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## Major Article

## Reducing inappropriate urine cultures through a culture standardization program

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## Key Words:

Urinary tract infection  
 Reflexive urine culture  
 CAUTI  
 Urine culture contamination

**Background:** The objective of this study was to evaluate the impact of a urine culture standardization program that included order indications and urinalysis (U/A) with reflexive culture. The program applied to all adult and pediatric inpatients at an academic medical center; emergency department and ambulatory clinic patients were excluded.

**Methods:** The analysis compared outcomes in the pre-implementation (January 2015–May 2016) and post-implementation (July 2016–September 2017) periods. The primary outcomes were urine culture and U/A orders per 1,000 patient days, catheter-associated urinary tract infection (CAUTI) rate per 1,000 catheter days, and urine culture contamination rate per 1,000 patient days. Catheter standardized utilization ratios (SURs) were also examined.

**Results:** The intervention was associated with a significant decrease in urine culture rates by 6.9 cultures per 1,000 patient days (95% CI –4.44, –9.44;  $P < .0001$ ). The U/A testing rate per 1,000 patient days significantly increased pre-intervention, was not affected acutely by the intervention institution, and significantly decreased post-implementation. The CAUTI rate was not significantly changed by the intervention but did significantly increase post-implementation by 0.2 per 1,000 catheter days (95% CI 0.01, 0.47;  $P = .04$ ); SURs significantly decreased (0.03; 95% CI –0.003, –0.05;  $P = .03$ ); and the urine culture contamination rate per month showed no significant change. Sixty-four percent of urine cultures ordered using the reflexive test did not reflex to culture by U/A criteria.

**Conclusions:** A urine culture standardization program led to a significant reduction in urine cultures and did not lead to an increase in U/A testing rates. CAUTI rates increased post-implementation, which may have been confounded by reduced catheter utilization.

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## BACKGROUND

Urinary tract infections (UTIs) account for approximately 10 million health care visits<sup>1</sup> and 100,000 hospitalizations annually,<sup>2</sup> and community-acquired UTIs cost the US health care system approximately \$1.6 billion annually.<sup>2</sup> Inappropriately ordered and/or collected urine cultures have been implicated in increased rates of urine culture

contamination, inappropriate use of antibiotics leading to adverse drug events and increasing pressure for the development of antimicrobial resistance, increased costs, increased catheter-associated UTI (CAUTI) rates, and increased *Clostridioides difficile* infections.<sup>3–6</sup> Accurately diagnosing a UTI is essential in appropriately managing these important patient harms.

Diagnostic test stewardship is an important concept that involves optimizing the process of ordering, performing, and reporting diagnostic tests. Potential benefits of such stewardship include fewer false-positive test results, more appropriate antibiotic use, fewer adverse effects of antibiotics, fewer unnecessary hospital admissions, and shorter lengths of stay.<sup>7</sup> A reflexive urine culture order, in which a urine culture is only processed if an associated urinalysis suggests

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the presence of a UTI, is an example of diagnostic stewardship. In the absence of reflexive testing, up to 35% of urine cultures may have a negative urinalysis in the emergency department setting.<sup>8</sup> In addition, inappropriately collected specimens can lead to increased patient morbidity, health care costs, and waste. A 1-year extrapolation of results at the current study's tertiary medical center noted that contaminated urine cultures (defined as the growth of 2 or more organisms) occurred in 5.1% of all urine cultures and resulted in substantial morbidity, including 385 unnecessary antibiotic courses, 73 additional cultures, 46 intravenous line placements for antibiotics, and 27 hospital admissions.<sup>4</sup> In addition, at the current study site, an estimated 20% of urine cultures were sent without a urinalysis (U/A). This contributed to difficulty assessing whether a positive urine culture was indicative of a true UTI. These factors led to the development of a urine culture standardization program that included order indications and urinalysis with reflexive culture. The purpose of this study was to examine the impact of this program within inpatient units.

## METHODS

### Study setting and participants

This study was conducted at a 685-bed adult and a 292-bed pediatric tertiary academic medical center, which together averaged 22,708 inpatient days per month. The study period consisted of pre-implementation (January 2015–May 2016) and post-implementation (July 2016–September 2017) periods. January 1, 2015, was chosen as the start date for the analysis to align with the National Healthcare Safety Network (NHSN) CAUTI definition revision. The intervention initiation month of June 2016 was excluded. Study subjects included all adult and pediatric inpatients admitted during the study period. Emergency department and ambulatory clinic patients were not included in this study.

