The Effect of Automated Electronic Reminders for the Withdrawal of Indwelling Urinary Catheters on the Rate of Catheter Associated Urinary Tract Infections

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A. Study Purpose and Rationale

Catheter associated urinary tract infections (CAUTI) are among the most common hospital acquired infections – with up to 15% of cases of hospital acquired bacteremia originating from the urinary tract[1] and are a source of significant morbidity in the acute care setting[2]. As the prevalence of multidrug resistant gram-negative organisms, such as KPC and NDM-1 carrying enterobactericea, rises and hospital acquired urinary tract infections become increasingly difficult to treat the morbidity and mortality associated with these infections may rise even higher. CA-bacteriuira may also provide an important reservoir for these and other hospital acquired multi-drug resistant organisms[3] and multidrug resistant CAUTI has occurred in epidemic form[4]. Catheter associated bacteriuria itself, in the absence of true urinary tract infection, represents a common cause of inappropriate antibiotic use in the acute care setting, with 31% of cases of catheter associated asymptomatic bacteriuiria being treated with antibiotics[5] thus fueling the cycle of the development and spread of multidrug resistant organisms.

CAUTI are also costly, with each episode of catheter associated bacteriuria costing approximately $700 and CAUTI related bacteremia costing at least $2800 as estimated in 2000 (unadjusted for inflation)[6]. As of 2008, the Center for Medicare and Medicaid Services considers CAUTI a "reasonably preventable" complication and hospitals are longer compensated for the extra cost of treating these infections[7].

The duration of catheterization is the most important determinant of the risk of developing a CAUTI[8] and the most important and simplest way of reducing the rate of CAUTI, in addition to avoiding unnecessary urinary catheterization, is minimizing the duration of catheterization[9]. However, urinary indwelling catheters frequently remain in place longer than is medically necessary and continued catheterization is inappropriate in up to one half of catheter-days[10]. Physicians are frequently unaware that their patients have indwelling urinary catheters, and catheters that are "forgotten" are more to be inappropriate[11]. It has been shown that prewritten stop orders placed in a patient's chart decrease the duration of inappropriate catheterization[12]; however, this study was underpowered to detect a difference in the incidence of CAUTI and in the age of electronic medical records, this intervention is outdated. Although numerous strategies have been proposed for the prevention of CAUTI including the development of institutional guidelines outlining appropriate indications for urinary catheters and the requirement that a physician order be in place for all urinary catheters, evidence is lacking for a simple computerized interventions aimed at decreasing the duration of inappropriate catheterization and thus the incidence of CAUTI.

Thus, the goal of this study is to evaluate the efficacy of a simple, low cost, electronic medical record based intervention to reduce the incidence of CAUTI in the acute care setting.

B. Study Design and Statistical Analysis

This study is an unmasked cluster-randomized controlled trial to evaluate the effect of automated reminders for indwelling urinary catheter removal (intervention) as compared with no electronic reminders (control) on the incidence of catheter associated urinary tract infection. All participating medical wards, surgical wards, and intensive care units will be randomly assigned to receive daily reminders for removal of urinary catheters if no longer clinically indicated or to no reminders. Randomization will occur in a 1:1 ratio and will be stratified based on historic incidence of catheter associated urinary tract infections and unit type (medical, surgical and intensive care unit). The study will consist of three periods: baseline, randomization and implementation, and intervention. The baseline period will consist of the twelve months preceding randomization and implementation. Historic data from this period will obtained from the medical records/department of infection control will be used to determine baseline rates of catheter associated urinary tract infections. This will be followed by a two-month period for stratification and randomization. The intervention period will begin when the automated reminder system is activated.

The primary outcome being investigated is the rate of urinary tract infection per urinary catheterization. Urinary tract infection is defined as presence of signs or symptoms compatible with urinary tract infection, which include suprapubic tenderness, costovertebral angle tenderness, dysuria, or otherwise unexplained signs/symptoms of systemic infection (temperature >= 38C, hypotension, altered mental status, SIRS) plus $\geq 10^3$ colony forming units of a single bacterial species from a single catheter urine specimen or in a midstream voided urine specimen in a patient with an indwelling urinary catheter or whose indwelling catheter has been removed within last 48 hours[9]. The secondary outcome will be the mean number of catheter days per episode of indwelling urinary catheterization in the intervention versus the control groups.

