

# Impact of a Pharmacist-Led Urinary Tract Infection Treatment Protocol in a Psychiatric Hospital Without Infectious Disease Support: A Before-After Study

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## Abstract

**Background:** Urinary tract infections (UTIs) are often misdiagnosed and inappropriately treated in psychiatric hospitals, largely due to challenges in patient communication, polypharmacy, and limited access to infectious disease specialists. In a psychiatric hospital setting in Tehran, Iran, ciprofloxacin was frequently prescribed despite guideline warnings, leading to a pharmacist-led intervention aimed at improving antimicrobial stewardship. This study aimed to evaluate the effectiveness of implementing a standardized urinary tract infection (UTI) treatment protocol, designed and supervised by a clinical pharmacist, on improving diagnostic accuracy and antibiotic prescribing in a psychiatric hospital setting.

**Methods:** This before–after study was conducted at Roozbeh Hospital over a six-month period. In phase one, urinary tract infection treatments were initiated without pharmacist consultation. In phase two, a mandatory pharmacist-led protocol was implemented based on the Infectious Diseases Society of America (IDSA) and Journal of the American Medical Association (JAMA) guidelines. Data on urine culture rates, antibiotic selection, dosage accuracy, and treatment appropriateness were compared across both phases.

**Results:** A total of 94 patients were included — 34 in phase I and 60 in phase II. Urine culture request rates improved from 26.5% to 95% ( $P < 0.001$ ), reflecting adherence to the new protocol rather than case complexity. Correct antibiotic selection increased significantly ( $P = 0.004$ ), with fosfomycin replacing ciprofloxacin as the preferred agent. High-dose errors decreased from 29.4% to 8.3% ( $P = 0.02$ ), and unnecessary treatment of asymptomatic bacteriuria declined from 23.5% to 2% ( $P < 0.01$ ).

**Conclusion:** Pharmacist-led interventions improved diagnostic precision and antibiotic use in this psychiatric setting, suggesting a critical role for clinical pharmacists in antimicrobial stewardship, particularly in resource-limited mental health facilities.

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**Keywords:** Urinary Tract Infection; Treatment Protocol; Pharmacist-Led Intervention; Antimicrobial Stewardship; Psychiatric Hospitals; Ciprofloxacin Stewardship; Asymptomatic Bacteriuria

## Introduction

Urinary tract infections (UTIs) are among the most prevalent bacterial infections worldwide, affecting over

150 million individuals each year (1). Women, particularly those over the age of 65, are disproportionately affected, and *Escherichia coli* remains the leading causative pathogen (2,3). In most clinical settings, UTIs are typically managed

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with empiric antibiotic therapy. However, inappropriate selection of antibiotics, incorrect dosing, and unnecessary treatment of asymptomatic bacteriuria remain common issues, especially in environments with limited infectious disease oversight (4,5).

Psychiatric hospitals present unique challenges for the diagnosis and management of UTIs. Many patients struggle with communication, self-care, and adherence, and are often on complex psychotropic regimens. These factors not only complicate symptom recognition and urine collection but also increase the risk of drug-drug interactions (6,7). Despite these challenges, few antimicrobial stewardship initiatives specifically target psychiatric inpatient settings. At Roozbeh Hospital, a major psychiatric referral center in Tehran, Iran, the hospital pharmacy observed a high rate of inappropriate antibiotic prescriptions for UTIs, particularly involving ciprofloxacin — a fluoroquinolone that is discouraged in uncomplicated cases by the Infectious Diseases Society of America (IDSA) (8). Additionally, urine cultures were rarely performed prior to initiating treatment, and antibiotic choices often disregarded established guidelines. Importantly, the hospital lacks access to on-site infectious disease specialists, placing greater responsibility on pharmacists and general physicians.

In response, a clinical pharmacist-led UTI treatment protocol was developed and approved by the hospital's Drug and Therapeutics Committee. The protocol, adapted from IDSA (2010) and JAMA (2014) guidelines, mandated pre-treatment urine culture and pharmacist consultation for all suspected UTIs. This study was designed to evaluate the impact of implementing the protocol on diagnostic accuracy and antibiotic prescribing behavior in a psychiatric inpatient setting.

