DNP Projects   College of Nursing

2016

Review of Current Mobility Practice in Non-Surgical Mechanically Ventilated Intensive Care Unit Patients

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REVIEW, APPROVAL AND ACCEPTANCE

The document mentioned above has been reviewed and accepted by the student's advisor, on behalf of the advisory committee, and by the Assistant Dean for MSN and DNP Studies, on behalf of the program; we verify that this is the final, approved version of the student's DNP Project including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

Catharine Morgan, Student

Dr. Elizabeth Burckardt, Advisor

Final Doctoral of Nursing Practice Project

Review of Current Mobility Practice in Non-Surgical Mechanically Ventilated Intensive

Care Unit Patients

Catharine Morgan

University of Kentucky

College of Nursing

Fall 2016

Dr, Elizabeth Burckardt DNP, APRN- Committee Chair/Academic Advisor

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Dedication

I would like to dedicate this work and my DNP project to the following individuals for their assistance and support with various components of this project and my stability throughout this journey:

Matt Deeds: my fiancé, who has defined patience over the last 3 years. Thank you for being supportive, understanding, and always pushing me to not give up on my dreams.

My Family: My parents, Nonie and Scott, Tim and Sheryl, who have always been my biggest supporters, and who often believed in me more than I did myself.

My siblings: Brooke, Tyler, Paul, Rachael, Kevin, Alex and Lucy, thank you all for your support, love, and laughter.

Table of Contents

List of Tables

List of Figures

Abstract

Purpose: The purpose was to: (i) conduct a retrospective electronic medical record review to evaluate current practice related to mobility, (ii) determine the association between current mobility practice patterns and characteristics specific to the patient population, and (iii) make recommendations for the implementation of an evidence-based progressive early mobility protocol for non-surgical mechanically ventilated patients.

Population: Non-surgical, ventilated patients in the Intensive Care Unit (ICU)

Inclusion Criteria: Ventilated patients at least 18 years old who have been ventilated for at least 48 hours and did not have major surgery lasting more than one hour at any point during their hospital stay from January 1, 2015- December 31, 2015.

Design and Methods: A retrospective electronic medical record review was conducted (*n=100*) in a large local hospital over a one-year time span. Electronic medical records were randomly selected, and were audited for the following variables: admission diagnosis, comorbidities, age, ethnicity, sex, ventilator days, invasive catheters, use of vasoactive or inotropic medications, physical therapy (PT) intervention, occupational therapy (OT) intervention, range of motion (ROM), sitting on the side of the bed, standing on the side of the bed, ambulation, RASS, CAM-ICU, ICU length of stay (LOS), hospital LOS, and discharge disposition. Descriptive statistics were used.

Results: No statistically significant relationships between the current mobility practices and characteristics specific to the patient population were found. The data revealed a low incidence of all mobility variables ICU admission. This study resulted in a recommendation for a development and implementation of a progressive early mobility program for ventilated patients in the ICU.

Background

Early mobility in ventilated patients has been linked to a decrease in length of stay in the intensive care unit (ICU) and in the hospital. One week of lying in bed can decrease muscle strength by at least 20%, with an additional 20% loss of remaining strength each subsequent week (Mendez-Tellez & Needham, 2012). In healthy older adults, only 10 days of bed rest resulted in a 3.3 pounds loss of lean body mass, and a 15% loss of quadriceps strength. For the geriatric population, loss of even a small amount of muscle strength may be the difference between going home and going to a nursing home (Milbrandt, 2008). The goal of this project is to assess the relationship between early mobilization and outcomes in non-surgical ventilated patients in the ICU with a focus on delirium, sedation, ventilator days, physical therapy intervention, occupational therapy intervention, and length of stay in the ICU and the hospital.

Decreased mobility in ventilated patients can have serious negative outcomes in the recovery of critically ill patients in the ICU. For example, Micheletti (2014) has found that immobility related to mechanical ventilation causes muscle weakness, increased time on ventilator, increased hospital length of stay, and increased delirium. Decreased mobility is also associated with increased morbidity and impaired physical function. One day in the ICU on the ventilator costs around $1,522, and if that patient develops ventilator-associated pneumonia the cost increases by $40,000 per day (Micheletti, 2014).

Delirium and weakness in the ICU can predict increased mortality, mechanical ventilator days, ICU length of stay (LOS), use of continuous sedation, and physical restraints (Balas et al., 2014, p. 1025). These complications can cause functional decline

and long-term cognitive impairment. Survivors of longer lengths of stay in the ICU may exhibit severe psychological and physical problems and can have a lower health-quality of life up to one year following discharge from the hospital (Kayambu, Boots, & Paratz, 2011).

Current mobility practice at the institution involves manual repositioning with two or more nurses, with patients getting out of bed with PT after removal of treatments related to ventilation. Mobilization of patients in the ICU often requires multiple staff members, due to the progressive weakness of this patient population and their generally poor response to getting out of bed. With the increased amount of staff involvement and easy decompensation of patients with mobility treatment, staff members find it hard to reattempt mobilization more than once per day.

