Educational In-Service on a Pre-Analytic Diagnostic Stewardship Protocol to Reduce Urine Contamination: A Quality Improvement Project

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Abstract

Background: Urine contamination is a widely established clinical problem that can generate unreliable results leading to misdiagnosis and improper or delayed treatments. Diagnostic stewardship programs focus on the pre-analytic phase with an aim to improve patient outcomes by reducing contamination rates and improving specimen collection and processing.
Methods: Utilizing Edward Deming's Plan-Do-Study-Act model for quality improvement, a retrospective chart review was conducted to evaluate if an educational in-service, introducing a 3-step pre-analytic diagnostic stewardship protocol, would affect the rates of urine contamination. Data collected was analyzed by a pre- and post-implementation method using Chi-Square test for independence.
Results: This project did not demonstrate a significant relationship between educational in-services on a pre-analytic protocol, and urinalysis contamination rates, (χ^2 (1, n = 1303) = .01, p = .93, *phi* = -.01). However, there was a significance association identified amongst culture contamination rates and implementation of such education sessions (χ^2 (1, n=791) = 3.78, p = 0.05, *phi* = -.07).
Conclusion: This project demonstrates that education can reduce urine contamination rates. These results, and those previously published in the literature, suggest that education in addition to mandating a pre-analytic protocol can prove to be both statistically and clinically significant. Future projects that have the ability to evaluate such combined methods may deliver a larger clinical impact.

Keywords: Urine collection, Urinalysis, Urine culture, contamination, diagnostic stewardship, pre-analytic, evidenced-based practice, specimen collection, specimen handling

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Urinary tract infection (UTI) is a bacterial infection involving any part of the urinary system including the kidneys, ureters, bladder, and urethra (National Kidney Foundation [NFK], 2016). In the United States UTI is one of the most common infections diagnosed (LaRocco et al., 2016). It is the fourth leading diagnosis in women over the age of 65 (Pallin et al., 2014). UTIs account for nearly 10 million healthcare visits and over 100,000 hospitalizations yearly, with an estimated financial burden of over $2 billion per year (NKF, 2016).

A urinalysis (UA) provides a microscopic evaluation of the chemical and molecular components within the urine (NKF, 2016). UA testing provides immediate results and is the most frequent specimen presented to the laboratory for analysis (Eley, Judge, Knight, Dimeski, & Sinnott, 2016). If a UTI is diagnosed via UA, a urine culture (UC) would be recommended to identify and quantify specific microorganisms present and provide antibiotic sensitivities to best guide treatment (LaRocco et al., 2016). Unlike UA, a UC may take up to three days to result.

Problem Description

Within a mid-Atlantic 176-bed non-profit community hospital hospitalist service, admitting nearly 10,000 patients yearly, it was identified that a large portion of UCs were contaminated and resulted no beneficial information for in-patient care, diagnoses, or treatments. UA contamination with excessive epithelial cell counts was also identified, prompting investigations and planning into a quality improvement initiative to reduce overall UA and UC contamination rates. Based on the concept that most admission workups are initiated in the emergency department (ED), a departmental specific focus was introduced to evaluate areas for improvement and change. After evaluation of the entire spectrum of urine testing from ordering

behaviors, collection practices, and result interpretations, the focus remained on the pre-analytic phase and improving collection technique and processes prior to laboratory analysis.

There are a number of pre-analytical steps taken to collect and maintain a valid urine sample for analysis. These steps include proper collection technique, labeling of specimen, and handling of the sample for analysis. Urine can be collected by different techniques including a voided clean-catch, catheterization, or a suprapubic puncture (Jackson, Dryden, Gillett, Kearney, & Weatherall, 2005). Since the late 1950s a voided mid-stream clean-catch (MSCC) method has been the most ideal collection technique for urine testing (Lifshitz & Kramer, 2000). It is a self-collected sample that provides the least amount of procedural risk for the patient; this compared to a catheterized or suprapubic collection method that achieves obtaining a sterile sample but can also increase the risk of procedural complications and associated infection.

More prevalent in women than men, urine specimens are prone to contamination due to a breakdown of any pre-analytical phase. Contamination can come from perineal, vaginal, fecal, or skin flora during the collection process (Jackson et al., 2005). Specimen contamination can lead to an incorrect diagnosis of UTI and "premature closure" of the case (Pallin et al., 2014). This misdiagnosis can result in unnecessary antibiotic use, subjecting the patient to adverse reactions and increase risk for additional complications (Frazee, Enriquez, Ng, & Alter, 2015). Klausing, Tillman, Wright, & Talbot (2016) performed a non-experimental, chart review that identified a significant rise in adverse effects due to urine contamination including inappropriate admissions, unnecessary antibiotic use, antibiotic-associated organ dysfunction, and additional financial strains already overshadowing the healthcare system. Dolan and Cornish (2013) revealed that reducing contamination rates in just one year showed a system savings of over $32,000 in laboratory fees and $750,000 in unnecessary antibiotic use.

Antibiotic stewardship programs (ASPs) are collaborative teams created within the hospital that focus on post-analytic processes to aid in laboratory result interpretations and treatment guidelines surrounding antibiotic use (Claeys, Blanco, Morgan, Leekha, & Sullivan, 2019). There are a vast number of ASPs within healthcare that evaluate ways to reduce unnecessary antibiotic use. Multidrug resistant organisms (MDRO) are developing rapidly due to overuse of antibiotics. In addition to MDRO, other adverse effects from antibiotics have been well documented including allergic reactions, organ failure, and development of *Clostridium difficile* infectious diarrhea, all of which can lead to serious injury including death of the patient.

More recently, diagnostic stewardship programs (DSPs) are becoming widespread and target the pre-analytic period. Each program, used separately or in a combined approach for urine testing, has been used to develop methods to reduce excessive ordering, lower contamination rates, and decrease unnecessary antibiotic prescribing (Claeys et al., 2019).

A misstep at any level of the pre-analytic pathway can lead to increased false-positive rates, misdiagnosis, and inappropriate antibiotic use. Therefore, close attention must be given to the accuracy in collection and processing of the urine sample. These pre-analytic steps include proper urine collection technique, correct labeling, and appropriate handling of the specimen prior to laboratory analysis.

Frazee et al. (2015) noted an alarming 87% of Emergency Department (ED) patients reported that they received no instructions from staff regarding steps of collection of MSCC. Pallin et al. (2014) found that even when provided with education, only approximately 6% of the patients performed the procedure correctly. This resulted 94% inaccurately collected specimens, thereby increasing the risk for contamination. Urine contamination is a challenge for many providers and patients, especially for those within the ED. Compared to a UA, a UC is the gold

standard diagnostic test for a UTI (Schmiemann, Kniehl, Gebhardt, Matejczyk, & Hummers-Pradier, 2010). The ED provider must rely on information gathered during the patients brief ED visit, therefore the quick turnaround time provided by a UA is crucial for efficient care (Gordon, Waxman, Ragsdale, & Mermel, 2013). The consequences of reporting inaccurate and contaminated UA results in the ED are costly and potentially detrimental to both the patient and healthcare system (Dolan & Cornish, 2013).

Gordon et al. (2013) identified 43% of patients diagnosed with UTI in the ED by UA had a negative culture, representing a false-positive UA associated with contamination. The interpretation of both the UA and UC can also be difficult for the provider. Multiple resources utilize different approaches to interpret both UAs and UCs for a UTI diagnosis, leaving some of the interpretation to the provider's clinical judgment.

High quality and uncontaminated specimens provide dependable results a provider can use for clinical decision-making regarding diagnosis and treatment. While a UC provides the ultimate identification of true UTI versus contamination, it is not utilized in the ED setting, as its untimely results are not conducive for the speedy throughput required of the ED. The UA, while providing necessary in-the-moment results, has limited interpretive ability to determine contamination versus infection, thereby making it essential to ensure specimens are collected and processed appropriately. Specimen contamination does not mean that a patient is without a UTI, but rather that the specimen, and therefore diagnosis, is unreliable.

Available Knowledge

A detailed evaluation of the literature at each stage of the pre-analytic process was preformed to identify areas for improvement that would lead to higher quality specimens and accuracy in the

diagnosis of UTI. In addition, a review of recommended diagnostic criteria was also evaluated to help aid in determining infection versus contamination results of UA and UC.

A comprehensive literature search was performed using PubMed, CINAHL, and Cochrane databases. If the individual database would allow, specific inclusionary criteria were used including human subjects, English language, full-text availability, and adults age 18 years and older. Year of publication was not restricted as hallmarks in current standard of care guidelines are far dated. Search terms including "urin*", "contaminat*", "specimen collection", and "culture" were used. Medical subject heading "specimen handling" was also utilized within the searches. For the gray literature search, additional terms included "antibiotic stewardship" and "diagnostic stewardship". The use of Google Scholar, Internet search engines, and exploration of national organization websites revealed additional guidelines specific to the proposed question.

After complete review of the above databases and a broader Internet search, a total of 137 articles were collected. The reduction screening process of articles for final utilization is displayed by the PRISMA flow diagram in *Figure* 1. Articles were excluded based on clinical setting, targeted age, primary language, unrelated topic, and if not original research. Ultimately a total of 19 references were used for this literature review; 15 qualitative studies and 4 additional best practice recommendations.

Johns Hopkins evidence-based practice guide, *Evidence Level and Quality Guide*, was used for reference quality grading for each article (Dearholt, Dang, & Sigma Theta-Tau International, 2012). Quality grading was categorized by five levels and three subcategories. Tables 1 and 2 both display the accredited level of evidence for each referenced work. Levels I-V identifies the evidence level by type of study or work that the reference represents. Level I

include experimental studies, randomized control trials (RCT), and systemic reviews. Level II represents quasi-experimental studies. Level III incorporates non-experimental, and qualitative studies. Those studies that are considered clinical practice guidelines are included in level IV. Finally, literature reviews, QI, and case reports represent level V. Subcategories A and B for level I – III identify quality of the reference denoted as high, good, or low quality, respectfully. All studies were categorized as A or B. Quality A was considered for works consistent and generalizable with sufficient sample size and adequate control. Quality B represents those works that still provide sufficient and consistent results, but may not be considered as strong as those in group A. For levels IV and V similar high, good, and low-level quality grading was applied, however, given these works were not research different grading criteria was used. For these levels on quality B evidence was found. Quality B represents works yielding clear objectives, consistent results, and material is sponsored by professional agencies.

The qualitative synthesis yielded 15 total studies that were incorporated in the review and analyzed in Table 1, including one meta-analysis, four randomized control trials (RCTs), one experimental non-random study, three prospective cohort studies, three quasi-experimental, and three non-experimental studies. These studies were selected based on relatability to the primary topic of interest, primary language, and if they were original research. The search also yielded four additional references including three best practice reviews and one national guideline related to the topic of interest (Table 2). Specific attention within the literature was placed on each pre-analytic phase including urine collection techniques, specimen labeling, and specimen handling prior to analysis.

Urine collection technique. Five articles focused on evaluating labia cleansing in women as a way to reduce urine specimen contamination. Blake and Doherty (2006) and

Lifshitz and Kramer (2000) both found no significant difference in contamination rates when evaluating perineal cleansing versus no cleansing prior to collection. A systematic review with meta-analysis by Larocco et al. (2016) included four observational studies and one RCT (one of each is included in this literature review) and concluded that there is no significant difference in the odds of contamination between cleansing or not, before a mid-stream collection. While there was no difference in UC contamination seen, Selek et al. (2017) did find a significant rise in UA contamination when not cleansed. Holiday, Strike, & Masterton (1991) were the only authors that showed a significant reduction in contamination rates of UCs when patients cleanse the labia.

Two articles evaluated the process of labia spreading before specimen collection. Lifshitz & Kramer (2000) found no significant difference in contamination rates between patients that performed labia spreading and those that did not. Frazee et al. (2015) compared UA and UC contamination rates between an initial void through un-spread labia versus mid-stream collection after spreading of the labia. The authors found no difference in culture contamination; however, they did find a significant increase in UA epithelial cell counts when labia were not spread prior to collection. It is unclear if the additional first-void versus mid-stream aspect of their intervention may have also had effects on the results.

Four total articles evaluated the differences in contamination rates between patients who provided a standard MSCC urine specimen versus those that were catheterized. Although the overall body of evidence was identified as "low" by the authors, Larocco et al. (2016) concluded no significant difference between MSCC and catheterized specimens. Similarly, Guss et al. (1985) showed no significant difference between MSCC and catheterized urines, but only when they eliminated female patients that were menstruating. Contrary to these studies, Pallin et al.

(2014) and Gordon et al. (2013) both found that MSCC yielded higher UC contamination rates and higher false-positive UA results. However, both articles note that catheterization procedure was less ideal for all patients due to patient discomfort and unclear risk of bacterial introduction into the bladder, thus catheterization was not recommended as the initial gold standard collection technique unless true MSCC could not be performed.

A number of alternative collection devices have been evaluated to promote reductions in contamination rates. Jackson et al. (2005) evaluated the use of a specialized urine collection device (UCD) that eliminates the patients need to comprehend a "mid-stream" collection by self-discarding the first void while simultaneously, without addition efforts from the patient, collects a true MSCC in an attached sterile container. They did find a significant reduction in contamination rates using the UCD compared to the standard MSCC technique.

Patient directed educational interventions on how to properly collect MSCC urine samples were evaluated by three different groups of authors. Jacob et al. (2018) evaluated the use of an instructional video in the ED to help patients visualize the proper technique for MSCC collection but found no significant difference in either UA or UC contamination rates. Similarly, the use of an instructional poster on the restroom wall revealed no significant difference in UC contamination rates seen in studies by Maher, Brown, and Gatewood (2017) and Eley et al. (2016). However, Eley et al. (2016) did find a significant reduction in UA contamination, specifically regarding epithelial counts, with the use of an instructional poster.

