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A Need for a Time-Out: A Consensus Statement From the Post-Acute and Long-Term Care Medical Association (PALTmed) on the Use of Urine Polymerase Chain Reaction Testing for Urinary Tract Infections

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A B S T R A C T

Identification and appropriate treatment of urinary tract infections (UTIs) is challenging in post-acute and long-term care (PALTC) settings. Urine polymerase chain reaction (PCR) has emerged as a rapid diagnostic alternative to standard urine culture, gaining increasing adoption in nursing homes despite limited guidance on its appropriate use. In response to concerns regarding clinical utility, a small workgroup composed of members of the Infection Advisory Subcommittee convened in 2024 to develop a consensus statement on urine PCR testing in PALTC settings. A comprehensive literature review identified several issues. Urine PCR demonstrated a high sensitivity for organism detection, including those of unclear clinical significance. This may lead to UTI overdiagnosis. Discrepancies between gene resistance data and phenotypical antibiotic susceptibilities may result in inaccurate antibiotic selection, with a lack of established treatment thresholds further complicating decision-making processes. Moreover, the cost of urine PCR testing is significantly higher than standard urine culture and much of the supporting literature is biased due to industry funding. Most importantly, no objective studies have demonstrated improved patient outcomes associated with the use of urine PCR. Based on these findings, we recommend against the routine use of urine PCR testing for UTI diagnosis in patients who are in PALTC settings. Its widespread use will likely drive unnecessary antibiotic use, increasing the risk of antimicrobial resistance and its associated harms. Further research is needed to firmly define the population of patients who are in PALTC settings who would benefit from urine PCR testing.

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Endorsements

This consensus statement is endorsed by the Society for Healthcare Epidemiology of America (SHEA), the Association for Professionals in Infection Control and Epidemiology (APIC), and the American Association of Post-Acute Care Nursing (AAPACN).

Executive Summary

- We recommend against the routine use of urine polymerase chain reaction (PCR) testing for the diagnosis of urinary tract infection (UTI)
- Evidence supporting urine PCR is often biased because of funding sources, and there is no objective evidence of patient benefit
- Urine PCR testing likely will lead to unnecessary antibiotic use, which drives antimicrobial resistance

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- Antibiotic stewardship programs should use the CDC's Core Elements of Antibiotic Stewardship for Nursing Homes as a framework to engage with the multidisciplinary team when making decisions on urine testing

Testing and treatment of urinary tract infections (UTIs) represent a frequent clinical challenge in post-acute and long-term care (PALTC) settings.[1] Inappropriate urine testing is often driven by concerns about missing an infection and misconceptions about the significance of nonspecific symptoms.[1,2] When ordered in the absence of clinical signs and symptoms of a UTI, these results are frequently misinterpreted as indicative of infection, leading to unnecessary antibiotic prescribing.[1,2] This practice puts patients at risk of significant harms, including *Clostridium difficile* infections and antibiotic resistance.[1,2] Furthermore, more than half of antibiotics prescribed in PALTC settings for UTI are considered inappropriate.[1]

Urine polymerase chain reaction (PCR) is a multiplex molecular testing method that uses pathogen-specific primers to identify a microbiological target within the urine sample. Marketed to PALTC settings as a faster and superior alternative to standard urine culture,[3] its use has risen sharply, with billing claims increasing by more than 60-fold since 2016 with the highest growth among nursing home residents.[4] Several factors including increasing use of urine PCR testing, emerging literature on its antimicrobial and diagnostic stewardship implications,[4-7] and clinical scenarios such as the one outlined in Table 1 prompted the Infection Advisory Subcommittee of the Post-Acute and Long-Term Care Medical Association (PALTmed) to evaluate the role of urine PCR testing within current best practices.

