

Outcomes of Urinary Tract Infection Management by Pharmacists (R_xOUTMAP): A study of pharmacist prescribing and care in patients with uncomplicated urinary tract infections in the community

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There is limited evidence on the outcomes of pharmacists assessing and managing urinary tract infections. We undertook this research to address this gap in the literature.

Les données sont limitées en ce qui concerne les résultats de l'évaluation et de la prise en charge des infections des voies urinaires par les pharmaciens. Nous avons entrepris cette recherche pour combler cette lacune dans la littérature.

ABSTRACT



Background: Pharmacists have the authorization to prescribe medications for the treatment of uncomplicated urinary tract infections (UTI) in some provinces. However, there are limited data on the outcomes of this care by pharmacists. Our objective was to evaluate the effectiveness, safety and patient satisfaction with pharmacist prescribing and care in patients with uncomplicated UTI.

Methods: We conducted a prospective registry trial in 39 community pharmacies in the Canadian province of New Brunswick. Adult patients were enrolled if they presented to the pharmacy with either symptoms of UTI with no current antibacterial treatment (Pharmacist-Initial Arm) or if they presented with a prescription for an antibacterial to treat UTI from another health care provider (Physician-Initial Arm). Pharmacists assessed patients and if they had complicating factors or red flags for systemic illness or pyelonephritis,

they were excluded from the study. Pharmacists either prescribed antibacterial therapy, modified antibacterial therapy, provided education only or referred to physician, as appropriate. The primary outcome was clinical cure at 2 weeks and the secondary outcomes included adverse events and patient satisfaction.

Results: A total of 750 patients were enrolled (87.4% in the Pharmacist-Initial Arm), average age was 40.9 (SD 16.0) years. Clinical cure was achieved in 88.9% of patients. Of those that did not have sustained symptom resolution, most (5.5% overall) had symptom recurrence after completion of therapy. Adverse events were reported by 7.2% of patients and 88.9% of those continued their medication. Most adverse events were gastrointestinal-related and transient. The patient satisfaction survey reflected very high levels of satisfaction for the care they received, as well as for trust and accessibility of the pharmacist.

Conclusion: Pharmacist management of uncomplicated UTI is effective, safe, and patient satisfaction appears very high. *Can Pharm J (Ott)* 2018;151:305-314.

Introduction

Urinary tract infection (UTI) is a common condition that often results in the initiation of antibacterial therapy.¹⁻³ It is also the eighth most

common reason for ambulatory clinic visits and the fifth most common reason for emergency department visits in Canada.^{4,5} UTI is a leading cause of inappropriate antimicrobial

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KNOWLEDGE INTO PRACTICE



- Pharmacists are accessible primary health care providers who are able to prescribe for uncomplicated urinary tract infections in some jurisdictions.
- In this large registry trial, pharmacist assessing and prescribing for uncomplicated urinary tract infections was found to be effective and safe, with high levels of patient satisfaction.
- This study provides justification for pharmacists' prescribing authority to include uncomplicated urinary tract infections.

prescription, frequently leading to both direct antimicrobial adverse events and secondary complications, including infection with *Clostridium difficile*.^{3,6,7} The incidence of UTI in women is 12% annually, with 50% of women reporting to have had a UTI by 32 years of age.² Recurrence of infection occurs in 25% of women within 6 months of the first UTI, and this rate increases when more than one prior UTI has been experienced.²

Pharmacists are accessible primary health care professionals who are well positioned to take on a larger role in the management of UTI. The ability of pharmacists to prescribe for UTI varies in Canada from province to province, with New Brunswick,⁸ Quebec,⁹ Saskatchewan¹⁰ and Alberta¹¹ all allowing pharmacists to prescribe for this indication, to varying extents. Regardless of the province or setting in which pharmacists practise, there are several ways that pharmacists can get actively involved in the management of patients with UTIs.¹² However, there is a paucity of studies on the impact of pharmacist management of UTI. The purpose of this study was to evaluate the effectiveness and safety of, and patient satisfaction with, pharmacist assessment and management of patients with uncomplicated UTI.