Immobility is widely documented in the literature as a cause of increased mortality and complication (Butcher, 2012). Early mobility program have shown to aid in patients returning to independent function at hospital discharge (Schweickert et al., 2009). Morris and colleagues found that early mobility and physical therapy is a safe and effective intervention that can have significant impact on function outcomes (2008). Many patients are mobile and live normal lives prior to their critical illness. Nurses help in returning patients to their maximal potential in the acute recovery phase. A nurse driven mobility protocol would aid in getting mobility initiated earlier, and more consistent initiatives throughout the day.

Description of Doctoral of Nursing Practice Project

This was a retrospective descriptive study in which the electronic medical record was used to determine following: the current state of clinical practice related to mobility

in the ICU with the non-surgical ventilated patient population, and the need for an evidenced-based mobility protocol.

The study included a random sample of 100 non-surgical ventilated patients, admitted to the Open Heart Unit (OHU) and ICU at a Kentucky hospital in 2015, who had been on the ventilator for greater than 48 hours. To be included in this study, patients were required to be, at least 18 years old, and ventilated for at least 48 hours. Patients who had major surgery, or surgery lasting more than one hour at any point during their hospital stay were excluded. Minor surgeries or procedures such as tracheostomy, percutaneous endoscopic gastrostomy (PEG) tube placement, or wound debridement were not considered major surgeries for the purpose of this study.

Objectives

The objective of this evidence-based project was to determine if there is a need for an evidence-based early mobility intervention for the non-surgical ventilated patient population.

Objectives:

a. Conduct a retrospective electronic medical record review to evaluate current practice related to mobility (defined by documentation of range of motion, sitting on side of bed, standing at side of bed, ambulation, physical therapy and occupational therapy intervention) in a random sample of 100 non-surgical mechanically ventilated patients in OHU and ICU at a Kentucky hospital between January 1, 2015 and December 31, 2015.

b. To determine the association between current mobility practice patterns and characteristics specific to the patient population (admission diagnosis,

comorbidities, age, ethnicity, sex, ventilator days, invasive catheters, use of

vasoactive or inotropic medications, physical therapy [PT] intervention,

occupational therapy [OT] intervention, range of motion [ROM], sitting on the

side of the bed, standing on the side of the bed, ambulation, Richmond Agitation

Sedation Score [RASS], Confusion Assessment Method for the ICU [CAM-ICU],

ICU length of stay [LOS], hospital LOS, and discharge disposition).

c. To make recommendations for the implementation of an evidence-based

progressive early mobility protocol for non-surgical mechanically ventilated

patients in the OHU and the ICU.

Methods

Approval Process

Following project development and committee approval, clearance was obtained

from the Norton Healthcare Office of Research Administration (NHORA). An expedited

proposal was approved by the University of Kentucky Institutional Review Board (IRB),

supporting that there was minimal risk involved for this study. The nurse manager of the

ICU's at the hospital was informed of the project via face-to-face meeting.

Study Design

The study design for this project was retrospective. Data were collected via a

retrospective electronic medical record review for patient admitted between January 1,

2015 and December 31, 2015.

Study Setting

Data were collected on patients who were on a ventilator in the ICU or OHU

located in a 432 bed hospital in Louisville, Kentucky in 2015. The ICU is an 18-bed unit,

and the OHU is a 16-bed unit. The nurse to patient ration is 1:2, occasionally 1:3 based on patient acuity, and there are 2 patient care associates on each unit each day. There is one respiratory therapist assigned to each unit every day.

Study Population

A total of 1,132 patients over the age of 18 were on the ventilator in the ICU during the study interval. A sample of 100 patients was chosen using a random number generator. The target population was non-surgical mechanically ventilated patients in the ICU. Inclusion criteria were ventilated patients at least 18 years old that had been ventilated for at least 48 hours, had a RASS score of -1 to +1, and did not have major surgery lasting more than one hour at any point during their hospital stay. Exclusion criteria were any surgery lasting more than one hour, palliative care order, hemodynamic instability defined by MAP <55, pulmonary instability defined by FiO_2 >60%, PEEP > 10 cmH_2O, femoral central catheter placement, open abdominal wounds, and patients with strict bed rest orders.

Procedures

Patient record selection: Medical records were identified by identifying all ventilated patient electronic medical records from 2015. Any patients who had surgery lasting more than one hour during their hospital stay were excluded. Each chart was screened to determine if the inclusion criteria were met. Data were collected each day that the patient was in the ICU, and if therapy was done more than once per day then the first measure of the day was used. All patients that met the inclusion criteria had data collected on the data collection form, and they were assigned a random number from a random number generator.

Data were collected related to the following study variables: ventilator days, delirium using the CAM-ICU, sedation using the RASS, PT intervention, OT intervention, ICU and hospital LOS, comorbidities, invasive catheters, use of vasoactive or inotropic medications, documentation of ROM, sitting on side of bed, standing at side of bed, ambulation, disposition at discharge from the hospital, admission diagnosis, gender, age and ethnicity (See appendix C for data collection tool). For privacy purposes, no patient identifying information was included in the data collection. All data were kept on a password and firewall protected H drive, which was password and firewall protected. The primary investigator was the only one that received the master list of patient demographics and data points.

Data Analysis

Data analysis from the retrospective electronic medical record review was performed using SPSS ® version 23.0 (SPSS Inc., Chicago, IL). Data were analyzed using descriptive statistics including frequencies, means, and percentages. These results were used to evaluate study objectives regarding current mobility practices.