Methods

The urine PCR consensus statement workgroup was formed in summer 2024. Its purpose was to review the currently available literature on urine PCR testing and develop recommendations on its role within antibiotic stewardship and urinary diagnostic processes. Although literature on urine PCR testing does not specifically address PALTC settings, most studies include older adults. The recommendations in this consensus statement are intended to provide guidance and do not replace clinical judgment.

The workgroup collectively outlined the scope of the statement. Literature review and creation of the initial draft was performed by J. Z., who submitted it for review to the current and past chairs (S.A. and G.D., respectively) and vice chair (N.O.) of the subcommittee. It was then edited and sent to the entire subcommittee for review. Consensus was achieved through incorporating the feedback into the draft document by a core group (J.Z., S.A, G.D., and N.O.). The draft was then sent to partner organizations (the Society for Healthcare Epidemiology of America, the Association for Professionals in Infection Control and Epidemiology, and the American Association of Post-Acute Care Nursing) and the PALTmed Board of Directors for their review and endorsements. The core group made some minor adjustments based on the suggestions received and finalized the consensus statement. It was then submitted for publication after receiving approval by the Infection Advisory Subcommittee and the PALTmed Board of Directors.

Table 1
Mock Urine Polymerase Chain Reaction Testing Report

Example Scenario:
Mrs Johnson is an 82-y-old woman with a diagnosis of stage 4 Parkinson's disease who is unable to ambulate without assistance. Her medical history is consistent with obesity, type 2 diabetes, and hypertension. She has no allergies to medications. Mrs Johnson's care team has noticed that she is acting confused today. After a call to the provider, an order is placed for a urine test for suspected urinary tract infection (UTI). The provider specifically requests urine polymerase chain reaction (PCR) testing, as she has heard this testing method finds bacteria that are often missed by standard culture and results are available more rapidly. The below result* is faxed to the provider 24 h later.

Pathogens found:	**Quantity detected:**
Actinobaculum schaalii	>100,000 cells/mL
Aerococcus urinae	>100,000 cells/mL
Escherichia coli	>100,000 cells/mL
Klebsiella oxytoca	>100,000 cells/mL
Enterococcus faecium	10,000-49,999 cells/mL

Antibiotic resistance genes found:
1. *CTX-M* group 1, group 2, group 9, group 8/25 (extended spectrum beta-lactamase producing organism)
2. *TEM* (beta-lactamase producing organism)
3. *Sul1*, *Sul2* (sulfonamide resistance)

Antibiotic Recommendations†:
First choice:
- Nitrofurantoin 100 mg PO BID × 5 d

Alternatives:
- Fosfomycin 3 g PO × 1 dose
- Levofloxacin 250-750 mg PO qd × 7 d + linezolid 600 mg PO BID × 7-10 d
- Meropenem 1 g IV q8h × 5 d + vancomycin per pharmacy dosing protocol

BID, twice a day; IV, intravenous; PO, orally; qd, once a day; q8h, every 8 hours.
*Results are from a single urine sample. Method of collection (eg, midstream void, catheterization) is unknown.
†Covers all organisms detected.

Current Best Practices for Diagnosing UTIs

UTI is a clinical diagnosis based on specific symptoms plus a positive urinalysis (UA) and urine culture as outlined in our previous UTI consensus statement (See Figure 1).[1] Nonspecific symptoms such as altered mental status, foul-smelling urine, and falls have low positive predictive values (PPVs) for the diagnosis of UTI.[8-11] Studies have shown no benefit for treating these symptoms with antibiotics, and guidelines recommend investigating alternative causes.[1,2]

Asymptomatic bacteriuria (ASB) is often misdiagnosed as UTI, leading to an overuse of antibiotics.[1,2] ASB is defined as a positive urine culture (with or without pyuria) in the absence of UTI symptoms and affects up to half of all patients in PALTC settings.[1] Antibiotic treatment is not recommended as it does not reduce the risk of death, altered mental status, or sepsis.[2] When it is difficult to differentiate between ASB and UTI in clinically stable patients without signs of sepsis, active monitoring and assessment for other causes are recommended.[1,2] The Loeb Minimum Criteria guide PALTC clinicians on when to consider antibiotic treatment.[12]

