining an ethical environment. The project manager and team members ensured accurate information dissemination. Necessary changes to the proposed project were made to keep the beneficence of patients a top priority.

Data Collection

The project manager collected the ECMO patients' data from the protocol implementation in December 2022 through March 31, 2023. Age, diagnosis, time on ECMO, sedation usage, RASS scores, nutritional status, and discharge status were collected on the ten patients placed on ECMO during the allotted period. Access to pre-protocol patients' unidentifiable information was provided through the ECMO coordinator. Details on when sedation and pain medication was received, nutrition via a transpyloric feeding tube began, and the patient's discharge status was collected. All information was organized in Microsoft Excel (version 16.75) spreadsheets and reviewed by a statistician, who analyzed the results discussed in Chapter IV.

Via Google Forms, participants (nurses caring for ECMO patients) completed an electronic six-question Likert scale survey on their knowledge of ECMO protocol best practices, including ERAS (See Table 1). The project manager created the survey. The choices for answers were numbers one through five. One equated to strongly disagree, and five equated to agree strongly. The same survey was given both before and after the protocol education/implementation was completed to see if the education and protocol implementation improved nurses' understanding and confidence in caring for the ECMO population. Responses remained confidential to ensure privacy. The Google Form was sent securely to nurses in the ECMO unit through the facility's email. Demographic data was not collected on ECMO patients or nurse participants in the project. Participation in the survey was confidential and voluntary.

Chapter IV: Results

The QI project implemented an ECMO protocol that addressed sedation, nutrition, and mobility. The project aimed to decrease the amount of sedation used, improve the nutritional status of the ECMO patient, and reduce overall mortality. The project also gave a pre- and post-implementation survey to the nurses caring for the ECMO patients (Figure 1). The Likert scale survey was administered to nurses before and after the education and implementation of the ECMO protocol described above. Ten patients at the project facility required ECMO during the protocol implementation. Post-implementation patient data was compared to 10 patients who required ECMO pre-implementation. ECMO patient results were collected pre- and post-protocol implementation. Patient data collected included age, primary diagnosis, time on ECMO, sedation usage, RASS scores, nutritional status, and discharge status.

Results of Data Collection/Analysis

The project survey intended to determine whether there were significant increases in confidence, knowledge, and understanding of ECMO best practice care after protocol implementation compared to before implementation.

Patient data pre- and post-implementation were compared to see if there was a significant improvement in RASS scores, time from ECMO cannulation to feeding tube placement, and improved mortality (more discharges to home). A significance level of $\alpha = 0.05$ was used throughout to assess statistical significance, and Statistical Analysis System (SAS) version 9.4 was used for all analyses.

Survey Results

All survey questions were analyzed and revealed significant changes from pre-implementation surveys to post-implementation surveys. Thirty-nine ECMO nurses completed the pre-survey, and 23 completed the post-survey. Results of an independent *t*-test showed a significant improvement in agreement ratings for most of the survey. The mean and standard deviation from all pre-implementation survey questions ranged from 3.18 to 4.00 (.96 to 1.37). Post-implementation survey question means, and standard deviations ranged from 3.74 to 4.78 (.42 to 1.10). All but one question showed significant improvement with *p*-values less than 0.05 (Table 1).

Table 1

Results of Participant Pre- and Post-Implementation Survey

1=Strongly Disagree, 2=Disagree, 3=Neither Agree nor Disagree 4=Agree, 5=Strongly Agree

Question	Pre-Implementation Mean and SD	Post-Implementation Mean and SD	p-value and effect size
I know what Enhanced Recovery After Surgery (ERAS) entails.	3.18 (1.30)	3.74 (1.10)	p = .09, d = -.46
Incorporating ERAS into the care of our ECMO patients is essential.	3.81 (.97)	4.78 (.42)	p < .001, d = -1.21
I feel confident implementing ERAS when caring for ECMO patients.	3.18 (1.37)	3.91 (1.04)	p = .03, d = -.58
Implementing ERAS when caring for our ECMO patients is beneficial to their outcomes.	4.00 (1.04)	4.70 (.77)	p = .01, d = - .74
Implementing ERAS into the care of ECMO patients is beneficial for nursing staff.	3.82 (1.01)	4.52 (.67)	p = .01, d = - .79

Implementing ERAS into the care of ECMO patients benefits our program and facility.	4.00 (.96)	4.78 (.42)	$p < .001$, $d = -.98$

