

Protocolized Urine Sampling is Associated with Reduced Catheter-associated Urinary Tract Infections: A Pre- and Postintervention Study

Jennifer A. Frontera,¹ Erwin Wang,² Michael Phillips,² Martha Radford,² Stephanie Sterling,² Karen Delorenzo,³ Archana Saxena,² Shadi Yaghi,¹ Ting Zhou,¹ D. Ethan Kahn,¹ Aaron S. Lord,¹ and Joseph Weisstuch²

¹Department of Neurology, New York University School of Medicine, New York, New York, USA, ²Department of Medicine, New York University School of Medicine, New York, New York, USA, and

³Department of Nursing, New York University School of Medicine, New York, New York, USA

Background. Standard urine sampling and testing techniques do not mitigate against detection of colonization, resulting in false positive catheter-associated urinary tract infections (CAUTI). We aimed to evaluate whether a novel protocol for urine sampling and testing reduces rates of CAUTI.

Methods. A preintervention and postintervention study with a contemporaneous control group was conducted at 2 campuses (test and control) of the same academic medical center. The test campus implemented a protocol requiring urinary catheter removal prior to urine sampling from a new catheter or sterile straight catheterization, along with urine bacteria and pyuria screening prior to culture. Primary outcomes were test campus CAUTI rates, compared between each 9-month pre- and postintervention epoch. Secondary outcomes included the percent reductions in CAUTI rates, compared between the test campus and a propensity score-matched cohort at the control campus.

Results. A total of 7991 patients from the test campus were included in the primary analysis, and 4264 were included in the propensity score-matched secondary analysis. In the primary analysis, the number of CAUTI cases per 1000 patients was reduced by 77% (6.6 to 1.5), the number of CAUTI cases per 1000 catheter days was reduced by 63% (5.9 to 2.2), and the number of urinary catheter days per patient was reduced by 37% (1.1 to 0.69; all *P* values $\leq .001$). In the propensity score-matched analysis, the number of CAUTI cases per 1000 patients was reduced by 82% at the test campus, versus 57% at the control campus; the number of CAUTI cases per 1000 catheter days declined by 68% versus 57%, respectively; and the number of urinary catheter days per patient decreased by 44% versus 1%, respectively (all *P* values $< .001$).

Conclusions. Protocolized urine sampling and testing aimed at minimizing contamination by colonization was associated with significantly reduced CAUTI infection rates and urinary catheter days.

Keywords. CAUTI; catheter-associated urinary tract infection; urine; infection; asymptomatic bacteriuria.

Catheter-associated urinary tract infection (CAUTI) is a reportable and preventable hospital-acquired condition that has an attributable cost ranging from \$1000–10 000 per patient [1, 2]. Since approximately 12–16% of adult hospitalized patients have an indwelling urinary catheter [3], and the risk of CAUTI increases by 3–7% per day of catheterization [4], the cost of CAUTIs translates into millions of dollars of hospital expense annually. Though bacteriuria occurs at a rate of 3–10% per urinary catheter day [5–10], only 10–25% of bacteriuric patients develop symptoms of a urinary tract infection (UTI)

[11–13]. These data suggest a high rate of urinary catheter and/or bladder colonization, which may not be of clinical significance. Furthermore, because most urine cultures are obtained for the nonspecific symptom of fever [11] in patients with a low pretest probability of UTI, a high rate of false positive CAUTI diagnoses is expected. Currently, the Centers for Disease Control and Prevention (CDC) and Centers for Medicare and Medicaid Services surveillance guidelines do not provide criteria to differentiate between urinary catheter/bladder colonization and CAUTI among symptomatic patients.

In this study, our primary aim was to determine whether a protocol for urine collection designed to minimize the detection of catheter colonization (in addition to standard CDC prevention measures) would reduce rates of CAUTI infection and urinary catheter days among high-risk patients. Our secondary aim was to compare the percent reduction in CAUTI rates at the test campus to a propensity score-matched population at a control campus, which applied only standard CDC prevention measures.