Results

Sample Characteristics

A total of 244 electronic medical records were reviewed during the data collection time period, and 100 met the inclusion criteria for this study. Complete sample demographics and admission diagnoses can be found in Table 1. Majority of the sample was Caucasian and male.

Study Results

Of the 100 patients that were on the ventilator in the ICU, two patients sat on the side of the bed and one patient stood by the side of the bed during their ICU admission while ventilated. There were no reporting of any patients ambulated in this sample during this time frame. Five percent of this sample had an intervention with PT while on the ventilator, and 3% had an intervention with OT. There were many patients that had PT/OT orders, but treatment was deferred until the patient was off the ventilator. Passive range of motion was performed 98% of the time, and active range of motion was performed 80% of the time.

The median ICU LOS was 7.5 days, and the median hospital LOS was 13 days. The minimum days on the ventilator was two days and the maximum was 15 days with the median being five days. Majority of this patient population had at least one invasive catheter, and 96% had a urinary catheter. Figure 1 describes the complete listing of invasive catheters for the sample. The mean comorbidities were 4.6, and those are outlined in Figure 2. Majority of the sample was discharged to a skilled nursing facility (32%), with 21% being discharged home. The complete sample discharge dispositions can be found in Figure 3.

There was very little data on the RASS and CAM-ICU to make any satisfactory conclusion on those variables. The CAM-ICU monitors the patient for the development or resolution of delirium in intensive care. This tool assesses four features: 1) acute change or fluctuation in mental status from baseline, 2) inattention, 3) altered level of consciousness, and 4) disorganized thinking (Ely et al., 2001). The CAM-ICU is positive, and the patient is considered to have delirium, if features 1 and 2 and *either* feature 3 or 4

are present. A positive result indicates that delirium is present and a negative result indicates that there is no delirium. RASS is a 10-point scale, with four levels of anxiety or agitation (+1 to +4 [combative]), one level to denote a calm and alert state (0), and five levels of sedation (-1 to -5 [unarousable]) (Sessler et al., 2002). A RASS of -2 is considered the target goal for continual sedation, which is considered light sedation. (See Figure 4 for CAM-ICU assessment tool, and Figure 5 for example RASS assessment tool).

Discussion

This aim of this study to understand the current mobility practices for non-surgical ventilated patients in the ICU. Overall, there was an inability to make a statistical association to demographic data and mobility practices related to the lack of data regarding mobility practices. The current practice of mobility in the specific units is to turn patients every two hours, and for PT to reevaluate patients once they are liberated from the ventilator. Research suggests that turning the patient every two hours only happens 2.7% of the time (Krishnagopalan, et al., 2002). Patients in the ICU can have medical orders for complete immobilization, sedative agents, and paralytics. The use of these orders impacts the ability to mobilize patients. This delays care for ventilated patients and can prolong their length of stay and rehabilitation time. A standardized approach to mobility of ICU patients is needed to improve patient outcomes and the overall quality of care.

Also, of the 100 patients in the sample, the majority of these patients were discharged to a skilled nursing facility rather than going home. In a study done by Winkleman et al. (2012) 60% of the control group was discharged to subacute

rehabilitation center and 40 % to long term skilled nursing facilities, while in the intervention group 74% went to subacute rehabilitation center, 12% went to long term skilled nursing facilities, and 3% went home.

While the exact cost of hospitalization is highly dependent on the individual needs of the patient, research suggests that the cost of hospitalization is between $1500 and $3000 per day (Rothberg, Abraham, Lindenauer & Rose, 2005). Winkleman et al. (2012) found that the ICU LOS was 19.6 days in the control group and 14.6 days in an early mobility intervention group. In a study done by Schweickert et al. (2009), the authors examined return to independent function at hospital discharge, 59% in the early mobility intervention group, and 35% in the control group.

The time between the PT/OT consult and treatment was not evaluated. These data would be beneficial in looking at when the patients are mobilized and how often. If there is a gap in this time frame, this is where a nurse driven mobility protocol would be advantageous to the process of early mobility.

Due to decreased charting on RASS and CAM-ICU data during the data collection period, increased sedation could be an influence on mobility in this sample. Sedation use was not a variable collected in this study, but would have been a valuable tool. Needham et al. (2010) encourage "a change in sedation practice from use of continuous intravenous infusion of benzodiazepines and narcotics to 'as needed bolus doses'" (p. 538).

Multidisciplinary team communication will also be a key step for successful implementation of any early mobility program. This involves nurses, providers, respiratory therapists, physical therapists, and nursing leadership. This team composition

could aid in a better understanding of each discipline in the process of early, safe mobilization of ventilated patients.

Implications for Practice

An early mobility program/algorithm for nurses to follow has been proven in the literature to be beneficial for this patient population. A mobility program is an intervention that can be nurse driven and can improve outcomes of ventilated ICU patients, such as decreased LOS and decreased ventilator days. This would give nursing ownership and leadership with their patients, and potentially decrease the LOS of the patient and contribute to overall cost savings. Robert Lord and colleagues (2013), looked at development of a financial model, based off data from the early rehabilitation program in the Johns Hopkins MICU, and they predicted net financial savings in 83% of possible scenarios when initiating a rehabilitation program. Overall, estimates ranged from $88,000 (net cost) to $3.8 million (net savings).

