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Original Research

Evaluating the management of urinary tract infections by community pharmacists in Queensland, Australia

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Abstract

Background: While workloads of general practitioners (family physicians) can be supported by allied health professionals treating minor ailments, there is a need to evaluate the quality of these primary care interventions. In Queensland, Australia, appropriately trained community pharmacists provided empirical management of uncomplicated urinary tract infections to people with a biologic female urinary tract, between 18-65 years of age using a structured model of care. **Objective:** The aim was to determine whether community pharmacists can safely and effectively manage uncomplicated urinary tract infections. **Methods:** A prospective, observational, mixed-methods evaluation was designed to collect data over an 18-month period. People with a biologic female urinary tract, between the ages of 18-65 years, who presented to a community pharmacy, and met the symptom definition of an uncomplicated urinary tract infection, and agreed to participate in the study, were included. **Results:** A total of 10,270 instances of service provision were analysed. These services were recorded by 588 pharmacies that delivered at least one service. Follow-up data were available for 28.9% (2,973/10,270) services. Most (93.0%) were prescribed 3-days of trimethoprim as per the structured model of care and of those followed-up 87.6% reported resolution of symptoms following antibiotic treatment. For eighty five follow-up consultations (2.9%), patients indicated experiencing adverse events from antibiotic treatment. Five patients visited an emergency department, and upon review by doctors on the Steering Advisory Group, pharmacists were found to have followed the structured model of care in all cases. **Conclusion:** This study provides evidence that provision of antibiotics by appropriately trained pharmacists using a structured model of care was safe and effective. Given the rise in antimicrobial resistance worldwide, regular audits of prescribing by all health practitioners are recommended.

Keywords: urinary tract infections; health services accessibility; primary health care; clinical audit

INTRODUCTION

Urinary tract infections (UTIs) are one of the top twenty reasons for visiting general practitioners (GPs)/family physicians in Australia.[1] Community pharmacy provides improved access to timely and effective treatment for a range of minor ailments, including uncomplicated UTIs, in Canada,[2] the United Kingdom,[3] Scotland,[4] and New Zealand.[5] In the state of Queensland, Australia, continuing GP workforce shortages and maldistribution, exacerbated by the COVID-19 pandemic response, has resulted in increased patient waiting times and emergency department presentations.[6] Increasing the scope of practice for pharmacists to treat minor ailments is therefore one strategy for health departments to decrease the workload of GPs. However, concerns of increasing antibiotic resistance from community acquired infections,[7] and the potential for misdiagnosis must be balanced with patient access and workforce demands.

A randomised controlled trial by Little and colleagues,[8] compared five different treatment approaches for UTI management, which included the option of delayed antibiotics. There was no evidence that either using midstream urine analysis as an initial strategy to guide antibiotic prescribing or the use of midstream urine samples by medical officers as part of their overall clinical management, improved patient symptom intensity and duration. Further, recent evidence has questioned the diagnostic accuracy of midstream urine culture, which has previously been considered the gold-standard diagnostic test.[9] The diagnosis of uncomplicated UTI is therefore primarily based on history and symptoms of dysuria, urgency, and frequency.[10,11] A meta-analysis by Bent and colleagues,[12] found women presenting to outpatient clinics with a least two symptoms of dysuria, urinary frequency or urinary urgency, the absence of vaginal discharge, had an approximately 90% probability of having an acute UTI. Thus, although in Australia it is still recommended to perform a midstream urinalysis before commencing with antibiotics,[13] treatment can be commenced empirically without urinalysis if clinically warranted.[13]

Several international and national guidelines outline current best practice for the management of uncomplicated UTIs.[13-15] In Australia, trimethoprim continues to be recommended first-line as empirical therapy for uncomplicated UTIs because the risk of adverse outcomes from treatment failure is low,[13] then nitrofurantoin for 5 days, with cefalexin for 5 days if trimethoprim or nitrofurantoin is not appropriate.[13]

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While services to treat uncomplicated UTIs through community pharmacy is already available in other international jurisdictions,[2-5] The Urinary Tract Infection Pharmacy Pilot – Queensland (UTIPP-Q) initiative, which was undertaken in the third most populous state of Australia,[16] is the first study undertaken in Australia to provide local evidence.[17-18]

AIM

The aim was to determine whether appropriately trained community pharmacists can safely and effectively manage uncomplicated UTIs. The findings related to effectiveness and safety, viz (i) pharmacist adherence to a structured model of care; (ii) safe and appropriate referral patterns; and (iii) effectiveness of first line treatment to achieve full symptom resolution are reported herein.