Note. Pre-Survey *n*=39; Post-survey *n*=23

ECMO Patient Data Analysis

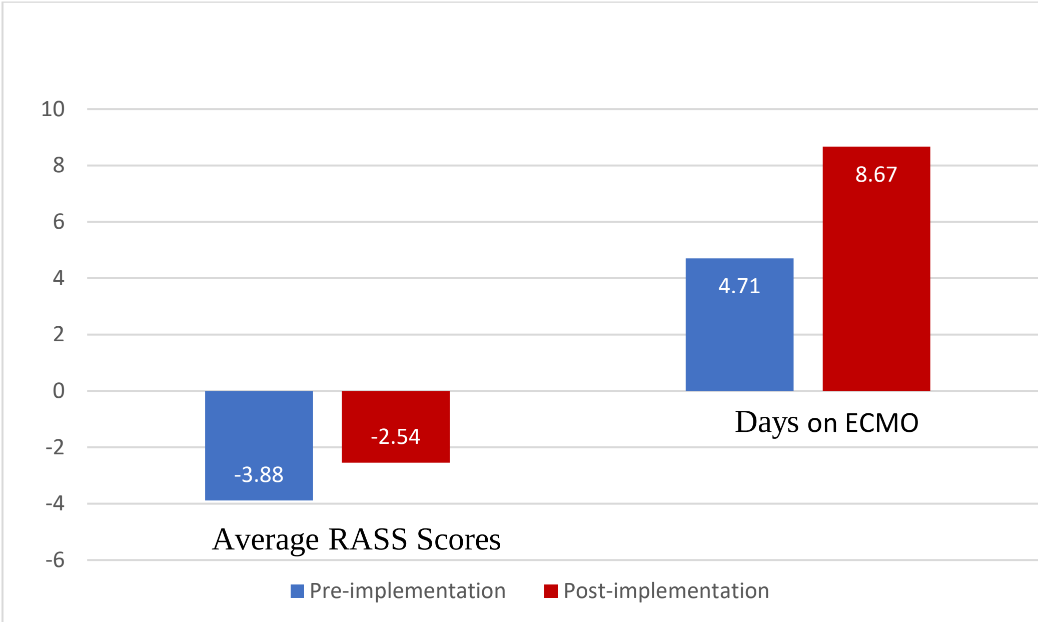
Patient data, including sedation levels, nutrition status, and survival rate, were compared to pre-implementation ECMO patients of similar age, gender, and primary diagnosis. Improved results were seen in each patient category analyzed.

RASS Scores

Results of an independent *t*-test revealed a statistically significant improvement in RASS scores between post-implementation participants ($M = -2.54$, $SD = 1.05$) and participants pre-implementation ($M = -3.88$, $SD = 1.09$), $t\ (14) = 2.49$, $p = .03$, $d = 1.25$. An unexpected finding revealed a statistically significant difference in number of days on ECMO between those in post-implementation ($M = 8.67$, $SD = 4.39$) and those in the pre-implementation group ($M = 4.71$, $SD = 1.98$), $t\ (14) = 2.20$, $p = .04$, $d = 1.11$. Patients were on ECMO an average of 8.67 days post-implementation where pre-implementation patients were on ECMO 4.71 average days (Figure 2).

Figure 1

Average RASS scores and Days on ECMO



A strong positive correlation exists between days on ECMO and average RASS score, *R* (14) = .73, p < .001, such that more days on ECMO predict higher RASS scores. Fifty-three percent of the variability in RASS scores can be explained by the number of days on ECMO.

Survival Rate

A Chi-Square analysis was performed to determine if there was a difference in the proportion of surviving patients between the pre-and post-implementation participants. The proportions did not differ statistically by diagnoses X^2 (1, 19) = 1.35, *p* = .24. 66% of patients survived post-implementation, and 40% survived pre-implementation. The survival rate improved by 26% post-protocol implementation.

