81st Medical Group
Keesler AFB, Mississippi

Exempt (Human) Research Protocol

This is a Progress Report ____ / Final Report ___XX___

1. Protocol Number: FKE20090021E

2. Title: “Using Human Patient Simulation to Improve Emergency Airway Management Safety in Post Anesthesia Nursing: A Pilot Project”

3. Principal Investigator (PI): Juanita Mullins, NSPS Civilian YH-02, Clinical Nurse, 81st MSGS/SGCQJ, Phone 228-376-6007 (Add your rank and full name, squadron/office symbol, telephone number, beeper number)

4. Purpose: Novice nurses who lack knowledge and experience in emergency airway management, a PACU core competency, are being assigned to the PACU. Human patient simulation will be used to improve and validate PACU staff competency in emergency airway management using scripted training scenarios. Training will be accomplished within a “culture of safety” as described by the Institute of Medicine as “lacking blaming and shaming” (IOM).

5. Status of the Study. Mark the status of the study (a-e).
   a. _____ Active with ongoing data collection. Request approval to remain open.
   b. _____ Active with data collection complete. Request approval to remain open.
   c. _____ Study was never initiated and request termination of the study.
   d. ___X__ Completed, research implemented and results available. Request approval to close.
   e. _____ Inactive, protocol never initiated, but want to keep in open. Request approval to remain open.

6. Summary of Progress: This report covers the following period of time: 10 August 2009 – 1 June 2010
   a. Since last progress report or initiation of study:

   All data has been collected and analyzed. Results of the NLN Simulation Design Scale surveys showed seven of eight nurses in the study responded Agree or Strongly Agree to all items of the Design Elements. The other respondent provided a positive comment, Agree or Strongly Agree with all items of the METI instrument, but marked all items on the NLN Instrument as Disagree. This respondent failed to complete the IMPORTANCE portion of the NLN instrument so will be excluded from the NLN analysis. Correlation analyses of the level of agreement with the objective statements and the respondents’ perceived importance of the objective were planned but were not possible because of the lack of variation in the objective responses.
### Abstract

Novice nurses who lack knowledge and experience in emergency airway management, a PACU core competency, are being assigned to the PACU. Human patient simulation was used to improve and validate PACU staff competency in emergency airway management using scripted training scenarios. The scripted training scenarios were conducted in the Sim Lab using a Medical Education Technologies, Inc. (METI) mannequin that responds physiologically to oxygen (or the lack thereof) and in the PACU using a portable, computer-programmed/reactive mannequin. Two qualitative research design instruments were used to investigate the perceived effectiveness. Eight nurses completed the training and returned the instruments. The pilot study to implement and evaluate an intervention to improve emergency airway management practices in the PACU has been deemed successful by KMC anesthesia management.
Results of the METI Center Mentor Evaluation and Post-Simulation (Patient Simulator Experience Student Evaluation): all nurses Strongly Agree with items 1-4, and 6. Seven of eight nurses Strongly Agree with item 5, “I was challenged in my thinking and decision-making skills by the patient simulator experience”. The eighth nurse Agreed with that statement, thus the median response is still Strongly Agree.

A Pearson Correlation Statistical Analysis cannot be computed because at least one of the variables is constant. The respondents agreed in importance of design elements. A Spearman non-parametric correlational regression analysis has a value of 1: agreement and importance are equal.

Anecdotal written comments included desire for more learning opportunities similar in design and presentation. Informal comments from participants to the DNP project leader included requests for additional training for other-than-airway emergency scenarios.

b. For the entire study: I have completed 100% of the study and request closure at this time.

c. If this is a FINAL REPORT:

1. Were the protocol objectives met and how will the outcome benefit the DoD/USAF?

Protocol objectives were met. PACU nurses are now providing care for intubated patients. Improvement in emergency airway management and nursing competency of PACU staff has been achieved. Outcome benefits to DOD/AF include greater nursing knowledge, safer patient care, and decreased turnover time to the next surgical case.