Ethics approval

Ethics approval for the evaluation of UTIPP-Q was obtained through the QUT Human Research Ethics Committee (Approval number 2000000140) on Friday 6 March, 2020.

METHOD

Model of care

The structured model of care for UTIPP-Q was developed collaboratively over a six-month period. Pharmacists registered and working in community pharmacies in Queensland, who had undertaken the required education and assessment, could provide a person with a biologic female urinary tract aged between 18 and 65 years, empirical antibiotic treatment for uncomplicated UTIs. Pharmacists were supported to implement the structured model of care by clinical recording software (GuildCare) and Professional Practice Guidelines (https://www.psa.org.au/wp-content/uploads/2022/12/Treatment-guideline-for-pharmacists-cystitis.pdf). The person presenting with symptoms must have met the inclusion criteria and consented to treatment. Optionally, they could have consented to having their data contribute to the evaluation of the service. Individuals who fell outside the inclusion criteria were referred to their GP for treatment, as required. A service fee of AUD$19.95, to be paid out of pocket by patients, was set.

Rationale for study design

Given the existing level of evidence of the intervention being successfully implemented in other countries,[2-5] and the difficulty in obtaining data for an appropriate control arm (GP management), a prospective observational study using a mixed methods approach to evaluate the safety and effectiveness of the intervention was designed, with the objective of gathering a large sample to ensure any concerning safety signals would be detected. We only report on the quantitative clinical aspects of the evaluation here; patient and provider experience of the service has been reported elsewhere.[19,20]

Intervention

A person with a biologic female urinary tract aged between 18-65 years, who self-identified at participating community pharmacies and met the symptomatic definition of an uncomplicated UTI i.e. 2 or more primary symptoms of acute UTI (dysuria, urinary urgency, urinary frequency, suprapubic pain or discomfort); and no other symptoms were eligible to participate. Training requirements have been detailed previously,[19-21] are congruent with national competency standards,[22,23] and have subsequently been mandated under the state legislation of Queensland.[24] The intervention was delivered between 19 June 2020 and 30 September 2022. Fully informed consent was obtained from patients to receive the UTIPP-Q service and to participate in the research evaluation; however, the service was not withheld if consent to participate in the research evaluation was declined.

Patients were referred to the GP if they did not meet the definition of an uncomplicated UTI in accordance with the Professional Practice Guidelines (https://www.psa.org.au/wp-content/uploads/2022/12/Treatment-guideline-for-pharmacists-cystitis.pdf) (Box 1), and where they could not be managed within usual scope of practice by pharmacists. If the patient met the definition of an uncomplicated UTI, a choice of three antibiotics for empirical treatment were available: trimethoprim 300 mg, daily for three days (first-line unless otherwise indicated); nitrofurantoin 100 mg every 6 hours for 5 days (second-line) or cefalexin 500 mg every 12 hours for 5 days (last line). Patients were given information about possible side effects of the medication and told to see their GP if symptoms were not resolved within 3 days.

As part of the evaluation, the pharmacist followed-up with the patient via telephone 7 days after completion of the initial service. Follow-up questions consisted of the main outcome of treatment (symptoms have resolved; symptoms have not resolved and care from GP already sought; symptoms have not resolved and care not yet sought; other), any medication side effects, reasons why a GP was consulted in the past 7 days (including for an unrelated reason), the time taken to access GP care, if a urinalysis was performed by the GP and if another antibiotic was prescribed.

The main outcome measure was the proportion of patients who received the intervention and reported complete resolution of symptoms at follow-up. Secondary outcome measures included the proportion of patients treated with first-line therapy (trimethoprim), and the proportion of patients with unresolved symptoms, who were referred to a GP. Repeat services were evaluated for fidelity with the structured model of care and Professional Practice Guidelines (Criterion 1: 2 or more UTIs within 6 months or Criterion 2: 3 or more UTIs within 12 months).