Methods

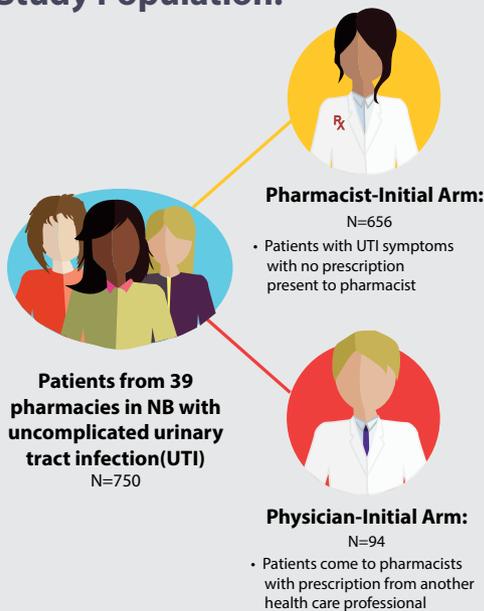
Study design and setting

The RxOUTMAP study was a prospective registry trial that was conducted in 39 community pharmacies from across the province of New

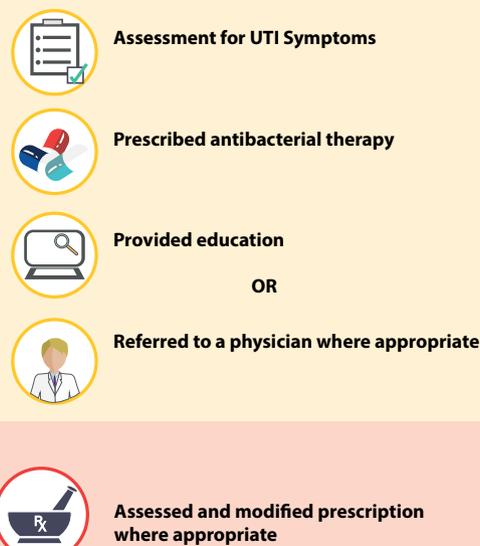
Outcomes of Urinary Tract Infection Management by Pharmacists: RxOUTMAP Study



Study Population:



Pharmacist's Interventions:



Outcomes:

Pharmacist-Initial arm had a sustained **clinical cure rate** of **88.9%**

Patients' satisfaction very high:

- quality of care received
- accessibility
- trust
- support pharmacists role

Management of uncomplicated **UTI by pharmacists is effective** and **safe** and **patients** express a **high level of satisfaction** with this care.

Public funding would improve **access** to this service



Outcomes of Urinary Tract Infection Management by Pharmacists (RxOUTMAP): A study of pharmacist prescribing and care in patients with uncomplicated urinary tract infections in the community Beahm et al. Can Pharm 2018;151:xx
#pharmUTI, #RxOUTMAP, @AbSPORU_CRS, @AbSPORU



Sponsors: New Brunswick Pharmacists Association and the Canadian Foundation for Pharmacy

Brunswick. Pharmacists in New Brunswick have the authority to prescribe for uncomplicated UTI. The study was designed to be pragmatic, capturing data that are reflective of real-world practice while integrating into the pharmacists' workflow.

