



Review of Pharmacy-Based Management of Uncomplicated Urinary Tract Infections (UTIS) In Community Pharmacy Settings

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Received on: 11-06-2018; Revised on: 25-06-2018; Accepted on: 09-07-2018

ABSTRACT

Urinary tract infections (UTIs) are among the most common infections affecting adult women. One-half of all women will experience at least one UTI in their lifetime. Recurrence of UTIs is common, with a reported rate of 25% within 6 months of the first occurrence. UTIs are responsible for nearly 10.5 million medical visits annually in the United States (US), accounting for 0.9% of ambulatory visits. Estimates show emergency room visits for UTIs lead to \$4 billion annually in unnecessary healthcare costs. Enhanced access to care at lower cost venues holds significant promise to improve patient care more efficiently.

Keywords: Urinary tract infections, Patient, Medical, Clinical, Pharmacy

INTRODUCTION

UTIs impacting the lower urinary tract (cystitis) are generally self-limiting and present with symptoms of dysuria, urinary frequency and urgency, suprapubic pain and/or hematuria [1-6]. Cystitis is typically distinguished from upper urinary tract (pyelonephritis) infections by assessing for systemic symptoms such as fever, chills, and/or flank pain. Cystitis is classified as complicated or uncomplicated, with complicating factors including male sex, immunosuppression, and pregnancy.

Escherichia coli is the most common (86%) causative pathogen associated with uncomplicated cystitis in women [7].

Given this, clinical guidelines often downplay the utility of obtaining urine cultures [8,9]. Clinical guidelines recommend empiric antibiotic treatment of cystitis based on the presence

of two or more symptoms, as the likelihood of cystitis is greater than 90% [6]. Further, an estimated 85-95% of women with a recurrent UTI can reliably self-diagnose the condition [10,11]. While most cases of uncomplicated cystitis resolve without sequelae, antibiotics can reduce the severity and duration of symptoms.

Despite their prevalence and straightforward nature of diagnosis, UTIs are frequently over-screened and mistreated [12].

This results in significant waste to the healthcare system while increasing the potential for antibiotic resistance and adverse events. Studies have estimated 40-75% of antibiotic use for purported UTIs in long-term care facilities was avoidable or inappropriate, as were 59% of antibiotics used for UTIs in an emergency department [13-15].

In an effort to improve convenient access to care and reduce the burden on the strained primary care health system, non-

traditional models have been suggested. Some physicians have suggested antibiotics to treat UTIs be available without the need for a prescription [16]. Others advocate for use of telemedicine managing uncomplicated cases of UTIs. Studies have demonstrated telephonic management of UTIs, in which a prescription generates based on self-reported symptoms without an office visit, yield similar clinical outcomes to traditional medical office care in roughly 2.5 minutes on average [5,17-20]. The decreased time to treatment may prevent the development of sequelae, such as pyelonephritis [20,21]. However, a potential downfall is the lack of physical assessment and difficulty assessing clinical stability over the telephone.

The use of pharmacy-based models to manage patients with uncomplicated UTIs has also been proposed. In these models, pharmacists assess the clinical stability of patients and improve the appropriate use of antimicrobials. Several studies have highlighted the ability of pharmacists in community pharmacy settings to manage patients with uncomplicated UTIs [22-26]. Similar care models have been proven safe and effective for administration of immunizations and management of acute conditions such as influenza and acute pharyngitis [27]. In UTI management models, pharmacists screen patients, refer individuals with complicated infections or who are at risk for complications, to appropriate venues of care and prescribe antibiotics in accordance with clinical guidelines to those meeting eligibility criteria. Such programs leverage the convenience and accessibility of pharmacists as well as relieve the burden on the healthcare systems while reducing treatment costs.

The purpose of this paper is to summarize the available literature, published and ongoing, with respect to community pharmacy-based management of uncomplicated UTIs.