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Correspondence: J. A. Frontera, NYU Department of Neurology, 150 55th St., Brooklyn, NY 11231 (jennifer.frontera@nyulangone.org).

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METHODS

Study Design and Population

A preintervention and postintervention comparison study of hospitalized patients was conducted from 1 January 2017–30 June 2018 at 2 campuses (test campus and control campus) of the same tertiary-care, academic, medical center (total 1100 beds). The study was divided into two 9-month time epochs: Epoch 1 was before (1 January 2017–30 September 2017) and Epoch 2 was after (1 October 2017–30 June 2018) the institution of a novel CAUTI protocol at the test campus. Both campuses have fully integrated electronic medical records (Epic); utilize the same clinical care management protocols; and have merged quality database systems, infrastructure, and quality committee and infection control oversight. Patients with historically high CAUTI rates were evaluated, including patients aged >18 years admitted to an intensive care unit (ICU; ie, critically ill patients); medical, surgical, or neurological stepdown unit; or neurology floor. Pediatric patients (<18 years) and patients admitted to other specialty service floors were excluded. This study was approved by the New York University Langone Hospitals' institutional review board.

Study Interventions

During Epoch 1, both campuses followed CDC guidelines for CAUTI prevention [14, 15] which included minimizing urinary catheter placement, as possible; sterile catheter insertion technique; and urinary catheter maintenance. Urine specimen collection was performed following CDC guidelines via aspiration from a needleless port using a sterile syringe after disinfecting the port [14, 15].

During Epoch 2, a novel CAUTI protocol was instituted at the test campus (Supplementary Table 1). This protocol included standard CDC CAUTI prevention measures utilized in Epoch 1, plus the following: (1) if a urinary catheter was in place >24 hours, it was removed prior to urine sampling and urine was collected either via sterile straight catheterization or new urinary catheter placement; and (2) urine was screened for bacterial load, and a urine culture was performed if the screening was positive (>325/μL bacteria and white blood cells >5/high-power field [hpf]). The control campus continued to follow the standard CDC CAUTI prevention measures and urine collection techniques that were applied during Epoch 1. We proposed urinary catheter removal prior to sterile urine sampling to minimize the detection of false positive CAUTIs due to catheter/bladder colonization (also known as catheter-associated asymptomatic bacteriuria, or positive urine cultures in the absence of symptoms). The 24-hour time frame for urinary catheter removal was based on the relatively high rate of bacteriuria (3–10%) per catheter day [5–10], as well as data in the surgical population [16] showing higher rates of UTI, longer lengths of

stay, and higher mortality rates in patients with indwelling catheters present for >2 days (which contributed to Surgical Care Improvement Project guidelines for urinary catheter removal within 24 hours of surgery). The reflex urine culture protocol was based on prior studies which tested using components of the urinalysis (eg, white cells, nitrites, bacteria presence) with reflex to culture to reduce unnecessary urine culture testing [17]. Studies have found a 60–70% reduction in urine cultures, while missing <10% of positive cultures [17, 18].

Outcome Measures

CAUTI was defined according to CDC/ National Healthcare Safety Network (NHSN) surveillance criteria [3] (see Supplementary Methods).

The primary outcome measure was the rate of CAUTI cases per 1000 catheter days, compared before (Epoch 1) and after (Epoch 2) the institution of the novel CAUTI protocol at the test hospital. Secondary outcomes included the rate of CAUTI per 1000 patients, number of catheter days per patient, total number of catheter days, total number of CAUTI infections, observed/expected length of stay (LOS), and discharge disposition (dichotomized as good [discharge either to home, home with rehabilitation, or an acute inpatient rehabilitation facility] versus poor [dead or discharged to a skilled nursing facility, subacute rehabilitation, long-term assisted care facility or hospice]). Outcome measures were compared between epochs and campuses.

In a secondary sensitivity analysis, the same CAUTI outcomes were compared in propensity score-matched cohorts between the test and control campuses from Epoch 1 to 2, in order to minimize the effect of any unmeasured practice changes that may have occurred over time and affected CAUTI rates.