Study population

Patients were included in the study if they were at least 19 years of age and either 1) presented to the pharmacy with symptoms suggestive of UTI without a current prescription to treat it from another health care provider (Pharmacist-Initial Arm) or 2) presented with a new prescription for the treatment of UTI from another health care provider (Physician-Initial Arm). There was no cap on the number of patients who could be enrolled per arm. Patients were excluded if they had signs or symptoms suggestive of pyelonephritis or systemic illness, the presence of complicating factors and if receiving an antibacterial for UTI prophylaxis. Complicating factors included male sex, pregnancy, indwelling urinary catheter, poorly controlled diabetes, chronic obstruction, nephrolithiasis, chronic renal insufficiency and immunosuppression. "Red flags" for pyelonephritis or systemic illness included flank pain or tenderness, fever ($\geq 38^{\circ}\text{C}$), rigors, significant nausea or vomiting, and frank hematuria. Patients were also excluded if it was their second or more recurrence of symptomatic UTI in the past 30 days. Pharmacists obtained informed consent from patients for study participation and collection of data before enrolling them in the study. At the time of the study, pharmacist assessments were not provincially funded services. Pharmacist assessment fees were reimbursed to pharmacies from the study budget to allow them to waive their pharmacist assessment fees for participating patients to enhance study enrollment.

Study intervention

The study intervention was based on recently published pharmacist guidelines for the management of UTI.¹² Pharmacists performed patient assessments for symptoms of UTI and prescribed antibacterial therapy, modified antibacterial therapy, provided education only or referred to physician, as appropriate. The preferred antibacterial regimen was nitrofurantoin monohydrate/macrocrystals 100 mg taken twice daily for 5 days. Alternative first-line options included sulfamethoxazole-trimethoprim 800-160 mg twice daily for 3 days, fosfomycin 3 g single dose

MISE EN PRATIQUE DES CONNAISSANCES



- Les pharmaciens sont des fournisseurs de soins primaires accessibles qui, dans certains territoires de compétence, peuvent prescrire un traitement dans les cas d'infection des voies urinaires non compliquée.
- Cette étude de registre de grande envergure a révélé que l'évaluation des cas d'infection des voies urinaires non compliquée par les pharmaciens et la prescription subséquente d'un traitement étaient efficaces et sûres, en plus d'être associées à un haut degré de satisfaction des patients.
- Cette étude appuie le pouvoir de prescription des pharmaciens pour le traitement des infections des voies urinaires non compliquées.

and cefuroxime axetil 500 mg twice daily for 7 days. Education was provided to all patients and included information on what to expect and instructions to come back if symptoms were not improving or worsening after a few days. Pharmacists conducted follow-ups with included patients at 2 weeks to assess for resolution of symptoms, adherence to therapy and any adverse events. Additional follow-ups were permitted, if necessary. Those failing to achieve clinical resolution at 2 weeks were again assessed for evidence of complication and provided with a modified treatment plan or physician referral, depending on the pharmacist's findings.

Study outcomes

The primary outcome was clinical cure (i.e., symptom resolution) at 2 weeks. Secondary outcomes included adverse events, patient adherence to therapy, number of follow-ups, treatment failures (and reasons for), time from decision to seek care until seen by pharmacist (Pharmacist-Initial Arm) or physician (Physician-Initial Arm) and patient satisfaction. Patient satisfaction was collected using a survey that has been used previously to gauge satisfaction in other general pharmacist prescribing activities,^{13,14} with slight modification.

Statistical analyses

We estimated that with a 95% confidence level and a 5% margin of error, the sample size required would be 384 patients. This number was inflated to 500 to allow for 20% loss to follow-up and was further increased to 750 for added power in the analyses of secondary outcomes.

The primary outcome for efficacy was compared to our hypothesis of 90% clinical cure

using the chi-squared test. Between-arm comparisons were conducted using the chi-squared test or Fisher's exact test for categorical variables, as appropriate, and *t*-test was used for continuous variables. When data deviated from normality, the Wilcoxon-Mann-Whitney test was used.

Data collection/management

Data were entered by the pharmacists into a secure, centralized, web-based database that was designed and maintained by the EPICORE Centre, University of Alberta. The database was designed as a practice tool and was intended to have data entered in real time while the pharmacist is with the patient. Pharmacists were able to print off a single-page documentation note that self-populated from the data that were entered into the database. This documentation note was sent to the patient's most responsible physician for all pharmacist assessments and could also be scanned into the patient's file on the pharmacy computer system. The satisfaction surveys were emailed to patients directly from the data management system following their baseline visit. For the few patients who did not have email access, paper surveys were mailed to the patient with a prepaid return envelope in which the patients mailed the surveys back to the EPICORE Centre to be manually entered into the database. Study pharmacists did not have access to the satisfaction survey results.