### Study procedures

A 4-step urine culture standardization program was initiated in June 2016 which included the following: (1) defined indications for urine culture ordering, (2) standardization of specimen collection, (3) implementation of a U/A with reflexive urine culture testing algorithm, and (4) tracking of urine culture contamination. The indications for urine culture ordering (Box) were distributed to all clinicians throughout the medical center and were visible in the order entry system whenever a urine culture order was placed. A standard process for collection of a specimen from a urinary catheter was developed and disseminated, requiring collection of specimens directly from the sampling port to collection tubes, minimizing the risk of contamination at the point of collection. Separate vacutainer tubes for the U/A and urine culture specimens were sent to the hematology and microbiology laboratory areas, respectively. The U/A was performed in the hematology lab, and the urine culture tube was stored in the microbiology laboratory pending the U/A results. If the U/A specimen results met predefined criteria, including positive nitrites, small or greater leukocyte esterase, or  $\geq 5$  white blood cells (WBCs) per high power field (HPF), an order to process the urine culture was automatically generated and sent to the microbiology lab. Clinicians had the ability to opt out of the U/A with reflexive urine culture and order a simple urine culture if the patient met certain exclusion criteria: a planned urologic procedure or current pregnancy (because of recommendations to treat asymptomatic bacteriuria in these populations)<sup>9,10</sup> or the presence of severe neutropenia (absolute neutrophil count [ANC]  $<100$  or total WBC count  $<500$ ). Severe neutropenia was selected based on the assumption that the immune system would have difficulty producing a

significant amount of pyuria in this setting, and the reflexive urine culture could potentially miss true UTIs (false omission). In addition, patients who were age  $<25$  months were excluded from the reflexive culture requirement.

The primary data source for the study was the Vanderbilt University Medical Center Infection Prevention Database. The primary outcomes analyzed were U/A testing and urine culture rates per 1,000 patient days, CAUTI rates per 1,000 catheter days, and urine culture contamination rates per month. CAUTI was defined by trained infection preventionists using the NHSN definition. Urine contamination was defined as the growth of  $\geq 2$  organisms from a single specimen. The secondary outcomes examined were catheter standardized device utilization ratios (SURs), reflexive order utilization, and cultures prevented by the reflexive order. The catheter SUR was calculated based on the NHSN guideline and defined as the observed catheter days divided by the predicted catheter days.<sup>11</sup> Reflexive

### Box. Indications for urine culture ordering

Urine cultures should be ordered only in the following patients:

- Patients with signs/symptoms of a urinary tract infection:
  - For example, dysuria, suprapubic pain/tenderness, urgency, frequency, or costovertebral angle pain/tenderness
- Part of an evaluation of sepsis without a clear source
- Workup of patients with isolated fever or altered mental status (only if other foci of infection are not identified on history, on examination, or from other lab testing)
- For bacteriuria screening in asymptomatic patients with the following underlying comorbidities:
  1. Prior to urologic procedures
  2. Pregnant women

Urine cultures should NOT be ordered for the following instances:

- Do NOT order solely based on concerns regarding urine quality, such as change in the character of the urine (color, smell, sediments, turbidity)
- Do NOT have standing orders for urine culture in the absence of an appropriate indication (eg, as part of standard fever workup)
- Do NOT repeat urine culture to document clearance of bacteriuria in the presence of symptomatic improvement
- In the absence of symptoms, screening urine cultures should NOT be ordered for:
  1. Non-pregnant women
  2. Patients with diabetes
  3. Elderly patients
  4. Patients with spinal cord injury
  5. Patients with an indwelling urinary catheter or who require chronic intermittent catheterization
  6. Renal transplant recipients

order utilization was defined as the total amount of all reflexive urine cultures divided by the total amount of all urine cultures (reflexive and non-reflexive) performed. Urine culture prevention was defined as the ratio of the number of cultures avoided (ie, that did not reflex to culture) over the total number of reflexive cultures ordered. This assumed that prior to standardization clinicians would typically order both a U/A and a urine culture at the same time prior to initiating empiric antibiotics for UTI in an inpatient. Following standardization, the reflexive order eliminated the need to order a urine culture empirically prior to receiving U/A results.