## Methods

### *Study Design and Setting*

This was a quasi-experimental before-after study conducted over a six-month period at Roozbeh Hospital, a major psychiatric teaching center affiliated with Tehran University of Medical Sciences. Both phases enrolled consecutive inpatients from the same psychiatric wards under unchanged admission policies and clinical workflows. Based on chart abstraction and routine ward records, the patient mix (e.g., age distribution, sex, and clinical complexity) was broadly similar across phases. The intervention was implemented and completed prior to the onset of the COVID-19 pandemic, specifically in late 2019. Since then, the protocol has remained in place and continues to be part of the hospital's routine practice. Given the absence of an on-site infectious disease specialist, antimicrobial decision-making at the hospital

has traditionally relied on general practitioners and clinical pharmacists. Both uncomplicated and complicated urinary tract infection (UTI) cases, as defined by the Infectious Diseases Society of America (IDSA) guideline, were included reference (8). As the study included all eligible patients during both phases, no formal sample size calculation or power analysis was deemed necessary.

### *Participants*

All inpatients diagnosed with UTI by their attending psychiatrist and for whom an antibiotic was prescribed were included. Patients aged 4 to 82 years were enrolled, covering all age groups admitted to psychiatric wards during the study period. Exclusion criteria included prophylactic antibiotic use unrelated to UTI and incomplete documentation. Uncomplicated UTI was defined as acute cystitis in nonpregnant females with no structural or functional urinary tract abnormalities. Complicated UTI included UTIs occurring in males, pregnant women, patients with urinary catheters, structural/functional abnormalities, immunocompromised patients, or individuals with significant comorbidities such as diabetes or chronic kidney disease.

### *Study Phases*

#### *- Phase I (Pre-intervention)*

During the first three months, prescriptions for urinary tract infections (UTIs) were issued independently by physicians without standardized criteria or pharmacist involvement. Retrospective analysis was conducted to assess drug choice, dosage, duration, and presence of urine culture.

#### *- Phase II (Post-intervention)*

Following a pharmacist-led review of inappropriate prescribing trends, especially the overuse of ciprofloxacin, a structured treatment protocol was proposed and approved by the hospital's Drug and Therapeutics Committee. The protocol was adapted from the 2010 Infectious Diseases Society of America (IDSA) guidelines (8) and the 2014 Journal of the American Medical Association (JAMA) outpatient UTI recommendations (9).

The implemented protocol required physicians to request a urine culture before initiating antibiotic therapy and to consult with a clinical pharmacist for all suspected UTI cases. Antibiotic selection was guided by established empirical treatment recommendations and recent evidence on the antimicrobial activity of common UTI agents (10), unless microbiological results (antibiogram) suggested an alternative approach. The finalized protocol was disseminated both digitally and in print to all clinical staff, including residents and attending physicians. During the post-intervention

phase, treatment commenced only after urine culture collection and pharmacist evaluation. The pharmacist assessed the necessity of antibiotics and recommended an appropriate regimen based on current guidelines and available microbiological data. A summary of the

empirical antibiotic recommendations based on patient group is provided in Table 1. Asymptomatic bacteriuria was not treated unless in pregnant women, recent renal transplant recipients (< 3 months), or patients undergoing urological procedures (8).

**Table 1. Empirical antibiotic regimens for urinary tract infections based on patient group**

| Patient Group                                         | Recommended Antibiotics                                                                   | Dosage and Duration                                                                                                                                                                                                   |
|-------------------------------------------------------|-------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Uncomplicated UTI (healthy women)</b>              | Nitrofurantoin, Fosfomycin, TMP/SMX, Ciprofloxacin, Levofloxacin, Amoxicillin-Clavulanate | Nitrofurantoin :100 mg BID × 5 days, Fosfomycin: 3 g once, TMP/SMX: 160/800 mg BID × 3 days, Ciprofloxacin: 250 mg BID × 3 days, Levofloxacin: 250 mg QD × 3 days, Amoxicillin-Clavulanate: 500/125 mg BID × 5–7 days |
| <b>Complicated UTI (i.e., men, elderly, diabetes)</b> | Ciprofloxacin, TMP/SMX, Levofloxacin                                                      | Ciprofloxacin: 250–500 mg BID × 7–10 days, TMP/SMX: 160/800 mg BID × 7–10 days, Levofloxacin: 250–500 mg QD × 7–10 days                                                                                               |
| <b>Acute Pyelonephritis</b>                           | Ciprofloxacin, Levofloxacin, TMP/SMX                                                      | Ciprofloxacin: 500 mg BID × 7 days, Levofloxacin: 250 mg QD × 10 days, TMP/SMX: 160/800 mg BID × 14 days                                                                                                              |
| <b>Pediatric Patients</b>                             | Pediatric ID-based therapy                                                                | Weight-based; consult pediatric infectious disease specialist                                                                                                                                                         |
| <b>Special Populations (e.g., transplant)</b>         | Antibiotics per culture and susceptibility                                                | Guided by antibiogram and clinical judgment                                                                                                                                                                           |