A descriptive analysis of the patient cohort including the number of patients screened for the service, details of their eligibility and symptom presentation, the number of services provided, and known outcomes was undertaken. All analyses were undertaken using Stata 17.[25]

Patient and Public Involvement

Patient and public involvement was achieved in the evaluation of the UTIPP-Q initiative through membership of a Steering Advisory Group, which was established at the start of the

- Signs and symptoms of pyelonephritis:
  - fever >38 °C
  - chills or rigors
  - back or side (flank) pain
  - nausea or vomiting
- Symptoms of cystitis persist 48–72 hours after starting appropriate antibiotic treatment
- Symptoms of cystitis reoccur within 2 weeks after finishing appropriate antibiotic treatment
- Only one primary symptom of acute cystitis
- Symptoms or medical history suggest a cause other than acute cystitis, vulvovaginal candidiasis or bacterial vaginosis
- Age <18 years or >65 years
- Previous episodes of pyelonephritis
- Risk of complicated urinary tract infection (UTI) – also see *F. Patient history:*
  - pregnancy
  - postpartum
  - immunocompromised
  - diabetes
  - renal disease or impaired renal function
  - urinary tract abnormality or obstruction
  - urinary catheter within last 48 hours
  - antibiotics within last 3 months
  - inpatient/resident of a healthcare or other care facility within last 3 months
  - overseas travel within last 3 months
- Recurrent UTI:
  - Two or more UTIs within 6 months
  - Three or more UTIs within 12 months
- Intrauterine device (IUD) in situ
- Risk factors for sexually transmissible infection

Box 1. Clinical decision guidance for referral to GP / family physician (https://www.psa.org.au/wp-content/uploads/2022/12/Treatment-guideline-for-pharmacists-cystitis.pdf)

evaluation and ran until its conclusion. The Steering Advisory Group comprised medical, pharmacy, nursing, consumer and government representatives.

RESULTS

Study population

The total study population for the UTIPP-Q was 12,509. Of these, 189 (1.5%) individuals were offered, but declined the initial service; 636 (5.1%) were ineligible for the service for clinical reasons; 119 (1.0%) were approached, but the service was not completed; and 1,295 (10.4%) completed the service but declined consent to have their data included in the analysis. Thus, 10,270 initial services were completed and included in the analysis (Figure 1).

There was a 28.9% (2,973/10,270) consultation follow-up rate of initial services. As indicated in the evaluation of the structured model of care,[19,20] pharmacists made three reasonable attempts to engage patients in a follow-up of the clinical service provided to them during the study. Of 7,297 consultations not followed-up, 0.9% (68/7,297) declined to participate in follow-up and 26.2% (1,909/7,297) were not contactable after three reasonable attempts. The reasons for why 5,320 of the participants were lost to follow-up are unknown.

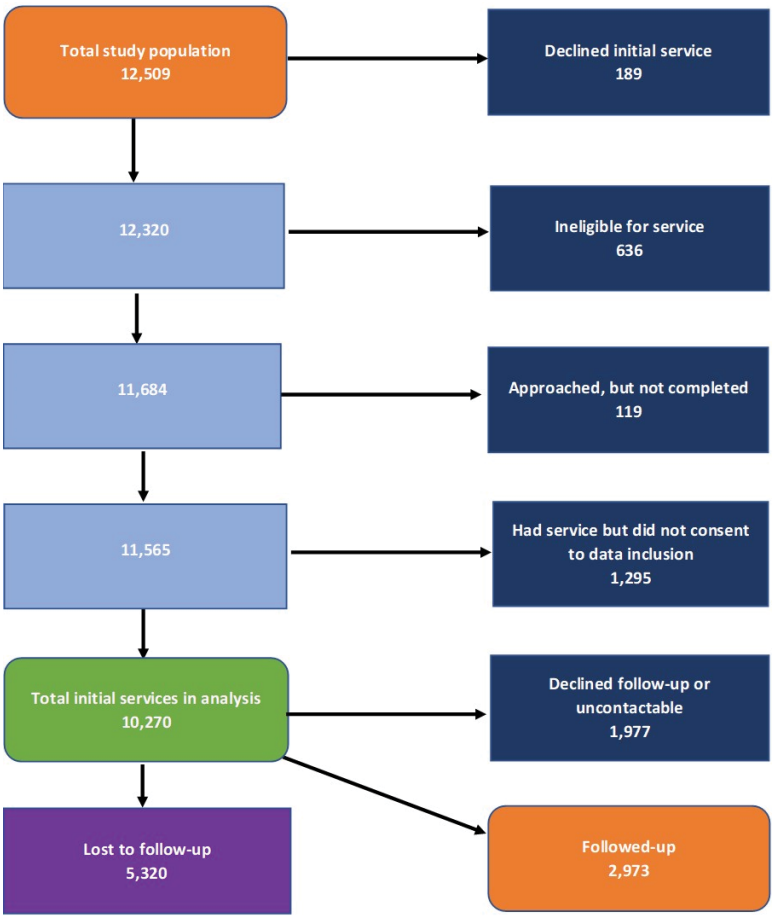

Figure 1. Study population of the Urinary Tract Infection Pharmacy Pilot – Queensland (UTIPP-Q)