A chi-square test will be performed to compare the proportion of patients with indwelling urinary catheters placed who develop urinary tract infections in the intervention versus control groups. A sample size of 6945 patients in each group will be required to reach a power of 80% to detect an effect size of 20% with an $\alpha = 0.05$, assuming a baseline incidence of catheter associated urinary tract infection of 5% per episode of indwelling catheterization. This number was calculated based on an incidence of catheter associated bacteriuiria of approximately 5% per day[13,14,15] with an average duration of catheterization of four days with 25% of those with bacteriuiria developing symptomatic urinary tract infection. Published data on which specifically reported the incidence of catheter associated urinary tract infection was not used in the power calculation as it is typically expressed in urinary tract infections per 1000 catheter rather than the incidence per episode of catheterization, which is the measure being used in this study. A t-test will

be used to compare mean days of urinary catheterization in the mean versus control groups.

C. Study Procedure

The intervention will consist of an automated reminder window reminding clinicians that urinary catheters should be removed as soon as no longer medically necessary, which appears starting on post-catheterization day one, when a clinician accesses the electronic medical record in order to place an order for a catheterized patient. The reminder window will appear only for clinicians who are placing orders for the specific patient. The reminder window will require that the clinician indicate, via a drop-down menu, an established indication for continued urinary catheterization or that the catheter has been removed/is to be taken out the same day. The window will appear as long as an order for a urinary catheter remains active in the system. The window will be able to be bypassed up to two times in order to prevent interference with the placement of emergency orders or requesting input from an inappropriate provider. However, the third time the window appears the clinician will be unable to proceed with placing orders until an option is selected from the drop down menu. The intervention should require less than 30 seconds per catheterized patient daily. Data obtained from the electronic medical records will include: age, gender, length of urinary catheterization, documentation of urinary tract infection during or within 48 hours of indwelling urinary catheterization, and data supporting the diagnosis of urinary tract infection (including temperature, respiratory rate, oxygen saturation, blood pressure, white blood cell count, symptoms of urinary tract infection including altered mental status, and urinary culture results).

Assuming that all eligible units in the NYP system participate in the study (approximately 1280 beds[16]) have an average occupancy of 80% and an average turnover of every 10 days with 15% of patients having indwelling urinary catheters placed, the study period will need to last approximately 30 months.

D. Study Drugs

No drugs will be used as part of this study.

E. Medical Device.

No medical devices will be used as part of this study.

F. Study Questionnaires

No questionnaires will be used as part of this study.

G. Study Subjects

Wards and intensive care units are eligible for inclusion in the study if they are medical or surgical wards with an estimated incidence of greater than 3 catheter associated

urinary tract infections per 1000 urinary catheter days based on historical data. Only wards/units with electronic medical records in use for greater than one year will be eligible for inclusion. Approval by the physician and nurse directors of each ward/unit is required for participation in the study. Only patients with indwelling catheters placed during the current hospitalization will be included in the analysis and patients with indwelling catheters in place for greater than thirty days will be excluded from analysis. Patients with chronic indwelling catheters will therefore be excluded from analysis.

H. Recruitment of Subjects

There will be no active recruitment of individual patients in this study. All patients for whom indwelling urinary catheters are placed during their current hospitalization will be automatically enrolled in the study. A waiver of informed consent is requested as this study presents limited risk to patients and does not require additional procedures or interventions.

I. Confidentiality of Study Data

All patients will be given unique study identification numbers. All data will be de-identified and stored securely in encrypted files on password-protected computers located in locked offices.

J. Potential Conflict of Interest

There are no potential conflicts of interest to disclose.

K. Location of the Study

This study will be conducted in medical and surgical wards and intensive care units of the New York-Presbyterian Hospital System (including NYP-Cornell, NYP-Columbia, and NYP-Allen Pavilion).

L. Potential Risks

The potential risks associated with this study are minimal. However, risks include that patients in the control wards/units who receive no intervention will continue to have urinary catheters in place longer than medically indicated and continue to have a high incidence of catheter associated urinary tract infections. Risks to the health care providers in the intervention wards/units include a decrease in work efficiency due to interruptions in order placement by automated reminders.

M. Potential Benefits

Potential benefits of this study include fewer catheter days per patient with urinary catheters and therefore a decrease in the rate of urinary tract infections as a result of the automated intervention group of the study.

N. Alternative Therapies

No therapeutic agent, procedure, or protocol is being investigated as part of this study thus no alternative therapies are available.

O. Compensation to Subjects

Participants, neither patients nor healthcare providers, will not be compensated for participation in this study.

P. Costs to Subjects

Participants, neither patients nor healthcare providers, will not incur any cost associated with participation in this study.

Q. Minors as Research Subjects

No participants under the age of 18 will be included in this study.

R. Radiation or Radioactive Substances

There will be no exposure to radiation or radioactive substances as part of this study.

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