2. Protocol Outcomes Summary:

Protocol Objectives:

Primary Objective: Improvement in emergency airway management competency of PACU Staff
Secondary Objective: Foster a “Culture of Safety” within the PACU

Design

The Iowa Model of Evidence-Based Practice to Promote Quality Care serves as a foundation for the project/study design (Titler et al., 2001). The Essentials of Doctoral Education for Advance Nursing Practice (2006) helped determine project criteria and design (American Association of Colleges of Nursing, 2006).

The project design incorporated current evidence-based research and expert, practical knowledge of the subjects at hand to create realistic training scenarios. Project/Study site was KMC’s PACU and HPS Laboratory (Sim Lab). Scripted training scenarios were conducted in the Sim Lab using a Medical Education Technologies, Inc. (METI)
mannequin that responds physiologically to oxygen (or the lack thereof) and in the PACU using a portable, computer-programmed/reactive mannequin.

**Method**

Two qualitative research design instruments were chosen to investigate the perceived effectiveness of using HPS to learn and improve emergency airway management skills, as scored by participating PACU nurses. Evaluations will be used to adapt, revise, and improve future scenario development. The survey designs were chosen for ease of use, lack of expense, and simplicity of time required to complete the surveys.

**Sample**

The target population encompassed all PACU nursing staff members (N-11). Due deployment of one nurse to the Global War on Terrorism and the absence of another nurse to post-partum leave, the actual sample was (N=9). Of the nine, eight nurses completed and returned both surveys.

**Instruments**

Permission was granted by the National League for Nursing (NLN, 2005) to use the *Simulation Design Scale (SDS)*. The SDS is a 20-item instrument using a five-point scale to evaluate five features of instructor-developed simulation. The five design features included in the survey are objectives/information, support, problem-solving, feedback, and fidelity. The SDS has two parts: one part asks whether certain features are present in the simulation, and the other part asks how important those features are to the learner. Content validity was established by ten experts in simulation design and testing. Reliability testing using Cronbach’s alpha found 0.92 for presence of features, and 0.96 for importance of features. The instrument will help determine if the design of the simulations was considered beneficial to the participants.

The second instrument, *METI Sim Center Mentor Evaluation and Post-Simulation*, is from the METI forum of simulation instructors (METI, 2009). Participants are asked six questions on a five-point scale to rate the simulation from the learners’ perspectives to help determine student satisfaction with learning during the scripted simulations. No data is available as to validity and reliability. Permission has been granted to use the survey.

**Procedure**

Nurses trained in groups of two to four participants. The training scenarios began once IRB approvals from both the University of South Alabama and KMC Clinical Research Laboratory (CRL) were received. The training sessions were planned for two 4-hour sessions in the HPS laboratory, and two 4-hour sessions in the PACU.
training scenarios included: Recognition of airway compromise, Receiving an intubated patient, Assisting with extubation, Assisting with re-intubation, Inserting an oropharyngeal airway, Inserting a nasopharyngeal airway, and Bag-valve-mask ventilation.

The actual training session timelines were adapted based on learner/group needs. Some groups met objectives sooner than others and all groups met objectives sooner than the scheduled training times. Surveys related to simulation design and student satisfaction with learning were conducted immediately after the training sessions. Consent was not required for completing the anonymous surveys. Data was analyzed with assistance of the KMC CRL research statistician.

Findings

Results of the NLN Simulation Design Scale surveys showed seven of eight nurses in the study responded Agree or Strongly Agree to all items of the Design Elements. The other respondent provided a positive comment, Agree or Strongly Agree with all items of the METI instrument, but marked all items on the NLN Instrument as Disagree. This respondent failed to complete the IMPORTANCE portion of the NLN instrument so will be excluded from the NLN analysis. Correlation analyses of the level of agreement with the objective statements and the respondents' perceived importance of the objective were planned but were not possible because of the lack of variation in the objective responses.