UA and urine culture are recommended only in patients who meet clinical criteria for a UTI (See Figure 1).[1,2] To ensure the integrity of the sample and minimize contamination, the collection process involves cleaning the genital area and collecting a midstream sample.[13] If unable to give a sample, in-and-out urinary catheterization may be utilized for women and a temporary condom catheter may be used for men.[1] Catheterized patients (especially those with the presence of a catheter for over two weeks) should have their catheters replaced prior to collection to ensure an accurate result.[1] Ordering a UA with reflex to culture is recommended, as it was shown to safely decrease inappropriate antibiotic usage.[14] After collection, the sample should be refrigerated and promptly tested either at the point of care or in the external laboratory.[13] Point-of-care testing is performed using a dipstick that measures specific chemical parameters (ie, nitrite and leukocyte esterase).[6] It is important to note that a UA that is negative for leukocyte esterase and nitrites rules out a UTI. However, UA that is positive for either leukocyte esterase or nitrite does not confirm a UTI.

Culture is warranted to identify organisms and their antibiotic sensitivities. *Escherichia coli* is responsible for 75-95% of uncomplicated UTIs, followed by *Klebsiella pneumoniae*, and *Proteus mirabilis*.[15] Other organisms are less common and usually associated with sample contamination, urinary colonization, or patients with special