Dolan and Cornish (2013) performed a QI project evaluating the use of a pre-analytical protocol to help reduce contamination rates. They evaluated three areas of clinical practice including specimen collection, specimen labeling, and transportation/storage of specimen. In regard to specimen collection, specific to this review, they found a decrease in contamination

rates when implementing a MSCC with cleansing or collecting a mid-stream catheterized specimen using a straight-catheter device instead of a quick-cath pre-attached system. Pallin et al. (2014) also proposed a pre-analytical 8-step protocol aimed at improving ordering styles, collection technique, laboratory interpretations, and treatment practices. As noted earlier, they identified that certain populations may not be able to perform MSCC accurately and may need collection by other means (ie: straight catheterization), but recommend MSCC with good instructions as the most ideal method of collection technique.

The gray literature identified additional best practice and national guidelines and is fully summarized in Table 2. Although not entirely specific to the collection technique process, the Society for Post-Acute and Long-term Care Medicine recommends against obtaining a UC unless there are clear signs and symptoms consistent with UTI since asymptomatic bacteriuria (ABU) is prevalent in long term care facility patients (American Medical Directors Association [AMDA], 2017). Ideal urine collection technique in women is a mid-stream, cleansed, with labia spreading specimen. Men should provide a mid-stream, with or without cleansing, after retraction of foreskin if uncircumcised (Meyrier, 2017). Similarly, a systematic review by Schmiemann et al. (2010) with meta-analysis, identified the gold standard of urine collection is a cleansed MSCC specimen in both men and women. Claeys et al. (2019) also supports cleansing before MSCC in their best practice recommendations. Finally, Harrington's (2014) literature review recommends using photographs during patient education to help reduce contamination. They also support the use of a sterile container for collection, as opposed to a bedpan, urinal, or catheter bag.

Specimen handling. One meta-analysis, two literature reviews, and one non-experimental QI project identified best practice recommendations for specimen handling after

collection, specifically looking at the time between collection and refrigeration for storage, if analysis is not preformed immediately. All articles identified that prolonged time at room temperature increased risk for organism overgrowth leading to higher rate of false-positive and contaminated results. Many common bacterial organisms will more than double in colony counts in as little as 20 minutes when kept at room temperature (Dolan & Cornish, 2013). The use of preservatives, such as boric acid, have shown to extend the shelf life of the urine specimen. LaRocco et al. (2016) meta-analysis revealed that boric acid preservative could allow up to 24 hours of safe storing before processing without significant differences in bacterial overgrowth rates. They also acknowledge national recommendations, by both the American Society of Microbiology and Infectious Disease Society of America, for immediate refrigeration after collection. Claeys et al. (2019) literature review concluded that a 2-hour limit be placed on unpreserved and unrefrigerated urine specimen storage at room temperature before overgrowth was significantly shown. Harrington's (2014) literature review recommended that a specimen must be refrigerated within two hours after collection. She further noted that specimen refrigeration was only appropriate for up to 24-hours. Based on evidence that organism replication begins within 20 minutes, Dolan and Cornish (2013) utilized a QI protocol that if unpreserved specimens were not received in the laboratory for analysis within 15 minutes of specimen collection time, that the specimens be rejected due to risk for bacterial overgrowth.

Specimen labeling. Once a specimen has been collected and placed in the appropriate container, the labeling process begins. Staff must correctly identify the patient, specimen, and collection technique on the label. While UA results are interpreted the same regardless of collection technique, UC results are construed differently with distinct organism colony counts identifying true infection based on collection method. The number of acceptable colony counts

is different based on collection method, specifically those collected via MSCC versus catheterization. Therefore, proper labeling is vital for the process of urine analysis to ensure the most accurate results provided. Dolan and Cornish (2013) recommended any failure of labeling process must prompt laboratory rejection of the specimen.

Diagnostic interpretation. Similar to many other diagnostic practices, interpretation of a UA or UC requires both laboratory knowledge and clinical judgment. The human body is comprised of a diverse microbial flora throughout all skin and mucous membrane areas, especially in the genitourinary region. As demonstrated previously, the importance of a valid urine specimen without the collection of normal microbial flora in or around the urethra is vital for accurate reporting and diagnosing.

Specific to UA results, presence of epithelial cells can increase the concern for contamination. Epithelial cells are a type of skin cell that lines the surface of the body. UA interpretation for UTI is commonly based on the presence of Leukocyte esterase, bacteria, nitrates, and white blood cell counts (WBCs). An elevated number of epithelial cells in a sample can skew any of these results, making reliable interpretation and diagnosing a challenge. Two studies utilized epithelial cell counts as a marker for UA contamination. Maher et al. (2017) preformed a study comparing MSCC to catheterized specimens and utilized an epithelial count of >5 cells per high-powered field (hpf) represented a contaminated UA. Eley et al. (2016) preformed a study evaluating illustrations for patient education during MSCC and used a broader epithelial count of >10 cells/hpf. The presence of epithelial cells does not indicate absence of UTI, but makes the sample unreliable for accurate interpretation and increases risk for culture contamination.

Diagnosis of UTIs via UA is clinically driven and evidence supports that patients should have signs and symptoms of urogenital infection, in combination with specific molecular properties of the UA for appropriate diagnosis (Pallin et al., 2014). Three studies utilized similar interpretations for positive UTI via UA. Pallin et al. (2014) and Gordon et al. (2013) both used a criteria for UTI including any combination of the presence of nitrates, leukocyte esterase, bacteria, and >10 WBCs/hpf. Dolan and Cornish (2013) also used similar criteria but did not include presence of bacteria within their diagnosis.

UCs have a more complicated interpretive process and numerous references utilize a range of diagnostic criteria for UTI versus contamination. Table 3 displays the nine studies utilized in this review that specifically defined contamination and infection based on specific quantitative analysis of the colony forming units (CFUs) of bacterial organisms. While most confirm a diagnosis of UTI with two or less organisms growing $\geq 10^5$ CFUs/mL, evidence does suggest that some organism growth is significant with counts as low as 10^2 CFU/mL (Holliday, Strike, & Masterton, 1991; Palin et al., 2014; Gordon et al., 2013). The method of urine collection also effects the interpretation of the UC results. A catheterized specimen, which ideally provides a sterile specimen, will at times yield fewer CFU/mL. This compared to the MSCC that is not sterile but "clean", has a higher risk of contamination and commonly holds a larger CFU growth count in most studies (Table 3). For purposes of this project, CFUs were not obtainable during data collection, thus true infection was considered present if ≤ 2 organisms were identified.

Gaps in literature. Despite the significant amount of evidence addressing the issue of urine contamination and the effects of misdiagnosis and inappropriate antibiotic use, a clear resolution has yet to be established. Furthermore, while each phase of the pre-analytical process

is dependent on the other, numerous studies only look at individual approaches evaluating a single step. There is a lack of research evaluating a combined approach utilizing all steps. Replicating a combined approach project could provide stronger evidence-based practice recommendations in the area of urine collection and analysis.

The extensive literature review for this project provided primarily levels I-III B quality evidence-based practice (EBP) results, see Table 1 and 2. This signifying that much of the available evidence around urine contamination reduction and EBP recommendations are good but not consistent. Additional studies that can replicate or add to the growing body of scientific evidence are needed.

Interpretation criteria for UA or UC results are complicated and a gold standard recommendation has yet to be established. Numerous studies utilize different molecular counts within the UA and quantitative colony counts in the UC for interpretation of infection and contamination. A more standardized approach nationwide would reduce diagnosis inconsistencies and misinterpretations.

Rationale

Theoretical framework. Change and quality improvement are fundamental elements of health care and are often complex. W. Edwards Deming, a distinguished scholar and academic teacher, is well known for his involvement during the post-world war II era aiding Japan in their business and economic transformation, specifically teaching managers and engineers how to work and learn together. He is known as a "master of continual improvement of quality" (*The W. Edwards Deming Institute*, 2020). In the 1950s, Dr. Deming introduced the 'Deming Wheel' cycle, a modified version of his long time mentor, Dr. Walter A. Shewhart's 'The Shewhart Cycle', later coined as the Plan-Do-Check-Act (PDCA) cycle (Moen, 2009, September). Dr.

Deming's 'The Deming Wheel' made changes to the earlier framework highlighting specific emphasis on a study period which can lead to additional change at any stage. In 1990s, this framework was termed Plan-Do-Study-Act (PDSA) model for quality improvement. In his 1982 book titled *Out of the Crisis*, Dr. Deming wrote, "The reason to study the results of a change is to learn how to improve tomorrow's product, or next year's crop." (Deming, 1982, p. 88). Unlike his mentor's model that focused primarily on a success or failure outcome, Dr. Deming's emphasis on step-3 "study" focuses more on implementation of change by evaluating results, developing new knowledge, and then comparing this knowledge and findings to implement permanent change or revise the initial plan/theory (Moen, 2009, September).

The four steps of the quality improvement PDSA model include Plan, Do, Study, Act. The *Plan* step involves identifying goals, purpose, and theory aimed at improving quality of work or outcomes. This is followed by the *Do* step which incorporates implementation of a proposed quality improvement theory or project. The *Study* step involves evaluation of data, results, and development of knowledge about these findings. The *Study* step also involves identification of additional problems and other areas of improvement. The final *Act* step includes an integration of all steps to adjust the goal, create permanent change, or reformat the original plan. The entire 4-step process is meant to be repeated over and over again as a continuous sequence of ongoing improvement and learning (*The W. Edwards Deming Institute*, 2020).

Figure 2 illustrates the use of Dr. Deming's PDSA model as applied to this project. The use of the 4-step PDSA model within this QI project provided direction and theoretical application in identifying urine contamination rates as a problem within the healthcare system, formulating an action plan for process change with specific goal of contamination rate reduction,

implementation of education and practice change within the emergency department, and evaluation of data by identifying successes and detecting additional areas for improvement. Finally, the PDSA model helped in formulating a revised plan and provided indication for future research and quality improvement opportunities, all for the purpose of improved patient care and outcomes.

Specific Aim

The aim of this project was to improve the current standard practice within the three phases of the pre-analytic process of urine collection, with a specific goal of reducing UA and UC contamination rates. This QI project evaluated the effects on UA and UC contamination rates using education on a 3-step pre-analytic diagnostic protocol that focused on collection, labeling, and handling of the specimen prior to laboratory analysis. Secondary gains of this project included improved diagnostic accuracy of urine specimens, reduced adverse outcomes from misdiagnosis, and decreased inappropriate antibiotic use. An assessment of each stage of the pre-analytic phase was performed to provide evidence-based practice recommendations during staff education in-services for urine collection technique, labeling, and specimen handling with the ultimate aim of reducing contamination rates.

Quality Improvement Question

In the adult patient population treated in a mid-Atlantic community hospital ED setting, who have both UA and UC testing ordered, will providing an educational in-service to nursing and ancillary staff on a 3-step pre-analytic diagnostic stewardship protocol effect the rates of specimen contamination when compared to the current standard clinical practice?

Methods

Context

This 176-bed non-profit community hospital is located in the mid-Atlantic region of the United States and admits approximately 10,000 patients yearly. Servicing the demands of the surrounding community, this community hospital has two primary EDs. The main ED, attached physically to the hospital, has 24 treatment beds. An off-campus, Free-Standing ED (FSED), provides an additional 13 beds. Collectively, they evaluate approximately 50,000 patients yearly.

Combined, the FSED and main ED analyze approximately 500-800 UAs and 100-150 UCs weekly. Given this volume of testing, when a UA or UC is contaminated and deemed unreliable or unhelpful in decision making related to patient care, this can easily lead to financial loss and additional costs for both the hospital and patient.

Intervention

This community hospital utilizes an organization-wide Epic charting system, which was used as the method of data collection for this project. Due to the time restrictions of this project, mandating changes within Epic to monitor compliance with the 3-step pre-analytic protocol was not feasible. To overcome this limitation, an educational intervention was formulated with the purpose of refining staff knowledge, improving the process of specimen collection and handling, and reducing contamination rates.

UTI committee. As part of the initial action plan, a multidisciplinary UTI committee was formed. Primarily made of members of the hospital Antibiotic Stewardship committee, members of the UTI committee included a Hospitalist nurse practitioner and physician, an Infectious Disease physician, an Infectious Disease coordinator, the Hospital Medical Director, a laboratory technician, and a pharmacist. The primary purpose of the meetings was to have open

dialogue, gain feedback on the protocol, evidence review, implementation practices, and clarify definition of terms. The committee met a total of three times prior to implementation.

To better comprehend the protocol, implementation process, and results specific to this project, numerous terms and definitions were required. The terminology used is based on the literature reviewed, feedback during UTI committee meetings, and formulated specifically for this QI project. A complete list of the definition of terms can be viewed in Appendix A: Definition of Terms.

3-Step Pre-analytic Protocol. The pre-analytic diagnostic protocol consists of three steps. The urine specimen collection phase of the protocol emphasized high quality collection technique performance via MSCC and indwelling or intermittent catheterization. The education sessions established clear guidelines surrounding collection via all methods, thereby ensuring staff possessed proper understanding for technique performance and to assist with educating patients. For MSCC, patient education performed by staff must be sufficient for the patient to comprehend the steps involved and to ensure suitable collection. For this project, MSCC was defined as a patient-collected sample obtained by retraction of the foreskin or labia, cleansing the urethral opening and surrounding skin with the antiseptic cloth provided in the collection kit, and ultimately collecting a mid-stream voided sample directly into a sterile container. The use of collection hats and urinals was discouraged, when possible, as these devices are not sterile, can cause environmental contamination, and lessen the odds of collecting a mid-stream specimen because the patient voids directly into them from the beginning. For the catheterized specimen, emphasis was placed on collection of the mid-stream sample when placing an indwelling foley catheter, and collecting urine from the device port, not the collection bag. A mid-stream

intermittent catheterized sample was not possible due to the design of the collection kit supplied at this facility.