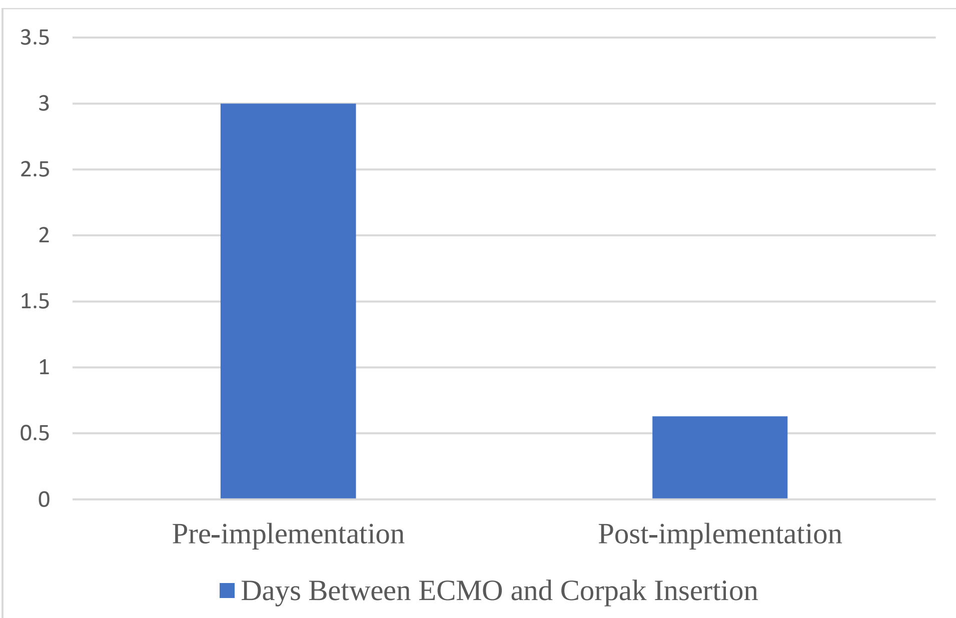
Days Between Start of ECMO and Enteral Tube (Corpak) Insertion

An independent *t*-test revealed a difference in the number of days between the start of ECMO and an enteral feeding tube (Corpak) insertion between the pre-implementation (*M* = 3.00, *SD* = 2.10) and post-implementation groups (*M* = .63, *SD* =

.74), *t* (12) = 3.00, *p* = .01, *d* = 1.62. See Figure 3 for details. There was no correlation between the number of days between ECMO and Corpak insertion and average RASS scores, *R* (9) = .05, *p* = 93. Although there was a difference in the survival rates based on the number of days between the start of ECMO and Corpak insertion, the difference was not statistically significant, *t* (12) = .90, *p* = .28, *d* = .49. Those who survived had an average of 1.25 days (*SD* = 1.04) between the start of ECMO and Corpak insertion compared to those who died who had an average of 2.17 days (*SD* = 2.64) between the start of ECMO and Corpak insertion.

Figure 2

Days between ECMO and Corpak Insertion



Discussion

This project evaluated a protocol implementation for the ECMO population at a Midwestern, level II trauma center. Patient outcomes and the nurses' knowledge of and confidence in using the protocol elements were analyzed. The protocol improved patient mortality, improved sedation (RASS) scores (Figure 2) and decreased the time between ECMO cannulation and nutritional intake via enteral feeding tube. (Figure 3). The project facility's survival rate is now 66%, exceeding the national adult survival average of 49% (ELSO, 2023). An unexpected finding was a correlation between the number of days on ECMO and sedation scores. The longer a participant was on ECMO, the lower (more improved) the RASS score. Significant differences existed between the pre-and post-implementation surveys given to the ECMO nurses (See Table 1); after implementation, nurses scored higher on their knowledge, understanding, and confidence of the protocol elements. The findings of this study are consistent with recent literature that supports using standard protocols to enhance patient outcomes in complex patient populations.

Implications for Practice

The use of ECMO therapy increased drastically during COVID-19. The ECMO patient requires critical thinking, attention to detail, and provider consistency in care to achieve optimal outcomes (Polastri et al., 2016). ICU protocols provide a framework for nurses to care for critically ill patients consistently, effectively, and efficiently. Nursing care directly impacts improving the clinical condition of ECMO patients. For nurses to effectively care for these complex patients, specific skills and standardized protocols are prioritized (Conceição et al., 2019).

Critical care units must emphasize the importance of protocol implementation for ideal patient results and consistent care. When specifically caring for the ECMO population, best practice sedation, timely nutrition, and early mobility are critical to success (Chavez et al., 2015; Conceição et al., 2019; Dzierba et al., 2019). When a lack of knowledge is identified, the Iowa model is a practical design method for implementing a new EBP practice (Buckwalter et al., 2017). The evidence from this project reinforces the benefits of a well-designed ICU protocol to improve outcomes.

