

## **Ricky Regalbuto – Medical ICU Outcomes by Calendar Month**

### **A. Study Purpose and Rationale**

In teaching hospitals, there is large turnover of staff at the end of June when a cohort of residents and fellows graduates and a new class arrives to start working. This transition is a period of great change, and can pose risks as the new physicians have less experience. There has been concern that as a result of inexperienced physicians, patients admitted to the hospital in July, at the start of the academic calendar, will have worse outcomes than those pts admitted later in the year (1). A recent meta-analysis (1) of 39 different studies that have looked at this issue found a wide variation in the quality of the studies, but a trend toward higher mortality in July in higher quality studies. However, only 3 of the 39 studies looked specifically at the ICU, and none of the 3 found a difference in outcomes based on the month of the year. The first was a 2003 study (2) looking at a variety of ICUs in the Cleveland metro area, and it found no difference in mortality when comparing July-September to the other 3 quartiles of the year in major teaching, minor teaching, and non-teaching hospitals. There was a very small (0.8%) decrease in adjusted length of stay in non-teaching hospitals in July-Sept as compared to major teaching hospitals (2). A 2004 study (3) performed in Rochester, Minnesota also did not find a difference in mortality in teaching hospitals ICUs when comparing July to the rest of the year. This study also did not find any differences in length of stay. Both of these studies attempted to adjust for differences in patient acuity by using APACHE III scores, a prognostic score used in the ICU. The third study (4) included in the meta-analysis that was specific to the ICU was a look at the rates of complications during central line placement in two teaching hospitals in Vancouver for various times of the year. This study found no differences in the rates of pneumothorax after central line placement depending on the month of the year.

All three of these studies were performed in only one region, and their findings may not be generalizable to other populations, such as the urban, Hispanic population at CUMC. Furthermore, new work hour regulations went into effect in 2011, limiting interns to 16 hour shifts. These new regulations have been controversial, with some residency program directors concerned that they may pose a potential detriment to resident education (5). Given these new regulations, interns at the start of the academic year may develop their clinical skills slower than previous residents, and second year residents may not be as experienced as residents in earlier classes. This inexperience would be especially apparent at the start of the academic year, and may lead to worse outcomes. This effect may be magnified in the ICU, where patients are more ill and can decompensate quickly. Alternately, supervising physicians and nursing staff may be more aware that there are new residents on duty at the start of the academic year and increase their vigilance and supervision. Given the new duty hour regulations, and the fact that the population at CUMC is different from those studied previously, it would be beneficial to again assess the effect of month of training on ICU mortality and length of stay. NYP-CUMC also provides a unique opportunity for a control population, as MICU-A is staffed by residents, and MICU-B is staffed by physician assistants and nurse practitioners, who would not be expected to show seasonal variation in outcomes.

### **B. Study Design and Statistical Analysis**

This study is a retrospective cohort study. The cohort would be all admissions to MICU-A and MICU-B at NYP-CUMC from June 2008 to present day. There are ~600 admissions per year to each of the MICU units. We would need ~3600 patients to detect a 3.5% difference in mortality from the first half of the year to the second by Chi-Square test, so going back to 2008 will give enough data. We would need ~500 subjects to detect a 0.5 day difference in length of stay (LOS) by the t-test, assuming a SD of 2 in LOS, and again, going back to 2008 will give enough data. Given that half of the sample

will be from before the changes in work hour regulations and half will be from after, given the number of patients in the MICU-A we will be able to detect a 5% difference in mortality from prior to June 2011 to after June 2011.

**C. Study Procedure.**

The study will consist of chart review of all patients admitted to MICU-A and MICU-B. Deidentified data is collected for each of the MICUs for monthly morbidity and mortality conference. This data set contains all the admissions, along with APACHE II scores, and clinical outcomes. This data set will be adapted for use in this study. Outcomes will be tracked by month, then regression analysis will be used to see if there are any significant differences in mortality or length of stay depending on the month, after adjusting by APACHE II score. Other potential confounds, such as age, functional status and if a patient is an outside hospital transfer, will also be collected. Data from MICU-A will then be compared to MICU-B to see if any of the monthly variations can be attributed to the effect of having residents staff the ICU.

**D. Study Drugs**

N/A

**E. Medical Device**

N/A

**F. Study Questionnaires**

N/A

**G. Study Subjects**

All patients admitted to MICU-A or MICU-B from June 2008 to the present day will be eligible to participate. Patients will only be excluded if they undergo extracorporeal membrane oxygenation, a specific type of advanced therapy that is only performed in MICU-B.

**H. Recruitment of Subjects**

This will be a retrospective review of deidentified data. No patient recruitment will take place.

**I. Confidentiality of Study Data**

All data will be deidentified and stored on secure computers and locked file cabinets. All database files will be password protected.

**J. Potential Conflict of Interest**

N/A

**K. Location of the Study**

Chart Review of MICU-A and MICU-B at NYP-CUMC

**L. Potential Risks**

Loss of data resulting in breach of confidentiality. As described above, we will take measures to minimize the risk of data losses.

**M. Potential Benefits**

Individual subjects will not derive a benefit from this study, but future work that develops as a result may benefit other patients.

**N. Alternative Therapies**

N/A

**O. Compensation to Subjects**

No compensation will be provided

**P. Costs to Subjects**

N/A

**Q. Minors as Research Subjects**

N/A

**R. Radiation or Radioactive Substances**

N/A

**References**

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2) Barry WA, Rosenthal GE. Is there a July phenomenon? The effect of July admission on intensive care mortality and length of stay in teaching hospitals. *J Gen Intern Med*. 2003;18:639-45.

3) Finkielman JD, Morales J, Peters SG, Keegan MT, Ensminger SA, Lymp JF, et al. Mortality rate and length of stay of patients admitted to the intensive care unit in July. *Crit Care Med*. 2004;32:1161-5.

4) Ayas NT, Norena M, Wong H, Chittock D, Dodek PM. Pneumothorax after insertion of central venous catheters in the intensive care unit: association with month of year and week of month. *Qual Saf Health Care*. 2007;16:252-5.

5) Drolet BC, Khokhar MT, Fischer SA. The 2011 duty-hour requirements--a survey of residency program directors. *N Engl J Med*. 2013; 368: 694-697.