The second phase of the protocol involved specimen handling. Specifically, this phase established an allocated timeframe between collection and transfer of the urine specimen into a preservative-base container. This hospital utilizes a prepackaged urine specimen collection kit that includes a standard sterile cup and preservative-based vacuum-sealed test tubes that urine must be transferred into before sending to the laboratory. This step emphasized a 30-minute window of opportunity, following urine collection, for transfer of urine into the preservative-base tubes. If a specimen was longer than the designated 30-minutes, the specimen must be discarded and is deemed inappropriate for further laboratory analysis. For this phase, staff were provided individual mini-markers and instructed to write the current time on the urine specimen cup. This aided in identification of the start of the 30-minute time limit.

The third and final phase of the protocol encompassed correct labeling of the specimen. This includes reiteration of the standard practice for specimen labeling including right patient, specimen, date, and time. Urine cultures are reported and interpreted differently depending on the method of collection, thus emphasis during the education session was placed on ensuring the collection technique used was appropriately identified on the label within Epic before printing. This is currently a commonly overlooked step because it is not a required data field in Epic and many times, depending on the order, defaults to a MSCC collection technique. System-wide processes are presently underway to make this a required field or “hard-stop" during labeling to ensure staff designate the correct collection technique, however, this was not a required field during this project time period.

Educational In-Services. The main ED and FSED staff were required to attend one of two mandatory department skills day, which included a 30-minute educational in-service on this protocol. The sessions were scheduled on September 18th and 26th, with a "go-live" date of September 29th. Due to unanticipated hospital staffing circumstances, the September 26th session was canceled and rescheduled for a date outside of the time constraints of this project. To accommodate for this, a more formative assessment approach was utilized, and the original design was altered. The remainder of staff who were scheduled for the September 26th session were educated during pre-shift huddles and on-site in-services.

The in-person mandatory 30-minute educational session included background findings illustrating the current problem of UA and UC contamination, the impact of contamination on patient care and treatment, the correct method of MSCC and catheterized collections, and review of the 3-step protocol for collecting, labeling, and handling of urine specimens. Additional time was allocated to allow for discussions of the implications for nursing for improved quality of care. For the remainder of the staff who were not able to attend the 30-minute presentation, brief but regular on-site in-services were provided. In-services were also held during shift change huddles, providing consistent 10-minute sessions for review of the protocol, importance of collecting quality specimens, and to allow for questions.

A handheld laminated reference card was created for staff to use as a quick reference guide. The card, displayed in *Figure 3*, was dispensed during all the education sessions and displayed at every computer desk throughout both EDs. The card contained condensed information on each phase of the pre-analytical process. The urine collection section incorporated the evidence-based standards for collection techniques for both MSCC and catheterized specimen collections. Outlined criteria that may constitute a catheterization instead

of a MSCC was also included. If a catheterized specimen is deemed more appropriate for a specific patient, then per hospital policy staff must obtain approval from an appropriate provider. The handling section of the card reiterated the importance of placing urine samples in the preservative-base testing tubes within 30-minutes of collection, otherwise it must be discarded and recollected. Lastly, the specimen labeling portion reminded staff to change the collection method within Epic prior to printing the label, to ensure the correct method of collection technique was identified for laboratory personnel accurately.

Study of the Intervention

A retrospective chart review QI project was conducted in the ED utilizing staff education on a 3-step pre-analytic diagnostic stewardship protocol and evaluation of the effects this education had on reducing contamination rates of UA and UCs collected among the adult patient population. Preliminary data analysis and chart review was performed for the month of July 2019, prior to implementation, to establish baseline contamination rates with the current standard of care. On September 29, 2019, the project was considered "live" and post-implementation data collection began. Educational in-services were ongoing at the time of "go-live". The majority of clinical staff completed at least one of the educational sessions by October 13th. Data collection was preformed weekly during the 2-month post-implementation period, concluding on November 30, 2019.

Data collected was used to calculate the frequency of UA and UC contamination rates before and after project implementation. To assess for an existing relationship between education and rates of UA and UC contamination, Chi-Square test of independence was utilized. Based on Edward Deming's PDSA model mentioned above, additional correlations between different UA and UC interpretations were also analyzed to identify areas for future growth and

improvement. To limit any outside influences on data findings, the project was implemented during a period of time when no other process changes were being introduced in the ED.

Measures

Sample population. The sample population for this project was a convenience sample that included adult patients, age 18 years and older, who received care in one of the two EDs. Each patient must have had both a UA and subsequent UC test ordered and resulted to be included. Specimens included in this project excluded any other outpatient or inpatient samples. Only specimens collected via the MSCC or catheterized (foley or intermittent) methods were included. All other collection techniques were excluded. Additional exclusionary criteria included children (age 17 years or less), presence of an indwelling foley catheter upon arrival, presence of a suprapubic catheter, presence or placement of a percutaneous nephrostomy tube, or urinalysis obtained by any other method. UCs that grew yeast or candida were excluded, as the interpretation of true infection with these organism growths is controversial. Pregnant patients were also excluded from this project, as recommendations for treatment and result interpretation are more complicated and asymptomatic bacteriuria has higher prevalence.

Data. Basic demographic information was collected on each patient and displayed in Table 4. Day shift represents any specimen collected during the hours of 0700 and 1900, therefore any urine specimen collected between 1900 and 0700 was considered a night shift specimen. Additional variables included urine test ordered, collection method, and UA and UC results and interpretation and are displayed in Table 5. Collection technique was also obtained to identify trends in accurate labeling practices.

Specific organism growth and “no growth” results on UCs was considered a specimen not contaminated. Multiple organisms and mixed genital flora were both considered

contaminated UCs. UA results, displayed separately in Table 6, were analyzed individually for purpose of trending, and included epithelial cell count, leukocytes, white blood cells, and the presence of bacteria and nitrates. For UCs, CFUs were not obtainable by this data collection process. Thus, for purposes of this project if ≤2 organisms were present, it was considered a true infection. Given the wide range of UC diagnostic criteria, displayed in Table 3, this interpretation is appropriate for this style project. Frequencies of specific UC growth outcomes are displayed in Table 7.

Analysis

The Gantt chart depicted in *Figure 4* displays the timeline for this project including development, implementation, and data analysis. As previously mentioned, modifications to the initial intervention were required due to unforeseen cancelation of the mandatory staff education sessions and the lack of ability to mandate steps within Epic charting.

The primary goal of this project was to evaluate if contamination rates of UA and UCs are affected by the use of educational in-services introducing a 3-step pre-analytical protocol to improve specimen collection, labeling, and handling practices. Data was analyzed both by a pre- and post-implementation method, and with the months of October and November individually. This breakdown was to assess for trends and to account for the educational intervention modifications that delayed observed changes.

Post-implementation data was collected for nine weeks. After preliminary review and comparison of the data, a meeting with the statistician was held to ensure appropriate statistical analysis and tests were being utilized. Data analysis was completed using SPSS version 26.

On both the pre- and post-implementation datasets, frequency statistics of the categorical variables was performed. Additionally, the means and standard deviations of continuous

variables were calculated. Age for both groups was analyzed using independent t-test, and all assumptions were met.

Chi-square test for independence was used to determine if a relationship between categorical data existed. To accommodate for the ongoing educational sessions at the beginning of the implementation period, data analysis is presented as pre-implementation, post-implementation, October, and November time periods. This further exemplified trends in observed changes and aided in identifying clinical significance.

An alpha level of $< .05$ was used for statistical significance. The effect size was identified using phi coefficient or Cramer's *V* depending on categorical variables used, with effect size criteria .01 = small, .3 = medium, and .5 = large. Both statistical and clinical significance was reported.

Ethical Considerations

This project was performed within a non-academic, non-profit, community hospital setting. In accordance with this hospital's policy, approval via the divisional Nursing Research entity was obtained. As this is a QI project and does not involve human subject testing, specific Institutional Review Board approval was not necessary. Project approval for implementation and data collection was approved by the Nursing Research entity (See Appendix B). Protected health information (PHI) was kept confidential and stored on a hospital locked and secured hard drive. Once de-identified, data was placed into SPSS version 26 for further analysis.

Results

Demographic information is displayed in Table 4. A total of 369 adult patients who had UA results during an ED visit in pre-implementation period with subsequent UC results, were selected for the project based on additional inclusionary and exclusionary criteria mentioned

earlier. The mean age in July was 60.3 years (SD = 22.0) with range of 83. Of the 369 participants 71.5% (n = 264) were female. The majority (61.2%) of urines were collected during day shift hours (n = 226). Similarly, 73.7% (n = 272) were collected from the main ED.

For the post-implementation participants, a total of 934 patients were included in this project. The mean age of patients during the post-implementation period was 58.7 years (SD = 23.7) with range 86. Of the 934 patients, 71.7% were female (n = 668). The majority of urine specimens were collected during day shift (63.5%) and within the main ED (75.4%).

Using an independent samples t-test, there was no significant difference in the mean age for pre- (M = 60.3, SD 22.0) and post-implementation (M = 58.7, SD 23.7; t (721) = 1.16, p = .25, two-tailed). Using a chi-square test for independence, there is no significant difference between genders in the pre- and post-implementation groups, χ^2 (1, n= 1303) = .00, p = 1.00, *phi* = .00). Similarly, there is no significant association between Shift or ED visited and the implementation groups (χ^2 (1, 1303) = .48, p = .49, *phi* = -.02) (χ^2 (1, 1303) = .31, p = .58, *phi* = -.02).

As shown in Table 5, a chi-square test for independence indicates no significant association between UA contamination and implementation of educational in-services, χ^2 (1, n = 1303) = .01, p = .93, *phi* = -.01. Similarly, a chi-square test for independence also indicates no statistically significant association between UC contamination and the implementation of educational in-services overall, (χ^2 (1, n=1303) = .74, p = .39, *phi* = -.03). However, accounting for the staff educational differences between the two months during the post-implementation period, the data was analyzed separately by month. Using a chi-square test for independence, the data does show a statistically significance relationship exists between UC contamination rates

and education sessions during the month of November (χ^2 (1, n=791) = 3.78, p = 0.05, *phi* = -.07).

A chi-square test for independence did also indicate a significant association between collection technique documented and educational in-services, (χ^2 (1, n = 1303) = 7.59, p = 0.02, *phi* = 0.76). For the post-implementation period, the number of intermittent and indwelling foley catheterizations documented nearly doubled. In the pre-implementation period, there were 14 (3.8%) intermittent and 4 (1.1%) indwelling foley documented collected specimens. Following program implementation, intermittent catheterizations increased to 7.4% (n=69), and foley placements to 2.1% (n=24).

Table 6 displays the frequencies of the molecular characteristics of urinalysis results. The aim of this chart and data was to add to the body of knowledge of urinalysis trends and to correlate specific cellular findings with contaminated cultures. For the pre-implementation period 11.4% (n=42) of the specimens were contaminated by epithelial cell count >5 cells/hpf, as compared to 59.9% (n=221) that had epithelial cell counts <5cells/hpf. For the post-implementation period, 10.7% (n=45) specimens had epithelial cell counts >5 cells/hpf.

Specific bacterial growth was widespread on UCs and organism occurrences throughout the data collection periods and can be viewed in Table 7. Escherichia Coli was the most common organism growth identified, yielding 17.6% (n=65) and 32.5% (n=108) for the pre- and post-implementation periods, respectfully.

Table 8 illustrates the occurrence rate of UC contamination based on UA Epithelial cell counts for all participants combined throughout the study period (n = 1303). Using a chi-square test for independence in a 3x2 cross table, there was a significant association between epithelial cell counts and contaminated UCs, χ^2 (1, n=1303) = 33.25, p = .00, V = .16. Of the contaminated

UC specimens (n = 740), 14.9% (n = 106) yielded epithelial cell counts >5 cell/hpf and were considered contaminated in this project. However, specimens with epithelial cell count of 3-5 cell/hpf made up almost similarly 15.6% (n = 116) of the UC contaminated specimens. Of those that had epithelial cell counts 3-5 cells/hpf (n = 169), 68.6% of them were contaminated. The specimens with ≤2 cells/hpf, revealed 47.6% were not contaminated compared to 52.4% that were.

Discussion

Summary

Urine specimen contamination is a clinical problem both for the patient and the healthcare system as a whole. It adds not only to the financial burden of healthcare with additional costs for further and repeat labs, but also adds unnecessary risk to the patient with treatments and possible misdiagnoses. Within this community hospital setting, urine contamination was identified as a clinical problem, leading to unreliable and unhelpful test results.

Evidence-based practice supports the use of a 3-step pre-analytic approach to reducing urine contamination. Since a mandated protocol could not be created during the time constraints of this project, the primary intervention was to hold educational in-services for staff introducing a pre-analytic protocol concept and to evaluate the effects on UA and UC contamination rates. Following implementation of education sessions in the ED, several key findings emerged. The primary aim of the project was to evaluate if education would show reduction in urine specimen contamination rates. A test of homogeneity revealed no significant differences between the sample populations selected, allowing for an accurate and unbiased comparison. While there

was no significant change in UA contamination rates, a 7.1% reduction in the UC contamination rate was observed and has shown to be both clinically and statistically significant.

A significant change in the collection technique documented during the labeling process between the time periods also showed to be clinically significant. Documented intermittent and foley catherization occurrences, identified on the label, more than doubled for both post-implementation months.

