Anna Krigel, PGY-1
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A Method for Catheter Associated Urinary Tract Infection (CAUTI) Prevention in the Medical Intensive Care Unit

A. Study Purpose and Rationale

Catheter associated urinary tract infections (CAUTI) account for one third of all health care associated infections and cost of about 350 million dollars per year.[1] In 2013, there were 225 CAUTI reported in one of the New York Presbyterian-Columbia University Medical Center medical intensive care units (MICU).[2] With about 700 admissions to the MICU during the year and an average length of stay of about five days, each patient in the MICU had a 6% chance of contracting a CAUTI each day and a 30% chance during the length of an average stay.[3]

CAUTI has been deemed "reasonably preventable" by the Centers for Medicare and Medicaid Services (CMS).[4] Prolonged catheterization is the primary risk factor for CAUTI. A meta-analysis published in 2010 looked at the effect of urinary catheter reminders and stop orders on the rate of CAUTI and the mean duration of catheterization and found a 52% decrease in CAUTI and 37% decrease in mean duration of catheterization.[5] Physician engagement has been shown to be one of the greatest barriers to implementing CAUTI prevention measures in hospitals.[6]

In the Columbia University Medical Center (CUMC) MICUs (both MICU-A and MICU-B), physicians are required to enter a reason for the urinary catheter when ordering the catheter in the electronic medical record (EMR). However, there is no current daily reminder system in the EMR to let physicians know how long urinary catheters have been in place for each patient.

Although reminder systems have been proven effective in prior studies in preventing CAUTI, most of the studies that have been performed have focused on nursing reminders or nurse-generated reminders to physicians about the dangers of urinary catheters and the length of time the urinary catheter has been in place.[4] A randomized, controlled trial is necessary to evaluate the potential benefits of daily reminders from the EMR directly to medical residents and other medical providers in the CUMC MICUs. We hypothesize that instituting this measure will decrease the rate of CAUTI and the total number of catheter days.

B. Study Design and Statistical Analysis

The study will be a prospective, randomized controlled trial comparing the current standard of care in the CUMC MICU-A and MICU-B versus an EMR reminder system that requires medical residents and/or physician assistants to manually enter the number of catheter days for each patient daily when they write the progress notes for those patients. The study length will be one year.

The study population will consist of all patients over 18 years of age admitted to either MICU-A or MICU-B over the course of the year. Patients will be excluded if they require a chronic indwelling urinary catheter for any reason, such as chronic urinary retention. The first two months of the study will consist of an introductory period. During the first month, patients in

both MICU-A and MICU-B will receive the intervention, with medical staff using the EMR reminder system. During the second month, patients in MICU-A and MICU-B will receive standard of care. At the end of two months, the number of catheter days between the two groups will be compared using a t-test. The introductory part of the study will be powered for an average of four catheter days in each patient in the standard care group and three catheter days in the intervention group with an expected variability (standard deviation) of one. Using a t-test for 80% power and significance at $p<0.05$, the number needed in each group is 17 patients. The introductory part of the study will need a total of 34 patients for randomization, though it will be likely to have more given the number of monthly admissions to both MICUs.

If the introductory portion of the study finds a significant difference in catheter days between the standard of care and the intervention arms, patients will continue to be randomized into the standard of care arm or the intervention arm based on the month in which they are admitted to MICU-A and MICU-B, with the months alternating between intervention and standard of care. As the medicine housestaff rotate through MICU-A in four-week blocks beginning in the month of June, it is possible that housestaff who are further along in the year may act differently than those who are just beginning the year based on experience. To avoid this variation in training based on time of year, the intervention will be implemented every other month with alternating months being standard of care.

At the end of one year, the rates of CAUTI in the two groups will be compared using a chi-square test for 80% power and significance at $p<0.05$. Assuming a rate of CAUTI of 30% over the average five day stay in the MICU for each patient in the standard of care arm and about 1400 patients total (700 patients randomized into each group based on the number of admissions to each MICU per year), the study will be able to detect an effect of 7%, or a 7% decrease in the rate of CAUTI in the intervention group.