Values represent recommended first-line empirical regimens according to IDSA (8) and JAMA (9) guidelines. TMP/SMX: Trimethoprim/Sulfamethoxazole, QD: Once Daily, BID: Twice Daily, UTI: Urinary Tract Infection, Pediatric ID: Pediatric Infectious Diseases.

### Data Collection and Statistical Analysis

Data were extracted from patient records: Antibiotic regimens, dosing, duration, urine culture results, and treatment appropriateness. Demographic and comorbidity variables were available in the medical record at the time of data abstraction and were used to adjudicate UTI classification, but were not retrieved again in structured tabulated format for this manuscript revision. Prescriptions were assessed according to protocol criteria. Appropriateness of each prescription was adjudicated based on its alignment with IDSA guidelines in terms of antibiotic selection, dosing, and duration. Two independent clinical pharmacists reviewed patient charts. Any discrepancies were resolved through discussion and consensus. Comparisons between phase I and phase II were performed using chi-square and Fisher's exact tests. A P-value of < 0.05 was considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA).

### Ethical Considerations

This study was approved by the ethics committee, Tehran University of Medical Sciences (IR.TUMS.TIPS.REC.1404.164).

### Results

A total of 94 patients were included in the study: Thirty-four in phase I (pre-intervention) and 60 in phase II (post-intervention). The majority of patients were female (88.3%,  $n = 83$ ), and patient age ranged from pediatric (4 years) to geriatric (82 years). All participants were hospitalized for psychiatric conditions and diagnosed with suspected or confirmed urinary tract infection (UTI) by the attending physician. Because demographic data were summarized narratively, no separate demographic table was included.

#### Urine Culture Request Rates

In phase I, urine cultures were requested in only 9 of 34 cases (26.5%). Following implementation of the pharmacist-led protocol in phase II, culture request rates increased significantly to 57 out of 60 patients (95.0%;  $P < 0.001$ , Fisher's exact test). A marked shift in antibiotic usage was observed after implementation. In phase I, ciprofloxacin was the most prescribed agent (61.7%), followed by co-trimoxazole and nitrofurantoin. In phase II, fosfomycin became the most frequently prescribed antibiotic (73.3%), and ciprofloxacin use dropped to 11.7%. The detailed distribution of prescribed antibiotics before and after protocol implementation is presented in Table 2.

Table 2. Distribution of prescribed antibiotics before and after protocol implementation

| Antibiotic     | Pre-Protocol (n=34) | Post-Protocol (n=60) |
|----------------|---------------------|----------------------|
| Ciprofloxacin  | 21 (61.7%)          | 7 (11.7%)            |
| Nitrofurantoin | 11 (32.4%)          | 2 (3.3%)             |
| Fosfomycin     | 0 (0.0%)            | 44 (73.3%)           |
| TMP-SMX        | 1 (2.9%)            | 2 (3.3%)             |
| Cefixime       | 1 (2.9%)            | 5 (8.3%)             |

**P < 0.001\***

Values are presented as n (%). \*Statistical test: Chi-square test. P < 0.05 considered statistically significant.

### Appropriateness of Prescribing

Prescription appropriateness significantly improved from phase I to phase II. In phase I, only 41% of prescriptions met criteria for appropriate antibiotic choice, dosing, and

duration. In Phase II, this figure increased to 83% (P = 0.004). Common reasons for inappropriate prescribing in both phases are summarized in Table 3.

Table 3. Reasons for inappropriate prescriptions

| Type of Error                                            | Pre-Protocol (n=34) | Post-Protocol (n=60) | P-value* |
|----------------------------------------------------------|---------------------|----------------------|----------|
| Incorrect dosage                                         | 10 (29.4%)          | 5 (8.3%)             | 0.02     |
| No culture ordered                                       | 25 (73.5%)          | 3 (5.0%)             | < 0.001  |
| Overtreatment of asymptomatic bacteriuria                | 8 (23.5%)           | 1 (1.7%)             | < 0.001  |
| Inappropriate empiric treatment despite negative culture | 2 (5.9%)            | 4 (6.7%)             | P>0.05   |

Values are presented as n (%). \*Statistical test: Fisher's exact test. P < 0.05 considered statistically significant.