A good starting point would be to create a delirium team to identify barriers to delirium screening, and provide re-education on CAM-ICU and RASS. Nurses with adequate knowledge of recognition and treatment of delirium can be key members of the ICU multidisciplinary team (Marino, Bucher, Beach, Yegneswaran, & Cooper, 2015). A multidisciplinary team approach could help to include key disciplines such at PT/OT accountable with this patient population by having an algorithm or protocol to follow.

A systemic change to management of ICU patients may aid in increasing mobility and reducing complications related to immobility. One "bundled" approach called the "ABCDEs" has shown success in this area (Balas et al., 2014). The ABCDEs bundle combines evidenced based components from ventilator weaning, sedation and

pain management, and PT and OT. The A is for assess, prevent, and management of pain. The B represents both spontaneous awakening trials and spontaneous breathing trials. Thee C is for choice of analgesia and sedation. The D is for delirium, assess, prevent and management. The E is for early mobility and exercise, and just recently F was added for family engagement and empowerment. Bounds and colleagues (2016), found that after implementation of the ABCDE bundle, the prevalence of delirium decreased significantly (from 38% to 23%, P=.01) and the mean number of days of delirium decreased significantly (from 3.8 to 1.72 days, P<.0001).

Implications for Future Inquiry

Future studies need to include a larger sample size, and include more than one hospital site. This will aid in a more complete clinical picture and include a more inclusive population by adding additional hospital sites. Additional considerations would be to develop and implement a mobility protocol and apply it to a group of patients to compare to the outcomes of this assessment. These findings should be compiled with surgical ventilated patients in the ICU, and findings should be published in medical and nursing journals to guide future practice and research.

Limitations

A major limitation of this study was the lack of mobility interventions performed with this patient population. Two of the variables, RASS and CAM-ICU, had very minimal charting and could not be analyzed secondary to the inconsistent data extracted from the electronic medical record. The study objective, "to determine the association between current mobility practice patterns and characteristics specific to the patient population", could not be analyzed. There were not sufficient data to support whether

there were any associations between mobility practice and characteristics of the patient population. Additional limitations include that this was a single site study, and surgical patients were excluded. The amount or type of sedation was not evaluated in this sample, and should be evaluated in a future sample.

Another consideration is that mobility was not properly documented if done with the patients. Without appropriate documentation in these categories, it is hard to make conclusions on nursing staff current practice as they may be actually be performing more mobility than documented.

Conclusion

Critically ill patients are subjected to long periods of immobility, which often leads to complications of mobility leading to prolonged intubation and increased LOS in the ICU and hospital. This review was designed to evaluate the current mobility practice in the ICU and develop interventions for a process improvement. Findings of this study revealed an inability to make a statistical significance between current mobility practice patterns and characteristics specific to the patient population. However, this study did reveal improvements that can be made in the current mobility practices, such as tighter control with delirium and sedation, increased use of PT and OT services in the ICU, and consistent charting of mobility treatment with each patient. Continued research on the positive outcomes of implementation of an early mobility program would benefit development of a program that would fit the needs of this population.

Table 1.

Demographic Variables

Characteristic	*n=100*
Age, years Mean (SD)	*63.3 (15.7)*
Ethnicity	
African American	*11%*
Caucasian	*85%*
Hispanic	*4%*
Gender	
Male	*57%*
Female	*43%*
Admission Diagnosis	
Cardiac Arrest	*7%*
Acute Respiratory Failure	*13%*
Shortness of Air	*17%*
Pneumonia	*8%*
Altered Mental Status/Seizure	*12%*
Sepsis	*12%*
Chest Pain/Arrhythmia/Congestive Heart Failure	*9%*
Chronic Obstructive Pulmonary Disease	*3%*
Abdominal Pain	*13%*
Overdose/Other	*7%*

Table 2.

Clinical Variables

Clinical Variables	*n=100*
Ventilator Days, Median	*5 (2-15)*
ICU LOS, Median	*7.5 (2-32)*
Hospital LOS, Median	*13 (2-70)*

Table 3.