Of the 189 individuals (189/12,509; 1.5% of the total study population) who declined the initial UTIPP-Q service, the key reasons were a lack of time to participate (47.1%) and a preference to see their GP (34.4%). Additionally, 11.1% of patients indicated the cost of the consultation / service was a reason to decline. Of the 636 participants identified as ineligible for the service, 283 were excluded due to age and/or sex and 353 due to clinical signs and symptoms. Of the 353 participants ineligible due to clinical symptoms, 43.1% (152/353) reported systemic symptoms, 27.5% (97/353) had frequent or recurrent UTIs and 2.5% (9/353) were considered at risk of a sexually transmitted infection (STI).

Initial consultations

A summary of all initial consultations included in the study population is shown in Table 1 (disaggregated by follow-up status to test for differences) and the number of services by age category in Table 2. The median age of participants who received an initial consultation was 36 years, with 58.3% (5,983/10,270) services provided to those under 40 years of age. The largest number of initial UTIPP-Q services (3,633 or 35.4%) were provided to those in the 18–29 year age group. A low proportion (6.5%) had health care concession cards, indicating lower income levels. The primary presenting symptoms recorded for patients were consistent with UTIs and the inclusion criteria for the structured model of care. These included urinary frequency (90.6%), dysuria (70.3%), urinary urgency (70.5%) and a smaller number with suprapubic pain (36.5%). The primary treatment recommended for patients was a three-day course of trimethoprim per the structured model of care (93.0%) with a small number receiving cefalexin (2.4%) and nitrofurantoin (1.1%). Hypersensitivity / allergy or previous treatment failure were most frequently recorded reasons for not prescribing first-line treatment.

There were 410 individuals (4.2% individuals) who accessed repeat services during the trial (Table 1), a total of 186 people received services that deviated from the structured model of care, with 156 services not conforming to criterion 1, and 30 to criterion 2.

Follow-up consultations

There was a 28.9% (2,973/10,270) consultation follow-up rate. The median time for follow-up was 6 days post-service. In most of the cases, patients reported they had taken the antibiotic according to how it was prescribed (96.2%) and their symptoms of the UTI had resolved (87.6%) (Table 3). Of those 2,973 services able to be followed-up, 209 (7.0%) did not have resolution of symptoms, but had already sought other

Table 1. Summary of initial consultations (N=10,270)