A subanalysis was performed to evaluate utilization of the reflexive order with the removal of units that contained a high proportion of patients that would meet the exclusion criteria (eg, neonatal intensive care unit, obstetrics units, urologic surgical unit, stem cell transplant units). For this subanalysis, a randomized 10% chart review was performed on patients who had a non-reflexive urine culture ordered to evaluate how often those patients met the allowed exclusion criteria. Pregnancy was determined if the patient had a positive pregnancy test within the 9 months prior to urine culture or was actively pregnant according to documentation available at the time of specimen collection. Patients who may have been suspected of pregnancy at the time of culture order (even if ultimately found not to be pregnant) were also assessed, as the clinical suspicion would be enough for a clinician to select that the patient may meet an accepted exclusion criterion. Suspected pregnancy was defined as present if the patient was female, was less than 60 years of age, and had a pregnancy test ordered within the first 48 hours of admission but the result was not entered prior to the urine culture order. Patients also met the exclusion criterion for severe neutropenia if they had an ANC <100 or WBC count <500 at the time of culture order or did not have a total WBC count or ANC result within 1 week prior to the urine culture order and had received chemotherapy within the 2 weeks prior to the urine culture (suspicion for severe neutropenia). A patient met exclusion criteria for a planned urologic procedure if they had undergone such a procedure in the 2 weeks following the urine culture order (by description in either the progress notes or a procedure note during that time frame). Some patient comorbidities associated with an unwarranted exclusion from the reflexive order were additionally assessed to understand the presence of any patterns in such ordering behaviors. The comorbidities were based on varying degrees of immunosuppression and the presence of structural urinary abnormalities (or chronic catheterization) because these conditions may be confused with the allowed exemption criteria by the ordering clinician. The Vanderbilt University Medical Center Institutional Review Board approved this study.

#### Statistical analysis

An interrupted time series analysis with Newey-West standard errors was used to compare testing and outcome rates over the course of the study period. Stata 13 (StataCorp; College Station, TX) was used for data analysis.

## RESULTS

As illustrated in both Figure 1 and Table 1, the urine culture rate per 1,000 patient days (Fig 1B), CAUTI rate per 1,000 catheter days (Fig 1C), and SUR (Fig 1D) were stable prior to implementation. The U/A testing rate per 1,000 patient days significantly increased (Fig 1A), and the urine culture contamination rate per month significantly decreased prior to the intervention. Implementation was associated with an immediate significant decrease in urine culture rates by 6.9 (95% CI –4.44, –9.44) cultures per 1,000 patient days ( $P < .0001$ ). The U/A testing rate, CAUTI rate, SURs, and urine culture contamination rate were not immediately impacted by the intervention. Following the intervention, the urine culture and urine

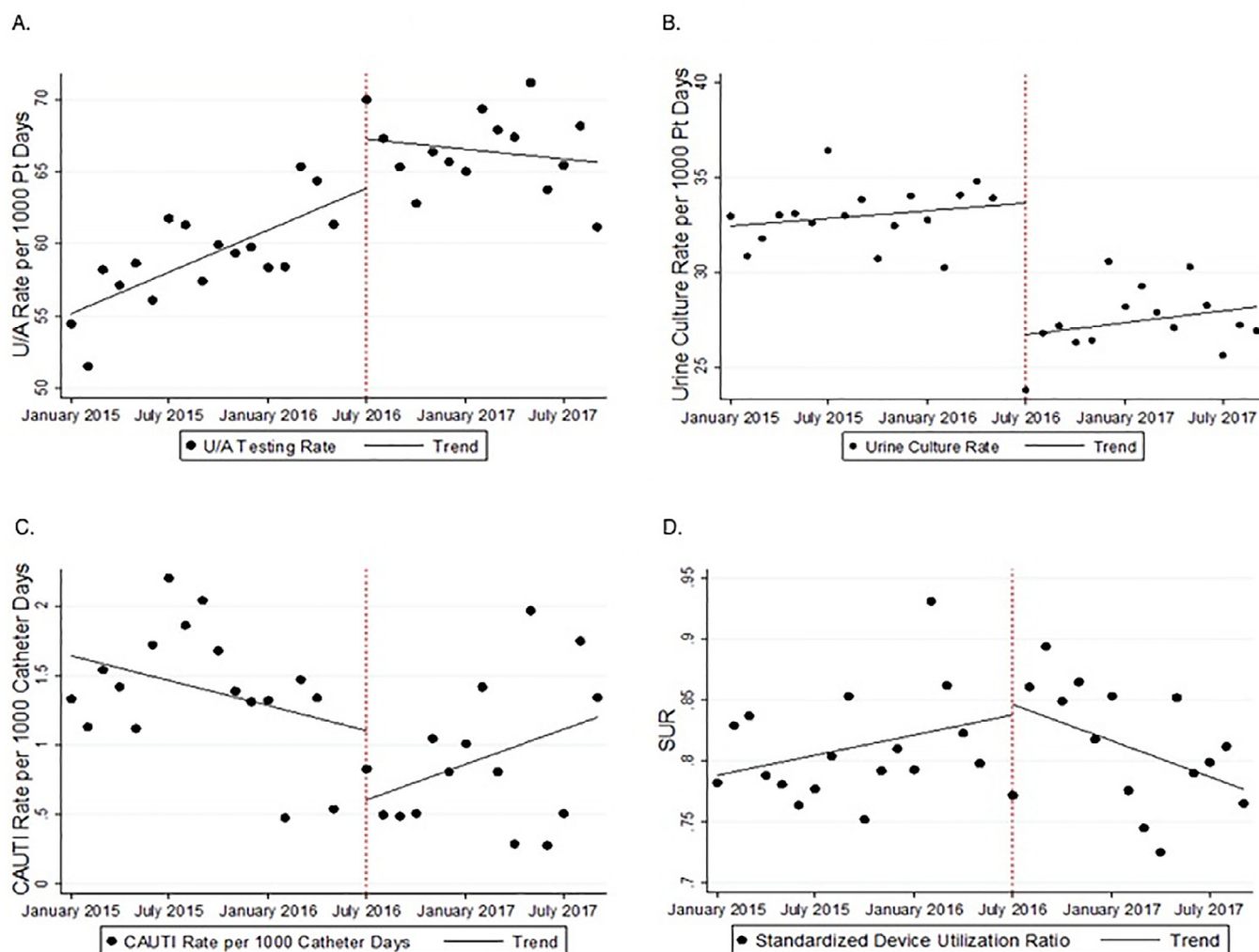
contamination rates did not significantly change, but the U/A testing rate significantly decreased by 0.02 per 1,000 patient days (95% CI –0.0004, –0.03;  $P = .01$ ). The CAUTI rate significantly increased post-implementation by 0.2 per 1,000 catheter days (95% CI 0.01, 0.47;  $P = .04$ ), and SURs significantly decreased by 0.03 (95% CI –0.003, –0.05;  $P = .03$ ).