Ethics

The study was approved by the Health Research Ethics Boards of the University of Alberta (Pro00072493) and the Horizon Health Network (New Brunswick) (RS 2017-2443). The study was also registered on Clinicaltrials.gov (NCT03184818).

Results

From June 2017 to April 2018, there were 818 patients assessed, of whom 750 met the study inclusion criteria (Figure 1). Of those, 87.5% were Pharmacist-Initial Arm patients. Baseline characteristics of included patients are depicted in Table 1. The average age was 40.9 (standard deviation [SD], 16.0) years, and the 2 most common presenting symptoms were new or increased urinary frequency and dysuria. The time from decision to seek care to accessing a pharmacist was 1.7 (SD 2.4) days compared to 2.8 (SD 3.8) days for a physician ($p = 0.0153$). Of the enrolled patients who received a prescription

from a physician first, pharmacists modified 40.4% of those initial prescriptions.

Of the 750 patients enrolled, 686 (91.5%) completed the 2-week follow-up. The average number of follow-ups per patient was 1.1 (SD 0.2). At 2-week follow-up, 88.9% had sustained symptomatic resolution (i.e., clinical cure) (Table 2). Of those who did not have sustained resolution of symptoms at 2 weeks, 51.3% (5.5% overall) experienced an initial resolution of symptoms but had recurrence of symptoms after completion of therapy (i.e., early recurrence of infection). Therefore, initial cure was achieved in 94.5% of patients ($p = 0.0025$), but 5.5% had early recurrence of infection, leading to the sustained clinical cure rate of 88.9%, which was not significantly different from our a priori hypothesis of 90%.

Adverse events were reported by 7.2% of patients (Table 3). Of these, 88.9% were still able to complete their course of medication. Most adverse events were gastrointestinal-related (59.3% of those reported) and transient. The next most commonly reported adverse events were secondary vaginal infections (14.8% of those reported) (e.g., vaginal candidiasis). A total of 5 (0.7%) reported adverse events resulted in a physician or emergency department visit (3 in the Pharmacist-Initial Arm and 2 in the Physician-Initial Arm).

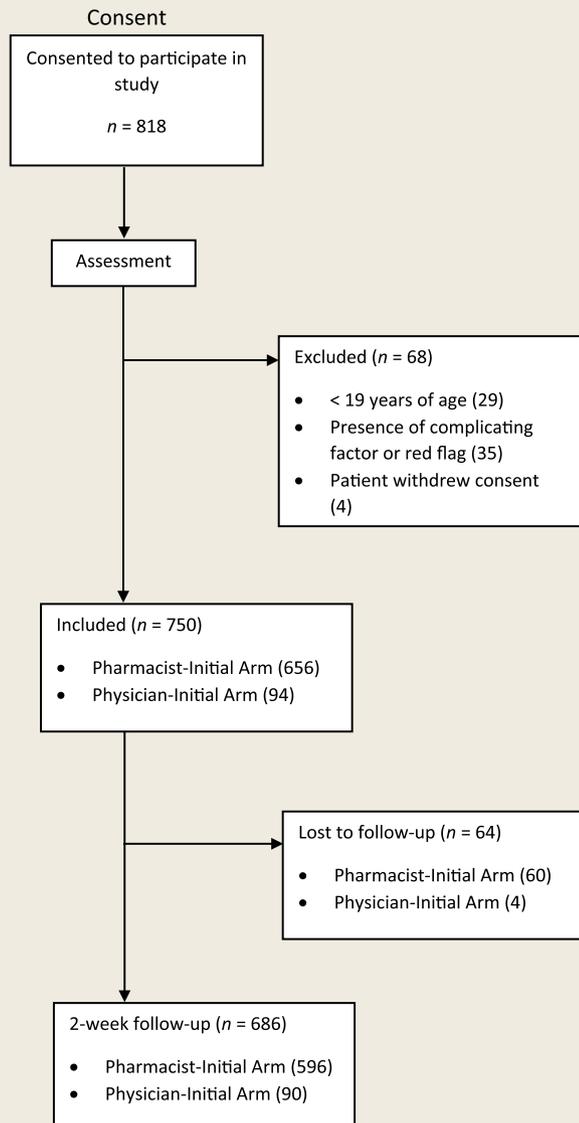
Most patients (96.5%) took their medication as prescribed (Table 4). Of the reasons for treatment failure, 6 (0.9% overall) were due to complications (Table 5), of which 2 were pyelonephritis. Treatment failure was possibly influenced by adherence in 6.8% of failures (0.7% overall), with 5 patients who either missed 50% or more of their doses or did not take them at all with subsequent treatment failure (Table 6).