Statistical Analysis

At the test campus, demographic and clinical characteristics, CAUTI outcomes, discharge dispositions, and LOS were compared between Epochs 1 and 2 using chi-squared tests for categorical values and Mann-Whitney U nonparametric tests for continuous, nonnormally distributed variables.

In the secondary, sensitivity analysis, propensity score matching of patients at the test and control campuses was utilized to minimize the effects of baseline confounders on the outcome of CAUTI rates over time. Propensity scores were calculated using logistic regression analysis, with time epoch, age, female sex, and urinary catheter days as covariates. These matching variables were selected based on established predictors of CAUTI. Patients at the test campus were matched to patients at the control campus in a 1:1 ratio (random matching without replacement), with a 0.005 propensity score-matching radius. Patients with missing data were excluded from propensity score matching. Baseline characteristics and hospital ward

location were compared between propensity score-matched groups to ensure a balance was achieved among potential confounders, using chi-square testing for categorical variables and Mann-Whitney U nonparametric testing for continuous variables. CAUTI outcomes, LOS, good discharge disposition rates, and the percent change in these metrics from Epoch 1 to 2 (difference in differences) were compared between the test and control campuses using chi-squared and Mann-Whitney U tests, as appropriate. All analyses were conducted using IBM SPSS Statistics V25 (IBM Corp., Armonk, NY).

RESULTS

A total of 16 824 patients were screened for inclusion at both campuses among patients admitted to an ICU; medicine, surgical, or neurological step-down unit; or neurology floor from 1 January 2017–30 June 2018. At the test campus, 7991 patients were included in the primary analysis ($n = 3967$ during Epoch 1 and $n = 4024$ during Epoch 2). Between Epochs 1 and 2, the populations were similar in regard to age, race, gender, and percentages with critical illness or admission to a medical floor (Table 1). At the test campus, the number of CAUTIs, CAUTIs per 1000 patients, and CAUTIs per 1000 catheter days were all reduced significantly, by 77%, 77%, and 63%, respectively, after the implementation of the novel CAUTI protocol (Table 2). Urinary catheter days per patient were also reduced by 37% (Supplemental Figure 1). Small but significant improvements occurred in observed to expected LOS and the percentage of good discharge dispositions after the institution of the novel CAUTI protocol (Table 2).

When examining CAUTI rates among different hospital floor services from Epochs 1 to 2 at the test campus, the CAUTI rates decreased significantly among the critically ill (12.9 to 3.7 CAUTI cases/1000 patients, respectively; 12.2 to 5.3 CAUTI cases/1000 catheter days, respectively; both P values $< .001$) and neurological patients on the floor or step-down unit (8.8 to 4.4 CAUTI cases/1000 patients, respectively; 61.7 to 33.3 CAUTI cases/1000 catheter days, respectively; both P values $< .001$), medicine step-down unit (1.5 to 0.5 CAUTI cases/1000 patients,

respectively; 4.1 to 2.5 CAUTI cases/1000 catheter days, respectively; both P values $< .001$), and surgical step-down unit (7.5 to 0 CAUTI cases/1000 patients, respectively; 19 to 0 CAUTI cases/1000 catheter days, respectively; both P values $< .001$).

There were 28% fewer urine culture tests performed in Epoch 2, compared to Epoch 1, at the test campus (1994 in Epoch 1 versus 1435 in Epoch 2; $P < .001$). The number of urine studies also decreased by 27% at the control campus from Epoch 1 to 2 (3111 in Epoch 1 versus 2259 in Epoch 2; $P < .001$).

Among 1435 urine culture screen tests performed in Epoch 2, 173 (12%) were randomly assessed to determine the proportion of patients that underwent urinary catheter exchange. In this sample, 6/173 (3.5%) patients underwent urinary catheter exchange at the time the urine specimen was collected. In 114/173 (66%) patients, the initial urinary catheter was placed at the time the urine specimen was collected; the urinary catheter was removed and not replaced in 53/173 (31%) patients prior to urine specimen collection.