Variable	Total initial consultations (N=10,270)	Had follow-up (N=2,973)	No follow-up (N=7,297)	p-value€
Age, years, median (range)	36 (18-65)	37 (18-65)	35 (18-65)	
Health care concession card (%)	671 (6.5)	191 (6.5)	480 (6.6)	0.75
Total number of individuals who accessed an initial UTI service	9,813	2,886	6,927	
Number of individuals who accessed repeat services	410	202 [at least one FU]	208	
1 service (number individuals)	9,403	2,709	6,694	
2 services (number individuals)	367	175	192	
3 services (number individuals)	39	25	14	
4 services (number individuals)	4	2	2	
Days between services (median, range)	199 (1-755) *			
Clinical symptoms (% patients experienced)				
Dysuria	7,222 (70.3)	2,114 (72.0)	5,078 (70.0)	0.95
Urinary frequency	9,301 (90.6)	2,711 (91.2)	6,590 (90.3)	0.14
Urinary urgency	7,244 (70.5)	2,132 (71.7)	5,112 (70.1)	0.63
Suprapubic pain	3,746 (36.5)	1,101 (37.0)	2,645 (36.2)	0.88
Treatment				
Trimethoprim	9,555 (93.0)	2,808 (94.5)	6,747 (92.5)	0.33
Nitrofurantoin	114 (1.1)	36 (1.2)	78 (1.1)	0.96
Cefalexin	248 (2.4)	79 (2.7)	169 (2.3)	0.96
No antibiotic treatment (ineligible – referred or advice given) **	353 (3.4)	50 (1.7)	303 (4.2)	**0.00**
Reasons why trimethoprim was not appropriate (% inappropriate)				
Hypersensitivity or allergy	132 (35.3)	43 (36.1)	89 (34.9)	**0.03**
Previous treatment failure	144 (38.5)	47 (39.5)	97 (38.0)	0.07
Bacterial resistance	18 (4.8)	6 (5.0)	12 (4.7)	0.17
Drug interaction	12 (3.2)	3 (2.5)	9 (3.5)	0.77
Reduced renal function	1 (0.3)	1 (0.8)	0	0.12
Megaloblastic anaemia	1 (0.3)	1 (0.8)	0	0.12
Other reason ǂ	66 (17.6)	18 (15.1)	48 (18.8)	0.35
Total (trimethoprim inappropriate/evaluated for trimethoprim)	**374/9,555 (3.9)**	**119/2,808 (4.2)**	**255/6,747 (3.8)**	0.29
Reasons why nitrofurantoin was not appropriate (% inappropriate)				
Hypersensitivity or allergy	35 (16.1)	8 (12.3)	27 (17.8)	0.08
Previous treatment failure	92 (42.4)	28 (43.0)	64 (42.1)	0.88
Bacterial resistance	4 (1.8)	2 (3.0)	2 (1.3)	0.15
Drug interaction	3 (1.4)	1 (1.5)	2 (1.3)	0.66
Other reason ɬ	83 (38.2)	26 (40.0)	57 (37.5)	0.53
Total (nitrofurantoin inappropriate/evaluated for nitrofurantoin)	**217/362 (59.9)**	**65/115 (56.5)**	**152/247 (61.5)**	0.36

FU = Follow-up
Note: Percentages for clinical symptoms do not add to 100 as they are not mutually exclusive.
€The p-value is for the difference in proportions between individuals who were followed-up compared to not followed-up. Statistically significant difference of p-value<=0.05 are **bolded**.
*Based on data for 453 observations (across 410 individuals) – 4 data points are excluded due to a difference of 0 days which suggests a recording error.
**Patients deemed ineligible due to clinical signs or symptoms. Does not include individuals who were ineligible for the service due to age or sex.
ǂThe reasons included: (i) dairy/lactose allergy (present in tablet) (N=2); (ii) trying to conceive, possibly pregnant, or breastfeeding (N=14); (iii) patient requested cefalexin (N=11); (iv) suspected prior allergy or side effect from antibiotic (N=12); medication not in stock (N=18); (v) other reason (N=9).
ɬ The reasons included: (i) allergy to lactose (N=1); (ii) trying to conceive, pregnant, or breastfeeding (N=5); (iii) patient requested cefalexin (N=22); (iv) suspected prior allergy or side effect from antibiotic (N=6); (v) cost (N=1); (vi) medication not in stock (N=40); and (vii) reason unknown (N=8).

Table 2. UTI Services provided by age category

Age category	Total initial service number (%)	Had follow-up number (%)	No follow-up number (%)	p-value
18-29 years	3,633 (35.4)	974 (32.8)	2, 659 (36.4)	**0.00**
30-39 years	2,350 (22.9)	680 (22.9)	1,670 (22.9)	0.99
40-49 years	1,964 (19.1)	588 (19.8)	1,376 (18.9)	0.28
50-59 years	1,614 (15.7)	489 (16.5)	1,125 (15.4)	0.19
60-65 years	709 (6.9)	242 (8.1)	467 (6.4)	**0.00**
Total	**10,270 (100)**	**2,973 (100)**	**7,297 (100)**	

Note: The p-value tests the difference in proportions between individuals who were followed-up compared to not followed-up. Statistically significant difference of p-value<=0.05 are **bolded**.

Table 3. Summary of follow-up consultations (N=2,973)