### Asymptomatic Bacteriuria Management

In phase I, antibiotics were prescribed for asymptomatic bacteriuria in 8 of 34 cases (23.5%). Following protocol enforcement, this was reduced to only 1 case in phase II (1.7%), showing a statistically significant improvement in diagnostic accuracy (P < 0.01). Additionally, the rate

of high-dose prescribing errors decreased substantially between the two phases, declining from 29.4% in phase I to 8.3% in phase II (P = 0.02). All primary outcome measures with their corresponding P-values and statistical tests are summarized in Table 4.

Table 4. Primary outcomes before and after protocol implementation

| Outcome                      | Phase I (n=34) | Phase II (n=60) | Effect* | P-value <sup>§</sup> |
|------------------------------|----------------|-----------------|---------|----------------------|
| Urine culture requested      | 9 (26.5%)      | 57 (95.0%)      | +68.5   | <0.001               |
| Appropriate prescribing      | 14 (41.2%)     | 50 (83.3%)      | +42.1   | 0.004                |
| ASB overtreatment            | 8 (23.5%)      | 1 (1.7%)        | -21.8   | <0.01                |
| High-dose prescribing errors | 10 (29.4%)     | 5 (8.3%)        | -21.1   | 0.02                 |

ASB: Asymptomatic Bacteriuria. <sup>§</sup>Statistical test: Fisher's exact test. Two-sided  $\alpha=0.05$ . \*Effect reported as absolute risk difference (post – pre) in percentage points.

### Discussion

This study demonstrates the significant impact of implementing a structured, pharmacist-led urinary tract infection (UTI) treatment protocol in a psychiatric hospital setting, leading to measurable improvements in diagnostic accuracy, antibiotic prescribing behavior, and overall appropriateness of therapy. The intervention proved effective even in the absence of an on-site infectious disease specialist, emphasizing the essential role of clinical pharmacists in optimizing antimicrobial stewardship in

resource-limited psychiatric institutions.

Prior to the intervention, ciprofloxacin was widely used despite its well-documented risks, especially in psychiatric populations with complex drug regimens (11,12). Following protocol implementation, there was a marked shift toward guideline-recommended agents like fosfomycin and nitrofurantoin. This change aligns with findings from psychiatric and long-term care institutions, where stewardship efforts have reduced reliance on high-risk antibiotics (13,14).

Fosfomycin was selected as a first-line option in this setting owing to its practical advantages for psychiatric inpatients. Its availability as a single-dose oral therapy made it especially suitable for individuals with poor adherence or difficulty tolerating multiple medications. Furthermore, the drug's minimal interaction with psychotropic agents reduced the risk of adverse events in patients receiving complex psychiatric regimens. These characteristics, combined with its observed effectiveness and favorable safety profile in our population, made it a rational choice for managing uncomplicated UTIs in this context (15,16). Definitions of uncomplicated and complicated UTI have evolved in recent years, and our classification was based on the criteria available at the time of study design. Although the overall reduction in ciprofloxacin use, its prescription remained necessary in select cases. In particular, some patients presented with complicated urinary tract infections or had overlapping conditions such as respiratory infections, where ciprofloxacin's broader antimicrobial coverage made it a pragmatic choice. In these scenarios, its oral availability and dual activity against both pathogens justified its use when more targeted alternatives were either unsuitable or unavailable.

Despite the structured, pharmacist-led protocol, a small number of errors continued to occur in the post-intervention phase. In several cases, attending physicians initiated antibiotic therapy before contacting the clinical pharmacist, which bypassed the intended consultation process. Additionally, newly rotating residents who joined during the intervention period were not yet familiar with the protocol and independently prescribed antibiotics prior to orientation and reinforcement. These two factors largely explain the residual inappropriate prescribing observed after protocol implementation.

In addition to improving antibiotic selection, the protocol contributed meaningfully to more appropriate clinical decision-making. One notable example was the sharp decline in antibiotic use for asymptomatic bacteriuria, a frequent challenge in both psychiatric and elderly patients (17-19). These results are in line with international findings, particularly from European and North American healthcare settings, where structured stewardship efforts have been shown to reduce unnecessary treatment and promote more targeted use of antimicrobials (20,21).