Results of the METI Center Mentor Evaluation and Post-Simulation (Patient Simulator Experience Student Evaluation): all nurses Strongly Agree with items 1-4, and 6. Seven of eight nurses Strongly Agree with item 5, “I was challenged in my thinking and decision-making skills by the patient simulator experience”. The eighth nurse Agreed with that statement, thus the median response is still Strongly Agree.

A Pearson Correlation Statistical Analysis cannot be computed because at least one of the variables is constant. The respondents agreed in importance of design elements. A Spearman non-parametric correlational regression analysis has a value of 1: agreement and importance are equal.

Anecdotal written comments included desire for more learning opportunities similar in design and presentation. Informal comments from participants to the DNP project leader included requests for additional training for other-than-airway emergency.
Conclusions

Proficiency in emergency airway management is a core skill competency required by nurses in a PACU. PACU nurses must be able to care for an intubated patient, assist with extubation, assist with re-intubation, determine size needed for oral and nasal artificial airways, provide effective ventilation via bag-valve-mask, and recognize airway compromise. Although airway emergencies rarely occur, the PACU nurse must possess the knowledge and skills needed if, or when, such an emergency occurs. Like firefighters, PACU nurses may never face the situations for which they are trained, but they must be ready at all times for emergency situations. During this pilot project, PACU nurses used HPS technology to learn managing patient care in high-risk, but low-frequency emergency airway management situations using scripted scenarios.

The pilot study to implement and evaluate an intervention to improve emergency airway management practices in the PACU has been deemed successful by KMC anesthesia management. Anesthesia providers, anesthesiologists and CRNAs, became enthusiastic about professional growth and development exhibited by PACU nursing staff, and now invite PACU nurses to observe and assist with intubations and extubations in the Operating Rooms. One nurse was able to both intubate and extubate a patient under direct provider supervision in the OR.

Anesthesia providers have exhibited and expressed new confidence in the PACU nurses. In the last month, three intubated patients have been admitted to the PACU and care managed appropriately by the PACU nurses. The self-confidence exhibited and expressed by PACU nurses has been much better than anticipated prior to initiation of the project. Development of a culture of safety has created a positive learning environment lacking blame and shame. Eager acceptance by PACU staff of new and highly technical training scenarios has been rewarding to the project leader and PACU management. PACU nurses are clamoring for additional scenarios on other high-risk, low-volume emergencies such as hypovolemic shock, malignant hyperthermia, and hypotensive/hypertensive crises. Sustainability of the project goals and outcomes is indicated by addition of the evidence-based competency checklist to the annual competency validation platform.

IF THIS IS A FINAL REPORT PROCEED TO # 9

7. Protocol Changes:
   a. No changes are anticipated and the project will continue as previously approved by the IRB.
   b. Changes are anticipated as described below:
   c. When do you anticipate PCSing or separating?
8. Protocol Personnel Changes:

Has there been any Principal or Associate Investigator (PI/Al) changes since approval of protocol or the last continuation review? _Yes _X____ No. If yes, complete the following sections (Additions/Deletions). For PI/Al changes, indicate whether or not the IRB approved this change.

a. Additions: (Include Name, Protocol function - PI/Al IRB approval - Yes/No)
b. Deletions: (Include Name, Protocol function - PI/Al. Effective date of deletion)

9. Status of Approved Funding: No funding from the Surgeon General Office (SGO) was requested.


11. Certification of Principal Investigator

My signature certifies that the above titled research has been conducted in full compliance with the HHS/FDA Regulations and IRB requirements/policies governing human subject research. I understand that a Progress Report is required in order to maintain continuation approval and any changes in the study/methodology must be approved by the IRB prior to implementation. If the study has never been initiated and I am requesting termination (Item 5.c. above), my signature certifies this request. If the study is completed (Items 5.d. & 6.c. above) and I am requesting closure, my signature certifies that the information provided on this form represents an accurate final report.

Juanita S. Mullins
Signature of Principal Investigator

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4 Aug 2010
Date