The responses to the patient satisfaction survey are depicted in Figure 2. The survey was completed by 398 of the enrolled patients (53.1%). Generally, patients felt that the pharmacists' assessments were thorough and they were very satisfied with the care they received. They also expressed a high level of trust in their pharmacist, as well as an appreciation of the accessibility of their pharmacist.

Discussion

UTI is an acute condition that is common and very often produces symptoms that are unpleasant and result in restricted activities.¹⁵ It is also

FIGURE 1 Study flow



a common reason for antibacterial use (and misuse). The R_xOUTMAP study is the first comprehensive evaluation of community pharmacist assessment and management, including prescribing, for uncomplicated UTI. We found that pharmacist management of UTI was highly efficacious and safe. Importantly, we also found that patient satisfaction with this clinical service was very high, especially in the areas of thoroughness of the assessment, accessibility and trust in the care provided by their pharmacists.

Our findings are consistent with previous work in this area. One Scottish study of pharmacist-directed UTI care reported time to symptom resolution to be ≤ 2 days in 49%, between 3 and 5 days for 34% and unresolved (at 7 days) in 15%, with no difference in these frequencies between

pharmacist-initiated and physician-initiated arms (note: pharmacists did not modify treatment from physicians in this study).¹⁶ They also found that, of the few patients who were followed up, 22% (4 patients overall) from the pharmacist-initiated arm planned to seek physician consultation after receiving the pharmacy service; however, they make no mention of how many from the physician-initiated arm planned to go back to the physician. This study was limited by small sample size (153) and high loss to follow-up (30%). Our study provides more robust data on the efficacy and safety of pharmacists prescribing for uncomplicated UTI. We also demonstrated that pharmacists are able to identify complicating factors and red flags for pyelonephritis or systemic illness and refer

TABLE 1 Baseline characteristics

	Pharmacist-Initial Arm (n = 656)	Physician-Initial Arm (n = 94)	Overall (n = 750)	p-value
Age, mean ± SD, y	40.4 ± 15.9	43.7 ± 16.1	40.9 ± 16.0	0.0692
Biological sex, female, n (%)	656 (100)	94 (100)	750 (100)	>0.99
Weight, mean ± SD, kg	70.0 ± 17.3	78.2 ± 35.8	71.0 ± 20.7	0.0585
Serum creatinine, mean ± SD, µmol/L	68.1 ± 16.4 n = 68	63.0 ± 7.1 n = 30	66.6 ± 14.4 n = 98	0.0345
Creatinine clearance, mean ± SD, mL/ min/72 kg	104.1 ± 31.6 n = 68	112.3 ± 25.1 n = 30	106.6 ± 29.9 n = 98	0.1715
Dysuria, n (%)	556 (84.8)	76 (80.9)	632 (84.3)	0.3308
New or increased urinary frequency, n (%)	597 (91.0)	86 (91.5)	683 (91.1)	0.8779
New or increased urinary urgency, n (%)	525 (80.0)	72 (76.6)	597 (79.6)	0.4396
Suprapubic pain, n (%)	277 (42.2)	53 (56.4)	330 (44.0)	0.0097
Time from decision to seek care until seen by pharmacist (Pharmacist-Initial Arm) or physician (Physician-Initial Arm), mean ± SD, days	1.7 ± 2.4	2.8 ± 3.8	NA	0.0153

p-values for between-arm comparisons. NA, not applicable.