Mobility Variables

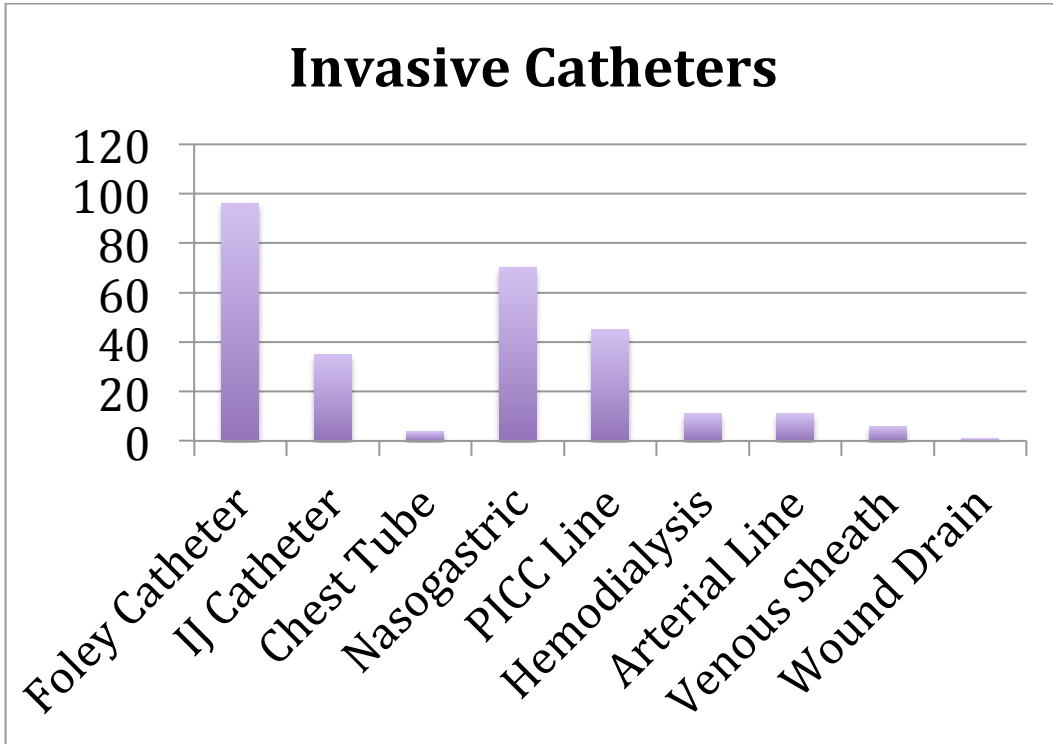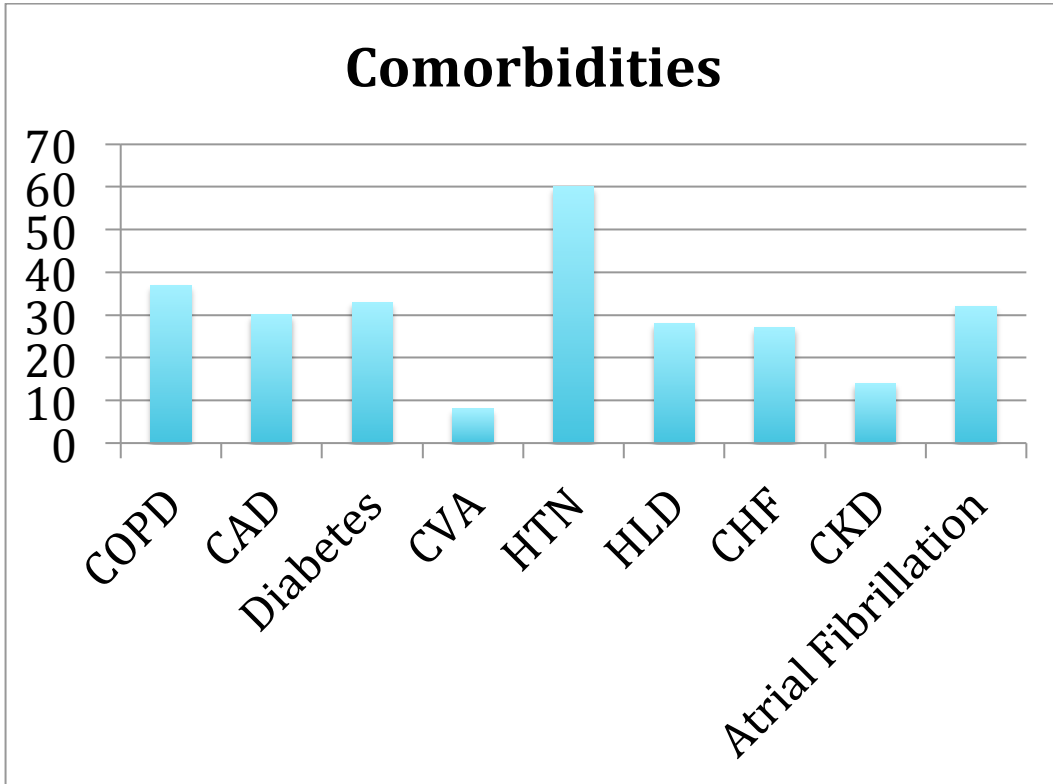| Mobility Variables	*n=100*
Active ROM	*80%*
Passive ROM	*98%*
Sat on the side of bed	*2%*
Stood by the side of the bed	*1%*
Ambulated	*0%*
PT Intervention	*5%*
OT Intervention	*3%*