An element of crossover between the two arms would be possible if medical residents who participate in the intervention arm speak to their co-residents about the intervention the following month. However, medical staff in the standard of care arms will not see the mandatory pop-up that will require them to manually enter the catheter days, thus they will be far less likely to do so on their own.

C. Study Procedure

The study intervention will be implemented during alternating months in both MICU-A and MICU-B. The patients admitted to the MICUs during non-intervention months will receive standard of care treatment in terms of the current urinary catheter EMR reminders, with medical providers being asked to choose among a menu of reasons for a urinary catheter when it is initially ordered. Throughout the rest of the patient's stay that month, medical providers will not receive EMR reminders on how long the urinary catheter has been in place.

During intervention months, medical providers will receive a pop-up on each patient with a urinary catheter when they go to write the progress note on that patient daily. The pop-up will be linked to the urinary catheter order and will begin to appear on the day after the order is placed. The pop-up will contain the date the catheter was placed, an empty box where medical providers

will enter the number of days the catheter has been in place, and an informational sentence stating, "The daily risk of catheter associated UTI for each patient in the MICU is 6%."

D. Study Drugs

No drugs will be used in this study.

E. Medical Device

No medical devices will be used in this study.

F. Study Questionnaires

No questionnaires will be used in this study.

G. Study Subjects

Study subjects will be all patients over 18 years of age admitted to the Columbia University Medical Center MICU-A and MICU-B over the course of the year of the study. Patients will be excluded if they require a chronic indwelling urinary catheter for any reason, such as chronic urinary retention.

H. Recruitment of Subjects

There will be no recruitment of subjects for this study.

I. Confidentiality of Study Data

All study data will be coded with unique coded number assignment for each patient. The identity and health information of the subjects will be kept confidential. Study data will be stored on password protected and encrypted devices only. Only study investigators will have access to the study data.

J. Potential Conflicts of Interest

There are no anticipated potential conflicts of interest among the study investigators.

K. Location of Study

The study will take place at New York Presbyterian-Columbia University Medical Center in MICU-A and MICU-B.

L. Potential Risks

There are no potential risks to the subjects of this study. The medical providers caring for patients in the intervention arm may experience a minimal delay in workflow with the implemented intervention.

M. Potential Benefits

This study may benefit patients admitted to the medical intensive care units by decreasing the chance of contracting a CAUTI during treatment in these units. Decreasing the number of CAUTI contracted in the MICU has the potential to save the hospital millions of dollars.

N. Alternative Therapies

None

O. Compensation to Subjects

Subjects will not be compensated for participation in this study.

P. Cost to Subjects

Subjects will not incur any additional costs by participating in this study.

Q. Minors as Research Subjects

Not applicable

R. Radiation or Radioactive Substances

None

S. References

1. Saint S, Gaies E, Fowler KE, Harrod M, Krein SL. Introducing a catheter-associated urinary tract infection (CAUTI) prevention guide to patient safety. *Am J Infect Control.* 2014 Feb 24. pii: S0196-6553(13)01494-6.

2. David Chong (personal communication, March 28, 2014)

3. Inter-ICU Committee. ICU Dashboard. Available at: http://teams.nyp.org/sites/Clinical/ICU/CustomPages/ICU-Dashboard.aspx. Accessed on April 7, 2014.

4. Meddings J, Rogers MA, Macy M, Saint S. Systematic review and meta-analysis: reminder systems to reduce catheter-associated urinary tract infections and urinary catheter use in hospitalized patients. *Clinical Infectious Diseases* 2010; 51(5): 550-560.

5. Krein SL, Kowalski CP, Harrod M, Forman J, Saint S. Barriers to Reducing Urinary Catheter Use: A Qualitative Assessment of a Statewide Initiative. *JAMA Intern Med.* 2013;173(10):881-886.

6. Saint S, Greene M, Kowalski CP, Watson SR, Hofer TP, Krein SL. Preventing Catheter-Associated Urinary Tract Infection in the United States: A National Comparative Study. *JAMA Intern Med.* 2013;173(10):874-879.