As illustrated in Figure 2, 64% of urine cultures ordered using the reflexive test did not reflex to culture by the U/A criteria (ie, the urine culture prevention rate). The mean reflexive order utilization rate for all inpatient units over the post-intervention period was 77.2% (Fig 3). The mean reflexive order utilization rate was higher (85.0%) when the high-exclusion units were removed (Fig 4). The reflexive order utilization rate was much lower than the overall mean in the first 2 months after implementation, suggesting gradual initial acceptance of the new test. From the randomized sample chart review, 78.7% of the time when the ordering clinician selected that the patient met one of the reflexive culture exclusion criteria the patient did not actually qualify for exclusion (Table 2). In 50.8% of these cases, the patient was not immunosuppressed, was not a solid organ or stem cell transplant patient, and had no urologic structural abnormality or chronic urinary catheter present. The presence of active malignancy and solid organ transplantation were associated with the highest percent of patients not meeting exclusion criteria yet being inappropriately selected by the ordering clinicians as meeting an exclusion to the reflexive culture.

## DISCUSSION

As anticipated during program development, the institution of a program to standardize urine culture ordering and collection led to a significant reduction in unnecessary urine culture orders while not significantly increasing U/A testing. Although not specifically assessed by the current evaluation, this reduction in unnecessary testing likely led to a reduction in antimicrobial use, repeat diagnostic testing, prolonged length of stay, and other morbidities related to false-positive urine cultures previously described from the same institution.<sup>4</sup> Somewhat unexpectedly, CAUTI rates increased post-implementation and device SURs decreased. Although it is concerning that the CAUTI rate did increase significantly after the intervention, this was potentially impacted by other variables such as a decrease in urinary catheter usage. There has been a noted concern that focusing on unnecessary urinary catheter placement as part of a CAUTI prevention program may result in an elevated CAUTI rate due to decreasing catheter days in those lower-risk patients who were less likely to develop a CAUTI (ie, impacting the denominator of the rate to a greater degree than the numerator). In addition, despite standardization of specimen collection, there was no significant effect on urine culture contamination rates.

The reflexive order was utilized frequently (with higher utilization when units with an expected higher rate of exclusion patients were removed), and nearly two-thirds of the time the U/A results indicated that a urine culture was unnecessary. Reflexive order utilization was much lower than the mean during the first 2 months after the intervention. This did not represent implementation error, as the new test was hardwired into the electronic medical record system, and clinicians could not bypass this order beginning the first day of implementation. One hypothesis is that clinicians may not have fully trusted the reflexive order in the first couple months following implementation and may have instead falsely noted the presence of an exclusion criterion to bypass the reflexive test. Even after the first few months of implementation, a high rate of patients who were noted to meet the allowed exclusion criteria did not qualify for exclusion upon chart review based on data available to the ordering clinician. An apparent concern for immunosuppression or the presence of a urologic abnormality without a planned urologic procedure was



**Fig 1.** Interrupted time series analysis of the implementation of a urine culture standardization program. Dashed line indicates time of intervention launch. (A) U/A testing rate per 1,000 patient days. (B) Urine culture rate per 1,000 patient days. (C) CAUTI rate per 1,000 catheter days. (D) SUR. CAUTI, catheter-associated urinary tract infection; SUR, standardized utilization ratio; U/A, urinalysis.

only associated with false exclusion from the reflexive order about 50% of the time. It remains unclear why clinicians falsely excluded the other 50% of patients that had no immunosuppression, transplantation, or urologic abnormality.