For the propensity-matched sensitivity analysis, 4264 patients were included in the analysis ($n = 2132$ at each campus). Patients were well matched for age, gender, and the number of urinary catheter days per patient. However, there were significantly more critically ill and medicine step-down patients at the test campus and significantly fewer neurological and surgical step-down patients (Supplementary Table 2). As in the primary analysis, the number of CAUTI infections, catheter days, CAUTI cases/1000 patients, and CAUTI cases/1000 catheter days were all significantly lower in Epoch 2 compared to Epoch 1 at the test campus, and both LOS and discharge disposition were significantly better (all P values $< .001$ comparing the percent change between Epochs 1 to 2 using Mann-Whitney U tests). In contrast, there were no significant reductions in any CAUTI rate, LOS, or discharge disposition at the control campus over the same time period (Table 3; Figure 1). The rate of CAUTI cases/1000 catheter days was reduced by 68% at the test campus compared to 57% at the control campus ($P < .001$), and the rate of CAUTI cases/1000 patients was reduced by 82% at the test campus versus 57% at the control campus ($P < .001$) from Epoch 1 to 2. The test campus also had significantly greater

Table 1. Demographics at Test Campus During Epochs 1 and 2

	Epoch 1 at Test Campus	Epoch 2 at Test Campus	<i>P</i>
<i>n</i>	3967	4024	
Age, median (range)	69 (19–107)	69 (19–106)	.070
Race, White, <i>n</i> (%)	1801 (45%)	1816 (45%)	.502
Female, <i>n</i> (%)	1962 (50%)	1965 (49%)	<.001
Critically ill, <i>n</i> (%)	1087 (27%)	1088 (27%)	.656
Neurological patient, <i>n</i> (%)	567 (14%)	227 (6%)	<.001
Medicine patient, ^a <i>n</i> (%)	2047 (52%)	2132 (53%)	.223
Surgery patient, ^a <i>n</i> (%)	267 (7%)	578 (14%)	<.001

n = 7991.

^aPatient group does not include critically ill patients.

Table 2. Comparison of CAUTI Rates at Test Campus Between Epochs 1 to 2

	Test Campus Epoch 1	Test Campus Epoch 2	% Change from Epoch 1 to 2	P Epoch 1 vs 2 at Test Campus
n	3967	4024	...	
CAUTI per 1000 catheter days	5.9	2.2	-63%	.001
CAUTI per 1000 patients	6.6	1.5	-77%	.001
Catheter days per patient	1.1	.69	-37%	<.001
Catheter days, total	4399	2758	-37%	<.001
CAUTI infections, total	26	6	-77%	.001
Observed/expected LOS, median (range)	.88 (.07-21.7)	.78 (.05-13.0)	-11%	<.001
Good discharge disposition, n (%)	2796 (71%)	2979 (74%)	+4%	.001

Abbreviation: CAUTI, catheter-associated urinary tract infections; LOS, length of stay.

reductions in the number of CAUTI infections, number of catheter days per patient, LOS (all *P* values < .001), and the total number of urinary catheter days (*P* = .043).

DISCUSSION

In this study, we found significant reductions in CAUTI cases/1000 catheter days and CAUTI cases/1000 patients by 63 and 77%, respectively, following institution of a protocol aimed at minimizing the detection of urinary catheter/bladder colonization. In a propensity score-matched sensitivity analysis, protocolized urine sampling led to greater reductions in CAUTI rates than standard CDC prevention tactics alone. Indeed, there were 82% fewer CAUTI cases/1000 patients at the test campus compared to 57% at the control campus from Epochs 1 to 2 (*P* < .001). A reduction in CAUTI rates was observed across all patient populations at the test site, including critically ill, neurology, medicine, and surgery patients, suggesting that colonization and false positive urine cultures are pervasive occurrences. The treatment of false positive urine cultures may be harmful, as studies of asymptomatic bacteriuria have demonstrated prolonged LOS with antibiotic treatment, and no outcome benefit [19]. Furthermore, inappropriate antibiotic use can lead to

resistant organism growth, *Clostridium difficile* (*Clostridioides difficile*), adverse drug side effects, and unnecessary pharmacy expenditures [12, 20-22].