MATERIALS AND METHODS

Different database sources were searched (MEDLINE, January 1980-January 2018, EMBASE, January 1980-January 2018, and Google Scholar, January 1980-January 2018) using the terms “pharmac* and urinary tract infection” and “pharmac* and cystitis.” Bibliographies of all identified articles were examined to identify additional relevant literature in and outside the US. In addition, the authors contacted representatives of national pharmacy professional

and trade organizations in the US to provide any information on known research in progress. Studies were included for further analysis if they were conducted primarily in a community pharmacy setting. Studies were excluded that were not in the English language, or if the practice model was in a non-community pharmacy setting.

RESULTS

Published studies

Five studies meeting inclusion criteria were identified [22-26]. Studies were most commonly excluded due to not involving pharmacist management of a UTI, or were not in a community pharmacy setting.

In 2010, a study supported by the National Health Service Greater Glasgow and Clyde engaged community pharmacies to improve access and effective treatment for patients with UTIs [22]. Data from a sampling of 10 pharmacies in Scotland were extracted to compare a care pathway for patients with UTI symptoms used in physicians' offices and community pharmacies. Pharmacists had the legal authority to supply a three-day course of trimethoprim to non-pregnant females with moderate-to-severe UTIs. Female patients were included in the study if they were between the ages of 16 and 65 and both dysuria and frequency were present, or if they had ≥ 3 of the following symptoms: dysuria, urgency, frequency, polyuria, hematuria, suprapubic tenderness. The study included a total of 153 patients, 63 of whom presented with a prescription from a general practitioner (GP) for a UTI, and 37 who presented for pharmacist management. In the GP-managed group, only 56% of the GP prescriptions met clinical guidelines whereas 76% of pharmacy-managed patients were treated according to guidelines and protocol. In the pharmacist-managed group, 73% of patients received trimethoprim, while the remaining received symptomatic management. Half of the pharmacist-managed patients presented on Friday through Sunday. Additionally, patients seeking direct pharmacy management for their symptoms sought healthcare assistance sooner than those with GP prescriptions ($P = 0.026$). Patients filling GP prescriptions ($n = 79, 92\%$) were more likely than those receiving pharmacy management ($n = 34, 67\%$) to believe an antibiotic was indicated for their current symptoms ($P < 0.001$). Nearly all patients reported preferring the pharmacist-management model “due to convenience, difficulties obtaining a GP appointment, and

reluctance to trouble GPs with a non-emergency problem.” The authors concluded the pharmacist-management model could “improve access to treatment, which may also maintain antibiotic stewardship and reduce GP workload.” [22]. Trimethoprim has been available without a prescription in New Zealand (NZ) since 2012 [28]. In NZ, pharmacists who complete a training program may furnish a 3-day supply of trimethoprim to women aged 16 to 65 to treat suspected UTI. Exclusion criteria include pregnancy, symptoms of pyelonephritis or complicated UTI, diabetes, or more than 3 UTIs in the past 12 months, and antibiotic use over the past six months [29]. Braund and colleagues surveyed 28 pharmacists trained to supply trimethoprim from 25 pharmacies across NZ [23]. Some participating pharmacists reported they provided supplies of trimethoprim to 2-3 patients per week. Pharmacists indicated the “vast majority” of patients seen required referral to other care settings, given the legal exclusion criteria. Pharmacists were positive about the opportunity to increase their clinical practice through reclassifications such as trimethoprim for cystitis. Pharmacists encountered mixed responses from GPs; however, patients appreciated the increased access to antibiotics for this acute condition [23].

Gauld and colleagues conducted a survey of 120 community pharmacies in NZ to assess how pharmacist-supplied trimethoprim affected antibiotic use. The survey used a pre- and post-implementation approach in which data was collected over a 14-day period in both 2012 and 2013, dates before and after the trimethoprim regulation change [24]. Participating pharmacies collected information on GP-prescribed UTI medications, as well as pharmacy-based medications during the study period. The inclusion and exclusion criteria followed the NZ legal criteria specified previously. In comparing the pre- and post-implementation periods, the composition of prescribed antibiotics changed: norfloxacin decreased from 24.6% of total prescriptions to 15.4% ($p < 0.001$), and nitrofurantoin increased from 16.3% to 21.5% ($p = 0.029$). There was no statistical increase in trimethoprim use despite its pharmacist-managed status (53% to 58.6%, $p = 0.061$); in women with no complicating factors, there was a non-significant increase in the use of first-line agents post-implementation (72.2% to 82.4%, $p = 0.16$). In the 14-day post-implementation period, pharmacists furnished 31