Figure 1. Invasive Cathethers
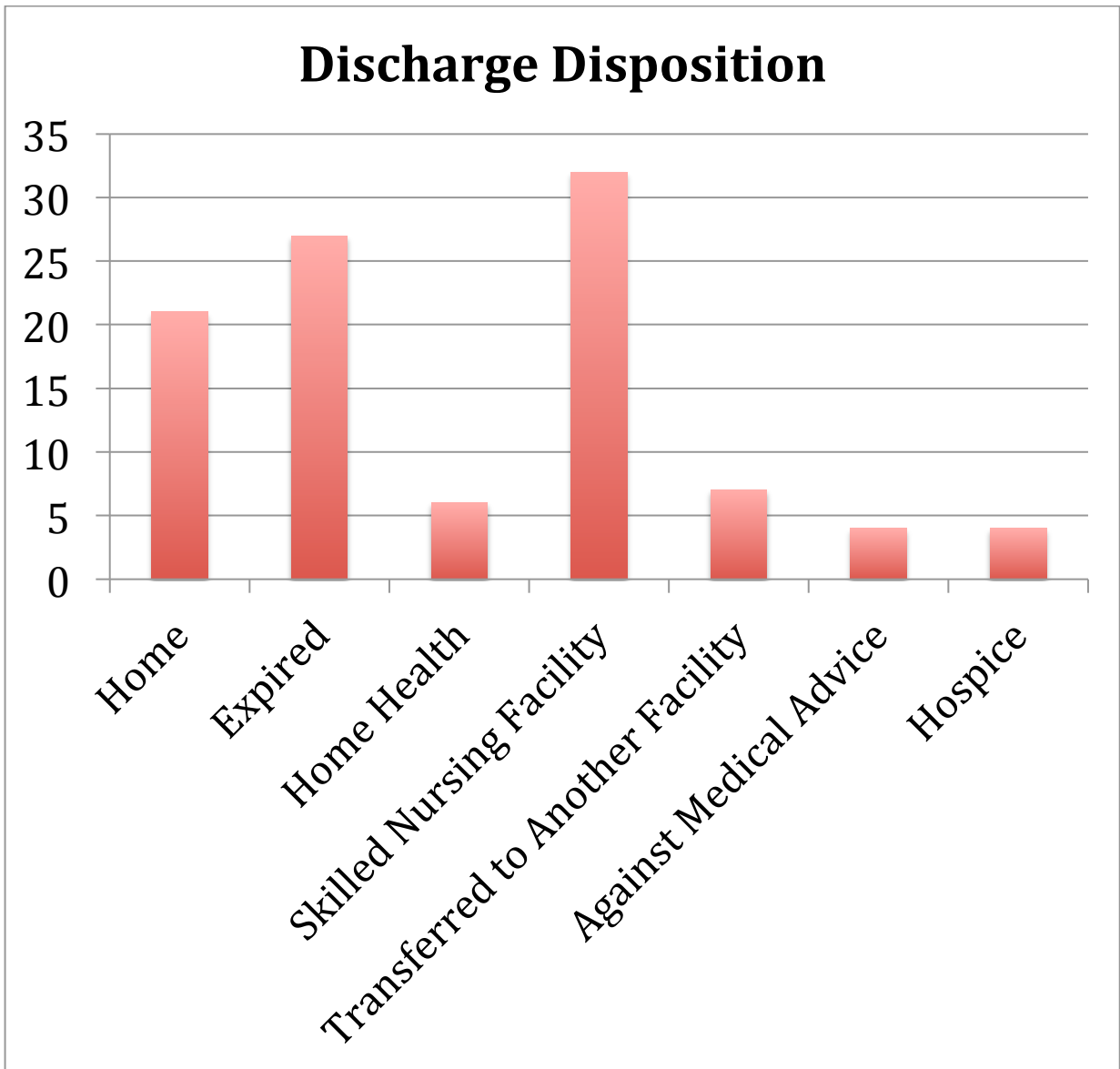
Figure 2. Comorbidities

Figure 3. Discharge Disposition

Table 1. The Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)

Features and Descriptions	Absent	Present
I. Acute onset or fluctuating course*		
A. Is there evidence of an acute change in mental status from the baseline? B. Or, did the (abnormal) behavior fluctuate during the past 24 hours, that is, tend to come and go or increase and decrease in severity as evidenced by fluctuations on the Richmond Agitation Sedation Scale (RASS) or the Glasgow Coma Scale?		
II. Inattention†		
Did the patient have difficulty focusing attention as evidenced by a score of less than 8 correct answers on either the visual or auditory components of the Attention Screening Examination (ASE)?		
III. Disorganized thinking		

Is there evidence of disorganized or incoherent thinking as evidenced by incorrect answers to 3 or more of the 4 questions and inability to follow the commands?
Questions
   1. Will a stone float on water?
   2. Are there fish in the sea?
   3. Does 1 pound weigh more than 2 pounds?
   4. Can you use a hammer to pound a nail?
Commands
   1. Are you having unclear thinking?
   2. Hold up this many fingers. (Examiner holds 2 fingers in front of the patient.)
   3. Now do the same thing with the other hand (without holding the 2 fingers in front of the patient).
   (If the patient is already extubated from the ventilator, determine whether the patient's thinking is disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject.)		

IV. Altered level of consciousness		
Is the patient's level of consciousness anything other than alert, such as being vigilant or lethargic or in a stupor, or coma? Alert: spontaneously fully aware of environment and interacts appropriately Vigilant: hyperalert Lethargic: drowsy but easily aroused, unaware of some elements in the environment or not spontaneously interacting with the interviewer; becomes fully aware and appropriately interactive when prodded minimally Stupor: difficult to arouse, unaware of some or all elements in the environment or not spontaneously interacting with the interviewer; becomes incompletely aware when prodded strongly; can be aroused only by vigorous and repeated stimuli and as soon as the stimulus ceases, stuporous subject lapses back into unresponsive state Coma: unarousable, unaware of all elements in the environment with no spontaneous interaction or awareness of the interviewer so that the interview is impossible even with maximal prodding		
Overall CAM-ICU Assessment (Features 1 and 2 and either Feature 3 or 4): Yes____ No____		