Although there is evidence for a high negative predictive value for the reflexive criteria that were used in this study, one study limitation was that there is currently no gold standard regarding the degree of pyuria or other U/A criteria that should be used to trigger a reflexive culture. Previous studies have noted that the absence of pyuria, leukocyte esterase, and nitrite on a U/A is a

strong predictor of a negative urine culture.<sup>8,12–14</sup> A study including 874 men noted that the absence of pyuria (defined as  $<5$  WBC/HPF) had a negative predictive value (NPV) of 97% for a positive urine culture.<sup>12</sup> Another study, which included 1,546 emergency department patients, showed that the NPV for the absence of pyuria was 77% if  $\leq 10$  WBC/HPF and was 92% if  $\leq 5$  WBC/HPF were used as the reflexive threshold.<sup>14</sup> The NPV for the absence of leukocyte esterase was 96%, for the absence of nitrite was 86%, and for the absence of bacteria was 96%. The absence of all 4 of these measures combined (pyuria  $\leq 10$  WBC/HPF, leukocyte

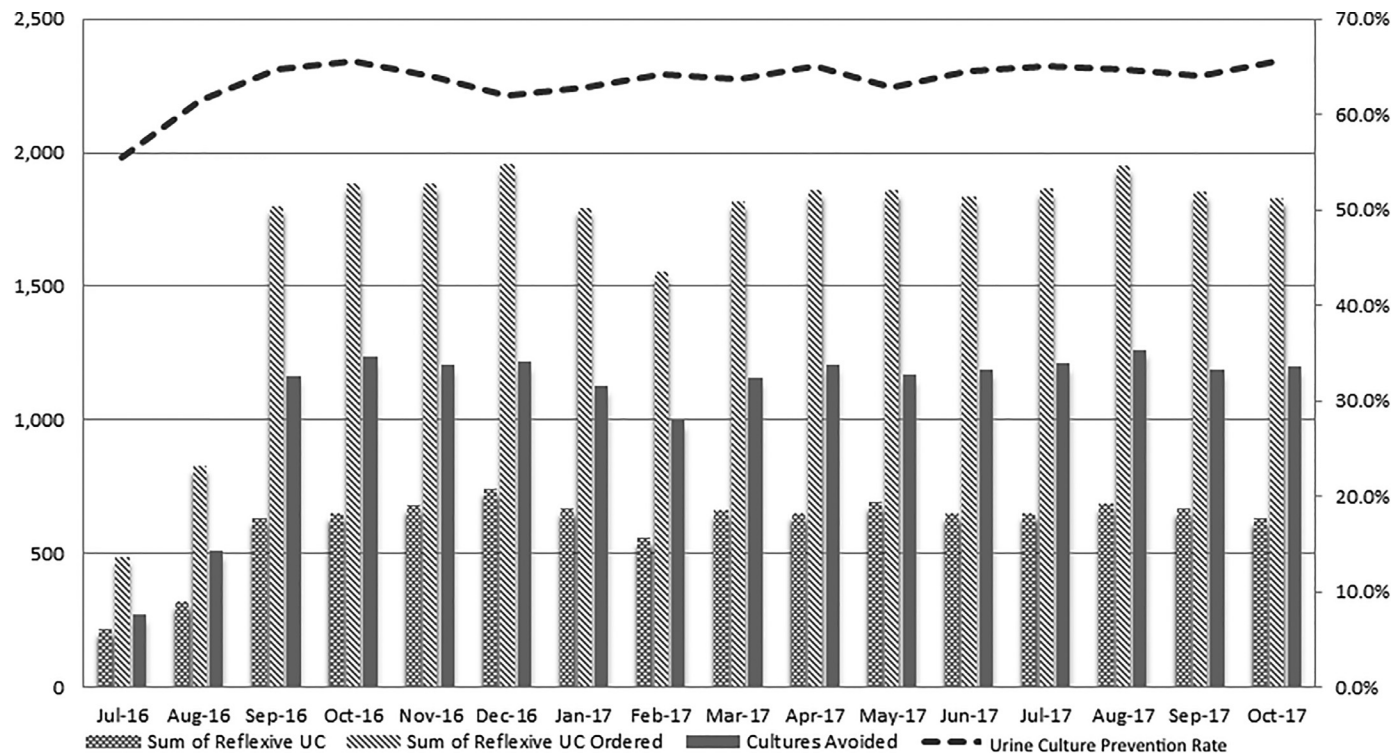
**Table 1**  
Interrupted time series analysis of outcomes used to assess the impact of a urine culture standardization program

