

ALEX ORTEGA, MD
ICCR PGY2 ROTATION
5/10/2010

IRB PROTOCOL – Comparison of Critical Care Nursing versus Standard Nursing in Medical Intermediate Care Units

STUDY PURPOSE AND RATIONALE-

Current clinical practice at CUMC employs the use of a four bed medical intermediate care unit (“Step Down Unit” or “SDU”) to provide closer patient monitoring for unstable patients either after leaving one of the two medical ICUs or when a patient becomes unstable in the emergency department or on the inpatient medical floors. Patients admitted to the SDU are triaged to that unit by a PGY3 medical resident (“ICU triage” or “med consult”) who also serves as the admitting triage physician for the two medical ICUs. The CUMC Medical SDU is currently staffed by a rotating schedule of ward RNs who when covering an SDU shift are responsible for the care of up to four patients in step down. The current pool of step down registered nurses has no additional training in critical care medicine.

This study would create a second four person medical step down unit at CUMC that would be identical to the current step down unit in terms of patient pool, triaging physician and available resources with the only difference being that it would be staffed full time with a rotating pool of critical care nurses from the medical intensive care units (MICUs). Both step down units would be open simultaneously on two different medical nursing stations with admission to either unit determined solely by bed availability and need for a higher level of care than a regular floor bed as determined by the triaging ICU consult resident. A review of Pubmed reveals that the comparison of critical care nursing to standard nursing for patients outside of an ICU has never been studied before. Our prediction is that given the additional training and experience possessed by ICU nurses, the use of a critical care trained nursing staff in our Medical SDUs would likely decrease length of overall hospital stay by at least two days as well as also decrease the composite rate of in hospital mortality and need to transfer patients from the Step Down Unit to a MICU by at least 10%. Not only will a critical care trained RN be more likely to identify a patient who is starting to decompensate but in the event a patient rapidly decompensates in step down, the critical care trained RN will likely be more comfortable in dealing with the situation and using medications such as pressors for example given their daily use of vasopressors in the MICU versus a standard trained RN who may not work with pressors for months at a time.

STUDY DESIGN AND STATISTICAL PROCEDURES-

Randomized prospective interventional non-blinded study planned for one year. By creating a second medical intermediate care unit at CUMC we will have a parallel arm to

compare to our current SDU which will serve as the control. Once a patient has been triaged to need a medical intermediate care unit by the ICU triage physician, patients will be admitted to either the critical care RN SDU or standard SDU based on bed availability. Effectively, the patient will go to the first SDU which has an open bed. In the event both units have open beds, the ICU triage physician will simply sequentially alternate admissions between the SDUs.

With regards to length of stay, we estimate that patients admitted to step down usually have a step down stay lasting on average from one to seven days (standard deviation of 3 days) depending on reason for SDU admission. We predict that having a critical care RN in step down may cut that time down by up to two days which will likely shorten overall length of hospital stay as well. Using an unpaired t-test we estimate we would be able to show this effect with approximately 40 patients.

Power analysis was used by Chi Square testing to determine we would need approximately 320 participants to show a 10% decrease in composite in hospital mortality and admission rate to ICU. Current estimate being a 30% composite ICU admission and mortality rate for patients in step down.

STUDY PROCEDURES-

Patients enrolled in the study will not be subjected to any additional testing or procedures in the critical care RN run SDU than they would have if admitted to the standard RN SDU. MD teams taking care of patients in either unit will have full access to hospital resources currently employed in the SDU regardless of which SDU their patients are triaged to. Our idea being that rather than a new invasive intervention or new medication, simply having an experienced ICU nurse monitor patients in the SDU will improve outcomes based on a higher level of training and ICU experience which will allow them to more easily and quickly identify patients who may be decompensating and require escalation to ICU admission.

STUDY DRUGS OR DEVICES-

Standard therapies employed in the medical intermediate medical care units will be used in the study, ie the same types of monitors and IV pumps, drug formulary and other devices. There will be no change to any of the standard drugs or devices employed for patient care during the study with both the critical care RN and traditionally trained RN having access to all the same devices and monitors.

STUDY QUESTIONNAIRES-

Questionnaires will not be employed in this study design.

STUDY SUBJECTS-

The only inclusion criteria will be admission to one of the medical intermediate care units based on the assessment of the ICU triage resident. No one admitted to an SDU will be excluded based on age, comorbidities or reason for SDU admission.

RECRUITMENT-

Patient's enrolled in the study would be those triaged for admission to either of the two medical intermediate care units by the ICU triage resident. This will include unstable patients in the emergency department, inpatient floors and ICUs who need an intermediate care bed.

CONFIDENTIALITY OF STUDY DATA-

Participants will be assigned identification numbers and all medical records and data obtained will be linked to this number with all personal identifiers besides age and sex removed. All data will be stored in a secure electronic database.

POTENTIAL RISKS-

Given that the current standard of nursing care and supervision will continue to be provided in the standard RN run intermediate care unit and that all patients in the critical care RN run unit will have the same MD teams managing their condition with access to all the same therapies and monitoring currently available, we do not foresee any potential risk to patients in either step down unit. At a minimum, the critical care RN will be able to provide at least the same level of care as the noncritical care trained RN in the other step down unit.

POTENTIAL BENEFITS-

Patients triaged to open beds in the critical care RN run unit may benefit from the additional critical care training and experience possessed by an ICU RN.

ALTERNATIVES-

No alternative therapies apply.