Lower than expected epithelial cell counts represented a large portion of contaminated UCs. UA epithelial cell counts of >5cells/hpf were marked as contaminated for purposes of this project. However, over 50% of the samples that yielded epithelial counts of 3-5cells/hpf resulted in contaminated UCs. This is a significant clinical finding as it adds to the evidence of interpretation recommendations and practice guidelines.

Particular strengths of this project included the setting and sample size. The ED provided a stationary and convenient sample collection atmosphere. The volume of samples available for analysis added to the overall effects and strength of this project.

Interpretation

The significance of this project rests on the influences of the UC contamination rates and improving patient outcomes. *Figure 5* illustrates the clinical significance and the declining trends observed during the 1-month pre- and 9-week post-implementation periods for both UA and UC. The late effects and inconsistent rate changes that were initially observed in the beginning weeks of the project are possibly due to the delay in education to the entire staff. After the majority of staff had received the educational information, a downward trend in UC contamination rates was observed. The downward trend in UC rates suggests that the protocol in fact does influence and reduce contamination. However, if the protocol could be mandated in a

way to test for and ensure staff compliance, a more significant change and clinical impact could be observed. Dolan & Cornish (2013) were able to mandate their pre-analytic protocol and discard samples that were not properly collected, labeled, or handled. They were also able to show clinically significant reductions in contamination rates and an increase in financial savings after implementation of their project.

Collection technique in this project refers to what was identified on the label at the time of printing. Labels routinely default to MSCC automatically within Epic, unless the provider identified a specific alternative collection method at the time of order placement. Again, there was no method to establish if staff were compliant during the labeling process of the protocol, and Epic did not, at the time, provide a "hard stop" for inputting data manually. However, intermittent and foley catherization occurrences, identified on the label, more than doubled for both months consistently during the post-implementation period. One would argue that it is unlikely that the incidence of catheterized specimens increased, but rather that the knowledge gained during the implemented educational sessions influenced correct labeling practices. This would again add to the idea that creating an approach to mandate accurate labeling practices could contribute to more substantial reduction in contamination rates. Dolan & Cornish (2013) were able to implement a new IT facilitated electronic labeling program that included required elements to mandate compliance from nursing staff. Furthermore, they developed a rejection policy that if any element of the label was found incomplete or inaccurate, the specimen be discarded.

To illustrate trends, and add to evidence-based recommendations and practices, Table 8 depicts the occurrence rate of UC contamination based on Epithelial cell counts for all participants combined throughout the project, both pre- and post-intervention. The purpose of

this chart is to add further to the evidence supporting interpretation of UA and best practice recommendations to reduce UC contamination rates. For this project, an epithelial cell count >5 cells/hpf was used to identify UA contamination. This limit was also utilized by Maher et al. (2017) in their study comparing contamination rates of MSCC and catheterized specimens. Of the contaminated UC specimens in this project, 14.3% yielded epithelial cell counts >5 cell/hpf. However, specimens with epithelial cell count of 3-5 cell/hpf made up a similar, if not slightly more, 15.6% of the overall UC contaminated specimens. Of the urine specimens that had epithelial cell counts 3-5 cells/hpf 68.6% of them were contaminated. Those ≤2 cells/hpf did not show a clinically significant difference between being contaminated and not. This would suggest that interpretation of UA contamination be considered at lower epithelial cell counts of ≥3 cells/hpf. This is clinically significant because if the desirable purpose of the subsequent UC is to help guide therapy and treatment options for a presumed UTI diagnosis, a high risk of contamination may delay and hinder patient treatment. Utilizing a lower threshold for epithelial cell count interpreting a UA contamination will prompt an increase in recollection rates but can improve specimen quality and reliability before culturing.

Limitations

Limitations to this QI project include a short 2-month analysis time frame. Additional data collection time may have shown an increase in both clinical and statistical significance. Another limitation was the inability to measure staff compliance with the protocol. Some of the above statistical and clinical findings do support the use of education and the protocol, but again a more significant clinical impact may be observed if the protocol steps could be mandated and assessed for compliance. Staff participation and compliance with any protocol is key for accurate and comparable analyses.

Conclusions

The process of urine collection begins with nursing regardless of the collection technique used. Whether performing the tasks personally or delegating appropriately to PCTs, the nurse is the primary leader and holds the responsibility of ensuring proper standards are upheld. A more lenient approach, or lesser standards can place the patient in a vulnerable situation, increasing risk for misdiagnosis and other complications associated with urine specimen contamination. This is a significant responsibility for nursing and highlights the impact nursing has on the quality of urine specimens obtained.

The application, dependability, and sustainability of this project and standards of urine collection are nurse driven. This QI project emphasizes the necessity for a high-quality standard of care and effective nursing education. The precise and standardized collection of a urine sample, accurate labeling, and consistent specimen handling procedures demonstrate the significant influence nursing has on the quality of patient care and outcomes.

This project identifies numerous advantages and disadvantages to the use of education alone to implement change in the clinical setting. Identification of barriers and flexibility to unforeseen circumstances are required in QI projects. Future studies should evaluate longer analytical periods and consider applications that can help to identify compliance with staff participation.

In clinical referencing, this project supports the use of a lower epithelial cell count for UA contamination interpretation. Based on the results analyzed, a UA has a higher likelihood of producing a contaminated UC if the epithelial cell count is ≥3 cells/hpf. Indicating clinical guideline recommendations for recollection of UA if the patient is still considered to have a UTI and UC would be beneficial in that clinical setting.

The generalizability of these results is somewhat limited to similar institutions. However, this project can easily be applied to larger academic organizations and implemented within the inpatient units. All or parts of this project can be utilized in other QI initiatives, specifically in healthcare associated infection programs addressing Catheter Associated Urinary Tract Infections.

Based on Dr. Deming's PDSA model, reevaluation of what is known now and reformatting another cycle through the continuous model is the key to success. Urine specimen contamination remains a clinical problem both within this institute and in supporting literature. This project confirms education and a pre-analytic protocol can create improved changes for patient care. It also demonstrates the limitations associated with a protocol that cannot be assessed for compliance. These results, and those previously published within the supporting literature, suggest that education in addition to mandating a pre-analytic protocol can be both clinically and statistically significant. Thus, additional projects that have the ability to evaluate such combined methods are recommended.

Dissemination of Information

There will be multiple direct products of this scholarly QI project. The full manuscript and a draft publication manuscript will be available for viewing in Libra, the University of Virginia scholarly institutional repository. In addition to the scholarly repository, publication within the Journal of Nurse Practitioners (JNP) will be pursued. Publication guidelines for the JNP can be found in Appendix C: JNP Publication Guidelines. The draft publication manuscript can be viewed in Appendix D: Draft Publication Manuscript.

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Table 1.

Qualitative Analysis of Literature Review

Author (Date)	Title	Design	Subjects Setting Time Period	Intervention Control/Comparison	Findings specific to outcome of interest (UA contamination)	Quality
Blake & Doherty (2006) *PubMed*	Effect of perineal cleansing on contamination rate of mid-stream urine culture	Experimental non-random	• 50 female patients age 14-23, asymptomatic • Outpatient clinic • 3 months	• Intervention = instructed on mid-stream collection. Cleanse their perineum, pass first part of voided urine into toilet, and collect next part in a sterile cup • Control = no instructions to cleanse. First void into sterile cup, then mid-stream void into separate sterile cup. Only mid-stream was tested.	• Perineal cleansing did not significantly effect contamination rates ($\chi 2 = 33$, $p = 0.56$)	IB
Frazee et al. (2014) *PubMed*	Abnormal urinalysis results are common, regardless of specimen collection technique, in women without urinary tract infections	Prospective crossover trial Subjects were also their own control	• 40 asymptomatic female subjects <40 years old • Emergency Department • Time unknown	• Each subject provided 2 separate samples of urine for comparison of contamination rates: "non-clean" versus "ideal" urinalysis collection • "non-clean" = simple initial voided urine in a sterile cup • "ideal" = instructed to void initially into toilet, then spread the labia and collect a mid-stream	• Urinalysis indices were often abnormal in disease free women regardless of collection technique • Culture contamination was common regardless of collection technique, and not predicted by urinalysis results • False positive results by WBC count were significantly reduced	IIB

Table 1 (continued).

Author (Date)	Title	Design	Subjects Setting Time Period	Intervention Control/Comparison	Findings specific to outcome of interest (UA contamination)	Quality
				specimen in a sterile cup • No cleansing was performed for either.	With "ideal" collection, 22.5% (95% CI 4 – 41) • False positive results by Epithelial cell count were significantly increased with "non-clean" collection 35% (95% CI 13-56)	
Jackson et al. (2005) *PubMed*	A novel mid-stream urine-collection device reduces contamination rates in urine cultures amongst women	Randomized Control Trial	• 2823 women requiring urinalysis testing • Outpatient clinics • Time unknown	• Intervention = use of Urine-Collection Device (UCD) • Control = standard mid-stream clean-catch	• 11% of UCD and 16% of conventional were contaminated and required retesting (p = 0.002) with relative reduction rate of 32%	IA
Jacob et al. (2016) *PubMed*	Use of a mid-stream clean-catch mobile application did not lower urine contamination rates in an ED	Quasi-experimental study	• 514 cases (257 in each group) • Urban academic ED in Washington, DC • Time unknown	• Intervention = Use of an instructional video application to show how to provide a mid-stream clean-catch urine • Control = No instructional video, standard care	• Urine Culture contamination rate overall 38% and not significantly different between the groups (p = .55). • Urinalysis contamination rate overall 8% and not significantly different	IIB

Table 1 (continued).

Author (Date)	Title	Design	Subjects Setting Time Period	Intervention Control/Comparison	Findings specific to outcome of interest (UA contamination)	Quality
					between the groups (p = .19).	
Klausing et al. (2016) *PubMed*	The influence of contaminated urine cultures in inpatient and emergency department settings	Retrospective chart review Non experimental	• 17,006 urine cultures included • Academic medical center • 1 year	• Evaluated urine cultures for contamination rates and adverse effects of inappropriate diagnosis	• Of the 17,006, 869 (5.1%) were contaminated, random cohort of 131 were evaluated. • 48.8% (64) of those developed complication from contaminated urine culture. • Contaminated urine culture resulted in 3.1% (4) admissions and 2.3% (3) antibiotic-associated acute renal failure	IIIB
Larocco et al. (2016) *PubMed* Meta-Analysis	Effectiveness of preanalytic practices on contamination and diagnostic accuracy of urine cultures: a laboratory medicine best practices Systematic	Systematic Review with Meta-analysis	• Meta Analysis	• 3 questions answered with meta-analysis: 1- What is the difference in % of contamination between mid-stream clean-catch with and without cleansing in women? 2- What is the diagnostic accuracy of mid-stream 41ersus catheterization? 3- What is the difference	• Findings to clinical questions: 1- 4 observational studies and 1 RCT found no significance difference in the odds of contamination between cleansing and not (OR 1.04 [0.63, 1.73]). And rated as “high” strength of evidence.	IB

Table 1 (continued).

Author (Date)	Title	Design	Subjects Setting Time Period	Intervention Control/Comparison	Findings specific to outcome of interest (UA contamination)	Quality
	Review and Meta-Analysis			in % of contamination between mid-stream clean-catch with and without cleansing, and first-void collection in men?	2- Mid-stream clean-catch had a sensitivity of 98-100% and specificity of 95-100%, using catheterization as a reference standard, however overall body of evidence was rated as low. 3- 3 published studies showed large 77% reduction in the odds of contamination in favor of Mid-stream catch over first void (OR 0.33 [0.15, 0.77]). No significant difference in cleansing or not with mid-stream collection (p = 0.19)	
Lifshitz & Kramer (2000) *PubMed*	Outpatient Urine Culture : Does collection technique matter ?	Randomized Control Trial	• 242 females with symptoms suggestive for UTI • Outpatient clinic, Rutgers University • Time unknown	• Subjects randomized to 3 groups Ÿ Group 1 = instructed to urinate into a clean non-sterile container (non cleansing, no mid-stream) Ÿ Group 2 = instructed to cleanse perineum, spread labia, discard first urine,	• Contamination rates for the 3 groups were almost identical at 29%, 32%m and 31%, respectively (p = 0.82)	IB

Table 1 (continued).

Author (Date)	Title	Design	Subjects Setting Time Period	Intervention Control/Comparison	Findings specific to outcome of interest (UA contamination)	Quality
				and collect mid-stream specimen in clean non-sterile container Ÿ Group 3 = identical instructions plus instructed to insert a vaginal tampon prior to collection		
Maher et al. (2016) *PubMed*	The effect of written posted instructions on collection of clean-catch urine specimens in the emergency department	Quasi-experimental, single center cohort study	• 754 adult (>18yo) seen in the emergency department with urinalysis testing • Emergency department Harborview Medical Center, large urban medical center • 3 months	• Intervention = Posted instructions in bathroom for procedure of obtaining correct clean mid-stream clean-catch sample • Control = historical control period, when posted instructions were not provided	• Contamination rates between the groups were not significantly found with urinalysis ($p = 0.99$) or with urine culture (0.13)	IIB
Selek et al. (2017) *PubMed*	Genital Region Cleansing Wipes: Effects on urine culture contamination	Randomized Control Trial	• 2655 patients with urinalysis and culture testing • Outpatient clinics, including emergency department • 5 months	• Subjects randomly selected to group • Intervention = used chlorhexidine-containing genital region cleansing wipe before sampling • Control = used no wipe before sampling	• Significant difference ($p = 0.0001$) in contamination rates when using specialized wipe (7.7%) compared to no wiping (15.8%) • Results were similarly significant regardless of	IB

Table 1 (continued).