Outcome	Prior to implementation	Implementation	After implementation
Urine culture rate per 1,000 patient days	0.002 (95% CI $-0.02, 0.07$ ; $P = .30$ )	<b><math>-6.94</math> (95% CI <math>-4.44, -9.44</math>; <math>P &lt; .0001</math>)</b>	0.001 (95% CI $-0.1, 0.1$ ; $P = .77$ )
U/A testing rate per 1,000 patient days	<b>0.016 (95% CI <math>0.01, 0.2</math>; <math>P = .001</math>)</b>	3.39 (95% CI $-0.41, 7.18$ ; $P = .08$ )	<b><math>-0.02</math> (95% CI <math>-0.004, -0.03</math>; <math>P = .01</math>)</b>
CAUTI rate per 1,000 catheter days	$-0.001$ (95% CI $-0.002, 0.001$ ; $P = .17$ )	$-0.50$ (95% CI $-1.1, 0.1$ ; $P = .09$ )	<b>0.23 (95% CI <math>0.01, 0.47</math>; <math>P = .04</math>)</b>
Standardized device utilization ratio	0.009 (95% CI $-0.0046, 0.02$ ; $P = .18$ )	0.8 (95% CI $-0.7, 0.8$ ; $P = .81$ )	<b><math>-0.03</math> (95% CI <math>-0.003, -0.05</math>; <math>P = .03</math>)</b>
Urine culture contamination rate per month	<b><math>-0.01</math> (95% CI <math>-0.001, -0.1</math>; <math>P = .023</math>)</b>	0.01 (95% CI $-0.01, 0.03$ ; $P = .42$ )	0.001 (95% CI $-0.01, 0.01$ ; $P = .8$ )

NOTE. Bold entries signify statistical significance with  $p \leq 0.5$ .

CAUTI, catheter-associated urinary tract infection; U/A, urinalysis.