TABLE 2 Efficacy outcomes*

	Pharmacist-Initial Arm (n = 596)	Physician-Initial Arm (n = 90)	Overall (n = 686)
Clinical cure, n (%)	528 (88.6) [†]	82 (91.1) [†]	610 (88.9) [‡]
Symptoms resolved but then recurred after completion of therapy, n (%)	36 (6.0)**	2 (2.2)**	38 (5.5)
Symptoms improved initially and then worsened, n (%)	16 (2.7)	1 (1.1)	17 (2.5)
Symptoms neither improved nor worsened, n (%)	13 (2.2)	4 (4.4)	17 (2.5)
Symptoms only worsened, n (%)	1 (0.2)	1 (1.1)	2 (0.3)

*At 2-week follow-up.

[†]Between-arm comparison. $p > 0.99$.

[‡]Primary comparison to 90% clinical cure hypothesis. $p = 0.3463$.

**Between-arm comparison. $p = 0.4776$.

these patients, when necessary. Another recent report of pharmacist prescribing in Scotland for UTI, chronic obstructive pulmonary disease and impetigo surveyed patients who received these services.¹⁷ Of the 797 patients who used those services during the study survey period, 73 (9%) responded, the majority of whom (61) received treatment of UTI. The responses from that survey showed high levels of satisfaction with the care provided by pharmacists and that

this was related to the quicker and more efficient access to treatment. This was also reflected in our study's patient satisfaction survey, through which patients expressed very high levels of satisfaction for the care they received.

Several clinical implications can be inferred from this study. One important implication is accessibility. The time from deciding to seek care to accessing a pharmacist was significantly shorter than accessing a physician by 1

TABLE 3 Safety outcomes

Adverse events	Pharmacist-Initial Arm (n = 44), n (%)	Physician-Initial Arm (n = 10), n (%)	Overall (n = 54), n (%)	p-value
Gastrointestinal*	27 (4.1)	5 (5.3)	32 (4.3)	0.7895
Vaginal candidiasis*	5 (0.8)	3 (3.2)	8 (1.1)	0.1079
Headache*	6 (0.9)	0 (0)	6 (0.8)	0.7551
Other*†	6 (0.9)	2 (2.1)	8 (1.1)	0.5963
Medication continued	39 (88.6)	9 (90.0)	48 (88.9)	>0.99
Resolved, no residual effects	38 (86.4)	9 (90.0)	47 (87.0)	0.7836
Physician or emergency department visit required*	3 (0.5)	2 (2.1)	5 (0.7)	0.2273

*Percentage in relation to the number of patients in this group at baseline.

†Other included events such as insomnia or rash.

TABLE 4 Adherence

	Pharmacist-Initial Arm (n = 596), n (%)	Physician-Initial Arm (n = 90), n (%)	Overall (n = 686), n (%)	p-value
Taken as prescribed	575 (96.5)	81 (90.0)	656 (95.6)	0.0008
Missed 1 or 2 doses	14 (2.4)	2 (2.2)	16 (2.3)	
Missed 50% or more doses	3 (0.5)	6 (6.7)	9 (1.3)	
Did not take	4 (0.7)	1 (1.1)	5 (0.7)	

TABLE 5 Reasons for treatment failure*

	Pharmacist-Initial Arm (n = 598), n (%)	Physician-Initial Arm (n = 90), n (%)	Overall (n = 688), n (%)
Delay in accessing care	2 (0.3)	1 (1.1)	3 (0.4)
Complication (e.g., pyelonephritis)	5 (0.8)	1 (1.1)	6 (0.9)
Missed baseline complicating factors	0 (0)	1 (1.1)	1 (0.2)

