IRB protocol
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Increased number of health care providers required by the new duty hours policy and continuity of care: did you check the aPTT?

A. Study purpose and Rationale

ACGME duty hour regulations for PGY1 residents have been implemented on July 2011 with the major change being the reduction of consecutive allowed work hours from 30 to 16 hours for long calls days. What this means practically is that the patient responsibility previously held by a single provider for the 30 hour shift are now 'passed on' to multiple secondary providers or cross covering physicians. These secondary providers assume care responsibility during the longer off time of the primary team. Although it is reasonable to advocate for less consecutive working hours for junior residents, the impact of such implementation on health care and residents' welfare is unknown. The initial goals of these ACGME regulations were the reduction of residents' fatigue, improvement of handover procedures, and the overall prevention of adverse events. Numerous studies have shown that sleep deprivation is associated with reduced clinical performance [1] and medical errors [2] but with the increase in the number of health care providers and shift workers for each given patient, the fragmentation of hospital care may actually increase preventable adverse events as previously reported [3, 4]. Most of handouts errors are 'content omission' in which critical information is not communicated [5]

At CUMC, compared to last year, adherence to the new regulation during inpatient ward rotations has required at least one additional health care provider (the night float intern) to participate in the care of patients each day. To complicate matters, several physician assistants have been utilized to cross-cover up to 40 patients during the evening hours that are then 'signed out' to the on-call intern at 7 PM and then signed out again at 9 PM to the night float intern. Although difficult to quantify, compared to last year there may be up to 160 additional patients that are 'signed out' each day and most of the sign outs done by cross-covering providers rather than the primary team (initial sign outs from each team to PAs for 4 teams each carrying a max of 10 patients, then from the PA to the intern on call then to the night float intern then to the day interns the next morning at completion of the night shift).

It is important to assess the new regulations' effects on patient care, medical errors and length of hospital stay at CUMC and in other medical centers facing similar problems with resident work hours.

One way to approach this issue is to focus on the most common tasks that are signed out between providers during change of shift. As reported in a preliminary survey among interns [6], the most common of these tasks include checking electrolyte abnormalities (particularly potassium), INR and aPTT checks, post-cath femoral site checks, etc. For all of them, the covering physician is required to follow laboratory results or perform a

physical exam and intervene whenever these findings are abnormal. Failure to do so because of insufficient/ imprecise instructions passed on during sign outs can potentially adversely affect patient health, prolong hospitalization and even cause death. It can be hypothesized that sign out inaccuracy increases proportionally with the number of handoffs between healthcare providers.

More specifically, activated partial thromboplastin time (aPTT) is a common laboratory value used to assess blood coagulability [7]. Apart from detecting abnormalities in the blood clotting cascade, it is also used to monitor the treatment effects of heparin, a major anticoagulant used in the treatment of several medical conditions such as deep vein thrombosis or pulmonary embolism, anti-phospholipid syndrome, peri-operative coronary stenting etc. Heparin has a short half-life and is administered as an infusion for full therapeutic anticoagulation and has to be constantly monitored with multiple blood draws, aPTT checks, and multiple dose adjustments according to a well establish protocol [8]. Lack of a timely intervention can result in sub-therapeutic drug levels and increased risk of clotting events or, on the contrary, supra-therapeutic values with increased risk of bleeding. In both circumstances the patient would be at risk for potentially life threatening complications.

In order to investigate the effects of multiple signouts on patient care, we can measure the number of times the aPTT laboratory values remained outside the therapeutic range for 2 consecutive blood draws on the inpatients on Gen Med 1 service during 2011 and compare it to data from 2010. We could then assess the effects of multiple signouts on a quantifiable outcome.

B. Study design and Statistical Analysis

Study design/patients

This would be a retrospective observational study evaluating the patient population admitted to CUMC on inpatient wards during the months of July through October 2010 and requiring anticoagulation with heparin drip and comparing these patients to a similar population admitted between July and October 2011. The same comparison would be carried for the same patient population from November to the next July. This distinction is necessary since changes are already in place to reduce the number of handoffs by shifting PAs working hours from 7AM to 7 PM to 9AM to 9PM. Patients identification can be achieved by reviewing admission dates and diagnoses through the medical records department or the bioinformatics department. Upon identification, each patient's electronic record could be reviewed to search for aPTT value outside the therapeutic range. The electronic record would also allow identification of the number of providers caring for a patient during a particular length of time. Another way to determine the number of providers involved would be to find out how many times the pager was transferred from a provider to the other signaling another transfer of care. Since the process is assisted by a pager operator and recorded electronically, the IT department could be of valuable assistance.

Outcome
The outcome measured would be the percentage of patients on heparin drip that had at any time during the hospitalization first aPTT outside the therapeutic range followed by a consecutive readings that was not corrected over the patients that had correction, i.e. only one value outside the chosen range. Each patient would be counted once. Since heparin has a short half life a timely intervention would likely restore the appropriate desired level of anticoagulation given the task was properly communicated.

Secondary outcomes could be bleeding events or clots but since these events require inappropriate heparin doses for an extended period of time we expect them to be infrequent.

Statistical analysis
Chi-square analysis would be used to compare proportion of patients on heparin with sub or supra-therapeutic aPTT for 2 consecutive readings out of the number of patients that had a first reading off goal that was promptly corrected. This comparison could be done in the patient population in the month July-October of 2010 and 2011 that experienced the highest difference in sign outs and repeated for the month Nov-July.

Power analysis.
Heparin drip is widely used for several medical conditions requiring anticoagulation. These include and they are not limited to ACS, A Fib, PE , DVT, valvular disease. It is reasonable to assume that about 10% of patients on inpatient services would be on Heparin drip during some part of their hospitalization. Considering that CUMC has an average of 101,966 annual admissions over several specialties [9] a rough estimate is about 1000 admission per month on the medicine services and about 100 patients per month on heparin.
It is impossible to know prior to this study how many patients on heparin would have aPTT values out of the therapeutic range but it is a frequent finding particularly early in treatment. Roughly, 2/3 of the patients on heparin drip may expect to have one aPTT value of target that is expected to be corrected promptly upon intervention. It is possible for this study to be underpowered and in this case the analysis could be combined for the entire year 2010 and 2011 and possibly involve other medical centers that had to face similar challenges with the new ACGME regulations.
For the months July-October we will assume that 95% of the patients on heparin with a first off goal aPTT became therapeutic in the consecutive reading in the year 2010 and that this would drop to 85% in the year 2011. According to this estimate we would need a total of 162 patients with a first off target aPTT in 2010 and the same number in 2011 to be able to detect a difference. As mentioned above we expect 100 patients per month on heparin therefore about 400 patients in the time interval considered and about 300 with one off target aPTT value. In the second time considered (Nov through July) since the number of handouts is decreasing we predict a reduction from 95% to 90% for the same outcome. For 80% power and P=0.05 we would require 482 patients per group. Again, we expect about 800 patients on heparin, of which a high percentage (about 550) will have one non-therapeutic aPTT.

C. Study procedure

N/A

D. Study Drugs

N/A

E. Medical Device

N/A

F. Study Questionnaires

N/A

G. Study Subjects

N/A

H. Recruitment of Subjects

N/A

I. Confidentiality of Study Data

N/A

J. Potential Conflict of interest

N/A

K. Location of the Study

N/A

L. Potential risks

N/A

M. Potential Benefits

N/A

N. Alternative therapies

N/A

O. Compensation to subjects

N/A

P. Cost to subjects

N/A

Q. Minors as research subjects

N/A

R. Radiation or radioactive substances

N/A

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