three-day supplies of trimethoprim, representing less than 5% of the total trimethoprim prescribed during the period. This finding would extrapolate to 6,380 pharmacist-supplied trimethoprim dispensing per year in NZ. The authors concluded that the “availability of trimethoprim from specially trained pharmacists for patients with cystitis without complicating features did not appear to affect medical prescribing of antibiotics or increase overall use of antibiotics” [24].

Hind reviewed patient assessment forms and surveys to evaluate the impact of pharmacist-provided trimethoprim for uncomplicated UTIs at community pharmacies in Scotland [25]. Pharmacists were able to supply trimethoprim to women between the ages of 16 and 65 in accordance with a protocol designed to guide treatment decisions based on patient presentation. Hind reported data separately for a pilot phase involving 41 community pharmacies from 2013 to 2014, and a broader rollout involving 72 pharmacies during 2016. For the pilot, surveys were completed by 24% of the 329 patients assessed by participating pharmacists. Respondents noted they received convenient care, with 90% treated in less than ten minutes, and 70% of patients received care within five miles of their home. In addition, 40.1% of patients were seen on evenings or weekends. If pharmacy-based treatment was not available, patients most commonly (49.4%) reported they would have otherwise gone to a GP and 9.4% would have sought emergency care. Of patients seen, 85.7% received trimethoprim and 9.7% were referred for treatment elsewhere, generally following the protocol’s exclusion criteria [25].

Hind reported separately on a broader UTI service rollout involving 72 community pharmacies from March to August 2016.²⁵ Of the 1,464 patients seen during this period, 72.6% were treated with trimethoprim and 18.1% were referred for further assessment. The study sought to determine whether patients receiving trimethoprim from a pharmacist received another antibiotic from their GP in the same or next month using the NHS Scotland Prescribing Information System. Hind found only 7.3% of patients received further antibiotics in the same or next month, a rate reported to be lower than those reported for GPs. Lastly, Hind notes continued growth of pharmacy-based UTI management. As of April 2017, 104 (>75%) of total Grampian pharmacies manage UTIs, and average 300-400 patients per month. Overall, the author concluded, “pharmacists were able to respond appropriately to UTI symptoms with

correct use of trimethoprim.”

Stewart and colleagues sought to evaluate the impact pharmacist assessment and prescribing for UTIs had on GPs [26]. Data was collected from March through July 2016 assessing ‘Pharmacy First’ services in Forth Valley, Scotland. Of the 897 women evaluated for UTI, 682 were prescribed a medication by the pharmacist (76%) and 38 women were referred to a GP (4.2%).

A survey of GPs and reception staff assessing their impression of the service found 67.6% of GPs and 59% of reception staff found the ‘Pharmacy First’ service useful, citing it lowered pressure on GP appointments [26].

Ongoing research

Pharmacists in Washington state have managed UTIs since at least 2013 [27-30]. An ongoing four-year research project is underway in Washington state, with pharmacists at more than 45 community pharmacies currently treating UTIs. Researchers will compare the quality and cost of care provided at pharmacies to that of primary care offices, urgent care clinics, and emergency rooms [31]. Preliminary data identified 39 women treated for UTIs at 11 pharmacies within the first 19 months of the service. Patients reported if the service was not available at pharmacies, “they would have gone to an urgent care facility or emergency department” suggesting this model may save overall healthcare costs. No negative health outcomes were identified [31].