Author (Date)	Title	Design	Subjects Setting Time Period	Intervention Control/Comparison	Findings specific to outcome of interest (UA contamination)	Quality
					race or age.	
Dolan & Cornish (2013) *CINHAL*	Urine specimen collection: How a multidisciplinary team improved patient outcomes using best practices	Non-experimental, Quality Improvement (QI) project	• No reported statistical data of patient population • Community hospital emergency department • 1 year	• Pre-analytic intervention based on 3 areas of improvement: 1- Urine specimen collection 2- Specimen labeling 3- Transportation of specimen • Comparison made of pre-post QI intervention	• Reduction in incidence of contaminated urine culture was noticed. (no statistical data)	IIIB
Holliday, Strike, & Masterton (1990) *Cochrane*	Perineal cleansing and mid-stream urine specimen in ambulatory women	Randomized control trial	• 192 asymptomatic patients • unknown location • unknown time	• Intervention = "Cleansing" = provided instruction and a genital wipe soaked in normal saline before collecting sample • Control = "Non-Cleansing" = No cleansing before sampling	• Of 192 patients, 96 in each group, there were no significant differences found between the two methods ($p > 0.1$) in culture contamination rates. • 4 of the "cleansing" and 12 "non-cleansing" had more than 50 epithelial, showing urinalysis contamination ($p = 0.017$)	IB

Table 1 (continued).

Author (Date)	Title	Design	Subjects Setting Time Period	Intervention Control/Comparison	Findings specific to outcome of interest (UA contamination)	Quality
Eley et al. (2016) *Random search*	Illustrations reduce contamination of mid-stream urine samples in the emergency department	Pseudo controlled trial	• 240 females, >18 yo • Emergency Department • unknown time	• Intervention = patients received printed illustrated instructions on clean-catch collection method • Control = no printed instructions	• Based on epithelial cells, fewer contamination rates were noted in the intervention group ($p < 0.05$)	IIB
Gordon et al. (2013) *Random search*	Overtreatment of presumed urinary tract infection in older women presenting to the emergency department	Retrospective chart review Non experimental	• 153 women >70yo diagnosed w/ UTI • Emergency Department in Providence, RI • 3 months	• Chart review evaluating proportion of older women diagnosed in the ED with UTI, whom do not ultimately have UTI by culture report. • Also evaluated contamination rates based on clean-catch vs catheterization	• Of the 153, 43% with ED diagnosed UTI by urinalysis had negative culture. 95% of those were treated with antibiotics. • Catheterization provided lower proportion of false-positive Uas ($p = 0.02$) • Clean-catch showed higher contamination rates than catheter ($p = 0.05$)	IIIB
Guss et al. (1985) *Random search*	Clean-Catch versus Straight-Catheter	Prospective Cohort study	• 50 adult females • Emergency Department at University of San	• Comparing urinalysis contamination rates between collection technique by MSCC vs	•42% had abnormal MSCC Uas compared to Cath (22%). • Disparities between	IIIB

Table 1 (continued).

Author (Date)	Title	Design	Subjects Setting Time Period	Intervention Control/Comparison	Findings specific to outcome of interest (UA contamination)	Quality
	Urinalysis Results in Women		Diego • 1 month	I&O cath from same patient	MSCC and Cath UA seen in 10 cases ($p < 0.05$) Contamination rate significantly higher in MSCC but only regarding RBC/hematuria. These patients were on active menses. • When eliminated from study, no significant difference was found.	
Pallin et al. (2014) *Random search*	Urinalysis in Acute Care of Adults: Pitfalls in Testing and Interpreting Results	Prospective Observational Study Convenience Sampling	• 195 Adult patients • Emergency Department urban teaching hospital • 9 months	• Patients classified into 3 groups: UTI symptoms present; UTI symptoms non specific; UTI symptoms absent. • Comparison of signs and symptoms leading to testing, urine sampling technique, test characteristics, and antibiotic use.	• 82% cases MSCC; 12% Cath specimens collection technique • 57% of MSCC cases had "false-positive" (contaminated)	IIIB

Note. Quality grading and level of evidence was identified using John Hopkins evidence-based practice guide, *Evidence Level and Quality Guide* (Dearhold, Dang, & Sigma Theta-Tau International, 2012)

Table 2.

Summary of Gray Literature

Author (Date)	Title	Summary	Quality
Claeys et al. (2019)	Advances and challenges in the diagnosis and treatment of urinary tract infections: the need for diagnostic stewardship	Best Practices: • Diagnostic stewardship aims to optimize ordering patterns, specimen collection and transport, testing practice, and test reporting • Asymptomatic bacteriuria (ASB) is defined as bacteria ≥10ˆ5 colony-forming units per milliliter (CFU/mL). Or ≥10ˆ2 in catheterized patients • Urine cultures should not be ordered in asymptomatic patients unless in pregnant women, prior to transurethral resection of the prostate, or other urological procedure is pending • Recommend cleansing before mid-stream clean-catch • Urine specimens should be discarded if not received in the lab within 2 hours of collection	VB
Harringon et al. (2014)	If specimen collection and processing guidelines fall, does anyone hear them? Pre-Analytical conundrums in clinical microbiology	Best Practices: • Written instruction with photographs have shown to be helpful for correct collection techniques • Patients should not be asked to drink fluids to produce specimen, as this dilutes specimen and can lead to false negative • Specimen should be collected into sterile container, not a bedpan, urinal, or catheter bag • Urine specimens should be in the lab within 2 hours, or discarded	VB

Table 2 (continued).

Author (Date)	Title	Summary	Quality
Schmiemann et al. (2010) Systematic Review	The diagnosis of urinary tract infection	Best Practices: • Gold standard for diagnosis of UTI is to perform a bacteriological urine culture, with identification of pathogen, with quantification and sensitivity testing, in the setting of clinical symptoms. • Gold standard collection technique is mid-stream clean-catch with or without cleansing, although cleansing has shown to reduce contamination rates in some studies and not provide any additional harm. • Screening for Asymptomatic Bacteriuria is only necessary in pregnant women and before urological operation • Use of diagnostic algorithms can be helpful in guiding ordering practices and treatment with antibiotics	IIIB
Meyrier (2017) Up-to-date	Sampling and evaluation of voided urine in the diagnosis of urinary tract infection in adult	• Ideal collection technique in women is mid-stream, clean-catch, with labia spread. • Ideal collection technique in men is mid-stream void catch with or without cleansing. • Specimens should be analyzed immediately, or placed in refrigerator at 4C, as cooling stops bacterial growth. •WBC count ≥2-5 cells/microL is considered positive. • Culture contamination or "non-infected" growth is considered a sample of <10^5 CFU/mL colony forming units. • The Society of Post-Acute and Long-Term Care Medicine (AMDA) national guideline: 1- Do not obtain a urine culture unless there is clear signs and symptoms localized to the urinary tract.	IVB

Table 2 (continued).

Author (Date)	Title	Summary	Quality
		2- Chronic Asymptomatic Bacteriuria is prevalent in as high as 50% of long-term care setting patients.	

Note. Quality grading and level of evidence was identified using John Hopkins evidence-based practice guide, *Evidence Level and Quality Guide* (Dearhold, Dang, & Sigma Theta-Tau International, 2012)

Table 3.

Diagnostic criteria for Urine Culture contamination versus infection.

	Urine Culture Infection	Urine Culture Contamination
Palin et al. (2014)	• 1 organism $\geq 10^5$ CFU/mL voided sample • 1 organism $\geq 10^2$ CFU/mL catheterized sample	
Claeys et al. (2019)	• 1 organism $\geq 10^4$ CFU/mL • 2 organisms $\geq 10^5$ CFU/mL of both	• ≥3 organisms $>10^4$ CFU/mL
Dolan & Cornish (2013)	• ≤2 organisms $\geq 10^3$ CFU/mL	
Holiday, Strike, & Masterton (1990)	• $\geq 10^3$ CFU/mL	
Maher et al. (2016)		• $\leq 10^4$ CFU/mL
Lifshitz & Kramer (2000)		• $\leq 10^4$ CFU/mL
Selek et al. (2017)	• $\geq 10^5$ CFU/mL	• ≥3 organisms or $\leq 10^4$ CFU/ml
Gordon et al. (2013)	• $\geq 10^4$ CFU/mL in voided sample • $\geq 10^2$ CFU/mL in catheterized sample	
Meyrier (2017)		• $\leq 10^5$ CFU/mL

Notes: CFU/mL = colony forming units per milliliter

Table 4.

Demographic Characteristics of Emergency Department Patients

Characteristics	n	%	Mean (SD)	Median	Range	*p*[a]
Age						
July	369	100	60.3 (22.0)	65	83	0.245
October/November	934	100	58.7 (23.7)	63	86	

	July		October/November		*p*[b]
	n	%	n	%	
Gender					
Male	105	28.5	266	28.5	1.0
Female	264	71.5	668	71.7	
Shift Treated					
Day Shift	226	61.2	593	63.5	0.489
Night Shift	143	38.8	341	36.5	
Emergency Department					
Main ED	272	73.7	704	75.4	0.581
FSED	97	26.3	230	24.6	

Notes. SD = Standard Deviation; p value for significance <0.05

[a]p value for age represents independent t test analysis.

[b]p value for gender, shift, and Emergency Department represents Chi-Square analysis

Table 5.

Characteristics of Urine specimens

Variable Label	July (n= 369) n	%	October (n=512) n	%	p[a]	November (n=422) n	%	p[b]	p[c]
Laboratory Test Ordered									
Urinalysis (UA)	73	19.8	70	13.7		79	18.7		
UA with Microscopy	84	22.8	86	16.8		73	17.3		
UA with Microscopic Reflex	212	57.5	356	69.5		270	64.0		
Collection Technique									
Mid-stream clean catch	351	95.1	462	90.2		383	90.8		
Intermittent Catheterization	14	3.8	39	7.6	0.03	30	7.1	0.06	0.02
Foley Placement	4	1.1	11	2.1		9	2.1		
Urinalysis Contamination									
Epithelial cell count <5 cells/hpf	327	88.6	454	88.7	1.0	377	89.3	0.84	0.93
Epithelial cell count >5 cells/hpf	42	11.4	58	11.3		45	10.7		
Urinalysis Interpretation									
Negative UTI criteria	69	18.7	22	4.3		16	3.8		
Positive UTI criteria	300	81.3	490	95.7		406	96.2		
Culture Interpretation									
Not contaminated	152	41.2	207	40.4	0.89	204	48.3	0.05	0.39
Contaminated	217	58.8	305	59.6		218	51.7		

Notes: p value for significance is <0.05

[a]Chi-Square analysis of July and October data.

[b]Chi-Square analysis of July and November data.

[c]Chi-Square analysis of July and October/November combined

Table 6.

Urinalysis Results

Variable label	July (n= 369) n	July (n= 369) %	October (n=512) n	October (n=512) %	November (n=422) n	November (n=422) %
Epithelial Cell Count						
Negative	106	28.7	175	34.2	117	27.7
<5 cell/hpf[a]	221	59.9	279	54.5	260	61.6
5-10 cell/hpf	22	6.0	27	5.3	20	4.7
>10 cell/hpf	20	5.4	31	6.0	25	6.0
Leukocyte Esterase Cell Count						
Negative	143	38.8	244	47.7	170	40.3
Present	226	61.2	268	52.3	252	59.7
Nitrates						
Negative	313	84.8	452	88.3	367	87.0
Positive	56	15.2	60	11.7	55	13.0
White Blood Cell Count						
Negative	26	7.0	34	6.6	28	6.6
<5 cell/hpf	163	44.1	252	49.2	180	42.7
5-10 cell/hpf	40	10.8	59	11.5	46	10.9
>10 cell/hpf	140	38.1	167	32.7	168	39.8
Bacteria						
Negative	132	35.8	184	35.9	154	36.5
Present	237	64.2	328	64.1	268	63.5

Note: hpf = high power field

Table 7.

Urine Culture Results by Growth Results

	July (n= 369)		October (n= 512)		November (n= 422)	
	n	%	n	%	n	%
Achromobacter xylosoxidans	1	0.3	-	-	1	0.2
Aerococcus urinae	-	-	3	0.6	2	0.5
Citobacter koseri	1	0.3	1	0.2	2	0.5
Enterobacter cloacae	1	0.3	4	0.8	-	-
Enterococcus faecalis	2	0.6	8	1.6	11	2.8
Enterocuccus species	-	-	-	-	1	0.2
Escherichia coli	65	17.6	53	10.4	55	22.1
Klebsiella aerogenes	5	1.4	-	-	-	-
Klebsiella oxytoca	-	-	-	-	2	0.4
Klebsiella pneumoniae	11	2.9	9	1.6	12	2.8
Morganella morganii	1	0.3	1	0.2	-	-
Proteus mirabilis	5	1.3	2	0.4	2	0.5
Proteus species	-	-	1	0.2	2	0.4
Providencia stuartii	1	0.3	-	-	-	-
Pseudomonas aeruginosa	2	0.6	7	1.4	7	1.7
Pseudomonas species	1	0.3	1	0.2	-	-
Serratia marcescens	-	-	-	-	1	0.2
Staphylococcus aureus	1	0.3	2	0.4	4	0.9
Staphylococcus capitus	-	-	1	0.2	-	-
Staphylococcus lugdunesnsis	-	-	-	-	1	0.2
Staphylococcus saprophyticus	2	0.6	-	-	2	0.5
Streptococcus agalactiae, Group B	5	1.4	7	1.4	7	1.7
Streptococcus mitis/oralis	1	0.3	-	-	-	-
Mixed urogenital and/or skin flora	192	52.0	251	49.0	185	43.8
Multiple organisms	25	6.8	54	10.5	33	7.8
No growth	47	12.7	108	21.1	89	21.1

Table 8.