This study is the first, to our knowledge, that focuses narrowly on a urine sampling technique for lowering CAUTI rates. Prior studies have identified bundles of interventions to reduce CAUTI rates, which primarily followed CDC guidelines [23-25]. However, it remains unclear which elements of these bundles are most effective. Our study built upon CDC/NHSN guidelines by adding 2 novel components (removal of the urinary catheter if in place >24 hours, followed by urine sampling from a new catheter or sterile straight catheterization, and urine screening with reflex culture), allowing us to focus on the effect of urinary catheter/bladder colonization on CAUTI rates. Our protocol also reduced the number of urine cultures performed, as other studies have demonstrated [17, 18], which likely contributed to lower CAUTI rates in the primary analysis at the test site. However, the change in urine culture volume probably does not fully explain the differences in CAUTI rates that were observed in the propensity score-matched analysis, since both sites had a ~28% reduction in the urine testing volume from Epoch 1 to 2. Urinary catheter removal prior to urine

Table 3. Propensity Score-Matched Comparison of Test and Control Campuses from Epoch 1 to Epoch 2

	Test Campus Epoch 1	Test Campus Epoch 2	% Change from Epoch 1 to 2 Test Campus	P Epoch 1 vs 2 at Test Campus	Control Campus Epoch 1	Control Campus Epoch 2	% Change from Epoch 1 to 2 Control Campus	P Epoch 1 vs 2 at Control Campus	P % Change Between Test and Control Campus
n	934	1198	...		1101	1031	...		
CAUTI per 1000 catheter days	27.4	8.8	-68%	<.001 ^a	17.5	7.5	-57%	.067	<.001 ^a
CAUTI per 1000 patients	27.8	5.0	-82%	<.001 ^a	13.6	5.8	-57%	.068	<.001 ^a
Catheter days per patient	1.02	.57	-44%	<.001 ^a	.78	.77	-1%	.341	<.001 ^a
Catheter days, total	950	678	-29%	<.001 ^a	857	796	-7%	.341	.043 ^a
CAUTI infections, total	24	6	-75%	<.001 ^a	15	6	-60%	.068	<.001 ^a
Observed/expected LOS, median (range)	1.07 (.09-21.7)	.83 (.09-13.0)	-22%	<.001 ^a	.77 (.13-11.1)	.76 (.1-10.5)	-1%	.478	<.001 ^a
Good discharge Disposition, n (%)	572 (61%)	881 (74%)	+13%	.001 ^a	937 (85%)	892 (87%)	+2%	.350	<.001 ^a

Abbreviation: CAUTI, catheter-associated urinary tract infections; LOS, length of stay.