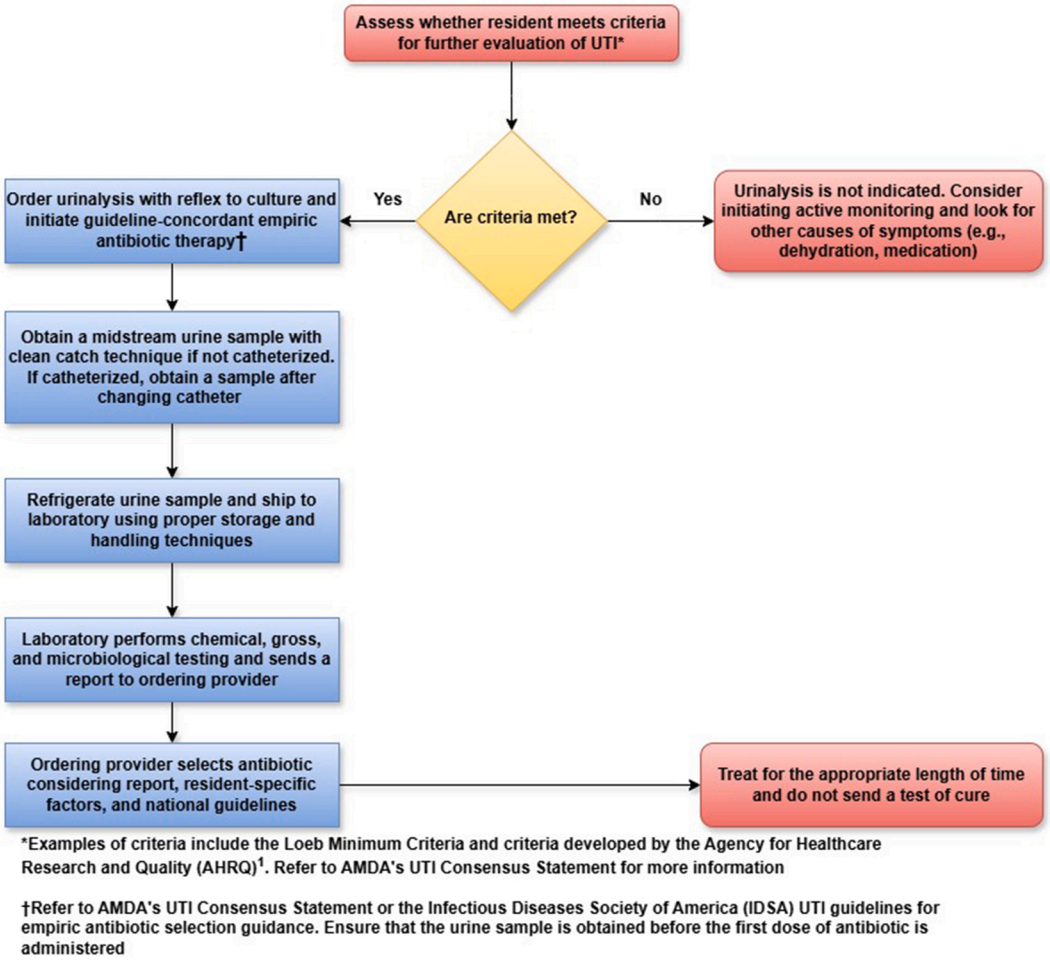

Fig. 1. Decision tool for diagnosis and treatment of suspected UTI in older adults.

conditions such as structural urinary tract abnormalities. Empiric antibiotic selection is based on patient-specific factors, prior urine culture results, and best practice guidelines. Urine culture results are used to initiate or adjust treatment based on the antibiotic susceptibility report. Tests of resolution of the infection are not recommended once treatment is completed.[1]

Comparing the Current Standard of Care & Urine Polymerase Chain Reaction Testing

UA + Urine Culture and Sensitivity (The Current Standard of Care)

UA plus culture and sensitivity techniques jointly allow for the examination of gross, chemical, and microbiological parameters.[16] UA has been used for over 200 years to assist in diagnosing UTI.[16] Urine culture is considered the gold standard diagnostic method as per multiple society guidelines and consensus-based criteria.[1,2,12,15] Results are reported in colony-forming units (CFUs) per milliliter or CFUs per liter, as culturing techniques only allow for the growth of live and replicating bacteria. Quantities greater than 10^5 CFUs/mL in both catheterized and noncatheterized patients are recommended by guidelines as treatment thresholds, although $\geq 10^2$ to $<10^5$ CFUs/mL may also indicate infection in catheterized patients and in those whose samples were collected by an in-and-out catheter.[1,2] When ordered in the presence of specific symptoms, it provides information to assist with the use of targeted antibiotic therapy. Although the current standard of care is well-established and recognizable to all clinicians, there are some notable strengths and weaknesses.

UA parameters are poor predictors of a UTI diagnosis.[17] The presence of leukocyte esterase, nitrites, bacteriuria, and pyuria is often interpreted as evidence of infection before culture results are available.[16,17] A multicenter, retrospective cohort study found that the PPV of these parameters for diagnosing UTI is low, varying between 20% and 43%.[18] The negative predictive value (NPV) for individuals aged ≥65 years was high, between 81% and 100%.[18] The PPV of these parameters for detecting the growth of *E coli* ranged between 38% and 51%.[18] Another analysis of approximately 33,000 UAs with cultures from a single hospital found that the PPV of these parameters ranged between 4% and 45% in all groups with an NPV approaching 100%.[17] Therefore, UA is primarily useful to rule out UTI rather than confirming its presence.

Urine culture is reliable for the detection of clinically significant organisms with a sensitivity of 90% and specificity of 89% for the diagnosis of UTI.[19] Routine use of specialized culture media (eg, anaerobic or fungal) is not recommended as the majority of UTIs in older adults are due to gram-negative bacteria.[20,21] Specialized culture methods may be considered for patients who have a higher pretest probability of less common organisms,[20] such as those with confirmed UTI who are not responding to standard antibiotic treatment.