A research project underway in New Brunswick Canada led by an inter professional team of physicians and pharmacists is entitled Outcomes of UTI Management by Pharmacists (OUTMAP) [32]. Community pharmacists recruit patients into two groups: 1) women who present with symptoms of an uncomplicated UTI; and 2) women presenting with a prescription for a UTI from another healthcare provider. With respect to the latter, the pharmacist assesses the patient and may optimize the patient’s regimen or discontinue the prescribed therapy in accordance with guidelines. The pharmacist follows-up with the patient two weeks after the initial presentation, with clinical outcomes the primary aim. A questionnaire assesses patient satisfaction. The researchers aim to enroll 750 patients over an 8-month period. The team has published practice guidelines for the assessment and

management of UTIs guiding pharmacists in ambulatory care settings [33].

DISCUSSION

Some pharmacists have managed patients with uncomplicated UTIs in community pharmacies since at least 2010 [24]. Demand has grown, with an average of 300-400 patients with symptoms of UTIs seen monthly in Grampian pharmacies [25]. The service has been well-received by patients, reporting convenient access, such as being seen in under 10 minutes at a pharmacy less than five miles from home [25]. Patients seeking treatment for a UTI frequently presented at night or weekends, reported they would have sought care from a GP or emergency care setting [22,25]. This suggests community pharmacies increase access to affordable care, as patients would have utilized a more expensive healthcare facility. In addition, patients reported presenting to the pharmacy with symptoms more quickly than the GPs office, potentially reducing the development of sequelae associated with UTIs [22].

Patient and pharmacist perceptions of pharmacy-based UTI management have been positive [22,24-26]. Gauld and colleagues reported mixed feedback from GPs, reporting some were “initially hesitant about the initiative” [24]. Concerns from medical stakeholders are likely to center on two primary points: 1) Are pharmacists able to appropriately differentiate between uncomplicated UTIs and more serious conditions like pyelonephritis and 2) Will pharmacist-supplied antibiotics increase antibiotic overuse?

The reviewed publications and ongoing research studies indicate pharmacists can successfully and safely manage uncomplicated UTIs in community pharmacies [22-26]. The studies reported no negative health outcomes in patients managed by pharmacists. Importantly, each of the prospective studies were anchored around a protocol designed to help pharmacists determine which patients can safely be treated in the pharmacy and identify those requiring a referral to a more appropriate venue of care. Table 1 presents referral criteria from available pharmacist UTI management protocols [28,29,34-36]. Protocols establish criteria for referral relative to patient age, immune status, symptoms, and frequency, among others. For example, the Saskatchewan protocol requires a pharmacist to refer a patient if she has had six UTIs in the past year, whereas the NZ protocol requires a referral if a patient has had more than three episodes in the past 12 months.

Table 1: Referral criteria for pharmacy-managed uncomplicated UTIs.

Referral Criteria	Saskatchewan	New Zealand	Idaho
Age	N/A	<16 or >65 yo	<18 yo or post-menopausal
Immune Status	Immunocompromised	N/A	Immunosuppressed
Pregnancy Status	Pregnant	Pregnant	Pregnant
Urinary Tract Status	Abnormal urinary tract structure or function (e.g., indwelling catheter, obstruction, neurologic bladder) or history of interstitial cystitis	N/A	Surgical changes or birth defects relevant to the urinary tract or has undergone instrumentation in the past 4 weeks or has any current catheterization
Kidney Function	Renal impairment	N/A	N/A
History of UTIs	No prior diagnosis of UTI	N/A	No prior history of uncomplicated UTI
UTI Frequency	>6 episodes per year or if symptoms developed within four weeks of previous UTI treatment	>3 episodes in past 12 months, or if patient had antibiotics in the past 6 months, or if patient had a hospitalization in the past 4 weeks	N/A, but refer if patient has had previous antibiotic therapy within the past 4 weeks
Symptoms	Fever, chills, nausea, vomiting, flank or back pain, malaise, vaginal discharge, pruritus, dyspareunia, or significant hematuria	Features suggestive of pyelonephritis or complicating UTI	Fever, sweating, flank pain, shaking chills, nausea, vomiting, systolic hypotension, tachypnea, tachycardia, oxygenation <90%, or body temperature >103 degrees Fahrenheit
Follow-up	Day 3 and no response	N/A	N/A

Similarly, if a patient has symptoms suggestive of pyelonephritis, such as a fever or flank pain, a referral is required. In addition, protocols can establish follow-up requirements. The Saskatchewan protocols require the pharmacist to follow-up with the patient after three days and facilitate a referral if the patient's health status has not improved [34].