Epithelial Cell Count and Urine Culture Contamination

Epithelial Cell Count (cell/hpf[b])	UC[c] Not contaminated n = 563		UC Contaminated n = 740		p[a]
	n	%	n	%	
≤2	471	47.6	518	52.4	
3-5	53	31.4	116	68.6	.00
>5	39	26.9	106	73.1	

Notes: ≤2 cells/hpf represents those specimens with negative and 0-2 analysis; Statistical significance = $p < .05$
[a]Chi-square 3x2 analysis for significance between Epithelial cell counts and urine culture contamination.
[b]hpf = "high power field"
[c]UC = urine culture

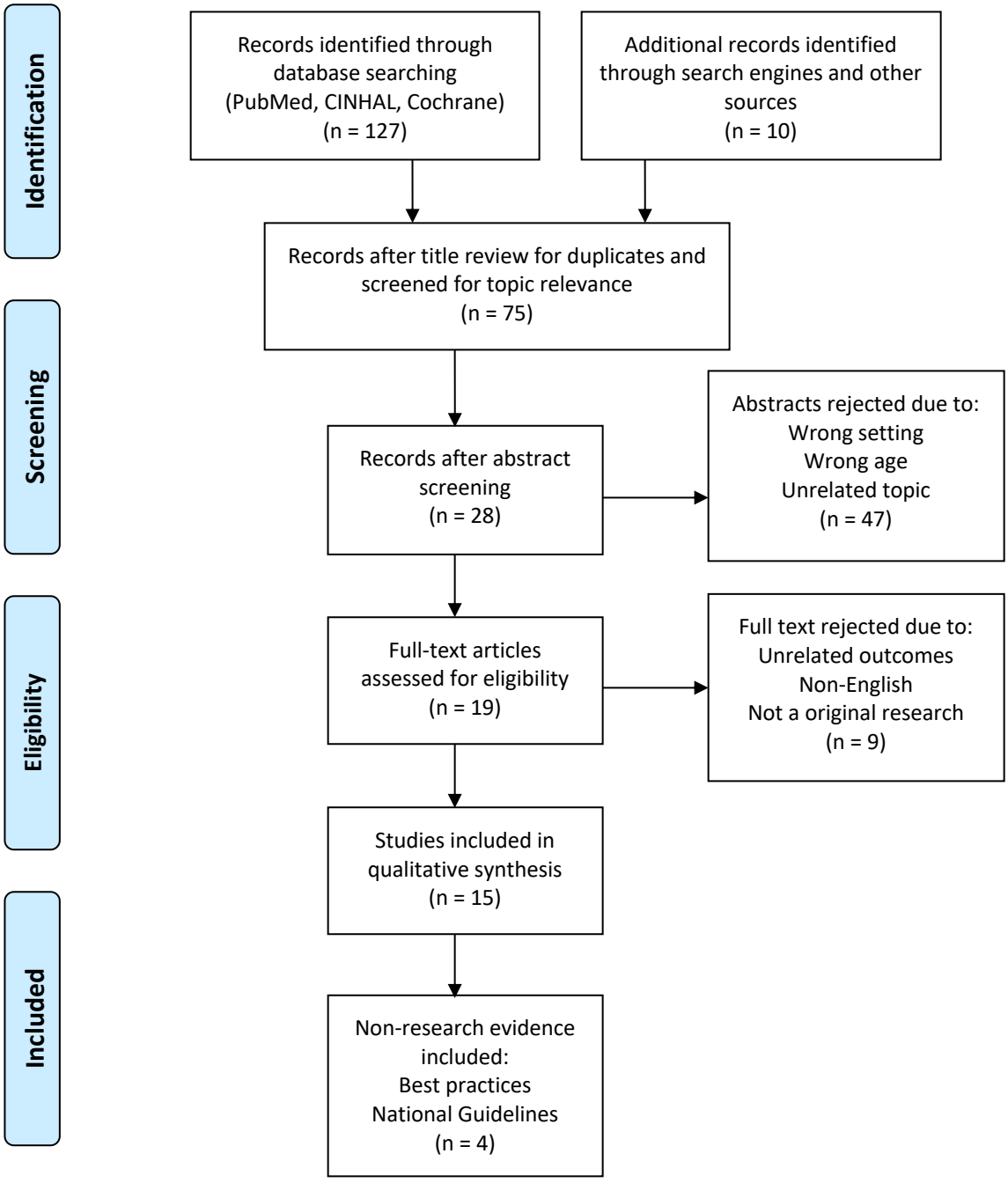

Figure 1. PRISMA flow diagram of scoping literature review

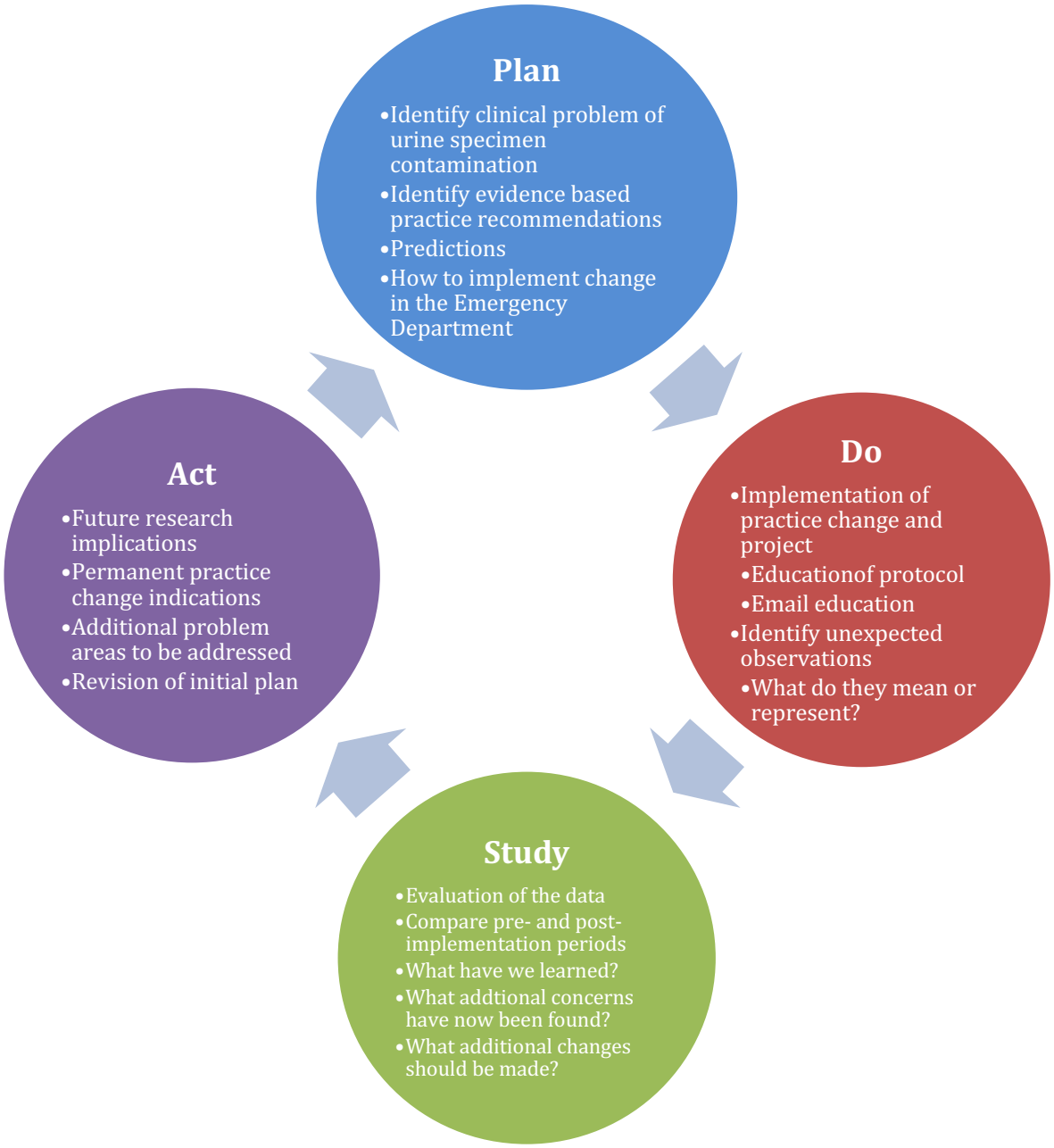

Figure 2. Dr. Deming's PDSA model for quality improvement in this QI project

Pre-Analytic Urine Collection Process

COLLECTION TECHNIQUE

Mid-Stream Clean-Catch Specimen	*Catheterized Specimen*
1. High quality patient education (If felt patient unable to perform clean-catch successfully, discuss catheterization method with provider) **2. Spread labia or retract foreskin** **3. Cleanse around urethral opening** **4. Void into commode** **5. Collect mid-stream specimen into sterile container** **Avoid urinals and hats if at all possible, as they are not sterile and less likely to obtain mid-stream sample.**	**1. Ensure sterile technique** **2. Intermittent straight cath – collect specimen from closed-system bag port directly into sterile container.** **3. New indwelling foley placement – allow 5-10mls of urine to pass into tubing/bag** **4. Clamp tubing and withdraw mid-stream sample into sterile syringe from collection port** **NEVER collect specimen from foley bag.**

HANDLING TECHNIQUE

1. **Write current time on the specimen cup when provided to patient for sample collection.**
2. **30 minute time limit to transfer specimen into preservative-base testing tube.**
3. **Discard specimen and recollect if greater than 30 minutes has passed from time of collection**

LABELING TECHNIQUE

1. **Prior to printing label in EPIC, ensure that the correct specimen collection technique is selected for appropriate laboratory analysis**
2. **Ensure the RIGHTs of specimen labeling – right patient, time, date, and specimen**
3. **Document in the chart whether the specimen was collection via foley placement or I&O cath.**

Figure 3. Pocket reference guide created for staff

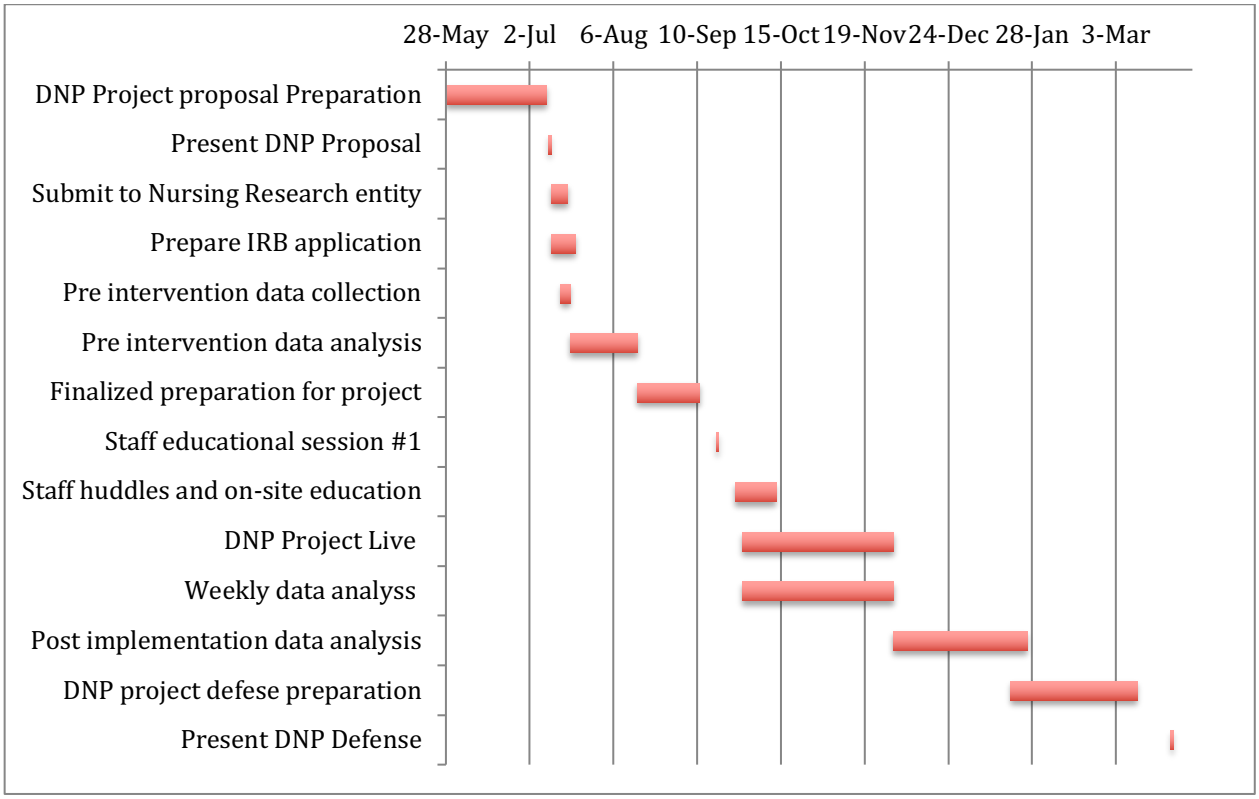

Figure 4. GANTT chart of project preparation, implementation, and evaluation.