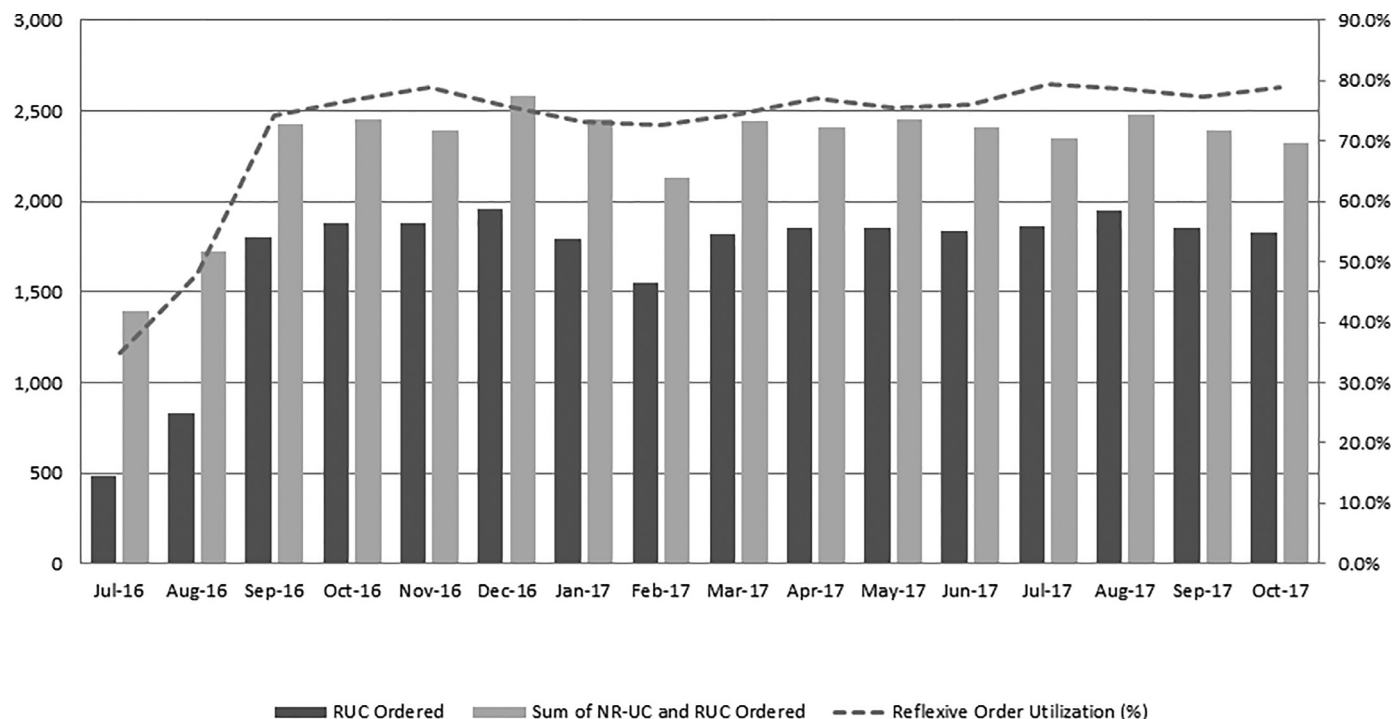




**Fig 2.** Urine culture prevention by use of the reflexive order among adult and pediatric inpatients. The sum of reflexive UC bars are orders that actually reflexed to culture. The sum of reflexive UC ordered bars are the total orders, including orders that reflexed and those that did not reflex by criteria. UC, urine culture.

esterase, nitrite, and bacteruria) had a NPV of 98%. The positive predictive value if any of these measures was present was 32%.<sup>14</sup> An external validation study of this protocol for urine culture reflex found a NPV of 95% for all 4 of these measures combined.<sup>8</sup>

One of the greatest concerns about the reflexive urine culture is the possibility of missing a true UTI (false omission rate). The criteria for a U/A to reflex to culture were intentionally set with a low threshold in this study ( $\geq 5$  WBC/HPF, positive leukocyte esterase, or positive nitrite) to have a low false omission rate. Prior studies have



**Fig 3.** Reflexive urine culture order utilization, all inpatient units. NR-UC, non-reflexive urine cultures; RUC, reflexive urine cultures.