The delay between ordering urine culture and receiving the results poses a challenge to timely diagnosis and targeted antibiotic treatment.[22] Many PALTC facilities are contracted with outside

laboratories, which extends the turnaround time of culture results. Organism identification and antimicrobial susceptibility testing can take up to 72 hours.[6,23] This delay in availability of culture results can hinder the ability to escalate therapy in response to an antibiotic-resistant organism, putting patients at risk of more significant illness.[22]

Urine PCR

Urine molecular testing for organisms by PCR has been available since 2016[4] and can detect up to 42 different organism types in a single sample, along with several antibiotic resistance genes.[5,24] Unlike standard urine culture, both dead and live genetic material are detected,[5,6] and results are reported as cells per milliliter or copies per microliter rather than CFUs per milliliter.[5] Results are often accompanied by antibiotic recommendations based on the detected organism and resistance gene(s) (see Table 1); however, they lack phenotypic susceptibility data.[5] The sensitivity and specificity of PCR for UTI diagnosis are currently unknown because of a lack of high-quality data.

Urine PCR tests are laboratory-developed tests (LDTs) that are neither approved nor regulated by the FDA. Unlike in vitro diagnostics, which are developed by commercial laboratories and regulated by the FDA, laboratory-developed tests are developed and validated by individual laboratories regulated under Clinical Laboratory Improvement Amendments through the Centers for Medicare and Medicaid Services.[4,25] Standards vary between laboratories, and no universal best practices exist for interpreting urine PCR results.[6] Although newer testing options are needed in PALTC settings for UTIs, other significant evidence gaps exist when comparing PCR to the current standard of care.

Limitations of Studies Supporting Urine PCR for Addressing False-Negative Rates in Urine Cultures

One argument supporting the use of urine PCR is its potential to address false-negative urine cultures.[6,26-29] However, studies supporting this claim have significant limitations. Several are surveillance studies that did not compare the sensitivity of PCR to urine culture and did not assess clinical outcomes in those without bacteriuria despite UTI symptoms (Supplementary Table 1).[27-29] These instead focused on regional or multinational susceptibility patterns of UTI organisms using urine samples that were sent only for culture, with only 1 study also assessing correlations between UTIs and clinical information. Studies directly comparing urine PCR to culture often detected bacterial genetic material in culture negative urine samples (Supplementary Table 2),[26,30-32] but did not use guidelines that defined clinical criteria for UTI symptoms to enroll patients and failed to assess clinical outcomes. The only study applying defined clinical criteria for patient selection focused exclusively on young, healthy adult women and specifically excluded older adults (Supplementary Table 2).[26] Additionally, quantification of the organisms detected varied significantly, and some PCR samples containing *E coli* genetic information ultimately grew a different bacterial species when cultured. Additional research is needed to define the role of PCR in older adults who have negative urine cultures with signs and symptoms suggestive of a UTI.

Comparison of Urine PCR and Culture in Detecting Clinically Significant Organisms

Detection of clinically significant organisms from PCR is comparable to urine culture.[5] Studies in which older adults were represented comparing urine PCR to urine culture have shown approximately a 5% difference in the detection of *E coli*[5] with an overall 82% to 90% agreement between the 2 methods (Supplementary Table 2).[5,6,30,32] Discrepancies typically involve organisms that are either contaminants (eg, *Actinobaculum schaalii*, coagulase-negative *Staphylococcus aureus*, viridans streptococci) or uncommon causes of uncomplicated UTI (eg, *Aerococcus urinae*),[5] contrasting with the targeted approach of urine culture.[20] Urine PCR has a 13% to 21% higher rate of polymicrobial results than urine culture,[6,30] with many of these microbes being considered common contaminants or rare causes of uncomplicated UTI (Supplementary Table 2).[30-32] By identifying organisms that are unlikely to be clinically relevant, PCR testing potentially leads to confusion about appropriate treatment and might lead to overtreatment. More data focused specifically on other organisms defined as significant by clinical guidelines (eg, *K pneumoniae*, *P mirabilis*) are needed to further assess the value of urine PCR.[5]

