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IRB protocol
Decreasing inappropriate discharge on stress ulcer prophylaxis

Study purpose: To evaluate if a computerized pop-up will decrease the amount of patients who are started on stress ulcer prophylaxis in the ICU and inappropriately continued on the medication through discharge.

Rationale: Patients are frequently and appropriately started on either a proton pump inhibitor (PPI) or histamine type-2 receptor blocker (H2 blocker) for stress ulcer prophylaxis in the ICU. Unfortunately, upon discharge out of the ICU, they are continued on these medications, which have been shown to have concerning side effects, inappropriately.

Background: Mucosal irritation can start within hours of trauma or severe illness. Major risk factors include intubation (OR 15.6) or coagulopathy (OR 4.3), which are common in ICU. The major concern is clinically significant bleeds at 1.5-8.5% of ICU patients but can occur up to 15% in ICU patients without stress ulcer prophylaxis. Therefore, stress ulcer prophylaxis, as per the American Society of Health-System Pharmacists (ASHP), has been indicated in patients with a significant coagulopathy, mechanical ventilation for > 48 hours, traumatic brain injury, traumatic spinal cord injury, or burn injury. Another indication for stress ulcer prophylaxis is by having two of the following minor causes – sepsis, ICU stay > 1 week, occult GI bleed > 6 days, or high-dose glucocorticoid therapy. In a survey of approximately 300 critical care physicians in 1999, the most common reasons given for starting SUP was severe burns (91%), shock (90%), and sepsis (88%). The most common treatment options include PPI's and H2 blockers.

A study by Zink et al showed 60% of patients started on a PPI on an inpatient general medicine floor lacked an indication and 34% were discharged on the medication. A study by Heidelbaugh and Inadomi in 2006 examined approximately 1800 inpatients admitted to the general floors, of which 22% started on stress ulcer prophylaxis inappropriately with over half of those patients being discharged on this medication. The estimated cost on the inpatient medications alone were over $11,000 over 4 months. Aside from the cost, there are many newly discovered adverse effects of PPI's including increased risk of hospital-acquired Clostridium difficile-associated diarrhea, suspected increased risk of community-acquired pneumonias, increased risk of hip fractures, drug interactions with clopidogrel, and hypomangnesemia to name a few. H2 blockers have been known to cause thrombocytopenia, myelosuppresion, B12 deficiency, CNS symptoms, and many other adverse effects.

Hypothesis: A computerized pop-up will decrease the amount of patients who are started on stress ulcer prophylaxis in the ICU and inappropriately continued on the medication through discharge.

Subjects: The inclusion criteria for this study are patients who are started on stress ulcer prophylaxis in an adult ICU at CUMC who are continued on the medication without an appropriate indication, as per ASHP criteria, until planned transfer to floor. The exclusion criteria are that the stress ulcer prophylaxis is discontinued before transfer out of ICU, the patient was already on the medication at home or before arrival to the ICU, or there is a new indication for the prophylaxis medication (GERD, new ulcer, gastritis, upper GI bleed).

Given the data that 34% of patients seen on the floors in the study by Zink et al are continued inappropriately on PPI's and discharged on the medication, it can be assumed that roughly 40% of ICU patients, who are very likely to have an indication requiring stress ulcer prophylaxis, will be maintained on stress ulcer prophylaxis inappropriately at the time of transfer to the floors. Using a power of 0.8 and type-I error of 0.05, a chi-squared test resulted in 400 patients being needed for each arm of the study. Approximately 50 patients are transferred out of each medical ICU each month, and 6 adult CUMC ICU's will be included in the study. Assuming at least 75% of patients meet an indication to start stress ulcer prophylaxis and 40% of those patients are maintained on it until transfer to the floor, it should take approximately 4 months to complete the recruitment.

Procedure: The last 400 ICU patients at CUMC meeting inclusion/exclusion criteria will have their charts retrospectively reviewed. The intervention will be applied to all ICU's, and the next 400 patients at CUMC meeting the inclusion/exclusion criteria will be prospectively added to the study. The intervention will be a comperized pop-up to the team accepting the patient on the floor. When the patient is transferred from the ICU, all the medications are discontinued and then reordered by the accepting team. The computerized pop-up will appear when the stress ulcer prophylaxis medication is being reordered by the accepting team. It will stop the physician from proceeding until it is acknowledged. It will question whether the PPI or H2 blocker should be continued and list the indications for evidence-based use of the medication. The primary outcome will be discharge from the hospital on the stress ulcer prophylaxis medication without an appropriate indication. The data will be analyzed by using a chi-squared test, since the outcome is dichotomous.

Conflict of Interest: None

Risks/Benefits: There are no risks to patients, and no informed consent will be needed since the entire hospital policy will change and there is no randomization. Potential benefits include decreased risk of PPI and H2 blocker adverse effects as well as decreased risk of decreased polypharmacy, decreased cost, and decreased drug-drug interactions.

Future studies: There are many other studies that can be considered after completion of this trial. A great follow-up trial would be to examine the occurrence of adverse effects experienced by patients who have had their stress ulcer prophylaxis discontinued appropriately or continued inappropriately. Another example is comparing ICU's against each other to evaluate their individual efficacy in discontinuing stress ulcer prophylaxis.

References

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