*The scores included in the 10-point RASS range from a high of 4 (combative) to a low of −5 (deeply comatose and unresponsive). Under the RASS system, patients who were spontaneously alert, calm, and not agitated were scored at 0 (neutral zone). Anxious or agitated patients received a range of scores depending on their level of anxiety: 1 for anxious, 2 for agitated (fighting ventilator), 3 for very agitated (pulling on or removing catheters), or 4 for combative (violent and a danger to staff). The scores −1 to −5 were assigned for patients with varying degrees of sedation based on their ability to maintain eye contact: −1 for more than 10 seconds, −2 for less than 10 seconds, and −3 for eye opening but no eye contact. If physical stimulation was required, then the patients were scored as either −4 for eye opening or movement with physical or painful stimulation or −5 for no response to physical or painful stimulation. The RASS has excellent interrater reliability and intraclass correlation coefficients of 0.95 and 0.97, respectively, and has been validated against visual analog scale and geropsychiatric diagnoses in 2 ICU studies.[37,38]

†In completing the visual ASE, the patients were shown 5 simple pictures (previously published[34]) at 3-second intervals and asked to remember them. They were then immediately shown 10 subsequent pictures and asked to nod "yes" or "no" to indicate whether they had or had not just seen each of the pictures. Since 5 pictures had been shown to them already, for which the correct response was to nod "yes," and 5 others were new, for which the correct response was to shake their heads "no," patients scored perfectly if they achieved 10 correct responses. Scoring accounted for either errors of omission (indicating "no" for a previously shown picture) or for errors of commission (indicating "yes" for a picture not previously shown). In completing the auditory ASE, patients were asked to squeeze the rater's hand whenever they heard the letter A during the recitation of a series of 10 letters. The rater then read 10 letters from the following list in a normal tone at a rate of 1 letter per second: S, A, H, E, V, A, A, R, A, T. A scoring method similar to that of the visual ASE was used for the auditory ASE testing.

This table may be reproduced without permission for clinical use only (Ely EW et al. *JAMA.* 2001;286:2707-2710).

Figure 4. CAM-ICU Assessment Methods   (Ely et al., 2001).

Score	Term	Description
+4	Combative	Overtly combative or violent; immediate danger to staff
+3	Very agitation	Pulls on or removes tube(s) or catheter(s) or has aggressive behavior toward staff
+2	Agitated	Frequent nonpurposeful movement or patient–ventilator dyssynchrony
+1	Restless	Anxious or apprehensive but movements not aggressive or vigorous
0	Alert and calm	
–1	Drowsy	Not fully alert, but has sustained (more than 10 seconds) awakening, with eye contact, to voice
–2	Light sedation	Briefly (less than 10 seconds) awakens with eye contact to voice
–3	Moderate sedation	Any movement (but no eye contact) to voice
–4	Deep sedation	No response to voice, but any movement to physical stimulation
–5	Unarousable	No response to voice or physical stimulation

Procedure

1. Observe patient. Is patient alert and calm (score 0)?

Does patient have behavior that is consistent with restlessness or agitation (score +1 to +4 using the criteria listed above, under DESCRIPTION)?

2. If patient is not alert, in a loud speaking voice state patient's name and direct patient to open eyes and look at speaker. Repeat once if necessary. Can prompt patient to continue looking at speaker.

Patient has eye opening and eye contact, which is sustained for more than 10 seconds (score –1).

Patient has eye opening and eye contact, but this is not sustained for 10 seconds (score –2).

Patient has any movement in response to voice, excluding eye contact (score –3).

3. If patient does not respond to voice, physically stimulate patient by shaking shoulder and then rubbing sternum if there is no response to shaking shoulder.

Patient has any movement to physical stimulation (score –4).

Patient has no response to voice or physical stimulation (score –5).

Figure 5. RASS Assessment   (Sessler et al., 2002).

Appendix A: IRB Approval Letter

U.K.
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Initial Review

Approval Ends
June 13, 2017

IRB Number
16-0295-P1G

TO: Catharine Morgan, RN, DNP
UK College of Nursing Academic Operations Office
c/o Tricia MacCallum
202 CON Bldg., 0232
PI phone #: (502)548-4172

FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)

SUBJECT: Approval of Protocol Number 16-0295-P1G

DATE: June 15, 2016

On June 14, 2016, the Medical Institutional Review Board approved your protocol entitled:

Needs Assessment of a Mobility Protocol in Non-Surgical Ventiliated Patients in the Intensive Care Unit

Approval is effective from June 14, 2016 until June 13, 2017 and extends to any consent/assent form,
cover letter, and/or phone script. If applicable, attached is the IRB approved consent/assent document(s) to be used when enrolling
subjects. **[Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless
special waiver has been obtained from the IRB.]** Prior to the end of this period, you will be sent a Continuation Review Report
Form which must be completed and returned to the Office of Research Integrity so that the protocol can be reviewed and approved for
the next period.