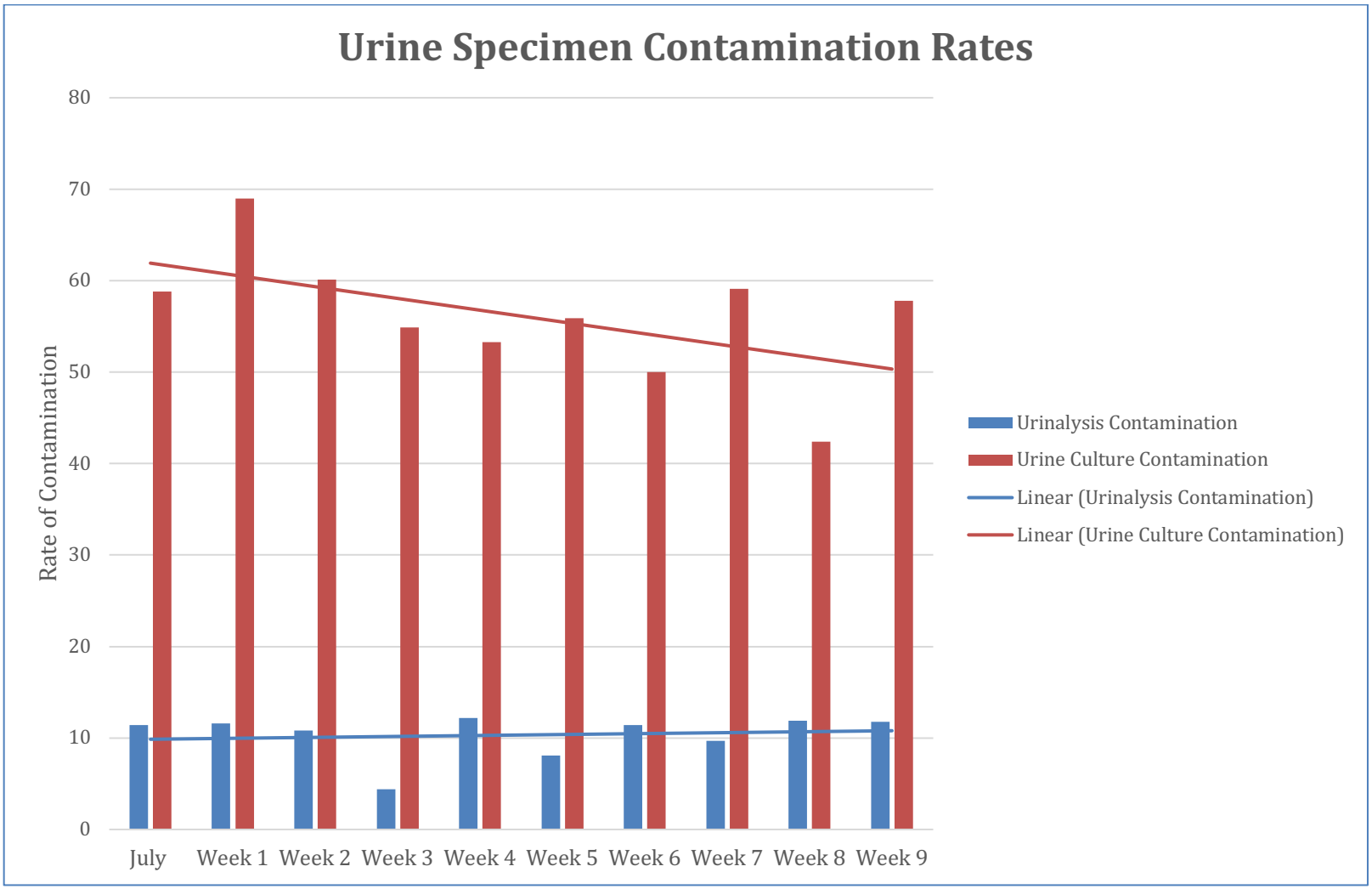

Figure 5. Urine contamination rate trends.

Appendix A

Definition of Terms

Catheterized mid-stream specimen: A sterile catheterized urine specimen collected after allowing for the first 5-10 mLs of urine to pass before collecting a mid-stream sample from the catheter port. The indwelling foley catheter, by nature of its design, is a closed-system device. A specimen collection port is accessible just distal to the catheter itself and allows for a mid-stream collection if performed correctly.

Contamination: Test results that are deemed unreliable for diagnosis of UTI.

D*iagnostic stewardship*: Defined by Claeys et al. (2019) as a stewardship program aimed at improving outcomes by improving ordering behaviors, specimen collection techniques, handling and transport of specimen, and test reporting.

Intermittent catheterized specimen: A sterile catheterized urine specimen collected via a closed-system device, but does not allow for a mid-stream specimen because a separate access port does not exist

Mid-stream clean-catch (MSCC): A multistep approach to a patient-collected urine specimen. For women subjects included in this project these steps include labia spreading, cleansed skin, and a middle of urine stream collection. For men, a MSCC is defined as a urine sample collected after retraction of the foreskin if uncircumcised, cleansing skin, and collecting a mid-urine stream collection.

Negative infection: UC results indicating “No Growth”.

Patient care technician (PCT): refers to ancillary staff whom perform regular duties with patients including education and urine specimen collection.

Pre-analytical: The process prior to analysis. Specific for this project, pre-analytical refers to the urine collection, labeling, and handling process prior to laboratory analysis.

UA contamination: For this QI project, is any UA with epithelial cell count >5 cells/hpf (Maher et al., 2017).

UC contamination: For this QI project, is any UC result indicating "Mixed urogenital and/or skin flora" and "Multiple organisms, please recollect".

Urinalysis (UA): A microscopic analysis of a urine sample to identify specific chemical and molecular composition.

Urine culture (UC): A microbiological test used to establish a quantitative presence of bacteria and other microorganisms within a urine sample.

UTI via UA: Specific for this QI project, is any UA showing any combination of the following: (a) positive Leukocytes, (b) positive Nitrate, (c) White Blood Cells >5 cells/hpf, (d) Bacteria present.

UTI via UC: UC results indicating growth of ≤2 specific organisms.

Appendix B

Quality Improvement Project Institution Approval

Jenny Hall

Guidelines: Launching Evidence-Based Practice Nursing Projects		
[redacted]	Manual:	Locations: [redacted]
Original Date:6/10/2019	Section:	
Owner: Nursing Education		
Approved By: DON/M	Revision Date:	

Purpose:
Nurses utilize the evidence-based practice (EBP) process to improve patient care and safety outcomes in a specific setting where healthcare services are delivered. Although these projects are typically considered quality improvement (QI), it is important for the person leading the project to ensure that proper documentation is in place differentiating the project as QI, and to ensure that those doing data collection have appropriate permissions to access protected patient information. The purpose of this job aid is to clarify the process for launching a new EBP project.

Definitions:
Evidenced- based practice: The conscientious use of current best evidence in making decisions about patient care.
Quality improvement: Outcomes management projects that focus on improving practice performance including changes in care delivery modalities, system supports for the healthcare team, and evaluation of the effect of practice change on patient outcomes within a particular environment.
Human Subjects Research: Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge
EBP Process: A systematic process used to incorporate evidence into nursing practice including (briefly) 1. Develop a clinical question, 2. Search for the best evidence, 3. Appraise the evidence, 4. Apply the evidence to practice, 5. Evaluate the implementation, and 6. Disseminate findings.

Process:
1. **All students enrolled in a School of Nursing program** (including those employed by [redacted]) must be approved to complete an EBP project by the IMPAACT Manager PRIOR and submit all required documents PRIOR to starting an EBP project.
2. **All nursing students and nurse employees conducting an EBP project** must first meet with the Nursing Research Coordinator before starting the project. All EBP projects must be approved by the Research Coordinator.
3. All EBP projects should follow the EBP Process (Melnyk and Fineout-Overholt, 2011).
4. Any communication describing the EBP project should utilize the term "quality improvement" or "practice improvement," to differentiate the study purpose from research (See Criteria, next page).
5. Any communication describing the EBP project should clarify that the intention of the project is to make improvements in a specific setting where healthcare is being delivered. EBP project leaders should not state directly or indirectly that the information gained is intended to be generalizable to other settings (See Criteria, next page).
6. Per [redacted] policy, employees accessing protected patient information either directly from patients or the electronic medical record, can only do so if they have a legitimate "need to know," regardless of their access to data. Employees wishing to access protected patient information for a student EBP project must first contact the IMPACT manager in Nursing Education to start this process. Employees accessing protected patient information for a student project may otherwise be in violation of [redacted] policy.

ATTENTION: FOR REFERENCE USE ONLY WHEN PRINTED; PLEASE REFER TO ELECTRONIC DOCUMENT FOR MOST CURRENT VERSION

7. Per [redacted] procedures, students must de-identify the hospital/division for any work describing the project (papers, posters, etc) within the school classroom setting. Any dissemination beyond the classroom must follow the procedure laid out in *Guidelines for Preparing and Disseminating Scholarly Work.*

Citations

Melnyk, B. M., & Fineout-Overholt, E. (Eds.). (2011). *Evidence-based practice in nursing & healthcare: A guide to best practice*. Lippincott Williams & Wilkins.

Related Documents:

Policy	Privacy of Protected Health Information
Procedure	Guidelines for Preparing and Disseminating Scholarly Work

Quality/Practice Improvement Criteria Jenny Hall

X	Does the intervention being evaluated have a strong evidence-base (i.e. a guideline or Cochrane review)?
X	Does the project purpose explicitly state that the project is a quality or practice improvement and not intended to be generalized?
X	Is there a manager or director aware of and in support of the project as part of the unit or hospital QI program? Kerry Hall

✓ Yes this qualifies as quality improvement and can proceed with data collection

Pam DeGuzman
Nursing Research Coordinator / date **all projects**

Jenn Tuld 8/6/19
IMPACT Manager / date **student projects only**

Appendix C

JNP Publication Guidelines

THE JOURNAL FOR NURSE PRACTITIONERS
An Official Publication of the American Association of Nurse Practitioners

AUTHOR INFORMATION PACK

TABLE OF CONTENTS

ISSN: 1555-4155

DESCRIPTION

JNP: The Journal for Nurse Practitioners offers high-quality, peer-reviewed clinical articles, original research, continuing education, and departments that help practitioners excel as providers of primary and acute care across the lifespan. Each issue meets their practice needs and encourages discussion and feedback with thought-provoking articles on controversial issues and topics. *JNP* supports advocacy by demonstrating the role that policy plays in shaping practice and delivering outcomes. The journal is an official publication of the American Association of Nurse Practitioners and also is affiliated with the Australian College of Nurse Practitioners.

The journal is published 10 times per year, distributed to approximately 100,000 readers in print form, and can be found online at www.npjournal.org. The journal is included in Scopus, CINAHL, and the Journal Citation Reports published by Thomson Reuters.

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AUDIENCE

Nurse Practitioners working in primary care, women's health, geriatrics, pediatrics, and other specialties within acute care and non-hospital settings.

IMPACT FACTOR

2018: 0.700 © Clarivate Analytics Journal Citation Reports 2019

ABSTRACTING AND INDEXING

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EDITORIAL BOARD

GUIDE FOR AUTHORS

Purpose

JNP: The Journal for Nurse Practitioners, offers high quality, peer-reviewed clinical articles, original research, continuing education, short communications, case reports and departments that help nurse practitioners (NPs) excel as providers of primary and acute care across the lifespan. Each issue meets their practice needs and encourages discussion and feedback with thought-provoking articles on controversial issues and topics. *JNP* supports advocacy by demonstrating the role that policy plays in shaping practice and delivering outcomes.

Article Types

Except as noted, all articles should be limited to 4,500 total words, inclusive of all headings, titles, author information, keywords, abstract, text, references, tables, and graphics. Authors should refer to the EQUATOR network (https://www.equator-network.org/) and follow the appropriate reporting guidelines for main study design. Authors will be guided stepwise through the submission process and must choose a category from the following options:

Original Research - follow standard research format using headings Introduction, Background and Significance (Review of literature), Purpose, Methods, Results, Discussion, Limitations, Conclusion. For quantitative studies, include a power analysis used to calculate needed sample sizes.

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Appendix D

DRAFT Manuscript for Publication Within the Journal of Nurse Practitioners

Educational In-Service on a Pre-Analytic Diagnostic Stewardship Protocol to Reduce Urine Contamination: A Quality Improvement Project

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There was no conflict of interest for any author listed above during the development, implementation, and analysis of this project.

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Author/Coauthor Names:
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_____Jennifer L Broyles MSN-RN, AGACNP-BC__ ____4/25/2020_____

Written or Typed Signature **Date**

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Dear editors of the Journal for Nurse Practitioners,

I am pleased to submit a *brief report* of an original quality improvement project article "Educational in-service on a pre-analytic diagnostic stewardship protocol to reduce urine specimen contamination: A quality improvement project" by Jennifer Broyles, MSN, AGACNP-BC, Elizabeth Friberg, DNP, RN, Pamela Deguzman, PhD, MBA, RN, CNL, and Keri Hall, M.D. for publication in the Journal for Nurse Practitioners. We recently uncovered, through an in-depth literature review, that a multi-disciplinary pre-analytic diagnostic stewardship approach to urine collection and handling proved to reduce urine contamination rates. The aim of this manuscript is to build on previously established knowledge and enhance evidence-based recommendations.

In this manuscript, we evaluated the use of educational in-services as a tool to introduce a 3-step pre-analytic diagnostic stewardship protocol, and add to the knowledge of appropriate urine collection, labeling, and handling techniques. This quality improvement project demonstrates numerous advantages to the use of education to implement change in the clinical setting. We did show both a statistically and clinically significant reduction in culture contamination rates with the use of staff education. Furthermore, we encourage future programs to evaluate a combined approach to include methods to mandate a similar protocol, which may show an increase in the clinical impact. We also demonstrate that the use of a lower epithelial cell count for identification of contamination should be used when considering specimen recollection for culturing.

We believe that this manuscript will add to the body of knowledge and evidence-based practice recommendations both clinically and within the diagnostic guidelines for the diagnosis of urinary tract infections. We provide a program framework and foundation for future studies that address the ongoing problem of urine contamination.