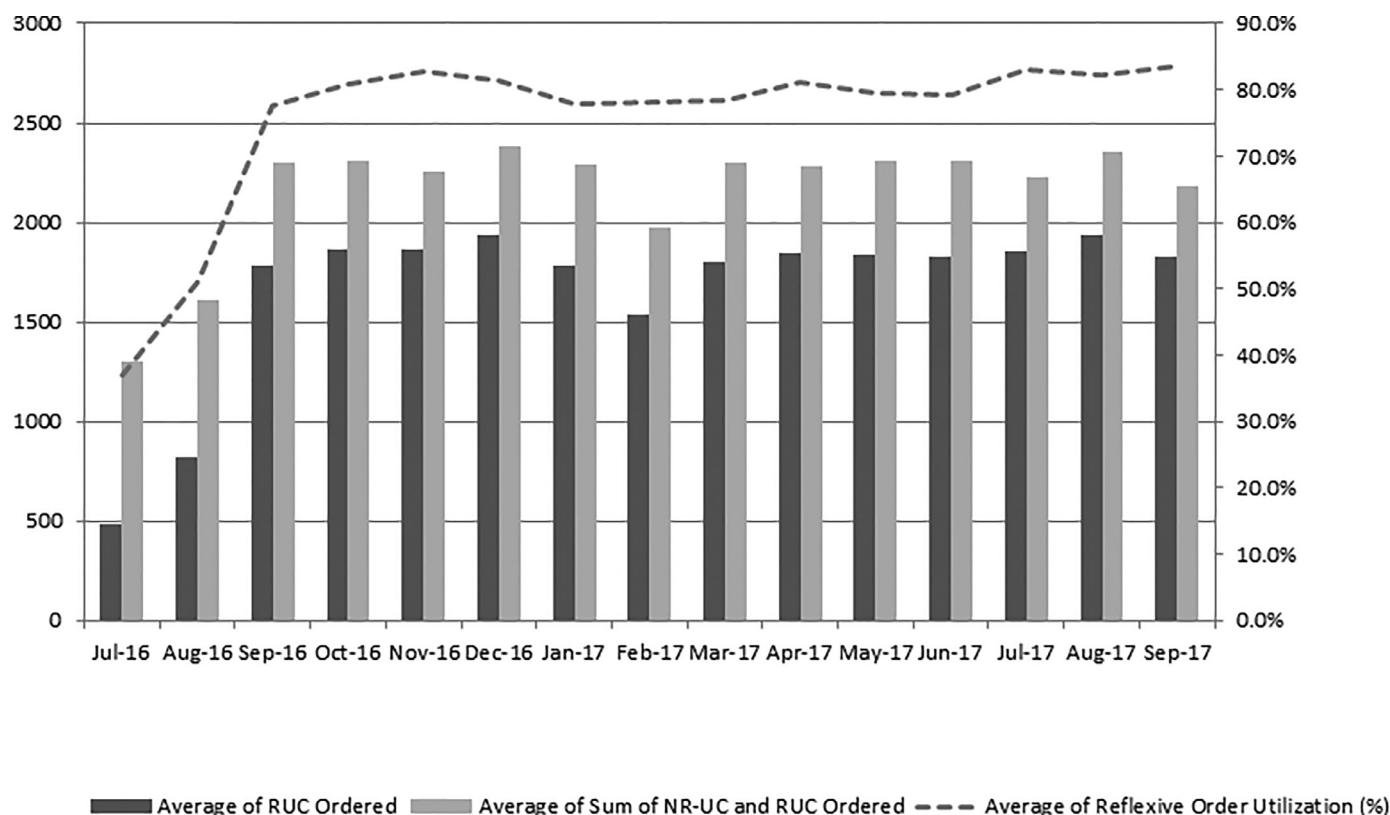


Fig 4. Reflexive urine culture order utilization, high exclusion units removed. NR-UC, non-reflexive urine cultures; RUC, reflexive urine cultures.

shown that even with a higher threshold for pyuria ( $\geq 10$  WBC/HPF), the false omission rate remains relatively low (3.5%–4.7%).<sup>8,14</sup> There have also been some concerns regarding the use of pyuria as a predictor for UTI in catheterized patients. In a study of 761 catheterized patients, the NPV for pyuria ( $>10$  WBC/HPF) was 90.5%.<sup>15</sup> Another study that analyzed 300 urine specimens from 106 catheterized patients showed a NPV for pyuria ( $>10$  WBC/HPF) of 92%.<sup>16</sup>

There are several limitations to the current study. It was conducted at a single center, and the intervention could have had a different effect in other patient populations. Additionally, there is no gold standard definition for a contaminated urine culture, so the

urine culture contamination dashboard may have included some true infections or missed some contaminated cultures that grew a single pathogen. This study was also limited to the inpatient setting. There are currently insufficient data regarding use of the reflexive urine culture in the outpatient setting, although studies have noted that there is utility for the reflexive urine culture to reduce unnecessary urine cultures in the emergency department setting.<sup>8,14</sup> Although this study was conducted with a retrospective database, the reporting of reflexive and non-reflexive urine culture data was accurately recorded in the electronic medical record system so that the retrospective nature of this study was not a major limitation.

Table 2

Analysis of urine cultures ordered by clinicians who noted patients met exclusion criteria for the reflexive urine culture order (random 10% sample)

Patient characteristics that did not meet order exclusion criteria	No. of patients that met exclusion criteria upon chart review (n = 86; 21.3%)	No. of patients that did not meet exclusion criteria (n = 317; 78.7%)	Total patients not meeting exclusion criteria*
No immunosuppression, solid organ, or stem cell transplantation or genitourinary anatomic abnormality—	—	161	50.8%
Immunodeficiency syndrome (not HIV/AIDS)	—	1	0.3%
Active malignancy/chemotherapy but not neutropenic with ANC < 100	—	54	17.1%
Rheumatologic/autoimmune condition on immunosuppression (prednisone 5 mg daily or greater)	—	15	4.8%
HIV/AIDS, not neutropenic	—	7	2.2%
Genitourinary anatomic abnormality/chronic catheter/intermittent self-catheter/neurogenic bladder	—	32	10.2%
Solid organ transplant recipient	—	50	15.9%
Admitted in preparation for solid organ transplant	—	9	2.9%
Stem cell transplant recipient	—	3	1.0%
Female gender	—	168	53.0%
Age > 60 y	—	137	43.2%

ANC, absolute neutrophil count.

\*15 patients qualified for multiple characteristics, so percentages do not add up to 100%.

## CONCLUSIONS

The urine culture standardization program that included a U/A with reflexive urine culture order was effective in preventing a large number of unnecessary urine cultures and, presumably, the subsequent harm related to such cultures. Despite ensuring that every non-exempted urine culture had an associated U/A, the program also did not significantly affect U/A testing rates. The standardization procedures used did not have a significant effect on urine culture contamination rates or CAUTI rates, although there were slight changes in these rates either prior to or after implementation. Further studies are needed to determine the impact of use of a reflexive urine culture in the outpatient setting.

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