Pharmacists in the reviewed studies generally demonstrated strong adherence to the protocols. Referral rates varied based on how stringent protocol parameters were set. In Grampian, patient referral rates were reported to be between 9.7%-18.1% [25]. The more conservative NZ protocol necessitated referral rates ranging from 20% to the "vast majority" of cases [24]. Thus, protocol developers should be mindful of the tradeoff of patient access as thresholds for referral are set, as too conservative a protocol may undermine the overall goals of pharmacy-based care. The first study on pharmacy-based UTI management found safe and effective care of UTIs at pharmacies while noting that pharmacist adherence to the protocol "required improvement." This suggests the potential role for targeted education to pharmacists on protocols,

specifically adherence to inclusion and exclusion criteria. While pharmacists report a high level of understanding and readiness to prescribe for UTIs, refresher training can ensure pharmacists appropriately identify patients necessitating referral [37].

It is important to note, available evidence indicated pharmacist prescribing for UTIs did not increase overall antibiotic use or resistance.

Booth and colleagues reported higher adherence to clinical guidelines in the pharmacist-managed group than the GP group [22]. Gauld and colleagues reported no difference in overall antibiotic use after one year of implementation, while reporting a statistically significant decrease in the use of certain agents (e.g., norfloxacin) [24]. These results are not surprising, as pharmacists have a history of engaging in outpatient antimicrobial stewardship initiatives [38,39]. Community pharmacists have demonstrated success in judiciously prescribing antimicrobials managing patients with symptoms of influenza and Group A streptococcal pharyngitis [40-42]. Moreover, pharmacists have a strong record of improving antibiotic stewardship for UTIs within emergency room and long-term care settings [43-46]. While some jurisdictions limit

pharmacists' to prescribe only trimethoprim for UTIs, this is not the case in Washington State where protocols include nitrofurantoin, sulfamethoxazole/trimethoprim, and additional antimicrobial therapy as recommended by the Infectious Diseases Society of America (IDSA) guidelines. A treatment algorithm to guide appropriate selection of antimicrobial, taking into account allergies and other patient factors, may be of benefit in these broader pharmacist-prescribing models. In order to make pharmacist-managed UTIs more broadly available in the US, it will require authorizing legislation. Two legal strategies have been employed to allow pharmacist management of UTIs in the U.S.: 1) Collaborative Practice Agreements (CPA), under which a pharmacist can prescribe certain agents under authority delegated by a physician; and 2) Autonomous prescriptive authority, either through a statewide protocol or through the independent exercise of pharmacist professional judgment [47,48]. CPAs are more common for pharmacist prescriptive authority in the US. Two primary types of CPAs are: 'patient-specific' and 'population-specific.' Patient-specific CPAs have limited utility in outpatient settings, as they require the CPA to

proactively identify the patients who may be treated. This is not feasible for a condition like UTIs, given the unpredictability as to who may contract the infection at any given time. While patient-specific CPAs may prove useful in closed settings, the 17 states allowing population-specific CPAs offer a feasible path to UTI management in outpatient settings. Idaho, by contrast, has enabled independent pharmacist prescriptive authority for antimicrobials indicated for uncomplicated UTIs [49]. Pharmacists exercising this authority, beginning July 1, 2018, are required to use a patient assessment protocol specifying inclusion, exclusion, and medical referral criteria based on clinical guidelines or evidence-based research.

CONCLUSION

With appropriate safeguards in place, pharmacists can safely assess and manage patients with uncomplicated UTIs while increasing access to care. Regulatory bodies in the US and elsewhere may consider pharmacist prescriptive authority of antimicrobials for the treatment of UTIs, adapting a patient assessment protocol similar to those proven successful in other jurisdictions.

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