^aStatistically significant at *P* < .05

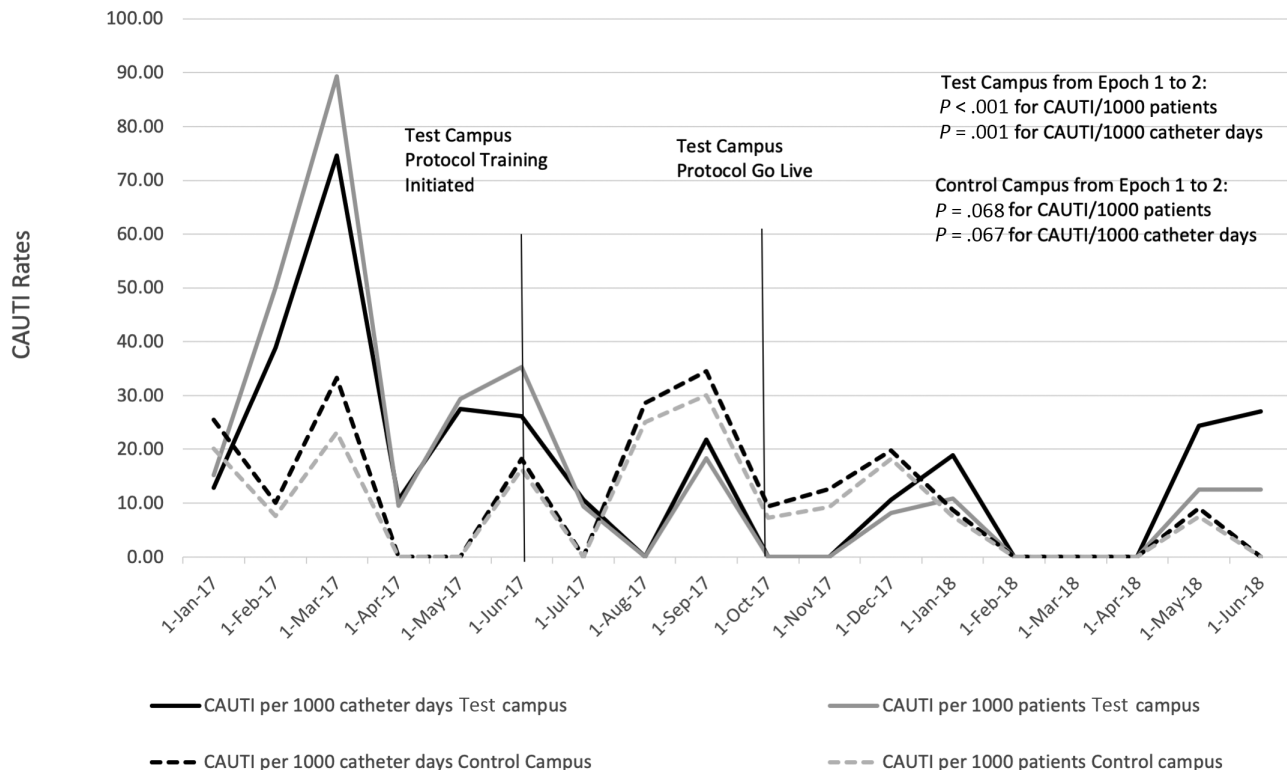


Figure 1. CAUTI Rates over time comparing propensity-matched subjects from the test and control campus. From Epoch 1 to 2, there was an 82% reduction in CAUTI/1000 patients at the test campus, compared to a 57% reduction at the control campus ($P < .001$), and a 68% reduction in CAUTI/1000 catheter days at the test campus, compared to a 57% reduction at the control campus ($P < .001$). Abbreviations: CAUTI, catheter-associated urinary tract infections.

sampling appeared to play a major role in lowering CAUTI rates. Though the Infectious Diseases Society of America recommends removing indwelling catheters in place for >2 weeks and obtaining a urine specimen from a freshly placed catheter or midstream urine sample [26], there are no prior studies, to our knowledge, evaluating standardized catheter removal prior to urine sampling at a time point this early. A particular strength of this study is that we verified our outcomes by measuring CAUTI not just as events per 1000 catheter days (which may demonstrate deceptively low CAUTI rates if there is a large denominator), but also as events per 1000 patients. We further demonstrated that our urine sampling protocol reduced catheter days as well, in part because once an indwelling catheter was removed to sample urine, many patients were identified as no longer requiring a catheter.

Another strength of our study design is that we compared CAUTI rates at the test campus to a propensity score-matched population at the control campus, which utilizes the same infection and quality control teams. This sensitivity analysis allowed us to control for unmeasurable factors that may change over time and affect CAUTI rates. Indeed, CAUTI rates were declining at both campuses prior to the protocol intervention at the test campus. However, the reductions in CAUTI rates were not significant between Epochs 1 and 2 at the control campus

compared to the test campus, underscoring the impact of our protocol at the test campus. Because the control campus was not blinded to the interventions at the test campus, some clinicians at the control campus may have changed their practices, leading to a trend toward reduced CAUTI rates.