Limitations of Resistance Gene Data for Antibiotic Recommendations in Urine PCR Testing

Antibiotic recommendations included in some reports are based solely on the detection of resistance genes, which may lead to inappropriate antibiotic treatment (Table 1).[24,33] Although resistance gene data are useful for targeted therapy decisions in select syndromes such as bloodstream infections,[34] they may be challenging for a noninfectious diseases trained provider to interpret.[6] Additionally, while genotype results inform phenotype, they are not equivalent.[35] Genotypic testing assesses for the presence of select

Table 2
Comparison of Urine Culture and Urine PCR for UTI Diagnosis and Decision Making

Factors Impacting Decision Making Between Using Urine Culture and Urine PCR	Urine Culture	Urine PCR
Sensitivity and specificity for UTI diagnosis	90% and 89%[19]	Unknown
Can independently diagnose a UTI	No[1,2]	No[1,2]
Scope	Live organisms only[5,6]	Live and dead organisms[5,6]
Organisms detected	Clinically significant organisms, with the option to order specialized testing[20]	Detects up to 42 different organism types regardless of clinical significance[5,24]
Turnaround time for final result	Up to 72 h[6,23]	24 h[3,5,6]
Detects antibiotic resistance genes	No	Yes
Phenotypic susceptibilities	Yes	No, but can be performed separately[5]
Standardized organism thresholds (eg, CFUs/mL) for UTI Diagnosis	Yes[1,2]	No[6]
Impact of contamination	Yes[5,6,38,41]	Yes, can lead to detection of clinically irrelevant organisms[5,6,38,41]
Available non−manufacturer-funded clinical outcomes data for older adults	Yes	No[5]

antibiotic resistance genes, whereas phenotypic testing provides detailed susceptibility information to guide antibiotic selection. As the absence of a resistance gene does not necessarily indicate susceptibility to alternative antibiotics,[35] studies of urine PCR have found a 13% to 40% disagreement between the two.[6,36,37]Therefore, phenotypic antibiotic testing is considered the gold standard for determining optimal antibiotic selection,[35] and recommendations based solely on resistance gene data without validation by phenotypic testing should not be relied upon for clinical decision making.[37]

Challenges in Interpreting Quantitative Urine PCR Results for Treatment Decisions

Unlike urine culture, there are no established treatment threshold levels for quantitative urine PCR results.[5,6] A culture result of $\geq 10^5$ CFUs/mL of $\leq$2 bacterial species in the presence of UTI symptoms is typically used to guide the decision to treat.[1] In contrast, PCR reports detect organisms quantitatively and often classify them as low, moderate, or high levels.[6] However, the clinical significance of any urine PCR results reported as cells per milliliter or copies per microliter is unknown, as these values reflect both live and dead genetic material.[5,6]

Further Evidence Gaps and Cost-Effectiveness of Urine PCR Testing for UTI Diagnosis

There are further evidence gaps regarding the overall clinical outcomes and cost-effectiveness of urine PCR testing. Existing literature on this topic is often biased because of funding sources and frequently fail to incorporate guidelines that define clinical criteria for UTI symptoms into their inclusion criteria.[5] More data are needed to better inform clinical outcomes.[5] Although the turnaround time of 24 hours for urine PCR results is advantageous,[5,6] the test is significantly more expensive. A nationwide analysis of Medicare claims data showed that the median cost of PCR in 2023 was $585 compared with $8 for urine culture.[4] Additionally, it remains unclear which patients would derive the greatest benefit from this testing.