This manuscript has not been published, nor will it be submitted for publication elsewhere. A draft manuscript will be submitted to the University of Virginia scholarly project repository. There are no conflicts of interest to disclose.

Thank you for your consideration

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Hospitalist Nurse Practitioner
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Highlights

- Contaminated urine results can lead to misdiagnosis and unnecessary antibiotic use.
- Pre-analytic diagnostic stewardship programs can reduce contamination rates.
- A combined educational and mandated protocol approach is recommended.
- Specimen recollection is recommended if epithelial cell count is ≥3 cells/hpf.

Keywords

Urine collection, Urinalysis, Urine culture, contamination, diagnostic stewardship, pre-analytic, evidenced-based practice

Word count

Total word count (including all tables, figures, text, and headings): 2494

Abstract

Background: Urine contamination is a widely established clinical problem that can generate unreliable results leading to misdiagnosis and improper or delayed treatments. Diagnostic stewardship programs focus on the pre-analytic phase to improve patient outcomes and reduce contamination rates by improving specimen collection and processing.
Methods: A retrospective chart review quality improvement project was conducted to evaluate if educational in-services, introducing a 3-step pre-analytic protocol, would affect the rates of urine contamination.
Results: This project did demonstrate a significant relationship between educational in-services and the reduction of urine culture contamination rates (χ^2 (1, n=791) = 3.78, p = 0.05, phi = -.07).
Conclusion: The results of this project suggest that education in addition to mandating a pre-analytic protocol may prove to be both statistically and clinically significant.

Introduction

Compared to a urinalysis (UA), a urine culture (UC) is the gold standard diagnostic test for a urinary tract infection (UTI).[1] In the Emergency Department (ED), a provider must rely on information gathered during the patients visit, therefore the quick turnaround time provided by a UA is crucial for efficient care.[2] The consequences of centering care on a contaminated UA result can be harmful for both the patient and healthcare system.[3] Furthermore, subsequent UC contamination can delay appropriate treatment options for the patient. Specimen contamination does not mean that a patient is without a UTI, but rather the specimen, and therefore diagnosis, is unreliable.

There are a number of pre-analytic steps taken to collect and maintain a valid urine sample for analysis. A misstep at any level of the pre-analytic pathway can lead to increased false-positive rates, misdiagnosis, and inappropriate antibiotic use.[4] Thus, close attention must be given to the pre-analytic steps which includes proper urine collection technique, correct labeling, and appropriate handling of the specimen prior to laboratory analysis.

Background

Within a mid-Atlantic, 176-bed not-for-profit community hospital, admitting nearly 10,000 patients yearly, approximately 58% of UCs obtained in the ED were identified as contaminated. A quality improvement (QI) initiative launched to evaluate evidence-based recommendations for reducing both UA and UC contamination, focusing on the pre-analytic phase.

Review of Literature

A comprehensive literature review of each stage of the pre-analytic process was performed.

Urine Collection Technique

Larocco et al[5] and Guss et al[6] showed no significant difference between midstream clean catch (MSCC) and catheterized specimens. Pallin et al[7] and Gordon et al[2] found that MSCC yielded higher UC contamination rates and higher false-positive UA results. Regardless of the difference in technique contamination rates, the preferred standard collection technique remains a cleansed, with labia spreading or foreskin retraction, mid-stream specimen.[1,8]

Specimen Handling Technique

Many common bacterial organisms will more than double in colony counts in as little as 20 minutes when kept at room temperature in an unpreserved container.[3] The use of preservatives, such as boric acid, have shown to extend the shelf life of the urine specimen.[5] If specimens are not transferred in a timely manner, they should be discarded and recollected.[3]

Specimen Labeling

The labeling process requires correct identification of the patient, specimen, and collection technique for every specimen. UC results are interpreted based on quantified organism colony counts, and yield different thresholds for diagnosis of UTI based on collection technique.[3] Therefore, proper labeling is vital to ensure the most accurate results provided.

Purpose

The purpose of this QI project was to evaluate the use of education on a 3-step pre-analytic protocol, and the effects this education would have on reducing UA and UC contamination rates.

Methods

Study design

A retrospective chart review QI project was conducted. In accordance with hospital policy, approval of the project as QI and for data collection was obtained via the Nursing Research entity, thus Institutional Review Board approval was not required.

W. Edward Deming's 4-step Plan-Do-Study-Act (PDSA) model was used for this QI project to provide direction and theoretical application. Identifying contamination rates as a problem, formulating an action plan for process change, implementation of education and practice change, and evaluation of data, were phases deployed within the context of his 4-step model for this project. This model revolves as a continuous sequence of improvement and learning based each time on knowledge gained.[9]

Study population

This was a convenience sample that included ED patients, age 18 years and older, who had both a UA and UC test resulted. Only specimens collected via the MSCC or new catheterizations were included. Exclusionary criteria included presence of an indwelling foley or suprapubic catheter, or percutaneous nephrostomy tube. UCs that grew yeast or candida, and pregnant women were excluded.

Study Protocol

A multidisciplinary UTI committee was formed to have open dialogue regarding literature review, implementation practices, and clarify definition of terms.

Two mandatory staff education sessions were initially planned. Due to unforeseen circumstances, one of the sessions was canceled and rescheduled outside the window of this project. To demonstrate flexibility required in QI endeavors, additional onsite education sessions were provided. These sessions included background on the current problem, nursing impact, and

review of the 3-step pre-analytic protocol. A handheld laminated card, displayed in *Figure 1*, was distributed to all staff to use as a quick reference guide.

The pre-analytic protocol consists of three steps: specimen collection, labeling, and handling. The first phase emphasizes high quality collection via MSCC and indwelling or intermittent catheterizations. The second phase establishes an allocated 30-minute timeframe between collection and transfer of the specimen into a preservative-base container, or it must be discarded and recollected. The final phase ensures the collection technique used is appropriately identified on the label.

Outcome Measures

Pre-implementation data extraction and analysis was performed for the month of July 2019. Post-implementation analysis was between September 29 and November 30, 2019. Once de-identified, data was analyzed using SPSS version 26.

Basic demographic information collected on each patient is displayed in Table 1. Additional variables included urine test interpretations, orders, and collection methods (Table 2). An epithelial cell count >5 cells/high power field (hpf) defined UA contamination. Colony forming units (CFU) were not obtainable by this data collection process, thus if >2 organisms or skin flora were present on UC, it was considered contaminated.

Data Analysis

Frequency statistics were performed on both the pre- and post- implementation datasets. Chi-square test for independence was used to determine if a relationship between categorical data existed. To accommodate for the ongoing educational sessions, both October and November were compared individually and collectively. An alpha level of $\leq .05$ was used.

Results

Demographic information is displayed in Table 1. The pre- and post- implementation samples were homogeneous.

As shown in Table 2, when comparing October and November collectively, a chi-square test for independence indicates no significant association between UA or UC contamination and implementation of educational in-services, (χ^2 (1, n = 1303) = .01, p = .93, *phi* = -.01; χ^2 (1, n = 1303) = .74, p = .39, *phi* = -.3, respectively). However, accounting for the staff education differences, there was a significant relationship between UC contamination rates and education during the month of November (χ^2 (1, n = 791) = 3.78, p = .05, *phi* = -.07). A significant association was also noted between collection technique documented and staff education, χ^2 (1, n = 1303) = 7.59, p = 0.02, phi = 0.76.

Illustrated in Table 3, a chi-square 3x2 cross-table test for independence demonstrated a significant association between epithelial cell counts and UC contamination, χ^2 (1, n=1303) = 33.25, p = .00, V = .16. Of the UC specimens stemming from an epithelial cell count 3-5 cells/hpf (n = 169), 68.6% of them were contaminated.

Discussion

The primary intervention of this QI project was to educate staff on a pre-analytic protocol and evaluate the effects on contamination rates. Several key findings emerged. Illustrated in Figure 2, there was no effect on UA contamination, however a 7.1% reduction in the UC contamination rate was demonstrated. Documented intermittent and foley catherization occurrences more than doubled for both post-implementation months, arguing increased knowledge produces clinical change. And, over 50% of the samples that yielded epithelial counts of 3-5cells/hpf resulted in contaminated UCs.

Limitations

Limitations to this QI project include a short 2-month analysis time frame. Additionally, the inability to measure staff compliance with the protocol limited the overall clinical effect and comparable analysis.

Conclusions

This project supports the use of staff education for the purpose of reducing urine contamination but demonstrates the additional need to mandate the pre-analytic protocol to produce stronger clinical impact. Furthermore, a lower epithelial cell count threshold of ≥ 3 cells/hpf should be used for UA interpretation, indicating clinical guideline recommendations for recollection of UA if a UC would be beneficial in that clinical setting. Standardized collection of urine samples, accurate labeling, and consistent specimen handling procedures demonstrate the significant influence nursing has on patient care and outcomes.

Returning to Deming's revolving PDSA model for QI, the recommendations for future endeavors should analyze longer investigative periods, evaluate true knowledge gained during education sessions, and add applications that would help to ensure staff compliance with the protocol. Education in addition to mandating a pre-analytic protocol can be both clinically and statistically significant in reducing urine contamination. Thus, additional projects that have the ability to evaluate such combined methods should be pursued.

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Table 1.

Demographic Characteristics of Emergency Department Patients

Characteristics	**n**	**%**	**Mean (SD)**	**Media**		***p*[a]**
Age						
July	369	100	60.3 (22.0)	65	83	0.245
October/November	934	100	58.7 (23.7)	63	86	

	July		October/November		
	n	%	n	%	*p*[b]
Gender					
Male	105	28.5	266	28.5	1.0
Female	264	71.5	668	71.7	
Shift Treated					
Day Shift	226	61.2	593	63.5	0.489
Night Shift	143	38.8	341	36.5	
Emergency					
Main ED	272	73.7	704	75.4	0.581
FSED	97	26.3	230	24.6	

Notes. SD = Standard Deviation; p value for significance <0.05

[a]p value for age represents independent t test analysis.

[b]p value for gender, shift, and Emergency Department represents Chi-Square analysis

Table 2.

Characteristics of Urine specimens

Variable Label	July (n= 369) n	July (n= 369) %	October (n=512) n	October (n=512) %	p[a]	November (n=422) n	November (n=422) %	p[b]	p[c]
Laboratory Test Ordered									
Urinalysis (UA)	73	19.8	70	13.7		79	18.7		
UA with Microscopy	84	22.8	86	16.8		73	17.3		
UA with Microscopic Reflex	212	57.5	356	69.5		270	64.0		
Collection Technique									
Mid-stream clean catch	351	95.1	462	90.2		383	90.8		
Intermittent Catheterization	14	3.8	39	7.6	0.03	30	7.1	0.06	0.02
Foley Placement	4	1.1	11	2.1		9	2.1		
Urinalysis Contamination									
Epithelial cell count <5 cells/hpf	327	88.6	454	88.7	1.0	377	89.3	0.84	0.93
Epithelial cell count >5 cells/hpf	42	11.4	58	11.3		45	10.7		
Urinalysis Interpretation									
Negative UTI criteria	69	18.7	22	4.3		16	3.8		
Positive UTI criteria	300	81.3	490	95.7		406	96.2		
Culture Interpretation									
Not contaminated	152	41.2	207	40.4	0.89	204	48.3	0.05	0.39
Contaminated	217	58.8	305	59.6		218	51.7		

Notes: p value for significance is <0.05

[a]Chi-Square analysis of July and October data.

[b]Chi-Square analysis of July and November data.

[c]Chi-Square analysis of July and October/November combined

Table 3.

Epithelial Cell Count and Urine Culture Contamination

Epithelial Cell Count (cell/hpf[b])	**UC[c] Not contaminated n = 563**		**UC Contaminated n = 740**		p[a]
	n	%	n	%	
≤2	471	47.6	518	52.4	
3-5	53	31.4	116	68.6	.00
>5	39	26.9	106	73.1	

Notes: ≤2 cells/hpf represents those specimens with negative and 0-2 analysis; Statistical significance = $p < .05$
[a]Chi-square 3x2 analysis for significance between Epithelial cell counts and urine culture contamination.
[b]hpf represents "high power field"
[c]UC – urine culture

Figure 1. Pocket reference guide created for staff.

Pre-Analytic Urine Collection Process

COLLECTION TECHNIQUE

Mid-Stream Clean-Catch Specimen	*Catheterized Specimen*
6. **High quality patient education (If felt patient unable to perform clean-catch successfully, discuss catheterization method with provider)** 7. **Spread labia or retract foreskin** 8. **Cleanse around urethral opening** 9. **Void into commode** 10. **Collect <u>mid-stream</u> specimen into sterile container**	5. **Ensure sterile technique** 6. **<u>Intermittent straight cath</u> – collect specimen from closed-system bag port directly into sterile container.** 7. **<u>New indwelling foley placement</u> – allow 5-10mls of urine to pass into tubing/bag** 8. **Clamp tubing and withdraw <u>mid-stream</u> sample into sterile syringe from collection port**
Avoid urinals and hats if at all possible, as they are not sterile and less likely to obtain mid-stream sample.	**NEVER collect specimen from foley bag.**

HANDLING TECHNIQUE

4. **Write current time on the specimen cup when provided to patient for sample collection.**
5. **<u>30 minute time limit</u> to transfer specimen into preservative-base testing tube.**
6. **Discard specimen and recollect if greater than 30 minutes has passed from time of collection**

LABELING TECHNIQUE

4. **Prior to printing label in EPIC, ensure that the <u>correct specimen collection technique is selected</u> for appropriate laboratory analysis**
5. **Ensure the RIGHTs of specimen labeling – right patient, time, date, and specimen**
6. **Document in the chart whether the specimen was collection via foley placement or I&O cath.**

Figure 2. Urine contamination rate trends.