**Our records indicate that Steven Peterson, listed on the research protocol as study personnel, has not completed initial human
subjects' protection (HSP) training. The University of Kentucky (UK) Institutional Review Board does not mandate the type of
HSP training for individuals who are NOT UK employees or students, therefore there are several options to meet the training
mandate. These option were provided to Dr. Peterson on April 7, 2016 via email from the Office of Research Integrity.**

**At this time, Dr. Peterson has not been added to the protocol. Should Dr. Peterson complete initial human subjects protection
training, a Modification Request must be submitted to the IRB, and approval issued before he can begin conducting research
activities.**

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The
research procedures should be implemented as approved in the IRB protocol. It is the principal investigators responsibility to ensure
any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes
made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB.
Furthermore, discontinuing a study or completion of a study is considered a change in the protocol's status and therefore the IRB
should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "PI Guidance
to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" from the Office of Research Integrity's
IRB Survival Handbook web page [http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#PIresponsibilities]. Additional
information regarding IRB review, federal regulations, and institutional policies may be found through ORI's web site
[http://www.research.uky.edu/ori]. If you have questions, need additional information, or would like a paper copy of the above
mentioned document, contact the Office of Research Integrity at (859) 257-9428.

Carol R. White/gc
Chairperson/Vice Chairperson

An Equal Opportunity University

Appendix B: NHORA Approval Letter

NORTON HEALTHCARE
Office of Research Administration (NHORA)

224 E. Broadway
Louisville, KY 40202
(502) 629-3501 Phone
(502) 629-3480 Fax
nhora@nortonhealthcare.org
www.nortonhealthcare.org

March 21, 2016

Catharine Morgan, RN
1 Audubon Plaza
Louisville, KY 40217

RE: NHORA # 16-N0081

Study Title: Needs Assessment of a Mobility Protocol in Non-Surgical Ventilated Patients in the Intensive Care Unit

Dear Ms. Morgan:

The Norton Healthcare Office of Research Administration (NHORA) has reviewed the submitted documents for the above study. Institutional approval has been <u>conditionally</u> issued for the above study at this time so that IRB review may be initiated.

Conditional Institutional approval indicates that some documents or issues <u>need to be resolved</u> <u>prior to the initiation</u> of the study at Norton Healthcare. **Final NHORA sign off must be completed before full institutional approval will be issued.**

IRB approval is also required before enrollment of subjects may begin.

If the study will include the use of sponsor provided and/or personal equipment of any type (for example: tablets, ECG machines, ePROs, personal laptops etc.), that equipment must be checked, tracked and/or inspected by Norton Healthcare's Clinical Engineering department prior to its use or placement in a patient care setting. Request an initial incoming inspection of the equipment as follows:

- Norton employed researchers – contact Clinical Engineering on NSITE at
  http://nsite/departments/clinicalengineering/SitePages/Home.aspx
- Non-Norton employed researchers – contact Clinical Engineering by calling 502-629-3590

In the event your study will utilize personal and/or sponsor provided equipment, please ensure that you comply with the procedure outlined above.

Institutional approval must be maintained throughout the life of the study. Human Subjects Protection Training and Conflict of Interest Declaration for all research personnel listed on this study must be updated and provided to the Norton Healthcare Office of Research Administration annually to maintain Institutional approval.

Please contact our office at 502-629-3501 if you have any questions.

Sincerely,

Rhonda Hoffman
System Director Research

Norton Hospital • Kosair Children's Hospital • Norton Audubon Hospital
Norton Suburban Hospital • Norton Immediate Care Centers • Norton Brownsboro Hospital

Appendix C: Data Collection Form

Data Collection Form

Patient Identification Code		Numeric
Gender		Male- 0, Female- 1
Age		Numeric
Ethnicity		See Key
Admission Diagnosis*		
Comorbidities (number)		Numeric
Type of Comorbidity*		
Ventilator days		Numeric
Invasive Catheters (number)		Numeric
Type of Invasive Catheters*		
Vasopressor (number)		Numeric
Type of Vasopressor*		
Inotrope (number)		Numeric
Type of Inotrope*		
Vasodilator (number)		Numeric
Type of Vasodilator*		
PT order		Yes-0, No-1
OT order		Yes-0, No-1
Active ROM		Yes-0, No-1
Passive ROM		Yes-0, No-1
Sat on side of bed		Yes-0, No-1

Stood on side of bed		Yes-0, No-1
Ambulate		Yes-0, No-1
RASS		Numeric
CAM-ICU		Negative- 0, Positive- 1
ICU LOS		Numeric
Hospital LOS		Numeric
Discharge Disposition		

Key:

Ethnicity

     White/Caucasian: 0
     African American/Black: 1
     Hispanic: 2
     Asian American: 3
     Native Hawaiian/Pacific Islander: 4
     Native American: 5
     Other: 6

Discharge Disposition

     Home/ Self Care: 0
     Expired: 1
     Home Health: 2
     Skilled Nursing Facility: 3
     Transferred to another facility: 4
     Short Term Hospital: 5
     Against Medical Advice: 6
     Hospice: 7

Admission Diagnosis

     Overdose/Other: 0
     Cardiac Arrest: 1
     Acute Respiratory Failure:2
     Shortness of Air: 3
     Pneumonia: 4

Altered Mental Status/Seizures: 5
Sepsis: 6
Chest Pain/Cardiac Arrhythmia/Congestive Heart Failure: 7
Chronic Obstructive Pulmonary Disease: 8
Abdominal Pain: 9

Will assign numeric code for SPSPP based on population data

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