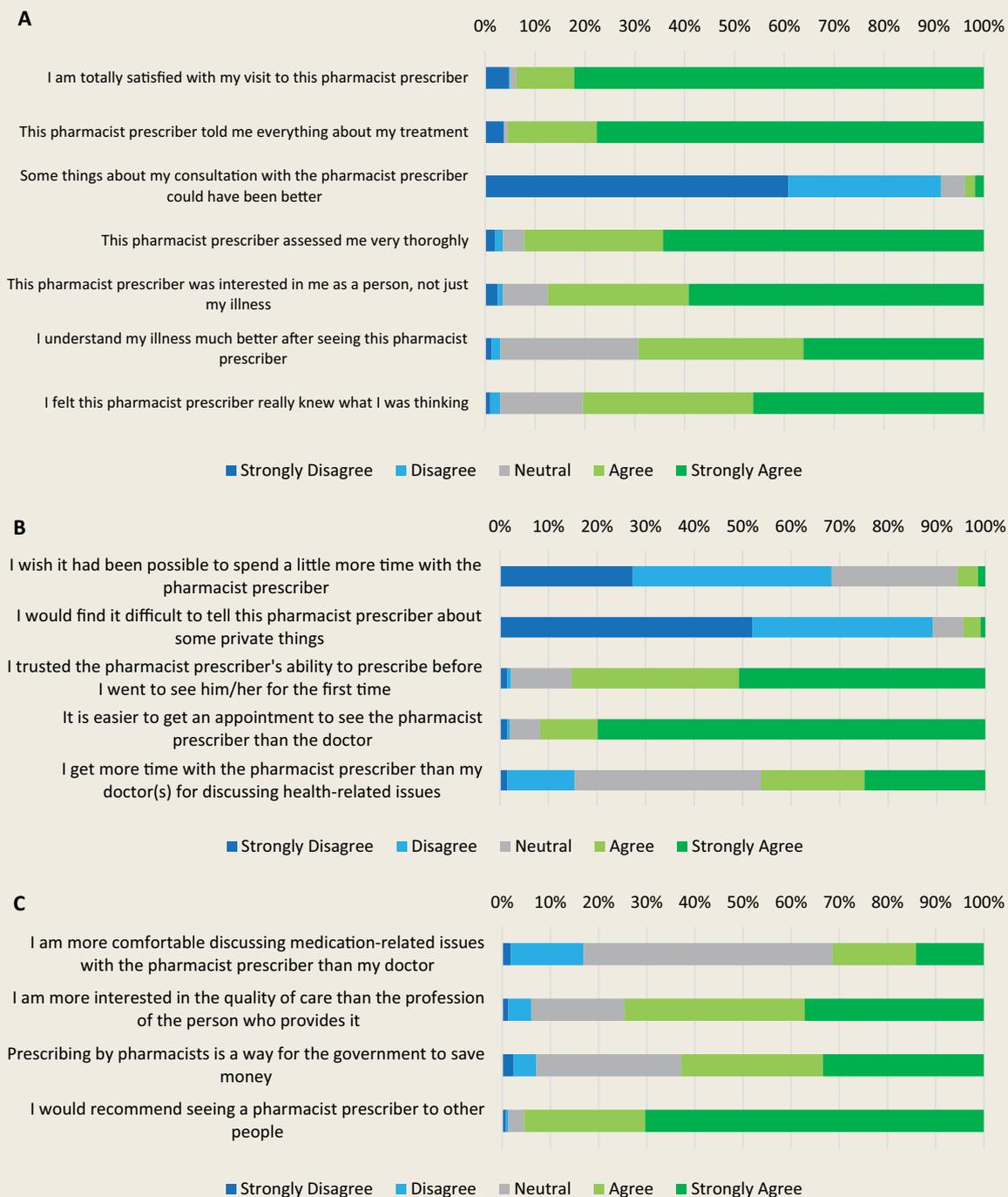
*When a reason identified, other than medication adherence reasons.