Both

Unnecessary urine specimen collection and contamination are concerns across all urine testing methods. Neither standard of care urine culture techniques nor urine PCR tests can independently diagnose a UTI, as the diagnosis relies primarily on clinical evaluation in conjunction with the urine test results. Urine testing should not be performed in patients who do not meet criteria for UTI, as it may promote unnecessary antibiotic use.[1,2]

Avoiding urine specimen contamination is essential. Contamination often occurs as a result of improper clean catch technique, lack of written collection instructions, and improper storage and transportation of the collected urine sample to an outside laboratory.[38] A study conducted of 127 laboratories found average sample contamination rates ranging from <1% to approximately 42% with a median rate of 14% in adults older than 50 years.[38] Currently, no data quantify contamination rates specific to urine PCR practices, which recommend storing the sample at room temperature or refrigeration.[37,39,40] However, contamination rates are expected to be higher as the methods to obtain these samples use the same collection methods as standard testing, and its high sensitivity increases the likelihood of detecting contaminants.[30,39] Some PCR manufacturers also advertise the option of swabbing adult diapers as a collection technique.[5,6,41,42] However, studies of urine samples from diapers did not account for the impacts of fecal and skin contamination on sample quality (Supplementary Table 3).[43-46] Furthermore, a slight increase in false positives was noted in 2 studies (Supplementary Table 3).[43,45] One also recommended further research before widespread clinical use to evaluate the potential impacts of external contamination on UTI overdiagnosis.[43] Studies in pediatric populations showed similar limitations.[47-49] Given those concerns, clinical guidelines do not recommend collecting urine specimens from diapers.[1,2,15] Table 2 highlights other factors that may impact decision making when considering between the use of urine culture and urine PCR for diagnostic testing.

The Role of the PALTC Antibiotic Stewardship Program

The goal of diagnostic stewardship is to decrease the use of tests in patients with a low pretest probability of infection, ultimately leading to improved antibiotic use.[50] The CDC's Core Elements of Antibiotic Stewardship for Nursing Homes contains practical recommendations that all PALTC programs can implement to achieve this objective.[51] Additional suggestions are outlined below.

Program leaders can provide tailored guidance to providers by setting up standards for diagnostic testing for the facility and developing facility-specific guidelines for empiric UTI treatment. These guidelines can help standardize first-line antibiotic choices and durations. Tools from national organizations such as the Agency for Healthcare Research and Quality (AHRQ) can assist with creating these guidelines. Empiric treatment should take into consideration the patient's past individual culture history.[1]

Multidisciplinary team members can educate patients, family members, and the entire multidisciplinary team on UTI. For providers and the clinical team, education should focus on best practices for urine testing and promote consistent communication with patients.[52] For patients and families, education should clarify the symptoms specific to UTI and emphasize individual risks of unnecessary antibiotic use.[52]

Facilities can coordinate with contract laboratories to ensure routine implementation of their diagnostic testing standards for UTI (eg, implementing process for UA with reflex to urine cultures). Monitoring urine culture ordering practices and sharing findings at quality assurance performance improvement (QAPI) committees can help secure leadership support and foster ongoing improvements.

Recommendations and Research Needs

Recommendations

On the basis of the identified evidence gaps, we recommend against the routine use of urine PCR at this time. PALTC settings should continue to use standard of care techniques when appropriate to diagnose and treat UTI. Additionally, antibiotic stewardship programs should use the CDC's Core Elements of Antibiotic Stewardship for Nursing Homes as a framework to engage with the multidisciplinary team when making decisions on urine testing.

Research Needs

New urinary diagnostic methods or biomarkers[2,22] are needed to assist PALTC practitioners in diagnosing UTI. Although urine PCR testing represents a step forward, significant evidence gaps remain in clearly defining its role in urinary diagnostics and antibiotic stewardship. Future research should focus on clinical outcomes associated with urine PCR testing[5,22] and explore strategies to optimize its application in older adults. Establishing thresholds for clinical relevance and treatment for organisms detected on urine PCR testing is also needed.[22] Additionally, the impact of urine PCR on antibiotic prescribing practices should be examined to determine the benefits or barriers to stewardship programs.[4,22] More data are needed to

identify the specific patients in PALTC settings that would benefit most from this test.[4,5]

Disclosure

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Supplementary Data

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