Limitations

When interpreting the results, the project manager considered several limitations. First, the project's research took place over just four months. Within that time, the facility only cared for ten ECMO patients. A larger sample size and fewer time constraints for data collection would benefit the study's results. Much of the data relied on nurses' documentation in the electronic medical record; the project manager found the protocol's mobility and passive range of motion documentation inconsistent and unreliable for analysis. Future research should prioritize linking mobility, the number of days on ECMO, and the survival rate.

Recommendations

In future projects, researchers should seek to replicate the process with a longer time frame for implementation and a larger sample size. A more reliable data collection method concerning patient mobility would benefit data accuracy. According to CVIC's unit manager, the daily charge for an ICU room at the project facility is $5,154 (personal communication, T. Rumple, August 9, 2022). This charge does not include the cost of an ECMO specialist or life-saving devices, such as an ECMO pump and ventilator. Future research could analyze patient and hospital cost savings with an ECMO protocol implementation which would solidify the economic benefit of a standard ECMO protocol.

There was a noticeable increase in ECMO use during COVID-19. With the rise of ECMO at the project facility, a need for a consistent ECMO protocol was identified. An

EBP protocol was implemented, including sedation parameters, timely nutrition, appropriate pain/anxiety management, and consistent mobility expectations. After implementation, improved sedation scores, nutrition status, and survival rates were noted. ECMO nurses surveyed had higher knowledge, understanding, and confidence in using the EBP protocol post-implementation. By using the ECMO protocol, ICU nurses have a reliable tool to guide their care and give attention to the critical needs of the ECMO patient.

References

Al-Dorzi, H. M., & Arabi, Y. M. (2021). Enteral nutrition safety with advanced treatments: Extracorporeal membrane oxygenation, prone positioning, and infusion of neuromuscular blockers. *Nutrition in Clinical Practice*, *36*(1), 88–97. https://doi.org/10.1002/ncp.10621

American Association of Nurse Anesthesiology. (2022). *Enhanced recovery after surgery.* https://www.aana.com/practice/clinical-practice-resources/enhanced-recovery-after-surgery

Balas, A. W., & Chapman, W. W. (2018). Road map for diffusion of innovation in health care. *Health Affairs, 37* (2), https://doi.org/10.1377/hlthaff.2017.1155

Buckwalter, K. C., Cullen, L., Hanrahan, K., Kleiber, C., McCarthy, A. M., Rakel, B., Steelman, V., Tripp-Reimer, T., & Tucker, S. (2017). Iowa model of evidence-based practice: Revisions and validation. *Worldviews on Evidence-Based Nursing*, *14*(3), 175–182. https://doi.org/10.1111/wvn.12223

Chavez, J., Johnson Bortolotto, S., Paulson, M., Huntley, N., Sullivan, B., & Babu, A. (2015). Promotion of progressive mobility activities with ventricular assist and extracorporeal membrane oxygenation devices in a cardiothoracic intensive care unit. *Dimensions of Critical Care Nursing, 34*(6), 348–355. https://doi.org/10.1097/DCC.0000000000000141

Conceição dos Santos, D. B., Costa Cardoso, L. da C., Alves Cássia, T. D., Santana Prata, M., & Santana Santos, E. (2019). Care for patients using extracorporeal membrane oxygenation. *Journal of Nursing UFPE / Revista de Enfermagem UFPE*, *13*, 1093–1102. https://doi.org/10.5205/1981-8963.2019.242035

Dalia, A. A., Ortoleva, J., Fiedler, A., Villavicencio, M., Shelton, K., & Cudemus, G. D. (2019). Extracorporeal membrane oxygenation is a team sport: Institutional survival benefits of a formalized ECMO team. *Journal of Cardiothoracic and Vascular Anesthesia*, *33*(4), 902–907. https://doi.org/10.1053/j.jvca.2018.06.003

Davis, R. C., II, Durham, L. A., III, Kiraly, L., & Patel, J. J. (2021). Safety, tolerability, and outcomes of enteral nutrition in extracorporeal membrane oxygenation. *Nutrition in Clinical Practice*, *36*(1), 98–104. https://doi.org/10.1002/ncp.10591

Dresen, E., Naidoo, O., Hill, A., Elke, G., Lindner, M., Jonckheer, J., De Waele, E., Meybohm, P., Modir, R., Patel, J. J., Christopher, K. B., & Stoppe, C. (2022). Medical nutrition therapy in patients receiving ECMO: Evidence-based guidance for clinical practice. *Journal of Parenteral and Enteral Nutrition*, *47*(2), 220–235. https://doi.org/10.1002/jpen.2467