TABLE 6 Treatment failure cross-referenced to adherence

	Taken as prescribed, n (%)	Missed 1 or 2 doses, n (%)	Missed 50% or more doses, n (%)	Did not take, n (%)
Symptoms resolved but then recurred after completion of therapy	35 (47.3)	1 (1.4)	2 (2.7)	0 (0)
Symptoms improved initially and then worsened	15 (20.3)	2 (2.7)	0 (0)	0 (0)
Symptoms neither improved nor worsened	16 (21.6)	0 (0)	1 (1.4)	0 (0)
Symptoms only worsened	0 (0)	0 (0)	0 (0)	2 (2.7)

Percentages out of 74 treatment failures.

FIGURE 2 Patient satisfaction survey



N = 398, 53.1%. Cronbach's alpha 0.84. (A) Questions relating to satisfaction with care received (during visit). (B) Questions relating to accessibility and trust. (C) Questions relating to pharmacists and the health care system.

day. Given the increasing constraints on urgent care clinics and emergency rooms, this option provides patients with an alternative assessment pathway for a common medical condition. Although the accessibility of community pharmacists is well known,¹⁸ coupling this with the high efficacy and safety data, as well as the very high level of patient satisfaction, should help to

justify the expansion of pharmacists' prescribing authority for UTI in other jurisdictions.

Several potential limitations to this study warrant discussion. First, the study lacked a comparator group. Although it is common for contemporary pharmacy practice research studies to have a "usual care" group as their comparator,^{19,20} this would not have been feasible for this

study because of the acute nature of the illness (i.e., it would not have been ethical to withhold pharmacist management). We instead compared our primary outcome to our hypothesized clinical cure rate of 90%, which was derived from published data on rates of cure in studies of the treatment of uncomplicated UTI.¹ Another potential limitation is that several aspects of this study relied on the patients' subjective description and recollection of symptoms. More objective tests, such as a urinalysis (or urine dipstick) for pyuria or a urine culture, could have been an option; however, neither pyuria nor a positive urine culture in the absence of symptoms would be indicative of infection, and if those tests were negative in conjunction with the presence of typical symptoms of UTI, then treatment would usually still be indicated. It is generally accepted clinical practice that urine culture confirmation is not necessary for most cases of uncomplicated UTI^{2,12,21} and pyuria is more useful for its negative predictive value in the elderly, but this negative predictive value is much lower in younger patients.^{2,12,21,22} Because of these considerations and the fact that this study was intended to be pragmatic, these tests were not required. Also, the high rate of clinical resolution observed in the study further supports management without adjunctive laboratory testing for cases of uncomplicated UTI. Another potential limitation is that loss to follow-up was

relatively moderate at 8.5%. However, the loss to follow-up is not completely unexpected for a pragmatic, practice-based trial, as follow-up is very rarely complete in real-world practice, especially for acute conditions such as UTI. It could also be argued that designing the study to capture real-world data is actually a strength. The patient satisfaction survey response rate of 53.1% could be considered low-moderate. However, there is little consensus as to what constitutes an acceptable survey response rate and some evidence to suggest that surveys with lower response rates very often carry comparable accuracy to that of surveys with larger response rates.²³ As an acute condition, it is also possible that patients felt less impetus to respond once they no longer required care, as compared to a chronic condition in which care would be ongoing.

Our findings demonstrate that the management of uncomplicated UTI by pharmacists is effective and safe and that patients express a high level of satisfaction with this care. One could postulate that this care by pharmacists is a cost-effective health delivery solution that can make the health care system more efficient—the planned future analyses of these results will include an economic analysis to further evaluate this notion. In addition, further review of these results will evaluate antimicrobial utilization and antimicrobial stewardship implications. ■

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the manuscript for intellectual content. R. T. Tsuyuki initiated the project, obtained funding from both sponsors, supervised the study conduct and critically revised the manuscript for intellectual content. All authors approved the final draft of the manuscript.

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