In addition to reduced CAUTI rates, we observed concomitant decreases in LOS and improved rates of good discharge dispositions at the test campus. While it is possible that other factors led to these improvements, it is notable that the control campus did not see any significant changes in these metrics over the same time frame. Notably, in a propensity score-matched analysis, the test campus had twice as many critically ill patients as the control campus. Since critical illness is associated with longer LOS and worse discharge dispositions, this would bias the test campus toward worse results on these metrics, but in fact, we observed the opposite.

Limitations

There are limitations to this study that should be noted. First, unlike a randomized, controlled trial, this was a pre- and postintervention study, and we cannot account for all patient-level differences. However, we did include similar patient populations in an attempt to minimize patient-level differences, and we performed a propensity score-matched analysis

that was adjusted for known predictors of CAUTI, including age, gender, and duration of catheter use. Second, in the primary analysis, there were significantly fewer neurological patients in Epoch 2 than Epoch 1. However, CAUTI rates were significantly reduced among all subtypes of patients from Epoch 1 to 2, with some of the largest decreases occurring among the critically ill and surgical patients. Additionally, having a neurological diagnosis is not an established risk factor for symptomatic CAUTI [15], and it seems unlikely that this imbalance would have a substantial effect on the overall analysis. Third, though the rate of CAUTI per 1000 patients was lower at the test site compared to the control site during Epoch 2, the rate of CAUTI per 1000 catheter days was lower at the control site. This may be related to higher use of urinary catheters and more catheter days per patient at the control site. The differences in these measures of CAUTI underscore the fact that reducing the denominator (catheter days) may falsely elevate CAUTI rates. Strategies to lower the numerator (number of CAUTIs) remain critical to overall CAUTI rate reduction. Fourth, absolute rates of good discharge dispositions and LOS were better at the control campus than the test campus during both epochs, though this may be related to a higher proportion of critically ill patients at the test campus. Finally, complications or unintended consequences related to urinary catheter removal and replacement or urinary straight catheterization that were mandated by the protocol were not collected. Overall, the rate of urinary catheter exchange was low (3.5%), suggesting that urethral trauma rates related to catheter exchange are likely also low. Additionally, frequent straight catheterization is well tolerated over as long as months to years, such as among populations with spinal cord injuries and neuro-urological bladder dysfunction [27, 28]. Indeed, the CDC CAUTI prevention guidelines state that “intermittent catheterization is preferable to indwelling urethral or suprapubic catheters in patients with bladder emptying dysfunction” [15], supporting the concept that the risks of long-term indwelling catheters outweigh the urological risks of intermittent straight catheterization. Serious adverse events related to chronic intermittent catheterization have been reported in 0–3% of patients [29–32]. In a study of foley catheter-related trauma, there were 32 trauma events out of 6513 catheter days (0.5% of catheter days) that required intervention (including false passage, gross hematuria, external trauma, or misplacement of the catheter), indicating that serious complications were a rare event [13]. Additionally, small trials of urinary catheterization in hospitalized patients support its safety and tolerability [33]. In 1 study, only 8% of patients reported discomfort, pain, bleeding, or trauma during catheter placement [34]. It therefore seems unlikely that the risks associated with clean urine sampling would outweigh the benefits of avoiding false positive CAUTIs and unnecessary exposure to antibiotics. Additionally, good discharge

dispositions and LOS were improved in Epoch 2, suggesting that major, life-threatening, unintended consequences did not outweigh the benefit of the protocol.

CONCLUSIONS

Protocolized urine sampling and testing aimed at minimizing contamination by urinary catheter/bladder colonization was associated with significantly reduced CAUTI infection rates and urinary catheter days. Future studies evaluating a cost analysis of protocolized urine sampling are warranted.

Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

Author contributions. J. A. F contributed to the study concept and design, data acquisition, statistical analysis, and first draft and finalization of the manuscript. J. W., M. P., S. S., K. D., A. S., and E. W. contributed to the study design, data acquisition, and finalization of the manuscript. M. R., S. Y., T. Z., D. E. K., and A. S. L. contributed to the data acquisition and finalization of the manuscript.

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