Dzeirba, A. L., Abrams, D., Madahar, P., Muir, J., Agerstrand, C., & Brodie, D. (2019). Current practice and perceptions regarding pain, agitation and delirium management in patients receiving venovenous extracorporeal membrane oxygenation. *Journal of Critical Care*, *53*, 98–106. https://doi.org/10.1016/j.jcrc.2019.05.014

Extracorporeal Life Support Organization. (2022, April 20). *ELSO live registry dashboard of ECMO patient data.* https://www.elso.org/Registry/ELSOLiveRegistryDashboard.aspx

Extracorporeal Life Support Organization. (2023, July 14). *ELSO live registry dashboard of ECMO patient data.* https://www.elso.org/registry/elsoliveregistrydashboard.aspx

Ellis, M. F., Pena, H., Cadavero, A., Farrell, D., Kettle, M., Kaatz, A. R., Thomas, T., Granger, B., & Ghadimi, K. (2021). Reducing intubation time in adult cardiothoracic surgery; Patients with a fast-track extubation protocol. *Critical Care Nurse*, *41*(3), 14–24. https://doi.org/10.4037/ccn2021189

Landolf, K. M., Rivosecchi, R. M., Goméz, H., Sciortino, C. M., Murray, H. N., Padmanabhan, R. R., Sanchez, P. G., Harano, T., & Sappington, P. L. (2020). Comparison of hydromorphone versus fentanyl-based sedation in extracorporeal membrane oxygenation: A propensity-matched analysis. *Pharmacotherapy*, *40*(5), 389–397. https://doi.org/10.1002/phar.2385

Liu, K., Ogura, T., Takahashi, K., Nakamura, M., Ohtake, H., Fujiduka, K., Abe, E., Oosaki, H., Miyazaki, D., Suzuki, H., Nishikimi, M., Lefor, A. K., & Mato, T. (2018). The safety of a novel early mobilization protocol conducted by ICU physicians: a prospective observational study. *Journal of Intensive Care*, *6*(10). https://doi.org/10.1186/s40560-018-0281-0

Lu, M. C., Yang, M. D., Li, P. C., Fang, H. Y., Huang, H. Y., Chan, Y. C., & Bau, D. T. (2018). Effects of nutritional intervention on the survival of patients with cardiopulmonary failure undergoing extracorporeal membrane oxygenation therapy. *In Vivo*, *32*(4), 829–834. https://doi.org/10.21873/invivo.11315

Mohammadi, M. M., Poursaberi, R., & Salahshoor, M. R. (2018). Evaluating the adoption of evidence-based practice using Rogers's diffusion of innovation theory: A model testing study. *Health promotion perspectives*, *8*(1), 25–32. https://doi.org/10.15171/hpp.2018.03

Muhamed Aleef, M. C., & Labib, A. (2017). Early mobilization and ICU rehabilitation of ECMO patients. *Qatar Medical Journal*, *2017*(1), 1–3.

https://doi.org/10.5339/qmj.2017.swacelso.71

Nigoghossian, C. D., Dzierba, A. L., Etheridge, J., Roberts, R., Muir, J., Brodie, D., Schumaker, G., Bacchetta, M., Ruthazer, R., & Devlin, J. W. (2016). Effect of extracorporeal membrane oxygenation uses on sedative requirements in patients with severe acute respiratory distress syndrome. *Pharmacotherapy*, *36*(6), 607–616. https://doi.org/10.1002/phar.1760

Polastri, M., Loforte, A., Dell'Amore, A., & Nava, S. (2016). Physiotherapy for patients on awake extracorporeal membrane oxygenation: A systematic review. *Physiotherapy Research International*, *21*(4), 203–209. https://doi.org/10.1002/pri.1644

Sole, M. L., Klein, D. G., & Moseley, M. J. (2021). *Introduction to critical care nursing* (8th ed.). Elsevier.