Variable	
Time between initial and FU service, days, median (range)	6 (1-588ǂ)
Medication prescribed	**Number patients (%)**
Patient was prescribed antibiotics	2,918 (98.1)
Patient reported taking medication as prescribed	2,861 (96.2)
Outcome summary	**Number patients (%)**
UTI symptoms have resolved, number (%)	2,603 (87.6)
UTI symptoms not resolved – care sought, number (%)	209 (7.0)
If care sought: accessed GP service	*162 (5.4)*
UTI symptoms not resolved – verbal GP referral, number (%)	112 (3.8)
Other*	49 (1.6)
Presentation to an Emergency Department	*5 (0.002)*
Total	**2,973**
Medication adverse effects (headache, migraine, dizziness, nausea, vomiting, constipation, reflux, dry mouth, thrush, tingling lips, fatigue, allergic reaction**)	85 (2.9)
Visited a medical practitioner ǂ	383 (12.9)
If yes: time to access GP service	
0-24 hours	131 (34.2)
24-48 hours	109 (28.5)
>48 hours	143 (37.3)
UTI GP follow-up	**Number patients (%)**
UTI symptoms not resolved and saw a GP (N=162) Urine Test Performed Urine Test Performed and received another antibiotic UTI symptoms not resolved and saw a GP (N=162) Urine Test not performed Urine Test not performed and received another antibiotic	 105 (64.8) 72 (44.4) 57 (35.2) 44 (27.2)

FU = follow-up; UTI = urinary tract infection; GP= general practitioner
Note: Percentages do not add to 100 as the categories are not mutually exclusive.
ǂ Excluding 47 observations where follow-up was recorded (presumably in error) as occurring prior to the initial service. There were an additional 41 observations where follow-up was >90 days after the Initial Service. It is unclear if these follow-up dates were recorded in error, so data are included in the analysis.
* Other outcomes included emergency department or hospital visit (N=5); symptom re-occurrence, no improvement or not fully resolved (N=19); referral to doctor (N=11); did not take antibiotics (N=2); other (N=12).
**1 case of allergic reaction reported (treated with trimethoprim), including swelling of eyes and lips, burning hands and feet. Care sought at ED the next day. A second case of anaphylaxis was treated in hospital, although unclear from report if it was due to trimethoprim (which is what was prescribed).
ǂ Reasons given for seeing the GP include: seeing the doctor for another reason (N=38); second opinion (N=34); symptoms not completely resolved or reappeared (N=54); adverse effect from medication (N=6); other (N=15); not recorded (N=236).

care. A further 112 (3.8%) follow-up consultations indicated no resolution of their symptoms and were verbally referred to their GP by the pharmacist during the follow-up call (Table 3). Of the 209 who had already appropriately sought follow-up care for their unresolved UTI symptoms, 162 (77.5%) had attended a GP for their follow-up. Patients also acknowledged that during the follow-up period there was a variety of other reasons for attending the GP (see footnote, Table 3). Of those who visited a GP, the time to access the service ranged from 0-24hrs (34.2%) to more than 48hrs (37.3%).

When patients were asked whether there were any specific interventions made in relation to their UTI management when attending the GP for follow-up care, patients indicated a urine test was performed on 64.8% (105/162) of occasions. Where patients received a urine test, 68.6% (72/105) of occasions went on to receive another antibiotic treatment. Of those who did not receive a urine test, 77.2% (44/57) also received another antibiotic. Overall, 71.6% (116/162) of follow-up consultations who had unresolved UTI symptoms and attended a GP from the follow-up group received another antibiotic treatment (Table 3).

During follow-up, patients were asked whether they experienced any medication related adverse events following treatment. Eighty-five consultations (2.9%) indicated they had experienced adverse events. The most reported events were nausea (n=26) and vaginal candidiasis (n=24) followed by gastrointestinal upset (n=9) and fatigue (n=8). Five patients, all prescribed trimethoprim reported visiting an emergency department (ED) or hospital at follow-up. The five ED or hospital presentations recorded during the follow-up were reviewed by two doctors from the pilot Steering Advisory Group (including a medical physician and sexual health practitioner). It was found on review that the pharmacists had provided treatment according to the symptom presentation from the patient in the pharmacy and that the structured model of care recommendations had been followed.[19]

Geographic distribution of services

A total of 817 pharmacies participated, with 588/817 (72.0%) providing at least one service (Supplementary Table 1). The mean number of services/pharmacy/week was 0.14 (+/- 0.21, range 0.01-2.12). Only three pharmacies provided more than 200 services across the 119-week trial period. During the UTIPP-Q study, access to services was available across all Modified Monash Model (MMM) classifications of remoteness (1-7).[26,27] Most pharmacies were in MMM1 (61.2%) and MMM2 (24.8%), which are urban areas, though services were provided across all geographical locations including very remote areas. Supplementary Figures 1 and 2 show a distribution of services offered geographically across Queensland.