The integration of a clinical pharmacist into the care team proved pivotal. Pharmacist consultation ensured correct dosing, timely urine culture collection, and guideline-adherent therapy. Studies from similar healthcare systems, including Iranian academic centers, have reported that pharmacist-led interventions decrease antimicrobial resistance and improve treatment outcomes (22-25). This is particularly relevant in institutions where infectious

disease consultation is not readily available.

Moreover, our results reflect broader institutional patterns. Previous research in psychiatric hospitals has reported alarmingly high rates of empirical and inappropriate urinary tract infection (UTI) treatment, especially when diagnostic tools are underutilized or unavailable (26,27). The present study contributes to this discourse by offering real-world data on the effectiveness of protocolized care, even in the absence of infectious disease specialists. Several pharmacist-led interventions in general hospital settings have shown meaningful improvements in antibiotic prescribing practices, antimicrobial consumption, and cost-effectiveness. While such models have been well-documented in internal medicine and surgical wards, their application in psychiatric hospitals remains relatively underexplored (28-30).

An educational component was integrated into the intervention to support consistent application of the protocol. It was made available both digitally and in print, and accompanied by staff orientation sessions and ward-based reinforcement strategies. Despite these efforts, a number of new residents were unfamiliar with the protocol during their early rotations, a finding that echoes previous studies underscoring the importance of continuous onboarding and periodic refresher training to maintain adherence (31).

Sustaining the long-term impact of this intervention will require ongoing institutional support. Plans are in place to implement regular audits, provide structured feedback, and include protocol training as part of the orientation process for new clinical staff. In psychiatric facilities where infectious disease specialists are not available on-site, pharmacist-led models such as this offer a practical and sustainable approach to improving antimicrobial stewardship.

Although the protocol was initially designed based on older guidelines available at the time, it is notable that its direction remains consistent with more recent recommendations. For instance, future updates may draw upon the 2024 Infectious Diseases Society of America (IDSA) draft guidelines, which further discourage the use of fluoroquinolones in uncomplicated urinary tract infections (UTIs) and advocate for culture-guided treatment in both inpatient and outpatient settings (8). Likewise, a 2024 consensus statement published in JAMA Network Open by the WikiGuidelines Group emphasizes individualized, patient-centered care and cautions against overtreatment, especially in pediatric and medically complex adult populations (32).

This study has several strengths. It represents one of the few pharmacist-led antimicrobial stewardship initiatives conducted in a psychiatric hospital, a setting often neglected

in infection management research. The intervention demonstrated measurable and sustained improvements in prescribing behavior despite limited infectious disease resources. Additionally, its real-world implementation and continued use beyond the study period highlight its practicality and long-term applicability.

This study was not without limitations. One challenge was inconsistent protocol adherence among newly rotating residents, some of whom were unfamiliar with the system during their early assignments. This issue was particularly noticeable during times of staff transition. In addition, incomplete microbiological documentation in several cases, such as missing culture or susceptibility data, limited the depth of protocol evaluation. Moreover, demographic and comorbidity data were available at the time of original chart abstraction and used for urinary tract infection (UTI) classification adjudication, they could not be retrieved again in a fully structured tabulated format during revision. This limited our ability to present baseline characteristics in a separate table and restricts full assessment of baseline equivalence between phases. Lastly, the study was conducted in a single psychiatric institution with a modest sample size ( $n = 94$ ), which may restrict the broader applicability of the results to other healthcare settings or patient populations.

## Conclusion

Implementing a pharmacist-led treatment protocol for urinary tract infections in a psychiatric hospital led to substantial improvements in diagnostic accuracy, antibiotic appropriateness, and culture-guided prescribing. The intervention significantly reduced unnecessary fluoroquinolone use and promoted adherence to evidence-based guidelines, demonstrating that pharmacist-driven stewardship can be both feasible and effective in mental health institutions lacking infectious disease specialists. These findings support the integration of clinical pharmacists as essential members of multidisciplinary care teams, particularly in resource-limited settings. Future efforts should focus on continuous staff training, periodic audit and feedback, and the adaptation of this model across other specialized healthcare centers to enhance antimicrobial stewardship practices.

## Conflict of Interest

The authors declare no conflict of interest related to this study.

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