Stoppe, C., Nesterova, E., & Elke, G. (2018). Nutritional support in patients with extracorporeal life support and ventricular assist devices. *Current Opinion in Critical Care*, *24*(4), 269–276. https://doi.org/10.1097/MCC.0000000000000512

Thanh, N., Nelson, A., Wang, X., Faris, P., Wasylak, T., Gramlich, L., & Nelson, G. (2020). Return on investment of the Enhanced Recovery After Surgery (ERAS) multi-guideline, multisite implementation in Alberta, Canada. *Canadian Journal of Surgery*, *63*(6), E542-550. https://doi.org/10.1503%2Fcjs.006720

Wall, R. J., Dittus, R. S., & Ely, E. W. (2001). Protocol-driven care in the intensive care unit: A tool for quality. *Critical Care*, *5*(6), 283. https://doi.org/10.1186/cc1048

Wells, C. L., Forrester, J., Vogel, J., Rector, R., Tabatabai, A., & Herr, D. (2018). Safety and feasibility of early physical therapy for patients on extracorporeal membrane oxygenator: University of Maryland Medical Center Experience. *Critical Care Medicine*, *46*(1), 53–59. https://doi.org/10.1097/CCM.0000000000002770

Appendices

Appendix A

Notice of Exemption

Institutional Review Board
4201 South Washington Street
Marion, IN 46953

Tel: 765-677-2090
Fax: 765-677-6647

Notice of Exemption

Extracorporeal Membrane Oxygenation: A Protocol Implementation for Quality Improvement Title of Research Topic

Melanie Gall, Debra Walker
Investigator(s)

1776.22
IRB ID Number

The IWU Institutional Review Board (IRB) has reviewed your proposal and has determined that your proposal is exempt from further review by the IRB because the proposed project does not constitute human subjects research. Federal regulations that establish the authority of the IRB provide a specific definition of human subjects research which defines the scope of IRB authority. Your project falls outside the federal definition of human subjects research and is therefore not subject to IRB review.

Please note that this exemption regards only the oversight of human subjects research by the IRB. The IRB has not reviewed any other aspects of the research project and makes no judgement on the merits of the project or its methodologies. All research executed at IWU must conform to all applicable state and federal laws and regulations and to all applicable IWU policies.

Comments:

Ph.D.
Chair, Institutional Review Board

September 22, 2022
Date

Appendix B

ECMO Protocol

Enhanced Recovery After Surgery (ERAS) Protocol post-ECMO cannulation

Sedation

- Diprivan, in combination with a paralytic, if necessary first 24-36 hours after ECMO cannulation. RASS level goal: -2
- Titrate Diprivan and discontinue paralytic 24-36 hours after cannulation. RASS level goal: 0/-1.

Nutrition

- Call Stat RN for Corpak enteral feeding tube insertion within 24 hours of ECMO cannulation.
- Consult the dietician for tube feed rate and goal.

Pain Medication

- Tylenol - 650 mg po or per rectum q 6 hours. Omit if total bili > 1.5
- traMADol- 50 mg tab po or via tube q 6hr. While intubated/change to q6 prn after extubation.
- gabapentin- **begin after extubation.**
  - 300 mg po TID for CrCl >60 ml/min
  - 300 mg po BID for CrCl 30-59 ml/min
  - 200 mg po BID for CrCl 15-29 ml/min
  - 100 mg po BID for CrCl < 15 ml/min
- Avoid continuous gtts of pain medication (i.e., Fentanyl) 24-36 hours after ECMO cannulation.
- Avoid the use of Opioids/Narcotics- use Tylenol and Tramadol first.

Anti-Anxiety/Anti-Psychotics:

- Clonazepam -1 mg po every 8 hrs.
- Seroquel- 50 mg po or via tube BID

Mobility

- Passive range of motion (ROM) BID is completed by nursing staff when the patient cannot mobilize out of bed due to hemodynamic instability.
- Active ROM BID is completed by physical therapy (PT) and nursing when the patient is hemodynamically stable.

Appendix C

RASS Scale

RASS score

Richmond Agitation & Sedation Scale				CAM-ICU
Score	Description			
+4	Combative	Violent, immediate danger to staff		RASS ≥ -2 Proceed to CAM-ICU assessment
+3	Very agitated	Pulls at or removes tubes, aggressive		
+2	Agitated	Frequent non-purposeful movements, fights ventilator		
+1	Restless	Anxious, apprehensive but movements not aggressive or vigorous		
0	Alert & calm			
-1	Drowsy	Not fully alert, sustained awakening to voice (eye opening & contact >10 secs)	Voice	
-2	Light sedation	Briefly awakens to voice (eye opening & contact < 10 secs)		
-3	Moderate sedation	Movement or eye-opening to voice (no eye contact)		RASS < -2 STOP Recheck later
-4	Deep sedation	No response to voice, but movement or eye opening to physical stimulation	Touch	
-5	Un-rousable	No response to voice or physical stimulation		