DISCUSSION

It is estimated that UTIs result in approximately 2.6 million visits to GPs in Australia each year.[28] Evaluation of the UTIPP-Q suggests appropriately trained pharmacists' management of uncomplicated UTIs is safe and effective. The first-line antibiotic therapy, trimethoprim, was prescribed for 93.0% of patients. This is in comparison with an estimated 46% of women with a UTI who were prescribed an antimicrobial being prescribed trimethoprim by physician prescribers in Australia,[29] suggesting that the structured model of care can be used to increase adherence to therapeutic guidelines. The majority (87.6%) of follow-up consultations reported a complete resolution of symptoms. For those whom symptoms had not resolved, 7.0% of follow-up consultations had sought care within 7 days of the initial consultation and 3.8% were subsequently referred to their GP by the pharmacist. These results support the conclusion that community pharmacists followed the structured model of care and referred appropriately to GPs when symptoms had not resolved. Most patients accessing UTIPP-Q were in the 18-29 years age group, which is consistent with epidemiological data for the United States of America, which shows the peak rate of uncomplicated UTIs is found in the 18–39-year age group, during the time of maximal sexual activity.[30]

One of the major strengths of this evaluation is the sample size of participants, which is the largest reported thus far in the literature.[2-5] Another strength is the design of the service, with pharmacists shown to follow the structured model of care with a high level of fidelity.

In terms of limitations, the pilot took place in only one state in Australia and therefore results may not be fully generalisable. However, Queensland is the third most populous state in Australia and has a good representation of urban, rural, and remote settings,[16] so this limitation is lessened. No clear differences have been found between pharmacies that provided no or few UTI services during the pilot and those that provided highest number. This is an ongoing area of research, but differences may be due to the skills and interests of participating pharmacists, time constraints and workflow management. From previous literature, resistance to change from GPs/family physicians and other health care practitioners may be a barrier to implementation, whereas consumer acceptance and enhanced job satisfaction of pharmacists may be enablers.[31]

The number of people recorded as being ineligible for the service was quite low (636/12,509; 5.1%; Figure 1), however anecdotal reports from the UTIPP-Q Steering Advisory Group reported that participating pharmacists were often not recording ineligible patients in the system, which may have impacted this estimate. Due to the lack of control group, a direct comparison of rates of misdiagnosis between pharmacists and doctors could not be undertaken; further, such a comparison would be difficult to measure in practice. As noted in the introduction, Bent and colleagues[12] found women presenting with a least two symptoms of dysuria, urinary frequency or urinary urgency, and the absence of vaginal discharge, had an approximately 90% probability of having an acute UTI, upon which evidence the structured model of care was based.

There was a substantial loss to follow-up of the cohort; pharmacists were not incentivised in any way to complete the follow-up. It is difficult to know if patients who were not followed-up were systematically different in some way to

those which were, which could bias the outcome results. Characteristics of the initial consultations are, however, known for all services recorded, which were disaggregated in Table 1 to look for systematic differences between those who were and were not followed up, but the groups were similar based on observable factors. No major differences were seen between the presentation and treatment of initial consultations by follow-up status, suggesting the outcomes for patients who were lost to follow-up could be very similar to those who were followed up, although the absence of a control arm means this is not conclusive.

The evaluation follow-up rate of 28.9% (2,973/10,270) is however, similar to, or higher than previous studies of pharmacist prescribing for UTIs including 14.6% in New Zealand,[5] 9.0% in the United Kingdom,[3] and 38.7% in Scotland.[4] The exception is the Canadian study called RxOUTMAP (Outcomes of Urinary Tract Infection Management by Pharmacists), a prospective registry study, which achieved a 91.5% follow-up after two weeks (686/750 patients enrolled).[2] Although the UTIPP-Q follow-up rate was lower than RxOUTMAP, the number of patients followed-up was around four times higher (2,973 vs 686) and represents the largest follow-up cohort in the literature to date. Resolution of symptoms between the studies were very similar: 88.9% for RxOUTMAP (at 14 days) and 87.6% for UTIPP-Q (at 7 days).

Similarly, in terms of medication related adverse events following treatment, the side effects reported were generally consistent with those expected for the antibiotics prescribed.[13] All five cases involving ED or hospital follow-up were reviewed by the two doctors from the Steering Advisory Group, and it was found the pharmacists had followed structured model of care recommendations. The size of the follow-up cohort and length of duration of the evaluation (18 months) is a valuable contribution to the literature, providing the opportunity to identify less common safety issues.

Repeat access to the service by some patients provides evidence that additional software alerts and pharmacist education to refer patients, who may be experiencing relapse or recurrent infections is warranted. Thus, it is important, as electronic medical record systems evolve, to look for opportunities to record and share relevant clinical information, reducing the chance of inappropriate antibiotic prescribing.

Evidence from placebo arms of randomised trials indicate a significant group of women under the age of 65 years who are treated symptomatically (without antibiotic therapy) for acute uncomplicated cystitis may become symptom free within 7-days.[13,32-34] However, the implications of UTI symptoms including urinary frequency, dysuria, urinary urgency, and suprapubic pain on activities of daily living and quality of life should not be discounted. Antibiotic resistance and not providing antibiotics have been shown to be associated with 50-60% longer duration of more severe symptoms and more severe symptoms of frequency.[35] As such, the non-treatment / wait-and-watch option was not actively pursued in the pilot, although remained an option in the structured model of care. Any updates to clinical treatment guidelines for uncomplicated UTI management to decrease antimicrobial resistance would need to be reflected in practice.

Any changes to routine diagnostic testing for UTIs would also need to be reflected in practice. Although midstream urine culture is considered the gold-standard diagnostic test for a UTI, emerging research suggests the diagnostic ability of midstream urine culture may not be good enough to differentiate between patients and controls, and new tests, such as genomic sequencing, are more reliable.[9] The authors of the study concluded that those responsible for UTI detection, diagnosis, and patient care 'may wish to use caution when interpreting a negative or mixed-growth midstream urine culture in symptomatic patients'.[9] Thus, the differential diagnosis of uncomplicated UTIs is an area for future research where the possibility of improved rapid diagnostic tests may mean changes to the UTIPP-Q service should be considered in the future.

Some evidence of deviation from the structured model of care was shown as repeat services, which may indicate treatment failure or recurrent infection. Steps should be taken to minimise such issues. Further investigation of why individuals were not consistently triggered and recorded as ineligible for subsequent services in the clinical software could include: 1) pharmacists were not alerted that individuals did not meet the eligibility criteria; 2) patients did not fully or accurately disclose previous treatments; or 3) pharmacists had not accurately recorded previous treatment. It is important to note this systemic issue is true of all prescribers, as primary health records in Australia are not well linked across providers. This result has not previously been shown and is an addition to the existing literature.

Due to the user-pay service model, most people (93.5%) who accessed the service were not eligible for a government health concession card, meaning that the improvement in access was inequitable for more vulnerable populations. This could be addressed by alternative funding models in the future.

Concerns about the potential for supplier-induced demand raised previously,[36] (as pharmacists were paid for the provision of the service and the cost of the medicines dispensed) were not supported by the evaluation. Given the mean number of services/pharmacy/week was 0.14 (range 0.01-2.12) and the price paid by patients was $19.95 per service, this resulted in revenue of $2.80 (range $0.16 - $42.20) per pharmacy/per week on average. We also note that the authors of this editorial[36] did not consider alternative explanations of why more women, in absolute terms, were treated by pharmacists than doctors in the Canadian RxOUTMAP study,[2] which may reflect patient preference and the inability to secure a GP appointment, rather than supplier-induced demand.

CONCLUSION

The findings of this study suggest there is an opportunity for pharmacists to decrease the workload of GPs managing minor ailments such as UTIs in Australia and confirms that about a third of patients who sought care from a GP practice reporting having to wait more than 2 days for an appointment.

Community pharmacists in Queensland were found to follow the structured model of care and referred appropriately to GPs when patients were not eligible for the service or UTI symptoms had not resolved. Thus, the availability of UTI treatment by community pharmacists increases access to safe and effective care. However, given the rise in antimicrobial resistance worldwide, regular audits of antibiotic prescribing should be ongoing, alongside monitoring and reporting of drug resistance rates. The evidence presented here reinforces the need for feedback on antibiotic prescribing patterns, perhaps within a quality improvement framework in primary care, an activity which should encompass all prescribers. In addition, it may be prudent to formally include a delayed antibiotic treatment option UTI models of care which may decrease antibiotic prescribing, while nonantibiotic treatment options are being investigated.[37]

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CONFLICTS OF INTEREST

JS & LN received support to present results to professional bodies.

AUTHORS CONTRIBUTION

All authors contributed to study design, evaluation and manuscript preparation. JS prepared the first draft of the manuscript and undertook data analysis. LN led the study with all coauthors.

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